

Survey of chemical substances in dandruff shampoo

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Survey of Chemical Substances in Consumer
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Preface

The Danish Environmental Protection Agency (Danish EPA) has initiated efforts to elucidate public exposure to chemical substances in consumer products and the risk associated with such exposure. The project "Survey of chemical substances in dandruff shampoo" is part of these efforts.

The study was carried out on behalf of, and financed by, the Consumer Section of the Danish EPA.

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The purpose of the project was to identify the ingredients in a selected number of dandruff shampoos. In the selection and collection of material for the study efforts were made to create as representative a selection of products as possible. Consequently, the survey should not be understood as an exhaustive mapping of dandruff shampoo on the Danish market. Rather, it is a survey of the most commonly occurring ingredients in Danish dandruff shampoos, their function, and the quantity in which they have been added to the individual product. The quantities referred to in this report are typical concentration intervals.

The entire project includes:

- A brief explanation of legislation pertaining to dandruff shampoo.
- A survey of ingredients, listed according to function in the relevant products, and typical quantities added.
- A comparison with regular shampoo.
- An assessment of human and environmental exposure.

In the period 30 May 2002 to 3 June 2002 a total of 12 shampoos were collected for examination.

In order to get an idea of which shampoos are on the market, the project included visits to a pharmacy, a beauty shop and a supermarket chain.

In accordance with the scope and financial framework of the project, the products collected are considered to be in accordance with project requirements for representativeness.

Requirements did not cover geographical representativeness, and thus all products were purchased in shops situated within the same geographical area.

In order to protect manufacturer identities, the products examined have been provided with a three-figure code between 354 and 365.

Summary and conclusion

Twelve different dandruff shampoos were collected for this project in order to identify their ingredients via the product declarations.

An initial overview of legislation pertaining to dandruff shampoo revealed that a distinction is made between, on the one hand, medical use of dandruff shampoo, and on the other hand, cosmetic use of dandruff shampoo. Dandruff shampoo for medical use is regulated by "bekendtgørelsen om mærkning m.m. af lægemidler" (Statutory Order on labelling etc. of drugs), whereas dandruff shampoo for cosmetic use is regulated by the Statutory Order on cosmetic products.

The main part of this report is a systematic outline of the ingredients found in the products. It appears from this outline that the 12 products together include 115 different substances, responsible for one or several of 14 randomly listed functions (solvents, surface active agents, emulsifiers, preservatives etc.)

On the basis of enterprise patent descriptions, the likely expected concentration intervals for the substances in the different categories of function were examined.

The following list represents a conclusive summary of the concentration intervals and the systematic categorization:

1. Solvents	(1 substance)	60 – 85 %
2. Surface active agents (surfactants)	(23 substances)	
Anionic		12 – 30 %
Amphoteric		1 – 8 %
Non-ionic		1 – 8 %
3. Emulsion stabiliser	(6 substances)	0.5 – 1 %
4. Fragrances (perfumes)		0.5 – 1 %
5. Emulsifiers	(24 substances)	0.4 – 4 %
6. Anti-dandruff agents	(7 substances)	0.3 – 2 %
7. Thickening agents and viscosity controlling agents (gelation agents)	(9 substances)	0.25 – 1.3 %
8. Softeners (emollients)	(9 substances)	0.2 – 3 %
9. Buffers	(5 substances)	0.1 – 1 %
10. Film formers and hair-care agents	(7 substances)	0.1 – 1 %
11. Soothing, skin-conditioning and astringent substances	(13 substances)	0.1 – 0.7 %
12. Preservatives and anti-microbial agents	(21 substances)	0.05 – 0.5 %
13. Colourants	(6 substances)	0.001 – 0.007 %
14. Humectants	(2 substances)	not found
15. Other substances	(4 substances)	varying

In order to identify other substances typical in dandruff shampoo which do not have direct anti-dandruff effects, the 12 dandruff shampoos were compared to 14 ordinary shampoos previously surveyed by the Danish EPA (Danish EPA, extracts from database - 2002).

The study indicated that in addition to active dandruff agents, dandruff shampoo contains more lipophile and lipophile-like substances than ordinary shampoo.

Finally, an exposure scenario for use of dandruff shampoo was established on the basis of e.g. EU risk assessment reports.

This scenario led to the following expression of skin exposure per incident where X represents the ingredient component stated in percentage of weight:

$$\begin{aligned} \text{Hands: } & 12 \text{ g} * (X/100) / 420 \text{ cm}^2 = 0.29 * X \text{ mg/cm}^2_{\text{dermal surface}}/\text{day} \\ \text{Scalp: } & 12 \text{ g} * (X/100) / 1200 \text{ cm}^2 = 0.1 * X \text{ mg/cm}^2_{\text{dermal surface}}/\text{day} \end{aligned}$$

EU's Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers (SCCNFP) has prepared guidelines for testing cosmetic ingredients in safety evaluation. These guidelines include the following exposure scenario:

One hair-wash requires 8 grams of shampoo. It is assumed the hair is washed daily. Since the shampoo is applied to wet hair and skin, it is assumed that approximately 1 per cent of the shampoo applied will be absorbed. This means that with a content of X (calculated in weight percentage) exposure is:

$$8 \text{ gram/day} * 0.01 * X = X * 0.08 \text{ g/day}$$

Due to insufficient data, environmental exposure was limited to an expected approximate 100 per cent discharge of the dandruff shampoo to the aquatic environment.

