Ministry of Environment and Food of Denmark
Environmental Protection Agency

Survey and health assessment of preservatives in toys

Corrected version

Survey of chemical substances in consumer products No. 124

October 2016

Publisher: The Danish Environmental Protection Agency

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ISBN: 978-87-93529-22-9

Corrections of “Survey of chemical substances in consumer products no. 124”, 2014 are to be found on page 45. See footnote no. 10.

Corrections of “Survey of chemical substances in consumer products no. 124”, 2016 are made on page 47, where this text is deleted: BIT is a so-called formaldehyde releaser, which means that the substance can release formaldehyde. Formaldehyde is classified as carcinogenic in category 2 and is allergenic.

Contents

Foreword

This project on preservatives in toys is carried out in the period June 2012 to April 2013.

This report describes the results of the project, including the survey of the market and the results of the survey. Furthermore, the report describes which products that were selected for chemical analyses for content of specific preservatives and the background for the selection of the preservatives. Results of the chemical analyses are presented and finally, a health assessment of selected preservatives has been made.

The project is carried out by FORCE Technology and Eurofins has been responsible for the chemical analyses of selected toys.

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The project was financed by the Danish Environmental Protection Agency.

Conclusion and Summary

Toys, like finger paint, modelling clay, cosmetics, face paint, glue, slime, soap bubbles and hobby paint, are typically added preservatives. The preservatives are added to avoid growth of micro-organisms in the product. There are neither in the new nor in the old Toy Safety Directive general restrictions on the use of preservatives in toys, except for products like finger paint, paint, glue and cosmetic products where toy safety standards set requirements for which preservatives that are allowed to be used and in which concentrations. All toys examined in this project seem to comply with these guidelines even if no uniform requirements for the examined product types exist.

Purpose and delimitation of the project

Some preservatives have shown to cause allergy and other preservatives are suspected of being endocrine disruptors. Therefore, the Danish Environmental Protection Agency has started this project to map the use of preservatives in selected toys and to examine whether the identified preservatives can constitute a health risk in selected toys.

The selected toys which are examined in this project are toys which are expected to contain preservatives, i.e. products like:

- Hobby articles (finger paint, modelling clay, face paint, window paint, glue, etc.)
- Slime
- Face paint and make-up
- Soap bubbles

Cosmetic products, i.e. products like shampoo, soap and creams, have not been included in this survey.

Approach and results

A number of relevant trade associations, research centres, organisations, distributors, suppliers and producers of toys with an expected content of preservatives were contacted and asked to deliver information about the content of preservatives in toys on the Danish market. Based on the collected information as well as information from the literature, 23 different preservatives being used today in the above-mentioned types of toys were identified. Furthermore, 11 selected pieces of toys with an expected content of preservatives were analysed for a content of 16 different preservatives.

The survey and the analyses showed that toys of this type typically contain one or more preservatives. Even if there are no requirements for which types and amounts of preservatives that are allowed to be added the toys for all the examined product types, the survey showed that the allowed preservatives and the allowed limits of concentration from the Cosmetic Products Directive seem to be used as a guideline as none of the toy products about which information was received in this project had higher concentrations or other preservatives than allowed in the Cosmetic Products Directive.

Based on the results of the survey, a few preservatives were selected (parabens, 2-phenoxyethanol, formaldehyde and bronopol) and assessed whether the content of the preservatives might constitute a health risk for children who play with the examined toys in a so-called worst case assessment.

Assessment of the risk with regard to allergy by use of preservatives in toys

The risk of allergic reactions when using toys containing parabens, 2-phenoxyethanol and bronopol is assessed to be low as the occurrence of allergy towards these preservatives is relatively low or minimal (for 2-phenoxyethanol). Formaldehyde is regarded as being strongly allergenic and persons who already are allergic to formaldehyde can get allergenic reactions already at low concentrations (60 ppm). Therefore, toys with a content of formaldehyde above this level are assessed to constitute a possible risk for allergic reactions for persons who already are allergenic to formaldehyde. Two of the 11 analysed products had a content of formaldehyde above this level.

For other preservatives than the selected substances, it is important to comment on Kathon as Kathon is regarded as being extremely allergenic. The EU's Scientific Committee on Consumer Safety (SCCS) assesses that the allergenic properties of the substance are the biggest problem of Kathon. The results from the survey show that Kathon is used in products like hobby paint, finger paint, window paint/glass paint, glue and soap bubbles. The EU's Scientific Committee on Health and Environmental Risks (SCHER) recommends that neither Kathon nor MI nor MCI (which are the constituents in Kathon) are used in toys due to the allergenic properties of the substances.

Kathon and the other assessed preservatives are also used as preservatives in cosmetics for which reason 1-year-old and 3-year-old children are expected to be exposed to these preservatives, also through cosmetic products.

Assessment of the health risk

In general, the risk assessment shows that for all the examined preservatives (except methyl and ethylparaben) and for a few product types (modelling clay, finger paint and slime) RCR values above 1 for the absolute worst case calculations might occur. RCR values above 1 mean that a risk of health effects in these situations might occur. However, several rough assumptions in connection with the worst case calculations have been made, for instance:

- Most cases with RCR values above 1 are based on assumptions that the maximum allowed concentrations according to the Cosmetic Products Directive are used. Often the actual concentration will be lower.
- For slime and modelling clay, 100% migration is assumed for substances where the migration is not measured. This is a clear overestimation of the risk.
- Generally, conservative assumptions on the use of the products have been made, especially regarding how large a quantity of the products the children will be exposed to during use.

All these rough assumptions in total mean that the examined preservatives most likely will not form any risk of health hazards in the examined product types when based on a realistic scenario. Neither as a whole, if the child plays with all the products.

However, it must be added that the risk assessment in this report exclusively assesses the risk of health effects for the investigated types of toys. The assessed preservatives are all preservatives which are also allowed in cosmetic products where especially the parabens, 2-phenoxyethanol and formaldehyde (deriving from various formaldehyde releasers) are frequently used preservatives. Therefore, it should be taken into account that both 1-year-old and 3-year-old children get an extra contribution (dermal absorption) of these substances through cosmetic products which contribute to the increase of the total risk of health effects for these substances. However, this contribution is not assessed further in this report.

1. Introduction

1.1 Background

Toys, like finger paint, modelling clay, cosmetics and glue might be added preservatives which prevent growth of micro-organisms in the product. Typically, products containing water have a need of addition of preservatives. There are neither in the new Toy Safety Directive (2009/48/EF) nor the old Toy Safety Directive (88/378/EØF) general legal requirements for the use of preservatives in toys – however, through the toys standards there are requirements for the use of preservatives but only for certain types of toys. Still, chemical substances in toys are not allowed to present a health risk.

Some preservatives have turned out to cause allergy and other preservatives are suspected of being endocrine disrupting. Therefore, the Danish EPA has started this project which is to map the use of preservatives in selected toys.

1.2 Purpose

The purpose of this project has been to:

- Map the use of preservatives in selected toys on the Danish market
- Analyse the content of preservatives in selected toys on the Danish market
- Assess if there is a possible health risk for the identified preservatives by use of selected toys

1.3 Definition of toys being examined in this project

The selected toys being examined in this project are toys which are expected to contain preservatives, i.e. products like:

- Hobby articles (finger paint, modelling clay, face paint, window paint, glue, etc.)
- Slime
- Face paint and make-up
- Soap bubbles

Cosmetic products like shampoo, soap and creams have not been included in the survey for two reasons. Earlier, some of this product types for children have already been examined (A survey and health assessment of cosmetic products for children – Survey no. 88, 2007) and furthermore, this group of cosmetic products is typically not toys. Therefore, it is exclusively cosmetic products which also are toys that have been included in the survey.

Products like felt-tip pens and crayons have not been included in the survey as they are not expected to contain preservatives. Crayons do not contain water for which reason it will not be necessary to add preservatives. Felt-tip pens can contain solvents which in themselves are preserving.

2. Legislation and labelling schemes

In this chapter the current legislation for preservatives in toys, the different labelling schemes existing within this area and the requirements they make on the content of preservatives are examined.

2.1 Legislation

This section only relates to the legislation which concerns preservatives in toys. The legislation in general for toys is not examined.

In certain areas there are requirements on declaration of constituents and there might be limitations in the form of which preservatives that are allowed to use as well as in which concentrations. These areas are:

- Make-up or similar, which is also covered by the Cosmetic Products Directive (Directive 76/768/EEC, 1976).
- Finger paint (EN 71-7, which belongs under the Toy Safety Directive).
- Oven hardening modelling clay as well as paint, glue and lacquer (EN 71-5 which belongs under the Toy Safety Directive).

In addition to this, toys are not allowed to contain substances in concentrations which constitute a health risk. Finally, existing, general regulations on classification and labelling of chemical substances and mixtures are described shortly below.

2.1.1 Classification and labelling

Hazardous chemical substances and mixtures have to be classified and labelled to inform and warn the consumers about the hazardous properties of these. Toys which also are to be regarded as chemical mixtures, like e.g. soap bubble liquid, finger paint etc., must also comply with the classification and labelling regulations which are described in the classification, packaging and labelling directive (Directive 67/548/EEC – applies for mixtures up to 2015) which in 2015 entirely is replaced by the CLP Regulation (Regulation no. 1272, 2008 – applies already for chemical substances and has to be applied for mixtures by 1.6.2015). This means that the products have to be labelled as hazardous including the relevant hazard symbols as well as hazard statements and precautionary statements if hazardous substances are constituents in chemical toy products in concentrations which exceed the concentration limits as described in the classification, packaging and labelling directive or the CLP Regulation.

2.1.2 The Cosmetic Products Directive

Toys which are also covered by the Cosmetic Products Directive (Directive 76/768/EEC, 1976), like eg. make-up sets for children or carnival make-up are also subject to the Cosmetic Product Directive. I.e. there is an obligation of labelling of the constituents (and thus also the preservatives). The Cosmetic Products Directive contains a list of allowed preservatives in cosmetic products (appendix 5) – a so-called “positive list”. Furthermore, this appendix 5 states the highest permitted concentrations of the preservatives as well as specific limitations and requirements.

Furthermore, it is required that all finished products containing formaldehyde or other preservatives which can split off formaldehyde must be provided with a label with the text "Contains formaldehyde" if the concentration of formaldehyde in the finished product exceeds 0.05%.

Examples of highest permitted concentrations of allowed preservatives from appendix 5 in the Cosmetic Products Directive are stated in Table 1 below. The examples are chosen because they all are preservatives which are identified in the survey.

TABLE 1
SELECTED ALLOWED PRESERVATIVES IN COSMETIC PRODUCTS ACCORDING TO THE COSMETIC PRODUCT DIRECTIVE (DIRECTIVE 76/768/EEC, 1976)

Allowed preservatives	Maximum permitted concentration
Benzoic acid and its salts and esters	0.5% (acid)
Parabens (Parahydroxybenzoic acid and its salts and esters)	0.4% (acid) for an ester, 0.8% (acid) for ester mixtures. But according to a special Danish regulation it is not permitted to use propylparaben, butylparaben, isopropylparaben or isobutylparaben in cosmetic products for children under 3 years in Denmark*.
Bronopol	0.1%
2-phenoxyethanol	1.0%
Mixture of MI and MCI with magnesium chloride and magnesium nitrate (Kathon)[1]	0.0015% (of a mixture in the ratio 3:1 of MCI and MI)
Methylisothiazolinone	0.01%
Formaldehyde (free)	0.2%
Iodopropynyl butylcarbamate (IPBC)	0.01%
DMDM Hydantoin	0.6%
Dichlorobenzyl alcohol	0.15%
Benzyl alcohol	1%
Diazolidinyl urea	0.5%
Polyaminopropyl biganuide	0.3%
Sodium hydroxymethyl glycinate	0.5%

* According to a change to the Danish cosmetic statutory order (BEK 166, 2011), which took effect as from 15 March 2011.

2.1.3 Toys – standards

Below is listed the relevant current standards relating to the Toy Safety Directive which make requirements to toys that are included in the survey, i.e. toys that are expected to contain preservatives.

[1] Kathon is a name for a preservative which consists of a mixture of 2-methyl-3(2H)-isothiazolinone (forkortet MI eller MIT) and 5-chloro-2-methyl-4-isothiazolinone (abbreviated CMI, MCI or CMIT) in the mixture proportion 1:3.In this report the names MI and MCI are used.

- EN 71-5 (1993): ”Toys – Safety requirements – Part 5: Chemical toys (sets) other than experimental sets”.
- EN 71-5/A2 (2009): ”Toys – Safety requirements – Part 5: Chemical toys (sets) other than experimental sets”.
- EN 71-7 (2009): ”Toys – Safety requirements – Part 7: Finger paints – Requirements and test methods”.

However, it is not a requirement to comply with the relevant standards but it gives a presumption of compliance with the requirements of the directive when relevant standards are complied with. The standards are revised continuously and an update is expected in connection with the entry into force of the new chemical requirements in the Toy Safety Directive 2009/48/EF which comes into force on 20 July 2013.

2.1.3.1 EN 71-5: Chemical toys (sets) other than experimental sets

The standard EN 71-5 (EN 71-5, 1993; EN 71-5/A2, 2009) makes specific requirements for chemical toys which can be formed or casted if it consists of the following materials: plaster, ceramics, oven-hardening modelling clay and plastic. Furthermore, EN 71-5 makes specific requirements to equipment for photographic development, as well as glue, solvent- and water-based paints, lacquers and solvents. The specific requirements which are relevant for toys that are expected to contain preservatives are:

- Paint, glue, lacquers and solvents are only allowed to contain preservatives which are permitted in foods and/or cosmetic products as described in the respective regulations (Regulation no. 1333/2008 on food additives and the Cosmetic Products Directive (Directive 76/768/EEC, 1976)). However, it is not allowed to use preservatives from the Cosmetic Products Directive which are solely allowed in products which are rinsed off after use. The preservatives have to be stated on the packaging of the product. Furthermore, a number of other requirements for use of certain polymers or solvents in this type of products exist.

2.1.3.2 EN 71-7: Finger paints – Requirements and test methods

The standard EN 71-7 (EN 71-7, 2009) covers solely finger paints and make specific requirements on the use of constituents, among others dyes, preservatives, binders, fillers etc. Furthermore, there are a number of requirements to taste, odour, pH value as well as limit values for migration of heavy metals. Specifically for preservatives the following requirements are relevant:

- Finger paints are only allowed to be preserved with the preservatives stated in annex B in EN 71-7. Furthermore, a maximum concentration, specific limitations and requirements for the preservatives are stated and these must also be complied with. A few of these permitted preservatives in finger paint are stated in Table 2 below. Only preservatives from EN 71-7 which are identified in the survey in this project are listed in the table below.
- Used preservatives have to be stated on the container.

TABLE 2
SELECTED ALLOWED PRESERVATIVES IN FINGER PAINT ACCORDING TO EN 71-7 (2009)

Allowed preservatives	Maximum permitted concentration	Maximum permitted concentration according to EN 71-7 which is expected to be put to the vote
Benzoic acid and its salts and esters	0.5% (acid)	Is no longer on the list of preservatives
4-hydroxybenzoic acid and its salts and esters (parabens)	0.4% (acid) for an ester, 0.8% (acid) for ester mixtures	Is no longer on the list of preservatives
Bronopol	0.1%	0.1%
2-phenoxyethanol	1%	1%
Mixture of MI and MCI with magnesium chloride and magnesium nitrate (Kathon)	0.0015% (of a mixture in the ratio 3:1 of MCI and MI)	0.0008%
DMDM Hydantoin	0.6%	0.6%
Diazolidinyl urea	0.5%	Is no longer on the list of preservatives
Paraformaldehyde	0.1% (stated as free formaldehyde)	Is no longer on the list of preservatives

2.2 Labelling schemes

In this section all the different requirements which labelling schemes make on the content of preservatives in toys which might contain preservatives are examined. Focus is on the Danish A label under the Danish trade association "Joint Council of Creative & Hobby Materials" (in Danish: FFFH) as well as the eco-labels (the Swan and the Flower) which are the most relevant for the Danish market when it comes to toys which might contain preservatives.

The German eco-label, Der Blaue Engel (the blue Angel), has also criteria for toys but according to the homepage, no toy products have Der Blaue Engel (November 2012). Therefore, the criteria for Der Blaue Engel are not examined.

2.2.1 The A label from the Joint Council of Creative & Hobby Materials (FFFH)

The A label is the trade association FFFH's own label. The A label is voluntary and self-declaring, i.e. no official control whether an A labelled product complies with the set criteria. The criteria were revised in May 2010 and are valid to and including May 2013. However, products which are A labelled according to the old criteria can still be found in the shops. The trade association FFFH has informed that products with the A label have to fulfil the new criteria when the data sheet is renewed which happens every third year. The A label scheme includes criteria sets for the following product types:

- Finger paints
- Dry colours (i.e. coloured crayons and crayons) – not relevant for this survey
- Wet dyes, lacquer and glue
- Modelling clay, molding mass, clay, plaster and plaster gauze
- Make-up colours (i.e. make-up)

The label solely makes requirements to constituents, among others the content of preservatives. The requirements to the content of preservatives are very alike in the five criteria sets. Therefore, the general requirements are examined first and then possible specific requirements for the different product types will be stated.

2.2.1.1 General requirements to A labelled products

These general requirements to preservatives in A labelled products apply to all five criteria sets except the criteria set for make-up colours which does not contain the requirements regarding classification. To illustrate the general requirements to A labelled products the trade association FFFH's criteria are in some places directly quoted (translated from Danish) and in other places rewritten to a more comprehensible and less technical text.

General requirements to A labelled products

Classification

- "The product must not be classified. This means that the product must not be assigned hazard symbols/pictograms, signal words or H- and P-sentences as well as EUH[2]-sentences".

Content of hazardous substances

- "The product must not contain substances which are classified as hazardous and which have a concentration that are higher or equal to the lower concentration limit for classification". With the concentration limit for classification is meant a limit of either 0.1 or 1% dependent on the hazard classification. The most hazardous substances have the lowest limit for classification of 0.1%[3]. If the substances have lower specific concentration limits in the CLP Regulation, these these lower limits have to be used.
- Hazardous substances are defined as substances which are on the harmonised list of hazardous substances, are self-classified according to the CLP Regulation, are classified on the European Chemicals Agency's (ECHAs) Classification & Labelling Inventory or are on the Norwegian List of Priority Substances.
- The product is not allowed to contain substances which are on the Danish EPAs List of undesirable substances.

Special general requirements on preservatives

- "When using preservatives attention has to be to substances which are formaldehyde releasers. If this type of substances is used, theoretically released formaldehyde has to be calculated". "The released amount of formaldehyde shall be a part of the assessment of the finished product".
- "The product must no contain 0.1% (w/w) or above of substances which are classified as carcinogenic (Carc. 1A, 1B and 2), mutagenic (Muta 1A, 1B and 2) or toxic to reproduction (Repr. 1A, 1B and 2)" are on specific lists as e.g. the List of occupational threshold limit values from Danish Working Environment Authority (list of substances which are considered to be carcinogenic).
- For preservatives which are classified as sensitising, content up to a specific stated limit is accepted (typically identical with the legislation for cosmetic products).
- "The product **must not** be added endocrine disrupting substances in category 1 and 2

[2] EUH sentences are H sentences which are special for the EU and which are not used in the rest of the world.
[3] With concentration limit for classification is meant 0.1% for the hazard classes very toxic, toxic, carcinogenic, mutagenic, toxic to reproduction, sensitizing, hazardous to environment (N, ozone) as well as for classification with R33 and R64,and 1% for corrosive, hazardous to health, local irritants, hazardous to environment (R52/53, R52 and R53), as well as classification with R66 and R67.

which are on EU priority list of potential endocrine disruptors".
- However, methylparaben and ethylparaben **may** be used.
- Propylparaben and butylparaben **must not** be used.

2.2.1.2 Specific requirements regarding preservatives to A labelled products

Furthermore, specific criteria for preservatives for some special products exist. These are stated in the boxes below. To illustrate the specific requirements to A labelled products, the trade association FFFH's criteria are in some places directly quoted (translated from Danish) and in other places rewritten to a more comprehensible and less technical text.

Beyond the general requirements, the following specific criteria for preservatives in finger paint exist.

Specific requirements to A labelled finger paints

Preservatives
- "Only preservatives which are in annex B in CEN EN 71-7 and with the mentioned concentration limits may be used".
- Butylparaben and propylparaben **must not** be used.

Standards
- Finger paints "must comply with current CEN standard for finger paints EN 71-7".

Beyond the general requirements, the following specific criteria for preservatives in dry colours, wet dyes, lacquer and glue as well as modelling clay exist.

Specific requirements to A labelled dry colours, wet dyes, lacquer and glue as well as modelling clay

Preservatives
- "Preservatives which are in appendix 1 and within the stated concentration limits may be used". *Appendix 1 is the trade association FFFH's own list of premitted preservatives and is described further below.*
- "Preservatives which are approved for use in the Cosmetic Products Directive and within the stated concentration limits may also be used". Be aware that the concentration limits in appendix 1 have to be used in preference to the concentration limits in the Cosmetic Products Directive".
- However, butylparaben and propylparaben **must not** be used.
- "If use of other preservatives than the above is requested, there must be applied for an exemption at the trade association FFFH. Toxicological and ecotoxicological documentation for the preservative and the information must be sent to the trade association FFFH".

Beyond the general requirements, the following specific criteria for preservatives in make-up colours (make-up) exist.

Specific requirements to A labelled make-up colours

Preservatives

- Only preservatives which are approved for use in the Cosmetic Products Directive must be used".
- "Preservatives may only be used according to the concentration limits that are mentioned in the Cosmetic Products Directive".
- However, butylparaben and propylparaben **must not** be used.

The trade association FFFH's appendix 1 with the permitted preservatives and permitted concentration limits contains a three-pages list of preservatives. An extract of the permitted preservatives is stated below. The mentioned preservatives below are selected as they are identified in products on the Danish market in this project.

The trade association FFFH's appendix 1: Permitted preservatives in A labelled products – an extract

- 2-methyl-3(2H)-isothiazolinone (MI) – 0.01%
- 5-chloro-2-methyl-4-isothiazolin-3-one (MCI) – 0.0015%
- Kathon (a mixture of MI and MCI in the ratio 1:3) – 0.0015%
- 1,2-Benzoisothiazol-3(2H)-one (BIT) – *no maximum limit*
- Parabens – 0.4% for one ester and 0.8% for ester mixtures. *However, in the actual criteria it is specified that propylparaben and butylparaben* ***must not*** *be used.*
- Bronopol – 0.10%
- Formaldehyde (free) – 0.1%
- 2-phenoxyethanol – 1.0%
- Benzoic acid and its salts and esters – 0.5% (acid)

For finger paint and make-up colours, where specific legislative requirements to content of preservatives already exist, reference to these legislative requirements (EN 71-7 and the legislation regarding cosmetic products respectively) is made. On the contrary, for the remaining group of products, i.e. dry colours, wet colours, lacquer and glue as well as modelling clay, moulding mass, clay, plaster and plaster gauze, the trade association FFFH's own list (appendix 1) of approved preservatives and the maximum permitted contration limits of these is to be used. However, preservatives which do not appear from this appendix 1 may also be used if they are permitted according to the legislation for cosmetic products, with the exception that propylparaben and butylparaben must not be used.

2.2.2 The Swan Label

The following environmental criteria under the Swan exist and they might have relevance for the stated product types defined in this report (toys with an expected content of preservatives):

- Cosmetic products – but no Swan-lablleled make-up products exist by November 2012.
- Toys – by November 2012 only toys made of plastics or wood are Swan-labelled.
- Indoor paint and varnishes – by November 2012 only wood and wall paints are Swan-labelled.
- Writing instruments – by November 2012 only felt-tip pens and ballpoint pens are Swan-labelled.

For Swan-labelling of **cosmetic products** there is the direct requirement that parabens are prohibited (defined as 4-Hydroxybenzoic acid and its salts and esters). Other preservatives may be limited because of their classification, as substances with the following properties (according to the CLP Regulation) are prohibited (Nordic Ecolabelling of cosmetic products, 2012).

- Sensitising (defined as substances classified as Resp. Sens 1 or Skin Sens 1).
- Carcinogenic, mutagenic or reproductive toxic (defined as category 1A, 1B and 2). This does however, not necessarily exclude the use of preservatives that release formaldehyde (Carc 2), as the requirement only applies for the constituent substances.
- Environmentally hazardous (defined as substances that in the EU have been assessed as PBT or vPvB). Substances that are classified as environmentally hazardous according to the CLP Classification are allowed in certain maxium percentage of the product (a formular for calculation is described – it depends on the degree of environmentally hazardousness).

For Swan-labelling of **toys** there is the direct requirement that the preservative Kathon (MI/MCI) is prohibited in a concentration of more than 0.0015% (i.e. 15 ppm). Moreover, isothiazolines are prohibited (including BIT) in concentrations above 0.05% (i.e. 500 ppm). Other preservatives may be limited because of their classification, as substances with the following properties are prohibited in Swan-lablled toys (Nordic Ecolabelling of toys, 2012):

- Carcinogenic, mutagenic or reproductive toxic (defined as category 1 and 2).
- Substances considered as endocrine disruptors (defined as category 1 and 2 according to the EU reports on endocrine disruptors).
- Substances considered as problematic SVHC and environmentally hazardous (defined as SVHC according to REACH and substances which meet the criteria for PBT and vPvB in accordance with the criteria in the REACH Regulation).

For glue in toys it is seperately listed that the glue must not be classified as environmentally dangerous, toxic, very toxic, carcinogenic, mutagenic, toxic to reproduction or sensitising (defined by specific hazard statements). Moreover, it is prohibited to use substances in the glue that are carcinogenic, mutagenic, toxic to reproduction, considered to be endocrine disruptors (i.e. certain parabens) – using the same definitions as listed above. Finally, a limit value of 0.2% is listed for free formaldehyde (which is formed by use of the so-called formaldehyde releasers which can be used as preservative).

The environmental criteria for Swan-labelling of **indoor paint and varnishes** cover solely paint for indoor use, which have the purpose to form a film on the surface having protective and decorative properties. I.e. they cover wall paints and not hobby paints – and therefore they are not relevant in this context.

The enviromental criteria for Swan-labelling of **writing instruments** cover solely writing instruments and not various hobby paints. Thus the criteria do not cover the types of toys which are included in the survey.

2.2.3 The Flower

For the Flower there are criteria for ”soaps, shampoos and hair conditioners”. However, these only cover the so-called ”rinse-off” cosmetic products and thus not make-up or carneval make-up which are included in the survey. For the time being, there are thus no environmental criteria under the Flower for the product types defined in this report (toys that can contain preservatives).

3. Survey of the market

3.1 Approach for the survey

The survey of the use of preservatives in toys (which are expected to contain preservatives) on the Danish market is conducted by means of the below elements:

- Search on the internet for toy products which are expected to contain preservatives
- Contact to relevant trade associations
- Contact to relevant knowledge centres, organisations etc.
- Contact to selected distributors, suppliers and producers of toys with an expected content of preservatives
- General information retrieval
- Shopping visits

The companies, trade associations, distributors, suppliers, producers, knowledge centres and other organisations who were contacted in connection with the survey to collect their experience with the use of preservatives in toys can be seen in Table 3 below.

TABLE 3
OVERVIEW OF CONTACTED COMPANIES, ORGANISATIONS ETC. IN CONNECTION WITH THE SURVEY OF PRESERVATIVES IN TOYS

Trade associations	Knowledge centres, organisaton etc.	Distributors, suppliers and producers
• The Nordic Association of toy manufacturers • Legetøjsbranchens Fællesråd (Joint council of the Danish toy sector) • Joint Council of Creative & Hobby Materials (FFFH)	• Danish National Allergy Research Centre • Danish Centre on Endocrine Disrupters • Informationscenter for Miljø og Sundhed (Danish information centre for Environment and Health) • Astma-Allergi Danmark (Asthma-Allergy Denmark) • Danish Consumer Council • Test laboratories	• Top Toy A/S (Toys`R´Us and BR) • Panduro Hobby • Legekæden • Hasbro • VN Legetøj A/S • COOP • Dansk Supermarked • IKEA • Schjerning Farver • Dana Lim A/S

Information from various companies, knowledge centres etc. was supplemented with an information retrieval as well as visits in various shops which sell toys that are expected to contain preservatives. Both fysical shops as well as shops on the internet have been checked for toys. Examples of shops are stated in Table 4. The list of all shops can be found in appendix 1.

TABLE 4
EXAMPLES OF SHOPS AND SHOPS ON THE INTERNET WHICH HAVE BEEN VISITED IN CONNECTION WITH THE SURVEY OF PRESERVATIVES IN TOYS.

Shops	Shops on the internet
• Toys `R´Us • BR Legetøj • Legekæden • Panduro Hobby • Søstrene Grene • Arnold Busck • Bog & Idé • Fest og farver • COOPs butikker • Dansk Supermarkeds butikker	• www.bilka.dk • www.legeakademiet.dk • www.babynature.dk • www.klodsmajor.dk • www.playforlife.dk • www.helsam.dk • www.kidzshop.dk • www.dekohuset.dk • www.Shop-a-toy.dk • www.mulius.com • www.godtlegetoej.dk • www.grafical.dk

3.2 Results from the survey: General information from contact to various organisations etc.

In Table 3 is stated which companies, knowledge centres etc. that have been contacted in connection with the survey of preservatives used in toys with an expected content of preservatives. Below the relevant information which we have received through contact to the various companies/knowledge centres is stated. Only the relevant and non-confidential received information is described. Confidential information received from companies is stated anonymously in the different tables in section 3.3 "Product-specific results from the survey". I.e. companies, trade associations, knowledge centres and other organisations which could not deliver relevant information on preservatives in toys are not described below.

Jeanne Duus Johansen from the Danish National Allergy Research Centre gives a general opinion as they cannot trace their observations on preservatives to be specifically derived from toys. Jeanne Duus Johansen informs that the use of Kathon today is often replaced by the single substance methylisothiazolinone (one of the two substances which form part of Kathon) in concentrations which are problematic with regard to allergy. The Allergy Research Centre gets reports on many cases of allergy to methylisothiazolinone but they have not traced the reason to be derived from toys with content of preservatives.

Ewa Daniel from Asthma-Allergy Denmark which works with risk assessment of cosmetic products mentions that especially methylisothiazolinone and formaldehyde (formaldehyde-releasers) are interesting as many get an allergic reaction to these substances. However, lately a number of allergic reations from airborne methylisothiazolinone have also been demonstrated after having painted with paint with a content of methylisothiazolinone.

3.3 Product-specific results from the survey

The information which was identified and received in the survey has been examined below. As described above, the survey of the market for preservatives in toys with an expected content of preservatives has been undertaken by visiting shops, making internet searches and by taking contact to various companies, distributors, suppliers, producers etc.

The result of this survey is that toys which contain preservatives can be divided into the following eight types of toys:

1. Modelling clay
2. Hobby paint
3. Finger paint
4. Window paint/glass paint
5. Face paint and make-up for children
6. Glue
7. Slime
8. Soap bubbles

Therefore, the results of the survey are divided into these different types of toys.

The category ”hobby paint” covers many forms of paints, e.g. textile paint, glass and window paint, porcelain paint, finger paint, board paint, magnet paint, metal paint, watercolours etc. In this project it is decided to describe window paint/glass paint and finger paint within their respective categories as these special forms of hobby paint have been examined earlier. The remaining types of hobby paints are described as a whole under the name “hobby paint”.

For each one of these types of toys, the toy group is first described generally. After this, examples of specific products within the toy group and which shops/internet shops that sell these products on the Danish market are given in tabular form. Subsequently, possible information from the literature, distributors or producers about content of preservatives in this type of toys is stated.

It should be remarked that the survey does not cover the entire Danish market. There is a large number of different products within the different toy groups. Below is solely stated a selection of the products available on the market.

3.3.1 Modelling clay

Modelling clay is a product type which has been on the market for many years. Several variants of modelling clay have come into the market, e.g. modelling clay which can be rolled thinly and be used as decoration on for instance cups as well as variants which remind of sand. Modelling clay is sold in countless number of colours and is sold either as modelling clay alone or with various tools to form the modelling clay. For instance, modelling clay is sold as pizza and pasta sets, a cake baking set or ice cream set.

In the survey, 17 different brands addressed to children down to one year of age have been identified, but modelling clay has typically the symbol which indicates that it is not advisable to be used by 0-3-year-old children. Within each brand there are many different products. As an example, Toys`R´Us has more than 50 different modelling clay products within the same brand. The price of the modelling clay is identified from 3.77 DKK to 349 DKK in the survey. The price depends on whether it is solely modelling clay which is sold or it is a set with various tools to form and play with the modelling clay.

While being used, modelling clay has direct contact to the children’s hands when they pug and form it. It is likely that it can be ingested in small amounts – especially when some of the modelling clay products are sold with the purpose that they are to be formed as food (cakes, pizza and ice cream).

In Table 5 below is a list of the distributors who were identified as distributors of modelling clay as well as a list with a selection of the different brands of modelling clay which were identified in the survey. Please note, that the table must not be read in such a way that the brand in the same line as the distributor belong together. This is not necessarily the case.

TABLE 5
SURVEY OF THE DANISH MARKET FOR MODELLING CLAY – A SELECTION OF DISTRIBUTORS AND BRANDS

Distributors	Selection of brands
• Panduros Hobby • Toys`R´Us • BR Legetøj • Legekæden • Arnold Busk • Søstrene Grene • www.helsam.dk • www.playforlife.dk • www.lillebi.dk • www.legeakademiet.dk • www.kidzshop.dk • www.dekohuset.dk • www.Grafical.dk • www.legbilligt.dk • www.lirumlarumleg.dk	• "Børneler" from STAEDTLER • My Dough • "Moon Sand" from Spin Master • "Color Kids ler" • "Artkids modellervoks" • "Modeling Clay" from Green Base ApS • "Barbapapa Modellervoks" frpm Petit Jour • "Modellervoks" from Djeco • "Modellervoks Eco" from SES Creative • "Nawaro Soft-Kneading and Modeling Mass" • "Bouncing Putty" from out of the Blue • "Anna og Claras Modellervoks" • "iClay" from AMOS

3.3.1.1 Existing knowledge

No earlier investigations which indicate content of possible preservatives in modelling clay were identified.

3.3.1.2 Examples of use of preservatives

Through contact to the trade association, various information on the content of preservatives in different types of modelling clay (see Table 6 below) was received. A single producer has informed that the variant of modelling clay which is a kind of sand that can be formed does not contain preservatives.

