

Survey of lip care products with fragrance and flavour

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Table of contents

TABLE OF CONTENTS	3
1 SUMMARY	5
2 DANSK RESUMÉ	7
3 PREFACE	9
4 PURPOSE	11
5 SURVEY RESULTS	13
5.1 SELECTION OF PRODUCTS	13
5.1.1 Definition of lip care products	13
5.1.2 Product purchase	13
5.1.3 Products	14
5.2 SALE	15
5.2.1 Sale of lip care products in Denmark	15
5.2.2 Product types	16
5.2.3 Target groups and marketing	18
5.2.4 Labelling and regulation	19
5.2.5 Overview	20
5.3 INGREDIENTS	21
5.3.1 Perfume	21
5.3.2 Pigments	23
6 ANALYSES	25
6.1 FRAGRANCES	25
6.2 ANALYTICAL METHODS	25
6.2.1 Methyl eugenol	25
6.2.2 Fragrances	25
6.3 RESULTS	26
6.3.1 Methyl eugenol	26
6.3.2 Fragrances	26
6.4 SUMMARY OF ANALYTICAL RESULTS	29
6.5 SELECTION OF SUBSTANCES FOR HEALTH ASSESSMENT	31
7 OILS AND FATS	32
7.1 OILS AND FATS	32
7.2 MINERAL-BASED OIL AND FATS	35
7.2.1 Mineral-based oils and fats in lip care products	35
7.2.2 Investigation of the hydrocarbon composition	36
7.2.3 Assessment of the safety	37
8 HEALTH ASSESSMENT	38
8.1 LINALOOL	38
7.2 GERANIOL	41
7.3 BENZYL BENZOATE	43
7.4 EUGENOL	45
8.5 METHYL EUGENOL	47

9	EXPOSURE ASSESSMENT	50
9.1	EXPOSURE CALCULATIONS	50
9.2	EXPOSURE ASSESSMENT OF THE SELECTED SUBSTANCES	53
10	SUMMARY AND CONCLUSION	55
	REFERENCES	57
	APPENDIX 1. NATURAL OCCURRENCE AND USE	61
	APPENDIX 2. ANALYTICAL RESULTS	63

1 Summary

In the spring of 2004, DTC chose a selection of 109 lip care products representative of lip care products on the Danish market. Approximately 46% of the products are marketed to children and approx. 78% to both children and the young. Coloured and scented products are seen particularly among products for children; 96% of the products for this target group are coloured and 92% contain perfume. A total of 86% of the purchased products contain perfume.

The analytical results of 20 lip care products, selected among the 109 products, with target groups children, the young or adults show that 19 of the 20 analysed products (95%) contain one or more sensitizing fragrances, and two out of three products (67%) selected for analysis of methyl eugenol contain this substance.

Exposure scenarios for two standard persons have been calculated for all 27 fragrances, and health assessments have been made for the substances linalool, geraniol, benzyl benzoate, eugenol and methyl eugenol. Although the exposure calculations show low daily exposure when using lip care products, it should be pointed out that as there is no lower concentration limit for the substances' ability to elicit sensitizing effects, exposure pose a risk of developing allergy in particular sensitive persons, including children, from products with a high content of fragrances. This is emphasised by the fact that obligation of labelling has been determined by the EU for these fragrances above a certain concentration limit in the finished product, and that several of the products contain sensitizing fragrances which by March 2005 must be stated on the products' INCI declarations according to the legislation on cosmetic products.

As it is not immediately possible to estimate the concentration and content of the sensitizing fragrances in a product, nor by smelling the product, the coming declaration of contents will provide consumers with the opportunity to obtain this information.

Based on the products' INCI declarations, oils and fats used in the products have also been examined. Oils and fats are classified according to whether they are made from oil/coal (mineral) or extracted from plants or animals. Based on the exposure scenarios and literature data, it is assessed that there are no health hazards when using mineral oils and fats in lip care products.

2 Dansk resumé

DTC har udtaget et repræsentativt udvalg på 109 læbeplejeprodukter i foråret 2004. Ca. 46 % af produkterne er markedsført til børn, og produkter markedsført til både børn og unge udgør ca. 78 %. De farvede og parfumerede produkter ses især hos børneprodukterne, hvor 96 % af målgruppens produkter er farvede og 92 % af målgruppens produkter indeholder parfume. Totalt er 86 % af de indkøbte produkter tilsat parfume.

Resultater af analyser af 20 læbeplejeprodukter med målgruppe børn, unge eller voksne udvalgt blandt de 109 viser, at 19 af de 20 analyserede produkter (95 %) indeholder en eller flere allergifremkaldende parfumestoffer, og to af de tre produkter (67 %) udvalgt og analyseret for methyleugenol indeholder stoffet.

Der er udregnet eksponeringsscenarier for to standardpersoner for alle 27 parfumestoffer, og opstillet sundhedsmæssige vurderinger for stofferne linalool, geraniol, benzyl benzoat, eugenol og methyleugenol. På trods af at eksponeringsberegningerne viser en lav daglig eksponering ved brug af læbeplejeprodukterne påpeges det, at da der ingen nedre koncentrationsgrænse er for stoffers evne til at virke sensibiliserende, kan der for de produkter, hvor der er fundet højt indhold af parfumestoffer, være risiko for udvikling af allergi hos særligt følsomme personer, herunder børn. Dette understreges af, at EU har fastlagt deklarationspligt for disse parfumestoffer over en bestemt koncentrationsgrænse i det færdige produkt, og at flere af produkterne har et indhold af allergifremkaldende parfumestoffer, der fra marts 2005 medfører pligt til at deklarere stofferne i INCI-indholdsdeklarationen ifølge kosmetikbekendtgørelsen.

Da det ikke umiddelbart er muligt at bedømme koncentrationen og indhold af de enkelte allergifremkaldende parfumestoffer i et produkt, heller ikke ved at lugte til det, vil den fremtidige indholdsdeklarering give forbrugeren mulighed for at få denne oplysning.

Ud fra produkternes INCI-indholdsstofdeklarationer er det desuden undersøgt, hvilke typer fedtstoffer, der anvendes i denne type produkter. Fedtstofferne er inddelt efter, om de er fremstillet ud fra olie/kul (mineralske) eller udvundet fra planter eller dyr. På baggrund af opstillede eksponeringsscenarier og data fra litteraturen vurderes de anvendte mineralske fedtstoffer ikke at være sundhedsmæssigt betænkelige ved anvendelse i læbeplejeprodukter.

3 Preface

There is a wide range of lip balms, lip salves, lipglosses, lipsticks, etc. The products are available in different colours, sheens, flavours and fragrances and appeal to different age groups, including children and the young. Product variants are common. In general, the use of fragrance in cosmetics, toys and school accessories is widespread. In a survey carried out by the Danish Information Centre on Health and Environment in March 2004, three different toys with fragrance and two scented children's cosmetics were tested for content of allergenic fragrances. All products contained at least one allergenic fragrance (1).

As attention is increasingly directed to children's sensitivity in using cosmetics, the Danish Environmental Protection Agency wants a survey of the presence of allergenic fragrances in cosmetics to children. As far as possible, the survey will provide information on the age group to which the products appeal.

Fragrance and flavour compounds used in cosmetic products must not be hazardous to the user's health and safety. Users are exposed to ingredients in lip care products through skin contact and consumption. The opinion is that consumers are exposed increasingly to fragrances and flavour chemicals and that a growing number of consumers experience health problems caused by fragrance allergy. In an allergy survey in Copenhagen carried out at an interval of 8 years, the occurrence of contact allergy as a result of exposure to cosmetic-related allergens rose from 2.4% in 1990 to 5.8% in 1998. The increase is primarily owing to an increase in the number of women reacting positively to Fragrance Mix which is used to diagnose fragrance allergy (2). A survey carried out at with an interval of 12 years showed that after nickel, fragrance compounds are the second-most cause of contact allergy among Danish patients with eczema (3).

The EU Scientific Committee on Cosmetic products and Non-food Products Intended for Consumers (SCCNFP) has estimated 26 different fragrance compounds as sensitizing. These fragrance compounds will shortly be entered on annex 3 of the cosmetics legislation demanding that the substances are stated on the declaration of contents when a specified content is exceeded in leave-on and rinse-off products.

To get a general view of the pigments, fragrance compounds and flavours used in lip care products today, the Danish Toxicology Centre has carried out a survey of the Danish market. The survey includes an assessment of possible health risks to the users, including children.

Based on the products' INCI declarations, oils and fats used in the products have also been examined. Oils and fats are classified according to whether they are made of oil/coal (mineral) or extracted from plants or animals and then sorted according to how frequently they are used. Particularly beeswax and castor oil are used in lip care products, but also vaseline is common. Subsequently, the health effects of vaseline and other oils and fats made of oil/coal have been investigated.

4 Purpose

The purpose of the project on survey and health assessment of chemical substances in lip care products with fragrances, flavours, etc. is

1. To survey the market of lip care products with fragrances, flavours and pigments and to analyse the age groups to which the products are aimed.
2. To examine which fragrances, flavours and pigments are used in lip care products and to get a health assessment of selected fragrances according to their use in cosmetics, particularly considering that children use these products.
3. To examine which types of oils and fats (paraffin oils, mineral oils, vegetable oils, etc.) are used in the products, including the quality of the oils and fats.

5 Survey Results

5.1 Selection of products

Lip care products cover a wide range of products marketed in retail outlets and on Danish websites. The main focus of this survey is on products to children and products claimed to have lip care effects. Consequently, make-up products such as lipsticks and lipglosses are excluded as their main purpose is cosmetic, i.e. to give colourful and shiny lips. Furthermore, sun protection sticks are excluded as they are regarded as sun products.

5.1.1 Definition of lip care products

In this survey lip care products are defined as products for application on the lips with the purpose to provide care for the lips and protect them from external influence such as wind, cold weather, etc.

Lip care products include lip salve, lip balm, lip butter, lip cream and lip nectar.

5.1.2 Product purchase

5.1.2.1 Selection criteria and purchase

The purpose of purchasing lip care products is to identify and survey the product range on the Danish market. Focus is on products to children and the young but in order to get a broad picture of the market, products marketed for adults were included. Prior to purchase, selection criteria were laid down due to the wide range of lip care products for sale in retail outlets. The all-important criterion was a **lip care effect** (lip care, lip balm, etc.). Next, products were selected if their colour, packaging and fragrance appealed to children and the young, but also products with a more exclusive appearance without specific information on fragrance appealing to adults.

Sun sticks, primarily intended to protect against UV light, and lipgloss products with and without colour were not selected unless it appeared from the labelling or the packaging that the product has a lip care effect.

Richly coloured products or products with a powerful fragrance and with a special appeal to children and the young were purchased in all colour and fragrance variants whether it was stated that the products had a lip caring effect or just a gloss effect. Concerning products for adults, individual assessment determined whether it was necessary to purchase all colour variants or to just make a note of these.

On the basis of the above criteria, the selected lip care products are believed to be representative of the Danish market in the spring of 2004.

4.1.2.2. Shop visit

Flere typer af butikker i detailhandlen er blevet besøgt og det blev vurderet, at de indkøbte produkter reflekterer det generelle udbud på det danske marked.

Several types of shops were visited and the bought-in products are believed to reflect the general supply on the Danish market.

4.1.2.3. Internet

An Internet search on Danish websites was performed in the spring of 2004 via Google. The search was carried out for the following words: "læbepleje", "lipgloss", "kosmetik", "læber" and "pleje". The search gave references both to well-known brands and to smaller suppliers. Lip care products have not been purchased on the Internet for this survey, as the products were not considerably different to the products purchased in shops.

5.1.3 Products

A total of 109 products were purchased in the 10 shops.

There is a wide range of products available on the market in 2004, ranging from simple products consisting of a few substances, e.g. vaseline, to more sophisticated products composed of several substances including a complex base of fats and oils, and from colourless and unscented products to richly coloured products in gaily coloured packaging containing glitter, mother-of-pearl, pigments, fragrances and flavours.

5.1.3.1 Prices

Product prices were registered on purchase. The price per kilo is calculated on the basis of the retail price and stated volume of contents. Prices range widely from DKK 10 for the lowest-priced product to DKK 265 for the most expensive product. When recalculating this to prices per kilo, prices range from DKK 1,595 for the lowest-priced product to DKK 17,778 for the most expensive product. Price ranges and average market prices are shown in table 4.1. The average market price per kilo product is based on 99 products, as volume of contents was not stated on 10 of the products in the survey or the product was part of a cosmetic kit for which it was not possible to calculate a price per kilo.

Table 4.1. The lowest-priced products and most expensive products in the survey. The lowest and most expensive kilo prices are calculated on the basis of purchase price and volume of contents stated on the product.

Price	Single product (DKK)	Average price (DKK)
Lowest price/product	10	40.15*
Highest price/product	265	
Lowest price/kilo	1,595	5358.15**
Highest price/kilo	17,778	

* The average market price/product is based on 109 products.

** The average market price/kilo is based on 99 products.

5.2 Sale

To estimate the consumption of lip care products in Denmark, information on sale of lip balms from the marketing research institute ACNielsen AIM has been used.

ACNielsen AIM defines lip balms as "lip balm intended for protection of lips against frost, dryness and sun", and this definition includes the product types stick, tube, roll on, and with factor/without factor. Lipsticks, lipglosses and vaseline are not included.

ACNielsen's product group "lip balm" corresponds to the product specifications in this project and the sales figures are estimated as indicative for the sale in Denmark. Some sales figures from speciality shops and actors on the groceries market are not included. Although this project does not include sun sticks, a large number of the purchased products have a sun protection factor (SPF), but it is estimated that sun sticks will not result in large deviations in the reported figures when comparing with this project.

5.2.1 Sale of lip care products in Denmark

The sales figures comprise the grocery trade (Coop and Aldi exclusive) and Matas and Magasin. Speciality shops such as The Body Shop are not included, nor are sales figures from Illum. The received sales figures give information on sale in value and sale in numbers for the total sale of lip salves as well as specification of the three largest brands (a total figure is given for all three brands). The sales figures are estimated from week 38 in 2002 to week 38 in 2004 inclusive. Week 38 has been chosen in order to include as much of the consumption in 2004 as possible. The sales figures can be seen in table 4.2.

