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Survey and risk assessment of slime toys

Survey of chemical substances in consumer products No. 181

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Foreword

Survey and risk assessment of slime toys

This project examined chemical substances which are contained in or released by slime toys marketed to children over three years of age. Chemical analyses of ingredients in slime toys and their migration were performed, and the health risks due to exposure to certain substances when children play with slime toys were evaluated.

Control analyses were also performed on slime toys. These control analyses focused on the migration of elements specified in the order on safety requirements for slime toys (Statutory order no. 309 of 03/04/2017) in annex II.

The results of the survey, chemical analyses, and risk assessment are presented in this report.

This project was conducted by FORCE Technology together with Eurofins Product Testing A/S as a subcontractor for certain chemical analyses.

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Summary

Survey on and risk assessment of slime toys

Slime toys typically consist of aqueous hydrogels, which means that preservatives are typically needed to prevent the growth of microorganisms and ensure the product has an adequate shelf life. Slime gets its particular stretchy, gelatinous consistency from a chemical reaction (cross-linking) between a binder (typically in the form of polyvinyl alcohol) and boron ions. Boron ions are added in the form of e.g. sodium borate, borax, or boric acid. Boron has a function as a preservative. Typically, slime toys additionally consist of water, other preservatives, and a colourant. Solvents and fragrances may also be added.

Purpose and scope
The purpose of this project was to investigate the content and migration of chemical substances from slime toys marketed to children over three years of age. The project focused on chemical substances which are currently not regulated in slime toys, and a risk assessment was performed on selected substances to evaluate the extent to which slime toys can constitute a health risk when children play with them.

The Danish EPA additionally desired an analysis of the extent of failures to comply with certain limit values established by law. For this reason, particular attention was given to the substances listed in Annex II of the Danish Statutory Order on Toys (and the EU Directive on Toys), including to the migration of boron from slime toys, both because of the use of boron compounds in slime in general and because historically, slime toys have been withdrawn from the market and consumers because of health risks posed by excessive boron migration. Lastly, one of the goals of the project was to examine whether there are differences in the chemical substances present in products purchased in Denmark, purchased in the EU (outside of Denmark), and purchased outside the EU.

The scope of the project was limited to ready-made slime toys. The Danish EPA's Chemical Inspection Service conducted a monitoring and supervision campaign that included slime toys on the Danish market concurrently with this project. For this reason, this project focused deliberately on slime toys other than the 25 slime toy products that were covered by the Chemical Inspection Service's ongoing campaign.

Slime toys belong to "category II", which includes "liquid or sticky toy materials". This category is relevant in determining the applicable regulatory limit values for e.g. boron migration.

Previous studies of slime toys
Because of the boron content in slime toys, boron migration has typically also been the focus of slime toy inspection campaigns performed by authorities, consumer organisations, and others, both in Denmark and abroad.

However, only a limited number of slime toy studies have been performed. Studies on the general use of preservatives in slime toys have been performed, but only two products were previously tested for non-boron preservative content. Additionally, studies have been performed to investigate off-gassing of chemical substances from slime toys. These studies identified off-gassing in general, as well as the off-gassing of fragrances. A previous report from the Danish

EPA concluded that the substances studied in slime toys do not off-gas at concentrations considered to constitute a health risk. Off-gassing of fragrances from slime toys has also been studied previously, but the off-gassed concentrations were not quantified.

Survey

The survey in this project focused on the content of preservatives not regulated in slime toys marketed to children over three years of age. Compliance with regulations regarding the migration of boron and other elements from the slime toys studied was also tested. In addition, the toy sector industry were questioned regarding the use of fragrances in slime; however, because relatively few slime toys (particularly those marketed in Denmark and the EU) were marketed as scented, and due to the analytical challenges posed by fragrances, it was decided to focus on preservatives.

The Danish toy industry association (LEG) and the European toy industry association (TIE), as well as the manufacturers/importers of purchased products, were contacted with queries regarding the use of preservatives in general in slime toys, as well as the preservatives contained in the particular products purchased. This was successful for 10 of the 27 products studied. For these 10 products, chemical analyses were performed only to determine the concentration of the preservatives present.

Overall, based on information from previous studies and communication with slime toy manufacturers/importers, 13 different preservatives (aside from boron) are or have been used in slime toys.

A total of 27 individual slime toy products were purchased, covering a range of product types and price points from 9.35 DKK to 180 DKK. They are divided as follows:

- Nine products from non-EU countries purchased on websites like Wish.com, Amazon.com, Gearbest.com, or Aliexpress.com
- Four products from EU countries (but not Denmark) purchased from sites like Amazon.de, as well as directly from German and British websites
- 14 products from Denmark; that is, products selected or purchased from Danish shops, primarily in the Copenhagen area, or from websites with Danish CVR (business registry) numbers

Analyses of boron migration from slime toys per EN 71-3

All of the 27 slime toys purchased were analysed for elemental migration according to EN 71-3. Migration levels below the limit values were identified for all elements apart from boron. Migration levels ranging from 116 to 4275 mg/kg were identified for boron. The limit value is 300 mg/kg for slime toys. Violations of the regulatory limit are distributed as follows:

- Eight out of nine products (89%) purchased outside the EU
- One out of four products (25%) purchased within the EU (but outside of Denmark)
- Four out of 14 products (29%) purchased in Denmark

The Danish EPA was informed of these violations during the project, whereupon the Danish EPA evaluated the health risk posed by each product and took the necessary measures based on these findings. The websites reported that these products were withdrawn from the sites. The matter of the EU product was forwarded to the relevant authority.

Chemical analyses

Initially, screening analyses (elemental determination) were performed on the 17 slime toys (out of 27) whose preservative content was unknown, to identify preservatives that may have been added to the products.

In addition, 24 of the 27 slime toys were analysed for the following preservatives, since the survey and information from the toy sector showed that these preservatives are commonly used in slime toys:

- Certain parabens (performed as a screening analysis)
- A package of preservatives consisting of phenoxyethanol, dehydroacetic acid, potassium sorbate, and sodium benzoate

Based on these initial results, information about preservatives from manufacturers/importers, and the elemental determinations, selected other quantitative analyses were then performed for selected preservatives.

Due to the presence of bromine in the elemental determinations for four slime toys, an investigation was conducted to determine whether the presence of bromine was due to the use of the brominated preservatives bronopol and methyldibromo glutaronitrile (MG), which are both allergenic. However, neither of these preservatives was identified at a concentration above the 0.01% (100 ppm) level of detection.

Additionally, an analysis for isothiazolinone content was performed for eight slime toys, identifying the isothiazolinones MI, CMI, and BIT.

The results of the chemical analyses, together with the information from manufacturers/importers, indicated that the 14 preservatives listed below were identified in slime toys.

Preservatives identified in slime toys

Dehydroacetic acid (in one product)
Sodium benzoate (in two products)
Phenoxyethanol (in eight products)
Methylparaben (in 13 products)
Ethylparaben (in one product)
Propylparaben (in three products)
DMDM hydantoin (in one product)
MI (in six products)
CMI (in three products) combined with MI
BIT (in one product) combined with MI
Propylene glycol (in five products)
Chlorphenesin (in three products)
Iodopropynyl butylcarbamate (in two products)
Imidazolidinyl urea (in two products)

Risk assessment

In the risk assessment, it was decided to focus on the isothiazolinone MI and the CMI/MI (Kathon™) mixture, due to their allergenic properties. Additionally, it was decided to perform a risk assessment of phenoxyethanol, since the permitted limit value for this preservative in cosmetic products has been subject to some discussion, and because France has adopted special regulations for cosmetic products containing phenoxyethanol marketed to children under three years of age.

The worst-case exposure scenarios for which the phenoxyethanol risk assessment was performed are as follows:

1. Children playing with ordinary slime
   - Skin contact with slime toy on hands
   - Oral intake of a small amount of slime, corresponding to finger-to-mouth transfer, when children place their fingers in their mouths after playing, without having washed their hands

2. Children playing with slime guns, shooting slime at each other and on large portions of their bodies:
   - Skin contact with slime on essentially the entire body
   - Oral intake of a slightly greater amount of slime, if struck by slime near the mouth

For the isothiazolinones (MI and Kathon), the risk assessment was performed exclusively for use in ordinary slime, since isothiazolinones were not identified above the limit of detection in the slime gun's slime. Children's exposure level (i.e., amount) per unit skin area is significant in the risk assessment for allergenic isothiazolinones. This applies to both sensitisation (the phase in which an allergic reaction is provoked) and elicitation (the phase in which an allergic reaction is provoked in a person who has already been sensitised).

Regarding methods, the evaluation from the EU's Scientific Committee on Consumer Safety (SCCS) was used to evaluate the risk for isothiazolinones. The dermal exposure level per unit skin area is also calculated in the risk assessment and compared with levels from the literature; that is, levels which are capable of provoking allergic reactions in humans. However, a limited amount of this data is available, since such experiments are not performed on humans for ethical reasons. For isothiazolinones, only a small amount of data is available regarding exposure levels at which elicitation was observed in humans. In contrast, there is no information about sensitisation levels. The so-called QRA (Quantitative Risk Assessment) method was additionally used. This method was originally developed by the fragrance industry to assess the risk of sensitisation for fragrances. The QRA method is not officially recognised by the SCCS (SCCS, 2018b), and the use of assessment factors, among other points, is still the subject of discussion.

Conclusion

This project studied the content and migration of chemical substances, including boron, phenoxyethanol, isothiazolinones (MI, CMI, and BIT) and parabens, from slime toys, for the purpose of assessing any health risk they may pose. The primary focus was preservatives that are currently unregulated. A secondary focus was an aspect of testing for elemental migration in cases where a limit value is established by law. The extent to which the ingredients differ among products purchased in Denmark, in the EU (aside from Denmark), and outside the EU was also studied.

Among the unregulated substances, phenoxyethanol content was quantified in eight out of the 24 products analysed (at concentrations between 0.26% and 0.65%), MI in six out of eight products (at concentrations between 4.5 and 16.0 mg/kg), and CMI in three out of eight products (at a concentration between 1.3 and 5.3 mg/kg) in selected slime products.

The risk assessment shows that when children play with the ordinary slime toys studied in this project, phenoxyethanol exposure from these slime products alone does not constitute a health risk in the realistic worst-case exposure scenarios established. Only when using the slime gun's slime product, a health risk may be possible. However, a lack of information — particularly regarding the actual uptake of phenoxyethanol through the skin when playing with slime toys — precludes making a more confident and final statement regarding the health risk in playing with slime toys. Additionally, experts disagree on the levels and effects on health that should serve as the basis of a risk assessment. For this reason, no firm conclusion can be reached as to the value that should be used. Similarly, no firm conclusion can be reached as to whether exposure to phenoxyethanol at the concentrations found in the slime gun's slime product may constitute a health risk when children play with the product.

Regarding **MI and Kathon,** the SCCS considers that neither MI nor Kathon is safe for use in leave-on cosmetic products due to the allergenic properties of the substances. As a realistic worst-case, the report considers slime toys comparable to leave-on products, since children

will not necessarily wash their hands or bodies after playing with them. For this reason, a risk of allergy when playing with these products cannot be excluded.
Additionally, when using the QRA method for the Kathon risk assessment, it can be seen that acceptable exposure levels for sensitisation are clearly exceeded. The acceptable exposure level for sensitisation is also exceeded for MI, but not to the same degree as for Kathon. In other words, there is a risk that children playing with slime toys containing Kathon at the concentrations found may become sensitised. The conclusion for MI is not as certain; however, it can be concluded that the calculations do not rule out the possibility of MI causing sensitisation in children when they are exposed to MI in various products (slime toys, other chemical toys, and cosmetic products containing MI).

It can thus be concluded that six out of eight slime toys analysed which were purchased either in Denmark or the EU may constitute a health risk to children when they play with these slime products. The remaining slime toys, including products purchased outside the EU, were not analysed for isothiazolinone content.

The inspection part of the project identified boron migration levels between 116 and 4275 mg/kg in all 27 of the slime products studied. For comparison, the limit value is 300 mg/kg. 13 of the 27 slime products studied did not comply with legislation, with a distribution of eight out of the nine products purchased outside the EU, one of the four products purchased within the EU (excluding Denmark), and four of the 14 products purchased in Denmark. Apart from two additional products, these are the same products considered to constitute a risk due to their MI and/or Kathon content. The results clearly show that more products purchased outside the EU may constitute a health risk than products purchased within the EU.

Abbreviations

BIT	Benzisothiazolinone, a preservative with chemical name 1,2-benzisothiazol-3(2*H*)-one. CAS no. 2634-33-5.
CMI	Methylchloroisothiazolinone, a preservative with chemical name 5-chlor-2-methyl-3(2*H*)-isothiazolone. CAS no. 26172-55-4. Also abbreviated as MCI or CMIT.
CMI/MI	Preservative with the trade name Kathon™, among other names. 3:1 mixture of CMI and MI. Has CAS no. 55965-84-9. Also abbreviated as CMIT/MIT. The term “Kathon” is used in this report.
CMR	Abbreviation for substances classified as carcinogenic (Carc.), mutagenic (Mut.), or toxic to reproduction (Rep.).
DNEL	Derived No Effect Level; the level to which one can be exposed without effect.
DSOT	The Danish Statutory Order on Toys (*Legetøjsbekendtgørelsen*) (Statutory Order No. 309 from 3 April 2017).
MG	Methyldibromo glutaronitrile, a preservative (CAS no. 35691-65-7).
MI	Methylisothiazolinone, a preservative with the chemical name 2-methylisothiazol-3(2*H*)-one. CAS no. 2682-20-4. Also abbreviated as MIT.
NOAEL	No Observed Adverse Effect Level; the lowest concentration at which no effects are observed.

1. Introduction

Slime toys are a popular type of toy among children. On YouTube, video reviews of slime toys can be found, as well as instructions on how to create one's own slime — including videos uploaded by Danish children. Previously (in 2006), the Danish EPA conducted a survey of chemical substances in "slimy" toys, including slimes (Svendsen et al., 2006). In both 2018 and 2019, the Danish Consumer Council *(Forbrugerrådet TÆNK)* wrote articles about slimes and the chemical substances they contain. In 2018, they also tested slime toys on the Danish market and called slime a "toy fad" among children and youths (Tænk, 2019; Tænk, 2018a; Tænk, 2018b). There exists also a variety of games (apps) in which one can produce one's own slime or interact virtually with slime in a game, which is a testament to the popularity of slime.

Slime toys come in many different colours, sizes, and types. The different types of slime include e.g. farting slime, magnetic slime, fluorescent neon slime, colour-changing slime, sets for creating one's own slime, and sets for slime experiments.

1.1 Background

According to the Danish EPA's earlier survey of "slimy" toys (Svendsen et al., 2006), slime typically consists of aqueous hydrogels. Aqueous products typically have preservatives added to them to prevent the growth of microorganisms (bacteria and fungi) and extend the useful life of the product. There exist restrictions on certain preservatives (BIT, MI, CMI, CMI/MI (Kathon), and phenol) in the Danish Statutory Order on Toys, appendix C (Statutory Order No. 309 of 3 April 2017). However, these restrictions apply exclusively to products for children younger than 36 months and toys intended to be placed in the mouth. The preservatives MI and CMI (and their combination Kathon), as well as BIT, are restricted only in aqueous toy materials. While slime is typically aqueous, the restrictions do not apply to slime because slime is not intended to be placed in the mouth, and it is typically marketed to children older than 36 months.

Previous surveys of toys (including slimes) have shown which preservatives are typically used in slime. Furthermore, they have revealed that fragrances are also added to certain products. Fragrances may either be deliberately added to give the product a particular scent, or to mask the "chemical" smell of the slime toy. Fragrances, like preservatives, can be allergenic, and only some fragrances are regulated in toys by the Danish Statutory Order on Toys.

1.2 Purpose

The purpose of this project is to examine the contents of, and migration of currently unregulated substances from, slime toys marketed to children over three years of age. This is done with a view toward evaluating the health risks present when children play with slime toys.
The Danish EPA additionally desires an analysis of the extent of failures to comply with certain limit values established by law (in the Danish Statutory Order on Toys (DSOT)). Lastly, one of the project's goals is to examine whether there are differences in the chemical substances present in products purchased in Denmark, purchased in the EU (outside of Denmark), and purchased outside the EU.

1.3 Scope and limitations

The slime toys that this project focuses on are slime toys that may be purchased pre-mixed in shops and online. Do-it-yourself (DIT) slime toys are not included because there may be a variety of ways in which such mixtures can be prepared; proportions of ingredients are significant to this project. Additionally, by not including do-it-yourself products, a more significant result may be obtained for slimes purchased in a ready-to-use form, by including as many products as possible. In the survey, Danish and foreign websites were identified where it appears that private individuals are producing and selling their own slime. These types of slime are not included in the project.

The project focuses exclusively on slime products that fall under category II; that is, "liquid or sticky toy materials". According to the guidance document for the toy directive, slime is described as a product that falls under category II, since it is here defined as a "sticky toy material" (European Commission, 2016). All the purchased products were evaluated, and if a product was evaluated as belonging to category I, the product was not examined in this project.

The Danish EPA's Chemical Inspection Service conducted a control campaign that included slime toys on the Danish market concurrently with this project. For this reason, this project focused deliberately on slime toys other than the 25 products that were covered by the Chemical Inspection Service's ongoing control campaign.

1.4 Definitions

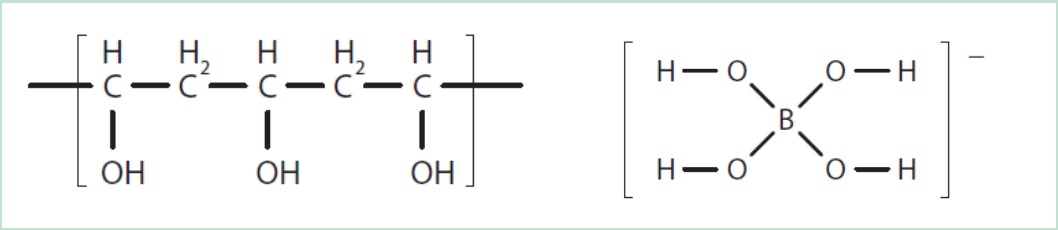
The term **"unregulated chemical substances"** is used in this report. In this report, by "unregulated substances" is meant chemical substances that are not directly subject to a restriction for toys for children over three years in the Danish Statutory Order on Toys (Statutory Order No. 309, 2017) or a restriction in other relevant legislation, such as REACH. It should be noted that if there are chemical substances in a toy that may constitute a danger to safety or health when children play with it (i.e., use it in a foreseeable way, bearing in mind the behaviour of children), the product does not comply with the Danish Statutory Order on Toys (§28), (Statutory Order No. 309, 2017).

For toys for children over three years, the regulated chemical substances (see chapter 3 "Legislation") include substances classified as CMR (categories 1A, 1B, and 2), nitrosamines, nitrosable substances, 66 specific allergenic fragrances, and 19 specific elements. "Unregulated substances" are defined as all chemical substances other than these. The substances regulated in Appendix C of the Danish Statutory Order on Toys, such as the preservatives BIT, Kathon™, MI, and CMI, are thus included by the designation of "unregulated chemical substances" for slime toys for children over three years, since these preservatives are not regulated in toys for children over three years.

2. What does slime consist of?

According to the Danish EPA's earlier survey of "slimy" toys, slime typically consists of aqueous hydrogels to which preservatives are often added, to prevent the growth of microorganisms and extend the useful life of the products (Svendsen et al., 2006).

According to information from manufacturers and the ingredients listed on slime toys, slime is typically made from polyvinyl acetate (PVA) or polyvinyl alcohol, with borate ions added in the form of e.g. sodium borate, borax powder (sodium tetraborate) or boric acid. Boron can be found in solution as boron ions, which will cross-link with polyvinyl alcohol in PVA to create the familiar, stretchy/elastic consistency that slime is known for. Water is also added to achieve the correct consistency (RSC, 2008). The reaction between polyvinyl alcohol and borate is shown in FIGURE 1 below.



Polyvinyl alcohol (left) reacts with boron ions (right)

Boron ions cross-linking with polymer chains (below)

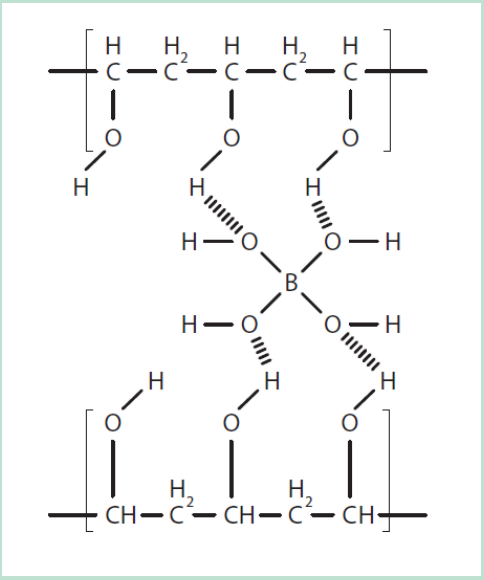


FIGURE 1. Illustration of cross-linking between polyvinyl alcohol and borate, giving slime its familiar, stretchy consistency (RSC, 2008)

The addition of e.g. borate means that there may be a high level of migration of boron from the slime toy. Boron is known to have a preservative effect

From the information sent by manufacturers or importers of slime toys in this project, and from the information in ingredient lists on products, it can be seen that slime toys typically consist of:

- A binding agent, such as
    - polyvinyl acetate or polyvinyl alcohol, possibly in combination with guar gum or
    - agar, possibly in combination with xanthan gum or
    - guar gum in combination with a melamine resin
- Water
- Boric acid or sodium borate
- Additional preservatives or, often, a mixture of different preservatives
- Optionally, a solvent (such as to dissolve colourants); for example, propylene glycol (some manufacturers describe this substance as a preservative)
- Colourant
- Optionally, a fragrance blend

3. Legislation

This chapter contains a description of the legislation that currently applies to slime toys. The relevant regulation is the Danish Statutory Order on Toys.

3.1 Danish Statutory Order on Toys (DK)

The Danish Statutory Order on Toys, no. 309 of 3 April 2017[1] (Statutory Order No. 309, 2017) with later amendments, implements the EU's Toy Safety Directive, no. 48/2009[2] (EU Dir. 48, 2009). According to the Danish Statutory Order on Toys, toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health as a result of a toy's physical and mechanical properties. This also applies to the exposure to chemical substances and mixtures that a toy consists of or contains. This applies when a toy is used in a foreseeable way, bearing in mind the behaviour of children (§27 with reference to particular safety requirements in Annex II and general safety requirements in §28.1).

According to Annex II, "Particular Safety Requirements"; part III, "Chemical Properties", the Danish Statutory Order on Toys imposes the following requirements (restrictions) on chemical substances contained in toys:

- Restriction on the use of CMR substances (part III, items 3-7)
- Restriction on the use of nitrosamines and nitrosable substances (part III, item 8)
- Restriction on the use of allergenic fragrances (part III, item 11)
- Restriction on the migration of certain elements (part III, item 13)

Nitrosamines and nitrosable substances are not the focus of this project, since these are relevant primarily to rubber-based products, such as balloons. For this reason, these restrictions will not be discussed.

Additionally, Appendix C of the Danish Statutory Order on Toys contains specific limit values for chemical substances (e.g., preservatives), but these limit values apply only to toys intended for use by children younger than 36 months, or for other toys intended to be placed in the mouth. These limitations are thus not relevant to slime toys, which are neither intended for children under three years nor intended to be placed in the mouth. Regardless, the limit values are mentioned briefly below, since e.g. the European toy industry association TIE recommends that chemical toy manufacturers among its members adhere to these limit values regardless of the age group a toy is intended for.

3.1.1 Restriction on the use of CMR substances

According to Annex II of the Danish Statutory Order on Toys (part III, "Chemical Properties"; items 3, 4, and 5), substances classified as CMR category 1A, 1B, or 2 may not be used in toys, in components of toys, or in micro-structurally distinct parts of toys.

CMR substances can be used at concentrations below the general classification limits established in the CLP regulation on classification, labelling, and packaging of substances and mixtures. If specific classification limits are set for individual substances, those specific classification limits apply. CMR substances may also be used if these substances and mixtures are not

[1] Order on safety requirements for toys, order no. 309 of 3 April 2017, with subsequent amendments, hereinafter referred to as the Danish Statutory Order on Toys

[2] The European Parliament's and Council's directive 2009/48/EF of 18 June 2009 on safety requirements for toys, with subsequent amendments, hereinafter referred to as the Toy Safety Directive

accessible to children (including via inhalation) when the toy is used in a foreseeable way, bearing in mind the behaviour of children. If no specific classification limit is set for individual substances, the general classification limits apply. These are:

- Carc. and Mut. categories 1A and 1B:0.1% (1000 ppm)
- Repr. categories 1A and 1B:0.3% (3000 ppm)
- Carc. and Mut. category 2:1.0% (10,000 ppm)
- Repr. category 2:3.0% (30,000 ppm)

However, a CMR substance may be exempted if the substance is not restricted under REACH, and if it is judged to be safe to use by the relevant scientific committee authorised by the Commission and listed in Appendix A of the order. For CMR 1A and 1B substances, exemptions may only be made if no alternatives are available. As of May 2019, Appendix A lists only the element nickel, which is classified as Carc. 2.

3.1.2 Restriction on the use of allergenic fragrances

According to annex II, part III, item 11 of the Danish Statutory Order on Toys, toys may not contain 55 specific allergenic fragrances (see Appendix 1) at concentrations above 100 mg/kg. An additional 11 fragrances (see Annex 1) shall be listed on the toy, on an affixed label, on the packaging, or in an accompanying leaflet if added to a toy, as such, at concentrations exceeding 100 mg/kg in the toy or components thereof.

3.1.3 Restriction on the migration of certain elements

According to annex II, part III, item 13, the listed limit values for the migration of certain elements from toys must not be exceeded. The limit values are listed in Annex 1.2. These limit values do not apply to toys or components of toys which, due to their accessibility, function, volume, or mass, clearly exclude any hazard due to sucking, licking, swallowing, or prolonged contact with skin, provided that the toy is used in a foreseeable way, bearing in mind the behaviour of children.

The limit values for the migration of elements are divided into several categories, depending on the physical form of the toy. For example, a toy may be liquid or sticky; dry, brittle, powdery, or flexible; or there may be material that can be scraped off the toy. The slime toys studied in this project belong to category II and must therefore comply with the corresponding limit values listed for category II.

3.1.4 Restrictions in Appendix C

Appendix C of annex II of the Danish Statutory Order on Toys contains specific limit values for chemicals used in toys intended for children under 36 months or in other toys intended to be placed in the mouth. These limit values are thus inapplicable to slime toys, as slime toys are neither for children under three years nor intended to be placed in the mouth. However, Appendix C does contain some limit values for preservatives that may be used in slime toys. For this reason, it is interesting to see whether preservatives that are restricted in products for children under 3 years are used in toys for children over 3 years, as well as whether they are used at higher concentrations and whether those concentrations constitute a risk. These preservatives and their limit values are given in TABLE 1 below.

3.2 Relevant standards concerning toys

In connection with the regulation on toys, a number of standards (the EN 71 series) have been developed. These may impose requirements on specific products, including requirements relating to chemical substances that are relevant to this project. These standards may also contain descriptions of analysis methods to be used when testing for regulatory compliance.

- In EN 71-3 (2013+A3:2018), "Migration of certain elements", requirements and testing methods for the migration of certain elements as described in section 3.1.3 above are described.

- In EN 71-7 (2014+A2:2018), "Finger paints — Requirements and test methods", a number of requirements are imposed on various chemical substances, such as the use of preservatives, colourants, binders, and other impurities.
- In EN 71-9 (A1: 2007), "Organic chemical compounds — Requirements", a number of requirements are imposed on various organic chemical substances for toys.
- In EN 71-10 (2006), "Organic chemical compounds — Sample preparation and extraction", procedures are given for preparing and extracting samples to determine the presence of organic chemical substances upon which EN 71-9 imposes requirements.
- In EN 71-11 (2005), "Organic chemical compounds — Methods of analysis", analysis methods are described for use in evaluating compliance with the requirements imposed by EN 71-9. EN 71-11 also specifies so-called "action limits" (limit values) for a number of substances described in EN 71-9.

3.2.1 Limit values for preservatives in Appendix C and EN 71-9

The table below gives the requirements listed in Appendix C of the Danish Statutory Order on Toys for preservative content. As mentioned above, these requirements apply only to toys for children under three years and are thus inapplicable to slime toys (which are marketed to children over three years). These preservatives are thereby included in the definition of "unregulated chemical substances", an area of focus for this project. The corresponding limit values in EN 71-9 are provided for the preservatives named in Appendix C.