The types of modelling clay which are seen in the shops did not declare the content of preservatives. It is unknown whether it is due to the fact that there are no preservatives in these products. However, some distributors of modelling clay have stated that their modelling clay most likely do not contain preservatives.

In Table 6 below, examples of content of preservatives in modelling clay are stated. These are examples from real products where information on the content of preservatives was received. However, the name of the product and distributor/producer are deliberately left out as several distributors/producers did not want to have this relation published.

TABLE 6
EXAMPLES OF CONTENT OF PRESERVATIVES IN MODELLING CLAY

Product type	Preservative	Concentration
Modelling clay A	*"Most likely it does not contain preservatives"*	
Modelling clay B	2-phenoxyethanol Ethylparaben Propylparaben Butylparaben Dichlorobenzyl alcohol Benzyl alcohol	0.0045% 0.0020% 0.0020% 0.0020% 0.0025% 0.0025%
Modelling clay C	Sodium benzoate	0.1 – 0.3%
Modelling clay D	Sodium benzoate Potassium sorbate	0.1 – 0.3% 0.1 – 0.3%
Sand which can be modelled	*"Does not contain preservatives (it is not necessary)"*	

The examples of content of preservatives in different modelling clays received from the trade association show that not all modelling clay necessarily contains preservatives. The examples also show that a mixture of a large number of different preservatives in modelling clay can occur but also that sodium benzoate alone can preserve modelling clay.

3.3.2 Hobby paint

This product type has a wide assortment and many different variants of hobby paints for children (and adults) exist on the market. Hobby paint can be divided into the following categories like it is done in different shops on the internet:

- Artistic paint
- Watercolours
- School and institution paint
- Textile paint
- Finger paint (described separately in section 3.3.3)
- Glass and window paint (described separately in section 3.3.4)
- Porcelain paint
- Special paint, like metal paint, board paint, magnet paint and similar types of paint

As described in the introduction to this chapter, finger paint and window paint/glass paint are described seperately as these special forms of hobby paint have been examined earlier and thus information on content of preservatives in these forms of hobby paint already exist (see secction 3.3.3 and 3.3.4).

Typically, artistic paint consists of water-based acrylic paint but in this category, oil colours have also been seen. Oil colours do not contain water and most probably it will not be needed to add preservatives to this type of products. However, like the name indicates, artistic paint is more for "professional use" or more targeted at the adult market even if children can of course use the products. For this reason, no focus was on artistic paint in the survey.

Watercolours are small compact coloured blocks which are used with a brush with water on. These watercolours do not contain water but water is added the blocks in small amounts by use. It is unknown if there is a need for preservatives in watercolours. However, a Dutch survey (Voedsel & Autoriteit, 2010) of a few watercolours shows that three out of three watercolours contained preservatives.

The trade association informs that the remaining forms of hobby paint on a whole solely consist of water-based acrylic paint. Thus, use of preservatives will be needed as the paints are water-based.

Hobby paint is sold separately or together with other products, e.g. hobby paint to paint model planes, small plastic pony-dolls etc. A paint set with special light brushes and paint which only emerges on special paper has been observed. Furthermore, products for painting of stickers have been seen. Finally, products with a special spray gun for felt-tip pens which sprays the colour onto paper have also been seen. However, felt-tip pens have not been included in the survey in this project.

The largest assortment of hobby paint for children is found in hobbyshops (both physical and internet shops). The large chains of toy shops have not a large assortment of hobby paint. A lot of hobby paint in the market is not directly addressed to children but it might be assumed that children also use this paint. Hobby paint for children is typically marketed to children above 3 years. In the survey 20 different brands addressed to children are identified. Within some of the brands, many different products are found. The price of hobby paint is identified from 14 DKK to 249 DKK where the most expensive price is a set with different material to paint stickers for children.

When using hobby paint much less skin contact is expected than when using e.g. finger paint as the paint is applied by means of brushes. However, some skin contact might still be expected. It is assessed that consumption of the product is most unlikely.

In Table 7 below is a list of the distributors who were identified as distributors of hobby paint as well as a list with a selection of the different brands of hobby paint which were identified in the survey. Please note, that the table must not be read in such a way that the brand in the same line as the distributor belong together. This is not necessarily the case.

TABLE 7
SURVEY OF THE DANISH MARKET FOR HOBBY PAINT – A SELECTION OF DISTRIBUTORS AND BRANDS

Distributors	Selection of brands
• Panduros Hobby • Toys `R´Us • BR Legetøj • Legekæden • Dansk supermarked • COOP • Schjerning Farver • www.slojd-detaljer.dk • www.playforlife.dk • www.babynature.dk • www.lilleg.dk • www.legeakademiet.dk • www.kidzshop.dk • www.Grafical.dk • www.legbilligt.dk • www.lirumlarumleg.dk • www.eurotoys.dk	• “Farveæske Noris Club” • “Tempera color” • “Flexi color” from Sløjd-detaljer • “Studio Acrylic” from Pebeo • “Tekstilpenne Marvy” from Fluo • ”Male- og keramiksæt” from COLOR KIDS • “Art Acrylic” from Schjerning • “Point Pen” from Schjerning • “Wonder magisk lyspensel” from CRAYOLA Color • “Style Pony” from COLOR KIDS • “Jumbo vandfarver” from Artkids • ”Kreativ æske - Chirp Chirp” from Djeco • “Tube flurocent green” from Art Proff • “Vandbaseret metallic acrylmaling” from A-Color • ”Swirl 'n Spin Art” from Melissa & Doug • “Glimmermalingsæt” from SES Creative • “Maling i glas” from Djeco • “Acryl dækfarve vandbaseret” • ”GELARTI aktivitetspakke” from COLOR KIDS

3.3.2.1 Existing knowledge

In 2008 the Danish EPA has carried out a survey of chemical substances in hobby products for children (Hansen et al., 2008). In this survey, felt-tip pens, glitter glue, acrylic paint and shrink plastic are examined. Chemical analyses show among other things that one acrylic paint contains the preservative 2-phenoxyethanol (identified in 1 of 20 products). The content has not been quantified.

In a product sheet from BASF regarding preservation of paint products is stated that a combination of bronopol and Kathon is highly effective. Tests show that a mixture of 0.006% of bronopol and 0.001% of Kathon is more effective than bronopol alone or Kathon alone in the same concentrations (BASF, 2000). The product sheet is primarily for industrial paints (e.g. wall paint) but contact to the hobby trade association in Denmark shows that this combination of preservative is also used within hobby paints.

In the report "Preservatives and bitter substances in finger paints" (Voedsel & Autoriteit, 2010), 38 different paints (29 finger paints and 9 other types of child paint such as watercolours and acrylic colours) on the Dutch market were examined. In the survey the kind of child paint is not specified. Out of the 9 child paint products:

- Free formaldehyde was measured in 7 of the products
- Kathon was measured in 8 of the products
- A declared content of bronopol was found in 1 of the products
- A declared content of sodium benzoate was found in 1 of the products

Three of the products in the Dutch survey exceeded the limit value for content of Kathon of 0.0015% as stated in EN 71-7 for finger paint.

It is not guaranteed that the child paints which are examined in the Dutch survey are found on the Danish market. However, it is assumed that there is no large difference between the Dutch market and the Danish market in this area. Therefore, the Dutch survey probably illustrates well which preservatives that can occur in child paint.

3.3.2.2 Examples of use of preservatives

In Table 8 the trade association has stated the following content of preservatives in different types of hobby paints.

TABLE 8
EXAMPLES OF CONTENT OF PRESERVATIVES IN HOBBY PAINT

Product type	Preservative	Concentration
Acrylic colour A (A labelled)	1,2-benzisothiazol-3(2H)-one (BIT) Formaldehyde	Approx. 0.045% Approx. 0.087%
Acrylic colour B (A labelled)	1,2-benzisothiazol-3(2H)-one (BIT) 2-phenylethanole Benzyl benzoate	0.012% 0.0035% 0.0015%
Acrylic colour C (A labelled)	Bronopol Kathon (MI/MCI)	Approx. 0.04% < 0.0015%
Glitter colour (A labelled)	1,2-benzisothiazol-3(2H)-one (BIT) Formaldehyde Kathon	Approx. 0.045% Approx. 0.081% Approx. 0.00098%

Product type	Preservative	Concentration
Dutch survey of child paints* (2010)	Free formaldehyde (7 of 9 products contained free formaldehyde when analysed)	Measured: 0.004 – 0.069%
	Kathon (8 of 9 products contained MCI/MI, i.e. Kathon when analysed)	Measured: MCI: 0.0004 – 0.0012% MI: 0.0001 – 0.0151%
	Bronopol	*No information*
	Sodium benzoate	*No information*

* The child paints in question are not specified further in the survey

The examples of content of preservatives in hobby paint received from the trade association show that typically several different types of preservatives are used in the same product and that Kathon, bronopol, BIT and formaldehyde are the most used preservatives in this type of products.

3.3.3 Finger paint

Compared to the other groups of toy product being investigated in this project, finger paint is a product type which is not especially distributed on the Danish market but most large chains of toy stores or hobby shops have one or two variants. Finger paint is sold in several different colours within each brand. In the survey, 10 different brands addressed to children at the age from 1 year and older were identified. Within some of the brands, many different products (colours) were found. As an example Panduro Hobby has approx. 24 different products within this category. In the survey the price of finger paint was identified from 15 DKK to 189 DKK but it depends on the amount of colours which are bought.

Children using finger paint might be smeared into the paint on hands, arms and possibly face as finger paint addresses to children under 3 years. It is assessed that intake of the finger paint can occur but according to standard EN 71-7 finger paint must contain a bitter substance which is to prevent intake of large amounts of finger paint.

I Table 9 below a list of the distributors being identified as distributors of finger paint is stated as well as a list with a selection of the different brands of finger paint being identified in the survey. Please note, that the table must not be read in such a way that the brand in the same line as the distributor belong together. This is not necessarily the case.

As described in section 2.1.3 ”Toys – standards”, it is a requirement according to EN 71-7 that it must appear from the container which preservatives that are in the finger paint. Furthermore, it is only certain preservatives which are allowed in finger paint and the preservatives are only allowed to be used in the concentrations which are stated in the appendices of the standard. The statements marked with ’*’ i Table 9 below are statements which are identified on homepages where the products are sold. Whether the statements are correct has not been examined further.

TABLE 9
SURVEY OF THE DANISH MARKET FOR FINGER PAINT – A SELECTION OF DISTRIBUTORS AND BRANDS

Distributors	Selection of brands
• Panduros Hobby • Toys `R´Us • BR Legetøj • Legekæden • www.helsam.dk • www.playforlife.dk • www.babynature.dk • www.lilleg.dk • www.legeakademiet.dk • www.kidzshop.dk • www.dekohuset.dk • www.Grafical.dk • www.lirumlarumleg.dk	• "Tactil" from Pebeo • "COLOR KIDS fingermaling" • "Finger paint" from Artkids • "Nawaro finger farbe" from ökoNORM • "Peinture à doigts" from Djeco • "ECO – Fingermaling" from SES-Creative* • "Fingermaling" from Schjerning** • "Nawaro finger farbe"

* According to homepage the product contains parabens
** According to homepage the produkt is marketed as "non-toxic and without parabens"

3.3.3.1 Existing knowledge

In the report"Preservatives and bitter substances in finger paints" (Voedsel & Autoriteit, 2010) 38 different paints, including 29 finger paints, on the Dutch market were examined. Out of the 29 finger paints:

- Free formaldehyde was measured in 20 of the products
- A content of parabens was declared in 11 of the products (however, which parabens were not stated)
- MCI/MI (Kathon) was measured in 9 of the products
- A content of bronopol was declared in 9 of the products
- A content of diazolidinyl urea was declared in 4 of the products
- A content of 2-phenoxyethanol was declared in 4 of the products
- A content of dichlorobenzyl alcohol was declared in 1 of the products
- A content of BIT (1,2-benzisothiazol-3(2H)-one) was not identified in any of the products.

Three of the products exceeded the limit value for content of Kathon of 0.0015% as stated in EN 71-7.

3.3.3.2 Examples of use of preservatives

Through contact to the trade association, the below content of preservatives in different types of finger paint was stated. Futhermore, on a few products for instance the statement "does not contain parabens" was found. Finally, information from the Dutch survey of finger paint is included. All this information is stated in Table 10 below.

There is no guarantee that the finger paints examined in the Dutch survey are found on the Danish market. However, it is assumed that within this area there is not much deviation between the Dutch market and the Danish market. Therefore, the survey gives probably a good picture of which preservatives that can occur in finger paint on the Danish market.

TABLE 10
EXAMPLES OF CONTENT OF PRESERVATIVES IN FINGER PAINT

Product type	Preservative	Concentration
Finger paint A	2-phenoxyethanol 2-amino-2-methylpropanol 1,2-benzisothiazol-3(2H)-one (BIT) (however, this constituent is only found in one of the colour variants)	Approx. 0.89% Approx. 0.098% Approx. 0.00018%
Finger paint B (A labelled)	5-chloro-2-methyl-2H-isothiazolone (MCI) Methyl-2H-isothiazol-3-one (MI) 2-phenoxyethanol Bronopol Denatonium benzoate	*No information*
Finger paint C (A labelled)	2-phenoxyethanol Bronopol	*No information*
Finger paint D (A labelled)	2-phenoxyethanol Bronopol	*No information*
Finger paint E	Parabens (which parabens are not specified in details)	*No information*
Finger paint for textiles	Bronopol	*No information*
Dutch survey of finger paint (2010)	Free formaldehyde (20 of 29 products contained free formaldehyde when analysed) Kathon (9 of 29 products contained MCI/MI i.e. Kathon when analysed) Parabens (which parabens are not specified in details) Bronopol Diazolidinyl urea 2-phenoxyethanol Dichlorobenzyl alcohol	Measured: 0.002 – 0.069% Measured: MCI: 0.0004 – 0.0031% MI: 0.0002 – 0.0095% MCI/MI: Up to 0.0095% *No information* *No information* *No information* *No information* *No information r*

Like the Dutch survey of 29 different kinds of finger paints also shows there are variations in the use of preservatives for finger paints. Most finger paints seem to contain parabens, Kathon and bronopol – usually separately, but in the Dutch survey, use of both bronopol and parabens in the same finger paint is seen as well as use of both bronopol and Kathon in the same finger paint. In products on the Danish market, use of parabens (alone), bronopol (alone) and bronopol togher with 2-phenoxyethanol and/or Kathon was seen.

3.3.4 Window paint/glass paint

Toy shops do not typically stock window paint or glass paint but the products can be found in large hobby shops or on the internet (both hobby and toy homepages). Window paint/glass paint is sold in different colours within each brand.

There are different variants of window paint/glass paint. The paint can be used by painting a subject on a sheet of plastic film. When the subject is dry it can be taken off and put on smooth surfaces such as glass and windows. Other variants of window paint/glass paint can be applied directly to the glass with brush/tube. Window paint/glass paint consists like other hobby paint of water-based acrylic paint.

In the survey 6 different brands addressed to children at the age from 3 years and older are identified. Within some of the brands many different products (colours) are found. Most paints for glass are not addressed directly to children. For instance, Panduro Hobby has about 90 different products for paint on glass and porcelain. In the survey, the price of window paint/glass paint was identified from 19.95 DKK to 85.75 DKK.

Window paint/glass paint is typically applied with the tube in which the paint is. Therefore, the skin contact is expected to be short. However, skin contact with the subject will occur when it is dry and it is transferred to glass surfaces. It is assessed that intake of the product is not very likely.

In Table 11 below, a list of the distributors being identified as distributors of window paint/glass paint is stated as well as a list with a selection of the different brands of window paint/glass paint being identified in the survey. Please note, that the table must not be read in such a way that the brand in the same line as the distributor belongs together. This is not necessarily the case.

TABLE 11
SURVEY OF THE DANISH MARKET FOR WINDOW PAINT/GLASS PAINT – A SELECTION OF DISTRIBUTORS AND BRANDS

Distributors	Selection of brands
• Panduros Hobby • Toys `R´Us • Bog&Ide • www.dekohuset.dk • www.Grafical.dk • www.legbilligt.dk • www.lirumlarumleg.dk • www.captoy.dk • www.foliehuset.dk • www.nethobby.dk	• "Vindueskridt" from CRAYOLA • "Window Paint" from Carioca • "Glas Art" from magic world • "Glasmaling" from Schjerning • "Funny Vinduesfarve" from Schjerning • "Vinduesmaling Fun & Fancy "

3.3.4.1 Existing knowledge

In 2004 the Danish EPA has made a survey of chemical substances in window paint on the Danish market (Mikkelsen et al., 2004). The following preservatives were at that time identified (through contact to the trade association) as the most frequent preservatives in window paints:

- Kathon (MI and MCI i the mixture ratio 1:3). An example of content percentages for the two substances of 0.0012% and 0.0004% respectively is stated
- 2-bromo-2-nitropropane-1,3-diol (bronopol)
- Formaldehyde

In Mikkelsen et al. (2004) it is stated that the content of formaldehyde most often comes from impurities in the raw materials or from release from formaldehyde releasers. Furthermore, a chemical analysis of 10 window paints was made. In this chemical analysis the preservatives dimethyloxazolidine and methenamin were found in concentrations between 0.0012 and 0.0075% as well as 0.00012 and 0.0013% respectively. MCI – one of the components in Kathon – was measured in concentrations of 0.00051 to 0.0014%.

This survey of window paints is nearly 10 years old and the market might have changed since then. However, contact to the trade association today shows that the preservatives Kathon and bronopol are still used in window paints which is also seen from the examples below.

3.3.4.2 Examples of use of preservatives

Through contact to the trade association, the below content of preservatives in different types of window paint was stated (see Table 12). In addition to this, information can be found in an earlier survey of window paints from the Danish EPA (2004). The contact to the trade association shows that the preservatives Kathon and bronopol which were identified in the earlier survey are still used in window paint today. However, the other preservatives identified in the earlier survey of window paints are not found in window paint today (based on the received information from the trade association).

TABLE 12
EXAMPLES OF CONTENT OF PRESERVATIVES IN WINDOW PAINTS

Product type	Preservative	Concentration
Window paint A (A labelled)	Kathon (MI/MCI)	*No information*
Window paint B (A labelled)	Kathon (MI/MCI) Bronopol	< 0.0015% Approx. 0.04%
Window paint C (Danish EPA Survey, 2004)	Kathon (MI/MCI) MCI Bronopol Formaldehyde	0.0016% 0.0014% *No information* *No information*

Thus, the examples of content of preservatives in window paints show that it is typically Kathon which is used as preservative, possibly also in combination with bronopol. The survey of the Danish EPA from 2004 shows the same picture – however, formaldehyde was also identified here as well as two other preservatives in two colours. As the survey from the Danish EPA on window paint is nearly 10 years old, the information on the preservatives found in the present survey (2012) is exclusively used.

3.3.5 Face paint and make-up

Face paint covers products like for instance carneval make-up and make-up sets for children. In the survey various glitter products such as glitter gel, i.e. a kind of face paint with glitter, were also found.

Face paint is used to paint children's faces so they look like for instance animals or creatures. Face paint is most often used in institutions or in theme parks like e.g. the Zoo. At Shrovetide and Halloween the use of the products is especially large. Make-up sets are sold to children but also as make-up sets for dolls.

Many different types of face paint are found on the Danish market. For instance, at Shrovetide and Halloween many different products for dressing up as a clown, tiger, witch etc. are sold. Make-up sets for children are not as common as face paint.

In the survey 16 different brands addressed to children at the age from 3 years and older are identified. Within some of the brands many different products are found. In the survey the price of face paint and make-up is identified from 19.95 DKK to 279.95 DKK. The most expensive products are large sets (as an example, suitcases with make-up or face paint with various books for inspiration).

The children can be exposed for a longer period as the face paint/make-up often remains on the skin for several hours. Face paint is expected to cover a larger part of the face than the make-up. For both face paint and make-up there might be a possibility of eating the product if the paint is applied close to the mouth or if lipstick is used.

Face paint and make-up have to be provided with a declaration of contents which states the ingredients in the product as the product type is also subject to the Cosmetic Products Directive. Therefore preservatives used in this product type will appear from the declaration of contents but the concentration has not to be stated. The statements indicated with '*' in Table 13 are statements which are identified on homepages where the products are sold. Whether the statements are indicated correctly according to the Cosmetic Products Directive on the actual products has not been examined as the products have not been examined physically (the products have not been bought).

I Table 13 below, a list of the distributors being identified as distributors of face paint and make-up is stated as well as a list with a selection of the different brands of face paint and make-up being identified in the survey. Please note, that the table must not be read in such a way that the brand in the same line as the distributor belong together. This is not necessarily the case.

TABLE 13
SURVEY OF THE DANISH MARKET FOR FACE PAINT AND MAKE-UP – A SELECTION OF DISTRIBUTORS AND BRANDS

Distributors	Selection of brands
• Panduros Hobby • Toys`R´Us • BR Legetøj • Dansk supermarked • COOP • www.legeakademiet.dk • www.kidzshop.dk • www.legbilligt.dk • www.lirumlarumleg.dk • www.lilleeg.dk www.faraos.dk	• "Glittergel" from Grim tout • "Ansigtsfarver" from Eulenspiegel • "Ansigts- og kropsfarve" from Eulenspiegel • "Sminkestifter" • "Sminkekuffert" from Fashion Girl • "Ansigtsfarve" from Grim tout* • "Ansigtsmaling SES Creative" • "Tynd sort stift" from Grim tout • "Ansigtsmaling" from Cherise • "Face painting make-up" from Rio • "Ansigtssminke blyanter" from Giotto** • "Sminkefarveblyanter" from Lyra*** • "Vandsminke" from Grimas • "Ansigtsfarve Snazaroo"

* According to homepage the product is marketed as "does not contain parabens"
** According to homepage the product is marketed as "tested for allergenic properties"
*** According to homepage the product is marketed as "free of parabens"

3.3.5.1 Existing knowledge

In 2011 Informationscenter for Miljø og Sundhed IMS (Danish information centre for Environment and Health) examined 66 different carneval make-ups for children and found that only four of the products were without problematic substances (Forbrugerkemi.dk, 2011). IMS defines problematic substances as substances which have problematic effects, i.e. substances which are allergenic, have an impact on the environment or are under suspicion of being endocrine disrupting[4]. IMS found parabens ((methyl-, ethyl-, propyl-, butyl- and isobutylparaben) used as preservative in about half the products. On their homepage (www.forbrugerkemi.dk) IMS has stated the full declaration of the products and therefore it has been possible to prepare a list of all of the preservatives which are

[4] http://www.forbrugerkemi.dk/test-og-rad/born/sminke/fastelavnssminke-2011-deklarationstest/uddybende-oplysninger-om-testen

used in the 66 products. In Table 14 below the 10 different preservatives being identified in the list of declaration in 2011 are stated.

In the present survey of this product type, several of the products from IMS' investigation are identified both on the internet and in physical shops today (summer 2012). Therefore it is assumed that this test from IMS is still adequate for this type of products today.

TABLE 14
PRESERVATIVES IDENTIFIED IN CARNEVAL MAKE-UPS IN TEST BY IMS IN 2011

Preservative	Number out of 66 products which contained the preservative
Methylparaben	26
Ethylparaben	18
Propylparaben	13
Butylparaben	13
Isobutylparaben	3
2-phenoxyethanol	17
Sodium benzoate	7
DMDM Hydantoin (formaldehyde releaser)	2
Potassium sorbate	2
Iodopropynyl butylcarbamate (IPBC)	2

3.3.5.2 Exampbles of use of preservatives

By means of IMS' declaration test of face paint in 2011 as well as by looking at the declaration of content of different face paints and make-up products in different shops, the preservatives stated in Table 15 were identified. No companies have delivered information on concentrations of the preservatives in the products.

TABLE 15
EXAMPLES OF CONTENT OF PRESERVATIVES IN FACE PAINT AND MAKE-UP

Product type	Preservative	Concentration
Face paint A	*"The product is without parabens"*	
Face paint B	2-phenoxyethanol	*No information*
Face paint C (A labelled)	Sodium benzoate	*No information*
Face paint D (A labelled)	Polymaniopropyl biguanide	*No information*
Face paint E (A labelled)	2-phenoxyethanol Sodium benzoate	*No information*
Face paint F	Polyaminopropyl biguanide	*No information*
Face paint G (glitter)	2- phenoxyethanol	*No information*

Product type	Preservative	Concentration
From IMS' declaration test of carnival make-up	Methylparaben Ethylparaben Propylparaben Butylparaben Isobutylparaben 2-phenoxyethanol Sodium benzoate DMDM Hydantoin Potassium sorbate Iodopropynyl butylcarbamate (IPBC)	*No information*

The survey shows that parabens, 2-phenoxyethanol and sodium benzoate are the most widespread preservatives in face paint and make-up. 2-phenoxyethanol and sodium benzoate may be used together.

3.3.6 Glue

Glue generally is a very widespread product type and glue which is specifically directed children exists on the market. Hobby glue and glitter glue for children are sold in chains of toy shops as well as in hobby shops. The glues which are either directed to children via marketing or sold in shops with child toys are included in this survey.

The glue can be found in tubes (liquid glue) or in sticks (glue sticks). Furthermore, glitter glue which either has the purpose to glue small pieces of glitter on to various surfaces or to decorate various surfaces can be found. The last type of glitter glue is glue which directly contains glitter, i.e. it is used to decorate various surfaces and has not exactly the purpose to glue things together.

Glue can be bought separately or as a product which is included together with other products, for instance building sets or other kinds of decoration sets for children. A few glues are directly addressed to children – in these cases it is e.g. glues for use in school and glitter glues. On the contrary, many examples of glues being included together with other products are found.

In the survey, more than 30 different glues addressed to children at the age from 3 years and older were identified. Many different products are found within some of the brands. The price of glues only is in the survey identified from 1.38 DKK to 79.95 DKK. For other products containing glues, e.g. building sets or decoration sets, the price will be significantly higher.

In the school age glue is often used by children. When using glue, there will often be skin contact primarily with the fingers. Glue that is plastered to the fingers might be unpleasant for which reason it is assessed that the fingers are washed quicklier after use of glue compared to other product types. Therefore it is assessed that there is no strong probability for intake of the product.

In Table 16 below a list of the distributors being identified as distributors of glues is stated as well as a list with a selection of the different brands of glues being identified in the survey. Please note, that the table must not be read in such a way that the brand in the same line as the distributor belong together. This is not necessarily the case.

TABLE 16
SURVEY OF THE DANISH MARKET FOR GLUE – A SELECTION OF DISTRIBUTORS AND BRANDS

Distributors	Selection of brands
• Panduros Hobby • Toys `R´Us • BR Legetøj • Legekæden • COOP • www.playforlife.dk • www.babynature.dk • www.lilleg.dk • www.legeakademiet.dk • www.kidzshop.dk • www.dekohuset.dk • www.Grafical.dk • www.lirumlarumleg.dk • www.eurotoys.dk	• "Glimmerlim" from Color Kids • "Skolelim" from DanaLim • "Deco Pets" from Hasbro • "Glimmerlim i My little Pony sæt" from Hasbro • "Broderi-sæt til børn Fugl m/lim" from Panduro Design • "Panduro limstift" • "Kids Glue (stift el. flydende)" from Panduro • "Glimmer tegnepen til dekoration på lys" from Marabu • "Glitter Glue" from Amos • "Glitterlim konfetti i tubepenne" • "Glitterstick" from Ranger • "Div. 3D-puslespil" from Revell • "Div. modelsæt" from Ravensburger • "DISNEY PRINCESS BLOpenne m/glimmerlim" from Disney • "Glitterglue" from Carioca Art, • "Top Model makeup malebog m/glimmerlim" from Depesche • "Glitter Tusser" from Djeco • "Papirlim" from ÔkoNORM, • "Hvid skolelim" from UHU • "Byggesæt med mursten m/lim (kit)" from SES • "Glimmerlim sampak" • "Limstift" from Form Line • "SkoleLim" from Dana Lim* • "Børnelim" from SES Creative • "Prinsesse lillefe limstift" from Spiegelburg • "Glue Stick" from Bantex • "Anna & Claras Limstift" • "Limstift" from Dana Lim • "Limstift" from Relief • "Sticky Limstift" • "Limstift" from Tesa

* This glue is A labelled

3.3.6.1 Existing knowledge

In 2008 the Danish EPA has made a survey of chemical substances in hobby products for children (Hansen et al., 2008). In this survey glitter glues were among others examined. A number of performed chemical analyses show that some of the examined glitter glues contain the preservative 2- phenoxyethanol. This preservative was identified in 4 of 11 products. A content of 0.024% was measured in a single product.

Furthermore, in 2003 the Danish EPA made a survey of chemical substances in hobby glue (Nilsson and Jensen, 2003). In this survey 5 selected types of hobby glues were analysed for a content of formaldehyde added as a preservative. Formaldehyde was measured in concentrations of between 0.00021 and 0.16%. Highest concentration was found in a wood glue for outdoor use. In the two analysed school glues as well as a glue stick, the formaldehyde concentration was between 0.00021 and 0.00034%.

3.3.6.2 Examples of use of preservatives

Through contact to the trade association, the below content of preservatives in different types of glue was stated (see Table 17). In addition to this, information can be found in a previous survey of hobby glue from the Danish EPA (2003) as well as in a survey of glitter glue from the Danish EPA (2008).

TABLE 17
EXAMPELS OF CONTENT OF PRESERVATIVES IN GLUES

Product type	Preservative	Concentration
Glue stick A	2-methyl-2H-isothiazol-3-one (MI) Kathon (MI/MCI)	0.00885% 0.0000813%
Glitter glue B	2-phenoxyethanol	0.3 – 0.8%
Glitter glue C	Sodium hydroxymethyl glycinate	0.2 - 0.5%
Glitter glue D	2-phenoxyethanol Methylparaben Ethylparaben Propylparaben Butylparaben Isobutylparaben	*In amounts allowed in cosmetic products*
Glitter glue (Danish EPA survey 2008)	2-phenoxyethanol	Maximum measured concentration was 0.024%
School glue and glue stick (Danish EPA survey 2003)	Formaldehyde	0.00021 – 0.00034%

The survey shows that 2-phenoxyethanol seems to be the most used preservative but also Kathon, parabens and sodium hydroxymethyl glycinate is used. Furthermore, formaldehyde is used in glue according to a previous survey from the Danish EPA (2003).

3.3.7 Slime

Different kinds of slime toys are on the Danish market. Slime is primarily sold in toy shops. Slime is sold alone or together with different figures or animals, e.g. “aliens” or spiders. Slime is a coloured product which is thinner than modelling clay. Some slime is sold e.g. as toilet slime which “farts” when it is pressed down in the enclosed plastic container formed as a toilet.

In the survey 7 different brands addressed to children at the age from 3 years and older were identified. Within some of the brands many different products can be found. Only a few internet shops have slime toys. The price of slime was identified from 3.90 DKK to 399 DKK. The most expensive products are sets for production of slime.

When using slime skin contact is primarily with hands/arms. Oral intake can occur if e.g. the children suck their fingers which have been in contact with the slime.

In Table 18 below a list of the distributors being identified as distributors of slime is stated as well as a list with a selection of the different brands of slimes being identified in the survey. Please note, that the table must not be read in such a way that the brand in the same line as the distributor belong together. This is not necessarily the case.

TABLE 18
SURVEY OF THE DANISH MARKET FOR SLIME – A SELECTION OF DISTRIBUTORS AND BRANDS

Distributors	Selection of brands
• Toys `R´Us • BR Legetøj • Legekæden • Søstrene Grene • www.legeakademiet.dk • www.legbilligt.dk • hoensefoedderog-guleroeder.dk	• "Mystery mates" from Scooby-Doo! • "Ooops Slimy" from JOKER AG/SA • "Slimy Power Light" • "Slim i Toilet" • "Spiderman web attack battle pack" from Spiderman • "Vild videnskab - Eksplosive eksperimenter" (contains slime powder) from Horrible Science • "Atomic Putty - glow in the dark" from Søstrene Grene Import

3.3.7.1 Existing knowledge

In 2006 the Danish EPA has made a survey of slimed toys on the Danish market (Svendsen et al., 2006). This survey includes toys which were rubbery and slimy, i.e. for instance slime balls and "sticky animals". A screening analysis identified a content of boron and sodium in some of the products. The report concludes that this boron can derive from boric acid or sodium borate which is used as preservative and the content of sodium can result from preservatives such as sodium borate or sodium benzoate.

Furthermore, a migration analysis of 20 different slimed products was made. This migration analysis identified the preservatives butylparaben, ethylparaben propylparaben and 2-phenoxyethanol. No quantitative analyses of the content itself in the slimed toys were made.

3.3.7.2 Examples of use of preservatives

Through contact to the trade association the following content of the preservatives in a single type of slime was stated (see Table 19). Furthermore, the information from the previous survey of slimed toys from the Danish EPA (2006) is stated.

TABLE 19
EXAMPLES OF CONTENT OF PRESERVATIVES IN SLIME

Product type	Preservative	Concentration
Slime A	Methylparaben Propylparaben Sodium benzoate Preventol D7 (is a mixture of isothiazolinones)	0.002% 0.002% 0.002% 0.0025%
Slimed toys (Danish EPA survey, 2006)	Butylparaben Ethylparaben Propylparaben 2-phenoxyethanol	*No information*

Not much information on preservatives in slime was received from the trade association in this survey. But the information from a single product shows the use of parabens as a preservative which the survey from the Danish EPA from 2006 also showed. In addition to this, it seems that sodium benzoate, isothiazolinones and 2-phenoxyethanol can also be used as a preservative in slime.

3.3.8 Soap bubbles

Soap bubbles are a product which is found in many various variants. It is sold in containers with different prints on – e.g. princesses, cars and super heroes. Soap bubbles are sold as the liquid alone or as a package with different tools to blow soap bubbles. The tools can be "manual", i.e. you can blow your own soap bubbles or they can be automatic, e.g. a gun making soap bubbles. As something new, guns changing the soap bubble liquid into foam are sold – with the purpose to have a "foam fight" in the garden. These foam guns are in the toy shops physically placed besides the other soap bubble products for which reason it is assumed that the used liquid is soap bubble liquid.

Soap bubbles are a product which is primarily used in the summer period but can also be used indoor all year. However, the foam guns are seasonal and are primarily used in the summer.

In the survey 18 different brands addressed to children at the age from 3 years and older were identified. Many different products are found within some of the brands. The price of soap bubbles was identified from 4.79 DKK to 179 DKK. The most expensive products contain various "tools" to blow soap bubbles.