Table 4.2. Sales figures on lip salves in Denmark for the period week 38, 2002 to week 38, 2004 inclusive.

Sale of lip salves in Denmark	Week 38, 2002	Week 38, 2004	Increase, %
The grocery trade (Coop and Aldi exclusive)			
Total sale in 1000 DKK	15.076,9	19.834,1	32
Total sale in 100 bar codes	8.864,0	11.009,1	24
Total sale in 100 units	14.858,6	17.990,8	21
Matas/Magasin			
Total sale in 1000 DKK	7.692,5	9.942,1	29
Total sale in 100 bar codes	3.892,5	4.565,6	17
Total sale in 100 units	5.265,2	6.697,2	27
Total sale			
Total sale in 1000 DKK	22.769,4	29.776,2	31
Total sale in 100 bar codes	12.756,5	15.574,7	22
Total sale in 100 units	20.123,8	24.668,0	23

The total sale of lip salves from week 38 in 2003 to week 38 in 2004 has been estimated at nearly DKK 30 million and covers a sale of nearly 2.5 million lip salves. If the sale is estimated in number of bar codes sold the sale is just over 1.5 million as there are often more units per bar code.

As can be seen from table 4.2 a significant increase of approx. 30% has taken place in the sale of lip salves over two year. This increase is evident both for the total sale and for the two sales areas comprised by the survey. The increase in sales estimated in pieces or bar codes shows a constant increase of twenty-odd percentage point.

The prices in table 4.3 are reached by calculating the average market price for lip salves in 2002 and in 2004 based on the informed figures. As can be seen from the table, an increase in the sale from 2002-2004 in general has resulted in a price development of up to 10% for this product category.

Table 4.3. Development of the average price for lip salves from week 38, 2002 to week 38, 2004 inclusive.

Lip salve prices in Danish kroner (DKK)	Week 38, 2002	Week 38, 2004	Increase, %
The grocery trade (Coop and Aldi exclusive)			
Average price per bar code sold	17 DKK	18 DKK	6
Average price apiece sold	10 DKK	11 DKK	10
Matas/Magasin			
Average price per bar code sold	20 DKK	22 DKK	10
Average price apiece sold	15 DKK	15 DKK	0
Total sale			
Average price per bar code sold	18 DKK	19 DKK	6
Average price apiece sold	11 DKK	12 DKK	9

The three largest brands have a market share of 97% in the grocery trade and 66% in Matas/Magasin. This suggests a larger selection of lip salves/lip care products in Matas and Magasin, e.g. products in the form of toys for children. Only one of the three largest brands is identical for the grocery trade and Matas/Magasin.

However, it should be mentioned that a comparison of the stated average prices (table 4.3) with the prices estimated for the purchased projects (table 4.1) gives a price difference of DKK 28 per product. Based on the information on the three largest brands, it can be concluded that very expensive products from well-established perfume houses, comprised by and bought for this project, are not included in the ACNielsen figures. In the light of the wide selection of lip care products in the shops and the fact that the products are called something else than lip salve (e.g. balm, cream, etc.), a demand for these products is assumed. However, it is not possible to estimate the size of the sale, as we have not had access to this information.

5.2.2 Product types

The 109 products were grouped in four different types according to packaging: stick, tube, roll-on and cans/jars. The types are described below. Distribution of the products according to type appears from table 4.5.

5.2.2.1 Sticks in case with screw

This group covers the majority of the purchased lip care products for children, the young and adults alike.

Packaging and appearance:

Products in this group are traditional lip salve sticks. The product is solid at room temperature and is packed in a case with removable cap and a bottom screw that gradually pushes the stick up as it is being used.

Colour and perfume:

Products come both with and without pigment and perfume.

Oils and fats:

These products contain fats whose melting point is higher than the application temperature. The stick may be damaged and no longer be homogeneous when stored at high temperatures for a long time (4).

Application:

The product is applied on the lips without finger contact, which may be an advantage.

5.2.2.2 Tubes

Tubes are used both for low-priced products for children and more expensive products for adults.

Packaging and appearance:

Tubes are made of plastic and come with a screw cap for protection of the tube opening. The opening may be dome shaped or the application end cut diagonally; both types have been purchased. Tubes come in coloured or transparent plastic.

Colour and perfume:

All purchased tubes in transparent plastic has richly coloured contents and a powerful fragrance, whereas the contents of the opaque tubes can be both coloured or uncoloured and with either a powerful fragrance or a more discreet fragrance.

Oils and fats:

The viscosity contents of the tube products vary significantly from thin liquid to a thick paste.

Application:

The product is applied on the lips without finger contact.

5.2.2.3 Glass or plastic tube with roll-on

All products give a glossy shine on application. Colour, fragrance, product labelling and marketing are assessed to be directed to children.

Packaging and appearance:

The products are liquid and applied to the lips by the roll-on ball.

Colour and perfume:

Purchased products in this group all have a strong colour reflecting the given flavour variation.

Oils and fats:

Products in this group all have low viscosity.

Application:

The product is applied on the lips without finger contact.

5.2.2.4 Cans/jars with lid

Compared with the layout of the packaging, most purchased products in this group are assessed to be aimed at children.

Packaging and appearance:

Most products are in a plastic can with a screw cap. The plastic can is either coloured or made of transparent plastic with highly coloured contents. A small number of the purchased products come in a metal can with lid. This group also includes products made as toys or key rings with special appeal to children.

Colour and perfume:

Most purchased products are coloured and with perfume.

Oils and fats:

These products contain fats whose melting point is higher than the application temperature.

Application:

Products in this group are applied with the fingers. Alternatively, products may be applied with a small brush but products with attached brush were not found during purchase.

5.2.3 Target groups and marketing

The focus of this project is on lip care products marketed at children and the young. Advertising material in the shops may be important. When purchasing the products, notice was given to the display of the products in the shops. Special advertisement boards or other eye-catching devices were noted to assess the intended target group.

In the survey 3 target groups have been appointed: children, the young and adults. Placing of products in the 3 target groups is based on the following product data: trade name, colour, flavour, number of variants, packaging, price as well as display and advertising in the shops. The products are often aimed at a broad target group, e.g. both the young and adults. In that case the product was placed in the youngest target group.

Products for children are colourful, smelling strongly of sweets or fruits and/or products in toylike packaging, e.g. packaging shaped as caramels, small teddy bears or dices.

Products for the young include both the above and products of well-know brands with a new innovative packaging and a more "young" appearance. A few expensive brands are found in this group but with a strong fragrance.

Products for adults are mainly the expensive products and more common, well-known brands without a particular specification of fragrance.

Concerning advertising in the shops, the expensive cosmetic brands are placed behind the counter together with the general range of products and with samples for product testing. Other products are exhibited in a stand or a box on the counter or on shelves in the shop, also with samples for product

testing. Stands and boxes are very colourful. In some cases, fragrance variants of products for children are only mentioned on the exhibition stand. Generally, the products that are not placed behind the counter are exhibited on a stand or a shelf at a level where the products can be seen or reached by all including children.

Table 4.4. Purchased products classified according to target group and perfume and colour contents.

Target group	Children	The young	Adults	Total
Colour				
coloured	48	29	11	88
"uncoloured"	2	6	13	21
Fragrance				
indefinable fragrance *	8	11	16	35
defined fragrance **	38	17	4	59
perfume-free	4	7	4	15
Number of products	50 (46%)	35 (32%)	24 (22%)	109

*: a pronounced flavour or fragrance variant is not stated on the packaging

**: a specific flavour or fragrance variant is stated on the packaging

In this survey 46% products marketed to children has been found and purchased, cf. table 4.4. Products to both children and the young make up approx. 78%. There is a predominance of coloured and scented products as this survey in particular covers these products. These make up 81% and 86% respectively of the total purchased products.

Coloured and scented products are common among products for children: 96% of the products for this target group are coloured and 92% contains perfume.

It is emphasized that the figures in table 4.4 gives the impression of a spring 2004 market with an emphasis on products for children but that the survey does not give a complete picture of this.

5.2.3.1 Outer packaging

Some of the purchased lip care products had an extra outer packaging. The most common outer packaging was a blister pack. The products are packed in transparent plastic glued on to colourful cardboard with printed information. Often the fragrance variant is illustrated with a printed image, e.g. a cherry or mint leaf, and the cardboard is in a colour similar to for instance the printed fruit. Other outer packaging is boxes with enclosed information sheets or co-packages.

The outer packaging is part of the marketing, either by adding an exclusive appearance to the product or by appealing visually with images and colours. Outer packaging was found mainly among products for the young and for adults.

5.2.4 Labelling and regulation

Lip care products are intended for care and protection of lips. Such products are covered by the Danish Environmental Protections Agency's statutory order on cosmetics, "Kosmetikbekendtgørelsen", cf. Annex 1 "Vejledende liste

over produkter, der betragtes som kosmetiske produkter” ”Make-up for lips, lip salves, etc.” (5). Consequently, lip care products must comply with the regulation on cosmetic products including labelling. All products must have a declaration of contents specifying all ingredients with their INCI name, (International Nomenclature of Cosmetic Ingredients), i.e. the agreed general names for cosmetic ingredients.

In connection with the survey, the declaration of contents and any other labelling of the purchased products were examined and possible violations of the regulation on labelling were pointed out.

5.2.5 Overview

To get an overview of the purchased products these were grouped according to perfume content, flavours, colour, target group, and type (see table 4.5).

In addition, the perfume and aroma content of the products were classified as follows:

- Indefinable fragrance:
When the INCI declaration states that the product contains perfume but a pronounced flavour or fragrance variant is not listed, e.g. orange, apple, melon, etc.
- Definable fragrance:
Perfume content is listed in the INCI declaration and a specific flavour or fragrance variant is stated on the packaging, e.g. orange, apple, etc.
- Unscented:
Products without declared perfume. However, some of these products contain very small amounts of extracts or essential oils giving the product a very weak fragrance.

Table 4.5. Purchased lip care products according to type. The table shows the number of products divided according to perfume content, colour and target group.

Type	Tube	Stick	Roll-on	Cans/jars	Total
Scent					
indefinable fragrance	14	13	0	8	35
definable fragrance	8	24	8	19	59
unscented	5	7	0	3	15
Colour					
colour	22	32	7	28	89
"uncoloured"	5	12	1	2	20
Target group					
children	8	15	8	19	50
the young	10	16	0	9	35
adults	9	13	0	2	24
Number of products	27 (25%)	44 (40%)	8 (7%)	30 (28)	109

5.3 Ingredients

Every single lip care product has been analysed with regard to flavour and fragrance, pigments, and fats. Below is an overall description of the substances for all products. Oils and fats are described separately in chapter 6.

5.3.1 Perfume

According to the "Kosmetikbekendtgørelsen", any fragrance in the products can be listed on the declaration of contents by the word "parfum", perfume or aroma.

Fifteen of the 109 purchased products (14%) did not list perfume or aroma on the declaration of contents, and consequently products have been registered as unscented. Even though some of the products contain small amounts of extracts or essential oils giving the products a very weak fragrance they are, however, not regarded as scented.

Products with perfume listing a specific fragrance or flavour make up 59 of the 109 purchased products (54%). Among these are approx. 38 different variants. Perfume is added to 35 of the purchased products but a specific fragrance or flavour is not listed on the product. Totally, perfume is added to 86% of the purchased products. See also table 4.4 and 4.5.

The fragrance and flavour variants listed on the products cover a wide spectrum and includes fruits and sweets (number in brackets): apple (2), Aloe vera, pineapple (2), orange (3), banana, Brazil nut, blackberry, bubble-gum, lemon balm, coca-cola, grape, grape seeds, fig, raspberry (2), honey, strawberry (4), cocoa butter, cherry, kiwi (2), coconut (2), tangerine (2), mango, mango/peach, melon, melon seeds, menthol, mint, marigold, papaya (2), passion fruit (3), peppermint, shea nut, tea tree oil, tropical fruit (3), tutti-frutti, herbs, water melon (3), and vanilla (3).

The perception of fragrance and flavour depends on numerous factors, including the character, intensity and perseverance of the fragrance (6), but also individual factors such as age, sex and race are important (7). When applying lip care products on the lips, the product is applied on warm skin close to the nose and volatile fragrances evaporate and are perceived by the sense of smell. Thus, the sense of smell is important when perceiving the product's fragrance. In order to taste the product, the product must be in direct contact with the tongue and the sense of smell must be reasonably. As many people moisten and lick their lips, it is very likely that they can taste the lip care product including the taste of both volatile and non-volatile ingredients in the perfume. Many fragrances give off an acceptable odour but when in direct contact with the gustatory bud the taste of the chemicals may be pricking and unpleasant. A test of the different samples of the selected lip care products showed that a pleasant fragrance is not always proportional to a pleasant flavour. However, a systematic testing of the 109 products was not carried out.

Various scientific literature has been consulted with a view to tracing the chemical substances in the different fragrance variants. Over the years, many attempts to classify fragrances have been endeavoured. Some of these also indicate which chemical substance gives off which fragrance. For instance the following classification by the German chemist Hans Henning, published in

1916 in his book "Der Geruch" and mentioned in a reference book on fragrances (8):

1. Flower-like: coumarin, geranium, heliotrope
2. Fruit-like: orange oil, oil of bergamot, citronella
3. Resin and balm fragrances: turpentine, eucalyptus oil, Canada balm
4. Burnt fragrances: pyridine, tar
5. Putrefaction/stench: hydrogen sulphide, carbon disulphide
6. Spicy: clover, fennel, aniseed

Another way of classifying fragrances is illustrated in the fragrance wheel in figure 4.1, which shows examples of chemical combinations of the said fragrances.

