Draft of new regulation of xx.xx.2006 concerning external healthcare products

As laid down by The Norwegian Food Safety Authority xx.xx.2006 pursuant to the Act of 21 December 2005 no. 126 concerning cosmetics and bodycare products etc. § 5 second subsection, § 7 second and third subsection, § 8, § 9, § 11 second subsection, § 12 first and third subsection, § 13 third subsection, § 14 third subsection, § 15, § 16 sixth subsection, § 19 and § 21, pursuant to the regulation of 29 December 2005 no. 1770 concerning delegation of authority to The Norwegian Food Safety Authority pursuant to the Cosmetics Act points 2 and 3.

I

Part I. Introductory decisions

§ 1. *Aim*

The aim of this regulation is to help ensure use of external healthcare products meant for treatment of humans or animals will not involve health threats.

This regulation shall also promote consumer interests, fair trading, animal welfare, ethics, the environment, food safety and quality.

§ 2. *Scope*

This regulation encompasses all situations associated with developing, producing, importing, processing, distributing, exporting and selling external healthcare products and health personnel's duty to report any side effects when using such products.

This regulation does not encompass products encompassed by the regulation of 26 October 1995 no. 871 (general regulation concerning production, import and sale etc..of cosmetics and bodycare products), pursuant to directive 76/768/EEC (The Cosmetics Directive), regulation xxxx concerning tattooing products, regulation xxx concerning products for cutaneous injection for cosmetic purposes or regulation xxxx concerning external products for care and marking of animals using chemical substances.

This regulation does not encompass products which are reckoned to be medicines or medical equipment pursuant to the applicable decisions on medicines and medical equipment.

In cases of doubt, the inspection authority can decide whether a product is encompassed by this regulation. Should doubt exist as to whether a product should be reckoned to be an external healthcare product or other product as mentioned in the third subsection, this question will be decided in cooperation with the competent authority in these product areas.

§ 3. *Definitions*

In this regulation the following definitions apply:

1. *Product:* An external healthcare product.
2. *An external healthcare product:* Substance or mixture of substances meant to come into contact with the surface of the body of humans or animals, teeth or mucous membranes in the mouth or nostrils solely or mainly to prevent, relieve or treat health problems not due to disease.
3. *Disease:* Those bodily states which the World Health Organization (WHO) has listed in "The International Statistical Classification of Diseases and Related Problems" (ICD), apart from certain conditions in accordance with the list of guidelines mentioned under

point 4 below as well as those bodily states which the World Organization for Animal Health (OIE) reckons to be animal diseases apart from certain conditions in accordance with the list of guidelines which is mentioned in point 4 below.

4. *Health problems not due to disease:* The inspection authority draws up, in association with competent expert authorities within medicines and medical device, a list of guidelines containing examples of health problems which shall not be reckoned to be due to disease. The inspection authority shall make this list available to the general public in a suitable fashion.
5. *Inspection authority:* The Norwegian Food Safety Authority is the inspection authority pursuant to this regulation.
6. *Side effect:* A reaction when using the product - stated in appendix I.
7. *Use:* Use of product which can reasonably be predicted. Purposeful misuse is not included.
8. *Sale*: Possession with the intention to sell, offer for sale, distribute, the sale itself and all other forms of taking possession, with or with out payment being made, including use in salons, etc and for the purposes of advertising.
9. *Business:* Private or public concern or individuals who perform an activity mentioned in § 2 first subsection, apart from private or non-commercial activities.
10. *Health claim:* Claim which says something about the link between a product and human or animal health.
11. *Medical claim:* Claim which says something about the link between a product and a disease.
12. *Ingredients:* Chemical substance or mixture of such of synthetic or natural origin which is used in a product.
13. *Preservative:* An ingredient which is added to hinder the growth of microorganisms.
14. *Coloring:* An ingredient which is added to imbue a product with a certain color
15. *INCI-name:* A pan-European name of an ingredient as drawn up by the EU Commission (INCI: International Nomenclature Cosmetic Ingredient).
16. *Health personnel:* Personnel defined as health personnel pursuant to the Act of 2 July 1999 no. 64 § 3.

