DANISH MINISTRY
OF THE ENVIRONMENT
Environmental
Protection Agency

Mapping of perfume in toys and children's articles

Dorte Glensvig
COWI A/S

Jane Ports
Eurofins Denmark A/S

Survey of Chemical Substances in Consumer Products, **No. 68** 2006

The Danish Environmental Protection Agency will, when opportunity offers, publish reports and contributions relating to environmental research and development projects financed via the Danish EPA.

Please note that publication does not signify that the contents of the reports necessarily reflect the views of the Danish EPA.

The reports are, however, published because the Danish EPA finds that the studies represent a valuable contribution to the debate on environmental policy in Denmark.

Contents

Preface

The project is forming part of a large investigation of various consumer products with the title "Mapping of chemical substances in consumer products".

The investigations were initiated in order to map the area and to shed light on people's exposure to chemical substances in consumer products and the risk involved.

The project has been carried out by a cross-functional team consisting of employees from COWI A/S and Eurofins Denmark A/S. These employees are as follows:

- COWI A/S: Dorte Glensvig, Anne Abildgaard, Christian Buck, Susanne Guldberg, Anne Rathmann Pedersen and Frank Stuer-Lauridsen
- Eurofins Denmark A/S: Jane Pors and Peter Mortensen

The success of the project has been dependent on information from a number of distributors, importers and producers of toys and children's articles containing flavour and fragrance. Special thanks to everybody who filled in the questionnaire and provided us with product information and samples.

The primary target group of the project is the Danish Environmental Protection Agency, producers and private consumers of toys and children's articles with flavour and fragrance.

The project report is also available in Danish.

Summary and conclusions

This consumer project deals with toys and children's articles containing scent for children aged 0 -10 years on the Danish market. The project elucidates the content of sensitizing fragrances as well as the content and emission of other chemical substances.

Toys and children's articles containing fragrances

In the project, a mapping of the market for toys and children's articles with fragrances has been carried out.

A number of toy products containing fragrances are available on the Danish market. The products cover a wide range of different play activities and target both small children under three years and older children.

Fragrances can be added to toys to differentiate the products from other similar products or the substances can be added to camouflage undesirable odour from the product. However, there are also examples of toys for children older than 5 years where bad smelling substances have been added to the products intentionally. In this case, the possibility of exposing people to the unpleasant smell constitutes the primary function of the toys.

Furthermore, the general trend is that fragrances are added to products of any kind in order that they become more attractive.

There are many fragrances and other substances with a natural low odour threshold that can be added to a product to obtain a scent effect.

The market changes all the time as new trends develop within the field of toys and children's articles. This means that there may be several other products on the market that have not been identified and that some of the already identified products no longer exist in a version with scent.

The market for toys and children's articles containing scent has been mapped via contact to retailers, suppliers and importers of toys and children's articles. The mapping has identified 15 product types in total where the scent is forming part of the marketing of the product. The 15 product types represent 68 different products containing scent on the market for children, as most of the product types represent the same product in several different scent variants, for instance erasers with different types of scents.

It has not been possible to provide data that elucidate the size of the market for toys and children's articles containing scent.

10 of the 15 identified product types were selected for laboratory analyses. The selection was made on the basis of preliminary, qualitative screenings for ingredient substances. The selection was made on the basis of the following criteria:

- The products have a declared content of one of the sensitizing substances on the EU list.
- The screening analysis has revealed content of one of the substances.
- The product has a strong odour/scent.
- The product is intended for babies.
- Use of the product involves a special risk of exposure (for instance soft toys, soap bubbles, fragrant rubber figures).
- The screening has demonstrated a content of a large number of substances.

Content of sensitizing fragrances in selected products

The 10 selected products were analyzed for content of the 24 substances on the EU list of sensitizing fragrances and two additional fragrances; oakmoss and treemoss. Oakmoss and treemoss have not been detected in any of the products.

The analysis of content of sensitizing fragrances has illustrated that 18 of the 24 sensitizing fragrances on the EU list occur in 7 of the selected 10 products. Each of the products contains between 2 and 9 of the 24 sensitizing fragrances.

Two of the four selected products for babies contained sensitizing fragrances.

The analysis shows that there is a large risk that children are exposed to sensitizing fragrances when using toys or children's articles containing scent.

Other ingredient substances in selected products

The selected products have been analyzed for content of other organic components. The analyses demonstrate a content of a large number of fragrances besides the sensitizing fragrances and organic solvents.

The analysis of ingredient substances has been used to select products for test for migration of chemical substances to sweat and test for emission. The test results have been applied to evaluate the exposure of children when playing with the products.

Four products intended for children below the age of three years have been analyzed for migration to sweat. The analyses show that all four products may liberate chemical substances to sweat. The concentration of the liberated substances is low for three of the products. One of the products liberates a substance of the type flame retardant in a relatively large concentration.

7 of the products have been tested with regard to emission of volatile organic components. The test shows that the products liberate many volatile organic components. These are fragrances and organic solvents.

Moreover, an analysis of ingredient substances has revealed a high content of phthalates in one of the products for children below the age of three years. The product has been withdrawn from the market by the distributor.

Exposure of the users to other chemical substances

To determine the exposure of users, in this case children below the age of 10 years, scenarios have been prepared for skin absorption and inhalation.

The exposure scenarios for skin absorption show that there is a risk of health effects due to skin absorption of tri(2-chloroethyl)phosphate that is probably added as flame retardant to one of the tested products. The substance can be absorbed in concentrations above the lower impact limit in relation to cancer-causing effects. The substance can be released from toy products intended for babies. It is assessed that the substance is not necessary in the type of product in question. The product has been withdrawn from the market by the distributor.

One substance, ethylbenzene, can occur in a concentration close to the lower impact limit for the substance at inhalation. Release of the substance has only been demonstrated from one product in a concentration that may be harmful. The product has been withdrawn from the market by the distributor.

Playing with the selected products may lead to exposure to many volatile organic components. However, the single substances occur in relatively low concentrations in the inhaled air of the child. The concentration is for most of the tested substances far below the relevant limits for mucosal irritation and other health impacts. This also prevails when the child plays with more products at the same time.

However, it should be noted that the combination effects from the substances are unknown.

Recommendations

In summary, the results of the investigation lead to a number of recommendations to the consumers, producers, suppliers and importers of toys and children's articles containing fragrance and flavour.

Recommendations to consumers:

- Buy toys without fragrances.
- Unpack the product some time before use, if it has an odour, it should be placed in a ventilated area before given to the child for play
- When a toy is bought for children under the age of three, it should be labelled "for children less than 3 years".

Recommendations to producers, suppliers and importers of toys and children's articles:

- Avoid the use of flame retardants in toys in case there is no real risk that the product catches fire, and/or make demands on sub-suppliers that the products are not containing any flame retardants.
- Minimize the use of volatile organic substances in toys and children's articles.

1 Background and objective

1.1 Background

The Danish Environmental Protection Agency has initiated a number of projects in order to have the content of chemicals mapped in a range of ordinary consumer products. One of these projects deals with fragrances and flavouring agents in toys and children's articles.

Today, fragrances are added to a lot of products like cosmetics, soap products, washing and cleaning products, toys and school articles such as speed markers, erasers, pencils, etc. (the National Allergy Research Centre 2004a, the Danish Environmental Protection Agency 2001, the Danish Environmental Protection Agency 2002 a, the Danish Environmental Protection Agency 2003, Environment & Health 2004). In this way, perfume has become a more essential part of children's everyday life than earlier.

By playing with toys containing perfume and flavouring agents, there is a risk that the consumers, especially children, are affected by the perfume and fragrances in the toys - either via skin absorption, inhalation or by ingestion of the substances via the saliva.

Children are generally more sensitive to chemicals than adults (the Danish Environmental Protection Agency 2001, Environment & Health 2004). In recent years, the number of children with perfume allergy has increased heavily (the Danish Asthma and Allergy Association 2004a, the National Allergy Research Centre 2004a). One of the reasons for that is children's intensified contact with perfume and fragrances (Iversen et al. 2000, the National Allergy Research Centre, 2004a).

This project deals with fragrances and flavouring agents added to toys and children's articles. The report comprises toys and children's articles to which fragrances or flavouring agents have been added to give the product a certain scent that is used in the marketing of the product.

Products containing perfume with the purpose of hiding unwanted odour from other ingredients in the product are not included in the present project. Neither are theatre make-up and ordinary make-up, including chap sticks, lip glosses and perfumes. The same applies to hygiene products like washing, skin and hair care products, nappies, towelettes, etc. Focus is on products intended for children aged 0-10 years.

As the preliminary inquiries to distributors of toys and children's products showed that the market for these products containing flavouring agents was very limited, it was agreed with the Danish Environmental Protection Agency to focus on fragrances.

1.2 Objective

The objective of the project is to create an overview of how widespread the use of perfume and fragrances in toys, babies' articles and other products for children is, and on the basis of analyses and test results to assess the health problems the substances can cause to children.

2 Contents of the project

This report presents an introduction to allergy and sensitivity in chapter 3, and chapter 4 gives an introduction to fragrances.

The project consists of 3 phases with the following overall content:

Phase 1: Preparation of a list of products containing fragrances and which are intended for children aged 0-10 years

Through contact to distributors, suppliers and importers and via Internet searches, a screening of the market for products containing perfume has been carried out (chapter 5).

Based on the results from the first phase, 18 products have been selected for a qualitative GC-MS screening analysis.

Phase 2: Introductory investigations of perfume substances

In phase 2, a qualitative GC-MS screening analysis was carried out with primary focus on fragrances. This screening forms the basis for the selection of 10 of the 18 products for the tests in phase 3 (chapter 6).

Phase 3: Quantitative and semi-quantitative analyses and exposure tests

In phase 3, tests and quantitative accredited analyses of the content of perfume substances on the EU list of sensitizing substances and other environmentally alien substances were carried out.

The tests comprise both content analyses and migration/emission tests (chapter 7).

Phase 4: Exposure scenarios and assessment of health conditions

Chapter 8 sums up the data for evaluation of health conditions when using the products. These data are used in chapter 9 for an evaluation of any health problems when playing with the tested products. Realistic worst-case scenarios have been prepared for children's exposure to selected ingredient substances in the analyzed products and the results have been compared with the present NOAEL values or estimates hereof.

In chapter 10, the results of the project are discussed and recommendations are made on precautions for the consumers to take when using toys and children's articles that contain perfume.

3 Allergy and sensitivity

Use of perfume substances in products for children constitutes a risk for development of sensitivity or allergic deceases by skin contact. The fragrances investigated in this project, are by the scientific committee for cosmetics assessed to be causing allergy by skin contact. Inhaling of the fragrances can cause respiratory irritation and nuisances. In the following, the terms sensitivity and allergy are described in brief.

3.1 Types of sensitivity reactions

Often the term allergy is used for the various types of sensitivity reactions. Medically, a distinction is made between the following reactions:

- Allergy
- Other sensitivity

Allergy is the reaction where an allergy-provoking substance affects the immune system of the body that overreacts and presents symptoms like reddening, itching, swelling or blistering (Allergy-Encyclopaedia 2004 a).

An allergy-provoking substance is called an allergen. An allergen can for instance be pollen, droppings of house dust mites, animal hair, metals (nickel, chrome, etc.) or certain chemicals, for instance colouring agents, flavouring agents, perfume substances and organic solvents. When the body is exposed to an allergen, the immune system is affected and IgE anti-substances are produced (Immunoglobulin E-anti-substances). This process is called sensitization and repeated contact with the allergen can lead to development of allergic symptoms (Allergy-Encyclopaedia 2004 b and c, the Danish Asthma and Allergy Association 2004 a, Smith & Hotchkiss, 2001).

Dependent on where in the body the allergens and anti-substances meet, various allergic deceases may be provoked: Asthma is triggered by reaction in the lungs, hay fever is provoked by reaction in the nose and urticaria by reaction on the skin (Allergy-Encyclopaedia 2004 a).

Other sensitivity includes all sensitivity reactions not followed by a reaction from the immune system. The sensitivity-provoking substance is thus the direct reason for the symptoms, whereas, in connection with allergy, it is the reaction of the substance together with IgE-anti-substances in the body that causes the symptoms (Allergy-Encyclopaedia 2004 d).

The symptoms of the two conditions are homogenous (Allergy-Encyclopaedia 2004 d).

It is characteristic for both allergy and sensitivity that the symptoms are provoked by substances that do not result in any dysfunction of healthy persons or by substances that are not harmful in themselves. (Iversen et al. 2000, Smith & Hotchkiss, 2001).

Investigations made by Johansen (2002) show that the period of time a fragrance allergen is tolerated by sensitized persons is increased when the concentration of the allergen is lowered. Exposure to several allergens at the same time can cause synergetic effect.

Contact allergy is a special form of allergy. The allergy is triggered by prolonged, direct contact with an allergen. The reaction is also called allergic contact eczema. Allergic contact eczema occurs at the place of contact as an inflammatory condition of the skin (Allergy-Encyclopaedia 2004 g).

The allergy type contact allergy differs from the other forms of allergy by being permanent, non-hereditary and without almost any hereditary tendency (Allergy-Encyclopaedia 2004 g). Contact allergy can be prevented by avoiding contact with allergy-provoking substances (the Danish Asthma and Allergy Association 2004 b, Iversen 2000).

3.2 Spread of allergy and sensitivity in Denmark

Allergy and sensitivity are widely spread in the Danish population. It is estimated that approximately 25 per cent of a birth cohort at one time or another in their life will experience allergy (Allergy-Encyclopaedia 2004 c).

Hay fever is the most common allergic decease. It is estimated that 10-20 per cent of the population has pollen hay fever (Allergy-Encyclopaedia 2004 e). Contact allergy and asthma are also widespread allergic deceases. It is estimated that approximately 15 per cent of the Danish population, both adults and schoolchildren, has contact allergy (Nielsen & Menné 1992, Mørtz et al. 2000), whereas 5 -10 per cent suffers from asthma (Allergy-Encyclopaedia 2004 f).

Iversen et al. (2000), Johansen (2002) and the Danish Asthma and Allergy Association (2004 b) point out that perfume is one of the most frequently reasons for contact allergy. The results of the earlier mentioned investigations by Nielsen and Menné (1992) demonstrated that about 2 per cent of the tested persons were sensitized to perfume substances.

Furthermore, several Danish investigations show that the occurrence of perfume allergy has doubled within the recent 10-15 years (National Allergy Research Centre 2004 b).

The ability of perfume substances to provoke allergy is not dependent on the substances being produced naturally or synthetically (National Allergy Research Centre 2004 a, the Danish Environmental Protection Agency 2002b).

4 Perfume and flavouring agents

4.1 Fragrances

The use of perfumes and fragrances was already described for the civilisations of ancient times. At that time, the use of perfumes was a luxury, reserved the elite of society. The perfumes were used in connection with mortuary rituals, anointments and - like today - as part of a beauty care (Frosch et al. 1998, Frosell 1982).

The perfumes of that time were produced on the basis of extracts of natural occurring substances from for instance flowers, trees, herbs and animal secretions. The development within the chemical industry - especially after the Second World War - has made it possible to produce the popular fragrances synthetically. This has lowered the price and increased the availability (Frosell 1982).

The fragrant single components of a perfume are called fragrances. The specific scents of certain perfumes are created by combining different fragrances. The number of fragrances in perfumes varies from a few to several hundred (Rastogi et al. 1994).

Perfume substances mainly consist of organic compounds that are synthetically or naturally produced (Frosell 1982).

4.2 Use of fragrances

Due to the lower price of fragrances, and thus increased availability for producers and consumers, the use of the substances has grown. Today, perfume and fragrances are used for a wide range of products that in earlier years were only available in unscented versions. This applies to toys and children's articles.

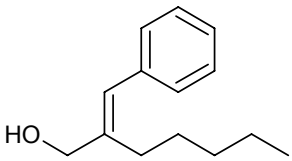
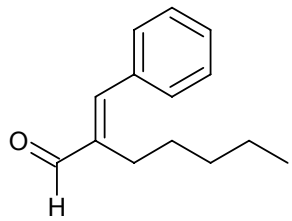
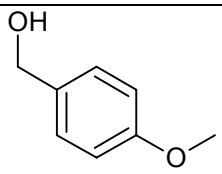
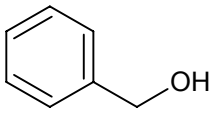
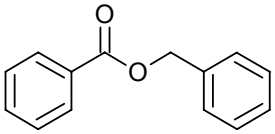
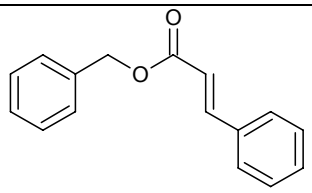
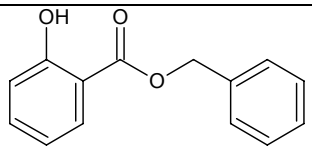
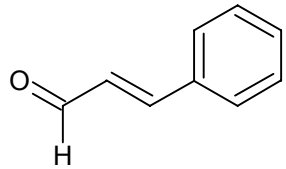
Perfumes are added to products to make them more attractive; either by giving the product a certain character or by camouflaging unpleasant odours from other ingredients in the product (Rastogi et al. 1994). There is also a tendency that fragrances are added to products for children to differentiate the products from other products of the same kind. Examples hereof are writing paper, erasers, speed markers, teddy bears, etc. to which fragrances are added to differentiate them from similar non-scented products on the market.