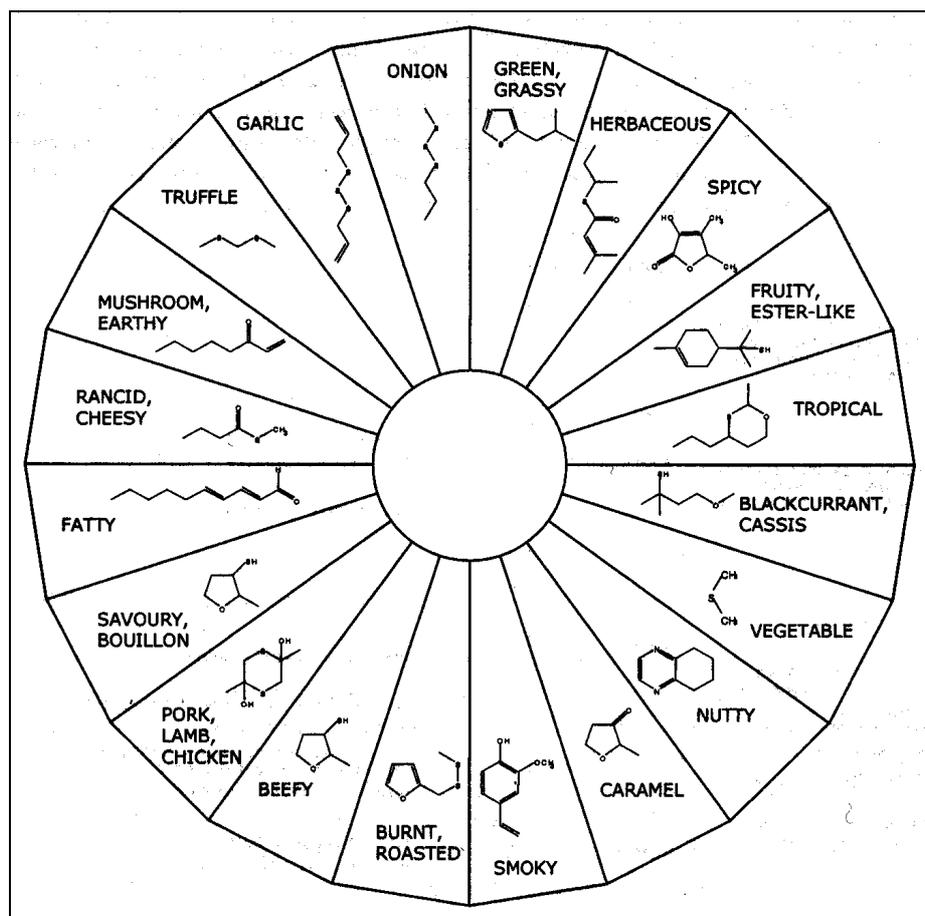


Figure 4.1. The fragrance wheel illustrates aroma chemicals typically associated with the depicted fragrance notes. The fragrances depicted on the right of the wheel are used in lip care products: fruity, tropical and blackcurrant. The figure is an adaptation of (9).

Fragrances used in lip care products are mainly those on the right of the wheel. The separate fragrance characters are represented by the ingredients in the figure, described in brackets below (9):

Fruit-like fragrances (e.g. esters such as ethyl butyrate and ethyl 2-methylbutyrate. In figure 4.1 is shown the structural formula of the fruit fragrance from grapefruit: p-1-menthen-8-thiol)

Blackcurrant-like fragrances (e.g. 2-methoxy-4-methyl-4-butanethiol)
Tropical fragrances (e.g. trophathiane, 2-methyl-4-propyl-1,3-oxathiane)

The following has also been used in part
Nut-like fragrances (pyrazines such as 5,6,7,8-tetrahydroquinoxaline (THQ))
Herbaceous fragrances (e.g. thioesters such as sec-butyl 3-methylbut-2-enethioate)

In addition to fragrances, many of the purchased lip care products also contain essential oils or other plant extracts, which may give fragrance to the products. The following flowers, fruits, and leaves, whose extracts may result in fragrance, are among those mentioned on the INCI declarations:

Watermelon (*Citrullus vulgaris*)
Tangerine (*Citrus nobilis*)
Fig (*Ficus carica*)
Strawberry (*Fragaria vesca*)
Passion-flower (*Passiflora incarnata*)
Dog rose (*Rosa canina*)
Moss rose (*Rosa centifolia*)
French rose (*Rosa gallica*)
Musk rose (*Rosa moschata*)
Raspberry (*Rubus idaeus*)
Tea tree (*Melaleuca alternifolia*)
Camomile (*Chamomilla recutita*)
Lemon balm (*Melissa officinalis*)
Lavender (*Lavandula angustifolia*)
Vanilla (*Vanilla planifolia*)
Peppermint (*Mentha piperita*)
Eucalyptus (*Eucalyptus globulus*)
Spearmint (*Mentha viridis*)
Papaya (*Carica papaya*)

Plant extracts contain many of the most common fragrance compounds. Several of the 26 fragrances listed by the EU as allergenic occurs naturally in extracts from plants, fruits, etc., particularly in citrus oil and essential oils from flowers, cf. Appendix 1. Based on the above list of plant extracts in lip care products, it is probable that several of the various fragrance variants of the products contain one or more of the allergenic fragrances.

In the last century only 150 fragrances were known, but with industrial development more than 4,000 fragrances have been identified of which approx. 2,500 are used today (3). This project focuses on the 26 fragrances listed by the EU as allergenic and which by March 2005 must be stated on the products' INCI declarations dependent on the concentration of the substance in the product.

5.3.2 Pigments

Pigments approved for use in cosmetics appear from the "Kosmetikbekendtgørelsen". The amount of pigments in lipsticks is estimated to make up 1-10 % (4) and the amount of pigment in coloured lip care products is estimated to be at the same level.

In this survey, 9 different colour variants were found, see table 4.6. Uncoloured products are products with an aqueous or waxlike appearance that may vary from glassy to milk-white or yellowish.

Table 4.6. Number of products in each colour group..

Colour	Multi coloured	Blue	Brown	Green	Yellow	White	Mauve (violet)	Pink	Orange	Red	"Uncoloured"	Total
Number products	3	4	2	14	11	21	4	16	7	6	21	109

The following colours are added in the form of pigments. Listed numbers are Color Index numbers (C.I.) stated in the INCI declarations for the different lip care products.

Red colours:

12150, 14700, 15800, 15850, 15850:1, 15850:2, 16255, 17200, 26100**, 45380, 45380:3, 45410, 45410:2, 45430, 73360, 75470, 77491

**Pigment 26100 is not allowed for contact with mucous membranes.

Blue colours

42090, 42090:2, 77007

Yellow colours:

15985, 19140, 19140:1, 47005, 75120, 77492, Beta carotene, Daucus carota

White colours:

77019 (mica), 77891, 77947

Green colours:

61565, 75810

Violet colours:

60725, 77742

Orange colours:

11920, 45370

Black colours:

77499

All pigments are on "Kosmetikbekendtgørelsens" positive list, Appendix 4, that also includes their CAS nos. (5).

Apart from C.I. 26100 all pigments are allowed in lip care products.

6 Analyses

6.1 Fragrances

Emphasis was placed on including both expensive and low-priced product as well as products for children and adults alike when selecting the products for analysis of the 26 fragrances. Twenty products were selected for analyses of the 26 fragrances. Furthermore, three products, which according to their declaration of contents contain rose oil, were selected for analysis of methyl eugenol. Based on the marketing of the products, the three rose oil-containing products are all assessed to be for adults. Of the 20 selected products for analysis, 3 products are assessed to appeal to adults, 7 to the young and 10 to children.

The following products were selected for analysis:

Two products with strawberry fragrance, 2 with orange fragrance, 2 with raspberry fragrance, 2 with melon fragrance, 1 with banana fragrance, 1 with pineapple fragrance, 1 with papaya fragrance, and 1 with "tropical" fragrance listed on the packaging. The remaining 8 products selected for analysis did not have a defined fragrance (cf. 4.1.3) listed on the packaging or in the declaration of contents. However, some of these products had a characteristic fragrance such as peppermint or orange while others merely had a sweet or flowerlike fragrance.

6.2 Analytical methods

6.2.1 Methyl eugenol

A part sample of the product is extracted with dichloromethane for two hours on a shaker followed by one-hour ultrasound treatment. A part sample of the extract is taken and analysed directly at combined gas chromatography and mass spectrometry (GC/MS). The content is calculated quantitatively. Uncertainty is 10-15% RSD. The analyses are performed as true double determinations. The limit of detection is 10 mg/kg.

6.2.2 Fragrances

A part sample of the products is taken and extracted with water and tert-butyl methyl ether by means of shaking, heating, cooling, and standing during a period of approximately 16 hours. A part sample of the extract is taken and analysed directly at combined gas chromatography and mass spectrometry (GC/MS). The analyses are performed as true double determinations. The limit of detection is 1-10 mg/kg and the uncertainty is 10-15% RSD.

6.3 Results

6.3.1 Methyl eugenol

Three products were analysed for methyl eugenol and the result of the analyses are given in table 5.1. The table contains two results due to double determination (A and B). The unit is mg/kg and the limit of detection is 10 mg/kg.

Table 5.1 The results of the analysis for methyl eugenol. The results are given in mg/kg.

	53		80		93	
	A	B	A	B	A	B
Methyl eugenol	< 10	< 10	12	12	36	36

<: means less than the stated limit of detection

Maximum allowed amount in this type of cosmetic products are 2 mg/kg (0,0002 %). The results shows that product 80 og product 93 contains illegal amounts of methyl eugenol. These offences are dealt with by the Chemical Inspection Service. The producers have subsequent changes the content of the product so the present products now are legal.

6.3.2 Fragrances

All 20 products were analysed for 26 fragrances. Only one product showed no content of any of the 26 components. The total content of all 26 fragrances are given at the bottom of the table. The total content varies from 6 to 26,000 mg/kg.

The two highest contents were determined in amounts ranging from 15,000 to 26,000 mg/kg corresponding to 1.5-2.6 weight%. Both accounts were due to an extremely high content of D-limonene compared to the other components.

A summary of the results of the analyses can be seen in table 5.2.

Table 5.2. Analytical results of the fragrances. The unit is mg/kg. The result states the average of the double determinations.

	LOD*	7**	10	20	32	33	35	37	45	51	53	57	66	75	80	86	91	93	94	97	106
Anisyl alcohol	1																				
Amyl cinnamal	1																				
Amylcinnamyl alcohol	1																				
Benzyl alcohol	1			31,5		9,5		11	8		5		23,5		14,5			9	1800	28	
Benzyl benzoate	1	12			103				6,5	115		7100	6650		13			6,5			
Benzylcinnamat	1								3	55					7						
Benzyl salicylat	1								6						6,5						
Cinnamyl alcohol	1																				
Cinnamal	1																	1,5			
Citral	1	1200			32,5						56	23									
Citronellol	1						54			45				745	220			410			
Coumarin	1																				5,5
Eugenol	1								15	40,5				86,5	46			26,5	21,5		
Farnesol	1														5,5			10,5			
Geraniol	1	10			6	3	185				4			725	97			140			
Hexylcinnamaldehyd	1																				
Hydroxycitronellal	1																				
α -Isomethylionon	1	68,5																			
Lillial	1																				
D-limonen	1	22500	140	3	420	73	75	3,5	465	9	15500	3,5	11,5	170	6		6	780	3	2600	20
Linalool	1	845			99	24	19		155		25	69,5		785	5			29,5	95,5	40,5	
Lyril	1																				
Isoeugenol	1	145								3											

Methyl heptin carbonat	1																				
Oakmoss	10																				
Treemoss	10																				
Sum		2450 0	14 0	34, 5	660	11 0	33 0	14, 5	66 0	175	1550 0	720 0	665 0	250 0	420		6	140 0	190 0	270 0	25, 5

* LOD: limit of detection

** Numbers indicate product numbers of the analysed products.

6.4 Summary of analytical results

Eleven of the 26 fragrances were not found in any of the 20 analysed lip care products. Total occurrence of fragrances in the 20 analysed lip care products is 84, i.e. an average of 4.2 fragrances per product. One or more of the tested fragrances occurred in 19 of the 20 analysed products.

The occurrence of fragrances were distributed like this:

-Isomethylionon, coumarin and cinnamal were found in 1 product; isoeugenol, farnesol and benzyl salicylat was found in 2 products; benzyl cinnamat was found in 3 products; citral in 4 products; citronellol in 5 products; eugenol in 6 products; benzyl benzoate and geraniol in 8 products; benzyl alcohol in 10 products; linalool in 12 products, and d-limonen in 19 products.

Anisyl alcohol, amyl cinnamal, amylcinnamal alcohol, cinnamyl alcohol, hexylcinnamaldehyd, hydroxycitronellal, lillial, lyral, methyl hoptin carbonal, oakmoss and treemoss were not found in any of the analysed products.

Table 5.3 shows the number of fragrances found in the products, including the target group of the product.

Table 5.3. Number of fragrances found per product and product target group.

Number of perfumery materials	Number of products	Target group
0 fragrances	1 product	the young
1 fragrance	2 products	children, children
2 fragrances	3 products	children, children, children
3 fragrances	2 products	the young, children
4 fragrances	4 products	the young, the young, children, children
5 fragrances	3 products	the young, adults, the young
6 fragrances	1 product	children
7 fragrances	2 products	children, the young
8 fragrances	0 products	-
9 fragrances	1 product	adults
10 fragrances	1 product	adults

A large spread of concentrations in the products is seen for both single substances and the total content of the 26 fragrances. It appears that a high content of D-limonen is also the cause of a high total content of perfume.

Total perfume content in percentage by weight was 0% in one product; between 0 and 0.1% in 11 products; between 0.1 and 1% in 6 products; and > 1% (1.55 and 2.45 percentage by weight) in 2 products.

The three products selected for analysis of the 26 fragrances and analysis of methyl eugenol were the only three selected products with adults as the target group. Of the remaining 17 products, 10 products are estimated to be products for children and 7 products to be products for the young. The three products were estimated to be products for adults based on their price, product appearance and placing of the product in the shops. These products

turned out to have a total perfume content of 15,500, 1,400 and 420 mg/kg respectively made of 5, 9 and 10 different fragrances. Consequently, the "adult products" represent the two products in the analysis in which the largest different number of the 26 allergenic fragrances was identified as well as the second highest total perfume content measured. The remaining content of 1,400 and 420 mg/kg is reasonably in line with the products for children and the young. In addition, plant extracts are typical ingredients in "adult products".