When using soap bubbles skin contact will occur, especially with the hands but also on the rest of the body when the soap bubbles burst on the body. There might be a small oral intake in cases when the user blows the soap bubbles himself. On the other hand there might be skin contact with nearly the whole body by use of the foam guns where the purpose is to shoot with soap bubble foam on each other.

In Table 20 below a list of the distributors being identified as distributors of soap bubbles is stated as well as a list with a selection of the different brands of soap bubbles being identified in the survey. Please note, that the table must not be read in such a way that the brand in the same line as the distributor belong together. This is not necessarily the case.

TABLE 20
SURVEY OF THE DANISH MARKET FOR SOAP BUBBLES – A SELECTION OF DISTRIBUTORS AND BRANDS

Distributors	Selection of brands
• Panduros Hobby • Toys `R´Us • BR Legetøj • Legekæden • Buddy Legetøj • Dansk supermarked • COOP • Arnold Busk • Søstrene grene • www.legeakademiet.dk • www.kidzshop.dk • www.legbilligt.dk • www.lirumlarumleg.dk • www.denlillebazar.dk, www.harald-nyborg.dk	• Hello Kitty • "Peter Plys Sæbebobler" from Disney • "Bubbles" from Bobble • "Buzz Lightyear" from Toy Story • "Cars boblepistol" from Disney (Simba) • "Askepot sæbeboblesæt" from Gazillion • "Bubble Science" from Go Science • "Bubble Robot" from Kidz Labs • "Sæbeboble Squeeze" • "Pustefix" from Seifenblasen • "Sæbebobler" from Rice • "Sæbeboble refill" from Rainbow Bobbles • "Mega Bubbles" (sword) from 4 Kids • "Pirat sæbebobler" from Seifenblasen • "Sæbeboble koncentrat" from Pegani • "Sea lite Bubbles" from Out of the blue • "Marvel Super Hero Bubbles" • "Gaz-zuds Foam-I-Nator" from Gazillion

3.3.8.1 Existing knowledge

No surveys of the content of preservatives in soap bubbles were identified.

3.3.8.2 Examples of use of preservatives

Through contact to the trade association the below content of preservatives in different types of soap bubble liquid (see Table 21) was stated.

TABLE 21
EXAMPLES OF CONTENT OF PRESERVATIVES IN SOAP BUBBLES

Product type	Preservative	Concentration
Soap bubbles A	Methylisothiazolinone (MI)	*No information*
Soap bubbles B	DMDM Hydantoin 2-phenoxyethanol	0.3034% 0.6896%
Soap bubbles C	Formaldehyde (Measured free formaldehyde. Derives most probably from formaldehyde releasers)	0.0025%
Foam gun D	2-phenoxyethanol Methylparaben Ethylparaben Propylparaben Butylparaben	0.005% 0.001% 0.001% 0.001% 0.001%

The survey shows that soap bubble can contain different types of preservatives. 2-phenoxyethanol seems to be the most widespread (solely based on the little information which is received from the industry).

3.3.9 Summery: Which preservatives are used in toys?

In this section it is summed up which preservatives that in this survey have been observed in the different groups of toys with an expected content of preservatives. The summary is stated in the table below (see Table 22) and covers both information received from the trade association as well as information from existing surveys (literature). However, information from surveys which are about 10 years old is not stated in the table below. It is the highest concentrations that are stated.

TABLE 22
IDENTIFIED PRESERVATIVES FOR THE DIFFERENT PRODUCT TYPES

Product type	Preservative	Highest concentraton
Modelling clay	2- phenoxyethanol Parabens (ethyl-, propyl- and butyl-) Dichlorbenzyl alcohol Benzyl alcohol Sodium benzoate Potassium sorbate	0.0045% 0.0020% 0.0025% 0.0025% 0.3% 0.3%
Hobby paint	Formaldehyde Kathon (MI/MCI) 1,2-benzisothiazol-3(2H)-one (BIT) 2-phenylethanol Benzyl benzoate Bronopol Sodium benzoate	0.087% < 0.0015% 0.0045% 0.0035% 0.0015% Approx. 0.04% *No information*
Finger paint	2-phenoxyethanol	Approx. 0.89%

Product type	Preservative	Highest concentraton
	2-amino-2-methylpropanol 1,2-benzisothiazol-3(2H)-one MCI MI Kathon (a mixture of the two above) Bronopol Denatonium benzoate Parabens (which ones are not stated) Diazolidinylureum Dichlorbenzyl alcohol Free formaldehyde	Approx. 0.098% Approx. 0.00018% 0.0031% 0.0095% 0.0095% *No information* *No information* *No information* *No information* *No information* 0.069%
Window paint/ Glass paint	Kathon Bronopol	< 0.0015% Approx. 0.04%
Face paint and make-up	2-phenoxyethanol Sodium benzoate Polymaniopropyl biguanide Parabens (methyl-, ethyl-, propyl-, butyl- and isobutyl-) DMDM Hydantoin Potassium sorbate Iodopropynyl butylcarbamate (IPBC)	*No information* *No information* *No information* *No information* *No information* *No information* *No information*
Glue	2-methyl-2H-isothiazol-3-on (MI) Kathon (MI/MCI) 2-phenoxyethanol Sodium hydroxymethyl glycinate Parabens (methyl-, ethyl-, propyl-, butyl- and isobutyl-) Formaldehyde	0.00885% 0.0000813% 0.8% 0.5% Approx. 0.4% 0.00034%
Slime	Methylparaben Ethylparaben Parabens (propyl- and butyl-) Sodium benzoate Preventol D7 (is a mixture of isothiazolinones) 2-phenoxyethanol	0.002% 0.002% *No information* 0.002% 0.0025% *No information*
Soap bubbles	Methylisothiazolinon (MI) DMDM Hydantoin 2-phenoxyethanol Free formaldehyde Parabens (methyl-, ethyl-, propyl- and butyl-)	*No information* 0.3034% 0.6896% 0.0025% 0.001%

4. Hazard assessment (screening) of the preservatives

A hazard assessment of the preservatives identified in the survey has been performed on a screening level. The purpose has been to be able to focus the chemical analysis on the most important preservatives. The hazard assessment contains therefore no in depth descriptions of each preservative, but only keywords. The hazard assessment has been based on a search in the following lists, reports and databases:

- ECHAs Classification & Inventory Database (C&L Inventory Database)[5]
- Opinions made by the EU Scientific Committee on Consumer Safety (SCCS)[6], that contain informaton about potential sensitising properties and other health effects
- The EU list of potential endocrine disruptors (cateogry 1 substances)[7]
- The List of undesirable substances from the Danish EPA (LOUS)[8]

The C&L Inventory Database from ECHA is a list of the classifications which the industry has notified to ECHA. The classifications are therefore not necessarily harmonised, but most often the classifications that the industry itself has given the substance. The C&L Inventory states the classifications that have been received from companies as well as the number of companies that have given the specific classification for the substances. There is always more than one classification in the database – most often 10-20 different classifications of the substance. Therefore the C&L Database does not give an unequivocal classification of the substances, but gives an idea of which classifications the industry believes that the substances should be classified with. Harmonised classifications are also listed in the database. For each of the preservatives identified in this survey, the classifications from the C&L Iventory Database are given. For each substance a list of the classifications notified by the different companies is given. If the substance has a harmonised classification this has been noted with italic and bold text. However, in these cases both the harmonised classification and other classifications notified by the industry are given.

The EU Scientific Committee on Consumer Safety (SCCS) prepares different opinions of different substances. The health effects from these opinions have been shortly summarised for the different preservatives in the sections below.

If the preservatives are on the EU list of potential endocrine disruptors as a category 1 substance, it has been noticed in the text below. A category 1 substance is substances for which endocrine activity have been documented in at least one study of a living organism. These substances are given the highest priority for further studies in the EU.

[5] http://echa.europa.eu/information-on-chemicals/cl-inventory-database
[6] http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm
[7] http://www.mst.dk/Virksomhed_og_myndighed/Kemikalier/Fokus+paa+saerlige+stoffer/Hormonforstyrrende+stoffer/eu_liste_hormonforstyrrende_stoffer/
[8] http://www.mst.dk/Virksomhed_og_myndighed/Kemikalier/Stoflister+og+databaser/listen_over_uoenskede_stoffer/

Finally it is stated if the different preservatives are on the List of undesirable substances from the Danish EPA (LOUS). LOUS is a list of substances/groups of substances that the Danish EPA regards as having problematic effects and/or are used in large amounts in Denmark. The substances on the list are in the longer run requested to be phased out or limited in their use.

4.1 Parabens

The effects of the parabens have been described in several opinions from SCCS. The health effects that are described as common for all parabens are initially described in this section. Health effects specific for the individual parabens are described in the section for the specific paraben.

All parabens are regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration of one paraben is 0.4% (as acid) and 0.8% (as acid) for a mixture of several parabens. According to a special Danish regulation (BEK 166, 2011) it is no longer allowed to use propylparaben, butylparaben, isopropylparaben or isobutylparaben in cosmetic products for children under 3 years in Denmark. This statutory order entered into force March 15, 2011.

Several opions from SCCS are made on the parabens (e.g. SCCS/1348/10, 2011; SCCP/1183/08, 2008; SCCP/1017/06, 2006; SCCP/0873/05, 2005). The newest opinion focuses, however, mostly on the endocrine disrupting properties of the parabens. According to SCCP/0873/05 the parabens are in general practically non-toxic, not carcinogenic, not genotoxic or not teratogenic, but according to SCCS/1348/10 all parabens show estrogenic activity *in vivo* and *in vitro*. The potency of the estrogenic activity is increased with increasing chain length. I.e. methylparaben is the less potent of the parabens and butylparaben the most potent of the parabens. Parabens are normally not regarded as being sensitising as very few people in Denmark are allergic to parabens[9].

4.1.1 Methylparaben (CAS 99-76-3)

Methylparaben is on the EU list of potential endocrine disruptors as a category 1 substance. Methylparaben has not a harmonised classification. Classification according to ECHAs C&L Inventory Database is given in the box below.

Classification according to ECHAs C&L Inventory

Skin Irrit. 2, H315 – Causes skin irritation
Eye Irrit. 2, H319 – Causes serious eye irritation
STOT SE, H335 – May cause respiratory irritation
Muta. 2, H341 – Suspected of causing genetic defects
Skin Sens 1, H317 – May cause an allergic skin reaction
Acute Tox 4, H302 – Harmful if swallowed
Aquatic Chronic 3, H412 – Harmful to aquatic life with long lasting effects

SCCS is of the opinion that methylparaben can be safely used up to the concentrations of maximum 0.4% (the existing limit for one single paraben in cosmetics), (SCCP/0873/05, 2005).

[9] http://www.videncenterforallergi.dk/allergi-konserveringsmidler-kosmetik-hyppighed.html

4.1.2 Ethylparaben (CAS 120-47-8)

Ethylparaben is on the EU list of potential endocrine disruptors as a category 1 substance. Ethylparaben has not a harmonised classification. Classification according to ECHAs C&L Inventory Database is given in the box below.

Classification according to ECHAs C&L Inventory

Skin Irrit. 2, H315 – Causes skin irritation
Eye Irrit. 2, H319 – Causes serious eye irritation
STOT SE, H335 – May cause respiratory irritation
Asp. Tox 1, H304 – May be fatal if swallowed and enters airways
Skin Sens. 1, H317 – May cause an allergic skin reaction
Acute Tox 4, H302 – Harmful if swallowed
Resp. Sens. 1, H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled

SCCS is of the opinion that ethylparaben can be safely used up to the concentrations of maximum 0.4% (the existing limit for one single paraben in cosmetics), (SCCP/0873/05, 2005).

4.1.3 Propylparaben (CAS 94-13-3)

Propylparaben is on the EU list of potential endocrine disruptors as a category 1 substance and is also on the List of undesirable substances (LOUS) from the Danish EPA. As previously described it is no longer allowed to use propylparaben in cosmetic products for children under 3 years in Denmark (BEK 166, 2011).

Propylparaben does not have a harmonised classification. Classification according to ECHAs C&L Inventory Database is given in the box below.

Classification according to ECHAs C&L Inventory

Skin Irrit. 2, H315 – Causes skin irritation
Eye Irrit. 2, H319 – Causes serious eye irritation
STOT SE, H335 – May cause respiratory irritation
STOT SE, H336 – May cause drowsiness or dizziness
Skin Sens. 1, H317 – May cause an allergic skin reaction
Aquatic Acute 1, H400 – Very toxic to aquatic life

Propylparaben is today allowed in a concentration of 0.4% (as acid) in cosmetic products (see Table 1). However, according to the latest SCCS opinion from 2011 this concentration should be reduced to 0.14% (as acid) in cosmetic products in order to be considered as safe to the consumer (SCCS/1348/10, 2011).

4.1.4 Butylparaben (CAS 94-26-8)

Butylparaben is on the EU list of potential endocrine disruptors as a category 1 substance and is also on the List of undesirable substances (LOUS) from the Danish EPA. As previously described it is no

longer allowed to use butylparaben in cosmetic products for children under 3 years in Denmark (BEK 166, 2011).

Butylparaben does not have a harmonised classification. Classification according to ECHAs C&L Inventory Database is given in the box below.

Classification according to ECHAs C&L Inventory

Skin Irrit. 2, H315 – Causes skin irritation
Eye Irrit. 2, H319 – Causes serious eye irritation
STOT SE, H335 – May cause respiratory irritation
Eye Dam. 1, H318 – Causes serious eye damage
Skin Sens. 1, H317 – May cause an allergic skin reaction
Aquatic Chronic 4, H413 – May cause long lasting harmful effects to aquatic life

Butylparaben is today allowed in a concentration of 0.4% (as acid) in cosmetic products (see Table 1). However, according to the latest SCCS opinion from 2011 this concentration should be reduced to 0.14% (as acid) in cosmetic products in order to be considered as safe to the consumer (SCCS/1348/10, 2011).

4.1.5 Isobutylparaben (CAS 4247-02-3)

Isobutylparaben does not have a harmonised classification. Classification according to ECHAs C&L Inventory Database is given in the box below. As previously described it is no longer allowed to use isobutylparaben in cosmetic products for children under 3 years in Denmark (BEK 166, 2011).

Classification according to ECHAs C&L Inventory

Eye Dam. 1, H318 – Causes serious eye damage
Aquatic Chronic 1, H400 – Very toxic to aquatic life
Skin Irrit. 2, H315 – Causes skin irritation
STOT SE, H335 – May cause respiratory irritation

4.2 2-phenoxyethanol (CAS 122-99-6)

A harmonised classification exists for 2-phenoxyethanol. This harmonised classification is listed in bold and italic below, but other classifications listed in ECHAs C&L Inventory Database are also listed in the box below.

2-phenoxyethanol is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration of 2-phenoxyethanol is 1.0%.

Classification according to ECHAs C&L Inventory

Aqute Tox. 4, H302 – Harmful if swallowed
Eye Irrit. 2, H319 – Causes serious eye irritation
Muta. 2, H341 – Suspected of causing genetic defects
Carc. 2, H351 – Suspected of causing cancer
Skin Irrit. 2, H315 – Causes skin irritation
STOT SE, H335 – May cause respiratory irritation

An older SCCS opinion exists on 2-phenoxyethanol (SCC 6th series, 1987). According to this opinion 2-phenoxyethanol is not skin irritating or skin sensitising. SCCS concludes that the available information suggests that 2-phenoxyethanol is relatively harmless. However, SCCS states that it is necessary to obtain information on genotoxicity and teratogenicity.

4.3 Sodium benzoate (CAS 532-32-1)

No harmonised classification exists for sodium benzoate. Classifications according to ECHAs C&L Inventory Database are listed in the box below.

Sodium benzoate is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration is 0.5% (calculated as benzoic acid) in products that are not rinsed off. In products for oral hygiene a concentration of 1.7% is allowed (calculated as benzoic acid) and in rinse-off products a concentration of 2.5% is allowed (calculated as benzoic acid).

Classification according to ECHAs C&L Inventory

Eye Dam. 1, H318 – Causes serious eye damage
Skin Sens. 1, H317 – May cause an allergic skin reaction
Skin Irrit. 2, H315 – Causes skin irritation
Acute Tox. 4, H302 – Harmful if swallowed

An SCCS opinion exists on sodium benzoate (SCCP/0891/05, 2005). According to this opinion sodium benzoate is not skin irritating and does not appear to be sensitising even though a few cases of positive reactions in human patch test have been observed. Sodium benzoate is not considered to be genotoxic, teratogenic or carcinogenic. SCCS is of the opinion that sodium benzoate is safe for use in cosmetic products in concentrations up to 2.5% in rinse-off products and up to 1.7% in oral-care products and in concentrations up to 0.5% in leave-on products.

4.4 DMDM Hydantoin (CAS 6440-58-0)

DMDM Hydantoin is a so-called formaldehyde releaser, which means that the substance can release formaldehyde. Formaldehyde is classified as carcinogenic in category 2 and is allergenic.

No harmonised classification exists for DMDM Hydantoin. Classifications according to ECHAs C&L Inventory Database are listed in the box below.

DMDM Hydantoin is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration of DMDM Hydantoin is 0.6%.

Classification according to ECHAs C&L Inventory

Acute Tox. 3, H301, H311, H331 – Toxic if swallowed, in contact with skin and if inhaled
Eye Irrit. 2, H319 – Causes serious eye irritation
Resp. Sens. 1, H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Skin Sens. 1, H317 – May cause an allergic skin reaction
Skin Corr. 1B, H314 – Causes severe skin burns and eye damage
STOT SE, H335 – May cause respiratory irritation
Muta. 2, H340 – May cause genetic defects
Carc. 2, H351 – Suspected of causing cancer
Aquatic Chronic 3, H412 – Harmful to aquatic life with long lasting effects

There is no SCCS opinon on DMDM Hydantoin.

4.5 Potassium sorbate (CAS 24634-61-5/590-00-1)

No harmonised classification exists for potassium sorbate. Classifications according to ECHAs C&L Inventory Database are listed in the box below.

Potasium sorbate is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration of potassium sorbate is 0.6% (calculated as acid)[10].

Classification according to ECHAs C&L Inventory

Acute Tox. 4, H302 – Harmful if swallowed
Eye Irrit. 2A, H319 – Causes serious eye irritation
Skin Corr. 1A, H314 – Causes severe skin burns and eye damage
STOT SE, H335 – May cause respiratory irritation

There is no SCCS opinion on potassium sorbate.

4.6 Iodopropynyl butylcarbamat (IPBC) (CAS 55406-53-6)

No harmonised classification exists for IPBC. Classifications according to ECHAs C&L Inventory Database are listed in the box below.

IPBC is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration of IPBC is 0.01%

[10] Corrected from: "*Potasium sorbate is not regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). This means that the substance is not allowed as preservative in cosmetic products.*" (Survey of chemical substances in consumer products no. 124, 2014).

in leave-on products (except in deodorants/antiperspirants, where the highest permitted concentration is 0.0075%). In rinse-off products the highest permitted concentration of IPBC is 0.02%. Furthermore, IPBC is not to be used in oral hygiene and lip care products or in products for children under the age of 3 (except in bath products/shower gels and shampoo). Finally, IPBC is not allowed to be used in body lotion and body cream.

Classification according to ECHAs C&L Inventory

Acute Tox. 3, H302, H331, H332 – Harmful if swallowed, toxic/harmful if inhaled
Eye Dam. 1, H318 – Causes serious eye damage
Skin Sens. 1, H317 – May cause an allergic skin reaction
STOT SE 3, H335 – May cause respiratory irritation
Aquatic Acute 1, H400 – Very toxic to aquatic life
Aquatic Chronic 1, H410 – Very toxic to aquatic life with long lasting effects

SCCS opinions exist on IPBC. IPBC is moderately acutely toxic if swallowed, but has a low dermal acute toxicity. IPBC is mildly to moderately irritating to the skin, but can give severe eye damage. However, in concentrations of 0.5% no eye irritation was noted. IPBC has shown no signs of being sensitising. IPBC shows no signs of being mutagenic or teratogenic (SCC 9th series, 2000). SCCS is of the opinion that IPBC is safe to use in cosmetic products in concentrations up to 0.05%, and that IPBC should not be used in products for oral hygiene or in lip products (SCCNFP/91, 1999).

4.7 Bronopol (CAS 52-51-7)

Bronopol (also called 2-bromo-2-nitropropane-1,3-diol) is a so-called formaldehyde releaser, which means that the substance can release formaldehyde. Formaldehyde is classified as carcinogenic in category 2 and is allergenic.

A harmonised classification exists for bronopol. This harmonised classification is listed in bold and italic below, but other classifications listed in ECHAs C&L Inventory Database are also listed in the box.

Bronopol is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration of bronopol is 0.1%.

Classification according to ECHAs C&L Inventory

Acute Tox. 4, H302, H312 – Harmful if swallowed and in contact with skin
Skin Irrit. 2, H315 – Causes skin irritation
Eye Dam. 1, H318 – Causes serious eye damage
STOT SE 1, H335 – May cause respiratory irritation
Aquatic Acute 1, H400 – Very toxic to aquatic life
Self-react. C, H242 – Heating may cause a fire
Acute Tox. 3, H331 – Toxic if inhaled
Flam. Sol. 2, H228 – Flammable solid

An older SCCS opinion exists on bronopol. According to this SCCS opinion bronopol has a moderate to high acute toxicity. Bronopol is irritating for skin and highly irritating to the eyes. Allergic reactions have been observed in human patch tests. Bronopol does not appear to be teratogenic. SCCS concludes that bronopol is safe to use in cosmetic products in a maxmimum concentration of 0.2% (SCC 6th series, 1987).

4.8 1,2-benzisothiazol-3(2H)-on (BIT) (CAS 2634-33-5)

A harmonised classification exists for BIT. This harmonised classification is listed in bold and italic below, but other classifications listed in ECHAs C&L Inventory Database are also listed in the box below.

BIT is not regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). This means that the substance is not allowed as preservative in cosmetic products.

Classification according to ECHAs C&L Inventory

Acute Tox. 4, H302, H312 – Harmful if swallowed and in contact with skin
Skin Irrit. 2, H315 – Causes skin irritation
Skin Sens. 1, H317 – May cause an allergic skin reaction
Eye Dam. 1, H318 – Causes serious eye damage
Aquatic Acute 1, H400 – Very toxic to aquatic life
Aquatic Chronic 1, H410 – Very toxic to aquatic life with long lasting effects
Acute Tox 3, H301 – Toxic if swallowed

An SCCS opinion exists on BIT (SCCS/1482/12, 2012). According to this opinon BIT is moderately irritating to the skin and can cause severe eye damage. BIT has a low acute toxicity. BIT is not mutagenic or clastogenic (*in vivo*), but has been found to be clastogenic *in vitro*, but the study was found to be inadequate. There is no information on the carcinogenic properties of BIT. BIT appears to be sensitising (moderate sensitiser), and SCCS expresses concern about the sensitising properties of the substance when used in cosmetic products, as BIT in concentrations of 0.01% can cause contact allergy in the consumer. SCCS recommends that the incidence of contact allergy to BIT is monitored, as there is no information on what may be safe levels of exposure to BIT in cosmetic products from the point of view of sensitisation. SCCS concludes that until safe levels of exposure have been established, the use of BIT in cosmetic products as a preservative or for other functions cannot be considered safe in relation to sensitisation.

4.9 Kathon (CAS 55965-84-9)

MI and MCI are ingredients in Kathon in the ratio 1:3. A harmonised classification exists for Kathon. This harmonised classification is listed in bold and italic below, but other classifications listed in ECHAs C&L Inventory Database are also listed in the box below.

Kathon is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I “List of preservatives allowed” the highest permitted concentration of Kathon is 0.0015% (of a mixture of MI and MCI in the ratio 1:3).

Classification according to ECHAs C&L Inventory

Acute Tox. 3, H301, H311, H331 – Toxic if swallowed, in contact with skin and if inhaled
Skin Corr. 1B, H314 - Causes severe skin burns and eye damage
Skin Sens. 1, H317 – May cause an allergic skin reaction
Aquatic Acute 1, H400 - Very toxic to aquatic life
Aquatic Chronic 1, H410 - Very toxic to aquatic life with long lasting effects
Eye Dam 1, H318 – Causes serious eye damage
Acute Tox. 2, H330 – Fatal if inhaled
Met. Corr. 1, H290 – May be corrosive to metals

An SCCS opinion exists on Kathon (SCCS/1238/09, 2009). According to this Kathon is corrosive and irritating in high concentrations, however, skin irritation is not a problem under the conditions of use in cosmetic products. Kathon is regarded as an extreme sensitiser. Contact allergy to Kathon remains high today, even though the maximum permitted concentration limit has been lowered to 0.0015%. Kathon does not appear to be mutagenic (even though data are equivocal) or carcinogenic. SCCS is of the opinion that Kathon (despite of inadequate testing) has a low general toxicity, and that it is the sensitising properties which are the biggest problem for Kathon. SCCS is of the opinion that Kathon is safe to use in rinse-off products in a maximal concentration of 0.0015% - except for its sensitising potential. However, the EU Scientific Committee on Health and Environmental Risks (SCHER) is of the opinion that Kathon, MI or MCI should not be used in toys because of their sensitising properties. (SCHER, 2007).

4.9.1 2-methyl-2H-isothiazol-3-one (MI) (CAS 2682-20-4)

MI is an ingredient in Kathon and is used in a concentration in the ratio 1:3 together with MCI in Kathon. MI is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration of Kathon is 0.0015% (of a mixture of MI and MCI in the ratio 1:3).

No harmonised classification exists for MI. Classifications according to ECHAs C&L Inventory Database are listed in the box below.

Classification according to ECHAs C&L Inventory

Acute Tox. 3, H301, H311, H331 – Toxic if swallowed, in contact with skin and if inhaled
Skin Corr. 1B, H314 - Causes severe skin burns and eye damage
Skin Sens. 1, H317 – May cause an allergic skin reaction
Eye Dam 1, H318 – Causes serious eye damage
STOT SE 1, H335 – May cause respiratory irritation
STOT SE 1, H373 – May cause damage to organs through prolonged or repeated exposure
Aquatic Acute 1, H400 - Very toxic to aquatic life
Aquatic Chronic 1, H410 - Very toxic to aquatic life with long lasting effects

There is no SCCS opinion only on MI, but an opinion exists for the mixture Kathon as described above. In this SCCS opinion on Kathon, it is stated that MCI is a significantly more potent allergen compared to MI. The EU Scientific Committee on Health and Environmental Risks (SCHER) is of the opinion that Kathon, MI or MCI should not be used in toys because of their sensitising properties. (SCHER, 2007).

4.9.2 5-chloro-2-methyl-2H-isothizol-3-one (MCI) (CAS 26172-55-4)

MCI is an ingredient in Kathon and is used in a concentration in the ratio 3:1 together with MI in Kathon. MCI is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration of Kathon is 0.0015% (of a mixture of MI and MCI in the ratio 1:3).

No harmonised classification exists for MCI. Classifications according to ECHAs C&L Inventory Database are listed in the box below.

Classification according to ECHAs C&L Inventory

Acute Tox. 2, H300, H330 – Fatal if swallowed and if inhaled
Skin Corr. 1B, H314 - Causes severe skin burns and eye damage
Skin Sens. 1, H317 – May cause an allergic skin reaction
Eye Dam 1, H318 – Causes serious eye damage
STOT SE 1, H335 – May cause respiratory irritation
Flam. Liq. 3, H226 – Flammable liquid and vapour
Aquatic Acute 1, H400 - Very toxic to aquatic life
Aquatic Chronic 1, H410 - Very toxic to aquatic life with long lasting effects

There is no SCCS opinion only on MI, but an opinion exists for the mixture Kathon as described above. In this SCCS opinion on Kathon, it is stated that MCI is a significantly more potent allergen compared to MI. the EU Scientific Committee on Health and Environmental Risks (SCHER) is of the opinion that Kathon, MI or MCI should not be used in toys because of their sensitising properties. (SCHER, 2007).

4.10 Dichlorobenzyl alcohol (CAS 1777-82-8)

No harmonised classification exists for dichlorobenzyl alcohol. Classifications according to ECHAs C&L Inventory Database are listed in the box below.

Dichlorobenzyl alcohol is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration is 0.15%.

Classification according to ECHAs C&L Inventory

Skin Irrit. 2, H315 – Causes skin irritation
Eye Dam 1, H318 – Causes serious eye damage
STOT SE 1, H335 – May cause respiratory irritation
Acute Tox. 4, H302, H312 – Harmful if swallowed and in contact with skin
Aquatic Chronic 3, H412 – Harmful to aquatic life with long lasting effects

An SCCS opinion exists on dichlorobenzyl alcohol (SCCNFP/0604/02, 2003). According to this dichlorobenzyl alcohol has a low acute oral toxicity. Dichlorbenzyl alcohol is irritating to skin in high concentrations. However, skin irritation is not a problem under the conditions of use in cosmetic products. Dichlorobenzyl alcohol does not seem to be sensitising or teratogenic. Data is lacking regarding the carcinogenic properties of the substance, and the genetoxic/mutagenic studies are inadequate. Based on this SCCS is of the opinion that the information submitted is insufficient to allow an adequate risk assessment of the substance to be carried out.

4.11 Benzyl alcohol (CAS 100-51-6)

Benzyl alcohol is listed on the List of undesirable substances from the Danish EPA, as benzyl alcohol is one of the 26 perfuming agents that must be listed on the product declaration. Benzyl alcohol is regarded as being allergenic. A harmonised classification exists for benzyl alcohol. This harmonised classification is listed in bold and italic below, but other classifications listed in ECHAs C&L Inventory Database are also listed in the box below.

Benzyl alcohol is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration of benzyl alcohol is 1%.

Classification according to ECHAs C&L Inventory

Acute Tox. 4, H302, H332 – Harmful if swallowed and if inhaled
Eye Irr. 2, H319 – Causes serious eye irritation
Acute Tox. 4, H312 – Harmful in contact with skin
Eye Dam. 1, H318 – Causes serious eye damage

An older SCCS opinion exists on benzyl alcohol, but the information is limited (SCC 6th series, 1987). According to this opinion benzyl alcohol is irritating to skin in high concentrations and acutely toxic if swallowed.

4.12 Formaldehyde (CAS 50-00-0)

Formaldehyde is on the List of undesirable substances from the Dansih EPA. A harmonised classification exists for formaldehyde. This harmonised classification is listed in bold and italic below, but other classifications listed in ECHAs C&L Inventory Database are also listed in the box below.

Formaldehyde is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration of formaldehyde is 0.2% (expressed as free formaldehyde) and 0.1% in oral hygiene products. Formaldehyde is prohibited in aerosol dispensers (sprays). Furthermore, all finished products containing formaldehyde or substances in the annex which release formaldehyde must be labelled with the warning "contains formaldehyde" where the concentration of formaldehyde in the finished product exceeds 0.05%.

Classification according to ECHAs C&L Inventory

Acute Tox. 3, H301, H311, H331 – Toxic if swallowed, in contact with skin and if inhaled
Skin Corr. 1B, H314 - Causes severe skin burns and eye damage
Skin Sens. 1, H317 - May cause an allergic skin reaction
Carc. 2, H351 - Suspected of causing cancer
STOT SE 3, H335 – May cause respiratory irritation
Eye Dam. 1, H318 – Causes serious eye damage
Resp. Sens. 1, H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

An older SCCS opinion on formaldehyde exists (SCC 5th series, 1987). According to his opinion formaldehyde is a severe eye irritant and a moderate skin irritant. Formaldehyde is regarded as being a strong sensitiser. Formaldehyde has a high acute oral and dermal toxicity. Formaldehyde is not considered to be teratogenic, but is mutagenic. In the older opinion the data on the carcinogenic properties of formaldehyde are regarded as being insufficient, but formaldehyde is today suspected of being carcinogenic (classified with Carc. 2).

4.13 2-phenylethanol (CAS 60-12-8)

No harmonised classification exists for 2-pheylethanol. Classifications according to ECHAs C&L Inventory Database are listed in the box below.

2-phenylethanol is not regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). This means that the substance is not allowed as preservative in cosmetic products.

Classification according to ECHAs C&L Inventory

Eye Dam. 1, H318 – Causes serious eye damage
Acute Tox. 3, H302, H311, H312 – Harmful if swallowed, toxic/harmful in contact with skin
Skin Irrit. 2, H315 – Causes skin irritation
Skin Sens. 1, H317 – May cause an allergic skin reaction
STOT SE 3, H335 – May cause respiratory irritation
STOT RE 2, H373 – May cause damage to organs through prolonged or repeated exposure

There is no SCCS opinion on 2-phenylethanol.

4.14 Benzyl benzoate (CAS 120-51-4)

Benzyl benzoate is on the List of undesirable substances from the Danish EPA, as benzyl benzoate is one of the 26 perfuming agents that must be listed on the product declaration. Benzyl benzoate is regarded as being allergenic. A harmonised classification exists for benzyl benzoate. This harmonised classification is listed in bold and italic below, but other classifications listed in ECHAs C&L Inventory Database are also listed in the box below.

Benzyl benzoate is not on the list of permitted preservatives in the Cosmetic Products Directive (Directive 76/768/EEC, 1976). However, the substance is regulated and permitted as perfuming agent in cosmetic products.

Classification according to ECHAs C&L Inventory

Acute Tox. 4, H302 – Harmful if swallowed
Aquatic Chronic 2, H411 – Toxic to aquatic life with long lasting effects
Skin Sens. 1, H317 – May cause an allergic skin reaction
Acute Tox. 4, H332 – Harmful if inhaled

There is no SCCS opinion on benzyl benzoate.

4.15 2-amino-2-methylpropanol (CAS 124-68-5)

A harmonised classification exists for 2-amino-2-methylpropanol. This harmonised classification is listed in bold and italic below, but other classifications listed in ECHAs C&L Inventory Database are also listed in the box below.

2-amino-2-methylpropanol is not regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). This means that the substance is not allowed as preservative in cosmetic products.

Classification according to ECHAs C&L Inventory

Skin Irrit. 2, H315 – Causes skin irritation
Eye Irrit. 2, H319 – Causes serious eye irritation
Aquatic Chronic 3, H412 – Harmful to aquatic life with long lasting effects
Aquatic Chronic 1, H410 - Very toxic to aquatic life with long lasting effects
Eye Dam. 1, H318 – Causes serious eye damage

There is no SCCS opinion on 2-amino-2-methylpropanol.

4.16 Denatonium benzoate (CAS 3734-33-6)

No harmonised classification exists for denatonium benzoate. Classifications according to ECHAs C&L Inventory Database are listed in the box below.

