DANISH MINISTRY
OF THE ENVIRONMENT
Environmental
Protection Agency

Survey and health assesment of chemicals substances in sex toys

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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.

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Preface

The project "Analysis and health risk assessment of chemical substances in sex toys" has been carried out from 15 April 2005 to 1 November 2005. This report presents the results of the assessment.

The project has been carried out by Danish Technological Institute, Materials Division, and been headed by project manager lic.scient. Nils H. Nilsson, who has also been the contact person to the Danish Environmental Protection Agency (EPA).

Laboratory manager Nils Bernth has been responsible for the laboratory analyses and the migration tests, assisted by laboratory technician Eva Pedersen, Chemistry and Water Technology with Head of Section Paul Lyck Hansen as quality controller.

For screening and assessment of health effects (consumer exposure) and risks M.Sc. Bjørn Malmgren-Hansen and B.Eng. Kirsten Pommer have formed the expert group with cand. scient. Ole Chr. Hansen as quality controller.

The project manager has been responsible for interviews, procurement of test products information retrieval and has been the DTI expert within rubber and plastics.

The aim of the project is to examine whether there are hazardous substances in sex toys in use based on worst case scenarios.

Summary

On behalf of the Danish EPA, DTI has made inquiries about the consumption pattern in connection with the use of sex toys made of rubber or plastics. Further, 16 different sex toys were procured for chemical screening for hazardous substances. 6 of these were finally selected for the actual migration test. Based on these analyses a health risk assessment of selected substances was carried out.

The survey shows that the choice of sex toys is very large – not only from shops selling sex/porno articles, but to a high extent also through sales on the Internet. The same distributor often has more Internet addresses which are adjusted to fit the specific customer segments.

A very large part of the sex toys is produced in the Far East (China) and there are mostly no material descriptions available. Jelly, which is a widely used material designation, has turned out to be plasticized vinyl (PVC). The plasticizer content may be very high up to 70%, which means that more than 2/3 of the materials consist of plasticizers. The plasticizers used are of the phthalate types (DEHP, DNOP; DINP).

The shops we have visited proved to possess very little knowledge of the materials. Their advice to customers in doubt of any hazardous effects of the material is to apply a condom to the device, e.g. a vibrator. Another recommendation is to clean the products before and after use with mild soapy water.

The criteria for selecting the sex toys were that both rubber and vinyl products as well as fetish clothing should be analysed in the screening and migration tests. Further, not only products from China but also toys from outside Europe or other, e.g. Canada should be included.

The element screening analyses showed that one product, a stick vibrator in hard ABS exceeded the allowed amount of cadmium considerably (200 ppm against a limit value of 75 ppm). Two products contained tin in substantial concentrations and for one of them a Gas Chromatography/Mass Spectroscopy (GC/MS) screening detected liberation of trimethyltin chloride.

Altogether the chromatographic screenings detected a substantial liberation of a number of hazardous substances.

The chemical substances include solvents, degradation products from accelerators and other rubber chemicals and plasticizers. Several of those are reprotoxic and a few have other injurious health effects, e.g. neurotoxic effects.

The screening results formed the basis for selecting the six products for the migration test. One selection criteria was that products in rubber, thermoplastic rubber and soft vinyl should be included in the tests. Further, the values for degassing or content of hazardous substances detected by the

screening analyses were considered, where products with high concentrations were selected.

The rate of occurrences of the specific identified chemical substances in all purchased products was also an important factor for selecting samples for the analyses.

The health assessment found that some of the products carried health risks in connection with the substances stated in Table 1.0:

Table 0.1 Hazardous substances and effects

Substance	Effects
DEHP (Bis -2-ethylhexyl phthalate)	Harmful effects on foetus and fertility, effects on liver and kidneys
2-ethylhexane acid	Suspicion of harmful effect on foetus
Phenol	
Carbon disulphide	Suspicion of harmful effect on foetus and on fertility
Trimethyltin chloride	Irreversible neurotoxic effects

Especially for DEHP the risk will depend on the use of lubricant cream, as oil based lubricant cream will increase the migration of the plasticizers.

The risk will depend on the use and the major part of the products carry no risk by normal use, see Table 0.2.

Table 0.2: Identified health effects for products

Product no	Type	Health effect Normal use [3]	Health effect Max. use [3]
1	Dildo	None	None
2	Dildo	Minor risk pregnant/breast feeding (trimethyltin chloride)	Risk for pregnant/breastfeeding, minor risk other adults (trimethyltin chloride)
3	Dildo	None	Minor risk for pregnant/breastfeeding (DEHP)[2] , possible minor risk (phenol, carbon disulphide)
4	Dildo	None	Minor risk for pregnant/breastfeeding (DEHP)[2] , possible minor risk (phenol, carbon disulphide, 2-ethylhexane acid)
5	Dress	None[1]	Possible minor risk [1]
6	Gloves	None [1]	None [1]
7	Dildo	None	Possible minor risk (carbon disulphide)
8	Dildo	None	Minor risk for pregnant/breastfeeding (DEHP) [2], possible minor risk (phenol)
9	Patent leather top	None [1]	None[1]
10	Art. Vagina	None	None
11	Dildo	None	Minor risk (phenol)
12	Dildo	None	None
13	Dildo	None	Possible minor risk (phenol)
14	Gag	None	None
15	Dildo	None	Minor risk for pregnant/breastfeeding (DEHP) [2], possible minor risk (phenol)
16	Dildo	None	None

1: Calculations indicate a risk of reprotoxic health effects from carbon disulphide exposure when using closed bodysuits for prolonged periods. No risk when using items which cover only a small part of the body, products No. 6, 9. There may be a minor risk with product No. 5 by max. use.
2: The risk is dependant on the use of lubricant cream; however, the risk is reduced by use of water-based lubricant cream.
3. Normal use of dildos and artificial vaginas has been determined to be once a week for 15 minutes. Max. use 1 hour per day. Gag is used for 1 hour per month by normal and by max. use. Fetish products (Nos. 5, 6, 7) are used for 3 h/month by normal use and 7 h/week by max. use.

As to the dildos it should be mentioned that the migration of DEHP in waterbased lubricant cream was 100 lower than in oil based lubricant cream, however, 8 times higher than in synthetic sweat. Thus the waterbased lubricant reduces the risk of health effects of substances as DEHP and DNOP with a very low degree of water solubility. The conditions applying to vaginal, anal and oral are expected to a certain degree to differ from the synthetic sweat, and expelled fluids as e.g. saliva will presumably increase the migration of substances with a low degree of water solubility such as DEHP.

Overall, only 7 products, nos. 1, 6, 9, 10, 12, 14 and 16, contained no health risks in worst case use but product no. 16 contains cadmium above the allowed level and is therefore not allowed on the European market.

Product no. 2 should not be used by pregnant/breastfeeding women due to its content of trimethyltin chloride which may cause irreversible neurotoxic effects (brain damage) to progeny. Additionally, there is a minor risk of neurotoxic effects to adults in worst case.

The other products, apart from product no. 2, involve no health risks by normal use.

1 Introduction

The Danes are one of the world's most educated, inquisitive and liberal people, also in the sexual area. (Bork E, 2003). Written and pictorial pornography was thus legalised in Denmark already in 1967 and 1969 (Larsen RE, 2000).

At the same time the Internet has made it incredibly easy anonymously to gain information about sex and marital relations (e.g. www.sexhealth.org), and consumers who are sexually experimenting or just broad-minded may choose freely among the many temptations of the Internet shops.

Sex toys are not only made of plastics and rubber but also glass and steel are being used. Sex toys are available in many geometries and designs; there is certainly no lack of inventiveness.

Most commonly known are the numerous versions of dildos with many different sizes, colours and designs. Many are battery-powered, e.g. massage devices (vibrator), and the most sophisticated are remote-controlled just as televisions and radios.

Intimate clothing (fetish) such as long gloves, boots, hoods and various lingerie and costumes in skin contact are offered to the customers in many variants.

Sex toys are mainly made of vinyl (soft PVC) or rubber latex. The most commonly known and cheapest latex is made of natural rubber and it is assumed that the majority of the rubber-based toys are made of natural rubber latex. Also silicone-based toys are available. A new skin-like material, Cyberskin, which is said to originate from the space industry, is gaining foothold in the market. An infrared analysis of this material has established that it is a thermo-elastic material (SEBS).

As to the origin of the sex toys it is characteristic that the major part is produced in the Far East, especially China, however, we also see Danish manufacturers of both dildos as well as intimate latex clothing.

Without exception recipes are unknown.

Use of sex toys is no new phenomenon. Dildos made of stone, jade or leather were used also in ancient time. The oldest are said to be 2000-4000 years old and originate from i.e. China.

The vibrator was invented in the 1880'ies and was used by doctors for treatment of women who at that time's diagnosis suffered from hysteria. With the knowledge we have today the effect has merely been stimulation to orgasm.

2 Analysis

2.1 Method

The consumption pattern is determined through interviews with relevant actors within sex toys and visits to web sites. Questionnaires formed the basis for the interviews.

The analysis covered both toys, which are getting in contact with the sexual organs as well as toys in the form clothing (fetish) in vinyl or rubber.

2.2 Result

2.2.1 Visit to sex fair

The sex fair ”Erotic World” is held at regular intervals not only in Copenhagen but also in the province. The fair gives a good impression of the multiplicity of sex toys in the market. An Erotic Guide can be bought at the fair; it is published once a year and gives a survey of the Danish actors within sales of sex toys with detailed information about their web sites.

The conclusion from visiting the fair is that most of the sex toys are produced in the Fair East and no product information is available in Danish.

2.2.2 Papers and magazines

Papers, monthly magazines and special issues appealing to both men and women bring topics about sex and maternal relations, either as letters to the editor or as articles. The language style and usage is of course depending on the target group. The topic sex toys appear regularly, but the few magazines we have frequented have not given an impression of the entire consumption pattern within sex toys in Denmark.

2.2.3 Internet

Searching for the word sex toys on the search machine Google (www.google.dk) resulted in a total of 359,000 hits.

By looking at the site visit frequency the web addresses can be limited to a few. It turned out that the same distributor have several sites, which are appealing to different customers segments.

2.2.4 Shops and interviews

Visits were paid to total 6 shops with sale of sex toys. the shops were located in Aarhus (1), Vejle (1), Kolding (1) and Copenhagen (3). A questionnaire was handed out to the shop personnel and they were inquired about "worst case use" scenario of the various types of toys.

The questions were:

Estimated sale of sex toys in Denmark classified as follows:

- Vibrators (electric powered dildos, single/double butterflies)
- Stationary dildos/plugs
- Artificial vaginas/dolls
- Love eggs/anal chains
- Other: Penis rings/breast cups

Estimated sale of fetish clothing in Denmark distributed on latex, patent leather and leather

Is there any informative labelling on the packing?

Is there a Danish manual?

Is guidance provided in connection with the sales of sex toys/fetish clothing?
If yes, what kind of guidance?

Which age groups buy (% distribution?)

- Under 15 years
- Between 15 and 18 years
- Between 19 and 30 years
- Between 31 and 40 years
- Between 41 and 60 years
- Over 60 years

Who are the primary customers?

- Male
- Female
- Couples

Are the customers repeat customers?

How is the material knowledge of the shop personnel in regard to sex toys and their chemical substances?

Where are the products manufactured?

- The Far East
- Europe
- USA
- Other

Is the purchase made directly or via importer/wholesaler?

2.3 Questionnaire Answers

2.3.1 Total consumption in Denmark distributed on product types

Of the six shops visited 4 returned the questionnaire.

From the answers it appears that the vibrator is far the most popular sex toy, totalling 40-50 % of the total sale of sex toys.

Dildos without vibrator function make up approx. 20 % of the sales, artificial vaginas between 0-15 %. Shops, which are exclusively appealing to women, have neither artificial vaginas nor dolls in their product range. The biggest sale of artificial vaginas and dolls does not surprisingly take place from shops exclusively appealing to men (wide range of porno films). Sale of love eggs/anal chains ranges between 5-15 %. The information about other toys such as penis rings etc. is varying from shop to shop, depending on the target group the range is 5 % to 40 %.

None of the shops had an idea of the size of the total market for sex toys in Denmark. Neither was there any information about sales from shops compared to purchase Internet sales.

When it comes to fetish clothing the estimate differs a lot from shop to shop regarding choice of material (latex, patent leather or leather). One shop states that 90 % of their sale is within patent leather (soft vinyl) and 5-10 % within leather. Another shop has a ratio of approx. 35 % latex, 50 % patent leather and 15 % leather, and a third one maintains their sale to be 60 % latex, 10 % patent leather and 30 % leather.

The sale of fetish clothing is moderate compared to sex toys, except of course for fetish-specialised shops.

The most expensive costumes/dresses in rubber are very sophisticated and may very well cost around 10,000 DKK.

2.3.2 Informative labelling and manuals in Danish

The general opinion is that information labelling on the products was insufficient or even lacking. Neither do the products come with a Danish manual. One shop informs us that normally a manual is not needed, but do the customers request one, it can be provided.

2.3.3 Sales guidance

All shops provide guidance on their sales of sex toys or fetish clothing, including advice on product care before and after use. Information about any allergic reactions is also included and the customer is recommended to apply a condom to the device if in doubt. Further, they give advice on lubricant cream for sex toys, primarily products in rubber, where they distinguish between use of water based and oil based lubricant creams. The guidance in the shops varies a bit. One shop advices against using oil based lubricant cream with products in soft vinyl (jelly) because experience shows that it will damage the product, another recommends to use whatever the cream the customer favours. Another advice is to wash the toys in mild soapy water before and after use.

2.3.4 Materials knowledge

All shops agreed that they lack information about the material composition of rubbers and plastics dildos. They all agreed on recommending silicone based sex toys as the most safe to use, they are, however, also the most expensive ones.

The shops were also very uncertain about the composition of the new material, Cyber skin, and expressed their wish that this project would bring

more information about this material. Further, the shops questioned whether a product material with a food-grade quality was qualified also for sex toys.

Their uncertainty about the materials is largely due to lack of product description from the manufacturer/importer. As far as fetish clothing is concerned, they stressed that the manufacturers declare it free of hazardous substances.

All the shops emphasized that they do no sell to people below the age of 15 years, but at the same time they admitted that it is difficult to check the customer's age when doing business over the Internet.

The largest customer segment is people between 19-60 years. But the answers on the distribution of sale within this age interval vary significantly. One shop informs about an evenly distributed sale, another estimates the sale to be biggest within the groups aged 31-40 and 41-60 years.

There are no big differences in the distribution on sex or couples, still the men are dominant in shops with a wide range of porn articles such as sex movies or special assortments appealing to "gays". One single shop states to have a majority of women customers buying toys for S&M.

The shops answered unanimously that their customers were mostly repeat customers.

2.3.5 Manufacture and Purchasing Agent

According to the questionnaires 2 of the shops state that 90% of their products are of Far Eastern origin, in another shop the Far Eastern products total 30%, 40% are from Europe/USA, the remaining from other countries.

They purchase their products either through wholesalers/importers or directly.

3 Purchased products

Based on the survey DTI purchased 16 different sex toys for analysis of content of hazardous substances. The products are listed in Table 3.1. Our purchase was aimed at the biggest market segment for sex toys, which are dildos and vibrators. Further, we have taken into consideration that soft vinyl (PVC) is used in most products.

Table 3.1 Purchased products classified according to shop type, function and material

No.	Type	Short description	Material	Comments	Shop type
1	Vibrator	Double dildo	Soft vinyl/natural rubber	Foam core composite. Oil odour	Lingerie etc.
2	Vibrator	Single dildo	Soft vinyl	Oil and toluene odour	Lingerie etc.
3	Vibrator	Single anal dildo	Soft vinyl	Oil and toluene odour	Lingerie etc.
4	Vibrator	Single dildo, grooved	Soft vinyl	Foam core composite. Diluent odour	Lingerie etc.
5	Dress	Fetish mini dress	Natural latex	Weak rubber odour	Lingerie etc.
6	Gloves	Fetish gloves, long,	Natural latex	Weak rubber odour	Fetish clothing
7	Vibrator	Single dildo	Natural latex	Foam core composite Weak rubber odour	Sex toys
8	Vibrator	Double dildo	Soft vinyl	Weak odour	Sex toys
9	Patent leather top	Transparent bra	Soft vinyl	Weak odour	Sex toys/fetish clothing
10	Vibrator	Artificial vagina	Thermoplastic rubber	Weak diesel oil odour	Sex toys/fetish clothing
11	Vibrator	Dildo	Soft vinyl	Perfumed odour The colour comes off	Sex toys/fetish clothing
12	Vibrator	Single dildo	Soft vinyl	Oil odour	Sex toys
13	Dildo	Stationary anal dildo	Soft vinyl	Diluent odour	Sex toys
14	Gag	Wire clamp mouth ball	Rubber	Rubber odour	Sex toys
15	Vibrator	Dildo	Soft vinyl	Heavy odour	Sex toys/porno
16	Vibrator	Dildo	Hard plastics	Odourless	Sex toys/porno

Further we sought to have the right balance between "normal" sex toys and fetish clothing, and it was secured that a number of the products was made of rubber. Articles which were selling extraordinary well, often because of press coverage, were also selected for the screening. One product in hard plastics (ABS) (no. 16) was selected only for the elemental screening as it was considered to liberate very few organic substances. Finally, an artificial vagina of "Cyberskin" was selected because it is a fairly new product in the market and because the shop personnel expressed great uncertainty about its "chemistry".

4 Screening analyses

The analysis programme for chemical substances will depend on whether the product is made of vinyl or rubber. Table 4.1 categorizes the products according to type and material. The categorisation is based on the product designation or an infrared spectroscopic analysis (styrene-ethene-butene-styrene (SEBS). For instance, some of the products, which were labelled jelly, were actually made of soft vinyl (PVC).

Due to the lacking informative labelling the products were subjected to a Beilstein halogen test, where an annealed cupper wire is entered into the material where after it is led into a gas flame. If the sample holds chlorine the flame will turn green. Vinyl has a high content of chlorine and therefore a positive test will give important information about the presence of vinyl.

Table 4.1 Analysed products acc. to function, material and number

Product type	Material	No.	Beilstein halogen test
Vibrator	Soft vinyl	2	+
Vibrator	Soft vinyl	3	+
Vibrator	Soft vinyl	4	-
Vibrator	Soft vinyl	8	-
Vibrator	Soft vinyl	11	+
Vibrator	Soft vinyl	12	+
Vibrator	Soft vinyl	15	+
Vibrator	Hard plastics	16	-
Vibrator	Rubber	1	-
Vibrator	Rubber (natural latex)	7	-
Stationary dildo	Soft vinyl	13	-
Artificial vagina	SEBS	10	-
Gag	Rubber	14	-
Fetish clothing mini dress	Natural latex	5	-
Fetish clothing long gloves	Natural latex	6	-
Transparent bra	Soft vinyl	9	+

As appears from the table the test was negative for the samples 4, 8, 13 and 16, and they were therefore screened for chlorine by a radiological analysis. Chlorine was detected in samples 4, 8 and 13, but not in 16. Based on the subsequent analyses it can be concluded that soft vinyl with a high content of plasticizers may give a negative Beilstein test result, even though the product contains chlorine. Further, it could be established that sample No. 16 mistakenly was assessed to be of hard vinyl because of the presence of cadmium, however, this has been found to be bound up with the yellow colour of the product.

4.1 Screening of element composition

Method description of ICP/MS

Principle
All materials have been subjected to an element screening by ICP/MS after chemical digestion of the samples with concentrated nitric acid in quarts

autoclaves with microwave induced heating. On basis of the screening quantitative analyses were made for elements, which alone are considered harmful (e.g. heavy metals), or are part of other harmful substances (e.g. organotin compounds, boron compounds or brominated substances). The element arsenic can only be identified in rubber products, as arsenic is drowned by the dominant chlorine peak from vinyl. The light elements such as oxygen, nitrogen, carbon and hydrogen cannot be detected by ICP/MS.

Sample preparation
Approx. 250 mg sample – precisely weighed out – was prepared with 5 ml 14 M HNO_3 (subboiling quality) in a quartz autoclave by microwave induced heating. The resulting solution was strained and then diluted to 25 ml with demineralised water (Milli-Q Plus).