Table 5.4 sums up the analytical results with the occurrence in number of products, minimum and maximum measured values and the maximum value as the fragrance's percentage by weight in the product.

Table 5.4. Summary of analytical results.

	Occurrence in products		Content in products (mg/kg)		percentage by weight (max. content) *
	Number	%	Min.	Max.	
Anisyl alcohol	0	0			
Amyl cinnamal	0	0			
Amylcinnamyl alcohol	0	0			
Benzyl alcohol	10	50	5	1800	0,18
Benzyl benzoate	8	40	6,5	6650	0,67
Benzylcinnamat	3	15	3	55	0,0055
Benzyl salicylat	2	10	6	6,5	0,00065
Cinnamyl alcohol	0	0			
Cinnamal	1	5	1,5	1,5	0,00015
Citral	4	20	23	1200	0,12
Citronellol	5	25	45	745	0,075
Coumarin	1	5	5,5	5,5	0,00055
Eugenol	6	30	15	86,5	0,0087
Farnesol	2	10	5,5	10,5	0,0011
Geraniol	8	40	3	725	0,073
Hexylcinnamaldehyd	0	0			
Hydroxycitronellal	0	0			
α -Isomethylionon	1	5	68,5	68,5	0,0069
Lillial	0	0			
D-limonen	19	95	3	22500	2,25
Linalool	12	60	5	845	0,085
Lyral	0	0			
Isoeugenol	2	10	3	145	0,015
Methyl heptin carbonat	0	0			
Oakmoss	0	0			
Treemoss	0	0			
Sum	84	-			
Methyl eugenol	2	67	12	36	0,00036

* Except for D-limonen, the weight percentage is given with 2 significant digits.

Even products, which do not contain sensitizing substances or contain these substances in very low concentrations, may have a strong fragrance. It is not possible here to estimate the concentration or the content of the individual sensitizing substances in a product by smelling the product.

According to the declaration of contents product no. 7, which has the highest content of D-limonen, also has an orange fragrance or flavour. For the remaining products the content of fragrances do not correspond clearly with the flavour/fragrance listed on the product.

Methyl eugenol is not on the list of the 26 allergenic fragrances. However, the substance has been included in the analysis due to its carcinogenic effects effekt and because the amount of the substatnce is regulated in the cosmetic directive (see 7.5 Health assessment of Methyl eugenol) and its natural occurrence in rose oil, which is found in three different products according to the INCI declarations.

6.5 Selection of substances for health assessment

The selection of fragrances for health assessment was based on occurrence in the products. Fragrances occurring in most products were selected for assessment. D-limonen and Benzyl alcohol have been assessed in a previous survey for the Danish Environmental Protection Agency, and besides these two substances the 4 fragrances found most often in the products were selected for health assessment. Methyl eugenol, analysed specifically for in 3 products, is also included in the assessment.

The five selected substances are: Linalool, Benzyl benzoate, Geraniol, Eugenol and Methyl eugenol.

7 Oils and fats

7.1 Oils and fats

The products' declarations of contents show that the purchased products contain both natural and synthetic waxes and oils, cf. table 6.1. From table 6.1 it appears that the most common oils and fats in lip care products are beeswax, castor oil, vaseline/petrolatum and the wax types candelilla wax, carnauba wax, and microcrystalline wax. These substances are often the main ingredients in lip care products. Also synthetic polymers are used often, particularly polybutene is seen as main ingredient in lip care products but also polydecene and polyisobutene

The various oils and fats have many different technical properties such as viscosity-improving or emulsifying properties. Many lip care products contain several oils and fats, both mineral and plant-based, to obtain the wanted technical properties. Among these castor oil that gives sheen and a good distribution of the pigments is pointed out (4). The use of wax, e.g. beeswax and carnauba wax, gives hardness and sheen to products in sticks and increases the products' melting point (4). Beeswax stays on the lips for a long time and prevents cracking of the product. Synthetic polymers increase the product viscosity depending on their molecular weight.

Fossil wax such as Ozokerite and Ceresin, extracted from coal and slate clay, paraffin wax and microcrystalline wax, extracted from petroleum, and synthetic wax are also used in lip care products and increases the products' strength. Among these Ozokerite and Ceresin absorb oil well and prevent crystallization (10). Paraffin wax, which has a crystalline structure different from microcrystalline wax (11), mixes badly with castor oil (4), which may be why it is not often used in lip care products cf. table 6.1.

Triglycerides are also used in many lip care products. Vegetable oils are primarily composed of triglycerides. Chemically, triglycerides are composed of three fatty acids varying in chain length and number of double linkings, i.e. the content of unsaturated fatty acids, depending on the seed or fruit from which the oils are extracted (12). This results in a large variation of the technical properties of the substances. When using unsaturated vegetable fatty acids it is important to notice that they may go rancid (4), therefore antioxidants are often added.

In addition to the above oils and fats many of the products contain fatty acid esters. This group includes different esters, e.g. stearates, palmitates, acetates, malates, myristates, etc. The substances are not real oils or fats but have various technical properties close to oils and fats. Esters may be added as solvents or viscosity-improving substances and often have an emollient effect (4). Myristyl myristate improves application and has an emollient effect, and isopropyl myristate makes the product less sticky (10).

Octyldodecanole is an aliphatic saturated fatty alcohol with a chain length of 20 carbon atoms used in several of the lip care products. Octyldodecanole

spreads easily on the skin and does not leave a greasy look. The substance may be used as a dispersing agent for pigments and as an emollient. It mixes well with wax and other fatty substances (13).

Silicone oil is a common name for organic polymers. Silicone oil is found in 7 of the purchased products. Silicone oil may have fatlike properties but is usually not characterized as a fatty substance (4).

Table 6.1. Most frequently used oil and fats in lip care products.

Name	Number of products	INCI	CAS no.
Beeswax	52	Cera Alba	8001-23-8
Castor oil	39	Ricinus communis Oil	8001-79-4
Vaseline	34	Petrolatum	8009-03-8
C8-10 Triglycerides	23	Caprylic/Capric Triglycerides	73398-61-5
Microcrystalline wax	22	Cera Microcristallina	63231-60-7
Carnauba wax	21	Cera Carnauba	218015-86-9
Candelila wax	19	Candelila Cera	8006-44-8
Octyldodecanole	19	Octyldodecanol	5333-42-6
Liquid paraffin	19	Paraffin Liquidum	8012-95-1
Polybutene	19	Polybutene	9003-28-5
Hydrogenated Castor oil	17	Hydrogenated Castor Oil	8001-78-3
Copolymers/ crosspolymers/ Synthetic polymers	16	-	-
Lanolin	13	Lanolin	8006-54-0
Ozokerite	12	Ozokerite	64742-33-2
Hydrogenated polydecene	10	Hydrogenated Polydecene	68037-01-4
Paraffin	9	Paraffin	8002-74-2
PEG-8 Beeswax	8	PEG-8 Beeswax	-
Polyglyceryl-3 beeswax	8	Polyglyceryl-3 Beeswax	-
Ceresine	7	Ceresin	8001-75-0
Silicone olie	7	Dimethicone	9006-65-9
Glycerol	7	Glycerin	56-81-5
Hydrogenated polyisobutene	5	Hydrogenated Polyisobutene	40921-86-6
Polydecene	4	Polydecene	37309-58-3
Polyisobutene	4	Polyisobutene	9003-27-4
Japanese varnish tree wax	4	Rhus verniciflua Cera	225234-38-8

When grouping the oils and fats in table 6.1 in hydrocarbon-based/mineral oil-based fats and in vegetable/animal fats, it can be seen that most of the purchased lip care products contain vegetable-based or animal-based fats, oils or waxes, cf. table 6.2 and 6.3 below. From table 6.2 it appears that hydrocarbon-based/mineral oil-based fats have been used 169 times in lip care products. Vegetable-based or animal-based oils and fats seem to be more popular, cf. table 6.3, as they have been used 338 times. Only the frequency of use of the oils and fats has been assessed, as there is no information on the amount of the different oils and fats in the various products.

Table 6.2. Mineral-based oils and fats in lip care products.

Name	Number products	INCI	CAS no.
Vaseline	34	Petrolatum	8009-03-8
Microcrystalline wax	22	Cera Microcristallina	63231-60-7
Paraffin oil	19	Paraffin Liquidum	8012-95-1
Polybutene	19	Polybutene	9003-28-5
Copolymers/ crosspolymers/ Synthetic polymers	16	-	-
Ozokerite	12	Ozokerite	64742-33-2
Hydrogenated polydecene	10	Hydrogenated Polydecene	68037-01-4
Paraffin	9	Paraffin	8002-74-2
Ceresine	7	Ceresin	8001-75-0
Hydrogenated polyisobutene	5	Hydrogenated Polyisobutene	40921-86-6
Polydecene	4	Polydecene	37309-58-3
Polyisobutene	4	Polyisobutene	9003-27-4
Polydodecanamide	3	Nylon-12	25038-74-8
Synthetic wax	3	Synthetic Wax	8002-74-2
Polyethylene	2	Polyethylene	9002-88-4
Number of times mineral-based oils and fats have been used	169		

Table 6.3. Vegetable-based/animal-based oils and fats in lip care products.

Name	Number products	INCI	CAS no.
Beeswax	52	Cera Alba	8001-23-8
Castor oil	39	Ricinus communis Oil	8001-79-4
Shea butter	28	Butyrospernum parkii butter	91080-23-8
C8-10 Triglycerides	23	Caprylic/Capric Triglycerides	73398-61-5
Carnauba wax	21	Cera Carnauba	218015-86-9
Candelila wax	19	Candelila Cera	8006-44-8
Octyldodecanole	19	Octyldodecanol	5333-42-6
Hydrogenated Castor oil	17	Hydrogenated Castor Oil	8001-78-3
Joboba oil	15	Simmondsia chinensis oil	61789-91-1
Lanolin	13	Lanolin	8006-54-0
PEG-8 beeswax	8	PEG-8 beeswax	-
Polyglyceryle-3 beeswax	8	Polyglyceryl-3 beeswax	-
Mango seed oil	8	Mangifera indica seed oil	90063-86-8
Almond oil	7	Prunus amygdalus dulcis oil	8007-69-0
Safflower oil	6	Carthamus tinctorius oil	8001-23-8
Hydrogenated coconut oil	6	Hydrogenated coconut oil	84836-98-6
Soya bean oil	5	Glycine soja oil	8001-22-7
Cocoa butter	5	Theobroma cacao butter	8002-31-1
Japanese varnish tree wax	4	Rhus verniciflua cera	225234-38-8
Sunflower oil (hybrid)	3	Helianthus annuus hybrid oil	164250-88-8
Macademia nut oil	3	Macadamia ternifolia seed oil	128497-20-1
Olive oil	3	Olea europaea oil	8001-25-0
Olus oil	2	Olus oil	68956-68-3
Vegetable oil	3	Vegetable oil	68956-68-3
Coco-glycerides	3	Hydrogenated coco-glyderides	91744-42-2
C18-36 triglycerides	3	C18-36 Triglycerides	
Groundnut oil	2	Arachil hypogaea oil	8002-03-7
Coconut oil	2	Cocos nicifera oil	8001-31-8
Avocado oil	2	Persea gratissima oil	8024-32-6
Sunflower seed oil	1	Helianthus annuus seed oil	8001-21-6
Babassu oil		Orbignya oleifera	-
Brazil nut oil	1	Bertholletia excelsa nut oil	-
Apricot seed oil	1	Prunus armeniaca kernel oil	72869-69-3
Grape seed oil	1	Vitis vinifera seed oil	8024-22-4
"Bush mango" seed butter	1	Irvingia gabonensis kernel butter	192230-28-7
Pistachio nut oil	1	Pistacia vera	-
Peach	1	Prunus persica	-
Lanolin oil	1	Lanolin oil	70321-63-0
Number of times vegetable-based/animal-based oils and fats have been used	338		

7.2 Mineral-based oil and fats

Mineral paraffin is used in many lip care products and other cosmetics and is also a common ingredient in foodstuffs (11). The German Bundesamt für Gesundheit and the Swiss Stiftung zur Förderung des Stillens recommend that paraffin and vaseline should not be used in breast care products (14). As a result, the Danish Environmental Protection Agency wanted an investigation of the distribution of hydrocarbon in the mineral-based oils and fast in the purchased lip care products in order to evaluate a possible influence on the safety when using these products.

A Swiss study showing that mineral paraffin can be detected in breast milk is the basis for the above recommendation. The study comprised 33 breast milk samples in which mineral C₁₅₋₄₅ paraffin were found in concentrations of an average of 95 ± 215 mg/kg fat and a maximum of 1300 mg/kg fat. The average paraffin chain length was between C₂₃ and C₃₃. In 1995, the EU Scientific Committee for Food (SCF) determined a provisional acceptable daily dose (t-ADI) of 0-4 mg/kg body weight for C₃₄- paraffin (15) (16). Generally, it is assumed that paraffin with a carbon chain length above C₂₉ is not absorbed in significant amounts (17). When estimating worst-case doses the content of mineral paraffin in breast milk fat is estimated at 200 mg/kg. Babies of 5 kg consuming 800 g milk/day with a fat content of 3% consume 24 g fat/day. This means that the babies consume approx. 1 mg/kg/day. This complies with the ADI determined by SCF, however, with the reservation that this study has proved mineral paraffin with a shorter carbon chain. It is believed that paraffin with a chain length above C₁₀ do not easily penetrate the stratum corneum, but this study indicates that even high molecular paraffin may be absorbed by breast skin. Consequently, the conclusion of this study is that high molecular paraffin are probably not suitable for use in nipple salves (17).

7.2.1 Mineral-based oils and fats in lip care products

The mineral-based oils and fats were identified based on the products' INCI declarations of contents and inquiries were made to the producers concerned. Consequently, this survey does not include chemical analysis of the used mineral oils and fats. The evaluation is based solely on voluntary participation of the producers and their information.

