

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCT (SCCP)

Request for a scientific clarification: Annex II, Entry 168, Choline salts and their esters e.g. choline chloride (INN)

1. Background

EFfCI¹ has asked for a clarification of Annex 11, entry 168: Choline salts and their esters e.g. choline chloride (INN) as a company has an interest in stearic acid choline ester for cosmetic applications.

Indeed, Annex II - list of substances which must not form part of the composition of cosmetic products - to Directive 76/768/EEC contains under entry n0 168: choline salts and their esters, e.g. choline chloride. The entry has been part of the Cosmetic Directive since its origin in 1976, and for that reason no scientific opinion is currently available for this entry.

The newly launched COM information database Cosing, contains *inter alia* the 2nd update of the inventory, which has not been reviewed by SCCP. The Commission Services as seen from the Cosing database considers that entry 168 would cover the following substances, listed in the inventory:

CAS number	Substance
67-48-1	Choline chloride
856676-23-8	Choline Fenofibrate
28319-77-9	Glycerophosphocholine
2016-36-6	Choline salicylate
507-30-2	Choline gluconate
4499-40-5	Cholinate Theophylline

But other "choline" containing substances also listed in the inventory like Hydrogenated lysophosphatidylcholine, hydrogenated phosphatidylcholine, phosphatidylcholine, polyphosphorylcholine glycol acrylate as well as lecithin, which are a well-known choline ester, are not, by the Commission Services, supposed to be part of entry 168 of Annex 11.

To make the picture complete the substance, acetylcholine, is covered separately under entry 2 of Annex II: 2-Acetoxyethyltrimethylammonium hydroxide (acetylcholine) (INN) and its salts.

No definitions are given for salts and esters in Annex II of the Cosmetics Directive. However, for salts and esters in connection with Annex VI, preservatives, a set of definitions are set out. They are:

- "Salts" is taken to mean: salts of the cations sodium, potassium, calcium, magnesium, ammonium and ethanolamines: salts of the anions chloride, bromide, sulphate, acetate.
- "Esters" is taken to mean: esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl and phenyl.

¹ EFfCI - The European Federation for Cosmetic Ingredients

2. Terms of reference

Does the SCCP consider that:

- the following substances currently mentioned in the database Cosing for the entry 168 of Annex II, are covered by the ban of the entry for use in cosmetic products:
 - Choline chloride
 - Choline Fenofibrate
 - Glycerophosphocholine
 - Choline salicylate
 - Choline gluconate
 - Choline Theophylline

- the following substances listed in the inventory are not covered by entry 168:

Hydrogenated lysophosphatidylcholine, hydrogenated phosphatidylcholine, phosphatidylcholine, polyphosphorylcholine glycol acrylate and lecithin.

- cholinesters of stearic acid, as asked for by EFfCI, and of other long alkyl chain carboxylic acid can be used in cosmetic products without limitations?