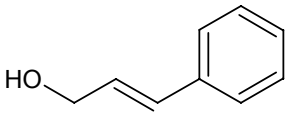
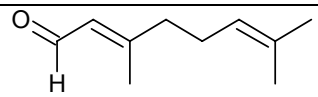
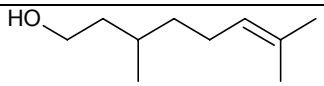
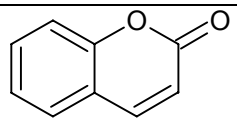
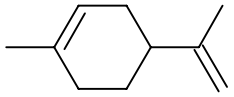
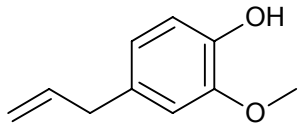
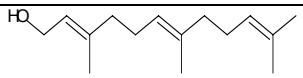
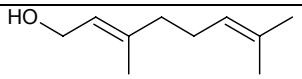
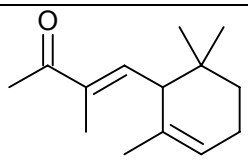
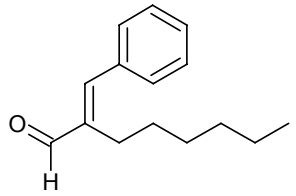
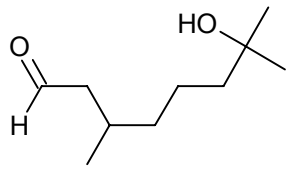
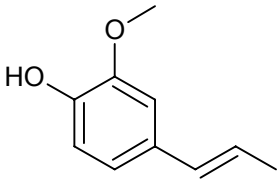
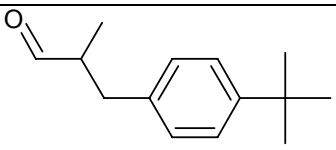
There are examples that the producers of fragrant babies' toys state in the marketing of their products that the scent contributes to stimulate the development of babies' senses when playing with the products. In extreme cases, the scent/odour of the toys constitutes the actual play function of the products. An example hereof is rubber figures which liberates a strong smell at mechanical pressure.

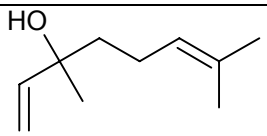
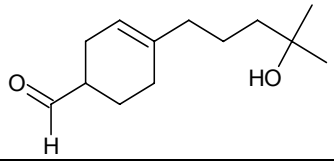
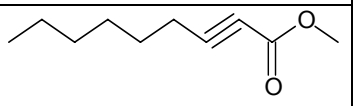
4.3 Classification of fragrances

There are several thousands of different fragrances. As some of these may provoke allergy, some authorities have chosen to focus on limiting the use of these substances to a minimum. EU's Scientific Committee on Cosmetics (SCCNFP) has classified 24 fragrances as sensitizing. These substances are listed in table 4.1 below and are in focus in this investigation.

Table 4.1: 24 substances classified as sensitizing by EU's Scientific Committee on Cosmetics (SCCNFP 1999).

Trade name	Systematic name	Scent character	Molar weight (g/mol)	CAS number	Structural formula
Amyl cinnamyl alcohol	2-(phenylmethylen)-1-heptanol	Gentle, flowerlike scent (jasmine, hyacinth) (1,2,4)	204	101-85-9	
Amyl cinnamal	2-(phenylmethylen)-1-heptanal	Flowerlike, jasmine (2,4,7)	202	122-40-7	
Anisyl alcohol	(4-methoxyphenyl) methanol	Gentle, sweet, flowerlike scent (2)	138	105-13-5	
Benzyl alcohol	Benzenmethanol	Weak, aromatic fruit scent (2)	108	100-51-6	
Benzyl benzoeat	Benzo acid phenylmethyl ester	Weak, sweet, balsamic scent (2)	212	120-51-4	
Benzyl	Benzyl-3-phenyl-2-propenoat	Sweet scent, flowers, fruit, cherry (5,9)	238	103-41-3	
Benzyl salicylate	2-hydroxybenzoesyre-benzylester	Weak, balsamic, sweet, flowerlike scent (2,4)	228	118-58-1	
Cinnamal	3-phenyl-2-propen-1-al	Strong cinnamon scent (2)	132	104-55-2	

Trade name	Systematic name	Scent character	Molar weight (g/mol)	CAS number	Structural formula
Cinnamyl alcohol	3-phenyl-2-propen-1-ol	Strong, aromatic, sweet, warm, spicy, flowerlike scent (2,7)	134	104-54-1	
Citral	3,7-dimethyl-2,6-octadienal	Strong lemon scent (3,5)	152	5392-40-5	
Citronellol	3,7-dimethyl-6-octenol	Rose (3,4)	156	106-22-9	
Coumarin	2H-1-benzopyran-2-on	New-mown hay (5)	146	91-64-5	
d-Limonen	4-isopropyl-1-methylcyclohexen	Gentle lemon scent (3)	136	5989-27-5	
Eugenol	2-methoxy-4-(propenyl)phenol	Strong, aromatic, spicy scent, geraniums, cloves (3,5). Dental clinic (7)	164	97-53-0	
Farnesol	3,7,11-trimethyldodeca-2,6,10-trienol	Flowers (6)	222	4602-84-0	
Geraniol	3,7-dimethyl-2,6-octadien-1-ol	Rose, geranium (5,7)	154	106-24-1	
g-Methylionon	3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-on	Tree/flowerlike scent (10)	206	127-51-5	
Hexyl cinnamaldehyde	2-(phenlylmethylen)-1-octanal	Gentle, flowerlike scent, jasmine (1,2)	216	101-86-0	
Hydroxycitronellal	3,7-dimethyl-7-hydroxyoctanal	Sweet, flowers, lily (2) Synthetic scent of flowers (7)	172	107-75-5	
Isoeugenol	2-methoxy-4-(1-propenyl)phenol	Geranium (7)	164	97-54-1	
Lilialò	2-methyl-4-(4-tertbytlypenyl)-butanal	Strong, fresh scent of flowers (5)	204	80-54-6	

Trade name	Systematic name	Scent character	Molar weight (g/mol)	CAS number	Structural formula
Linalool	3,7-dimethyl-1,6-octadien-3-ol	Flowers, herbs, rose tree (5)	154	78-70-6	
Lyralò	4-(4-hydroxy-4-methylphenyl) -3-cyclohexen carboxaldehyd	Sweet flowerlike scent (8)	211	31906-04-4	
Methyl heptin carbonate	Methyl-2-octenoate	Hay/straw (11)	154	111-12-6	

(1)Noweon Kalama Inc., www.biveib.com/products/kalama/acapbn.htm
(2) Joint FAO/WHO Expert Committee on food additives (JECFA) -Specifications for flavouring agents www.fao.org/es/ESN/Jecfa/database/xover.htm
(3) Joint FAO/WHO Expert Committee on food additives (JECFA) -Specifications for food additives agents www.fao.org/es/ESN/Jecfa/database/xover.htm
(4) International Flavour and Fragrance Inc., www.iff.xom/Ingredients.nst/FragIngredients!OpenForm.htm
(5) Chemical Land 21, www.chemicalland21.com, Products>Speciality Chemicals>Performance chemicals>Flavour & Fragrance Processings
(6) Physical and Theoretical Laboratory, University of Oxford
Safety (MSDS) data for farnesol, http://physchem.ox.ac.uk/MSDS/FA/farnesol.html
(7) Contact Dermatitis Clinic, Department of Dermatology, University Hospital of Wales, www.ukdermatology.co.uk/downloads/Fragrances.doc
(8) Reichstoff-Lexicon, www.omicron-online.de/cyberchem/aroinfo/lyral.htm
(9) The Good Scents Company, www.thegoodscentscompany.com/data/rw1014311.htm
(10) Bureau of Indian Standards, www.bis.org.in/sf/pcd/2252.pdf
(11) Bedoukian Research Inc., www.bedoukian.com/products/products.asp?id=483

4.4 Investigations of perfume substances in children's articles

Whereas a large number of investigations have been focussing on fragrances and perfume substances in cosmetics, creams, soaps and shampoos (Rastogi et al. 1994, Rastogi et al. 1995a, Rastogi et al. 1995b, Rastogi et al. 1998, Rastogi et al. 2001, the Danish Environmental Protection Agency 2002 b) and cleaning products and air fresheners (the Danish Environmental Protection Agency 2002 a, the Danish Environmental Protection Agency 2003), there is only a few examples in literature of investigations aimed at children's products.

Rastogi et al. (1999) has investigated the content of fragrances in cosmetics for children, skin and body care products and cosmetic toys. 25 cosmetic products for children have been tested for content of sensitizing substances, etc. The products included shampoo, cream, bath gel, eau de toilette, eau de perfume, deodorant, baby oil, chap stick, lipstick, lip gloss and a perfume mixing set (toys), etc. Nearly all the tested products contained one or more sensitizing substance(s). The lowest concentrations were found in shampoos, bath gels and lip products (typically from below 0,001-0.02 %). The concentrations of the eau de toilette, eau de perfume and deodorant were between 0.01 and 0.5 %, whereas the highest concentrations of sensitizing substances were identified in the perfume mixing set (0.4-3.7 %).

The Danish Environmental Protection Agency (2001) has made a review of children's contact with chemical substances - including perfume substances - in everyday life. The result of the investigation indicated that children to a wide extent are exposed to perfume, etc. in everyday life. The review also demonstrated that many of the product types are available in both scented and unscented versions. This applies to products like soaps, creams, shampoos, make-up, nappies and towelettes.

5 Mapping of fragrant children's articles

5.1 Sub-activities of the mapping

The mapping was divided into the following 3 activities:

- An overall mapping of the Danish market for toys and children's articles that both contain perfume and appeal to children aged 0-10 year.
- Procuring declarations, if possible.
- Estimating the size of the sale of the above products in Denmark.

The activities are described in the following.

5.2 The mapping

5.2.1 Introductory overview

An overview of products containing fragrances or flavouring agents, appealing to children aged 0-10 years and sold in Denmark, was prepared via Internet searches, distributor contact and contact to selected families with young children.

This preliminary mapping resulted in a list of approximately 15 named fragrant products for children.

5.2.2 First contact to the trade

From the list of products, addresses and telephone numbers of retailers, suppliers and importers of the products searched for were found. These distributors, suppliers and importers were subsequently contacted on the phone. It was not possible to find the telephone number of two of the distributors. These distributors were contacted via e-mail instead.

At this introductory contact, the content of the project was described and the ones contacted were asked if they would fill in a questionnaire on their range of toys and children's products containing fragrances or flavouring agents. The persons contacted were informed that the investigation did not include theatre make-up, ordinary make-up or body care products.

When the distributors, suppliers and importers were contacted, they were asked if they had any knowledge of other similar fragrant products.

In total, 23 distributors, importers and suppliers were contacted, distributed as 9 distributors and 14 importers/suppliers:

Two of the distributors represented convenience stores, three represented specialty shops for children's products and one represented trading in books and paper articles, whereas the remaining three distributors all were characterized by having a large selection of cheap products. Among the 14 importers/suppliers, 4 were specialized within books, office and writing articles, 7 were specialized within toys and children's products (2 of them within babies' products). The 3 last suppliers/importers were dealing with accessories for mobile telephony, toys sold together with sweets and mixed leisure and furniture and fittings.

5.2.3 Questionnaire and inquiries for declarations and sales figures

The questionnaire contained questions about product names, producers, importers/suppliers and the size of the sale of the products. In the covering letter of the questionnaire, the contacted persons were also asked to enclose any declarations of contents and/or safety sheets for the single products.

The questionnaire was sent to 18 distributors, importers or suppliers. Furthermore, 5 distributors, importers or suppliers were interviewed on the phone, corresponding to 23 contacts in total.

Of the 18 questionnaires, seven were duly filled in and returned.

5 of the 18 contacted distributors, importers or suppliers informed that they did not want to participate in the investigation. The remaining 6 of the 18 contacted distributors, viz. Danish Supermarket (Nielsen 2004), Coop Denmark (Kirchhoff 2004), Jysk (Bank 2004), Nokia (Hylstofte 2004), Søstrene Grene (Grene 2004) and Tiger (Nielsen 2004), informed that they do not sell products containing fragrances or flavouring agents.

When the distributors, importers or suppliers were subsequently contacted on the phone or via mail, declarations and sales figures were asked for.

5.3 Products located in the mapping

In total, information on 15 product types containing fragrances was received.

Some of these product types contained several product components with different scents. Examples hereof are speed markers and mechanical pencils with various scents of fruit. Furthermore, there is a series of fragrant rubber figures with 14 different scents. If all single products of the product series are included, 68 products containing scent have been identified.

The products identified occur from table 5.1 below.

As the market for toys and children's articles containing fragrances changes very quickly, the present mapping should thus be seen as a snapshot of a moving picture. That the market changes quickly can be seen from the fact that product D03 (space hoppers with scent) was no longer available at the time of investigation in spite of information about the marketing of the product in Denmark. Furthermore, the products D10-D14 were being phased out and it could be established that the products only were available in non-scented versions in the autumn of 2004 (about 5 months after the start-up of this investigation) The D15 product (flower) is no longer on the market.

The distributors informed that some products are only available on the market for a very short period of time. The distributors refer to these products as "crazes". As examples of crazes can be mentioned products like slime with coke scent and fragrant stick-on labels with certain figures. Moreover, there are seasonal articles like school timetables and products with "Christmas scents". No seasonal goods were identified during this mapping.

Table 5.1 only includes products where the scent is intended and forms part of the marketing of the product. This means that for instance Pokémon figures in Pokémon balls are not included in spite of a clear scent of coconut, as the scent is not used for the marketing of the product.

Table 5.1: Result of the mapping of fragrant toys and children's articles, June 2004. Overview of products, product series and scents.

Product type number	Product	Scent
D01	Soap bubbles	Lemon & Lime, Chocolate chip, Bubblegum, Banana Split, Tropical punch, Strawberries & Cream
D02	Rubber figures	The Duke of Puke, Pizza Face Pat, Oli Slick Rick, Dude Boy Doug, Dandy Doo Dave, Clammy Cliff, Zoo Boy Zach, Elephant Drop Eric, Camel Mouth Chris, Monkey Cage Mike, Ra Boy Rob, Winnie the Vulture, Ear Wax Max, Fartasarus Frank, Billy Bob Booger, Toxic Tyler, Spewy Huey, Jurassic Josh, Rotten Onion Ollie, Chill E. Dawg Joey, Never Wash Nick, Rankin' Ryan, Wart Hog Henry
D03	Space hoppers	Watermelon, kiwi, citron, orange
D04	Writing paper	Perfumed scent
D05	Mechanical pencil	Apple, grape, kiwi, banana, orange, strawberry
D06	Eraser lipstick	Apple, grape, kiwi, banana, orange, strawberry
D07	Eraser pen	Apple, grape, kiwi, banana, orange, strawberry
D08	Speed markers	Orange, lemon, strawberry, blackberry, violet, rose, chocolate, pine and two unnamed scents
D09	Rabbit	Chocolate
D10	Stacking rings	Apple
D11	Activity box	Apple
D12^	Soft cube	Apple
D13	Cuttlefish	Vanilla
D14^	Soft toy	Vanilla
D15	Flower	Vanilla

^ Is no longer on the Danish market

5.3.1 Declarations and sales figures for fragrant products

Several distributors, importers or suppliers informed that declarations and sales figures were confidential and therefore could not be disclosed. Information relating to the received declarations has been treated confidentially.

In total, declarations of two products/product series and sales figures for eight products/product series were received. As none of these producers wanted the declarations published, the declarations were conveyed to the Danish Environmental Protection Agency as confidential material. The received declarations have been controlled for declared sensitizing substances according to the list in table 4.1 and it can be established that four of the products in the product series D08 (speed markers) have a declared content of sensitizing substances, viz. the speed markers with lemon, rose, chocolate and violet scent. From the confidential declarations, it appears that four of the five declared fragrances in the speed marker with lemon scent are on EU's list

of sensitizing substances. As to the other speed markers, two of four, one of six and one of eight fragrances are on the list.

Data sheets for CE labelling of 8 products were submitted. However, the content of fragrances in the products does not appear from these data sheets.

Information about sales figures has been submitted for 8 of the products/product series. These sales figures are confidential and have been conveyed to the Danish Environmental Protection Agency. From the data provided, it has not been possible to estimate the size of the market for fragrant toys and children's articles in Denmark.

6 Screening of products for ingredient substances

6.1 Selection of products for qualitative screening

Selection of products for qualitative screening with GC-MS was made on the basis of the following criteria.

