Denaturants in cosmetic products – health is secondary

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Concerning the ingredients of cosmetic products their purity is essential. The fact that the products may also contain additives that are mandatory, have nothing to do with skin care and may even cause counterproductive effects is discussed in the following paper.

The term "denaturants" already points toward the issue. We are dealing with substances that are designed to spoil our appetite or in other words to make edible substances unfit for consumption. The focus of attention here is on alcohol (ethanol), a substance that we know very well from alcoholic beverages. Basically, ethanol is a comparatively low-priced article. However, there is the alcohol tax[1]. This tax on spirits even is collected if ethanol is not consumed but used for other purposes as e.g. for the manufacturing of cosmetic products. The result is that it turns out to be a high-priced ingredient although cosmetic products in general are not intended for oral consumption.

Taxed or denatured

While it is possible to establish tax warehouses for similar cases as e.g. mineral oil, and to apply for a license for alcohol storage according to § 132, subparagraph 1, law on alcohol monopoly, in Germany this only refers to food but not to cosmetic products. § 139 (tax exempted use) says that "anyone intending to use tax exempted products according to § 132, subparagraph 1, shall apply for a license. Said license shall be granted to persons on request subject to revocation provided that there are no objections regarding their tax reliability. Said license involves the storage of these goods in the establishment." This license is refused for cosmetic products due to the fact that there simply are no regulations with respect to the complete balancing of incoming and outgoing quantities of alcohol used by the manufacturers of cosmetics in order to prove that the alcohol has been used for cosmetic products only and not for oral consumption.
Neither is it possible to get an alcohol tax refund. The Federal Ministry for Finances has answered an inquiry as follows: "Without a denaturing process in proper form the tax exempted use for the manufacturing of cosmetic products is impossible"[3].

Phthalates – a potential risk

A consequence of this regulation is a widespread use of denaturing additives. The most frequently used denaturants are phthalic acid esters (phthalates). Primarily diethyl phthalate (phthalic acid ethylester, DEP) is added to cosmetic products. According to the German alcohol tax law the minimum concentration in alcohol is 0.5 %. In connection with plasticizers and toys made in China the pros and cons have been publicly discussed over and over again. As a matter of fact, annex 1 of the Cosmetic Decree (KVO) [4] entitled as "substances banned from the use in the manufacturing or treating of cosmetic products" particularizes the following substances:

- Dibutyl phthalate (CAS registry number 84-74-2) (ref.no. 675)
- Bis-(2-ethylhexyl)-phthalate (CAS no. 117-81-7) (ref.no. 677)
- Bis-(2-methoxyethyl)-phthalate (CAS no. 117-82-8) (ref.no. 678)
- 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear (CAS no. 84777-06-0), n-pentylisopentyl phthalate, di-n-pentyl phthalate (CAS no. 131-18-0), Diisopentyl phthalate (CAS no.. 605-50-5) (ref.no. 1151)
- Benzyl butyl phthalate (BBP) (CAS no. 85-68-7) (ref.no. 1152)
- 1,2-Benzenedicarboxylic acid di-C 7-11, branched and linear alkyl esters (CAS no. 68515-42-4 (ref.no. 1153)

Note: 1,2-Benzenedicarboxylic acid is a synonym for phthalic acid.

It is an interesting fact that in 2002[5] and still in December 2006[6] the American **C**osmetic, **T**oiletry and **F**ragrance **A**ssociation (CTFA) explicitly rated the use of dimethyl phthalate (DMP), DEP and dibutyl phthalate (DBT) as "safe". In Germany, in 2005 still 64 medical drugs contained DBP although in animal tests toxic effects on development, reproduction and on embryos had been proved[7]. In a general statement published in 2007, the Federal Envi-

ronmental Agency (UBA) warned of the use of phthalates ("Phthalates – The useful plasticizers with unwanted properties") as they affect the sexual reproduction among others, particularly bis-(2-ethylhexyl)-phthalate (DEHP) that is used as a softener in PVC. The Federal Environmental Agency also recommends replacing DMP and DEP in cosmetics with less critical alternatives[8]. In 2004, the Bavarian State Office for Health and Food Safety summarized in a web statement: "Against the backdrop of this scientific evaluation across-the-board commentaries on the health risks of diethyl phthalate in perfumes obviously are not applicable[9]. In an updated paper published 22.05.2006, the Federal Institute for Drugs and Medical Devices (BfArM) concludes: "In numerous animal studies on the toxicity of DEHP various negative effects of DEHP could be proved. Significant in this context obviously is the negative effect on the sexual reproduction of the male offspring. Although there are no studies that clearly prove a comparable negative effect of DEHP on humans it should be pointed out that there is increasing evidence to support the conclusion. With respect to a preventive health care though the BfArM holds the opinion that it is imperative to minimize DEHP exposure in connection with the use of medical devices." ("DEHP as a plasticizer in medical devices made of PVC").[10] DEHP is another term for phthalate which is the most frequently used plasticizer. In the field of medicine it is used as a plasticizer in flexible tube systems and containers among others whereas the solvability in watery liquids is regarded as negligible. As to the contact with the skin, the BfArM states: "It can generally be assumed that the DEHP permeation through healthy skin depends on the skin condition (dry, moist or oily), on the size of the contact area as well as on the duration of the skin contact"[10]. The BfArM continues "As DEHP specifically affects the sexual development, it is assumed that the following groups with high sensitivity are most likely to suffer potential health risks from exposure to DEHP

