

Survey of Chemical Substances in Consumer Products

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Analysis of chemical hair-removal products

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1 Foreword

After receiving several complaints from consumers and the Danish Consumer Council regarding injuries resulting from the use of hair-removal products, the consumer section of the Environmental Protection Agency decided an analysis of hair-removal products on the Danish market was called for. Initially, focus was given to a specific product. This investigation was completed last autumn. The Environmental Protection Agency has subsequently carried out a general examination of chemical hair-removal products.

Several types of hair-removal products are on the market. Creams and foams are available which remove hair by means of a chemical reaction. Waxes are also available which are not chemical hair-removal products, but which work by pulling out the hairs, and finally, various machines and shavers are available which remove hairs by other mechanical means, often in connection with the use of shaving cream.

Only the chemical hair-removal products have been included in this project.

The mechanical methods involving the use of shaving cream or wax have not been considered as part of this project. The Environmental Protection Agency has previously examined the use of wax which has to be heated before use. A number of useful tips on the use of wax for hair removal can be found on the Environmental Protection Agency's website. Useful tips on the use of chemical hair-removal products have also been provided, based on this report.

Manufacturers/importers of hair-removal products have been given copies of this report for public hearing before publication. Their comments have subsequently been incorporated into this report.

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2 Approach

In order to ascertain what chemical hair-removal products are available on the Danish market, various retailers were visited. Products were purchased from supermarkets, druggists, chemists, health/natural cosmetics shops and on the Internet.

3 Relevant legislation

Hair-removal products are covered by Statutory Order no. 594 of 6 June 2000 on cosmetic products. The Statutory Order implements in Denmark the regulations set in the EU Directive on cosmetic products, cf. Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products.

Hair-removal products marketed in Denmark must comply with the regulations of the Statutory Order, which apply to the products' content of dangerous substances (section 9), labelling (sections 16-23), safety directions for use (section 20), and the information the manufacturer or marketing entity must have in their possession for use by the authorities in their administration of the regulations (section 32).

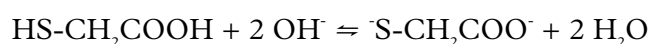
4 Products

4.1 CHEMICAL HAIR-REMOVAL PRODUCTS

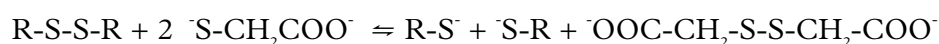
Chemical hair-removal products work by breaking down the hair's keratin. It is not difficult to break down the keratin in hair, since it is sensitive to strongly alkaline, aqueous solutions and deoxidation agents. However, skin also contains keratin in the outer layers (corneum). This means that it is difficult to produce a chemical product which can remove/break down keratin in hair, without affecting keratin in the skin at the same time. However, it has been shown that products which combine a strongly deoxidising reaction with a strongly alkaline (basic) effect can break down the hair in a short time, while leaving the skin almost unaffected.

When producing hair-removal products, it is not enough that the active ingredients attack the keratin in the hair faster than the keratin in the skin. It must also be ensured that the constituents are not dangerous and only very rarely cause eczema or allergic reaction. It must also be ensured that the product neither has an unpleasant odour nor develops odour during use, and other undesirable effects must be avoided.

The principle employed in hair-removal products is to break down the sulphur bonds in the hair's keratin. The sulphur bonds are deoxidised using a salt of thioglycolic acid. In order to enable thioglycolic acid to deoxidise the bonds, it has to exist as an active dianion in the product. This requires a high concentration of hydroxide ions, which react with the thioglycolic acid as follows:



The dianion can then react with keratin as follows:



This reaction is reversible, which means that it does not run to completion, but settles at an equilibrium where both the reactants and the reaction products are present in the solution.

$$K = \frac{[\text{reaction products}]}{[\text{reactants}]}$$

In practise, this means that if one increases the concentration of one of the reactants in the equilibrium state, the concentration of the other reactant will reduce correspondingly, until equilibrium is again established. It is thus possible to reduce the quantity of undeoxidised keratin by increasing the concentration of thioglycolic acid in the above equilibrium.

However, during hair-removal, it is not just the sulphur bonds in keratin which have to be broken, but also salt, hydrogen, and amide bonds. This is achieved using a strongly alkaline environment. As described above, the high

concentration of hydroxide ions is also necessary to get the thioglycolic acid into active form as dianion.

The concentration of the dianion of thioglycolic acid is therefore dependent on the initial concentrations of both thioglycolic acid and hydroxide ions, and hence on the strong alkali.

