Request for a scientific opinion: Diethylene glycol (CAS 111-46-6). Notification

1. Background

Diethylene glycol (DEG) (CAS 111-46-6) is listed in the Inventory with functions as solvent, viscosity controlling and masking/perfuming. Furthermore, it is listed in section II, perfume and aromatic raw materials.

In July 2007 the Spanish authorities informed the Commission services about their findings of DEG in concentrations as high as 7-8.3% in toothpaste products.

Following these findings also in other Member States, informations including risk assessment of DEG in tooth paste and oral hygiene products have been provided by the Spanish, the French and the Swiss Authorities.

The French authorities have at the same time proposed a regulation i.e. a ban of DEG as ingredient in oral hygiene products and a limitation of DEG as a residue in glycerine of up to max 0.1% and for polyethylene glycols a residue content of diethylene glycol of up to 0.4% for the sum of diethylene glycol and ethylene glycol.

Colipa\(^1\) has informed the Commission Services by letter primary October 2007 "…that DEG is not intentionally added as an ingredient to oral care products. However, DEG can be present as an impurity in glycerol and polyethylene glycols, which are common ingredients in oral care products". Colipa also submitted an evaluation: "Risikobewertung zu Diethylenglycol in Zahnpasta" done by the BfR\(^2\) and proposes a similar regulation as the French Authorities.

In literature, several reported cases of death after the intake of glycerol contaminated by DEG has been reported.

The European Pharmacopoeia defines limits for DEG in glycerol (0.1% DEG) and polyethylene glycols (0.4% sum of ethylene glycol and DEG).

DG ENTR has asked Industry to submit data, if they would like to defend the continued use of DEG as an ingredient in cosmetic products.

2. Terms of reference

1. Does SCCP consider that a limit for the safe use of DEG as an ingredient in cosmetic products including oral care products can be set taking into account the provided risk assessments and the fatal cases reported in the enclosed literature?

2. If no safe limit for DEG as an ingredient in cosmetic products can be set, and taken into account that DEG exists as an impurity in commonly used

\(^1\) Colipa - The European Cosmetic Toiletry and Perfumery Association

\(^2\) BfR - Federal Institute for Risk Assessment, Germany
cosmetic ingredients like glycerine and polyethylene glycols, does SCCP consider a maximum concentration up to 0.1% of DEG in a finish cosmetic product as safe?