DANISH MINISTRY
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Survey and health assesment of chemicals substances in pleasure gel

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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 called ”Survey and Health Assessment of Chemical Substances in Pleasure Gel” was carried out during the period from April 2005 till December 2005.

This report describes the project results, comprising a product and consumption survey, chemical analyses and a health assessment on a number of selected products.

As a starting point, the products existing on the Danish market within the category of pleasure gel were surveyed. In addition, it was investigated which chemical substances appear from the informative labelling on the products. A screening phase followed, and then - in connection with problematic substances in a number of selected products - quantitative analyses were carried out on selected substances. Finally, a health assessment was performed on a number of problematic substances.

The project was carried out by Danish Technological Institute with architect MMA Kathe Tønning as project manager, laboratory manager Paul Lyck Hansen, B.Eng. Kirsten Pommer and Chem.Eng. and B.Malmgren-Hansen as project co-workers. In addition, M.Sc. Ole Christian Hansen and M.Sc. Mikael Poulsen contributed with quality assurance.

The project was followed by a reference group consisting of the following persons:
Lise Møller, the Danish Environmental Protection Agency (chairman of the reference group)
Anette Ejersted, the Danish Environmental Protection Agency
Kathe Tønning, Danish Technological Institute

The project is financed by the Danish Environmental Protection Agency.

A head of publication the report was sent for commenting to producers/retailers who had produced or sold the analysed products. The Danish EPA has received the information that product 24 is no longer purchased on the market in Denmark. The evaluation in the report showed that there might be a risk of health effects (kidney.-damage) due to the use of this product.

Summary and conclusions

The product group covering pleasure gels comprises a wide range of different products that are marketed for various purposes.

The products can roughly be divided into 3 main groups:

- Pleasure gels sold as possessing special pleasure and performance promoting properties. That is to say, gel that promises an effect in excess of a glide effect, flavour and/or fragrance.
- Glide lubricants, i.e. lubricants that solely promise glide properties.
- Flavour and fragrance creams that contrary to the two above-mentioned types are not marketed as functional, but solely promise flavour and/or fragrance.

In this project, focus has concentrated on pleasure gels that promise an effect in excess of glide properties and/or flavour and fragrance. Therefore, distinct glide lubricants and creams that solely have a flavour and/or fragrance are not included in this project.

Besides pleasure gels, erotic massage oils are also included in the project's section on analysis.

Survey

The survey comprised the following activities:

- Contact with the retail trade. A total of 11 shops were visited; including 6 sex shops, 2 chemist's shops, 2 health food shops and 1 pharmacy.
- Search on the Internet – It has turned out that the shops visited on the Internet to a high degree sell the same products.
- Contact with sexologists. The contacted sexologists (practitioners and letters editors) only have scarce knowledge of the use of pleasure gel and they have only been approached a few times in that connection. On the other hand, the contacted sexologists have good knowledge of glide lubricants and their use.
- Utilisation of questionnaires – the questionnaire was shown on a Danish Internet Portal in a forum for debate that is directly connected to a Danish periodical for women. App. one fourth of the answers concerned pleasure gels while a larger part comprised glide lubricants and erotic massage oils.

Consumption of pleasure gel

It has not been possible via the contacted Internet shops to receive information about how much they sell and therefore it has not been possible to estimate the extent of the products sold.

Likewise, it has not been possible to carry out a quantitative survey of the consumption of pleasure gels via Statistics Denmark and therefore it has not been possible to estimate the total consumption of pleasure gels in Denmark.

However, the visited physical shops (incl. their Internet shops) have unambiguously expressed that the sale of pleasure gel is poorer than the sale of glide lubricants.

Selection of products for further examination

The survey resulted in the registration of 37 products, including 26 pleasure gels, 1 glide lubricant and 10 erotic massage oils/massage creams.

In consultation with the Danish Environmental Protection Agency, 22 products were chosen for further examination in the project. 15 pleasure gels and 7 erotic massage oils/massage creams are in question.

Chemical analyses

The survey showed that it was probable that the most critical substances were volatile, organic components and therefore it was decided that the analysis part should focus on these substances.

Due to the extremely varying composition of the examined products right from aqueous systems to glycerine and paraffin based products it was decided to use an analysis method with a starting point in a headspace measurement.

In order to obtain sufficient sensitivity with the applied analysis method and through that obtain the lowest possible detection limit it was chosen to use Solid Phase Micro Extraction (SPME) combined with GC/MS.

Initially, a screening was carried out with the objective to ascertain which volatile, organic substances exist in the selected products. The initial screening demonstrated more than 60 different organic substances. It was agreed with the Danish Environmental Protection Agency to quantify app. one third.

Quantification was carried out according to the same analysis principle as used in connection with the screening. However, another type of SPME fibre was used.

Tabel 0.1 shows the results of the quantitative analyses of the products with the largest content of substances.

Table 0.1 Results of the quantitative analyses of the products with the largest content of substances.

	Content in weight%										
	1	2	4	6	8	11	12	13	23	24	27
2-Phenoxyethanol	0.25	0.14	-	-	0.83	0.68	0.70	0.51	0.13	10.00	-
α-Pinene	-	-	-	0.03	-	-	-	-	-	-	-
Benzyl acetat	-	0.24	-	-	-	-	-	-	-	0.01	0.03
Camphor	-	-	-	0.09	-	-	-	-	-	-	-
Cinnamal	-	-	0.62	1.70	-	-	-	-	-	-	-
Coumarin		-	-	-	-	-	-	-	-	-	0.02
D-Limonene	-	-	-	0.04	-	-	-	-	-	-	0.02
Estragole	-	-	0.55	-	-	-	-	-	-	-	-
Eugenol			0.05	1.80	-	-	-	-	-	-	0.08
Isoeugenol	-	-	-	0.05	-	-	-	-	-	-	-
Linalool	-	0.14	0.02	0.12	-	-	-	-	-	-	0.13

Legislation

In Denmark, pleasure gels are controlled by the Law on chemical substances and products. Due to this the Statutory Order on classification and labelling (Bekendtgørelsen om klassificering og mærkning) applies to this type of product. In this case it should especially be noted that from enclosure 2, item 2.13 of the Statutory Order it appears that products that are not classified as sensitizing but that contain at least 0.1% sensitizing substances require a special label warning of the content of an allergic agent and the substance has to be specified.

5 of the tested product contains between 0.1 – 1 % of a substance which by the scientific committee of cosmetics are evaluated as sensitizing. These substances are however not classified according as sensitizing. Therefore the producer has to evaluate and perform a selfclassification of the used substances. If this evaluation shows that the substance is sensitizing (allergy-causing) the product must be labelled with the sentence "Contains (substance). Allergic reaction can arise".

If the requirements in the Statutory Order on cosmetics (*Cosmetics, 2006*) had been in force, 8 out of the 22 products would have been confronted with stricter requirements to informative labelling and one product would not have been permitted as the concentration of 2-Phenoxyethanol was 10 times above the allowed value.

Health assessment of specific substances

Among the identified substances in the 22 products, 7 substances were chosen for closer assessment:

- Camphor is a substance that causes irritation and it might also cause allergic reactions. The amounts found in the samples will not give rise to health effects.
- Cinnemaldehyde may cause irritation and can cause allergic reactions. If the substance is absorbed through the skin the content might cause adverse health effects. The amounts found in sample 4 and 6 may for sensitive persons cause irritation to mucous membranes and skin or it may cause contact allergies. No further health effects are likely.
- Eugenol may cause allergy. The amounts found in sample no. 6may cause allergies by skin contact for sensitive persons. No further health effects may be expected.
- D-Limonene may cause allergy. The amounts observed in the samples will only to a very limited extent cause health effects.
- Linalool may cause irritation and can cause allergic reactions. The amounts found in the samples will only to a very limited extent give rise to health effects.
- 2-Phenoxyethanol may cause irritation. In one product the content was so high that health effects may occur.
- α-Pinene may cause irritation and can cause allergic reactions. The amounts found in the samples will not give rise to health effects.

Dangerous products

Product no. 24 is identified as giving a potential health risk (kidney damage) by oral intake or intake through the skin due to the content of phenoxyethanol .

Several products contain substances that may cause sensitization by skin contact and about 25% of the tested products contain a relatively large amount of these substances (products no.2, 4, 6, 27 and 30).

According to the Statutory Order on classification, all products containing more than 0.1% of a substance classified or estimated to be sensitizing (allergy-causing) have to be marked with "Contains (substance). Allergic reaction can arise".

Sammenfatning og konklusioner

Produktgruppen sexcremer omfatter en lang række forskellige produkter, der markedsføres til forskellige formål.

Produkterne kan groft deles op i 3 hovedgrupper:

- Sexcremer, der markedsføres til at have specielle lyst- og præstationsfremmende egenskaber. Dvs. cremer, der lover en effekt ud over glideeffekt, smag og/eller duft
- Glidecremer, dvs. cremer, der alene lover glideegenskaber
- Smags- og duftcremer, der i modsætning til de 2 ovenstående typer, ikke markedsføres som funktionelle, men som alene lover smag og/eller duft.

Der er i nærværende projekt fokuseret på sexcremer, der lover en effekt ud over glideegenskaber og/eller smag og duft. Dvs. at deciderede glidecremer og cremer, der alene har smag og/eller duft, ikke er medtaget i projektet.

Ud over sexcremer indgår erotiske massageolier i analysedelen af projektet.

Kortlægning

I kortlægningen indgår følgende aktiviteter:

- Kontakt til detailhandel – I alt 11 butikker er besøgt; heraf 6 sexbutikker, 2 materialister, 2 helsekostbutikker og 1 apotek
- Søgning på Internet – På de besøgte Internetbutikker har det vist sig, at det i høj grad er de samme produkter, der forhandles
- Kontakt til sexologer – De kontaktede sexologer (praktiserende samt brevkasseredaktører) har kun i meget beskedent omfang haft kendskab til og henvendelser om brugen af sexcremer. Derimod har de kontaktede sexologer et godt kendskab til glidecremer og brugen af disse
- Anvendelse af spørgeskemaer – Spørgeskemaet har været vist på en dansk Internetportal i et debatforum, der knytter sig direkte til et dansk magasin for kvinder. Ca. en fjerdedel af besvarelserne omhandlede sexcremer, mens en større del omfattede glidecremer og erotiske massageolier.

Forbrug af sexcremer

Det har ikke været muligt via de kontaktede Internetbutikker at få oplyst, hvor stort deres salg er, og det har således ikke været muligt at estimere omfanget af solgte produkter.

Da det heller ikke via Danmarks Statistik har været muligt at foretage en mængdemæssig kortlægning af forbruget af sexcremer, har det ikke været muligt at estimere det samlede forbrug af sexcremer i Danmark.

Der har dog fra de besøgte fysiske butikker (inkl. disses Internetbutikker) entydigt været tilkendegivelser om, at salget af sexcremer ligger betydeligt lavere end salget af glidecremer.

Udvælgelse af produkter til videre undersøgelse

Kortlægningen resulterede i registrering af 37 produkter, heraf 26 sexcremer, 1 glidecreme og 10 erotiske massageolier/massagecremer.

I samråd med Miljøstyrelsen blev der udvalgt 22 produkter med henblik på videre undersøgelse i projektet. Der er tale om 15 sexcremer og 7 erotiske massageolier/massagecremer.

Kemiske analyser

Den udførte kortlægning viste, at det var overvejende sandsynligt, at de mest kritiske indholdsstoffer var flygtige, organiske komponenter, hvorfor det blev valgt at fokusere analysedelen omkring denne stofgruppe.

Pga. den meget varierende basisformulering af de undersøgte produkter, fra vandige systemer til glycerin- og paraffinbaserede, blev det valgt at anvende en analysemetode med udgangspunkt i en headspace-måling.

For at opnå en tilstrækkelig følsomhed med den anvendte analysemetode og derigennem opnå den lavest mulige detektionsgrænse, blev det valgt at benytte Solid Phase Micro Extraction (SPME) kombineret med GC/MS.

Der blev først gennemført en screening med det formål at konstatere, hvilke flygtige, organiske stoffer der findes i de valgte produkter. Ved den indledende screening blev der konstateret mere end 60 forskellige organiske stoffer. Det blev aftalt med Miljøstyrelsen at kvantificere ca. en tredjedel af stofferne.

Kvantificeringen blev foretaget med samme analyseprincip, som blev anvendt i forbindelse med screeningen, dog med anvendelse af en anden type SPME-fiber.

I Tabel 0.1 ses resultaterne af de kvantitative analyser for produkterne med de største indhold.

Tabel 0.1 Resultaterne af de kvantitative analyser for produkterne med de største indhold

	Indhold i vægt%										
	1	2	4	6	8	11	12	13	23	24	27
2-Phenoxy ethanol	0,25	0,14	-	-	0,83	0,68	0,70	0,51	0,13	10,00	-
α-Pinen	-	-	-	0,03	-	-	-	-	-	-	-
Benzyl acetat	-	0,24	-	-	-	-	-	-	-	0,01	0,03
Camphor	-	-	-	0,09	-	-	-	-	-	-	-
Cinnamal	-	-	0,62	1,70	-	-	-	-	-	-	-
Coumarin		-	-	-	-	-	-	-	-	-	0,02
D-Limonen	-	-	-	0,04	-	-	-	-	-	-	0,02
Estragole	-	-	0,55	-	-	-	-	-	-	-	-
Eugenol			0,05	1,80	-	-	-	-	-	-	0,08
Isoeugenol	-	-	-	0,05	-	-	-	-	-	-	-
Linalool	-	0,14	0,02	0,12	-	-	-	-	-	-	0,13

Lovgivning

Sexcremer er i Danmark reguleret af Lov om kemiske stoffer og produkter. Dertil kommer, at bekendtgørelsen om klassificering og mærkning gælder for denne type produkter. Her skal især bemærkes, at det af bekendtgørelsens bilag 2 pkt.2.13 fremgår, at produkter, der ikke er klassificeret som sensibiliserende, men som indeholder mindst 0,1 % sensibiliserende stoffer, skal forsynes med en særlig påskift, der advarer om indhold af et allergisk stof med angivelse af stoffet.

5 af de analyserede produkter indeholder mellem 0,1-1 % af et stof, som den videnskabelige komite for kosmetik har vurderet som sensibiliserende (allergifremkaldende). Disse stoffer er dog ikke klassificerede som sensibiliserende, Producenten skal derfor lave en selvvurdering og selvklassificering af det anvendte stof. Hvis denne vurdering viser at stoffet er sensibiliserende skal produktet mærkes med sætningen "Indeholder (stofnavn). Kan fremkalde allergisk reaktion".

Hvis kravene i kosmetikbekendtgørelsen var gældende, ville 8 ud af 22 produkter være underlagt skærpede deklarationskrav, og 1 produkt ville ikke være tilladt, idet koncentrationen af 2-phenoxyethanol er 10 gange over den tilladte værdi.

Sundhedsvurdering af udvalgte stoffer

Blandt de identificerede stoffer i de 22 produkter er der udvalgt 7 stoffer til en nærmere vurdering:

- Camphor er et irriterende stof, der også kan forårsage allergiske reaktioner. De mængder, der er fundet i prøverne, vil ikke give anledning til helbredsmæssige effekter
- Cinnemaldehyd kan virke irriterende og kan forårsage allergiske reaktioner. Indholdet kan, hvis stoffet optages gennem huden, muligvis forårsage helbredsmæssige risici. De mængder der er fundet i prøve 4 og 6 kan for følsomme personer forårsage hudirritation/allergi og irritation af slimhinder; men de vil ikke give anledning til andre sundhedsmæssige effekter.
- Eugenol kan forårsage allergi. De mængder der er fundet i prøve 6 kan for følsomme personer forårsage allergi; men eugenol vil ikke give anledning til andre sundhedsmæssige effekter.
- D-Limonen kan forårsage allergi. De mængder, der er fundet i prøverne, vil kun i meget begrænset omfang give anledning til helbredsmæssige effekter
- Linalool kan virke irriterende og kan forårsage allergiske reaktioner. De mængder, der er fundet i prøverne, vil kun i meget begrænset omfang give anledning til helbredsmæssige effekter
- 2-phenoxyethanol kan virke irriterende. I et produkt er indholdet så højt, at sundhedsmæssige effekter kan forekomme
- α-Pinen kan virke irriterende og kan forårsage allergiske reaktioner. De mængder, der er fundet i prøverne, vil ikke give anledning til helbredsmæssige effekter.

Farlige produkter

Indholdet af phenoxyethanol i produkt nr. 24 er vurderet til at kunne forårsage helbredsmæssige risici (nyreskader) ved indtagelse og ved optagelse gennem huden.

Flere produkter indeholder stoffer, der kan medføre allergi ved hudkontakt. Omkring 25 % af de testede produkter indeholder forholdsvis store mængder af disse stoffer.