TABLE 1. Limit values for preservative content according to the Danish Statutory Order on Toys (Appendix C) and standard EN 71-9

Substance name	CAS no.	Limit value per Appendix C	Limit value in EN 71-9
Benzisothiazolinone (BIT), or 1,2-benzisothiazol-3(2*H*)-one	2634-33-5	5 mg/kg In aqueous toy materials, in accordance with the methods laid down EN 71-10:2005 and EN 71-11:2005	5 mg/kg
Kathon™, or CMI/MI, or CMIT/MIT, or a reaction mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2*H*-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9	1 mg/kg In aqueous toy materials	15 mg/kg
Chloromethylisothiazolinone (CMI), or CMIT, or 5-chloro-2-methyl-isothiazolin-3(2*H*)-one	26172-55-4	0.75 mg/kg In aqueous toy materials	10 mg/kg
Methylisothiazolinone (MI), or MIT, or 2-methylisothiazolin-3(2*H*)-one	2682-20-4	0.25 mg/kg In aqueous toy materials	10 mg/kg
Phenol	108-95-2	10 mg/kg As a preservative, in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005	10 mg/kg

The limit values, or so-called "action limits", given in EN 71-9 do not presuppose compliance with the Danish Statutory Order on Toys. Standard EN 71-9 is not referenced in the Official Journal of the European Union, and thereby does not presuppose compliance with the directive.

The limit values set for MI, CMI, and Kathon in Appendix C of the Danish Statutory Order on Toys correspond to the detection limits for these substances, since these preservatives are generally undesirable in toys for children under three years due to their allergenic properties.

3.2.2 Limit values for preservatives in EN 71-7

Standard EN 71-7 for finger paints imposes requirements on the preservatives that may be used in finger paints. Requirements in standards are not legislative and should thus not be considered as regulatory requirements for slime toys, but they can be used for the purpose of presupposing compliance with the directive in the case of harmonised standards referenced in the Official Journal of the European Union, such as EN 71-7.

The toy industry, including TIE, recommends that for chemically based toys — including slime toys — its members comply with the requirements listed in EN 71-7 for finger paints. For this reason, selected preservatives allowed in finger paints according to EN 71-7 are given below in TABLE 2. Annex B of EN 71-7 contains a list of preservatives allowed in finger paints and the concentrations at which they are allowed. Annex B lists a total of 38 preservatives or groups of preservatives. The selected, relevant preservatives for this project are given in TABLE 2 below. The selected, relevant preservatives are selected amongst the preservatives listed in annex B of EN 71-7, but only those preservatives identified as being used in slime toys in this project, are listed below.

TABLE 2. Limit values for selected preservatives allowed for use in finger paints according to standard EN 71-7 (finger paints)

Reference no. per Annex B of EN 71-7	Substance name	CAS no.	Maximum concentration permitted
1	Sodium benzoate Benzoic acid	532-32-1 65-85-0	0.5% (acid)
8	Parabens Methylparaben Ethylparaben Propylparaben	99-96-7 99-76-3 120-47-8 94-13-3	Max. 0.8% total 0.4% (acid) 0.14% (acid) 0.14% (acid)
9	Dehydroacetic acid	520-45-6	0.6% (acid)
14	Bronopol	52-51-7	0.1%
18	Imidazolidinyl urea	39236-46-9	0.6%
19	2-phenoxyethanol	122-99-6	1.0%
23	DMDM hydantoin	6440-58-0	0.6%
32	Diazolidinyl urea	78491-02-8	0.5%
35	Chlorphenesin	104-29-0	0.3%

4. Survey: method

This chapter describes the approach taken to the survey of slime toys in this project. The following activities were carried out:

- Contact with relevant industry organisations
- Literature review/internet searches
- Shop visits
- Contact with importers/manufacturers

4.1 Contact with relevant industry organisations

One of the first steps in the project involved contact to the Danish industry association for toys, LEG *(Legebranchen)* and the European industry organisation, TIE (Toy Industries of Europe). Both LEG and TIE agreed to send an inquiry to their members requesting information about slime toys for this project. Questions were asked regarding:

- Which preservatives are used in slime toys (name, CAS number, concentration, and the name of the particular slime product in question, if possible)
- Which fragrances are used in slime toys (name, CAS number, concentration, and the name of the particular slime product in question, if possible)

The Danish toy industry association, LEG, encouraged its members to contact the project group directly with this information, while the European toy industry association, TIE, gathered information from its members and collected it into a single document that was sent to the project group.

4.2 Literature review / internet searches

A literature review was undertaken to investigate what previous studies of slime toys found with regard to the content, migration, and off-gassing of chemical substances from slime toys. This literature review was performed exclusively by searching the internet for earlier slime toy studies.

An internet search for different types of slime toys was also performed, partially to study the market for slime toys and partially to identify examples of slime toys for selection, purchase, and analysis in this project. As described in the introduction, one of the purposes of this project was precisely to determine whether there are differences in the chemical substances present in products purchased in Denmark, purchased in other EU countries, and purchased outside the EU. For this reason, the internet search also included searches of foreign websites that ship products to Denmark (such as Amazon, eBay, AliExpress, GearBest, and Wish).

Examples of slime toys identified in the search were recorded in an Excel sheet with the following information:

- Product name
- Product description, including an image of the product
- Type of slime (e.g., neon slime, farting slime, slime with figure inside, etc.)
- The country in which the slime product was produced
- Geographical purchase category; that is, where was the product bought? (In Denmark, in another EU country, or outside the EU)
- Name, address, and email address of the product's vendor
- Price

- Link to website

4.3 Shop visits

As a supplement to the internet search for examples of slime toys on the market in Denmark, individual visits to selected shops were carried out. These shops included supermarkets, toy shops, other shops, etc. The following shops were visited, and examples of slime toys in these shops were recorded in the cumulative list in Excel.

- Kvickly
- Føtex
- Bilka
- Meny
- BR
- Legekæden
- Bog & Ide
- Fest & Farver
- Billig-Billy
- Flying Tiger
- Søstrene Grene
- Humørshoppen

4.4 Contact with importers/manufacturers

Based on the prepared list of more than 90 different examples of slime toys, 30 slime toy products were selected in co-operation with the Danish EPA and purchased with the intention of analysing them with regard to their chemical substance content and migration thereof in this project. Some extra products were purchased on the internet as a backup, in the event that some products did not arrive before the start-up of the chemical analyses, or in case of other unforeseen events. The selection criteria are described in greater detail in chapter 6 “Selection of products for analysis".

An inquiry was sent to the importer/manufacturer of each purchased product, with questions regarding the ingredients in their slime toys. The same questions about preservative and fragrance content posed to the toy industry organisations (LEG and TIE) were posed here as well.

However, for products purchased directly from China via (e.g.) Wish, GearBest, and AliExpress, there was generally insufficient information about the products' manufacturers. For this reason, ingredient inquiries were not sent for these products.

5. Survey: results

This chapter describes the results of the survey, and is divided into the following sections:

- Portrait of the market for slime toys
- Types of slime toys on the market
- Information about slime toys from previous studies
- Information about slime toys from shop visits
- Information from contact with the industry

5.1 Portrait of the market for slime toys

Based on shop visits in Denmark and an internet search for examples of slime toys, it appears that the market for slime toys experiences a relatively large product turnover; that is, that new types of slime toys are constantly appearing on the market. The general impression obtained from purchasing products in Denmark was that both physical and online shops order a shipment of a particular type of slime toy without necessarily ordering it again once it sells out. Instead, new types of slime toys are ordered. Over the relatively short period of time (less than one month) from when the internet search was performed (and the Excel sheet with examples of slime toys was prepared) through to when the products were selected to be ordered, there were some cases in which it was not possible to purchase the necessary quantity of identical products, or in which the product had already been removed from the website because it had sold out. The resulting impression is not that the market for slime toys is declining, but that there are constantly new slime toys appearing with new appearances, shapes, types, and so on.

The internet search also showed that many of the same types of slime toys are present on both non-EU websites (such as Amazon, eBay, AliExpress, GearBest, and Wish) and EU websites. For example, the types of slime toys sold on Amazon and eBay are largely the same, regardless of whether the sites in question are based in the USA, India, the UK, or Germany. Many of the slime toys seen in Danish shops or on Danish websites can be found not only on other EU websites, but also on non-EU websites.

5.2 Types of slime toys on the market

In general, the survey showed that an extensive variety of slime toy types exists on the market. In addition, large differences in the amount of slime sold individually have been observed. Variations from about 30-40 g to 1.5 kg have been identified. In this project, we chose to divide slime toys into the types of slime listed below. Some slimes belong to several categories, since some slimes are sold e.g. as both farting slime and fluorescent slime. In these cases, only one of the categories below was chosen. As a rule, the category receiving the greatest emphasis in the product's description was chosen:

1. Ordinary slime (category used when other types of slime are not appropriate)
2. Farting slime (slime which produces farting noises when pressed into its container)
3. Inflatable slime (slime into which bubbles can be blown with a straw)
4. Glitter slime (slime containing glitter)
5. Magnetic slime (slime which is magnetic; a magnet is typically included with the product)
6. Scented slime (slime sold with a particular fragrance)
7. Foamy or "puffy" slime (slime that appears foamy and has a consistency perhaps more like that of modelling clay, but is nonetheless sold as slime)
8. "Pokey slime" (slime sold as being especially good for poking holes in with one's fingers)

9. Slime resembling food (there were examples of slime made to look like honey, slime made to look like ice cream with pieces of Oreo biscuits inside, etc.)
10. Slime with figures inside (e.g., slime containing cars, dinosaurs, etc.)
11. Colour-changing slime (which changes colour, such as from purple to blue, when exposed to heat from one's hands)
12. Fluorescent/neon slime (i.e., slime in neon colours or which glows in the dark)

A list was prepared in Excel comprising more than 90 different examples of slime toys, but the impression this survey produced was that many more slime toy products exist on the Danish, European, and global markets. The vast majority of slime types recorded in the Excel file were defined as the following types of slime (given in order of frequency, from greatest to least, with the number of occurrences in parentheses):

- Ordinary slime (21)
- Fluorescent/neon slime (12)
- Scented slime (11)
- Slime with figures inside (10)
- Glitter slime (8)
- Magnetic slime (8)
- Farting slime (7)
- Foamy slime (7)
- Inflatable slime (6)

It should be noted that the examples of slime toys that were recorded in the Excel file consisted primarily of slime toys to be selected for purchasing in this project. This means that the following types of slime were not observed particularly frequently:

- Slime with a firmer consistency; these are often modelling clay products, rather than slime, but they may still be marketed as slime.
- Slime whose colour could not be chosen during ordering. This is because we needed a minimum of five to seven identical examples of each slime toy product to be able to perform all of the analyses on the same batch. In many cases, it was stated that a random colour would be shipped. This occurred regardless of whether a website was Danish, EU-based, or non-EU-based.

5.3 Information about slime toys from previous studies

A search was performed for previous studies of slime toys which investigated topics including the preservatives and (unregulated) fragrances used in slime toys. This search identified the relevant studies listed below. Common to these studies is a primary focus on preservatives.

- Previous consumer projects under the Danish EPA:
    - "Survey and release of chemical substances in 'slimy' toys" (Svendsen et al., 2006), in which five slime products were analysed to determine, among other things, their total boron content, the off-gassing of chemical substances from them, and the migration of such substances into artificial sweat and artificial saliva.
    - "Survey and health assessment of preservatives in toys" (Poulsen and Nielsen, 2014), in which two slime products were analysed to determine the amount of certain preservatives they contained.
    - "Survey of allergenic substances in products targeted children: toys and cosmetic products" (Poulsen et al., 2016), in which seven slime products were analysed in relation to the release of certain fragrances.
- TÆNK's test of slime products from 27 September 2018 (TÆNK, 2018a and 2018b), in which 15 slime products were analysed for the migration of boron according to EN 71-3, and in which information about preservatives was obtained from manufacturers/importers.
- Foreign tests:

- A slime control test performed by the Norwegian Environment Agency (Miljødirektoratet, 2018), in which nine slime products were inspected for the migration of boron and the presence of the preservatives MI and CMI.
- Öko-Test: Slime toy test (Germany) (Öko-test, 2018), in which 13 slime products were inspected for the migration of boron.
- Stiftung Warentest: Slime toy test (Germany) (Stiftung Warentest, 2018), in which five slime products purchased on Amazon were inspected for the migration of boron.
- Which?: Two slime toy tests (England) (Which?, 2018a and 2018b), in which 11 and 10 different slime products, respectively, were inspected for the migration of boron.

In the sections below (from TABLE 3 through TABLE 6), the results of the previous slime toy studies listed above have been collected and presented in tables.

5.3.1 Information about preservatives, including the migration of boron

TABLE 3 below contains an overview of preservatives (not including boron) identified in slime in previous studies.

TABLE 3. Overview of preservatives (not including boron) identified in slime toys in the literature. The concentrations given are content concentrations unless otherwise indicated.

Substance name	CAS no.	Concentration	Comments	Reference
Methylparaben	99-76-3	2.2 – 3.9 mg/kg	Based on two slime products analysed for migration into sweat	Svendsen et al., 2006
		845 – 1965 mg/kg	Based on two slime products whose contents were analysed. In two out of two products.	Poulsen and Nielsen, 2014
		20 mg/kg	Indicated by importer	Poulsen and Nielsen, 2014
		Not specified	Indicated by importer	TÆNK, 2018b
Propylparaben	94-13-3	1.9 – 5.3 mg/kg	Based on two slime products analysed for migration into sweat	Svendsen et al., 2006
		975 mg/kg	Based on two slime products whose contents were analysed. In one out of two products.	Poulsen and Nielsen, 2014
		20 mg/kg	Indicated by importer	Poulsen and Nielsen, 2014
		Not specified	Indicated by importer	TÆNK, 2018b
Parabens (unspecified)	-	Not specified	Indicated by importer	TÆNK, 2018b
Sodium benzoate	532-32-1	20 mg/kg	Indicated by importer	Poulsen and Nielsen, 2014

Substance name	CAS no.	Concentration	Comments	Reference
Preventol D7 (isothiazolinones)	-	25 mg/kg	Indicated by importer	Poulsen and Nielsen, 2014
MI (methylisothiazolinone)	2682-20-4	2.3 mg/kg	Based on nine slime products whose contents were analysed. One product out of nine contained MI.	Miljødirektoratet, 2018
		Not specified	Indicated by importer	TÆNK, 2018b
CMI (chloromethylisothiazolinone)	26172-55-4	6.4 – 7.56 mg/kg	Based on nine slime products whose contents were analysed. Two out of nine products contained CMI.	Miljødirektoratet, 2018
		Not specified	Indicated by importer	TÆNK, 2018b
Formaldehyde (free)	50-00-0	19 – 355 mg/kg	Caused by the presence of formaldehyde releasers. Identified in two out of two products examined.	Poulsen and Nielsen, 2014
Imidiazolidinyl urea	39236-46-9	Not specified	Indicated by importer	TÆNK, 2018b
Iodopropynyl butylcarbamate (IPBC)	55406-53-6	Not specified	Indicated by importer	TÆNK, 2018b

TABLE 4. Overview of boron migration identified in the literature. Note, however, that for the 2006 study, the total boron content is given, rather than the boron released.

Substance name	CAS no.	Concentration	Comments	Reference
Boron	7440-42-8	653 – 1170 mg/kg	The total content of two slime toys was analysed. Two out of two products contained boron.	Svendsen et al., 2006
		700 – 880 mg/kg	This concentration is for the four slime products with high boron migration. Four out of 15 slime products had excessive migration.	TÆNK, 2018a
		19 – 970 mg/kg	Boron migration occurred in all nine products. Three out of nine were above the permitted limit.	Miljødirektoratet, 2018
		Not specified, but exceeded the limit value by more than 50%	Nine out of 13 slime products with excessive boron migration	Öko-Test, 2018

Substance name	CAS no.	Concentration	Comments	Reference
		Not specified, but limit values were exceeded by two to three times in the worst cases	Five out of five slime products with excessive boron migration	Stiftung Warentest, 2018
		75 – 1400 mg/kg	Eight out of 11 slime products with excessive boron migration	Which, 2018a
		110 – 1400 mg/kg	Five out of 10 slime products with excessive boron migration. Three of these five were purchased on Amazon or eBay.	Which, 2018b

5.3.2 Information about off-gassing from slime toys

Off-gassing of chemical substances from slime toys was examined in two of the Danish EPA's previous projects (Svendsen et al., 2006 and Poulsen et al., 2016), but only screening analyses were performed in both cases. In the first project, off-gassing of chemical substances from two slime products was examined; the second merely identified off-gassing of certain fragrances from seven slime products. Substances identified as released (emitted) from slime toys in the two previous studies are listed in TABLE 5 below. The concentrations of emitted substances were not measured, but the substances in Svendsen et al. (2006) identified at the highest concentrations are listed first (cyclohexanone represented 63% and 30%, respectively, of the total off-gassing from the two products).

TABLE 5. Overview of chemical substances identified as released (emitted) from slime toys in the literature. Concentrations were not measured, since only a screening was performed.

Substance name	CAS no.	Comments	Reference
Cyclohexanone	108-94-1	Based on two products	Svendsen et al., 2006
Toluene	108-88-3	Based on two products	Svendsen et al., 2006
Ethylbenzene	100-41-4	Based on two products	Svendsen et al., 2006
2-ethyl-1-hexanol	104-76-7	Based on two products	Svendsen et al., 2006
Styrene	100-42-5	Based on two products	Svendsen et al., 2006
2-ethylbutanal	97-96-1	Based on two products	Svendsen et al., 2006
Hexanal	66-25-1	Based on two products	Svendsen et al., 2006
n-Butylether	142-96-1	Based on two products	Svendsen et al., 2006
Octanal	124-13-0	Based on two products	Svendsen et al., 2006
Octane	111-65-9	Based on two products	Svendsen et al., 2006
1-propanol	71-23-8	Based on two products	Svendsen et al., 2006
1-Methoxy-2-propanol	107-98-2	Based on two products	Svendsen et al., 2006
Butanal	123-72-8	Based on two products	Svendsen et al., 2006
2-Octen-1-ol	18409-17-1	Based on two products	Svendsen et al., 2006
2-Heptenal	18829-55-5	Based on two products	Svendsen et al., 2006
Xylene	108-38-3 106-42-3	Based on two products	Svendsen et al., 2006
N,N-dimethylformamide	68-12-2	Based on two products	Svendsen et al., 2006
3-Methylbutanal	590-86-3	Based on two products	Svendsen et al., 2006

Substance name	CAS no.	Comments	Reference
2-cyclohexen-1-one	930-68-7	Based on two products	Svendsen et al., 2006
α-Terpineol	98-55-5	Based on screening of seven products	Poulsen et al., 2016
Benzyl alcohol	100-51-6	Based on screening of seven products	Poulsen et al., 2016
Linalool	78-70-6	Based on screening of seven products	Poulsen et al., 2016
Coumarin	91-64-5	Based on screening of seven products	Poulsen et al., 2016
Hexyl cinnamal	101-86-0	Based on screening of seven products	Poulsen et al., 2016
Ethylvanillin	121-32-4	Based on screening of seven products	Poulsen et al., 2016

In the Danish EPA's project on "slimy" toys (Svendsen et al., 2006), five of the substances identified as emitted from the two slime toys (including cyclohexanone) were selected for a more detailed risk assessment due to the substances' concerning health-related properties. It was evaluated that none of these substances constitute a health risk for children when playing with slime toys. The report concludes that the most alarming aspect of slime toys is their boron content, since it may be released in quantities that pose a health risk.

5.3.3 Information about migration into artificial sweat

In the Danish EPA's project on "slimy" toys (Svendsen et al., 2006), migration analyses were also performed using artificial sweat and artificial saliva, and in which many of the same substances found in the emission analyses were identified. Below (in TABLE 6), only the results for artificial sweat are given. This is presumed to be most relevant for slime toys, since it is expected that children over three years will not place their fingers in their mouths as often as children under 3 years of age. The substances found to be present in the greatest quantities are listed first.

TABLE 6. Overview of chemical substances which migrate into artificial sweat from slime toys, according to the literature

Substance name	CAS no.	Concentration	Comments	Reference
Diethylene glycol dibenzoate or similar	120-55-8	4.1 – 127 mg/kg	Substance is not defined unambiguously	Svendsen et al., 2006
Cyclohexanone	108-94-1	0.6 – 57 mg/kg	Based on two slime products	Svendsen et al., 2006
Benzoic acid, butyl ester	136-60-7	0.7 – 10 mg/kg	Based on two slime products	Svendsen et al., 2006
Benzoic acid, propyl ester	2315-68-6	0.8 – 12 mg/kg	Based on two slime products	Svendsen et al., 2006
1,2-Propanedione-1-phenyl-2-oxime	119-51-7	0.2 – 5.8 mg/kg	Based on two slime products	Svendsen et al., 2006
Propylparaben	94-13-3	1.9 – 5.3 mg/kg	Based on two slime products	Svendsen et al., 2006
Methylparaben	99-76-3	2.2 – 3.9 mg/kg	Based on two slime products	Svendsen et al., 2006
N-Propylbenzamide + N-acetylbenzamide	10546-70-0, 1575-95-7	0.7 – 2.4 mg/kg	Based on two slime products	Svendsen et al., 2006

Substance name	CAS no.	Concentration	Comments	Reference
Benzoic acid, phenyl ester	93-99-2	0.3 – 1.1 mg/kg	Based on two slime products	Svendsen et al., 2006

5.4 Information about slime toys from shop visits

In a press release from late 2018[3], COOP indicated that they would be introducing ingredient declarations for all chemically based toys in their shops. Locations belonging to this supermarket company were therefore visited, but the selection of slime toys was not particularly large. However, three different slime toy products with ingredient declarations were identified. The ingredient declarations are given below in TABLE 7.

TABLE 7. Ingredient declarations given on three different slime toy products seen at the supermarket during the project

Substance group	Slime toy 1	Slime toy 2	Slime toy 3
Water	Water	Water	Water
Binder	Guar gum Glycerine Melamine resin	Guar gum Polyvinyl alcohol	Guar gum Polyvinyl alcohol
Viscosity regulator or solvent	Glycerine	Propylene glycol*	Propylene glycol*
Boron	Borax	Sodium tetraborate	Sodium tetraborate
Preservative (other than boron)	DMDMH	Phenoxyethanol	Phenoxyethanol
Colourant	Basic red 1 (CI 45160)	CI 15985 CI 18050 CI 45100 CI 45350 CI 74180	CI 21290 CI 45100 CI 45350 CI 74180 CI 77000 CI 77019 CI 77499

* It should be noted that one importer indicated that it uses propylene glycol as a preservative in its slime toys
CI stands for the Colour Index number

5.5 Information from contact with the industry

The Danish toy industry association LEG and the European industry association TIE were contacted for the purpose of acquiring information about the preservatives and fragrances used in slime toys.

There were generally not many businesses that responded with information. There was a total of two responses from the Danish businesses indicating that they would provide information, but one business ultimately gave up because it could not obtain the information from its suppliers within the available time frame. The European industry association indicated that the inquiry came at an unfortunate time, given the generally busy state of the industry. Moreover, the inquiry submitted to TIE's members showed that only a small number of members currently produce or have produced slime toys. For this reason, TIE contacted the EU-certified toxicologist it works with for toy risk assessments to request their input as well. Thus, the materials received from TIE are based exclusively on information from a single business and on the EU-certified toxicologist's knowledge of slime toys on which they performed risk assessments.

[3] https://om.coop.dk/presse/pressemeddelelser.aspx?nyhedid=14059

In addition, individual importers/manufacturers were contacted regarding the products chosen for chemical analyses in this project. Of the 12 importers/manufacturers contacted, five responded with information about preservative and/or fragrance content. These five importers/manufacturers were responsible for 10 of the purchased slime toys.

5.5.1 Information about preservatives received from the industry

Information about preservatives received from manufacturers and importers contacted through LEG and TIE is summarised in TABLE 8 below.

The information in TABLE 8 is representative of:

- One importer that has imported more than 50 different slime toys from various manufacturers in China
- One manufacturer of a certain slime toy brand under which more than 60 different slime toys are sold
- One manufacturer/importer of a certain slime toy brand under which approximately 10 different slime toys are sold
- Two manufacturers or importers of single slime toys

However, exactly how many slime toys are covered by the information received is unknown, since such information was not supplied in all cases. Based on information from these companies' websites, it covers more than 100 slime toys.

In TABLE 8 below, the preservatives and their concentrations are listed. For comparison, the permitted concentrations for each preservative according to cosmetics regulations and EN 71-7 (for finger paints) are also given.

TABLE 8. Preservatives used in slime toys (based on more than 100 slime products from different importers in the EU)

Substance name	CAS no.	Concentration interval (w/w %)	Permitted concentration in cosmetic products / permitted per EN 71-7
2-phenoxyethanol	122-99-6	0.08 - 0.8%	1% / 1%
Methylparaben*	99-76-3	0.05 - 0.4%	0.4% / 0.4%
Propylparaben*	94-13-3	0.05 - 1%	0.14% / 0.14%
Diazolidinyl urea	78491-02-8	0.2 - 0.5%	0.5% / 0.5%
Chlorphenesin 2-phenoxyethanol Propylene glycol** Ethylhexylglycerin**	104-29-9 122-99-6 57-55-6 70445-33-9	< 0.25% < 1% < 0.4% < 0.1%	0.3% / 0.3% 1% / 1% *Not relevant* *Not relevant*
Sodium benzoate	532-32-1	0.2%	0.5% / 0.5%
Calcium sorbate	24634-61-5	0.02 - 0.4%	0.6% / 0.6%
Propylene glycol***	57-55-6	13 - 17%	- / no
Iodopropynyl butylcarbamate 2-phenoxyethanol Imidazolidinyl urea	55406-53-6 122-99-6 39236-46-9	*No information*	0.02%**** / no 1% / 1% 0.6% / 0.6%
DMDM hydantoin	6440-58-0	*No information*	0.6% / 0.6%

* When multiple parabens are mixed, their total concentration must not exceed 0.8% according to regulation 1223/2009 on cosmetic products and EN 71-7.
** The importer indicated that the substance is a preservative, but according to the CosIng database (a database of ingredients in cosmetic products), the substance does not act as a preservative.
*** The substance is used as a solvent or viscosity regulator, according to the CosIng database. It is not listed as a preservative, as an importer or manufacturer has indicated here.

**** This concentration applies to products intended to be washed off. The permitted concentration is lower for products not intended to be washed off.

TIE indicated that it recommends its members to ensure that preservatives used are exclusively those recommended for use in finger paints; that is, those listed in EN 71-7. This is because TIE considers exposure to be relatively similar for the two types of toys.

TIE and the EU member countries have agreed that the Commission's guidance on toy safety assessments should be revised to add a provision stating that those preservatives regulated by appendix C of the toy safety directive should not be used in toys for children over three years, either. The Commission has yet to update its guidance at this time.

5.5.2 Information about fragrances received from the industry

TABLE 9 below contains an overview of the fragrances contained in the slime toys covered by the information received from contacting LEG, TIE, and importers/manufacturers of products selected for chemical analysis.
The information in TABLE 9 is representative of:

- One importer that has imported more than 50 different slime toys from various manufacturers in China.
- One manufacturer of a certain slime toy brand under which more than 60 kinds of slime toy are sold.
- One manufacturer/importer of a certain slime toy brand under which approximately 10 different kinds of slime toy are sold.
- Two manufacturers or importers of single slime toys.

One of the manufacturers provided detailed information about the fragrance blends it uses. As shown in the table below, there are four specific products that contain fragrances, out of perhaps more than 60 different slime products. The manufacturer supplied ingredient lists for all of the 14 different fragrance blends it uses. Multiple fragrance blends may be added to each slime product, but the total concentration of these fragrance blends lies between 0.05% and 0.15%, such that the limit value of any regulated fragrance component is not exceeded. Each fragrance blend consists of 12 to 37 different chemical substances, one of which is a solvent at a concentration of 50% to 100% (according to the safety data sheet). Solvents used in these fragrance blends are either propylene glycol or isopropyl myristate. This means that the total concentration of fragrances does not exceed 0.075% (or 750 ppm) in the slime product. Each individual fragrance appears to be present in fragrance blends at a concentration of no more than 20%; that is, the maximum concentration of any one fragrance is 0.03% (300 ppm), but it may be as low as 0.00005% (0.5 ppm) or less — however, the fragrances listed in the Danish Statutory Order on Toys may not be present at concentrations above the permitted level of 100 ppm.