Deantonium benzoate is not regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). This means that the substance is not allowed as preservative in cosmetic products.

Classification according to ECHAs C&L Inventory

Eye Dam. 1, H318 – Causes serious eye damage
Acute Tox. 4, H302, H332 – Harmful if swallowed and if inhaled
Skin Irrit. 2, H315 – Causes skin irritation
Skin Sens. 1, H317 – May cause an allergic skin reaction
STOT SE 3, H335 – May cause respiratory irritation
Aquatic Chronic 3, H412 – Harmful to aquatic life with long lasting effects

There is no SCCS opinion on denatonium benzoate.

4.17 Diazolidinylureum (CAS 78491-02-8)

Diazolidinylureum is a so-called formaldehyde releaser, which means that the substance can release formaldehyde. Formaldehyde is classified as carcinogenic in category 2 and is allergenic.

No harmonised classification exists for diazolidinylureum. Classifications according to ECHAs C&L Inventory Database are listed in the box below.

Diazolidinylureum is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration is 0.5%.

Classification according to ECHAs C&L Inventory

Skin Sens. 1, H317 – May cause an allergic skin reaction
Skin Irrit. 2, H315 – Causes skin irritation
Eye Dam. 1, H318 – Causes serious eye damage
STOT SE 3, H335 – May cause respiratory irritation
Aquatic Chronic 3, H412 – Harmful to aquatic life with long lasting effects

There is no SCCS opinion on diazolidinylureum.

4.18 Polyaminopropyl biguanide (CAS 32289-58-0 / 70170-61-5 / 133029-32-0 / 28757-47-3)

No harmonised classification exists for polyaminopropyl biguanide. Classifications according to ECHAs C&L Inventory Database are listed in the box below.

Polyaminopropyl biguanide is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration is 0.3%.

Classification according to ECHAs C&L Inventory

Skin Irrit. 2, H315, H319 – Causes skin irritation and serious eye irritation
Skin Sens. 1, H317 – May cause an allergic skin reaction
Acute Tox. 4, H302 – Harmful if swallowed
Eye Dam. 1, H318 – Causes serious eye damage
STOT SE 3, H335 – May cause respiratory irritation
Aquatic Chronic 1, H410 – Very toxic to aquatic life with long lasting effects

There is no SCCS opinion on polyaminopropyl biguanide.

4.19 Sodium hydroxymethyl glycinate (CAS 70161-44-3)

No harmonised classification exists for sodium hydroxylmethyl glycinate. Classifications according to ECHAs C&L Inventory Database are listed in the box below.

Sodium hydroxymethyl glycinate is regulated by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I "List of preservatives allowed" the highest permitted concentration of sodium hydroxymethyl glycinate is 0.5%.

Classification according to ECHAs C&L Inventory

Skin Irrit. 2, H319 – Causes serious eye irritation
Skin Sens. 1, H317 – May cause an allergic skin reaction
Acute Tox. 4, H302 – Harmful if swallowed

There is no SCCS opinion on sodium hydroxymethylglycinate.

4.20 Selection of preservatives

The hazard assessment of the identified preservatives was used to select the preservatives which in this project were to be in focus in the analyses of selected toys with an expected content of preservatives.

According to the hazard assessement it is the below preservatives (see Table 23) which are the most interesting, solely based on their health effects. The preservatives stated in Table 23 are either on the EU list of potential endocrine disruptors, the list of undesirable substances from the Danish EPA or have other concerning health properties such as being classified by the industry for being allergenic or as suspected carcinogenic or mutagenic substances.

The survey in chapter 3 has shown that some preservatives are more frequently used than others (at least in the products where information has been received in this project). Table 24 shows the preservatives which were used the most based on information which was received in connection with this survey.

By comparing the most interesting preservatives based on their health effects as well as how often they were identified in this survey, it has thus been possible to work out a list of preservatives which

have been in focus in the analyses in this project (i.e. preservatives on both lists). In Table 25 is stated the preservatives which were selected for the chemical analyses.

A last element which, however, is also important in relation to the selection of relevant preservatives for the chemical analyses is to assess which of the eight toy product groups being focused on in this project that are the most interesting in relation to children's exposure to the preservatives which might occur in the products. Therefore, exposure scenarios for the eight selected toy groups are described more closely in the next chapter.

TABLE 23
THE MOST INTERESTING PRESERVATIVES FROM THEIR CLASSIFICATION AND HEALTH EFFECTS

Preservative	Remark
Methylparaben	The EU list of potential endocrine disruptors, Classification ECHA C&L Inventory: Muta. 2, Skin Sens. 1
Ethylparaben	The EU list of potential endocrine disruptors, Classification ECHA C&L Inventory: Skin Sens. 1
Propylparaben	LOUS, The EU list of potential endocrine disruptors, Classification ECHA C&L Inventory: Skin Sens. 1
Butylparaben	LOUS, The EU list of potential endocrine disruptors, Classification ECHA C&L Inventory: Skin Sens. 1
2-phenoxyethanol	Harmonised classification: Aqute Tox. 4, Classification ECHA C&L Inventory: Muta. 2, Carc. 2
DMDM Hydantoin	Classification ECHA C&L Inventory: Skin Sens. 1, Muta. 2, Carc. 2
BIT	Classification ECHA C&L Inventory: Skin Sens. 1, Aqute Tox. 4
MI	Classification ECHA C&L Inventory: Skin Sens. 1, Aqute Tox. 3
MCI	Classification ECHA C&L Inventory: Skin Sens. 1, Aqute Tox. 2
Kathon	Harmonised classification: Skin Sens. 1, Aqute Tox. 3
Benzyl alcohol	LOUS (perfuming agent that must be declared), Harmonised classification: Acute Tox 4.
Formaldehyde	Harmonised classification; Carc. 2, Skin Sens. 1, LOUS
2-phenylethanol	Classification ECHA C&L Inventory: Skin Sens. 1, Acute Tox. 3
Benzyl benzoate	LOUS (perfuming agent that must be declared), Harmonised classification: Acute tox. 4, Classification ECHA C&L Inventory: Skin Sens. 1
Denatonium benzoate	Classification ECHA C&L Inventory: Skin Sens. 1, Acute Tox. 4
Diazolidinyureum	Classification ECHA C&L Inventory: Skin Sens. 1
Polyaminopropyl biguanide	Classification ECHA C&L Inventory: Skin Sens. 1, Acute Tox. 4
Sodium hydroxymethylglycinat	Classification ECHA C&L Inventory: Skin Sens. 1, Acute Tox. 4

TABLE 24
THE MOST FREQUENTLY USED PRESERVATIVES (ON THE BASIS OF THE SURVEY)

The most frequently used preservatives (based on results from the survey)	**The less frequently used preservatives** (base don results from the survey)
Methylparaben	Isobutylparaben
Ethylparaben	Potassium sorbat
Propylparaben	Iodopropynyl butylcarbamate (IPBC)
Butylparaben	Benzyl alcohol
2-phenoxyethanol	Phenylethyl alcohol
Sodium benzoate	Benzyl benzoate
DMDM Hydantoin	Aminomethyl propanol
Methylisothiazolinone (MI)	Denatonium benzoate
Methylchloroisothiazolinone (MCI)	Diazolidinylureum
Kathon (mixture of MCI and MI)	Polyaminopropyl biguanid
Bronopol	Sodium hydroxymethylglycinate
Benzisothiazolinone (BIT)	Dichlorbenzyl alcohol
Formaldehyde	

TABLE 25
PRESERVATIVES WHICH WERE SELECTED FOR THE ANALYSES

Preservative
Methylparaben
Ethylparaben
Propylparaben
Butylparaben
2-phenoxyethanol
Sodium benzoate
Bronopol
Methylisothiazolinone (MI)
Methylchloroisothiazolinone (MCI)
Kathon (a mixture of MCI and MI)
Benzisothiazolinone (BIT)
Formaldehyde
DMDM Hydantoin – *could however not be analysed for which reason this preservative was not selected (see chapter* 6*)*

5. Exposure scenarios

As described in the survey the focus in this project has been on the following eight types of toys that are expected to contain preservatives:

1. Modelling clay
2. Hobby paint
3. Finger paint
4. Window paint/glass paint
5. Face paint and make-up for children
6. Glue
7. Slime
8. Soap bubbles

How large the exposure of the preservatives in the products will be depends on among other things the following parameters:

- The route of exposure (how the consumers are exposed to the preservatives)
- The duration of the exposure
- The frequency of the exposure
- The amount of product used/swallowed
- The amount of preservatives in the products
- Accessible fraction of the preservatives (i.e. the fraction that is in contact with the skin or is migrating out of the products)
- Body weight
- Absorption of the substance

These parameters are more closely described below and summarised in Table 26.

As basis for the exposure scenarios children at the age of 3 years have been selected as most of the investigated toy products are addressed to children from the age of 3 years. However, modelling clay and finger paint can be used by children down to the age of 1 year for which reason exposure scenarios for children both at the age of 1 year and 3 years are made.

The exposure from the preservatives in the toys will primarily take place through skin contact – primarily for hands but for certain types of paint also face and arms might also be exposed and for face paint there might be an exposure of the whole face. For soap bubbles skin contact will primarily take place through the hands but if the soap bubbles are used in connection with the so-called "foam guns" the whole body can be exposed. For some products the fact is that a small oral in-take of the product can occur if the children suck on their fingers after use of the products or if they lick their lips while the face has been painted with face paint or make-up.

5.1 Formulas of calculation

The exposure of the children is calculated according to the below formulas dependent on if it is a dermal exposure or oral intake – and dependent on if it is products which are for skin application (finger paint, face paint/make-up, hobby paint, window paint/glass paint, glue and soap bubbles) or more solid products where an exposure for the preservatives exclusively takes place if they migrate out of the product (i.e. for modelling clay and slime). Formulas for the following scenarios are stated:

- Dermal exposure for a substance with skin application
- Dermal exposure for a substance migrating from a product
- Oral exposure if the substance is swallowed

5.1.1 Dermal exposure for a substance with skin application

According to the REACH guidance on consumer exposure (ECHA R.15, 2012) the dermal exposure for a substance that is applicated on the skin can be calculated by the equation below (equation R.15-4). In this calculation an amount of liquid product applicated on the skin is assumed and thereby potentially can be absorbed through the skin. It is thus assumed that the entire amount applicated on the skin is potentially absorbed through the skin.

$$D_{der} = \frac{Q_{prod} \times Fc_{prod} \times n \times 1000}{BW}$$

where

D_{der}	The dermal dose. I.e. the amount of substance that can potentially be taken up per kg bw. Later is accounted for the actual dermal rate of absorption of the substance.	mg/kg bw/day
Q_{prod}	Amount of product used	g
Fc_{prod}	Weight fraction of substance in the product before dilution	-
n	Mean number of events per day	/day
BW	Body weight	kg

5.1.2 Dermal exposure for a substance migrating from a product

The equation is different for modelling clay and slime as these products are not directly applicated on the skin. In these cases there will only be an exposure if the substances are migrating from the product. According to the REACH guidance on consumer exposure (ECAH R.15, 2012), the dermal exposure for a substance migrating from a product can be calculated by the equation listed below (a combination of equation R.15-7 and R.15-8. The surface area of the exposed skin ends up being irrelevant for the equation (is left out of the equation).

$$D_{der} = \frac{Q_{prod} \times Fc_{prod} \times Fc_{migr} \times F_{contact} \times T_{contact} \times 1000 \times A_{skin} \times n}{A_{skin} \times BW}$$

$$= \frac{Q_{prod} \times Fc_{prod} \times Fc_{migr} \times F_{contact} \times T_{contact} \times n \times 1000}{BW}$$

where

D_{der}	The dermal dose. I.e. the amount of substance that can potentially be taken up per kg bw. Later is accounted for the actual dermal rate of absorption of the substance.	mg/kg bw/day
Q_{prod}	Amount of product used	g
Fc_{prod}	Weight fraction of substance in the product before dilution	-
Fc_{migr}	Rate fraction of a substance migrating to skin per unit time	g/g
$F_{contact}$	Fraction of contact area for skin to account for the fact that the product is only partially in contact with the skin (default = 1)	cm^2/cm^2
$T_{contact}$	Contact duration between the product and the skin	days
A_{skin}	Area of contact between the product and the skin	cm^2
n	Mean number of events per day	/day
BW	Body weight	kg

As stated in the equation the skin area which is exposed by use of the products will be irrelevant (is left out of the formula). The exposure is only a question of how large an amount of the toy products which is used each time and how large a part of this that ends on the skin.

5.1.3 Oral exposure if the substance is swallowed

Children can unintentionally swallow small amounts of the products. For example the face paint that is painted close to the mouth or the modelling clay shaped as a cake. According to the REACH guidance on consumer exposure (ECHA R.15, 2012) the oral intake of a substance being swallowed can be calculated by the following equation (R.15-11):

$$D_{oral} = \frac{Q_{prod\ ingestion} \times Fc_{prod} \times n \times 1000}{BW}$$

where

D_{oral}	Intake per day and body weight	mg/kg bw/day
$Q_{prod\ ingestion}$	Amount of product being swallowed	g
Fc_{prod}	Weight fraction of substance in the product	-
n	Mean number of events per day	/day
BW	Body weight	kg

5.2 Clarification of relevant exposure parameters

In the text below the different relevant exposure parameters are explained. Data for the exposure parameters are found with background in the recommendations in the report from the Nordic Exposure Group for Health (NEGh). In the report ”Existing Default Values and Recommendations for Exposure Assessment” (Norden, 2011) NEGh has examined standard values for exposure calculations used in among others REACH (the EU) as well as outside the EU. The purpose of the report was to harmonise the use of standard values with the intension to use them in e.g. exposure assessments in REACH. Therefore, the basis in this report has been the NEGh’s recommendations and not the standard values which are stated in REACH. Another reason to use the values in the report from NEGh is that they are much more detailed than the data in REACH and have among other things specific data for body weight for children in different ages where REACH has only these data for adults.

5.2.1 Amount of product used (Q_{prod})

For the product types paint, make-up, glue and soap bubbles the total amount of preservatives in the products will also be the amount of preservatives which the children are exposed to as it is assumed that the character of the product means that 100% of the preservatives will be accessible for dermal absorption. For modelling clay and slime which both are much more solid the question is how large an amount of preservatives which in fact migrates out of the product and which the skin is thus exposed to when children play with the products. These amounts are found at the migration analyses.

In their report the Nordic Exposure Group for Health (NEGh) states the below default amounts which are used each time the products are used (Norden, 2011). The values for make-up are based on the report ”Children’s Toys Fact Sheet” (RIVM, 2002).

- Modelling clay: 350 g
- Finger paint: 20 g (here it is assumed that all the finger paint which is used each time ends on the skin and is accessible for dermal absorption)
- Make-up: lipstick 0.03 g, eye-shadow 0.03 g and rouge 0.3 g, i.e. in total 0.36 g
- Face paint: 1.4 g

For the other product types, no corresponding values are stated for which reason assumptions have been made in this report:

- Paint (window paint/glass paint and hobby paint): here it is assumed that the same amount is used as for finger paint, i.e. 20 g each time but it will not be all the used paint that will end on the skin and be accessible for dermal absorption as the paint is applied with a paint brush or tube. Therefore it is assumed that 20% of the used paint will end on the skin, i.e. in total 4 g.
- Glue: there will be a difference whether it is use of glue stick or liquid glue. Here worst case is assumed, i.e. use of liquid glue. Here it is assumed that the same amount as for finger paint is used, i.e. 20 g each time. Correspondingly it will not be all the used glue which will end on the skin and be accessible for dermal absorption as the glue is added with the tub/tube. Therefore it is assumed that 20% of the used glue will end on the skin, i.e. in total 4 g.
- Slime: here it is assumed that the same amount is used as for modelling clay, i.e. 350 g each time.
- Soap bubbles: here is assumed that a tub of soap bubble liquid is used each time (especially if the liquid is used in a soap bubble gun, larger amounts can be used), i.e. 60 ml or 60 g. If using soap bubble liquid in a soap bubble gun in order to have a foam fight (as a realistic worst case) it might be possible that all of the 60 g of soap bubble liquid end on the skin. By more "normal" use of the soap bubble liquid to blow soap bubbles the skin contact with the soap bubble liquid will be considerably less. As a realistic worst case it is, however, calculated to 60 g.

5.2.1.1 Specially for oral exposure ($Q_{prod\ ingestion}$)

For some products a smaller oral intake of the product can occur if the children suck on their fingers after use of the products or if they lick their lips while the face is painted with face paint or make-up. However, for some products the possibility of oral intake is larger than for others. It is assumed that an oral intake can occur for the following products:

- Modelling clay – here is sold e.g. sets for making cakes or ice creams of modelling clay
- Slime – as the fingers can be smeared with slime
- Finger paint – as the fingers are smeared with the paint
- Face paint/make-up – as intake can occur if the children lick their lips
- Soap bubbles – as the soap bubbles are blown with the mouth

For hobby paint, window paint and glue it is assumed that no oral intake of importance will occur.

In the report from NEGh (Norden, 2011) the following values for oral intake are stated – either as direct intake (modelling clay) or as intake via hand to mouth:

- Modelling clay: In the report it is estimated that children ingest 1 g of modelling clay each time.
- Finger paint: In the report it is estimated that children ingest 30 mg/minute, i.e. 1.35 each time when finger paint is used for 45 minutes (as described later in section 5.2.4)
- Face paint: In the report it is estimated that 15% of the 1.4 g which is used each time (described above in section 5.2.1) will be ingested each time, i.e. in total 0.21 g each time.

These values are directly used as oral intake in the calculations for the different categories of toys. However, no values for oral intake of make-up, slime or soap bubbles exist and therefore these values have been estimated. The following assumptions are made for the remaining product types:

- Make-up: As it is assumed in the report from NEGh for face paint, the same assumption that 15% of make-up is ingested is used here. I.e. it is estimated that children ingest 15% of the make-up which is used each time, i.e. 15% of 0.36 g = 0.054 g (the 0.36 g is described above in section 5.2.1).
- Slime and soap bubbles: It is estimated that the same amount as for modelling clay is ingested, i.e. 1 g each time.

For comparison, in the new toy safety directive – for setting of the migration limits for the metals – the following amounts, which children ingest daily as a maximum, have been used (RIVM, 2008):

- 8 mg from scraped off toy material
- 400 mg from liquid or sticky toy material
- 100 mg from dried, brittle, powder-like or pliable toy material

In the assessment of the preservatives it is thus worst case values when in total the following values are used:

- Liquid or viscous toy material: 1.35 g (finger paint) + 1 g (slime and soap bubbles) = 2.35 g. I.e. in total an amount which is 5.9 times higher as the one being used for the setting of the migration limits in the toy safety directive.
- Dried, brittle, powder-like or pliable toy material: 1 g (modelling clay) + 0.21 g (face paint) + 0.054 g (make-up) = 1.264 g. I.e in total an amount which is 12 times higher than the one being used for the setting of the migration limits in the toy safety directive.

5.2.2 Weight fraction of substance in the product (Fc_{prod})

Weight fraction of the substance in the product will be a result of the chemical analyses made in this project. The amount of the preservatives in the products are found through quantitative analyses or through information received from the industry.

5.2.3 Migration rate of substance in the product (Fc_{migr})

For slime and modelling clay where migration analyses have been made, the result of the migration analyses is equal to the weight fraction Fc_{prod} multiplied with the migration rate.

5.2.4 Contact duration ($T_{contact}$) and frequency (n) of exposure

For how long time and how often the children will be exposed to the preservatives will of course be dependent of how long time and how often they play with the different types of toys. However, for face paint/make-up it might be a considerably longer time of exposure as these products stay on the skin for many hours during a day.

As basis the recommendations from NEGh are used. In this report (Norden, 2011) is stated that children use:

- Finger paint 45 minutes each time 100 times a year.
- Face paint 480 minutes each time 12 times a year.
- Modelling clay 60 minutes each time 52 times a year.

In the report from NEGh no duration of exposure for other of the investigated products in this project is stated. Therefore the following frequencies and durations of exposure for the remaining products are assumed:

- Frequency and duration of exposure for hobby paint and window paint/glass paint is assumed to be the same as for finger paint – i.e. 45 minutes each time 100 times a year.
- Frequency and duration of exposure for glue and slime is assumed to be the same as for finger paint – i.e. 45 minutes each time 100 times a year.
- Frequency and duration of exposure for make-up is assumed to be the same as for face paint, i.e. 480 minutes each time 12 times a year.
- Frequency and duration of exposure for soap bubbles is assumed to be 45 minutes each time 20 times a year as the use of this product is primarily assessed to be seasonal.

5.2.5 Body weight (BW)

As a value for the weight of a 1-year-old and a 3-year-old child the weight is chosen which is recommended by NEGh who has compared different values for children's weight in both Europe (among others REACH) and the USA. NEGh recommends use of the American values which are the most detailed despite that the Americans often have a higher weight than the Europeans.

From the NEGh report it is seen that children at the age of 1 year to < 2 years have an average weight of 11.4 kg with a 5% percentile of 8.9 kg and a 95% percentile of 14.0 kg (Norden, 2011). As the target group of this project (for the products finger paint and modelling clay) is children of the age of 1 year (and no specific body weight for 1-year-old children is stated) the 5% percentile value is chosen as 1 year lies in the lowest part of the value for the 1 - < 2-year-old children.

Correspondingly it is seen that children at the age of 3 years to < 6 years have an average weight of 18.6 kg with a 5% percentile of 13.5 kg and a 95% percentile of 26.2 kg (Norden, 2011). As the target group of this project is children at the age of 3 years (and no specific body weight for 3-year-old children is stated) the 5% percentile value is chosen as 3 years lies in the lowest part of the value for the 3 - < 6-year-old children.

5.3 Summary of data relevant for the migration analyses and exposure calculations

In the tables below is stated the parameters which are relevant in connection with the execution of migration analyses and exposure calculations. Values relevant for dermal exposure are stated as well as values for oral exposure in Table 26 and Table 27 respectively.

TABLE 26
OVERVIEW OF RELEVANT PARAMETERS FOR EXPOSURE CALCULATIONS FOR DERMAL EXPOSURE (SOURCE: NORDEN, 2011)

Product type	Amount available (Q_{prod})	Migration (Fc_{prod} x Fc_{migr})	Duration ($T_{contact}$) and frequency of the exposure (n)	Body weight (BW)
Modelling clay	350 g	Content and migration to sweat are measured at the analyses	**Contact time 60 minutes per day 52 times a year** Analysis for 60 minutes	1-year-old: 8.9 kg 3-year-old: 13.5 kg
Hobby paint	4 g	Irrelevant	**Contact time 45 minutes per day 100 times a year**	3-year-old: 13.5 kg
Finger paint	20 g	Irrelevant	**Contact time 45 minutes per day 100 times a year**	1-year-old: 8.9 kg 3-year-old: 13.5 kg
Window paint/glass paint	4 g	Irrelevant	**Contact time 45 minutes per day 100 times a year**	3-year-old: 13.5 kg
Face paint	1.4 g	Irrelevant	**Contact time 480 minutes per day 12 times a year**	3-year-old: 13.5 kg
Make-up	0.36 g	Irrelevant	**Contact time 480 minutes per day 12 times a year**	3-year-old: 13.5 kg

Product type	Amount available (Q_{prod})	Migration (Fc_{prod} x Fc_{migr})	Duration ($T_{contact}$) and frequency of the exposure (n)	Body weight (BW)
Glue	4 g	Irrelevant	**Contact time 45 minutes per day 100 times a year**	3-year-old: 13.5 kg
Slime	350 g	Content and migration to sweat are measured at the analyses	**Contact time 45 minutes per day 100 times a year** Analysis for 45 minutes	3-year-old: 13.5 kg
Soap bubbles	60 g	Irrelevant	**Contact time 45 minutes per day 20 times a year**	3-year-old: 13.5 kg

TABLE 27
OVERVIEW OF RELEVANT PARAMETERS FOR EXPOSURE CALCULATIONS FOR ORAL EXPOSURE (SOURCE: NORDEN, 2011)

Product type	Amount ingested (Q_{prod})	Weight fraction (Fc_{prod})	Duration and frequency of the exposure (n)	Body weight (BW)
Modelling clay	1 g	Content identified in survey or at analysis	**Contact time 60 minutes per day 52 times a year** Analyse for 60 minutes	1-year-old: 8.9 kg 3-year-old: 13.5 kg
Hobby paint	No ingestion			
Finger paint	1.35 g	Content identified in survey or at analysis	**Contact time 45 minutes per day 100 times a year**	1-year-old: 8.9 kg 3-year-old: 13.5 kg
Window paint/glass paint	Nothing			
Face paint	0.21 g	Content identified in survey or at analysis	**Contact time 480 minutes per day 12 times a year**	3-year-old: 13.5 kg
Make-up	0.054 g	Content identified in survey or at	**Contact time 480 minutes per day 12**	3-year-old: 13.5 kg

Product type	Amount ingested (Q_{prod})	Weight fraction (Fc_{prod})	Duration and frequency of the exposure (n)	Body weight (BW)
		analysis	**times a year**	
Glue	No ingestion			
Slime	1 g	Content identified in survey or at analysis	**Contact time 45 minutes per day 100 times a year** Analyse for 45 minutes	3-year-old: 13.5 kg
Soap bubbles	1 g	Content identified in survey or at analysis	**Contact time 45 minutes per day 20 times a year**	3-year-old: 13.5 kg

6. Selection of preservatives and products for analysis

The selection of preservatives and products for analysis was based on the following aspects:

- Focus on preservatives which are in products with skin contact
- Focus on preservatives which according to the survey are most frequently used
- Focus on preservatives which according to the hazard assessment (screening) have the most serious health properties

The exposure scenarios in chapter 5 have shown that the dermal exposure for the preservatives depends on a combination of the concentration of the preservatives in the products, the amount of product being used as well as frequency of exposure. For modelling clay and slime which cannot be directly "smeared" onto the skin, the exposure highly depends on whether the preservatives migrate out of the product at use.

The most interesting preservatives seen from their classification and health effects are stated in Table 23. The preservatives which based on the survey seem to be frequently used are stated in Table 24. When these two tables are compared it results in the conclusion that focus ought to be on the following preservatives:

- Parabens (in general)
- Methylisothiazolinone (MI), methylchloroisothiazolinone (MCI), Kathon (MCI and MI)
- Benzisothiazolinone (BIT)
- 2-phenoxyethanol
- Sodium benzoate
- Bronopol
- Formaldehyde (free)
- DMDM Hydantoin (however, it was not analysed)

Unfortunately, it was not possible in this project to find an analysis method for DMDM Hydantoin and therefore this was not analysed. However, DMDM Hydantoin was indirectly analysed as this preservative is a formaldehyde releaser[11] and there was analysed for content of free formaldehyde. On the other hand, dehydroacetic acid[12] and potassium sorbate can be analysed by the same method as 2-phenoxyethanol, bronopol and sodium benzoate. Therefore, these two preservatives were a part of the analysis package.

With a focus on these preservatives in total 11 pieces of toys were analysed for the above preservatives. This procedure was chosen as from the start it is not possible to know which preservatives that are a part of which toy – however, with the exception of finger paint and face paint/make-up where the preservatives in the product must appear from the packaging.

[11] Ifølge http://www.videncenterforallergi.dk/ordbog-alle.html
[12] Konserveringsmiddel med CAS 520-45-6

In co-operation with the Danish EPA, it was decided that these 11 pieces of toy were to include:

- 2 soap bubble products
- 2 face paints
- 2 slime products
- 3 modelling clay products (one of the chosen was a modelling clay which can bounce, i.e. be used as a bouncy ball)
- 1 glitter gel
- 1 paint product (for painting of own stickers)

The products were chosen in co-operatin with the Danish EPA based on the following purchase strategy:

1. Products from different producers were purchased
2. Both cheap and expensive products were purchased
3. A labelled products were also purchased
4. Only products were purchased where information on the constituents and their concentrations was not already provided through the survey

7. Analysis of selected products

Selected products were analysed quantitatively for content of specific preservatives. On the basis of the quantitative analyses of the content, two products were selected for an additional migration analysis. Background, methods and analyse results for both the quantitative analyses and the migration analyses are described in this chapter.

7.1 Quantitative analyses

11 products were selected for quantitative analysis for content of the following preservatives:

- Parabens (methylparaben, ethylparaben, propylparaben, butylparaben, isopropylparaben, isobutylparaben and phenylparaben)
- Isothiazolinones (methylisothiazolinone (MI), methylchloroisothiazolinone (MCI), Kathon (MCI and MI) and benzisothiazolinone (BIT))
- 2-phenoxyethanol
- Sodium benzoate
- Bronopol
- Dehydroacetic acid (is analysed by the same analysis method as 2-phenoxyethanol, sodium benzoate and bronopol, and is therefore included for “free”)
- Potassium sorbate (is analysed by the same analysis method as 2-phenoxyethanol, sodium benzoate and bronopol, and is therefore included for “free”)
- Formaldehyde (free formaldehyde)

The 11 products which were selected were:

- 1 paint product (for painting of own stickers) – is named ”1-Stick” below
- 2 slime products – are named ”2-Slime” and ”3-Slime” below
- 3 modelling clays (one of the chosen was a modelling clay which can bounce, i.e. be used a bouncy ball) – are named ”4-MClay”, ”5-MClay” and ”6-MClay” below
- 1 glitter gel – is named ”7-Gel” below
- 2 soap bubble products – are named ”8-SoapB” and ”9-SoapB” below
- 2 face paints – are named ”10-MakeUp” and ”11-MakeUp” below

7.1.1 Analysis method: Quantitative analyses

The preservatives are analysed quantitatively by “true” duplicate determination by use of internal Eurofins methods. “True” duplicate determination means that two identical samples from the same product are taken and subsequently they are treated as two individual samples through the whole analysis procedure. The sample material was extracted with solvent and the content in the solvent was after this identified through the method stated in the table below (Table 28). Applied solvent as well as detection limit and measurement uncertainty are also stated in Table 28.

In the cases where the sample consists of different colours (i.e. for ”1-Stick”, ”5-MClay”, ”6-MClay”, ”7-Gel”, ”11-MakeUp”) a mixed sample was made consisting of equal shares of each sample material and the content analysis was in these cases made on the mixed sample. I.e. in practice equal parts of the different colours were mixed together to one overall sample. This procedure was chosen for all

products consisting of several different colours as it is assumed that there is no difference in the content of or choice of preservative in the different colours of modelling clay, glitter gel or similar.

It should be noted that the detection limit for MI and MCI (20 ppm) is higher than the allowed limit for Kathon in cosmetics (15 ppm). This is among other things due to the fact that the texture of the products is special (they swell during the extraction).

TABLE 28
APPLIED ANALYSIS METHODS

Solvent	Principle	Analysis parameter	Detection limit	Measure-ment uncer-tainty (U_m)
Ethanol:water (9:1)[13]. Approx. 1 g of sample dissolved in 50 ml solvent[14].	HPLC-UV	Parabens	50 mg/kg	20-30%
Water or dichlormethan. Shaken with methanol:water[15] Approx. 1 g of sample to 66 ml of water.	HPLC-UV	Methylisothiazolinone (MI) Methylchloro-isothiazolinone (MCI)	20 mg/kg	20-30%
Water or dichlormethan. Shaken with methanol:water. Approx. 1 g of sample to 33 ml of water.	HPLC-DAD LC-MS/MS	2-phenoxyethanol Sodium benzoate Dehydroacetic acid Bronopol Potassium sorbate	100 mg/kg	20-30%
Water or dichlormethan. Shaken with methanol:water. Approx. 1 g of sample to 33 ml of water.	HPLC-UV Formaldehyde is derivated with 2,4-dinitro-phenylhydrazine before analysis	Formaldehyde	2 mg/kg	20-30%

[13] Samples which were indissoluble in water were dissolved in chloroform before addition of ethanol:water.
[14] For slime, a modelling clay,glue and a make-up, 5 ml of water is used for dissolution of the sample before addition of the 9:1 ethanol:water mixture er.
[15] The dichlormethan was shaken up with a methanol:water mixture before analysis.

Solvent	Principle	Analysis parameter	Detection limit	Measure-ment uncer-tainty (U_m)
Water or dichlormethan. Shaken with methanol:water. Approx. 1 g of sample to 66 ml of water.	HPLC-UV	Benzisothiazolinone (BIT)	20 mg/kg	20-30%

U_m (%) = The expanded degree of accuracy = 2 x RSD%. See also www.eurofins.dk. Search key: "måleusikkerhed".

7.1.2 Analysis results: Quantitative analyses

The analysis results for the 11 analysed products are stated in the tables below (Table 29 to Table 33). For each product, two values are stated – the two values which are measured at "true" duplicate determination. "True" duplicate determination means that two identical samples from the same product are taken and subsequently they are treated as two individual samples through the whole analysis procedure. Whereever possible the products are grouped as a whole, i.e. analysis results for slime, modelling clay, soap bubbles and make-up are presented as a whole. For the paint product (to decorate own stickers) and the glitter gel where only one product in these product groups is analysed the analysis results are presented in the same table.

Analysis results above the detection limit are marked in bold in the tables below.

TABLE 29
ANALYSIS RESULTS FOR PRODUCT "1-STICK" (PAINT PRODUCT TO PRODUCE OWN STICKERS) AND "7-GEL" (ONE GLITTER GEL PEN)

Preservative	1-Stick (mg/kg)		7-Gel (mg/kg)	
Methylparaben	< 50	< 50	< 50	< 50
Ethylparaben	< 50	< 50	< 50	< 50
Isopropylparaben	< 50	< 50	< 50	< 50
Propylparaben	< 50	< 50	< 50	< 50
Phenylparaben	< 50	< 50	< 50	< 50
Isobutylparaben	< 50	< 50	< 50	< 50
Butylparaben	< 50	< 50	< 50	< 50
Methyl-isothiazolinone (MI)	< 20	< 20	< 20	< 20
Methylchloro-isothiazolinone (MCI)	< 20	< 20	< 20	< 20
Benzisothiazolinone (BIT)	< 20	< 20	< 20	< 20
Formaldehyde	**8.4**	**7.7**	**21.2**	**21.2**
2-phenxoyethanol	< 100	< 100	< 100	< 100
Sodium benzoate	< 100	< 100	< 100	< 100
Dehydroacetic acid	< 100	< 100	< 100	< 100
Bronopol	< 100	< 100	< 100	< 100
Potassium sorbate	< 100	< 100	< 100	< 100

< means less than the stated detection limit.
Analysis results above the detection limit are marked in bold.