Produkter, som indeholder mere end 0,1 % af et stof, som er klassificeret eller vurderet som værende sensibiliserende (allergifremkaldende), skal i henhold til klassificeringsbekendtgørelsen mærkes med "Indeholder (stofnavn), kan udløse allergisk reaktion".

1 Survey

1.1 Introduction

1.1.1 Objective

The objective of the survey was to identify the products that are used most often and to try to assess the popularity of pleasure gel.

The examination of which products within the category of pleasure gel exist on the market and of which chemical substances are used in the gels has formed the basis of the further evaluation of the products.

1.1.2 Delimitation

The Danish Environmental Protection Agency chose to focus on the so-called pleasure gels (creams that promise an effect in excess of glide properties and/or flavour and fragrance). That means that distinct glide lubricants and creams that solely have flavour and/or fragrance were not included in the project.

Besides pleasure gels, erotic massage oils were also included in the project's section on analysis.

1.1.3 Method/procedure

The following activities formed part of the survey:

- Contact with the retail trade
- Search on the Internet
- Contact with sexologists
- Use of questionnaires.

In connection with pleasure gel it is in general difficult to chart the consumption pattern.

It was not possible to carry out a quantitative survey of the consumption of pleasure gel via Statistics Denmark. The Danish Ministry of Taxation informed that there is no KN code[1] that merely deals with these products.

Consumption is closely correlated with the sexual behaviour of the individual consumer and therefore it was chosen – in addition to the other traditional analysis methods – to use questionnaires. As the survey involved tabooed behavioural patterns anonymous questionnaires were used.

The purchasing culture is expected to be strongly influenced by the selection on the Internet and therefore it was decided to base a substantial part of the survey on the possibilities existing on the Internet.

[1] KN code is a 8-figure product code number (KN ~ combined nomenclature)

Participation in the investigation was advertised for through a Danish Internet Portal in a forum for debate, which is linked to a printed Danish periodical for women, and participation required the completion of a questionnaire with 12 questions.

Information was searched for about pleasure gels and erotic massage oils/creams - partly through Internet based shops and partly in physical shops.

1.1.4 Product purchase

The selection criteria for the purchase of products mainly comprised products that through advertisements on the Internet or other modes of advertising promise an effect in excess of glide properties, flavour or fragrance. In addition, products sold to a certain extent have been chosen. It has only been possible to include this criterion to the extent it has been possible to obtain information about sales through the dealer – most often in the form of information such as e.g. ”this product sells well”.

1.2 Purchase

The part of the survey concerning the purchase of products comprises:

- Internet search – purchase in Internet shops and contact with dealers
- Shop visits – purchase in physical shops and interviews given by dealers.

1.2.1 Internet search process and trade

A search was performed via Google.dk with different words and combinations.
In addition, a list of Danish Internet shops appeared on the E-guiden.dk when a search was made with the word ”sex”.

Table 1.1 Words searched for and combinations carried out via Google.dk

Word	No. of pages
Sexcremer (pleasure gels)	259
Sex cremer (pleasure gels)	39.500
Erotiske cremer (erotic creams)	48.400
Erotiske olier (erotic oils)	7.690
Erotiske massageolier (erotic massage oils)	398
Sex-gel (pleasure gel)	18.500
Pleasure gel (pleasure gel)	510

As it appears from Table 1.1, many pages are in question. Subsequently, it was chosen to limit the search so Danish home pages and/or pages with Danish text were in focus.

A rough scan was carried out of the Danish pages concerning sex articles. 29 Internet shops were the object of a detailed analysis. On the home pages of the shops all advertisements/references concerning pleasure gel and massage oils were examined with a view to investigating if the product in question ”promised” an effect.

When studying the home pages of the Internet shops, it appeared that the different shops often offered the same products for sale.

1.2.1.1 Communication with dealers

In the light of the search on the Internet a number of the businesses behind the Internet shops dealing with pleasure gel were contacted. The enquiries partly dealt with information about the substances of each product and partly with information about the extent of sales. The enquiries gave rise to very few reactions from the dealers.

1.2.2 Shop visits

A total of 11 shops were visited, including:

- 6 sex shops
- 2 chemist's
- 2 health food shops
- 1 pharmacy.

In connection with the shop visits an interview form was prepared, i.a. in order to create an overview of the sales extent of pleasure gel.

The interview form included questions about:

- Which products form part of the shop's product range?
- How is the sales distribution of the different products evaluated?
- Estimated total sale of the category?
- Is resale in question?
- Which age and sex distribution applies to the purchasers of the products?
- How is the sale of pleasure gel compared to the sale of glide creams?
- How is the sale of pleasure gel compared to the sale of cream with fragrance and/or flavour?
- Which advice is offered in connection with sales?

Table 1.2 shows an outline of the shops that were visited, their product range within the category and an estimate of units sold per month. In addition, each shop has given an evaluation of the sales related distribution between pleasure gels and glide lubricants and creams with flavour and/or fragrance, respectively.

Table 1.2 Outline of visited shops, products within the category of pleasure gel and the total amount of units sold per month.

Shop	Product No.	Units sold per month	Sale of pleasure gel compared to glide lubricant	Sale of pleasure gel compared to cream with flavour and/or fragrance
Sex shop 1	9, 10, 19, 20, 21, 22 and 24	60-100	Largest sale of glide lubricant	Few creams with flavour and/or fragrance are sold
Sex shop 2	9, 10, 12, 13 and 28	50	30/70	40/60
Sex shop 3	34, 35, 36 and 37	12	10/90	No creams sold with flavour and/or fragrance
Sex shop 4	Pleasure gel not carried	0		
Sex shop 5	Pleasure gel not carried	0		
Sex shop 6	Pleasure gel not carried	0		

Shop	Product No.	Units sold per month	Sale of pleasure gel compared to glide lubricant	Sale of pleasure gel compared to cream with flavour and/or fragrance
Chemist's 1	19, 20 and 21	1	Largest sale of glide lubricant	No creams sold with flavour and/or fragrance
Chemist's 2	Pleasure gel not carried	0		
Health food shop 1	19, 20 and 21	0-1	Cannot be estimated	Cannot be estimated
Health food shop 2	Pleasure gel not carried	0		
Pharmacy	Pleasure gel not carried	0		

As it appears from Table 1.2, the main part of what is sold from physical shops takes place through sex shops. In connection with sex shops, 5 out of 6 of the shops that were visited also have an Internet shop besides the physical shop.

The age distribution of the customer groups in the 5 shops that sell pleasure gels is characterised by having an even distribution from app. 20 years and upwards.

Two of the visited shops estimate that most of their customers are women while two other shops estimate that their customer group mainly consists of men. Finally, the fifth shop believes that the customer group has an even distribution of men and women.

It has not been possible through the contacted Internet shops to obtain information of the scope of their sales and therefore it has not been possible to estimate the extent of the products sold.

However, the visited physical shops (incl. their Internet shops) have unambiguously expressed that the sale of pleasure gel is poorer than the sale of glide lubricants.

1.3 Sexologists

In the course of the survey, various consultative bodies were contacted in order to obtain insight into their experience with pleasure gel. The following were contacted:

- Sexological Clinic at Rigshospitalet (The State University Hospital in Copenhagen)
- Danish Association for Clinical Sexology
- A number of letters editors at Danish magazines.

1.3.1 Sexological Clinic, Rigshospitalet

The Sexological Clinic[2] at Rigshospitalet treats people who have sexological problems of e.g. psychiatric, psychological, somatic or social nature. The clinic mainly deals with examinations, counselling and treatment. In 2004, the clinic had just fewer than 3.000 outpatient consultations.

[2] www.rigshospitalet.dk/rh.nsf/Content/sexologiskklinik

We communicated with the Sexological Clinic and an employee at the clinic informed us that the clinic never recommends distinct pleasure gels as the clinic does not believe that they have an effect.

The Sexological Clinic has received the prepared questionnaire about experience with pleasure gel and has commented on the structure and the contents.

1.3.2 Danish Association for Clinical Sexology

The Danish Association for Clinical Sexology[3] was contacted in order to get into touch with sexologists to find out if they in connection with their work had encountered/or had actual experience with the use of pleasure gel.

The Danish Association for Clinical Sexology referred to 2 sexologists who subsequently were contacted.

1.3.2.1 Sexologist 1

Sexologist 1 is a qualified classic sexologist and couple therapist with handicap sexology as specialist area.

By e-mail the sexologist informed that neither he nor his business partner (who is a specialist within sex appliances) have encountered the use of pleasure gels through their work with clients at the clinic.

1.3.2.2 Sexologist 2

Communication with sexologist 2 took place by mail and telephone. Sexologist 2 is a specialist within gynaecology and obstetrics and has several years of experience with sexological counselling at Danish Public Health Authorities.

Through series of lectures, sexologist 2 has been in touch with many women. The sexologist recommends silicone based glide lubricants but not distinct pleasure gels. In connection with massage, sexologist 2 recommends almond oil.

In relation to pleasure gel, sexologist 2 never recommends this type of product and points out to his customers that pleasure cannot be purchased as a remedy.

The sexologist has commented on the questionnaire.

1.3.3 Letters editors at Danish magazines

Many Danish weekly and monthly magazines have a correspondence that deals with sex and marital relationships or health-related questions.

A number of these magazines were contacted with regard to uncovering the letters editors' knowledge of pleasure gels, the extent of counselling concerning their use and inquiries about them.
The magazines were graded according to whether they mainly aim at women, at both women and men or mainly at men.

[3] www.klinisksexologi.dk

1.3.3.1 Magazines that mainly aim at women

In the category of magazines that mainly aim at women, 3 magazines were contacted.

The letters editors at the 3 magazines informed that they have no knowledge of pleasure gels neither in relation to enquiries from readers nor in relation to the editorial content of the magazine in question.

1.3.3.2 Magazines that aim at both women and men

In the category of magazines that aim at both women and men, 3 magazines were contacted – one of the magazines is for homosexuals.

None of the magazines have received enquiries from readers with questions concerning the use and effect of pleasure gels. Likewise, it has not been a topic that has been treated editorially.

1.3.3.3 Magazines that mainly aim at men

In the category of magazines that aim at men, 4 magazines were contacted. One letters editor at one of the magazines informed that 9 out of 10 questions concern glide lubricants. So far, none of the questions have concerned pleasure gels. Most of the people who write to the correspondence are male. The letters editor in question also runs a home party business where sex toys are sold - especially to women. The letters editor also informed that the interest in pleasure gel is very poor at the home parties.

Another two magazines have not received enquiries from readers with questions concerning the use or effect of pleasure gels, and it is not a topic that has been treated editorially.

One of the magazines that had received questions from readers no longer answers questions concerning sex or martial relationships.

1.4 Investigation by questionnaire

A questionnaire was prepared consisting of 12 questions. The questionnaire was commented on by the Sexological Clinic at Rigshospitalet and by one of the sexologists from the Danish Association for Clinical Sexology who was contacted.

1.4.1 Implementation

The questionnaire was accessible on a Danish Internet Portal in a forum for debate which is linked to a printed Danish periodical for women. The questionnaire received high priority in the particular forum for 4 weeks.

During the period, 226 users entered the questionnaire. 137 users answered all or part of the questionnaire (45 participants answered all questions).

1.4.2 Results

The questionnaire consisted of the following questions:

- Due you use pleasure gel?
- How often do you use pleasure gel?
- For how long have you used pleasure gel?

- To which extent do you use pleasure gel today compared to when you started?
- Which type of pleasure gel do you use?
- Where do you buy pleasure gel?
- Which products/brands do you use?
- In which connection do you use pleasure gel?
- Which positive experience do you have from using pleasure gel?"
- Which negative experience do you have from using pleasure gel?"
- Sex?
- Age?

82 % of the participants in the investigation were female and 18 % were male.

With regard to positive experience from the use of pleasure gel (here there were several crosses per answer), 83 % stated that it increases moistness. 50 % stated that it is different and exciting. 40 % stated that pleasure gel increases sensitivity, 10 % stated that it improves erection and 40 % stated that it increases the feeling of pleasure. With regard to negative experience from the use of pleasure gel, 91 % stated that they have no negative experience. 7 % stated that the use of pleasure gel results in burning, 2 % stated that the use results in itching and 4 % stated that using pleasure gel results in fungal infection.
80 % of the participants who use pleasure gel and who stated their age were between 19 and 40 years of age.

From the answers it appeared that pleasure gel is purchased in sex shops just as often as on the Internet – however, slightly more is purchased on the Internet.

1.5 Products

Acquaintance was made with the main part of the products through the Internet. It was not possible to find information about the substances in the products on the home pages of the Internet shops and therefore it was necessary to purchase more products than the amount finally selected for analysis – merely in order to obtain knowledge of the informative labelling on the products.

A total of 33 products were purchased. Furthermore, knowledge of 4 additional products was obtained through one of the sex shops.

1.5.1 Product outline

Table 1.3 shows the labelled substances stated on each of the purchased pleasure gels. The information shown is a direct copy from the label on the product.

Table 1.3 Outline of purchased pleasure gels.

Product nr.	Contents cf. manufacturer (labelled substances)	Remarks
1	Glyceryl Polyacrylate, Aqua, L-Argine HCL, Prunus Armeniaca Kemel Oil, Menthol, Dehydroacetic Acid, Phenoxyethanol, Benzoic Acid	Note enclosed with the directions for use, etc.
2	100 g contains: Isopropylnicotinat 0,01 g, Cayennepfeffertinktur 0,50 g	Directions for use in English, German and French, but not in Danish. Warning (children).

Product nr.	Contents cf. manufacturer (labelled substances)	Remarks
3	100 g contains: Arzneilich wirksamer Bestandteil: Lidocainhydrochlorid 0,18 g. Sonstige Bestandteile: Polysorbat 60, Cetylstearylalkohol, Glycerol 85 %, weisses Vaselin, gereinigtes Wasser, bitteresFenchelöl, Parabene:Metyl (4-hydroxybenzoat) (E218), Propyl (4-hydroxybenzoat) (E216). Enthält unter anderem Methyl (4-hydroxybenzoat) und Propyl (4-hydroxybenzoat)	Note enclosed with the directions for use in 14 languages including Danish. Extended information, including side effects and warning (children). Only in German.
4	Petrolatum, Parafinum Liquidum,Benzyl Nicotinate, Cinnamomum Zeylanicum, Capsicum Frutescens	Note enclosed with directions for use in 13 languages, including Danish. Information on tube and wrapping in German.
5	100 g contains: Isopropylnicotinat 0,005 g; Cayennepfeffertinktur 0,250 g	Directions for use in English, German, Italian, Russian, Dutch, Polish and French but not in Danish. Warning (children).
6	Petrolatum, Parafinum Liquidum, Cinnamon Oil, MenthaPiperita, Ocinum Basilicum, Rosmarinus Officinalis	Note enclosed with directions for use in 13 languages, including Danish. Information on tube and wrapping in German.
7	Petrolatum, Aqua, Paraffinum Liquidum, Alcohol, Ceteth-20, Panax Ginsing, Glycerin, Propylene Glycol, Polysorbate 60, Muirapuama, Damianae, Capsicum Frutescens, Methylparaben, Propylparaben, Cymbopogon Nardus, Melissa Officinalis, Eugenia Caryophyllus, Cinnamon Oil	Note enclosed with directions for use in 13 languages, including Danish. Information on the product and wrapping in German.
8	Aqua, Cetearyl Alcohol, Ceteareth-20, Macadamia Ternifolia, Glycerin, Phenoxyethanol, Methylparaben, Butylparaben,Ethylparaben,Propylparaben,Isobuthylparaben, Piper Frutescens, Lactic Acid	Directions for use in German, English and Danish.
9	100 % natural ingredients, vegetable oil, chili extract	Directions for use in Danish.
10	100 % natural ingredients, vegetable oil, peppermint extract	Directions for use in Danish.
11	Aqua, Propylene Glycol, PEG 6, Damiana Leaf Extract (and) Muira Puama Extract (and) Turmeric Root Extract (and) Cassia Bark Extract (and) Vegetable Oil, Ginko Biloba Alcohol Denat, Acrylates / C 10-30 Alkyl Acrylate Crosspolymer, Tromethamine, Lactose Cellulose Hydroxypropyl Methylcellulose Ultramarin Tocopherol Acetate Retinyl Palmitate, Phenoxyethanol (and) Methylparaben (and) Ethylparaben (and) Propylparaben (and) Butylparaben.	Directions for use in Danish.
12	Aqua, Cetearyl Isonanoate, Glyceryl Stearate, PEG-20 Glyceryl Stearate, Cetearyl Alcohol, Ceteareth-20, Cetyl Palmitate, Hydroxyethylcellulose, Propylene Glycol, Ginkgo Biloba Leaf Extract, Simmondsia chinensis, Phenoxyethanol, Methylparaben, Ethylparaben, Butylparaben, Propylparaben, Isobutylparaben, Lactic Acid.	Directions for use in Danish.
13	Aqua, Propylene Glycol, Hydroxyethylcellulose, Ginkgo-Extract, Muira Puama Extract, Avena Sativa, Panax Ginseng, Aloe Barbadensis, Phenoxyethanol, Methylparaben, Butylparaben, Ethylparaben, Propylparaben, Isobutylparaben, Carbomer, FD&CBlue No. 1 C.I. 42090	Directions for use in Danish.
14	Aqua, Glycerin, Xanthan Gum, Dimethicone, Dimethiconol, Phenoxyethanol, Methylparaben, Ethylparaben, Butylparaben, Propylparaben, Isobutylparaben, Benzyl Salicylate.	Directions for use in Danish.
19	Natural product “name” is a pleasure stimulating love philtre made of chili and virgin olive oil.	Directions for use in Danish.
20	Natural product “name”is a pleasure stimulating love philtre made of chili and virgin olive oil.	Directions for use in Danish.
21	Natural product “name”is a pleasure stimulating love philtre made of chili and virgin olive oil.	Directions for use in Danish.