The 14 different fragrance blends for which information was sent contain a total of 140 unique ingredients. Of these, two are solvents; that is, 138 unique fragrances are used in the 14 fragrance blends. The manufacturer indicates that it uses exclusively so-called "Class 1" fragrances, according to the IFRA definition; that is, fragrances designed for use in toys and cosmetic products applied to the lips.

TABLE 9. Fragrances used in slime toys (based on more than 100 slime products from different importers in the EU)

Name of fragrance blend	How often are the fragrances used in slime?	CAS no.	Concentration interval (w/w %) in slime product	Listed in DSOT* Annex II, section III, item 11
Strawberry	In a single one out of > 50 slime products	Unknown — mixture of several substances	0.03%	Unknown
None	In zero out of two slime products	-	0%	Not relevant
Strawberry Melon Chocolate Bubble Gum Apple Etc.	In four out of > 60 slime products	138 different numbers	0.05 - 0.15% Each individual fragrance is present at a concentration of 0.5 – 300 ppm.	Yes; 10 out of 138 fragrances listed
None	In zero out of 11 slime products	-	0%	Not relevant
None	In zero out of > 7 slime products	-	0%	Not relevant

* DSOT = the Danish Statutory Order on Toys (*Legetøjsbekendtgørelsen*)

The total of 138 fragrances in the 14 fragrance blends have been reviewed in detail and compared to the regulated fragrances in the Danish Statutory Order on Toys. Listed in the table below are the 10 fragrances (out of the total of 138 fragrances) which are both contained in the 14 fragrance blends received from a manufacturer and listed in Annex II, section III, item 11 of the Danish Statutory Order on Toys; that is, they are regulated in toys.

TABLE 10. The 10 fragrances used by a manufacturer in selected slime toys and which are regulated in toys

Substance name	CAS no.	Concentration used in fragrance blend (%)	Concentration used in slime toy (ppm)	Restrictions per Annex II, section III, item 11 of the DSOT*
Linalool	78-70-6	0.1 - < 1% Used in 10 out of 14 blends	0.5 - 300 ppm	May only be used if indicated on product, or at concentrations < 100 ppm
Eugenol	97-53-0	0.1 - < 1% Used in three out of 14 blends	< 0.5 - 15 ppm	Content of < 100 ppm
Benzyl alcohol	100-51-6	5 - < 10 % Used in one out of 14 blends	25 - 150 ppm	Content of < 100 ppm
Benzyl cinnamate	103-41-3	0.1 - < 1% Used in two out of 14 blends	0.5 - 15 ppm	May only be used if indicated on product, or at concentrations < 100 ppm
trans-3-Phenylallyl alcohol	104-54-1	0.1 - < 1% Used in nine out of 14 blends	0.5 - 15 ppm	Content of < 100 ppm

Substance name	CAS no.	Concentration used in fragrance blend (%)	Concentration used in slime toy (ppm)	Restrictions per Annex II, section III, item 11 of the DSOT*
Citronellol	106-22-9	0.1 - < 1% Used in one out of 14 blends	0.5 - 15 ppm	May only be used if indicated on product, or at concentrations < 100 ppm
Geraniol	106-24-1	0.1 - < 1% Used in one out of 14 blends	0.5 - 15 ppm	Content of < 100 ppm
Benzyl salicylate	118-58-1	10 - < 20 % Used in one out of 14 blends	50 - 300 ppm	Content of < 100 ppm
iso-α-Methylionone	127-51-5	0.1 - < 1% Used in one out of 14 blends	0.5 - 15 ppm	May only be used if indicated on product, or at concentrations < 100 ppm
Limonene	5989-27-5	1 - < 5 % Used in one out of 14 blends	5 - 75 ppm	May only be used if indicated on product, or at concentrations < 100 ppm

* DSOT = the Danish Statutory Order on Toys (*Legetøjsbekendtgørelsen*)

It can be seen that for all 10 of these fragrances regulated by the Danish Statutory Order on Toys, the concentration of each individual fragrance is under 100 ppm — often far below 100 ppm, when the lower concentration limits are used. It should be noted that the concentrations of the fragrances are supplied both as an interval for the content of each individual fragrance in the fragrance blend and as an interval for the fragrance blend itself used in the slime toy. The manufacturer has indicated that naturally, it never adds the regulated fragrances at concentrations greater than 100 ppm, the permitted limit value.

5.5.3 Evaluation of industry information

TIE itself declared[4] that the information it sent regarding preservatives and fragrances in slime toys came from a toy manufacturer/importer in the EU which is aware of the EU regulations on slime toys and its obligations. While the slime upon which this information is based was also produced outside the EU (in China), as with most slime sold in Europe, TIE asserts that it comes from some of the better Chinese factories. Thus, this information is hardly representative of all slime toys on the market.

Correspondingly, our evaluation is that the few manufacturers or importers who responded to our inquiry regarding ingredients in their slime toys are manufacturers who comply with the regulations of the Danish Statutory Order on Toys and are thus willing to share such information.

It can be seen in TABLE 3 and TABLE 8 that many of the same preservatives which the industry indicated (in connection with this project) it uses in slime toys were identified in previous studies of slime toys. The following preservatives appeared throughout this study and previous studies:

- Methylparaben and propylparaben
- 2-phenoxyethanol
- Sodium benzoate
- Imidazolidinyl urea

[4]Correspondence with Dominique Billeret, TIE, in the early phases of the project.

It can be seen in TABLE 8 that the following preservatives are used today, but were not mentioned in previous surveys of slime toys:

- Diazolidinyl urea
- Chlorphenesin

Isothiazolinones and IPBC in particular were not identified through contact with the industry in this project, but were identified in previous studies. These preservatives were identified by TÆNK in 2018 (TÆNK, 2018b) among others; thus, they most likely remain in use today. It should be noted that information regarding preservatives was received from just three sources in this project, so this information is hardly representative of the entire market.

Regarding the use of fragrances in slime toys, the general evaluation obtained from the survey is that less than 5-10% of the slime toys (perhaps even less) have fragrances added deliberately to give the slime toys a particular smell. In the search for examples of slime toys, 11 out of the 96 examples of slime toys were sold with an indication that they have a particular scent, corresponding to about 11%. It should be noted that the examples listed were chosen to represent a variety of manufacturers and/or importers. For this reason, scented slime toys may be over-represented in this list. It should also be noted that all 11 example of scented slime toys were found either on websites based outside of the EU (nine) or websites based in the EU, but outside of Denmark (two).

5.6 Summary of survey results

The survey showed that a vast array of slime toys can be purchased either in Denmark or from websites outside of Denmark. The slime toy market appears to shift rapidly; that is, new products are constantly appearing on the market. However, certain large manufacturers of slime toys appear to sell the same types of slime toys over a longer period of time, supplemented regularly by new products.

It is not our impression that a particularly large number of slime toys contain fragrances added deliberately to give products a particular scent. Scented slime toys were primarily identified on websites based outside of the EU, while certain scented slime toys were identified on websites based in the EU (but not Denmark).

TABLE 11 below presents a summary of the preservatives identified as being used in slime toys during the survey phase of this project. The source of the information for each preservative is given. Certain preservatives were found to be in use exclusively by previous studies, and were not otherwise identified in this project, such as through contact with the industry. The preservatives indicated as being used (by manufacturers and/or importers) or seen in use via ingredient listings in the survey portion of this project are listed in boldface in the table below.

TABLE 11. Overview of preservatives identified as being used in slime toys. Preservatives listed in boldface were identified in slime toys in this project.

Substance name	CAS no.	Concentration	Comments	Reference/year
Methylparaben	99-76-3	845 – 1965 mg/kg	Based on two slime products whose contents were analysed	Poulsen and Nielsen, 2014
		Not specified	Indicated by importer	TÆNK, 2018b
		500 – 4,000 mg/kg	Indicated by manufacturer	2019

Substance name	CAS no.	Concentration	Comments	Reference/year
Propylparaben	94-13-3	975 mg/kg	Based on two slime products whose contents were analysed	Poulsen and Nielsen, 2014
		Not specified	Indicated by importer	TÆNK, 2018b
		500 – 10,000 mg/kg	Indicated by manufacturer	2019
Parabens (unspecified)	-	Not specified	Indicated by importer	TÆNK, 2018b
Sodium benzoate	532-32-1	20 mg/kg	Indicated by importer	Poulsen and Nielsen, 2014
		2,000 mg/kg	Indicated by manufacturer	2019
Phenoxyethanol	122-99-6	Not specified	Found in ingredient listing on product in shop	2019
		< 10,000 mg/kg	Indicated by manufacturer	2019
		800 – 8,000 mg/kg	Indicated by manufacturer	2019
Preventol D7 (isothiazolinones)	-	25 mg/kg	Indicated by importer	Poulsen and Nielsen, 2014
MI (methylisothiazolinone)	2682-20-4	2.3 mg/kg	Based on 14 slime products whose contents were analysed. One product contained MI.	Miljødirektoratet, 2018
		Not specified	Indicated by importer	TÆNK, 2018b
CMI (chloromethylisothiazolinone)	26172-55-4	6.4 – 7.56 mg/kg	Based on 14 slime products whose contents were analysed. Two products contained CMI.	Miljødirektoratet, 2018
		Not specified	Indicated by importer	TÆNK, 2018b
Chlorphenesin	104-29-9	< 2,500 mg/kg	Indicated by manufacturer	2019
Formaldehyde (free)	50-00-0	19 – 355 mg/kg	Caused by the presence of formaldehyde releasers	Poulsen and Nielsen, 2014
Imidiazolidinyl urea	39236-46-9	Not specified	Indicated by manufacturer	2019
		Not specified	Indicated by importer	TÆNK, 2018b
Diazolidinyl urea	78491-02-8	2,000 – 5,000 mg/kg	Indicated by manufacturer	2019
Iodopropynyl butylcarbamate (IPBC)	55406-53-6	Not specified	Indicated by importer	TÆNK, 2018b
DMDM hydantoin	6440-58-0	Not specified	Found in ingredient listing on product in shop	2019
Propylene glycol*	57-55-6	13 – 17%	Indicated by importer	2019

* According to the CosIng database, propylene glycol is used as a solvent or viscosity regulator. It is not listed as a preservative, as an importer or manufacturer has indicated here.

6. Selection of products for analysis

This chapter contains a description of the slime toys that were selected for analysis in this project.

6.1 Description of approach to selection

As described earlier, a document was created with more than 90 different examples of slime toys. There were some challenges in selecting examples of slime toys, such as:

- It was not always possible to determine the consistency of a product from images of it and its accompanying product description online (i.e., whether the product was liquid or sticky)
- It was not always possible to order sufficiently uniform products (same batch number) for analysis (five to seven units) because, for example, it was not always possible to select a product's colour when ordering
- It was decided in advance that the 25 slime toys included in the Chemical Inspection Service's ongoing control campaign would be excluded from this project

The slime products were selected to cover:

- Purchases from Denmark, non-EU countries, and EU countries other than Denmark
- Different types of slime toys (scented, neon slime, farting slime, ordinary slime, etc.)
- Slime toys at various price levels
- Slime toys from various manufacturers (to the extent that such information was available when purchasing)
- Slime products that appeared sufficiently liquid to belong to category II of the Danish Statutory Order on Toys (initially evaluated using only images and product descriptions on the internet)

Using this list of examples of slime toys, a total of 33 products were selected in co-operation with the Danish EPA to be purchased for this project. These 33 products were divided into 23 products purchased by the project group and 10 products selected by the Chemical Inspection Service in Denmark. They were also divided as follows:

- Ten products from physical shops in Denmark
- Five products from online shops in Denmark
- 13 products from non-EU countries — the goal was to examine 10, but extra products were purchased in case of long shipping times or other unforeseen obstacles
- Five products from EU countries other than Denmark – however, here, when examined more closely later on, it turned out that one of the five EU products was actually purchased from a Danish company with a Danish CVR (business registry) number, even though their website was embedded in another country and the language was not Danish.

However, the selection of 33 products had to be modified during the purchasing process, as we found that many slime products had sold out before ordering, and that some merchants indicated that they could not send five to seven identical products.

The result of the purchasing process was that a total of 28 slime toys were acquired by either the project group or the Chemical Inspection Service. Several of the 33 selected products were dropped from the project along the way, for various reasons:

- For two of the products selected by the Chemical Inspection Service, one vendor never replied and the other was unable to provide five to seven identical slime toys.
- Two products ordered from non-EU countries never arrived, even though they were ordered at least 35 days before chemical analyses were to begin.
- One product ordered from a non-EU country turned out to be identical to a product collected by the Chemical Inspection Service; only one of these products was selected for chemical analysis.
- Some units of products ordered from outside the EU were ultimately damaged during shipping.

One of the products was not liquid enough to be considered a member of category II in the Danish Statutory Order on Toys (Statutory Order No. 309, 2017), for which reason the product was excluded and not studied further in this project.

Thus, the result was that a total of 27 slime toys were analysed.

6.2 Overview of products selected for analysis

TABLE 12 below gives an overview of the 27 slime toy products selected for analysis. It should be noted that the products are named ("Lab no.") based on where they were purchased, which does not necessarily indicate that they were produced in the same place. More specifically,

- the nine "N-EU" products were purchased from non-EU countries, typically on Wish.com, Amazon.com, Gearbest.com, or Aliexpress.com
- The four "EU" products were purchased in the EU (excluding Denmark), including on Amazon.de, as well as directly from German and British websites
- The 13 "DK" products are from Denmark, either collected from Danish shops or purchased from other Danish shops in the Copenhagen area or at web sites with Danish CVR (business registry) numbers

A number of "holes" occur in the marking order (particularly for the N-EU products), due to these products being excluded after marking/naming.

TABLE 12. Names and descriptions of the 27 products selected for analysis

Lab no.	Product type	Manufactured in*	Unit price excl. shipping
N-EU 2	Scented slime	USA	80.00 DKK
N-EU 3	Glitter slime	China	16.54 DKK
N-EU 4	Scented slime	China	19.51 DKK
N-EU 6	Glitter slime	China	18.50 DKK
N-EU 7	Fluorescent neon slime	China	9.91 DKK
N-EU 8	Slime resembling food	China	14.79 DKK
N-EU 9	Glitter slime	China	9.35 DKK
N-EU 10	Scented slime	China	11.12 DKK
N-EU 11	Scented slime	China	14.34 DKK
EU 1	Fluorescent neon slime for slime gun	Netherlands?	78.50 DKK
EU 2	Ordinary slime	UK	90.50 DKK
EU 3	Scented slime	China	77.00 DKK
EU 4	Slime with figure inside	China	21.70 DKK
EU 5**	Fluorescent neon slime	China	31.20 DKK
DK 1	Ordinary slime	China	20.00 DKK

Lab no.	Product type	Manufactured in*	Unit price excl. shipping
DK 2	Fluorescent neon slime	Germany?	19.50 DKK
DK 3	Slime with figure inside	China	10.00 DKK
DK 4	Slime with figure inside	China	20.00 DKK
DK 5	Inflatable slime	China?	60.00 DKK
DK 6	Foam/"puff" slime	China	79.00 DKK
DK 7	Fluorescent neon slime	China	180.00 DKK
DK 8	Farting slime	China	69.00 DKK
DK 9	Ordinary slime	China	10.00 DKK
DK 10	Glitter slime	No information	20.00 DKK
DK 11	Foam/"puff" slime	China	99.00 DKK
DK 12	Ordinary slime	China	39.00 DKK
DK 13	Farting slime	China	39.00 DKK

* "?" in the "Manufactured in" column indicates that the company named on the product is based in that country, but there is no information on where specifically the product was produced

** EU 5 turned out to be purchased from a company with a Danish CVR (business registry) number

The distribution of slime types for the 27 slime toys to be analysed is given below:

- 5 units of scented slime
- 5 units of fluorescent/neon slime
- 4 units of ordinary slime
- 4 units of glitter slime
- 3 units of slime with figures inside
- 2 units of farting slime
- 2 units of foam/"puff" slime
- 1 units of inflatable slime
- 1 units of slime resembling food

7. Initial analyses

According to the survey, slime is typically composed of a relatively small range of ingredient types (binders, water, boron, other preservatives, colourants, and occasionally solvents and fragrances). The survey also showed that not very many slime toys on the market contain fragrances. They are primarily found on websites outside the EU, and not in Denmark.

As part of the sampling process, boron release from slime toys was investigated. Allergy risks are another relevant area of focus, since skin contact occurs when playing with slime. For this reason, it was decided that the analyses in this project would also focus on unregulated preservative content in slime.

The following chemical analyses were performed as initial analyses for this project:
- Screening analyses for the purpose of approaching possible identifications of preservatives used
- Content analyses for certain preservatives
- Boron release (migration according to EN 71-3)

7.1 Selection of analyses

It is not possible to perform a single simple screening analysis, such as a GC-MS screening, to identify the presence of all the preservatives in the products, since most preservatives are not volatile; thus, they will not evaporate and be identifiable by this method. As a result, the screening analyses below were selected for general material determination and elemental determination, to be able to provide a more qualified assessment of the preservative content in the slime toys:
- FT-IR-ATR screening (Fourier Transform Infrared Spectroscopy Attenuated Total Reflection)
- ICP-OES screening (Inductive Coupled Plasma Optical Emission Spectrometry)

FT-IR is a spectroscopic measurement technique capable of providing information as to the base material used in a slime toy and indicating which products can be expected to contain parabens. The result is a spectrum that is read and evaluated to obtain an indication of the material and contents.

ICP-OES is an elemental analysis. The elements identified can indicate the potential presence of certain preservatives. For example:
- chlorine and sulphur content may indicate the presence of CMI
- sulphur content (in the absence of chlorine) may indicate the presence of the isothiazolinones BIT and/or MI
- magnesium, chlorine, and sulphur content may indicate the presence of the preservative Kathon, a mixture of CMI and MI at a ratio of 3:1, since Kathon can also contain magnesium salts (magnesium chloride and magnesium nitrate)[5]
- iodine content may indicate the presence of iodopropynyl butylcarbamate (IPBC)
- bromine content may indicate the presence of brominated compounds, such as bronopol, methyldibromo glutaronitrile (MG), or other bromine-containing preservatives or compounds

[5] http://msdssearch.dow.com/PublishedLiteratureDOWCOM/dh_0988/0901b80380988b37.pdf?filepath=biocides/pdfs/noreg/253-02698.pdf&fromPage=GetDoc; https://www.chemical.net/content/images/uploaded/sds/Kathon%20CG%20ICP%20Preservative.pdf

- chlorine content may indicate the presence of chlorphenesin, in the absence of e.g. sulphur or other chlorinated compounds

It was decided that the screening analyses would be performed on the 17 products for which we did not have any previous knowledge of the preservative content. Screening analyses for elemental preservative components were not performed on the 10 products for which the manufacturer/importer provided information on preservative content.

Apart from the screening analyses, it was decided to perform a quantitative content analysis for the preservatives phenoxyethanol, sodium benzoate, potassium sorbate, and dehydroacetic acid; as well as a screening for certain parabens which can all be identified and determined using the same analytical method. According to the survey, out of these preservatives, phenoxyethanol, sodium benzoate, and methyl- and propylparaben are particularly commonly seen in slime toys. This analysis was performed on a total of 24 products from the selection. Even if selected products were known to contain e.g. phenoxyethanol, sodium benzoate, or propylparaben, the concentrations of these substances were not necessarily known. There were only three products on which the analysis was not performed, since the manufacturers/importers indicated that the products did not contain these preservatives.

7.2 Screening analysis procedure

A quantity of the slime toy was placed in a heated chamber at 40°C for 3-4 days to allow the majority of the water to evaporate from the slime. This was done partially to facilitate the performance of the screenings (on dry material) and partially to increase the sensitivity of the screening analyses. In theory, this may mean that substances other than water also evaporated, but the purpose of the screening analyses was to aid in identifying certain preservatives which are not expected to evaporate at this temperature.

7.2.1 FT-IR screening analyses

A small amount of the dried slime, about half of one gram, was analysed using FT-IR-ATR spectroscopy to produce a spectrum for the product. Materials and component substances were identified by comparing the FT-IR spectrum for the product with spectra for the individual substances (including by use of the material and substance reference library that accompanies the FT-IR software used). This produces a qualitative indication of the substances/materials in the slime toy. The certainty of the identification depends partially on the concentrations of the component materials and substances. Preservatives were difficult to identify due to the low concentrations at which they were present.

7.2.2 ICP-OES screening analyses

A precisely weighed amount (approximately 0.5 g) of the dried slime was subjected to microwave-assisted digestion with nitric acid. In practice, the nitric acid decomposes an insoluble material, cleaving it into soluble constituents which can subsequently be analysed using the ICP technique. An OES analysis was performed on the resulting material; that is, an elemental determination — here, for bromine, chlorine, potassium, magnesium, sodium, sulphur, and iodine. The uncertainty of an elemental determination using this method is approx. 25%.

This method was not sensitive enough for iodine and chlorine, therefore it was supplemented by an XRF analysis for these elements. The results presented in section 7.5.2 "Analysis results for ICP-OES screening analyses" are thus the combined results for ICP-OES and XRF. The uncertainty of XRF is approx. 25%, but it increases to approx. 50% for small samples.

7.3 Procedure for quantitative determination of selected preservatives

The following preservatives can be determined by extraction with an appropriate solvent followed by HPLC analysis with UV detection:

- Dehydroacetic acid
- Potassium sorbate
- Sodium benzoate
- Phenoxyethanol
- Methylparaben
- Ethylparaben
- Propylparaben
- Butylparaben
- Iso-Butylparaben

The quantitative component analysis was performed based on external calibration standards. The level of detection varies between 0.00007% and 0.0033% (percent weight) depending on the substance. The analytical uncertainty was 30%. The determination of the four preservatives previously named was performed as a duplicate determination, and the paraben content determination was initially performed as a single determination (screening). The content analysis for the previously named preservatives was performed by Eurofins Product Testing A/S.

It should be noted that other parabens, such as iso-propylparaben, are not identified by this analysis. However, the five parabens named are considered to be among those most commonly used in toys, according to such sources as Poulsen and Nielsen (2014); and in cosmetic products, according to Uter et al. (2013).

7.4 Procedure for migration per EN 71-3

The elemental migration test was performed by Eurofins Product Testing A/S according to EN 71-3 (EN 71-3: 2013 + A3: 2018). The sample was extracted with a hydrochloric acid solution to imitate exposure to stomach acid after ingestion. The extraction liquid was then analysed using ICP/MS.

According to EN 71-3, a so-called de-waxing (boiling with n-heptane) of the toy material must be performed if it contains any kind of oil, wax, or similar material. In the standard, it is mentioned that it is possible to compare results for each sample with and without de-waxing, but there is no clear procedure for which results are to be reported and when. For this reason, initial analyses were performed both with and without de-waxing according to the standard, since the composition of the material was unknown. Subsequently, a second determination was performed using the method that gave the highest result from a worst-case perspective. For all the analysed samples, this was the sample with preparatory de-waxing. The migration analyses were performed as true duplicate determinations. The level of detection varies across constituents, from approx. 0.05 to 10 mg/kg. The analytical uncertainty was 20%.

7.5 Analysis results for initial analyses

The analysis results for the initial analyses are presented below in TABLE 13 to TABLE 15.

7.5.1 Analysis results for FT-IR screening analyses

The FT-IR analysis is a screening analysis and was thus performed as a single analysis. The analysis results for the FT-IR screening analyses show that the majority of the slime toys are based on polyvinyl alcohol, a binder, as also described in chapter 2 “What does slime consist of?”. Due to the low paraben concentrations in the products, paraben identification via FT-IR

was not unambiguous; rather, it was exclusively an indication of possible paraben content. The results are presented below in TABLE 13.

TABLE 13. Result of FT-IR screening

Slime no.	Binder in product	Indications of paraben content
N-EU2	Polyvinyl acetate (PVA)	
N-EU3	Polyvinyl alcohol	
N-EU4	Polyvinyl alcohol	
N-EU6	Polyvinyl alcohol	
N-EU7	Polyvinyl alcohol	Yes
N-EU8	Polyvinyl alcohol	
N-EU9	Polyvinyl alcohol	
N-EU10	Polyvinyl alcohol	
N-EU11	Polyvinyl alcohol	
EU1	Polyvinyl alcohol, likely with a cellulose-based thickening agent	Yes
EU2	Polyvinyl alcohol	Yes
EU3	Polyvinyl alcohol	Yes
EU5	Polyvinyl alcohol	Yes
DK2	Polyvinyl alcohol — slightly uncertain	Yes
DK4	Polyvinyl alcohol, likely with a cellulose-based thickening agent	Yes
DK5	Polyvinyl alcohol	
DK10	Polyvinyl alcohol, likely with a cellulose-based thickening agent	Yes

7.5.2 Analysis results for ICP-OES screening analyses

The ICP-OES analysis is a screening analysis and was thus performed as a single analysis. The analysis results for ICP-OES screening analyses are presented below in TABLE 14 for the 17 slime toys whose preservative content was not known in advance.

TABLE 14. The results of combined ICP-OES and XRF screening. The results given are percentages relative to the original sample by weight

Slime no.	Br	Cl (XRF)	K	Mg	Na	S	I (XRF)
N-EU 2	0.0142	2.2	0.028	0.0071	0.36	0.085	0.0064
N-EU 3	<0.003	0.010	<0.003	0.0149	0.25	0.0075	<0.001
N-EU 4	<0.003	0.015	0.0047	0.0093	0.39	0.0047	n.d.
N-EU 6	<0.003	0.016	0.083	0.142	3.1	0.047	n.d.
N-EU 7	<0.003	0.011	0.0081	0.0040	2.7	0.69	0.0151
N-EU 8	<0.003	0.012	0.0021	0.021	0.42	0.0171	n.d.
N-EU 9	<0.003	0.004	0.0037	<0.0005	0.50	0.0037	<0.001
N-EU 10	<0.003	0.008	0.0019	0.0007	0.37	0.0037	0.0013
N-EU 11	0.0051	0.008	<0.003	0.020	0.46	0.0051	n.d.
EU 1	<0.0001	0.001*	0.0006	0.0010	0.042	0.0029	n.d.*

Slime no.	Br	Cl (XRF)	K	Mg	Na	S	I (XRF)
EU 2	0.103	0.022	<0.002	<0.0003	0.22	0.0164	<0.001
EU 3	0.0063	0.58	<0.004	0.0188	0.61	0.0125	n.d.
EU 5	<0.003	0.029	0.0030	0.048	0.72	0.0121	n.d.
DK 2	<0.0003	-	0.0033	0.0103	0.051	0.89	-
DK 4	<0.0003	0.144*	0.0011	0.0075	0.46	0.049	<0.001*
DK 5	<0.002	0.011	0.0114	0.0114	0.34	0.0057	<0.001
DK 10	<0.001	0.018*	0.034	0.064	0.59	0.0069	n.d.*

* Results are uncertain (uncertainty of approx. 50%) because they are based on a sample weight which is too low to obtain optimal results via XRF
- There was not a sufficient amount of sample material to perform XRF
n.d. stands for "not detected"

7.5.3 Analysis results for content of selected preservatives

Analysis results for quantitative determination of the content of selected preservatives are described in general above, and presented in their entirety in Appendix 2 “Analysis results".

The quantitative analysis for the preservatives dehydroacetic acid, potassium sorbate, sodium benzoate, and phenoxyethanol was performed using true duplicate determination. The average of the two single determinations is given. The analysis was performed on 24 out of the 27 products, since the last 3 products did not contain these preservatives, according to information from the manufacturer.

The results of the quantitative analyses show the following:
- Dehydroacetic acid was identified in one product at a concentration of 0.09%
- Potassium sorbate was not identified in any of the 24 products examined
- Sodium benzoate was identified in two products at concentrations of 0.12% and 0.16%
- Phenoxyethanol was identified in eight products at concentrations between 0.26% and 0.65%
- One of the products contained several of the four preservatives named above (both dehydroacetic acid and sodium benzoate)
- 10 out of 24 products contained one or two of the preservatives named above; that is, the preservatives named above were not identified in 14 out of 24 products

The quantitative analysis for parabens was performed as a single determination (screening). The analysis was performed on 24 out of the 27 products, since the last 3 products did not contain these preservatives, according to information from the manufacturer. Since the result of the screening for parabens showed that these were not present at particularly high concentrations, it was decided that additional determinations (duplicate determinations) would not be performed.