- children before completing sexual maturity
  - premature babies and newborns
  - infants and toddlers
  - children and adolescents until puberty
- pregnant women
- breastfeeding mothers[10]

Based on own measurements[9] the above mentioned Bavarian State Office for Health and Food Safety reports on DEP concentrations of more than 1 percent in cosmetic products which is more than twice as much as the German alcohol tax law stipulates. In a study carried out in 2008 the urine of 163 toddlers born between 2000 and 2005 was tested for phthalates with the result that monoethyl phthalate, monomethyl phthalate and monoisobutyl phthalate were found in concentrations that increased with the number of skin care products used[11]. In the body these compounds are formed by eliminating the alcohol residues. Hence they correspond with the metabolization of long chained or high molecular phthalates like DEHP. From the toxicological point of view the above mentioned recommendation of the Federal Environmental Agency has to be taken seriously and the manufacturers of cosmetic products are therefore advised to avoid the use of DEP.

Alternatives for phthalates

The German alcohol tax law[1] states the following denaturing alternatives for DEP:

- 0.5% thymol
- 0.0008 % denatonium benzoate and 0.078 % tert-butanol
- 5% isopropyl alcohol and 0.078% tert-butanol
- 0.039 % musk ketone and 0.078 tert-butanol

Thymol (2-isopropyl-5-methyl-phenol; CAS no. 89-83-8) is a monoterpene with aromatic scent, **tert-butanol** (CAS no. 75-65-0) smells similar to camphor, **isopropyl alcohol** (CAS no. 67-63-0) is associated with hair tonic, **musk ketone** (3-methylcyclopentadecanon; CAS no. 541-91-3) is the major component of natural musk and therefore identified as a typical scent. **Denatonium benzoate** (CAS no. 3734-33-6) is a synthetic substance that tastes extremely bitter even in minimal concentrations. All the substances offered as denaturing alternatives are unacceptable additives in a dermatological cosmetic that is free of perfumes and only contains a minimum of non-physiological additives.
However, the alcohol tax law provides for another individual solution: "In individual cases where the denaturants quoted in paragraph 4 are inappropriate for the requirements of the license bearer the Federal Monopoly Administration is entitled to release other denaturants upon request. If the denaturing agents requested are verifiably licensed in other member states of the European Union the license will be granted unless safeguarding of tax revenue or health protection is at risk. The applicant has to provide free samples for testing purposes if requested by the Federal Monopoly Administration." As far as perfumes are concerned this option can be applied quite easily for mixtures of alcohol and odorous sub-

stances ("denaturants") as the mixtures are inappropriate for oral consumption and the alcohol contained is quite complicated to recycle. For a multitude of cosmetic products this option is not applicable as there are no components in the finished product that allow to denature alcohol in the first place. Relevant applications submitted by the manufacturing companies of the author of this article have been turned down by the Federal Monopoly Administration for spirits (BfB) which is affiliated to the Federal Ministry of Finances. Hence, the manufacturers of such cosmetic products only have two options: One of them is to use DEP to denature the alcohol (low manufacturing costs) and hence accept potential health risks, or to use taxed alcohol for the manufacturing process (high manufacturing costs).

Declaration of the denaturants

The use of denatured alcohol is only marked in the INCI as "alcohol denat". In contrast to the American FDA the European Cosmetic Decree does not provide for a specification of the type of denaturant used. In other words: the consumer never knows what kind of denaturant is contained in the product. Just to add an example: According to the American declaration, SD alcohol 39-C is indicated as "**s**pecially **denatured** alcohol", denatured with 1.0 % diethyl phthalate (DEP). SD alcohol 39-B contains 0.5 % DEP and 0.125 % tert-butanol.

Avoiding alcohol altogether?

Of course, a further option is to avoid alcohol in cosmetic products. It is a solubilizer and represents the most frequent extracting agent for natural extracts besides propylene glycol. Additionally it has antimicrobial properties in concentrations of more than 10 percent which means that it can replace preservatives. Compared to the preservatives approved by the Cosmetic Decree, alcohol is non-allergenic. In contrast to the widely held opinion, alcohol used in the above mentioned concentrations will not dehydrate the skin. This effect only occurs in higher concentrations as for instance those used in shaving tonics, fitness products and perfumes.
Conclusion: It is quite incomprehensible why legislative authorities do not license the use of untaxed alcohol in cosmetics under customs supervision which would avoid the imminent health risks associated with non-essential substances. The present approach provides no incentives for manufacturers of cosmetic products to stop the use of those substances that are officially approved but meanwhile rated as a risk for the human health.

References

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