Product nr.	Contents cf. manufacturer (labelled substances)	Remarks
22	Propylene glycol USP, hydroxyethylcellulose NF, purified water USP, L-arginine USP, niacin (vitamin B3), menthol USP, methylparaben USP, peppermint, tromethamine USP.	Directions for use only in English.
23	Deionized Water, Propylene Glycol, Hydroxyethylcellulose, L-arginine, Menthol, Phenoxyethanol, Methylparaben and Tertrasodium EDTA.	Directions for use in English.
25	Deionized water, Lanolin oil, Stearyl Alchohol, Cetyl Alchohol, Sorbitol, Polysorbate 80, Petrolatum, Benzocaine, Sorbitan Wonooleate, Methylparaben.	Directions for use only in English.
28	Aqua, Propylene Glycol, Hydroxyethylcellulose, Tromethamine, Phenoxyethanol, Methylparaben, Butylparaben, Ethylparaben, Propylparaben, Isobutylparaben, Carbomer, Lactose, Cellulose, Hydroxypropyl Methylcellulose, CI 77007, Tocopherol Acetate, Retinyl Palmitate.	Directions for use in Danish.
31	Paraffinum liquidum, isopropyl Palmitate, Perfume.	Directions for use in Danish.

Table 1.4 shows the labelled substances stated on each of the purchased massage oils/massage creams. The information shown is a direct copy from the label on the product. In addition, remarks concerning the directions for use appear from the table.

Table 1.4 Outline of purchased erotic massage oils/massage creams

Product no.	Contents cf. manufacturer (labelled substances)	Remarks
15	Paraffinum liquidum, Trilaureth-4 Phosphate, Isopropyl Palmitate, Polyglyceryl-2 Sesquiisostearate, Simmondsia chinensis, Parfum.	Directions for use in Danish.
16	Glycerol, Sorbitol, Purified Wather, Na Carboxymethyl Cellulose, Na Cyclamat, Saccharin, Na Citricum (Lemon Acid), Flavour Natural/Natural Identical (Wild Cerry).	Directions for use only in English.
17	Aqua, Glycerin, Xanthan Gum, Dimethicone, Dimethiconol, Phenoxyethanol, Benzyl Alcohol, Potassium Sorbate, Tocopherol, Carbomer, Tromethamine, Benzyl Salicylate.	Directions for use in Danish.
18	No description of contents.	No directions for use in Danish.
24	Vanilla Créme, Raspberry Créme og Cool Mint. May contain: Water, Safflower Oil, Sorbitol, Glyceryl Stearate, Cetyl Alcohol, Polysorbate 60, Sucrose Cocoate, Hydroxyethylcellulose, Phenoxyethanol, Flavor, Dimethicone, Polysorbate 20, Stearie Acid, Carbomer, Methylparaben, Potassium Sorbate, Sodium Saccharin, Propylparaben, Blue #1, Yellow #5, Yellow #6, Red #33	Directions for use only in English.
26	Paraffinum liquidum, Trilaureth-4 Phosphate, Isopropyl Palmitate, Polyglyceryl-2 Sesquiisostearate, Simmondsia chinesis, Prunus Dulcis, Parfum.	Directions for use in Danish.
27	Paraffinum liquidum, Trilaureth-4 Phosphate, Isopropyl Palmitate, Polyglyceryl-2 Sesquiisostearate, Simmondsia chinensis, Benzyl Alcohol, Benzyl Salicylate, Citral, Eugenol, Coumarin, Geraniol, Butylphenyl Methylpropional, Linalool, Benzyl Benzoate, Citronellol, Hexyl Cinnamal, Limonene.	Directions for use in Danish.
29	Paraffinum liquidum, Trilaureth-4 Phosphate, Isopropyl Palmitate, Polyglyceryl-2 Sesquiisostearate, Prunus Dulcis, Benzyl Alcohol, Geraniol, Linalool, Citronellol, Hexyl Cinnamal, Limonene.	Directions for use in Danish.

Product no.	Contents cf. manufacturer (labelled substances)	Remarks
30	Paraffinum liquidum, Trilaureth-4 Phoaphate, Isopropyl Palmitate, Polyglyceryl-2 Sesquiisostearate, Simmondsia chinensis, Cinnamyl Alcohol, Citral, Benzyl Salicylate, Coumarin, Butylphenyl Methylpropional, Linalool, Citronellol, Hexyl Cinnamal, Limonene, Alpha-isomethyl Ionone.	Directions for use in Danish.
32	Cyclomethicone, Dimethiconol, Mineral Oil, Fragrance, Pheromones, Titanium Dioxide, D&C Yellow #11, D&C Red #17	Directions for use only in English.
33	Glycerine, Sorbitol, Flavors, Potassium Sorbate, Sodium Benzoate, Xantham Gum, Assorted Colors.	Directions for use only in English.

1.5.2 Selection criteria

The survey resulted in the purchase/registration of 33 products, comprising 22 pleasure gels, one glide lubricant and 10 erotic massage oils/massage creams.

In consultation with the Danish Environmental Protection Agency, 22 products were selected with regard to further examination in the project. 15 pleasure gels and 7 erotic massage oils/massage creams were in question. Selection took place on the basis of information concerning the contents of the products – the substances that had been informed by the manufacturer.

In addition, selection took place according to the following criteria:

1. If two or several products contained the same substances, only the one product was chosen.
2. Products containing substances that immediately are regarded as irritating and/or allergy-causing in contact with skin were given high priority – e.g. cayenne pepper extract, limonene.
3. Several different manufacturers are represented.
4. Popular products.

1.5.3 Selected products

The following 22 products were selected for further analysis:

In the category of pleasure gels the following 17 products were chosen: Product no. 1, 2, 3, 4, 6, 7, 8, 9, 11, 12, 13, 21, 22, 23, 24, 25 and 32.

In the category of erotic massage oils the following 5 products were chosen: Product no. 15, 18, 27, 29 and 30.

In the following, the product numbers from the survey have been maintained.

2 Screening of substances

With a starting point in the selection criteria described in chapter 1.5.2, chemical screening was carried out to identify the content of organic substances in the selected products stated in chapter 1.5.3 with the objective to identify the most essential substances of importance to health.

Screening took place partly as a chemical screening analysis and partly as an initial health assessment of the substances found, based on few chosen data.

2.1 Chemical screening analysis

2.1.1 Method

As the composition of the analysed products varied, cf. Table 1.3 and Table 1.4, a headspace based analysis method was chosen for the selection of applied analysis principle.

The applied sampling method, on the basis of Solid Phase Micro Extraction (SPME), measures organic compounds from volatile, organic solvents (ethanol, acetone etc.) to the more semi-volatile compounds (parabenes, phthalates etc.).

In connection with the survey of the informative labelling of the examined products no indication of substances appeared that had not been included in the applied measuring method.

In connection with the test preparation, a 1.0 g sample was weighed in a 20 ml membrane glass. Headspace was sampled for 15 min. at SPME and subsequently analysed by means of gas chromatography with mass spectrometric detection (GC/MS). The following parameters were applied:

GC/MS Instrument	Thermo Finnigan, DSQ
MS parameters	Autotune, 35-300 m/z, solvent delay: 0.1 min.
GC parameters	Oven prog: 35 ºC for 3 min, 10 ºC/min to 260 ºC hold for 5 min. Injector: 290 ºC, splitless time: 0.50 min. Carrier gas: Helium, constant flow: 1.0 ml/min. Column: Valcobond VB-1, 30 m x 0.25 mm, film: 1.5 µm
SPME parameters	Fibre: 85 µm carboxen/PDMS Headspace temperature: 35 ºC

The demonstrated components were solely identified by using NIST library (The NIST Mass Spectral Search Program) covering mass spectra and manual interpretation of the spectra and the use of AMDIS deconvolation software. Therefore, it is very probable that the substances identified in connection with the performed screening exist where they were demonstrated.

In connection with the performed qualitative screening no quantitative evaluation of the content of the identified, organic compounds was carried out.

2.1.2 Results

The total results from the screening of the 21 analysed products appear from Table 2.1. Due to delayed delivery, product 24 was not included in the screening phase.

Table 2.1 Initial chemical screening of pleasure gels

Substance name	CAS no.	Sample no.										
		1	2	3	4	6	7	8	9	11	12	13
1-Phenooxy propan-2-ol	770-35-4											
α-Pinene	7785-70-8			x		x						
2-Phenoxyethanol	122-99-6	x	x	x	x			x	x	x	x	x
3-Phenoxy 1-propanol	122-97-4					x	x					
4-Methyl benzaldehyd	104-87-0											
4-Tertbutyl cyclohexyl acetat	32210-23-4		x									
β-Myrcen / β-pinen	123-35-3			x	x	x	x					
β-Methyl benzylalkohol acetat	93-92-5		x									
β-Guiene	88-84-6											
Benzaldehyde	100-52-7		x		x	x	x	x	x	x	x	x
Benzophenon	119-61-9	x								x	x	
Benzosyre 2-aminomethylester	134-20-3		x									
Benzosyre methyl ester	93-58-3											
Benzyl alcohol	100-51-6		x		x	x	x					
Butylparaben	94-26-8									x		
Camphene	79-92-5					x						
Camphor	76-22-2					x						
Caryophyllen	87-44-5				x	x	x					
Cinnamal	104-55-2				x	x	x	x	x	x	x	x
Cinnamic acid	140-10-3							x	x			
Cinnamyl alcohol	104-54-1				x							
Cinnamyl alcohol acetat	103-54-8				x							
Cis geraniol	106-25-2											
Citral	5390-40-5											
Citronellal	106-23-0						x					
Citronellol	106-22-9						x					
Coumarin	91-64-5											
Dehydro acetic acid	520-45-6	x										
Diethyl phthalate	84-66-2											x
D-Limonene	5989-27-5			x	x	x	x		x			
Acetic acid 2-phenyl ethyl ester	103-45-7		x	x								
Acetic acid benzyl ester	140-11-4		x	x	x							
Estragole	140-67-0			x		x						
Ethylparaben	120-47-8									x	x	x
Eucalyptol	470-82-6					x						
Eugenol	97-53-0				x	x	x	x				
Geraniol acetat	105-87-3											
Hexyl Cinnamaldehyde	101-86-0				x	x						
Hydroxy citronellal	107-75-5		x									
Isobornyl acetat	125-12-2											
Isoeugenol	97-54-1				x	x	x	x				

Substance name	CAS no.	Sample no.										
		1	2	3	4	6	7	8	9	11	12	13
Isopropyl nicotinat	553-60-6		x									
Isopulegol	89-79-2						x					
L-Fenchone	126-21-6			x								
Linalool	78-70-6		x		x	x	x			x		
Linalool acetat	115-95-7		x									
Lidocain	137-58-6			x								
Menthol	1490-04-6	x	x			x						
Menthol acetat	16409-45-3					x						
Menthone	10458-14-7					x						
Methylparaben	99-76-3	x	x	x	x	x	x	x	x	x	x	
Phenol	108-95-2									x	x	x
Phenyl ethyl alkohol	60-12-6		x	x	x							
Pyrazin	290-37-9											
p-Amino benzosyre ethyl ester (anaesthesin)	94-09-7											
p-Anisaldehyd	123-11-5			x	x							
p-Cymen	99-87-6			x			x					
p-Propenyl anisol	104-46-1			x	x	x	x	x	x	x		
Salicylic acid	69-72-7											
Terpinene	99-85-4					x						
Toluen	89-83-8											
Trans geraniol	106-24-1						x					
Vanillin	121-33-5											

Table 2.1 continued – Initial chemical screening of pleasure gels

IstofnSubstance name	CAS no.	Sample no.									
		15	18	21	22	23	25	27	29	30	32
1-Phenoxy propan-2-ol	770-35-4				x						
α-Pinene	7785-70-8										x
2-Phenoxyethanol	122-99-6	x	x	x	x	x	x	x	x		
3-Phenoxy 1-propanol	122-97-4										
4-Methyl benzaldehyd	104-87-0					x					
4-Tertbutyl cyclohexyl acetat	32210-23-4										
β-Myrcen / β-pinen	123-35-3	x						x		x	x
β-Methyl benzylalkohol acetat	93-92-5							x			
β-Guiene	88-84-6							x			
Benzaldehyde	100-52-7	x		x	x	x	x	x	x	x	x
Benzophenon	119-61-9	x		x	x	x	x	x	x	x	x
Benzosyre 2-aminomethylester	134-20-3										
Benzosyre methyl ester	93-58-3							x			
Benzyl alcohol	100-51-6							x	x	x	
Butylparabene	94-26-8										
Camphene	79-92-5										
Camphor	76-22-2						x				
Caryophyllene	87-44-5										
Cinnamal	104-55-2										
Cinnamyl alcohol	104-54-1										
Cinnamyl alcohol acetat	103-54-8										
Cinnamic acid	140-10-3										
Citral	5390-40-5										x
Citronellal	106-23-0										
Citronellol	106-22-9							x			x

IstofnSubstance name	CAS no.	Sample no.									
		15	18	21	22	23	25	27	29	30	32
Cis geraniol	106-25-2							x			
Coumarin	91-64-5	x						x	x		x
Dehydro acetic acid	520-45-6										
Diethyl phthalate	84-66-2										
D-Limonene	5989-27-5	x		x			x	x		x	x
Acetic acid 2-phenyl ethyl ester	103-45-7										
Acetic acid benzyl ester	140-11-4	x			x			x	x	x	x
Estragole	140-67-0										
Ethylparaben	120-47-8										
Eucalyptol	470-82-6						x				
Eugenol	97-53-0							x			
Geraniol acetat	105-87-3										x
Hexyl Cinnamaldehyde	101-86-0										
Hydroxy citronellal	107-75-5										
Isobornyl acetat	125-12-2										x
Isoeugenol	97-54-1										
Isopropyl nicotinat	553-60-6										
Isopulegol	89-79-2										
L-Fenchone	126-21-6										
Linalool	78-70-6	x			x			x		x	x
Linalool acetat	115-95-7	x			x			x		x	x
Lidocain	137-58-6										
Menthol	1490-04-6				x	x	x				
Menthol acetate	16409-45-3										
Menthone	10458-14-7					x	x				
Methylparaben	99-76-3					x	x		x		
p-Amino benzosyre ethyl ester (anaesthesin)	94-09-7						x		x		
p-Anisaldehyde	123-11-5										
p-Cymene	99-87-6										
Phenol	108-95-2					x	x				
Phenyl ethyl alcohol	60-12-6	x						x	x		x
p-Propenyl anisol	104-46-1										
Pyrazin	290-37-9						x				
Salicylic acid	69-72-7							x			
Terpinen	99-85-4									x	
Toluen	89-83-8			x			x		x		
Trans geraniol	106-24-1										
Vanillin	121-33-5									x	

2.2 Health screening

2.2.1 Initial selection

It was not anticipated that so many different substances would be identified at the initial chemical screening and therefore substances were selected for the health screening.

The selection was carried out in the light of information stated in Table 2.2 in consultation with the Danish Environmental Protection Agency.

