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Is Propanediol a safer molecule than some other glycols in personal care and anti-aging biocosmeceutical products?

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ABSTRACT

Propanediol (1,3-propanediol) is an ingredient increasingly used by the industry for electronic cigarettes, personal care creams and anti-aging serums among many other products. For some skin care purposes, it is used to enhance the transdermal absorption of other ingredients (e.g., the actives) enabling moisturizing effects and skin smoothness to be improved. Propanediol may be derived from corn although synthetic forms also exist. It is a chemical similar to other glycols such as propylene glycol (1,2-propanediol) but generally believed to be safer. This short communication reveals in fact that only limited scientific evidence of safety is available. Preliminary signs of toxicity have been found following administration of propanediol in humans although its dose-dependent toxicity and long-term side effects on health have not been significantly explored. Consequently, as of today, skin care and anti-aging products for elderly, a vulnerable population, should not automatically be considered as safe. Those comprising 1,3-propanediol should probably be used with caution until scientifically-proven safety data for the intended purposes are obtained by independent scientists.

Keywords: glycols, 1,3- propanediol, dermatology, anti-aging, organic products, elderly, safety, toxicity

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Main text :

Propanediol, also known as 1,3-propanediol, trimethylene glycol, methylpropanediol, propane-1,3-diol, 1,3-dihydroxypropane, and 2-deoxyglycerol, is a molecule similar to other glycols such as 1,2-propanediol (a.k.a. propylene glycol) well known, in the latter case, to be associated with serious safety issues (1-5). Indeed, 1,2-propanediol, derived from petroleum, is an allergenic substance that can irritate eyes and skin. Central nervous system depression, seizures, renal and hepatic toxicity have also been reported with high doses administered orally. Intravenously, 1,2-propanediol was reported to cause hypotension, hemolysis, and bradycardia (3-5). Because comparable data do not yet exist for 1,3-propanediol, it is increasingly used by the industry of biocosmetics and presented as a safe alternative to its biosimilars. Further contributing to its 'organic' and 'safe' reputation, 1-3, propanediol is generally derived from corn using E. coli-induced degradation (6). The conversion of glycerol (a biodiesel biproduct) to 1,3-propanediol using clostridium diolis, a bacteria, also exists (7). The two chemicals (1,3-propanediol and 1,2-propanediol) have the exact same molecular formula ($C_3H_8O_2$) but their structures differ slightly (Fig.1).

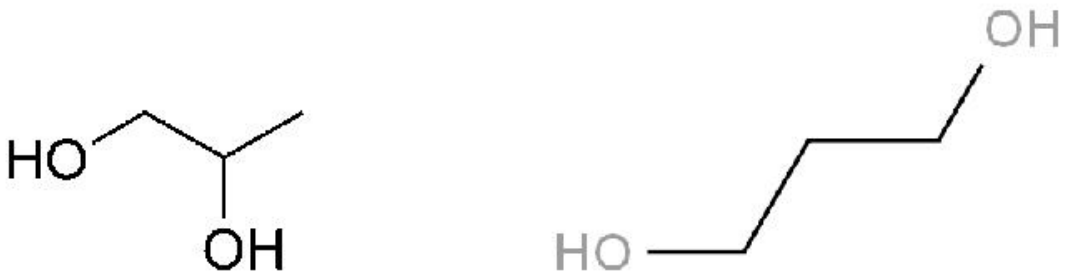

Fig.1. Molecular structures of 1,2-propanediol (left) and 1,3-propanediol (right).

1,3-propanediol is sold as a clear or yellowish odorless product. Beyond its use by the cosmeceutical industry, it is found also as a solvant to produce ink for printers or antifreeze liquids for cars (8). It has been approved in US and Europe as an ingredient in personal care products based essentially on 'lack of evidence' (i.e., no significant evidence of toxicity or safety concern). But, is it really safer than other comparable ingredients such as 1,2-propanediol? In other words, are there solid safety data from clinical studies in humans that demonstrate its lack of side effects and toxicity when topically applied daily on the skin? The short answer is no or at least not yet. There is no data for and no data against its use for dermatological indications. This said, preliminary evidence may suggest to remain cautious.

Indeed, we know from a few studies that topical application of 1,3-propanediol on human skin may occasionally cause mild irritation as shown also in other species such as rabbits (9). When using other routes of administration such as

inhalation , preclinical tests with 1,3-propanediol have failed to show signs of toxicity - rodents exposed almost daily (6 hours per day) during 2 weeks to vapors with either 0, 41, 650, or 1800 mg propanediol/cubic meters did not reveal unusual external signs of response and no deaths were encountered (10,11). Other tests (e.g., micronucleus test in mice) have shown an absence of mutagenic effect (i.e., no proven carcinogenicity; 10,11, see also data published at : toxnet.nlm.nih.gov). The lethal dose in mice is high – e.i., 4,780 mg/kg (12). A case report published in 2008 provided evidence, nonetheless, that it can potentially lead to death in humans - a woman who drank the content of two antifreeze containers comprising 1,3-propanediol died shortly after (13).

In conclusion, no ethically-approved clinical studies have yet been undertaken to study the safety and toxicity of 1,3-propanediol when regularly applied on human skin. For other applications in humans such as with electronic cigarettes, 1,3-propanediol is increasingly used in replacement of 1,2-propanediol to improve the thermal stability, nicotine delivery and to decrease inhaled flavors concentrations (14). Again, efficacy data has been reported but safety has not been explored. Thus, 1,3-propanediol has not been demonstrated scientifically to be safe as an ingredient entering in the composition of skin care and anti-aging products. It has been commonly used by the industry for more than 10 years as a cost-effective alternative to 1,2-propanediol. This may suggest that, unless it is forced to – e.g., by regulatory agencies (e.g., FDA, EMA, Health Canada, etc.) –, the industry may not find strong incentives or commercial interests in seeking valuable safety data through the conduct of potentially risky and expensive clinical studies.

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