The results of the quantitative analyses show the following:
- Methylparaben was identified in 13 out of 24 products at concentrations between 0.008% and 0.16%
- Ethylparaben was identified in a simple product at a concentration of 0.01%
- Propylparaben was identified in three products at concentrations between 0.02% and 0.07%
- Butylparaben and isobutylparaben were not identified in any of the 24 products examined
- Two of the products contained several of the parabens named above (methyl- and propylparaben in one; and methyl-, ethyl-, and propylparaben in another)
- 14 out of 24 products contained one, two, or three of the parabens named above; that is, the preservatives named above were not identified in 10 out of 24 products

7.5.4 Analysis results for elemental migration, per EN 71-3

The analysis results for elemental migration according to EN 71-3 are presented below in TABLE 15. The results given are averages of the duplicate determinations performed. It should be noted that each result is the average of results obtained using de-waxing, since in all cases, this produced the highest results (approx. 8% higher on average than results without de-waxing; however, in certain cases, this was not significant in relation to assessing health risks — see Appendix 3). The results for the 27 slime toys are given in percent weight mg/kg.

It should be noted that for a number of elements, migration above the level of detection was not identified. Thus, migration analysis results per EN 71-3 are not given for these elements in TABLE 15. This applies to the following elements, whose levels of detection are given in parentheses:

- Antimony, barium, copper, manganese, and nickel (10 mg/kg)
- Arsenic and lead (0.5 mg/kg)
- Cadmium and organic tin (0.1 mg/kg)
- Chromium (Cr III) (5 mg/kg)
- Chromium (Cr VI) (0.005 mg/kg)
- Cobalt, mercury, and selenium (1 mg/kg)

TABLE 15. Results for elemental migration per EN 71-3 with de-waxing. The results are given in mg/kg. Boldface numbers indicate values exceeding the limit values in the Danish Statutory Order on Toys given the uncertainty of 20%. Only elements with migration shown above the level of detection are listed

Slime no.	Aluminium (mg/kg)	Boron (mg/kg)	Strontium (mg/kg)	Tin (mg/kg)	Zinc (mg/kg)
Limit value for category II per EN 71-3	1406	300	1125	3750	938
N-EU 2	-	357	-	0.4	-
N-EU 3	-	**591**	-	0.1	12
N-EU 4	-	**504**	-	-	-
N-EU 6	-	**4025**	-	-	-
N-EU 7	48	**4275**	93	-	21
N-EU 8	-	**599**	-	-	-
N-EU 9	-	**1150**	-	-	11
N-EU 10	-	**703**	-	-	-
N-EU 11	-	**848**	-	-	-
EU 1	-	355	-	-	-
EU 2	-	224	-	-	-
EU 3	-	**807**	-	-	-
EU 4	-	116	-	6.8	-
EU 5	-	**903**	-	3.4	-
DK 1	-	148	-	9.9	-
DK 2	-	220	-	4.3	-
DK 3	-	**377**	-	1.6	-
DK 4	-	241	-	1.0	-
DK 5	-	**638**	-	0.5	-
DK 6	-	221	-	1.0	-

Slime no.	Aluminium (mg/kg)	Boron (mg/kg)	Strontium (mg/kg)	Tin (mg/kg)	Zinc (mg/kg)
DK 7	-	198	-	1.1	-
DK 8	-	210	-	0.5	-
DK 9	-	156	-	7.3	-
DK 10	368	**635**	642	2.9	-
DK 11	31	207	60	1.4	-
DK 12	15	211	-	0.8	-
DK 13	21	248	-	0.5	-

- means that migration above the level of detection was not identified. Levels of detection for the listed elements are as follows: aluminium, boron, strontium, and zinc, 10 mg/kg; tin, 0.08 mg/kg.

It can be seen in TABLE 15 that the limit value for boron is exceeded in several instances. These instances were presented to the Danish EPA during the project, whereupon the agency evaluated the risk posed by each product. For products posing a serious risk to health purchased in Denmark, this resulted in two bans on sale and one recall of a product from the market. The Danish EPA cannot impose sale bans on websites outside the EU, so the websites from which products were purchased were contacted; cf. an agreement the European Commission has with some of these. A single foreign website wrote directly to its customers to inform them that the product is unsafe. For products purchased from other EU countries, these matters were forwarded to the relevant authorities in those countries. Furthermore, all products with violations and/or serious risks were reported to the common European warning systems ICSMS/RAPEX.

Since the uncertainty of these analyses is 20%, a value of 375 mg/kg or below is within the uncertainty range for the limit value of 300 mg/kg for boron. Thus, N-EU 2 and EU 1 have values above the limit value, but within the uncertainty range, so they are not considered to be violations. Products considered to be violations; that is products with boron migration greater than 375 mg/kg, are distributed as follows:

- Eight out of nine products (89%) purchased outside the EU exceed the EU's limit values for boron migration from the slime toy.
- One out of four products (25%) purchased in the EU (but outside Denmark) exceeds the EU's limit values for boron migration from the slime toy.
- Four out of 14 products (29%) purchased in Denmark exceed the EU's limit values for boron migration from the slime toy.

These violations are not otherwise reported on or further considered in this report. The results for the initially performed single determinations with and without de-waxing are presented in Appendix 3. They show that the results with de-waxing are generally between 0.3% and 23% higher than those obtained without de-waxing. The average difference is approx. 8%. Thus, the difference between the results with and without de-waxing is not very large, and this difference is smaller than the uncertainty of the analysis itself.

7.6 Discussion of results for preservatives

Information about preservatives is summarised in TABLE 16 below, originating from product manufacturers and importers, as well as from the initial analyses for preservatives as described above. An empty field indicates that no information was available from the manufacturer or importer; a dash (–) in the column for the initial analyses indicates that none of the preservatives of interest (dehydroacetic acid, potassium sorbate, sodium benzoate, phenoxyethanol, or the five parabens) were identified in a product above their respective levels of detection.

For the 10 products for which the manufacturers supplied information about the preservatives used, "not analysed" is listed under ICP-OES, and considerations of possible preservatives used are unnecessary because they would be based on this analysis.

TABLE 16. Overview of information regarding preservative content or expected preservative content in the 27 slime toys

Slime no.	Information from manufacturer or ingredient list	Information from content analyses	ICP-OES XRF	Possible preservatives based on ICP-OES / XRF
N-EU 2		-	Cl, Br, S, I	CMI Chlorinated Bronopol — other brominated Iodopropylyl butylcarbamate
N-EU 3		Methylparaben	Mg, S, Cl	Kathon™
N-EU 4		Methylparaben	Mg, S, Cl	Kathon™
N-EU 6		-	Mg, S, Cl	Kathon™
N-EU 7		Methylparaben Phenoxyethanol	S, I, Mg, Cl	MI, CMI Iodopropylyl butylcarbamate
N-EU 8		Methylparaben	Mg, S, Cl	Kathon™
N-EU 9		Methylparaben	S, Cl	MI, CMI
N-EU 10		-	I, (Cl, S)	Iodopropylyl butylcarbamate
N-EU 11		Methylparaben	Br, S, Cl, Mg	Bronopol — other brominated CMI
EU 1		Phenoxyethanol	(S, Mg, Cl)	No others Kathon™
EU 2		-	Br, S, Cl	Bronopol — other brominated MI, CMI
EU 3		Methylparaben	Br, Cl, Mg, S	Bronopol — other brominated Kathon™
EU 4	Sodium benzoate	Sodium benzoate Dehydroacetic acid	*Not analysed*	Not necessary
EU 5		Methylparaben	Mg, Cl, S	Kathon™
DK 1	Propylparaben Sodium benzoate	Methylparaben Propylparaben Sodium benzoate	*Not analysed*	Not necessary
DK 2		Methylparaben	S, Mg	MI Kathon™
DK 3	Propylene glycol	*Not analysed*	*Not analysed*	Not necessary
DK 4		Methylparaben Ethylparaben Propylparaben Phenoxyethanol	Cl, S, Mg	No others Kathon™
DK 5		Methylparaben	Mg, Cl, S	Kathon™
DK 6	DMDM hydantoin	*Not analysed*	*Not analysed*	Maybe analysis for concentration info
DK 7	Phenoxyethanol	Phenoxyethanol	*Not analysed*	Not necessary

Slime no.	Information from manufacturer or ingredient list	Information from content analyses	ICP-OES XRF	Possible preservatives based on ICP-OES / XRF
	Iodopropynyl butylcarbamate Imidazolidinyl urea			
DK 8	Phenoxyethanol Chlorphenesin Ethylhexylglycerine Propylene glycol	Phenoxyethanol	*Not analysed*	Maybe analysis for concentration info
DK 9	Propylene glycol	*Not analysed*	*Not analysed*	Not necessary
DK 10		Methylparaben	Mg, Cl, S	Kathon™
DK 11	Phenoxyethanol Iodopropynyl butylcarbamate Imidazolidinyl urea	Phenoxyethanol	*Not analysed*	Not necessary
DK 12	Phenoxyethanol Chlorphenesin Ethylhexylglycerine Propylene glycol	Phenoxyethanol	*Not analysed*	Maybe analysis for concentration info
DK 13	Phenoxyethanol Chlorphenesin Ethylhexylglycerine Propylene glycol	Phenoxyethanol	*Not analysed*	Maybe analysis for concentration info

An empty field indicates that no information was available from manufacturers/importers regarding the preservative content of a product.
- indicates that none of the nine preservatives of interest from the initial analyses of the project were identified in the product.

First and foremost, it should be noted that the presence of such elements as chlorine, sulphur, and bromine does not necessarily and unambiguously indicate that the product contains chlorinated, sulphurous, or brominated preservatives. These elements may originate from other ingredients in the slime, such as colourants; for example, numerous colourants contain sulphur.

The initial analyses show that in general, preservatives occur at relatively low concentrations. This may be because all of the products contain boron, which also has a preservative effect; for this reason, large quantities of other preservatives may not be required. In fact, some products (DK 3 and DK 9) contain none of the common preservatives. According to the importer, only propylene glycol is used in these cases. It is neither considered to be a preservative by the CosIng database, nor listed as an approved preservative in the EU's cosmetics regulations. According to the CosIng database, propylene glycol is used primarily as a solvent. Propylene glycol can have antibacterial properties[6], but only at concentrations greater than 10% (De Villiers, 2009).

Different preservatives are typically added in particular combinations, partially to "spread out" the usage by avoiding high concentrations of individual preservatives, and partially because some preservatives work better when combined with others. For example, the combination of MI and CMI is well-known (and is marketed under the name Kathon), while a combination of phenoxyethanol and parabens is commonly used in cosmetic products (Uter et al., 2013). Other combinations are used somewhat less, such as the combination of isothiazolinones and parabens (Uter et al., 2013). Product ingredients may also be sold with preservatives already

[6] https://www.naturallycurly.com/curlreading/curl-products/curlchemist-the-truth-and-fiction-about-propylene-glycol

added, a practice known from the paint industry. This may increase the use of different types of preservatives. However, how widespread this practice is in slime toy production has not been investigated in this project.

Thus, there are many aspects related to the use of preservatives. Based on the identified elements and their combinations, the preservatives that may have been used are discussed below.

For N-EU 2, the screening showed high chlorine content, as well as the presence of sulphur, bromine, and iodine. The high chlorine content suggests that other ingredients in the product also contain chlorine, but preservatives such as CMI, chlorphenesin, cetrimonium chloride, or other chlorinated preservatives may have been used in this product. This product is one of only three (out of 17) products containing bromine and iodine, which may also indicate the presence of e.g. the preservatives bronopol, MG, or iodopropynyl butylcarbamate (IPBC).

In N-EU 3, N-EU 4, and N-EU 8, small amounts of magnesium, sulphur, and chlorine, respectively, were detected. The content analysis also found that methylparaben was present in these products, but only in small amounts for all of them (between 0.02 and 0.04%). This may indicate that the preservative Kathon™ was also added.

N-EU 6 has greater magnesium content and also contains both chlorine and sulphur which may indicate the use of the preservative Kathon™. Since other preservatives were not identified, an analysis for isothiazolinones in N-EU 6 is suggested.

N-EU 7 has the greatest iodine content out of the three products in which the screening identified iodine. This may indicate the presence of IPBC. Elevated sulphur content may also indicate the presence of MI and possibly CMI, since a small amount of chlorine was also detected. However, the magnesium content is low. On the other hand, both methylparaben and phenoxyethanol were identified in the content analyses, and it is unknown whether other preservatives were added together with these.

N-EU 9 contains small amounts of chlorine and sulphur which may indicate the presence of MI and possibly CMI. The preservative methylparaben was identified in the product, but at a low concentration (<0.01%).

Generally speaking, some of the lowest values for chlorine, magnesium, and sulphur were measured in N-EU 10. This product is one of three products containing iodine, but in small amounts. This may indicate the presence of the preservative iodopropynyl butylcarbamate. None of the preservatives investigated in the initial analyses were identified in the product.

N-EU 11 is one of the few products in which the presence of bromine was identified. This may indicate the presence of a brominated preservative, such as bronopol. Magnesium, chlorine, and sulphur are also present, but not in large quantities. This may indicate the presence of Kathon™, but not in large quantities. On the other hand, methylparaben was found in the product at a concentration of 0.02%. Bronopol has been found to be used in combination with parabens[7].

EU 1 contains generally small amounts of the elements of interest; however, it contains a combination of chlorine, sulphur, and magnesium which may indicate the presence of Kathon™. Since phenoxyethanol was already detected at a concentration of 0.65%, this may be the only preservative that was used.

[7] http://www.sharon-labs.com/parabens___paraben_blends

EU 2 contains a large amount of bromine, which may indicate the presence of the preservative bronopol, or other brominated preservatives. Sulphur and chlorine were also identified, potentially indicating the presence of e.g. MI and CMI. Other preservatives were not identified in this product, so a combination of bronopol, MI, and CMI may be a possibility.

EU 3 is one of the few products containing bromine, but at low levels. This may indicate the presence of e.g. bronopol. Chlorine, magnesium, and sulphur were also identified, possibly indicating the presence of Kathon™. On the other hand, methylparaben was found in the product at a concentration of 0.04%.

EU 5 contains magnesium, sulphur, and chlorine, which may indicate the presence of Kathon. However, methylparaben was found in the product at a concentration of 0.16%.

DK 2 contains a greater amount of sulphur and a lesser amount of magnesium. This may indicate the presence of MI, or possibly Kathon. On the other hand, the product contains methylparaben at a concentration of 0.05%.

In DK 4, the presence of three different parabens (totalling 0.06%) and phenoxyethanol (0.27%) was identified. Additionally, the product contains some chlorine, magnesium, and sulphur. This may indicate the presence of Kathon, but the probability of so many preservatives being used in a single product is uncertain.

DK 5 and DK 10 contain magnesium, chlorine, and sulphur, which may indicate the presence of Kathon. Both products, however, contain methylparaben at concentrations of 0.03% and 0.07%, respectively.

7.6.1 Selection of follow-up analyses

Based on the information acquired by contacting manufacturers/importers and from the initial analyses of the 27 slime toy products (see TABLE 16), together with the Danish EPA, it was decided that in general, the follow-up analyses would focus on products containing isothiazolinones and brominated preservatives. The reason for this is that these substances are considered allergenic, and this is relevant given the relatively large amount of dermal contact that occurs when playing with slime.

According to the screening, several slime toys contained elements that may indicate the presence of isothiazolinones. Together with the Danish EPA, it was thus decided that the following DK and EU products would be more closely analysed to investigate the presence of isothiazolinones (specifically MI, CMI, and BIT):

- EU 1
- EU 2
- EU 3
- EU 5
- DK 2
- DK 4
- DK 5
- DK 10

Lastly, together with the Danish EPA, it was decided that the products containing bromine (i.e., N-EU-2, N-EU-11, EU-2, and EU-3) would be more closely examined to determine whether their bromine content might originate from brominated preservatives. It was also decided that bronopol and MG would be the focal substances, since both are considered allergenic (Danish Allergy Research Centre, 2019a; Danish Allergy Research Centre, 2019b). Bronopol is a pre-

servative. It is used in cosmetics, as well as in many other kinds of consumer products, including such toys as modelling clay, soap bubble solutions, and finger paints (Danish Allergy Research Centre, 2019a; Poulsen & Nielsen, 2014). Bronopol combined with Kathon is considered an extremely effective preservative (according to BASF, cited in Poulsen & Nielsen, 2014). MG has not been permitted as a preservative in cosmetic products in the EU since 2005, but it may still occur in other consumer products, such as cleansers and glues, and in products purchased outside the EU (Danish Allergy Research Centre, 2019b and 2018). For these reasons, it may be appropriate to investigate whether the presence of bromine in the elemental screenings of the four slime products is due to the presence of one of these two brominated preservatives. For these analyses, it was decided that all four slime products containing bromine would be analysed.

8. Follow-up analyses

This chapter describes the follow-up analyses. Together with the Danish EPA, it was decided that these would be performed on a selection of slime toys:

- Quantitative isothiazolinone content determination (MI, CMI, and BIT) in eight slime products (DK and EU products)
- Screening for bronopol and MG content in the four slime products in which bromine was found in the elemental screening (N-EU and EU products)

It should be noted that in general, quantitative analyses are difficult to perform on slime toys. This is due to the particular consistency and composition of slime products. In some cases, it is explicitly undesirable to allow slime products to enter the analysis equipment, because they may contaminate the equipment. The products can also dissolve during migration analyses, making a proper migration analysis impossible (Poulsen & Nielsen, 2014). These are some of the reasons for which not all quantitative analysis methods work on slime products, even if they were e.g. designed to quantify preservative content in cosmetic products. There have been previous attempts to quantify isothiazolinones in slime products, while there have been no previous attempts to quantify bronopol and MG in slime products. For this reason, an initial analysis was attempted to determine whether it is possible to determine the presence of bronopol and MG in slime toys at all. This is described below in greater detail.

8.1 Quantitative determination of isothiazolinone content

For eight selected slime toys (four DK and four EU products), a quantitative isothiazolinone determination was performed (i.e., for CMI, MI, and BIT). These eight products were selected based on the elemental screening, which indicated possible isothiazolinone content. The procedure for and results of these analyses are described below in greater detail.

8.1.1 Procedure for quantitative determination of isothiazolinones

A 1 g sample was dissolved in 10 ml of MilliQ water, and the solution was then allowed to remain in a heated chamber at 90°C for 2 hours. The samples were briefly agitated to distribute the samples throughout the liquid. Subsequently, 1 ml was extracted and diluted with 1 ml methanol. This solution was centrifuged, and the liquid phase was extracted into vials. Standards and controls were prepared in the same manner, with 1:1 methanol and MilliQ water. The samples were then analysed by HPLC with a UV detector. The quantitative component analysis was performed based on external calibration standards. The analyses were performed as true duplicate determinations.

The levels of detection for individual substances are presented below:

- MI: 0.01 mg/kg
- CMI: 0.01 mg/kg
- BIT: 0.1 mg/kg

The expanded uncertainty for the method (Um) is increased to between 20% and 30%, since slime is a special matrix.

8.1.2 Analysis results — isothiazolinone content

The analysis results are presented below in TABLE 17. The following identifications were made:

- MI, in six out of eight products

- CMI, in three out of eight products
- BIT, in one out of eight products

The analysis results show that both MI and CMI were found in three out of eight products. The analyses and information about CMI suggest that the substance was not used alone, but in combination with MI. According to Aerts (2017), CMI is never used alone; instead, it is always used in combination with MI. This is supported by the fact that CMI is not registered, while the mixture known as Kathon (CMI/MI) is; the mixture has its own CAS number. Kathon is a 3:1 mixture of CMI and MI. However, this ratio does not align with the values measured. This may be due to analytical uncertainties, which are unusually high because of the consistency of slime, making the analyses more difficult. It may also be due to the addition of both Kathon and extra MI to achieve the desired product preservation characteristics. The concentration of the Kathon mixture can be calculated based on the ratio; that is, one-third of the CMI concentration is added.

TABLE 17. Analysis results for quantitative content determination of certain isothiazolinones in selected slime toys

Product	MI content (mg/kg)	CMI content (mg/kg)	BIT content (mg/kg)
EU 1	< 0.01	< 0.01	< 0.1
EU 2	< 0.01	< 0.01	< 0.1
EU 3	4.5	5.3	< 0.1
EU 5	16.0	< 0.1	0.55
DK 2	7.7	1.3	< 0.1
DK 4	4.7	< 0.01	< 0.1
DK 5	7.9	4.7	< 0.1
DK 10	9.9	< 0.01	< 0.1

According to manufacturer specifications for the preservatives Kathon and MI, it is recommended that these preservatives be used at the following concentrations to achieve an optimal preservative effect. The supplied concentrations are for when Kathon and MI are used as the only preservatives; thus, lower concentrations are likely if they are used together with other preservatives:

- Kathon (CMI/MI)[8]:
  - 15 mg/kg for long-term preservation
  - 5-10 mg/kg for most personal care items (such as shampoo, conditioner, hair gel, etc.)
  - However, it is also specified that for many bacteria, a use concentration between 2 and 5 mg/kg is required for effective preservation. Some bacteria require lower or higher use concentrations (as low as 0.75 and as high as 9 mg/kg).
- MI[9]:
  - 25-250 mg/kg should be used as a so-called "in-can preservative" in products other than cosmetic products

[8] https://nshosting.dow.com/doc-archive/business/pcare/kathon_for_personal_care/kathon_cg/tds/kathon_cg.pdf; http://msdssearch.dow.com/PublishedLiteratureDOW-COM/dh_0988/0901b80380988b37.pdf?filepath=biocides/pdfs/noreg/253-02698.pdf&fromPage=GetDoc

[9] http://msdssearch.dow.com/PublishedLiteratureDOW-COM/dh_093b/0901b8038093b2a3.pdf?filepath=productsafety/pdfs/noreg/233-00792.pdf&fromPage=GetDoc; http://msdssearch.dow.com/PublishedLiteratureDOW-COM/dh_08e5/0901b803808e5017.pdf?filepath=microbial/pdfs/noreg/253-03194.pdf&fromPage=GetDoc

- 48-95 mg/kg for cosmetic products
- However, it is also specified that for many bacteria, a use concentration between 20 and 40 mg/kg is sufficient for effective preservation.

Thus, the analysed concentrations of CMI may well indicate that the levels of Kathon are sufficient to have a preservative effect, whereas the levels for those products in which only MI content was identified may not be high enough to have a preservative effect on their own. It is not known whether this is a sign that the product ingredients were already preserved with MI, as opposed to something used deliberately to preserve the slime toy. However, it cannot be ruled out that MI was added to the final product for a preservative effect, since all slime products contain boron which itself has a preservative effect. The combination and quantity of boron, together with the measured levels of MI, may be sufficient to have a preservative effect. There is, however, no clear link between the concentration of boron and the concentration of MI. This relationship was not studied further.

8.2 Screening for bronopol and MG content

For four selected slime toys (two N-EU and two EU products), a screening analysis for the presence of the preservatives bronopol and MG was performed. These analysis methods were not previously tested on slime toys, making it necessary to perform an initial test and develop the methods to ensure that they were usable on slime toys. Standard curves and controls were thus run to check for recovery. A detection level test was also performed to establish the levels of detection of the methods.

8.2.1 Procedure for bronopol content screening

A 1 g sample was dissolved in 10 ml of MilliQ water, and it was then allowed to remain in a heated chamber at 90°C for 2 hours. The samples were briefly agitated to distribute the samples throughout the liquid. Subsequently, 1 ml was extracted and diluted with 1 ml 0.1% H_3PO_4. This solution was centrifuged, and the liquid phase was extracted into vials. Standards and controls were prepared in the same manner, with 1:1 of 0.1% H_3PO_4 and MilliQ water. The samples were then analysed by HPLC with a UV detector. This analysis method is not accredited.

The level of detection for bronopol was 0.01% weight (w/w).

8.2.2 Procedure for MG content screening

A 1 g sample was dissolved in 10 ml of MilliQ water, and it was then allowed to remain in a heated chamber at 90°C for 2 hours. The samples were briefly agitated to distribute the samples throughout the liquid. 2 ml were then extracted and agitated with 4 ml of dichloromethane for 30 minutes on an agitator table. This was then centrifuged, and the dichloromethane phase was extracted into vials. Standards and controls were prepared in the same manner, with 1:1 dichloromethane and MilliQ water. The samples were then analysed by GC-MS. This analysis method is not accredited.

The level of detection for MG was 0.01% weight (w/w) or 100 ppm, corresponding to the level of detection used in other Danish EPA survey projects[10].

8.2.3 Analysis results — screening for bronopol and MG content

The analysis results show that neither bronopol nor MG was identified in any of the four products (N-EU 2, N-EU 11, EU 2, and EU 3) above the level of detection, 0.01% (w/w).

[10] e.g., Survey of chemical substances in hand soaps. Survey no. 69, 2006. https://www2.mst.dk/udgiv/publications/2006/87-7052-062-3/pdf/87-7052-063-1.pdf

According to section 7.5.2 "Analysis results for ICP-OES screening analyses", bromine was identified at low concentrations of 0.005% and 0.1% (weight) bromine, corresponding to a content concentration of between 0.02% and 0.33% (weight) if all the bromine is present as bronopol, and between 0.01% and 0.17% (weight) if all the bromine is present as MG. With a 0.01% (weight) level of detection for both bronopol and MG, their presence ought to have been detected if the preservatives bronopol and MG were used in the four slime products studied.

According to NICNAS (2009), MG was used in cosmetic products in the USA in 1994, at use concentrations between 0.0075% and 0.06%; according to later information, MG was used in 2011 at concentrations between 0.005% and 0.04%, typically above 0.01% (Burnett, 2017). For bronopol, manufacturers indicate that its use is recommended at a concentration of 0.03% to 0.1%[11], but that it may also be used at concentrations as low as 0.01%[12]. If bronopol is to be used as the only preservative, the recommended concentration is no less than 0.03%[13].

Because the calculated bronopol and MG content in the screening results ought to be 0.01% or greater, and because information about the use of both MG and bronopol shows that they are typically used at concentrations exceeding 0.01%, this may indicate that the presence of bromine is due to other brominated substances, rather than the presence of bronopol or MG below the level of detection. However, it cannot be ruled out that these substances are present at lower concentrations.

8.3 Summary and discussion of analysis results

The information about preservatives in the 27 slime toys studied is summarised below in TABLE 18, including information from manufacturers/importers, as well as from both the initial and follow-up analyses in this project. An empty field indicates that no information was available from the manufacturer or importer; a dash (–) in the column for the initial analyses indicates that none of the preservatives of interest (dehydroacetic acid, potassium sorbate, sodium benzoate, phenoxyethanol, or the five parabens) were identified in a product. For EU 2, which was analysed with regard to the presence of several preservatives in the follow-up analyses, a double dash (- -) indicates that none of the 14 preservatives of interest to the project (i.e., dehydroacetic acid, potassium sorbate, sodium benzoate, phenoxyethanol, the five parabens, bronopol, MG, and the isothiazolinones MI, CMI, and BIT) were identified in the product.