The products were selected so that they in combination:

- Covered a wide spectrum of the declared fragrances.
- Covered the entire target group of children from 0 to 10 years.
- Were intended for as many different types of play activities as possible (writing/drawing, outdoor activity, soft toys, development and collector's items).
- Potentially exposed the child for both long and short periods of time.
- Resulted in different types of exposure (solid or floating product).

The selected products appear from table 6.1.

Only in the declarations for the selected products in the D08 product series (speed markers), sensitizing substances have been declared, also see section 5.3.1.

Table 6.1: Selected products for the screening analysis

Product type number	Product	Scent	Selected for screening analyses
D01	Soap bubbles	Lemon & Lime, Chocolate chip, Bubblegum, Banana Split, Tropical punch, Strawberries & Cream	Lemon & Lime
D02	Fragrant rubber figures	The Duke of Puke, Pizza Face Pat, Oli Slick Rick, Dude Boy Doug, Dandy Doo Dave, Clammy Cliff, Zoo Boy Zach, Elephant Drop Eric, Camel Mouth Chris, Monkey Cage Mike, Ra Boy Rob, Winnie the Vulture, Ear Wax Max, Fartasarus Frank, Billy Bob Booger, Toxic Tyler, Spewy Huey, Jurassic Josh, Rotten Onion Ollie, Chill E. Dawg Joey, Never Wash Nick, Rankin' Ryan, Wart Hog Henry	Dandy Doo Dave, Camel Mouth Chris, Rankin' Ryan
D04	Writing paper	Perfume	Perfume
D05	Mechanical pencil	Apple, grape, kiwi, banana, orange, strawberry	Kiwi
D06	Eraser lipstick	Apple, grape, kiwi, banana, orange, strawberry	Strawberry scent
D07	Eraser pen	Apple, grape, kiwi, banana, orange, strawberry	Apple scent
D08	Speed markers	Orange, lemon, strawberry, blackberry, violet, rose,	Lemon, rose and strawberry

Product type number	Product	Scent	Selected for screening analyses
		chocolate, pine and 2 additional unnamed scents	
D09	Rabbit	Chocolate	Chocolate
D10	Stacking rings	Apple	Apple
D11	Activity box	Apple	Apple
D12^	Soft cube	Apple	Apple
D13	Cuttlefish	Vanilla	Vanilla
D14^	Soft toy	Vanilla	Vanilla
D15	Flower	Vanilla	Vanilla

^ Is no longer on the Danish market

6.2 Screening methodology and results

Products were analyzed qualitatively for content of the 24 fragrances on the list of sensitizing substances prepared by SCCNFP (1999) and for any other volatile, organic compounds.

The analysis was a screening analysis limited to substances with masses between 45 and 300 g/mol.

The analysis was carried out as a head space analysis. The samples were packed separately in nitrogen atmosphere in Rilsan bags that were hermetically closed with a strip.

To minimize the risk of pollution of the air in the Rilsan bag, the bag containing the product was filled with nitrogen gas and was subsequently emptied again. This "scavenging" process was carried out three times before the bag was filled with nitrogen for the last time and closed.

Erasers and pencil leads (the D05, D06 and D07 products) were taken out of their plastic cases, as the cases did not contain any fragrances. The speed markers (D08) were packed without caps in a Rilsan bag. When handling the bags, the speed markers gave off some colour to the inner side of the bags. All price and cardboard tags and similar were removed from the textiles. Sewed on labels were not removed.

After the rubber figures (D02) were put in the Rilsan bags, they were exposed to one single high pressure before the analyses were carried out. The figures were not exposed to any further pressures as the analyses were repeated.

6.2.1 First screening

The preliminary screening tests were carried out without up-concentrating the air in the bags. The column temperature was maintained at 50 or 60˚ C during the entire analysis.

The result of these tests demonstrated a content of many different substances in all tested products. The substances included alkanes, alkenes, alcohols, estre, ketones, ethere and aromatic compounds, meaning that all groups of volatile organic compounds were detected. An exception was the analyses of the mechanical pencil with kiwi scent (D05), which only showed traces of volatile, organic compounds. None of the 26 selected sensitizing substances were identified in any of the tested products.

6.2.2 Second screening

The substances identified in the preliminary analyses were generally detected with low signals, which made it difficult to identify single components. To increase the security of the identifications and the chance of identifying substances occurring in lower concentrations, the air in the bags was up-concentrated 10 times prior to the analysis. The air from the bags with rubber figures (D02) was not up-concentrated, as the signals from these tests were apparent already at the first screening test.

To increase the chance of detecting the substances that only move slowly through the column, the analyses were made by heating the up-concentrated air gradually in the column from 60 to 160˚C. Again, the results showed a content of many different substances in the tested products. A possible content of the sensitizing substance, D-limonen, could be demonstrated in the soap bubbles (D01) and in the erasers with strawberry and apple scent (D06 and D07) respectively.

6.2.3 Third screening

The yellow and pink speed markers (D08) had a declared content of sensitizing substances (benzylalcohol, citral, geraniol and linalool). As these substances were not identified during the earlier mentioned screening tests, the speed markers were tested once more.

In this test, the air was up-concentrated 250 times in the bags containing the product. However, it was not possible to detect any of the declared sensitizing substances. No further tests were made to identify the substances searched for in the speed markers.

6.3 Selection of products for exposure tests and accredited analyses

Based on the results from the qualitative analysis, 10 products were selected for qualitative analysis and exposure test.

The following criteria were used at the selection:

- The screening analysis showed a possible content of at least one of the substances on the EU list of sensitizing substances or a content of harmful substances.
- The product had a declared content of sensitizing substances.
- The product gave off heavy odour/scent.
- The product is intended for babies.
- Use of the product causes risk of heavy exposure from for instance soft toys, soap bubbles and fragrant rubber figures.
- The screening analyses demonstrated a content of a large number of substances.

Furthermore, attempts were made to select products that represented a broad section of the market, aiming at the entire target group and covering the largest possible spectrum of play activities. Special focus was, however, on the product for babies.

The soft cube (D12) and the soft toy (D14) were not analyzed in the screening tests. These products were selected for further analysis solely on the basis of them being intended for babies.

The mechanical pencil (D05) with kiwi scent was excluded due to its weak scent and missing identification of substances during the screening test.

The 10 selected products are listed in the below table.

Table 6.2: Selected products for laboratory experiments and accredited analyses

Product type number	Product	Selected for laboratory experiments and accredited analyses
D01	Soap bubbles	Lemon & Lime
D02	Rubber figures	Camel Mouth Chris
D04	Writing paper with scent	Perfume
D06	Eraser lipstick	Strawberry scent
D08 yellow	Fragrant speed markers	Lemon
D08 red	Fragrant speed markers	Strawberry
D09	Rabbit	Chocolate
D12^	Soft cube	Apple
D14^	Soft toy	Vanilla
D15	Flower	Vanilla

^ Is no longer on the Danish market

7 Laboratory test

7.1 Analytical methods and test

The products have been analysed for content of sensitising fragrance substances, however, also a more general screening of chemicals in the 10 products has been carried out. The screening was performed prior to selection of products for migration test and emission test. Migration and emission test were selected performed on products aimed at children less than 3 years. Based on screening results rubber figure, Writing paper, and yellow scented ink (D02, D04, D08) were selected for emission test. The latter products are all products directed at children above 3 years. Among other things the GC/MS screening detected a high content of phthalates in erasers (D06). However, erasers were not further tested, as there are only regulations for content of these compounds in toys aimed at children under the age of 3 years.

7.1.1 Fragrance

The content of the sensitised fragrances was analysed in one sample. A partial sample was taken and extracted with water and tert-butylmethylether by means of suspension, cooling, and standing during a period of approximately 16 hours. A partial sample of the extract was taken and analysed directly through combined gaschromatography and mass spectrometry (GC/MS). The limit of detection is 1-10 mg/kg and uncertainty is 10-15% (relative standard deviation). If the product consists of more parts the analysis has been performed on the scented part of the product. The specific part is given in the results table.

7.1.2 GC/MS screening (extractable organic compounds)

The content of extractable organic compounds in the samples was analysed. A sample consisting of partial amounts of all components in the product was extracted with dichloromethane added internal standards. The selection of partial samples was determined from an assessment of the proportion of the materials in the product. A partial sample was taken and analysed directly at combined gas chromatography and mass spectrometry (GC/MS) by scanning over a larger mass area. The content of a large number of specific compounds was calculated semi quantitatively as C_8 or C_{30} depending on retention time. The limit of reporting is 10-100 mg/kg depending on the single sample; the limit of reporting is usually higher than the limit of detection. The specific limit of reporting is given in the results section. A description of the parts included in the analysis is given in the results table.

7.1.3 Screening for content of solvents

A screening for content of solvents and quantification of these was performed in order to determine the content of solvents in a particular product (D02, rubber figure).

A partial sample is extracted with DMF (Dimethylformamide) added internal standards. A partial sample of the extract is taken and analysed directly at combined gas chromatography and mass spectrometry (GC/MS) by scanning over a larger mass area. All identifications of compounds are performed from retention time and the mass spectra by comparing with mass spectra in a data library. The content if calculated quantitatively. The limit of reporting is 50 mg/kg and uncertainty is 10-15%RSD.

7.1.4 Specific migration

At the test for specific migration the potential emission of compounds from the sample to sweat is tested. A sample of approximately 5 gram consisting of partial amounts of all components in the product under consideration of the proportion of the material in the product was added 100 ml artificial sweat and incubated at 40°C for 24 hours. Artificial sweat was prepared from NaCl, ammonia, lactic acid, carbamide, and water according to DS/EN 1811. Following incubation the artificial sweat (simulant) was extracted with dichloromethane added internal standards. A partial sample of the extract was taken and analysed directly at combined gas chromatography and mass spectrometry (GC/MS) by scanning over a larger mass area. The content was calculated semi quantitatively as C_8 or C_{30} depending on retention time. Generally the unit mg/dm^2 is used when reporting migration results. However, as the sample consisted of different part as e.g. filler where the area could not be specified, the unit is given as component per kg sample used for the migration test. The limit of reporting is 1 mg/kg.
The test is performed in triple with blank. A description of the parts included in the analysis is given in the results table.

7.1.5 Emission test

The emission test collects volatile compounds emitting from the sample to the air. Approximately 1 gram sample was placed in a 600 ml purifying bottle. A charcoal tube was fitted onto the lid with a Tenax-TA tube serial combined with a CS-tube for collection of volatile and semi volatile compounds at the exhaust. The air was absorbed through the test container with an air change of 2.9 times per hour.

The exposed CS- and Tenax-TA-tubes were desorbed at heating and analysed directly using GC/MS by scanning over a larger mass area. The content of the determined components were calculated by means of relative response factors (tables) or semi quantitatively as toluene (molar weight for toluene used for semi quantitative determination).

The products were stored in original packaging until initiation of emission test preparations.

The limit for achievable reliable quantitative results is set to 10 $\mu g/m^3$ air. This limit was raised to 20 $\mu g/m^3$ for one sample as the uncertainty was assessed too high due to noise peaks on the GC-chromatogram.

7.2 Results

7.2.1 Classification of products

As all products were toys aimed at emitting scent, the location of the odorant in the product was tested. In several cases the toys were equipped with odorant balls, however, there were also cases of drenched gauze and textile. All results tables are added a column with information as to the analysed part the product.

7.2.2 Odorants

The ten tested products were all analysed for 26 odorants. Three products did not contain a content of any of the 26 odorants. The total content of all 26 odorants is given in table 7.1 and varies from 32 to 5,500 mg/kg.
The two largest contents were found in amounts from 2,500 to 5,500 mg/kg corresponding to 0.25-0.55 weight percentage, while the highest content of one single odorant in a product was 4,000 mg/kg corresponding to 0.4 weight percentage.

Table 7.1: Results from the analysis for odorants. The unit is mg/kg.

	LOD	D 01	D 02	D 04	D 06	D 08 gul
Product		Soap bubbles	Rubber figure	Writing paper	Eraser	Speed marker
Description of the sample		Liquid	Gauze	Paper	Eraser	Insides from speed marker
Anisyl alcohol	1	-	-	-	-	-
Amyl cinnamal	1	-	-	-	-	-
Amylcinnamyl alcohol	1	-	-	-	-	-
Benzyl alcohol	1	-	-	14	10	-
Benzyl benzoate	1	-	-	-	-	-
Benzylcinnamate	1	-	-	-	-	-
Benzyl salicylate	1	-	-	-	-	-
Cinnamyl alcohol	1	-	-	-	-	-
Cinnamal	1	-	-	-	-	-
Citral	1	27	-	-	-	-
Citronellol	1	-	-	1	-	-
Coumarin	1	-	-	9	-	-
Eugenole	1	-	-	-	-	-
Farnesol	1	-	-	-	-	-
Geraniol	1	-	-	3	-	2
Hexylcinnamaldehyde	1	-	-	-	-	-
Hydroxycitronellal	1	-	-	-	-	-
α-Isomethylionon	1	-	-	-	-	-
Lillial	1	-	-	-	-	-
D-limonen	1	7	-	-	22	800
Linalool	1	-	-	5	63	18
Lyral	1	-	-	-	-	-
Isoeugenole	1	-	-	-	-	-
Methyl heptine carbonate	1	-	-	-	-	-
Oakmoss	10	-	-	-	-	-
Treemoss	10	-	-	-	-	-
Sum		34	-	32	95	820

LOD: Means limit of detection
-: Means not determined above the limit of detection

Tabel 7.1 Continued. Results from the analysis for odorants. The unit is mg/kg.

	LOD	D 08 red	D 09	D 12^	D 14^	D 15
Product		Speed marker	Bunny	Soft cube	Soft toy	Flower
Description of the sample		Insides from speed marker	Odorant balls	Odorant balls	Textile	Odorant balls
Anisyl alcohol	1	-	-	-	-	-
Amyl cinnamal	1	11	-	1500	-	-
Amylcinnamyl alcohol	1	-	-	-	-	-
Benzyl alcohol	1	67	-	-	-	-
Benzyl benzoate	1	-	-	7	-	-
Benzylcinnamate	1	-	-	-	-	-
Benzyl salicylate	1	36	-	-	-	87
Cinnamyl alcohol	1	90	-	-	-	37
Cinnamal	1	-	-	-	-	3
Citral	1	-	-	-	-	-
Citronellol	1	8	-	-	-	-
Coumarin	1	-	-	-	-	280
Eugenole	1	14	-	-	-	-
Farnesol	1	-	-	-	-	-
Geraniol	1	11	-	-	-	3
Hexylcinnamaldehyde	1	-	-	4000	-	-
Hydroxycitronellal	1	40	-	-	-	270
α-Isomethylionon	1	-	-	-	-	950
Lillial	1	2	-	-	-	-
D-limonen	1	-	-	-	-	220
Linalool	1	-	-	-	-	-
Lyral	1	-	-	-	-	610
Isoeugenole	1	-	-	-	-	-
Methyl heptine carbonate	1	-	-	-	-	-
Oakmoss	10	-	-	-	-	-
Treemoss	10	-	-	-	-	-
Sum		280	-	5500	-	2500

LOD: Means limit of detection
-: Means not determined above the limit of detection
^ No longer available on the Danish market

7.2.3 GC/MS-Screening

The screening for extractable organic compounds detected odorants that are already given in table 7.1 for some of the products. These are thus omitted from table 7.2.
The content is calculated semi quantitatively in which case the results must be considered guiding. Unit is mg/kg. The limit of reporting for the single product is given in the table.

Following there has been quantitative determination of the content of tris(2-chloroethyl)phosphate in product D12. This is also seen in the table.

Table 7.2: Results from GC/MS-screening. Unit is mg/kg.

	D 01	D 02	D 04	D 06	D 08 Yellow
Product	Soap bubbles	Rubber figure	Writing paper	Eraser	Speed marker
Description of the sample	Liquid	Gauze	Paper	Eraser	Speed marker
Limit of reporting (mg/kg)	3	30	30	140	100
2-Butoxy-ethanol	-	160	-	-	-
Butyldiglycol	-	-	-	230	-
Butyleret hydroxy toluene (BHT)	-	-	-	160	-
C_{12}- hydro carbon (unsaturated/cyclic)	120	180	-	-	-
C_{14}- hydro carbon (unsaturated/cyclic)	85	35	-	140	-
C_{16}- hydro carbon (unsaturated/cyclic)	3.7	100	-	-	-
C_{18}- hydro carbon	-	-	-	200	-
Chlordecan+ C_{12} hydro carbon	-	-	-	170	-
Cyclohexanon	-	360	-	-	-
Dibutylphthalate	-	-	180	3.500	-
Diethylhexyl adipate (DEHA)	-	-	-	1,200	-
Diethylhexyl phthalate (DEHP)	-	-	-	6,100	-
Diheptadecylketone	-	-	36	-	-
Dihexadecylketon	-	-	92	-	-
Diisononyl/decylphthalate	-	680	410	320,000	-
Dipentadecylketone	-	-	53	-	-
Dipropylenglycol	-	-	-	-	200*
Dodecanamine, N,N-dimethyl-	30	-	-	-	-
Ethyl-hexanol	-	28	-	-	-
Glycerine	-	690	-	-	-
Indole	-	430	-	-	-
Kodaflex	-	1,500	-	-	-
Oil acid	-	-	-	160	-
Propylenglykol	-	12,000	46	-	-
Stearic acid	-	-	-	1.900	-
Sum of unidentified	17	96	170	150	100
Sum of unidentified phthalates	-	76	-	-	-
Tetradecanic acid	-	-	-	140	-
Tetradecylamine, N,N-dimethyl-	22	-	-	-	-
Toluene	-	500	-	-	-

-: Means not determined above the limit of detection
*: sum of isomer compounds

Table 7.2 - Continued. Results from GC/MS-screening. Unit is mg/kg.