Table 2.2 Substances found during screening of selected products

Name	CAS no.	Classification	Occurrence Number of products	Selected
α-Pinene	7785-70-8	N;R50/53**	3	
1-Phenoxy propan-2-ol	770-35-4	Xn;R22**	1	X
2-Phenoxyethanol	122-99-6	Xn;R22 Xi;R36	17	X
3-Phenoxy 1-propanol	122-97-4	-	2	
4-Methyl benzaldehyde	104-87-0	-	1	
4-Tertbutyl cyclohexyl acetat	32210-23-4	N;R51/53**	1	
β-Guiene	88-84-6	N;R50/53**	1	
β-Myrcen/-pinen	123-35-3	-	8	
β-Methyl benzylalkohol acetat	93-92-5	-	2	
Benzaldehyde	100-52-7	Xn;R22	18	X
Benzophenon	119-61-9	-	12	
Benzosyre methyl ester	93-58-3	-	1	
Benzosyre 2-aminomethylester	134-20-3	-	1	
Benzyl alcohol*	100-51-6	Xn;R20/22	7	X
Butylparaben	94-26-8	N;R51/53	1	
Camphen	79-92-5	N; N;R50/53**	1	
Camphor	21368-68-3	-	2	
Caryophyllen	87-44-5	-	3	
Cinnamic acid *	140-10-3	-	2	X
Cinnamal*	104-55-2	R43 N;R50**	8	X
Cinnamyl alcohol *	104-54-1	R43 N;R50**	1	X
Cinnamyl alcohol acetat	103-54-8	N;R50**	1	
Cis geraniol	106-25-2	N;R50**	1	
Citral *	5392-40-5	Xi;R38 R43	1	X
Citronellal	106-23-0	R43 N;R51/53**	1	X
Citronellol *	106-22-9	-	3	X
Coumarin *	91-64-5	-	4	X
Dehydro acetic acid	520-45-6	Xn;R22	1	X
Diethyl phthalate	84-66-2	-	1	
D-Limonene *	5989-27-5	R10 Xi;R38 R43 N;R50/53	11	X
Acetic acid 2-phenyl ethyl ester	103-45-7	-	2	
Acetic acid benzyl ester	140-11-4	-	9	
Estragole	140-67-0	Xn;R22**	2	X
Ethylparaben	78-70-6	-	3	
Eucalyptol	470-82-6	-	2	
Eugenol *	97-53-0	Xn;R22 Mut.3;R40 R43**	5	X
Geraniol acetat	105-87-3	N;R50/53**	1	
Hexyl Cinnamaldehyde *	101-86-0	-	2	X
Hydroxy citronellal *	107-75-5	R43**	1	X
Isobornyl acetat	125-12-2	-	1	
Isoeugenol *	97-54-1	Xn;R22 R43**	4	X
Isopropyl nicotinat	553-60-6	R43**	1	X
Isopulegol	89-79-2	-	1	
L-Fenchone	126-21-6	-	1	
Linalool *	78-70-6	-	10	X
Linalool acetat	115-95-7	-	6	

Name	CAS no.	Classification	Occurrence Number of products	Selected
Menthol	1490-04-6	-	6	
Menthol acetat	16409-45-3	N;R51/53**	1	
Menthon	10458-14-7	-	3	
Methylparaben	99-76-3	-	13	
p-Amino benzosyre ethyl ester (anaesthesin)	94-09-7	R43**	2	x
p-Anisaldehyd	123-11-5	-	2	
p-Cymen	99-87-6	N;R51/53**	2	
Phenol	108-95-2	Mut.3: R68 T;R23/24/25 Xn;R48/20/21/22 C;R34	5	x
Phenyl ethyl alkohol	60-12-6	-	7	
p-Propenyl anisol*	104-46-1	R43**	7	x
Pyrazin	290-37-9	R43**	1	x
Salicylic acid	69-72-7	-	1	
Terpinene	99-85-4	-	2	
Trans geraniol *	106-24-1	N;R50**	1	x
Thymol	89-83-8	Xn;R22 C;R34 N;R51/53	3	x
Vanillin	121-33-5	-	1	

Substances that EU scientific committee for cosmetics has evaluated as allergic odorous substances have been marked with ”*”. In connection with substances marked with”**” classification was obtained from the Danish advisory list for self-classification (V*ejledende liste, 2001*).

An ”-” stated under the column "Classification" means that the substance neither was entered on the dangerous substance list nor on the Danish advisory list.

Selection took place among the 63 substances. Allergy-causing odorous substances and other substances classified with regard to danger to health were given priority.

In connection with product 15 it was declared that it contained Spanish fly (cantharides). In connection with the performed chemical screening no content of cantharides was found in the product.

2.2.2 Health screening

A health screening was carried out for the 28 selected substances.

Table 2.3 shows selected physical-chemical data of the substances.

The physical-chemical data of the selected substances was found by searching in chemid and HSDB under TOXNET. Molecule weight was found in HSDB, unless something else is stated. Data about boiling point, melting point, Log K_{OW}, water solubility and steam pressure was found in TOXNET/chemid/physical prop.

Table 2.3 Physical-chemical data of selected substances in pleasure gel

Name	CAS no.	Melting point °C	Boiling point °C	Steam pressure mmHg	Water solubility mg/l	Log K_{OW}
1-Phenoxy propan-2-ol	770-35-4	<25	242,7	-	11000	1,52
2-Phenoxyethanol	122-99-6	14	245	0,007	26700	1,16
Benzaldehyde	100-52-7	-26	179	0,127	6570	1,48
Benzyl alcohol	100-51-6	-15,2	205,3	0,094	42900	1,1
Cantharidin	56-25-7	218	* 84	-	30	1,22
Cinnamal	104-55-2	-7,5	246	0,029	1420	1,90
Cinnamic acid	140-10-3	133	300	0,00005	546	2,13
Cinnamyl alcohol	104-54-1	33	250	0,024	-	1,95
Citral	5392-40-5	-10	227	0,091	1340	3,45
Citronellal	106-23-0	-	-	0,28	-	3,53
Citronellol	106-22-9	<25	224,5	-	-	3,91
Coumarin	91-64-5	71	301,7	0,00098	1900	1,39
Dehydro acetic acid	520-45-6	109	270	0,00125	690	0,78
D-Limonene	5989-27-5	-74	176	1,98	13,8	4,57
Eugenol	97-53-0	-7,5	253	0,0226	2460	2,27
Estragole	140-67-0	-	215,5	-	178	3,47
Hexyl cinnemaldehyde	101-86-0	-	-	-	-	4,82
Hydroxy citronellal	107-75-5	-	-	-	-	2,11
Isoeugenol	97-54-1	-10	266	0,012	-	3,04
Isopropyl nicotinat	553-60-6	-	-	-	-	1,55
Lidocain	137-58-6	68,5	-	$1* 10^{-6}$	4100	2,44
Linalool	78-70-6	<25	197	0,16	1590	2,97
p-Amino benzosyre ethyl ester (benzoecain)	94-09-7	92	310	-	1310	1,86
Phenol	108-95-2	40,9	181,8	0,35	82800	1,46
p-Propenyl anisole	104-46-1	21,3	235	0,0705	111	3,39
Pyrazin	290-37-9	55	115	10,8	200000	-0,26
Thymol	89-83-8	51,5	232,5	0,0022	900	3,3
Trans geraniol	106-24-1	-15	230	0,030	-	3,56

* Sublimation

As it appears from Table 2.3, 10 substances are fixed substances at room temperature and 13 substances are liquid at room temperature. Data is missing for 5 substances.

For most of the substances, the boiling point is in the area of/or above 200 °C. Only the substance pyrazin has a boiling point of 115 °C. In addition, the substance cantharides changes from fixed substance to gas phase at 84 °C (sublimes).

A steam pressure was found for rather few substances. The steam pressures are low – for D-Limonene it is 2 mm Hg and less than 1 mm Hg for all others. Therefore, only a limited amount of the substances will evaporate and be taken in through the respiratory passages.

None of the selected substances are fully miscible with water. Half of the substances have a solubility in water of between 1 and 200 g while the other half has a solubility of less than 1 g per litre water.
The substance pyrazin, with a solubility of 200 g/litre, has a negative Log K_{OW}, meaning that the substance is much more soluble in water than in fatty substances (octanol).

Only one single substance, D-Limonene, has a Log K_{OW} of more than 4, which according to the directions for risk assessment (TGD, 2003) means that the substance to a limited degree can be absorbed through the skin. A rather large amount of substances with high water solubility have a Log K_{OW} of between 1 and 2, while the substances with low water solubility have a Log K_{OW} of between 3 and 4.

With regard to classification a search was performed in the list of dangerous substances and in the advisory list for self-classification from the Danish Environmental Protection Agency. The data found in the advisory list is marked with"**".

All substances were searched for in the INCI database (*INCI , 2005*). It is stated if the substances are on the list and which information the list gives about the function and limitations of the substances. The limitations etc. in the law on cosmetics are also stated. In addition, it is mentioned if the substance appears on the EU's scientific committee for cosmetic's list of allergenic perfume substances.

If the requirements in the Statutory Order on cosmetics were valid for pleasure gel, all substances would have to be declared. If e.g. the 26 allergy-causing perfume substances are in question, then the name of the substance should be stated, when the concentration exceeds 0.001 % in products that are not cleaned off, and 0.01 % in products that are cleaned off. All other types of perfume have to be declared as perfume.

According to the Statutory Order on classification, enclosure 2, item 2.13, it is a requirement for all products that allergy-causing substances forming part of concentrations > 0.1 % have to be provided with the following informative labelling "Contains (substance). Allergic reaction can arise".

Table 2.4 Classification, function, requirements and limitations of selected substances in pleasure gel

Name	CAS no.	Classification	EU allergy list	INCI	Requirements and limitations cf. Statutory Order on cosmetics
1-Phenoxy propan-2-ol	770-35-4	Xn; R22**		Preservative/ solvents with III/1.54-VI/1.43	67, III/54: Only to be used in products that are cleaned off after use. Forbidden in dental hygiene products. Max concentration 2 %. 39, VI, 1/43: As preservative max 1 %
2-Phenoxyethanol	122-99-6	Xn; R22 Xn; R36		Preservative	VI/1,29 Max 1 %
Benzaldehyde	100-52-7	Xn; R22		Solvent	
Benzyl alcohol	100-51-6	Xn, R20/22	Yes [1]	Preservative/ solvent; III/1,45-VI/1,34 and perfume	Max 1 %. If used as perfume labelling is necessary when the concentration exceeds 0.001 % in products that are not cleaned off and 0.01 % in products that are cleaned off.

Name	CAS no.	Classification	EU allergy list	INCI	Requirements and limitations cf. Statutory Order on cosmetics
Cantharidin	56-25-7	Xn; R22**		Nonexistent on INCI	Forbidden in cosmetics included in enclosure 2, serial number 82
Cinnamal	104-55-2	R43 N; R50**	Yes [1]	Denaturants, perfume	23, III/76: If used as perfume labelling is necessary when the concentration exceeds 0.001 % in products that are not cleaned off and 0.01 % in products that are cleaned off.
Cinnamic acid	140-10-3	-		Fragrance as t-cinnamic acid	
Cinnamyl alcohol	104-54-1	R43 N; R50**	Yes [1]	Additives, perfume	24, III/69: If used as perfume labelling is necessary when the concentration exceeds 0.001 % in products that are not cleaned off and 0.01 % in products that are cleaned off.
Citral	5392-40-5	Xi; R38, R48	Yes [1]	Additives, perfume	25, III/70: If used as perfume labelling is necessary when the concentration exceeds 0.001 % in products that are not cleaned off and 0.01 % in products that are cleaned off.
Citronellal	106-23-0	R43 N; R51/53**	[1]	Additives	
Citronellol	106-22-9	-	Yes [1]	Additives, perfume	26, III/86: If used as perfume labelling is necessary when the concentration exceeds 0.001 % in products that are not cleaned off and 0.01 % in products that are cleaned off.
Coumarin	91-64-5	-	Yes [1]	Additives, perfume	28, III/77: If used as perfume labelling is necessary when the concentration exceeds 0.001 % in products that are not cleaned off and 0.01 % in products that are cleaned off.
Dehydro acetic acid	520-45-6	Xn; R22		Preservative, VI/1.13	Max 0.6 % as acid. Forbidden in aerosol cans.
D-Limonene	5989-27-5	R10 Xi; R38, R43 N; R50/53	Yes [1]	Perfume, (R)-p-Mentha-1.8-diene	27, III/58: If used as perfume labelling is necessary when the concentration exceeds 0.001 % in products that are not cleaned off and 0.01 % in products that are cleaned off.
Estragole	140-67-0	Xn; R22**		Fragrance as 4-allylanisole	

Name	CAS no.	Classification	EU allergy list	INCI	Requirements and limitations cf. Statutory Order on cosmetics
Eugenol	97-53-0	Xn; R22 Mut.3; R40	Yes [1]	Denaturants	36, III/71: If used as perfume labelling is necessary when the concentration exceeds 0.001 % in products that are not cleaned off and 0.01 % in products that are cleaned off.
Hexyl cinnemaldehyde	101-86-0	-	Yes [1]	Duft, optages som a-hexylcinnam-aldehyde	41, III/87: If used as perfume labelling is necessary when the concentration exceeds 0.001 % in products that are not cleaned off and 0.01 % in products that are cleaned off.
Hydroxy citronellal	107-75-5	R43**	Yes [1]	Fragrance under 7-hydroxycitronellal	45, III/72: If used as perfume labelling is necessary when the concentration exceeds 0.001 % in products that are not cleaned off and 0.01 % in products that are cleaned off.
Isoeugenol	97-54-1	Xn; R22, R43**	Yes [1]	Additives, perfume	47, III/73: If used as perfume labelling is necessary when the concentration exceeds 0.001 % in products that are not cleaned off and 0.01 % in products that are cleaned off.
Isopropyl nicotinat	553-60-6	R43**	[1]	Nonexistent on INCI	
Lidocain	137-58-6	-		Nonexistent on INCI	Forbidden in cosmetics, included in enclosure 2, serial number 276
Linalool	78-70-6	-	Yes [1]	Deodorants/additives	If used as perfume labelling is necessary when the concentration exceeds 0.001 % in products that are not cleaned off and 0.01 % in products that are cleaned off.
p-Amino benzosyre ethyl ester (anaesthesin)	94-09-7	R43**	[1]	Nonexistent on INCI	
Phenol	108-95-2	Mut.3: R68 T; R23/24/25 Xn; R48/20/21/22 C; R34		Antimicrobials/ denaturants/deodoran t agents; III/1,19	66, III/19: For soap and shampoo max 1 % calculated as phenol
p-Propenyl anisole	104-46-1	R43**	[1]	Fragrance	
Pyrazin	290-37-9	R43**	[1]	Nonexistent on INCI	
Trans geraniol	106-24-1	N; R50**	Yes [1]	Fragrance under geraniol	40, III/78: If used as perfume labelling is necessary when the concentration exceeds 0.001 % in products that are not cleaned off and 0.01 % in products that are cleaned off.

Name	CAS no.	Classification	EU allergy list	INCI	Requirements and limitations cf. Statutory Order on cosmetics
Thymol	89-83-8	Xn; R22 C; R34 N; R51/53		Hair dye/denaturant/ additives	

1: According to the EU's scientific committee for cosmetic's list of allergenic perfume substances or the Danish advisory list for self-classification the product has to be provided with the following labelling "Contains (substance). Allergic reaction can arise" if the concentration is > = 0.1 %.

Table 2.4 shows that 21 out of 28 substances were classified either on the list of dangerous substances or on the Danish advisory list for self-classification.

Among the classified substances there is one substance, phenol, and one self-classified substance, eugenol, for which it is stated that there is a risk of genetic damages.

A number of substances are classified R43: Can cause allergy when in contact with the skin. 10 substances are in question. In addition, 13 substances have been entered on the EU's scientific committee for cosmetics list of allergenic perfume substances. Some substances have been both R43 classified and entered on the EU list. A total of 18 substances are known to cause or suspected of causing allergy when in contact with the skin.

On the most recent list of dangerous substances phenol has been upgraded from poisonous and caustic in pure condition to also being injurious to health during prolonged exposure (R48) and with possible permanent damage to health (R68). As the substance appears in very small amounts such acute or chronic health effects will hardly manifest themselves.

A number of substances are classified R22: Intake is dangerous. This risk specification is considered less essential as the substances are assumed to appear in very small quantities.

As it appears from the results from the search on the INCI list, 23 out of the 28 substances have been entered on the list. From the list it appears that four preservatives (2-Phenoxyethanol, Benzyl alcohol, Dehydro acetic acid, 1-Phenoxy propan-2-ol) may exist in a given amount. The substances cantharides and lidocain have not been entered on the INCI list and according to the Statutory Order on cosmetics they are forbidden.

In addition, there are a number of substances that are entered on enclosure 3 of the Statutory Order on cosmetics concerning limitations and conditions. 13 substances exist that have to be labelled when they appear in concentrations exceeding 0.001 % (10 µg/gram) in products that are not washed off and 0.01 % (100 µg/gram) in products that are washed off.