1. Introduction

1.1 Formation of dandruff, treatment and products for treatment

Dandruff is a condition that many people, at some point in their life, suffer from. Dandruff shows as an itching of the scalp and as excessive flaking of dead skin cells.

It is important to discern between dandruff requiring direct medical treatment and dandruff as a result of dry skin.

This report discerns between shampoos bought as medicinal products (in the following termed *medical dandruff shampoo*) and shampoos bought as cosmetic products (*cosmetic dandruff shampoo*).

1.1.1 Dandruff requiring medical treatment

Dandruff requiring medical treatment (seborrhoeic dermatitis) is a condition in which the skin is affected by a small lipophile yeast fungus of the *Malassezia species, also known as Pityosporum*. The most common development of the condition includes the occurrence of oily, red and flaky patches¹ on the scalp, in the nasolabial folds (the skin between the upper lip and the nose), on the exterior ears, eyebrows, and/or eyelid edges.

The most significant clinical symptoms in people suffering from dandruff of the scalp typically vary from person to person. Some "only" experience profuse reddening of the skin, while others experience extreme symptoms such as sore scalp and purulent blisters. When the skin naturally rejects dead skin cells from its most outward layer - stratum corneum - the cells disappear as microscopic waste in connection with brushing, washing and mere touching of the hair. However, when this mechanism is weakened, as in the case of dandruff, instead of microscopic dead skin cells the skin rejects oily flakes of accumulated dead skin cells (Clinical Exp. Der. 1997).

1.1.2 Dry scalp

White flakes falling from the scalp is not necessarily a sign of dandruff in the medical definition. If you suffer from dandruff as described above, the dandruff will often stick to the hair, whereas rejected skin flakes in connection with dry scalp will fall from the hair as snow. Moreover, there will not be itching to the same degree in connection with dry scalp. A dry scalp is often caused by shampoos that are too rough on the scalp, or due to chemical hair treatment products (e.g. perm or dye).

¹ Also termed papule - small, solid circumscribed elevation of the skin or mucous membrane.

1.1.3 Cosmetic dandruff shampoo

According to legislation, cosmetic dandruff shampoo is a product made exclusively or mainly for hair and scalp-caring and hair-beautifying purposes, and which can prevent cosmetic dandruff.

1.1.4 Medical dandruff shampoo

Contrary to the definition above, medical dandruff shampoo is defined as a product the primary purpose of which is to treat clinical symptoms that are clearly defined for the product, in this case dandruff and skin irritation. In order to apply the active remedies to the hair and scalp, the remedies have been integrated into the shampoo. According to the manufacturer, this is the easiest and most comfortable way to perform the treatment.

However, defining which type of product belongs to the cosmetic category and which to the medical category presents a legal grey zone. This means it is possible to buy dandruff shampoos containing the same active agent (e.g. zinc pyrithion), however which are subject to two different Statutory Orders: namely the Statutory Order on cosmetic products and the Statutory Order on labelling etc. of drugs.

This is often explained by the fact that products are registered as either medicinal or cosmetic products, depending on whether the manufacturer predominantly makes medicinal or cosmetic products.

Following the development of this type of cosmetic/medicinal products is interesting, not the least from a health and environment perspective. This is partly because the market is demographically representative of all of Denmark, and partly because manufacturers are constantly developing existing products further in order to differentiate them from other dandruff shampoos on the market, as well as to satisfy consumer needs. Seen in relation to legislation on dandruff shampoo, that is the Statutory Order on cosmetic products and the Danish Medicines Act, it would moreover be interesting to identify which substances pose a risk in terms of discharges to the environment, since both sets of rules only take account of human health.

1.2 Substance groups and their function

Anti-oxidants: substances that prevent the product's constituents from oxidating and thus changing the chemical composition of the product. Examples are e.g. acetyl cystein, different acids, such as e.g. derived compounds of citric acid and ascorbin acid, diammonium EDTA, BHA, and BHT.

Softeners (emollients): added to the cosmetic product in order to make hair more flexible. Examples are: hydrogenated castor oil, Chamomile Recutita extract and dimethicone.

Buffers: substances which are added to the cosmetic product in order to give it the same pH value as skin (pH 5-6), or to maintain the most optimal pH value.

Examples are: citric acid and sodium citrate.

Emulsifiers: emulsifiers are added so that oil mixtures which are not readily soluble in aqueous solutions can be mixed with such solutions thereby creating an emulsion. The mixture is now a cream or lotion, which will not separate into oil and water.