Blank tests were prepared in the same way.

Standards
Standards and control tests were produced based on a Merck multiple element standard solution by diluting with 2.8 M HNO_3.
The internal standard mixture was produced from Perkin-Elmer single-element standards of Ge, Rh and Re by dilution with 0.14 M HNO_3.

Equipment
Perkin-Elmer Sciex Elan 6100 DRC Plus ICP mass spectrometer with FIAS 400 flow injection system and auto sampler AS 93 Plus.

Screening analysis
With addition of germanium, rhodium and rhenium as internal standards ”on-line”, the prepared solutions were screened for trace elements by inductively coupled plasma - mass spectrometry (ICP-MS) using the expert programme TotalQuantIII, which based on an instrument response curve for elements from mass 6 (Li) to mass 238 (U) quantifies the content. The instrument response curve was updated by means of a multiple element standard listing 30 elements, which covers the whole mass spectre. The elements Br, C, Cl, F, I, N, O, P and S do not quantify because of the interferences.

4.2 Element screening results

The results are shown in Table 4.2.

Table 4.2 Screening for content of chemical elements, samples 1-8 in mg/kg

Sample name	1	2	3	4	5	6	7	8	DL*
Sodium	100	5.1	-	120	19	24	-	14	5
Magnesium	1100	1.9	6.3	4.9	430	380	230	5.3	0.5
Aluminium	170	3.9	11	18	37	11	91	5.4	1
Silicium	280	53	110	130	330	310	380	83	2
Potassium	460	-	-	-	1400	2500	170	11	5
Calcium	11000	13	970	670	4500	12000	47000	420	5
Titanium	1.7	0.3	7.1	40	42	4.8	4.6	3.3	0.1
Chromium	0.4	-	2.6	1.2	0.2	-	0.2	-	0.2
Mangane	5.7	0.1	0.3	0.2	0.5	0.3	21	0.1	0.05
Iron	51	-	20	24	22	18	190	21	5

Sample name	1	2	3	4	5	6	7	8	DL*
Cobalt	0.1	-	-	-	-	-	4.6	-	0.05
Nickel	0.4	0.1	1.2	0.6	0.4	0.4	0.5	0.3	0.1
Copper	2.1	0.6	0.2	0.3	2.4	2.3	0.9	0.6	0.1
Zinc	2800	7.8	600	380	1600	2100	16000	270	1
Arsenic	-	-	-	-	-	-	0.5	-	0.2
Selenium	0.3	-	-	-	0.2	0.2	1.3	-	0.2
Rubidium	3.2	-	-	-	8.2	11	0.8	-	0.05
Strontium	5.3	-	0.4	0.3	2.1	7.8	85	0.1	0.05
Yttrium	0.1	-	-	-	-	-	0.7	-	0.05
Zirconium	0.1	-	-	0.7	0.9	-	0.2	-	0.05
Molybdenum	-	-	0.1	-	-	0.1	-	-	0.05
Cadmium	0.2	-	-	-	0.1	0.1	0.1	-	0.05
Tin	260	310	3.1	16	1.5	0.1	1.7	7.2	0.2
Antimony	-	0.1	0.6	-	-	-	0.2	-	0.05
Barium	2.1	0.8	4.2	3.7	0.5	1.7	280	0.6	0.05
Lanthanum	0.1	-	-	-	0.1	-	0.5	-	0.05
Cerium	0.1	-	-	-	0.2	-	0.5	-	0.05
Lead	0.7	-	0.3	-	0.3	0.2	0.2	0.2	0.05

*DL = detection limit

Table 4.2 continued – Screening for content of chemical elements, samples 9-16 in mg/kg

Sample name	9	10	11	12	13	14	15	16	DL*
Sodium	-	75	-	22	76	-	78	33	5
Magnesium	1.6	65	1.4	1.6	220	810	3.6	3.2	0.5
Aluminium	-	32	-	15	84	63	72	39	1
Silicium	52	99	440	95	410	93	120	94	2
Potassium	11	38	-	-	13	120	29	51	5
Calcium	16	87	39	130	61000	25000	310	21	5
Titanium	11	-	5.2	0.5	52	7.6	3	76	0.1
Chromium	0.8	31	-	-	0.5	3.1	-	-	0.2
Mangane	0.1	2.4	0.1	0.1	11	2.4	0.1	0.1	0.05
Iron	20	110	17	17	230	120	13	30	5
Cobalt	-	0.22	-	-	-	0.1	-	-	0.05
Nickel	0.3	39	0.2	-	0.8	6.2	-	0.3	0.1
Copper	0.1	4.1	0.3	0.1	0.4	4.6	31.2	0.3	0.1
Zinc	200	65	250	95	590	20000	230	33	1
Arsenic	-	-	-	-	0.2	0.6	-	-	0.2
Selenium	-	-	-	-	-	1.6	-	0.6	0.2
Rubidium	-	-	-	-	-	-	0.1	-	0.05
Strontium	15	2.1	17	0.1	14	21	0.1	0.6	0.05
Yttrium	-	-	-	-	1.2	0.1	-	-	0.05
Zirconium	-	-	-	-	0.1	1.4	-	1	0.05
Molybdenum	-	6.5	-	-	0.1	0.1	-	-	0.05
Cadmium	-	-	-	-	0.1	0.1	-	200	0.05
Tin	13	9.3	56	3.3	0.4	0.4	3.1	-	0.2
Antimony	-	-	0.3	-	-	0.4	0.2	-	0.05

Sample name	9	10	11	12	13	14	15	16	DL*
Barium	810	1.9	500	1.3	21	1.8	2.7	22	0.05
Lanthanum	-	-	-	-	0.4	1	-	-	0.05
Cerium	-	-	-	-	0.1	0.2	-	-	0.05
Lead	0.1	2.5	-	-	0.8	1.1	0.1	0.1	0.05

*DL = detection limit

Regarding content of lead and cadmium used as stabilisers for vinyl, the screening identified a cadmium content of 200 ppm in sample no. 16 (dildo in hard plastics). The high content was verified by a subsequent quantitative analysis (double determination), which showed a content of 218 ppm determined with a relative uncertainty of 1.4 %. According to "Statutory order from the Ministry of the Environment on prohibition of sale, import and production of cadmium-containing products" (Statutory order no. 1199 of 23/12/1992,), it is prohibited to sell products with such a high cadmium content in Denmark.

Apart from identification of lead and cadmium the element screening has the purpose of detecting other compounds harmful to environment and health.

It was established that samples 1 and 2 had a relatively high content of tin (maybe as trimethyltin chloride), in sample 11 the content was low.

With the exception of samples 2 and 16, all samples contained considerable amounts of zinc, which, however, should have no negative health effect. It is a well-known fact that zincosid is part of most rubber recipes and of the vulcanization system, the biggest concentrations are therefore found in the samples 1, 5, 6, 7 and 14, which are all rubber based.

4.3 Analysis of chemical substances by GC/MS

Except for sample 16, vibrator in hard plastics, all products were GC/MS analysed for solvents and other chemical substances, light as heavy volatiles, either direct on headspace or on a dichloromethane extract (DCM). The DCM extracts were further used directly for quantitative determination of phthalates.

4.3.1 Method description:

4.3.1.1 Test preparation and parameters for analysis of volatile organic substances (VOC) by headspace analysis

A weighed-out sample amount (0.6-6 g) was put in a glass jar. A glass tube with adsorbent (tenax TA) was placed besides the sample. The Tenax filters were passively exposed for different time periods (30, 90, 120 and 180 minutes resp.).

The Tenax tubes were subsequently analysed by thermal desorption combined with a Gas Chromatography/Mass Spectroscopy (ATD/GC/-MS in scan mode).

The chemical substances were identified by comparing the respective mass spectres with spectres from the NIST Library.

The amount of the detected substances was determined against the standards for toluene. The detection limit is estimated to 2-5 ng per component per tube and the relative uncertainty to 10-15%, relatively.
The analyses were made on Perkin-Elmer TurboMass Spectrometer with Perkin Elmer ATD 400.

4.3.1.2 Test preparation and parameters for analysis of volatile substances in dichloromethane extracts
A weighed-out sample amount (0.6-6 g) was extracted by dichloromethane added deuterium marked internal standards (benzene-d_6, toluene-d_8, p-xylene-d_1, pyrene-d, and DEHP- d)$_4$ by ultrasonic extraction and mechanical shaking.

The extracts were analysed by a Gas Chromatography/Mass Spectroscopy GC/-MS in scan mode.

The amount of the detected organic substances was determined against the internal standards and standards of the selected analytes.
The amount of the detected phthalates was quantitatively determined against the respective phthalates standards - DEHP, DOP and DINP.

The detection limit and relative uncertainty estimated to 0.2-1 µg/g and for other organic substances to 0.001% w/w in the product. Relative uncertainty 10%.

Test equipment was a HP Gas Chromatography 5890 with HP Mass Spectroscopy 5972.

4.4 Analysis results

4.4.1.1 Results of quantitative analysis of phthalates
Sex toys in soft vinyl have been quantitatively analysed for content of plasticizers in the form of phthalates, as described above. The results can be seen from table 4.3. No other than the stated phthalates was detected in the screenings.

Table 4.3 Survey of Phthalate content in sex toys in mg/gram

Sample No.	DEP (CAS no. 84-66-2)	DEHP (CAS no. 117-81-7)	DNOP (CAS no. 117-84-0)	DINP (CAS no. 28553-12-0)
1	i.d.	i.d.	i.d.	i.d.
2	i.d.	0.73	i.d.	>500
3	i.d.	610	i.d.	i.d.
4	i.d.	363	i.d.	i.d.
5	i.d.	i.d.	i.d.	i.d.
6	0.12	i.d.	i.d.	i.d.
7	i.d.	i.d.	i.d.	i.d.
8	i.d.	702	i.d.	i.d.
9	i.d.	265	i.d.	i.d.
10	i.d.	i.d.	i.d.	i.d.
11	i.d.	3,5	239	i.d.
12	i.d.	i.d.	i.d.	600
13	i.d.	i.d.	161	i.d.
14	i.d.	176	i.d.	i.d.
15	i.d.	200	i.d.	i.d.

i.d. = not detected

4.4.2 Screening results of volatiles by headspace GC/MS

A number of volatile organic substances were identified in the initial headspace analyses for organic substances by GC/MS of the 15 products, which have been alphabetically listed in Table 4.4 and 4.5. Results are stated in ng after degassing for 180 minutes at room temperature.

Table 4.4 Survey of volatiles content in sex toys of soft vinyl (headspace) in ng/180 min.

		Vibrator							Transparent bra	Stationary dildo
Name	CAS no.	2	3	4	8	11	12	15	9	13
Acetaldehyde	75-07-0									
Acetone	67-64-1		74	68						
Benzene	71-43-2				1121					
Butanal/Isobutanal	123-72-8/78-84-2									
Butanol	71-36-3									
2-Butanone	78-93-3	12879	13016	1605	926					
Butylacetate	123-86-4	9568	516		1026			218		
2-Butyle-1-octanole	3913-02-8					84				149
Butylized Hydroxytoluene (BHT)	128-37-0									
C11-C14 hydrocarbons					342	423	272			340
C16H30O4	74381-40-1									265
C6H12O3 e.g. Ethyl 2-methyllactate	80-55-7	29758			837					
C8-C10 hydrocarbons				474	268	203	204	244		75
Carbon disulfide	75-15-0		111	121					455	
Cyclohexanone	108-94-1	50958	57653	489	39095	45				
Cyclopentanone	120-92-3									
Decahydro-2-methylnaphthalene	91-57-6					284				
Decahydro-naphthalene	493-02-7					136				
Decamethylcyclo-pentasiloxane	541-02-6									
1,2-Dichloroethane	107-06-2						1698			
Dichloromethane	75-09-2	242								
Diethyl acetal	E105-57-7									
Diethylamine	109-89-7									
Diethylformamide	617-84-5									
2,3-Dimethyloctane	7146-60-3							1176		
2,4-Dimethylhexane	589-43-5							459		
Dodecamethylpen-tasiloxane	141-63-9									
Ethanol	64-17-5			79	105					
1-Ethoxy-2-propanol	1569-02-4									
Ethylacetate	141-78-6									
Ethylbenzene	100-41-4				505			299		
2-Ethyl-1-hexanol	104-76-7	126	1616	258	389	1561		816	15	205
2-Ethyl hexanoic acid	149-57-5			568						
Guanidine	113-00-8		1316							
Heptane	142-82-5	463	105	668	105		55	2086		
Heptanal	111-71-7									

		Vibrator							Transparent bra	Stationary dildo
Name	CAS no.	2	3	4	8	11	12	15	9	13
Hexadecamethylhep-tasiloxane	541-01-5									
Hexanal	66-25-1				47					
2-Hexanone	591-78-6									
3-Hexen-1-ol	544-12-7					76				
Iso-Pentane	78-78-4						59			
Isopropylcyclohexane	696-29-7									
Methoxy-2-propanone	5878-19-3						38			
2-Methoxy-1-propene	116-11-0							1959		
1-Methoxy-2-propyl acetate	108-65-6		616		205			171		
3-Methoxypropyl acetate	84540-57-8	12868								
2-Methyl-1-butanol	137-32-6		326	184	79					
3-Methyl-1-butanol	123-51-3									
3-Methyl-2-butanone	563-80-4									
3-Methylcyclopentanone	1757-42-2									
Methylcyclohexane	108-87-2		68	1511	121					
2-Methylheptane	592-27-8									
6-Methyl-2-heptanone	928-68-7									
2-Methylhexane	591-76-4	458		379				1351		
3-Methylhexane	589-34-4	595		168	116			1727		
4-Methyl-2-hexanone	105-42-0									
2-Methyl-2-propanole	75-65-0									
MIBK	108-10-1									
Naphthalene	91-20-3									
Nonanale	124-19-6									
1-Octanol, 3,7-dimethyl- (C10H22O isomers)	106-21-8									1610
Pentanal	110-62-3									
2-Pentanone	107-87-9									
Phenol	108-95-2		989	468	689	2393		272		695
Phenyl caproate	7780-16-7									
1.2-Propandiol/ Propylenglycol	57-55-6					219				
Si-subst.										
Styrene	100-42-5									
Terpene e.g. à-Pinene										
tert-Butyl methyl ether	1634-04-4									
Tetradecamethylhexasilox ane	107-52-8									
Tetrahydrofurane	109-99-9	2163	4521	358	5384			2330		
Tetramethylbutane	594-82-1							167		
Toluene	108-88-3	28121	27505	165332	15821	69	1745	29320	147	
Trimethylbenzene	526-73-8									
2,3,4-Trimethylpentane	565-75-3							290		
Xylenes, ethylbenzene	1330-20-7		300	305	489			849		

Table 4.5 Survey of volatiles content in rubber sex toys (1, 5, 6, 7 and 14) and thermoplastic rubber (10) (headspace) in ng/180 min.

		Vibrator	Fetish clothing		Vibrator	Gags	Artificial vagina
Name	CAS no.	1	5	6	7	14	10
Acetaldehyde	75-07-0						149
Acetone	67-64-1				47		205
Benzene	71-43-2						
Butanal/Isobutanal	123-72-8/78-84-2	105					
Butanol	71-36-3				53		
2-Butanon	78-93-3		384	605	295		174
Butylacetate	123-86-4						
2-Butyl-1-octanol	3913-02-8						
Butylized Hydroxytoluene (BHT)	128-37-0	1	279	95			
C11-C14 hydrocarbons				305		8277	
C16H30O4	74381-40-1						
C6H12O3 eg Ethyl 2-methyllactate	80-55-7						
C8-C10 hydrocarbons			68				
Carbon disulfide	75-15-0		458	405	179	138	
Cyclohexanone	108-94-1	247	211	268	884		22
Cyclopentanone	120-92-3						17
Decahydro-2-methylnaphthalene	91-57-6						
Decahydro-naphthalene	493-02-7						
Decamethylcyclopentasiloxane	541-02-6						
Dichloromethane	75-09-2						
Diethyl acetate	105-57-7		326				
Diethylamine	109-89-7					230	
Diethylformamide	617-84-5	63					
2,4-Dimethylhexane	589-43-5						
2,3-Dimethyloctane	7146-60-3						
Dodecamethylpentasiloxane	141-63-9				21		
Ethanol	64-17-5				558		
1-Ethoxy-2-propanol	1569-02-4						
Ethylacetate	141-78-6				84		
Ethylbenzen	100-41-4						
2-Ethyl-1-hexanol	104-76-7					54	
2-Ethyl hexanoic acid	149-57-5	142					
Guanidine	113-00-8						
Heptane	142-82-5		316	42			
Heptanal	111-71-7				42		
Hexadecamethylheptasiloxane	541-01-5						
Hexanale	66-25-1						
2-Hexanone	591-78-6						14
3-Hexen-1-ol	544-12-7						
Iso-Pentane	78-78-4						
Isopropylcyclohexane	696-29-7					84	
Methoxy-2-propanone	5878-19-3						
2-Methoxy-1-propene	116-11-0						
1-Methoxy-2-propyl acetate	108-65-6						
3-Methoxypropyl acetate	84540-57-8						
2-Methyl-1-butanol	137-32-6						
3-Methyl-1-butanol	123-51-3		147				
3-Methyl-2-butanone	563-80-4						52
2-Methyl-2-propanol	75-65-0						10
Methylcyclohexane	108-87-2				26		
3-Methylcyclopentanone	1757-42-2						6
2-Methylheptane	592-27-8		126				
2-Methylhexane	591-76-4		432				
3-Methylhexane	589-34-4		421				
4-Methyl-2-hexanone	105-42-0						9
MIBK	108-10-1					23	
Naphthalene	91-20-3					112	

Name	CAS no.	Vibrator	Fetish clothing		Vibrator	Gags	Artificial vagina
		1	5	6	7	14	10
Nonanal	124-19-6						
1-Octanol, 3,7-dimethyl- (C10H22O isomers)	106-21-8						
Pentanal	110-62-3	132					
2-Pentanone	107-87-9						42
Phenol	108-95-2						
Phenyl caproate	7780-16-7						20
1,2-Propandiol/Propylenglycol	57-55-6			895			
Si-subst.							38
Styrene	100-42-5	32			126		
Terpene e.g. à-Pinene			37				
Tert-Butyl methyl ether	1634-04-4						22
Tetradecamethylhexasiloxane	107-52-8				26		
Tetrahydrofurane	109-99-9		132	26	189		
Tetramethylbutane	594-82-1						
Toluene	108-88-3	384	1.016	705	363	80	20
Trimethylbenzenes	526-73-8						48
2,3,4-Trimethylpentane	565-75-3						
Xylener, ethylbenzenes	1330-20-7		147		53		

4.4.3 Screening for chemical substances by dichloromethane extraction (DCM)

Screening analyses by GC/MS were made of the more heavy volatiles in the 15 products through DCM extraction. The result of these analyses is listed alphabetically in Table 4.6 and 4.7.