As the above equations show, larger amounts of the hair's keratin are deoxidised with higher concentrations of the thioglycolic acid's dianion. This means that the higher the concentration of the alkali and hence the higher the pH value, and the higher the concentration of the thioglycolic acid, the more effective the product will be. However, there are other factors to take into account. Thioglycolic acid is toxic, and restrictions have therefore been placed on its use in cosmetics. The high pH value can, in itself, also be harmful to the skin in the form of corrosive burning, and as already mentioned, its effect on the skin's keratin must also be considered.

The Statutory Order on cosmetics sets a limit value for the content of thioglycolic acid (max 5% by weight) in products designed to remove hair, and a limit value for the maximum permitted pH value (pH=12.7). In setting these limit values, consideration has been given to the fact that it is necessary to have a high pH value in order to turn the thioglycolic acid into the active form. The limit values mentioned above therefore only apply to products designed for hair removal, while other limit values apply to other types of cosmetic products.

4.1.1 Constituents

The constituents in hair-removal creams are shown in the list of ingredients on the packaging or on the product itself. As described above, hair-removal products contain several active ingredients which are necessary in order to achieve the desired effect. Thioglycolic acid is added as various salts, such as calcium and potassium thioglycolate as well as pure thioglycolic acid.

In order to attain the high pH value, and thereby also the high concentration of hydroxide ions, strong alkalis are used, such as calcium, potassium, and sodium hydroxide.

In addition to these active ingredients, hair-removal products contain a large number of other substances, on par with other types of creams. These are ingredients such as water, emollients, emulsifiers, moisturisers, antioxidants, plant extracts, colouring agents, preservatives and perfumes. These groups of substances are not very different from the contents of other creams, but each product has its own unique constitution.

4.1.2 pH measurements

As explained above, products must have a certain pH value in order to be functional. The regulations set some limit values for the pH value when the particular substances are used. With regard to the content of thioglycolic acid, the content must not exceed 5% (by weight) and strong alkali can be added only so that products have a maximum pH value of 12.7.

The pH value can have a big impact on how the product affects the skin. The Environmental Protection Agency has therefore checked the pH value for all the chemical hair-removal products. The pH level has been measured directly

in the samples using a pH electrode for solid matrices. The measurements have been performed using repeat determination, with an analysis uncertainty of ± 0.1 pH units. The measurements have been carried out at room temperature and are shown in table 1.

Table 1: pH measurements in hair-removal products

Product ID	Product description	pH	Recommended period of application*	Maximum period of application
H	Hair-removal foam	11.6	8-10 min	10 min
I	Hair-removal cream for the bikini line	12.5	5-7 min	10 min
J	Hair-removal foam	11.6	8-10 min	10 min
K	Hair-removal gel	12.5	5-8 min	10 min
L	Hair-removal cream for sensitive skin	12.5	5-7 min	10 min
M	Hair-removal cream	12.5	5-7 min	10 min
N	Hair-removal cream	12.5	5-7 min	10 min
O	Hair-removal cream	12.0	3-10 min**	not specified**
P	Hair-removal cream for the bikini line	12.4	5-7 min	10 min
Q	Hair-removal cream for the body	12.3	5-8 min	10 min
R	Hair-removal cream	12.5	5-6 min	10 min
S	Hair-removal cream for the face	12.3	1-4 min	5 min
T***	Hair-removal cream	12.0	10-15 min	15 min

* according to the manufacturer's directions for use

** according to the enclosed Danish directions for use, the package was not labelled in Danish

*** no longer available on the Danish market

As can be seen from the results above, no products exceed the current pH limit of 12.7.

4.1.3 Compliance with the regulations

With regard to their constituents, all the chemical hair-removal products comply with the current regulations.

With regard to product labelling, the Environmental Protection Agency has closely examined the labelling on each product, and the enclosed directions for use. According to section 20 in the Statutory Order on cosmetics, all cosmetic products must be labelled with safety directions for use.

In addition to the phrases which are compulsory according to appendix 3 to the Statutory Order on cosmetics, the Environmental Protection Agency has also focused on the marketing of each product and the contents of the directions for use. It is the verdict of the Environmental Protection Agency that it is not reasonable to market hair-removal products using designations such as gentle, soft, mild, or the like, given the composition of these products. It is the high pH value, in particular, which provides the basis for this verdict. This is described in more detail below.