Part II. Ban on products which are not safe from the point of view of health, certain substances and testing on animals

§ 4. *Ban on products which are not safe from the point of view of health*

It is forbidden to develop, produce, import, distribute, export and sell products which, when used, are not safe for humans or animals from the point of view of health.

§ 5. *Ban on products which contains certain substances*

It is forbidden to develop, produce, import, distribute, export and sell products which contain one or more of the following substances:

a) ingredients or combinations of ingredients which are listed in appendix II,
b) ingredients or combinations of ingredients which are listed in appendix IIa of the regulation of 26 October 1995 no. 871 (general regulation concerning production, import and sale etc of cosmetics and bodycare products), re. 76/768/EEC,
c) carcinogenic, mutagenic and reprotoxic substances in category 1, 2 and 3 in accordance with 67/548/EEC,

d) substances which are classified as medicines pursuant to the decisions given in the Medicines Act, with regard to the exceptions which follow from the regulation of 26 October 1995 no. 871 (general regulation concerning production, import and sale etc. of cosmetics and bodycare products),
e) preservatives, apart from those listed in appendix III. Appendix III states restrictions on the use of the preservatives which are permitted for use.
f) colorings apart from those which are listed as permitted in appendix IV. Requirements for purity for colorings are those which are permitted pursuant to the regulation of 21 December 1993 no. 1378 concerning additives in foodstuffs.

§ 6. *Ban on testing on animals*

It is forbidden to test finished products on animals.

It is forbidden to test ingredients or combinations of ingredients in products on animals, unless minor testing of the individual substances contained is permitted pursuant to the regulation of 26 October 1995 no. 871 (general regulation concerning production, import and sale etc of cosmetics and bodycare products) §§ 6a and 6b in accordance with appendix IX, re. 2003/15/EC.

It is forbidden to produce and sell products which have been tested on animals in contravention of this decision.

Part III. Labelling

§ 7. *Location and language*

When selling a product, both the container and the packaging shall have the information mentioned in §§ 9-12 added to them, unless otherwise is stated in this regulation. This information shall be easily visible, easy to read and difficult to remove.

The information mentioned in §§ 9-13 shall be stated in Norwegian or a language which in meaning and spelling resembles Norwegian. The information in § 11 as well as in any directions for use shall be stated in a language which is easy for the person who is going to use the product to understand.

§ 8. *Name and address*

The company name and complete address, including the telephone number, of the manufacturer and the person in Norway who is responsible for the marketing of the product, shall be stated.

The information may be abbreviated, if the abbreviation makes identifying the business possible.

§ 9. *Contents*

The nominal amount on the day of packaging shall be stated in weight or volume, except for packaging of free samples and packaging of products which are intended to be used once only.

Stating the contents may be omitted for ready-packed items which are usually sold in packs of more than one. If the number of items can be readily ascertained without breaking open the packaging, or the product is usually sold individually, it is not necessary to state this.

§ 10. *Expiry date*

A product's expiry date shall be the latest dates an unopened product, or a product which has already been used, is still in accordance with § 4, provided the product is stored under suitable conditions up to these dates.

If necessary, which conditions which must be fulfilled to ensure the product meets the stated expiry date, shall be stated.

The expiry dates shall be stated using the words ”an unopened product should be used by...” and ”an opened product should be used by”, followed by the relevant dates or an explanation of where the dates may be found on the packaging.

Stating the date shall consist of month and year, in that order.

§ 11. *Special precautions which should be taken when using product*

Special precautions which shall be taken to ensure safe use shall be stated by using directions for use or warning labelling which in each individual case is necessary to ensure safe use. This includes statutory labelling as shown for certain preservatives mentioned in appendix III.

Information in the first subsection may, because of the products' size or shape, be stated on the label, in an attached brochure, ribbon or card which is affixed to the product.

§ 12. *Identification labelling*

The consignment's production number, or other reference which makes it possible to identify the production, shall be stated. This information may be stated on the product's packaging.