Prior to the inquiry to the producers, the following three mineral oils and fats were identified in the purchased lip care products:

- Paraffin (9 products)
- Paraffinum Liquidum (19 products)
- Petrolatum (33 products)

The mineral-based oils and fats were found in 43 of the purchased lip care products and in several cases they were mixed with vegetable oils and fats. Inquiries were made in the relevant language (Danish, English or Spanish) to 16 different producers. If a Danish importer was identified in connection with the inquiry to the producers, an inquiry was also made to the Danish importer.

Information on mineral oils and fats was received from 10 producers. One producer reported that the product in question was no longer part of their Danish range and that products for sale in the shops are a surplus stock. Six producers did not participate in the survey; three producers with a Danish address; two with an address in the EU, and one in the USA.

It is clear from the material from the 10 different producers that some producers use the same raw materials for several products in their product range and that several producers use the same raw materials supplier. The information received on the used mineral-based oils and fats covers 33 of the purchased 43 products.

Safety data sheets or extracts from safety data sheets were received for all mineral oils and fats.

7.2.2 Investigation of the hydrocarbon composition

Paraffinum Liquidum, mineral oil

Information was received on four different qualities of mineral oil from five producers/importers, all stating CAS no. 8042-47-5 as for white mineral oils. These oils are estimated neither to be carcinogenic, mutagenic nor genotoxic and are not covered by the regulations concerning CMR substances. The used white mineral paraffin oils are all of pharmaceutical quality. Generally, Paraffinum Liquidum consists primarily of two types of saturated hydrocarbons: the paraffin ones (often the branched hydrocarbon chains) and the naphthene ones (cycloalkanes), and the majority has a hydrocarbon chain length of C_{16-22} (4). A chain length of C_{20} after 5% distillation is reported for one of the used oils and the remaining oils are assumed to have a similar hydrocarbon composition. As a result, the used mineral oils are not comprised by SCF's ADI, which concerns mineral paraffin with a longer hydrocarbon chain length.

Petrolatum

Information was submitted on six different petrolatum raw materials with CAS no. 8009-03-8. Petrolatum is covered by the regulations on CMR substances unless it can be proved that the substance from which it is made is not carcinogenic. There is no immediate information on this or on the hydrocarbon composition in the received safety data sheets or information on the petrolatum, however, it appears that petrolatum is not classified as hazardous according to the regulations on chemical substances and products (18). Three of the petrolatums were the white type, three the yellow type. Generally, petrolatum like mineral oil consists of two types of saturated hydrocarbons: the paraffin ones and the naphthene. The distribution of hydrocarbons depends on the oil from which the petrolatum is derived and the method used for isolating petrolatum from the oil. The hydrocarbon chain length in petrolatum is between C_{17} and C_{51} , the majority of the hydrocarbons with a chain length of C_{28} (12).

Paraffin (wax)

Information is received on three different paraffin wax with CAS nos. 64742-51-4 and 8002-74-2. These are estimated neither to be carcinogenic, mutagenic nor genotoxic and are not covered by the regulations concerning CMR substances. The hydrocarbon composition of the paraffin wax was not stated in the received safety data sheets. Generally, paraffin consists of two types of saturated hydrocarbons: the paraffin ones and the naphthene. Just as

petrolatum the distribution of hydrocarbons depends on the oil from which the wax is derived and the method used for isolating wax from the oil. The hydrocarbon chain length in paraffin wax is between $C_{18} - C_{36}$ (11).

7.2.3 Assessment of the safety

As mentioned above, the EU Scientific Committee for Food (SCF) assessed mineral and synthetic hydrocarbons in 1995 and determined a provisional acceptable daily dose (t-ADI) of 0-4 mg/kg body weight for white paraffin oils with a hydrocarbon chain length larger than 25 at 5% distillation. ADI for paraffin wax is determined at 0-20 mg/kg body weight (16).

If ADI for white paraffin oils is taken as a guide for a worst-case scenario of oral consumption as the only exposure channel of the used mineral oils and fats, the following can be calculated:

Weight of person, woman:	60 kilo
Weight of person, child 3-5 years (19):	18 kilo
Number of daily applications (20):	6
Amount used per application (20):	10 mg
Absorption through oral consumption:	100%

Highest recommended daily exposure (ADI), mineral oil, child:
 $18 \times 4 \text{ mg/kg} = 72 \text{ mg}$

Highest recommended daily exposure (ADI), mineral oil, woman:
 $60 \times 4 \text{ mg/kg} = 240 \text{ mg}$

As can be seen, ADI for children is of the same size as the consumption of lip care products per day, but even if the product should consist solely of mineral oil, which will not occur in practice, ADI would still be observed. ADI for adults will not be exceeded, as application of 240 mg is 4 times higher than the daily amount of lip care products even if the lip care product should be made of pure mineral oil.

Based on the above and based on other data from literature (11) it is assessed that the used mineral oils and fats are not hazardous to health when used in lip care products.

It was not possible in this survey to obtain an accurate picture of the hydrocarbon composition of the mineral-based oils and fats in the purchased lip care products.

8 Health assessment

In the following toxicological profiles have been drawn up of the 5 fragrances comprised by the health assessment.

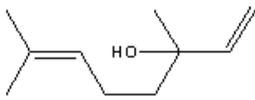
8.1 Linalool

Occurrence and use

Linalool is used as a fragrance in perfumes, most often as a substitute for bergamot or lavender oil. Occurs naturally in e.g. orange juice, peach, tomatoes and carrot, as well as in a number of flower oils such as orange flower and bergamot. Linalool is the main component of rosewood oil (21). Flavour characterization of linalool is stated as fruity, citrus-like and woody (22).

Identification

Linalool is an acyclic terpenalcohol (23).

Chemical name	Linalool
Synonyms	3,7-dimethyl-1,6-octadien-3-ol
CAS-No.	78-70-6
EINECS No.	201-134-4
Molecular formula	C ₁₀ H ₁₈ O
Molecular structure	
Legislation: Classification according to the List of hazardous substances (Stat. Order 439 of 3 June 2002) The List of unwanted substances. Danish Environmental Protection Agency (24). Cosmetics (25)	Not classified On the list as the substance is considered to be dangerous to the health and the environment As of 11 March 2005, the fragrance must be declared in cosmetics if it is used in amounts above 0.01 % in products that are cleaned off and 0.001 % in products that are not cleaned off.

Physical-chemical properties (26)

Physical state	Liquid
Molecular weight (g/mol)	154.25
Melting point, °C	-
Boiling point, °C	195-199 °C (720 mmHg)
Evaporation (Pa)	0.16 mmHg (21 Pa) at 22-25 °C 21 Pa. at 25 °C (21)
Octanol-water distribution, (log Pow)	2.84 at 25 °C (22) Log Kow = 2.97
Water solubility (g/L)	1.45 g/l at 25 °C (22)

WHO has laid down a NOEL (No Observed Effect Level) for linalool of 50 mg/kg bw/d (27).

Acute toxicity

LD₅₀-values (the exposure dose at which half the experimental animals die) at oral exposure of rats has been found to be 2790 and 4180 mg/kg bw (body weight) (21,22). LD₅₀ at oral exposure of mice is approximately 3500 mg/kg bw when administered in oil and 1700 mg/kg bw when administered in aqueous solution. Observed toxic effects were dose dependent and included anaesthetization, depression and hyper mobility with uncoordinated movements (26).

At exposure of rabbit skin, LD₅₀ has been stated at 5610 mg/kg bw (21,22).

Inhalation experiments on mice, where 20-50 mg linalool is inhaled in combined amount during 1 hour of exposure, reduced mobility was observed and linalool was measured in the blood in a concentration of 4.22 ng/ml (22).

Linalool is absorbed through the skin and is effectively excreted, mainly through the kidneys. 10 minutes of massage with lavender oil of a 376 cm² skin area of a 60 kg man resulted in a calculated percutaneous absorption of 7.23 mg linalool. After 5 minutes, linalool could be detected in the blood, after 20 minutes a blood concentration of 211 ng/ml was measured and after 90 minutes, all linalool was eliminated from the bloodstream (22). It has not been evaluated whether inhalation took place in connection with the massage.

Chronic, repeated exposure

Several oral experiments on rats are stated (22):

Exposure to 1500 mg/kg bw/d for 5 days led to enzyme changes in peroxisomes and increased liver weight.

Exposure to 600 mg/kg bw/d for 3 days led to enzyme changes in the liver.

Exposure to 500 mg/kg bw/d for 64 days led to enzyme changes in the liver and increased liver weight.

A No Observed Adverse Effect Level (NOAEL), the highest exposure dose not to cause observed critical effects on the animals, of 50 mg/kg bw/d has been laid down based on a 90-day oral exposure study with rats where a reduced food intake and growth was observed. These effects were attributed to poor tasting food (28).

At oral exposure of mice of 375 mg/kg bw/d for 5 days, no effects were observed on body weight, spleen and thymus weight and in addition no clinical signs of toxicity (22).

Linalool has been stated as possibly having effects on the liver in humans at chronic or repeated exposure (21).

A 13-week dermal exposure experiment on rats established a NOAEL of 250 mg/kg bw/d with effects such as momentary blushing and reduced activity as critical effects. At an exposure of 1000 mg/kg bw/d, reduced growth, reduced activity and blushing was observed (28). No dose level was mentioned at which a critical effect occurs or what the critical effect was assessed to be.

Upon exposure to linalool in a concentration of 1% of the diet for 20 weeks in rats, no changes in the development of tumors in the animals was observed (22).

In vitro mutagenicity test for chromosome changes in mammalian cells is negative in doses of up to 0.25 mg/ml (21). Linalool has tested negative in Ames test, mouse micronucleus test, Chinese hamster ovary or fibro blast cells and in DNA assay with rat liver cells (28).

No data has been found for inhalation of linalool.

Local irritation

0.5 ml on shaved rabbit skin in concentrations of 100 %, 30 %, 10 % and 3 % for 24 hours lead to a slight irritation for the 100% and 30% solutions and no irritation for the 10% and 3% solutions (26). The substance has been stated as being mildly irritating in patch tests on human skin in a concentration of 32% (21).

No irritation and sensitization has been observed at application of 20% linalool in petrolatum (28).

0.1 ml in rabbit eyes in concentrations of 100%, 30%, 10% and 3% for an unspecified time period lead to moderate irritation at 100%, slight irritation at 30%, very slight irritation at 10% and no irritation at 3% (26). The substance has been stated as being irritating to human eyes, concentration not stated (21).

Linalool and its esters do not absorb UV light at wave lengths in the interval 290-400 nm and does therefore not display potential for photo irritation or allergy when used as a fragrance (28).

Allergy

The EU scientific committee, SCCNFP, has included linalool on the list of fragrances that are known allergens but for which not many reports are found of allergy in consumers. 1 and 3 cases respectively of contact allergy have been reported from two examinations of 119 and 75 patients corresponding to 0.8 and 5 % of the patients with cosmetic eczema (29).

Critical effect

The critical effect of linalool is estimated to be liver damage. Due to the allergenic effect of linalool, people who are allergic to the substance should avoid skin contact as there is no lower limit to this side effect.

Table 7.1. Summary of data used to calculate MoS for linalool using EUSES.

Toxicological data (animals)	
LD ₅₀ , (mg/kg bw), oral, rat	2790 (22)
NOAEL, (mg/kg bw/d), ingestion	50 (28)
LOAEL*, (mg/kg bw/d), ingestion liver damage	500 (22)

*Lowest Observed Adverse Effect Level (LOAEL), the lowest exposure dose where effects were seen in the animals.

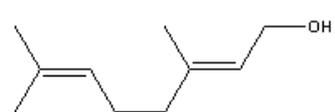
7.2 Geraniol

Occurrence and use

Geraniol occurs in many ethereal oils, e.g. rose oil, geranium oil, palmarosa oil, lemon grass and it is the main component in citronella oil (21,30). The substance smells sweetly of roses or flowers and can bring out lemon scents (26,31). One source states that it tastes like apple (26). Geraniol is used as fragrance in perfumes as well as in cosmetics, cleaning and washing agents and in perfumed air fresheners as well as an insect lure (21,22).

Identification

Geraniol is an acyclic terpenalcohol (23).

Chemical name:	Geraniol
Synonyms:	(E)-3,7-dimethyl-2,6-octadien-1-ol; 2,6-dimethyl-2,6-ectadien-8-ol
CAS-No.:	106-24-1
EINECS No.:	203-377-1
Molecular formula:	C ₁₀ H ₁₈ O
Molecular structure:	
Legislation: Classification according to the List of hazardous substances (Stat. Order 439 of 3 June 2002) The List of unwanted substances. Danish Environmental Protection Agency (24). Cosmetics (25)	Not classified On the list as the substance is considered to be dangerous to the health and the environment As of 11 March 2005, the fragrance must be declared in cosmetics if it is used in amounts above 0.01 % in products that are cleaned off and 0.001 % in products that are not cleaned off.

Physical-chemical properties (26)

Physical state	Oily liquid
Molecular weight (g/mol)	154.24
Melting point, °C	< -15 °C
Boiling point, °C	230 °C (760 mmHg)
Evaporation (Pa)	< 1 hPa at 20 °C (22). A more specific specification of evaporation has not been found.
Octanol-water distribution, (log Pow)	
Water solubility (mg/L)	Slightly soluble. 100 mg/l at 25 °C 686 mg/l at 20 °C (22)

Acute toxicity

Geraniol is low acute toxic with an LD₅₀ of 3600 mg/kg bw at oral exposure of rats (21). Inhalation studies with dogs at an exposure of 500 mg/m³ for 4 hours did not lead to any enzymatic changes in the olfactory epithelium (21). At dermal exposure of rabbit skin, LD₅₀ is > 5000 mg/kg bw.

Furthermore, acute toxicity experiments have been carried out with intramuscular, intraperitoneal and subcutaneous administration to mice and intravenous administration to rabbits. The lowest value is LD₅₀ of 50 mg/kg bw with intravenous administration to rabbits and an LD₅₀ of 1090 mg/kg bw at subcutaneous administration to mice (22).