TABLE 18. Overview of information regarding contents of the 27 slime toys

Slime no.	**Information from manufacturer or ingredient list**	**Information from content analyses**	**ICP-OES XRF**	**Possible preservatives** (apart from boron, which also has a preservative effect)
N-EU 2		-	Cl, Br, S, I	CMI Chlorinated Brominated compounds Iodopropylyl butylcarbamate
N-EU 3		Methylparaben	Mg, S, Cl	Kathon™
N-EU 4		Methylparaben	Mg, S, Cl	Kathon™
N-EU 6		-	Mg, S, Cl	Kathon™

[11] http://www.nardev.com/UploadSection/ProdCat-181-1444116567.pdf

[12] http://www.schulkemicrosites.de/media-cosmetic-preservation/Leaflets/PRI_S-M-Bronopol-GB.pdf

[13] http://msdssearch.dow.com/PublishedLiteratureDOW-COM/dh_087c/0901b8038087c6de.pdf?filepath=/pdf&fromPage=GetDoc

Slime no.	Information from manufacturer or ingredient list	Information from content analyses	ICP-OES XRF	**Possible preservatives** (apart from boron, which also has a preservative effect)
N-EU 7		Methylparaben Phenoxyethanol	S, I, Mg, Cl	MI, CMI Iodopropylyl butylcarbamate
N-EU 8		Methylparaben	Mg, S, Cl	Kathon™
N-EU 9		Methylparaben	S, Cl	MI, CMI
N-EU 10		-	I, (Cl, S)	Iodopropylyl butylcarbamate
N-EU 11		Methylparaben	Br, S, Cl, Mg	Brominated compounds CMI
EU 1		Phenoxyethanol	(S, Mg, Cl)	No others Does not contain Kathon™
EU 2		- -	Br, S, Cl	Brominated compounds Does not contain MI and/or CMI above the level of detection
EU 3		Methylparaben CMI/MI	Br, Cl, Mg, S	No others
EU 4	Sodium benzoate	Sodium benzoate Dehydroacetic acid	*Not analysed*	Not necessary
EU 5		Methylparaben MI and BIT	Mg, Cl, S	No others
DK 1	Propylparaben Sodium benzoate	Methylparaben Propylparaben Sodium benzoate	*Not analysed*	Not necessary
DK 2		Methylparaben CMI/MI	S, Mg	No others
DK 3	Propylene glycol	*Not analysed*	*Not analysed*	Not necessary
DK 4		Methylparaben Ethylparaben Propylparaben Phenoxyethanol MI	Cl, S, Mg	No others
DK 5		Methylparaben CMI/MI	Mg, Cl, S	No others
DK 6	DMDM hydantoin	*Not analysed*	*Not analysed*	Maybe analysis for concentration info
DK 7	Phenoxyethanol Iodopropynyl butylcarbamate Imidazolidinyl urea	Phenoxyethanol	*Not analysed*	Not necessary
DK 8	Phenoxyethanol Chlorphenesin Ethylhexylglycerine Propylene glycol	Phenoxyethanol	*Not analysed*	Maybe analysis for concentration info
DK 9	Propylene glycol	*Not analysed*	*Not analysed*	Not necessary
DK 10		Methylparaben MI	Mg, Cl, S	No others
DK 11	Phenoxyethanol	Phenoxyethanol	*Not analysed*	Not necessary

Slime no.	Information from manufacturer or ingredient list	Information from content analyses	ICP-OES XRF	**Possible preservatives** (apart from boron, which also has a preservative effect)
	Iodopropynyl butylcarbamate Imidazolidinyl urea			
DK 12	Phenoxyethanol Chlorphenesin Ethylhexylglycerine Propylene glycol	Phenoxyethanol	*Not analysed*	Maybe analysis for concentration info
DK 13	Phenoxyethanol Chlorphenesin Ethylhexylglycerine Propylene glycol	Phenoxyethanol	*Not analysed*	Maybe analysis for concentration info

An empty field indicates that no information was available from manufacturers/importers regarding the preservative content of a product.
- indicates that none of the nine preservatives of interest from the initial analyses of the project were identified in the product.
- - indicates that none of the 14 preservatives of interest from both the initial analyses and the follow-up analyses were identified in the product.

Thus, the results of the analyses in this project show that even though products in the project were analysed for the presence of at least nine and as many as 14 different preservatives, there are still four products in which no possible preservatives were identified apart from boron. The information acquired can be summarised as follows:

- 23 out of 27 slime toys contain at least one preservative apart from boron, which itself has a preservative effect (if propylene glycol is considered to be a preservative)
- Four out of 27 slime toys contain none of the 9 or 14 preservatives of interest in this project
- The maximum number of preservatives identified in one product was five (including three different parabens)
- A total of 14 different preservatives were identified in the 23 slime toys in which preservatives were identified (either through analyses or using information from manufacturers/importers). These preservatives are:
  - Dehydroacetic acid (in one product)
  - Sodium benzoate (in two products)
  - Phenoxyethanol (in eight products)
  - Methylparaben (in 13 products)
  - Ethylparaben (in one product)
  - Propylparaben (in three products)
  - MI (in six products)
  - CMI (in three products) combined with MI
  - BIT (in one product)
  - Propylene glycol (in five products, according to manufacturers. Analyses for this preservative were not performed in this project)
  - Chlorphenesin (in three products, according to manufacturers. Analyses for this preservative were not performed in this project)
  - Iodopropynyl butylcarbamate (in two products, according to manufacturers. Analyses for this preservative were not performed in this project)
  - Imidazolidinyl urea (in two products, according to manufacturers. Analyses for this preservative were not performed in this project)
  - DMDM hydantoin (in one product, according to manufacturers. Analyses for this preservative were not performed in this project)
- The preservatives bronopol, MG, potassium sorbate, and butyl- and isobutylparaben were not identified in any of the analysed products.

9. Initial hazard assessment

This section contains an initial hazard assessment; i.e., a screening-level hazard assessment of the substances found in slime toys, as well as a selection of substances for risk assessment.

9.1 Initial hazard assessment of the identified substances

The initial hazard assessment includes the following aspects, listed for the individual substances in TABLE 19 below:

- Classification
- DNEL (Derived No Effect Level) value for registered substances
- Health effects related to the calculated DNEL value

The harmonised classification, where one exists, is given in TABLE 19 below. If one does not exist, the notified classification from ECHA's C&L database is given instead. Only health-related classifications are indicated; that is, physical and environmental hazard classifications are excluded. For notified classifications, the most commonly reported health-related classifications were selected, and classifications indicated by a lead registrant have registered substances marked in boldface. The most common classifications are listed first for each substance. Note that "not classified" may appear along with different classifications for the same substance. This indicates that different businesses have notified different classifications for the substance; that is, they have different assessments of how the substance should be classified.

TABLE 19. Overview of the substances identified in slime toys. The classification from the lead registrants is marked in bold for the registered substances.

Substance name	CAS no.	Harmonised classification[14]	Notified classification[15]	DNEL[16] (mg/kg bw/day)	Effect related to DNEL	Concentrations measured in this project (% w/w)	Limit value in cosmetics or toys (0-3 years or finger paints, EN 71-7)	Comments
Binder								
Guar gum	9000-30-0	None	Not classified Eye Irrit. 2, H319	Not registered	-	-	-	
Polyvinyl alcohol	9002-89-5	None	Not classified STOT SE 2, H371	Not registered	-	-	-	
Polyvinyl acetate	9003-20-7	None	Not classified	Not registered	-	-	-	
Other substances								
Glycerine	56-81-5	None	**Not classified** Eye Irrit. 2, H319 Skin Irrit. 2, H315 STOT RE 1, H372	Oral: 229 Dermal: No info	Liver hypertrophy	-	-	
Preservatives								
Propylene glycol	57-55-6	None	**Not classified** Eye Irrit. 2, H319 Acute Tox. 4, H302 Skin Irrit. 2, H315	Oral: no hazard Dermal: no hazard	None. NOAEL = highest dose tested.	-	-	

[14] Only health-related classifications are listed in the table; environmental classifications are excluded.

[15] Only health-related classifications are listed in the table; environmental classifications are excluded. For notified classifications, the most commonly reported health-related classifications were selected. Classifications from lead registrants are marked in boldface for registered substances. The most common classifications are listed first.

[16] DNEL values for the general public, for both oral and dermal exposure, are taken from ECHA's database of registered substances, if they are listed for a substance.

Substance name	CAS no.	Harmonised classification[14]	Notified classification[15]	DNEL[16] (mg/kg bw/day)	Effect related to DNEL	Concentrations measured in this project (% w/w)	Limit value in cosmetics or toys (0-3 years or finger paints, EN 71-7)	Comments
Ethylhexyl glycerine	70445-33-9	Eye Dam. 1, H318		Oral: no data Dermal: 0.5	Not specified. The critical effect is not specified for the study where NOEL is used.	-	-	
Phenoxyethanol	122-99-6	Acute Tox. 4, H302 Eye Irrit. 2, H319		Oral: 9.23 Dermal: 10.42	DNEL is based on haemolytic effects Other effects related to oral intake are liver toxicity (Poulsen & Nielsen, 2014), which France bases its special regulations on.	0.27 – 0.65% in eight products	1% (cosmetic products and finger paints)	Discussion on lowering the limit to 0.4% in cosmetic products for children under 3 years (Poulsen & Nielsen, 2014). But, according to the SCCS opinion (2016), 1% in cosmetic products is still considered safe, even for children. However, exposure to phenoxyethanol from other sources was not considered. France has adopted special domestic regulations in spite of the SCCS opinion.
Methylparaben	99-76-3	None	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Not classified **(Aquatic Chronic 4, H412)**	Oral: 1.04 Dermal: 1.23	None specified	0.006 – 0.16% in 13 products	0.4% 0.8% as the sum of all parabens (applies to both cosmetic products and finger paints)	Not allergenic according to registration files.
Ethylparaben	120-47-8	None	**Not classified** Asp. Tox. 1, H304 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317	Oral: 15 Dermal: 19.7	None. NOAEL = highest dose tested.	0.01% in one product	0.14% (finger paints) 0.4% (cosmetic products) 0.8% as the sum of all parabens	Not allergenic according to registration files, though some classify the substance as Skin Sens. 1.

Substance name	CAS no.	Harmonised classification[14]	Notified classification[15]	DNEL[16] (mg/kg bw/day)	Effect related to DNEL	Concentrations measured in this project (% w/w)	Limit value in cosmetics or toys (0-3 years or finger paints, EN 71-7)	Comments
Propylparaben	94-13-3	None	Not classified Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 **(Aquatic Chronic 4, H412)**	Oral: 43.47 Dermal: 31.25	None. NOAEL = highest dose tested.	0.02 – 0.07% in three products	0.14% 0.8% as the sum of all parabens (applies to both cosmetic products and finger paints)	Not allergenic according to registration files. Suspected endocrine disruptor.
Sodium benzoate	532-32-1	None	None listed **Eye Irrit. 2, H319**	Oral: 16.6 Dermal: 31.25	None. NOAEL = highest dose tested.	0.12 – 0.16% in two products	0.5% (leave-on cosmetic products and in finger paints)	Not allergenic according to registration files.
Dehydroacetic acid	520-45-6	Acute Tox. 4, H302		Oral: 0.78 Dermal: 1.56	Blood in mouth when ingested orally, membrane damage	0.09% in one product	0.6% (finger paints and cosmetic products)	
DMDM hydantoin	6440-58-0	None	**Acute Tox. 4, H302** Not classified Eye Irrit. 2, H319 Resp. Sens. 1, H334 Skin Sens. 1, H317	Oral: 10 Dermal: 10	None. NOAEL = highest dose tested.	-	0.6% (finger paints and cosmetic products)	Requirement in finger paints: 0.5% Not allergenic according to registration files.
IPBC	55406-53-6	Acute Tox. 4, H302 Eye Dam. 1, H318 Skin Sens. 1, H317 Acute Tox. 3, H331 STOT RE 1, H372		Oral: no hazard Dermal (labourers): 2.0	Dermal: chronic ulceration Oral: no serious effects observed	-	0.01% (leave-on cosmetic products)	No hazard identified for consumers — covered by regulation on cosmetic products, and that assessment should be used.
Imidazolidinyl urea	39236-46-9	None	**Skin Sens. 1B, H317** Not classified	Oral: 1.4 Dermal: low hazard	No data. DNEL based on read across.	-	0.5% (finger paints and cosmetic products)	Considered skin sensitising according to registration files.
Diazolidinyl urea	78491-02-8	None	Skin Sens. 1b, H317 **Eye Irrit. 2, H319**	Oral: 5 Dermal: unknown	Effects in stomach when ingested orally.	-	0.5% (finger paints) Not allowed in cosmetic products	Not allergenic according to registration files.

Substance name	CAS no.	Harmonised classification[14]	Notified classification[15]	DNEL[16] (mg/kg bw/day)	Effect related to DNEL	Concentrations measured in this project (% w/w)	Limit value in cosmetics or toys (0-3 years or finger paints, EN 71-7)	Comments
Chlorphenesin	104-29-0	None	**Eye Irrit. 2, H319** **Skin Irrit. 2, H315** Not classified Acute Tox. 4, H302, H312, H332	Oral: 0.167 Dermal: 0.167	Serious effects (lab animals had to be euthanised) at doses 10 times higher. Study not available; effect not described.	< 0.25% (indicated by a single manufacturer)	0.3% (finger paints and cosmetic products)	CIR report from 2012 considers a concentration of 0.32% in rinse-off products to be safe for use in cosmetic products.
MI	2682-20-4	Acute Tox. 3, H301, H311 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Acute Tox. 2, H330		Oral: 0.027 Dermal: no hazard beyond allergy	Reduced nutrient intake and bodyweight Dermal: allergy	4.5 – 16 mg/kg in six products	0.25 mg/kg (Toys, appendix C: 0-3 years)	Allergenic according to registration files.
CMI	26172-55-4	None	Acute Tox. 3, H301, H311 Skin Corr. 1B, H314 Skin Sens. 1, H317 Eye Dam. 1, H318 STOT SE 3, H335	Not registered	-	1.3 – 5.3 mg/kg in three products	0.75 mg/kg (Toys, appendix C: 0-3 years)	Requirement in EN 71-9: 10 mg/kg Considered to be allergenic
Kathon™	55965-84-9	Acute Tox. 3, H301 Acute Tox. 2, H310, H330 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317		Oral: 0.09 Dermal: no hazard beyond allergy	Stomach irritation Dermal: allergy	*Not analysed, but sum of CMI and MI at ratio 3:1*	1 mg/kg (Toys, appendix C: 0-3 years)	Requirement in EN 71-9: 15 mg/kg Highly allergenic according to registration files.
BIT	2634-33-5	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1, H317		Oral: no hazard Dermal: 0.345	Reduced nutrient intake and bodyweight Dermal: allergy	0.55 mg/kg in one product	5 mg/kg (Toys, appendix C: 0-3 years)	Requirement in EN 71-9: 5 mg/kg Moderately allergenic according to registration files.

Harmonised = harmonised classification
No harmonised = no harmonised classification

Not classified = i.e., some notifiers indicate that the substance is not classified

9.2 Selection of substances

The general criteria for selecting substances for inclusion in an exposure and risk assessment of these particular products were partially whether they had concerning health-related effects, and partially the availability of information on preservatives in the products. For this last reason, such preservatives as DMDM hydantoin were not selected, since insufficient information is available about its presence in slime toys.

Parabens were excluded because of the relatively low concentrations identified. Methyl- and ethylparaben are not normally considered to have concerning health-related properties, whereas propylparaben is considered an endocrine disruptor.

The preservatives MI and Kathon (a mixture) were selected due to their allergenic properties, and because the concentrations identified in slime exceed the recommended values for toys for children under 3 years. The Kathon mixture was selected for the risk assessment despite not having been analysed; as described, it is calculated as the concentration of CMI plus one third (due to the 3:1 mixture ratio). The preservative BIT was excluded due to its low concentration, relative to the concentration permitted in products for children under 3 years in Appendix C of the Danish Statutory Order on Toys.

Phenoxyethanol has been discussed previously; among others, France (via ANSM) has recommended that the concentration permitted in cosmetic products for children under three years should be reduced to 0.4%. However, this was rejected by SCCS in its opinion on the substance (SCCS, 2016), which maintains that a concentration of 1% is acceptable in cosmetic products. This is in spite of the fact that the calculated MoS (margin of safety) for children was 41 for the use of cosmetic products on children at weights down to 7 kg. While an MoS of 100 is normally required, SCCS concludes that an MoS of 25 is sufficient even for children, since the human capacity to metabolise phenoxyethanol in the body is much higher than that of the animals (rabbits) used in the animal experiments upon which the established NOAEL (No Observed Adverse Effect Level) value is based. However, in its opinion on the substance, SCCS does mention that their evaluation does not take into account the use of phenoxyethanol in products other than cosmetic products. For this reason alone, an evaluation of the extra contribution from exposure from slime toys is appropriate. For this reason, phenoxyethanol was selected for the risk assessment.

Chlorphenesin has a very low DNEL value according to the registration files, but this is probably due to the fact that there is limited data available on the substance. The only existing study on chlorphenesin only tested its toxicity given repeated exposure to three different doses. A CIR (Cosmetic Ingredient Review) report for the substance is available. It concludes that the substance is safe to use at the concentrations (between 0.1 and 0.3%) used in cosmetic products. Because the information received in this project shows that chlorphenesin is only used at concentrations below 0.25%, and because we did not perform chemical analyses of chlorphenesin content in this project, it was decided that a risk assessment of this substance would not be performed.

Together with the Danish EPA, it was decided to proceed with the substances listed below in the exposure and risk assessment:

- Phenoxyethanol
- MI
- Kathon

10. Exposure scenarios

The exposure scenarios presented in this project are based on the realistic worst-case scenarios already formulated in the Danish EPA's previous consumer projects that studied slime (Poulsen & Nielsen, 2014; Svendsen et al., 2006). This project focuses on dermal and oral exposure.

The general exposure scenarios used for risk assessment in this project are:

1. Children playing with ordinary slime
   - Skin contact with slime toy on hands
   - Oral intake of a small quantity of slime, corresponding to finger-to-mouth transfer, when children place their fingers in their mouths while or after playing, without having washed their hands
2. Children playing with slime guns, shooting slime at each other and on large portions of their bodies:
   - Skin contact with slime on essentially the entire body
   - Oral intake of a slightly greater quantity of slime, if struck by slime near the mouth

The relevant values for the exposure scenarios in the two previous survey reports for the Danish EPA, used here, are presented below in TABLE 20. Because there are variances from the values previously used in slime toy exposure scenarios, the column to the far right gives the value chosen for the exposure scenarios in this project. The values chosen are justified in the text below.

TABLE 20. Values used for exposure scenarios in previous Danish EPA survey projects (Poulsen & Nielsen, 2014; Svendsen et al., 2006.) and values used in this project

Parameter	Values used in "slime-like toys" (Svendsen et al., 2006)	Values used in "preservatives in toys" (Poulsen & Nielsen, 2014)	Values used in this project
General values regardless of exposure type			
Body weight	10 kg	13.5 kg	15 kg
Quantity of slime in dermal contact during play	-	-	20 g
Exposure time	1 hour per day	45 min 100 times per year	1 time per day (for 1 hour)
Values relevant for dermal exposure			
Exposed skin area	-	-	200 cm^2 (both palms and between fingers) 1725 cm^2 (one fourth of body surface area) for slime gun
Values relevant for oral exposure			
Oral intake per occurrence	Weight of toy (for slime here, 10-15 g)	1 g	400 mg (0.4 g) 2 g for slime gun

10.1 Discussion of values chosen for exposure scenarios

10.1.1 Body weight

In the project on "slime-like toys" (Svendsen et al., 2006), a body weight of 10 kg was chosen, corresponding to the body weight of a 1-year-old child who most likely does not play with slime toys. In Poulsen & Nielsen (2014), 13.5 kg was chosen, which is the 5th percentile for a child between the ages of three and six years.

The Chemicals subgroup of the European Commission's expert group on toy safety[17] has reached a consensus as to the parameters to be used in risk assessment for boron in slime toys[18]. The subgroup references a document from RIVM (RIVM, 2008) which specifies that the standard for evaluating toys for children over three years of age should be a body weight of 15 kg, corresponding to the average of the 50th percentiles for 3-year-old boys and girls. The same value is given in RIVM's more recent report (RIVM, 2014).

Because slime toys are sold to children over three years of age, the 15 kg value given by RIVM (2014) was chosen as a worst-case value (minimum value) for the exposure scenarios in this report.

10.1.2 Quantity of slime in dermal contact during play

The quantity of slime relevant in terms of exposure is the quantity of slime in contact with the skin during play. Children may hold a large amount of slime in their hands without the entirety of the slime necessarily making contact with the skin.

For finger paints, Norden (2011) considers that skin contact occurs with 20 g of the substance per day. Presently, there is no corresponding value for slime, so this value is used as a worst-case value for the quantity of slime in dermal contact with a child's skin during play with ordinary slime and slime gun slime.

10.1.3 Exposure time

Initially, we assume that children play with slime toys every day — at least for some period of time. We further assume that the duration of play does not influence the quantity of slime in contact with the skin during play, but studies on this do not exist. For modelling clay, Norden (2011) considers an exposure time of 1 hour per day. A corresponding value does not currently exist for slime toys, so the same exposure time is presumed to apply for slime toys. Due to the consistency of slime toys, it has not been possible to perform a migration analysis for slime (unlike when played with, slime dissolves when placed in water to perform a migration analysis). As described in the REACH guidelines (ECHA, 2016), the migration rate is to be used in calculating exposure over a given period of time. As a worst-case rate, exposure to slime toys once per day (for an entire year) was used for both ordinary slime and slime gun slime.

10.1.4 Exposed skin area

The exposed skin area is not specified in either of the two previous survey reports. Instead, formulas based on quantities of slime were used. The NEGh report (Norden, 2011), used in Poulsen & Nielsen (2014), describes the use of an exposed skin area of 390 cm^2, corresponding to the surface area of both hands of a 4.5-year-old child weighing 16.3 kg. A value of 0.033 m^2, or 330 cm^2, is given in RIVM (2014) as a standard value for the hands of children ages 3 to 6 (based on averages of children ages 2 and 4). This value is for both hands. Since the skin

[17] Expert Group on Toy Safety – “Chemicals” subgroup

[18] Draft of document received by the Danish EPA, dated 23 October 2018.

exposed here is primarily that of the palms and the area between the fingers, a value of **200 cm^2,** slightly above half of these reference values, was used.

In the case of the slime gun slime, the exposed skin area may be significantly greater. If we suppose that slime guns are used outdoors (with little to no clothing on), we can use a value corresponding to one fourth of the body surface area of a 3 to 6-year-old as given in RIVM (2014); that is, one fourth of 0.69 m^2 (which equals 0.1725 m^2, or **1725 cm^2**).

10.1.5 Oral intake

Oral intake is the quantity of slime toy which children eat/consume when playing with a slime toy; that is, by finger-to-mouth transfer. In the project on "preservatives in toys" (Poulsen & Nielsen, 2014), an oral intake of 1 g per occurrence of play with a toy was used. This figure was taken from NEGh (Norden, 2011), corresponding to the estimated intake of modelling clay. Meanwhile, in the project on "slime-like toys" (Svendsen et al., 2006), the total weight of a slime toy, between 10 g and 14 g, appears to be used.

In this report, a value of 400 mg (0.4 g) per day was used for oral intake because this is the value presented in the guidance document for toys from the Commission on Category II Toys (European Commission, 2016), which is also used as a standard oral intake value for slime toy risk assessments by the Chemicals subgroup of the European Commission's expert group on toy safety.

In the case of the slime gun slime, it should be expected that the oral intake of slime may be significantly higher if e.g. a child is hit by slime from a slime gun in the area near the mouth. In this instance, a worst-case value of 2 g is used, since slime is rather fluid; a child may not have the opportunity to react and spit it out if it should enter the mouth.

11. Approach to exposure and risk assessment

This chapter describes the approach applied to exposure and risk assessment, as well as the method used to assess the risk posed by selected substances in slime toys.

11.1 Exposure and risk assessment approach

Slime toys are a special case, as they are chemical toys. On one hand, the ingredients are "available" to some extent for intake through the skin when touched; on the other hand, unlike cosmetic products, these products are not rubbed into the skin. It is not possible to perform a dermal migration analysis for substances in slime toys, since aqueous slime dissolves in an aqueous solution. This does not occur when children play with slime using their hands - the slime remains intact. For this reason, a dermal migration analysis would not give an accurate picture of the migration that occurs during play with slime in this situation. A previous project (Poulsen and Nielsen, 2014) that studied slime toys showed that a migration analysis performed on a slime toy produces results corresponding to those of a content analysis, since the slime dissolves in the aqueous migration liquid.

The situation is that a portion of the substances in slime is accessible for skin uptake during play. Additionally, in a realistic worst case, a portion of the aqueous base of the slime toy may remain on the skin after play. Provided that children do not wash their hands immediately after use, slime toys can be compared to leave-on cosmetic products.

The approach taken in this project is to use worst-case exposure scenarios as a starting point. If the worst-case scenarios constitute a risk, these scenarios will be refined to realistic worst-case scenarios. In these exposure scenarios, dermal and oral exposure are considered to be the relevant exposure pathways for slime products. Exposure via inhalation is not considered relevant in this context for the substances undergoing risk assessment.

There is also a difference in the risk assessment approaches for the substances selected for risk assessment; namely, phenoxyethanol and isothiazolinones; because the critical effect (the lowest dose at which a health effect is observed) for isothiazolinones is allergy, while the critical effect for phenoxyethanol is liver and kidney toxicity following oral intake, and haemotoxicity following dermal exposure. The differences in risk assessment methods for the two types of substance are described in greater detail in the following sections.

11.2 Risk assessment method for phenoxyethanol

This section describes the method used to calculate exposure for the exposure scenarios presented. In the risk assessment (as calculated in chapter 13), exposure is compared with relevant values from the hazard assessment (as established in chapter 12).

11.2.1 Dermal risk assessment method for phenoxyethanol

The dermal risk assessment method given in the ECHA's consumer exposure guidelines, R.15 (ECHA, 2016) was used. This document explains that when it is unknown exactly how skin will be exposed to a product, the external dermal dose D_{der} can be calculated using the formula below. In the case of slime toys, it is unknown how large an amount of slime toy substances that will migrate from the slime toy (in contact with the skin) and be absorbed through the skin.

The external dermal exposure is used to calculate the internal dose; that is, the quantity of substances expected to be absorbed into the body. The internal dose is calculated by accounting for dermal absorption; that is, multiplication by a factor in the range from 0 to 1 in order to account for this. The internal dermal dose can thus be calculated using the formula below (ECHA, 2016).

$$D_{dermal} = \frac{Q_{prod} \times FC_{prod} \times n \times F_{DA} \times 1000\, mg/g}{BW}$$

where

D_{dermal}	is the external exposure accessible for skin uptake from the product	measured in mg/kg bw/day
Q_{prod}	is the quantity of the product used - in the case of slime toys, this is the quantity of slime in contact with the skin, and thus accessible for skin uptake	measured in g
FC_{prod}	is the concentration (fraction) of the substance in the product	measured in g/g
n	is the number of occurrences per day - here, we presume one occurrence per day, since the quantity of product used is specified per day	measured in no. per day
F_{DA}	is the dermal absorption; that is, the proportion of substances absorbed through the skin (as a fraction between 0 and 1)	
BW	is the child's body weight	measured in kg bw

11.2.2 Oral risk assessment method for phenoxyethanol

Exposure to slime toys is primarily through skin contact, but it can also reasonably be presumed that children may swallow a small amount of a slime toy. Slime toy EU 1 distinguishes itself from the other slime products, since this product is a very thin, fluid slime for use in a slime gun. The exposure scenario for this product is therefore different: greater exposure may occur if children in swimwear shoot slime at each other, possibly hitting the mouth or the surrounding area and swallowing some portion of the slime.

According to the ECHA's consumer exposure guidance, R.15 (ECHA, 2016), the oral dose can be calculated using a formula similar to the one above, accounting for oral absorption of the substance:

$$D_{oral} = \frac{Q_{prod} \times FC_{prod} \times n \times F_{OA} \times 1000\, mg/g}{BW}$$

where

D_{dermal}	is the external exposure accessible for skin uptake from the product	measured in mg/kg bw/day
Q_{prod}	is the quantity of the substance used - in the case of slime toys, this is the quantity of slime consumed (or swallowed) when playing with slime	measured in g
FC_{prod}	is the concentration (fraction) of the substance in the product	measured in g/g
n	is the number of occurrences per day - here, we presume one occurrence per day, since the quantity of product used is specified per day	measured in no. per day
F_{OA}	is the oral absorption; that is, the proportion of the substance absorbed following oral intake (as a fraction between 0 and 1)	
BW	is the child's body weight	measured in kg bw

11.2.3 Combined risk assessment method for phenoxyethanol

The combined exposure is obtained by adding the dermal and oral exposure when considering systemic effects. For dermal effects alone, only the dermal exposure is considered:

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

In the risk assessment, the so-called RCR value (risk characterisation ratio) is calculated by comparing the combined exposure with the DNEL value, using the following formula:

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

If the RCR > 1 (i.e., exposure is greater than the DNEL), then the exposure constitutes a risk. If the RCR < 1, the exposure is not considered to constitute a risk.

Exposure from other sources should also be accounted for in the exposure assessment on phenoxyethanol from slime toys; this exposure is primarily expected to come from cosmetic products. Children using e.g. cleaning products containing phenoxyethanol is not considered realistic.

11.3 Approach to exposure and risk assessment for MI and Kathon

The usual approach to assessment of allergenic substances is to compare known sensitising levels (at which one develops an allergy) and elicitation levels (at which an allergic reaction is provoked in a person already familiar with the allergy) with the concentrations that consumers are exposed to. Generally, a higher dose per unit area is required for sensitisation than for elicitation (see Appendix 5). This means that there will be a difference between the sensitising and elicitation levels of an allergenic substance. The elicitation dose additionally depends on underlying sensitisation factors, such as the sensitising dose and exposure frequency (Friedmann, 2007).