Table 4.6: Analyses results of heavy volatiles in the samples 1-7 in g/kg sample

Name	CAS no.	Sample no.						
		1	2	3	4	5	6	7
Benzophenone	119-61-9							
Benzyl acetate	140-11-4							
Bisphenol A	80-05-7							
Butyl acetate	123-86-4		0.09					
Butylated Hydroxytoluene (BHT)	128-37-0	0.7	0.01			1.31	1.44	0.06
Trimethyltin chloride	1066-45-1		0.04					
Cyclohexanone	108-94-1		2.02	2.5	0.04			
Diisopropylamine	108-18-9					0.18		
3,7-Dimethyl-1-oktanol	106-21-8							
1,3-Diphenyl-1,3-propandione	120-46-7							
Dipropylenglycol monomethyl ether	20324-32-7							
Dodecanol	112-53-8				7.52			
Dodecan acid	143-07-7						0.15	
2-Ethyl-1-hexanol	104-76-7		0.12	1.2	0.2			
2-Ethyl-hexanoic acid	149-57-5	3.1		2.4	14.1			
Ethyl isothiocyanate	542-85-8							
Guanidine	113-00-8		1.09	0.1				
Hexadecanole	36653-82-4							
Hexadecyl acetate	629-70-9							0.09
2-Hexanone	591-78-6							
Isobenzofuranone	87-41-2		0.05					
N,N-Dibutylethylenediamine	3529-09-7						0.09	
3-Methoxypropyl acetate	84540-57-8		0.33					

Name	CAS no.	Sample no.						
		1	2	3	4	5	6	7
6-Methyl-2-heptanone	928-68-7							
2-Methyl-1-hexadecanol	2490-48-4				3.1			
Naphthalene	91-20-3							
N-Ethylethanamine	109-89-7							
Nonadecyl acetate	1577-43-1	0.1						
Nonanol	143-08-8		0.15					
Nonylphenol	25154-52-3							
9,12-Octadecadienoic acid, methyl esters	2566-97-4	0.2						
Octadecanamide	124-26-5					0.16	0.15	
Octadecyl acetate	822-23-1	0.2				0.25	0.27	
Octadecene	112-88-9							
9-Octadecenamide	301-02-0					0.33	0.28	
2-Pentanone	107-87-9							
Phenol	108-95-2		0.02	0.7	0.9			
4-(1-Phenylethyl)-phenol	1988-89-2							
Phosphonic acid, bis(2-ethylhexyl) ester	3658-48-8							
Phosphorous acid, triphenyl ester=phenylphosphite	101-02-0							
Phthalic acid anhydride	85-44-9		0.03					
Propylenglycol	57-55-6						0.15	
p-tert-Butyl benzoic acid	98-73-7							
Toluene	108-88-3		0.26	0.3	2.1			
Tributylphosphate	126-73-8							
Tridecanol	112-70-9				2.6			
Triethylphosphate	78-40-0							0.48
Tripropylene glycol	1638-16-0							0.05
Tripropylene glycol mono methylether	20324-33-8			3.8	3.4			0.08
TXIB (1-isopropyl-2,2-dimethyltrimethylene diisobutyrate)	6846-50-0							
Undecane	1120-21-4							
Xylenes, ethylbenzen	1330-20-7			0.02				

Table 4.6: Analysis results of heavy volatiles in the samples 8-15 in g/kg sample

Name	CAS no.	8	9	10	11	12	13	14	15
Benzophenone	119-61-9			0.29			0.87		
Benzyl acetate	140-11-4					0.02			
Bisphenol A	80-05-7				0.17				
Butylacetate	123-86-4								
Butyleret Hydroxytoluene (BHT)	128-37-0						0.12		
Trimethyltine chloride	1066-45-1								
Cyclohexanone	108-94-1	0.51						0.02	1.5
Diisopropylamine	108-18-9								
1,3-Diphenyl-1,3-propanedione	120-46-7		1.4						
3,7-Dimethyl-1-oktanol	106-21-8						6.48		
Dipropylenglycol monomethyl ether	20324-32-7								2.2
Dodecanol	112-53-8								
Dodecan acid	143-07-7								
2-Ethyl-1-hexanol	104-76-7				1.18	0.03	0.13		0.8
2-Ethyl-hexanoic acid	149-57-5	0.50			1.47	1.12	0.55	0.16	1.5
Ethyl isothiocyanate	542-85-8							0.01	
Guanidine	113-00-8								
Hexadecanol	36653-82-4						0.95		
Hexadecyl acetate	629-70-9								
2-Hexanone	591-78-6			0.04					
Isobenzofuranone	87-41-2								
3-Methoxypropyl acetate	84540-57-8								
6-Methyl-2-heptanone	928-68-7			0.06					
2-Methyl-1-hexadecanol	2490-48-4								
N,N-Dibutylethylenediamine	3529-09-7								
Naphthalene	91-20-3							0.11	
N-erthylethanamine	109-89-7							0.90	
Nonadecyl acetate	1577-43-1								
Nonanol	143-08-8								
Nonylphenol	25154-52-3		0.3		2.51	1.61			
9,12-Octadecadienoic acid, methyl ester	2566-97-4								
Octadecanamide	124-26-5								
Octadecyl acetate	822-23-1								
Octadecene	112-88-9						0.73		
Octadecenamide	301-02-1								
2-Pentanone	107-87-9			0.01					
Phenol	108-95-2	0.19			3.50		1.06	0.07	0.7
4-(1-Phenylethyl)-phenol	1988-89-2							1.10	
Phosphonic acid, bis(2-ethylhexyl) ester	3658-48-8				0.14				
Phosphorous acid, triphenyl ester=phenylphosphite	101-02-0								0.1
Phthalic acid anhydride	85-44-9					0.38			
Propylenglycol	57-55-6								
p-tert-Butyl benzoic acid	98-73-7		0.3	0.30					
Toluene	108-88-3	0.04				0.02		0.03	1.3
Tributylphosphate	126-73-8				0.14				
Tridecanol	112-70-9								
Triethylphosphate	78-40-0								
Tripropylene glycol	1638-16-0								
Tripropylene glycol mono methylether	20324-33-8								
TXIB (1-isopropyl-2,2-dimethyltrimethylene diisobutyrate)	6846-50-0				0.96		14.2		

Name	CAS no.	8	9	10	11	12	13	14	15
Undecane	1120-21-4				0.26				
Xylenes, ethylbenzene	1330-20-7								0.2

4.5 TLC-screenings

Sex toys of rubber have been subjected to a thin-layer chromatography (TLC) screening for accelerators and antioxidants/antiozonants.

4.5.1 Applied TLC-methods

The screening has been carried out according to BgVV chapter XXI (Kunststoffe im Lebensmittelverkehr, Empfehlungen des Bundesinstitutes für Risikobewertung) and ASTM D 3156-96: Standard Practice for Rubber - Chromatographic Analysis of Antidegradants (Antioxidants, Antiozonants and Stabilizers).

Developing solvents
The following developing liquids have been used:

- Toluene/n-hexane (50:50) BgVV XXI developing solvent B
- Toluene/n-hexane/methanol (58:30:12) BgVV XXI l developing solvent C
- Toluene/acetone/ammonium hydroxide (100:10:0,2), ASTM D 3156-96 item 7.4.3.2

Stationary phase
Merck (article 1.11798) 20 x 20 cm Silica 60 F 254 with concentration zone 5 µl of solvents and standards are applied. After elution of the plates the developing solvent is evaporated in a fume cupboard before visual evaluation.

Visualization
The identification is made acc. to the Rf-value (the distance from origin to developing solvent front). The Rf value is thus between 0 and 1 in the chosen TLC systems. The evaluation of the results is made under UV light and by colour reactions (exposure to iodine vapours in closed chamber, colouring with Gibbs reagent or with a solution of copper sulphate). The preparation of reagents is described above under the mentioned standardised methods.

4.5.2 Examined products and applied reference substances

The following samples are screened by TLC: 1, 5, 6, 7 and 14, as they according to the shop personnel or the labelling should be made of rubber. The labelling of the first four samples said that the product contained natural rubber (latex). The rubber quality of sample No. 14 was said to be food-grade quality (also used for gaskets for pressure cookers).

For the TLC-screening the below listed reference substances were used. Further, the screening included rubber from rubber nipples (previously analysed by DTI for accelerators) and natural latex in food-grade quality.

Table 4.4 Applied reference substances in TLC-screening.

Reference substance	Abbrev.	CAS no.
Accelerators		
Dibenzothiazolyl disulfide	MBTS	120-78-5
2-Mercaptobenzothiazol	MBT	149-30-4
N-Morpholinyl-2-benzothiozol sulfenamide	MBS	102-77-2
Tetramethyl thiurammonosulfide	TMTM	97-74-5
Zink dibenzyl dithiocarbamate	ZBEC	14726-36-4
Zink dibutyl dithiocarbamate	ZDBC	136-23-2
Zink diethyl dithiocarbamate	ZDEC	14324-55-1
Zink dimethyl dithiocarbamate	ZDMC	137-30-4
Zink ethylphenyl dithiocarbamate	ZEPC	14634-93-6
Antiozonants		
N(1,3-dimetyl-butyl)N´-phenyl-p-phenylen-diamine	6-PPD	793-24-8
N,N´-di-2-naphtyl-p-phenylene diamine	DNPD	93-46-9
N´-isopropyl-N´-phenyl-p-phenylene diamine	IPPD	101-72-4
Octylated diphenylamine	ODPA	101-67-7
Antioxidants		
2,6-ditertbutyl-4-metylphenol	BHT	128-37-0
2,2,4-Trimetyl-1,2-dihydroquinoline (polymerized)	TMQ	26780-96-1

4.5.3 Result of TLC-screenings

Samples nos. 5 and 6 are based on the same recipe and it also turned out that they were made by the same manufacturer, which was not evident when purchasing. ZDBC is used as sulphur accelerator (a substance which is able to cross-link the rubber molecules by sulphur bridges faster than with pure sulphur and at lower temperatures). This has been tested by developing solvents Nos. B and C and visualisation with copper sulphate. It is a known fact that ZDBC is used as accelerator for medical gloves of natural latex. ZDBC has been used in the co-analysed references (latex solution and rubber nipples). FDA (Food and Drug Administration, USA) allows ZDBC to be used in quantities up to 1.5 % in products with repeated food contact.

Sample No. 7 shows indication of ZDBC presence in the recipe. Sample no. 1 does not give any uniform impression of the sulphur accelerator type. TLC screening of sample no. 14 indicates that more than one sulphur accelerator type has been used and there is positive indication of ZDMC/ZDEC. The latter is mostly known as antabuse in the form of disulfide. The TLC is not able to distinguish between disulfide and zinc salt in the dithiocarbamine acids, as they have the same Rf-value.

The TLC-screening did not reveal any of the other reference substances used in the screening. This applies not only for 2-MBT and MBS but also BHT, which was positively detected by GC/MS on some of the products.

4.5.4 Verification of TLC-results by headspace GC/MS

For verification of TLC the tested samples have been analysed by headspace GC/MS method for an hour at 150 ºC, and at this temperature a partial decomposition of the dithiocarbamate-based accelerators will take place.

The analysis detected carbon disulfide in samples 1, 5, 6 and 14, but none in sample 7. Dibutylamine was found in samples 5, 6 and 7. No. 6 further contained N,N-dibutylformamide. Carbon disulfide, dibutylamine and N,N-dibutylformamide are all known decomposition products from ZDBC.

Dibutylamine and carbon disulfide were detected in the reference latex samples and di-isobutylamine and carbon disulfide in the rubber nipples.

Degassing of diethylamine, dibutylamine, dimetyl ethyldiamine, dimetylpropylamine and triethyl phosphate was found in sample 7. No degassing of carbon sulfide. The degassing of triethyl phosphate was later found to originate from the inner foam core of the product. As the foam material may be polyurethane, degassing of amines may occur.

Degassing of carbon sulphide, diethylamine and dimethylamine were found in sample 14. Also the TLC screening indicates that the associated thiuram accelerators (ZDMC/ZDEC or similar mono/disulfides of dithiocarbamine acid) have been applied.

5 Health risk screening and prioritization

A health risk screening has been made of the substances identified at the screening analysis. The screening is categorised according to the analytical method.

5.1.1 Elements

The results from the elements analyses are found in table 4.2 above, showing that sample 16 showed cadmium of 218 ppm with a relative uncertainty of 1.4 %. Tin of 250 and 310 ppm Tin was also detected in samples 1 and 2 with 260 ppm and 310 ppm respectively, and it is therefore important to know whether it is an organotin compound. According to the GC/MS screening it is the case for sample no. 2, as it contained trimethyltin chloride. By the GC/MS screening it is possible to detect other volatile organotin compounds, but only trimethyltin chloride and no other has been detected in sample 2.

5.1.2 Phthalate-based plasticizers

In the preliminary analytical screening phase the following phthalates identified and quantitatively determined: DEP, DEHP, DNOP and DINP.

The results are listed in Table 4.3 in chapter 4 and from this it appears that 10 of the 15 tested samples contain phthalates, even in rather large quantities, the samples being 2, 3, 4, 8, 9, 11, 12, 13, 14, and 15. The quantities varied from 0.12 g/kg to 702 g/kg, i.e. up to 70.2 %w/w.

It appears from the product labelling that samples nos. 1, 5, 6, 7 and 14 are latex-based products with no presence of phthalate plasticizers, except from nitrilbutadiene rubber (NBR). It is therefore assumed that sample 14 is manufactured from nitrile rubber. Migration of 3.3´-oxydipropionitrile (CAS no. 1656-48-0) from sample 14 the migration test mentioned in chapter 6 supports this assumption, as the substance is a difunctional nitrile.

Based on these results stated in Table 4 our further health risk assessment will be concentrated on:

- DEHP, Di-(2-ethylhexyl)-phthalate, CAS no.: 117-81-7
- DNOP, Di-n-octylphthalate, CAS no.: 117-84-0
- DINP, Di-iso-nonylphthalate, CAS no.: 28 553

5.1.3 Volatiles determined by headspace GC/MS

The results from the headspace-analyses at room temperature for 3 hours' exposure appear from table 4.4 and 4.5.

Based on the identified substances and their occurrences we have made a preliminary screening of the identified volatiles in order to make a selection of the most relevant substances. The screening comprised the classification and

the determined limit values of the substances as workplace hygienic occupational value. The result is shown in Table 5.1.

Table 5.1 Volatiles in sex today, their classification etc. listed alphabetically

Name	CAS no.	EF-no.	No. of products	Max. conc. NG/180 min	Classification	GV (mg/m^3)	GV-comment
Acetaldehyde	75-07-0	200-836-8	1	149	F+;R12 Carc3;R40 Xi;R36/37	45	LK
Acetone	67-64-1	200-662-2	5	205	F;R11 Xi;R36 R66 R67	600	
Benzene	71-43-2	200-753-7	1	1.121	F;R11 Carc1;R45 Mut2;R46 T;R48/23/24/25 Xn;R65 Xi;R36/38	1,6	HK
Butanal/Isobutanal	123-72-8	204-646-6	1	4.005	F;R11		
Butanol	71-36-3	200-751-6	1	95	R10 Xn;R 22 Xi;R37/38-41 R67	150	LH
2-Butanone	78-93-3	201-159-0	8	13.016	F;R11 Xi;R36 R66 R67	145	H
Butylacetate	123-86-4	204-658-1	5	9.568	R10 R66 R67	710	
Butyleret Hydroxytoluene (BHT)	128-37-0	204-881-4	3	305	Xn;R22 N;R50/53*	10	
2-Butyl-1-octanol	3913-02-8	223-470-0	2	149			
C11-C14 hydrocarbons			4	8.277			
C16H30O4	74381-40-1		1	265			
C6H12O3 fx Ethyle 2-methyllactate	80-55-7	201-290-3	1	837			
C8-C10 hydrocarbons			8	474			
Carbondisulfide	75-15-0	200-843-6	7	768	F;R11 Rep3;R62-63 T;R48/23 Xi;R36/38	15	H
Cyclohexanone	108-94-1	203-631-1	12	50.958	R10 Xn;R20	40	H
Cyclopentanone	120-92-3	204-435-9	1	17	R10 Xi;R36/38	90	
Decahydro-2-methylnaphthalene	91-57-6	202-078-3	1	284			
Decahydro-naphthalene	493-02-7	207-771-4	1	136		25 (ppm)	Tentative
Decamethylcyclopenta-siloxane	541-02-6	208-764-9	1	2.937			
1,2-Dichlorethane	107-06-2	203-458-1	1	1.698	Carc2;R45 F;R11 Xn;R22 Xi;R36/37/38	4	HK
Dichloromethane	75-09-2	200-838-9	2	242	Carc3;R40	122	HK
Diethyl acetal	105-57-7	203-310-6	1	326	F;R11 Xi;R36/38		
Diethylamine	109-89-7	203-716-3	1	230	F;R11 Xn;R20/21/22 C;R35	15	H
Diethylformamide	617-84-5	210-533-2	1	3.995			
2,4-Dimethylhexane	589-43-5	203-892-1	1	459	F;R11 Xi;R38 Xn;R65 R67 N;R50/53		
2,3-Dimethyloctane	7146-60-3	not in EINECS	1	1.176			
Dodecamethylpentasiloxane	141-63-9	205-492-2	1	42			
Ethanol	64-17-5	200-578-6	3	847	F;R11	1900	
1-Ethoxy-2-propanol	1569-02-4	216-374-5	1	11	R10 R68	100 (ppm)	Tentative

Name	CAS no.	EF-no.	No. of products	Max. conc. NG/180 min	Classification	GV (mg/m^3)	GV-comment
Ethylacetate	141-78-6	205-500-4	1	168	F;R11 Xi;R36 R66 R67	540	
Ethylbenzene	100-41-4	202-849-4	2	505	F;R11 Xn;R20	217	K
2-Ethyl-1-hexanol	104-76-7	203-234-3	9	1.616			
2-Ethyl hexanoic acid	149-57-5	205-743-6	2	12.884	Rep3;R63		
Guanidine	113-00-8	204-021-8	2	1.316	Xn;R22*		
Heptane	142-82-5	205-563-8	8	2.086	F;R11 Xn;R65 Xi;R38 R67 N;R50-53	820	
Heptanal	111-71-7	203-898-4	1	11			
Hexadecamethylhepta-siloxane	541-01-5	208-763-3	1	26			
Hexanal	66-25-1	200-624-5	3	653			
2-Hexanone	591-78-6	209-731-1	1	14	R10 Rep3;R62 T;R48/23 R67	4	H
3-Hexen-1-ol	544-12-7	208-860-0	1	76			
Iso-Pentane	78-78-4	201-142-8	1	59	F+;R12 Xn;R65 R66 R67 N;R51-53	1500	
Isopropylcyclohexane	696-29-7	211-792-4	1	84	Xn;R22 N;R51/53 *		
Methoxy-2-propanone	5878-19-3	227-549-0	1	38			
2-Methoxy-1-propene	116-11-0	204-125-3	1	1.959			
3-Methoxypropyl acetate	84540-57-8	283-152-2	1	12.868			
1-Methoxy-2-propyl acetate	108-65-6	203-603-9	4	616	R10 Xi;R36	275	H
3-Methyl-1-butanol	123-51-3	204-633-5	1	147		360	
2-Methyl-1-butanol	137-32-6	205-289-9	3	326		360	
3-Methyl-2-butanone	563-80-4	209-264-3	1	52	F;R11	705	
Methylcyclohexane	108-87-2	203-624-3	5	1.511	F;R11 Xn;R65 Xi;R38, R67 N;R51-53	805	
3-Methylcyclopentanone	1757-42-2	217-148-9	1	6			
2-Methylheptane	592-27-8	209-747-9	1	126	F;R11 Xn;R65 Xi; R38, R67 N;R50-53		
2-Methylhexane	591-76-4	209-730-6	4	1.351	F;R11 Xn;R65, Xi;R38 R67 N;R50-53		
3-Methylhexane	589-34-4	209-643-3	5	1.727	F;R11 Xn;R65 Xi;R38 R67 N;R50-53		
4-Methyl-2-hexanone	105-42-0		1	9			
6-Methyl-2-heptanone	928-68-7	213-179-7	1	10			
4-Methylpentan-2-on	108-10-1	203-550-1	1	23	F;R11 Xn;R20 Xi;R36/37 R66	83	H
2-Methyl-2-propanol	75-65-0	200-889-7	1	10	F;R11 Xn;R20	150	LH
Naphthalene	91-20-3	202-049-5	1	112	Carc3;R40 Xn;R22 N;R50-53	50	K
Nonanal	124-19-6	204-688-5	1	32	N;R50 *		
1-Octanol, 3,7-dimethyl-(C10H22O isomers)	106-21-8	203-374-5	1	1.610			
Pentanal	110-62-3	203-784-4	1	7.216		175	

Name	CAS no.	EF-no.	No. of products	Max. conc. NG/180 min	Classification	GV (mg/m^3)	GV-comment
Phenol	108-95-2	203-632-7	6	2.393	Mut3;R68 T;R23/24/25 Xn;R48/20/21/22 C;R34	4	H
2-Pentanone	107-87-9	203-528-1	1	42		700	
Phenyl caproate	7780-16-7		1	20			
1,2-Propandiol /Propylenglycol	57-55-6	200-338-6	2	3.032			
Si-subst.			1	38			
Styrene	100-42-5	202-851-5	2	1.347	R10 Xn;R20 Xi;R36/38	105	LHK
Terpene fx à-Pinene			2	47			
tert-Butyl methyl ether	1634-04-4	216-653-1	1	22	F;R11 Xi;R38	144	
Tetradecamethyl-hexasiloxane	107-52-8	203-499-5	1	47			
Tetrahydrofuran	109-99-9	203-726-8	8	5.384	F;R11-19 Xi;R36/37	148	H
Tetramethylbutane	594-82-1	209-855-6	1	167	F;R11 Xn;R65 Xi;R38, R67 N;R50-53		
Toluene	108-88-3	203-625-9	14	165.332	F;R11 Rep3;R63 Xn;R48/20-65 Xi;R38 R67	94	H
Trimethylbenzenes	526-73-8	208-394-8	1	48	Xn;R22 N;R51/53 *	100	
2,3,4-Trimethylpentane	565-75-3	209-292-6	1	290	F;R11 Xi;R38 Xn;R65 R67 N;R50/53		
Xylenes, ethylbenzenes	1330-20-7	215-535-7	6	849	R10 Xn;R20/21 Xi;R38	109	H

* : Classification from recommended list from EPA
H: Skin penetration, GV-list 2005 (C.0.1. 2005))
L: Limit value, GV-list 2005 (C.0.1. 2005))
K: Carcinogenic, GV-list 2005 (C.0.1. 2005))
Tentative: C.0.1. 2005)

5.1.4 Prioritization of light volatiles

Table 5.2 gives a prioritization of the substances according to their occurrences (quantity and no. of products) and their degree of health risk expressed through classification and data from the list of limit values.