TABLE 30
ANALYSIS RESULTS FOR THE TWO SLIME PRODUCTS "2-SLIME" AND "3-SLIME"

Preservative	2-Slime (mg/kg)		3-Slime (mg/kg)	
Methylparaben	**1940**	**1965**	**845**	**850**
Ethylparaben	< 50	< 50	< 50	< 50
Isopropylparaben	< 50	< 50	< 50	< 50
Propylparaben	**985**	**965**	< 50	< 50
Phenylparaben	< 50	< 50	< 50	< 50
Isobutylparaben	< 50	< 50	< 50	< 50
Butylparaben	< 50	< 50	< 50	< 50
Methyl-isothiazolinone (MI)	< 20	< 20	< 20	< 20
Methylchloro-isothiazolinone (MCI)	< 20	< 20	< 20	< 20
Benzisothiazolinone (BIT)	< 20	< 20	< 20	< 20
Formaldehyde	**355**	**355**	**19.2**	**19.0**
2-phenxoyethanol	< 100	< 100	< 100	< 100
Sodium benzoate	< 100	< 100	< 100	< 100
Dehydroacetic acid	< 100	< 100	< 100	< 100
Bronopol	< 100	< 100	< 100	< 100
Potassium sorbate	< 100	< 100	< 100	< 100

< means less than the stated detection limit.
Analysis results above the detection limit are marked in bold.

Compared to the results from the survey (Table 22), the content of formaldehyde in slime is new compared to knowledge obtained from literature and producers.

TABLE 31
ANALYSIS RESULTS FOR THE THREE MODELLING CLAYS "4-MCLAY", "5-MCLAY" AND "6-MCLAY"

Preservative	4-MClay (mg/kg)		5-MClay (mg/kg)		6-MClay (mg/kg)	
Methylparaben	< 50	< 50	*	*	< 50	< 50
Ethylparaben	< 50	< 50	< 50	< 50	< 50	< 50
Isopropylparaben	< 50	< 50	< 50	< 50	< 50	< 50
Propylparaben	< 50	< 50	< 50	< 50	< 50	< 50
Phenylparaben	< 50	< 50	< 50	< 50	< 50	< 50
Isobutylparaben	< 50	< 50	< 50	< 50	< 50	< 50
Butylparaben	< 50	< 50	< 50	< 50	< 50	< 50
Methyl-isothiazolinone (MI)	< 20	< 20	< 20	< 20	< 20	< 20
Methylchloro-isothiazolinone (MCI)	< 20	< 20	< 20	< 20	< 20	< 20
Benzisothiazolinone (BIT)	< 20	< 20	< 20	< 20	< 20	< 20
Formaldehyde	**6.1**	**6.2**	**11.0**	**11.0**	**895**	**1220**
2-phenxoyethanol	< 100	< 100	< 100	< 100	< 100	< 100
Sodium benzoate	**4050**	**3760**	< 100	< 100	< 100	< 100
Dehydroacetic acid	< 100	< 100	< 100	< 100	< 100	< 100
Bronopol	< 100	< 100	**305**	**305**	< 100	< 100
Potassium sorbate	< 100	< 100	**2250**	**2240**	< 100	< 100

< means less than the stated detection limit.
Analysis results above the detection limit are marked in bold.
* Content cannot be determined due to interference from the sample material.

Compared to the results from the survey (Table 22), the content of formaldehyde and bronopol in modelling clay is new compared to knowledge obtained from literature and producers.

Product "6-MClay" contains approx. 1000 ppm or 0.1% formaldehyde.

TABLE 32
ANALYSIS RESULTS FOR THE SOAP BUBBLE LIQUIDS "8-SOAPB" AND "9-SOAPB"

Preservative	8-SoapB (mg/kg)		9-SoapB (mg/kg)	
Methylparaben	< 50	< 50	< 50	< 50
Ethylparaben	< 50	< 50	< 50	< 50
Isopropylparaben	< 50	< 50	< 50	< 50
Propylparaben	< 50	< 50	< 50	< 50
Phenylparaben	< 50	< 50	< 50	< 50
Isobutylparaben	< 50	< 50	< 50	< 50
Butylparaben	< 50	< 50	< 50	< 50
Methyl-isothiazolinone (MI)	< 20	< 20	< 20	< 20
Methylchloro-isothiazolinone (MCI)	< 20	< 20	< 20	< 20
Benzisothiazolinone (BIT)	< 20	< 20	< 20	< 20
Formaldehyde	**39.9**	**40.5**	**3.5**	**3.5**
2-phenxoyethanol	**4160**	**4060**	< 100	< 100
Sodium benzoate	< 100	< 100	< 100	< 100
Dehydroacetic acid	< 100	< 100	< 100	< 100
Bronopol	**970**	**1000**	< 100	< 100
Potassium sorbate	< 100	< 100	< 100	< 100

< means less than the stated detection limit.
Analysis results above the detection limit are marked in bold.

TABLE 33
ANALYSIS RESULTS FOR THE TWO MAKE-UP PRODUCTS "10-MAKEUP" AND "11-MAKEUP"

Preservative	10-MakeUp (mg/kg)		11-MakeUp (mg/kg)	
Methylparaben	< 50	< 50	**920**	**920**
Ethylparaben	< 50	< 50	**3745**	**3785**
Isopropylparaben	< 50	< 50	< 50	< 50
Propylparaben	< 50	< 50	< 50	< 50
Phenylparaben	< 50	< 50	< 50	< 50
Isobutylparaben	< 50	< 50	< 50	< 50
Butylparaben	< 50	< 50	< 50	< 50
Methyl-isothiazolinone (MI)	< 20	< 20	< 20	< 20
Methylchloro-isothiazolinone (MCI)	< 20	< 20	< 20	< 20
Benzisothiazolinone (BIT)	< 20	< 20	< 20	< 20
Formaldehyde	**4.6***	**4.3***	**34.7***	**30.1***
2-phenxoyethanol	**10900**	**11300**	< 100	< 100
Sodium benzoate	**450**	**470**	< 100	< 100
Dehydroacetic acid	< 100	< 100	< 100	< 100
Bronopol	< 100	< 100	< 100	< 100
Potassium sorbate	< 100	< 100	< 100	< 100

< means less than the stated detection limit.
Analysis results above the detection limit are marked in bold.
* The make-up products belong under the Cosmetic Products Directive and have thus a declaration of content. On this declaration of content, the identified preservatives are all declared except for the content of free formaldehyde. There are no declared preservatives which are formaldehyde releasers.

Make-up products contain a declaration of content as they belong under the Cosmetic Products Directive. There is compliance between the declared preservatives and the preservatives which are identified in the quantitative analysis apart from the content of free formaldehyde. None of the declared preservatives are formaldehyde releasers.

7.1.3 Summary of analysis results: Quantitative analyses

8 different preservatives were thus identified in the 11 analysed products. These 8 preservatives are listed in the table below (Table 34) where the lowest values (above the detection limit) and the highest values from the previous tables are summarised.

TABLE 34
SUMMARY OF ANALYSIS RESULTS

Preservative	Lowest value (mg/kg)	Highest value (mg/kg)	Identified in number of products out of 11
Methylparaben	845	1965	3
Ethylparaben	3745	3785	1
Propylparaben	965	985	1
Formaldehyde	3.5	1220	11
2-phenoxyethanol	4060	11.300	2
Sodium benzoate	450	4050	2
Bronopol	305	1000	2
Potassium sorbate	2240	2250	1

Preservatives are thus identified in many of the 11 analysed products. For most of the product types, no use of ”new” preservatives is identified compared to knowledge obtained from literature and producers (listed in Table 22). However, content of formaldehyde and bronopol in modelling clay as well as content of formaldehyde in slime is new compared to knowledge obtained from literature and producers.

All the 11 analysed products contained free formaldehyde to a larger or lesser extent. Four of the 11 analysed products contained only free formaldehyde and thus none of the other analysed preservatives.

Eurofins who has made the analyses assesses that the content of formaldehyde in product ”2-Slime” and ”6-MClay” is so high (355 and 1058 mg/kg respectively on average) that the measured content of formaldehyde derives from an added formaldehyde releaser (i.e. a preservative which is not analysed but which releases formaldehyde). The products ”7-Gel”, ”8-SoapB” and ”11-MakeUp” have a somewhat smaller content of formaldehyde (between 20 and 50 mg/kg) which according to Eurofins can be derived from either intentionally added formaldehyde or from the raw materials in the product. The remaining products (i.e. ”1-Stick”, ”3-Slime”, ”4-MClay”, ”5-MClay”, ”9-SoapB” and ”10-MakeUp”) have all a content of free formaldehyde below 20 mg/kg which according to Eurofins is due to the raw materials in the product and not that formaldehyde intentionally has been added the product.

Four of the 11 analysed products contained solely free formaldehyde (”1-Stick”, ”6-MClay”, ”7-Gel” and ”9-SoapB”). The content of free formaldehyde in product “6-MClay” (1058 mg/kg on average) strongly indicates that the product contains a formaldehyde releaser. On the other hand, the lower

concentrations of formaldehyde in the remaining three products do not indicate a content of formaldehyde releaser (21.2 mg/kg on average in product ”7-Gel”, 8.1 mg/kg in product ”1-Stick” and 3.5 mg/kg in product ”9-SoapB”). However, it cannot be ruled out that the products possibly contain other preservatives than those being analysed for in this project.

The analysis results thus confirm what the survey has also shown that toys which can be expected to contain preservatives also contain preservatives in the vast majority of cases. Eight of the 11 analysed products in this project contained preservatives. Possibly in total nine products if it is assumed that the content of free formaldehyde in the product “7-Gel” indicates that formaldehyde is intentionally added to give a preserving effect. It cannot be ruled out that the other products do not contain other preservatives as analyses for all preservatives have not been made.

7.2 Migration analyses

Based on the analyses two products were selected and migration analyses were made for these. Migration analyses of slime and modelling clay were made as these product types are the only ones of the analysed types where it makes sense to make migration analyses as they are more solid products.

The two products which were selected for migration analyses were:

- ”2-Slime”, as this product has the highest content of parabens of the two slime products. Migration analyses were only made for the parabens which were identified at the content analysis.
- ”5-MClay”, as this product had a content of the most interesting preservatives (bronopol) of the three modelling clay products with regard to the risk assessment. The product also contained potassium sorbate which can be seen at the same analysis used for analysing for bronopol. For this reason migration analysis for bronopol and potassium sorbate has been made.

7.2.1 Analysis method: Migration analyses

The migration took place in a sweat simulant at 37 °C by use of an internal Eurofins method. Preparation of sweat simulant has taken place as described in DS/EN ISO 105-E04. The samples (10.0 g of each product distributed on 10 balls of same size) were placed in a cup containing 50.0 ml sweat simulant. For product “5-MClay” which consists of several parts (several colours) a mixing sample was made. As described in Table 26 regarding relevant parameters for the exposure calculations, an exposure time/migration time of 45 minutes has been used for the slime product (“2-Slime”) and a time of 60 minutes for the modelling clay (“5-MClay”). No stirring during the migration was made to avoid the samples being dissolved in the sweat simulant.

After the migration/shaking the preservatives in the sweat simulant was subsequently determined by the method stated in the table below (Table 35). Detection limit and measurement uncertainty are also stated in Table 35. A “true” duplicate determination for both samples was made.

TABLE 35
USED ANALYSIS METHODS FOR MIGRATION ANALYSIS FOR ARTIFICIAL SWEAT

Sweat simulant	Principle	Analysis parameter	Detection limit	Measure-ment uncertainty (U_m)
DS/EN ISO 105-E04	HPLC-UV	Methylparaben and propylparaben	5 mg/kg sweat simulant	20-30%
DS/EN ISO 105-E04	HPLC-DAD LC-MS/MS	Bronopol Potassium sorbate	approx. 80 mg/kg sweat simulant	20-30%

U_m (%) = The expanded measurement uncertainty = 2 x RSD%. See also www.eurofins.dk. Search key: "måleusikkerhed".

7.2.2 Analysis resultats: Migration analyses

The analysis results for the two migration analyses are stated in Table 36 below. For each product two values are stated – the two values which are measured at "true" duplicate determination. "True" duplicate determination means that two that two identical samples from the same product are taken and subsequently they are treated as two individual samples through the whole analysis procedure.

TABLE 36
ANALYSIS RESULTS FOR THE TWO MIGRATION ANALYSES FOR THE PRODUCTS"2-SLIME" AND "5-MCLAY".

Preservative	2-Slime (µg/g)		5-MClay (µg/g)	
Methylparaben	854	885	-	-
Propylparaben	205	230	-	-
Bronopol	-	-	449	550
Potassium sorbate	-	-	1297	1300

- means not analysed.

Note that for product no. "5-MClay" a migration of 449 and 550 ppm (for the two samples) is found but the quantitative content was measured to be 305 and 320 ppm respectively (for the two samples). I.e. in fact more bronopol migrates out than what is found in the product. This is not quite logical but it can be explained by the following circumstances:

- At the migration analyses no periodic stirring was made because the sample otherwise clumped together and a part of the sample dissolved in the sweat solution. This condition shows that the samples were very close to being completely dissolved in the sweat simulant and therefore the analysis reminds more about a quantitative analysis than a real migration analysis.
- The sweat simulant has perhaps been better as a solvent than the chosen solvent for the quantitative method.
- There is 20-30% uncertainty on both analyses. If it is estimated that the quantitative values are 30% larger than stated and that the values for the migration analysis is 30% smaller than

stated, the migration of bronopol is smaller than the quantitative values and is between 80 and 90% of the total content. I.e. the uncertainty of the results can alone be the explanation.

As worst case the values from the migration analyses are used in the exposure calculations even if the migration is larger than the stated total content.

8. Health and risk assessment

Based on the analysis results a number of preservatives were selected for a health assessment. Based on the results from the survey and the analyses, exposure calculations were carried out for these substances and a risk assessment of whether the use of the substances in the toy products can be considered to be safe, were made.

The method for calculation of the risk for the use of the preservatives in toys investigated in this project is described in section 8.1. The health assessment of selected preservatives is described in section 8.2 and the exposure calculations and the risk assessment are described in section 8.3 and **Fejl! Henvisningskilde ikke fundet.** respectively.

8.1 Method for calculation of risk

Children who play with the toys being investigated in this project can be exposed for the same substance via different exposure pathways as described in chapter 5.1 "Formulas of calculation". According to the REACH guidance (ECHA R.15, 2012 (p.9)), the different exposure pathways is added up to find the total exposure. In this project both oral and dermal exposure is calculated whereas exposure through inhalation is presumed to be zero for the examined products.

$$D_{total} = D_{oral} + D_{der} + D_{inh}$$

According to the REACH guidance for risk assessment (ECHA Part E, 2012 (p.8)) it is estimated in each case whether there might be a risk for the health based on the following formula which calculates the Risk Characterisation Ratio (RCR) by use of the Derived No Effect Level (DNEL):

$$RCR = \frac{Exposure\ (D_{total})}{DNEL}$$

If RCR > 1 (i.e. the exposure is larger than DNEL) there might be a risk. If RCR < 1 the exposure is not considered to constitute a risk.

For a single substance addition of the different exposure pathways followed by division by DNEL will correspond to the RCR being calculated for different exposure pathways and after this is added up.

$$RCR = \frac{Exposure\ (D_{total})}{DNEL} = \frac{D_{oral}}{DNEL} + \frac{D_{der}}{DNEL} + \frac{D_{inh}}{DNEL}$$

$$RCR = RCR_{oral} + RCR_{der} + RCR_{inh}$$

DNEL is calculated as described in ECHAs REACH Guidance Chapter R.8 (ECHA R.8, 2012 (p.32)) from the NO(A)EL value (No Observed (Adverse) Effect Level) for the substance. DNEL is the NO(A)EL value which is adjusted for differences between the experimental and the expected human exposure conditions. DNEL is calculated as the NOAEL value divided by the different assessment factors (AF).

$$DNEL = \frac{NOAEL}{AF_1 \times AF_2 \times AF_3 \times AF_4 \times AF_5}$$

The following types of assessment factors (AF) can be used:

- Interspecies differences
- Intraspecies differences
- Differences in duration of exposure
- Issues related to dose-response
- Quality of whole database

The calculated DNEL values are seen from the health assessment of the substances on the coming pages. The assessment factors are specified in the REACH guidance as stated in Table 37 below.

TABLE 37
ASSESSMENT FACTORS (AF) USED FOR CALCULATION OF DNEL

Parameter	Description	Used value
Interspecies	Allometric scaling Correction for difference in metabolic rate per kg body weight	4 for rats 1.4 for dogs
Interspecies	Remaining differences between the species	2.5
Intraspecies	Differences between individuals	10
Duration of exposure	Sub-chronic to chronic If a sub-chronic study is used instead of a chronic study (which typically gives the lowest NOAEL)	2
Dose-response	LOAEL to NOAEL If LOAEL is used because a NOAEL has not been determined	3

8.1.1 Conversion to internal dose

When doses administered in animal studies are compared to human exposure data, it is relevant to use internal doses for both animals and humans. The internal dose is the amount of substance absorbed into the body, and an absorption fraction must be used to determine such an internal dose. For the substances assessed in this project, there is insufficient data to determine internal doses in the animal studies. The ideal data material would be information about the amount of substance in the blood at a known oral dosing. Such data is, however, sparse for both animals and humans. In risk assessments the internal dose in laboratory animals is often assumed to be 100% of the dose given to the animal, e.g. through the feed. This is also assumed in this project because of lack of data (and was also assumed in the project "Exposure of pregnant consumers to suspected endocrine disruptors" (Andersen et al., 2012)). In this way, it is possible to convert an oral exposure for a substance given to an animal to an internal dose, so it is possible to compare it to a calculated human exposure by either oral or dermal exposure. For the dermal exposure of humans is used the absorption fractions, which are listed in the section concerning absorption and distribution for the different substances. This means that here there has been accounted for that only a percentage of the substance is being absorbed through the skin and thereby becomes available as internal dose.

SCCS has prepared notes of guidance for the safety evaluation of cosmetic substances (SCCS/1501/12, 2012). In these notes of guidance they acknowledge that an assumption of 100% oral absorption can be used where there is no available data, when a dermal exposure is compared to an oral NOAEL value in the risk assessment. However, SCCS also states that it is regarded as being appropriate to assume that only 50% of the oral dose will be systemically available. In the calculations in this project 100% bioavailability is assumed, as earlier mentioned, i.e. that the entire

oral dose is available as internal dose. This can result in an overestimation of the internal DNEL value and thereby an underestimation of the human risk.

8.2 Health assessment of selected preservatives

The criteria for the selection of the substances were:

1. they were identified in the analysis or in the survey
2. they were identified in several products or several product types
3. the preservatives that according to the hazard assessment (screening) have the most severe health related properties were in focus

On the basis of the results of the analysis and the survey, the following preservatives were selected for a health assessment in cooperation with the Danish EPA:

- Parabens (methyl-, ethyl-, propyl-, butyl- and isobutylparaben)
- 2-phenoxyethanol
- Formaldehyde
- Bronopol

8.2.1 Parabens

Five of the six prevalent parabens were identified in the analysis or in the survey and are therefore examined more closely below. The primary source for the description of the parabens is the LOUS survey of the parabens from the Danish EPA, which has been conducted in 2012. This report has described the health effects of the parabens based on the most recent literature and assessments from SCCS. The final edition of the LOUS survey of the parabens has not yet been published (February 2013), but the version for public hearing is available at the website of the Danish EPA (Andersen & Larsen, 2012).

8.2.1.1 Occurrence and use

Parabens are used as preservatives in a wide range of products like cosmetic products, pharmaceuticals, other consumer products and in foods. World-wide the main uses are cosmetic products, pharmaceuticals and foods. They are used as single compounds and in combination to exert an antimicrobial effect. Methyl- and propylparaben are the most widely used parabens, and methylparaben is used in the highest volume (Andersen & Larsen, 2012).

Parabens (4-hydroxybenzoic acid and its salts and esters) are allowed as preservative in cosmetic products by the Cosmetic Products Directive (Directive 76/768/EEC, 1976). According to annex VI Part I “List of preservatives allowed” the highest allowed concentration of one of the parabens is 0.4% (as acid) and 0.8% (as acid) for a mixture of various parabens. Moreover it is no longer allowed in Denmark to use propylparaben, butylparaben, isopropylparaben or isobutylparaben in cosmetic products for use by children under the age of 3 (Stat. Order 166, 2011). This means that methyl- and ethylparaben are still allowed in cosmetic products for use by children under the age of 3. This change in the Danish Statutory Order for cosmetic products entered into force in Denmark March 15 2011.

In foodstuff (in the EU) today it is only methyl- and ethylparaben that are allowed as an additive and only for special uses (confectionary, surface treatment of dried meat products, cereal- or potato-based snacks and coated nuts). These two parabens are allowed in a concentration of 300 ppm, i.e. 0.03% (Andersen & Larsen, 2012).

8.2.1.2 Identification, legislation and physical-chemical properties

Parabens are esters of 4-hydroxybenzoic acid. Identification, legislation and physical-chemical properties are described for the five parabens in the two tables below (Table 38 and Table 39).

TABLE 38
IDENTIFICATION, LEGISLATION AND PHYSICAL-CHEMICAL PROPERTIES FOR METHYL- AND ETHYLPARABEN (REFERENCE: ANDERSEN & LARSEN (2012) IF NOT STATED OTHERWISE)

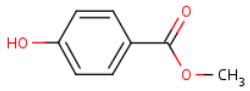
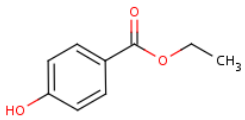
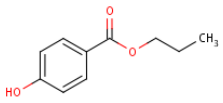
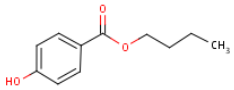
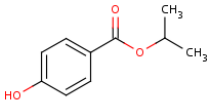
Chemical name	Methyl 4-hydroxybenzoate	Ethyl 4-hydroxybenzoate
Synonyms	Methylparaben p-hydroxybenzoic methyl ester	Ethylparaben p-hydroxybenzoic ethyl ester
CAS no.	99-76-3	120-47-8
Molecule structure		
Molecule formular	$C_8H_8O_3$	$C_9H_{10}O_3$
Legislation: **Harmonised classification (Regulation 1272, 2008)** **Cosmetic Products Directive (Directive 76/768/EEC, 1976)**	None See section 4.1.1 for classification according to ECHA C&L Inventory. Is to be declared by INCI name (methylparaben). Maximum allowed concentration is 0.4% alone or 0.8% for all parabens (as acid).	None See section 4.1.2 for classification according to ECHA C&L Inventory. Is to be declared by INCI name (ethylparaben). Maximum allowed concentration is 0.4% alone or 0.8% for all parabens (as acid).
Physical state	Colourless crystals or white crystalline powder	Colourless crystals or white powder
Molecular weight	152.15 g/mol	166.17 g/mol
Melting point	131 °C	116 °C
Boiling point	270-280 °C	297-298 °C
Vapour pressure	2.37 x 10^{-4} mmHg	9.29 x 10^{-5} mmHg
Partition coefficient octanol-water (log P_{OW})	1.96	2.47
Water solubility	2.5 g/L	0.885 g/L

TABLE 39
IDENTIFICATION, LEGISLATION AND PHYSICAL-CHEMICAL PROPERTIES FOR PROPYL-, BUTYL- AND ISOBUTYLPARABEN
(REFERENCE: ANDERSEN & LARSEN (2012) IF NOT STATED OTHERWISE)

Chemical name	Propyl 4-hydroxybenzoate	Butyl 4-hydroxybenzoate	Isobutyl 4-hydroxybenzoate
Synonyms	Propylparaben p-hydroxybenzoic propyl ester	Butylparaben p-hydroxybenzoic butyl ester	Isobutylparaben p-hydroxybenzoic isobutyl ester
CAS no.	94-13-3	94-26-8	4191-73-5
Molecule structure			
Molecule formular	$C_{10}H_{12}O_3$	$C_{11}H_{14}O_3$	$C_{10}H_{12}O_3$
Legislation: **Harmonised classification (Regulation 1272, 2008)** **Cosmetic Products Directive (Directive 76/768/EEC, 1976)**	None See section 4.1.3 for classification according to ECHA C&L Inventory. Is to be declared by INCI name (propylparaben). Maximum allowed concentration is 0.4% alone or 0.8% for all parabens (as acid).	None See section 4.1.4 for classification according to ECHA C&L Inventory. Is to be declared by INCI name (butylparaben). Maximum allowed concentration is 0.4% alone or 0.8% for all parabens (as acid).	None See section 4.1.5 for classification according to ECHA C&L Inventory. Is to be declared by INCI name (isobutylparaben). Maximum allowed concentration is 0.4% alone or 0.8% for all parabens (as acid).
Physical state	White crystals	Colourless crystals or powder	
Molecular weight	180.20 g/mol	194.23 g/mol	180.20 g/mol
Melting point	96-97 °C	68-69 °C	No data
Boiling point	No data	No data	No data
Vapour pressure	5.55 x 10^{-4} mmHg	1.86 x 10^{-4} mmHg	No data
Partition coefficient octanol-water (log Pow)	3.04	3.57	3.4

Chemical name	Propyl 4-hydroxybenzoate	Butyl 4-hydroxybenzoate	Isobutyl 4-hydroxybenzoate
Water solubility	0.5 g/L	0.207 g/L	No data

8.2.1.3 Absorption and distribution

Overall, parabens are well absorbed after oral and subcutaneous administration, and an **absorption fraction of 1 for all parabens** corresponding to an internal dose of 100% of the dose administered at animal experiments (e.g. through the feed) is assumed. In the body the parabens are hydrolised to para-hydroxybenzoic acid (PHBA). Data indicates that parabens are not accumulated in the body, but are excreted as PHBA in urine. Total levels of metabolites and parent compounds excreted in urine of orally and dermally exposed rats and rabbits are high, indicating that parabens and/or their metabolites are taken up in considerable amounts but rapidly metabolised and excreted (Andersen & Larsen, 2012).

It has also been argued that parabens are quickly and nearly 100% hydrolised into PHBA after dermal application to human skin so the systemic absorption of the parent compound is very low. However, other studies indicate that the biotransformation of the different parabens into PHBA is not as efficient as claimed. According to SCCS data for dermal absorption is in general of poor quality and data for human absorption and/or toxicokinetic studies are not available. SCCS has established **dermal absorption of all parabens to be 3.7%**. This value is derived from the available results of *in vitro* dermal absorption studies (Andersen & Larsen, 2012).

8.2.1.4 Irritation and allergy

In individuals with normal skin, parabens are for the most part non-irriating and non-sensitising. However, application of products containing parabens to damaged or broken skin has resulted in sensitisation (Andersen & Larsen, 2012).

In a study from Switzerland from 1990, 2,295 patients with suspected contact dermatitis were examined for allergic reactions for 13 common preservatives. For a mix of parabens positive reactions were seen in 1.7% of the cases. Parabens (a mix) were hence one of the 13 preservatives that were in the middle of the field when it comes to positive reactions. For comparison formaldehyde gave the most positive reactions (5.7%) and bronopol gave close to the lowest number of positive reactions (1.2%) (Perrenoud et al., 1994). According to the Danish National Allergy Research Centre parabens are the most commonly used preservatives, but the incidents of allergic reactions are relatively low (0.5%)[16].

None of the parabens has a harmonised classification, but a large part of the companies classifies some or all parabens as Skin Irrit. 2, H315 (”Causes skin irritation”), Eye Irrit. 2, H319 (”Causes serious eye irriation”), STOT SE, H335 (”May cause respiratory irriation”) and Skin Sens 1, H317 (”May cause an allergic skin reaction”) according to ECHAs C&L Inventory database[17].

8.2.1.5 Acute and chronic effects

Acute, subchronic, and chronic studies in rodents generally indicate that parabens has a low toxicological potential (Andersen & Larsen, 2012). None of the parabens have a harmonised classification, but some of the companies classify methyl- and ethylparaben as Acute Tox. 4, H302 (”Harmful if swallowed”) according to ECHAs C&L Inventory database[18].

[16] http://www.videncenterforallergi.dk/allergi-konserveringsmidler-kosmetik-hyppighed.html
[17] http://echa.europa.eu/information-on-chemicals/cl-inventory-database
[18] http://echa.europa.eu/information-on-chemicals/cl-inventory-database

Several genotoxic studies, both *in* vitro and *in* vivo primarily gave negative results. The paraben structure is not indicative of carcinogenic potential, and experimental studies support these observations (Andersen & Larsen, 2012). According to SCCS the parabens are in general not teratogenic (SCCP/0873/05, 2005).

It is the endocrine disrupting effects of the parabens that are much debated. According to SCCS all parabens are known to be estrogenic *in vivo* and *in vitro*. However, studies of more recent date do not confirm these findings, and in general there seems to be a controversy about the endocrine disrupting potential of parabens. The potency of the endocrine disruption potential seems to increase with side chain length, and generally methyl- and ethylparaben are considered to have a much lower potential for causing endocrine disrupting effects compared to propyl- and butylparaben – and propylparaben is generally considered to be less potent than butylparaben. Studies in young male rats have shown adverse effects on sperm production and testosterone levels following oral exposure to butyl- and propylparaben. Several studies have shown that propylparaben has estrogenic and/or antiandrogenic effects *in vivo* and *in vitro*. Antiandrogene effects have also been seen for butylparaben in a few studies, but some studies also indicate a lack of antiandrogene effects (Andersen & Larsen, 2012).

According to SCCS EFSA (the European Food Safety Authority) has determined an ADI (Acceptable Daily Intake) for methyl- and ethylparaben of 10 mg/kg bw/day based on an oral NOAEL of 1000 mg/kg bw/day. The safety of these two parabens was considered well-documented, whereas the SCCS did not find data for propyl-, isopropyl-, butyl- and isobutylparaben sufficient for an assessment. Moreover, there is in general a disagreement about the method for evaluation the endocrine disrupting potential of parabens and the kinetics of the substances. The existing maximum authorised concentration of 0.4% (as acid) for one ester and 0.8% (as acid) for a mixture of esters are assessed by the SCCS to be safe for methyl- and ethylparaben. Whereas in 2010 on the basis of a NOAEL value of 2 mg/kg bw/day for butylparaben and a dermal absorption of 3.7% SCCS has calculated that the maximum limit for propyl- and butylparaben should be lowered to 0.14% (as acid). A LOAEL value of 10 mg/kg bw/day is stated for propylparaben. The iso-compounds could not be assessed because of lack of data. On the basis of previous assessments from SCCS from 2010 and 2011, together with a recent study on propylparaben, SCCS will prepare an updated risk assessment of propyl- and butylparaben in cosmetic products (Andersen & Larsen, 2012).

8.2.1.6 The critical effect

The critical effect of the parabens is their endocrine disrupting potential. Methyl- and ethylparaben are by SCCS considered to be safe to use in cosmetic products in the current maximum allowed concentrations of 0.4% (as acid) for one ester. NOAEL (oral) for methyl- and ethylparaben is stated to be 1000 mg/kg bw/day. For the rest of the parabens there is today a lack of data and a general disagreement about which NOAEL values to use for the endocrine disrupting potential, and which dermal absorption fraction that should be used. However, in general the literature refers to a NOAEL of 2 mg/kg bw/day for both propyl- and butylparaben (SCCS/1348/10, 2011).

8.2.1.7 Calculation of DNEL

The NOAEL value for methyl- and ethylparaben is established to 1000 mg/kg bw/day and is based on an assessment from SCCS from 2005 (SCCP/0873/05, 2005). The NOAEL value is based on several subchronic or chronic studies with rats, dogs or mice. Therefore an assessment factor (AF) of 4 for rats and a factor of 2.5 for interspecies differences are used as stated in ECHA ”Guidance on information requirements and chemical safety assessment – Chapter R.8” (ECHA R.8, 2012 – Table R.8-3). Likewise a default assessment factor of 10 is used for intraspecies differences. Hence a total assessment factor of 100 is used, which gives a **DNEL value for methyl- and ethylparaben of 10 mg/kg bw/day**.

As mentioned there is a disagreement on which NOAEL values that should be used for butyl-, propyl-, isobutyl- and isopropylparaben. In order to be able to perform an assessment of the risk of the parabens, it was decided in cooperation with the Danish EPA and DTU Food (National Food Institute) that for propyl- and butylparaben two different DNEL values should be used, which were also used in the project "Exposure of pregnant consumers to suspected endocrine disruptors" (Andersen et al., 2012): A conservative NOAEL of 2 mg/kg bw/day, which in the above-mentioned project was converted to a **DNEL value of 0.02 mg/kg bw/day**, and an alternative higher LOAEL of 100 mg/kg bw/day, which was converted to a **DNEL value of 0.330 mg/kg bw/day**. Hence, in the risk assessment two RCR values for the two different DNEL values are calculated for **propyl- and butylparaben**.

For isobutyl- og isopropylparaben no calculation of DNEL values has been performed and no risk assessment of these substances has been carried out, as there is no data available for determination of the NOAEL values for these parabens.

8.2.1.8 Calculation of the internal dose DNEL

As previously described the parabens are easily absorbed, and therefore an oral absorbtion factor for alle parabens of 1 has been used. Therefore the internal dose DNEL is equal to the DNEL values as listed above. All values are listed in Table 40 below.

TABLE 40
INTERNAL DOSE DNEL WHICH IS USED IN THE CALCULATIONS

Name of substance	Internal dose DNEL (mg/kg bw/day)
Methylparaben	10
Ethylparaben	10
Propylparaben	0.02 Alternative value: 0.330
Butylparaben	0.02 Alternative value: 0.330

8.2.1.9 Assessment of the risk of sensitisation

The incidents of allergic reactions towards parabens are relatively low (0.5%) according to the Danish National Allergy Research Centre, and it is typically in individuals with damaged or broken skin that has resulted in skin sensitisation (Andersen & Larsen, 2012). Other studies have shown positive reactions in 1.7% of the cases, but this is for patients with suspected contact dermatitis (Perrenoud et al., 1994). No studies showing at which concentration parabens can induce allergic reactions have been identified. However, allergic reactions have been seen with the allowed concentrations for cosmetic products today, i.e. 0.4% (as acid).

In this survey the individual parabens have been identified in concentration of about 0.001-0.2% (at both chemical analysis and from information from producers), and in one single product of 0.38% (identified by the chemical analysis). This means that in most cases the concentration of the parabens used is well below the allowed concentration of 0.4% for the individual parabens in cosmetic products. The risk of sensitisation for use of toys containing parabens is therefore assessed to be low.