§ 13. *Ingredients*

The ingredients shall be stated in the form of a list of such in declining order, according to their weight at the time they were added to the product. The list shall be started with the word ”ingredients” or other definition approved by the inspection authority. The list shall be stated on both the packaging and the container.

If the product's size or form necessitates it, the ingredient list can be stated on the label, an attached brochure, ribbon or card which are attached to the product. Attention shall be drawn to this by adding a reference to the packaging or container to the ingredients list.

The following are not regarded to be ingredients:

1. Impurities in the raw ingredients used.
2. Technical media used to help manufacture the product during production but which are not present in the finished product.

Perfumes or aromas and combinations thereof and their raw ingredients shall be stated using the word ”perfume” or ”aroma” in the ingredients list. Perfumes which are listed in appendix V must be stated in the ingredients list, if the concentration in the finished product is greater than 0.001 % (10 ppm).

Ingredients at a concentration lower than 1 % can be stated in any order, after those whose concentration is higher than 1%.

Substances which are used as active ingredients shall be stated separate from the ingredients list as well, stating the concentration of the active ingredient.

Ingredients shall, apart from perfumes and aromas, be stated using the INCI name in accordance with the EU Commissions list of such. If no INCI name has been decided upon, another name can be used in consultation with the inspection authority.

Part IV. Duties in relation to marketing, notification and information etc.

§ 14. *Misleading marketing*

Labelling and the presentation of, advertising for and other marketing of products shall be correct, give the recipient enough information and not be misleading.

When selling a product, texts, definitions, brands, pictures or other signs which imbue the product with qualities it does not have shall not be used.

§ 15. *Duties regarding notification and information*

The business shall notify the inspection authority immediately if it is suspected that the product is not safe for humans or animals from the point of view of health.

The business shall, when the inspection authority requires it, at no cost give or send in necessary information, samples or results of analyses performed. The inspection authority can decide how the information should be stated, e.g. as far as the form, level of detail etc are concerned.

To facilitate swift and correct medical treatment in cases of acute poisoning, the information mentioned in the first subsection can be given to the Directorate of Health and Social Affairs' Section for Information on Poisoning, provided that such information is only used in this context.

§ 16. *Duty to report*

The Norwegian manufacturer, or importer of a product which is meant to be sold on the Norwegian market, shall on a special report form provide the inspection authority with the following:

1. Name or company name and address of Norwegian producer or importer.
2. Producer and country of production.
3. An exact statement of the name of the product.

This report shall already have been provided when the product is marketed.

The inspection authority shall immediately be informed if any changes in the information mentioned in point 1 take place.

§ 17. *Statutory reporting of side effects*

Health personnel who, when working with patients at institutions, suspect that a product has led to a side effect as defined in § 3, shall send a report about this to the inspection authority on a special form.

§ 18. *Dossier*

The Norwegian manufacturer, or importer of a product which is meant to be sold on the Norwegian market, and the person responsible for marketing the product in Norway shall ensure the inspection authority has easy access to the following information, which is to be found at the address stated on the label pursuant to § 8. This information shall be at a Norwegian address:

1. The qualitative and quantitative composition of the product.

   As far as substances are concerned which are included in the finished product, identification can be limited to the trade name and the supplier's code number for the mixture which has been added to the product. In addition, the company name and address of the supplier of the mixture shall be stated.
2. The physical/chemical specifications of the raw substances and the finished product; this includes stating the raw substances chemical purity. Microbiological purity and test method shall be stated.
3. The production method in accordance with national or international GPP for the relevant product.
4. Documentation of the safety of using the finished product from the point of view of health. When performing a safety assessment, consideration should be paid to the ingredients' general toxicological profile, chemical structure and level of exposure. Particular consideration shall be paid to the effects of exposing those parts of body to the product on which the product is meant to be used. Consideration shall also be paid to the substance's ability to be absorbed by the circulation system and tissue, and to the substance's ability to migrate and be stored in organs other than the skin. Particular attention shall be paid to those groups of the population for whom the product is meant.
5. Name and address of those persons who are responsible for the documentation which is mentioned in point. 4. These persons must have documentary evidence that they are qualified within one or more of the following areas of expertise: toxicology, medicine, pharmacy or pharmacology.
6. Existing data on undesirable health effects due to the use of the product.
7. Documentation of the effect the product is claimed to have, re. §§ 19 og 20.
7. Data on tests carried out by the manufacturer, its representatives or suppliers in connection with the development or safety assessment of the product or its constituent parts.