Table 5.2 volatiles in sex toys prioritised for health assessment

Name	CAS no.	No. of products (and nos.)	Max. quantity ng/180 min	Classification	GV	Com-ments to GV list
Phenol	108-95-2	6 (3,4,8,11,13, 15)	2.393 (no.11)	Mut3;R68 T;R23/24/25 Xn;R48/20/21/22 C;R34	4	H
Toluene	108-88-3	14 (all except no.13 and 14)	29.320 (no.15)	F;R11 Rep3;R63 Xn;R48/20-65 Xi;R38 R67	94	H
2-Butanone	78-93-3	8 (2,3,4,5,6,7,8,10)	13.016 (no.3)	F;R11 Xi;R36 R66 R67	145	H
Carbon disulfide	75-15-0	6 (3,4,5,6,7,14)	458 (no.5)	F;R11 Rep3;R62-63 T;R48/23 Xi;R36/38	15	H
Heptane	142-82-5	8 (2,3,4,5,6,8, 11,15)	2.086 (no.15)	F;R11 Xn;R65 Xi;R38 R67 N;R50-53	820	
Cyclohexanone	108-94-1	10 (1,2,3,4,5,6,7,8,10, 11)	50.958 (no.2)	R10 Xn;R20	40	H
Tetrahydrofuran	109-99-9	8 (2,3,4,5,6,7,8,12)	5.384 (no.8)	F;R11-19 Xi;R36/37	148	H
Styrene	100-42-5	2 (1,7)	126 (no.7)	R10 Xn;R20 Xi;R36/38	105	LHK

In addition the following substances:

- Benzene, Carc1;R45 Mut2;R46 HK, 1 product (no.8)
- 1,2-Dichlorethane, Carc2;R45 1 product (no.12)
- Dichloromethane, Carc3;R40 HK, 2 products (nos.2 and 7)
- Diethylformamide, 1 product (no.1)

5.1.5 Screening of semi and heavy volatile substances from DCM extracts

The subject phthalate plasticizers has been dealt with in paragraph 5.1.2 A preliminary health risk screening of the other semi and heavy volatile substances from the extracts has been made in order to select the most relevant substances. The results are shown in Table 5.3. Some of the chemical substances have also been detected by a headspace analysis (Table 5.1).

Table 5.3 Semi to heavy volatile matters in sex toys and their classification

Name	CAS no.	EF no.	No. of products	Max. conc. mg/g	Classification	GV (mg/m^3)	GV- com-ment
1,3-Diphenyl-1,3-propandione	120-46-7	204-398-9	1	1,4	N;R50*		
2-Ethyl hexanoic acid	149-57-5	205-743-6	1	14,1	Rep3;R63		
2-Ethyl-1-hexanol	104-76-7	203-234-3	7	1,2			
2-Hexanone	591-78-6	209-731-1	8	3,1	R10 Rep3;R62 T;R48/23 R67	4	H
2-Methyl-1-hexadecanol	2490-48-4	-	1	0,04			
2-Pentanone	107-87-9	203-528-1	1	3,1		700	
3,7-Dimethyl-1-oktanol	106-21-8	203-374-5	1	0,01			
3-Methoxypropyl acetate	84540-57-8	283-152-2	1	6,48			
4-(1-Phenylethyl)-phenol	1988-89-2	217-864-1	1	0,33	R43 N;R50/53*		
6-Methyl-2-heptanone	928-68-7	213-179-7	1	1,10			
9,12-Octadecadienoic acid, methyl ester	2566-97-4	219-901-7	1	0,06	N;R51/53*		

Name	CAS no.	EF no.	No. of products	Max. conc. mg/g	Classification	GV (mg/m^3)	GV- comment
9-Octadecenamide (=oleamide)	301-02-0	206-103-9	2	0,33	R43 N;R51/53*		
Benzophenone	119-61-9	204-337-6	1	0,28			
Benzyl acetate	140-11-4	205-399-7	2	0,87		61	
Bisphenol A	80-05-7	201-245-8	2	0,7	Rep3;R62 Xi;R37-41 R43		
Butylacetate	123-86-4	204-658-1	1	0,17	R10 R66 R67	710	
Butylized Hydroxytoluene(BHT)	128-37-0	204-881-4	1	0,02	Xn;R22 N;R50/53*	10	
Trimethyltin chloride	1066-45-1	213-917-8	4	1,44			
Cyclohexanone	108-94-1	203-631-1	1	0,04	R10 Xn;R20	40	H
Diisopropylamine	108-18-9	203-558-5	6	2,5	F;R11 Xn;R20/22 C;R34	20	H
Dipropylenglycol monomethyl ether	20324-32-7	243-733-3	1	0,18			
Dodecanol	112-53-8	203-982-0	1	2,2	N;R51/53 *		
Dodecanoic acid	143-07-7	205-582-1	1	2,2			
Ethyl isothiocyanate	542-85-8	208-831-2	1	0,15	Xn;R22 *		
Guanidine	113-00-8	204-021-8	1	0,01	Xn;R22*		
Hexadecanol	36653-82-4	253-149-0	2	1,09	N;R51/53 *		
Hexadecyl acetate	629-70-9	211-103-7	1	0,95			
Isobenzofuranone	87-41-2	201-744-0	1	0,09	Xn;R22 *		
N,N-Dibutylethylenediamine	3529-09-7	222-558-6	1	0,05	Xn;R22 R43*		
Naphthalene	91-20-3	202-049-5	1	0,09	Carc3;R40 Xn;R22 N;R50-53	50	K
N-Ethylethanamine	109-89-7	203-716-3	1	0,11	F;R11 Xn;R20/21/22 C;R35	15	H
Nonadecyl acetate	1577-43-1		1	0,90			
Nonanol	143-08-8	205-583-7	1	0,1	N;R51/53 *		
Nonylphenol	25154-52-3	246-672-0	1	0,15	Rep3;R62 - 63 Xn;R22 C;R34 N;R50/53		
Octadecanamide	124-26-5	204-693-2	3	2,51	R43 N;R51/53 *		
Octadecene	112-88-9	204-012-9	2	0,27			
Octadecylacetate	822-23-1	212-493-1	3	0,73			
Phenol	108-95-2	203-632-7	1	0,2	Mut3;R68 T;R23/24/25 Xn;R48/20/21/22 C;R34	4	H
Phosphonic acid, bis(2-ethylhexyl) ester	3658-48-8	222-904-6	8	3,50	N;R50/53 *		
Phosphorous acid, triphenyl ester = Triphenylphosphite	101-02-0	202-908-4	1	0,14	Xi;R36/38 N;R50/53		
Phthalic acid anhydride	85-44-9	201-607-5	1	0,1	Xn;R22 Xi;R37/38-41 R42/43	1	
Propylenglycole (=1,2-propandiol)	57-55-6	200-338-0	2	0,38			
p-tert-Butyl benzoic acid	98-73-7	202-696-3	1	0,15	Xn;R22 R43		

Name	CAS no.	EF no.	No. of products	Max. conc. mg/g	Classification	GV (mg/m^3)	GV- comment
Toluene	108-88-3	203-625-9	2	0,30	F;R11 Rep3;R63 Xn;R48/20-65 Xi;R38 R67	94	H
Tributylphosphate	126-73-8	204-800-2	7	2,1	Carc3;R40 Xn;R22 Xi;R38	2,5	K
Tridecanol	112-70-9	203-998-8	1	0,14	N;R50/53 *		
Triethylphosphate	78-40-0	201-114-5	1	2,6	Xn;R22		
Tripropylene glycol	1638-16-0	216-670-4	1	0,48			
Tripropylene glycol mono methylether	20324-33-8	243-734-9	3	3,80			
TXIB (1-isopropyl 2,2-dimethyltrimethylenediisobutyrate)	6846-50-0	229-934-9	1	3,4	R43 *		
Undecane	1120-21-4	214-300-6	2	14,2	N;R50/53 *		
Xylenes, ethylbenzene	1330-20-7	215-535-7	1	0,26	R10 Xn; R20/21 Xi; R38	109	H

* Classification from the recommendation list

5.1.6 Prioritisation of semi and heavy volatile substances

Among the below chemical substances a few have been picked out according to their occurrences and assumed health risk.

Table 5.4 Selected chemical substances among the heavy volatile organic compounds for health assessment

Name	CAS no.	No. of products and number	Max. conc. g/kg	Classification
Bisphenol A	80-05-7	1 (no.11)	0,17	Rep3;R62 Xi;R37-41 R43
Trimethyltin chloride	1066-45-1	1 (no.2)	0,04	
Diisopropylamine	108-18-9	1 (no.5)	0,18	F;R11 Xn;R20/22 C;R34
2-Ethyl hexanoic acid	149-57-5	3 (no. 1,3,4)	14,1	Rep3;R63
2-Hexanon	591-78-6	1 (no.10)	0,04	R10 Rep3;R62 T;R48/23 R67
Octadecanamide	124-26-5	2 (no. 5,6)	0,16	R43 N;R51/53 *
9-Octadecenamide	301-02-0	2 (no. 5,6)	0,33	R43 N;R51/53*
Phenol	108-95-2	8 (no.2,3,4,8,11,13,14,15)	3,50	Mut3;R68 T;R23/24/25 Xn;R48/20/21/22 C;R34
Toluene	108-88-3	7 (no.2,3,4,8,12,14,15)	2,1	F;R11 Rep3;R63 Xn;R48/20-65 Xi;R38 R67
Tributylphosphate	126-73-8	1 (no.11)	0,14	Carc3;R40 Xn;R22 Xi;R38

Of the substances listed in Table 5.5, the following are prioritized for the following reasons:

- 2-Hexanone, as it may have long-term negative effects
- Trimethyltin chloride, as organotin compounds may be harmful

5.2 Selection criteria for the migration analysis

5.2.1 Products

Selection of products for migration tests has been effected on basis of the results of the analytical screening of the purchased products and the above health risk screening of the detected chemical compounds. In order to make the project as many-sided as possible we have included different material types (vinyl, rubber, SEBS) and functions (dildo, artificial vagina, and gag). The country of origin has been a second parameter in the selection (China, Germany, Canada mm).

The most sold product group is vibrators functioning as dildos. In this group soft vinyl is the material group which contains most different critical health risk substances. The selection for migration studies has been based on information from interviews in the shops on product popularity among the users. Other considerations have been the content of different plasticizer types and differences of other hazardous substances with regard to both chemistry and concentrations.

Regarding products of rubber, neither the GC/MS on the DCM-extracts nor the headspace-analyses have detected such a large number of different hazardous substances as has been found in the vinyl-based products.

Based on the above selection criteria the following products have been selected for migration analysis.

No. 2 Vibrator in soft vinyl (dildo): The DINP-content is higher than 50 % w/w and the following substances are found in not inconsiderable amounts: toluene, guanidine, cyclohexanone, 2-butanone and trimethyltin chloride.

No. 8 Vibrator (dildo): DEHP 70.2 % w/w. Other substances: toluene, cyclohexanone, phenol, tetrahydrofuran.

No. 10 Artificial vagina and anus were selected for screening because it is made of a rather ”slimy” material which is gaining ground within manufacture of sex toys today. The screening analysis detected only a few substances (benzophenone and p-tert-butylbenzoic acid).

No. 11 Vibrator in soft vinyl (dildo): DNOP 23.9 % w/w. Other problematic substances: phenol, nonylphenol, tributylphosphate.

No. 14 Gag manufactured from rubber: DEHP 17.6 % w/w. Other problematic substances: phenol, toluene, naphtalene. The thin-layer chromatographic screening indicates that the accelerator may be of the "antabuse" type.

No. 15 Waterproof vibrator (dildo) in soft vinyl: DEHP 21 % w/w. Other problematic substances: toluene, o-xylene, cyclohexanone.

5.2.2 Hazardous substances

Based on the health screenings the below chemical substances have been estimated to be of interest for the actual health risk assessment.

Based on the health screenings and the selected products, the below chemical substances have been selected for health risk assessment:

Chemical substances indirectly determined by elements analysis

- Tin

Chemical substances identified in the headspace-analysis

- 2-Butanone
- Carbon disulfide
- Cyclohexanone
- Heptane
- 2-Hexanone
- Phenol
- Tetrahydrofuran
- Toluene

Chemical substances identified in dichloromethane extraction

- Bisphenol-A
- Trimethyltin chloride
- 2-Ethylhexanoic acid
- DEHP, Di-(2-ethylhexyl)-phthalate
- DINP, Di-iso-nonylphthalate
- DNOP, Di-n-octylphthalate

6 Migration analyses

6.1 Determination of worst case exposures and selection of simulant

The migration analyses are based on realistic *worst case*-scenario under relatively controlled conditions. The exposure is made with due consideration to contact time, surface area, temperature, etc, but for experimental reasons the contact period has been set to one hour, although the shops indicated more precise contact periods for the individual products (dildos/vibrators and artificial vaginas 10-15 minutes, gag ½-1½ hours). As to frequency of use the shops estimated that once a week was the normal for vibrators (dildos and vaginas). The use frequency of gag was estimated to 12 times a year.

As contact stimulant for products to be inserted into the vagina was used artificial sweat according to DS/ISO 12870:1997(E). 1st edition, adjusted to pH 4.5 with hydrochloric acid, which is the vaginal pH level of healthy women according to www.menstruation.com due to lactic acid bacterial flora. For artificial vagina artificial sweat with a pH level of 6.5 has been used and for gags with oral contact, we have used artificial saliva. The exposure period in all tests has been one hour and the temperature 40 °C.

The analyses have been based on CEN final draft prEN-1400-3 (2002), however, this standard does not comprise artificial sweat, and the analysis method has therefore been adjusted accordingly. The results appear from Table 6.1-Table 6.3 with indication of exposed area and amount of contact simulant.

Experimental test set-up is shown in the photos below.

Photo 1 Dildo test

Photo 2 Artificial vagina

6.2 Description of migration analysis method

6.2.1 Sample preparation and exposure conditions

The test samples were immersed in the liquid simulant according to ”worst case” use, the vibrators being exposed at highest speed for an hour at 40º C. Test sample no. 8 was after treatment tested with water based and oil based lubricant cream.
For the gag the test was carried out for one hour at 40 ºC in contact with artificial saliva.

A test portion of the extracts was added deuterium marked internal standards (benzene-d_6, toluene-d_8, p-xylene-d_1, and DEHP-d_4 and subsequently extracted with dichloromethane (DCM) in a separating funnel.

6.2.2 Analysis method

The resulting extracts were analysed by gas chromatography-mass spectrometry (GC-MS in scan mode).

The quantities of the detected substances were determined by comparing the peak areas of the internal standards and standards of the selected analytes. Further, a test portion was analysed for content of volatile organic component by a headspace analysis.

6.2.3 Equipment

HP gas chromatography 5890 with a HP mass spectrometer 5972.

6.2.4 Analysis results

The results of the migration tests are summarised in the below tables.

Table 6.1 Migration analysis results for vibrators/dildos in vinyl in µg per dm^2 by 1 hour exposure

Substance	CAS no.	Method	Sample No.			
			2	8	11	15
Exposed area in cm^2			163	120	168	164
Artificial sweat, pH =4,5 iml			214	244	213	214
Plasticizers/Esters						
DEHP	117-81-7	K	1	6	<0,5	5
DNOP	117-84-0	K			8	
DINP	28-553-12-0	K	<5			
Dimethyladipate	627-93-0	SK	17			
Dimethyl-glutarate	1119-40-0	SK	106			
1-Methoxy-2-propyl-acetate	108-65-6	SK	439	36		18
Dimethyl butanedioate	106-65-0	SK	53			
Acids and Alcohols						
2-Ethylhexanoic acid	149-57-5	SK		220	423	113
2-Ethylhexanole	104-76-7	SK			58	53
Phenylethyl alcohol	60-12-8	SK				
Ketones						
2-Butanone	78-93-3	SK/HS	49	12		
Cyclohexanone	108-94-1	SK	1320	1001		382
Iso-benzofuranone	84-41-2	SK	72	64		33
Coumarine	91-64-5	SK			25	
Aromatic hydrocarbons						
Toluene	108-88-3	K	22	38		54
Other substances						
Guanidine	133-008	SK	925	32		36
Tetrahydrofuran(THF)	109-99-9	SK/HS	<0,5	12		12
Phenol	108-95-2	SK	26	182	866	264
Bisphenol A	80-05-7	SK			21	
Vanilline	121-33-5	SK			52	
Ethylvanilline	121-32-1	SK			19	
2-Ethoxy-propane	625-54-7	SK			40	
Dipropylen-glykolmono-methyl ether	20324-32-7	SK		309		471
Tripropylene-glykolmonomethylether	20324-33-8	SK		341		475
Trimethyltin chloride	1066-45-1	SK	99			

SK = Semi-quantitative. K = Quantitative, HS = headspace

The migration value of water based lubricant is 40 µg per dm^2, for oil based lubricant the migration value is 5480 µg per dm^2, i.e. almost a 1000 times higher than without lubricant oil.

Table 6.2 Analysis results for artificial vagina in SEBS (no. 10) in µg per dm^2

	CAS no.	Methods	Result
Exposed area in cm^2			
Artificial sweat in ml			
DEHP	117-81-7	K	4,5
2-Butanone	78-93-3	SK	17
Benzophenone	119-61-9	SK	20 –100
p-tert-Butylbenzoic acid	98-73-8	SK	20-100

Table 6.3 Analysis results for gag (no. 14) in rubber in µg per dm^2

	CAS no.	Method	Result
Exposed area in cm^2		38	
Artificial saliva in ml		99	
Plasticizers			
DEHP	117-81-7	K	6
Sulphur compounds			
Carbon disulphide	75-15-0	K	500
Ethylisothiocyanate	542-85-8	SK	5
Tetramethylthiurammono-sulphide	97-74-5		19
Phenols			
Phenol	108-95-2	SK	55

o-(1-Phenylethyl)phenol	4237-44-9	SK	35
4-(1-Phenylethyl)phenol	1988-89-2	SK	14
Other compounds			
3,3´-Oxydipropionitrile	1656-48-0	SK	50

Based on the migration analyses the following substances have been selected for the health assessment:

- Plasticizers: DEHP (CAS no. 117-81-7) and DNOP (CAS no. 117-84-0)
- Cyclohexanone (CAS no. 108-94-1)
- 2-Ethylhexanoic acid (CAS no. 149-57-5)
- 3,3´-Oxydipropionitrile (CAS no. 1656-48-0)
- Phenol (CAS no. 108-95-2)
- Carbon disulfide (CAS no. 75-15-0)
- Tetrahydrofuran (THF) (CAS no. 109-99-9)
- Trimethyltin chloride (CAS no. 1066-45-1)

By the selection due consideration has been paid to the expected long-term effects and the concentrations detected by the migration analysis.