	D 08 red	D 09	D 12^	D 14^	D 15
Product	Speed marker	Bunny	Soft cube	Soft toy	Flower
Description of the sample	Speed marker	Odorants + fur+filler	Textile+ plastic+foam rubber	Textile+ plastic+filler	Plastic+ textile+filler
Limit of reporting (mg/kg)	80	40	120	90	30
Benzaldehyde	89	-	-	-	-
2H-1-Benzopyran-2-on	-	-	-	-	33
Butyldiglycol	210	-	-	-	-
Butylated hydroxy toluene (BHT)	-	-	-	-	60
C_{14}- hydro carbon (unsaturated/cyclic)	-	-	-	100	-
C_{16}- hydro carbon (unsaturated/cyclic)	-	-	-	1,800	-
C_{18}- hydro carbon (unsaturated/cyclic)	-	-	-	530	-
C_{22}-C_{29} pure mineral oil	-	-	320	-	-
Dibutylphthalate	-	-	120	-	-
Diethylphthalate	-	-	-	-	310
Diisononyl/decylphthalate	-	-	-	73,000	-
Dipropylenglycol	480*	-	-	-	-
n-Dodecan	-	82	-	-	-
Acetic acid, phenylmethylester	150	-	-	-	-
Ethylvanillin	-	85	-	540	440
Glycerol Tricaprylate	-	330	-	-	-
n-Heneicosan	-	77	-	-	-
n-Hexadecan	-	110	-	-	-
n-Icosan	-	42	-	-	-
Piperonal	-	-	-	-	60
2-Phenylethanol	1,400	-	-	-	-
2-Propen-1-ol, 3-phenyl	140	-	-	-	-
Sum of unidentified	-	230	210	98	490
Sum of unidentified phthalates	89	58	-	100	120
α-Terpineol	210	-	-	-	-
n-Tetradecan	-	130	-	-	-
Tris(2-chlorethyl)phosphate	-	-	5,800**	-	-
Tris(3-chlorpropyl)phosphate	-	-	430	-	-
Tris(chlorpropyl)phosphate(isomers of Tris(2-chlorethyl)phosphate)	-	-	150	-	-
Unidentified phosphate	-	-	130	-	-
Unidentified triglyceride	-	470	-	-	-
Vanillin	-	71	-	-	-

-: Means not determined above the limit of detection
*: sum of isomer compounds
**: Quantitative determination
^ No longer available on the Danish market

7.2.4 Solvents

There were further analyses for solvent content in the product D02. Quantitative analysis is solely performed in double determination as given in table 7.3. Gauze from 2 products have been applied – one for each double determination, which most likely cause the relatively large difference in some of the components. Unit is mg/kg and the limit of detection is 10-50 mg/kg.

Table 7.3. Quantitative analysis of solvents in product D02. Unit is mg/kg.

	D02	
Product	Rubber figure	
Description of sample	Gauze	
Sample	A	B
Acetone	42	48
n-Butylacetat	58	< 10
Cyclohexanon	350	350
Dichlormethane	< 50	< 50
Ethanol	660	120
Toluene	140	140

7.2.5 Migration

Four products were selected for migration test based on the identified substances in the screening, penetration, and the fact that they were aimed at children under 3 years. Migration test with artificial sweat as simulant was performed as the products are considered used for e.g. soft toys and in close skin contact during use. The test was performed in triple determination and the results in table 7.4 are averages of the three determinations.

The content is calculated semi-quantitatively, thus the results must be considered guiding. Unit is mg of the component in the simulant per kg product used for the migration test.

Accordingly a quantitative determination of the compound tris(2-chlorethyl)phosphate was performed. The substance was detected in the analysis of artificial sweat. The below mentioned table provides the quantitative value for content of tris(2-chloroethyl)phosphate in the simulant from the migration test performed on the three part components: Textile, fill, and plastic part of the product D12. The unit is calculated as mg of the compound per kg of the product used for the migration test. The average value for content of tris(2-chlorethyl)phosphate in product D12 is calculated to 5,900 mg/kg.

Table 7.4: Results from GC/MS-screening of the simulant from the migration test. Unit is mg/kg.

	D 09	D 12^	D 14^	D 15
Product	Bunny	Soft cube	Soft toy	Flower
Description of the sample	Textile + fill	Textile+ fill+plastic	Textile+ fill+plastic	Textile+ fill+plastic
2H-1-Benzopyran-2-on	-	-	-	8
2-(2-chlorethoxy)ethyl bis(2-chlorethyl)phosphate	-	34	-	-
Cyclohexanon	-	-	1	-
Diethylphthalate	-	-	-	28
Ethylvanillin	7	-	140	37
7-Hydroxy-3,7-dimethyl octanal	-	-	-	5
1(H)-isobenzofuranon	-	-	3	-
Piperonal	-	-	-	18
Sum of unidentified	-	38	-	-
Tris(2-chlorethyl)phosphate	-	4,900/6,500/ 6,300*	-	-
Tris(3-chlorpropyl)phosphate	-	10	-	-
Vanillin	4	-	-	-

-: Means not determined above the limit of detection
*: Quantitative determination performed on the three parts of the product

^ No longer available on the Danish market

7.2.6 Emission test

Seven products were selected based on the screening analyses and consumption pattern for emission tests. The tests were performed by collection on solid adsorbents and analyses at GC/MS screening. The result of the screening is given in table 7.5.

The content is calculated as toluene (semi-quantitative) for the components marked with *. The other components are calculated quantitatively. The unit of µg per m^3 air. The limit for achievement of reliable results is set to 10 µg/m^3 air with the exception of sample D02, where this limit was raised to 20 µg/m^3 due to "noise"-peaks on the GC chromatogramme.

Table 7.5: Results from emission test. The unit is µg/m^3.

	D 02	D 04	D 08	D 09
Product	Rubber figure	Writing paper	Speed marker	Bunny
Description of the sample	Gauze	Paper	Internal fittings in yellow speed marker	Odorants+ fur+fill
Acetone	-	160	-	-
Sum of acetone and ethanol	14,000	-	-	-
Benzen	-	-	-	12
Benzylalcohol	-	20	-	-
Borneol	-	-	1,100	-
Bornylacetat	-	-	4,100	-
n-Butanol	510	59	-	-
1-Butanol, 2-methyl-, acetat*	250	-	-	-
2-Butanol, 3-methyl-, acetat*	-	-	3,200	-
tert-Butanol (2-methyl-2-propanol)	-	-	2,800	-
Butansyre, ethyl ester*	-	-	490	-
n-Butylacetat	5,900	-	-	-
Butylglykol (2-Butoxyethanol)	9,400	27	-	-
C_{10}-aromater*	1,800	-	-	-
C_9-aromates*	840	-	-	-
α-Caryophyllen*	-	-	21	-
Citral	-	-	400	-
Cyclohexane, 1-ethyl-1-methyl-2,4-bis(1-methylethenyl)-,[1S-(1. α.,2. β.,4. β,4. β)]-	-	-	110	-
Cyclohexanon	24,000	38	-	-
Cyclohexen-1-one, 2-methyl-5-(1-methylethenyl)-, (S)*	-	-	330	-
Cyclopentanon, 3-methyl-*	-	-	410	-
Cyclotrisiloxan, hexamethyl-*	44	-	-	-
Cyclotetrasiloxan, octamethyl-*	21	-	-	-
n-Decan	-	-	-	93
2,4-Dimethyl-1-heptene*	-	-	-	-
Diphenylether*	-	-	2,200	-
n-Dodecan	-	-	-	340
n-Dodecen*	-	-	-	20
Acetic acid	-	43	-	-
Ethyl acetate	100	-	-	-
Ethylbenzene	1,100	-	-	-
2-Ethyl-1-hexanol	-	27	-	-
Eucalyptol*	-	-	-	15
Fenchol	-	-	2,400	-

	D 02	D 04	D 08	D 09
Product	Rubber figure	Writing paper	Speed marker	Bunny
Description of the sample	Gauze	Paper	Internal fittings in yellow speed marker	Odorants+ fur+fill
Geranyl nitril*	-	-	1,500	-
n-Heptane	-	-	220	-
Heptanal	-	-	190	-
Heptane, 4-methyl-*	-	-	310	-
Hexanal	100	16	-	-
Isobutylacetate	-	-	520	-
Isopropanol*	-	-	-	220
Hydrocarbon mixture*	7,100	1,400	-	-
Linalool	-	-	3,800	-
Limonen	35	14	-	21
Longifolen	-	-	89	-
Menthol*	-	-	450	-
Methylcyclohexane*	-	-	47	-
Methylethylketon (MEK)	990	-	1,100	-
4,7-Methano-1H-inden, octahydro-*	340	-	-	-
4-Methyl-2-pentanon (Methylisobutylketon/MiBK)	-	40	-	-
Naphthalene, 2-methoxy*	-	-	480	-
Neryl nitril*	-	-	1,800	-
2,6-Octadienal, 3,7-dimethyl-*	-	-	380	-
n-Octane	-	-	440	-
Octanal	-	14	-	-
n-Pentanol*	-	-	1,200	-
β-Pinen*	-	-	390	-
Propane, 2-ethoxy-2-methyl*	-	-	530	-
Propylenglykol (1,2-Propandiol)	2,500	-	-	-
Sum of unidentified	1,100	-	19,000	58
Sum of other terpenes incl. Limonen	-	-	34,000	-
α-Terpineol	-	-	1,100	-
n-Tetradecan	-	-	-	76
Toluene	6,700	32	-	24
n-Undecane	-	-	-	10
Xylenes	620	-	-	-

-: Means not determined above the limit of detection
*: Means calculated as toluene

	D 12^	D 14^	D 15
Product	Soft cube	Soft toy	Flower
Description of the sample	Textile+ fill+plastic	Textile+ fill+plastic	Textile+ fill+plastic+ odorants
Benzene	14	12	-
3-Buten-2-on,4-phenyl-, (E)-*	10	-	-
n-Butylacetate	-	14	-
3-Caren	-	20	19
Cyclohexanon	-	37	-
Cyclotrisiloxan, hexamethyl-*	-	14	-
n-Decan	-	10	-
n-Dodecan	20	16	-
Acetic acid	-	50	60
Ethylbenzene	540	-	-
n-Heptane	49	-	-

	D 12^	D 14^	D 15
Product	Soft cube	Soft toy	Flower
Description of the sample	Textile+ fill+plastic	Textile+ fill+plastic	Textile+ fill+plastic+ odorants
Hexane	-	16	-
Hexanal	19	-	-
Hydrocarbon mixture *	-		580
Limonen	14	16	1,500
Longifolen	32	-	11
4-Methyl-2-pentanon (Methylisobutylketon/MiBK)	27	-	-
n-Octan	21	-	-
Octanal	22	12	16
α-Pinen	-	53	21
Styrene	37	-	18
Sum of unidentified	480	-	-
n-Tetradecan	18	-	11
Toluene	47	68	45
n-Tridecan	21	-	-
n-Undecan	17	24	-
Xylener (sum of isomers)	520	11	11

-: Means not determined above the limit of detection
*: Means calculated as toluene
^ No longer available on the Danish market

8 Exposure scenarios

8.1 Selection of substances for exposure scenarios

To investigate a potential exposure to harmful substances when using the selected products, an analysis of migration to sweat was made of extracts from the products to elucidate a potential exposure in case of touch and skin contact. An emission analysis was also conducted to shed light on exposure via inhalation. The migration test has been carried out for 4 products intended for children below the age of three years, whereas the emission analysis was conducted for 7 products, of which 4 products were for children below the age of 3 years and 3 products were for children older than three years. The results of the two tests appear from chapter 7 and form the basis for selection of substances for further analysis of exposure in typical use scenarios.

It has been decided not to make any exposure scenarios for the sensitizing fragrances due to their already documented dangerous nature.

Exposure scenarios for absorption through the skin have been selected on the basis of migration tests made on four products especially intended for children under the age of three years (D09, D12, D14, and D15). GC/MS screening of the simulant for sweat shows occurrence of the fragrances cyclohexanon, ethylvanillin, 7-hydroxy-3,7-dimethyl octanal, piperonal and vanillin distributed among the four products in concentrations of or below 140 mg/kg (140 ppm). In addition to this, appearance of diethylphthalate and tris(2-chlorethyl)phosphate has been demonstrated.

Based on the health characteristics and classification of the substances, it is assessed that the appearance of the fragrances demonstrated in the migration test of the four products does not constitute a health risk by contact with the skin.

Tris(2-chlorethyl)phosphate is used as flame retardant in one of the products (D12) and has been detected during the migration test in high concentrations in the sweat simulant (3,000 ppm). Tris(2-chlorethyl)phosphate is under suspicion of being carcinogenic (carc3) and is assessed to constitute the highest health risk of the four tested products when in contact with the skin. On the basis of this, it has been decided to carry out an exposure scenario for the flame retardant in product D12.

The emission test shows evaporation of a wide range of organic compounds represented by for example fragrances and solvents. The function of the single substances has only been identified for the group of fragrances. The evaporation of substances is especially high for the D02 and D08 products where a large variation in the chemicals being evaporated is also seen.

When the chemical substances were selected for the inhalation exposure scenario, the content and the liberation from the products and the classification of the substances were taken into consideration. This applies to all the substances and not only the fragrances. On the basis of the health

characteristics of the substances at inhalation, 10 substances have been selected for analysis of exposure scenarios. 5 of these 10 substances may probably have been used in the products as fragrances (see table 8.1).

The table below gives an overview of the selected substances and their classification (the list of dangerous substances, the Danish Environmental Protection Agency), stating in which products they occur. All the selected substances are on the list of dangerous substances of the Danish Environmental Protection Agency, whereas hexane and tris(2-chlorethyl)phosphate are also on the list of unwanted substances.

Table 8.1: Substances selected for exposure scenarios on the basis of migration and emission tests

Chemical	CAS number	Classification	Health effect	Product
Tris(2chlor-ethyl)phosphate[2]	115-96-8	Xn;R22 Carc3;R40 N;R51/53	Toxic if swallowed Potential carcinogenic effect	D12^
Cyclohexanon[1]	108-94-1	R10 Xn;R20	Dangerous at inhalation	D02, D04, D14^
Tert-butanol (2-methyl-2-propanol)[1]	75-65-0	F;R11 Xn;R20	Dangerous at inhalation	D08
n-butylacetate[1]	123-86-4	R10 R66 R67	Steams may cause apathy and dizziness	D02, D14^
Butylglycol (2-butoxyethanol)	111-76-2	Xn;R20/21/22 Xi;R36/38	Dangerous at inhalation	D02, D04
Hexane	110-54-3	F;R11 Xi;R38 Xn;R48/20-65 Rep3;R62 R67 N;R51/53	Very dangerous to health at long-term exposure through inhalation May be harmful to the capacity for reproduction Steams may cause apathy and dizziness	D14^
Methylisobutylketone (MiBK)[1]	108-10-1	F;R11 Xn;R20 Xi;R36/37 R66	Dangerous at inhalation Irritates the eyes and the respiratory organs	D04, D12^
Methylethylketone (MEK)[1]	78-93-3	F;R11 Xi;R36 R66 R67	Steams may cause apathy and dizziness	D02
Toluene	108-88-3	F;R11 Xn;R20	Dangerous at inhalation	D02, D04, D09, D12^, D14^, D15
Xylenes	1330-20-7	R10 Xn;R20/21 Xi;R38	Dangerous at inhalation	D02, D12^, D14^, D15
Ethylbenzene	100-41-4	F;R11 Xn;R20	Dangerous at inhalation	D02, D12^

[1] Fragrance
[2] Flame retardant
^ Is no longer on the Danish market

8.2 Exposure of the skin

Exposure of the skin may take place when playing with the toys where the chemical substances can get in contact with the skin via sweat. The migration analyses carried out have demonstrated that some of the chemical substances in the toys can be transferred to sweat. Via the sweat, they can subsequently get in contact with the skin. As also mentioned in section 8.1, focus will be on tris(2 chlorethyl)phosphate.

The calculation of the absorption through the skin has been made according to the principles in Technical Guidance Document (TGD 2003). The calculation has been made for children below the age of three years.