The inspection authorities shall be familiar with the dossier address before the product is released onto the Norwegian market.

The inspection authority can stipulate additional guidelines to implement the decisions in this section.

§ 19. *Use of health claims and medical claims*

When labeling and marketing a product, it is forbidden to claim or give the impression that it prevents, treats or relieves health complaints due to disease. Additionally, when labeling or marketing a product it is forbidden to claim or give the impression that the product has an effect on health complaints which are not due to disease in organs other than the skin.

This includes adverts for and the presentation of the product or the packaging's shape and appearance and material which is used for packaging.

Health claims which are not encompassed by the first subsection may be used if the purported link between the product and health can be documented in accordance with § 20 second subsection and the claim is not misleading pursuant to § 14 and § 20 first subsection.

§ 20. *Requirements for documentation of health claims*

The business is responsible for ensuring any health claim in accordance with §19 third subsection is not misleading in accordance with § 14.

The product's effect on health shall be adequately documented in accordance with one or more of the methods stated in appendix VI, and when asked to do so by the inspection authority, the business shall be able to produce documentation for this.

The documentation shall exist when the product is marketed and be included in the product dossier, re. § 18.

§ 21. *Access to premises, duty to assist etc*

The business shall give the inspection authority unimpeded access to the place or premises where activities take place encompassed by this regulation, so that the inspection authority can perform the necessary examinations. Foreign inspectors may also be in attendance on inspections etc when this is necessary to fulfill Norway's international obligations.

The business shall at no cost provide the premises, inventory, help and devices necessary so that inspection can be performed and otherwise help the inspection to be performed.

Part V. Administrative decisions

§ 22. *Inspection and decisions*

The Norwegian Food Safety Authority performs inspection and may make the decisions necessary to forbid development, production, import, processing, distribution, export and sale of a product, and decisions to sequestrate, destroy and close down the business.

The Norwegian Food Safety Authority can instruct the person responsible for the business to cover the actual costs associated with the sequestration, destruction and closing down of the business.

If the instructions are not followed, if it is unknown who is responsible or if it is necessary to take action swiftly, The Norwegian Food Safety Authority can implement the measures mentioned in the first subsection. The measures can be performed at the person responsible's cost. Monies owed are grounds for execution.

§ 23. *Dispensation*

The Norwegian Food Safety Authority may in special cases grant dispensations from this regulation, provided this is not in conflict with Norway's international obligations, including the EEA agreement.

§ 24. *Penalties*

Deliberate or careless breach of this regulation, or of decisions made pursuant to it, are punishable pursuant to the Cosmetics Act § 21.

II

§ 25. *Coming into force*

This regulation comes into force 1.1.2007.

APPENDIX I: REACTIONS WHICH ARE RECKONED TO BE SIDE EFFECTS, PURSUANT TO § 3:

1. Allergic contact eczema
2. Toxic/irritative contact eczema
3. Eczema, unspecified
4. Photoallergic contact eczema
5. Phototoxic contact eczema
6. Acne/folliculitis
7. Hyperpigmentation
8. Hypopigmentation
9. Urticaria
10. Central nervous system side effects
11. Hair loss
12. Eye infection (conjunctivitis)
13. Loss of nails (onycholysis, sub-ungal hemorrhage, anonychia)
14. Granuloma
15. Desquamation in mouth
16. Irritation of mouth's mucous membranes
17. Sensitivity of teeth (e.g.after bleaching)
18. Misc.