Among others, ethoxylating C14-C22 saturated or unsaturated fatty alcohols are used as emulsifiers. Examples of these are polysorbate 80, laureth-10, trideceth-12 and sodium lauryl sulphate.

Emulsion stabilisers: added in order to ensure that the products maintain stable consistencies. Examples of substances are cocamid DEA and carbomer.

Colourants: added to give the product a certain colour. Colourants are typically added to shampoos so that the shampoo appears glossy or transparent. Example of these are CI 42090, CI 15985 and lactoflavin.

Film formers: film formers cover a number of substances that are added to cosmetic products in order to form a thin film over the skin surface. Examples of these are: polyquaterium compounds, panthenole, and sodium styrene/acrylates copolymer.

Thickening agents/binding agents/viscosity controlling substances (gelation agents): substances that are added in order to improve the consistency, stability, and viscosity of the shampoo. These can be e.g. carbomer, sodium lauroyl sarcosinate, and stearamide MEA.

Humectants (hygroscopic compounds): function to bind moisture in the lotion as well as to the skin. Examples are glucose and propylene glycol.

Preservatives: substances that inhibit bacterial growth, and thereby prevent the product and its ingredients from changing into unintended substances. Examples are e.g. derived compounds of p-hydroxy-benzoic acid (parabenes) and Kathon.

Solvents: solvents are used to ensure that all substances added together constitute a homogeneous mixture. The solvents used in the majority of all dandruff shampoos are deionized and distilled water.

Fragrances (perfumes): an aromatic mixture of selected oils, which together give the product the desired scent. Fragrances are sometimes added in order to disguise the smell of other components in the product.

Plant extracts and oils: These substances can have many different functions in cosmetics. Some stimulate the skin, others act as disinfectants and some contain vitamins. Examples are Tussilago Farfara extract (coltsfoot), Citrus Aurantium Dulcis extract (orange), and Quercus Robur extract (English oak).

Soap components/surfactants: Soap components have several functions. Soap is cleansing due to its properties as a hydrofile/hydrofobic substance and contributes to the foaming effect of the shampoo. The soap component in shampoo is often compounds of sulphates, sulphonates, sarcosinates, or mixtures of these. The functions of the sulphates are anionic surfactants, and are e.g. alkyl and alkyl ether sulphates that contains between 12 and 16 carbon atoms. The counter-ion of the anion, the cation, is typically a mono or

divalent ion, such as sodium, potassium, calcium, ammonium, or magnesium. Sodium is used most often.

2 Legislation

2.1 Dandruff shampoo subject to regulations under the Statutory Order on cosmetic products

Dandruff shampoos which are not declared as products for medical treatment are subject to regulation under the Statutory Order on cosmetic products – Statutory Order no. 489 of 12 June 2003,² which implements European provisions concerning cosmetics.

In Danish legislation, dandruff shampoo is categorised under "Hair-Care Preparations - hair-washing agents (lotion, dry shampoo, and shampoo)".³

The Statutory Order on cosmetic products lays down rules concerning product composition and use, in addition to containing a number of provisions pertaining to labelling.

According to section 9 of the Statutory Order on cosmetic products, cosmetic products marketed in the EU must not pose a harm to human health when used under normal conditions. The Statutory Order on cosmetic products stipulates a number of limitations on the use of chemical substances in cosmetic products.

The person or enterprise marketing a cosmetic product is responsible for complying with the regulations as they are stipulated in the Statutory Order.

2.2 Labelling of dandruff shampoo

Cosmetic products, including dandruff shampoo, must be labelled with the following information:

- Company name and address of the manufacturer responsible for marketing the product within the EU (section 17).
- Ingredients by weight or volume (if more than 5 g or more than 5 ml (section 18)).
- Use-by date (if the durability is less than 30 months (section 19)).
- Safety instructions for use (section 20).
- Manufacture serial/batch number or reference, so that the time and place of manufacture can be identified (section 21).
- Function (unless this is clear from the presentation of the product (section 22)).
- List of ingredients; that is, a list of product ingredients in descending order of weight at the time the ingredients were added to the cosmetic product (section 23).

² Statutory Order no. 489 replaces Statutory Order no. 594, in force at the time of procurement of products for this project. In January 2005 statutory order no. 489 was replaced by no. 74 of 14. of January 2005

³ Annex 1 of the Statutory Order on cosmetic products, item 10) d).

2.3 List of ingredients

The following special terms apply to the list of ingredients for cosmetic products (Statutory Order no. 594, section 23, 2000):

- Impurities are not considered ingredients.
- Fragrant (perfuming) and aromatic compounds must be referred to by the words "parfume" (or "parfum") or "aroma".
- Ingredients present in concentrations of less than 1% can be listed in any order after those in concentrations of more than 1%.
- As a main rule, colourants should be listed by their Colour Index Numbers in any order after the other ingredients.
- Ingredients must be stated by common names in accordance with the common nomenclature for cosmetic ingredients (INCI name).