It is presupposed that the contact area is the palms of the child's hands, corresponding to 2.2 % of the total surface area (the total surface area for

children is specified as 60.3 dm^2). Furthermore, it is assumed that the entire migrated quantity is absorbed at the same time (n=1).

The exposure is calculated according to the following formula (TGD 2003):

(1) $E = C/a * A$

Calculation of the actual absorption per kg body weight is made according to the following formula (TGD, 2003):

(2) $U_{der, pot} = E * n / BW$

The following parameters form part of the assessment of the extent of the skin exposure:

C	*Weight of the chemical substance stated per weight of the product*	*mg/kg*
a	*Area per weight of the product*	*dm^2/kg*
A	*Area of exposed skin*	*dm^2*
n	*Number of times the exposure takes place*	*per day*
E	*Potential exposure*	*mg*
BW	*Body weight*	*kg*
$U_{der,pot}$	*Quantity of chemical substance that may be absorbed*	*mg per kg body weight per day*

The following data have been used to calculate the skin absorption for children:

A	*40.2 * 0,022*	*dm^2*
n	*1 time*	*per day*
BW	*10*	*kg*

8.3 Exposure via inhalation

When playing with toys containing fragrances and other chemical substances, an emission of volatile, organic components to the air may take place, whereupon the substances can be inhaled by the child. It is especially interesting to assess the concentration of the single substances in the volume around the child in connection with the exposure.

The emission test was conducted with 1 g material in a small chamber from which air has been sucked, corresponding to an air change of 2.9 times per hour. The results appear from table 7.4 in chapter 7 as a concentration in the air specified as µg/m^3.

The obtained concentrations can be converted to a source strength, R, from the single product:

(3) $R = C_0 * n_0 * V_0$, *where C_0 is the measured concentration in the test, n_0 is the air change in the test chamber and V_0 is the volume of the test chamber.*

The source strength R is used for calculating the concentration in the air at a given exposure. It is expected that the volume around the person is 2 m^3 (V)

and that the air change is (n) 0.5 times per hour, which is a normal air change in a house, compare with TGD (2003).

The concentration around the person is thus:

(4) $C = R / (V * n) = C_0 * n_0 * V_0 / (V * n)$, *where n is the air change in the house and V is the volume around the person.*

The calculations were made for the substances that have been selected on the basis of the emission test for further estimation of a typical exposure scenario.

Outline of the applied parameters for estimating concentration in the air around a person at a given exposure:

R	*Source concentration*	*µg/t*
C_0	*Concentration in emission test*	*µg/m³*
n_0	*Air change in the test chamber*	*pr. time*
V_0	*Volume of test chamber*	*m³*
C	*Concentration in the air around a person*	*µg/m³*
V	*Volume around a person*	*m³*
n	*Number of exposures*	*pr. time*

The following data were used to calculate the concentration around the person:

n_0	*2.9 times per hour*
V_0	*0,0006 m³ (600 ml)*
n	*0.5 times per hour*
V	*2 m³*

The values for n_0 *and* V_0 are data for the test, but the values for *n* and *V* are values from TGD (2003).

8.4 Data for evaluation of health conditions at exposure

The extent of the exposure when using the products is compared with the known limit values for effects on the health. NOAEL (No Observed Adverse Effect Level) values or LOAEL (Lowest Observed Adverse Effect Level) defined in animal tests often carried out on rats or mice are used. The NOEAL values state the highest investigated concentration where adverse health impacts have not been found, either stated as the concentration in the air or as absorbed quantity. By extrapolation of NOAEL values defined in animal tests to humans, the means of exposure and the seriousness of the effects should be taken into consideration. LOAEL is the lowest investigated concentration where effects have been detected. If it is not possible to define a NOAEL value in the tests, LOAEL is used in the assessment of the risk.

To illustrate the harmful effects and expected effect levels of the selected substances, searches have been made in EU risk assessments, IUCLID and US EPA (Toxnet, Riskline, IRIS, HSDB). NOAEL values found in literature appear from the below key tables. With regard to tris(2-chlorethyl)phosphate, which was demonstrated during the migration test, NOAEL values are shown

for intake, supplemented with information from a draft of the EU risk assessment of TCEP.

For substances detected during the emission test, limit values have been found in literature for content in the air of the substances in question. These are the limit values of the National Labour Inspection (AT 2002), LCI (Lowest Concentration of Interest) (EU 1997) and reference concentrations for inhalation, RfC (IRIS 2004).

The limit values of the National Labour Inspection have been stated for content in the air in a working environment (AT 2002) whereas LCI (Lowest Concentration of Interest) has been stated especially for indoor climate. The LCI values have been defined as the lowest concentration of a given substance, which, based on the present knowledge, does not cause any risk of harmful effects on human beings (EU 1997). LCI is calculated on the basis of harmful effects in the working environment and is therefore not considered a real limit value for the indoor climate, but an estimate of when it may be expected to cause inconvenience, typically mucosal irritation and skin irritation, in a given indoor climate. The LCI values are often calculated from the limit values for the working environment with a typical safety factor of 100. For teratogenic, reproduction toxic or carcinogenic substances, the safety factor is, however, 1,000.

Reference concentrations for inhalation, RfC (IRIS 2004), are an estimate of a daily exposure at inhalation where no risk of harmful effects is expected through the lifetime of a normal human being. The inhalation reference concentrations are stated on the basis of toxic effects on the respiratory system as well as effects outside the respiratory system.

Furthermore, odour thresholds values have been stated for the single substances. They are included, as focus is on fragrances, i.e. substances that may be expected to have a low odour threshold. The odour threshold values are from VOCBASE (VOCBASE, 1996).

8.4.1 Tris(2-chlorethyl)phosphate, CAS number 115-96-8

Exposure to tris(2-chlorethyl)phosphate has been investigated in mice and rats. The tests show effects on liver and kidneys. By repeated intake (oral dosing or via a pump directly to the stomach), NOAEL values of 88-400 mg/kg body weight/d have been demonstrated. During an investigation of effects in the foetal stage of rats, NOAEL of 200 mg/ kg body weight/d has been found for the mother animal (IUCLID 2000), observed as a reduction in the food intake. No significant effects on the foetus were demonstrated.

At present, TCEP is being risk assessed in EU with Germany as rapporteur country. The results of the health assessment is available as first draft. From this a LOAEL of 12 mg/kg body weight/d appears as the lowest toxicity value and used as basis for the risk assessment (RAR 2004). The LOAEL values has been found by repetitive intake of TCEP in test with mice over a period of 18 months, where injuries to the kidneys were observed. A NOAEL value for these effects was not determined (RAR2004).

Table 8.2: NOAEL values found in literature for Tris(2-chlorethyl)phosphate selected on the basis of the migration test

Experimental animals	Exposure/duration	Dosing mg/kg body weight	Effect/organ	NOAEL mg/kg body weight/d	Reference
Rat	Oral Daily, 3 months	400; 1,000; 3,000; 8,000	RDT*, weight, food intake, liver/kidneys	400	IUCLID 2000
Rat	Via pump 5 d/w, 16-18 weeks	22; 44; 88; 175; 350	RDT, death, liver/kidneys	88	IUCLID 2000
Mouse	Via pump 5 d/w, 16 weeks	44; 88; 175; 350; 700	RDT, kidneys	350	IUCLID 2000
Mouse	Via pump Daily, 2 -16 weeks	44; 88; 175; 350; 700	RDT, liver/kidneys	88	IUCLID 2000
Rat	Via pump Daily, day 7-15 of pregnancy	50; 100; 200	Teratogenicity, food intake	Mother: 200 Foetus: >200	IUCLID 2000
Mouse	Oral via food Daily, 18 months	12; 60; 300; 1500	Kidney injuries	LOAEL: 12	RAR 2004
Rat	Oral via pump Daily in 103 weeks	44, 88	Kidney cancer Brain damages	LOAEL: 44 NOAEL: 44	RAR 2004

* repeated dose toxicity

8.4.2 Tert-butanol (2-methyl-2-propanol), CAS number 75-65-0

Effect from inhalation of tert-butanol has been investigated in tests for illustration of foetal malformation of rats. During the tests, reduction in food intake and loss of weight were observed for the mother as well as reduction in the bone formation of the foetus. NOAEL was determined at 6,053 mg/m^3 (2,000 ppm) for the mother animal and at 15,133 mg/m^3 (5.000 ppm) for the foetus (IUCLID 2000).

Table 8.3: NOAEL values found in literature for Tert-butanol selected on the basis of the emission test

Experimental animals	Exposure/ duration	Dosing mg/m^3	Effect/organ	NOAEL mg/m^3	Reference
Rat	Inhalation 7h/d, day 1-19 of pregnancy	6,053; 10,593; 15,133	Teratogenicity, food intake/bone formation	Mother: 6,053 Foetus: 15,133	IUCLID 2000

Limit values and odour threshold for tert-butanol:

Limit value (AT 2002):	150 mg/m3
LCI (EU 1997):	1 mg/m3
RfC (IRIS 2004):	-
Odour threshold (VOCBASE 1996):	70,000 µg/m3

8.4.3 n-butylacetate, CAS number 123-86-4

Only a few tests for determination of NOAEL at inhalation of n-butylacetate have been found in literature. Effect on the foetal stage was investigated during tests with rats and rabbits. There were no significant effects on the foetus at the tested concentration of 7,230 mg/m^3 (1,500 ppm), whereas the mother animals showed reduced food intake and loss of weight (IUCLID 2000).

Table 8.4: NOAEL values found in literature for n-butylacetate selected on the basis of the emission test

Experimental animals	Exposure/ duration	Dosing mg/m^3	Effect/organ	NOAEL mg/m^3	Reference
Rat	Inhalation 7h/d, day 1-16/day 7-16 of pregnancy	7,230	Teratogenicity , food intake, loss of weight	Mother: >7,230 Foetus: 7,230	IUCLID 2000
Rabbit	Inhalation 7h/d, day 1-19/day 7-19 of pregnancy	7,230	Teratogenicity , food intake, loss of weight	Mother: >7,230 Foetus: 7,230	IUCLID 2000

Limit values and odour threshold for n-butylacetate:

Limit value (AT 2002):	710 mg/m3
LCI (EU 1997):	7 mg/m3
RfC (IRIS 2004):	-
Odour threshold (VOCBASE 1996):	47 µg/m3

8.4.4 Butylglycol (2-butoxyethanol), CAS number 111-76-2

NOAEL values determined during inhalation studies by repeated exposure of rats and guinea pigs are in the interval of 98-610 mg/m^3 (IUCLID 2000, IRIS 2004). Effects on the blood, liver and kidneys were demonstrated. Also effects on the foetus at exposure of the mother animal were observed during pregnancy and NOAEL for the foetus was determined at 970 mg/m^3 (IUCLID 2000).

Table 8.5: NOAEL values found in literature for butylglycol selected on the basis of the emission test

Experimental animals	Exposure/ duration	Dosing mg/m^3	Effect/organ	NOAEL mg/m^3	Reference
Rat	Inhalation 6h/d, 5d/w, 9 days	98; 420; 1.200	RDT	98	IUCLID 2000
Rat	Inhalation 6h/d, 5d/w, 90 days	24; 121; 372	RDT	121	IUCLID 2000
Rat	Inhalation 6h/d, 5d/w, 3 weeks	98; 250; 490	RDT	250	IUCLID 2000
Guinea pigs	Inhalation 7h/d, 5d/w, 6 weeks	300; 610; 1.230	RDT	610	IUCLID 2000
Rat	Inhalation 6h/d, day 6-15 of pregnancy	120; 240; 480; 970	Teratogenicity	Mother: 240 Foetus: 970	IUCLID 2000
Rat	Inhalation 6h/d, 5d/w, 14 weeks	151; 304; 609; 1,218; 2,436	RDT, blood	151	IRIS 2004

Limit values and odour threshold for butylglycol:

Limit value (AT 2002):	98 mg/m3
LCI (EU 1997):	1 mg/m3
RfC (IRIS 2004):	13 mg/m3
Odour threshold (VOCBASE 1996):	5 µg/m3

8.4.5 Cyclohexanon, CAS number 108-94-1

Only few data are available for health effects at inhalation of cyclohexanon. A test of volunteers exposed to different levels of cyclohexanon in the air showed that most of the volunteers complained about irritation of the eyes, nose and throat at concentrations of 300 mg/m^3, whereas a concentration of 100 mg/m^3 was considered acceptable (Riskline 2004). A long-term study with rabbits demonstrated injuries to the central nervous system after repeated

exposure. A NOAEL of 2,450 mg/m^3 (Riskline 2004) was determined. An 8 hours time-weighted average limit value is specified as 20 mg/m^3 intended for a working environment (Riskline 2004).

Table 8.6: NOAEL values found in literature for cyclohexanon selected on the basis of the emission test

Experimental animals	Exposure/ duration	Dosing mg/m^3	Effect/organ	NOAEL mg/m^3	Reference
Rabbit	Inhalation 6h/d, 5d/w, 6 weeks	-	RDT, central nervous system	2,450	RISKLINE 2004

Limit values and odour threshold for cyclohexanon:

Limit value (AT 2002):	40 mg/m3
LCI (EU 1997):	1 mg/m3
RfC (IRIS 2004):	-
Odour threshold (VOCBASE 1996):	-

8.4.6 Ethylbenzene, CAS number 100-41-4

Changes to liver and kidneys as well as weight changes were observed in mice and rabbits repeatedly exposed to gaseous ethylbenzene in concentrations of 100-3,350 mg/m^3 (23-750 ppm). Changes in the blood composition were observed at 100 mg/m^3. NOAEL was determined in the interval of 10-2,370 mg/m^3 (2.3-500 ppm) (IUCLID 2000).

Table 8.7: NOAEL values found in literature for ethylbenzene selected on the basis of the emission test

Experimental animals	Exposure/ duration	Dosing mg/m^3	Effect/organ	NOAEL mg/m^3	Reference
Mouse	Inhalation 6h/d, 5d/w, 13 weeks	470; 1,180; 2,370; 3,350; 4,740	RDT, liver/kidneys	2,370	IUCLID 2000
Rabbit	Inhalation 6h/d, 5d/w, 4 weeks	1,700; 3,400; 7,100	RDT, weight	3,400	IUCLID 2000
Rabbit	Inhalation 4h/d, 7d/w, 7 days	10; 100; 1,000	RDT, liver/kidneys, blood	10	IUCLID 2000

Limit values and odour threshold for ethylbenzene:

Limit value (AT 2002):	217 mg/m3
LCI (EU 1997):	1 mg/m3
RfC (IRIS 2004):	1 mg/m3
Odour threshold l (VOCBASE 1996):	-

8.4.7 Hexane, CAS number 110-54-3

In spite of risk of hexane's harmful effect at inhalation, only few data have been found of NOAEL values determined in inhalation tests. During inhalation of hexane, irritation of the mucous membranes of the nose was observed in a test with repeated exposure and a NOAEL value of 1,762 mg/m^3 (IRIS 2004) was determined. For use in a working environment (exposure in 8 hours), an average limit value of 73 mg/m3 (IRIS 2004) is stated.

Table 8.8: NOAEL values found in literature for Hexane selected on the basis of the emission test

Experimental animals	Exposure/ duration	Dosing mg/m^3	Effect/organ	NOAEL mg/m^3	Reference
Mouse	Inhalation 6h/d, 5d/w, 90 days	1,762; 3,525; 14,099; 35,247	RDT, irritation	1,762	IRIS 2004

Limit values and odour threshold for hexane:

Limit value (AT 2002): 90 mg/m3
LCI (EU 1997): 0.7 mg/m3
RfC (IRIS 2004): 0.2 mg/m3
Odour threshold (VOCBASE 1996): 79,000 µg/m3

8.4.8 Methylethylketone (MEK), CAS number 78-93-3

Loss of weight was observed in rats repeatedly exposed to MEK in the air during a period of 90 days. A NOAEL value was determined at 7,362 mg/m^3 (2,500 ppm). Reduced increase in weight of pregnant rats exposed to MEK in the air during pregnancy was observed, whereas the bone formation of the foetus showed deviations (IUCLID 2000). No significant effects were detected in mice at the tested concentrations of MEK in the air of 8,834 mg/m^3 (3,000 ppm).

Table 8.9: NOAEL values found in literature for methylethylketone (mek) selected on the basis of the emission test

Experimental animals	Exposure/ duration	Dosing mg/m^3	Effect/organ	NOAEL mg/m^3	Reference
Rat	Inhalation 6h/d, 5d/w, 90 days	3,681; 7,362; 14,724	RDT, loss of weight	7,362	IUCLID 2000
Rat	Inhalation 7h/d, day 6-15 of pregnancy	1,178; 2,945; 8,834	Teratogenicity , weight, bone formation	Mother: 2,945 Foetus: 8,834	IUCLID 2000
Mouse	Inhalation 7h/d, day 6-15 of pregnancy	1,178; 2,945; 8,834	Teratogenicity	Mother: 8,834 Foetus: 8,834	IUCLID 2000

Limit values and odour threshold for methylethylketone (MEK):

Limit value (AT 2002): 145 mg/m3
LCI (EU 1997): 1 mg/m3
RfC (IRIS 2004): 5 mg/m3
Odour threshold (VOCBASE 1996): 870 µg/m3

8.4.9 Methylisobutylketone (MiBK), CAS number 108-10-1

Inhalation of MiBK in the air showed a weight reduction of liver and kidneys of exposed rats and mice. Also changes in the blood composition of some animals were demonstrated. When testing pregnant rats, loss of weight of the mother animal was demonstrated. NOAEL for rats and mice was found in the interval of 208 - 2,080 mg/m^3 (50-500 ppm) at repeated exposure to MiBK in the air (IUCLID 2000).