Final prioritization result:

- DEHP
- DNOP
- Cyclohexanone
- 2-Ethylhexanoic acid
- 3,3´-Oxydipropionitrile
- Phenol
- Carbon disulfide
- Tetrahydrofurane
- Trimethyltin chloride
- Toluene

7 Health risk assessment

7.1 Introduction

In this section, potential health effects from identified and selected substances are assessed. The focus of the assessment is aimed towards adults only.

For each of the identified and quantified substances information of the substances' identity as well as chemical and physical properties are presented. This will include data on material state, melting point, boiling point, octanol/water partition coefficient, vapour pressure and solubility.

A search in the open literature has been performed. Focus has been on the ability of skin absorption and effects by oral intake. The most important test results, the effects, and circumstances are presented. The aim has been to find data for NOAEL/LOAEL (No or Low Observed Adverse Effect Levels) for the selected substances or other relevant data if available.

Based on NOAEL or similar data and the amount of the substances it can be assessed whether the substance may cause a negative health effect from the use of the tested products.

7.2 Method

It is assumed that the substances can be absorbed in the body by oral intake and by penetration through skin and mucous membranes.

From the information on the products no special directions regarding the recommended use was given for all products. In order to assess all products and compare these, the exposed area is related to relative product size. The exposure period is based on normal use and realistic worst case per day (Table 7.1).

Regarding exposure, one common scenario has been selected.

A scenario, where product no. 2, 8, 11, 15 (Vibrators) is used in the vagina/orally and product no. 14 (Gag) is used in the mouth. It is assumed that use in vagina and mouth will be comparable to oral use. No. 10 (Artificial vagina) is used in skin contact. The exposed area and time of use depends on product as given in Table 7.1. A bodyweight of 70 kg is assumed. It is assumed that 100 percent of the substances are absorbed to the body. The exposed area in cm^2 is shown in the table for products and the time of exposure for normal use and worst case use.

Table 7.1 Data for products and time of exposure

Product	2 vibrator	8 vibrator	11 vibrator	15 vibrator	14 gag [3]	10 Artificial vagina
Area of exposure (cm^2)	163	120	168	164	38	Assumed to correspond to 150 cm^2
Time of exposure normal use (Hours/day) [1]	0.0357	0.0357	0.0357	0.0357	0.033	0.0357
Time of exposure worst case (Hours/day)[2]	1	1	1	1	0.033	1

1 For normal use, product no. 2, 8, 11, 15 and 10 is used 52 times a year for 15 minutes; Product no. 14 is used 1 hour 12 times a year
2 For worst case, use product no. 2, 8, 11, 15 and 10 is used 1 hour each day; product 14 is used 1 hour 12 times a year
3 For product no. 14 the same time of exposure was assumed in normal and worst case.

The exposure scenarios are defined according to the EU's Technical Guidance Document (*TGD, 2003*).

The uptake is calculated as:

The exposure from the scenario is calculated by:

Intake per day per kg b.w. = [M × A × H × F] / b.w. {equation 1}

b.w.: Body weight (kg)
M: Migrated amount of substance ($mg/cm^2 \times h$)
A: Exposed skin area (cm^2)
H: Time of exposure per day (hours)
F: Fraction absorbed

Equation 1 can be reduced to:

Intake per day per kg body weight (mg/kg)

$$= M \times A \times F \times H \times 0.014 \text{ (mg/kg)} \quad \{\text{equation 2}\}$$

by using 70 kg of average body weight.

The variable M in equation is measured in the migration experiments (chapter 6). For the products 2, 8, 11, 14, 15 which is used orally the variable F is assumed to be 100 percent (*TGD, 2003*). For product 10 the fraction absorbed is assumed to be somewhere between skin contact and oral use. Based on a worst case scenario F is set to 100%.

In some cases the migrated amount is not available, but only analysis of content by extraction with solvent.

The dependence between migration and concentration is dependent on characteristics of the product, the chemical substance and the simulant contact medium (etc artificial sweat) and the exact dependence can only be found from experiments.

In some cases the migration of substances from materials may be explained by using Ficks law $J=-D \times dc/dx$ where

D is diffusion coefficient of the substance
J is the flux (mole of substance per time unit)
dc/dx is the concentration difference of the substance over the diffusion distance

From Ficks law a linear relation between concentration and flux can be expected for some products.

Therefore, in order to obtain an indication of the migration for products where only the content has been measured, it is assumed that there is a linear depence between migration and concentration.

In case the migration is known for a comparable product M(2), an indicative migration can be estimated for the product M(1) as

$$M(1)=M(2) \times C(2)/C(1) \times T(2)/T(1) \times A(2)/A(1)$$

where
M: Migrated amount of substance (mg/cm^2 *h)
C : Content (mg/g)
A: Exposure area (cm^2)
T: Time of use (h)

There will be a considerable uncertainty in the estimate especially as the material characteristics can be different and therefore the estimate must only be used as a crude estimate of the migration.

Assessment of risk
In the health risk assessment the calculated absorption is compared with NOAEL or a similar value. As NOAEL typically is based on examinations on animals and for different periods, an uncertainty factor is used (typically a factor of 10) to bring the values at a comparable level.

An uncertainty factory of 10 is used for extrapolation between species (interspecies) and a factor 10 to protect particularly sensitive species i.e. children (intraspecies). If data are inferior or based on LOAEL, additional uncertainty factors can be used (typically a factor of 10).

In the health risk assessment, NOAEL is compared to the calculated absorption. The relation between NOAEL and the exposure (the absorption of the substance) is defined as MOS (Margin of Safety). If the data are valid a MOS of 100 will be satisfactory, whereas inferior data will require further safety factors. The overall uncertainty factor is the total product of the individual uncertainty factors.

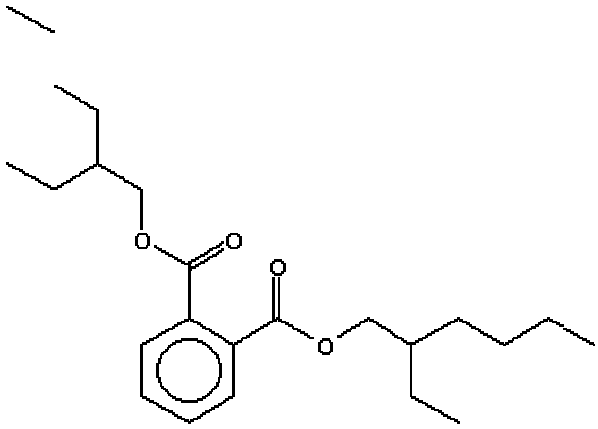
7.3 Selected substances

The substances described in the following subsections are selected as the most significant substances for potential health risks from using these products.

7.3.1 DEHP

7.3.1.1 Identity

Name	Bis (2-ethylhexyl)phthalate
CAS-number	117-81-7
EINECS number	204-211-0
Molecular formula	$C_{24}H_{38}O_4$
Molecular structure	



Molecular weight	390.56
Synonyms	1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester Bis(2-ethylhexyl) phthalate DEHP Di(2-ethylhexyl) phthalate Di-(2-ethylhexyl) phthalate Di-2-ethylhexyl phthalate Di-2-ethylhexylphthalate Di-sec-octyl phthalate Diethylhexyl phthalate Ethyl hexyl phthalate Octyl phthalate Phthalic acid, bis(2-ethylhexyl) ester

The substance is a colourless, oily liquid. It has a boiling point of 230ºC (*Clayton, 1981-1982*) and a melting point of -55ºC (*Lide, 1995-1996*).

The substance is more soluble in organic solvents than in water. The solubility in water according to (*Yalkowsky, 1992*) is 0.285 mg/l at 24ºC.

The partition coefficient Log K_{OW} is determined to be 7.6 (*Debruijin, 1989*).

Vapour pressure is determined to be 7.23 $X10^{-8}$ mm Hg at 25ºC (*Daubert, 1989*).

The substance has a slight odour (*NIOSH, 1994*).

7.3.1.2 Detected quantities

DEHP has been detected in quantitative analysis for phthalates in 8 of the 15 products. In sample no. 8, 702 mg/g has been determined and in the products

2, 3, 4, 9, 11, 14 and 15, the concentration was between 0.73 mg/g and 610 mg/g (0.07 to 61 % w/w).

In migration tests, DEHP has been detected in 5 out of 6 products with the highest value for product no. 8 (6 µg/dm^2). The migration for product no.14, 15 was on the same level. The migration for product no.8 increased to 40 µg/dm^2 when water based lubricant was used and to 5480 µg/dm^2 when oil based lubricant was used. It is assumed that the increase is caused by a somewhat higher solubility of DEHP in the water based lubricant than in the extraction media (artificial perspiration solution) as the cream may have some content of emulsifiers etc. The solubility in oil based cream is much higher than in water as DEHP has a low solubility in water of 285 µg/l and a Log K_{OW} of 7.6.

7.3.1.3 Function of substance
The function of the substance is as plasticizer.

7.3.1.4 Classifications and TLV's
Bis(2-ethylhexyl)phthalate is included in the List of dangerous substances and classified as:

Repr.Cat. 2;R60-61	May impair fertility and may cause harm to the unborn child

The Danish threshold limit value is 3 mg/m^3 (The Danish Working Environment Service, 2005).

7.3.1.5 Health Effects
DEHP is in the process of being evaluated by EU in the Programme on existing chemical substances. Sweden is the rapporteur country. The risk assessment report is not yet finalised, but a draft can be found at the ECB homepage.

Data regarding health effects is included in IUCLID. The following is based on the data sheet, databases in TOXNET and the risk evaluation above.

Acute toxicity
Test for acute toxicity in animals shows that DEHP is not acute toxic.

LD_{50} Mouse oral >30,000 mg/kg (*WHO, 1992*)
LD_{50} Rat oral ca. 25,000 mg/kg (*WHO, 1992*)

Sub-chronic toxicity
DEHP has been shown to be a weak irritant to mammalian skin when administered topically or intradermally (0.2 mL of an emulsion of 100 g/L) (*WHO, 1992*).

Data for fertility showed a statistically significant reduction of sperm for rats in all doses >250 mg/kg/day in a 15 day test. Based on this the following No Adverse Observed Effect Level was found: NOAEL<250 mg/kg/day (*IUCLID*).

Chronic toxicity
DEHP is classified as A3 Confirmed animal carcinogen with unknown relevance to humans (*American Conference of Governmental Industrial*

Hygienists TLVs and BEIs. Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, 2005).

Studies for carcinogenity in animals have been found in the dataset for DEHP (*IUCLID*).

A 2 year study was performed with continuous feeding of 50 male and 50 female Fischer 344 rats with either 400 or 800 mg/kg/d DEHP for 103 weeks. Incidents of hepatocellular carcinomas and neoplastic nodules was 3/50 (male) and 0/50 (female) in controls, 6/49 (male) and 6/49 (female) in rats exposed for 400 mg/kg/d and 12/49 (male), 13/50 (female) in rats exposed for 800 mg/kg/d. An increased level of hepatocellular tumours was also present at the two dose levels. Similar results were found for B6C3F1 mouse with doses of 375 mg/kg/d and 750 mg/kg/day for 103 weeks. (*IUCLID)*

According to (*IARC, 2000*), the mechanism by which DEHP increases the incidence of hepatocellular tumours in rats and mice is not relevant to humans and therefore the overall evaluation was: Bis (2-ethylhexyl)phthalate is not classifiable as to its carcinogenicity to humans (Group 3).

Studies on fertility effects are also reported in the data set for DEHP (*IUCLID):*
Effects on fertility of mouse was shown with 200 mg/kg/day oral feed and no effect was observed with 20 mg/kg/day for 105 day period experiment giving a value of NOAEL parental of 20 mg/kg/day.

A 78 day two generation test of rats with oral feed of DEHP gave a value of NOAEL parental = 95 mg/kg/day and NOAEL offspring F1 of 48 mg/kg/day.

Tests for teratogen effects on CD-1 mouse with oral feed of DEHP gave a value of NOAEL maternal toxicity = 91 mg/kg/d and NOAEL teratogen = 44 mg/kg/d from day 0-17 of gestation.

The Reference Dosis for Chronic oral exposure RfD = 0.02 mg/kg/day. (*IRIS*)

This value is based on a study with guinea pigs which seems to be more sensitive than rats (*Carpenter, 1953*). In the study, male and female guinea pigs were fed diets containing DEHP for a period of 1 year with dietary levels corresponding to 64, 19 or 0 mg/kg bw/day based on measured food consumption. No treatment-related effects were observed on mortality, body weight, kidney weight, or gross pathology and histopathology of kidney, liver, lung, spleen, or testes. Statistically significant increases in relative liver weights were observed in both groups of treated females (64 and 19 mg/kg bw/day). A LOAEL value for guinea pigs is therefore determined to be 19 mg/kg/day.

In the determination of RfD value factors of 10 each were used for interspecies variation and for protection of sensitive human subpopulations. An additional factor of 10 was used since the guinea pig exposure was longer than subchronic but less than lifetime, and because, while the RfD is set on a LOAEL, the effect observed was considered to be minimally adverse.

In the risk assessment on bis(2-ethylhexyl) phthalate (*Risk assessment, 2003*), a 3 generation rat guideline study is reported.

Testicular as well as developmental toxicity was found with increased incidences of small testes, epididymes, and seminal vesicles, as well as cases of minimal testes atrophy. The toxicity was aggravated by exposure during the gestational/pup-period. LOAEL was estimated to 14 mg/kg/day and NOAEL 4.8 mg/kg/day. (*Wolfe, 2003*). Other effects reported (*Risk assessment, 2003*) are kidney effects in a two year oral study in rats with NOAEL= 29 mg/kg/day.

Summary
Values for teratogenicity are given for short term studies with animals. The lowest value of NOAEL was 44 mg/kg b.w. per day based on oral feeding.

Values for fertility showed a lowest value of NOAEL 20 mg/kg/day based on oral feeding.

In the new draft for risk assessment on DEHP the value of NOAEL is 4.8 mg/kg/day for testicular and developmental effects.

Kidney effects at NOAEL of 29 mg/kg/day have also been reported.

Values for carcinogenicity for mouse and rats showed effects at approximately 400 mg/kg/day.

Values for increase in liver weight was observed in guinea pigs with a value of LOAEL =19 mg/kg/day.

7.3.1.6 Exposure scenarios
The maximum value found in the migration experiments for product 8 was 5480 µg/dm^2*h corresponding to 0.055mg/cm^2*h for oil based lubricant cream. With an area A = approx. 120 cm^2 for vibrators (no. 2,3,4,8,11,15), an area of 38 cm^2 for gag (no.14), and assuming 50% absorption, values for oral uptake has been calculated as shown in Table 7.2.

The value for absorption is based on data for oral absorption in adults (Risk assessment, 2003, chapter 4.1.1)

Table 7.2 Calculated and estimated intake for products

Product no	Content (mg/g)	Migration artificial sweat (µg/dm^2)	Migration oil based lubricant (µg/dm^2)	Internal dose normal use (mg/kg b.w.)	Internal dose worst case (mg/kg b.w.)
2	0.73	1	Not analysed		<0.02 [1,2]
3	610	Not analysed	Not analysed		<0.05 [1]
4	363	Not analysed	Not analysed		<0.05 [1]
8	702	6	5480	0.0017	0.047
9	265	Not analysed	Not analysed		Low
11	3.5	<0.5	Not analysed		<0.005 [1,2]
14	176	6	Not analysed		<0.0005 [3]
15	200	5	Not analysed		<0.05 [1,2]

1 Estimate based on content, area and migration results for product no.8 in oil based lubricant
2 Estimate supplemented with migration results of this product in artificial sweat
3 Estimate based on content area and migration results for product no.8. It is assumed that migration is significantly lower when used in the mouth than in the products which may be used with oil based lubricant.

Based on the content and the migration results, the products 3, 4, 15 are assumed to give an intake within the same range as product no.8. For product no. 2, 11, 14 the intake is expected to be lower.

7.3.1.7 Assessment

DEHP is a substance that may cause reprotoxic effects including fertility or teratogenic effects in humans. Indications for other long term effects have not been found.

DEHP has been detected in 8 out of 15 samples with the concentrations from 0.07 to 70%.

Based on the NOAEL data for teratogenicity a margin of safety (MOS) is 26000 for normal use and 934 for worst case use.

Using the new data for testicular and developmental effects in (*Risk assessment, 2003*) MOS is 4.8/0.047 = 100 in the worst case scenario (max. use). In the risk evaluation p.296 a safety factor of 250 is recommended for pregnant women and breastfeeding women, whereas the safety factor is 100 for other adults.

Table 7.3 Estimate of margin of safety for products

Product no.	MOS (Normal use)	MOS (worst case use)
8 (oil based lubricant)	2850	100
3,4,15 (oil based lubricant)	Estimate :approx. 2850	Estimate:approx. 100
2 (oil based lubricant)	Estimate:>16000	Estimate:>600
11 (oil based lubricant)	Estimate:>32000	Estimate:>1200
14	Estimate >9500	Estimate:>9500

It is concluded that by worst case use of product no. 8 there is a minor risk of developmental health effects from DEHP for pregnant and breastfeeding women if oil based gliding cream is used as MOS = 100 is lower than the safety factory of 250. As to the comparable products 3, 4, and 15, the uncertainty when calculating the internal dose (thus also MOS) is higher, as the calculation of the internal dose is based on migration in oil based lubricant for product no. 8. It is estimated that the internal dose for products nos. 3, 4, and 15 will be at the same level or lower than for product no. 8 due to the lower concentration in the products and because they are made of comparable materials. Just as for product no. 8, these products contain a minor risk of developmental health effects from DEHP for pregnant and breastfeeding women if oilbased lubricant is used and in worst case scenario. For product no. 2 and 11 MOS is higher than the safety factory, why there will be no risk at maximum use.

For adults (not pregnant or breastfeeding) the health risk is less as the NOAEL values according to the risk evaluation (*Risk assessment, 2003*) are higher and because the safety factor used for comparison is 100. For this group it is estimated that the products 3, 4, and 15 carry no risk within the uncertainty in calculation of the internal dose.

Product no.14 (gag) is not used as frequently as the other products in worst case use and is further used without oil based lubricant. It is not known, how much the content of substances in the saliva will increase migration in comparison to artificial sweat. It is assessed that product no. 14 involves no risk.

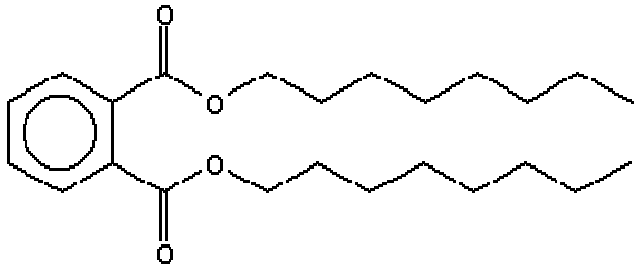
Product no.9 (fetish) is used with skin contact and here the migration will be much lower than for vibrators which are used in vagina/anally and with or

without oil based lubricant. Therefore, there is no risk with DEHP for product no. 9.

7.3.2 DNOP

7.3.2.1 Identity

Name	Dioctyl phthalate
CAS-number	117-84-0
EINECS number	204-214-7
Molecular formula	$C_{24}H_{38}O_4$
Molecular structure	



Molecular weight	390.56
Synonyms	1,2-Benzenedicarboxylic acid, dioctyl ester Di-n-octyl phthalate Dioctyl phthalate Phthalic acid, dioctyl ester

The substance is a Colourless, oily liquid. It has a boiling point of 220ºC (*Callahan, 1979*) and a melting point of -25ºC. (*Callahan, 1979*)

The substance is more soluble in organic solvents than in water. The solubility in water according to (*Wolfe, 1980*) is 3 mg/l at 25ºC. The value is high when compared with DEHP.