INCI is short for "International Nomenclature of Cosmetic Ingredients", a common nomenclature for declaration of ingredients in cosmetic products within the EU. An INCI name can denote a single chemical substance or mixtures, extracts etc. The INCI list is indicative, which means it is not a list of approved ingredients in cosmetics, but a list indicative of the ingredients normally used in cosmetics. In the absence of an INCI name for the ingredient, the ingredient must be identified by its chemical name, and application for an INCI name must be made (Statutory Order no. 594, 2000).

2.4 Limitations on use of chemical substances in dandruff shampoo

As described above, the Statutory Order on cosmetic products sets up a number of limitations on the use of chemical substances in cosmetic products, including limitations as to which substances are allowed in cosmetic products, which substances are allowed only under certain conditions (e.g. allowed max. concentration), and which of the substances within certain groups are allowed in cosmetic products (positive lists concerning e.g. colourants and preservatives).

Substances not allowed in dandruff shampoo

According to section 10 of the Statutory Order on cosmetic products, substances that are listed in Annex 2 of the Statutory Order are not permitted as ingredients in cosmetic products.

Colourants allowed in dandruff shampoo

According to section 12 of the Statutory Order on cosmetic products (with the exception of cosmetic products containing colourants intended solely for colouring hair), cosmetic products may only contain colourants as well as lakes, salts and pigments thereof, which are included in the lists in Annexes 3 and 4 of the Statutory Order, and in accordance with the limitations and terms set out in said Annexes.

Preservatives allowed in dandruff shampoo

According to section 13 of the Statutory Order on cosmetic products, cosmetic products must not contain preservatives other than those listed in Annex 5 of the Statutory Order.

2.5 Dandruff shampoo subject to regulation under the Statutory Order on labelling etc. of drugs

As this project exclusively reviews and assesses the ingredients of dandruff shampoo, clarification of legislation pertaining to medical dandruff shampoo will only concentrate on regulation and declaration requirements pertaining to these. Therefore, the following does not include an assessment of the pharmacological properties of the products, nor of their clinical information, requirements for handling etc.

The review of relevant legislation will concentrate on the Statutory Order on labelling etc. of drugs (Statutory Order no. 7 of 8 January 2002). According to sections 16-17, labelling must include a quantitative declaration of the active substance, on the inner as well as the outer packaging of the product. In the case of dandruff shampoo, this means that labelling must contain a description in terms of quantity of the agent added to the product in order to treat dandruff. This description must be visible on the container as well as on any packaging.

Sections 33-34 moreover prescribe that ancillary substances are declared qualitatively on an enclosed information leaflet (section 34(2)). If one or more of the ancillary substances are included in Annex 1 of the Statutory Order on labelling etc. of drugs, these must in addition bear a quantitative declaration (section 34(3)).

Other relevant legislation on regulation of medical dandruff shampoo include Lov om lægemidler (the Danish Medicines Act), cf. Consolidated Act no. 656 of 28 July 1995, the Act to amend the Medicines Act (Act no. 297 of 15 May 2002), and bekendtgørelse om bivirkningsovervågning af lægemidler (the Statutory Order on adverse effects of medicinal products; Statutory Order no. 567 of 28 June 2002).

3 Ingredients and their function

The primary objective of this project was to identify the constituent ingredients of dandruff shampoo. The ingredients declared in the ingredient lists on the products served as starting point.

The ingredients declared were examined and results are illustrated below in tables on cosmetic and medical dandruff shampoos respectively. The tables are not listings of the ingredients contained in each product; rather they represent a collocation of all the substances present in the twelve shampoos examined.

Moreover, the tables illustrate which substances perform which function (cf. the functions mentioned in section 1.2). This includes the typical quantities in which the substances are added to the products, stated as intervals.

The INCI list has been used primarily to determine the function of substances, and a substance may therefore appear in several tables, since several of the substances in the INCI list are labelled with more than one function.

3.1 Substance groups

In the tables below the substances found have been divided into groups according to the function they are assumed to have in the product. Furthermore, a subsection follows each table stating the concentration interval within which the substance group in question is expected to occur in the products. All weights and measures are stated as the weight percentage of the total product, exclusive of packaging. Information concerning the quantities added has been found primarily in patents for shampoo and dandruff shampoo. A given concentration interval therefore does not reflect data on a specific product in a single patent, but is rather a general overview of information about product composition from the patents seen as a whole. In the section called References is a total list of references.

3.1.1 Solvents

Solvents in cosmetic and medical dandruff shampoo

Substance name	CAS no.	Frequency per 9+3 products
Aqua	7732-18-5	12

The information available indicates that water is the only solvent used in dandruff shampoo.

3.1.1.1 Concentration interval

Typically, between 60 and 85 % w/w water is added.

