



Scientific Committee on Consumer Safety

SCCS

OPINION ON

DIETHYLENE GLYCOL MONOETHYL ETHER

(DEGEE)



The SCCS adopted this opinion at its 8th plenary meeting
of 21 September 2010

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCCS

The Committee shall provide opinions on questions concerning all types of health and safety risks (notably chemical, biological, mechanical and other physical risks) of non-food consumer products (for example: cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.).

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ISSN 1831-4767
doi:10.2772/26133

ISBN 978-92-79-12749-6
ND-AQ-09-021-EN-N

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http://ec.europa.eu/health/scientific_committees/consumer_safety/index_en.htm

ACKNOWLEDGMENTS

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Keywords: SCCS, scientific opinion, diethylene glycol monoethyl ether, DEGEE, directive 76/768/ECC, CAS 111-90-0, EC 203-919-7

Opinion to be cited as: SCCS (Scientific Committee on Consumer Safety), Opinion on diethylene glycol monoethyl ether, 21 September 2010

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1. BACKGROUND

A risk assessment on diethylene glycol monoethyl ether (DEGEE) with the chemical name 2-(2-ethoxyethoxy)ethanol and the INCI-name Ethoxydiglycol was done by a Member State (France). The risk assessment was based mainly upon data from the open scientific literature and on the skin absorption studies performed by industry. This risk assessment led the Member State to put certain restrictions on the use of this substance.

According to the notification to the Commission, DEGEE is currently used in cosmetic products in shampoos (rinse-off) in a concentration up to 5% and in creams (leave-on) in a concentration up to 2%, excluding products intended to be used in the vicinity of the eyes. The notifying Member State concluded that the substance could be considered safe for the consumers, when used in a concentration up to 1.5% in cosmetics product except products for oral hygiene.

As a consequence of the notification, the SCCP was asked to give its opinion on Diethylene glycol monoethyl ether (DEGEE). The first opinion was adopted on 19 December 2006 by the SCCP (SCCP/1044/06) with the following conclusion:

"Based on the information provided, the SCCP is of the opinion that the use of diethylene glycol monoethyl ether (DEGEE) in all cosmetic products, except products for oral hygiene and eye products at a concentrations up to 1.5% does not pose a risk to the health of the consumer, provided that the level of ethylene glycol in DEGEE used is < 0.2%. The opinion relates to the dermal application. It does not include any other cosmetic exposure, such as exposure from possible aerosol/spray products."

In December 2007 an updated risk assessment was submitted by COLIPA¹. In addition to the overall use of DEGEE in a concentration up to 1.5%, the applicant applied for a specific use of DEGEE as a solvent in hair dyes formulations at a concentration up to 7.0% and to support this application, additional percutaneous absorption data was provided.

A second opinion (SCCP/1200/08) on Diethylene glycol monoethyl ether (DEGEE) for its use as solvent in hair dye formulations was adopted on 16 December 2008 with the conclusion that:

"The SCCP is of the opinion that the use of diethylene glycol monoethyl ether (DEGEE) as a solvent in an on-head concentration of up to 7.0% in oxidative hair dye formulations and in an on-head concentration of up to 5.0% in non-oxidative hair dye formulations in addition to the use of DEGEE at concentrations up to 1.5% in all cosmetic products except products for oral hygiene and eye products does not pose a risk to the health of the consumer, provided that the level of ethylene glycol in DEGEE used is < 0.2%.

The opinion relates to the dermal application of cosmetic products only and does not include any other cosmetic exposure, such as exposure from possible aerosol/spray products.

Aggregate exposure to diethylene glycol monoethyl ether (DEGEE) from non-cosmetic sources has not been considered".

In January 2009 an additional submission was presented by EFCI², providing a subchronic 3-month toxicity study in dogs. Based on this dossier, the applicant considers that DEGEE can be used safely in concentration up to 5.5% in leave-on products and up to 10.0% in rinse-off products.

¹ COLIPA – The European Cosmetic Association

² EFCI The European Federation for Cosmetic Ingredients

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