In this project, three different approaches are described for evaluating exposure and allergy risk for allergenic substances:

1. The use of the SCCS assessment for elicitation and sensitisation for MI and Kathon in leave-on cosmetic products
2. Calculation of dermal exposure (dermal load, L_{dermal}) compared to elicitation levels in the literature (since sensitising levels are unknown)
3. Quantitative risk assessment for sensitisation (QRA method, quantitative risk assessment)

The risk assessment for the allergenic substances is based partially on assessments from scientific committees (SCCS) (item 1 above) and available data (item 2 above). This is described in sections 12.1.1 and 12.3.1 in greater detail.

Another approach found to be in use for risk assessments of allergenic substances is the QRA method. This method is used to calculate a quantitative sensitisation risk assessment. It was originally developed by the industry for quantitative assessments of fragrance-associated sensitisation (Api et al., 2008) and has since been expanded and described by Ezendam et al. (2018). SCCS has commented on the method numerous times, most recently in 2018 (SCCS, 2018). SCCS concludes that a progress of the method has been made, but that further development is still necessary. In particular, a description of the uncertainties in the method is nec-

essary for it to be recognised for the assessment of substances other than fragrances in cosmetic products. The method is thus not recognised by SCCS or another scientific committee, given that it is subject to uncertainties (SCCS, 2018b). As the QRA method is nonetheless discussed and used in this report, this is done for the purpose of obtaining knowledge regarding the risk of sensitisation using a quantitative approach, as well as to compare the results of doing so with other available knowledge.

11.3.1 Calculation of dermal exposure (L_{dermal}) relative to sensitisation and elicitation levels

The exposure that is significant from an allergy perspective (both for sensitisation and elicitation) is the concentration of the substance per unit skin area, known as the dermal load (L_{dermal}). The risk of sensitisation and elicitation thus depends on the quantity of the allergenic substance per unit skin area and is largely independent of the size of the exposed area[19].

This calculation is used both to compare dermal exposure

1. with elicitation levels in the literature, and
2. to calculate the sensitisation risk using the QRA method.

According to the ECHA (2016), the dermal load is calculated using the formula below:

$$L_{dermal} = \frac{Q_{prod} \times FC_{prod} \times 1000\, mg/g}{A_{skin}}$$

where

L_{dermal}	is the dermal load; that is, quantity of substance per unit skin area	measured in mg/cm^2
Q_{prod}	is the quantity of the product used - in the case of slime toys, this is the total quantity of slime in contact with the skin every day	measured in g
FC_{prod}	is the concentration (fraction) of the substance in the product	measured in g/g
A_{skin}	is the surface area of the skin exposed to the substance	measured in cm^2

11.3.2 Quantitative risk assessment for sensitisation using the QRA method

The QRA method is described in brief in this section and is discussed further in Appendix 4. The same principles as described by the ECHA (2016) for risk assessments of chemical substances are used in this method. Specifically, exposure is calculated using the dermal load (L_{dermal}) (see section 11.3.1), and this is then compared to an acceptable exposure level (AEL), established based on a NOAEL value (here, the NESIL value) divided by a number of safety factors. The dermal load is compared to the acceptable exposure level in a manner similar to that of the usual risk assessment approach. If the acceptable exposure level is exceeded, the exposure constitutes a risk.

[19]Website of the Danish Allergy Research Centre

12. Values used for the risk assessment

This section describes the selected substances subjected to risk assessments in the present report. The most significant effects of these substances are described based on pre-existing assessments of the substances. The emphasis is on a more thorough, follow-up endpoint hazard assessment. The relevant terms and values used in the risk assessment are presented below:

- Absorption/uptake; that is, the proportion of substances that can be absorbed through the skin upon skin contact, or systemically upon oral intake
- DNEL value, based on either a NOAEL value for phenoxyethanol, or a NESIL value (no expected sensitisation induction level) for allergenic substances
- Established sensitisation and elicitation levels — only for isothiazolinones

12.1 Phenoxyethanol

Phenoxyethanol has a harmonised classification as:

- Acute Tox. 4, H302 (harmful if swallowed)
- Eye Irrit. 2, H319 (causes serious eye irritation)

The effects of exposure to phenoxyethanol depend on the exposure pathway. According to the SCCS (2016), inhalation of phenoxyethanol is not considered problematic. The only effects of this are mucous membrane irritation at high concentrations. Liver and kidney effects have been observed (in rats) following oral intake of phenoxyethanol, and the dominant effect following dermal exposure is haemotoxicity (in rabbits).

The SCCS (2016) concludes that when comparing studies on rats, mice, and rabbits, it appears that rabbits are the most sensitive animals in terms of haemotoxic effects. The SCCS emphasises that particularly in the case of rats, phenoxyethanol is rapidly metabolised by the liver and kidneys, resulting in an accumulation of the metabolite of phenoxyethanol (phenoxyacetic acid) in the liver and kidneys following oral exposure to phenoxyethanol, which may be the cause of the effects observed in the liver and kidneys. In contrast, a different distribution of the substance is seen following dermal exposure (greater blood concentration compared to oral exposure), which may also be relevant to humans. The SCCS concludes that dermal exposure is the most relevant exposure pathway for humans for cosmetic products. Therefore, in a risk assessment of phenoxyethanol, there should be a preference for the use of dermal studies with rabbits over oral exposure-based experiments with rats. However, for slime toys, there may also be a risk of oral exposure (finger-to-mouth exposure); in the case of the slime gun, a person may also be hit on or near the mouth. Therefore, oral exposure is also significant in this context.

In the SCCS's opinion on phenoxyethanol from 2016 (SCCS, 2016), data for the substance is reviewed. Here, the substance is assessed to be absorbed, distributed, metabolised, and rapidly excreted in the body. Registration files indicate that the substance is easily absorbed through the skin. The dermal absorption in rats is stated to be 75-76%, and the SCCS concludes that a dermal absorption of 47% should be used for rinse-off products, and 85% for leave-on products. However, the SCCS also concludes that the dermal absorption should not be used in calculating the internal dose, since the NOAEL value for calculating the DNEL is based on a dermal toxicity study.

ANSM (2012) uses a skin absorption of 80% for phenoxyethanol for leave-on products. The registration files for phenoxyethanol indicate a value of approx. 59% for dermal uptake in humans, but the SCCS (2016) emphasises that this study should not be used because it is based on an insufficient amount of data.

Thus, in the exposure calculations in this report, a **factor of 1 is used for dermal exposure** when using a NOAEL value based on dermal exposure, while a factor of 0.85 is used for dermal exposure when using a NOAEL value based on oral exposure.

Absorption by oral exposure is described to a limited extent by the SCCS (2016), since oral exposure is not considered a significant exposure pathway for cosmetic products. However, this report deals with toys, for which oral exposure is significant. This is because children can be expected to place toys and/or e.g. fingers with slime residue in their mouths. According to the SCCS (2016), there are studies describing how phenoxyethanol is absorbed quickly and completely following oral exposure. Other studies (SCCS, 2016) indicate that somewhere between 60% and 80% of the metabolite of phenoxyethanol can be found; as described, the metabolite is the significant substance in relation to effects on the liver and kidneys observed following oral exposure in animal experiments. For oral exposure, an **absorption factor of 0.8** is used as a realistic worst case.

Examples have been observed in which phenoxyethanol allergies are developed, but the risk of developing an allergy to the substance is low, even if the most significant source of phenoxyethanol exposure is considered to be skin contact with cosmetic products (SCCS, 2016).

According to the SCCS (2016), phenoxyethanol is considered neither genotoxic, nor carcinogenic, nor toxic to reproduction.

12.1.1 Determining the DNEL for phenoxyethanol

The DNEL for phenoxyethanol; that is, the exposure level not considered to result in health effects, has been determined based on existing risk assessments of the substance. The following previous risk assessments of the substance were identified:

- The French organisation ANSM uses a NOAEL value for phenoxyethanol of 164 mg/kg bw/day for oral exposure in rats (ANSM, 2012). This value is based on a 90-day oral study in rats. The critical effect here is indicated as liver toxicity.
- The SCCS's opinion on phenoxyethanol (SCCS, 2016) argues for the use of a NOAEL value of 357 mg/kg bw/day for cosmetic products. This value is based on dermal studies in rabbits, which the SCCS considers most appropriate to use for dermal exposure to cosmetic products. This value is based on a 90-day dermal toxicity study in rabbits. The critical effect is local effects on the skin.

The French assessment of phenoxyethanol is also discussed in the SCCS's opinion (SCCS, 2016). The assessment of ANSM is that the lower NOAEL value of **164 mg/kg bw/day** should be used for dermal assessments of cosmetic products. This is in spite of the fact that the study supporting this NOAEL value is based on oral exposure. The critical effect here is indicated as liver toxicity. Hence, the French assessment is that phenoxyethanol should not be used at concentrations higher than 0.4% in cosmetic products for babies (for children under 3 years of age, for use in the nappy area [20]). This assessment is partially based on the fact that the skin in the nappy area may be more sensitive. For comparison, the permissible concentration of phenoxyethanol in all cosmetic products today is 1%.

[20] https://cosmeticobs.com/en/articles/ansm-47/ansm-a-mandatory-warning-on-leave-on-cosmetics-containing-phenoxyethanol-4720/

The SCCS concludes that the study on which France's assessment is based is not satisfactory and should therefore be supported by more data. The study referred to is based on oral intake for rats. The SCCS argues that NOAEL values from studies based on dermal experiments in rabbits should be preferred over oral studies, since it is considered questionable whether the effects observed in rats following oral intake are relevant to humans, and because rabbits are more sensitive to phenoxyethanol. Additionally, the SCCS concludes that humans have a much greater ability to metabolise phenoxyethanol in the body than rabbits do, making a margin of safety[21] of 100 unnecessary; instead, a margin of safety of 25 is sufficient. The SCCS also considers this margin to be sufficient for the exposure of babies and young children to phenoxyethanol from cosmetic products. As mentioned previously, oral exposure is a relevant exposure pathway for children playing with toys. Therefore, it may be relevant to investigate whether indications in this study regarding a possible lower NOAEL value are relevant for slime toys studied in this project.

The NOAEL values used are converted to DNEL values using the relevant AFs (assessment factors), as described by the ECHA (2012):

- For the DNEL value obtained by the SCCS (referred to here as "SCCS"), safety factors (AFs) of 2.4 for allometric scaling for rabbits, 2.5 for residual differences between species, 10 for intraspecies differences, and 2 to account for the sub-chronic (90-day) nature of the study are used. According to the ECHA (2012), when discussing local effects on skin, the allometric scaling factor of 2.4 should not be used. This means that a combined AF of 50 (2.5 x 10 x 2) is used, corresponding to a **DNEL value of 7.14 mg/kg bw/day**.
- For the DNEL value obtained by France (referred to here as "France"), safety factors (AFs) of 4 for allometric scaling for rats, 2.5 for residual differences between species, 10 for intraspecies differences , and 2 to account for the sub-chronic (90-day) nature of the study are used. This means that a combined AF of 200 (4 x 2.5 x 10 x 2) is used, corresponding to a **DNEL value of 0.82 mg/kg bw/day.**

It should be noted that as a worst case, safety factors of 4 are used for allometric scaling for rats, as prescribed by the ECHA (2012) for systemic effects. However, in its opinion (SCCS, 2016), the SCCS concludes that these kinetically related safety factors do not necessarily need to be this high. This is because it is known that 2-phenoxyethanol is metabolised in the liver (and kidneys) to a greater extent in rats than in humans. The SCCS thus argues that the effects observed in the liver in rats are due to this rapid metabolism in the liver (and thereby caused by the metabolite of phenoxyethanol). This effect is therefore not expected (to the same degree) in humans, but no data is available to confirm or reject the process of phenoxyethanol metabolism in humans, and for this reason, the allometric scaling safety factor is used when using the French DNEL value.

12.2 MI — methylisothiazolinone

Methylisothiazolinone has a harmonised classification as:

- Acute Tox. 3, H301 (Toxic if swallowed) and H311 (Toxic in contact with skin)
- Skin Corr. 1B, H314 (Causes severe skin burns and eye damage)
- Eye Dam. 1, H318 (Causes serious eye damage)
- Skin Sens. 1A, H317 (May cause an allergic skin reaction)
- Acute Tox. 2, H330 (Fatal if inhaled)

[21] A corresponding, but slightly different, approach is used for risk assessments of cosmetic products, with other margins of safety (MoS) compared to the risk assessment described by the ECHA, which is used in this report.

Despite the fact that MI is classified as acutely toxic if consumed, brought into contact with skin, or inhaled, the substance has not been evaluated by the SCCS for its toxicological properties. Only allergenic properties of MI have been evaluated, since the critical effect for the substance is allergy. In this project, the focus is solely on the allergic properties of the substance, partly because the primary exposure pathway is dermal when playing with slime products.

12.2.1 Knowledge of sensitisation and elicitation levels

In the SCCS opinion on MI (SCCS, 2015), it is stated that there is no knowledge of safe levels for sensitisation and elicitation for MI as far as leave-on products are concerned. The SCCS concludes, however, that the use of MI at a maximum concentration of 15 mg/kg (0.0015%) is considered safe in rinse-off products in terms of induction of allergy; that is, sensitisation.

Aerts (2017) refers to a study from 2010 in which patients (who were already sensitised) were observed reacting to levels of MI as low as 10 mg/kg for leave-on cosmetic products and other non-cosmetic products. As this concentration was the lowest concentration tested, this means that the minimum level for elicitation is less than 10 mg/kg (the actual concentration on the skin in µg/cm^2 is not given).

A study by Lundov (2010) found that under repeated daily exposure, reactions were observed in patients with MI allergies (2 people, corresponding to 18% of the test subjects) exposed to a MI concentration of 0.021 µg/cm^2, corresponding to a 5 mg/kg concentration in a cosmetic product used twice daily. No further studies have been found which investigate dose/response relationships for elicitation in the low-dose range. Due to a lack of data, a safe level cannot be specified, but it is known that there is a risk of elicitation at these levels.

A search for sensitisation and elicitation levels for MI did not identify other sources that listed specific levels.

12.2.2 Determination of the acceptable MI exposure level for calculation of the risk using the QRA method

When the QRA method (described in section 11.3.2) is used for quantitative assessment of the risk of sensitisation, an acceptable exposure level must be established for MI. This is described in greater detail in Appendix 5. In this appendix, the acceptable exposure level for MI is calculated as the NESIL (no expected sensitisation induction level) divided by the combined safety factor (of 450) for an end result of **0.22 µg/cm^2.**

It should be emphasised here that the main point of contention in this method is the establishment of safety factors. The SCCS has indicated that descriptions of uncertainties in this method are lacking, and that safety factors should be discussed (SCSS, 2016). However, some of this criticism has been taken into account for the safety factors used here, as described in Ezendam et al. (2018).

12.2.3 Sensitisation versus elicitation for MI (QRA method)

In the quantitative risk assessment for sensitisation using the QRA method, a sensitisation level for MI of 0.22 µg/cm^2 is predicted; that is, at this level, there will be a risk of persons developing allergies towards MI. No data has been identified in the literature indicating the actual sensitisation level, so reservations must be made in light of the discussions about the use of necessary safety factors when using this method. Specifically, whether this sensitisation level ought to be lower could be questioned. This project takes no stance on the issue in this report.

Elicitation has been observed at levels of 0.021 µg/cm^2 per day, corresponding to a concentration of 5 ppm in a cosmetic product used twice a day. This level of elicitation is thus lower than

the sensitisation level predicted by the QRA method by a factor of about 10. However, the sensitisation level is greater than the elicitation level, which is the common understanding (Friedmann, 2007).

12.3 Kathon (CMI/MI)

Kathon has a harmonised classification as:

- Acute Tox. 3, H301 (Toxic if swallowed)
- Acute Tox. 2, H310 (Fatal in contact with skin) and H330 (Fatal if inhaled)
- Skin Corr. 1C, H314 (Causes severe skin burns and eye damage)
- Eye Dam. 1, H318 (Causes serious eye damage)
- Skin Sens. 1A, H317 (May cause an allergic skin reaction)

In 2009, the SCCS assessed the risk (of effects other than allergy) when using the Kathon mixture in cosmetic products, arriving at a MoS (margin of safety) above 7000, while a MoS of 100 is considered safe use. The calculation was based on the use of rinse-off cosmetic products with a maximum concentration of 15 mg/kg. The SCCS (2009) describes that the risk of allergy is one of the main health effects of the mixture. The critical effect is allergy. Today (2019), Kathon is not permitted in leave-on cosmetic products, but it is permitted in rinse-off cosmetic products at a maximum concentration of 15 mg/kg. In this project, the focus is solely on the allergenic properties of the substance, partly because this is the critical effect for the substance, and partly the primary exposure pathway is dermal when playing with slime products.

12.3.1 Knowledge of sensitisation and elicitation levels

In the SCCS opinion of Kathon (SCCS, 2009) it is indicated that the elicitation level for Kathon is less than 2 mg/kg in already sensitised individuals. This value is based on a Danish study by Zachariae et al. (2006), which indicates that a level of about 0.025 µg/cm^2 (corresponding to 2 mg/kg) must be considered an elicitation level, though an actual elicitation level cannot ultimately be determined based on their study. This is because lower levels were not investigated. Due to a lack of data, a safe level cannot be specified, but it is known that there is a risk of elicitation at this level.

A search for sensitisation and elicitation levels for Kathon did not identify any other sources than the listed specific levels.

12.3.2 Determination of the acceptable Kathon exposure level for calculation of the risk using the QRA method

The determination of the acceptable exposure level for Kathon is described in more detail in Appendix 5. In this appendix, the acceptable exposure level for Kathon is calculated as the NESIL divided by the combined safety factor (of 450) for an end result of **0.0028 µg/cm^2.**

It should be emphasised here that the main point of contention in this method is the establishment of safety factors, as described above in the case of MI.

12.3.3 Sensitisation versus elicitation for Kathon (QRA method)

The quantitative risk assessment for sensitisation for Kathon gives the same result based on data from mice (LLNA) or data from humans (HRIPT) and predicts a sensitisation level for Kathon of 0.0028 µg/cm^2. No data has been identified in the literature which indicates the actual sensitisation level. The calculated level of sensitisation for Kathon is thus a best estimate, but it should be taken with reservations due to discussions about the use of necessary safety factors in this method. Specifically, whether this sensitisation level ought to be lower has been called into question.

From the elicitation data for Kathon described above, a LOAEL value of 0.025 µg/cm^2 (corresponding to 2 mg/kg) has been identified. This elicitation level is thus higher than the sensitisation level predicted by the QRA method by a factor of almost 10. As it is commonly held that higher quantities are required for sensitisation than to provoke an allergic reaction in a person who already has an allergy to a given substance (Friedmann, 2007), this suggests that the QRA method is conservative in determining the sensitisation level.

13. Exposure and risk assessment

In this chapter, an exposure and risk assessment is conducted for the selected substances in slime toys, based on the methods described in the previous chapter. The exposure assessment comprises worst-case calculations of the exposure children are expected to be subjected to when playing with slime toys. If this reveals a risk, the exposure scenario is refined to yield a more realistic worst-case scenario. As part of the risk assessment, an assessment is made as to whether the calculated exposures may constitute a health risk by comparing them to knowledge of the levels considered to cause health effects for the individual substances.

The exposure calculations are based on the values presented partly in chapter 10 "Exposure scenarios", and the values presented for levels not considered to constitute a risk in chapter 12 "Values used for the risk assessment".

13.1 Exposure calculations and risk assessment

Exposure and risk calculations are presented in a single table for each substance described below. Phenoxyethanol is reviewed first, followed by a combined description of the isothiazolinones MI and Kathon based on the three approaches to evaluate exposure and allergy risk (as described in chapter 11).

13.1.1 Phenoxyethanol

The calculations for the two exposure scenarios, 1) play with ordinary slime and 2) play with slime using a slime gun, are presented in TABLE 21 and TABLE 22 below, respectively. Both dermal and oral exposure are presented for both scenarios, and these are later added into a single combined exposure. In addition, two different DNEL values are used as starting points for the calculations: One DNEL value is set by the SCCS (2016) based on dermal exposure in rabbits, and the other DNEL value is set by the French ANSM (2012) based on oral exposure in rats. When using the SCCS DNEL value based on dermal studies with local effects on the skin, only the dermal exposure is considered in the assessment, since oral exposure will not contribute to local dermal effects.

Both the lowest and highest concentrations identified in the quantitative analyses for different types of slime toys have been used; that is, for both ordinary slime and slime gun slime. Additionally, a value of 20 g is used as a worst-case value for the quantity of slime in contact with the skin for both ordinary slime and slime gun slime. Lastly, the evaluated absorption ratios have been used; specifically, 0.80 for oral absorption and 0.85 for dermal absorption (unless the DNEL value is based on the dermal study, in which case dermal absorption is accounted for, so the absorption factor is set to 1). Exposure is calculated based on the assumption that slime is played with once per day.

The tables below (TABLE 21 and TABLE 22) present calculations for both the lowest and highest concentrations identified for ordinary slime (0.26% and 0.57%, respectively) and the only concentration measured for slime gun slime, which is 0.65%.

TABLE 21. Exposure calculations and RCR calculation for phenoxyethanol when playing with **ordinary slime** using the hands. In the table, use of the French DNEL value is indicated by a green background, while use of the SCCS DNEL value is indicated by a white background.

Exposure	**Concentration** FC_{prod} (g/g)	**Quantity of slime on skin / ingested** Q_{prod} (g/day)	**Absorption** DA/OA (-)	**Body weight** BW (kg)	**Internal dose** (mg/kg bw/day)	**DNEL** (mg/kg bw/day)	**RCR** (-)
Dermal	0.0026	20	1	15	3.47	7.14	0.49
			0.85		2.95	0.82	**3.59**
	0.0057	20	1	15	7.60	7.14	**1.06**
			0.85		6.46	0.82	**7.88**
Oral	0.0026	0.4	0.8	15	0.06	0.82	0.07
	0.0057	0.4	0.8	15	0.12	0.82	0.15
Sum	0.0026	20 g dermally	-	15	3.47	7.14	0.49
		20 g dermally / 0.4 g orally			3.00	0.82	**3.66**
Sum	0.0057	20 g dermally	-	15	7.60	7.14	**1.06**
		20 g dermally / 0.4 g orally			6.58	0.82	**8.03**

DA = dermal absorption; OA = oral absorption; Sum = sum of dermal and oral exposure.
RCR values above 1 are shown in boldface.

TABLE 22. Exposure calculations and RCR calculation for phenoxyethanol when playing with **slime gun slime**. In the table, use of the French DNEL value is indicated by a green background, while use of the SCCS DNEL value is indicated by a white background.

Exposure	**Concentration** FC_{prod} (g/g)	**Quantity of slime on skin / ingested** Q_{prod} (g/day)	**Absorption** DA/OA (-)	**Body weight** BW (kg)	**Internal dose** (mg/kg bw/day)	**DNEL** (mg/kg bw/day)	**RCR** (-)
Dermal	0.0065	20	1	15	8.67	7.14	**1.21**
			0.85		7.37	0.82	**8.98**
Oral	0.0065	2	0.8	15	0.69	0.82	0.85
Sum	0.0065	20 g dermally	-	15	8.67	7.14	**1.21**
		20 g dermally / 2 g orally			8.06	0.82	**9.83**

DA = dermal absorption; OA = oral absorption; Sum = sum of dermal and oral exposure.
RCR values above 1 are shown in boldface.

In TABLE 21 and TABLE 22, it can be seen that the RCR values calculated for phenoxyethanol in slime products fall within the range 0.49–1.21 when using the high DNEL value based on the SCCS opinion for the sum of oral and dermal exposure[22]. Using the lower French DNEL value, the calculated RCR values for phenoxyethanol in slime products fall within the range 3.66–9.83. RCR values greater than 1 indicate that products constitute a risk

[22]When using the SCCS's DNEL value, only dermal exposure is calculated, since this DNEL value is based on local effects on the skin. When using the French DNEL value, both dermal and oral exposure are calculated. See section 11.2.

of health effects when children play with them if the products are used as described in the exposure scenarios. However, there are uncertain parameters in these worst-case calculations, so these scenarios are later refined into more realistic worst-case scenarios.

One of the main uncertainties in these calculations is the assumption that all phenoxyethanol contained in 20 g of slime will be absorbed when children play with slime. The assumption that children play with 20 g of slime at a time is realistic, but the assumption that all the phenoxyethanol contained in the 20 g of slime will be fully absorbed is not realistic. However, there are no realistic assessments of how much of a given substance that will actually migrate to the skin from slime during play, thereby making its uptake into the body possible.

Ordinarily, the amount of phenoxyethanol available for skin uptake would be evaluated based on a migration analysis. However, it is not possible to perform an accurate migration analysis on a slime toy because the slime dissolves in an aqueous migration liquid, though it does not dissolve in the hands during play.

As an alternative, a small "study" of the amount of slime remaining on the fingers after play was conducted (see Appendix 6 “Quantity of slime on hands after play”). According to this small study, about 0.3 to 0.4 g of slime toy liquid remain on the hands after play when the slime has been in contact with the hands for about half of one minute. When playing with a slime toy for an hour (the exposure time used), more than 0.3 to 0.4 g of slime will realistically remain on the hands. In a realistic worst-case scenario, we suppose that 2 g of slime will remain on the hands, and thus we assume that the quantity of phenoxyethanol present in 2 g of slime will be fully absorbed when children play with it.

The tables below (TABLE 23 and TABLE 24) present calculations for both the lowest and highest concentrations identified for ordinary slime (0.26% and 0.57%, respectively) and the only concentration measured for slime gun slime, which is 0.65%. Unlike the calculations in TABLE 21 and TABLE 22, these calculations are based on realistic worst-case scenarios, using 2 g of slime instead of 20 g. Appendix 7 presents calculations for all the identified concentrations of phenoxyethanol in the slime toys analysed.

TABLE 23. Exposure calculations and RCR calculation for phenoxyethanol when playing with **ordinary slime** using the hands, based on **realistic worst-case assumptions**. In the table, use of the French DNEL value is indicated by a green background, while use of the SCCS DNEL value is indicated by a white background.

Exposure	**Concentration** FC_{prod} (g/g)	**Quantity of slime on skin / ingested** Q_{prod} (g/day)	**Absorption** DA/OA (-)	**Body weight** BW (kg)	**Internal dose** (mg/kg bw/day)	**DNEL** (mg/kg bw/day)	**RCR** (-)
Dermal	0.0026	2	1	15	0.35	7.14	0.05
			0.85		0.29	0.82	0.36
	0.0057	2	1	15	0.76	7.14	0.11
			0.85		0.65	0.82	0.79
Oral	0.0026	0.4	0.8	15	0.06	0.82	0.07
	0.0057	0.4	0.8	15	0.12	0.82	0.15
Sum	0.0026	2 g dermally	-	15	0.35	7.14	0.05
		2 g dermally / 0.4 g orally			0.35	0.82	0.43
Sum	0.0057	2 g dermally	-	15	0.76	7.14	0.11

		2 g dermally / 0.4 g orally			0.77	0.82	0.94

DA = dermal absorption; OA = oral absorption; Sum = sum of dermal and oral exposure.

TABLE 24. Exposure calculations and RCR calculation for phenoxyethanol when playing with **slime gun slime**, based on **realistic worst-case assumptions**. In the table, use of the French DNEL value is indicated by a green background, while use of the SCCS DNEL value is indicated by a white background.

Expo-sure	**Concentration** FC_{prod} (g/g)	**Quantity of slime on skin / in-gested** Q_{prod} (g/day)	**Absorp-tion** DA/OA (-)	**Body weight** BW (kg)	**Internal dose** (mg/kg bw/day)	**DNEL** (mg/kg bw/day)	**RCR** (-)
Dermal	0.0065	2	1	15	0.87	7.14	0.12
			0.85		0.74	0.82	0.90
Oral	0.0065	2	0.8	15	0.69	0.82	0.85
Sum	0.0065	2 g dermally	-	15	0.87	7.14	0.12
		2 g dermally / 2 g orally			1.43	0.82	**1.74**

DA = dermal absorption; OA = oral absorption; Sum = sum of dermal and oral exposure.
RCR values above 1 are shown in boldface.

In TABLE 23 and TABLE 24, it can be seen that after the exposure scenarios are refined into more realistic scenarios, the RCR values fall within the range 0.05-0.12 when using the high DNEL value based on the SCCS opinion for the sum of oral and dermal exposure. Using the lower French DNEL value, the calculated RCR values for phenoxyethanol in slime products fall within the range 0.47–1.74. It can also be seen that in the more realistic exposure scenario, only the slime gun product has a calculated RCR value greater than 1 (1.74).