3.1.2 Surfactants / soap components

Surfactants in cosmetic dandruff shampoo

Substance name (INCI)	CAS NO.	Frequency per 9 products
Sodium Laureth Sulphate	9004-82-4 /133	7
Cocamidopropyl Betaine	61789-40-0	5
Disodium Laureth Sulphosuccinate	39354-45-5	2
PEG-7 Glyceryl Cocoate	68201-46-7 /66	2
Sodium Shale Oil Sulphonate	1340-06-3	2
Cocamidopropylamine Oxide	68155-09-9	1
Coco-Betaine	68424-94-2	1
Decyl Polyglucose	-	1
Hydrogenated Castor Oil	8001-78-3	1
Laureth-10	9002-92-0 /654	1
Laureth-2	3055-93-4 /900	1
PEG-15 Cocamine	61791-14-8	1
Polysorbate 20	9005-64-5	1
Polysorbate 80	9005-65-6	1
Sodium Cetearyl Sulphate	59186-41-3	1
Sodium Lauroyl Sarcosinate	137-16-6	1
Sodium Lauryl Sulphate	151-21-3	1
Sodium PEG-6 Cocamide Carboxylate	-	1

Surfactants in medical dandruff shampoo

Substance name	CAS NO.	Frequency per 3 products
Sodium cocoyl sarcosinate	61791-59-1	1
Sodium lauryl sulphate	151-21-3	1
Plantaren PS 10 ⁴	-	1
Texapon T42 and Texapon A ⁴	-	1

3.1.2.1 Concentration interval

Anionic surfactants typically comprise between 12 and 30 % w/w, whereas amphoteric and non-ionic surfactants comprise typically between 1 and 8 % w/w.

3.1.3 Softeners

Softeners in cosmetic dandruff shampoo

⁴ commercial trade name. Medical dandruff shampoo is not obliged to have an inci-declaration as cosmetic dandruff products are.

Substance name (INCI)	CAS NO.	Frequency per 9 products
Chamomilla Recutita Extract	84082-60-0	2
Glyceryl Distearate	1323-83-7	2
Cetyl Alcohol	36653-82-4	1
Dimethicone	9006-65-9 /631	1
Glycol Distearate	627-83-8	1
Hydrogenated Castor Oil	8001-78-3	1
Prunus Amygdalus Dulcis Extract	90320-37-9	1
Tussilago Farfara Extract	84624-50-3	1

Softeners in medical dandruff shampoo

Substance name	CAS NO.	Frequency per 3 products
Glyceryl Monoricinoleate	-	2

3.1.3.1 Concentration interval

The contents of softeners in shampoo typically comprise between 0.2 and 3% w/w.

3.1.4 Emulsifiers

Emulsifiers in cosmetic dandruff shampoo

Substance name (INCI)	CAS NO.	Frequency per 9 products
Cocamide DEA	68603-42-9	4
Trideceth-5	24938-91-8	4
PEG-7 Glyceryl Cocoate	68201-46-7 /66	2
Cetyl Alcohol	36653-82-4	1
Cocamide MEA	68140-00-1	1
Cocamide MIPA	68333-82-4	1
Glycol Distearate	627-83-8	1
Hydrogenated Castor Oil	8001-78-3	1
Laureth-10	9002-92-0 /654	1
Laureth-2	3055-93-4 /900	1
PEG-10 Olive Glycerides	-	1
PEG-15 Cocamine	61791-14-8	1
PEG-15 Glyceryl Isostearate	68958-58-7	1
PEG-3 Distearate	9005-08-7	1
PEG-80 Glyceryl Tallowate	68553-11-7	1
Polysorbate 20	9005-64-5	1
Polysorbate 80	9005-65-6	1
Sodium Lauryl Sulphate	151-21-3	1
Sodium PEG-6 Cocamide Carboxylate	-	1
Trideceth-6	24938-91-8	1
Trideceth-7	24938-91-8	1

Trideceth-9	24938-91-8	1
Trideceth-12	24938-91-8	1

Emulsifiers in medical dandruff shampoo

Substance name	CAS NO.	Frequency per 3 products
Cocamide MEA	68140-00-1	1
Glycol Distearate	627-83-8	1
Sodium lauryl sulphate	151-21-3	1
Texapon T42 and Texapon A ⁴	-	1

3.1.4.1 Concentration interval

Contents of emulsifiers in shampoo typically comprise between 0.4 and 4% w/w.

3.1.5 Humectants

Humectants in cosmetic dandruff shampoo

Substance name (INCI)	CAS NO.	Frequency per 9 products
Propylene Glycol	57-55-6	5
Glucose	50-99-7	1

3.1.5.1 Concentration interval

No data.