3 Quantitative chemical analyses

3.1 Quantitative determination of volatile and semi-volatile compounds

The same analysis principle was used as in connection with qualitative screening, SPME combined with GC/MS. However, in connection with quantitative measurements another SPME fibre with greater capacity was used. The application of this SPME fibre was necessary in order to carry out the quantification which simultaneously resulted in reduced sensitivity of the analysis method compared to the applied method during screening. Due to these conditions, individual components identified in connection with the qualitative examination could not be quantified.

Three different isotope marked internal standards were added to the sample (toluen-d_8, phenol-d_6 and naphthalen-d_8).

The method was calibrated at 6 different levels of concentration from 0.1 to 50 µg per headspace glass.

The sample was weighed in a 20 ml membrane glass. Different amounts were weighed depending on the content of organic components in the investigated products from 0.05 g to 0.05 mg sample per headspace glass. Headspace was sampled for 15 min. at SPME and subsequently analysed at gas chromatography with mass spectrometric detection (GC/MS). The following parameters were applied:

GC/MS Instrument	Thermo Finnigan, DSQ
MS parameters	Autotune, 35-300 m/z, solvent delay: 4.0 min.
GC parameters	Oven prog: 40 ºC for 1 min., 10 ºC/min. to 260 ºC hold for 2 min. Injector: 290 ºC, splitless time: 0.50 min. Carrier gas: Helium, constant flow: 1.0 ml/min. Column: Valcobond VB-1, 30 m x 0.25 mm, film: 1.5 µm
SPME parameters	Fibre: 100 µm PDMS Headspace temperature: 35 ºC

The detection limit: 1 mg/kg. Analysis uncertainty: 10-25 % RSD, depending on component.

3.2 Analysis results

The quantified contents from the performed GC/MS analysis appear from Table 3.1.

Please note that product no. 24 merely was included in the quantitative measurement as it could not be procured earlier in the project. The product consists of 3 different flavours (in the same package) and only one variety was analysed.

Table 3.1 Results from GC/MS screening of pleasure gel

Component	Sample marking [mg/kg]										
	1	2	3	4	6	7	8	9	11	12	13
1-Phenoxy propan-2-ol	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
2-Phenoxyethanol	2,500	1,400	<1	<1	<1	<1	8,300	<1	6,800	7,000	5,100
3-Caren	<1	<1	<1	<1	16	<1	<1	<1	<1	<1	<1
α-Pinene	<1	<1	1,2	<1	260	<1	<1	<1	<1	<1	<1
Benzaldehyde	<1	17	<1	28	200	4,0	<1	<1	<1	<1	<1
Benzyl acetate	6.5	2,400	3.1	<1	<1	3.5	<1	<1	2.8	3.8	2.7
Benzyl alcohol	<1	9.6	<1	45	140	<1	<1	<1	<1	<1	<1
Camphen	<1	<1	<1	<1	46	<1	<1	<1	<1	<1	<1
Camphor	<1	<1	<1	<1	900	<1	<1	<1	<1	<1	<1
Cinnamal	<1	<1	<1	6,200	17,000	270	<1	<1	<1	<1	<1
Cinnamyl alcohol	<1	<1	<1	12	<1	<1	<1	<1	<1	<1	<1
Citral	<1	<1	<1	<1	<1	40	<1	<1	<1	<1	<1
Citronellal	<1	<1	<1	<1	<1	240	<1	<1	<1	<1	<1
Citronellol	<1	<1	<1	<1	<1	180	<1	<1	<1	<1	<1
Coumarin	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Dehydro acetic acid	9.2	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
D-Limonene	<1	<1	4.9	56	400	20	<1	<1	<1	<1	<1
Estragole	<1	<1	3.0	5,500	<1	<1	<1	<1	<1	<1	<1
Eugenol	<1	<1	<1	500	18,000	380	<1	<1	<1	<1	<1
Hexyl cinnemaldehyde	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Hydroxy citronellal	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Isoeugenol	<1	<1	<1	8,3	500	18	<1	<1	<1	<1	<1
Linalool	<1	1,400	<1	200	1,200	9.0	<1	<1	<1	<1	<1
Methyl salicylate	<1	1.5	<1	<1	<1	<1	<1	<1	<1	<1	<1
Phenol	8.4	1.8	1.5	<1	<1	<1	10	2.3	5.3	7.5	4.6
p-Methylanisol	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
P-Propenyl anisol	<1	<1	64	<1	43	<1	<1	<1	<1	<1	<1
Pyrazin	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Toluen	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1

"<1" means that the content is less than the detection limit of the applied analysis method.

Table 3.1 - continued – Results from GC/MS screening of pleasure gel

Component	Sample marking [mg/kg]										
	15	18	21	22	23	24	25	27	29	30	32
1-Phenoxy propan-2-ol	<1	<1	<1	23	<1	<1	<1	<1	<1	<1	<1
2-Phenoxyethanol	<1	61	<1	<1	1,300	100,000	<1	<1	<1	<1	<1
3-Caren	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
α-Pinen	<1	<1	<1	<1	<1	<1	<1	<1	<1	560	<1
Benzaldehyde	<1	<1	<1	<1	<1	6.3	<1	16	6.1	71	5.0
Benzyl acetate	40	<1	5.2	4.6	3.9	96	5.5	290	300	480	250
Benzyl alkohol	<1	<1	<1	<1	<1	1.9	<1	22	6.2	<1	17
Camphen	<1	<1	<1	<1	<1	<1	<1	<1	15	<1	<1
Camphor	<1	<1	<1	<1	<1	<1	3.9	<1	<1	<1	<1
Cinnamal	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Cinnamyl alkohol	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Citral	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Citronellal	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Citronellol	<1	<1	<1	<1	<1	<1	<1	340	<1	<1	210
Coumarin	36	<1	<1	<1	<1	<1	<1	190	<1	<1	460
Dehydro acetic acid	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
D-Limonene	8.1	<1	<1	<1	<1	<1	<1	150	51	220	23
Estragole	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Eugenol	<1	<1	<1	<1	<1	<1	<1	830	<1	<1	<1
Hexyl Cinnamaldehyde	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Hydroxy citronellal	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Isoeugenol	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Linalool	36	<1	<1	<1	<1	<1	<1	1,300	99	1,400	340
Methyl salicylate	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Phenol	4.6	1.0	2.2	20	7.1	19	3.3	2.7	2.5	1.7	1.7
p-Methylanisol	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	18

Component	Sample marking [mg/kg]										
	15	18	21	22	23	24	25	27	29	30	32
P-Propenyl anisol	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Pyrazin	<1	<1	<1	<1	<1	<1	2.4	<1	<1	<1	<1
Toluen	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1

”<1” means that the content is less than the detection limit of the applied analysis method.

Detection limit: 1 mg/kg. Analysis uncertainty: 10-25 % RSD, depending on the component.

3.3 Order of priority of substances in pleasure gel

In the light of the performed health screening and the quantitative analysis, a number of substances were chosen for additional health assessment.

It was estimated that the most interesting substances are:

- Eugenol
- Cinnamal
- Linalool
- 2-phenoxyethanol
- D-Limonene.

Furthermore, there are substances that were estimated in connection with the survey of sports creams and the following substances are relevant for pleasure gels:

- Camphor
- α-Pinene.

4 Legislation

4.1 Introduction

The regulations governing special products such as pleasure gels etc. are not always obvious. The products are regulated by the law on chemical substances and products (LBK nr. 21 af 16/01/1996 om kemiske stoffer og produkter). Due this the pleasure gels are also regulated by the general Statutory Order on classification and labelling of chemical substances and products (*Klassificering, 2005*). Some of the substances in the products are required to have a warning label and therefore, all the products are assessed with respect also to classification and labelling.

The Statutory Order on cosmetics (*Cosmetics, 2006*), however, does not regulate pleasure gels, although the exposure route seems a like, §2[4]. Section 4.3 describes the requirements to labelling of ingredients, restrictions, etc. if the products were regulated by the Statutory Order on cosmetics.

4.2 Classification of products

In the assessment of which products should be classified only substances detected in more than 0.01 percent (100 mg/kg) have been considered.

A table for each of the 22 samples is shown below. For substances included in the EU-list on allergic fragrances (*SCCNFP, 1999*) is stated "potential R43" and the substance and its effect are included in the classification for the product. Substances included on the Danish advisory list for classification (*Vejledende liste*) are marked with an *.

Table 4.1 Classification for Pleasure-gel number 1

Sample number: 1		
Substance	Amount (w%)	Classification
2-Phenoxyethanol	0.25	Xn;R22 Xi;R36
Product classification		None

[4] §2 The statutory order is not applicable for products which have to be applied to humans or animals to prevent, realise, ease, treat or cure sickness, sickness symptoms or pain or to affect the functions of the body. §3 Cosmetic products means any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with the view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours. *Statutory Order on cosmetic products No.422 of 4 May, 2006.* Ministry of the Environment, Denmark.

Table 4.2 Classification for pleasure-gel number 2

Sample number: 2		
Substance	Amount (w%)	Classification
2-Phenoxyethanol	0.14	Xn;R22 Xi;R36
Benzyl acetate	0.24	None
Linalool	0.14	Potential R43
Product classification		None

In sample no. 3, no problematic substances have been detected in amounts exceeding 100 mg/kg.

Table 4.3 Classification for pleasure-gel number 4

Sample number: 4		
Substance	Amount (w%)	Classification
Cinnamal	0.62	R 43 *
Estragole	0.55	Xn;R22*
Eugenol	0.05	Xn;R22 Mut3;R40 R43*
Linalool	0.02	Potential R43
Product classification		None

Table 4.4 Classification for pleasure-gel number 6

Sample number: 6		
Substance	Amount (w%)	Classification
α-Pinene	0.026	R50/R53*
Benzaldehyde	0.020	Xn;R22
Benzyl alcohol	0.014	Xn;R20/22
Camphor	0.090	None
Cinnamal	1.700	R43 *
D-Limonene	0.040	Xi;R38 R43
Eugenol	1.800	Xn;R22 Mut3;R40 R43*
Isoeugenol	0.050	Xn;R22 R43*
Linalool	0.120	Potential R43
Product classification		Xn R40-R43

Table 4.5 Classification for pleasure-gel number 7

Sample number: 7		
Substance	Amount (w%)	Classification
Cinnamal	0.027	R43 *
Eugenol	0.038	Xn;R22 Mut3;R40 R43*
Product classification		None

Table 4.6 Classification for pleasure-gel number 8

Sample number: 8		
Substance	Amount (w%)	Classification
2-phenoxyethanol	0.83	Xn;R22 Xi;R36
Product classification		None

In sample no. 9, no problematic substances have been detected in amounts exceeding 100 mg/kg.

Table 4.7 Classification for pleasure-gel number 11

Sample number: 11		
Substance	Amount (w%)	Classification
2-phenoxyethanol	0.68	Xn;R22 Xi;R36
Product classification		None

Table 4.8 Classification for pleasure-gel number 12

Sample number: 12		
Substance	Amount (w%)	Classification
2-phenoxyethanol	0.70	Xn;R22 Xi;R36
Product classification		None

Table 4.9 Classification for pleasure-gel number 13

Sample number:13		
Substance	Amount (w%)	Classification
2-phenoxyethanol	0.51	Xn;R22 Xi;R36
Product classification		None

In samples 15, 18, 21, and 22, no problematic substances have been detected in amounts exceeding 100 mg/kg.

Table 4.10 Classification for pleasure-gel number 23

Sample number: 23		
Substance	Amount (w%)	Classification
2-phenoxyethanol	0.51	Xn;R22 Xi;R36
Product classification		None

Table 4.11 Classification for pleasure-gel number 24

Sample number: 24		
Substance	Amount (w%)	Classification
2-phenoxyethanol	10.00	Xn;R22 Xi;R36
Product classification		None

In or sample no. 25 no problematic substances have been detected in amounts exceeding 100 mg/kg.

Table 4.12 Classification for pleasure-gel number 27

Sample number: 27		
Substance	Amount (w%)	Classification
Benzyl acetate	0.029	None
Citronellol	0.034	Potential R43
Coumarin	0.019	Potential R43
D-Limonen	0.015	Xi;R38 R43
Eugenol	0.083	Xn;R22 Mut3;R40 R43*
Linalool	0.130	Potential R43
Product classification		None

Table 4.13 Classification for pleasure-gel number 29

Sample number: 29		
Substance	Amount (w%)	Classification
Benzyl acetate	0.030	None
Product classification		None

Table 4.14 Classification for pleasure-gel number 30

Sample number: 30		
Substance	Amount (w%)	Classification
α-Pinene	0.056	R50/53*
Benzyl acetate	0.048	None
D-Limonen	0.022	Xi;R38 R43
Linalool	0.140	Potential R43
Product classification		None

Table 4.15 Classification for pleasure-gel number 32

Sample number: 30		
Substance	Amount (w%)	Classification
Benzyl acetate	0.025	None
Citronellol	0.021	Potential R43
Coumarin	0.046	Potential R43
Linalool	0.034	Potential R43
Product classification		None

Conclusion
As it can be seen from tables above more products contains substances which by the scientific committee are evaluated as sensitizing, and 5 product contains one or more of these substances in concentrations above 0.1 %. 6 should be classified because of the relative high content of cinnamal and eugenol.

For substances that are not included at ”the list of dangerous substances” it is required that the producers of products must perform an evaluation and selfclassification of the substances. If this evaluation shows that the substance is sensitizing (allergy-causing) the products containing this must be labelled according to the concentration of the substance in the product. If the product contains 0.1-1 % of the sensitizing substance the product must be labelled with the sentence "Contains (substance). Allergic reaction can arise". If the product contains mire the 1 % of the substance the product has to be classified.

4.3 Requirement from the Statutory Order on cosmetics

The Statutory Order on cosmetics (*Cosmetics, 2006*), does not regulate pleasure gels, although the exposure route seems a like. Here it is described which requirements to labelling of content of perfume; the products were regulated by if covered by the Statutory Order on cosmetics.

The basic requirements in the Statutory Order on cosmetics are:

- some substances are prohibited; none of the these which were analysis were identified in the qualitative analysis
- some substances can be used in limited quantities; a few substances of this category have been identified
- some substances like perfume and flavours must be declared by name on the package if the content exceeds the limit value. If the content is below the limit value it shall only be specified that the product contains perfume or flavour.

A number of perfume substances have to be declared on the package if the content is more than 0.001% (10 mg/kg) for products which are not meant to be cleaned off the skin again (“Leave on products”). Substances in pleasure-gels are assumed not to be cleaned off the skin.

In the following all the products are assessed with respect to content of substances that has to be declared. Only substances determined at higher amounts than 0.001% (10 mg/kg) are considered.

Sample no. 1
None of substances have to be declared with respect to appendix 3 in the Statutory Order on cosmetics.

Sample no. 2

Linalool	0.14 w% has to be declared

The product declaration did not include the required substance.

Sample no. 3

None of the substances have to be declared according to appendix 3 in the Statutory Order on cosmetics.

Sample no. 4

Benzyl alcohol	0.004 w% has to be declared
Cinnamal	0.620 w% has to be declared
Cinnalmyl alcohol	0.001 w% has to be declared
D-Limonene	0.005 w% has to be declared
Eugenol	0.050 w% has to be declared
Linalool	0.020 w% has to be declared

The product declaration did not include the required substances.

Sample no. 6

Benzyl alcohol	0.014 w% has to be declared
Cinnamal	1.700 w% has to be declared
D-Limonene	0.040 w% has to be declared
Eugenol	1.800 w% has to be declared
Isoeugenol	0.050 w% has to be declared
Linalool	0.120 w% has to be declared

The product declaration did not include the required substances.

Sample no. 7

Citral	0.004 w% has to be declared
Cinamal	0.027 w% has to be declared
Citronellol	0.018 w% has to be declared
D-Limonene	0.002 w% has to be declared
Eugenol	1.800 w% has to be declared
Isoeugenol	0.002 w% has to be declared

With respect to the declaration on the product the name Eugenia was included. This may be the same as Eugenol. The other substances were not mentioned.

Sample no. 8, 9, 11, 12, and 13

None of substances have to be declared according to appendix 3 in the Statutory Order on cosmetics.

Sample no. 15

Coumarin	0.004 w% has to be declared
Linalool	0.004 w% has to be declared

The product declaration did not include the required substances.

Sample no. 18, 21, 22, and 23

None of substances have to be declared according to appendix 3 in the Statutory Order on cosmetics.

Sample no. 24

The content of 2-phenoxyethanol is 10% and the maximal allowed concentration in cosmetics is 1%

Sample no. 25

None of substances have to be declared according to appendix 3 in the Statutory Order on cosmetics.