8.2.2 2-phenoxyethanol

A health assessment of 2-phenoxyethanol has been made in an OECD SIDS-report from 2004 (OECD, 2004). In addition a draft assessment of REL (Reference Exposure Level) for 2-phenoxyethanol has been identified at the website of California EPA (California EPA, 2010). However, this assessment has been based on the OECD SIDS-report and other reference quoated in this. Finally, a recent French assessment of 2-phenoxyethonol in cosmetic products has been identified (ANSM, 2012). The OECD report and the recent French assessment are the primary sources used for the description of the substance below.

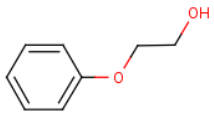
8.2.2.1 Occurrence and use

OECD has reported a long list of uses of 2-phenoxyethanol – primarily as solvent or as preservative. Paints/coatings, cleaners and dyes seem to be the largest areas of application (OECD, 2004).

8.2.2.2 Identification, legislation and physical-chemical properties

2-phenoxyethanol is an aromatic ether compound.

TABLE 41
IDENTIFICATION, LEGISLATION AND PHYSICAL-CHEMICAL PROPERTIES FOR 2-PHENOXYETHANOL (REFERENCE: OECD (2004) IF NOT STATED OTHERWISE)

Chemical name	2-phenoxyethanol
Synonyms	Ethylene glycol monophenyl ether Phenoxyethanol 1-hydroxy-2-phenoxyethane
CAS no.	122-99-6
Molecule structure	
Molecule formular	$C_8H_{10}O_2$
Legislation: **Harmonised classification (Regulation 1272, 2008)** **Cosmetic Products Directive (Directive 76/768/EEC, 1976)**	 Acute Tox. 4, H302 – Harmful if swallowed Eye Irrit. 2, H319 – Causes serious eye irritation Is to be declared by INCI name (phenoxyethanol). Maximum allowed concentration is 1.0% in cosmetic products.
Physical state	Liquid
Molecular weight	138.17 g/mol
Melting point	14 °C

Boiling point	245.6 °C
Vapour pressure	0.007 mmHg (at 25 °C) (Reference: TOXNET)
Partition coefficient octanol-water (log Pow)	1.16
Water solubility	28.9 g/L (at 20 °C)

8.2.2.3 Absorption and distribution

Dermal absorption in humans of phenoxyethanol in methanol was tested *in vitro* and shows that approximately 60% of the substance was absorbed by 6 hours (Roper et al, 1997). In a more recent French assessment of 2-phenoxyethanol (ANSM, 2012), the following values are reported for dermal absorption: 80% for cosmetic products that are not being rinsed off after use and 40% for cosmetic products that are being rinsed off after use. Therefore a **dermal absorption of 40%** is used as no toy products are expected to stay on the skin, but are expected to be washed off after use.

2-phenxoyethanol is rapidly absorbed after oral exposure and is primarily excreted in the urine. An **absorption fraction of 1** is assumed corresponding to an internal dose of 100% of the dose administered at animal experiments (e.g. through the feed). Studies with rats show that after oral administration, between 95-98% of 2-phenoxyethanol was recovered (91-94% in the urine, 0.8-1.3% in the feces and 1.3-2.2% exhaled as carbon dioxide. With dermal application the recovery rate was between 65-99% (again the major portion was in the urine and only small amounts were in the feces). 2-phenoxyethanol is either recovered unchanged as 2-phenoxyacetic acid (more than 75%) or as small amounts as other metabolised products (Howes, 1988).

8.2.2.4 Irritation and allergy

2-phenoxyethanol is not irritating for human skin, but moderately irritating for rabbit skin and rabbit eyes (OECD, 2004). This is also confirmed by a recent French assessment of the substance, in which 2-phenoxyethanol is described as non-irritating for human skin, but is able to cause severe eye irritation (ANSM, 2012). 2-phenoxyethanol is classified as ”Eye Irrit. 2, H319 – Causes serios eye irritation”. A study showed that of 2,736 patients patch-tested with 1% 2-phenoxyethanol in petrolatum, none of the patients had signs of irritant reactions 2 and 4 days after application (Lovell et al., 1984).

Several studies (for both animals and humans) show that 2-phenoxyetahnol is not sensitising (OECD, 2004; ANSM, 2012). In the study with the 2,736 patients (described above), none of the patients had allergic reactions at 1% 2-phenoxyethanol (Lovell et al., 1984). In another patch-test study with 5% 2-phenoxyethanol in petrolatum, one out of 3,726 patients experienced an allergic reaction corresponding to 0.03% (Fusch et al., 1991). In a third study of patch-testing of 501 patients suspected for contact dermatitis, one patient experienced a positive reaction corresponding to 0.2% (DeGroot et al., 1986).

8.2.2.5 Acute and chronic effects

According to OECD (2004) the most reliable LD_{50} values for the rat (oral) are 1,386 and 2,563 mg/kg bw in fasted males and females respectively, and 2,937 and 4,013 mg/kg bw in fed males and females respectively. This means that 2-phenoxyethanol has a moderately acute toxicity in animals (ANSM, 2012), which is expressed in the classification of the substance “Acute Tox. 4, H302 – Harmful if swallowed”.

Symptoms of toxicity of 2-phenoxyethanol in animals include a slight to severe reduction of activity, weakness, decreased reflexes and labored respiration. At high doses animals appeared comatosed

before death or recovery, just like lethargy, ataxia (loss of full control over body movements) and body tremors have been observed at high doses. No abnormalities were found in the dead animals (OECD, 2004).

In a 90-day repeated-dose dermal toxicity study, rabbits did not show effects except for erythema at the test site at doses of 50 to 500 mg phenoxyethanol/kg bw/day. Therefore the NOAEL value was considered to be 500 mg/kg bw/day for systemic toxicity (Breslin et al., 1991). A 90-day repeated-dose oral toxicity study with rats at doses of 80, 400 and 2000 mg/kg bw/day showed no effects at 80 mg/kg bw/day (NOAEL value). 400 mg/kg bw/day was associated with inflammation of the kidney and changes in grooming behavior. At doses of 2000 mg/kg bw/day toxicity was seen to red blood cells and other effects associated with this phenomenon (Ben-Dyke et al, 1977). ANSM (2012) refers to another sub-chronic 90-day study from 1996. In this study rats were exposed to 2-phenoxyethanol (orally through feeding) 7 days a week for 13 weeks at doses of 0, 40, 81, 164 and 419 mg/kg bw/day. The study was carried out according to OECD guidelines. The following effects were reported: an increase of serum enzyme activity in females at the highest dose, and a decrease in the concentration of lipids in the liver and cholesterol level for both sexes. The only non-reversable effect was the decrease in chlosterol level. Furthermore, reversible effects like haematological changes (decrease of platelets) were observed at all doses. The NOAEL value was set at 164 mg/kg bw/day. ANSM (2012) concludes on the basis of this study from 1996 that 2-phenoxyethanol induces systemic effects such as blood toxicity and liver toxicity, and that the NOAEL value of 2-phenoxyethanol should be established at 164 mg/kg bw/day, despite the fact that the ANSM report also refers to a 90-day study (from 1997) that deduce a NOAEL value of 80 mg/kg bw/day. However, in this older study there are high intervals between the level of the doses (80 and 400 mg/kg bw/day respectively), and this study was not fully accessible.

2-phenoxyethanol tested negative for mutagenicity in the conducted Ames test. *In vivo* cytogenicity study in rats and mice was also negative, and other *in vitro* gene mutation assays were also negative (OECD, 2004).

Studies regarding the carcinogenic properties of phenoxyethanol have not been identified. However, the Danish EPA has used the FDA cancer models on phenoxyethanol and a negative result was predicted (OECD SIDS, 2004). This means that phenoxyethanol is not expected to be carcinogenic.

Testicular toxicity was tested in 6-week old male mice. The animals were administered up to 2000 mg/kg bw by gavage 5 days/week for 5 weeks. No effects on weights of testes, morphology of the testes, seminal vesicles or coagulating gland were observed (OECD, 2004).

A 2-generation continous breeding, oral feeding study in mice resulted in an NOAEL value of 400 mg/kg bw/day for both parental animals and offsprings. The effects were decreased body weight (at 2000 or 4000 mg/kg bw/day dependant on the sex) and increased liver weight (males and females at both 2000 and 4000 mg/kg bw/day). Decreased absolute weight of seminal visicles was noted in males treated with 2000 mg/kg bw/day, but not at 4000 mg/kg bw/day. Developmental toxicity was seen in offspring of mice treated with 2000 mg/kg bw/day, which had lower birth weights and at 4000 mg/kg bw/day also the effects of decreased numbers of live pups per litter as well as decreased proportion of live pups born were seen. (Heindel et al., 1990). Other studies regarding develpmental toxicity show mixed results. Two studies show signs of developmental toxicity, but in a third study with rabbits neither teratogenicity nor developmental toxicity are seen in dose up to 600 mg/kg bw/day. This concentration induced death in 5 of 25, but appeared to have no adverse effect on the remaining maternal animals. NOAEL was established at 600 mg/kg bw/day (Scorticini et al., 1987).

The recommendations in the OECD SIDS report regarding phenoxyethanol are that the substance is a candidate for further work with regard to human health, as the substance has properties that indicates a hazard for human health (eye irritation and developmental toxicity at high doses associated with maternal toxicity) (OECD SIDS, 2004). SCCS concludes in an older assessment from SCCS (SCC 6th series, 1987) that 2-phenoxyethanol seems to be relatively harmless based on the available information. However, SCCS states that it is necessary with data on the genotoxic and teratogenic effects of the substance.

In a more recent French assessment of 2-phenoxyethanol it is concluded that the used safety margins to determine the concentration limit value of 1% in cosmetic products is sufficient, but not when it comes to children under the age of 3 (ANSM, 2012). ANSM therefore concludes that 2-phenoxyethanol should not be used in cosmetic products for children under the age of 3 which is designed to be used on the bottom. Furthermore, ANSM concludes that the allowed concentration for 2-phenoxyethanol should be reduced to 0.4% (instead of the allowed concentration of 1% today) in all other cosmetic products for children under the age of 3 (ANSM, 2012).

8.2.2.6 The critical effect

The critical effect of 2-phenoxyethanol is assessed to be lever toxicity by ingestion. The NOAEL value used by the recent French assessment (ANSM, 2012) is used, i.e. 164 mg/kg bw/day on the basis of an oral study from 1996.

8.2.2.7 Calculation of DNEL

The NOAEL value (oral) for 2-phenoxyethanol is determined to be 164 mg/kg bw/day and is described in the more recent French assessment of 2-phenoxyethanol from 2012. The NOAEL value is based on a sub-chronic study with rats for which reason an assessment factor (AF) of 4 for rats, a factor of 2.5 for the interspecies differences and a factor of 2 to allow for use of a sub-chronic study are used, as stated in ECHA ”Guidance on information requirements and chemical safety assessment – Chapter R.8” (ECHA R.8, 2012 – Table R.8-3 og Table R.8.5). Similarly a default assessment factor of 10 is used for the intraspecies differences. In total an assessment factor of 200 is used which results in a **DNEL value of 0.82 mg/kg bw/day for 2-phenoxyethanol**.

8.2.2.8 Calculation of the internal dose DNEL

As described above 2-phenoxyethanol is easily absorbed in the body after oral administration for which reason an oral absorption fraction of 1 is assumed, i.e. the internal dose DNEL is equal to the DNEL value as stated above. See Table 42.

TABLE 42
INTERNAL DOSE DNE WHICH IS USED IN THE CALCULATIONS

Name of substance	Internal dose DNEL (mg/kg bw/day)
2-phenoxyethanol	0.82

8.2.2.9 Assessment of the risk of sensitisation

2-phenoxyethanol is not regarded as being sensitising. In larger patch-test studies none or one single patient had allergic reactions because of 2-phenoxyethanol corresponding to 0, 0.03 or 0.2% of the patients having allergic reactions at concentrations of 1 and 5% 2-phenoxyethanol.

In this survey 2-phenxoyethanol has been identified in concentrations of 0.0045 – 0.89% based on information from producers and in concentrations of up to 0.42% in the chemical analyses. This means that the concentrations of 2-phenoxyethanol in toys are below the allowed 1% concentration for cosmetic products. The risk of sensitisation when using toys containing 2-phenoxyethanol is therefore regarded as being minimal.

8.2.3 Formaldehyde

A health assessment of formaldehyde has been carried out in an OECD SIDS report from 2002 (OECD, 2002) and in a report from US Agency for Toxic Substances Disease Register in 1999 (ATSDR, 1999). Furthermore, BfR (Bundesinstitut für Risikobewertung) has performed a risk assessment of formaldehyde in 2006 with a focus on the carcinogenic effects of the substance (BfR, 2006), and US National Research Council has also carried out an assessment of formaldehyde in 2011 (NRC, 2011). Finally, SCCS has performed more assessments of formaldehyde (SCC 5th series, 1987; SCCNFP/586/02, 2002; SCCNFP/587/02, 2002). The latest assessments, however, primarily cover formaldehyde releasers. For the description of formaldehyde below, it has mainly been the assessment from OECD that has been used, but also the references from ATSDR, BfR and US National Research Council.

8.2.3.1 Occurrence and use

Exposure for formaldehyde is generally speaking unavoidable as formaldehyde can be found in the air both inside and outside. Formaldehyde is used in many different products, e.g. building materials and as preservatives in consumer products. Formaldehyde is released from many different sources such as power plants, cars, wood stoves, cigarettes and is found natural in some food. Formaldehyde is produced naturally in the human body and in animals as a part of the normal metabolism (NRC, 2011). Consumers are primarily exposed for formaldehyde via food (or cooking), tobacco smoke, consumer products such as cosmetic products or cleaning agents, as well as construction materials or furniture made of wood (OECD, 2002).

8.2.3.2 Identification, legislation and physical-chemical properties

Formaldehyde is an aldehyde. Formaldehyde is a colourless gas at normal temperature and pressure. Formaldehyde has a sharp and pungent odour (OECD, 2002). Formaldehyde is easily dissolved in water and is a reactive chemical with a short half time (NRC, 2011).

TABLE 43
IDENTIFICATION, LEGISLATION AND PHYSICAL-CHEMICAL PROPERTIES FOR FORMALDEHYDE (REFERENCE: TOXNET (2013) IF NOT STATED OTHERWISE)

Chemical name	Formaldehyde
Synonyms	Methanal Formalin Methylaldehyde
CAS no.	50-00-0
Molecule structure	
Molecule formular	CH_2O
Legislation: **Harmonised classification**	 Carc. 2, H351 – Suspected of causing cancer

(Regulation 1272, 2008) **Cosmetic Products Directive (Directive 76/768/EEC, 1976)**	Acute Tox. 3, H331, H311, H301 – Toxic if inhaled, in contact with skin and if swallowed Skin Corr. 1B, H314 – Causes severe burns and aye damage Skin Sens. 1, H317 – May cause an allergic skin reaction Is to be declared by INCI name (formaldehyde). Max concentration allowed in cosmetic products is 0.2% (expressed as free formaldehyde) and 0.1% for products for oral hygiene. Formaldehyde is prohibited in aerosol dispensers (sprays). Furthermore, all products containing formaldehyde or other preservatives, which release formaldehyde must be labelled with the warning ”contains formaldehyde”, where the concentration of formaldehyde in the finished products exceeds 0.05%.
Physical state	Gas
Molecular weight	30.03 g/mol
Melting point	- 92.0 °C
Boiling point	- 19.1 °C
Vapour pressure	3,886 mmHg (at 25 °C)
Partition coefficient octanol-water (log P_{OW})	0.35
Water solubility	40 g/L

8.2.3.3 Absorption and distribution

Dermal absorption is relatively small. In the assessment from SCCS (SCC 5th series, 1987) it is stated that test with rats has shown a dermal absorption of 5% from a cream within 48 hours. In the subsequent calculations the **dermal absorption of 5%** for rats is assumed for humans as well.

In the body formaldehyde is rapidly metabolised for which reason exposure to high concentrations of formaldehyde does not result in increased blood concentrations in rats, monkeys or humans (at exposures at 15, 6 and 2 ppm respectively). Test with carbon-14 marked formaldehyde shows that about 40% of the inhaled formaldehyde was exhaled in the expired air during 70 hours. 17% was excreted in the urine, 5% was eliminated in the faeces and 35-39% remained in the tissues. Formaldehyde is rapidly oxidised in the body to formate (salt of formic acid) through different enzymatic reactions (OECD, 2002).

No information has been found about the oral absorption of formaldehyde. For this reason an **absorption fraction of 1** is assumed corresponding to an internal dose of 100% of the dose administered at animal experiments (e.g. through the feed).

8.2.3.4 Irritation and allergy

Formaldehyde causes irritation of eyes, skin and the mucous membrane (OECD, 2002) and has also a harmonised classification as Skin Corr. 1B, H314 (”Causes severe skin burns and eye damage”).

Formaldehyde is allergenic (skin) according to several animal tests and is assessed by SCCS as being a strong sensitiser (SCC 5th series, 1987). Formaldehyde has a harmonised classification as Skin Sens. 1, H317 ”May cause an allergic skin reaction”. A threshold for induction has not been clearly established, but it is estimated to be less than 5% aqueous solution (OECD, 2002). SCCS states that sensitising properties have been noticed at use concentrations of 0.1% (SCC 5th series, 1987), i.e. at lower concentrations than allowed in cosmetic products (according to the Cosmetic Products Directive (Directive 76/768/EEC, 1976) the highest allowed concentration of formaldehyde is 0.2% (expressed as free formaldehyde)).

According to ATSDR (1999) several examples illustrate that formaldehyde is sensitising to the skin in concentrations between 1 and 2% (aqueous solution) in human patch tests. More than 30 years of experience with patch testing shows that about 1-4% of the tested subjects is sensitive to formaldehyde. In a study from Switzerland from 1990, 2,295 patients with suspected contact dermatitis were examined for allergic reactions for 13 common preservatives. Formaldehyde was the preservative that gave the majority of the positive reactions (in 5.7% of the cases) (Perrenoud et al., 1994). According to ATSDR (1999) studies show that allergic skin responses in sensitised subjects exposed to formaldehyde in aqueous solutions at concentrations below 0.025–0.05% are rare. However, according to OECD (2002) the threshold for elicitation of allergic contact dermatitis in sensitised subjects ranges from 30 ppm (aqueous solution), i.e. 0.003% or at 0.006% for products containing formaldehyde.

In specially designed study with mice formaldehyde does not show any sign of respiratory sensitisation (OECD, 2002), and formaldehyde does not have a harmonised classification as Resp. Sens, even though some companies are classifying formaldehyde as such according to ECHA’s (C&L Inventory Database)[19].

8.2.3.5 Acute and chronic effects

Formaldehyde has a high acute toxicity, which is shown by the LD_{50}/LC_{50} values: LD_{50} values (oral, rats) for formaldehyde lie between 600-800 mg/kg bw according to OECD (2002), but according to the assessment from SCCS LD_{50} values of 100-200 mg/bw have been found (SCC 5th series, 1987). Dermal LD_{50} values for rabbits have been determined to be 270 mg/kg bw (SCC 5th series, 1987). LC_{50} values (inhalation, rats, 4 hours) for formaldehyde lie at 578 mg/m^3 (480 ppm) (OECD, 2002). Formaldehyde has a harmonised classification as Acute Tox. 3, H301, H311, H331 ”Toxic if swallowed, in contact with skin, and if inhaled”.

Inhalation of high concentrations of formaldehyde (> 120 mg/m^3) has caused hypersalivation, acute dyspnea, vomiting, muscular spasms, convulsions and finally death (OECD, 2002).

Repeated formaldehyde exposure caused toxic effects only in the tissues of direct contact after inhalation, oral or dermal exposure. The effects are characterised by local cytotoxic desctruction and subsequent repair of the damage. The typical locations of lesions in experimental animals were the nose after inhalation, the stomach after oral administration and the skin after dermal application. The nature of the lesions depended on the inherent abilities of the tissues involved to respond to the noxious event and on the local concentration of the substance (OECD, 2002). The lowest NOAEL values observed after repeated exposure to formaldehyde are according to OECD (2002) between 1 and 2 ppm (1-2.5 mg/m^3) for inhalation exposure and about 260 mg/l by oral intake of drinking water corresponding to 15 mg/kg bw. No systemic toxicity for formaldehyde has been observed by dermal studies in concentrations up to 1% (highest tested concentrations). The

[19] http://echa.europa.eu/information-on-chemicals/cl-inventory-database

study with drinking water was a 2 year duration study, where rats were given formaldehyde in the drinking water in concentrations of 20, 260 and 1900 mg/l. Rats receiving the highest dose had decreased food consumption and reduced body weight development. Lesions like hyperplasia and ulceration were found in the stomach. NOAEL was determined to be 15 mg/kg bw.

Formaldehyde is weakly genotoxic and has induced gene mutations and chromosomal aberrations in mammalian cells. However, the genotoxic effects were limited to those cells, which are in direct contact with formaldehyde. For this reason OECD concludes that formaldehyde is a direct acting locally effective mutagen (OECD, 2002).

Several studies show that exposure to formaldehyde by inhalation is carcinogenic for humans and produce tumours in the upper respiratory tract (BfR, 2006; OECD, 2002). Formaldehyde is classified as Carc. 2, H351 (”Suspected of causing cancer”). Chronic inhalation of concentrations of 10 ppm (12 mg/m^3) and higher led to clear increases in nasal tumour incidence in rats. No increased incidence of tumours was found in other organs after inhalation, and administration routes other than inhalation did not result in local or systemic tumour formation (OECD, 2002). In epidemiological studies in occupationally exposed human populations, there is limited evidence of a causal association between formaldehyde exposure and nasal tumours (OECD, 2002). OECD concludes that formaldehyde is not likely to be a potent carcinogen to humans under low exposure conditions. Other epidemiological studies indicate that there is a causal relation between exposure of formaldehyde by inhalation and leukaemia. No plausible mechanism that can explain this correlation exists at the moment. Therefore, it is concluded in BfR (2006) that these epidemiological studies describe only an association rather than a causal relationship.

Long-term testing with rats (oral, chronic) does not show any indications of formaldehyde being toxic to foetal development or toxic to reproduction (OECD, 2002). Several studies described in ATSDR (1999) show that formaldehyde is neither teratogenic nor toxic to reproduction by inhalation or by dermal exposure. In a study with dermal exposure with hamsters a minor (3-8%) increased incidence of resorption (absorption of liquid, air or particles through blood or lymph pathways) in treated litters was observed. It was, however, concluded that this effect may have been caused by the stress of treatment during pregnancy rather than to a direct effect of formaldehyde.

8.2.3.6 The critical effect

Induction and allergenicity are considered as being the critical effect by dermal exposure to formaldehyde. No induction threshold has been clearly established.

A NOAEL value has been established at 15 mg/kg bw/day for rats that orally have been administered formaldehyde through drinking water. The effects were lesions in the stomach and the derived effects were decreased food consumption and reduced body weight development.

Formaldehyde has a carcinogenic potential, but is only expected to be carcinogenic by inhalation. Exposure to formaldehyde from the toys in this project is only expected to occur by dermal contact or by oral intake. The content of formaldehyde can evaporate from the products, by which formaldehyde can be inhaled, but this level is expected to be very little and the carcinogenic potential of formaldehyde is therefore assessed not to be relevant.

8.2.3.7 Calculation of DNEL

The NOAEL value (oral) of formaldehyde is determined to be 15 mg/kg bw/day and is described in the assessment from OECD (2002). The NOAEL value is based on a chronic study with rats for which reason an assessment factor (AF) of 4 for rats, together with a factor of 2.5 for the interspecies differences are used, as stated in ECHA "Guidance on information requirements and chemical safety assessment – Chapter R.8" (ECHA R.8, 2012 – Table R.8-3). Similarly a default assessment factor of 10 is used for the intraspecies differences. In total an assessment factor of 100 is used which results in a **DNEL value for formaldehyde of 0.15 mg/kg bw/day.**

8.2.3.8 Calculation of the internal dose DNEL

As described above an absorption fraction of 1 is assumed for formaldehyde, as no data on oral absorption has been found. This means that the internal dose DNEL is equal to the DNEL value as stated above. The value is listed in Table 44 below.

TABLE 44
INTERNAL DOSE DNEL WHICH IS USED IN THE CALCULATIONS

Name of substance	Internal dose DNEL (mg/kg bw/day)
Formaldehyde	0.15

8.2.3.9 Assessment of the risk of sensitisation

Formaldehyde is regarded as being a strong sensitiser. Between 1 and 4% of the tested individuals gets allergic reactions. An induction threshold has not been clearly established, but has been estimated to less than 5% aqueous solution. Sensitising properties have been seen at use concentrations of 0.1%, i.e. in lower concentrations than allowed in cosmetic products. Studies show that allergic skin responses in sensitised subjects exposed to formaldehyde in aqueous solutions at concentrations below 0.025–0.05% are rare. However, according to OECD (2002) the threshold for elicitation of allergic contact dermatitis in sensitised subjects ranges from 30 ppm (aqueous solution), i.e. 0.003% or at 0.006% for products containing formaldehyde.

In this survey (free) formaldehyde has been identified in concentrations between 0.0025 and 0.087% from the information given by producers and in concentrations between 0.00035 and 0.122% in the chemical analyses. Two of the analysed products had a content of formaldehyde of more than 0.006%, which is the concentration, where already sensitised persons can have allergic reactions. As formaldehyde is a strong sensitiser and in small concentrations, toys containing formaldehyde are assessed of being able to pose a risk of sensitisation, especially for products that expose the skin for the formaldehyde content in longer periods of time, i.e. products like finger paint, face paint, make-up and perhaps soap bubbles.

8.2.4 Bronopol

An older SCCS opinion on bronopol exists (SCC 6th series, 1987). Beside this, it is mainly older literature that has been identified for bronopol. As an example, a medical handbook from 2009 primarily makes references to literature on bronopol from before 1990 (Rowe et al., 2009). These sources of information have been used for the description of the substance.

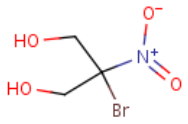
8.2.4.1 Occurrence and use

Bronopol which is also named 2-bromo-2-nitropropane-1,3-diol has preserving properties as it functions as e.g. a bacteriostat, microbiostat and fungicide. In the USA bronpol is registered for use as a preservative in a long range of product, such as glue, pigments, paints, water-based printing inks, paper, pharmaceuticals, cosmetic products and other personal care products (US EPA, 2011).

8.2.4.2 Identification, legislation and physical-chemical properties

Bronopol is a nitrosubstituted compound. Bronopol is a so-called formaldehyde releaser, which means that the substance can release formaldehyde, which is classified as carcinogenic category 2 and allergenic. Even though bronopol can release formaldehyde under certain conditions, it does not appear to be the main mechanism of antimicrobial action of bronopol (US EPA, 2011).

TABLE 45
IDENTIFICATION, LEGISLATION AND PHYSICAL-CHEMICAL PROPERTIES FOR BRONOPOL (REFERENCE: TOXNET (2013) IF NOT STATED OTHERWISE)

Chemical name	**2-Bromo-2-nitropropane-1,3-diol**
Synonyms	Bronopol 2-Nitro-2-bromo-1,3-propanediol 1,3-Propanediol, 2-bromo-2-nitro-
CAS no.	52-51-7
Molecule structure	
Molecule formular	$C_3H_6BrNO_4$
Legislation: **Harmonised classification (Regulation 1272, 2008)** **Cosmetic products Directive (Directive 76/768/EEC, 1976)**	 Acute Tox 4, H312, H302 – Harmful if swallowed and in contact with skin STOT SE 3, H335 – May cause respiratory irritation Skin Irrit. 2, H315 – Causes skin irritation Eye Dam. 1, H318 – Causes serious eye damage Aquatic Acute 1, H400 – Very toxic to aquatic life Is to be declared by INCI name (2-bromo-2-nitropropane-1,3-diol). Maximum concentration allowed in cosmetic products is 0.1%. Furthermore, all products containing formaldehyde or other preservatives, which release formaldehyde must be labelled with the warning ”contains formaldehyde”, where the concentration of formaldehyde in the finished products exceeds 0.05%.
Physical state	White crystals (Chemicalbook, 2013)
Molecular weight	199.99 g/mol
Melting point	131.5 °C

Boiling point	388 °C (Chemicalbook, 2013)
Vapour pressure	0.000126 mmHg (at 20 °C)
Partition coefficient octanol-water (log Pow)	- 0.64 (at 20 °C)
Water solubility	250 g/L

8.2.4.3 Absorption and distribution

Test with carbon-14 labelled bronopol in rats shows that bronpol, administered either orally or intravenously, is rapidly eliminated from the body. 70-80% was excreted in urine and 6-10% in expired air during 24 hours (Buttar & Downie (1980) (quoated in Madsen et al., 2001)). No information about the oral absorption of bronopol has been identified, for which reason an **absorption fraction of 1 is assumed** corresponding to an internal dose of 100% of the dose administered at animal experiments (e.g. through the feed).

The highest concentration of radioactivity, 24 hours after the percutaneous application, was found in kidneys, liver and lung. Within 24 hours approximately 40% of the topically applied dose of carbon-14 labelled bronopol was absorbed through the skin of rats. About 19% of the applied radioactivity was excreted in the urine (15%), faeces and expired air (2%) at the end of 24 hours. It is therefore concluded that bronopol is easily absorbed through skin of rats (Buttar & Downie (1980) (quoated in Madsen et al., 2001)). In contrast, it is stated in the SCCS opinion that bronopol is relatively slowly absorbed through skin (of rats and rabbits) – 11% of radioactive labeled bronopol was absorbed through skin in 24 hours. Use of aceton as solvent seems to lead to a somewhat more rapid and greater absorption through skin. In the risk assessment calculations the highest **dermal absorption of 40%** as listed for rats, is used. It is hence assumed that human dermal absorption is identical with dermal absorption seen for rats.

8.2.4.4 Irritation and allergy

Bronopol is irritating for skin and highly irritating to the eyes (SCC 6th series, 1987) and irritating to the airways (HSDB). Bronopol is also classified as Skin Irrit. 2, H315 – Causes skin irritation, Eye Dam. 1, H318 – Causes serious eye damage and STOT SE 3, H335 – May cause respiratory irritation. Skin irritation has been seen in concentrations from 0.5% (SCC 6th series, 1987). Generally, bronopol is not regarded as being irritating in concentrations under 0.1% (Rowe et al., 2009), which is the concentration allowed in cosmetic products. A 0.1% solution was not irritating for skin in guiniea-pig testing (SCC 6th series, 1987).

Allergic reactions to bronopol have been seen in human patch test (SCC 6th series, 1987; Madsen et al., 2001). In a study from Switzerland from 1990, 2,295 patients with suspected contact dermatitis were examined for allergic reactions for 13 common preservatives. For bronopol positive reactions were seen in 1.2% of the cases. Bronopol was hence one of the 13 preservatives that gave the fewest positive reactions (both formaldehyde and parabens (a mix) gave more positive reactions than bronopol, 5.7% and 1.7% respectively (Perrenoud et al., 1994). In an European study based on information from seven European clinics (mostly from London) 8,149 patients were patch-tested for allergic reactions to bronopol. Reactivity was low, with a total of 38 allergic reactions corresponding to 0.47%. On the basis of this study, it was therefore concluded that the rate of sensitisation in Europe is comparatively low. However, this can be connected to the fact that bronopol is not used to such a great extent as parabens and isothiazolinones (Frosch et al., 1990). A more recent study based on 1,937 patients also shows that bronopol can give allergic reactions. In this study 113 patients with poor tolerance of cosmetics were investigated. 5.3% of these patients

were allergic to bronopol (Kiec-Swierczynska et al., 2006). Generally, bronopol is not regarded as being allergenic in concentrations below 0.1% (Rowe et al., 2009), which is the concentration allowed in cosmetic products. According to Rowe et al. (2009) bronopol is used in hypoallergenic formulations in a concentration of 0.02%.

Bronopol can release formaldehyde (which is allergenic) under certain conditions (US EPA, 2011). It is not evident from the investigated references if it is this mechanism that determines the allergic reactions seen for bronopol.

8.2.4.5 Acute and chronic effects

According to an earlier SCCS opinion on bronopol (SCC 6th series, 1987), bronopol has a moderate to high acute toxicity. An LD_{50} value for rats and mice of between 300-350 mg/kg (oral) is stated and an LD_{50} value for dogs of 250 mg/kg (oral). In a medical handbook (Rowe et al., 2009), LD_{50} values of 270 mg/kg (mice, oral) and 180 mg/kg (rats, oral) respectively are stated. LD_{50} values stated by HSDB are 307 and 342 mg/kg (oral) respectively for male and female rats.

A 9-day study with rabbits showed gastric irritation and pulmonary effects after various doses by gavage (however which doses are not stated). NOEL for the study was 3.3 mg/kg/day (SCC 6th series, 1987).

In a 13-week study, up to 20 mg/kg/day were given to dogs by gavage. SCCS states that the probable NOEL was 4 mg/kg/day. Higher doses induced increased relative weights of liver and spleen, and some leucopenia (reduction of number of white bloodcells in the blood) (SCC 6th series, 1987). However, in a similar test with dogs (in 1995) described in HSDB with the same effects, a NOAEL of 8 mg/kg/day is given. Here doses of 0, 4, 8 and 20 mg/kg/day were given to beagle dogs. In dogs (both sexes) given the highest dose, increased liver weight (15%) and increased spleen weight (39%) were observed. There are far more details on this study from HSDB than the study reported by SCCS, where it is not possible to se which doses are given. The NOEL value of 8 mg/kg bw/day is therefore used.

In a 13-week study with rats groups of 40 rats were given 20, 80 and 160 mg/kg/day by gavage. There were severe symptoms and mortality at the top dose. At 20 mg/kg/day one animal showed transitory respiratory distress, but apart from this no abnormalities were noted at this dose (SCC 6th series, 1987). In another 13-week study with rats from 1995 groups of 20 rats were given 0, 20, 80 and 160 mg/kg/day by gavage respectively. Due to high mortality at the highest dosing, tests with this dose were stopped after 8 days. In the low-dose group, one female rat died during week 10 and two male rats had effects on the kidneys. At the mid-dose 35% of the male rats and 45% of the female rats died. Other toxic signs observed in the mid-dose were respiratory distress, gasping and wheezing for the animals that did not die. NOEL was determined to be 20 mg/kg/day for both sexes (HSDB).