3.1.6 Thickening agents and viscosity controlling substances (gelation agents)

Thickening agents (T) and viscosity controlling substances (V) in cosmetic dandruff shampoo

Substance name (INCI)	CAS NO.	Frequency per 9 products
Sodium Chloride (V)	7647-14-5	5
Carbomer (V)	9007-20-9 /900	1
Guar Hydroxypropyl-trimonium chloride (V)	65497-29-2	1
PEG-55 Propylene Glycol Oleate (V)	86481-08-5	1
Sodium Carbomer (T and V)	-	1
Sodium Lauroyl Sarcosinate (V)	137-16-6	1
Stearamide MEA (V)	111-57-9	1

Thickening agents (T) and viscosity controlling (V) substances in medical dandruff shampoo

Substance name	CAS NO.	Frequency per 3 products
Sodium chloride (V)	7647-14-5	2
Bentonite (V)	1302-78-9	1

Carbomer 1342 (T)	-	1
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3.1.6.1 Concentration interval

Contents of thickening agents and viscosity controlling substances in shampoos typically comprise between 0.25 and 1.3 % w/w.

3.1.7 Emulsion stabilisers

Emulsion stabilisers in cosmetic dandruff shampoo

Substance name (INCI)	CAS NO.	Frequency per 9 products
Cocamide DEA	68603-42-9	4
Carbomer	9007-20-91 /900	1
Cocamide MEA	68140-00-1	1
Cocamide MIPA	68333-82-4	1
Decyl Polyglucose	-	1

Emulsion stabilisers in medical dandruff shampoos

Substance name	CAS NO.	Frequency per 3 products
Bentonite	1302-78-9	1
Cocamide MEA	68140-00-1	1

3.1.7.1 Concentration interval

Emulsion stabilisers are typically present in quantities between 0.5 and 1.0 % w/w.

3.1.8 Preservatives and anti-microbial agents

Preservatives and anti-microbial agents (AM) in cosmetic dandruff shampoo

Substance name (INCI)	CAS NO.	Frequency per 9 products
Piroctone Olamine	68890-66-4	3
Sodium Benzoate	65-85-0	3
Benzene Alcohol	100-51-6	2
Methylchloroisothiazolinone	26172-55-4	2
Methylisothiazolinone	2682-20-4	2
Methylparabene	99-76-3	2
Propylparabene	94-13-3	2
Sodium Salicylate	54-21-7	2
Allium Sativum Extract (AM)	8008-99-9	1
Butylparabene	94-26-8	1
Diazolidinyl urea	78491-02-8	1
DMDM Hydantoin	6440-58-0	1
Ethylparabene	120-47-8	1
Hedera Helix (AM)	-	1
Melaleuca Alternifolia Oil (AM)	85085-48-9	1
Phenoxyethanol	122-99-6	1

Salicylic acid	69-72-7	1
Sodium Formate	64-18-6	1
Sorbic acid	110-44-1	1

Preservatives in medical dandruff shampoo

Substance name	CAS NO.	Frequency per 3 products
BHT	128-37-0	1
Quaternium-15	4080-31-3 /512	1

Methylisothiazolinone and methylchloroisothiazolinone are seldom used as individual ingredients but rather as a mixture (also termed Kathon) in a 1:3 ratio.

3.1.8.1 Concentration interval

Preservatives and anti-microbial agents typically comprise between 0.05 and 0.5% w/w.

In the Statutory Order on Cosmetic Products preservatives feature on a so-called positive list. This means that rules have been laid down stipulating which preservatives may be used and the maximum concentration at which a preservative may be added to products. Provided the maximum authorized concentration level for individual components is not exceeded, no maximum limit for addition of mixtures of preservatives is given.

3.1.9 Buffers

Buffers in cosmetic dandruff shampoo

Substance name (INCI)	CAS NO.	Frequency per 9 products
Citric Acid	77-92-9	7
Sodium Citrate	68-04-2	1

Buffers in medical dandruff shampoo

Substance name	CAS NO.	Frequency per 3 products
Citric acid	77-92-9	1
Citric acid monohydrate	-	1
Sodium hydrogen phosphate	7558-80-7	1
Sodium hydroxide	1310-73-2	1
Hydrochloric acid	7647-01-0	1

3.1.9.1 Concentration interval

Buffers are normally added in quantities adequate to change the pH value of the mixture to between 4 and 6.5 - values similar to that of the skin. For example, sodium hydroxide is added in a 25 % solution in quantities corresponding to between 0.5 and 1 % w/w, and citric acid may be added in quantities between 0.1 and 0.2 % w/w.

3.1.10 Soothing, skin-conditioning and astringent substances

Soothing (S), skin-conditioning (SC) and astringent (A) substances in cosmetic dandruff shampoo

Substance name (INCI)	CAS NO.	Frequency per 9 products
Acorus Calamus Extract (SC)	84775-39-3	1
Arctium Lappa Extract (SC) (S)	84012-13-5	1
Bisabolol (S)	515-69-5	1
Buxus Sempervirens Extract (SC)	84012-17-9	1
Citrus Aurantium Dulcis Extract (SC)	8028-48-6	1
Hedera Helix (A) (S)	84082-54-2	1
Hydrolyzed Wheat Protein (SC)	94350-06-8 /70	1
Maris Sal (sea salt) (SC)	-	1
Panthenole (SC)	81-13-0	1
Pyrus Malus Extract (SC)	89957-48-2	1
Quercus Robur Extract (A)	-	1
Tussilago Farfara Extract (A)	84625-50-0	1

3.1.10.1 Concentration interval

Soothing, skin-conditioning and astringent substances are added in quantities between 0.1 and 0.7 % w/w.

