

OPINION OF THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD
PRODUCTS INTENDED FOR CONSUMERS

CONCERNING

ETHOXYETHANOL, ETHOXYETHANOL ACETATE, 2-METHOXYETHANOL
AND 2-METHOXYETHANOL ACETATE
(GLYCOL ETHERS AND THEIR ACETATES)

Adopted by the SCCNFP during the 23rd plenary meeting
of 18 March 2003

1. Terms of Reference

The EU Commission has received a notification from the Norwegian Authorities in which they inform that a ban has been introduced in Norway on the use of ethoxyethanol, ethoxyethanol acetate, 2-methoxyethanol and 2-methoxyethanol acetate (glycol ethers and their acetates) in cosmetic products.

The EU Commission would therefore ask the SCCNFP for a safety evaluation of these compounds when used in cosmetic products.

Ethoxyethanol, ethoxyethanol acetate, 2-methoxyethanol and 2-methoxyethanol acetate (glycol ethers and their acetates) have been used as solvent and/or viscosity decreasing agents in cosmetic products. The substances are classified as toxic to reproduction, category 2 according to Directive 67/548/EEC.

2. Request to the SCCNFP

The SCCNFP was requested to answer following questions :

- * Do the safety profiles of the compounds ethoxyethanol, ethoxyethanol acetate, 2-methoxyethanol and 2-methoxyethanol acetate (glycol ethers and their acetates) support their use in cosmetic products?
- * Does SCCNFP propose any restriction in their use in cosmetic products?

3. Chemicals

The chemicals concerned are identified as described below :

2-ethoxyethanol :

Emp. Formula : C₄H₁₀O₂
CAS n° : 110-80-5
EINECS n° : 203-804-1
Synonyms : Ethylene glycol monoethyl ether

2-ethoxyethyl acetate:

Emp. Formula : C₃H₈O₂
CAS n° : 111-15-9
EINECS n° : 203-839-2
Synonym : Ethoxyethanol acetate, ethylene glycol monoethyl ether acetate

2-methoxyethanol :

Emp. Formula : C₃H₈O₂
CAS n° : 109-86-4
EINECS n° : 203-713-7
Synonym : Ethylene glycol monomethyl ether

2-methoxyethyl acetate :

Emp. Formula : C₅H₁₀O₃
CAS n° : 110-49-6
EINECS n° : 203-772-9
Synonym : Methoxyethanol acetate, ethylene glycol monomethyl ether acetate

4. Safety Evaluation

The toxicity of 2-methoxyethanol, 2-ethoxyethanol and their acetates has been evaluated in a number of reviews in the past 20 years (1 - 7). All four substances have been demonstrated to exert adverse haematological, neurological and reproduction toxic effects both in rodents and in humans. It has also been demonstrated that 2-methoxyethanol, 2-ethoxyethanol and their acetates can readily absorb through the skin (1 - 12). The concern over the use of reproduction toxic substances in the formulation of cosmetic products has been expressed in a recent Opinion of SCCNFP (13).

5. Opinion

The SCCNFP is of the opinion that ethoxyethanol, ethoxyethanol acetate, 2-methoxyethanol and 2-methoxyethanol acetate (glycol ethers and their acetates) do pose a health risk when used in cosmetic products.

Ethoxyethanol, ethoxyethanol acetate, 2-methoxyethanol and 2-methoxyethanol acetate (glycol ethers and their acetates) are classified as toxic to reproduction, category 2 according to Directive 67/548/EEC. As a consequence, the Opinion of SCCNFP concerning Chemical Ingredients in Cosmetic Products classified as Carcinogenic, Mutagenic or Toxic to Reproduction according to Directive 67/548/EEC (doc. n° SCCNFP/0747/01 of 25 September 2001) does apply to the above-mentioned chemicals as well.

6. References

1. U.S. Department of Health and Human Services (1983) The glycol ethers with particular reference to 2-methoxyethanol and 2-ethoxyethanol: evidence of adverse reproductive effects. DHHS (NIOSH), Publication No. 83-112.
2. U.S. Environmental Protection Agency (1984) Health effects assessment for glycol ethers.
3. IPCS (1990) Environmental Health Criteria 115: 2-methoxyethanol, 2-ethoxyethanol and their acetates. International Program on Chemical Safety, WHO, Geneva, Switzerland

4. U.S. Environmental Protection Agency (1993) Integrated Risk Information System (IRIS) on 2-methoxyethanol.
5. U.S. Environmental Protection Agency (1993) Integrated Risk Information System (IRIS) on 2-ethoxyethanol
6. ECETOC (1995) The toxicity of glycol ethers and its relevance to man. ECETOC Technical Report No. 64
7. Johanson G (2000) Toxicity review of ethylene glycol monomethyl ether and its acetate ester. Crit Rev Toxicol 30: 307-345
8. Dugard PH, Walker M, Mawdsley SJ and Scott RC (1984) Absorption of some glycol ethers through human skin *in vitro*. Environ Health perspect 57: 193-197.
9. Figa-Talmanca I, Cini C, Traina ME and Peterelli G (1997) Effects of glycol ethers on the reproductive health of occupationally exposed individuals: Review of present day evidence. J Clean Technol, Environ Toxicol & Occup Med 6: 323-337.
10. Kezic S, Mahieu K, Monster AC and de Wolff F (1997) Dermal absorption of vapours and liquid 2-methoxyethanol and 2-ethoxyethanol in volunteers. Occup Env Med 54 : 38-43
11. Filon FL, Fiorito A, Adami G, Barbieri P, Coceani N, Bussani R and Reisenhoefer E (1999) Skin absorption *in vitro* of glycol ethers. Int Arch Occup Env Health 72: 480-484
12. Shih TS, Wang PY, Chen CY, Smith TJ and Hu YP (2000) Measurement of percutaneous uptake of 2-methoxy ethanol vapor in humans. J Occupat Environ Med 42: 475-482.
13. SCCNFP (2001) Opinion concerning chemical ingredients in cosmetic products classified as carcinogenic, mutagenic or toxic to reproduction according to the chemicals Directive 67/548/EEC. SCCNFP/0474/01, Final.