APPENDIX II: THE FOLLOWING SUBSTANCES ARE NOT PERMITTED IN PRODUCTS PURSUANT TO THIS REGULATION , RE. §5

Substance	CAS Number[1]
Triclosan	3380-34-5
Boric acid, borates and tetraborates	10043-35-3
Phenol	108-95-2

[1] CAS stands for Chemical Abstract Service Number. This numbering facilitiates the unambiguous identification of chemicals. Using a CAS number helps one find a number of synonyms for the individual substance.

APPENDIX III: PRESERVATIVES PERMITTED IN PRODUCTS PURSUANT TO THIS REGULATION WITH STATED HIGHEST PERMITTED CONCENTRATION IN FINISHED PRODUCT AND STATUTORY DIRECTIONS FOR USE AND WARNING LABELLING, RE. §5

Substance or substance group	Highest permitted concentration in finished product	Statutory directions for use and warning labeling
Ammonium(C12-C22)trimethyl-ammonium bromide and chloride (including cetrimonium bromide) CAS-no. 57-09-0	0.1%	
5-Amino-1,3-di(2-ethylhexyl)-5-methyl-n-hexahydropyrimidine (Hexetidine) CAS-no. 141-94-6 INCI: Hexetidine	0.1%	
Benzoic acid and its salts and esters CAS-no. 65-85-0 INCI: Benzoic Acid	0.5% (acid)	
Benzyl alcohol CAS-no. 100-51-6 INCI: Benzyl Alcohol	1 %	
2-Benzyl-4-chlorphenol (Chlorophene) CAS-no. 120-32-1 INCI: Chlorophene	0.2%	
1,6-Bis(4-amidinophenoxy)-n-hexane and its salts (including isethionate and 4-hydroxybenzoate) (Hexamidine) CAS-no. 3811-75-4 INCI: Hexamidine	0.1%	
1,3-Bis(hydroxymethyl)-5,5-dimethylhydantoin CAS-no. 6440-58-0 INCI: DMDM Hydantoin	0.6%	"CONTAINS FORMALDEHYDE" if the concentration of formaldehyde in the finished product is higher than 0.05%.
1-[(1,3-Bis(hydroxymethyl)-2,5-dioxoimidazolidin-1-yl]-1,3-di(hydroxymethyl)urea CAS-no. 78491-02-8 INCI: Diazolidinyl urea	0.5%	"CONTAINS FORMALDEHYDE" if the concentration of formaldehyde in the finished product is higher than 0.05%.
3,3'-Dibromo-5,5'-dichloro-2,2'-dihydroxy-diphenylmethane (Bromo Chlorophene) CAS-no. 15435-29-7 INCI: Bromo Chlorophene	0.1%	
3,3' - Dibromo - 4,4'-hexamethylenedioxy-benzamidine (dibromohexamidine) and its saltS including isethionate	0.1%	
2,4-Dichlorobenzyl Alcohol CAS-no. 1777-82-8 INCI: Dichlorobenzyl Alcohol	0.15 %	
2-Phenoxyethanol CAS-no. 122-99-6 INCI: Phenoxyethanol	1.0%	