3.1.11 Film formers and hair-conditioners

Film formers (F) and hair-conditioners (H) in cosmetic dandruff shampoo

Substance name (INCI)	CAS NO.	Frequency per 9 products
Polyquaternium-10 (F)	81859-24-7 /53	3
Polyquaternium-7 (F)	26590-05-6	2
Guar Hydroxypropyl Trimonium Chloride (F)	65497-29-2	1
Hydrolyzed Wheat Protein (H)	94350-06-8 /70	1
Panthenole (H)	81-13-0	1
Sodium Styrene/Acrylates Copolymer (F)	-	1
Urtica Dioica (H)	84012-40-8	1

Film formers (F) and hair-conditioners (H) in medical dandruff shampoo

Substance name	CAS NO.	Frequency per 3 products
Polyquaternium-7 (F)	26590-05-6	1

3.1.11.1 Concentration interval

Film formers and hair-conditioners are added in quantities between 0.1 and 1 % w/w.

3.1.12 Colourants

Colourants in cosmetic dandruff shampoo

Substance name (INCI)	CAS NO.	Frequency per 9 products
CI 42090	2650-18-2 3844-45-9 68921-42-6	3
CI 15985	15790-07-5 2783-94-0	1
CI 16255	2611-82-7	1
CI 60730	4430-18-6	1
CI 73015	860-22-0 16521-38-3	1

Colourants in medical dandruff shampoo

Substance name	CAS NO.	Frequency per 3 products
Patent Blue V (E131)	3536-49-0	1

3.1.12.1 Concentration interval

Colourants are added in quantities between 0.001 and 0.007 % w/w.

3.1.13 Anti-dandruff agents

Anti-dandruff agents in cosmetic dandruff shampoo

Substance name (INCI)	CAS NO.	Frequency per 9 products
Zinc Pyrithione	13463-41-7	3
Sodium Shale Oil Sulphonate	1340-06-3	2
Arctium Lappa Extract	84012-13-5	1
Climbazole	38083-17-9	1
Sulphite	7704-34-9	1

Anti-dandruff agents in medical dandruff shampoo

Substance name	CAS NO.	Frequency per 3 products
Ketoconazole (1-2 % w/w)	65277-42-1	1
Selenium disulfide (1-2.5 % w/w)	7488-56-4	1
Zinc pyrithion (2 % w/w)	13463-41-7	1

3.1.13.1 Concentration interval

Anti-dandruff agents in cosmetic shampoo typically comprise between 0.3 and 2 % w/w.

3.1.14 Fragrances (perfumes)

Fragrances in cosmetic dandruff shampoo

Substance name (INCI)	CAS NO.	Frequency per 9 products
Fragrances	-	6

Fragrances in medical dandruff shampoo

Substance name	CAS NO.	Frequency per 3 products
Parfumeolie Yvonne (perfumed oil)	-	2
Perfume Bouquet	-	1

3.1.14.1 Concentration interval

Dandruff shampoos typically contain up to 1 % w/w fragrance mixture. Three of the products (numbers 359, 364⁵ and 365) did not contain any perfumes.

3.1.15 Other substances

Other substances in cosmetic dandruff shampoo

Substance name (INCI)	CAS NO.	Frequency per 9 products
Hydroxystearyl Cetyl Ether	-	1
Thymus Vulgaris	84929-51-1	1

Other substances in medical dandruff shampoo

Substance name	CAS NO.	Frequency per 3 products
Esters Copolymer	-	1
Tetrasodium EDTA (forms metal complexes)	64-02-8	1

3.1.15.1 Concentration interval

Tetrasodium EDTA is added in quantities of around 0.5 % w/w and acrylate copolymers are added in quantities of about 1 - 1.5 % w/w.

3.2 Comparison with ordinary shampoo

In order to identify substances typical in dandruff shampoo but which do not have direct anti-dandruff effects, the 12 dandruff shampoos were compared to 14 ordinary shampoos surveyed by the Danish EPA. Not surprisingly, an examination of substances found in ordinary shampoo but not in dandruff shampoo, suggested that there are no substance components specific to ordinary shampoos.

According to the examination, the fourteen ordinary shampoos contained over 50 different substances not present in the dandruff shampoos. These

⁵ no. 364 has gone out of stock

substances are relatively evenly distributed between surfactants, emollients (softeners), plant extracts, preservatives, emulsifiers, and buffers.