Table 8.10: NOAEL values found in literature for methylisobutylketone (mibk) selected on the basis of the emission test

Experimental animals	Exposure/ duration	Dosing mg/m^3	Effect/organ	NOAEL mg/m^3	Reference
Rat Mouse	Inhalation 6h/d, 5d/w, 90 days	208; 1,040; 4,160	RDT, blood, liver/kidneys	208	IUCLID 2000
Rat	Inhalation 6h/d, 5d/w, 11 days	416; 2,080; 8,320	RDT, liver/kidneys	416	IUCLID 2000
Mouse	Inhalation 6h/d, 5d/w, 11 days	416; 2,080; 8,320	RDT, liver/kidneys	2,080	IUCLID 2000
Rat	Inhalation 6h/d, day 6-15 of pregnancy	1,248; 4,160; 12,480	Teratogenicity , loss of weight	Mother: 4,160 Foetus: 12,480	IUCLID 2000

Limit values and odour threshold for methylisobutylketone (MiBK):

Limit value (AT 2002): 83 mg/m3
LCI (EU 1997): 1 mg/m3
RfC (IRIS 2004): 3 mg/m3
Odour threshold (VOCBASE 1996): 540 µg/m3

8.4.10 Toluene, CAS number 108-88-3

Inhalation of toluene can affect the nervous system. A wide range of tests have been made with rats and mice to illustrate the effect of toluene. NOAEL values in the interval of 377-3,770 mg/m^3 (100-1,000 ppm) have been determined during tests with repeated dosing. In tests carried out to investigate the effect on reproduction, NOAEL was 1,508-1,885 mg/m^3 (400-500 ppm). During tests to illustrate the effects at the embryonic stage of rats, mice and rabbits, NOAEL of 500-2,830 mg/m^3 (131-750 ppm) has been demonstrated for both the mother animal and the foetus (IUCLID 2000).

Table 8.11: NOAEL values found in literature for toluene selected on the basis of the emission test

Experimental animals	Exposure/ duration	Dosing mg/m^3	Effect/organ	NOAEL mg/m^3	Reference
Rat	Inhalation 6,5h/d, 5d/w, 15 weeks	377; 2,360; 4,720; 9,440; 11,300	RDT	<377	IUCLID 2000
Rat	Inhalation 6h/d, 5d/w, 13 weeks	113; 377; 1.130; 3,770	RDT	3.770	IUCLID 2000
Rat	Inhalation 6h/d, 5d/w, 26 weeks	377; 5,655; 7,540	RDT, central nervous system	377	IUCLID 2000
Rat	Inhalation 6h/d, 7d/w, before and during mating	377; 1,885; 7,540	Reproduction	Parent: 1,885 F1 offspring: 1,885 F2 offspring: 1,885	IUCLID 2000
Rat	Inhalation 6h/d, 5d/w, 8 weeks	377; 1,508	Reproduction	1,508	IUCLID 2000
Rat	Inhalation 6h/d, day 6-15 of pregnancy	944; 2,830; 5,660; 11,300	Teratogenicity	Mother: 2,830 Foetus: 2,830	IUCLID 2000
Mouse	Inhalation 7h/d, day 7-16 of pregnancy	750; 1,500	Teratogenicity	Mother: 1,500 Foetus: 1,500	IUCLID 2000
Mouse	Inhalation 3*4/h/d, day 6-15 and 24h7d, day 7-15 of pregnancy	500; 1,000; 1,500	Teratogenicity	Mother: 1,500 Foetus: <500	IUCLID 2000

Experimental animals	Exposure/ duration	Dosing mg/m^3	Effect/organ	NOAEL mg/m^3	Reference
Rabbit	Inhalation 6/h/d, day 6-18 of pregnancy	113; 377; 1,130	Teratogenicity	Mother: 1,130 Foetus: 1,130	IUCLID 2000
Rabbit	Inhalation 6/h/d, day 6-18 of pregnancy	113; 1,885	Teratogenicity	Mother: 1,885 Foetus: 1,885	IUCLID 2000
Rabbit	Inhalation 24h/d, day 0-20 of pregnancy	500; 1,000	Teratogenicity	Mother: 500 Foetus: >500	IUCLID 2000

Limit values and odour threshold for toluene:

Limit value (AT 2002):	94 mg/m3
LCI (EU 1997):	1 mg/m3
RfC (IRIS 2004):	0,4 mg/m3
Odour threshold (VOCBASE 1996):	644 µg/m3

8.4.11 Xylenes, CAS number 1330-20-7

During tests with mice inhaling xylenes in a mixture, reduced bone formation was observed in the foetus. No effect on the mother animal was reported. Inhalation of xylenes caused death, abortion or foetal death at concentrations of 1,120 mg/m^3 (230 ppm), whereas no effects were observed at 560 mg/m^3 (115 ppm) (IUCLID 2000).

Table 8.12: NOAEL values found in literature for xylenes selected on the basis of the emission test

Experimental animals	Exposure/ duration	Dosing mg/m^3	Effect/organ	NOAEL mg/m^3	Reference
Mouse	Inhalation 4h 3x/d, day 6-15 of pregnancy	560; 1,120	Teratogenicity, bone formation	Foetus: 560	IUCLID 2000
Rabbit	Inhalation 24h/d, day 7-20 of pregnancy	560; 1,120	Teratogenicity, death, abortion	Mother: 560 Foetus: 560	IUCLID 2000

Limit values and odour threshold for xylenes:

Limit value (AT 2002):	109 mg/m^3
LCI (EU 1997):	1 mg/m^3
RfC (IRIS 2004):	0.1 mg/m^3
Odour threshold (VOCBASE 1996):	-

9 Evaluation of health conditions when using toys containing fragrance or flavour

9.1 Fragrances in toys

The 10 products that were selected due to their scent characteristics in phase 2 were analyzed for 26 sensitizing fragrances. Of the 26 fragrances, 24 have been assessed as sensitizing by EU's Scientific Committee for Cosmetics (SCCNFP) and two additional fragrances, oakmoss and treemoss, have been selected for analysis.

18 substances in total were detected, contained in 7 products. The below table sums up the results of the analysis described in chapter 7, including the found concentrations. An X in the table indicates that occurrence of the fragrance in question has been demonstrated in the product. No sensitizing fragrances were found in the products D02, D09 and D14.

Table 9.1: Occurrence of sensitizing fragrances in selected products

Product	D 01	D 04	D 06	D 08 yellow	D 08 red	D 12*^	D 15
Description of the test	Liquid	Paper	Eraser	Internals of speed marker	Internals of speed marker	Scent balls	Scent balls
Amyl cinnamal	-	-	-	-	X	X	-
Benzyl alcohol	-	X	X	-	X	-	-
Benzyl benzoat	-	-	-	-	-	X	-
Benzyl salicylate	-	-	-	-	X	-	X
Cinnamyl alcohol	-	-	-	-	X	-	X
Cinnamal	-	-	-	-	-	-	X
Citral	X	-	-	-	-	-	-
Citronellol	-	X	-	-	X	-	-
Coumarin	-	X	-	-	-	-	X
Eugenol	-	-	-	-	X	-	-
Geraniol	-	X	-	X	X	-	X
Hexylcinnamaldehyde	-	-	-	-	-	X	-
Hydroxycitronellal	-	-	-	-	X	-	X
α-Isomethylionon	-	-	-	-	-	-	X
Lillial	-	-	-	-	X	-	-
D-limonen	X	-	X	X	-	-	X
Linalool	-	X	X	X	-	-	-
Lyral	-	-	-	-	-	-	X

* The product is now available without any fragrances
^ Is no longer on the Danish market

No exposure scenarios have been worked out for the sensitizing fragrances, as they are already unwanted in toys for children irrespective of concentration level. It is recommended, however, that consumers avoid these products until the producers have removed the sensitizing fragrances from the products. This has already been done for one of the tested products (D12) and for other small children's (below the age of 3 years) articles of the producer that are now available without any fragrances.

9.2 Evaluation of health conditions in relation to single substances in toys containing fragrance or flavour

When playing with the toys, fragrances or flavouring agents may be released to the air, from where they can be inhaled or transferred to the skin via sweat, compare chapter 7.

Tests of migration to sweat show that single substances can be transferred to sweat from the products D09, D12, D14 and D15. All these products are intended for children below the age of three years.

The emission tests show that the products selected for test, viz. D02, D04, D08, D09, D12, D14 and D15, all contain volatile substances that are liberated to the air in different concentrations. The volatile substances are as also mentioned earlier fragrances and organic solvents.

Exposure scenarios have been made and calculations have been carried out for the potential absorption of single substances via the skin or through inhalation. The calculations have been made for the 11 selected substances described in chapter 8.4.

To assess the health effects from the substances at absorption via the skin or the health effects when inhaling volatile substances liberated from the toys, the calculated absorption and the concentration of the single substance in the air respectively, have been compared with relevant NOAEL/LOAEL values and/or relevant Lowest Concentration of Interest (LCI values). A safety margin has been calculated (Margin of Safety, MoS) which is the margin between the exposure level and the relevant NOAEL/LOAEL value. MoS is calculated as NOAEL/LOAEL divided by the calculated intake or the concentration in the air. MoS must take the extrapolation from animals and humans, the variation in sensitivity in the population and the seriousness of the effect into consideration. Where health effects such as carcinogenic, reproductive, allergic or neuro toxic effects are suspected, the safety margin should be at least 1,000, while the safety margin for the other substances should be at least 100 as all the utilize NOALE/LOAEL values are based on animal tests.

Only one of the 11 selected substances, tris(2-chlorethyl)phosphate, is liberated by migration to sweat, while 10 substances were liberated during the emission test and may be inhaled when playing with the toys. Tris(2-chlorethyl)phosphate is not demonstrated in the emission test.

9.3 Evaluation of health conditions in relation to tri(2-chlorethyl)phosphate at skin absorption

Tris(2-chlorethyl)phosphate was detected in the migration test in a quantity of 5,900 mg/kg product in product D12 (average of the 3 quantitative determinations, table 7.4).

Exposure scenarios for use of toys (D12) containing the substance show that the substance can be absorbed at levels of 5.8 mg/kg body weight/day for a child below the age of three years.

$U_{der,\ pot}$ = *C/a * A * n / BW = 5900/(9/0,1)*60,3*0,022*1/15 = 5,8 mg/kg/day*

The acceptable daily intake of the substance is specified as NOAEL with a safety factor of 1,000 due to suspicion of carcinogenic effect.

Table 9.2: Calculated absorption of tris(2-chloroethyl)phosphate, and margin of safety

Person group	Calculated intake µg/kg/day	LOAEL µg/kg body weight/day	Margin of safety[1]
Children below the age of three years	5,800	12,000	2

[1] Margin of safety is the estimated LOAEL divided by the calculated intake

A MoS at 2 must be regarded as low for a substance even if the calculations are based on a worst-case exposure assumption. Usually, a much higher safety margin is required for calculation of a tolerable exposure level as, in this specific case, the following should be taken into consideration: 1) extrapolation of animal tests to humans, 2) individual sensitivity differences from man to man, and 3) that the basis of the calculations is an effect level (a LOAEL) and that the substance can cause serious effects such as cancer. The first two circumstances alone, would, normally, result in a safety margin (Margin of Safety) of at least 100

Migration tests are as described carried out during 24 hours. Consequently, it is not know when and how fast the substance is liberated to the sweat solution. The total quantity of the substance is therefore regarded as available. If the liberation is regarded as linear during 24 hours, the contact period with the toys will be important. If a linear deviation is assumed, and it is included that the child is in contact with the toy 3 hours per day, it will indicate a MoS at 17. This is far below 100. Furthermore, it is anticipated that this type of toy can also be put in the mouth, and as it is marketed for small children, it is anticipated that they will such on the product and hereby be exposed to the substance both via the skin and orally. This means that the intake can become even higher than the 5,800 µg/kg/day.

Conclusion

Assessments show that intake of tris(2-chlorethyl)phosphate can cause risk of health effects. The substance can be absorbed in concentrations not far from the lowest concentration that, after long-term exposure, can cause kidney injuries in animal test. Furthermore, the substance has been found to be carcinogenic both in mice and rats after long-term exposure. It is also assessed that the substance is not necessary in this type of product for babies.

9.4 Evaluation of health conditions at exposure to single substances via inhalation

The exposure at inhalation can be calculated on the basis of the results from the emission test. The calculated exposure can subsequently be evaluated in regard to potential health effects.

In the following table, the results from the emission test are shown for the substances that have been selected for a further evaluation. The concentration of the selected single substances is shown for each of the 7 products included in this test.

Table 9.3: Concentrations of selected single substances liberated during emission test (compare table 7.5). The concentration is related to 1 g of the product or the fragrant part.

Chemical substance	Emission in µg/m^3 (per g tested toys for the single product)						
	D02[2]	D04[1]	D08[2]	D09[1]	D12[1] ^	D14[1] ^	D15[1]
tert-butanol	-	-	1.300	-	-	-	-
n-butylacetate	5,900	-	-	-	-	14	-
Butylglycol	9,400	27	-	-	-	-	-
Cyclohexanon	24,000	38	-	-	-	37	-
Ethylbenzene	1,100	-	-	-	540	-	-
Hexane	-	-	-	-	-	16	-
Methylethylketone (MEK)	990	-	1,100	-	-	-	-
Methylisobutylketone (MiBK)	-	40	-	-	27	-	-
Toluene	6,700	32	-	24	47	68	45
Xylenes	590	-	-	-	500	10	11

[1] The results are per g of the entire product, as a subset of all parts has been tested
[2] The result is per g of the fragrant part
^ Is no longer on the Danish market

Data in table 9.3 originate from the emission test reported in chapter 7.

On the basis of data from table 9.3, the exposure at inhalation when playing with the product is calculated according to formula 4 (see chapter 8.3). When making the calculation, it is assumed that all fragrances in the product are liberated. The calculation results of the exposure at inhalation of the selected substances are shown in table 9.4 for the seven products, D02, D04, D08, D09, D12, D14 and D15, that liberate one or more of the selected substances during emission.
The calculation of exposure at inhalation can be illustrated for emission of tert-butanol from product D08 as follows:

$$C = C_0 * n_0 * V_0 / V * n = 1.300 * 2,9 * 0,0006/2 * 0,5 = 2,3\ \mu g/m^3$$

Table 9.4: Exposure at inhalation calculated according to formula 4 (compare chapter 8.3). The concentration is related to 1 g of the product or the fragrant part.

Chemical substance	Calculated exposure µg/m^3 (per g tested toys for the single product)						
	D02[2]	D04[1]	D08[2]	D09[1]	D12[1] ^	D14[1] ^	D15[1]
tert-butanol	-	-	4.9	-	-	-	-
n-butylacetate	10.3	-	-	-	-	0.02	-
Butylglycol	16.4	0.05	-	-	-	-	-
Cyclohexanon	41.8	0.07	-	-	-	0.06	-
Ethylbenzene	1.9	-	-	-	0.94	-	-
Hexane	-	-	-	-	-	0.03	-
Methylethylketone (MEK)	1.7	-	1.9	-	-	-	-
Methylisobutylketone (MiBK)	-	0.07	-	-	0.05	-	-
Toluene	11.7	0.06	-	0.04	0.08	0.12	0.08
Xylenes	1.0	-	-	-	0,87	0.02	0.02

[1] The results are per g of the entire product, as a subset of all parts has been tested
[2] The result is per g of the fragrant part
^ Is no longer on the Danish market

The emission test was carried out for a subset of the products, being a representative subset of the whole product or only of the fragrant part of the product.

Evaluation of health in relation to exposure to the single substances is commented in the following sections, comparing the exposure from playing with the tested products with LCI values and estimated NOAEL values when calculating the safety margin. The higher the margin, the lesser the risk for health effects.. Some of the substances have been compared with the odour threshold values.

9.4.1 Tert-butanol

Tert-butanol was detected from product D08 during the emission test. The substance was probably added to release scent.

The calculated concentration at inhalation in table 9.4 applies to 1 g of the product. The part of the product that releases scent weighs 1.8 g. This means that the total exposure when using the product is estimated at 8.8 1 µg/m^3.

Table 9.5: Calculated concentration at inhalation of tert-butanol.