The substance has been stated as moderately toxic to humans with an estimated deadly dose of 0.5–5 g/kg bw (26). This corresponds to a deadly dose in the interval of 35-350 g for a person weighing 70 kg. The unintentional ingestion by a child of an unknown amount of citronella oil containing 93% geraniol lead to vomiting, shock, seizures and death. The mucous membrane of the stomach was severely damaged (26).

Chronic, repeated exposure

A NOAEL of 10,000 ppm (corresponding to 10 g/kg feed) has been stated for oral exposure of rats for 16 weeks and a NOAEL of 1000 ppm has been stated for oral exposure of rats for 28 weeks (22). The critical effect has not been stated. Average weight of 16 and 28 week old rats is approximately 275 g and daily feed intake is approximately 22 g (20). Ingestion of 10000 ppm corresponds to 1 % of geraniol in the feed, i.e. a dose of 0.22 g geraniol per 275 g rat and thus equal to a dose of 800 mg/kg bw/d.

A NOAEL of 1000 ppm corresponds to 78.3 mg/kg bw/d. The critical effect has not been stated.

Geraniol has tested negative in Ames test. *In vitro* tests with mammalian cells has been positive to chromosome changes in Chinese hamster fibroblast cells and negative in mouse micronucleus test (21,22).

No data has been found for geraniol and cancer. No data has been found regarding reproduction toxicology for mammals but chicken embryos injected on the 3rd incubation day with 190 µg geraniol showed weak embryo-toxic effects, mainly malformations in the skeletal or limb structure (21,22).

No data has been found for inhalation of geraniol.

Local irritation

Literature states four studies regarding skin irritation. Two of the studies conclude that geraniol is not irritating and two of the studies that geraniol is irritating in contact with rabbit skin. One of the studies, which conclude that geraniol is irritating in contact with rabbit skin, has stated a complex test substance in which geraniol comprises 50 %, nerol 30% and citronellol 20 % (22).

No data has been found discussing geraniol's effects on eyes.

Allergy

The EU scientific committee, SCCNFP, has included geraniol on the list of fragrances that are known allergens Geraniol is found on the list of well-known and often reported consumer allergens and is a component in Fragrance mix (29).

Geraniol leads to sensitization in 0.4% eczema patients and is responsible for 3-7% of the reactions to Fragrance mix. Geraniol has lead to contact allergy reactions in 1.2-30% of patients with cosmetic eczema (29).

Critical effect

The critical effect for geraniol is estimated to be the extensive sensitizing effect. Due to geraniol's allergenic effect, people who are allergic to the substance should, however, completely avoid skin contact as there is no lower limit for this side effect.

Table 7.2. Summary of data used to calculate MoS for geraniol using EUSES.

Toxicological data (animals)	
LD ₅₀ , (mg/kg bw), oral, rat	3600 mg/kg bw (22)
NOAEL, (mg/kg bw/d), ingestion, 28 weeks	78.3 (22)
NOAEL, (mg/kg bw/d), ingestion, 16 weeks	783(22)
LOAEL, (mg/kg bw/d), ingestion	-

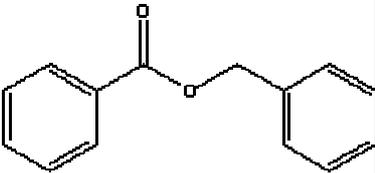
7.3 Benzyl Benzoate

Occurrence and use

Benzyl benzoate is one of the main components in Peru Balsam (29) and is also found in leaves from cinnamon, in the flowers carnation, tuberose, hyacinth and in ylang-ylang. The substance is used as perfume and aroma substance and as a fixative and it is often found in heavy flower scents (29). The substance has a balsamic scent and a sweet and sharp, burning taste (8). Is used in i.e. cosmetics, pharmaceuticals and pesticides (8,32).

Identification

Benzyl benzoate is an ester of Benzyl alcohol and an aromatic acid, Benzoic acid (23).

Chemical name	Benzyl Benzoate
Synonyms	Phenylmethyl Benzoate, Benylate, Benzoic acid, Benzyl ester
CAS-No.	120-51-4
EINECS No.	204-402-9
Molecular formula	C ₁₄ H ₁₂ O ₂
Molecular structure	
Legislation: Classification according to the List of hazardous substances (Stat. Order 439 of 3 June 2002)	Xn;R22
The List of unwanted substances. Danish Environmental Protection Agency (24).	On the list as the substance is considered to be dangerous to the health and the environment

Cosmetics (25)	As of 11 March 2005, the fragrance must be declared in cosmetics if it is used in amounts above 0.01 % in products that are cleaned off and 0.001 % in products that are not cleaned off.
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Physical-chemical properties

Physical state	Colourless liquid with a weak aromatic scent (8)
Molecular weight (g/mol)	212.25 (21)
Melting point, °C	18 - 20 °C (21)
Boiling point, °C	323 °C (21)
Evaporation (Pa)	0,000224 mm Hg (0,03 Pa) at 25 °C (26), 1.3 mm Hg (173 Pa) at 44 °C (21),
Octanol-water distribution, (log Pow)	Log Pow: 3.97 (21)
Water solubility (mg/L)	15.3 mg/L (20 °C) (22)

Acute toxicity

Benzyl benzoate is hazardous to health by ingestion. LD₅₀ oral rat has been measured from 500 mg/kg bw to >2000 mg/kg bw in rats (22). Symptoms of poisoning of rats, cats and rabbits is impact on the central nervous system, uncoordinated muscle movements, paralyzing of hind legs, convulsions, trouble when breathing and death (22). The substance penetrates the skin; 54% of the applied dose penetrated human skin in a 24 h occlusive test (26).

Chronic, repeated exposure

A 90-day test where 556 mg/kg bw/d was applied to rabbit skin has shown slight dermatitis and weakening, at higher doses slight to moderate atrophy of the testicles was observed as well as elevated leucocyte numbers. There were suggestions of kidney damage. Lethal dose was measured to be > 2,2 g/kg bw/d (22).

There are no signs of mutagenic effects in Ames test (22).

Tests on pregnant rats with a daily dose of 595 mg/kg bw from gestation day 0 until day 21 after birth showed no harmful effects to foetuses and young (22).

No data was found for inhalation of benzyl benzoate.

Local irritation

Benzyl benzoate is irritating to eyes and mucous membranes and may lead to irritation of the skin (21,26).

Allergy

The EU scientific committee, SCCNFP, has included benzyl benzoate on the list of fragrances that are known allergens. The substance may cause allergy by skin contact in humans (21,29). Most reports about allergy are caused by allergy to Peru Balsam in which the substance is the main component. In addition, Peru Balsam contains benzylcinnamat which is also a known allergen (29).

Critical effect

Dermatitis and atrophy of tests are described by doses, which animals survived. Due to the allergenic effects of benzyl benzoate, people who are allergic to the substance should, however, completely avoid skin contact as there is no lower limit for this side effect.

Table 7.3. Summary of data used for calculation of MoS for benzyl benzoate using EUSES.

Toxicological data (animals)	
LD ₅₀ , oral	1000 - 1700 (rat, mouse, rabbit, guinea pig) (21) 500 (rat) (22) 1891 (rat) (22) > 2000 (rat, OECD 401)(22) 2800 (rat)(22)
LD ₅₀ (mg/kg bw), dermal	4000 - 4448 (rabbit) (21,22) 4000 (rat) (22)
NOAEL, (mg/kg bw/d), ingestion, embryonic damage (rat)	595 (22)
LOAEL, (mg/kg bw/d), skin contact, dermatitis (rabbit)	556 (22)

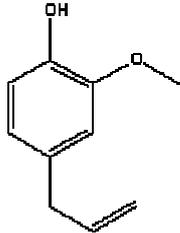
7.4 Eugenol

Occurrence and use

Eugenol is found in many ethereal oils from plants. The substance is the main component of clove oil and is also found in cinnamon and rose oil. The substance is used as perfume and aroma substance and gives off a clove-like, spicy and oriental scent and flavour (8,32). Is also used as a pain killer in dental care, as insect allurement and in chemical syntheses (21).

Identification

The substance is a substituted phenol (23).

Chemical name	Eugenol
Synonyms	2-Methoxy-4-(2-Propenyl)Phenol; 4-Allyl-2-Methoxyphenol; Caryophyllic Acid; Eugenic Acid; 2-Methoxy-1-Hydroxy-4-Allylbenzene; Allylguaiacol
CAS-No.	97-53-0
EINECS No.	202-589-1
Molecular formula	C ₁₀ H ₁₂ O ₂
Molecular structure	
Legislation: Classification according to the List of hazardous substances (Stat. Order 439 of 3 June 2002)	Xn;R22
The List of unwanted substances. Danish Environmental Protection Agency (24).	On the list as the substance is considered to be dangerous to the health and the environment
Cosmetics (25)	As of 11 March 2005, the

	fragrance must be declared in cosmetics if it is used in amounts above 0.01 % in products that are cleaned off and 0.001 % in products that are not cleaned off.
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Physical-chemical properties (26)

Physical state	Clear, colourless or slightly yellowish liquid. Characteristic fragrance.
Molecular weight (g/mol)	164.20 (21)
Melting point, °C	-9.2 – 9.1°C (21)
Boiling point, °C	254 °C (760 mmHg) (21)
Evaporation (Pa)	0.009 mm Hg (1,2 Pa) at 20 °C (21)
Octanol-water distribution, (log Pow)	Log Kow: 2.27
Water solubility (mg/L)	Almost insoluble in water

Acute toxicity

Eugenol poses a health hazard by inhalation. LD₅₀ oral rat has been measured to be 1930 mg/kg bw. Poisoned rats have shown signs of kidney damage, demonstrated by urine incontinence as well as slight paralysis of hind legs and jaw, exhaustion and coma (26). Ingestion of aqueous emulsions of the substance may lead to nausea and promote the secretion of mucin, in dogs vomiting has been observed at ingestion of 250 mg/kg bw and 500 mg/kg bw (26). The substance is strongly irritating to the mucous membrane of the stomach. By oral ingestion in rats and guinea pigs, peeling of the epithelium of the stomach and punctiform bleeding in pyloric and glandular areas of the stomach have been observed (26).

Chronic, repeated exposure

20 rats' ingestion of eugenol in doses from 1.4 g eugenol/kg gradually increasing to 4.0 g/kg, 8 rats survived for 34 days and 12 rats long enough to obtain the maximum dose. It has not been described how the dose gradient was increased. Damage to the liver and gastrointestinal tract was seen, particularly to the fore stomach (33). Rats that ingested doses of eugenol of ≤ 6000 ppm in the feed for 13 weeks showed no side effects. Ingestion of 12.000 ppm lead to loss of weight loss (21). As a 13 week rats weighs approximately 275 g and eats approximately 22 g feed per day (20), their ingestion is 12000 ppm which is the same as 1.2% of the feed corresponding to a dose of 0.264 g eugenol per 275 g rat, thus equal to a dose of 0.96 g/kg bw. There were no side effects in groups of 15 male rats and 15 female rats fed with eugenol in doses of 79.3 mg/kg bw/d for 12 weeks (33).

IARC has classified eugenol in group 3: insufficient evidence of carcinogenic effect in humans, limited evidence of carcinogenic effects in animals (34).

Eugenol has not shown any mutagenic effects in several bacteria tests. *In vitro* tests have show chromosome changes in Chinese hamster ovary cells and a slight increase in sister chromatide changes (34).

No data has been found for inhalation of eugenol.

Local irritation

Eugenol may irritate the air passage by inhalation. The substance has shown slight skin irritation in patch tests on humans (21).

Allergy

Eugenol is a well-known contact allergen and the substance forms part of Fragrance Mix which is used for screening of patients for perfume allergy (29). Numerous tests have been carried out of the sensitizing properties of the substance and the EU has informed that eugenol has caused allergic reactions in 0.7-20% of patients with eczema from cosmetic products (26,29).

Critical effect

Based on the above, the critical effect for eugenol is estimated to be liver damage. However, due to the allergenic properties of eugenol, people who are allergic to the substance should completely avoid skin contact as there is no lower limit for this side effect.

Table 7.4. Summary of data used for calculation of MoS for eugenol using EUSES.

Toxicological data (animals)	
LD ₅₀ , (mg/kg bw), oral, rat	1930 (rat) (26)
LD ₅₀ (mg/kg bw), dermal	1200 (21)
NOAEL, (mg/kg bw/d), ingestion, liver damage	79.3 (33)
LOAEL, (mg/kg bw/d), ingestion, liver damage	960 mg/kg bw/d (12.000 ppm in feed) (21)

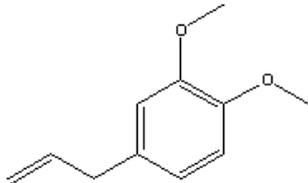
8.5 Methyl eugenol

Occurrence and use

Methyl eugenol is used as fragrance in perfumes. It is not added directly in cosmetic products but is only added as a fragrance raw material. In addition, it is used as an aromatic substance in food and drinks and as an insect allurement (21,35,36). Methyl eugenol is found in many ethereal oils, in concentrations of up to 90% or more in oil extracts from pine trees. The substance smells mildly spicy with a slight herbal-like scent and is used e.g. in scent compositions of clove and lilac. The substance can be produced synthetically through methylation of eugenol (31).

Identification

Methyl eugenol is a phenylether.

Chemical name	Methyl eugenol
Synonyms	4-allyl-1,2-dimethoxybenzen
CAS-No.	93-15-2
EINECS No.	202-223-0
Molecular formula	C ₁₁ H ₁₄ O ₂
Molecular structure	
Legislation: Classification according to the List of hazardous substances (Stat. Order 439 of 3 June 2002)	Not classified
The List of unwanted substances. Danish	Not listed

Environmental Protection Agency (24).	
Cosmetics (25)	Recommended maximum concentration of 0.0002% in leave-on products (36)

Physical-chemical properties (26)

Physical state	Liquid
Molecular weight (g/mol)	178.23
Melting point, °C	-4 °C
Boiling point, °C	255 °C (760 mmHg)
Evaporation (Pa)	1 mm Hg (133 Pa) at 85 °C 0,02 mm Hg (2,7 Pa) at 20 °C (21)
Octanol-water distribution, (log Pow)	2.9 (37)
Water solubility (mg/L)	500 mg/l < 1 mg/ml (21)

Acute toxicity

LD₅₀-values by oral exposure of rats and mice has been found from 850-1560 mg/kg bw for rats and 540 mg/kg bw for mice (37).