In its examination of the directions for use, the Environmental Protection Agency has focused on the description of how to use the products. It is important that this contains:

- a description of a test consumers should perform before using the product
- maximum limits for how long the product is permitted to be in contact with the skin
- information about the need for thorough rinsing with plenty of water after treatment, as alkaline products can be difficult to rinse off the skin.
- information about the fact that if the consumer experiences a painful or burning sensation in the skin, they should immediately discontinue treatment, and that the product should not be used on irritated or damaged skin.

After an examination of the product labelling, directions for use and marketing, the Environmental Protection Agency has concluded that some products do not comply with the current regulations. These breaches have been passed on to the Chemical Inspection Service. All manufacturers have already indicated, either prior to or after being approached by the Chemical Inspection Service, that they will voluntarily change the labelling and marketing of their products in accordance with the guidelines from the Environmental Protection Agency.

4.1.4 Evaluation of the products during use

There is a risk of allergy associated with the use of cosmetic products, including various types of creams, and this is linked to various constituents such as preservatives and perfumes. Naturally this risk is also associated with the use of hair-removal products. This risk will not be discussed further, as it is no different from the risk associated with the use of other creams.

However, chemical hair-removal products are significantly different from other creams, due to their thioglycolic acid content and high pH value.

There is no official declaration regarding thioglycolic acid from the EU's Scientific Committee for Cosmetic Products, and Non-food Products (SCCNFP) in connection with the current regulation of the substance in the EU Directive on cosmetics (76/768/EEC).

However, in connection with the EU Directive on the classification, packaging and labelling of dangerous substances (67/548/EEC), various restrictions for thioglycolic acid have been adopted, based on an evaluation of the substance.

Thioglycolic acid in pure form is classified as T: *toxic* and C: *corrosive*. The classification of, for example, a cleaning product containing 2-5 % thioglycolic acid would be T: *toxic*, with risk phrases R23/24/25: *Toxic if absorbed by skin contact, inhaled or swallowed*. It is also worth noting that according to Statutory Order no. 329 on the classification, packaging, labelling, sale and storage of chemical substances and products, chemical products which are classified as T: *toxic*, are not permitted to be sold to private consumers by retailers. However, it is important to emphasise that cosmetics are not covered by this Statutory Order, but by the other legislation described above, and there is therefore no requirement for cosmetics to be labelled as dangerous. For hair-removal products, the content of thioglycolic acid in the finished product must be less than 5 %.

The pH value of the products lies between 11.6 and 12.5, and the pH value of the skin is around 5-6, so there is a big difference between this value and the values for the products. According to Statutory Order no. 329, described

above, products such as cleaning products with a pH greater than or equal to 11.5 must be classified as C: *Corrosive* with risk phrase R35: *Causes severe burns*, purely on the basis of the product's high pH value.

As already mentioned, hair-removal products and other cosmetics are not covered by Statutory Order no. 329, but by the Statutory Order on cosmetics. It assigns the following limits and conditions for the use of thioglycolic acid and hydroxide ions in hair-removal products:

Substance	Highest permitted concentration in the finished cosmetic product	Limits and requirements	Compulsory directions for use and warnings on the label
Thioglycolic acid and salts of the same	5% of finished product pH 7-12.7	The directions for use must contain the following phrases: - Must not come into contact with the eyes - If the product comes into contact with the eyes, rinse immediately with large quantities of water and consult a specialist	Contains salts of thioglycolic acid - Follow the directions for use - Keep out of reach of children
Potassium and sodium hydroxide	Up to pH 12.7		Must not come into contact with the eyes. Keep out of reach of children
Calcium hydroxide		pH value must not exceed 12.7	Contains alkali Must not come into contact with the eyes. Keep out of reach of children

Based on the above, it is felt that careful attention must be given to how the products are used. Hair-removal products should never be used on skin which is already irritated or damaged. The directions for use must be followed very closely, and it is important not to exceed the recommended application times. The longer the creams are in contact with the skin, the longer the high pH value will affect the skin. The manufacturers' safety evaluations of the products are based on the recommended application times.

It is therefore important to be aware that the time starts from when you begin to rub on the product, until you have finished rinsing it off. If, during use, you experience the slightest burning or stinging, or skin irritation, the product must be removed using plenty of water. Due to the alkaline properties of these products, a greasy film can form on the skin which can make the products more difficult to remove than normal creams. However, it is very important to completely remove the product, so that it ceases to affect the skin.