The partition coefficient Log K_{OW} is determined to be 8.1. *(Ellington, 1996)*

Vapour pressure is determined to be $7.6X10^{-6}$ mm Hg at 25ºC. (*Perwak, 1981*)

7.3.2.2 Detected quantities

DNOP has been detected in quantitative analysis for phthalates in 2 of the 15 products. In sample no. 11, 239 mg/g has been analysed and in sample no. 13, 161 mg/g.

In migration tests, DNOP has been detected from product no.11 with a value of 8 $\mu g/dm^2$.

7.3.2.3 Function of substance

The function of the substance is as plasticizer.

7.3.2.4 Classifications and TLV's
This chemical substance is not classified in the Annex I of Directive 67/548/EEC.

7.3.2.5 Health Effects
The following is based on databases in TOXNET.

Acute toxicity
Test for acute toxicity in animals shows that DNOP is not acute toxic.

LD50 Mouse oral 13,000 mg/kg (*International Labour Office, 1983*)
LD50 Rat oral ca. 30,000 mg/kg (*International Labour Office, 1983*).

DNOP has shown no irritating effects at normal temperatures of use.

DNOP produces no ill effects at normal temp but may give off irritating vapour at high temperature. (*Prager, 1996*)

Sub-chronic toxicity
Published data shows only effects at high concentrations:

Young male Wistar rats were fed diets containing 2% di-n-octyl phthalate for one week. An increase in absolute and relative liver weights was observed. This was also observed in similar tests with other phthalates like di-n-butyl phthalate. Rats treated with di-n-octyl phthalate had decreased zinc concentrations in the tests. (*USEPA/ECAO, 1980*)

Studies show that there is a high cumulative toxicity as expected from the high octanol/water ratio:

The results of a study of the cumulative toxicity of different esters for the mouse revealed that di-n-octylphthalate is the compound with the highest cumulative toxicity among the eight substances tested. Results for the di-n-octyl ester were: LD50 (acute) 67.18 ml/kg; LD50 for 12 week study (different doses 5 days/week) was 3.09 ml/kg with a factor of cumulative toxicity of acute to chronic of 21.74.
(*International Labour Office, 1983*)

Chronic toxicity
Test for reproductive toxicity has shown no effects of DNOP even at high concentrations.

In a continuous breeding protocol CD-1 mice where given diets with DNOP in concentration 0, 1.25, 2.5 and 5% in a 7 day period prior to and during a 98 day cohabitation period. There was no apparent effect on reproductive function in the animals exposed to di-n-octyl phthalate at dose levels sufficient to cause a significant increase in liver weight. A comparison of seven phthalate esters tested using this continuous breeding protocol indicates the relative order of reproductive toxicity as diethylhexyl, dihexyl, dipentyl, dibutyl, dipropyl; diethyl and dioctyl are nontoxic. (*Heindel, 1989*)

Di-N-octylphthalate (DNOP) was tested using the RACB protocol in Swiss CD-1 mice as part of a structure-activity evaluation of a variety of phthalates. Body weights, food and water consumptions, and clinical signs in a dose-range-finding study were used to set doses for the main study of 0.0, 1.25%, 2.5% and 5% in feed (1.8, 3.6 and 7.5 g DNOP/kg bw/day).

There was no effect of DNOP exposure on the number of litters/pair, the mean number of live pups/litter, proportion born alive, live pup weight adjusted for litter size or days to deliver each litter. In the F1 mice, growth and viability were unaffected by DNOP consumption. Reproduction was also unaffected. The same proportion of treated and control mice mated, and bore live litters.

Epididymal sperm concentration and motility were unchanged by DNOP exposure at 5%. The single finding of a slight reduction in F1 seminal vesicle weight is interesting in light of current concerns about second-generation reproductive toxicity, but needs confirmation. Overall, these data show that, at doses that induced significant hepatomegaly, DNOP was without any adverse reproductive effect in Swiss mice.
(*Department of Health,1985*)

Summary
Studies have shown that there are no reprotoxic effects even at doses of 7500 mg DNOP/kg bw/day in animals.

No evidence for carcinogenity was found.

Studies show a high cumulative toxicity with a factor of 22 from acute effects to chronic effects.

Based on the lowest LD_{50} value for mice =13000 mg/kg and studies of cumulative toxicity, chronic toxicity effects is expected at less than 13000/22 = 600 mg/kg in mice.

From the studies the lowest values for chronic effects will probably be effects on the liver like seen for DEHP. The information in the studied data has not been sufficient to find a NOAEL for chronic liver effects. However, from the similarity of DEHP and DNOP the value may be in the same range.

7.3.2.6 Exposure scenarios
When comparing with DEHP a similar migration in oil based cream is expected.

From this a worst case uptake of approx. 0.05 mg/kg b.w. is expected.

7.3.2.7 Assessment
DNOP is a plasticizer which has shown less reprotoxic effects in studies than DEHP.

As with DEHP and other phthalates there will be effects on the liver weight. Based on the estimated LOAEL value for mice for liver effects of 600 mg/kg, a margin of safety (MOS) = 12000 can be calculated for the worst case.

The NOAEL value for liver effects is expected to be lower and may be based on a level comparable to DEHP i.e. 20 mg/kg/day.

Table 7.4 Estimates margin of safety for products

Product no.	MOS (normal use)	MOS (worst case use)
11,13 (oil based lubricant)	Estimate:>5600	Etimate:400

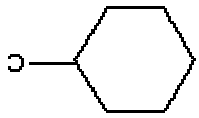
Within the considerable uncertainty when estimating the internal dose and NOAEL for liver effects from the comparable substance DEHP, MOS will be

>400, and it is thus concluded that there will be no risk in using products nos. 11 and 13 in the worst case scenario and if used with oil based lubricant.

7.3.3 Cyclohexanone

7.3.3.1 Identity

Name	Cyclohexanone
CAS-number	108-94-1
EINECS number	203-631-1
Molecular formula	$C_6H_{10}O$
Molecular structure	



Molecular weight	98.14
Synonyms	Cyclohexyl ketone Ketohexamethylene

The substance is an oily liquid. It has a boiling point of 155.6ºC (*Budavari, 1989*) and a melting point of -31˚C (*Lide, 1994-1995*).
The substance is soluble in water and polar media like ethanol, acetone and ethyl ether. The solubility in water is 50 g/l at 30ºC.
(*Lide, 1994-1995*).

The partition coefficient Log K_{OW} is determined to be 0.81 (*Hansch, 1995*).

Vapour pressure is determined to be 5 mm Hg at 26.4ºC (*The Merck Index, 1983*).

The substance has an odour with a reminiscent of peppermint and acetone (*Budavari, 1989*).

7.3.3.2 Detected quantities
The substance is detected by headspace analysis in 9 of the 15 products. In sample no. 3 , the highest value of 58 µg was found in headspace after 180 min. Sample no 2 and 8 gave comparable levels in headspace (51 and 39 µg) where the other samples gave values at least 40 times lower.

Extraction with dichloromethane showed cyclohexanone in 6 samples with values in sample 2,3,8,15 from 0.5 to 2.5 mg/g sample.

In migration tests cyclohexanone is detected in 3 of 6 products. The highest migration was for product no.2 with 1320 µg/dm^2, followed by product no.8 with 1000 µg/dm^2 and no.15 with 382 µg/dm^2.

7.3.3.3 Function of substance
The function of the substance is as solvent in the production process.

7.3.3.4 Classifications and TLV's
Cyclohexanone is included in the list of dangerous substances and classified as:
R10 Flammable
Xn;R20 Harmful by inhalation

The Danish threshold limit value is 40 mg/m^3. The substance is marked H for penetration through skin.

7.3.3.5 Health Effects
Data regarding health effects is included in IUCLID. The following is based on the data sheet and databases in TOXNET.

Acute toxicity
Test for acute toxicity on animals for cyclohexanone shows a low acute oral toxicity:

LD_{50} Mouse oral 1600-3200 mg/kg (*IUCLID*)
LD_{50} Rat oral ca. 1300-2700 mg/kg (*IUCLID*)
LC_{50} Rat inhalation 10-32 mg/l, 4 hours (*IUCLID)*

According to (*Farm Chemicals Handbook 87, 1987*) vapours of cyclohexanone may irritate mucous membranes and contact with the liquid may produce dermatitis in sensitive individuals.

Allergic contact dermatitis to cyclohexanone resin has been reported (*IARC, 1989*).

Chronic toxicity
Cyclohexanone is classified as A3 Confirmed animal carcinogen with unknown relevance to humans (*American Conference of Governmental Industrial Hygienists TLVs and BEIs. Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, 2005*).

Studies reported in IUCLID for teratogeniticity (inhalation) did not show any effect on mice in the range up to 1400 ppm (5.6 mg/l).

A two-generation study with 6 hours daily exposure by inhalation showed effects on fertility. No effects were observed for1000 ppm (4.1 mg/l) for the first generation and for 500 ppm (2mg/l) for the second generation.

The reference dose for chronic oral exposure RfD=5 mg/kg b.w./day (*IRIS*). The RfD value is based on a chronic bioassay study with cyclohexanone which was conducted with F344 rats and B6C3F1 mice. Cyclohexanone was administered as a solution in the drinking water. Rats were dosed at 3300 or 6500 ppm levels, male mice at 6500 or 13,000 ppm, and female mice at 6500, 13,000 or 25,000 ppm levels. Each treatment group consisted of 52 animals/sexes (males and females) both mice and rats. Survival and weight gain were similar to the controls in both sexes of either species treated with the lowest dosage of cyclohexanone, but weight gain was depressed at all of the higher doses. Female mice treated with both the higher doses (13,000 or 25,000 ppm) and male mice treated with the high dose (13,000 ppm) exhibited increased mortality as compared with controls. 50% of the females treated with 25,000 ppm cyclohexanone survived beyond 1 year. Based on these effects, the 3300 ppm level dose of cyclohexanone (converted to 462

mg/kg/day) in rats is considered as the NOAEL value, whereas the high dose (6500 ppm or 910 mg/kg/day) that causes decreased body weight gain was considered the LOAEL in rats. (*Lijinsky, 1986*). In the determination of RfD an uncertainty factor of 100 was applied; 10 for interspecies extrapolation and 10 for intraspecies variability among the human population.

Summary
Cyclohexanone is an animal carcinogen with unknown relevance to humans.

There is some data on effects on fertility by inhalation.

It may produce allergic contact dermatitis in sensitive individuals.

The NOAEL for chronic effects seen as decreased body weight gain by intake with drinking water has been estimated to 462 mg/kg/day in rats.

7.3.3.6 Exposure scenarios
The maximum value found in the migration experiments for product no. 2 was 1320 ug/dm^2*h, i.e. M = 0.013 mg/cm^2*h. With an area A =163 cm^2 and assuming 100% uptake values for intake has been calculated as shown in Table 7.5.

Table 7.5 Calculated and estimated intake for products

Product no	Extraction Dichloromethane (mg/g)	Migration artificial sweat (μg/dm^2)	Intake normal use (mg/kg b.w.)	Intake worst case (mg/kg b.w.)
2	2.02	1320	0.001	0.03
3	2.5	Not analysed	0.001 [1]	0.03 [1]
8	0.51	1001	0.001	0.02
15	1.5	382	0.0003	0.009

1 Based on extraction in dichloromethane

All other products are expected to give much lower values based on headspace analysis.

7.3.3.7 Assessment
Based on the data for chronic oral exposure with a NOAEL of 462 mg/kg/day a marginal of safety (MOS) is more than 420000 for normal use and 15000 for worst case use.

The ratio between RfD and the calculated intake is 162 in the worst case scenario.

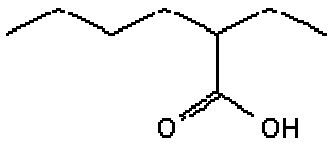
Use of either water or oil based gliding cream with better solubility characteristics for substances with low water solubility is not expected to increase the migration significantly of cyclohexanone as log K_{OW} =0.81 and cyclohexanone therefore should have a good solubility (50 g/l) in the used migration medium.

It is concluded that there is no health effects for cyclohexanone based on the data for chronic oral exposure and the observed migration. However, it must be mentioned that the compound in 2005 has been classified as a confirmed animal carcinogen with unknown relevance for humans and that the compound may produce allergic contact dermatitis in sensitive individuals.

7.3.4 2-Ethylhexanoic acid

7.3.4.1 Identity

Name	2-ethylhexanoic acid
CAS-number	149-57-5
EINECS number	205-743-6
Molecular formula	$C_8H_{16}O_2$
Molecular structure	



Molecular weight	144.22
Synonyms	2-Ethylhexanoic acid 2-Ethylhexoic acid Ethyl hexanoic acid, 2- Hexanoic acid, 2-ethyl-

The substance is a clear liquid. It has a boiling point of 228ºC (*Lide, 1995-1996*).

The substance is more soluble in organic solvents than in water. It is soluble in ethyl ether, carbon tetrachloride and slightly soluble in ethanol. The solubility in water is 1.4 g/l at 25ºC (*Ashford, 1994*).

The partition coefficient Log K_{OW} is determined to be 2.64 (*Hansch, 1995*).

Vapour pressure is determined to be 0.03 mm Hg at 20ºC (*Flick, 1991*).

The substance has a mild odour (*Flick, 1991*).

7.3.4.2 Detected quantities

2-Ethylhexanoic acid was detected in headspace from product 1 and 4.

The substance is detected in 9 of the 15 products when extracted with dichloromethane. Sample no. 4 showed the highest value with 14.1 mg/g sample. The samples 1, 3, 8, 11, 12, 13, 14 and 15 gave values from 0.16 to 3.1 mg/g.

In migration tests 2-ethylhexanoicacid was found in 3 of 6 products. The highest migration was for product no.11 with 423 µg/dm^2 followed by product no.8 with 220 µg/dm^2 and no.15 with 113 µg/dm^2.

7.3.4.3 Function of substance

The function of the substance is as stabiliser for PVC products.

7.3.4.4 Classifications and TLV's

2-Ethylhexanoic acid is included in the list of dangerous substances and classified as:

Repr.cat.3;R63	Possible risk of harm to unborn child

No Danish threshold limit value for the substance has been found.

7.3.4.5 Health Effects
Data regarding health effects are included in IUCLID. The following is based on the data sheet and databases in TOXNET.

Acute toxicity
Tests for acute toxicity on animals show that 2-ethylhexanoic acid has a low acute toxicity by ingestion.

- LD_{50} Rat oral 1,600-3,000 mg/kg *(Clayton, 1993-1994*)
- LD_{50} Rabbit oral 1,300 mg/kg *(Clayton, 1993-1994*)

The pure substance is harmful if swallowed, inhaled or absorbed through the skin and is extremely destructive to tissues of mucous membranes and upper respiratory tract, eyes, and skin. (*Prager, 1996*)

Some results on rabbits in the IUCLID data set show the component is irritating, other not.

Subchronic toxicity
Data in HSDB and IUCLID report teratogenic effects of 2-ethylhexanoic acid.

Results with continuous administration in drinking water for Wistar rats up to day 20 of gestation show skeletal malfunctions in offspring like clubfoot, absence of fibula etc. for doses from 100 mg/kg/day and above. The number of affected foetuses was control: 2.4%, 100 mg/kg/day: 4.9%, 300 mg/kg/day: 8.9% and 600 mg/kg/day: 15.3%. The NOAEL for teratogenic effects was set to 100 mg/kg/day.

The developmental toxicity of 2-ethylhexanoic acid was studied in animals treated by gavage with doses 0, 100, 250, 500 mg/kg bw/day on gestation day 6-15 for rats and with doses 0, 25, 125, 250 mg/kg bw/day on gestation day 6-18 for rabbits. The results suggest that 2-ethylhexanoic acid induces developmental toxicity in rats only at doses that cause maternal toxicity. 2-Ethylhexanoic acid causes maternal toxicity in rabbits without affecting foetal development. The no observable effect levels for maternal and developmental toxicity in rats are 250 and 100 mg/kg, respectively. The no observable effect levels for maternal and developmental toxicity in rabbits are 25 mg/kg and 250 mg/kg or more.
(*Hendrickx, 1993*)

Data is also reported in IUCLID for fertility effects for rats with 100, 300 or 600 mg/kg/day added in drinking water with a premating exposure of 10 weeks for male and 2 weeks for female. The result was a value of NOAEL parental = 300 mg/kg/day and NOAEL offspring = 100 mg/kg/day.

No data was found for carcinogenic or sensitising effects.

Summary
2-Ethylhexanoic acid is a substance that may cause reprotoxic effects including fertility or teratogenic effects in humans. Indications for other long term effects have not been found.

Values for teratogenic effects in rats gave NOAEL = 100 mg/kg bw/day.

Values for fertility effects in rats gave NOAEL = 100 mg/kg/day whereas values for developmental toxicity in rabbits was NOAEL = 25 mg/kg b.w. per day.

7.3.4.6 Exposure scenarios

The maximum value found in the migration experiments for product 11 was 423 ug/dm^2*h i.e. M=0.00423mg/cm^2*h. With an area A =168 cm^2 and assuming 100% uptake values for intake has been calculated as shown in Table 7.6.

Table 7.6 Calculated and estimated intake for products

Product no	Extraction Dichloromethane (mg/g)	Migration artificial sweat (μg/dm^2)	Intake normal use (mg/kg b.w.)	Intake worst case (mg/kg b.w.)
1	3.1	Not analysed		
3	2.4	Not analysed		
4	14.1	Not analysed	0.0036 [1]	0.1 [1]
8	0.5	220		
11	1.47	423	0.00036	0.01
12	1.12	Not analysed		
13	0.55	Not analysed		
14	0.16			
15	1.5	113		

1 Based on extraction in dichloromethane

When looking at the results of analysis by extraction with dichlorometane, a 10 times higher concentration is found in product 4 (14.1 mg/g) than in product no.11 (1.47 mg/g). This may lead to 10 times increased migration results for product no.4 if analysed.

7.3.4.7 Assessment

Based on a subchronic study with a NOAEL = 25 mg/kg/day for developmental toxicity in rabbits and the highest measured migration of product no. 11, the margin of safety (MOS) is more than 69000 for normal use and 2500 for worst case use.

For product no.4 the migration may be up to 10 times higher which gives a value of MOS of 250.

Use of either water or oil based gliding cream with better solubility characteristics for substances with low water solubility is only expected to increase the migration of 2-ethylhexanoic acid a little as log K_{ow} = 2.64 and the substance therefore have some solubility (1.4 g/l) in the used migration medium.

Table 7.7 Estimates margin of safety for products

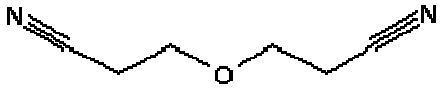
Product no.	MOS (Normal use)	MOS (worst case use)
4	6900	250
11	69000	2500

Based on the data above and the uncertainty regarding a possible increased migration in oil based lubricant, as well as a safety factor of 1000 for data from a subchronic study it is concluded that there may be a minor risk of developmental effects from 2-ethylhexanoic acid for product no. 4 by worst case use and by use of oil based lubricant, and no risk involved with the products 1, 3, 8, 11, 12, 13, 14 and 15.

7.3.5 3,3'-Oxydipropiononitril

7.3.5.1 Identity

Name	3,3'-Oxydipropiononitril
CAS-number	1656-48-0
EINECS number	216-750-9
Molecular formula	$C_6H_8N_2O$
Molecular structure	



Molecular weight	124.14
Synonyms	Propanenitrile, 3,3'-oxybis- Propionitrile, 3,3'-oxydi- 2-Cyanoethyl Ether

The substance is a colourless liquid. It has a boiling point of 143ºC. (*Safety datasheet, 2000*)

The solubility in water is high with 900 g/100 ml water indicating a negative Log K_{OW} (*Safety datasheet, 2000*)

7.3.5.2 Detected quantities
The substance is detected in migration experiments with product 14 at a value of 50 µg/dm^2.

7.3.5.3 Function of substance
The function of the substance is not known.

7.3.5.4 Classifications and TLV's
3,3'-Oxydipropiononitrile is not included in the list of dangerous substances and there is no Danish threshold limit value.

7.3.5.5 Health Effects
Data regarding health effects is very limited with no information in HSDB and IUCLID. There is some limited data in ChemID.

Acute toxicity
Test for acute toxicity on animals shows that 3,3'-Oxydipropiononitril is not acute toxic.