Product	Calculated concentration[1] µg/m^3	LCI µg/m^3	Odour threshold µg/m^3	1/100 NOAEL µg/m^3	Margin of safety[2]
D08	8.8	1,000	70,000	60,530	$6.9 \cdot 10^5$

[1]The concentration at inhalation is calculated on the basis of the emission test, compare formula 4
[2] Margin of safety is NOAEL divided by the calculated concentration

As the level is far below the LCI value (EU 1997), it is assessed that use of the product will not cause any acute inconvenience like mucosal irritations due to emission of tert-butanol.

The level is also far below the estimated NOAEL value and the odour threshold for the substance. MoS is sufficiently high as to conclude that there is no risk of inconvenience due to liberation of tert-butanol when using D08.

9.4.2 n-butylacetate

n-butylacetate has been demonstrated in emission from products D02 and D14. The substance has probably been added to release scent. The calculated concentration in table 9.4 applies to 1 g of the product.

Considering the weight of the product and the part of the product that releases scent, the total exposure when using the product is 10.3 µg/m^3 from product D02 and 3.3 µg/m^3 from product D14.

Table 9.6: Calculated concentration at inhalation of n-butylacetate

Product	Calculated concentration[1] µg/m^3	LCI µg/m^3	Odour threshold µg/m^3	NOAEL µg/m^3	1/100 NOAEL µg/m^3	Margin of safety[2]
D02	10.3	7,000	47	7,230.000	72,300	$7.0 \cdot 10^5$
D14	3.3	7,000	47	7,230.000	72,300	$2.2 \cdot 10^6$

[1]The concentration at inhalation is calculated on the basis of the emission test, compare formula 4
[2] Margin of safety is NOAEL divided by the calculated concentration

The levels are far below the LCI value and the odour threshold for the substance. Furthermore, MoS is considerably higher than (>100) for both products. It is therefore assessed that emission of butylacetate from the two products will not cause any mucosal irritations.

9.4.3 Butylglycol

Butylglycol has been demonstrated in the emission from D02 and D04. When the weight of the products in question is included, the concentration around the person is 16.4 µg/m^3 from product D02 and 5 µg/m^3 from product D04.

Table 9.7: Calculated concentration at inhalation of butyglycol

Product	Calculated concentration[1] µg/m^3	LCI µg/m^3	Odour threshold µg/m^3	NOAEL µg/m^3	Margin of safety[2]
D02	16.4	1,000	5	240,000	$1.5 \cdot 10^4$
D04	5.0	1,000	5	240,000	$4.8 \cdot 10^4$

[1]The concentration at inhalation is calculated on the basis of the emission test, compare formula 4
[2] Margin of safety is NOAEL divided by the calculated concentration

For both products, the level is below the LCI value of 1,000 µg/m^3 (EU 1997).

The NOAEL value for harmful effects is 240 mg/m^3. MoS is sufficiently high to assess that there is no risk of any harmful effects due to liberation of butylglycol from the two products.

As the odour threshold for the substance is very low (5 µg/m^3), the liberation of butylglycol from product D02 will cause an odour/scent. The calculated concentration when inhaling butylglycol liberated from product D04 is close to the odour threshold for the substance.

9.4.4 Cyclohexanon

Cyclohexanon has been found in the emission from products D02, D04 and D14. The substance was probably added to release scent.

The calculation of the concentration around the person using the product shows levels of 41.8 µg/m^3 (D02), 0.07 µg/m^3 (D04) and 0.05 µg/m^3 (D14) in case of 1 g of the product. If these levels are converted to the weight of the actual products, this corresponds to concentrations in the inhalation air of 41.8 µg/m^3 for D02, 7 µg/m^3 for D04 and 9.9 µg/m^3 for D14.

Table 9.8: Calculated concentration at inhalation of cyclohexanon

Product	Calculated concentration[1] µg/m^3	LCI µg/m^3	NOAEL µg/m^3	Margin of safety[2]
D02	41.8	1,000	2,450.000	$5.9 \cdot 10^4$
D04	7.0	1,000	2,450.000	$3.5 \cdot 10^5$
D14	9.9	1,000	2,450.000	$2.5 \cdot 10^5$

[1]The concentration at inhalation is calculated on the basis of the emission test, compare formula 4
[2] Margin of safety is NOAEL divided by the calculated concentration

The concentration in the inhalation air is far below the LCI value for cyclohexanon for all three products, i.e. there is no risk of any health effects like mucosal irritations.

Animal trials have demonstrated a risk of health effects where the NOAEL value is determined at 2,450 mg/m^3. The calculated MoS will therefore be higher than 1,000 for all three products.

It is therefore assessed that the use of products D02, D04 and D14 does not imply any health effects due to liberation of cyclohexanon.

9.4.5 Ethylbenzene

Ethylbenzene was found in the emission from products D02 and D12. Calculation of the concentration around the person using the products shows

levels of 1.9 µg/m^3 for product D02 and 94 µg/m^3 for product D12, taking the weight of the products into consideration.

Table 9.9: Calculated concentration at inhalation of ethylbenzene

Product	Calculated concentration[1] µg/m^3	LCI µg/m^3	NOAEL µg/m^3	Margin of safety[2]
D02	1.9	1,000	10,000	$5.3 \cdot 10^3$
D12^	94	1,000	10,000	100

[1]The concentration at inhalation is calculated on the basis of the emission test, compare formula 4
[2] Margin of safety is NOAEL divided by the calculated concentration
^ Is no longer on the Danish market

The concentration of ethylbenzene is for both products far below the LCI value. The NOAEL value for effects on kidneys, liver and blood at inhalation has been determined at 10 mg/m^3 during animal trials. The concentration of ethylbenzene is far below this value for D02. with a MoS above 1,000. There is therefore no risk of harmful effects due to liberation of ethylbenzene from the D02 product.

The liberation of ethylbenzene from product D12 is close to the lower effect limit for harmful effects with a MoS at 100. This is the least acceptable safety margin for ethylbenzene and it is therefore concluded that there may be a risk of health effects when using the product. Product D12 is intended for children below the age of three years.

9.4.6 Hexane

Hexane was found in the emission from product D14. Calculation of the concentration around the person shows a concentration in the inhalation air of 3 µg/m^3 when including the weight of the product.

Table 9.10: Calculated concentration at inhalation of hexane

Product	Calculated koncentration[1] µg/m^3	LCI µg/m^3	RfC mg/m^3	NOAEL µg/m^3	Margin of safety[2]
D14^	3.0	700	200	1,762.000	$5.9 \cdot 10^5$

[1]The concentration at inhalation is calculated on the basis of the emission test, compare formula 4
[2] Margin of safety is NOAEL divided by the calculated concentration
^ Is no longer on the Danish market

The concentration of hexane is far below the LCI and RfC values. The concentration is also far below the NOAEL value which is the lower effect limit for irritation. There is therefore no risk of inconvenience or health effects from the emission of hexane from the two products.

9.4.7 Methylethylketone (MEK)

Methylethylketone was found in the emission from products D02 and D08. The substance was probably added to release scent.

Calculation of the concentration around the person using the products shows levels of 1.7 µg/m^3 for product D02 and of 3.4 µg/m^3 for product D08, taking the weight of the products into account.

Table 9.11: Calculated concentration at inhalation of methylethylketone (MEK)

Product	Calculated concentration [1] µg/m^3	LCI µg/m^3	Odour threshold µg/m^3	NOAEL µg/m^3	Margin of safety[2]
D02	1.7	1,000	870	2,945,000	$1.7 \cdot 10^6$
D08	3.4	1,000	870	2,945,000	$8.7 \cdot 10^5$

[1]The concentration at inhalation is calculated on the basis of the emission test, compare formula 4
[2] Margin of safety is NOAEL divided by the calculated concentration

The concentration of methylethylketone (MEK) liberated from products D02 and D08 is far below the LCI value and odour threshold for the substance. The concentrations are also far below the lower effect limit for harmful effects, and the safety margin (MoS) is therefore sufficiently high for playing with the two products.

It is therefore assessed that there is no risk of inconvenience or health effects from methylethylketone from the two products.

9.4.8 Methylisobutylketone (MiBK)

Methylisobutylketone was found in the emission from products D04 and D12. The substance was probably added to release scent.

Calculation of the concentration around the person using the products shows levels of 7 µg/m^3 for product D04 and of 5 µg/m^3 for product D12, taking the weight of the products into consideration.

Table 9.12: Calculated concentration at inhalation of methylisobutylketone (MiBK)

Product	Calculated concentration[1] µg/m^3	LCI µg/m^3	NOAEL µg/m^3	Margin of safety[2]
D04	7.0	1,000	208,000	$3.0 \cdot 10^4$
D12^	5.0	1,000	208,000	$4.2 \cdot 10^4$

[1]The concentration at inhalation is calculated on the basis of the emission test, compare formula 4
[2] Margin of safety is NOAEL divided by the calculated concentration
^ Is no longer on the Danish market

Both levels are very low and far below the LCI value for the substance. The levels are also far below the NOAEL value for effects on blood, liver and kidneys and on the basis of the calculated MoS it is assessed that there is no risk of health effects due to emission of methylisobutylketone from the two products.

9.4.9 Toluene

Toluene was found in the emission from products D02, D04, D09, D12, D14 and D15. Calculation of the concentration around the person using the products shows levels of 11.7 µg/m^3 for product D02, 6 µg/m^3 for product D04, 4 µg/m^3 for product D09, 8 µg/m^3 for product D12, 20 µg/m^3 for product D14 and 8 µg/m^3 for product D15, considering the weight of the products.

Table 9.13: Calculated concentration at inhalation of toluene

Product	Calculated concentration[1] µg/m^3	LCI µg/m^3	NOAEL µg/m^3	Margin of safety[2]
D02	11.7	1,000	377,000	$3.2 \cdot 10^4$
D04	6.0	1,000	377,000	$6.3 \cdot 10^4$
D09	4.0	1,000	377,000	$9.4 \cdot 10^4$
D12^	8.0	1,000	377,000	$4.7 \cdot 10^4$
D14^	20.0	1,000	377,000	$1.9 \cdot 10^4$
D15	8.0	1,000	377,000	$4.7 \cdot 10^4$

[1]The concentration at inhalation is calculated on the basis of the emission test, compare formula 4
[2] Margin of safety is NOAEL divided by the calculated concentration
^ Is no longer on the Danish market

The concentrations in the inhalation air are low for products D02, D04, D09, D12, D14 and D15. The concentrations are far below the LCI value of 1,000 µg/m^3 for the substance. The concentrations are also far below the lower effect limit for effects on the central nervous system stated as the NOAEL with a MoS in an acceptable order of magnitude (> 1,000).

It is therefore assessed that there is no risk of health effects due to emission of toluene from products D02, D04, D09, D12, D14 and D15.

9.4.10 Xylenes

Xylenes have been demonstrated in the emission from products D02, D12, D14 and D15. Calculation of the concentration around the person using the products shows levels of 1 µg/m^3 for D02, 90 1 µg/m^3 for D12, 3.3 1 µg/m^3 for D14 and 2 µg/m^3 for D15, taking the weight of the products and the tested parts into consideration.

Table 9.14: Calculated concentration at inhalation of xylenes

Product	Calculated concentration[1] µg/m^3	LCI µg/m^3	NOAEL µg/m^3	Margin of safety[2]
D02	1.0	1,000	560,000	$5.1 \cdot 10^5$
D12^	90	1,000	560,000	$6.2 \cdot 10^3$
D14^	3.3	1,000	560,000	$1.7 \cdot 10^5$
D15	2.0	1,000	560,000	$2.8 \cdot 10^5$

[1]The concentration at inhalation is calculated on the basis of the emission test, compare formula 4
[2] Margin of safety is NOAEL divided by the calculated concentration
^ Is no longer on the Danish market

The concentrations are far below the LCI value for the substance of 1,000 µg/m^3. For product D12, the concentration is close to the RfC value of 100 µg/m^3 (IRIS 2004). This means that there may be a risk of toxic effects.

The concentrations for all four products are far below the lower effect limit for teratogenic effects and the calculated MoS is at an acceptable order of magnitude (>1,000).

It is therefore assessed that there may be a risk of health effects due to emission of xylenes from product D12, but not from products D02, D14 and D15.

9.5 Total evaluation of health conditions in relation to products D02 and D08

The D02 and D08 products liberate a large number of volatile, chemical substances during the emission test. Some of these substances show high concentrations in the test.

Conversion to realistic worst-case situations gives lower values. The calculated concentrations for the volume (2 m^3) around the person appear from the table for the identified and quantified substances in the emission test.

Table 9.15: Concentrations in the inhalation air when playing with products D02 and D08

Chemical substance	Concentration in the inhalation air in µg/m^3 from the product		LCI (EU, 1997) µg/m^3
	D02	D08	
n-butanol	0.9	-	1,000
tert-butanol	-	8.8	1,000
n-butylacetate	10.3	-	7,000
Butylglycol	16.4	-	1,000
Cyclohexane, 1-ethyl-1-methyl-2,4-bis(1-methylethenyl)	-	0.4	-
Cyclohexanon	41.8	-	1,000
Ethylacetate	0.2	-	5,000
Ethylbenzene	1.9	-	1,000
Fenchol	-	7.6	-
n-heptane	-	0.7	8,000
Heptanal	-	0.5	400
Hexanal	0.2	-	400
Limonen	0.1	-	1,000
Longifolene	-	0.4	1,000
Methylethylketone (MEK)	1.7	3.4	1,000
n-octane	-	1.4	9,000
Propylenglycol	4.4	-	4,000
α-terpineol	-	3.4	1,000
Other terpenes	-	106	1,000
Toluene	11.7	-	1,000

There is no recommended LCI value or other limit value for a total exposure with VOC in the indoor climate.

Many volatile, organic components are liberated from product D02. All the single substances appear in concentrations in the inhalation air that are far below the LCI values. There is therefore no risk that the substances are available in the inhalation air in concentrations that may cause health effects. Unidentified and non-quantified substances are not included in the table. Combination effects cannot be excluded. It has not been possible to assess this in the present project.

Product D08 also liberates some volatile, organic compounds. Unidentified and non-quantified substances are not included in the table. None of the single substances are liberated in concentrations that may cause health effects. Combination effects cannot be excluded.

10 Discussion

10.1 Toys with fragrances

This investigation has identified 15 different product types for children which have been marketed as containing scent.

The market changes constantly and several of the products are only available on the market in a very short period of time (under 6 months). Five of the products that were identified at the start of the investigation are no longer available on the market in their original form. Today, the products are only available in a variant without scent.

It has not been possible to provide any data that shed light on the size of the market for toys and children's articles containing fragrances.

The market for toys changes all the time and new product types frequently occur. New products available on the market today may not have been available at the time of the investigation.

10.2 Ingredient substances in toys

The identified products have undergone preliminary screenings to assess the ingredient substances qualitatively and subsequently select the products for detailed analysis.

10.2.1 Content of sensitizing fragrances

The analyses of the 24 specific fragrances, considered sensitizing by EU's Scientific Committee on Cosmetics (SCCNFP 1999), have shown that 18 of these substances are available on the Danish market in products for children. 7 of the 10 analyzed products, viz. D01, D04, D06, D08 (red and yellow variant), D12 and D15, contained between 2 and 9 of the 24 fragrances. The product D12 has now been removed from the market and is only available in unscented versions at the Danish market.

Analyses have also been conducted for two other fragrances that are not on the EU list; oakmoss and treemoss. None of these two substances have been detected in the 10 tested products or in the 18 products from the screening test.

10.2.2 Content of other chemicals

Screening for ingredient substances in 10 selected products has demonstrated a content of many different chemical substances, including organic solvents, fragrances and phthalates.

Four of the products for children below the age of three years have been selected for migration analysis in order to test if the substances can migrate from the toys via the sweat of the child to be absorbed by the skin. The

migration analysis has been conducted for products D09, D12, D14 and D15. The analyses have shown that substances from all four products can be liberated to sweat. The concentrations of the liberated substances are, however, relatively low, except for tris(2-chlorethyl)phosphate that has been demonstrated in a relatively high concentration from product D12. The substance was probably added to act as a flame retardant in the foamed plastics that the product contains.

7 of the products have been tested for emission of volatile substances to the air. All 7 products liberate volatile, organic components in varying concentrations, mainly organic solvents and fragrances besides the 26 analyzed fragrances. Especially products D02 and D08 liberate a large number of volatile, organic substances.

10.3 Health conditions when using toys with fragrances

The results of the tests for migration and emission have been used for estimating if there can be any adverse health effects when playing with the tested products.

Exposure scenarios have been made and calculations have been carried out for potential skin absorption and inhalation of the 10 selected chemical substances. The substances were selected on the basis of their harmful effects and a relatively high emission or migration.

10.3.1 Health conditions during migration

Calculations have been made for the potential skin absorption in a typical exposure situation with one chemical substance, viz. tris(2-chlorethyl)-phosphate, that has been demonstrated during migration from product D12. The substance is on the list of the Danish Environmental Protection Agency of unwanted substances and is undergoing a risk assessment by EU. The substances are classified as Xn;R22 Carc3;R40 N;R51/53 on the list of dangerous substances.