After treatment, the skin can often be slightly irritated or more sensitive than normal. This means that you need to be careful about what other creams are applied to the skin in the following 24 hours. If the skin's protective oil has been removed or it is irritated, it will be more susceptible to foreign substances. This increases the risk that allergy-causing or irritating substances can penetrate the skin and cause eczema. For this reason, the Environmental Protection Agency recommends that people avoid using creams containing potential allergens such as perfume and/or large quantities of plant extracts. Al-

cohol will dry out the skin even more. If the skin is very dry after treatment, it is recommended to use an oily, unperfumed cream.

4.2 POST-TREATMENT CREAMS

A number of the manufacturers include post-treatment creams designed to be used on the area of the skin from which the hair has been removed. The contents declarations for each of these post-treatment creams have been examined. They fulfil the requirements of the cosmetic Statutory Order and are not very different to normal creams and body lotions. A few contain special vegetable oils which the manufacturers claim soothe the skin.

Several of them also contain perfume, despite the fact that the manufacturers advise against the use of products containing perfume on the skin for up to 24 hours after treatment. However, what perfumes are used, and in what quantities, is not specified, and it is also very individual whether and how one reacts to, for example, various perfumes.

5 Conclusion

All of the hair-removal products investigated comply with the current legislation with regard to their constituents. Many also comply with the legislation regarding the labelling and marketing of these products, and in the cases where breaches were discovered, the manufacturers have chosen to make changes voluntarily. With regard to directions for use, the Environmental Protection Agency has contacted the particular manufacturers and asked them to make additions or corrections to the existing directions for use, so that they fulfil the Environmental Protection Agency's guidelines.

Regardless of the type of hair-removal product one chooses to use, it is very important to follow the entire directions of use carefully. It is also important to be aware of how one's skin reacts, both during and after treatment. Unpleasant effects such as burning, stinging, or itching are not meant to occur in connection with use of these products. If unpleasant effects are experienced, the treatment must be immediately discontinued and the hair-removal product must be removed using plenty of lukewarm water.

In order to safeguard consumers as far as possible, the Environmental Protection Agency has prepared a number of useful tips which should be followed when using hair-removal products.

6 Useful tips when using hair-removal products

6.1 CHEMICAL HAIR-REMOVAL PRODUCTS:

- ❑ Read all the supplied information and directions for use thoroughly before commencing application, and closely follow all instructions.
- ❑ Test the product on a small area of skin where you wish to remove the hair, 24 hours before use. The product should only be used if, after 24 hours, there are no signs of hypersensitivity or irritation. However, the test is no guarantee against a later reaction, so even if you have used hair-removal products before, you should perform the test each time.
- ❑ The products should not be applied to acne, varicose veins, moles, or warts, or to damaged, irritated, thin, or dry skin.
- ❑ Check also in the directions of use whether the product may be used on the face, breasts, or around the "bikini line", as this is dependent on the product formulation (cream, gel or spray), and the skin is particularly sensitive in these areas.
- ❑ Ensure that the skin is completely clean and dry before applying the product.
- ❑ Always observe the specified time limit for how long the product is permitted to be on the skin. Note that it might be necessary to treat one leg or patch of skin at a time, to ensure that the time limit is observed. The time should be counted from the moment you begin applying the product to the skin, until it has been removed again, not from when you have finished applying cream to a large area of skin, until you start scraping it off. Even if the hair is not satisfactorily removed on the first attempt, you should wait at least 48 hours before repeating treatment.
- ❑ Make sure you rinse off the hair-removal product thoroughly, using plenty of lukewarm water, at the end of the treatment. A greasy layer can form on the skin due to the high pH value, and this can be difficult to rinse off.
- ❑ If you experience a burning or stinging sensation, or skin irritation, the product must be immediately removed using plenty of water. If there is subsequent, clear irritation of the skin, or burns, you should consult a doctor.
- ❑ After treatment, the skin can be extra sensitive. You should therefore avoid using creams or other cosmetic products containing alcohol, perfume, or other potentially irritating or dehydrating ingredients on the treated skin.

6.2 WAX

- ❑ Always read through all the supplied information and directions for use thoroughly and follow them closely.
- ❑ When using hot wax, you must take care that the wax is not too hot when it is applied to the skin, to avoid burning.
- ❑ If there are signs of irritation, eczema, or a burning sensation, the treatment must be immediately discontinued and all wax removed.
- ❑ If you experience a burning or stinging sensation, or skin irritation, the product must be immediately removed using plenty of water. If there is subsequent, clear irritation of the skin, or burns, you should consult a doctor.
- ❑ After treatment, the skin can be extra sensitive. You should therefore avoid using creams or other cosmetic products containing alcohol, perfume, or other potentially irritating or dehydrating ingredients on the treated skin.