Substance or substance group	Highest permitted concentration in finished product	Statutory directions for use and warning labeling
1,1-Hexamethylenebis-(5-(p-chlorphenyl)biguanide) and its digluconate, diacetate and dihydrochloride (Chlorhexidine) CAS-no. 55-56-1	0.3% calculated as chlorhexidine	
Hexamethylenetetramine CAS-no. 100-97-0 INCI: Methenamine	0.15%	"CONTAINS FORMALDEHYDE" if the concentration of formaldehyde in the finished product is higher than 0.05
4-Hydroxybenzoic acid and its salts and esters CAS-no. 99-96-7 INCI: 4-Hydroxybenzoic Acid	0,4% (acid) for a ester. 0.8% (acid) for ester mixtures.	
Imidazolidinyl urea CAS-no. 39236-46-9 INCI: Imidazolidinyl Urea	0.6%	"CONTAINS FORMALDEHYDE" if the concentration of formaldehyde in the finished product is higher than 0.05
4-Isopropyl-m-cresol CAS-no. 3228-02-2 INCI: Isopropyl Cresols	0.1%	
1-(3-Chlorallyl)-3,5,7-triaza-1-azonia-adamantane chloride (Methenamine-3-chlorallylchloride) CAS-no. 4080-31-3	0.2%	"CONTAINS FORMALDEHYDE" if the concentration of formaldehyde in the finished product is higher than 0.05
4-Chloro-m-xylenol CAS-no. 88-04-0 INCI: Chloro Xylenol	0.5%	
3-(4-Chlorophenoxy)-1,2-propanediol (Chlorphenesin) CAS-no. 104-29-0 INCI: Chlorphenesin	0.3%	
Formic acid and its natrium salt CAS-no. 64-18-6 INCI: Formic Acid	0.5% expressed as acid	
N-hydroxymethyl aminoacetate CAS-no. 70161-44-3 INCI: Sodium Hydroxymethylglycinate	0.5%	
Poly(1-hexamethylendi-guanide)hydrochloride CAS-no. 70170-61-5 INCI: Polyaminopropyl Biguanide	0.3%	
Propionic acid and its salts CAS-no. 79-09-4 INCI: Propionic Acid	2% (acid)	
Sorbic acid and its salts (2,4-Hexadienic acid) CAS-no. 110-44-1 INCI: Sorbic Acid	0.6% (acid)	
Undecylenic acid and its salts CAS-no. 112-38-9 INCI: Undecylenic Acid	0.2% (acid)	

APPENDIX IV: PERMITTED COLOURINGS, RE. §5

Substances permitted as colourings in products pursuant to this regulation are those which are licensed for use pursuant to both the regulation of 21 December 1993 no. 1378 concerning additives in foodstuffs and the regulation of 26 October 1995 no. 871 (general regulation concerning production, import and sale etc of cosmetics and bodycare products), appendix IV row 1, with the exception of the following colourings:

Colour index number (CI)[2]	Colour index name	CAS – no.	E-number and name pursuant to regulation 21 December 1993 no. 1379
15850:1	Pigment red 57 : 1	5281-04-1	E 180, Litolrubin BK
45430	Acid red 51	16423-68-0	E127, Erythrosine
40850		514-78-3	E160g, Canthaxanthine
77000	Pigment metal 1	7429-90-5	E 173, Aluminium
77480	Pigment metal 3	7440-57-5	E 175, Gold
77820		7440-22-4	E 174, Silver

Permitted colouring substances are:

Colour index number (CI)	Colour index name	CAS - no	E-number and name pursuant to regulation of 21 December 1993 no. 1379
14720	Acid red 14	3567-69-9	E 122, Azo rubine
15985		2783-94-0	E 110, Para orange
16185	Acid red 27	915-67-3	E 123, Amaranth
16255		2611-82-7	E 124, Cochineal red A
19140	Acid yellow 23	1934-21-0	E 102, Tartrazine
40820		1107-26-2	E160e, Beta-apo-8'-carotenal (C30)
40825		1109-11-1	E160f, Ethyl ester of Beta-apo-8'-carotenic acid (C30)
42051	Acid blue 3	3536-49-0	E131, Patent blue V
44090	Acid green 50	3087-16-9	E 142, Green S
47005	Acid yellow 3	8004-92-0	E 104, Quinoline yellow
75120	Natural orange 4	542-40-5	E 160b, Annatto
75125	Natural yellow 27	502-65-8	E 160d, Lycopene
75130	Natural yellow 26	116-32-5	E 160a, Betacarotene
75300	Natural yellow 3	458-37-7	E 100, Curcumin
75470	Natural red 4	1260-17-9	E 120, Carmine
75810	Natural green 3	8049-84-1	E 140, Chlorophyll
77220	Pigment white 18	471-34-1	E 170, Calcium monocarbonate
77268:1	Pigment black 8	1345-12-6	E 153, Vegetable carbon
77489 , 77491, 77492, 77499			E 172, Iron oxides and hydroxides
77891	Pigment white 6	13463-67-7	E 171, Titanium dioxide
	Lactoflavin	83-88-5	E 101, Riboflavin-5'-phosphate
	Caramel	8028-89-5	E 150a, Caramel
	Capsanthin/ Capsorubin	465-42-9	E 160c, Capsathin
	Beetroot red	89957-89-1	E 162, Beetroot red