LD₅₀ by dermal exposure of rabbits has been found to be > 2025 mg/kg bw (21) and > 5000 mg/kg bw (26).

A single exposure of 88 mg/kg bw lead to neurological effects in mice and a single exposure of 200 mg/kg bw for mice and rats (strain not specified) lead to the animals falling asleep but not dying (26). LD₅₀ for administration in the abdominal cavity in mice has been stated at 540 mg/kg bw (21).

Methyl eugenol is absorbed quickly after oral exposure, converted in the liver and excreted with the urine (35).

Chronic, repeated exposure

Daily dosage in the abdominal cavity at an exposure of 100 mg/kg bw/d in rats and mice for 26 and 42 days, respectively, did not lead to any effects in mice but a reduced growth in rats (26).

Methyl eugenol has been tested by NTP (National Toxicology Programme) for toxicity and carcinogenicity based on the structural similarity with safrol (CAS No. 94-59-7) which is a known carcinogen (35). These tests have been reported below:

Tests have been carried out with oral exposure of rats in doses of 0, 10, 30, 100, 300 and 1000 mg/kg bw, 5 days/week for 14 weeks. At an exposure of 100 mg/kg bw/d, effects such as increased liver weight in male animals and enzyme changes and liver cell damage in both sexes were observed. Furthermore, at a dose of 300 mg/kg bw/d, reduced body weight, increased bile amount, inflammation of the mucous membrane of the stomach was seen in both sexes along with an increased liver weight in females. Exposure to 1000 mg/kg bw/d furthermore lead to an increased testicular weight (35). The same tests on mice showed the same type of effects (35). NOEL for methyl eugenol has been set at 10 mg/kg bw/d for both species with effects on the liver and not cancer as the critical effect (37).

Tests carried out during 2 years with oral exposure of rats in doses of 37, 75, 150 and 300 mg/kg bw, 5 days/week for 105 weeks showed reduced body weight at all doses. 100% of the male animals died before the end of the test at exposures of 150 and 300 mg/kg bw/d At these dosage levels, an increased mortality was also observed in the female animals. Pathological examinations showed effects from

exposures of 37 mg/kg bw/d. These effects include neoplasms and cell changes in the liver, atrophy of the mucous membranes, kidney failure and adenomas in the kidneys. At 75 mg/kg bw/d, neuroendocrine tumours were seen in females, an effect observed at 150 mg/kg bw/d in males (35). When carrying out the same test on mice, the same type of effects was seen (35).

Based on the above, NTP concludes that there is clear evidence of carcinogenic effect of methyl eugenol in rats and mice (35).

Methyl eugenol is not mutagenic in Ames test at the highest test concentration of 0.33 mg/plate. The substance has shown that it may introduce sister chromatid exchange in Chinese hamster ovary cells with activation, but it did not introduce chromosome changes in Chinese hamster ovary cells with and without activation. 14-week *in vivo* micronucleus tests with blood cells in mice were negative.

No data have been found regarding reproduction toxicology (26,35,37,38).

The SCCNFP evaluation regarding the use of methyl eugenol in cosmetics is that the substance should not continue to be added to cosmetics as an ingredient. If the substance occurs naturally, e.g. in fragrances, the highest concentration of methyl eugenol in the finished product should not exceed 0.01% in fine fragrance, 0.004% in eau de toilette, 0.002% in a fragrance lotion, 0.0002% in other leave-on products and oral care product and 0.001% in rinse-off products (36). It is therefore evaluated that lip care products are allowed to contain up to 0.0002% methyl eugenol.

The European Medicines Agency for evaluation of medical products (EMA) estimates that ingestion of natural medicine containing methyl eugenol due to the widespread occurrence of the substance in plant oils does not pose a significant cancer risk in adults. It is, however, recommended that exposure of children as well as pregnant and nursing women should be minimised and that the absorption of methyl eugenol through the skin be investigated (37).

No data has been found on inhalation of methyl eugenol.

Local irritation

No data has been found on the irritating properties of methyl eugenol.

Allergy

No data has been found on the sensitizing properties of methyl eugenol. The substance has not been listed by the SCCNFP as one of the substances for which there are reports on allergenic effects in consumers (29).

Critical effect

The critical effects for methyl eugenol are effects on the liver and the carcinogenic effect. As the SCCNFP has set out guidelines for the use of the substance in cosmetic products, exposure must be evaluated according to these limits (0.0002 %) as exposure below these must be expected to be of no concern to health.

Table 7.5. Summary of data used for calculation of MoS for methyl eugenol using EUSES.

Toxicological data (animals)	
LD, (mg/kg bw), oral, rat	850 (37)
NOAEL, (mg/kg bw/d), ingestion, liver damage	10 (37)
LOAEL, (mg/kg bw/d), ingestion, liver damage	37 (35)

9 Exposure assessment

For the exposure assessment, the substances' toxicological profiles, analysis results and guidelines for e.g. application frequency and amount as stated in EU's Technical Guidance Document (TGD) (20) and the SCCNFP guidelines (39) are used to estimate the actual exposure in a worst case scenario for one or more standard persons.

9.1 Exposure calculations

Table 8.2 gives an overview of the results of the worst case calculations of the oral and dermal exposure using EUSES. EUSES is a data base programme used for exposure calculations. Summaries of the exposure data can be seen in table 7.1. The modelling results are supplemented by manual calculations for all 26 fragrances + Methyl eugenol, cf. table 8.2.

Exposure through the use of lip care products can occur by absorption through the skin and oral intake, but it is relevant to include exposure through inhalation as fragrances are volatile at room and skin temperature and thus may be inhaled through evaporation from the lips close to the nose.

It has not been possible to establish exposure scenarios for exposure through inhalation and for skin exposure to fragrance due to a lack of data in the literature for the individual substances. The EUSES exposure evaluations have calculated with 100 % absorption through both types of exposure. This means that the two scenarios correspond to an ingestion of the entire product.

Therefore, it has been chosen to use oral absorption as the total absorption in the body as this is the exposure supported by most data in the literature. In addition, the model assumes exposure of the hands when dermal exposure is modelled. The skin of the lips and thus absorption through them differs from the skin on the hands and it is hard to accurately estimate the impact of this route of exposure.

Table 8.1. Summary of exposure data calculated by EUSES.

Exposure	
Amount of substance on the skin (lips), all substances	60 mg/day
Max. concentration in the ingested product:	
Linalool	0.845 mg/cm ³
Geraniol	0.725 mg/cm ³
Benzyl Benzoate	6.7 mg/cm ³
Eugenol	0.0865 mg/cm ³
Methyl eugenol	0.036 mg/cm ³

Total absorption in the body (Corresponds to exposure calculated for absorption through ingestion or the potential skin absorption):	
Linalool	7.24×10^{-4} mg/kg bw/d
Geraniol	6.21×10^{-4} mg/kg bw/d
Benzyl Benzoate	0.00574 mg/kg bw/d
Eugenol	7.41×10^{-5} mg/kg bw/d
Methyl eugenol	3.09×10^{-5} mg/kg bw/d
Margin of safety (MoS) , repeated exposure, oral or dermal exposure:	
Linalool	6.9×10^4
Geraniol	1.26×10^5
Benzyl Benzoate, oral exposure	9.68×10^4
Eugenol	1.07×10^6
Methyl eugenol, oral exposure	3.24×10^5

When comparing the NOAEL and LOAEL values found for the analysed fragrances it can be seen that the calculated total intake in the body is very low. For the substances evaluated, the lowest ratio between the NOAEL value found and the calculated value for total absorption in the body has been found for Linalool and this value is 69.000. It can also be seen from the MoS values that the health risk from obtaining the most critical effects seen in literature by oral ingestion of the substances is very low.

The daily exposure to the 26 fragrances, which EU has declared to be allergenic, as well as Methyl eugenol has been calculated for two standard persons. A 60 kg woman and a 18 kg child (3-5 years old). The daily exposure has been calculated as the highest measured content of the fragrance and the persons have been chosen based on the assumption that women use lip care products more frequently than men and that the use may start as early as kindergarten due to dry lips or play with cosmetic products. Furthermore, sensitizing is rarely seen in children during the first 2-3 years of life, but exposure to perfume containing contact allergen fragrances early in life may lead to a clinical problem later in life (40).

The following calculation method shows the worst case scenario with oral intake as the only route of exposure:

Person weight, woman:	60 kilos
Person weight, child, 3-5 years (19):	18 kilos
Number of daily applications (20):	6
Amount used per application (20):	10 mg
Highest measurement of the fragrance (example: Benzyl benzoate cf. table 5.2):	6650 mg/kg
Absorption by oral ingestion:	100 %

Daily exposure, Benzyl benzoate, woman:

$$\frac{6 \times 0,00001 \text{ kg lipcareproduct} / \text{day} \times 6650 \text{ mg Benzyl Benzoat} / \text{kg lipcareproduct}}{60 \text{ kg bw}} = 0,0067 \text{ mg} / \text{kg bw} / \text{day}$$

Daily exposure, Benzyl benzoate, child, 3-5 years:

$$\frac{6 \times 0,00001 \text{ kg lipcareproduct} / \text{day} \times 6650 \text{ mg Benzyl Benzoat} / \text{kg lipcareproduct}}{18 \text{ kg bw}} = 0,022 \text{ mg} / \text{kg bw} / \text{day}$$

The daily exposure to the 17 fragrances found in the analysis is calculated per kg body weight per day for the two standard persons. The results can be seen in table 8.2.

Table 8.2. Daily exposure for two standard persons to the 17 fragrances found in the lip care products analysed.

Fragrance	Weight-% (highest value measured)	Daily exposure, woman, 60 kg (mg/kg bw/day)	Daily exposure, child, 18 kg, (mg/kg bw/d)
Benzyl alcohol	0.18*	0.0018	0.006
Benzyl benzoate	0.67*	0.0067	0.022
Benzylcinnamat	0.0055*	0.000055	0.00018
Benzyl salicylat	0.00065	0.0000065	0.000022
Cinnamal	0.00015	0.0000015	0.000005
Citral	0.12*	0.0012	0.004
Citronellol	0.075*	0.00074	0.0025
Coumarin	0.00055	0.0000055	0.000018
Eugenol	0.0087*	0.000087	0.00029
Farnesol	0.0011*	0.000011	0.000035
Geraniol	0.073*	0.00073	0.0024
α - Isomethylionon	0.0069*	0.000069	0.00023
D-limonen	2.25*	0.0225	0.075
Linalool	0.085*	0.000845	0.0028
Isoeugenol	0.015*	0.000145	0.00048
Methyl eugenol	0.0036**	0.000036	0.00012

* Maximum weight% measured is above 0.001% which is the declaration limit for the 26 allergenic fragrances.

** Maximum weight% measured is above 0.0002% which is the limit for allowed content of Methyl eugenol in this type of products.

The results of the analysis show (table 8.2) that the total content of the 26 allergenic fragrances is in concentrations from 0-2.45 weight-% with an average of 0.32 weight-% and a median value of 0.042 weight-%. The median value is lopsided towards lower concentration and it can be seen that few products have a very high content of perfume. A comparison with other cosmetic products than lip care products shows an average value close to the perfume content in face creams (including make up and foundation). Face creams are stated as having the lowest content of perfume among 11 other types of cosmetic products (41).

Exposure to the combined amount of fragrances through the use of a lip care product is estimated to be equal to exposure at the highest value measured as the contribution from other fragrances are negligible, cf. table 8.2.

When comparing the calculations of the daily exposure per kg body weight for linalool, geraniol, benzyl benzoate, eugenol and methyl eugenol with the model calculated values using EUSES for total absorption in the body it can be seen that the numbers are basically identical, cf. tables 8.1 and 8.2. We therefore estimate that the calculated values for d-limonene, benzyl alcohol and children give a realistic worse case picture of the exposure to these fragrances when using lip care products.

9.2 Exposure assessment of the selected substances

D-limonen and benzyl alcohol have previously been evaluated by the EPA mapping projects. These state a NOAEL value for d-limonen of 10 mg/kg bw/day, which compared to the calculated daily exposure gives an MoS of > 133 for children and > 444 for women. MoS should be above 100 in order for the product to be considered safe and the calculation for children shows that the margin of safety is close to being exceeded. SCCNFP has listed d-limonen as a fragrance that causes allergy. Oxidation products of d-limonen are very potent allergens with a frequency of contact allergy of 1-2% in eczema patients. According to SCCNFP, benzyl alcohol is a documented allergen causing allergy in 1.2-15% (2-4 cases in each study) in patients with cosmetic eczema (29). The substance has not been evaluated further. Both substances are included on the EPA list of unwanted substances (24).

Due to the carcinogenic effect of methyl eugenol, SCCNFP has established a limit for content of methyl eugenol in leave-on cosmetic products of 0.0002 weight% (5,36). For 2 of the 3 products analysed for Methyl eugenol, the content was above the detection limit of 0.0012 and 0.0036 weight%, respectively. This means that both products (no. 80 and 93) are above the legislative maximum limit for methyl eugenol in leave-on products. Therefore, the content of methyl eugenol may pose a potential health risk when using the products in question.

Linalool, geraniol, benzyl benzoate and eugenol have been evaluated by SCCNFP as being allergenic by skin contact and as no "zero effect level" exists for this effect it is important to point out that skin contact with these substances should be avoided (29).

Despite the fact that the exposure calculations show low daily exposure for both children and adults when using the lip care products, it has to be concluded that as the substances in question are allergenic the use of products with a high content of perfume may pose a health risk. This view is supported by the fact that EU has established a mandatory declaration of these fragrances when present above a given concentration in the finished cosmetic product.

10 Summary and conclusion

According to "Kosmetikdirektivet", the concentration of the 26 allergenic fragrances must be stated on the product's declaration of contents if they are found in concentrations of > 0.001% in leave-on products, i.e. products that are not washed off. The future regulation will enable consumers allergic to fragrances to avoid fragranced products and as a result reduce the number of allergic reactions.