LD_{50} Rat oral 2800 mg/kg (*AMA Archives, 1954*)
LD_{lo} rabbit skin 4200 mg/kg (*National Technical Information Service*)

A draize test on rabbit has shown mild irritant effects on eye and skin at 500 mg/24 h (*Marhold, 1986*).

Sub-chronic toxicity
No tests were found.

Chronic toxicity
No tests were found.

Summary
Very limited data exists for this compound with data for acute toxicity of older date. Data suggests that the substance is irritating for eyes and skin.

7.3.5.6 Exposure scenarios
The maximum value found in the migration experiments for product 14 was 50 ug/dm^2*h i.e. M=0.0005 mg/cm^2*h. With an area A =38 cm^2 and assuming 100% uptake the following worst case value can be calculated:

Table 7.8 Calculated intake

Product no	Migration artificial sweat (µg/dm^2)	Intake worst case (mg/kg b.w.)
14	50	0.009

7.3.5.7 Assessment
Very limited data exists showing a low acute toxicity and some irritating effects.

Based on the acute toxic values any chronic effects in humans is expected a factor 1000 lower which means that NOAEL may be around 2 mg/kg.

Based on this the margin of safety (MOS) is 221000.

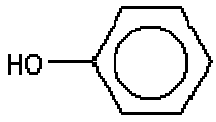
The migration is not expected to increase significantly when using water or oil based cream as the substance is very water soluble.

It is concluded that there is no health effects of the substance based on the present knowledge.

7.3.6 Phenol

7.3.6.1 Identity

Name	Phenol
CAS-number	108-95-2
EINECS number	203-632-7
Molecular formula	C_6H_5OH
Molecular structure	



Molecular weight	94.1
Synonyms	Carbolic acid Hydroxybenzene Phenyl alcohol

The substance is colourless acicular crystals or white, crystalline mass.

It has a boiling point of 181.8ºC and a melting point of 40.9ºC (*Kirk-Othmer, 1996*).

The substance is very soluble in alcohol, chloroform, ether, glycerol, carbon disulfide, petrolatum, volatile and fixed oils, and aqueous alkali hydroxides. The solubility in water is 82.8 g/l at 25ºC (*Southworth, 1986*).

The partition coefficient Log K_{OW} is determined to be 1.46 (*Hansch, 1995*).

Vapour pressure is determined to be 0.03 mm Hg at 25ºC (*Lide, 2002-2003*)

The substance has a mild odour (*Flick, 1991*)

7.3.6.2 Detected quantities
The substance is detected in headspace in 6 of the 15 products with the highest concentration in product no.11. Results of extraction with dichloromethane gave a value of 3.5 mg/g for product 11 with values for product no. 3, 4, 8, 13 and 15 larger than 0.19 mg/g.

In migration tests, phenol has been detected in 5 out of 6 products with the highest value for product no.11 (866 µg/dm^2) followed by product no 15 and 8.

7.3.6.3 Function of substance
The function of the substance is not known but it may be a residue from the production process.

7.3.6.4 Classifications and TLV's
Phenol is included in the list of dangerous substances and classified as:

T;R23/24/25	Toxic by inhalation, in contact with skin and if swallowed
Xn;R48,20/21/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed
C;R34	Causes burns
Muta. cat.3; R68	Possible risk of irreversible effects

The Danish threshold limit value is 4 mg/m^3 and it is marked with H for penetrable through skin.

7.3.6.5 Health Effects
Data regarding health effects is included in IUCLID. The following is based on the data sheet and databases in TOXNET and (*Nilsson, 2004*).

Acute toxicity
Phenol is classified as toxic by skin contact and by ingestion and the substances is also classified corrosive (R34).

Phenol is toxic with a lethal dose of 50-500 mg/kg for humans. Some persons can be hypersensitive with serious effects or death caused by exposure to even lower doses.

Tests for acute toxicity on animals shows:

LD_{50} Rat oral 530 mg/kg (*O'Neil, 2001*)
LD_{50} Rat dermal 669 mg/kg (*Lewis, 1996*)
LD_{50} Mouse oral 270 mg/kg (*Lewis, 1996*)
LD_{50} Mouse i.v. 112 mg/kg (*Lewis, 1996*)
LD_{50} Cat oral 100 mg/kg (*Verschueren, 1983*)

Chronic toxicity
Phenol is included in the IUCLID database from 2000. From the data set comes the following information. Tests show that phenol is not a sensitizer. In a 28-days test with mice were shown that oral intake cause effects on red blood cells and on the level of antibodies in the blood. LOAEL was estimated to 1.8 mg/kg body weight.

Phenol is not recognised as a carcinogen (IARC, group3) based on insufficient evidence for both humans and animals (*IARC, 1999*)).

In a test with rats (*Argus Research Laboratories, 1997*) the effects on the development of the offspring was analysed. A NOAEL of 60 mg/kg per day was estimated. A benchmark dose level (BMDL) of 93 mg/kg was calculated.

Another developmental and reproductive toxicity study gave NOAEL = 70 mg/kg/day for male rats and 93 mg/kg/day for female rats

Based on these studies, the BMDL value and by including a safety factor of 300 the reference dose was estimated to:
RfD = 0.3 mg/kg/day (*IRIS database*).

Summary
Phenol produces developmental effects in offspring from rats with a NOAEL value of 60 mg/kg/day.

The lowest effect level however is on blood cells and antibodies with LOAEL = 1.8mg/kg/day for mice.

7.3.6.6 Exposure scenarios
The maximum value found in the migration experiments for product 11 was 866 ug/dm^2*h i.e. M=0.00866mg/cm^2*h. With an area A =168 cm^2 and assuming 100% uptake values for intake has been calculated as shown in Table 7.9

Table 7.9 Calculated and estimated intake for products

Product no	Extraction Dichloromethane (mg/g)	Migration artificial sweat ($\mu g/dm^2$)	Intake normal use (mg/kg b.w.)	Intake worst case (mg/kg b.w.)
2	0.02	26		
3	0.7	Not analysed		0.004 [1]
4	0.9	Not analysed		0.005 [1]
8	0.19	182		0.004
11	3.5	866	0.0007	0.021
13	1.06	Not analysed		0.006 [1]
14	0.07	55		
15	0.7	264		0.006

1 Based on extraction in dichloromethane

The migration from the products 8,15 was approximately 25% of this value. Based on extraction in dichloromethane, the products 3,4,8,13,15 are assumed to give an intake comparable within a decade.

7.3.6.7 Assessment

Phenol is a substance which has shown developmental and immunotoxic effects in animals and is classified as having a risk of irreversible effects (mutagenic) in humans.

Based on the data for LOAEL on effects on blood cells and antibodies in mice a margin of safety (MOS) is more than 2700 for normal use and 96 for worst case use.

The ratio between RfD and the calculated intake is 14 in the worst case.

Use of either water or oil based gliding cream with better solubility characteristics for substances with low water solubility is only expected to increase the migration of phenol a little as log K_{OW} = 1.46 and the substance therefore have some solubility (83 g/l) in the used migration medium.

Table 7.10 Estimates margin of safety for products

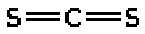
Product no.	MOS (normal use)	MOS (worst case use)
11	2700	96
3,4,8,13,15	>9450	>280

It is concluded that there are minor health risk effects from phenol by max. use of product no. 11 and a possible minor risk with the products 3, 4, 8, 13, and 15, considering the uncertainty in connection with estimating intake and migration in the relevant migration liquid.

7.3.7 Carbon disulfide

7.3.7.1 Identity

Name	Carbon disulphide
CAS-number	75-15-0
EINECS number	204-843-6
Molecular formula	CS_2
Molecular structure	



Molecular weight	76.14
Synonyms	Carbon bisulphide Dithiocarbonic anhydride

The substance is a clear, colourless or faintly yellow liquid. It has a boiling point of 46ºC (*Lide, 1995-1996*) and a melting point of -111.5ºC (*Lide, 1995-1996*).

The substance is more soluble in organic solvents than in water. The solubility in water according to (*Yalkowsky, 1992*) is 2860 mg/l at 25ºC.

The partition coefficient Log K_{OW} is determined to be 1.94 (*Hansch, 1995*).

Vapour pressure is determined to be 359 mm Hg at 25ºC (*Yaws, 1994*).

The odour of carbon disulphide depends on grade. Commercial grades have a foul smelling whereas pure distillates have a sweet, pleasing and etherial odour (*Budavari, 1996*).

7.3.7.2 Detected quantities
Carbon disulphide is detected in 7 of the 15 products in headspace with the highest concentration from product no.5 (458 ng). In all the products 3, 4, 5, 6, 7, 9 and 14 the concentration in headspace was larger than 110 ng.

In migration experiments carbon disulphide was only detected for product no.14 with 500 μg/dm^2.

7.3.7.3 Function of substance
The function of the substance is a pyrolysis product from dithiocarbamate based sulphur accelerators used in the vulcanisation of rubber.

7.3.7.4 Classifications and TLV's
Carbon disulphide is included in the list of dangerous substances and classified as:

F;R11	Highly flammable
Xi;R36/38	Irritating to eyes and skin
T;R48/23	Toxic: Danger of serious damage to health by prolonged exposure through inhalation
Repr. Cat. 3;R62-63	Possible risk of impaired fertility and of harm to the unborn child

The Danish threshold limit value is 15 mg/m^3 and it is marked with H which means that the substance can be absorbed through the skin.

7.3.7.5 Health Effects
Data regarding health effects is included in IUCLID. The following is based on the data sheet and databases in TOXNET.

Acute toxicity
Test for acute toxicity on animals shows that carbon disulphide is not acute toxic.

- LD_{50} Mouse oral >2,780 mg/kg
- LD_{50} Rat oral 3,188 mg/kg
- LD_{50} Rat inhalation 27 g/m^3, 2 hr (*Lewis, 1996*)

The substance is severely irritating to eyes, skin and mucous membranes and skin sensitization may occur (*Sittig, 1985*).

Chronic toxicity
The substance is a potent nerve toxin. Chronic long-term exposures may result in elevated blood cholesterol, retinopathy, peripheral neuropathy, decreased glucose tolerance, reduced serum thyroxine levels, and parkinsonism. (*Ellenhorn, 1988*)

Long-term exposure to levels in excess of 20 ppm may result in atherogenic and diabetogenic changes (*Ellenhorn, 1988*).

Adverse effects of carbon disulfide exposure on reproductive function have been reported in exposed workers, with significantly lower sperm counts and more abnormal spermatozoa than in unexposed control subjects. (*Rom, 1992*)

Studies on reproductive effects include a study on rats and rabbits which showed no effect when the animal was exposed to 20 ppm or 40 ppm which was estimated to correspond to oral doses of 5 or 10 mg/kg for rats and 11 or 22 mg/kg for rabbits (*Hardin, 1981*).

The reference dosis for chronic oral exposure RfD = 0.1 mg/kg/day (*IRIS*). The value is based on a NCTR-NTP oral study (*Jones-Price, 1984 a,b*). In which was observed 25 mg/kg/day in rabbits as an FEL (foetal resorption). Foetal malformations in this study were not observed in rats at the lowest level (100 mg/kg/day) of carbon disulphide exposure. The data from this study also suggest that the rabbit foetus is more sensitive than the rat foetus to carbon disulphide induced toxicity. These data were supplemented with an epidemiologic study by (Johnson, 1983) to support a NOAEL of 11 mg/kg for foetal toxicity/malformations from carbon disulphide oral exposure. By using an uncertainty factor of 100 (10 for interspecies and 10 for intraspecies variation) the RfD value was derived.

Summary
Carbon disulphide is irritating to eye and skin.

Chronic effects of carbon disulphide include possible risk of impaired fertility and of harm to the unborn child and long term nerve toxic effects

7.3.7.6 Exposure scenarios
The maximum value found in the migration experiments for product 14 was 500 ug/dm^2*h i.e. M=0.005mg/cm^2*h. With an area A =38 cm^2 and assuming 100% uptake values for intake has been calculated in Table 7.11

For other products with vagina/anal use, carbon disulphide was also found in headspace. The exposed area was 4 times higher for product no. 3, 4 and 7. As these products are used more frequently in worst case, the intake shown in Table 7.11 has been calculated by assuming the same migration as for product no.14.

For the product no. 5, 6 and 9 the uptake will be through skin. The area of the products is large and the products are applied in a way where carbon disulphide cannot evaporate easily.

Assuming a worst case scenario with a whole body suit of area 20000 cm^{2}and 100% penetration through skin, values for intake has been calculated in Table 7.11. As time of exposure for worst case use was assumed a use of 7 hours each week (1 hour/day) and for normal use 3 hours each month.

Table 7.11 Calculated and estimated intake for products

Product no	Headspace analysis (ng)	Migration artificial sweat (μg/dm^2)	Intake normal use (mg/kg b.w.)	Intake worst case (mg/kg b.w.)
3 (vibrator)	111	Not analysed	0.00036 [1]	0.01 [1]
4 (vibrator)	121	Not analysed	0.00036 [1]	0.01 [1]
5 (fetish)	458	Not analysed		
6 (fetish)	405	Not analysed		

Product no	Headspace analysis (ng)	Migration artificial sweat (μg/dm^2)	Intake normal use (mg/kg b.w.)	Intake worst case (mg/kg b.w.)
7 (vibrator)	179	Not analysed	0.00036 [1]	0.01 [1]
9 (fetish)	455	Not analysed		
14 (gag)	138	500	0.00009	0.00009
Fetish whole body coverage			0.14 [2]	1.4 [2]

1 Estimate based on headspace analyses and migration results from product no.14.
2 Estimate based on headspace analyses of product no 5,6,9,14 and migration results from product no.14

7.3.7.7 Assessment

Carbon disulphide is a substance that may cause reprotoxic effects and nerve toxic effects. Indications for other long term effects have not been found.

Carbon disulphide has been detected in migration experiments from 1 sample (Gag).

Based on the data for foetal toxicity a margin of safety (MOS) is 121000 and a ratio between RfD and the calculated intake is 1100.

For the products 3, 4, 7 (vibrators) the margin of safety can be estimated to MOS= 963 in the worst case and the ratio between RfD and the calculated intake is 9.

For use of fetish products, a calculation has been made for a whole body coverage and by assuming an intake through skin comparable to oral uptake.

This gives MOS =8 for a worst case scenario with a use of 1 hour each day and RfD=0.07.

Table 7.12 Estimates margin of safety for products

Product no.	MOS (Normal use)	MOS (worst case use)
3,4,7	27000	963
14	121000	121000
Fetish products like no.5,6,9 with whole body coverage	80	8

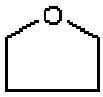
It is concluded that there is no health risk with exposure of the given levels of carbon disulphide for product no.14. Regarding products 3, 4, and 7 there may be a minor risk by max. use, when the uncertainty regarding estimation of intake based on migration from a quite different material (no. 14) and the uncertainty regarding migration in the actual migration fluids are considered.

For fetish products like no. 5,6,9 the estimations suggest there is probably a risk of health effects, especially if the products are used for longer periods covering a large part of the body.

7.3.8 Tetrahydrofuran

7.3.8.1 Identity

Name	Tetrahydrofuran
CAS-number	109-99-9
EINECS number	203-726-8
Molecular formula	C_4H_8O
Molecular structure	



Molecular weight	72.11
Synonyms	Tetramethylene oxide 1,4-Epoxybutane Butane, 1,4-epoxy- Butane, alpha,delta-oxide Butylene oxide Cyclotetramethylene oxide Diethylene oxide Furan, tetrahydro- Furanidine Oxacyclopentane Oxolane

The substance is a colourless, mobile liquid. It has a boiling point of 65ºC (*Lide, 2000*) and a melting point of --108.3ºC (*Lide, 2000*).

The substance has a solubility of 30% in water 25ºC (*International Labour Office, 1983*)

The partition coefficient Log K_{OW} is determined to be 0.46 (*Hansch, 1995*).

Vapour pressure is determined to be 162 mm Hg at 25ºC (*Daubert, 1989*).

The substance has an ether like odour (*Budavari, 1996*).

7.3.8.2 Detected quantities

The substance is detected in 8 of the 15 products in headspace with the highest concentration for product no.8 (5384 ng) and product 2,3,15 at comparable levels. The rest of the products gave more than a decade lower headspace concentrations.

In migration experiments tetrahydrofuran was detected in product 8,15 with 12 µg/dm^2 in both products.

7.3.8.3 Function of substance

The function of the substance is a solvent for PVC.

7.3.8.4 Classifications and TLV's

Tetrahydrofuran is included in the list of dangerous substances and classified as:

F;R11-19 Highly flammable; May form explosive peroxides
Xi;R36/37 Irritating to eyes and respiratory system

The Danish threshold limit value is 148 mg/m^3.

7.3.8.5 Health Effects
Data regarding health effects are included in IUCLID. The following is based on the data sheet and databases in TOXNET.

Acute toxicity
Test for acute toxicity on animals shows that tetrahydrofuran is not acute toxic.

- LD_{50} Rat oral 1,650 mg/kg
- LD_{50} Mouse ip >1,900 mg/kg (*Lewis, 1996*)
- LC_{50} Rat inhalation =21,000 ppm/ 3hr

Tetrahydrofuran is a strong irritant to skin and mucous membranes (*Gosselin, 1984*).

Chronic toxicity
Tetrahydrofuran is classified as A3 Confirmed animal carcinogen with unknown relevance to humans (*American Conference of Governmental Industrial Hygienists TLVs and BEIs. Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, 2005).*

Tetrahydrofuran can cause dermatitis on prolonged exposure (*Mackison, 1981*).

Two inhalation studies for 105 weeks with rats and mouse with doses 0.6, 1.8 and 5.4 mg/l (200, 600, and 1800 ppm) is reported in the IUCLID data set. It was found that there was some evidence for carcinogenic activity in the two high doses for male rats (increased renal tubule epithelial adenoma and carcinomas). For female mouse, the incidents of hepatocellular neoplasms (adenoma and carcinoma) was significantly greater (85%) for high doses than in control groups and was evaluated as clear evidence. Based on this the NOAEL level for mice, rats is around 600 ppm (1.8 mg/l).

In a two generation study on Wistar rats, developmental toxicity in the form of reduced pup growth and delayed eye opening were noted at tetrahydrofuran doses administered with water at 782 mg/kg/day but not at 305 mg/kg/day (*IUCLID*).

Summary
New evaluations of results from 2005 have classified tetrahydrofuran as a confirmed carcinogen for animals with unknown relevance to humans.

Indications for other long term effects have not been found.

Data for carcinogenic effects by inhalation giving a NOAEL value around 600 ppm.

No data was found for oral uptake. Assuming a 100% uptake of tetrahydrofuran by inhalation and orally, the NOAEL can be roughly

estimated as NOAEL (oral) = NOAEL (inhalation) * LD_{50} (oral)/LC_{50}(inhalation) =600*1650/21000=47 mg/kg/day.

7.3.8.6 Exposure scenarios

The maximum value found in the migration experiments for product 8 and 15 was 12 µg/dm^2*h i.e. M=0.00012 mg/cm^2*h. With an area A =164 cm^2 and assuming 100% uptake values for intake has been calculated in Table 7.13

Table 7.13 Calculated and estimated intake for products

Product no	Headspace analysis (ng)	Migration artificial sweat (µg/dm^2)	Intake normal use (µg/kg b.w.)	Intake max. use (µg/kg b.w.)
2	2163	<0.5	<0.001	<0.03
3	4521	Not analysed	0.01	0.3
8	5384	12	0.01	0.28
15	2330	12	0.01	0.28

Based on the head space analyses and migration analyses, the product 3 is assumed to give an intake in the same range as for no. 8 and 15 whereas no. 4, 5, 6 and 7 would be at least a decade lower.

7.3.8.7 Assessment

Based on the estimated NOAEL of 47 mg/kg/day the margin of safety (MOS) is 4.7 mill. for normal use and 167000 for worst case use.

Use of either water or oil based gliding cream with better solubility characteristics for substances with low water solubility is only expected to increase the migration of tetrahydrofuran a little as log K_{OW} = 0.46 and the substance therefore have some solubility (300 g/l) in the used migration medium.