The calculations of skin absorption show that the substance can be absorbed in quantities which gives reason to assess that there may be a risk of harmful effects when playing with this product. However, it has to be stressed that this is provided that the entire available quantity is liberated at the same time. The product is no longer available on the Danish marked.

The substance was probably added to avoid flame spread in case the product catches fire. In Denmark, it is, however, not usual that flame retardants are added to consumer products that are not intentionally exposed to high temperatures or are not heated like for instance electronic equipment, including televisions.

It is more appropriate to avoid that children play near to open fire than to add flame retardants to toys and children's articles.

The results may therefore lead to a recommendation to the producers, importers and suppliers of the importance of obtaining information about the content of toys and children's articles including possible flame retardants, perfumes and other chemical substances.

10.3.2 Health conditions at emission of volatile, organic components

7 of the selected products have been analyzed during emission tests to estimate the liberation of volatile, organic components (VOC). The different products are for both small children below the age of three years and for older children.

The emission tests show that a number of volatile, organic compounds are liberated from the toys, especially fragrances and organic solvents.

At first glance, the concentrations from the test results look high. The test was conducted in a container with a small volume. When data from the emission tests are converted to realistic situations, the concentrations of most of the substances in the air around the child are, however, relatively low. This applies to 8 of the selected substances. The concentration in the air around the child will thus be low for the substances tert-butanol, n-butylacetate, cyclohexanon, hexane, methyletylketone, methylisobutylketone and toluene liberated from the products. The Margin of Safety (MOS) factors for these substances vary from 5,300 to 1,700,000.

Ethylbenzene is liberated from product in concentrations that may cause adverse effects. Converted to realistic situations, the concentration in the inhalation air is close to the lower effect limit for harmful effects. The liberation of xylenes from this product is also close to the lower effect limit for effects at inhalation. This product is no longer available on the Danish market.

However, it has to be noted that the emission test only has been made once and for new products in original packaging. The time interval from production to purchase is unknown. However, it must be expected that the emission rate decreases as a function of time upon unpacking, meaning that the measured concentration will probably be short.

The substance butylglycol is liberated from product D02 in a concentration that may cause odour nuisances. However, there are no adverse effects involved at the concentration in which the substance butylglycol occurs.

Volatile, organic components from the other products, viz. D04, D08, D09, D14 and D15, are liberated in concentrations that are not assessed to cause any inconvenience or adverse effects.

10.3.3 Toys with soft plastic parts

One of the analyzed products (D14) contains phthalates in a concentration of 7.3 %. As the product is intended for children below the age of three years, it must at a maximum contain 0.05 % phthalates according to the order on classification and marking ((Ministerial Order no 151). Two of the other products are also undergoing a supplementary analysis for the content of phthalates. The results are reported separately.

10.3.4 Legislation on toys

Toys are regulated by the Council Directive 88/378/EØF on about mutual approximation of the member states to the legislation about safety requirements for toys; converted into Danish legislation in Ministerial Order

no 1116 of 12 December 2003. The directive does, however, not deal with hazardous substances and unwanted substances in toys.

A special order applies to the content of phthalates in toys. The content of phthalates must not exceed 0.05 % in toys and other articles intended for children below the age of three years (Ministerial Order no 151). There are at present no rules when it comes to content of phthalates in toys for children older than three years. But new rules have been decided and are expected to come into force within a year.

Children can therefore be exposed to phthalates when they have passed the age of three years. Children are generally a very vulnerable group - also when they are older than three years. Furthermore, children and adults can be exposed to phthalates in the environment and from other products and building materials.

There is no application limitation for the fragrances. Many of the fragrances are on the preliminary list of flavouring agents that are allowed in food. At present, the substances on this list are undergoing a health assessment. A new positive list for flavouring agents is expected in 2006 (the Danish Veterinary and Food Administration 2004).

Children can therefore be exposed to sensitizing fragrances from other products than toys, including food, cosmetics and nature.

10.4 Recommendations when purchasing and playing with toys

In summary, the results of the investigation lead to a number of recommendations to consumers and producers, suppliers and importers of toys and children's articles containing fragrance and flavour.

Recommendations to consumers:

- Buy toys without fragrances.
- Unpack the product some time before use, if it has an odour, it should be placed in a ventilated area before given to the child for play
- When a toy is bought for children under the age of three, it should be labelled "for children less than 3 years".

Recommendations to producers, suppliers and importers of toys and children's articles:

- Avoid the use of flame retardants in toys in case there is no real risk that the product catches fire and/or make demands on sub-suppliers that the products are not containing any flame retardants.
- Minimize the use of volatile organic substances in toys and children's articles.
- Always obtain documentation from the producers about the content of chemical substances in toys.

11 References

Allergi-leksikon (2004 a): www.allergi-leksikon.dk/Allergi/Definition/Den allergiske reaktion, hjemmeside besøgt 9. juni 2004. www.allergi-leksikon er udarbejdet af Rigshospitalets Allergiklinik, projektleder Karin Hamberg Rasmussen.

Allergi-leksikon (2004 b): www.allergi-leksikon.dk/Allergi/Definition, hjemmeside besøgt 9. juni 2004. www.allergi-leksikon er udarbejdet af Rigshospitalets Allergiklinik, projektleder Karin Hamberg Rasmussen.

Allergi-leksikon (2004 c): www.allergi-leksikon.dk/Allergi, hjemmeside besøgt 21. juni 2004. www.allergi-leksikon er udarbejdet af Rigshospitalets Allergiklinik, projektleder Karin Hamberg Rasmussen.

Allergi-leksikon (2004 d): www.allergi-leksikon.dk/Allergi/Definition/Den ikke-allergiske reaktion, hjemmeside besøgt 9. juni 2004. www.allergi-leksikon er udarbejdet af Rigshospitalets Allergiklinik, projektleder Karin Hamberg Rasmussen.

Allergi-leksikon (2004 e): www.allergi-leksikon.dk/Allergi/Definition/Høfeber, hjemmeside besøgt 21. juni 2004. www.allergi-leksikon er udarbejdet af Rigshospitalets Allergiklinik, projektleder Karin Hamberg Rasmussen.

Allergi-leksikon (2004 f): www.allergi-leksikon.dk/Allergi/Definition/Astma, hjemmeside besøgt 21. juni 2004. www.allergi-leksikon er udarbejdet af Rigshospitalets Allergiklinik, projektleder Karin Hamberg Rasmussen.

Astma-Allergi Forbundet (2004 a): www.astma-allergi.dk, For fagfolk/For sundhedsplejesker/Allergi, hjemmeside besøgt 15. juni 2004.

Astma-allergi Forbundet (2004 b): www.astma-allergi.dk, Eksem/Kontakteksem / håndeksem/Kontakteksem / allergi, hjemmeside besøgt 15. juni 2004.

AT (2002): C.0.1 Oktober 2002. Grænseværdier for stoffer og materialer, Arbejdstilsynet, 2002.

Bank, S. (2004): Telefonisk samtale med Susanne Bank, indkøber hos Jysk maj 2004.

Bedoukian Research Inc. (2004): www.bedoukian.com/products/products.asp?id=483. Hjemmeside besøgt 3. august 2004

Bekendtgørelse nr. 151 om forbud mod phthalater i legetøj til børn i alderen 0-3 år samt i visse småbørnsartikler m.v. (Ministerial Order no 151 about prohibition of phthalates in toys for children at the age 0-3 and in certain baby articles)

Bureau of Indian Standards (2004): www.bis.org.in/sf/pcd/2252.pdf. Hjemmeside besøgt 5. juli 2004

Chemical Land 21 (2004): www.chemicalland21.com, Products>Speciality Chemicals>Performance chemicals>Flavour & Fragrance Processings. Hjemmeside besøgt 5. juli 2004

Contact Dermatitis Clinic, Department of Dermatology, University Hospital of Wales (2004): www.ukdermatology.co.uk/downloads/Fragrances.doc. Hjemmeside besøgt 5. juli 2004

EU (1997). Evaluation of VOC Emissions from Building Products. Report no. 18. European Commission.

Frosch, P. J.; Johansen J. D. & White, I. R. (eds.), (1998): Fragrances: Beneficial and adverse effects. Springer, Berlin.

Frosell, P. H. (1982): Fra duftenes verden: Parfumerne og deres historie. Hernov, København.

Fødevarestyrelsen (2004). Artikel på hjemmesiden www.fvst.dk om aromastoffer fra juli 2003.

Grene, M. (2004). E-mail fra Mikkel Grene, marketingchef hos Søstrene Grene, maj 2004

Hylstofte, K. (2004). Telefonisk samtale med Kristine Hylstofte, Nokia, maj 2004

International Flavour and Fragrance Inc.(2004): www.iff.xom/Ingredients.nst/FragIngredients!OpenForm.htm. Hjemmeside besøgt 5. juli 2004

IRIS (2004): Integrated Risk Information System, US National Library of Medicine, http://toxnet.nlm.nih.gov

IUCLID (2000): International Uniform Chemical Information Database, Public data on high volume chemicals, European Commission, Joint Research Centre, Institute for Health and Consumer Protection, European Chemicals Bureau.

Iversen, L. Taudorf, E.; Halken, S.; Knudsen, L. E.; Skov, P. Lydeking-Olsen, E.; Espersen, A. & Agner, T. (2000): Handlingsplan for forebyggelse af overfølsomhed og allergiske sygdomme i Danmark 2001-2005, Teknologirådets rapporter 2000/7.

Johansen, J. D. (2002): Contact Allergy to Fragrances: Clinical and Experimental Investigation of the Fragrance Mix and its Ingredients, Contact Dermatitis 2002: 46: supplement no. 3: 1-31.

Joint FAO/WHO Expert Committee on food additives (JECFA) - Specifications for flavouring agents (2004): www.fao.org/es/ESN/Jecfa/database/xover.htm. Hjemmeside besøgt 5. juli 2004

Joint FAO/WHO Expert Committee on food additives (JECFA) - Specifications for food additives agents (2004): www.fao.org/es/ESN/Jecfa/database/xover.htm. Hjemmeside besøgt 5. juli 2004.

Kirchhoff, A. B. (2004): Telefonisk samtale med Anne Britt Kirchhoff, Coop Danmark, maj 2004.

Miljø og Sundhed (2004): Miljø og Sundhed/børn/børn og miljø/grønne råd om produkter til baby, www.miljoeogsundhed.dk, hjemmeside besøgt 3. maj 2004.

Miljøministeriet (2002): BEK nr. 329 af 16/05/2002. Bekendtgørelse om klassificering, emballering, mærkning, salg og opbevaring af kemiske stoffer og produkter.

Miljøstyrelsen (2001a): Children and the unborn child, exposure and susceptibility to chemical substances - an evaluation, Environmental Project no. 589, 2001 Danish Environmental Protection Agency

Miljøstyrelsen (2001b): Kemi i børns hverdag, Miljøtema nr. 23, 2001, Miljøstyrelsen.

Miljøstyrelsen (2002 a): Indholdet af udvalgte duftstoffer i rengøringsprodukter og andre forbrugerprodukter, Kortlægning af kemiske stoffer i forbrugerprodukter, Kortlægning nr. 8 - 2002.

Miljøstyrelsen (2002 b): Naturkosmetik giver også allergi, MiljøDanmark nr. 2/2002, www.mst.dk/udgiv/12080400.htm, hjemmeside besøgt 11. juni 2004.

Miljøstyrelsen (2003 a): Kortlægning af kemiske stoffer i duftkuger/airfreshener og andre produkter der afgiver duft, Kortlægning af kemiske stoffer i forbrugerprodukter nr. 30, 2003.

Miljøstyrelsen (2004 a): Faktaark nr. 5: Mærkning af kosmetik, www.mst.dk/kemi/02060105.htm, hjemmeside besøgt 4. maj 2004.

Miljøstyrelsen (2004 b): Direktivet om 7. ændring af kosmetikdirektivet, www.mst.dk/kemi/02060801.htm, hjemmeside besøgt 4. maj 2004.

Miljøstyrelsen (2004 c): Notat om mærkning af produkter, der afgiver duft, www.mst.dk/kemi/02054407.htm, hjemmeside besøgt 4. maj 2004.

Miljøstyrelsen (2004 d): Kommunikation med Anette Orloff, Miljøstyrelsen om Begrænsninger for duftstoffer i bilag III i medfør af 7. ændring af kosmetikdirektivet.

Mørtz, C.G; Lauritsen, J.M.; Bindslev-Jensen, C. & Andersen, K.E.(2001): Preavalence of atopic dermatitis, asthma, allergic rhinitis, hand and contact dermatitis. The Odense adolescence cohort study on atopic diseases and dematitis, *British Journal of Dermatology 2001, 144, 3, 523-532.*

Nielsen, A. (2004): Telefonisk samtale med Annabell Nielsen, Dansk Supermarked, maj 2004.

Nielsen, J.(2004): Telefonisk samtale med Jane Nielsen, Lagerchef, Dansk Supermarked, maj 2004.

Nielsen, N. H.; Menné, T. (1992): Allergic Contact Sensitization in an Unselected Danish Population. The Glostrup Allergy Study, Denmark, *Acta Derm Venereol 1992, 72, 456-460*

Noweon Kalama Inc (2004): www.biveib.com/products/kalama/acapbn.htm. Hjemmeside besøgt 5. juli 2004.

Physical and Theoretical Laboratory, University of Oxford (2004): Safety (MSDS) data for farnesol, http://physchem.ox.ac.uk/MSDS/FA/farnesol.html. Hjemmeside besøgt 5. juli 2004.

Rastogi, S. C.; H., S.; J., J. D. & B., D. A. (2001): Fragrance Chemical in domestic and occupational products, *Contact Dermatitis 2001, 45, 221-225.*

Rastogi, S. C.; Jensen, G. H. & Johansen, E (1994):; Chromatographic analysis of some fragrances in cosmetics and toiletries, NERI Technical Report No. 106, DMU, 1994.

Rastogi, S. C. & Jensen, G. H. (1995 a): Contents of some skin sensitizing fragrances in selected cosmetics, NERI Technical Report No. 129, DMU, 1995.

Rastogi, S. C. & Jensen, G. H. (1995 b): Investigation of selected fragrance substances in cosmetics based on natural ingredients, NERI Technical Report No. 143, DMU, 1995.

Rastogi, S. C., Johansen, J. D.; Menné, T.; Bruze, M.; Lepoittevin, J. P.; Dreier, B.; Andersen, K. E. & White, I. R. (1998): Deodorants on the European market: quantitative chemical analysis of 21 fragrances; *Contact Dermatitis, 1998,38, 29-35.*

Rastogi, S. C., Johansen, J. D.; Menné, T.; Frosch, P.; Bruze, M.; Andersen, K. E.; Lepoittevin, J. P.; Wakelin, S. & White, I. R. (1999): Contents of fragrance allergens in children's cosmetics and cosmetic-toys; *Contact Dermatitis, 1999, 41 ,84-88.*

Reichstoff-Lexicon (2004): www. omicron-online.de/cyberchem/aroinfo/lyral.htm. Hjemmeside besøgt 5. juli 2004

Riskline (2004): Toxline special, US National Library of Medicine, http://toxnet.nlm.nih.gov

TGD (2003): Technical guidance document in support of Commission Directive 93/67/EEC on risk assessment for new notified substances and Commission Regulation (EC) No. 1488/94 on risk assessment for existing substances. European Chemicals Bureau. (http://ecb.jrc.it)

SCCNFP (1999): The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, Opinion concerning Fragrance Allergy in Consumers, appendix s. 33-34.

http://europa.eu.int/comm./food/fs/sc/scco/out98_en.pdf, hjemmeside besøgt 22. juni 2004.

Smith, C.K. & Hotchkiss, S.A.M., Allergic Contact Dermatitis, Chemical and Metabolic Mechanisms (2001): Kap. 1 Allergic Contact Dermatitis to Small Molecule Xenobiotics, 2001, Taylor & Francis, London and New York, ISBN 0-415-25047-1

The Good Scents Company (2004): www.thegoodscentscompany.com/data/rw1014311.htm. Hjemmeside besøgt 5. juli 2004

Videncenter for Allergi (2004 a): www.videncenterforallergi.dk, Om allergi/parfumeallergi, hjemmeside besøgt 14. maj 2004. Videncenter for allergi er etableret af Miljøministeriet, centeret er oprettet i samarbejde mellem hudafdelingen og lungemedicinsk afdeling, Amtssygehuset i Gentofte og hudafdelingen, Odense Universitetshospital.

Videncenter for Allergi (2004 b): Nationale allergidata/aktuelle data/allergi over for parfumestoffer, hjemmeside besøgt 14. maj. Videncenter for allergi er etableret af Miljøministeriet, centeret er oprettet i samarbejde mellem hudafdelingen og lungemedicinsk afdeling, Amtssygehuset i Gentofte og hudafdelingen, Odense Universitetshospital.

VOCBASE (1996). Lugttærskel værdier, grænseværdier for slimhindeirritationer og fysisk-kemiske parametre for flygtige organiske komponenter. Arbejdsmiljøinstituttet.