From table 8.2 it appears that the obligation to declare content of fragrances will apply to the fragrances marked with an asterisk*. This means that the obligation to declare applies to 12 of the 16 fragrances found in the analysed lip care products.

As it is not immediately possible to estimate the concentration and content of the individual sensitizing fragrances in a product, nor by smelling the product, the future declaration of contents will enable consumers to obtain information on the content, however, not the concentration in the product.

In a survey of cosmetic products based on natural ingredients, a number of fragrances were identified which are also included in this survey, e.g. geraniol, eugenol and hydroxycitronellal (42). This is in agreement with the fact that the analysed products containing vegetable oils/plant extracts contained a selection of allergenic fragrances. As a result, consumers allergic to fragrances must be careful when using cosmetic products based on natural ingredients as an alternative to "ordinary" cosmetics, including lip care products.

Products with a high content of fragrances may pose a risk of allergy to particularly sensitive persons, including children.

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Appendix 1. Natural occurrence and use

Natural occurrence and use of the 26 fragrances, which the EU considers to be allergenic, as well as methyl eugenol.

Number, alphabetic order	CAS No.	Fragrance	Use in fragrances (1, 2)	Naturally occurring (2, 3, 4)
1	105-13-5	Anisyl alcohol (anise alcohol)	Flower fragrances in drinks and confectionary.	Tomato, anise seed, honey, vanilla.
2	122-40-7	Amyl cinnamal		Soy bean.
3	101-85-9	Amylcinnamyl alcohol		No data.
4	100-51-6	Benzyl alcohol	Weak sweet scent. Solvent, starter material for synthesis of benzyl esters.	Apple juice, fruits.
5	120-51-4	Benzyl benzoate	Fixative, modifier in heavy flower fragrances.	Main component in Peru Balsam, Cranberries.
6	103-41-3	Benzylcinnamat	Fixative, in heavy, oriental fragrances.	No data.
7	118-58-1	Benzyl salicylat	Fixative. In flower/spicy fragrances and in aromas.	Cranberries, clove.
8	127-51-5	3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-on	"Highly valued fragrance material". In flower and "fantasy" fragrances.	No data.
9	104-54-1	Cinnamyl alcohol	In many flower fragrances (lilac, hyacinth, lily of the valley). Cinnamon notes. As "rounder".	Blueberries, cranberries.
10	104-55-2	Cinnamal (cinnamic aldehyde)		Blueberries, cranberries.
11	5392-40-5	Citral	Heavy lemon scent.	Orange juice, lemon oil, lemon grass.
12	106-22-9	Citronellol	Rose scent, widespread use, often in lemon fragrances.	Rose, geranium, blackcurrant, fruits.
13	91-64-5	Coumarin	"Spicy green notes". In perfumes for soaps and as "brightener".	
14	97-53-0	Eugenol	Clove fragrance, "oriental", "spicy" fragrances.	Clove and cinnamon, strawberries, fruits, nutmeg.
15	4602-84-0	Farnesol	In flower scents. Fixative, deodorizing.	Grapefruit juice.
16	106-24-1	Geraniol	Flowery/rose scent. May bring out citrus scent. Widespread use.	Rose, geranium, citronella, apple juice, fruits.
17	101-86-0	Hexylcinnamaldehyd	Jasmine scent. In flower fragrances.	Rice, cooked.

Number, alphabetic order	CAS No.	Fragrance	Use in fragrances (1, 2)	Naturally occurring (2, 3, 4)
18	107-75-5	Hydroxycitronellal	In many flower scents (incl. lily of the valley, honeysuckle, lily, cyclamen).	Synthetic.
19	97-54-1	Isoeugenol	In flower scents (clove). "Oriental", "spicy".	Beer, rum, coffee, nutmeg.
20	80-54-6	Lillial (trade name) 2-(4-tert-butylbenzyl) propionaldehyd	In flower scents (cyclamen, lily of the valley). Widespread use.	Synthetic.
21	5989-27-5	d-limonen	Lemon scent. From citrus fruit peel.	Orange juice, fruits, celery, vegetables.
22	78-70-6	Linalool	In flower scents. Widespread use.	Freesia, lily of the valley, lavender, orange juice, carrot.
23	31906-04-4	Lylal (trade name) Hydroxymethylpentyl-cyclohexencarboxal dehydr.	In flower scents, lily of the valley.	Synthetic.
24	111-12-6	Methyl heptin carbonat	Melon scent.	Synthetic.
25	90028-68-5	Oakmoss	Dry, sweet, leather. Base note. Fixative.	Moss (<i>Evernia prunastri</i>) on oak.
26	90028-67-4	Treemoss		Moss on pine (<i>Evernia barbata</i> and <i>Evernia furfuracea</i>)
27	93-15-2	Methyl eugenol	Mildly spicy, weak herbal scent. In flower scents of clove and lilac.	Pine.

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Appendix 2. Analytical results

Table 1 The results of the analysis for methyl eugenol. The results are given in mg/kg.

	53		80		93	
	A	B	A	B	A	B
Methyl eugenol	< 10	< 10	12	12	36	36

<: means less than the stated limit of detection

Table 2. The results from the analysis for fragrances. Unit is mg/kg. The two results indicate double determination.

	LOD	7		10		20		32		33	
		A	B	A	B	A	B	A	B	A	B
Anisyl alcohol	1	-	-	-	-	-	-	-	-	-	-
Amyl cinnamal	1	-	-	-	-	-	-	-	-	-	-
Amylcinnamyl alcohol	1	-	-	-	-	-	-	-	-	-	-
Benzyl alcohol	1	-	-	-	-	30	33	-	-	9	10
Benzyl benzoate	1	8	16	-	-	-	-	110	96	-	-
Benzylcinnamat	1	-	-	-	-	-	-	-	-	-	-
Benzyl salicylat	1	-	-	-	-	-	-	-	-	-	-
Cinnamyl alcohol	1	-	-	-	-	-	-	-	-	-	-
Cinnamal	1	-	-	-	-	-	-	-	-	-	-
Citral	1	1300	1100	-	-	-	-	33	32	-	-
Citronellol	1	-	-	-	-	-	-	-	-	-	-
Coumarin	1	-	-	-	-	-	-	-	-	-	-
Eugenol	1	-	-	-	-	-	-	-	-	-	-
Farnesol	1	-	-	-	-	-	-	-	-	-	-
Geraniol	1	9	11	-	-	-	-	6	6	3	3
Hexylcinnamaldehyd	1	-	-	-	-	-	-	-	-	-	-
Hydroxycitronellal	1	-	-	-	-	-	-	-	-	-	-
α -Isomethylionon	1	66	71	-	-	-	-	-	-	-	-
Lillial	1	-	-	-	-	-	-	-	-	-	-
D-limonen	1	24000	21000	140	140	4	2	420	420	73	73
Linalool	1	880	810	-	-	-	-	98	100	23	25
Lylal	1	-	-	-	-	-	-	-	-	-	-
Isoeugenol	1	150	140	-	-	-	-	-	-	-	-
Methyl heptin carbonat	1	-	-	-	-	-	-	-	-	-	-
Oakmoss	10	-	-	-	-	-	-	-	-	-	-
Treemoss	10	-	-	-	-	-	-	-	-	-	-
Sum		26000	23000	140	140	34	35	670	650	110	110

LOD: means limit of detection

-: means not detected above the LOD

Table 2 continued.

The results of the analysis for fragrances. Unit is mg/kg. The two results indicate double determination.

	LOD	35		37		45		51		53	
		A	B	A	B	A	B	A	B	A	B
Anisyl alcohol	1	-	-	-	-	-	-	-	-	-	-
Amyl cinnamal	1	-	-	-	-	-	-	-	-	-	-
Amylcinnamyl alcohol	1	-	-	-	-	-	-	-	-	-	-
Benzyl alcohol	1	-	-	10	12	8	8	-	-	6	4
Benzyl benzoate	1	-	-	-	-	7	6	100	130	-	-
Benzylcinnamate	1	-	-	-	-	3	3	6	5	-	-
Benzyl salicylate	1	-	-	-	-	6	6	-	-	-	-
Cinnamyl alcohol	1	-	-	-	-	-	-	-	-	-	-
Cinnamal	1	-	-	-	-	-	-	-	-	-	-
Citral	1	-	-	-	-	-	-	-	-	57	55
Citronellol	1	56	52	-	-	-	-	5	4	-	-
Coumarin	1	-	-	-	-	-	-	-	-	-	-
Eugenol	1	-	-	-	-	16	14	41	40	-	-
Farnesol	1	-	-	-	-	-	-	-	-	-	-
Geraniol	1	180	190	-	-	-	-	-	-	4	4
Hexylcinnamaldehyde	1	-	-	-	-	-	-	-	-	-	-
Hydroxycitronellal	1	-	-	-	-	-	-	-	-	-	-
α -Isomethylionon	1	-	-	-	-	-	-	-	-	-	-
Lillial	1	-	-	-	-	-	-	-	-	-	-
D-limonene	1	76	74	3	4	460	470	9	9	16000	15000
Linalool	1	19	19	-	-	150	160	-	-	24	26
Lylal	1	-	-	-	-	-	-	-	-	-	-
Isoeugenol	1	-	-	-	-	-	-	3	3	-	-
Methyl heptine carbonate	1	-	-	-	-	-	-	-	-	-	-
Oakmoss	10	-	-	-	-	-	-	-	-	-	-
Treemoss	10	-	-	-	-	-	-	-	-	-	-
Sum		330	330	13	16	650	670	160	190	16000	15000

LOD: means limit of detection

:- means not detected above the LOD

Table 2 continued.

The results of the analysis for fragrances. Unit is mg/kg. The two results indicate double determination.

	LOD	57		66		75		80		86	
		A	B	A	B	A	B	A	B	A	B
Anisyl alcohol	1	-	-	-	-	-	-	-	-	-	-
Amyl cinnamal	1	-	-	-	-	-	-	-	-	-	-
Amylcinnamyl alcohol	1	-	-	-	-	-	-	-	-	-	-
Benzyl alcohol	1	-	-	23	24	-	-	14	15	-	-
Benzyl benzoate	1	7200	7000	6700	6600	-	-	14	12	-	-
Benzylcinnamate	1	-	-	-	-	-	-	8	6	-	-
Benzyl salicylate	1	-	-	-	-	-	-	-	-	-	-
Cinnamyl alcohol	1	-	-	-	-	-	-	6	7	-	-
Cinnamal	1	-	-	-	-	-	-	-	-	-	-
Citral	1	24	22	-	-	-	-	-	-	-	-
Citronellol	1	-	-	-	-	760	730	220	220	-	-
Coumarine	1	-	-	-	-	-	-	-	-	-	-
Eugenol	1	-	-	-	-	86	87	46	46	-	-
Farnesol	1	-	-	-	-	-	-	5	6	-	-
Geraniol	1	-	-	-	-	720	730	98	96	-	-
Hexylcinnamaldehyde	1	-	-	-	-	-	-	-	-	-	-
Hydroxycitronellal	1	-	-	-	-	-	-	-	-	-	-
α -Isomethylionon	1	-	-	-	-	-	-	-	-	-	-
Lillial	1	-	-	-	-	-	-	-	-	-	-
D-limonene	1	4	3	12	11	170	170	6	6	-	-
Linalool	1	70	69	-	-	800	770	5	5	-	-
Lylal	1	-	-	-	-	-	-	-	-	-	-
Isoeugenol	1	-	-	-	-	-	-	-	-	-	-
Methyl heptine carbonaet	1	-	-	-	-	-	-	-	-	-	-
Oakmoss	10	-	-	-	-	-	-	-	-	-	-
Treemoss	10	-	-	-	-	-	-	-	-	-	-
Sum		7300	7100	6700	6600	2500	2500	420	420	-	-

LOD: means limit of detection

:- means not detected above the LOD

Table 2 continued.

The results of the analysis for fragrances. Unit is mg/kg. The two results indicate double determination.

	LOD	91		93		94		97		106	
		A	B	A	B	A	B	A	B	A	B
Anisyl alcohol	1	-	-	-	-	-	-	-	-	-	-
Amyl cinnamal	1	-	-	-	-	-	-	-	-	-	-
Amylcinnamyl alcohol	1	-	-	-	-	-	-	-	-	-	-
Benzyl alcohol	1	-	-	8	10	1800	1800	27	29	-	-
Benzyl benzoate	1	-	-	7	6	-	-	-	-	-	-
Benzylcinnamate	1	-	-	-	-	-	-	-	-	-	-
Benzyl salicylate	1	-	-	-	-	-	-	-	-	-	-
Cinnamyl alcohol	1	-	-	-	-	-	-	-	-	-	-
Cinnamal	1	-	-	2	1	-	-	-	-	-	-
Citral	1	-	-	-	-	-	-	-	-	-	-
Citronellol	1	-	-	410	410	-	-	-	-	-	-
Coumarine	1	-	-	-	-	-	-	-	-	6	5
Eugenol	1	-	-	29	24	22	21	-	-	-	-
Farnesol	1	-	-	11	10	-	-	-	-	-	-
Geraniol	1	-	-	140	140	-	-	-	-	-	-
Hexylcinnamaldehyde	1	-	-	-	-	-	-	-	-	-	-
Hydroxycitronellal	1	-	-	-	-	-	-	-	-	-	-
α -Isomethylionon	1	-	-	-	-	-	-	-	-	-	-
Lillial	1	-	-	-	-	-	-	-	-	-	-
D-limonene	1	6	6	770	790	3	3	2600	2600	20	20
Linalool	1	-	-	31	28	97	94	42	39	-	-
Lylal	1	-	-	-	-	-	-	-	-	-	-
Isoeugenol	1	-	-	-	-	-	-	-	-	-	-
Methyl heptine carbonate	1	-	-	-	-	-	-	-	-	-	-
Oakmoss	10	-	-	-	-	-	-	-	-	-	-
Treemoss	10	-	-	-	-	-	-	-	-	-	-
Sum		6	6	1400	1400	1900	1900	2700	2700	26	25

LOD: means limit of detection

:- means not detected above the LOD