

Denatured!!? – Use pure alcohol!

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Legislative authorities suspiciously regulate and survey the use of alcohol, even in cosmetic products. Both quality and safety of skin care products do not benefit from this policy.

Only a few people probably know why there is an INCI denomination "denatured alcohol" and what exactly hides behind it. That we are talking of mandatory additives here which result from a loophole in the tax laws only becomes clear after intensely dealing with this issue.

As is generally known, alcohol belongs to the group of semi luxury food which is the reason why it is subject to high taxes. Accordingly, the money is rolling into the cash register of the Federal Ministry of Finance year in and year out. Subject to taxes is not only the alcohol we consume but also the alcohol used in cosmetic products.

No exceptions

Such policy turns alcohol into a rather expensive component although cosmetics generally are not intended for oral consumption. While there is an option to establish tax warehouses and to apply for an alcohol storage license according to § 139 law on alcohol monopoly (paragraph 1, tax exempted use) in similar cases as for instance mineral oils, the German legislation does not allow for tax-exempted use in cosmetic products.

And the reason is that there is no statutory regulation for cosmetics manufacturers to document the complete balancing of incoming and outgoing quantities in order to prove that the alcohol is not used for oral consumption but for the manufacturing of cosmetic products. Neither is there a tax refund.

There was a rather lapidary answer of the Federal Ministry of Finances to an inquiry in this matter: "Without a denaturing process in proper form a tax exempted use for the manufacturing of cosmetic products is impossible".

The only option to escape this tax is to use denatured alcohol which contains substances that are supposed to spoil the appetite for it.

Rather acrid

The consequence of this statutory regulation is a widespread use of denaturing substances. Mostly used and licensed denaturing substances are phthalic acid esters (phthalates).

Cosmetic products mostly contain phthalic acid diethyl ester (diethyl phthalate) abbreviated DEP. According to the alcohol tax law the minimal concentration in alcohol is 0.5 %. Phthalates are used as plasticizers e.g. and frequently critically discussed in connection with toys. That is why annex 1 of the Cosmetic Decree lists a number of phthalates that are not allowed for the manufacturing of cosmetic products: dibutyl phthalate (DBP), bis-(2-ethylhexyl)-phthalate, bis-(2-methoxyethyl)-phthalate, 1,2-benzenedicarboxylic acid dipentyl-ester, (branched and linear), n-pentylisopentyl phthalate, di-n-pentyl phthalate, diisopentyl phthalate, benzylbutyl phthalate (BBP) and 1,2-benzenedicarboxylic acid (di-C7-11, branched and linear alkyl esters). Note: 1,2-benzenedicarboxylic acid is a synonym for phthalic acid.

Critical evaluation

In 2002 and 2006 the American CTFA (Cosmetic, Toiletry and Fragrance Association) still rated the use of dimethyl phthalate (DMP), diethyl phthalate (DEP) and dibutyl phthalate (DBP) as "safe".

Still in 2005, 64 German pharmaceutical drugs contained DBP although toxic effects on development, reproduction and on embryos had been proved in animal tests. In a general statement published in 2007, the Federal Environmental Agency (UBA) warned against 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 substituting DMP and DEP in cosmetics by less critical alternatives. In a conclusion published in 2004 the Bavarian State Office for Health and Food Safety stipulates: "Against the backdrop of such scientific evaluation across-the-board statements in some media reports on the health risks of diethyl phthalate in perfumes are not applicable."

Consequences for humans

In a paper entitled “DEHP as a plasticizer in medical devices made of PVC” and updated on 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 development 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.” In terms of quantities, DEHP is the most frequently used phthalate. In the field of medicine it is used as a plasticizer in flexible tube systems and containers.

Effects after skin contact

Regarding the direct contact with the skin the BfArM states: “It can generally be assumed that a DEHP contamination via intact skin depends on the skin condition, the size of the contact area and the duration of contact.” There is a high probability that the following risk groups are negatively influenced: children before puberty, pregnant and breast feeding mothers”.

Harmful additives

Based on own measurements 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 correlated with the number of skin care products used. 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 recommendation of the Federal Environmental Agency to avoid the use of DEP has to be taken seriously.

Besides DEP, the German alcohol tax law states some alternatives for denaturing like e.g. 0.5% thymol, 0.0008% denatonium benzoate with 0.078% tert-butanol, 5% isopropyl

alcohol in combination with 0.078% tert-Butanol as well as 0.039% musk ketone with 0.078% tert-butanol.

A strong smell

In my opinion, all the denaturing alternatives mentioned are not acceptable for the use in cosmetic products that are free from perfumes and physiological additives and formulated for the sensitive skin. Thymol is a monoterpene with aromatic scent; tert-butanol smells like camphor, isopropyl alcohol generally is associated with hair tonic. Musk ketone is the major component of natural musk and hence identified as a typical scent. Denatonium benzoate is a synthetic substance that tastes extremely bitter even in minimal concentrations.

The Federal Monopoly Administration is entitled to release other denaturants upon request “unless the safeguarding of tax revenue or health protection is at risk”. As far as perfumes are concerned this option can be used quite easily with an application for mixtures of alcohol and odorous substances (“denaturants”) because these mixtures are inappropriate for oral consumption and the alcohol contained can only be recycled in a rather complicated procedure.

This option, however, is not applicable for manufacturers of cosmetics for the care of sensitive and irritated skin as there are no components in the finished product that allow to denature alcohol a priori. 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).

Poor information

In the INCI the use of denatured alcohol is only marked as “alcohol denat”. This means that the German consumer is not informed about the type of denaturant contained. The American declaration is different though: the term SD alcohol 39-C means “specially denatured alcohol”, denatured with 1.0% diethyl phthalate (DEP). SD alcohol 39-B contains 0.5% DEP and 0.125% tert-butanol.

Of course, a further option is to avoid alcohol in cosmetic products. However, it is the most frequently used extracting agent for natural extracts besides propylene glycol, has antimicrobial properties in concentrations of more than 10 percent and no allergenic effects which means that it can replace preservatives. There are no dehydrating effects to observe when using these concentrations.

Based on these facts, it is quite incomprehensible that legislative authorities refuse to license tax-exempted alcohol for the use in cosmetic products under customs supervision, thus avoiding the looming health risks involved with the use of unnecessary substances. The present approach provides no incentives for the manufacturing industry to stop the use of officially licensed but critical substances.

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