Sample no. 27

Benzyl alcohol	0.002 w% has to be declared
Citronellol	0.034 w% has to be declared
Coumarin	0.019 w% has to be declared
D-limonene	0.015 w% has to be declared
Eugenol	0.083 w% has to be declared
Linalool	0.130 w% has to be declared

The declaration included all required substances according to appendix 3 in the Statutory Order of cosmetics.

Sample no. 29

D-limonene	0.005 w% has to be declared
Linalool	0.010 w% has to be declared

The declaration included all required substances according to appendix 3 in the Statutory Order of cosmetics. The product declaration included also substances present in amounts less than 1 mg/kg; for instance Citronellol.

Sample no. 30

D-Limonene	0.022 w% has to be declared
Linalool	0.140 w% has to be declared

The declaration included all required substances according to appendix 3 in the Statutory Order of cosmetics. The product declaration included also substances present in amounts less than 1 mg/kg; for instance Citronello and Coumarin.

Sample no. 32

Benzyl alcohol	0.002 w% has to be declared
Citronello	0.021 w% has to be declared
Coumarin	0.046 w% has to be declared
D-Limonene	0.002 w% has to be declared
Linalool	0.034 w% has to be declared

The product declaration did not include the required substances.

Conclusion

For 8 of the 22 products the declaration did not meet the requirements in the Statutory Order on cosmetics.

In one product a content of 10 times the allowed amount of the preservative 2-ethoxyethanol was detected.

5 Health Assessment

5.1 Introduction

In this section, the potential health effects from identified and selected substances are assessed. The assessment is aimed at 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, density, vapour pressure and solubility.

A search in the open literature has been performed with focus on the ability of skin absorption and effects by oral intake and the most important test results, the effects, and circumstances are presented in this report. 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 the margin of safety (MOS) can be calculated, and it can be assessed whether the substances of the tested products may cause a negative health effect.

5.2 Method

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

None of the product labellings give directions on recommended amounts to use. For assessment and comparison purposes it is assumed that the same amount of product is used per day. The amount used is based on the TGD (2003) setting 1 g product per day for general purpose creams.

Regarding exposure, two scenarios have been selected:

A. One scenario, where 1 gram of product is ingested per day. It is assumed that 100 percent of the substances are absorbed to the body.

B. One scenario, where 1 gram of the product is absorbed through the skin or mucous membranes. It is assumed that 100 percent of the substances are absorbed by the body.

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

The uptake is calculated as:

Intake per day per kg body weight =
Content of substance × [mg/gram] * 1 gram per day / body weight [kg]
The body weight (b.w.) is assumed to be 70 kg.

There is no variable for “fraction absorbed” because is it assumed to be “1” (100 %) in all scenarios.

The equation can be reduced to:

Intake per day per kg b.w. = 0.0143 * Content of substance × [mg/kg b.w.]

The intake per day has then to be compared with data for oral intake and, if available, with data for absorption through skin and mucous membranes.

Evaluation of risk
In the evaluation of health risks the calculated intake has to be compared with the NOAEL or similar values. As NOAEL typically is based on tests on animals a safety factor (MOS:Margin of safety) is introduced by dividing NOEAL in mg/kg b.w by the intake.

If the data for animals is a chronic long term study of high quality the safety factor in the risk assessment is typically MOS=100. This is based on a factor of 10 for extrapolation between species (interspecies) and a factor of 10 meant to protect sensitive individuals like children (intraspecies). If the data is of less quality etc. based on LOAEL or a subchronic study an additional safety factor is applied (typically 10). The total safety factor is the combined product of the individual safety factors.

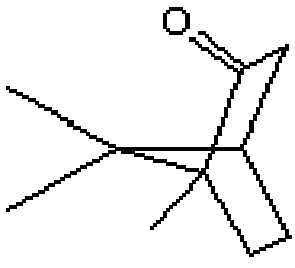
5.3 Selected substances

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

5.3.1 Camphor

5.3.1.1 Identity

Name	Bornan-2-one
CAS-number	76-22-2
EINECS number	200-945-0
Molecular formula	$C_{10}H_{16}O$
Molecular structure	



Molecular weight	152.23

Synonyms	Bicyclo(2.2.1)heptan-2-one, 1,7,7-trimethyl- 1,7,7-Trimethylbicyclo(2.2.1)heptan-2-one 2-Bornanone Gum camphor Spirit of camphor

The substance consists of colourless or white crystals. It has a boiling point of 204ºC and a melting point of 179ºC *(The Merck Index, 1983).*

The substance is more soluble in organic solvents than in water. Yalkowsky and Yan (2003) state that 1.6 gram of camphor can be dissolved in 1 litre water at 25ºC. In another reference the following is given: At 25ºC one gram dissolves in about 800 ml water, in 1 ml alcohol, 1 ml ether, 0.5 ml chloroform. The substance is freely soluble in carbon disulphide, petroleum, fixed and volatile oils. It is also soluble in concentrated mineral acids, in phenol, in liquid ammonia, and in liquid sulphoxide (*O'Neil, M.J., 2001*).

The partition coefficient Log K_{OW} is determined to be 2.38 (*Daylight Chemical Information Systems, 2004*).

Vapour pressure is determined to be 0.65 mm Hg @ 25ºC (*Jones AH, 1960*).

Some values are given for odour threshold values. The lowest odour value is 0.0026 ppm and the highest is 0.96 ppm. Both odour values are below TLV (*Haz-map, 2005*).

5.3.1.2 Detected quantities

The substance is detected in two products. In sample no. 6, 900 mg/kg has been detected and in sample no. 25 only 3.9 mg/kg.

5.3.1.3 Function of substance

The substance is included in the INCI-database. Here it is stated that the function of the substance can be denaturants / film formers and as a fragrance. O'Neil, M.J. (2001) states that the substance is normally used as an odorant and flavourant and it can be used as emollient in cosmetics and as a preservative.

5.3.1.4 Classifications and TLV's

This chemical substance is not classified in the Annex I of Directive 67/548/EEC.

The Danish threshold limit value is 2 ppm equal to 12 mg/m^3. The same limit is set in USA (*ACGIH, 2005*).

5.3.1.5 Health Effects

Data regarding health effects has been retrieved from TOXNET and the databases related to this host. The substance is not included in IUCLID.

Acute toxicity

The substance is irritating to the eyes, the skin, and the respiratory tract (*IPCS, 2003*). Camphor applied to the skin of volunteers as a 20% solution in alcohol produced no significant sensation of irritation or pain at normal skin temperatures. It did appear to have a slight sensitising effect on the perception of temperature change during heating and cooling, and increased the

sensation of burning at high temperatures (*National Poisons Information Service Center, 1996*).

Acute toxicity by ingestion based on test with animals indicates that camphor may be slightly toxic:

- LD_{50} Mouse oral 1,310 mg/kg (*Lewis, R.J. 1996*)
- LD_{50} Rat subcutaneously 70 mg/kg (*Lewis, R.J. 1996*)
- LD_{50} Mouse ip 3,000 mg/kg (*ACGIH, 2001*)

Several exposure studies with humans have been reported. In one study, 1.5 g camphor has been ingested in an adult, who recovered. In children 0.7 to 1.0 g has proved fatal. Urinary retention, albuminuria, and anuria are described in non-fatal cases, but kidney lesions in fatal poisonings are not always prominent. Mild and transient hepatic derangements may occur and widespread hemorrhages are described in one fatal case. Fetal death resulted after camphor ingestion by mother and postmortem exam revealed severe atelectasis and central neuronal necrosis (*Gosselin et al., 1984*).
Camphor remains in over 950 products listed in Poisindex. A review of all camphor ingestions estimated to be 2 mg/kg or greater was made. Seventy-three patients (90%) remained asymptomatic, three (4%) developed minor symptoms, and five (6%), all ingesting over 59 mg/kg, developed major symptoms. There were no deaths reported (*Geller RJ et al., 1984*).

From IPCS, Poisons Information Monograph the following has been retrieved

- Camphor crosses the placenta and has been implicated in fetal and neonatal death. It has been used to induce abortions. Camphor poisoning during pregnancy was reported in four cases and, in each case, camphorated oil was mistaken for castor oil. The topical use of camphorated oil in pregnancy was not associated with teratogenic effects.

- Deafness has been reported in association with camphor. Ulceration of the mucous membranes has been reported following the use of toothache solutions containing camphor (along with menthol, phenol, clove oil and chloroform).

- Camphor administered in doses of 60 mg to 4 g was reported to cause flickering, darkening or veiling of vision along with noises in the ears. Corneal erosions have been reported in association with the use of inhalant capsules containing camphor.

Sub-chronic toxicity
D-Camphor elicited no evidence of teratogenicity when administered orally during the fetal period of organogenesis to pregnant rats at doses up to 1,000 mg/kg b.w./day, and to pregnant rabbits at doses up to 681 mg/kg b.w./day. The NOEL for the fetal organism for the rat was above 1,000 mg/kg b.w., and for the rabbit above 681 mg/kg b.w. (*Leuschner J, 1997*).

Chronic toxicity
With chronic dermal exposure, systemic effects and contact dermatitis can occur as well as significant allergic responses. Ocular exposure results primarily in irritation only, although oral intake has been associated with visual problems (*Ford MD et al., 2001*).

Camphor is classified as “A4; Not classifiable as a human carcinogen” (*ACGIH, 2005*).

Summary
Only values for NOEL for teratogenicity are given for short term studies with animals. The lowest value was 680 mg/kg b.w. per day.

Observations on humans showed that ingestion of 2 mg/kg b.w. gave none or minor symptoms.

References show that camphor may cause irritation by skin contact and may by chronic exposure cause allergies.

5.3.1.6 Exposure scenarios
The maximum content in a sample was 900 mg/kg equal to 0.9 mg per gram.

Intake per day per kg b.w. = 0.0143 * 0.9 = 0.013 mg/kg b.w.

It is assumed that the estimated amount can either be ingested or absorbed through skin or membranes.

5.3.1.7 Assessment
Camphor is a substance that may cause irritations and allergies by skin contact. It may be toxic if ingested in relative large amounts - more than 1 mg/kg b.w. Camphor may cause teratogenic effects; NOEL based on a subacute test is estimated to 680 mg/kg. Indications for other long term effects have not been found.

Camphor has been detected in two samples. Based on intake of 1 gram of product the maximum daily uptake will be 0.01 mg per kg b.w.

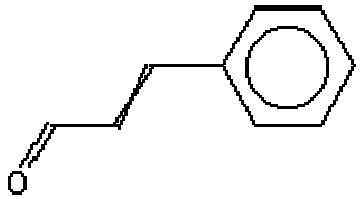
Based on the data for teratogenicity a marginal of safety (MOS) is more than 50,000. Compared with the observations on humans with 2 mg/kg b.w. MOS is 200. From this it can be concluded that oral ingestion will cause no health risks.

Based on the available data there is a risk that camphor may cause irritations and allergic reactions.

5.3.2 Cinnamaldehyde

5.3.2.1 Identity

Name	Cinnamaldehyde
CAS-number	104-55-2
EINECS number	203-213-9
Molecular formula	C_9H_8O
Molecular structure	



Molecular weight	132.15

Synonyms	2-Propenal, 3-phenyl- 3-Phenyl-2-propenal Cinnamaldehyde Cinnamic aldehyde

Cinnamaldehyde is a yellow oily liquid with a strong odour of cinnamon (*Budavari, S. 1989*). The boiling point is 253ºC at 760 mm HG and the melting point is -7.5ºC (*Lide, DR 1990*).

The partition coefficient Log K_{ow} is estimated to be 1.90 (*Hansch et al., 1995).* The vapour pressure is 1 mmHg at 25ºC. The substance is soluble in most organic solvents. Water solubility is 1.42 g/l at 25ºC (*Valvani, 1981*).

5.3.2.2 Detected quantities
The substance is detected in large amounts in two products and in small amounts in one product.
In sample no. 4 6,200 mg/kg equal to 0.62 weight percent has been detected.
In sample no. 6 17,000 mg/kg equal to 1.7 weight percent has been detected.
In sample no. 7 only 270 mg/kg has been detected.

5.3.2.3 Function
In general, cinnamaldehyde is added to food and beverage as a cinnamon flavour and as a perfume.

Cinnamaldehyde is included in INCI as a denaturant, which means that the substance is mostly added to products containing ethanol in order to render them unpalatable.

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

The substance is included in the EU-list of allergenic perfumesubstances (*SCCNFP, 1999*).

Cinnamaldehyde is included in the Danish advisory list for classification (*Vejledende liste ,2001*) with the classification:

R43 May cause sensitization by skin contact.
N;R50 Hazardous to the environment; Very toxic to aquatic organisms.

DSM Special products BV advises a provisional TLV of 5 ppm to prevent irritation and toxic effects (IUCLID, 2000). No other data for TLV was found.

5.3.2.5 Health Effects
Data regarding health effects has been retrieved from TOXNET and the databases related to this host. Data from IUCLID has been included as well as from other sources.

Acute toxicity
Cinnamaldehyde is known to be an irritant and causes allergy. From the EU-study on allergens (*SCCNFP, 1999*) it is concluded:

- The substance causes allergic reactions in 2-3 percent of the tested patients.

- It causes allergic reactions in 1-30 percent in patients with eczema from cosmetic products.
- The test concentration is 1 percent - higher concentrations may cause irritations.

Test for irritation has shown that the highest non-irritating concentration of cinnamaldehyde was 0.5 percent in vaseline and 1 percent in acetone (*IUCLID, 2000*).

Regarding oral intake a few older data is reported in IUCLID. LD_{50} is determined to be between 1,160 to 3,400 mg/kg for rats, mice and guinea pigs. For acute dermal toxicity values of more than 2,000 mg/kg was reported for rats and rabbits.

Cinnamaldehyde is regarded as moderately toxic (*Gosselin et al., 1984*). Probable oral lethal dose for humans is 0.5 to 5 gram per kg b.w.

Sub-chronic toxicity
In a 16 weeks test from 1964 rats were orally fed with 1, 2.5 and 10 gram per kg bw (*IUCLID, 2000*). NOAEL was determined to be 2.5 gram per kg b.w. LOAEL was determined to be 10 gram per kg b.w. At this dose level hyperkeratosis of the fore stomach and light swelling of hepatic cells were observed.

Cinnamaldehyde was evaluated for developmental toxicity in a short-term in vivo animal bioassay. In this assay, pregnant mice were dosed with the test agent in mid-pregnancy and allowed to go to term. Observations were then made on litter size as well as the birth weight, neonatal growth, and survival of pups as indicators of developmental toxicity. Forty-nine pregnant CD-1 mice were given 1200 mg/kg/day cinnamaldehyde in corn oil by gavage on days 6-13 of gestation and were allowed to deliver. No toxic effect was observed in the dams or in their offspring for the parameters assayed (*Hardin et al., 1987*).

In another short-term for developmental toxicity, rats were exposed from day 7 to day 17 of gestation with doses of 5, 25 and 250 mg/kg. NOAEL for the adult was determined to be 5 mg/kg and less than 5 mg/kg for the foetuses, because they were slightly more sensitive (*IUCLID, 2000*).

Chronic toxicity
In the database NCI Chem. Carcinogenesis Res Info System 5 negative results of Ames test is reported.

A two-generation study on reproduction toxicity from 1965 is reported in IUCLID. Based on exposure for 433 days with a dose of 5 mg/kg b.w. NOAEL for the parents were 5 mg/kg and less than 5 mg/kg for first and second generation offspring's. Only observed effects were increased lipid content in the liver of the offspring's.

The Joint FAO/WHO Expert Committee on Food Additives (1967) published a monograph and specifications, given a conditional Acceptable Daily Intake of 0 to 1.25 mg/kg.

Summary
Cinnamaldehyde causes irritations to skin in concentrations of more than 1 percent. The substance also causes sensitization by skin contact.

Sub-acute and chronic test for reproduction toxicity shows a NOAEL of 5 mg/kg b.w. for the adults (parental generation) and less than 5 mg/kg for foetus / 1st and 2nd generation of offspring.

No other data on long term effects has been found.

A value for ADI is referred to be from 0 to 1.25 mg/kg.

5.3.2.6 Exposure scenarios

The maximum content in sample no. 6 was 17,000 mg/kg equal to 17 mg per gram.

Intake per day per kg b.w. = 0.0143 * 17 = 0.243 mg/kg b.w.

For sample no. 4:

Intake per day per kg. b.w. = 0.089 mg/kg b.w.

It is assumed that the estimated amount can either be ingested or absorbed through skin or membranes.

5.3.2.7 Assessment

Regarding skin irritation the content of 0.6 w% and 1.7 w% may cause irritation. It is shown that skin contact causes allergic reactions in 2-3 percent of all people. People with eczema from cosmetic products are more sensitive.

Regarding intake of products with cinnamaldehyde the maximal intake is less than 0.1 mg/kg b.w. The ADI is 0-1.25 mg/kg.