In contrast, the examination of whether dandruff shampoos contain substance components not present in ordinary shampoos, revealed a difference between the two types of shampoo. The latter examination showed that dandruff shampoo, in addition to the declared active anti-dandruff agents, contains more lipophile and lipophile-like substances than ordinary shampoo. These are often derivatives of fatty acids, acetylated mono glycerides, and di- and triglycerides, such as olive oil, castor oil, coconut oil, and tallow. Not all more or less exotic plant extracts and oils have been included, since it is difficult to ascertain the contents and function of these substances. The table shows results of the comparison.

Substances present in the 12 dandruff shampoos examined, which were not found in the 14 ordinary shampoos previously surveyed by the Danish EPA. The remaining 17 of the 27 substances in total are lipophile substances. Plant extracts and oils, as well as active dandruff ingredients have not been included in the table.

Substance name	The number of products in which the substance was found, including product name
CI 42090	3 (358, 361 and 363)
Piroctone Olamine	3 (354, 362 and 363)
Polyquaternium-10	3 (359, 360 and 361)
Carbomer	2 (357, 359)
Bisabolol	1 (363)
Diazolidinyl urea	1 (358)
Quaternium-15	1 (357)
Bentonite	1 (356)
Sodium Formate	1 (358)
Sorbic acid	1 (362)
Glyceryl Distearate	2 (362 and 363)
Glyceryl Ricinoleate	2 (355 and 356)
Sodium Shale Oil Sulphonate	2 (359 and 361)
Hydrandenated Castor Oil	1 (361)
PEG-10 Olive Glycerides	1 (360)
PEG-15 Cocamine	1 (364 ⁶)
PEG-15 Glyceryl Isostearate	1 (359)
PEG-3 Distearate	1 (358)
PEG-80 Glyceryl Tallowate	1 (362)
Polysorbate 20	1 (362)
Polysorbate 80	1 (362)
Sodium Cocoyl Sarcosinate	1 (357)
Sodium PEG-6 Cocamide Carboxylate	1 (363)
Sodium Styrene/Acrylates Copolymer	1 (363)
Stearamide MEA	1 (362)
TEA Lauryl Sulphate	1 (356)
Trideceth	1 (363)

⁶ no. 364 has gone out of stock

4 Exposure

In order to compare the following toxicity values to actual use, it is necessary to make assumptions as to how much dandruff shampoo is applied per hair wash, the frequency of use, and to make estimates as to the size of the area exposed.

Other complications are involved in developing a realistic scenario of environmental exposure, including primary aquatic concentrations etc., because this requires knowledge about the overall consumption of dandruff shampoo, as well as about the concentrations of the relevant substances before and after water treatment etc. at water treatment plants. Such data is most easily collected via direct measurements, which have not been possible in this project.

In the considerations below concerning human exposure, dermal area has been established on the basis of the values stated in the US EPA Exposure Factors Handbook (United States Environmental Protection Agency, 1997). Quantities and frequencies of use have been established partly on the basis of exposure scenario for use of shampoo in the risk assessment for 1,4-dioxane (Risk Assessment Report, 1999), and partly on the basis of data from the EU Technical Guidance Document TGD 2000) for use of rinse-off (nonpermanent) cosmetic products.

4.1 Human exposure

It is assumed a typical exposure scenario includes one hair-wash per day, for men and for women.

Consumption per hair-wash is an estimated **12 grams** of shampoo. The exposed dermal area during hair-washing assumedly includes the palm of both hands: that is, half of the area of both hands ($840 \text{ cm}^2/2 = 420 \text{ cm}^2$, and all of the scalp (1200 cm^2), which gives a total area of **1620 cm²**.

A component comprising X % w/w of a product will therefore be present on:

Hands: $12 \text{ g} * (X/100) / 420 \text{ cm}^2 = 0.29 * X \text{ mg/cm}^2_{\text{dermal surface}}/\text{event}$

Scalp: $12 \text{ g} * (X/100) / 1200 \text{ cm}^2 = 0.1 * X \text{ mg/cm}^2_{\text{dermal surface}}/\text{event}$

EU's Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers (SCCNFP) has prepared guidelines for testing cosmetic ingredients in safety evaluation. These guidelines include the following exposure scenario:

One hair-wash requires 8 grams of shampoo. It is assumed the hair is washed daily. Since the shampoo is applied to wet hair and skin, it is assumed that approximately 1 per cent of the shampoo applied will be absorbed. This means that with a content of X (calculated in weight percentage) exposure is:

$$8 \text{ gram/day} * 0.01 * X = X * 0.08 \text{ g/day}$$

4.2 Environmental exposure

Naturally, it is expected that a rinse-off shampoo is discharged approximately 100 per cent to the aquatic environment either directly or via a wastewater treatment plant. For a total quantitative assessment of the discharge, it is essential we know how much dandruff shampoo is consumed per time unit per household. Moreover, it is equally important that we know which type of wastewater treatment plant the water passes through before ending up in the aquatic environment.

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