[2] Colour index number in accordance with the Rowe Colour Index, 3rd edition, Society of Dyers and Colourists, Bradford, England, 1979

	Antocyanins	11029-12-2	E 163, Anthocyanins

APPENDIX V: PERFUMES WHICH MUST BE STATED IN THE LIST OF INGREDIENTS IF THE CONCENTRATION IN THE FINISHED PRODUCT EXCEEDS 0.001 % (10 ppm), RE. §13

Substance	**CAS -number**
alpha-hexylcinnamaldehyde INCI: Hexyl cinnamal	101-86-0
Amylcinnamaldehyde INCI: 2- Benzylideneheptanal	122-40-7
Amylcinnamyl alcohol INCI: Amylcinnamyl alcohol	101-85-9
Anise alcohol INCI: Anise Alcohol	105-13-5
Benzyl alcohol INCI: Benzyl Alcohol	100-51-6
Benzyl benzoate INCI: Benzyl benzoate	120-51-4
Benzyl cinnamate INCI: Benzyl cinnamate	103-41-3
Benzyl salicylate INCI: Benzyl salicylate	118-58-1
2-(4-tert-Butylbenzyl)-propionaldehyde INCI: Butylphenyl methylpropional	80-54-6
Citral INCI: Citral	5392-40-5
Citronnellol INCI: Citronnellol	106-22-9
d-Limonene INCI: Limonene	5989-27-5
Evernia Prunastri INCI: Evernia Prunastri	90028-68-5
Eugenol INCI: Eugenol	97-53-0
Farnesol INCI: Farnesol	4602-84-0

Geraniol INCI: Geraniol	106-24-1
Hydroxycitronellal INCI: Hydroxycitronellal	107-75-5
Hydroxymethylpentyl Cyclohexen Carboxaldehyde INCI: Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde	31906-04-4
Isoeugenol INCI: Isoeugenol	97-54-1
Cinnamal INCI: Cinnamal	104-55-2
Cinnamyl alcohol INCI: Cinnamyl alcohol	104-54-1
Coumarin INCI: Coumarin	91-64-5
Linalool INCI: Linalool	78-70-6
Methyl heptine carbonate INCI: Methyl 2-octynoate	111-12-6
3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-on INCI: Alpha-isomethyl ionone	127-51-5
Evernia Furfuracea INCI: Evernia Furfuracea	90028-67-4

APPENDIX VI: METHODS WITH WHICH TO DOCUMENT EFFECTS ON HEALTH, RE. §20

Documentation based on scientific studies of the product.
Claims of a physiological effect require documentation in the form of scientific examinations. Tests shall preferably be performed on the relevant product and shall be documented in the main by using human studies which are performed in accordance with recognized, scientific methods.
The studies shall be reproducible, include a large enough population and be of a duration long enough to reveal effects. Dosing groups shall be relevant in relation to the expected effect. If the health claim is directed at specific subpopulations e.g. babies, the studies shall be conducted on the same or comparable subpopulations.
Statistical analysis of the data shall be performed in accordance with recognized scientific methods for the applicable type of study. The biological effect must be statistically significant and of a size which indicates that the effect must be assumed to be of biological, physiological or epidemiological significance.
If few human studies exist, in-vitro studies can be used in individual cases in addition to support the human studies.
The documentation shall be based on a systematic review of the relevant literature, which involves an overall assessment both of the literature which supports and which does not support any given effect.

Documentation based on generally known, scientifically based knowledge of substances' effect on normal bodily functions
Some substances' effects on physiological functions when applied to the skin are in some cases well known and well documented.