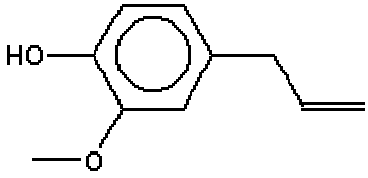
NOAEL for reproductive toxicity is 5 mg/kg b.w., which gives a marginal of safety of more than 500.

It can be concluded that cinnamaldehyde in sample 4 and 6 may cause irritation to skin and mucous membranes. It is also likely to expect that skin contact may cause allergies. Intake will not cause any major health problems and no long term effects besides allergies can be expected.

5.3.3 Eugenol

5.3.3.1 Identity

Name	Eugenol
CAS-number	97-53-0
EINECS number	202-589-1
Molecular formula	$C_{10}H_{12}O_2$
Molecular structure	



Molecular weight	164.2

Synonyms	2-Methoxy-4-(2-propenyl)phenol Allylguaiacol Phenol, 2-methoxy-4-(2-propenyl)-

Eugenol is a colourless or pale yellow liquid with an odour of cloves. The substance has a boiling point of 253ºC and a melting point of -9.2ºC. (*Budavari, 1989*).

The partition coefficient Log K_{OW} is 2.27 (*Sangster, 1994*).
Eugenol has a solubility in water of 2.43 gram per litre (*Yalkowsky, 1992*).

The substance is soluble in most organic solvents.

5.3.3.2 Detected quantities
Eugenol is detected in 4 products. In sample no. 6 was found 18 000 mg/kg equal to 1.8 weight percent. 3 samples held relatively small amounts, - sample no. 4 500 mg/kg, no. 7 380 mg/kg and sample no. 27 830 mg/kg.

5.3.3.3 Function
Eugenol is principally used as a fragrance and flavouring agent, as an analgesic in dental materials and non-prescription drug products, as an insect attractant, and as a chemical intermediate (*IARC, 1985*).

Eugenol is included in INCI as a denaturant, which means that the substance is mostly added to products containing ethanol in order to render them unpalatable.

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

The substance is included in the EU-list of allergenic perfume substances (*SCCNFP, 1999*).

With respect to the Statutory Order on cosmetic products (*Cosmetics, 2006*) it has to be mentioned, that eugenol must be specified on the product contents list, when the concentration of eugenol exceeds

- 0.001% in products which are not cleaned off after use
- 0.01% for products which are cleaned off

5.3.3.5 Health Effects

Acute toxicity
In IARC (1985) data for acute oral intake is given. LD_{50} for rats is 1,930 mg/kg, for mice it is 3000 mg/kg and for guinea pigs it is 2,130 mg/kg. It means that eugenol is slightly harmful by ingestion.

Dogs given oral doses of 0.25 g/kg of eugenol demonstrated vomiting, weakness, lethargy, and ataxia. At 0.5 g/kg eugenol is capable of causing coma and death within 24 hr. The LD_{50} in eugenol in rats has been determined to be 1.8 ml/kg (1.93 g), with post-mortem findings consistent with sudden cardiovascular collapse (*Haddad, 1990*).

No relevant data for irritations caused by skin contact has been found.

Eugenol is one of 8 constituents of a fragrance mix that is used for diagnosing contact allergy to fragrances (*SCCNFP, 1999*). 1.2 percent of a group of test patients had a positive reaction to 1% eugenol. People with eczema from cosmetic products are more likely to react positively with allergic reactions to eugenol.

Sub-chronic toxicity
Some sub-chronic tests are briefly described in Patty's Industrial Hygiene (*Clayton and Clayton, 1981*).

- A test with rats given daily doses of 900 mg/kg b.w. showed minor liver damages. No liver damages were observed in rats fed with 1% eugenol in the diet for about 4 month. Exposure to 0.1 or 1% in the diet to rats for 19 weeks exhibited no effects. No effects were seen in rats fed 79.3 mg/kg per day for 12 weeks. NOAEL is 79.3 mg/kg with liver damages as the critical effect.

- Twenty male rats were given an oral dose of 1.4 gram per kg, gradually increasing to 4 gram per kg. Fifteen of the rats lived long enough to receive maximal dose. Enlargement of liver and adrenal glands were observed.

In a survey of lip care products (*Larsen JR and Holmberg RD, 2005*) it is stated that LOAEL is 960 mg/kg b.w. also based on liver effects.

Chronic toxicity
IARC (1987) has classified eugenol as group 3: The agent is not classifiable as to its carcinogenicity to humans.

In the database Gene-tox, 3 tests are mentioned. One micro-nucleus test was positive. A Sister-chromatid exchange (SCE) *in vitro* showing no conclusion and a Forward and reverse gene mutation, also showed no conclusion. Therefore, the substance has a slight risk of gene-toxic effects.

No other data regarding long-term effects has been found.

Summary
Eugenol is a substance that by skin contact may cause allergy. It may be harmful if swallowed in large quantities. No indications for long-term effects have been seen. NOAEL is estimated to 79 mg/kg b.w. per day based on liver effects. LOAEL is estimated to 960 mg/kg b.w. per day.

5.3.3.6 Exposure scenarios
The maximum content in sample no. 6 was 18,000 mg/kg equal to 18 mg per gram.

Intake per day per kg b.w. = 0.0143 * 18 = 0.26 mg/kg b.w.

The content in sample 27 was 830 mg/kg:

Intake per day per kg. b.w. = 0.01 mg/kg b.w.

It is assumed that the estimated amount can either be ingested or absorbed through skin or membranes.

5.3.3.7 Assessment

Regarding skin contact, the content of 1.8 w% may cause allergy. It is shown that skin contact causes allergic reactions in 1-2 percent of all people. People with eczema from cosmetic products are more sensitive.

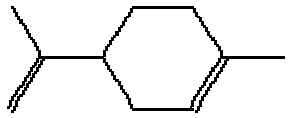
NOAEL for liver damages is 79 mg/kg b.w. which gives a margin of safety of 300 for sample no. 6 and a margin of safety for the other samples of 8,000 or more.

It can be concluded that eugenol may cause allergies by skin contact for sample no. 6. Intake will not cause any major health problems and no long-term effects besides allergies can be expected.

5.3.4 D-Limonene

5.3.4.1 Identity

Name	D-Limonene
CAS-number	5989-27-5
EINECS number	227-813-5
Molecular formula	$C_{10}H_{16}$
Molecular structure	



Molecular weight	136.23
Synonyms	(+)-(4R)-Limonene (+)-4-Isopropenyl-1-methylcyclohexene (+)-Dipentene (+)-Limonene Citrene (+)-alpha-Limonene (+)-p-Mentha-1,8-diene

D-Limonene is a liquid with a fresh citrus odour. The substance has a boiling point of 176°C (*Budavari, 1989*) and a melting point of -74.35°C (*Lide, 1992*).

The vapour pressure is 1.44 mmHg (*Hansen and Eggert, 2003*). Solubility in water is 13.8 mg/litre at 25°C. The partition coefficient Log K_{OW} is measured to 4.57.

5.3.4.2 Detected quantities

D-Limonene was found in 9 products. The largest amount was found in sample 6, where 400 mg/kg equal to 0.04 w% was detected. In two other samples the amount was also relative high, - sample no. 27 150 mg/kg and sample no. 30 220 mg/kg. In sample no. 3, 4, 7, 15 29 and 32 between 5 and 100 mg/kg were detected.

5.3.4.3 Function

D-Limonene is used as a fragrance in cosmetics and as a flavouring agent in food and beverage.

D-Limonene is included in INCI as a fragrance.

5.3.4.4 Classifications and TLV's
D-Limonene is included in the list of dangerous substances and classified as:

R10	Flammable
Xi; R38	Irritant; Irritating to skin.
R43	May cause sensitization by skin contact.
N; R50/53	Dangerous for the environment; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

A general TLV is given for terpenes, 25 ppm equivalent to 140 mg/m^3 (*C.0.1, 2005*). No specific values have been found for d-limonene.

The substance is included in the EU-list of allergenic perfume substances (*SCCNFP, 1999*).

5.3.4.5 Health Effects
D-Limonene is included in IUCLID, but the data sheet consists of relatively few data. The following is based on the data sheet, data bases in TOXNET and two previous survey reports, - one on printed matter (*Hansen OC and Eggert T, 2003*) and one on stain removers (*Engelund et al., 2004*).

Acute toxicity
Data for acute toxicity by ingestion is determined by LD_{50} to more than 4000 mg/kg. This indicates no major potential health risk (*Hansen and Eggert, 2003*).

Oxidisation products of d-limonene are strong allergens. A number of cases of contact allergy from occupational exposures to d-limonene are reported. The frequency of contacts allergy to oxidised limonene is 1-2 % in consecutive eczema patients. The relationship between contact allergy to oxidised d-limonene and fragrances in cosmetic products need to be further examined (*SCCNFP, 1999*).

Chronic toxicity
There is inadequate evidence for carcinogenicity in humans. There is evidence for carcinogenicity in animals, but the mechanism is not relevant for humans. Therefore D-Limonene is not classifiable as to its carcinogenicity to humans (Group 3) (*IARC, 1999*).

Data for NOAEL and LOAEL is included in the report on stain removers (*Engelund et al., 2004*). Data are given for ingestion with liver damage as the critical effect.

NOAEL: 250 mg/kg b.w. per day
LOAEL: 500 mg/kg b.w. per day

The type of test that the data is based upon is not described in the reference.

IUCLID do no provide data for estimating NOAEL or similar threshold limits for ingestion or dermal uptake. The same applies for TOXNET data bases.

Summary
D-Limonene is a substance that by skin contact may cause allergy. It is not harmful by ingestion and there has been found no indication for long-term effects. NOAEL is 250 mg/kg (liver damages) and LOAEL is 500 mg/kg (liver damages).

5.3.4.6 Exposure scenarios
The maximum content in sample no. 6 was 400 mg/kg equal to 0.4 mg per gram.

Intake per day per kg b.w. = 0.0143 * 0.4 = 0.006 mg/kg b.w.

Because of the relative high value of Log K_{OW} (>4) it seems reasonable to expect that not 100% of the substance will be absorbed by skin contact.

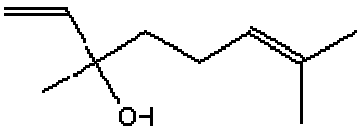
5.3.4.7 Assessment
After oxidation of D-Limonene the substances formed are allergens. The relative low content of d-limonene (0.04 w%) may cause allergy.

NOAEL for liver damages is 250 mg/kg b.w. which gives a margin of safety of more than 4000 for sample no. 6 and higher for the remaining samples.

It can be concluded that D-Limonene might cause allergies by skin contact. It is assumed that the risk is minor because of the relative low concentrations. Intake will not cause any major health problems and no long-term effects besides allergies can be expected.

5.3.5 Linalool

5.3.5.1 Identity

Name	Linalool
CAS-number	78-70-6
EINECS number	201-134-4
Molecular formula	$C_{10}H_{18}O$
Molecular structure	
Molecular weight	154.24
Synonyms	1,6-Octadien-3-ol, 3,7-dimethyl- 2,6-Dimethyl-2,7-octadien-6-ol 2,7-Octadien-6-ol, 2,6-dimethyl- 3,7-Dimethyl-1,6-octadien-3-ol Linalyl alcohol

Linalool has an odour similar to bergamot oil and French lavender. It has a boiling point of 195°C (*Lewis, 1993*). The melting point is less than 25°C.

The partition coefficient Log K_{OW} is 2.97 (*Li J, Perdue EM, 1995*). The water solubility of linalool is 1590 mg/litre (*Yalkowsky and Dannenfelser, 1992*). The vapour pressure is 0.16 mm Hg 25°C (*ChemIDplus*).

5.3.5.2 Detected quantities
Linalool was found in 9 products. The largest amount was found in sample no. 2 and 30, where 1400 mg/kg equal to 0.14 w% was detected. In two other samples the determined amounts were also relative high, - sample no. 6 1200 mg/kg and sample no. 27 1300 mg/kg. In sample no. 4, 7, 15, 29 and 32 between 10 and 100 mg/kg were detected.

5.3.5.3 Function
Linalool is used in perfume, as a synthetic flavouring agent, and modifier in citrus and carbonated beverages and by natural occurrence. The general population can be exposed dermally and by inhalation to linalool through foodstuffs and various household products.

Linalool is included in INCI as a deodorant and additive.

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

The substance is included in the EU-list of allergenic perfume substances (*SCCNFP, 1999*).

With respect to the Statutory Order on cosmetic products (*Cosmetics, 2006*) it shall be mentioned that linalool must be specified on the product declaration, when the concentration of linalool is more than

- 0.001% in products which are not cleaned off after use
- 0.01% for products which are cleaned off

5.3.5.5 Health Effects
For linalool an IUCLID data-set, data in HSDB, CCRIS and ChemIDplus in TOXNET and a description of the substance in Survey of lip care products has been detected (*Larsen & Holmberg, 2005*).

Acute toxicity
Acute oral toxicity for rats, LD_{50} is determined to be between 2,790 and 4,180 mg/kg. For acute dermal toxicity, LD_{50} is more than 5,000 mg/kg (*IUCLID, 2000*).

Linalool is absorbed through the skin and effectively excreted, mainly through the kidneys. A 60 kg man was massaged 10 minutes with lavender oil (amount not given) at a 376 cm^2 skin area resulted in a calculated absorption of 7.24 mg linalool. After 5 minutes linalool was detected in the blood and after 20 minutes the concentration was 211ng/ml. After 90 minutes no linalool was detected in the blood stream (*IUCLID, 2000*).

In IUCLID several tests for skin irritation were reported - some positive and some negative. Reported tests for eye irritation showed no irritation.

Linalool was evaluated for primary dermal irritation (*Rhone-Poulenc Inc, 1992*). The test substance was applied (0.5 ml) to the occluded-shaved skin of 6 New Zealand white rabbits per concentration at 100%; 30%; 10%; or 3% for 24 hours. The test substance was slightly irritating at 100% and 30%; and no irritation was noted at 10% and 3%. Linalool was also evaluated for primary eye irritation. The test substance was applied (0.1 ml) to the conjunctive sac of 6 New Zealand white rabbits per concentration at 100%; 30%; 10%; or 3%.

Irritation was moderate at 100%, slightly at 30%; very slightly at 10%; and no irritation at 3%.

Linalool is a potential allergen. One study with one case and one study with 3 cases of contact allergy to linalool were found among patients with eczema from cosmetic products (*SCCNFP, 1999*).

Chronic toxicity
In the survey of lip care products (*Larsen & Holmberg, 2005*), a description of tests based on repeated exposure is given. The main results from this description are:

- Oral exposure of 500 mg/kg b.w. per day and more led to enzyme changes in liver and increased liver weight.
- A NOAEL of 50 mg/kg b.w. per day is based on a 90 day oral exposure study with rats. Reduced food intake and growth was observed. These effects were attributed to poor tasting food.
- A 13 week dermal exposure study with rats established a NOAEL of 250 mg/kg b.w. per day with effects such as momentary blushing and reduced activity as critical effects.
- A study with mice exposed orally 5 days with 375 mg/kg b.w. per day no effects were observed.
- Linalool has been stated as possibly having effects on the liver in humans at chronic or repeated exposure.
- No data for mutagenicity or other long-term effects has been found.

Summary
Linalool may be irritating by skin and eye contact and the substance causes allergy. NOAEL is 50 mg/kg b.w. per day with liver damage as the critical effect. No data for other long-term effects has been found.

5.3.5.6 Exposure scenarios
The maximum content in sample no. 2 and 30 was 1,400 mg/kg equal to 1.4 mg per gram.

Intake per day per kg b.w. = 0.0143 * 1.4 = 0.02 mg/kg b.w.

It is assumed that the estimated amount can either be ingested or absorbed through skin or membranes.

5.3.5.7 Assessment
The concentrations vary from 0.001 w% to 0.14 w% and there is a potential risk for allergy, - especially for the highest concentrations.

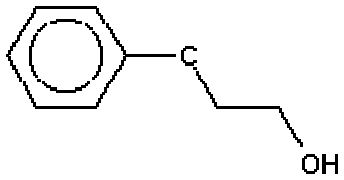
It is not expected that the amounts of linalool detected will cause irritations.

NOAEL for liver damages is 50 mg/kg b.w., which gives a marginal of safety of more than 2,500 for sample no. 2 and 30 and higher for the other samples.