Table 7.14 Estimates margin of safety for products

Product no.	MOS (Normal use)	MOS (worst case use)
3,8,15	4700000	167000

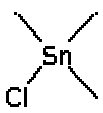
It is concluded that there is no health risk of carcinogenic effects with the observed concentration of tetrahydrofurane.

However, it must be mentioned that the compound may produce allergic dermatitis in prolonged exposure.

7.3.9 Trimethyltin chloride

7.3.9.1 Identity

Name Trimethyltin chloride
CAS-number 1066-45-1
EINECS number 213-917-8
Molecular formula C_3H_9ClSn
Molecular structure



Molecular weight 199.26

Synonyms	Stannane, chlorotrimethyl- Trimethylchlorostannane Trimethylchlorotin Trimethylstannyl chloride

The substance consists of colourless needles. It has a boiling point of 154-156ºC (*Kirk-Othmer Encyclopedia of Chemical Technology, 1997*) and a melting point of 37.5ºC *(Kirk-Othmer Encyclopedia of Chemical Technology, 1997*).

The substance is soluble in chloroform and other organic solvents (Lide, 1994) and is miscible with water (*Kirk-Othmer Encyclopedia of Chemical Technology, 1997*).

7.3.9.2 Detected quantities
Trimethyltin chloride was only detected in sample no. 2 with a value of 0.04mg/kg

The migration experiment confirmed this with a detected amount of 99 $\mu g/dm^2$.

7.3.9.3 Function of substance
The function of the substance is probably as a PVC stabilizer as triethyltin chloride is used for this purpose

7.3.9.4 Classifications and TLV's
Trimethyltin chloride is not included in the list of dangerous substances and no Danish threshold limit value exists.

7.3.9.5 Health Effects
Data regarding health effects is not included in IUCLID. The following is based on the data sheet and databases in TOXNET.

Acute toxicity
Trimethyltin chloride is highly neurotoxic according to the literature (*Seiler, 1988*).

Test for acute toxicity on animals shows that trimethyltin chloride is acute toxic.

- LD_{50} Mouse intravenous >1,8 mg/kg (*Lewis, 1996*)
- LD_{50} Rat oral ca. 12 mg/kg (*Lewis, 1996*)
- LD_{50} Rat ip. 7.45 mg/kg (*Lewis, 1996*)

From the values it can be seen that trimethyltin chloride should have a classification for acute toxicity as Tx/R28 if included on the hazardous substance list.

Intoxication incidents in a chemical company where 6 workers where exposed to trimethyl chloride showed a number of neurotoxic symptoms 2-3 days after exposure including loss of hearing, difficulties in finding right words etc. The symptoms grew worse with one death caused by cerebral edema, pulmonary edema and kidney failure. The intoxication resulted in permanent damage for two patients (*Seiler, 1988*).

Sub-chronic toxicity

The neurotoxic effects of trimethyltin chloride have been studied in a number of references.

Comparison of tri-organotin compounds showed that trimethyltin chloride and triethyltinchloride was neurotoxic whereas tri-n-propyl chloride and n-butyltin chloride induced a dose related decrement in weights of thymus and spleen. Tri-n-propyltin chloride and triphenyltin chloride were immunotoxic (*Snoeij, 1985*).

In another study, effects of trimetyltin chloride were studied in mice and rats. The effect on rats with a dose of 7.5 mg/kg was much less than on mice with a dose of 3 mg/kg. Generative changes in brain stem neurons and spinal cord were observed in all mice 3-5 days after the dosage (*Chang, 1983*).

Trimethyltin chloride was given to Syrian hamsters, gerbils and marmosets and changes in the brain were studied from day 1 to 7 weeks later. The signs of poisoning included whole-body tremors and prostration. Within the marmoset brain, trimethyltin chloride was found to be uniformly distributed, similar to that in the rat. In all three species, signs of poisoning included whole-body tremors and prostration, while death might occur in 3-4 days. In Marmosets ataxia, agitation, aggression and occasional fits were also observed. Bilateral symmetrical neuronal necrosis and chromatolysis were seen in the majority, which involved the hippocampus, pyriform cortex, amygdaloid nucleus, neocortex, various brain stem nuclei and in marmosets the retina. The lethal dose for the three species was around 3 mg/kg which is lower than for rats. This is explained by a partial binding of trimethyltin chloride to haemoglobin in rats which is not found for the studied species and human haemoglobin. Therefore, the lethal dose for humans is expected to be around 3 mg/kg. The dose required to produce neuronal damage will be less (*Brown, 1984*).

Trimethyltin chloride treatment produced severe and permanent damage in the central nerve system which was characterised by neuronal necrosis rather than intramyelinic edema. Neuronal degeneration and necrosis was observed in rats treated with 15 ppm trimethyltin acetate in the diet for 2 weeks. Similar results were reported in rats orally exposed to trimethyltin chloride in a single dose at 10 mg/kg, in multiple doses at 4 mg/kg/week for 4 weeks and at 1 mg/kg/day for 2 weeks.
(*Boyer, 1989*)

The data indicates that trimethyltin chloride accumulates which is also found in tests of the clearance half-time in brain and blood concentration which has been estimated to at least 16 days (*Friberg, 1986*).

Developmental effects were studied in THA rats with 0, 5, and 7 mg/kg single dose injected on gestational day 12. In Sidman avoidance test, the avoidance rate of the treated offspring rats was lower when compared to the controls. This result suggests that prenatal trimethyltin chloride administration disrupts learning ability (*Miyake, 1989*).

A 56 days' study (The U.S. Department for Health and Human Services, 2005) states a LOAEL value of 0.05 mg/kg regarding significant drop in the learning ability of rats with oral intake through drinking water. Further it states a LOAEL of 0.8 mg/kg for neurological effects on rats by continuous oral intake over 25 days.

For tributylinchloride the same reference determines a NOAEL for developmental effect of 0.025 mg/kg and chronic effect also of 0.025 mg/kg for rats.

Chronic toxicity
Trimethyltin chloride is classified as A4; Not classifiable as a human carcinogen (*American Conference of Governmental Industrial Hygienists TLVs and BEIs. Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, 2005*).

Summary
Trimethyltin chloride is a substance that may cause neurotoxic effects in animals and humans. Indications for other long term effects have not been found.

Values are only given for acute toxic effects in short term studies with animals. The lowest value was 1.8 mg/kg b.w. per day for LD_{50} intravenous in mouse.

Data for LD_{50} (oral) in a single dose are low with values around 2-3 mg/kg for the most sensitive animals (mouse and hamsters). The human LD_{59} (oral) is expected to be in the same range.

Neuronal degeneration and necrosis was observed at multiple oral doses of 1 mg/kg/day.

Data for long-term chronic effects (neurotoxic) by long-term continuous exposure are not found.

A subchronic study shows significant neurological effects on rats with LOAEL of 0.8 mg/kg and another study shows effects on the learning ability with LOAEL = 0.05 mg/kg on rats.

Trimethyltin chloride will accumulates in the body at daily exposure as the clearance half-time is approximately 16 days.

A NOAEL value for neurotoxic effects has not been found.

7.3.9.6 Exposure scenarios
The maximum value found in the migration experiments for product 2 was 99 µg/dm^2*h i.e. M=0.00099mg/cm^2*h. With an area A =163 cm^2 and assuming 100% uptake the following intake has been calculated as seen in Table 7.15.

Table 7.15 Calculated and estimated intake for products

Product no	Extraction Dichloromethane (mg/g)	Migration artificial sweat (µg/dm^2)	Intake normal use (mg/kg b.w.)	Intake worst case (mg/kg b.w.)
2	0.04	99	0.000082	0.002

7.3.9.7 Assessment
The margin of safety (MOS) of the expected LD_{50} value for humans is 24000 for normal use and 867 for worst case use.

Based on the subchronic LOAEL value 0.05 mg/kg for learning ability effect on rats, a MOS of 0.05/0.002=25 at maximum use and MOS=610 at normal use can be calculated.

For the subchronic LOAEL value for neurological effects on rats, the safety margins were calculated to MOS=400 at maximum use and MOS=9800 at normal use.

A uncertainty factor of 1000-10000 may be expected at extrapolation to humans originating from a factor 10 for interspecies extrapolation, 10 for intraspecies variation in humans and a factor 10-100, as it is both a LOAEL value and a subchronic study. A NOAEL value of 0.025 mg/kg for the related substance trimethyltin chloride indicates that a safety factor of 1000 is satisfactory.

It is not known whether use of oil based or water based cream will increase the migration which will further increase the risk.

Table 7.16 Estimates margin of safety for products

Product no.	MOS (Normal use)	MOS (worst case use)
2	10 [1]	0.36 [1]

1 NOAEL =0.8 µg/kg/day is estimated from LD_{50} as explained above

It is concluded that for product no.2 there is a health risk of developmental effects (learning ability) on progeny and a minor risk of neurological effect on adults by worst case use. By normal use there may be a risk of developmental effecs within the uncertainty factor.

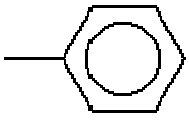
7.3.10 Other components

Toluene was found in a number of products.

The health effects of toluene has been assessed in (*Nilsson, 2004)* and only the data necessary for assessment is shown here.

7.3.10.1 Identity

Name	Toluene
CAS-number	108-88-3
EINECS number	203-625-9
Molecular formula	C_7H_8
Molecular structure	



Molecular weight	92.14
Synonyms	Benzene, methyl-

The boiling point of toluene id 110.6ºC.

Toluene is more soluble in organic solvents than water with a partition coefficient Log K_{OW} of 2.73 and solubility in water of 526 mg/l, 25˚C.

7.3.10.2 Detected quantities
Toluene is detected in 14 of the 15 products in headspace. The highest concentration is for product no.4. Migration in dichloromethane shows 2.1 mg/g from sample 4, 1.3 mg/g from no 15, 0.3 mg/g from no.3 and 0.26 mg/g from sample no.2. The rest is much lower.

In migration experiments toluene was detected in 3 of 6 products with 54 μg/dm^2 for product 15 and comparable levels for product no. 2 and 8.

7.3.10.3 Function of substance
The function of the substance is as solvent in the production process.

7.3.10.4 Classifications and TLV's
Toluene is included in the list of dangerous substances:

F; R11	Highly flammable
Repr. Cat.3; R63	Possible risk of harm to unborn child
Xn; R48/20-R65	Harmful: danger of serious damage to health by prolonged exposure through inhalation, may cause lung damage if swallowed
Xi; R38 - R67	Irritating to skin, vapours may cause drowsiness and dizziness

7.3.10.5 Health Effects
A reference dose for chronic oral exposure has been calculated in IRIS with the newest revision in September 2005.

The value is based on a 13 week rat gavage study with changes in liver and kidney weight as critical effect giving a LOAEL of 446 mg/kg/day. A benchmark approach gave BMD=238 mg/kg/day. Based on this value and an uncertainty factor of 3000 the following value calculated (*IRIS*):

RfD= 0.08 mg/kg/day.

7.3.10.6 Exposure scenarios
The maximum value found in the migration experiments for product 15 was 54 μg/cm^2*h i.e. M=0.00054 mg/cm^2*h. With an area A =164 cm^2 and assuming 100% uptake the following intake has been calculated as seen in Table 7.17.

For the products 5, 6 and 9 the uptake will be through skin. The area of the products is large and the products are applied in a way where toluene cannot evaporate easily. Products 5 and 6 gave a concentration in headspace which was 30 lower than for product no. 15.

Assuming a worst case scenario with a whole body suit of area 20000 cm^{2}and 100% penetration through skin, values for intake has been calculated in Table 7.17. As time of exposure for worst case use was assumed a use of 7 hours each week (1 hour/day) and for normal use 3 hours each month.

Table 7.17 Calculated and estimated intake for products

Product no	Head space analysis (ng)	Extraction Dichloromethane (mg/g)	Migration artificial sweat (μg/dm^2)	Intake normal use (mg/kg b.w.)	Intake worst case (mg/kg b.w.)
2 (vibrator)	28121	0.26	22	0.00002	0.0006
3 (vibrator)	27505	0.3	Not analysed	<0.000045[1]	<0.0012[1]

4 (vibrator)	165332	2.1	Not analysed	<0.00009[1]	<0.0024[1]
5 (fetish)	1016		Not analysed		
6 (fetish)	705		Not analysed		
8 (vibrator)	15821	0.04	38	0.00003	0.0009
9 (fetish)	147		Not analysed		
12 (vibrator)	1745	0.02	Not analysed		
14 (gag)	80	0.03			
15 (vibrator)	29320	1.3	54	0.000045	0.0012
Fetish whole body coverage				0.0005	0.005

1 Based on headspace data and data for extraction in dichloromethane

7.3.10.7 Assessment

Based on the bench mark value of 238 mg/kg/day the margin of safety MOS can be calculated to 188000 for product 15.

The ratio between RfD and the calculated intake is 63 in the worst case.

However in product no.4, the migration seems to be the double from extraction in dichloromethane giving MOS=90000 in the worst case.

For use of fetish products a calculation has been made for whole body coverage and by assuming an intake through skin comparable to oral uptake

This gives MOS =46000 with a ratio between RfD and the calculated intake of 15 for worst case use.

Use of either water or oil based gliding cream with better solubility characteristics for substances with low water solubility is only expected to increase the migration of tetrahydrofuran to a minor extent as log K_{OW} =2.73 and the substance therefore have some solubility (0.5 g/l) in the used migration medium.

Table 7.18 Estimates margin of safety for products

Product no.	MOS (Normal use)	MOS (worst case use)
4	2521000	90000
Fetish products like no.5,6,9 with whole body coverage	460000	46000

It is concluded that there is no health effects from toluene.

7.4 Overall Assessment

7.4.1 Substances

In Table 7.19 the found health effects of the evaluated substances are shown

Table 7.19 Effects of evaluated substances

Substance	Irritating and sensitizing effects	Reprotoxic effects	Carcinogenic effects	Mutagenic effects	Neurotoxic effects
DEHP		R60-61 (may impair fertility/ cause harm to unborn child)			
DNOP					
Cyclohexanone	Irritating to mucous membranes /risk of contact dermatitis in sensitive individuals		A3 confirmed animal carcinogen-unknown relevance in humans		
2-Ethylhexanoic acid		R63 possible harm to unborn child			
3,3'oxydipropiono nitrile					
Phenol				R68 possible risk of irreversible effects	
Carbon disulphide	R36/R38 Irritating to eyes and skin Other: irritating to mucous membranes	R62-63 possible risk of impaired fertility/ harm to unborn child			
Tetrahydrofuran	R36/37 Irritating to eyes and respiratory system Other: irritating to skin and mucous membranes		A3 confirmed animal carcinogen-unknown relevance in humans		
Trimethyltin chloride					Produces permanent neurotoxic effects. Expected classification as Tx;R28
Toluene	R38 Irritating to skin	R63 possible risk of harm to unborn child			

In the following an overview of the evaluations of the substances in section 7.3 is given. Data in the table are given for the sample with the highest determined concentration of the actual substance.

Table 7.20: Toxic effects for selected substances in sex toys

Substance	Max Uptake mg per kg b.w.	NOAEL mg/kg b.w. per day	MOS (worst case use)	RfD/MaxUptake	Remarks
DEHP	0.094	4.8	100	0.4	Pregnant/breastfeeding women, max. use, oil based lubricant, developmental/testicular health effects. Minor risk (products nos. 3,4,8,15.
DNOP	0.1	19	200	No value	No risk of health effect, but MOS is subject to uncertainty as it is based on data for DEHP (Estimate based on similarities.
Cyclohexanone	0.03	462	15000	162	No risk of health effects
2-Ethylhexanoic acid	0.1	25	250	No value	Possible minor risk of health effects for product no.4 by max use, oil based lubricant.
3,3'oxydipropiononitrile	0.009	2	221000	No value	No risk of health effect based on very few data.
Phenol	0.02	2	96	14	Minor risk of health effects (product no. 11) by max. use. Possible minor risk (products 3, 4, 8, 13, and 15) by max. use.
Carbon disulphide	0.01 (vibrator)	11	963 (vibrator), 8(fetish)	9 (vibrator), 0.07 (fetish)	Possible minor risk of health effects for product no.3,4,7 and probably a risk by products 5,6,9 when a large part of the body is covered and by max. use.
Tetrahydrofuran	0.28	47	167000	No value	No risk of health effects
Trimethyltin chloride	0.002	0.0008	0.36		Risk of developmental effects and minor risk of neurological effects on adults by max. use. Minor risk of developmental effect by normal use.
Toluene	0.0024	238	90000 (vibrator) 46000 (fetish)	63	No risk of health effects

7.4.2 Products

Table 7.21 contains the assessment of the health effect of each product.

Table 7.21: Identified health effects for products

Product no	Type	Health effect Normal use [3]	Health effect use Max. use [3]
1	Dildo	None	None
2	Dildo	Minor risk pregnant/breast feeding (trimethyltin chloride)	Risk for pregnant/breastfeeding, minor risk other adults (trimethyltin chloride)
3	Dildo	None	Minor risk for pregnant/breastfeeding (DEHP)[2] , possible minor risk (phenol, carbon disulphide)
4	Dildo	None	Minor risk for pregnant/breastfeeding

			(DEHP)[2] , possible minor risk (phenol, carbon disulphide, 2-ethylhexane acid)
5	Dress	None[1]	Possible minor risk [1]
6	Gloves	None [1]	None [1]
7	Dildo	None	Possible minor risk (carbon disulphide)
8	Dildo	None	Minor risk for pregnant/breastfeeding (DEHP) [2], possible minor risk (phenol)
9	Patent leather top	None [1]	None[1]
10	Art. Vagina	None	None
11	Dildo	None	Minor risk (phenol)
12	Dildo	None	None
13	Dildo	None	Possible minor risk (phenol)
14	Gag	None	None
15	Dildo	None	Minor risk for pregnant/breastfeeding (DEHP) [2], possible minor risk (phenol)
16	Dildo	None	None

1: Calculations indicate a risk of reprotoxic health effects from carbon disulphide exposure when using closed bodysuits for prolonged periods. No risk when using items which cover only a small part of the body, products No. 6, 9. There may be a minor risk with product No. 5 by max. use.
2: The risk is dependant on the use of lubricant cream; however, the risk is reduced by use of water-based lubricant cream.
3. Normal use of dildos and artificial vaginas has been determined to be once a week for 15 minutes. Max. use 1 hour per day. Gag is used for 1 hour per month by normal and by max. use. Fetish products (Nos. 5, 6, 7) are used for 3 h/month by normal use and 7 h/week by max. use.

As to the dildos it should be mentioned that the migration of DEHP in waterbased lubricant cream was 100 lower than in oil based lubricant cream, however, 8 times higher than in synthetic sweat. Thus the waterbased lubricant reduces the risk of health effects of substances as DEHP and DNOP with a very low degree of water solubility. The conditions applying to vaginal, anal and oral are expected to a certain degree to differ from the synthetic sweat, and expelled fluids as e.g. saliva will presumably increase the migration of substances with a low degree of water solubility such as DEHP.

Overall, only 7 products, nos. 1, 6, 9, 10, 12, 14 and 16, contained no health risks in worst case use but product no. 16 contains cadmium above the allowed level and is therefore not allowed on the European market.

Product no. 2 should not be used by pregnant/breastfeeding women due to its content of trimethyltin chloride which may cause irreversible neurotoxic effects (brain damage) to progeny. Additionally, there is a minor risk of neurotoxic effects to adults in worst case.

The other products, apart from product no. 2, involve no health risks by normal use.

Abbreviations

BMD	Benchmark dosage level
Carc	Carcinogenic
HDSB	Hazardous Substance Data Bank
IRIS	Integrated Risk Information System
IUCLID	International Uniform Chemical Information Database
LC_{50}	Lethal concentration 50 %
LD_{50}	Lethal dose 50 %
LOAEL	**L**owest observed adverse effect level
LOEL	Low-observed-effect-level
MOS	Safety margin LOAEL
Mut	Negative mutagenic effect
NOAEL	No adverse effect level, lowest level of permanent damages
NOEL	0-Effect level
Rep	Reproductive, hazardous to foetus development and/or reproduction
RfD	Reference dose
TLV	Limit value

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