In a 2-year rat study, groups of 60 male and 60 female rats received 10, 40 and 160 mg/kg/day in drinking water. All treatment groups showed a reduction in water intake. The top dose group showed clear signs of toxicity including mortality. There was a dose-related increase in the incidence of metaplasia of the salivary glands. No significant changes at the low dose were found by comparison with the controls (SCC 6th series, 1987).

In a reproductive toxicity rat study from 1995 bronopol was administered in drinking water in concentrations of 0, 25, 70 and 200 mg/kg/day. Systemic toxicity was observed mostly in the mid-dose (70) and high-dose (200) groups, in both generations. For the high-dose group a slight decrease in the female fertility index was observed (75% versus 87.5% in the control group). NOEL was therefore determined to be 25 mg/kg/day for systemic toxicity and 70 mg/kg/day for reproductive toxicity (HSDB).

In tests with rodents bronopol has not shown evidence of tumor occurrence when bronopol is being applied topically or administered orally. Nor does bronopol show evidence of mutagenicity, neither *in vitro* nor *in vivo* (Rowe et al., 2009; HSDB). According to animal tests described in HSDB there are signs of bronopol being non-carcinogenic (HSDB). Bronopol does not show any evidence of being teratogenic (SCC 6th series, 1987).

SCCS concludes that bronopol is safe to use in cosmetic products in concentrations of up to 0.2% (SCC 6th series, 1987). Today the allowed concentration in cosmetic products is 0.1%.

8.2.4.6 The critical effect

The lowest NOEL value (oral) for bronopol, (where the study has been described in more details), is stated in an older study with dogs at 8 mg/kg bw/day. The effect was here increased relative weights of liver and spleen. This value is used as NOEL value in the exposure calculations.

8.2.4.7 Calculation of DNEL

The NOEL value (oral) for bronopol has been determined to 8 mg/kg bw/day and is stated in a study from 1995 in HSDB. The NOEL value is based on a sub-chronic study with dogs for which reason an assessment factor (AF) of 1.4 for dogs, a factor of 2.5 for the interspecies differences together with a factor 2 to account for the use of a sub-chronic study are used, as stated in ECHA "Guidance on information requirements and chemical safety assessment – Chapter R.8" (ECHA R.8, 2012 – Table R.8-3 and Table R.8.5). Similarly a default assessment factor of 10 is used for the intraspecies differences. In total an assessment factor of 70 is used which results in a **DNEL value for bronopol of 0.114 mg/kg bw/day.**

8.2.4.8 Calculation of the internal dose DNEL

As described above an absorption fraction of 1 is assumed for bronopol, as no data on oral absorption has been found. This means that the internal dose DNEL is equal to the DNEL value as stated above. The value is listed in Table 46 below.

TABLE 46
INTERNAL DOSE DNEL WHICH IS USED IN THE CALCULATIONS

Name of substance	Internal dose DNEL (mg/kg bw/day)
Bronopol	0.114

8.2.4.9 Assessment of the risk of sensitisation

Bronopol is a so-called formaldehyde releaser which means that the substance can release formaldehyde which is highly allergenic. Allergic reactions have been observed by use of bronopol in human patch tests. In a large European study from 1990, allergic reactions have been observed in 0.47% of the patients. In a more recent study from 2006 allergic reactions have been observed in 5.3% of the cases, but it was patients with poor tolerance of cosmetics that were investigated more closely. Generally, bronopol is not regarded as being sensitising in concentrations below 0.1% (Rowe et al., 2009), which is the concentration that is allowed in cosmetic products.

In this survey bronopol has been observed in concentrations of about 0.04% (information from producers) and in concentrations between 0.03 and 0.1% in the chemical analysis. All concentrations observed are below the 0.1% value for which reason the risk of sensitisation, when using toys that contain bronopol in these concentrations, is assessed to be low.

8.3 Exposure calculations

The amount of the selected substances which the children will be exposed to is calculated according to the formulas stated in chapter 5 ”Exposure scenarios”. The formula of calculation depends on the situation, i.e. whether they are products which can be “smeared onto the skin” (finger paint, face paint/make-up, hobby paint, window paint/glass paint, glue and soap bubbles) or products which are more solid, where an exposure for the preservatives is solely a question of whether they migrate out of the product (i.e. for modelling clay and slime). Furthermore, exposure calculations are made for the products where it is assumed that an oral intake can occur, e.g. when children suck their fingers after use of finger paint.

The amount of the selected substances which can be absorbed in the body is calculated for each single substance and for each single type of the examined product types. Generally the exposure calculations are made for 3-year-old children as the products are generally targeted children from the age of 3 years and older. For modelling clay and finger paint which are also targeted children down to the age of 1 year, exposure calculations for children of the age of both 1 year and 3 years are made.

The results are stated in the following tables (Table 49 to Table 71). An example of calculation is stated below for the three different formulas of calculations, i.e.:

- Dermal exposure for a substance in a product which is smeared onto the skin
- Dermal exposure for a substance which migrates out of a product
- Oral exposure for a substance in a product where ingestion may occur

In connection with the exposure calculations a number of assumptions were made. There are partly assumptions for the different product types and partly assumptions concerning the different preservatives. These assumptions are stated in the tables below (Table 47 and Table 48).

For the different product groups, assumptions for the exposure calculations are made with regard to children’s weight, how often and how long children play with the products, how large amounts of the products that are used each time as well as how large amounts that are ingested as worst case each time the children play with the products. Note that in this project the used amounts are 6 or 12 times higher than the amounts which are used to determine the migration limit values for the metals in the new Toy Safety Directive (see section 5.2.1.1 ”Specially for oral exposure ($Q_{prod\ ingestion}$)”).

TABLE 47
OVERVIEW OVER ASSUMPTIONS REGARDING THE PRODUCT TYPES WHICH ARE USED IN THE EXPOSURE CALCULATIONS

Assumptions Product type	Body weight: (1-year-old/ 3-years-old)	Exposure: (duration and frequency)	Amount product: (dermal/oral)
Modelling clay	8.9 kg/13.5 kg	60 minutes per day 52 times a year	350 g/1 g
Hobby paint	Not relevant/13.5 kg	45 minutes per day 100 times a year	4 g/nothing
Finger paint	8.9 kg/13.5 kg	45 minutes per day 100 times a year	20 g/1.35 g
Window paint/glass paint	Not relevant/13.5 kg	45 minutes per day 100 times a year	4 g/nothing
Fase paint	Not relevant/13.5 kg	480 minutes per day 12 times a year	1.4 g/0.21 g
Make-up	Not relevant/13.5 kg	480 minutes per day 12 times a year	0.36 g/ 0.054 g
Glue	Not relevant/13.5 kg	45 minutes per day 100 times a year	4 g/nothing
Slime	Not relevant/13.5 kg	45 minutes per day 100 times a year	350 g/1 g
Soap bubbles	Not relevant/13.5 kg	45 minutes per day 20 times a year	60 g/1 g

For the different preservatives assumptions are made on how large a part of the substances that is absorbed by oral intake and dermal exposure. In addition to this there are in some cases made assumptions regarding the weight fraction of the preservatives in the product. The following situations occur:

1. Analysis results are used, i.e. the measured concentrations of the preservative are used in the measured product type. The highest measured concentration has been used.
2. The stated, used concentrations of the preservative in the product type from the survey are used. The highest stated concentration has been used.
3. If no ”real” information has been available, the maximum allowed concentration according to the Cosmetic Products Directive has been used.

In most cases concentrations from all three situations for the preservatives has been used. It depends on the individual product types which concentration, from which situation, that has been used.

TABLE 48
OVERVIEW OVER ASSUMPTIONS CONCERNING THE PRESERVATIVES WHICH ARE USED IN THE EXPOSURE CALCULATIONS

Assumptions Preservative	Dermal intake	Oral intake (and conversion to internal dose)	Weight fraction in the product (depends on the product type, which concentraton, that has been used)
Methylparaben	3.7%	100%	1. Analysis results 2. Information from survey 3. Highest allowed concentration
Ethylparaben	3.7%	100%	1. Analysis results 2. Information from survey 3. Highest allowed concentration
Propylparaben	3.7%	100%	1. Analysis results 2. Information from survey 3. Highest allowed concentration
Butylparaben	3.7%	100%	2. Information from survey 3. Highest allowed concentration
2-phenoxyethanol	40%	100%	1. Analysis results 2. Information from survey 3. Highest allowed concentration
Formaldehyde	5%	100%	1. Analysis results 2. Information from survey 3. Highest allowed concentration
Bronopol	40%	100%	1. Analysis results 2. Information from survey 3. Highest allowed concentration

8.3.1 Examples of calculation

8.3.1.1 Example of calculaton for dermal exposure for a product which is smeared onto the skin

The example shows the calculation of the dermal exposure for ethylparaben in make-up. The following values are used in the calculation:

- Q_{prod}: The amount of make-up, which is used each time make-up is used, is 0.36 g (see section 5.2.1 "Amount of product used (Q_{prod})").
- Fc_{prod}: According to Table 33 a concentration of ethylparaben of 3785 mg/kg (0.3785%) corresponding to a fraction of 0.003785 is measured in a make-up product.
- n: The average number of occurrences per day is as stated in section 5.2.4 "Contact duration ($T_{contact}$) and frequency (n) of exposure" 12 times per year, i.e. 12/365 = 0.033.

- BW: The body weight is as stated in section 5.2.5 ”Body weight (BW)” 13.5 kg for a child at the age of 3 years.
- It is not all ethylparaben which ends on the skin that is absorbed through the skin. According to section 8.2.1.3 ”Absorption and distribution” for the parabens, a dermal absorption of 3.7% is stated. I.e. the dermal absorbtion is 0.037.

The dermal dose which potentially can be absorbed is thus:

$$D_{der} = \frac{Q_{prod} \times Fc_{prod} \times n \times 1000}{BW} = \frac{0.36\ g \times 0.003785 \times 0{,}033\ per\ day \times 1000\ mg/g}{13.5\ kg}$$

= 0.003 mg/kg/day

As the dermal absorption for ethylparaben is 3.7% the real intake will only be 3.7% of the above value, i.e.:

$D_{der\ abs.}$ = 0.003 mg/kg/day x 0.037 = 0,0001 mg/kg/day.

All values used in the calculations can be seen from the tables below (Table 49 to Table 71).

8.3.1.2 Example of calculation for dermal exposure for a substance which migrates out of a product

The example shows the calculation of the dermal exposure for bronopol in modelling clay. The following values are used in the calculation:

- Q_{prod}: The amount of modelling clay which is used each time a child plays with modelling clay, is 350 g (see (see section 5.2.1 ”Amount of product used (Q_{prod})”).
- Fc_{prod} x Fc_{migr}: The product of the two parameters, the weight fraction in the product and the migration rate, corresponds to the result from the migration analysis, i.e. the results as stated in Table 36. For bronopol a migration of 550 mg/kg (0.055%) is measured in modelling clay corresponding to a fraction of 0.00055.
- $F_{contact}$: The fraction of the contact area of the skin is a fraction which can be used to take into account if the skin is only partly in contact with the product. For all calculations for modelling clay and slime this fraction is set to 1 as worst case as it can be assumed that the products are “pugged” so much that the children are in contact with the whole product.
- $T_{contact}$: The contact time between the product and the skin as described in section 5.2.4 ”Contact duration ($T_{contact}$) and frequency (n) of exposure” is 60 minutes. For the cases where the migration is directly measured during the time which the products are assumed used, this factor will be 1.
- n: The average number of occurrences per day is as stated in section 5.2.4 ”Contact duration ($T_{contact}$) and frequency (n) of exposure” 52 times a year, i.e. 52/365 = 0.142.
- BW: The body weight is as stated in section 5.2.5 ”Body weight (BW)” 8.9 kg for a child at the age of 1 year and 13.5 kg for a child at the age of 3 years.
- It is not all bronopol which ends on the skin that is absorbed through the skin. According to section 8.2.4.3 ”Absorption and distribution” for bronopol, a dermal absorption of 40% is stated. I.e. the dermal absorbtion is 0.4.

The dermal dose which potentially can be absorbed is thus:

$$D_{der} = \frac{Q_{prod} \times Fc_{prod} \times Fc_{migr} \times F_{contact} \times T_{contact} \times n \times 1000}{BW}$$

$$= \frac{350\ g \times 0.00055 \times 1 \times 1 \times 0.142\ per\ day \times 1000\ mg/g}{8.9\ kg}$$

= 3.08 mg/kg/day for a child at the age of 1 year and correspondingly

= 2.03 mg/kg/day for a child at the age of 3 years

As the dermal absorption for bronopol is 40% the real intake will only be 40% of the above value, i.e.:

$D_{der\ abs.}$ = 3.08 mg/kg/day x 0.4 = 1.23 mg/kg/day for children at the age of 1 year and correspondingly 0.81 mg/kg/day for children at the age of 3 years.

All values used in the calculations can be seen from the tables below (Table 49 to Table 71).

8.3.1.3 Example of calculation for oral exposure if a product is ingested

The example shows the calculation of the oral exposure for methylparaben by use of finger paint. The following values are used in the calculation:

- $Q_{prod\ ingestion}$: The amount of finger paint which is used each time finger paint is used, is 1.35 g (see section 5.2.1.1 "Specially for oral exposure ($Q_{prod\ ingestion}$)").
- Fc_{prod}: The weight fraction of methylparaben in the product is assumed to be 0.004 based on an assumed concentration of 0.4% (i.e. the maximum allowed concentration in cosmetic products), as the survey has not given specific information about percentages of content in finger paint.
- n: The average number of occurrences per day is as stated in section 5.2.4 "Contact duration ($T_{contact}$) and frequency (n) of exposure" 100 times a year, i.e. 100/365 = 0.274.
- BW: The body weight is as stated in section 5.2.5 "Body weight (BW)" 8.9 kg for a child at the age of 1 year and 13.5 kg for a child at the age of 3 years.

The oral dose which potentially can be absorbed is thus:

$$D_{oral} = \frac{Q_{prod\ ingestion} \times Fc_{prod} \times n \times 1000}{BW} = \frac{1.35\ g \times 0.004 \times \frac{0{,}274}{day} \times 1000\ mg/g}{8.9\ kg}$$

= 0.166 mg/kg/day for a child at the age of 1 year and correspondingly
= 0.110 mg/kg/day for a child at the age of 3 years

8.3.2 Results: Exposure calculations

The results of the exposure calculations are arranged for the individual selected substances and for each selected substance a table per method of calculation is stated (i.e. a table for dermal exposure of products which are smeared onto the skin, a table for modelling clay and slime (when there is a migration of the substances) as well as a table for oral ingestion).

For finger paint and modelling clay which are also used by children at the age of 1 year, two values are stated for children at the age of 1 year and at the age of 3 years.

8.3.2.1 Methylparaben

TABLE 49
RESULT OF EXPOSURE CALCULATIONS FOR METHYLPARABEN DERMAL ABSORPTION FOR PRODUCTS WHICH ARE SMEARED ONTO THE SKIN

Product	Q_{prod} (g)	Fc_{prod} (-)	n (per day)	BW (kg)	Dermal absorp. (-)	$D_{der\ abs.}$ (mg/kg/day)
Hobby paint	*Methylparaben is not seen in this product type*					
Finger paint (1-year-old)	20	0.004*	100/365	8.9	0.037	0.091
Finger paint	20	0.004*	100/365	13.5	0.037	0.060
Window paint/glass paint	*Methylparaben is not seen in this product type*					
Face paint	1.4	0.00092**	12/365	13.5	0.037	0.0001
Make-up	0.36	0.00092**	12/365	13.5	0.037	0.00003
Glue	4	0.004***	100/365	13.5	0.037	0.012
Soap bubbles	60	0.00001***	20/365	13.5	0.037	0.00009

* No concentration is stated here and finger paint is not analysed. Therefore the highest allowed concentration of methylparaben in finger paint is used (see Table 2).
** The analysis results from make-up are used here (see Table 33).
*** The maximum concentration as stated in the survey is used here (see Table 22).

TABLE 50
RESULT OF EXPOSURE CALCULATIONS FOR METHYLPARABEN DERMAL ABSORPTION FOR MODELLING CLAY AND SLIME WHERE MIGRATION IS CALCULATED

Product	Q_{prod} (g)	Fc_{prod} x Fc_{migr} (-)	n (per day)	BW (kg)	Dermal absorp. (-)	$D_{der\ abs.}$ (mg/kg/day)
Modelling clay (1-year-old)	*Methylparaben is not seen in this product type*					
Modelling clay	*Methylparaben is not seen in this product type*					
Slime	350	0.000885*	100/365	13.5	0.037	0.233

* The result from the migration analysis is used here (see Table 36).

TABLE 51
RESULT FO EXPOSURE CALCULATIONS FOR METHYLPARABEN ORAL ABSORPTION

Product	Q_{prod} (g)	Fc_{prod} (-)	n (per day)	BW (kg)	$D_{oral\ absorption}$ (mg/kg/day)
Modelling clay (1-year-old)	*Methylparaben is not seen in this product type*				
Modelling clay	*Methylparaben is not seen in this product type*				
Hobby paint	*Here it is assumed that no ingestion occurs*				
Finger paint (1-year-old)	1.35	0.004*	100/365	8.9	0.166
Finger paint	1.35	0.004*	100/365	13.5	0.110
Window paint/glass paint	*Here it is assumed that no ingestion occurs*				
Face paint	0.21	0.0092**	12/365	13.5	0.005
Make-up	0.054	0.0092**	12/365	13.5	0.001
Glue	*Here it is assumed that no ingestion occurs*				
Slime	1	0.001965***	100/365	13.5	0.040
Soap bubbles	1	0.00001****	20/365	13.5	0.00004

* Here no concentration is stated and finger paint has not been analysed. Therefore the highest allowed concentration of methylparaben in finger paint has been used (see Table 2).
** Here the analysis results from make-up have been used (see Table 33).
*** Here the analysis results have been used (see Table 28 to Table 33)
**** Here the maximum concentration as stated in the survey has been used (see Table 22).

The total intake for methylparaben is calculated as the sum of the dermal and the oral absorption. This is stated in the section 8.3.2.8 ”Total absorption of the substances” at the end of this section (see Table 70).

8.3.2.2 Ethylparaben

TABLE 52
RESULT OF EXPOSURE CALCULATIONS FOR ETHYLPARABEN DERMAL ABSORPTION FOR PRODUCTS WHICH ARE SMEARED ONTO THE SKIN

Product	Q_{prod} (g)	Fc_{prod} (-)	n (per day)	BW (kg)	Dermal absorp. (-)	$D_{der\ abs.}$ (mg/kg/day)
Hobby paint	*Ethylparaben is not seen in this product type*					
Finger paint (1-year-old)	20	0.004*	100/365	8.9	0.037	0.091
Finger paint	20	0.004*	100/365	13.5	0.037	0.060
Window paint/glass paint	*Ethylparaben is not seen in this product type*					
Face paint	1.4	0.003785**	12/365	13.5	0.037	0.0005
Make-up	0.36	0.003785**	12/365	13.5	0.037	0.0001
Glue	4	0.004***	100/365	13.5	0.037	0.012
Soap bubbles	60	0.00001***	20/365	13.5	0.037	0.00009

* Here no concentration is stated and finger paint has not been analysed. Therefore the highest allowed concentration of ethylparaben in finger paint has been used (see Table 2).
** Here the analysis results from make-up have been used (see Table 33).
*** Here the maximum concentration as stated in the survey has been used (see Table 22).

TABLE 53
RESULT OF EXPOSURE CALCULATIONS FOR ETHYLPARABEN DERMAL ABSORPTION FOR MODELLING CLAY AND SLIME WHERE MIGRATION HAS BEEN CALCULATED

Product	Q_{prod} (g)	Fc_{prod} x Fc_{migr} (-)	n (per day)	BW (kg)	Dermal absorp. (-)	$D_{der\ abs.}$ (mg/kg/day)
Modelling clay (1-year-old)	350	0.0002* x 0.6	52/365	8.9	0.037	0.0025
Modelling clay	350	0.0002* x 0.6	52/365	13.5	0.037	0.0016
Slime	350	0.00002* x 0.45	100/365	13.5	0.037	0.0024

* Here the maximum concentration as stated in the survey has been used (see Table 22).

TABLE 54
RESULT OF EXPOSURE CALCULATIONS FOR ETHYLPARABEN ORAL ABSORPTION

Product	Q_{prod} (g)	Fc_{prod} (-)	n (per day)	BW (kg)	$D_{oral\ absorption}$ (mg/kg/day)
Modelling clay (1-year-old)	1	0.00002*	52/365	8.9	0.0003
Modelling clay	1	0.00002*	52/365	13.5	0.0002
Hobby paint	*Here it is assumed that no ingestion occurs*				
Finger paint (1-year-old)	1.35	0.004**	100/365	8.9	0.166
Finger paint	1.35	0.004**	100/365	13.5	0.110
Window paint/glass paint	*Here it is assumed that no ingestion occurs*				
Face paint	0.21	0.003785***	12/365	13.5	0.002
Make-up	0.054	0.003785***	12/365	13.5	0.0005
Glue	*Here it is assumed that no ingestion occurs*				
Slime	1	0.00002*	100/365	13.5	0.0004
Soap bubbles	1	0.00001*	20/365	13.5	0.00004

* Here the maximum concentration as stated in the survey has been used (see Table 22).
** Here no concentration is stated and finger paint has not been analysed. Therefore the highest allowed concentration of ethylparaben in finger paint has been used (see Table 2).
*** Here the analysis results from make-up have been used (see Table 33).

The total intake for ethylparaben is calculated as the sum of the dermal and the oral absorption. This is stated in the section 8.3.2.8 ”Total absorption of the substances” at the end of this section (see Table 70).

8.3.2.3 Propylparaben

TABLE 55
RESULT OF EXPOSURE CALCULATIONS FOR PROPYLPARABEN DERMAL ABSORPTION FOR PRODUCTS WHICH ARE SMEARED ONTO THE SKIN

Product	Q_{prod} (g)	Fc_{prod} (-)	n (per day)	BW (kg)	Dermal absorp. (-)	$D_{der\ abs.}$ (mg/kg/day)
Hobby paint	*Propylparaben is not seen in this product type*					
Finger paint (1-year-old)	20	0.004*	100/365	8.9	0.037	0.091
Finger paint	20	0.004*	100/365	13.5	0.037	0.060
Window paint/glass paint	*Propylparaben is not seen in this product type*					
Face paint	1.4	0.004**	12/365	13.5	0.037	0.0005
Make-up	0.36	0.004**	12/365	13.5	0.037	0.0001
Glue	4	0.004**	100/365	13.5	0.037	0.012
Soap bubbles	60	0.00001**	20/365	13.5	0.037	0.00009

* Here no concentration is stated and finger paint has not been analysed. Therefore the highest allowed concentration of propylparaben in finger paint has been used (see Table 2).
** Here the maximum concentration as stated in the survey has been used (see Table 22).

TABLE 56
RESULT OF EXPOSURE CALCULATIONS FOR PROPYLPARABEN DERMAL ABSORPTION FOR MODELLING CLAY AND SLIME WHERE MIGRATION IS CALCULATED

Product	Q_{prod} (g)	Fc_{prod} x Fc_{migr} (-)	n (per day)	BW (kg)	Dermal absorp. (-)	$D_{der\ abs.}$ (mg/kg/day)
Finger paint (1-year-old)	350	0.0002* x 230/965 per 45 min. x 60 min.**	52/365	8.9	0.037	0.0013
Modelling clay	350	0.0002* x 230/965 per 45 min. x 60 min.**	52/365	13.5	0.037	0.0009
Slime	350	0.00023***	100/365	13.5	0.037	0.060

* Here the maximum concentration as stated in the survey is used (see Table 22).
** Here the migration rate from the analysis of slime is used (the ratio between the migration value from Table 36 and the content value from Table 30) for propylparaben and it has been taken into account that migration of slime is 45 minutes but that modelling clay is used for 60 minutes.
*** Here the value from the migration analysis is used (see Table 36).

TABLE 57
RESULT OF EXPOSURE CALCULATIONS FOR PROPYLPARABEN ORAL ABSORPTION

Product	Q_{prod} (g)	Fc_{prod} (-)	n (per day)	BW (kg)	$D_{oral\ absorption}$ (mg/kg/day)
Modelling clay (1-year-old)	1	0.00002*	52/365	8.9	0.0003
Modelling clay	1	0.00002*	52/365	13.5	0.0002
Hobby paint	*Here it is assumed that no ingestion occurs*				
Finger paint (1-year-old)	1.35	0.004**	100/365	8.9	0.166
Finger paint	1.35	0.004**	100/365	13.5	0.110
Window paint/glass paint	*Here it is assumed that no ingestion occurs*				
Face paint	0.21	0.004*	12/365	13.5	0.003
Make-up	0.054	0.004*	12/365	13.5	0.0005
Glue	*Here it is assumed that no ingestion occurs*				
Slime	1	0.000985***	100/365	13.5	0.020
Soap bubbles	1	0.00001*	20/365	13.5	0.00004

* Here the maximum concentration as stated in the survey is used (see Table 22).
** Here no concentration is stated and finger paint has not been analysed. Therefore the highest allowed concentration of propylparaben in finger paint has been used (see Table 2).
*** Here the analysis result from slime has been used (see Table 30).

The total intake for propylparaben is calculated as the sum of the dermal and the oral absorption. This is stated in the section 8.3.2.8 ”Total absorption of the substances” at the end of this section (see Table 70).

8.3.2.4 Butylparaben

TABLE 58
RESULT OF EXPOSURE CALCULATIONS FOR BUTYLPARABEN DERMAL ABSORPTION FOR PRODUCTS WHICH ARE SMEARED ONTO THE SKIN

Product	Q_{prod} (g)	Fc_{prod} (-)	n (per day)	BW (kg)	Dermal absorp. (-)	$D_{der\ abs.}$ (mg/kg/day)
Hobby paint	*Butylparaben is not seen in this product type*					
Finger paint (1-year-old)	20	0.004*	100/365	8.9	0.037	0.091
Finger paint	20	0.004*	100/365	13.5	0.037	0.060
Window paint/glass paint	*Butylparaben is not seen in this product type*					
Face paint	1.4	0.004**	12/365	13.5	0.037	0.0005
Make-up	0.36	0.004**	12/365	13.5	0.037	0.0001
Glue	4	0.004**	100/365	13.5	0.037	0.012
Soap bubbles	60	0.00001**	20/365	13.5	0.037	0.00009

* Here no concentration is stated and finger paint has not been analysed. Therefore the highest allowed concentration of butylparaben in finger paint has been used (see Table 2).
** Here the maximum concentration as stated in the survey is used (see Table 22).

TABLE 59
RESULT OF EXPOSURE CALCULATIONS FOR BUTYLPARABEN DERMAL ABSORPTION FOR MODELLING CLAY AND SLIME WHERE MIGRATION IS CALCULATED

Product	Q_{prod} (g)	Fc_{prod} x Fc_{migr} (-)	n (per day)	BW (kg)	Dermal absorp. (-)	$D_{der\ abs.}$ (mg/kg/day)
Modelling clay (1-year-old)	350	0.0002* x 230/965 per 45 min. x 60 min.**	52/365	8.9	0.037	0.0013
Modelling clay	350	0.0002* x 230/965 per 45 min. x 60 min.**	52/365	13.5	0.037	0.0009
Slime	350	0.0002* x 230/965 per 45 min. x 45 min.**	100/365	13.5	0.037	0.0013

* Here the maximum concentration as stated in the survey is used (see Table 22).
** Here the migration rate from the analysis of slime is used (the ratio between the migration value from Table 36 and the content value from Table 30) for propylparaben and it has been taken into account that migration of slime is 45 minutes but that modelling clay is used for 60 minutes.

TABLE 60
RESULT OF EXPOSURE CALCULATIONS FOR BUTYLPARABEN ORAL ABSORPTION

Product	Q_{prod} (g)	Fc_{prod} (-)	n (per day)	BW (kg)	$D_{oral\ absorption}$ (mg/kg/day)
Modelling clay (1-year-old)	1	0.00002*	52/365	8.9	0.0003
Modelling clay	1	0.00002*	52/365	13.5	0.0002
Hobby paint	*Here it is assumed that no ingestion occurs*				
Finger paint (1-year-old)	1.35	0.004**	100/365	8.9	0.166
Finger paint	1.35	0.004**	100/365	13.5	0.110
Window paint/glass paint	*Here it is assumed that no ingestion occurs*				
Face paint	0.21	0.004*	12/365	13.5	0.003
Make-up	0.054	0.004*	12/365	13.5	0.0005
Glue	*Here it is assumed that no ingestion occurs*				
Slime	1	0.00002*	100/365	13.5	0.0004
Soap bubbles	1	0.00001*	20/365	13.5	0.00004

* Here the maximum concentration as stated in the survey is used (see Table 22).
** Here no concentration is stated and finger paint has not been analysed. Therefore the highest allowed concentration of butylparaben in finger paint has been used (see Table 2).

The total intake for butylparaben is calculated as the sum of the dermal and the oral absorption. This is stated in the section 8.3.2.8 ”Total absorption of the substances” at the end of this section (see Table 70).

8.3.2.5 2-phenoxyethanol

TABLE 61
RESULT OF EXPOSURE CALCULATIONS FOR 2-PHENOXYETHANOL DERMAL ABSORPTION FOR PRODUCTS WHICH ARE SMEARED ONTO THE SKIN

Product	Q_{prod} (g)	Fc_{prod} (-)	n (per day)	BW (kg)	Dermal absorp. (-)	$D_{der\ abs.}$ (mg/kg/day)
Hobby paint	4	0.000045*	100/365	13.5	0.4	0.001
Finger paint (1-year-old)	20	0.0089*	100/365	8.9	0.4	2.19
Finger paint	20	0.0089*	100/365	13.5	0.4	1.44
Window paint/glass paint	*2-phenoxyethanol is not seen in this product type*					
Face paint	1.4	0.0113**	12/365	13.5	0.4	0.015
Make-up	0.36	0.0113**	12/365	13.5	0.4	0.004
Glue	4	0.008*	100/365	13.5	0.4	0.260
Soap bubbles	60	0.006896*	20/365	13.5	0.4	0.672

* Here the maximum concentration as stated in the survey is used (see Table 22).
** Here the analysis results from make-up are used (see Table 33).

TABLE 62
RESULT OF EXPOSURE CALCULATIONS FOR 2-PHENOXYETHANOL DERMAL ABSORPTION FOR MODELLING CLAY AND SLIME WHERE MIGRATION IS CALCULATED

Product	Q_{prod} (g)	Fc_{prod} x Fc_{migr} (-)	n (per day)	BW (kg)	Dermal absorp. (-)	$D_{der\ abs.}$ (mg/kg/day)
Modelling clay (1-year-old)	350	0.000045*	52/365	8.9	0.4	0.101
Modelling clay	350	0.000045*	52/365	13.5	0.4	0.066
Slime	350	0.01**	100/365	13.5	0.4	28.41

* Note that here the concentration from the survey (Table 22) is used as no migration analyses of 2-phenoxyethanol are made. Thus a 100% migration is assumed which will be overestimated.
** Note that here the maximum allowed concentration in cosmetic products is used as the survey has not given any information about the concentration of 2-phenoxyethanol in slime. Furthermore, no migration analyses are made for which reason a 100% migration is assumed which will be overestimated.

TABLE 63
RESULT OF EXPOSURE CALCULATION FOR 2-PHENOXYETHANOL ORAL ABSORPTION

Product	Q_{prod} (g)	Fc_{prod} (-)	n (per day)	BW (kg)	$D_{oral\ absorption}$ (mg/kg/day)
Modelling clay (1-year-old)	1	0.000045*	52/365	8.9	0.0007
Modelling clay	1	0.000045*	52/365	13.5	0.0005
Hobby paint	*Here it is assumed that no ingestion occurs*				
Finger paint (1-year-old)	1.35	0.0089*	100/365	8.9	0.370
Finger paint	1.35	0.0089*	100/365	13.5	0.244
Window paint/glass paint	*Here it is assumed that no ingestion occurs*				
Face paint	0.21	0.0113**	12/365	13.5	0.006
Make-up	0.054	0.0113**	12/365	13.5	0.001
Glue	*Here it is assumed that no ingestion occurs*				
Slime	1	0.01***	100/365	13.5	0.203
Soap bubbles	1	0.006896*	20/365	13.5	0.028

* Here the maximum concentration as stated in the survey is used (see Table 22).
** Here the analysis results from make-up are used (see Table 33).
*** Here no concentration is stated and for slime no 2-phenoxyethanol is seen in the analysed products. Therefore the highest allowed concentration of 2-phenoxyethanol in cosmetic products is used (see Table 1).

The total intake for 2-phenoxyethanol is calculated as the sum of the dermal and the oral absorption. This is stated in the section 8.3.2.8 ”Total absorption of the substances” at the end of this section (see Table 71).

8.3.2.6 Formaldehyde

TABLE 64
RESULT OF EXPOSURE CALCULATIONS FOR FORMALDEHYDE DERMAL ABSORPTION FOR PRODUCTS WHICH ARE SMEARED ONTO THE SKIN

Product	Q_{prod} (g)	Fc_{prod} (-)	n (per day)	BW (kg)	Dermal absorp. (-)	$D_{der\ abs.}$ (mg/kg/day)
Hobby paint	4	0.00087****	100/365	13.5	0.05	0.004
Finger paint (1-year-old)	20	0.001*	100/365	8.9	0.05	0.031
Finger paint	20	0.001*	100/365	13.5	0.05	0.020
Window paint/glass paint	*Formaldehyde is not seen in this product type*					
Face paint	1.4	0.0000347**	12/365	13.5	0.05	0.00001
Make-up	0.36	0.0000347***	12/365	13.5	0.05	0.000002
Glue	4	0. 0000034****	100/365	13.5	0.05	0.00001
Soap bubbles	60	0.0000405***	20/365	13.5	0.05	0.0005

* Here no concentration is stated and finger paint has not been analysed. Therefore the highest allowed concentration of formaldehyde in finger paint has been used (see Table 2).
** Here the analysis results from make-up are used (see Table 33).
*** Here the analysis results are used (see Table 28 to Table 33)
**** Here the maximum concentration as stated in the survey is used (see Table 22).