The calculated exposure and risk values for the two types of slime toys are only meaningful in terms of the risk of exposure to phenoxyethanol when playing with slime toys. However, phenoxyethanol is a widely used preservative that can be found in many cosmetic products. For this reason, daily exposure to phenoxyethanol from cosmetic products, as calculated by the SCCS (2016), is also included in TABLE 25 and TABLE 26. The SCCS (2016) has calculated the total exposure to phenoxyethanol from a large number of cosmetic products which both babies and adults can be expected to use. Because the target group for this project is children over three years of age, the combined daily external dose of 1.46 mg/kg bw/day is used, listed as the daily external exposure for non-nappy area cosmetic products for babies (SCCS, 2016). This external exposure can be converted to an internal dose using the dermal uptake of phenoxyethanol with a factor of 1 for dermal exposure when using the DNEL value based on dermal exposure; or a factor of 0.85 for dermal exposure when using the DNEL value based on oral exposure. The results are presented in TABLE 25 and TABLE 26 below.

TABLE 25. Exposure and RCR calculations for phenoxyethanol: combined exposure from play with **ordinary slime and cosmetic products - realistic worst case**. In the table, use of the French DNEL value is indicated by a green background, while use of the SCCS DNEL value is indicated by a white background.

Exposure	**Concentration** FC_{prod} (g/g)	**Quantity of slime on skin / ingested** Q_{prod} (g/day)	**Absorption** DA/OA (-)	**Body weight** BW (kg)	Internal dose (mg/kg bw/day)	**DNEL** (mg/kg bw/day)	**RCR** (-)
Ordinary slime (dermal and oral)	0.0026	2 g dermally	-	15	0.35	7.14	0.05
		2 g dermally / 0.4 g orally			0.29	0.82	0.36
	0.0057	2 g dermally	-	15	0.76	7.14	0.11
		2 g dermally / 0.4 g orally			0.65	0.82	0.79
Cosmetic products (dermal)			1	8*	1.46	7.14	0.20
			0.85		1.24	0.82	**1.51**
Total for ordinary slime and cosmetic products	0.0026	2 g dermally	-	-	1.81	7.14	0.25
		2 g dermally / 0.4 g orally			1.59	0.82	**1.94**
	0.0057	2 g dermally	-	-	2.22	7.14	0.31
		2 g dermally / 0.4 g orally			2.01	0.82	**2.45**

DA = dermal absorption; OA = oral absorption; Sum = sum of dermal and oral exposure.
* Note that data for babies with a body weight of 8 kg was used here, since no corresponding calculations for children over three years of age were available. However, the quantity of body lotion, etc. is adjusted for the body surface area of a baby. The actual exposure for a child over 3 years of age will thus be higher due to the higher quantity but distributed over a greater body weight.
RCR values above 1 are shown in boldface.

TABLE 26. Exposure and RCR calculations for phenoxyethanol: combined exposure from play with **slime guns and cosmetic products — realistic worst case**. In the table, use of the French DNEL value is indicated by a green background, while use of the SCCS DNEL value is indicated by a white background.

Exposure	**Concentration** FC_{prod} (g/g)	**Quantity of slime on skin / ingested** Q_{prod} (g/day)	**Absorption** DA/OA (-)	**Body weight** BW (kg)	Internal dose (mg/kg bw/day)	**DNEL** (mg/kg bw/day)	**RCR** (-)
Slime gun slime (dermal and oral)	0.0065	2 g dermally	-	15	0.87	7.14	0.12
		2 g dermally / 0.4 g orally			1.43	0.82	**1.74**
Cosmetic products (dermal)			1	8*	1.46	7.14	0.20
			0.85		1.24	0.82	**1.51**
Total for slime gun slime and cosmetic products		2 g dermally	-	-	2.33	7.14	0.33
		2 g dermally / 0.4 g orally			2.67	0.82	**3.26**

DA = dermal absorption; OA = oral absorption.
RCR values above 1 are shown in boldface.

It can be seen from these tables that an RCR value of about 0.2 is calculated for cosmetic products when using the SCCS DNEL value, while the RCR value is greater than 1 (1.5) when using the French ANSM DNEL value. This is the reason for their restriction on phenoxyethanol in cosmetic products for children under three years of age.

It should be noted that the daily exposure used for phenoxyethanol from cosmetic products is calculated by the SCCS (2016) as a worst-case value applicable to children under three years of age (babies). However, in this report, exposure from products used in the nappy area has been excluded because the target group for this project (children over three years of age) does not use these products. The worst-case exposure is thus based on a qualified estimate of maximum expected exposure. The SCCS supposes that the products used daily by babies in the worst-case situations (apart from products used in the nappy area) are: shampoo, shower gel, body lotion, facial crème, facial cleanser, and body cleansers. These are thus worst-case values, and they suppose that all these products contain phenoxyethanol at the maximum permitted concentration (from cosmetic product legislation; i.e., 1%).

13.1.1.1 Discussion of and conclusion on phenoxyethanol

From the calculations in TABLE 21 through TABLE 26, it can be seen that when children play with ordinary slime products in line with realistic worst-case assumptions, phenoxyethanol exposure from slime products alone does not constitute a risk to children. This is regardless of whether the SCCS DNEL value or the French ANSM DNEL value is used. An RCR value greater than 1 (1.7) was calculated only for the slime gun slime, and only when using the French ANSM DNEL value. However, a firm conclusion cannot be reached as to which DNEL value should be used. Similarly, no firm conclusion can be reached as to whether exposure to phenoxyethanol at the concentrations found in the slime gun slime product may constitute a health risk when children play with the product.

However, it is known that phenoxyethanol is used in a number of other products, including cosmetic products, which are considered to be the largest exposure source. For this reason, a risk assessment of phenoxyethanol exposure should include exposure from other exposure sources (TABLE 25 and TABLE 26). When these are accounted for, RCR values for ordinary slime remain below 1 when using the SCCS DNEL value. However, when using the ANSM DNEL value, the RCR values for the same products lie between 1.94 and 2.45. The same applies for the slime gun slime; specifically, when using the SCCS DNEL value, the RCR value is below 1 (0.33), but it is above 1 (3.26) when using the ANSM DNEL value.
These calculations thus show that depending on the DNEL value chosen, a risk may or may not be present. The SCCS has determined that a NOAEL value based on oral intake should not be used because the oral intake of phenoxyethanol from cosmetic products is not considered significant (despite the fact that such products as mouthwash also contain phenoxyethanol).

When using the French DNEL value, RCR values higher than 1 are obtained (for the total of slime toy products and cosmetic products). These values are greater than those based on the SCCS DNEL value. However, a firm conclusion cannot be reached as to which DNEL value should be used. Similarly, no firm conclusion can be reached as to whether exposure to phenoxyethanol at the concentrations found in slime products, plus exposure from cosmetic products, may present a risk of health effects when children play with the products. To be able to assess the health effects with greater certainty, more knowledge and data is needed, particularly regarding the actual uptake of phenoxyethanol through the skin when playing with slime toys. Additionally, a more precise risk assessment of exposure from cosmetic products for children over three years of age should be performed. The exposure used in this project consists of an approximate exposure based on exposure for children under three years of age.

13.1.2 MI and Kathon

MI and Kathon are described together based on the three approaches to assess exposure and allergy risk (as described in chapter 11). These three approaches are discussed below in greater detail.

13.1.2.1 Use of the SCCS assessment for elicitation and sensitisation

In the SCCS opinion on MI (SCCS, 2015), and the SCCS opinion on Kathon (SCCS, 2009), it is stated that there is no knowledge of safe levels for sensitisation and elicitation for MI or Kathon as far as leave-on products are concerned. The previously permitted limit value for MI in leave-on cosmetic products, which was 100 ppm, was evaluated as unsafe for both sensitisation and elicitation of allergic reactions to MI. For this reason, the SCCS considers that this is not a safe level for MI use in leave-on products. The SCCS evaluation is supported by Aerts (2017) and Lundov (2010).

As indicated previously, slime toys can be compared to leave-on cosmetic products because in the worst case, children do not wash their hands after playing with slime. The liquid slime base will therefore remain on their skin and be available for skin uptake. Children additionally play with slime toys for longer periods of time - in the worst case, one hour per day. Today, the use of MI and Kathon in leave-on cosmetic products is prohibited because, according to the SCCS, there is no knowledge of safe sensitisation and elicitation levels for these preservatives in leave-on products. For this reason alone, slime toys containing MI or Kathon should similarly not be considered safe in terms of the risk of allergic reactions (both sensitisation and elicitation).

13.1.2.2 Calculation of dermal exposure

In this section, the dermal exposure (dermal load, L_{dermal}) is calculated and compared to elicitation levels in the literature, since sensitisation levels are unknown.

The dermal load L_{dermal} is calculated using the formulas described in section 11.3.1 "Calculation of dermal exposure (L_{dermal}) relative to sensitisation and elicitation levels". The calculations are presented below in TABLE 27 for the exposure scenario involving play with ordinary slime. Neither MI nor Kathon was identified in the slime gun slime, so no calculations were performed for that scenario. Two different calculations are given for the scenario with ordinary slime, with the highest and lowest concentrations of MI and Kathon identified, using 20 g of slime in contact with the skin.

TABLE 27. Dermal load calculations (L_{dermal}) for MI and Kathon for play with ordinary slime using the hands, compared with elicitation levels from the literature

Substance	Concentration FC_{prod} (g/g)	Quantity of slime in contact with skin Q_{prod} (g/day)	Surface area of exposed skin A (cm^2)	Dermal exposure (dermal load) L_{dermal} (µg/cm^2/day)	Lowest elicitation level in the literature (µg/cm^2/day)
MI	0.0000045	20	200	**0.450**	0.021
	0.000016	20	200	**1.600**	0.021
Kathon	0.0000017	20	200	**0.170**	0.025
	0.0000071	20	200	**0.710**	0.025

For both MI and Kathon, it can be seen that the calculated dermal load exceeds the lowest levels indicated to cause elicitation in the literature (see sections 12.2.1 and 12.3.1 "Knowledge of sensitisation and elicitation levels" for MI and Kathon, respectively). This is true even for the lowest measured concentrations of MI and **Kathon.** Furthermore, the calculated values exceed these levels by a factor of seven to 76. Therefore, based on these calculations, there is a

risk that children who have already developed an allergy to MI or Kathon may experience allergic reactions when playing with slime toys that contain these preservatives.

However, it should be noted that the same uncertainty mentioned in the discussion of the phenoxyethanol risk assessment is also present here; namely, the use of 20 g in contact with the skin, which may be an overestimate. Even so, for MI and Kathon, the extent to which known elicitation levels are exceeded is more significant. Together with the fact that there may not be any knowledge of the precise elicitation level (which may be lower still, since experiments on humans are not conducted), this means that there is a risk of elicitation when children play with slime toys containing either MI or Kathon at the measured concentrations (about 5 to 16 mg/kg for MI, and about 2 to 7 mg/kg for Kathon).

13.1.2.3 Quantitative sensitisation risk assessment (QRA method)

As mentioned previously (in section 11.3), the QRA method is used in this report solely for the purpose of obtaining knowledge regarding the sensitisation risk using a quantitative approach (because sensitisation data for these substances is lacking in the literature) and comparing the results with an assessment of these substances from the SCCS. The SCCS considers the method to be subject to a number of uncertainties, and it has not been developed sufficiently to be useful in assessing risks for substances other than fragrances in cosmetic products. One of the major points of contention for the QRA method is which safety factors should be used. In the SCCS most recent assessment of the QRA method (SCCS, 2018), critical points include the use of safety factors and a lacking description of the uncertainties of the method. The safety factors used for the calculations in this report are those presented by Ezendam et al. (2018), developed in response to the SCCS critique (2018); thus, they attempt to account for the SCCS criticism by using different, higher safety factors.

When using the QRA method, the calculated dermal exposure (the dermal load) is compared with the established acceptable exposure level (AEL) for sensitisation (established in Appendix 4.2 and Appendix 4.3 for MI and Kathon, respectively). The dermal load is calculated in exactly the same manner as described above in section 13.1.2.2 "Calculation of dermal exposure". For this reason, the underlying data supporting it is not presented here, but it can be seen in TABLE 27.

TABLE 28. Dermal load (L_{dermal}) calculations for MI and Kathon for ordinary play with slime using the hands, compared to the calculated acceptable exposure level for sensitisation using the QRA method

Substance	**Concentration** FC_{prod} (g/g)	**Quantity of slime / exposed skin surface area** Q_{prod} (g/day) / A (cm^2)	**Dermal exposure (dermal load)** L_{dermal} (µg/cm^2/day)	**Acceptable exposure level for sensitisation, via QRA method** AEL (µg/cm^2/day)	**Dermal exposure versus acceptable sensitisation dose (QRA method)** L_{dermal} / AEL (-) Corresponds to RCR
MI	0.0000045	20 g / 200 cm^2	0.450	0.22	**2.0**
	0.000016	20 g / 200 cm^2	1.600	0.22	**7.3**
Kathon	0.0000017	20 g / 200 cm^2	0.170	0.0028	**60.7**
	0.0000071	20 g / 200 cm^2	0.710	0.0028	**253.6**

An extra contribution from MI, identified in products containing both CMI and MI, must also be taken into account (see TABLE 17). The quantities analysed in the products do not align with

the 3:1 ratio of the Kathon mixture. Whether this is due to analytical uncertainties or the addition of MI beyond that contained in the Kathon mixture is unknown.

As described in sections 12.2.1 and 12.3.1 "Knowledge of sensitisation and elicitation levels", knowledge of sensitisation levels for MI and Kathon were not identified in the literature. In this case, only the QRA method and the acceptable sensitisation level predicted by the method are available as a reference. Here, the calculations in TABLE 28 show that in the use of 20 g of slime, which is the quantity to which children's hands are exposed, the acceptable sensitisation exposure level is clearly exceeded at both the lowest and highest measured concentrations of both MI and Kathon in slime toys. For MI, the acceptable level is exceeded by at least a factor of two, and for Kathon, the acceptable level is exceeded by at least a factor of 61 using the lowest concentrations identified.

Here, too, the same uncertainty as mentioned previously is present, in terms of the quantity of 20 g in contact with the skin, which may be an overestimate as a worst-case assumption. Particularly for Kathon, however, the acceptable level for sensitisation (AEL) is exceeded more significantly. It should also be noted that the point of the QRA method is to account for the total exposure to MI or Kathon per day in the calculations, not only exposure from individual types of products. For this reason, a conclusion cannot be drawn regarding the sensitisation risk by calculating only dermal exposure to slime toys. It is necessary to include dermal exposure from other products as well.

MI and Kathon are preservatives and are used in many different products. One or both preservatives have been observed in the consumer products listed below, among other products (based on the Danish EPA's database on chemical substances in consumer products); they have also been identified in other products by other sources:

- Many types of cosmetic products
- Ceramic paints
- Carnival/theatrical makeup
- Interior paint
- Plaster primer
- Wallpaper adhesive
- Household cleaners (Ezendam et al., 2018)
- Acrylic paint (Poulsen & Nielsen, 2014)
- Finger paint (Poulsen & Nielsen, 2014)
- Window paint (Poulsen & Nielsen, 2014)
- Glue sticks (Poulsen & Nielsen, 2014)
- Soap bubble liquid (Poulsen & Nielsen, 2014)

Because children just over the age of three are not expected to be in significant contact with interior paint products or cleaners, it is expected that the most significant additional contribution to dermal exposure will come from cosmetic products and other chemical toys containing MI and/or Kathon. However, dermal exposure to MI and Kathon from other chemical toys, such as window paints and soap bubble liquids, is unknown, and so it is not included in the calculations in this report.

In its assessment of MI (SCCS, 2015), the SCCS calculated the dermal exposure in $\mu g/cm^2/day$ for a long list of cosmetic products which, in a modified form, can be used to estimate exposure to MI from cosmetic products. Corresponding calculations for dermal exposure to Kathon in cosmetic products do not exist, but levels can likely be expected to be more or less the same, since the same concentration of 0.0015% is allowed today in rinse-off products. However, these calculations are unnecessary because the contribution of Kathon to the dermal load in slime toys already exceeds the acceptable exposure level for sensitisation by a

factor of at least 61. For this reason, calculations for the dermal load from cosmetic products are presented below only for MI.

However, it is not clear from the SCCS dermal exposure data on MI (2015) whether these calculations are based exclusively on adults' usage. It is presumed that these calculations are generally for adults (particularly when referring to such products as face masks), or for babies when referring to such products as cleansing lotions for the nappy area. Because MI is only permitted at a maximum concentration of 0.0015% in rinse-off products today, only figures for the selected rinse-off products listed by the SCCS (2015) are used, except with an adjustment from a concentration of 0.0100%, which was allowed at the time the SCCS developed its opinion on MI for the maximum concentration allowed today.

TABLE 29. Dermal exposure (L_{dermal}) for MI as calculated by the SCCS (2015) for selected cosmetic products which children are presumed to use

Product type	**Consumer exposure L_{dermal} as indicated by the SCCS** ($\mu g/cm^2/day$)	**Correction factor** 0.0015 / 0.0100	**Corrected consumer exposure, L_{dermal}** ($\mu g/cm^2/day$)
Shampoo	0.0073	0.15	0.001
Conditioner (rinse-off)	0.0278	0.15	0.004
Toothpaste	0.1245	0.15	0.019
Hand soap (bar)	0.0057	0.15	0.001
Sum			**0.025**

The calculation in TABLE 29 indicates that a dermal exposure of 0.025 $\mu g/cm^2/day$ from cosmetic products should be added. These values are most likely calculated for adults, but it can be supposed that a correlation exists between the amount used and the body surface area on which a product is used.

Below, in TABLE 30, the extra contribution to dermal exposure is added to the slime toy exposure for only MI.

TABLE 30. Calculations of dermal load (L_{dermal}) for ordinary play with slime using the hands, plus contribution from cosmetic products (CP) compared to calculated acceptable exposure level for sensitisation using QRA method

Substance	**Concentration** FC_{prod} (g/g)	**Quantity of slime / exposed skin surface area** Q_{prod} (g/day) / A (cm^2)	**Dermal exposure (dermal load)** L_{dermal} ($\mu g/cm^2/day$)	**Acceptable exposure level for sensitisation, via QRA method** AEL ($\mu g/cm^2/day$)	**Dermal exposure versus acceptable sensitisation dose (QRA method)** L_{dermal} / AEL (-) Corresponds to RCR
MI (slime)	0.0000045	20 g / 200 cm^2	0.450	0.22	**2.0**
	0.000016	20 g / 200 cm^2	1.600	0.22	**7.3**
MI (CP)	-	-	0.025	0.22	0.11
MI (total)	0.0000045	20 g / 200 cm^2	0.475	0.22	**2.2**
	0.000016	20 g / 200 cm^2	1.625	0.22	**7.4**

Here, the calculations in TABLE 30 show that for the combined contribution from cosmetic products and the use of 20 g of slime, which is the quantity to which children's hands are exposed, the acceptable exposure level for **sensitisation** is clearly exceeded at both the lowest and highest measured concentrations of MI and Kathon in slime toys. Additionally, any contribution from other chemical toys for which previous studies have demonstrated potential MI and/or Kathon content should also be added. This means that when playing with slime toys containing MI or Kathon, children may develop an allergy towards these substances.

The quantity of 20 g of slime may be an overestimate, as previously discussed, but this does not change the conclusion for Kathon. For MI, on the other hand, due to the uncertainties in the calculations and the method in general, as well as the uncertainties regarding the quantity of slime which children's skin is exposed to, it can be concluded that these calculations do not preclude the possibility of MI causing sensitisation in children when exposed to MI in various products.

Reflection on the AEL levels used for MI and Kathon (QRA method)
While a very conservative acceptable exposure level (AEL) appears to be used in the QRA method for sensitisation (see sections 12.2.3 and 12.3.3), the AEL is exceeded to such a great extent for the calculated dermal exposures that the results nonetheless suggest that the Kathon content in slime toys may constitute a risk of sensitisation for children playing with these slime toys; that is, they may develop an allergy towards Kathon.

13.1.2.4 Combined conclusion for MI and Kathon

Overall, we can conclude that because the SCCS (SCCS, 2013 and SCCS, 2009) considers that there are no safe levels for sensitisation and elicitation for MI and Kathon in leave-on cosmetic products, slime toys can also constitute a risk, given that slime toys are comparable to leave-on cosmetic products.

Dermal exposure (dermal load) calculations with known **elicitation** values from the literature support the SCCS conclusion for both MI and Kathon regarding elicitation.

In using the QRA method, it is only possible to draw conclusions regarding the risk of **sensitisation.** These calculations demonstrate that the acceptable exposure level for sensitisation is clearly exceeded for the Kathon mixture. The acceptable exposure level for sensitisation is also exceeded for MI, but not nearly to the same extent as for Kathon. Therefore, in the worst-case scenario, the uncertainties are not significant for the conclusion regarding Kathon sensitisation — there is a risk that children playing with slime toys containing Kathon at concentrations of about 2 to 7 mg/kg may become sensitised. The conclusion for MI is not quite as certain, but we can nonetheless conclude that these calculations do not rule out the possibility of MI causing sensitisation in children when they are exposed to MI by the products studied (which contain MI at concentrations as high as 16 mg/kg). This is particularly because exposure is also possible from other chemical toy products, such as soap bubble liquid, which have not been included in this report. It should, however, be noted that the QRA method, which was used to evaluate the potential for sensitisation, is not an officially recognised method. Among other issues, the use of safety factors in the method is still subject to discussion.

13.2 Conclusion

In this project, the migration of boron from slime toys was assessed. Additionally, a risk assessment was conducted on the use of phenoxyethanol in slime toys, and a risk assessment was conducted on the use of the isothiazolinones MI and Kathon, focusing exclusively on the

risk of allergy. Furthermore, this project investigated whether differences exist between products purchased in Denmark, in other EU countries, and outside the EU regarding their ingredients and whether they constitute a risk to children when playing with slime toys.

The control analyses for boron migration showed that the permitted limit value for boron migration was exceeded by 13 out of 27 slime toys. They were also divided as follows:

- Eight out of nine products (89%) purchased outside the EU
- One out of four products (25%) purchased within the EU (but outside of Denmark)
- Four out of 14 products (29%) purchased in Denmark

It was considered that six of the 13 products presented a serious risk, resulting in these products being recalled from consumers. Four of these six products were purchased outside the EU, one was purchased within the EU (but outside of Denmark), and the last product was purchased from a Danish website.

The risk assessment of phenoxyethanol shows that when children play with ordinary slime products in line with realistic worst-case assumptions, phenoxyethanol exposure from slime products alone does not constitute a health risk to children. This is regardless of whether the SCCS DNEL value or the French ANSM DNEL value is used. A RCR value greater than 1 (1.7) was calculated only for the slime gun slime, and only when using the French ANSM DNEL value. However, a firm conclusion cannot be reached as to which DNEL value should be used. Similarly, no firm conclusion can be reached as to whether exposure to phenoxyethanol at the concentrations found in the slime gun slime product may constitute a health risk when children play with the product.

When contributions from exposure from cosmetic products are added to the risk assessment for phenoxyethanol, this results in RCR values higher than 1 (indicating a risk) when using the French DNEL value. When using the SCCS DNEL value, we obtain RCR values less than 1, even when including the contribution from cosmetic products, indicating that health effects are not expected. However, a firm conclusion cannot be reached as to which DNEL value should be used. Similarly, no firm conclusion can be reached as to whether exposure to phenoxyethanol at the concentrations found in slime products, plus exposure from cosmetic products, may present a risk of health effects when children play with the products. To be able to assess the health effects with greater certainty, more knowledge and data is needed, particularly regarding the actual uptake of phenoxyethanol through the skin when playing with slime toys. Additionally, a more precise risk assessment of exposure from cosmetic products for children over three years of age should be performed, rather than using the approximate value used in this report.

Regarding the isothiazolinones (MI and Kathon), the SCCS considers that neither of these substances is safe to use in leave-on cosmetic products for allergy-related reasons. As a realistic worst case, if a 3-year-old child does not wash its hands and/or body after play, slime toys can be considered a leave-on product. In that case, six of the 18 slime toys studied that were purchased in either Denmark or the greater EU[23] may constitute the risk of children developing allergies to these isothiazolinones due solely to their inclusion in a slime toy. The dermal exposure (dermal load) calculations using known **elicitation** values from the literature support the SCCS conclusion for both MI and Kathon regarding elicitation, even considering the uncertainties.

In using the QRA method, it is only possible to draw conclusions regarding the risk of **sensitisation.** These calculations demonstrate that the acceptable exposure level for sensitisation is

[23]The remaining nine products purchased from non-EU countries were not analysed for isothiazolinone content because virtually all of them exceeded the permitted limit value for boron migration.

clearly exceeded for the Kathon mixture. The acceptable exposure level for sensitisation is also exceeded for MI, but not nearly to the same extent as for Kathon. When considering the uncertainties, the risk of Kathon sensitisation cannot be excluded. The conclusion for MI is not as certain; however, it can be concluded that the calculations do not rule out the possibility of MI causing sensitisation in children when they are exposed to MI in various products, particularly when exposure from other sources, such as other chemical toys, may also occur.

It should, however, be noted that the QRA method, which was used to evaluate the potential for sensitisation, is not an officially recognised method. Among other issues, the use of safety factors in the method is still subject to discussion. The sensitisation risk assessment is thus uncertain; nonetheless, it supports the SCCS assessment.

Combining the conclusions from the phenoxyethanol and isothiazolinone risk assessments with the products that constituted a risk due to the measured levels of boron migration, more than half (15 out of 27) of all the slime toys may constitute a health risk. They are divided as follows:

- Eight out of nine products (89%) purchased outside the EU - these were not evaluated for isothiazolinone content because the corresponding analyses were not performed
- One out of four products (25%) purchased within the EU (but outside of Denmark)
- Six out of 14 products (43%) purchased in Denmark

The results clearly show that more products purchased outside the EU may constitute a health risk than products purchased within the EU.

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Appendix 1. Danish Statutory Order on Toys

The chemical substances listed below are restricted in the Danish Statutory Order on Toys (and in the EU) according to Annex II part III "Chemical properties".

Appendix 1.1 Allergenic fragrances

Toy products are not allowed to contain the allergenic fragrances listed in TABLE 31. However, traces of these fragrances are allowed provided that their presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg.

In addition, the names of the allergenic fragrances listed in TABLE 32 must be listed on the toy, on an affixed label on the packaging or in an accompanying leaflet, if added to a toy at concentrations exceeding 100 mg/kg in the toy or components of the toy product.