5.3.6 2-Phenoxyethanol

5.3.6.1 Identity

Name	2-Phenoxyethanol
CAS-number	122-99-6
EINECS number	204-589-7

Molecular formula	$C_8H_{10}O_2$
Molecular structure	
Molecular weight	138.16
Synonyms	Hydroxy-2-phenoxyethane 2-Fenoxyethanol 2-Hydroxyethyl phenyl ether 2-Phenoxyethanol 2-Phenoxyethyl alcohol Ethylene glycol phenyl ether Arosol Dowanol EP Dowanol EPH EGMPE

The substance 2-phenoxyethanol is a colourless liquid with a faint aromatic odour. Boiling point is 245.2°C and melting point is 14°C (*Budavari, 1989*)

The partition coefficient Log K_{OW} is measured to 1.16 (*Leo, 1985*). 2-phenoxyethanol is freely soluble in alcohol, ether and sodium hydroxide. The solubility in water is 26.7 gram per litre (*Budavari, 1989*).

The vapour pressure for 2-phenoxyethanol is measured to be 0.07 mm Hg at 25°C (*Dow Chem Co, 1990*).

5.3.6.2 Detected quantities

2-Phenoxyethanol was found in 9 products. The largest amount was found in sample 24, where 100,000 mg/kg equal to 10 w% was detected.

Sample no. 8, 11, 12 and 13 consists of 5-8,000 mg/kg equal to 0.5 to 0.8 w%. Sample no. 1, 2 and 23 consists of 1-2,500 mg/kg equal to 0.1 to 0.25 w%. For sample no. 18 only 61 mg/kg was detected.

5.3.6.3 Function

2-Phenoxyethanol is used for a number of purposes. It is common as fixative for perfumes, as solvent for inks, textile dye carrier and as bactericide.

The substance is included in INCI as a preservative and can as a preservative be used in concentrations up to 1 percent in cosmetics.

5.3.6.4 Classifications and TLV's

2-Phenoxyethanol is included on the list of dangerous substances and classified as:
Xn;R22 Harmful; Harmful if swallowed.
Xi;R36 Irritating; Irritating to eyes.

With respect to the Statutory Order on cosmetic products (*Cosmetics, 2006*) it can be used as a preservative in up to 1 percent. It can also be used with

others functions than preservation in cosmetics if the purpose is stated on the product.

5.3.6.5 Health Effects

For 2-Phenoxyethanol an IUCLID data-sheet is found, data in TOXNET and a description of the substance in Screening for health effects from chemical substances in textile colorants (*Hansen OC, 2005*).

Acute toxicity

In IUCLID a number of tests with rats where LD_{50} by oral exposure was determined have been reported. The data range is between 1,200 mg/kg and 5,500 mg/kg. By dermal exposure LD_{50} was determined to 2,300 mg/kg and up to more than 10,000 mg/kg.

Several negative tests for skin irritation on animals are reported (*IUCLID, 2000*). Also a 3 week patch-test on humans did not cause irritations. Test on rabbits showed eye irritation. Several tests for sensitizing were reported, - all with a negative result.

Sub-chronic toxicity

Several sub-chronic studies are reported in IUCLID. Some of these are briefly referred in the following:

- In a 13 week study with rats orally exposed NOAEL was determined to 200 mg/kg b.w. per day based on changes in blood parameters and weight loss.
- In another 13 week study with rats orally exposed NOAEL was determined to 80 mg/kg b.w. per day based on kidney damages.
- A 13 week study with dermal exposure to rabbits showed no adverse effects at the doses 50, 150 and 500 mg/kg per day. NOAEL was determined to be 500 mg per kg b.w. per day.

Chronic toxicity

- determined to be 500 mg per kg b.w. per day.

Chronic toxicity

Pregnant New Zealand white rabbits were treated dermally with 300, 600, or 1,000 mg/kg/day of undiluted 2-phenoxyethanol on days 6 through 18 of gestation (25 animals per dose group). 2-Phenoxyethanol was toxic to the dams (maternal death) at the 600 and 1,000 mg/kg doses. No adverse effects on pregnancy rate, resorptions, or foetal body measurements were observed at any dose. 2-Phenoxyethanol did not cause malformations in the foetuses as compared with controls (*Scortichini et al., 1987*).

2-Phenoxyethanol was tested for reproductive toxicity in Swiss CD-1 mice in a 2 generation test. The dose levels were 0.0, 0.25, 1.25, 2.5% in feed equal to 0, 375, 1875 and 3700 mg/kg/day. 2-Phenoxyethanol produced significant reproductive and developmental toxicity. Liver weight increased in treated F0 mice. The substance caused significant toxicity in growing animals, as evidenced by the reduced body weight in neonates and the large increase in post-natal lethality as the F1 animals grew to the age of mating (*Department of Health & Human Services, 1984*).

Teratogenicity was evaluated in pregnant New Zealand White rabbits. They were (25/group) dermally exposed to 2-phenoxyethanol at treatment levels of

0, 300, 600, and 1000 mg/kg/day on gestation days (GD) 6-18. Surviving animals were sacrificed on GD 28. Significant differences were observed between treated and control animals in the following: slight to moderate reddening of the skin at the application site (all treated animals), maternal mortality with dead animals exhibiting kidney damages, evidence of anorexia, changes in the gastric mucosa, decreased feed and fecal material in the intestines as well as changes in the blood parameters (high- and mid-dose groups). No significant differences were observed between treated and control animals in the following (mid- and low-dose groups) unless otherwise noted. No statistical evaluations were performed on the five high-dose groups of rabbits which survived until GD 28 (*Dow Chemicals, 1984*).

Summary
The substance will cause irritation by eye contact and may be harmful when ingested. NOAEL based on oral intake was determined to be 80 mg per kg b.w. per day based on kidney damages. Test showed reproductive and developmental effects in long-term studies with dermal exposure.

5.3.6.6 Exposure scenarios
The maximum content in sample no. 24 was 100,000 mg/kg equal to 100 mg per gram.

Intake per day per kg b.w. = 0.0143 * 100 = 1.43 mg/kg b.w.

For the sample no. 8, 11, 12 and 13 with of 5-8.000 mg/kg equal to 0.5 to 0.8 w% the intake per day will be 0.07 to 0.1 mg/kg b.w. per day.

It is assumed that the estimated amount can either be ingested or absorbed through skin or membranes.

5.3.6.7 Assessment
One sample contains 10 percent 2-phenoxyethanol, would be prohibited according to the Statutory Order on cosmetics.

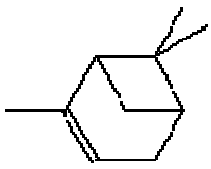
Compared with NOAEL of 80 mg/kg b.w. per day for kidney damages for sample no. 24 it results in a margin of safety of 56 and for the other samples of at least 800. The assessments shows that there might be a heath risk for product 24.

Besides sample no. 24 it is assessed that the content of 2-phenoxyethanol will cause no or minor health problems.

5.3.7 α-Pinene

5.3.7.1 Identity

Name	α-Pinene
CAS-number	80-56-8
EINECS number	201-291-9
Molecular formula	$C_{10}H_{16}$
Molecular structure	



Molecular weight	136.24
Synonyms	2-Pinene 2,6,6-Trimethylbicyclo(3.1.1)-2-hept-2-ene 2,6,6-Trimethylbicyclo(3.1.1)hept-2-ene 4,6,6-Trimethylbicyklo(3,1,1)hept-3-en Bicyclo(3.1.1)hept-2-ene, 2,6,6-trimethyl Acintene A Monoterpenes

α-Pinene is a colourless liquid with a characteristic odour of pine. The boiling point is 156°C and melting point is -62.5°C (*Fenaroli, 1975*).

Log K_{OW} for α-Pinene is determined to 4.83 (*Li and Perdue, 1995*).
The solubility of the substance in water is 2.49 gram/l at 25°C. α-Pinene is soluble in alcohol, chloroform, ether and concentrated acetic acid. It is almost insoluble in propylene glycol and glycerine (*Fenaroli, 1975*).

The vapour pressure of α-Pinene is 4.75 mm Hg at 25°C (*Daubert and Danner, 1989*).

5.3.7.2 Detected quantities
α-Pinene was detected in two samples, sample no. 5, where 260 mg/kg was found and sample no. 21, where 560 mg/kg was found.

5.3.7.3 Function
α -Pinene has many functions and is widely used. Common uses are as solvent, emollient, in pesticides as base for synthetic oils and perfumes

The substance is included in INCI as a fragrance.

5.3.7.4 Classifications and TLV's
α-Pinene is not classified in the Annex I of Directive 67/548/EEC. The substance is included in the Danish advisory list for classification (*Vejledende liste, 2001*) with the classification:

R43	May cause sensitization by skin contact.
N;R50/53	Dangerous for the environment; Very toxic to aquatic organisms, may cause long-term adverse effects in aquatic environments.

No TLV are given for α-Pinene. For terpenes in general like turpentine TLV in Denmark is 140 mg/m^3 or 25 ppm (C.0.1, 2005). In USA TLV as a 8 hr Time Weighted Avg (TWA) is set to 20 ppm (*ACGIH, 2003*).

5.3.7.5 Health Effects
Data for α-Pinene is relatively limited. The following is based on a data set from IUCLID, the databases in TOXNET and a general search at the internet. A general search of terpenes is also included.

Acute toxicity
Acute oral toxicity has been tested in studies with rats, which showed LD_{50} of 2,100 mg/kg and up to 5,100 mg/kg. Dermal toxicity based on test with rabbits showed results of LD_{50} of more than 5,000 mg/kg (*IUCLID*).

α-Pinene has essentially the same toxicity as turpentine *(Gosselin et al., 1984).* Fatal dose for humans is about 180 gram orally as turpentine, which contains 58-65% α-Pinene (*The Merck Index, 1976*).

It is mentioned that α-Pinene irritates skin and mucous membranes and cause skin eruption and irritation of the respiratory system (*Budavari, 1989*). In IUCLID it is mentioned some tests on rabbits, mice and rats, where some were positive and some negative. A patch test on 5 humans tested with 10% α-Pinene in petrolatum for 48 hours showed no effects.

In IUCLID a test of eye irritation with the result "moderate irritation" is described. Another source states that α-Pinene is an eye, mucous membrane, and severe human skin irritant (*Lewis, 1996*).

Several tests on sensitizing on humans have been reported (*IUCLID, 2000*). Most of the patch tests showed that several people reacted positive. Turpentine oil, which normally has a high content of α-Pinene is labelled R43: May cause sensitization by skin contact.

Sub-chronic toxicity
In a 14 day test rats were orally exposed daily with 0, 250 and 500 mg/kg. In the group exposed to 500 mg per kg reduced body weight and increased weight of liver was observed.

No relevant data for turpentine oil were found.

Chronic toxicity
No data on chronic toxicity for α-Pinene were found.

From OSHA's Health Guidelines (2005) the following information has been retrieved for turpentine and it is assumed to be valid for α-Pinene as well.

- In one study, dermal application of turpentine produced skin tumours in rabbits but not in mice. In another experiment, however, painting the skin of mice with 240 g/kg turpentine did cause tumours
- Turpentine is a skin, eye, mucous membrane, and upper respiratory tract irritant in humans. It may also cause skin sensitization and central nervous system, gastrointestinal, and urinary tract effects. The lowest estimated oral dose reported to be lethal in humans is 441 mg/kg.
- A case-control study of workers in particle-board, plywood, sawmills, and formaldehyde glue factories demonstrated a statistically significant association between chronic exposure (longer than 5 years) to terpenes (the principal component of turpentine) and the development of respiratory tract cancers.

Summary
α-Pinene causes irritation by skin and eye contact and may cause allergies by skin contact.

Data on long-term effects are very limited and risk of cancer and other longterm effects from skin contact and ingestion are very uncertain.

Based on the one sub-chronic test NOAEL is determined to be 250 mg/kg with increased liver weight as the critical effect.

5.3.7.6 Exposure scenarios

The maximum content in sample no. 30 was 560 mg/kg equal to 0.56 mg per gram.

Intake per day per kg b.w. = 0.0143 * 0.56 = 0.008 mg/kg b.w.

5.3.7.7 Assessment

In two samples, no. 65 and 30, the contain of α-Pinene is less than 0.06 percent. α-Pinene is a potential skin sensitizer and therefore there is a minor risk of allergic reaction when contact with the two products.

NOAEL is estimated to 250 mg/kg based on limited data for increased liver weight.

The marginal of safety is more than 30,000. Despite the limited data the MOS is acceptable and it can be concluded that the risk for uptake of the substance is minimal.

5.4 Overall Assessment

5.4.1 Substances

In the following an overview of the assessments of the substances in section 5.3 is given. Data in the tables are given for the sample with the highest determined concentration of the actual substance.

Table 5.1 Irritation and allergy effects for selected substances in pleasure-gels

	Max conc. W%	Sample no.	MOS	Irritation to skin and eyes	Sensitization by skin contact	Remarks
Camphor	0.09	6	>50,000	May cause an effect	May cause an effect	No risk of irritation and minor risk of sensitization based on the actual concentrations.
Cinnamaldehyde	1.7	6	>500	May cause an effect	May cause an effect	Risk of irritation and of sensitization at the actual concentrations.
Eugenol	1.8	6	300	No data	May cause an effect	Risk of sensitization at the actual concentrations.
D-Limonene	0.04	6	>4,000	No data	May cause an effect	Minor risk of sensitization at the actual concentrations.
Linalool	0.14	2,30	>2,500	May cause an effect	May cause an effect	No risk of irritation and risk of sensitization based on the actual concentrations.
2-phenoxyethanol	10.0	24	>56	May cause an effect	No effect	Risk of irritation
α-Pinene	0.056	30	>30,000	May cause an effect	May cause an effect	No risk of irritation and minor risk of sensitization based on the actual concentrations.

From Table 5.1 can be seen that one sample contained an extreme high amount of 2-phenoxyethanol. The sample contained 10% - according to the Statutory Order on cosmetics only 1% is allowed. Other samples contained less than 1% of the substance.

Most of the selected substances can cause sensitization to skin almost at all levels of concentration.

Table 5.2 Toxic effects for selected substances in pleasure-gels

Substance	Max Uptake Mg per kg b.w.	Sample no.	NOAEL Mg/kg b.w. per day	MOS	Remarks
Camphor	0.013	6	680	>50,000	No risk of health effects.
Cinnamaldehyde	0.243	6	5	>500	Minor risk of health effects from sample no 6 (reprotox).
Eugenol	0.260	6	79	300	Minor risk of health effects for sample 6 (liver damage).
D-Limonene	0.006	6	250	>4,000	Small risk of health effects (liver damage).
Linalool	0.020	2,30	50	>2,500	Small risk of health effects (liver damage).
2-phenoxyethanol	1.430	24	80	>56	Major risk of health effects for product no. 24 (kidney damage).
α-Pinene	0.008	30	250	>30,000	No risk of health effects.

From Table 5.2 it also can be seen that the amount of 2-phenoxyethanol in sample no. 24 is very high. The effects seen are kidney damages.

In sample no. 6 a relatively high content of eugenol (18g/kg) is found and for the other 3 samples the content is max. 0.8 g/kg. The critical effect for eugenol is liver damages.

5.4.2 Products

Among the 22 test products one product should be classified and labelled according to the Statutory Order on classification. Further, for 5 products a marking is required with a sentence specifying that an allergic reaction can arise as specified in appendix 2 point 2.13 of the statutory order on classification.

The Statutory Order on cosmetics does not regulate pleasure-gels. If pleasure-gels were covered by the Statutory Order certain requirements for declaration of ingredients should be met as well as observing restrictions on certain substances. If the Statutory Order were in force the following were found:

- The declaration for 8 out of 22 products were insufficient
- Too much of the preservative 2-phenoxy-ethanol was found in one product

With respect to irritation this effect is seen for camphor and 2-phenoxyethanol. The amounts of camphor are so limited that there is no risk of this effect for any of the products. With respect to 2-phenoxyethanol it will cause risk of irritation in product number 24.

The substances Cinnamaldehyde, eugenol, d-limonene and linalool can cause sensitization by skin contact. In general there is no lower limit for risk of sensitization and therefore all products, where the substances are found will be potential sensitizers. The products for which this is particular relevant is:

- Product no. 2
- Product no. 4
- Product no. 6
- Product no. 27
- Product no. 30

With respect to the toxic effects for the selected substances especially eugenol and 2-phenoxyethanol are problematic. For both substances the margin of safety is determined to be less than 1000. For eugenol there is a minor potential health risk for product number 6. For 2-phenoxyethanol, there is a potential health risk for product number 24.

Conclusion

Product no. 24 is identified as giving a potential health risk (kidney damage) by oral intake or intake through the skin due to the content of phenoxyethanol .

Several products contain substances that may cause sensitization by skin contact and about 25% of the tested products contain a relatively large amount of these substances (products no.2, 4, 6, 27 and 30).

According to the Statutory Order on classification, all products containing more than 0.1% of a substance classified or estimated to be sensitizing (allergy-causing) have to be marked with "Contains (substance). Allergic reaction can arise".

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