TABLE 65
RESULT OF EXPOSURE CALCULATIONS FOR FORMALDEHYDE DERMAL ABSORPTION FOR MODELLING CLAY AND SLIME WHERE MIGRATION IS CALCULATED

Product	Q_{prod} (g)	Fc_{prod} x Fc_{migr} (-)	n (per day)	BW (kg)	Dermal absorp. (-)	$D_{der\ abs.}$ (mg/kg/day)
Modelling clay (1-year-old)	350	0.00122*	52/365	8.9	0.05	0.342
Modelling clay	350	0.00122*	52/365	13.5	0.05	0.225
Slime	350	0.00355**	100/365	13.5	0.05	1.261

* Note that here the concentration from the survey (Table 31) is used as no migration analyses of formaldehyde are made. Thus a 100% migration is assumed which will be overestimated.
** Note that here the concentrations from the analyses (Table 30) are used as no migration analyses of formaldehyde are made. Thus a 100% migration is assumed which will be overestimated.

TABLE 66
RESULT OF EXPOSURE CALCULATIONS FOR FORMALDEHYDE ORAL ABSORPTION

Product	Q_{prod} (g)	Fc_{prod} (-)	n (per day)	BW (kg)	$D_{oral\ absorption}$ (mg/kg/day)
Modelling clay (1-year-old)	1	0.00122*	52/365	8.9	0.020
Modelling clay	1	0.00122*	52/365	13.5	0.013
Hobby paint	*Here it is assumed that no ingestion occurs*				
Finger paint (1-year-old)	1.35	0.001**	100/365	8.9	0.042
Finger paint	1.35	0.001**	100/365	13.5	0.027
Window paint/glass paint	*Here it is assumed that no ingestion occurs*				
Face paint	0.21	0.0000347***	12/365	13.5	0.00002
Make-up	0.054	0.0000347****	12/365	13.5	0.000005
Glue	*Here it is assumed that no ingestion occurs*				
Slime	1	0.000355****	100/365	13.5	0.007
Soap bubbles	1	0.0000405****	20/365	13.5	0.0002

* Here the maximum concentration as stated in the survey is used (see Table 22).
** Here no concentration is stated and finger paint has not been analysed. Therefore the highest allowed concentration of formaldehyde in finger paint is used (see Table 2).
*** Here the analysis results from make-up are used (see Table 33).
**** Here the analysis results are used (see Table 28 to Table 33)

The total intake for formaldehyde is calculated as the sum of the dermal and the oral absorption. This is stated in the section 8.3.2.8 ”Total absorption of the substances” at the end of this section (see Table 71).

8.3.2.7 Bronopol

TABLE 67
RESULT OF EXPOSURE CALCULATIONS FOR BRONOPOL DERMAN ABSORPTION FOR PRODUCTS WHICH ARE SMEARED ONTO THE SKIN

Product	Q_{prod} (g)	Fc_{prod} (-)	n (per day)	BW (kg)	Dermal absorp. (-)	$D_{der\ abs.}$ (mg/kg/day)
Hobby paint	4	0.0004*	100/365	13.5	0.4	0.013
Finger paint (1-year-old)	20	0.001**	100/365	8.9	0.4	0.246
Finger paint	20	0.001**	100/365	13.5	0.4	0.162
Window paint/glass paint	4	0.0004*	100/365	13.5	0.4	0.013
Face paint	*Bronopol is not seen in this product type*					
Make-up	*Bronopol is not seen in this product type*					
Glue	*Bronopol is not seen in this product type*					
Soap bubbles	60	0.001***	20/365	13.5	0.4	0.097

* Here the maximum concentration as stated in the survey is used (see Table 22).
** Here no concentration is stated and finger paint has not been analysed. Therefore the highest allowed concentration of bronopol in finger paint is used (see Table 2).
*** Here the analysis results are used (see Table 32).

TABLE 68
RESULT OF EXPOSURE CALCULATIONS FOR BRONOPOL DERMAL ABSORPTION FOR MODELLING AND SLIME WHERE MIGRATION IS CALCULATED

Product	Q_{prod} (g)	Fc_{prod} x Fc_{migr} (-)	n (per day)	BW (kg)	Dermal absorp. (-)	$D_{der\ abs.}$ (mg/kg/day)
Modelling clay (1-year-old)	350	0.00055*	52/365	8.9	0.4	1.233
Modelling clay	350	0.00055*	52/365	13.5	0.4	0.813
Slime	*Bronopol is not seen in this product type*					

* Here the result from the migration analysis is used (see Table 36).

TABLE 69
RESULT OF EXPOSURE CALCULATIONS FOR BRONOPOL ORAL ABSORPTION

Product	Q_{prod} (g)	Fc_{prod} (-)	n (per day)	BW (kg)	$D_{oral\ absorption}$ (mg/kg/day)
Modelling clay (1-year-old)	1	0.000305*	52/365	8.9	0.005
Modelling clay	1	0.000305*	52/365	13.5	0.003
Hobby paint	*Here it is assumed that no ingestion occurs*				
Finger paint (1-year-old)	1.35	0.001**	100/365	8.9	0.042
Finger paint	1.35	0.001**	100/365	13.5	0.027
Window paint/glass paint	*Here it is assumed that no ingestion occurs*				
Face paint	*Bronopol is not seen in this product type*				
Make-up	*Bronopol is not seen in this product type*				
Glue	*Here it is assumed that no ingestion occurs*				
Slime	*Bronopol is not seen in this product type*				
Soap bubbles	1	0.001***	20/365	13.5	0.004

* Here the maximum concentration as stated in the survey is used (see Table 22).
** Here no concentration is stated and finger paint has not been analysed. Therefore the highest allowed concentration of bronopol in finger paint is used (see Table 2).
*** Here the analysis results are used (see Table 32).

The total intake for bronopol is calculated as the sum of the dermal and the oral absorption. This is stated in the section 8.3.2.8 "Total absorption of the substances" at the end of this section (see Table 71).

8.3.2.8 Total absorption of the substances

The total absorption of the substances is calculated as the sum of the dermal and the oral absorption. This is stated in Table 70 and Table 71 below.

It has to be noted that for the calculations a number of worst case assumptions have been made about the use of the products which are summarised in Table 47 as well as a number of assumptions about the preservatives which are summarised in Table 48. For assumptions about the products, especially the assumptions about the amounts, which are ingested, are worst case (a factor 6 or 12 higher than the amounts which are used for determination of the migration limits for metals in the new Toy Safety Directive). For the assumptions about the preservatives it is especially the assumptions about use of maximum allowed concentrations (either according to the toy standards or according to the Cosmetic Products Directive) when no other values are identified that may be considered to be worst case. In addition to this if no migration analyses are made, it is assumed for

modelling clay and slime that 100% of the assumed worst case content of the preservative migrates out of the product.

All in all it means that these exposure calculations which are made are so-called ”Tier 1” calculations, i.e. a very rough calculation which is used to illustrate whether the use of the preservatives in toys in worst case scenarious might constitute a risk to the consumer. Thus it does not seem to be very probable or realistic that all worst case scenarious will appear at the same time which it is assumed in the calculations.

TABLE 70
THE TOTAL ABSORPTION OF THE PARABENS – THE SUM OF DERMAL AND ORAL ABSORPTION IN MG/KG/DAY. THE ABSORPTION HAS BEEN CALCULATED FOR 3-YEAR-OLD UNLESS OTHERWISE STATED.

Product type	Methyl-paraben	Ethylparaben	Propyl-paraben	Butylparaben
Modelling clay (1-year-old)		0.003	0.002	0.002
Modelling clay		0.002	0.001	0.001
Hobby paint				
Finger paint (1-year-old)	0.257	0.257	0.257	0.257
Finger paint	0.170	0.170	0.170	0.170
Window paint/glass paint				
Face paint	0.005	0.002	0.004	0.004
Make-up	0.001	0.001	0.001	0.001
Glue	0.012	0.012	0.012	0.012
Slime	0.272	0.003	0.080	0.061
Soap bubbles	0.0001	0.0001	0.0001	0.0001

Empty spaces indicate that the stated preservative is not seen in the product type in question.

TABLE 71
THE TOTAL INTAKE OF THE REMAINING SUBSTANCES – THE SUM OF DERMAL AND ORAL ABSORPTION IN MG/KG/DAY. THE ABSORPTION IS CALCULATED FOR 3-YEAR-OLD UNLESS OTHERWISE STATED.

Product type	2-phenoxyethanol	Formaldehyde	Bronopol
Modelling clay (1-year-old)	0.102	0.361	1.24
Modelling clay	0.067	0.238	0.82
Hobby paint	0.001	0.004	0.013
Finger paint (1-year-old)	2.56	0.072	0.288
Finger paint	1.69	0.048	0.190
Window paint/glass paint			0.013
Face paint	0.021	0.00002	
Make-up	0.005	0.00001	
Glue	0.260	0.00001	
Slime	28.61	1.27	
Soap bubbles	0.700	0.001	0.101

Empty spaces indicate that the stated preservative is not seen in the product type in question.

8.4 Risk assessment

In the risk assessment the calculated intake is set in relation to the internal DNEL value (the lowest value where an effect of the substance is seen in animal experiments divided by a number of assessment factors) as described in section 8.1 ”Method for calculation of risk”. The RCR value is calculated as the ratio between the total absorption and the internal DNEL value. If RCR > 1 (i.e. the exposure is larger than DNEL) there is a risk. If RCR < 1 the exposure is not considered to constitute a risk.

The calculated RCR values for all selected substances for all examined product types are stated in Table 73 and Table 74 below based on the internal DNEL values stated in Table 72.

TABLE 72
INTERNAL DOSE DNEL WHICH IS USED IN THE CALCULATIONS

Name of substance	Internal dose DNEL (mg/kg bw/day)
Methylparaben and ethylparaben	10
Propylparaben and butylparaben	0.02 Alternative value: 0.330
2-phenoxyethanol	0.82
Formaldehyde	0.15
Bronopol	0.114

In all the tables a sum of the RCR value for both children at the age of 1 year and at the age of 3 years is calculated. The sum for the children at the age of 3 years is a sum of all the RCR values for the substance in question for all 9 product groups. I.e. for this total sum it is taken into account that the children can play with all product types and thus be exposed to the same substance if this substance is found in all the product types. However, for the children at the age of 1 year the total value only covers modelling clay and finger paint as these two product groups are the only groups which are intended for children under the age of 3 years.

In Table 73 and Table 74 the RCR values are calculated. But as described earlier, the calculations are based on a number of rough assumptions. One of the assumptions refers to the used concentration of content of the preservatives for the calculations. The concentration of content is either based on:

1. Analysis results or
2. Stated used concentrations of the preservative in the product type from the survey or
3. Maximum allowed concentration according to the Cosmetic Products Directive if no information from the analyses or the survey was available.

With three different background colours in the tables it is marked which kind of concentration of content that are used in the calculations (1. = white background, 2. = light green background colour and 3. = dark green background colour).

TABLE 73
CALCULATED RCR VALUES FOR THE PARABENS. THE VALUES ARE CALCULATED FOR CHILDREN AT THE AGE OF 3 YEARS UNLESS OTHERWISE STATED. FOR PROPYLPARABEN AND BYTYLPARABEN TWO COLUMNS ARE STATED, FOR CONSERVATIVE NOAEL (LEFT COLUMN) AND ALTERNATIVE NOAEL (RIGHT COLUMN) RESPECTIVELY.

Product type	Methyl-paraben	Ethyl-paraben	Propylparaben		Butylparaben	
			Cons.	Alt.	Cons.	Alt.
Modelling clay (1-year-old)		0.0003*	0.082*	0.005*	0.082*	0.005*
Modelling clay		0.00019*	0.054*	0.003*	0.054*	0.003*
Hobby paint						
Finger paint (1-year-old)	0.026	0.026	**12.87**	0.780	**12.87**	0.780
Finger paint	0.017	0.017	**8.48**	0.514	**8.48**	0.514
Window paint/glass paint						
Face paint	0.0005	0.0002	0.180	0.011	0.180	0.011
Make-up	0.0001	0.00006	0.033	0.002	0.033	0.002
Glue	0.0012	0.0012	0.601	0.036	0.601	0.036
Slime	0.027	0.0003*	**4.02**	0.244	0.083	0.005
Soap bubbles	0.00001	0.00001	0.007	0.0004	0.007	0.0004
Sum 1-year-old: modelling clay and finger paint	0.026	0.026	**12.95**	0.785	**12.95**	0.785
	0.052		Sum conservative DNEL: **25.90** Sum alternative DNEL: **1.57**			
Sum 3-year-old: all products	0.046	0.019	**13.38**	0.811	**9.44**	0.572
	0.065		Sum conservative DNEL: **22.82** Sum alternative DNEL: **1.38**			

* Indicates that here an assumption of 100% migration is used as no migration analyses for the substance in this product type are available. Thus the concentration of content is used as basis for the calculation.
Empty spaces indicate that the stated preservative is not seen in the product type in question.
RCR values above 1 are marked in bold.
RCR values based on analysis results are stated with white background (unmarked).
RCR values based on information received in the survey are stated with a light green background colour.
RCR values based on an assumption of content of maximum allowed concentration according to the Cosmetic Products Directive are marked with a dark green background colour.

TABLE 74
CALCULATED RCR VALUES FOR THE REMAINING SELECTED SUBSTANCES. THE VALUES ARE CALCULATED FOR CHILDREN AT THE AGE OF 3 YEARS UNLESS OTHERWISE STATED.

Product type	2-phenoxy-ethanol	Formaldehyde	Bronopol
Modelling clay (1-year-old)	0.124*	**2.41***	**10.86**
Modelling clay	0.082*	**1.59***	**7.16**
Hobby paint	0.0018	0.024	0.114
Finger paint (1-year-old)	**3.12**	0.482	**2.53**
Finger paint	**2.06**	0.318	**1.66**
Window paint/glass paint			0.114
Face paint	0.026	0.0002	
Make-up	0.007	0.00004	
Glue	0.317	0.00009	
Slime	**34.90***	**8.45***	
Soap bubbles	0.853	0.004	0.890
Sum 1-year-old: modelling clay and finger paint	**3.25**	**2.89**	**13.38**
Sum 3-year-old: all products	**38.24**	**10.39**	**9.94**

* Indicates that here an assumption of 100% migration is used as no migration analyses for the substance in this product type are available. Thus the concentration of content is used as basis for the calculation.
Empty spaces indicate that the stated preservative is not seen in the product type in question.
RCR values above 1 are marked in bold.
RCR values based on analysis results are stated with white background (unmarked).
RCR values based on information received in the survey are stated with a light green background colour.
RCR values based on an assumption of content of maximum allowed concentration according to the Cosmetic Products Directive are marked with a dark green background colour.

From Table 73 and Table 74 it is seen that some of the calculated RCR values are higher than 1 which means that in these worst case calculations (Tier 1 calculations) a risk of hazardous effects might occur. In these cases it is therefore necessary to have a closer look at the assumptions which are used in the calculations to assess whether these worst case assumptions are realistic. The product types with a RCR value larger than 1 are only finger paint, modelling clay and slime and only with a content of certain of the preservatives (all except methyl- and ethylparaben).

The worst case calculations show that for the following preservatives and product types *no* health risk is found:

- Methylparaben and ethylparaben do not constitute a health risk in any of the examined product types. Neither as a whole where the RCR values for methyl- and ethylparaben are

added up or summed up for all product groups, i.e. where it is taken into account that the children play with all 9 product groups with a possible content of these parabens which have the same health effect.
- Propylparaben and butylparaben do not constitute a health risk in any of the examined products by use of the alternative DNEL value.
- 2-phenoxyethanol does not constitute any health risk in modelling clay, hobby paint, face paint, make-up, glue or soap bubbles.
- Formaldehyde does not constitute any health risk in hobby paint, finger paint, face paint, make-up, glue or soap bubbles.
- Bronopol does not constitute any health risk in hobby paint, window paint/glass paint and soap bubbles.

For the preservatives and product types where the RCR value exceeds 1 in the worst case calculations it is thus necessary to refine the calculations by using some more realistic values. In many cases the worst case calculations have been based on missing data on e.g. concentrations of content for which reason it is not possible to make more refined calculations – however, below the assumptions are discussed more detailed in each single case with a RCR value higher than 1. The most substantial assumptions which have importance for the final assessment of the risk are:
- In certain situations the maximum allowed concentration (according to the Cosmetic Products Directive) is used as no information on the real used concentration was received. These situations are marked with a dark green background colour in Table 73 and Table 74 above. The real concentrations can thus be substantially smaller but how much is unknown. In certain situations where no legal requirement to the content of the preservative in the toy product exists, the concentration of the preservative may, however, in worst case be higher than the allowed concentration according to the Cosmetic Products Directive.
- For slime and modelling clay a 100% migration of certain substances is assumed if no migration analyses for the substance/product type have been made. This is a clear overestimation of the risk. It can easily be an overestimation with a factor 10-100 or more.
- For most of the assessed substances the dermal intake is based on values which have appeared after 24 or 48 hours' dermal exposure. The dermal exposure for the preservatives in the toy is typically much loweer, especially if the parents see to that their children have their hands, arms or face (as for make-up and face paint) washed after the use of the toy. For finger paint and slime this may thus mean that the dermal intake will be a factor 32 or 64 smaller as it is assumed that children are exposed to finger paint and slime for 45 minutes and not for 24 or 48 hours on which the dermal absorption is based. Correspondingly, this can mean that the dermal absorption for modelling clay will be a factor 24 or 48 lower as it is assumed that children are exposed to modelling clay for 60 minutes each time.
- For all types of toys which are assessed in this project, the NOAEL values are not based on a daily exposure. Of course, this will mean an overestimation of the risk. On the contrary, the preservatives which are assessed in this project are typical preservatives which are also used in cosmetic products that children can also be exposed to daily via cosmetic products. Therefore, it has been taken into account that both children at the age of 1 year and of 3 years get an extra contribution (dermal absorption) of these substances via cosmetic products which contributes to an increase of the total risk of health effects for these substances. However, this contribution is not assessed in details in the report.
- Generally in this report, there are used high values for amounts of products in use in relation to the values which are used for determination of the migration limits for metals in the new Toy Safety Directive. The amounts for finger paint and slime are 6 times higher whereas the amounts for modelling clay are 10 times higher than the values used for determination of the migration limits in the new Toy Safety Directive.
- Measurement uncertainties in this project are of approx. 20-30%.

The sum of all these uncertainties and the fact, that the highest RCR value is calculated to approx. 35, mean that the examined preservatives most likely will not constitute any risk of hazardous effects in the examined product types; neither as a whole, if a child plays with all the products (here the highest RCR value is approx. 38). However, both children at the age of 1 year and of 3 years can daily be exposed to the same preservatives via cosmetic products. Therefore, it shall be taken into account that both children at the age of 1 year and of 3 years get an extra contribution (dermal absorption) of these substances via cosmetic products which contributes to an increase of the total risk of health effects for these substances. However, this contribution is not assessed in details in this report.

8.4.1 Discussion of propyl- and butylparaben

For both propyl- and butylparaben, the maximum allowed concentration today per paraben of 0.4% is used at the calculations of the product types, finger paint, face paint and make-up. For glue no maximum allowed concentration of these parabens exists but the maximum allowed concentration from the Cosmetic Products Directive is used in the calculations. For modelling clay, slime and soap bubbles where producers have stated examples of the factual concentration this much lower concentration of maximum 0.002% is used. However, for propylparaben in slime a higher concentration has been used, as the chemical analysis of propylparaben in slime detected a higher concentration than given in the survey. The use of the maximum concentration of 0.4% in finger paint means that for both propylparaben and butylparaben the RCR values for both children at the age of 1 year and of 3 years are substantially above 1 (12.9 and 8.5 respectively).

It shall be noted that here the oral absorption constitutes approx. 65% of the total absorption. As mentioned earlier there are ongoing discussions on which NOAEL value and thus which DNEL value that is the right to use for propyl- and butylparaben. Therefore, the calculations for an alternative higher DNEL value are made. If this alternative DNEL value is used the use of propyl- and butylparaben will not constitute a health risk in finger paint when looking at one of these parabens alone. But as several parabens can be used at the same time (and in a concentration up to 0.8% according to the Cosmetic Products Directive and in finger paint) the sum of the parabens will mean a RCR value of just above 1 for both children at the age of 1 year and of 3 years by use of the alternative DNEL value. Similarly, the sum of the parabens from several products in use at the same time will mean a RCR value of above 1 for the calculated worst case scenarios.

For slime applies that the RCR value is above 1 (4.0) for propylparaben by use of the conservative DNEL value but under 0.25 by use of the alternative DNEL value. The RCR values for the other parabens for slime are all substantially below 1. The value which is used for propylparaben for the calculations is the measured migration of propylparaben in slime. For this calculation a migration value of 0.023% is used whereas it for e.g. butylparaben is assumed that the basic concentration is 0.002%. As earlier described these migration analyses are close to a regular quantitative analysis because of problems with the slime which dissolved in the sweat simulant. Therefore, the migration is most probably overestimated and thus the RCR value is unrealistic high.

To this must be added the extra assumptions which are made for these worst case calculations, among others:

- That an assumption of 6 times higher intake is used for finger paint and slime than used for determination of the migration limits for metals in the new Toy Safety Directive.
- That the exposure time is far under the time which the dermal absorption rates typically are based on.

All things considered this means that propyl- and butylparaben most probably will not constitute any risk of hazardous effects in the examined product types; neither as a whole, if a child plays with all the products. However, both children at the age of 1 year and of 3 years can daily be exposed to the same preservatives via cosmetic products. Therefore, it shall be taken into account that both

children at the age of 1 year and of 3 years get an extra contribution (dermal absorption) of these substances via cosmetic products which contributes to an increase of the total risk of health effects for these substances. However, this contribution is not assessed in details in this report.

8.4.2 Discussion of 2-phenoxyethanol

For 2-phenoxyethanol in finger paint where the RCR value exceeds 1 (is on 3.1 and 2.1 for a child of age of 1 year and children at the age of 3 years respectively) applies that in the calculation a concentration of 2-phenoxyethanol of 0.89% which was identified in the survey is used. The highest allowed concentration in finger paint according to EN 71-7 is 1%.

For 2-phenoxyethanol in slime applies that in this survey information was received saying that 2-phenoxyethanol is found in slime. However, no information about the concentration is received and 2-phenoxyethanol is not seen in the two analysed slime products. However, the survey confirms that slime products with a content of the substance may be found. Therefore, for the exposure calculation of slime absolute worst case was assumed, i.e. it was assumed that 2-phenoxyethanol is used in a concentration of 1% which is the maximum allowed concentration in finger paint and in cosmetic products and finally it was assumed that there is a 100% migration as no migration data for 2-phenoxyethanol in slime was available. Especially the last assumption is a huge overestimation of the expected exposure even when 2-phenoxyethanol has relatively high water solubility. With a RCR value of nearly 35 for slime the migration must be a factor 35 smaller if a concentration of 2-phenoxyethanol in slime of 1% shall not constitute any health risk. This is not unrealistic but as mentioned no migration data for the substance in slime is available.

To this must be added the extra assumptions which are made for these worst case calculations, among others:

- That an assumption of 6 times higher amount of use is used for finger paint and slime than used for determination of the migration limits for metals in the new Toy Safety Directive.
- That ths exposure time is far under the time which the dermal absorption rates typically is based on.

All things considered this means that 2-phenoxyethanol most probably will not constitute any risk of hazardous effects in the examined product types; neither as a whole, if a child plays with all the products. However, both children at the age of 1 year and of 3 years can daily be exposed to the same preservatives via cosmetic products. Therefore, it shall be taken into account that both children at the age of 1 year and of 3 years get an extra contribution (dermal intake) of these substances via cosmetic products which contributes to an increase of the total risk of health effects for these substances. However, this contribution is not assessed in details in this report.

As described in the healt assessment of 2-phenoxyethanol a recent French survey (ANSM, 2012) concludes that the used margins of safety to determine a concentration limit of 1% in cosmetic products is sufficient but not for children under the age of 3 years. Therefore, ANSM concludes that 2-phenoxyethanol must not be allowed in cosmetic products for children under the age of 3 years when it is to be used on the bottom. Furthermore, ANSM concludes that the allowed limit for 2-phenoxyethanol ought to be reduced to 0.4% (instead of the allowed 1% of today) in all other cosmestic products for children under 3 years. However, SCCS has not made an assessment of the French suggestion. A reduction of the maximum allowed concentration of 2-phenoxyethanol would of course mean that the calculated RCR values in this project would be a little more than the half of the calculated value.

8.4.3 Discussion of formaldehyde

For formaldehyde in slime and modelling clay applies that in this survey a content of formaldehyde is seen in all the analysed slimes and modelling clays. In two of the products (one slime and one

modelling clay) formaldehyde was found in a concentration which indicates a content of a formaldehyde releaser as preservative.

However, no migration analyses of formaldehyde from neither slime nor modelling clay are made and therefore worst case is assumed for the exposure calculation of slime and modelling clay i.e. that measured concentration of formaldehyde is assumed to migrate 100%. This assumption is a huge overestimation of the expected exposure. With a RCR value of 8.5 for slime and 2.4 for modelling clay the migration must be a factor 8.5 or 2.4 smaller if the measured concentration of formaldehyde in slime of 355 mg/kg and in modelling clay of 1220 mg/kg shall not constitute any health risk. This is absolutely not unrealistic but as mentioned no migration data for the substance in neither slime nor modelling clay is available.

The RCR sum value for both children at the age of 1 year and of 3 years is also above 1 for formaldehyde (2.9 and 10.4 respectively). For the group of the children at the age of 3 years it is primarily due to the RCR value for slime of 8.5 and partly the RCR value for modelling clay of 2.4 as described above. For the group of children at the age of 1 year it is primarily due to the RCR value for modelling clay which is 1.6.

In addition to this comes that even if a relatively small dermal absorption of 5% is used this value is found for a cream and shows the dermal absorption after 48 hours after application. None of the investigated product types is expected to dermally expose the children for up to 48 hours. Even if the children might not wash their hands immediately they will most probably be bathed, washed or have their hands washed within 48 hours. Therefore this will cause that the dermal absorption of formaldehyde from the products will be significantly smaller.

Finally for modelling clay and slime there is used an ingestion which is a factor 10 and 6 respectively higher than the values which has provided the basis for determination of the migration limits for metals in the new Toy Safety Directive.

All things considered the risk assessment therefore indicates that the content of formaldehyde in toys most probably will not constitute a health risk neither for children at the age of 1 year nor of 3 years - neither as a whole, if a child plays with all the products.

8.4.4 Discussion of bronopol

For bronopol in finger paint applies that no products of the type finger paint have been analysed. Furthermore, no examples of a factual used concentration of bronopol in finger paint have been seen in the survey.It is solely identified that bronopol is used in finger paint. For the exposure calculations the highest allowed concentration of bronopol in finger paint according to EN 71-7 is therefore used which is 0.1%. This concentration results in a RCR value of 2.5 for children at the age of 1 year and 1.7 for children at the age of 3 years.

For bronopol in modelling clay applies that the value from the migration analysis of 550 mg/kg is used in the calculations. However, here is the special circumstance that the quantitative content was measured to only 320 mg/kg. As mentioned earlier this is due to the fact that the modelling clay almost dissolved in the sweat simulant. Therefore, it is more a quantitative analysis than a regular migration analysis. The migration which will thus be overestimated results in a RCR value of 10.9 for children at the age of 1 year and 7.2 for children at the age of 3 years.

Thus the total RCR value for both children at the age of 1 year and of 3 years is also above 1 (13.4 and 9.9 respectively). If in reality there is a lower concentration of bronopol in finger paint the RCR values will thus be smaller. In both window paint and hobby paint concentrations of bronopol of approx. 0.04% are seen, i.e. in a concentration of below half of the allowed concentraton in finger paint.

In the calculations a dermal absorption of 40% after 24 hours is used but another study states only an intake of 11% after 24 hours. Thus the real dermal absorption can possibly be significantly lower than the 40% which is used in the exposure calculations at an exposure of 45 minutes and 60 minutes respectively for finger paint and modelling clay. None of the investigated product types is expected to cause that children are dermally exposed for up to 24 hours. Even if the children might not wash their hands immediately they will most probably be bathed, washed or have their hands washed within 24 hours. Therefore it will give the result that the dermal absorption of bronopol from the products will be smaller.

In addition to this, an ingestion for modelling clay and finger paint is used which is a factor 10 and 6 respectively higher than the values which have provided the basis for a determination of the migration limits for metals in the new Toy Safety Directive.

All things considered the risk assessment therefore indicates that the content of bronopol in toys probably will not constitute a health risk neither for children at the age of 1 year nor of 3 years.

8.4.5 Summary of risk assessment

In general, the risk assessment shows that for all the examined preservatives (except methyl and ethylparaben) and for a few product types (modelling clay, finger paint and slime) RCR values above 1 for the absolute worst case calculations might occur. However, several assumptions have been made which together mean that the examined preservatives most probably will not constitute any risk for hazardous effects in the examined product types; neither as a whole, if a child plays with all the products.

However, to this must be added that the risk assessment in this report solely assesses the risk of health effects for the investigated types of toys. The assessed preservatives are all preservatives which are also allowed in cosmetic products where especially the parabens, 2-phenoxyethanol and formaldehyde (originating from various formaldehyde releasers) are frequently used preservatives. Therefore, it should be taken into account that both 1-year-old and 3-year-old children get an extra contribution (dermal absorption) of these substances through cosmetic products which contribute to the increase of the total risk of health effects for these substances. However, this contribution is not assessed further in this report.

8.5 Summary and conclusion

In the risk assessment it is evaluated whether the identified content of the selected substances in the investigated product types can constitute a health problem. This assessment focuses on other heath effects than allergy. The risk of allergy is separately discussed in a section in the health assessment of the individual substances in section 8.2 ”Health assessment of selected preservatives”.

8.5.1 Allergy

As described earlier the risk of allergenic reactions when using toys containing parabens is assessed to be low as the occurrence of allergy towards parabens is relatively low. 2-phenoxyethanol is not considered to be sensitising for which reason the risk of allergenic reaction when using toys which contain 2-phenoxyethanol is assessed to be minimal. Formaldehyde is regarded as being strongly allergenic and persons who already are allergenic to formaldehyde can get allergenic reactions already at low concentrations (60 ppm). Therefore, toys with a content of formaldehyde above this level are assessed to constitute a possible risk for allergic reactions for persons who already are allergenic to formaldehyde. Two of the 11 analysed products had a content of formaldehyde above this level. Bronopol is a formaldehyde releaser and thus splits off formaldehyde which is assessed to be strongly allergenic. However, bronopol is not regarded to be allergenic in concentrations below 0.1% which is the concentration that is allowed in cosmetic products and is as the maximum

concentration seen in the analyses in this project. The risk of allergenic reactions when using toys containing bronopol in these concentrations is therefore assessed to be low.

For other preservatives than the selected substances it is essential to make a remark to Kathon as Kathon is regarded as being extremely allergenic (see the hazard assessment (screening) of Kathon in section 4.9 ”Kathon (CAS 55965-84-9)”). SCCS assesses that the allergenic properties of the substance is the largest problem of Kathon and that Kathon is safe to use in “rinse-off” cosmetic products in a maximum concentration of 0.0015% (15 ppm) – however, except from its sensitising potential. At the analyses in this project the detection limit for MI and MCI was 20 ppm as the texture of the products is special (they swell during extraction). Thus it has not been possible to confirm or disprove whether Kathon is used in the analysed products in a concentration of below 20 ppm but the results from the survey show that Kathon is used in products like hobby paint, finger paint, window paint/glass paint and glue in concentrations below 15 ppm. MI is seen in soap bubbles but there is no information about in which concentration. EU’s Scientific Committee on Health and Environmental Risks (SCHER) recommends that neitherKathon, MI nor MCI are used in toys because of the allergenic properties of the substances (SCHER, 2007). Thus there may be a risk of allergenic reactions when using toys with a content of Kathon.

Kathon and the other assessed preservatives are also used as preservatives in cosmetic products and 1-year-old and 3-year-old children are therefore expected to be exposed to these preservatives via cosmetic products as well.

8.5.2 Other health effects

As described above the risk assessment generally shows that for all the examined preservatives (except for methyl- and ethylparaben) and for a few product types (modelling clay, finger paint and slime) RCR values may occur above 1 for the absolute worst case calculations. However, several rough assumptions have been made which altogether mean that the examined preservatives will most likely not constitute any risk for hazardous effects in the examined product types; neither as a whole, if a child plays with all the products.

However, to this must be added that the risk assessment in this report solely assesses the risk of health effects for the investigated types of toys. The assessed preservatives are all preservatives which are also allowed in cosmetic products where especially the parabens, 2-phenoxyethanol and formaldehyde (originating from various formaldehyde releasers) are frequently used preservatives. Therefore, it should be taken into account that both 1-year-old and 3-year-old children get an extra contribution (dermal absorption) of these substances through cosmetic products which contribute to the increase of the total risk of health effects for these substances. However, this contribution is not assessed further in this report.

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Appendix 1: Shops which were visited in connection with the survey

This appendix contains a total overview of shops and shops on the internet which were visited in connection with the survey of preservatives in toys. The overview is a total list and thus also contains the shops and internet pages which are mentioned in Table 4.

TABLE 75
OVERVIEW OF SHOPS AND SHOPS ON THE INTERNET WHICH WERE VISITED IN CONNECTION WITH THE SURVEY OF PRESERVATIVES IN TOYS

Shops	Shops on the internet
• Toys `R´Us • BR Legetøj • Legekæden • Panduro Hobby • Kvickly • Føtex • Søstrene Grene • Arnold Busck • Bog & Idé • Fest og farver • COOP's shops • Dansk Supermarked's shops	• www.bilka.dk • www.legeakademiet.dk • www.babynature.dk • www.klodsmajor.dk • www.playforlife.dk • www.helsam.dk • www.kidzshop.dk • www.dekohuset.dk • www.Shop-a-toy.dk • www.mulius.com • www.godtlegetoej.dk • www.grafical.dk • www.legbilligt.dk • www.cdon.dk • www.hobbyogfritid.dk • www.vinduesmaling.jj-trade.dk • www.lillebi.dk • www.grafical.dk • www.lirumlarumleg.dk • www.lilleeg.dk • www.faraos.dk • www.slojd-detaljer.dk • www.eurotoys.dk • www.hoensefoederogguleroeder.dk • www.denlillebazar.dk • www.harald-nyborg.dk • www.buddy-leg.dk • www.br.dk • www.toysrus.dk • www.abcleg.dk • www.krea.dk • www.lekmer.dk • www.legekaeden.dk • www.gladeunger.dk • www.speedtoys.dk • www.legetoejsgiganten.dk

Survey and health assessment of preservatives in toys
The study is dealing with preservatives in toys for children that are expected to contain preservatives. The toys in focus were finger paints, modeling clay, face paint, window paint/glass paint, glue, slime and soap bubbles.

Environmental
Protection Agency
Strandgade 29
DK-1401 København K

www.mst.dk