Examples of this:

Menthol for itching
Zinc oxide for nappy rash
Saline for blocked noses
Salicyl acid or urea for callouses
Sulphur for spots

This knowledge is based on epidemiological studies which show the link between exposure and health. The knowledge is based on a significant number of studies including prospective observational studies, and where is relevant, randomised, controlled studies of adequate size, duration and quality. The studies must show correlating results. This type of knowledge will be described in scientific articles and in recognized, updated textbooks. It may be enough to refer to such stating the name of the textbook and periodical, year of publication, page number etc.
Traditional use in folk medicine is not regarded to be generic documentation.

Documentation based on traditional use in folk medicine
To have enough knowledge about the effect, the active component in the product should have been in traditional use for at least 15 years in the EEA area, with a probable effect.
The documentation concerning traditional use must be related to the relevant product and describe that products which have been in traditional use:
- contain the same substances
- have been used in the same areas
- have been used in the same strength and dosages

- have had the same form (e.g. cream, lotion etc.)
The following types of documentation can be used to show that a corresponding product has been used in Europe or North America for at least 30 years:
a) whole, parts or extracts of herbs, etc. information about area of use, production method, and dosage
b) Official expert committee reports or monographs from scientific organizations such as information from works of reference within medicine, pharmacology, pharmacognosy, phytotherapy, WHO, Commission E, ESCOP and official pharmacological handbooks/works of reference etc. Information about area of use, method of production and dosage will be able to use this as a reference. For more information, see part 3.4. ”Use of scientific monographs as a part of the documentation”.
c) If the drug or preparation is described in a monograph in The European Pharmacoepia, this can be used as documentation of the use of the relevant drug from the year the monograph was endorsed. Such a monograph will also be able to provide relevant information on the strength/type of extract.
d) Product-related documentation, such as ”post marketing” studies, sales catalogues, sales statistics etc. can be used to document that the preparation has been used since the publication date of the documentation. However, a prerequisite for this is that the product has been legally sold in the relevant country from which the documentation has been collected. References must show that it was permitted to sell the product for human use at the relevant point in time. This might consist of, e.g. production permits, marketing permits, printouts from national lists of products.
Traditional use can take place, not just right before the launching of the marketing campaign, but also prior to that.

Use of scientific monographs
Recognized scientific reference works can be used if the actual area of use is described in the scientific monograph. The documentation from these monographs must be related to the actual product in that it describes that it has:
- the same active ingredients
- the same area of use
- a corresponding strength and dosage
- the same form (e.g. cream, lotion, etc.)

A scientific monograph is a compendium of a number of sources where, based on the clinical data, it has been concluded that there is a given effect. The scientific monograph must meet the same standard as official expert committee reports or monographs from scientific organizations or official pharmaceutical handbooks/works of reference. Examples of relevant works of reference:
• ESCOP monographs: The Scientific Foundation for Herbal Medical Products, European Scientific Co-operative on Phytotherapy1
• WHO Monographs on Selected Medicinal Plants, by the World Health Organization2
• The Complete German Commission E Monographs; Therapeutic Guide to Herbal Medicines;
German Federal Institute for Drugs and Medical Devices Commission3
• Bradley, P.R. (Ed.): British Herbal Compendium Volume 1; The British Herbal Medical Association4
• Bisset, G.N. and Wichtl M.: Herbal drugs and phytomedicines, Medpharm

Appendix to hearing letter 3 July 2006 from The Norwegian Food Safety Authority regarding a hearing of a proposed regulation to regulate external health products pursuant to the Cosmetics Act. Re: §3 (definitions) point 4 in this regulation.

Provisional draft of a list of guidelines with examples of health problems which shall not be reckoned to be due to disease

Minor sores and rifts in the skin
Burst blood vessels in skin
Reduced circulation in skin
Dry skin (xeroderma) (relief)
Itching
Nappy rash
Sore skin
Sore nipples will breastfeeding
Minor and light burns
Blocked nose
Frostbite
Mouth sores, mouth scalding
Stretch marks (striae)
Disfiguring scars
Light spots (pimples, light version of acne vulgaris)
Snoring (not apnaeic)
Light induced dermatosis due to using medicines (only prevention)
Itching and discomfort in skin due to lice and insect bites
Callouses on feet
Extreme mouth dryness (xerostomia) after radiation treatment