TABLE 31. Allergenic fragrances restricted in toy products according the Danish Statutory Order on Toys (Statutory Order no. 309, 2017)

No.	Name of the allergenic fragrance	CAS number
1.	Alanroot (Inula helenium)	97676-35-2
2.	Allylisothiocyanate	57-06-7
3.	Benzyl cyanide	140-29-4
4.	4 tert-Butylphenol	98-54-4
5.	Chenopodium oil	8006-99-3
6.	Cyclamen alcohol	4756-19-8
7.	Diethyl maleate	141-05-9
8.	Dihydrocumarin	119-84-6
9.	2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0
10.	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
11.	4,6-Dimethyl-8-tert-butyl-cumarin	17874-34-9
12.	Dimethyl citraconate	617-54-9
13.	7,11-Dimethyl-4,6,10-dodecatrien-3-on	26651-96-7
14.	6,10-Dimethyl-3,5,9-undecatrien-2-on	141-10-6
15.	Diphenylamine	122-39-4
16.	Ethyl acrylate	140-88-5
17.	Fig leaf, fresh and preparations	68916-52-9
18.	trans-2-Heptenal	18829-55-5
19.	trans-2-Hexenal diethyl acetal	67746-30-9
20.	trans-2-Hexenal dimethyl acetal	18318-83-7
21.	Hydroabietyl alcohol	13393-93-6
22.	4-Ethoxy-phenol	622-62-8
23.	6-Isopropyl-2-decahydronaphthalenol	34131-99-2
24.	7-Methoxycumarin	531-59-9
25.	4-Methoxyphenol	150-76-5

No.	Name of the allergenic fragrance	CAS number
26.	4-(p-Methoxyphenyl)-3-buten-2-one	943-88-4
27.	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
28.	Methyl trans-2-butenoate	623-43-8
29.	6-Methylcumarin	92-48-8
30.	7-Methylcumarin	2445-83-2
31.	5-Methyl-2,3-hexanedione	13706-86-0
32.	Costus root oil (Saussurea lappa Clarke)	8023-88-9
33.	7-Ethoxy-4-methylcumarin	87-05-8
34.	Hexahydrocumarin	700-82-3
35.	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9
36.	2-Pentyliden-cyclohexanone	25677-40-1
37.	3,6,10-Trimethyl-3,5,9-undecatrien-2-one	1117-41-5
38.	Verbena oil (Lippia citriodora Kunth)	8024-12-2
39.	Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
40.	4-Phenylbut-3-en-2-one	122-57-6
41.	Amyl cinnamal	122-40-7
42.	Amyl cinnamyl alcohol	101-85-9
43.	Benzyl alcohol	100-51-6
44.	Benzyl salicylate	118-58-1
45.	Cinnamyl alcohol	104-54-1
46.	Cinnamal	104-55-2
47.	Citral	5392-40-5
48.	Cumarin	91-64-5
49.	Eugenol	97-53-0
50.	Geraniol	106-24-1
51.	Hydroxy-citronellal	107-75-5
52.	Hydroxy-methylpentylcyclohexencarboxaldehyde Hydroxyisohexyl 3–cyclohexene carboxaldehyde	31906-04-4
53.	Isoeugenol	97-54-1
54.	Oarkmoss extracts Evernia prunastri extract	90028-68-5
55.	Treemoss extracts Evernia furfuracea extract	90028-67-4

TABLE 32. Allergenic fragrances, which toy products must not contain according to the Statutory Order on Toys, unless the name of the fragrance is listed on the toy, or unless the concentration used is below 100 mg/kg (Statutory Order No. 309, 2017)

No.	Name of the allergenic fragrance	CAS number
1.	Anisyl alcohol	105-13-5
2.	Benzyl benzoate	120-51-4
3.	Benzyl cinnamate	103-41-3
4.	Citronellol	106-22-9

No.	Name of the allergenic fragrance	CAS number
5.	Farnesol	4602-84-0
6.	Hexylcinnamaldehyde Hexyl cinnamal	101-86-0
7.	Lilial Butylphenyl methylpropional	80-54-6
8.	d-Limonene	5989-27-5
9.	Linalool	78-70-6
10.	Methyl heptine carbonate Methyl 2–octynoate	111-12-6
11.	3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one alpha–Isomethyl ionone	127-51-5

Appendix 1.2 Migration of elements from toy products

The limit values listed below of the migration of elements from toy products or toy components must not be exceeded.

TABLE 33. Limit values for elemental migration from toy materials

Element	Category I Dry, brittle, powder-like or pliable toy material (mg/kg)	Category II Liquid or sticky toy material (mg/kg)	Category III Scraped-off toy material (mg/kg)
Aluminium	5,625	1,406	70,000
Antimony	45	11.3	560
Arsenic	3.8	0.9	47
Barium	1,500	375	18,750
Boron	1,200	300	15,000
Cadmium	1.3	0.3	17
Chromium (III)	37.5	9.4	460
Chromium (VI)	0.02	0.005	0.053
Cobolt	10.5	2.6	130
Cupper	622.5	156	7,700
Lead	2.0	0.5	23
Manganese	1,200	300	15,000
Mercury	7.5	1.9	94
Nickel	75	18.8	930
Selenium	37.5	9.4	460
Strontium	4,500	1,125	56,000
Tin	15,000	3,750	180,000
Organic tin	0.9	0.2	12
Zinc	3,750	938	46,000

Appendix 2. Analysis results

This appendix contains the detailed analysis results described in section 7.5 ”Analysis results for initial analyses”

Appendix 2.1 Analysis results for content of selected preservatives

In the two tables below, the results for the quantitative content of the preservatives dehydroacetic acid, potassium sorbate, sodium benzoate and phenoxyethanol (TABLE 34), as well as selected parabens (TABLE 35) are listed. For description of the analysis methods, see section 7.3 ”Procedure for quantitative determination of selected preservatives”.

It should be noticed that only 24 of the 27 products were analysed for these preservatives, as the remaining 3 products (DK 3, DK 6 and DK 9) did not contain these preservatives according to the producer.

TABLE 34. Results regarding content of selected preservatives in 24 of the 27 slime toy products. Results are presented in weight percentage.

Slime no.	Dehydroacetic acid (% w/w)	Potassium sorbate (% w/w)	Sodium benzoate (% w/w)	Phenoxyethanol (% w/w)
N-EU 2	-	-	-	-
N-EU 3	-	-	-	-
N-EU 4	-	-	-	-
N-EU 6	-	-	-	-
N-EU 7	-	-	-	0.29
N-EU 8	-	-	-	-
N-EU 9	-	-	-	-
N-EU 10	-	-	-	-
N-EU 11	-	-	-	-
EU 1	-	-	-	0.65
EU 2	-	-	-	-
EU 3	-	-	-	-
EU 4	0.09	-	0.12	-
EU 5	-	-	-	-
DK 1	-	-	0.16	-
DK 2	-	-	-	-
DK 4	-	-	-	0.27
DK 5	-	-	-	-
DK 7	-	-	-	0.27
DK 8	-	-	-	0.54
DK 10	-	-	-	-
DK 11	-	-	-	0.26

Slime no.	Dehydroacetic acid (% w/w)	Potassium sorbate (% w/w)	Sodium benzoate (% w/w)	Phenoxyethanol (% w/w)
DK 12	-	-	-	0.47
DK 13	-	-	-	0.57

- means that the preservative was not identified above the quantification limit: dehydroacetic acid: 0.005% (w/w); potassium sorbate and sodium benzoate: 0.01%; phenoxyethanol: 0.004%

TABLE 35. Results regarding content of selected parabens in 24 of the 27 slime toy products. Results are presented in weight percentage.

Slime no.	Methylparaben (% w/w)	Ethylparaben (% w/w)	Propylparaben (% w/w)	Butylparaben (% w/w)	Isobutylparaben (% w/w)
N-EU 2	-	-	-	-	-
N-EU 3	0.03	-	-	-	-
N-EU 4	0.02	-	-	-	-
N-EU 6	-	-	-	-	-
N-EU 7	0.008	-	-	-	-
N-EU 8	0.04	-	-	-	-
N-EU 9	0.006	-	-	-	-
N-EU 10	-	-	-	-	-
N-EU 11	0.02	-	-	-	-
EU 1	-	-	-	-	-
EU 2	-	-	-	-	-
EU 3	0.04	-	-	-	
EU 4	-	-	0.05	-	-
EU 5	0.16	-	-	-	-
DK 1	0.01	-	0.07	-	-
DK 2	0.05	-	-	-	-
DK 4	0.03	0.01	0.02	-	-
DK 5	0.03	-	-	-	-
DK 7	-	-	-	-	-
DK 8	-	-	-	-	-
DK 10	0.07	-	-	-	-
DK 11	-	-	-	-	-
DK 12	-	-	-	-	-
DK 13	-	-	-	-	-

- means that the preservative has not been identified above the quantification level: methylparaben and ethylparaben: 0.0015% (w/w); propylparaben, butylparaben and isobutylparaben: 0.002%

Appendix 3. De-waxing and EN 71-3

In this appendix, the detailed analysis results for migration of boron according to EN 71-3 – with and without dewaxing, are presented. It should be noticed that the analyses without de-waxing only have been carried out as single determinations, and that the analyses with de-waxing have been carried out as duplicate determinations. This is because all results with de-waxing were higher than without de-waxing.

The results show that there is a variation in the difference between the two results of between 0.3 and 23%, with an average deviation of 7.8%. The highest deviations can be found for the lowest results of migration of boron. Only for six products, the deviation is higher than 10% between the results with and without de-waxing. In general, the deviation between the two analyses (with and without de-waxing) is below the general analysis uncertainty of 20%.

TABLE 36. Difference in migration of boron according to EN 71-3 – with/without de-waxing

Slime toy no.	Results with de-waxing (mg/kg)	Results without de-waxing (mg/kg)	Deviation (%)
N-EU 2	365	314	15.0
N-EU 3	575	523	9.5
N-EU 4	500	439	13.0
N-EU 6	4020	3697	8.4
N-EU 7	4370	4287	1.9
N-EU 8	615	583	5.3
N-EU 9	1180	1119	5.3
N-EU 10	717	701	2.3
N-EU 11	856	806	6.0
EU 1	348	306	12.8
EU 2	217	209	3.8
EU 3	804	802	0.3
EU 4	118	109	7.9
EU 5	884	781	12.4
DK 1	150	119	23.1
DK 2	228	214	6.3
DK 3	389	350	10.6
DK 4	242	227	6.4
DK 5	623	621	0.3
DK 6	224	201	10.8
DK 7	200	196	2.0
DK 8	202	195	3.5
DK 9	151	122	21.3
DK 10	635	607	4.5
DK 11	206	198	4.0

Slime toy no.	Results with de-waxing (mg/kg)	Results without de-waxing (mg/kg)	Deviation (%)
DK 12	210	201	4.4
DK 13	244	222	9.4

Appendix 4. QRA method

This appendix describes the calculations behind the QRA (quantitative risk assessment) method, used in calculation of the quantitative risk assessment for sensitisation. As stated in the report, this method is not recognised by the SCCS or another scientific committee because it is subject to uncertainties. Ezendam et al. (2018) has accepted the SCCS criticism and released a publication accounting for some of the SCCS criticism. However, the SCCS has yet to publish an opinion recognising that the method has developed sufficiently to warrant recognition.

The QRA method is nonetheless discussed in this report. This is done for the purpose of obtaining knowledge regarding the risk of sensitisation using a quantitative approach, as well as to compare these results with other available knowledge.

Appendix 4.1 Method for quantitative risk assessment for sensitisation (QRA)

The QRA method, as described by Ezendam et al. (2018), is a method developed for quantitative assessment of the risk of sensitisation. Therefore, the method deals exclusively with the risk of development of an allergy towards allergenic substances, and it cannot be used for elicitation; that is, once a person has already developed an allergy.

The method is a refinement of the original QRA method (developed for fragrances) by Api et al. (2008), and the SCCS has commented on the method numerous times, most recently in 2017 (SCCS, 2018). Among other things, the SCCS concludes that the method has developed significantly, but that it still requires further development, particularly including a description of the uncertainties of the method, before it can be recognised for the assessment of substances other than fragrances in cosmetic products.

Ezendam et al. (2018) describes how the QRA method can be adapted to the use of MI in consumer products. In this article (Ezendam et al., 2018), the authors have accepted a number of the critical points regarding such aspects as the magnitude of the safety factors, and the authors perform calculations for consumers' combined exposure to MI from both cosmetic products and cleansers. However, exposure to MI from paint products is not included.

The method of calculation is given by the formula below, beginning with an estimate of the acceptable exposure level:

$$AEL = \frac{NESIL}{SAF}$$

where

AEL	is the acceptable exposure level	measured in µg/cm^2
NESIL	is the value at which sensitisation is not expected (no expected sensitisation induction level)	measured in µg/cm^2
SAF	is the combined safety factor (safety assessment factors)	-

Thereafter, exposure to the allergenic substance per unit skin area (DL) is calculated using the formula below:

$$DL = \frac{q \times EF \times C}{A_{hud}}$$

where

DL	is the quantity of allergenic substance on the skin per unit surface area (dermal load)	measured in µg/cm^2
q	is the quantity of the product used	measured in µg
EF	is the exposure fraction, which is identical to the retention factor used for cosmetic products; i.e., 1 for leave-on products	-
C	is the concentration of the allergenic substance in the product	measured in µg/g
A_{skin}	is the exposed skin area	measured in cm^2

$$Risk\ of\ sensibilisation\ if\ DL > AEL$$

To evaluate whether or not a risk exists, the acceptable exposure level (AEL) is compared with the quantity of the allergenic substance per unit skin area (DL) to which consumers are exposed. If the DL is greater than the AEL, then there is a risk that consumers may develop an allergy towards the substance.

In the description of the method, it is emphasised that the total exposure to the substance should be evaluated for all exposures. That is, it is important to account for all sources in this assessment. For the preservatives chosen, at a minimum, these sources are toys and cosmetic products, since children are not expected to use cleansers or interior paints. All types of toys that may contain isothiazolinones as preservatives must be accounted for; these are primarily chemical toys.

In the QRA method described, the total exposure (DL) is thus calculated as the sum of the exposure per unit skin area for each product the consumer is exposed to. In the article by Ezendam et al. (2018), complicated calculations are performed to account for the typical concentration of the preservative MI in different types of products, how often the products are used, what quantities the products are used in per day, and how many of these product types typically contain the preservative. The final parameter is used to calculate the probability of consumers being exposed to the preservative, thus making it possible to calculate the distribution of the total exposure for different percentiles of the population. It should be noted that Ezendam et al. (2018) focuses on exposure of adults; that is, calculations only involve exposure to MI from cleansers and cosmetic products, not toys. In the article, Ezendam et al. (2018) calculates the total exposure to MI both before and after MI was regulated in cosmetic products, since the total exposure to MI has fallen as a result of its regulation in cosmetic products.

Appendix 4.2 Establishing the NESIL for MI

The NESIL and safety factors (SAF) must be established in order to perform a quantitative risk assessment for sensitisation for MI in slime toys. The process here is based on Ezendam et al. (2018), in which safety factors are discussed and established, while the assessment is based on the paper on quantitative risk assessment for slime toys for sensitisation and elicitation produced by Charlotte B. Madsen from the National Food Institute at DTU (given as Appendix 5). The paper describes which EC3[24] value should be used to establish the NESIL for MI (the lowest EC3 value in SCCS (2015)). The lower the EC3 value, the more potent an allergen a substance is.

[24]The EC3 value is the concentration of the tested substance sufficient to produce a threefold increase in cell activity compared with a control; that is, a sufficient immunological reaction related to sensitisation (ECHA, 2017)

The acceptable exposure level (AEL) for MI is calculated as **0.22 µg/cm^2** as given in Appendix 5.

Here, it should be added that Ezendam et al. (2018) has accounted for the SCCS criticism of the QRA method, described in SCCS (2018b) regarding the addition of an extra SAF for interspecies variation with a minimum value of 3. In this case, Ezendam et al. (2018) uses an SAF of 15.

If we were to compare this with the safety factors used according to the ECHA (2012), typical factors would be 10 for interspecies differences, 10 for intraspecies differences, and 3 for exposure from sub-acute to sub-chronic. In total, this is a safety factor of 300, whereas a total safety factor of 450 is used here. However, the ECHA specifies (2012) that in some cases, the EC3 value is considered a LOAEL value, requiring an extra safety factor between 3 and 10. ECHA nonetheless indicates (2012) that there are disagreements regarding this, and that the EC3 value is considered a NOAEL value by other sources; that is, no extra safety factor is required.

Appendix 4.3 Establishing the NESIL for Kathon (CMI/MI)

The NESIL and safety factors (SAF) must be established in order to perform a quantitative risk assessment for sensitisation for Kathon in slime toys. As a starting point, we use the method described in Ezendam et al. (2018) and the paper presented as Appendix 5.

The acceptable exposure level (AEL) for Kathon is calculated as **0.0028 µg/cm^2** as given in Appendix 5.

Towle et al. (2018) performed a quantitative risk assessment for Kathon for individual cosmetic products; that is, it is neither additive nor as advanced as the QRA method presented by Ezendam et al. (2018). Towle et al. (2018) established a NESIL of 0.83 µg/cm^2 based on weight-of-evidence data from HRIPT (Human Repeat Insult Patch Test) testing, though the SCCS (2018) does not recommend the use of the HRIPT for ethical reasons. Towle et al. (2018) used different SAF values for different types of cosmetic products, ranging from 100 to 300 depending on skin condition considerations. Using the highest SAF, the AEL can be calculated as 0.83 µg/cm^2 / 300 = 0.0028 µg/cm^2, which is the same AEL as was calculated using LLNA data as a starting point for the QRA method.

Appendix 5. Memorandum from DTU

This appendix contains the memorandum that Charlotte B. Madsen from the Danish National Food Institute has prepared regarding sensitisation and elicitation in this project about slime toys. In the risk assessment of MI and Kathon, this memorandum has been used as the underlying basis material.

Please notice that the memorandum was prepared in Danish, and the text on the next pages is a translation into English. Details may have been lost in translation.

Memorandum

Concerning: **Sensitisation, slime toys – quantitative risk assessment Elicitation**

From: Charlotte B. Madsen

29. oktober 2019

Introduction

The perfuming industry has developed a method in several iteration to predict the sensitising properties of fragrances. The method has been discussed by SCCS, which has had both positive and negative comments; recently presented in an opinion from 2018, where it is mentioned that the method also in the long term can be used for other substances than fragrances. RIVM has accepted the challenge and prepared a quantitative risk assessment for methylisothiazolinone (MI). They have developed a probabilistic method for exposure that includes (almost) all exposure scenarios and a hazard assessment that accounts for the criticism raised in the SCCS opinion (Ezendam 2018). Janine Ezendam has been rapporteur on the SCCS opinion.

Terminology

A special terminology is used in this area:
No Expected Sensitisation Induction Level (NESIL) is the point of departure (PoD) in the assessment. This is the dermal load in µg/cm^2, where no sensitisation is expected. Either a NOEL from a Human Repeated Insult Patch Test (HRIPT) or EC2 from a Local Lymph Node Assay (LLNA) is converted to µg/cm^2.
Acceptable Exposure Level (AEL) is calculated by dividing the NESIL by the total Sensitisation Assessment Factors (SAF). SAF is used to account for the difference between experimental exposures and exposures in the real world.
Afterwards, AEL can be compared with the Consumer Exposure Level (CEL). This value should include all exposure for the substance and is calculated as a daily exposure in µg/cm^2.

AEL for methylisothiazolinone (MI) as described in Ezendam (2018)

NESIL is based on EC3 from a LLNA of 0.4%, which is converted to a dose per area through multiplication by 250. This result is a NESIL value for MI of 100 µg/cm^2.
Data from HRIPT is not used, as these are not applicable according to SCCS.

Sensitisation Assessment Factors (SAF)
SAF = 10 for inter-individual variation
SAF = 15 for inter-species variation
SAF = 3 for exposure frequency (daily exposure)
Total SAF = 450

AEL = NESIL/SAF = 100 µg/cm^2/450 = **0.22 µg/cm^2**

AEL for chloromethylisothiazolinone/methylisothiazolinone (CMI/MI) (75%+25%) ad modum Ezendam (2018)

In the SCCS opinion on CMI/MI, data from two LLNA tests is listed. These tests result in an EC3 value of 0.75 µg/cm^2 (30 ppm) and 1.75 µg/cm^2 (70 ppm). The (apparently) same studies

can be found in the registration dossier of ECHA. In documents where CMI/MI are used for validation of LLNA, the EC3 value is listed to be 0.009% (90 ppm) corresponding to 2.25 µg/cm^2. By review of additional literature, I found a study where CMI/MI is tested in different vehicles. The lowest EC3 value of 50 ppm is found by AAO, which is the recommended vehicle (Warbrick et al 1999, Gerberick et al 2004). As this study has the most convincing dose-response, this study is used below.

NESIL is based on EC3 from a LLNA of 50 ppm = 0.005% = 1.25 µg/cm^2.

Sensitisation Assessment Factors (SAF)
SAF = 10 for inter-individual variation
SAF = 15 for inter-species variation
SAF = 3 for exposure frequency (daily exposure)
Total SAF = 450

AEL based on LLNA data: AEL = NESIL/SAF = 1.25 µg/cm^2/450 = 0.0028 µg/cm^2 = **0.003 µg/cm^2**

Subsequently, I found a study by Towle et al. (2018) who has prepared a quantitative risk assessment of CMI/MI based on human HRIPT test. Towle carries out a less advance estimation of the exposure compared to Ezendam and prepares a hazard assessment for each product type.

AEL based on human data: NESIL is set at 0.83 µg/cm^2 for a MCI/MI 3:1 mixture based on weight-of-evidence data from Human Repeat Insult Patch Test (HRIPT). In this study, SAF is listed between 100 and 300 based on considerations about skin conditions. SAF for a face cream is listed as 100, but as 300 for a body lotion (Towle et al 2018). If the high SAF is used, AEL is calculated as:
AEL = 0.83 µg/cm^2/300 = 0.0028 µg/cm^2 = **0.003 µg/cm^2**

Elicitation
The other aspect of contact allergy is elicitation, i.e. the concentration of allergen that can trigger an allergic reaction in an individual previously sensitised. Generally, it is assumed that a larger dose per area is needed to sensitise than to elicit a reaction. However, it is important to emphasise that the elicitation dose depends on the underlying sensibilization e.g. the sensitising dose and the frequency of the exposure.

In standard patch tests, the concentration used is the concentration that is assumed to give the clearest picture of an individual is sensitised. This means that such data cannot be used to conclude anything about dose-response relationship. This requires special studies that particularly investigate dose-response.

Methylizothiazolinone (MI)
In a Danish study (Lundov et al 2011), a Repeated Open Application Test (ROAT) was conducted where 7 persons with MI allergy were applied 20 µl of a solution of MI on four areas of the underarm twice per day for 21 days. When converted to concentration per area, the doses were 0.21, 0.105 and 0.0105 µg MI/cm^2 per application, i.e. 0.42, 0.21 and 0.021 µg MI/cm^2 per day. All 7 individuals reacted to the top two dosages and 2 individuals also reacted to the lowest dosage. It is not stated, how many days it took before the reactions showed. The solution also contained phenoxyethanol, but this does not influence the reaction to MI. This was illustrated by a patch test in the same study.
LOAEL of this study is 0.021 µg MI/cm^2 per day (for an unknown number of days < 21 days) and there is no NOAEL.

No other dose-response studies concerning elicitation with MI was identified than the above-mentioned.

Chloromethylizothiazolinon/methylizothiazolinone (CMI/MI)
In a former Danish ROAT study from the same group, individuals with contact allergy towards CMI/MI were exposed twice a day to 0.0125 µg/cm^2, i.e. in total 0.025 µg/cm^2/day (2 ppm) for 4 weeks. 7 of 25 individuals with contact allergy reacted towards the daily application of CMI/MI. In average the reaction appeared after 16.4 days.
LOAEL of this study is 0.025 µg CMI/MI/cm^2 per day and there is not NOAEL.

The authors concluded that on the basis of the study, it is not possible to determine a definite limit for elicitation, but the limit is close to 0.025 µg/cm^2 (Zachariae et al. 2006).
It was not possible to identify other studies.

Sensitisation vs elicitation
MI
The quantitative risk assessment of sensitisation for MI predicts that 0.22 µg MI/cm^2 can sensitise. This dosage is 10 times higher than LOAEL for elicitation in humans with contact allergy towards MI of 0.021 µg MI/cm^2 per day. This is consistent with the usual assumption that larger amounts are needed to sensitise than to trigger an allergic reaction (Friedmann 2007).

CMI/MI
For CMI/MI, it can be seen, that the quantitative risk assessment for sensitisation gives the same result based on either data from mouse (LLNA) or data from humans (HRIPT); 0.003 µg/cm^2.

LOAEL for elicitation in humans with contact allergy towards CMI/MI is 0.025 µg/cm^2 and hence close to a factor of 10 higher than the dosage predicted to be sensitising by the quantitative risk assessment. This indicates that the quantitative risk assessment of CMI/MI does not underestimate the risk of sensitisation.

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Appendix 6. Quantity of slime on hands after play

When children are finished playing with slime and put it down, a certain quantity of the aqueous base of the slime will remain on the hands. The hands may feel slightly damp, but they will dry relatively quickly. Therefore, it cannot be expected that children will necessarily wash their hands after playing with slime.

No standards exist regarding how much slime remains on the skin after children have played with slime toys. It is clear, that the amount remaining on a child's hands after play will not be large, regardless of whether a small tub of perhaps 80 g of slime (corresponding to one handful for a child) or a large tub containing 1.5 kg of slime is played with. The slime is, of course, intended to be put back in the tub until the next time it is played with. A small amount of slime will remain on the skin (primarily hands and forearms) after play, available for skin uptake.

To obtain a measure of the quantity of slime that remains on the hands after play, a small weighing experiment was performed in this project using three kinds of slime. A lump of slime (weighing from 75 to 250 g) was placed in an adult's hands, and the slime was kneaded for about 30 to 60 seconds. The slime was weighed both before and after, and the difference was used as a measure of the amount remaining on the hands. The hands feel moist after the slime is put down, so some amount of the aqueous base of the slime remains on the hands after play. The results were as follows for the three types of slime:

1. Between 0.27 and 0.55 g of slime disappeared (based on 10 trials; mean 0.37 g)
2. Between 0.23 and 0.43 g of slime disappeared (based on 10 trials; mean 0.32 g)
3. 3.9 g of slime disappeared (based on a single trial in which only the fingers were dipped in the slime). However, this slime was stickier than any of the other slime toys purchased, such that a large amount sticks to fingers. We expect that children would have to immediately wipe the slime off or wash it away immediately after, so the use of such a large amount of slime available for skin contact is not realistic.

Variations in the quantities that disappeared, i.e. remains that were left on the skin, appear to depend primarily on how much the slime is kneaded between the fingers. However, it is not unlikely that the disappearing quantity is also the result of evaporation. How much of this quantity is due to evaporation was not studied. If the disappearing quantity is due to evaporation, this means that the disappearing quantity is accessible for skin uptake as a worst case.

The experiment above was based on adult hands, but children will likely use both their hands and a portion of their forearms when playing. This experiment was also based on play lasting for half a minute to one minute, while children play with slime for longer periods of time. It is unknown whether the quantity of slime that "disappears" during play would be significantly higher if the same experiment were performed for an hour, which is the presumed worst-case daily duration of play for children playing with slime.

In the case of slime toy EU 1, which is a thin, liquid slime for use in a slime gun, worst-case situations would involve a completely different quantity of slime remaining on the body and available for skin uptake. The skin surface area that is hit is significantly larger; however, the slime

sticks together in clumps when it is fired and will fall directly to the ground when one is struck by the slime.

Appendix 7. RCR values for phenoxyethanol

In this appendix, the calculated RCR-values for the single concentrations of phenoxyethanol measured by chemical analyses are presented.

TABLE 37. Calculated RCR values for phenoxyethanol for the analysed products with a content of this preservative. In this table, use of the French DNEL value has been indicated with a green background colour and use of the DNEL value from SCCS has been indicated with a white background colour.

Product no.	Concentration of phenoxyethanol (% w/w)	Used DNEL value	Comment	Calculated sum of RCR value
N-EU 7	0.29	7.14	Only dermal exposure	0.05
		0.82	Dermal and oral exposure	0.48
EU 1 (slime for slime gun)	0.65	7.14	Only dermal exposure	0.12
		0.82	Dermal and oral exposure	1.74
DK 4	0.27	7.14	Only dermal exposure	0.05
		0.82	Dermal and oral exposure	0.44
DK 7	0.27	7.14	Only dermal exposure	0.05
		0.82	Dermal and oral exposure	0.44
DK 8	0.54	7.14	Only dermal exposure	0.10
		0.82	Dermal and oral exposure	0.89
DK 11	0.26	7.14	Only dermal exposure	0.05
		0.82	Dermal and oral exposure	0.43
DK 12	0.47	7.14	Only dermal exposure	0.09
		0.82	Dermal and oral exposure	0.77
DK 13	0.57	7.14	Only dermal exposure	0.11
		0.82	Dermal and oral exposure	0.97

Survey and risk assessment of slime toys
The purpose of this project was to investigate the content and migration of chemical substances from slime toys marketed to children over three years of age.

The survey in this project focused on the content of preservatives not regulated in slime toys marketed to children over three years of age. Compliance with regulations regarding the migration of boron and other elements from the slime toys studied was also tested. In addition, the toy sector industry were questioned regarding the use of fragrances in slime; however, because relatively few slime toys (particularly those marketed in Denmark and the EU) were marketed as scented, and due to the analytical challenges posed by fragrances, it was decided to focus on preservatives.

A total of 27 individual slime toy products were purchased, and analyzed amongst other for boron, phenoxyethanol, isothiazolinones (MI, CMI and BIT) and parabens.

The inspection part of the project identified boron migration levels between 116 and 4275 mg/kg in all 27 of the slime products studied. For comparison, the limit value is 300 mg/kg. 13 of the 27 slime products studied did not comply with legislation, with a distribution of eight out of the nine products purchased outside the EU, one of the four products purchased within the EU (excluding Denmark), and four of the 14 products purchased in Denmark. Apart from two additional prod-ucts, these are the same products considered to constitute a risk due to their MI and/or Kathon content. The results clearly show that more products purchased outside the EU may pose a health risk than products purchased within the EU.

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