1. Background

B-phenyl-2-ol and its salts, covering o-Phenylphenol, Sodium o-phenylphenate, Potassium o-phenylphenate, MEA o-Phenylphenate (CAS n. 90-43-7, 132-27-4, 13707-65-8, 84145-04-0) as preservatives are regulated in Annex V, entry 7 of the Cosmetics Regulation (EC) n. 1223/2009 at a maximum concentration of 0.2 % (as phenol).

In February 2013, the Commission received a risk assessment submitted by the French Agency ANSM (Agence nationale de sécurité des médicaments et des produits de santé) which rose concerns about the use of o-Phenylphenol as preservatives in cosmetic products.

In the ANSM report, o-Phenylphenol was identified as a potential endocrine disruptor. The report concluded that the maximum authorised concentration (currently of 0.2 %) of o-Phenylphenol for use as a preservative should be revised due to a low margin of safety.

In January 2014, in response to a call for data on o-Phenylphenol by the Commission, Industry submitted a safety dossier to defend the current use of o-Phenylphenol, Sodium o-phenylphenate, Potassium o-phenylphenate as preservatives in cosmetic formulations at a maximum concentration of 0.2 % (as phenol).

2. Terms of reference

1. Does SCCS consider o-Phenylphenol, Sodium o-phenylphenate, Potassium o-phenylphenate safe for use as preservatives with a maximum concentration of 0.2 % (as phenol), taking into account the information provided?

2. Does SCCS consider that the same conclusion on the safety of o-Phenylphenol, Sodium o-phenylphenate, Potassium o-phenylphenate may be applicable to MEA o-Phenylphenate?

   Does the SCCS have any further scientific concerns with regard to the use of o-Phenylphenol, in particular on its potential endocrine disruptor properties as raised in the ANSM report?

3. Deadline:

4. Annex

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1. ANSM report (Evaluation du risque lié à l'utilisation l'ortho-phénylphénol dans les produits cosmétiques)

2. Industry dossier on o-Phenylphenol – Submission I