

Addendum to the scientific opinion on o-Phenylphenol, Sodium o-phenylphenate and Potassium o-phenylphenate SCCS/1555/15



Scientific Committee on Consumer Safety

SCCS

**ADDENDUM
to the scientific opinion on o-Phenylphenol, Sodium o-phenylphenate and Potassium o-phenylphenate
(SCCS/1555/15)**

Here: the use as preservative of

**Sodium o-phenylphenate, Potassium o-phenylphenate,
MEA o-Phenylphenate**

(CAS n. 132-27-4, 13707-65-8, 84145-04-0)



The SCCS adopted this document
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In agreement with the mandating DG, there is no commenting period for this Addendum.

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In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines 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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TABLE OF CONTENTS

1.	MANDATE FROM THE EUROPEAN COMMISSION	4
2.	OPINION.....	7
3.	CONCLUSION	7
4.	MINORITY OPINION.....	8
5.	REFERENCES.....	9
6.	GLOSSARY OF TERMS.....	36
7.	LIST OF ABBREVIATIONS	36

1. MANDATE FROM THE EUROPEAN COMMISSION

Background

Biphenyl-2-ol and its salts, covering o-Phenylphenol (OPP), 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).

The substance MEA o-phenylphenate is also regulated through entry 61 of Annex III on Monoalkylamines, monoalkanolamines and their salts which are restricted for use in cosmetic products to a maximum secondary amine content of 0,5% in ready for use preparation.

The SCCS Committee adopted an opinion on o-Phenylphenol, Sodium o-phenylphenate and Potassium o-phenylphenate (SCCS/1555/15) in June 2015, later revised on 15 December 2015, with the following conclusion:

"o-Phenylphenol as preservative with a maximum concentration of 0.2 % in leave-on cosmetic products is not safe. Also, in view of further exposures including non-cosmetic uses, the maximum concentration of o-Phenylphenol in leave-on cosmetic products should be lowered.

However, the proposed maximum use concentration of up to 0.15% by the applicant can be considered safe.

The use of o-Phenylphenol as preservative with a maximum concentration of 0.2 % in rinse-off cosmetic products is considered safe.

Based on the information provided, no conclusions of safe use can be drawn for Sodium o-phenylphenate and Potassium o-phenylphenate."

Following this SCCS opinion, several Member States raised specific concerns as regards the potential risk to human health of Sodium o-phenylphenate, Potassium o-phenylphenate and MEA o-phenylphenate.

In December 2017, the German Federal Institute for Risk Assessment submitted a document providing information on the safety of Sodium o-phenylphenate, Potassium o-phenylphenate and MEA o-phenylphenate when compared to OPP.

Terms of reference

- 1. Does SCCS consider Sodium o-phenylphenate, Potassium o-phenylphenate and MEA o-Phenylphenate safe at the current use as preservatives with a maximum concentration of 0.2 % (as phenol)?*
- 2. Does the SCCS consider that the same conclusion for OPP, as reported in SCCS/1555/15, may also be applied to Sodium o-phenylphenate, Potassium o-phenylphenate and MEA o-Phenylphenate concerning the proposed maximum use concentration (i.e. 0.15% in leave-on and 0.2% in rinse-off cosmetic products as preservatives)?*

2. OPINION

The SCCS opinion (SCCS/1555/15) relates to the safety of o-Phenylphenol (OPP), sodium-OPP, and potassium-OPP for use as preservatives, and is based on the information received in response to the Commission's call for further data. The available information mainly relates to OPP and sodium-OPP, limited information on potassium-OPP, and virtually no information on MEA-OPP. Also the document provided by the German Federal Institute for Risk Assessment did not contain any further information on sodium-OPP, potassium-OPP or MEA-OPP.

3. CONCLUSION

1. Does SCCS consider Sodium o-phenylphenate, Potassium o-phenylphenate and MEA o-Phenylphenate safe at the current use as preservatives with a maximum concentration of 0.2 % (as phenol)?

Due to the lack of relevant information, the SCCS is unable to answer the question on the safe use level of sodium-OPP, potassium-OPP and MEA-OPP. In SCCS view, a direct comparison between the safety of o-phenylphenate (OPP) and its 3 compounds cannot be made due to the following concerns:

- From the limited available information, it is clear that both sodium and potassium salts of OPP have much higher water solubility than OPP (no information available on MEA-OPP). This can potentially alter their absorption and biokinetics, compared to OPP.
- From the available information, the SCCS has noted that, compared to the strongly skin irritating nature of OPP, both sodium OPP and potassium-OPP are corrosive to the skin, and sodium OPP is also corrosive to the eye. This indicates that both sodium and potassium salts of OPP may have greater skin penetration and potentially more potent toxic effects than OPP due to higher systemic exposure. No relevant information on skin irritation is available for MEA-OPP but the presence of monoethyleneamine (MEA) moiety can also be expected to alter the skin absorption and biokinetics of MEA-OPP compared to OPP, and as a consequence also systemic exposure. For OPP, the SCCS has derived dermal absorption value of 45% from toxicokinetic information. However, such information is not available for sodium-OPP, potassium-OPP or MEA-OPP, and data would be needed to allow drawing any comparisons from the safe use levels of OPP.
- The available in vivo studies in rat have also indicated that the adverse effects of OPP and its sodium salt are different. For the sodium salt, there is clear indication that the substance is more potent with respect to urinary bladder carcinoma and data point to mechanistic differences between OPP and SOPP. Amongst other factors, SOPP leads to higher sodium concentrations in urine and also to higher urinary pH. There is insufficient dose-response data available to draw a conclusion on the possibility of setting a threshold for sodium-OPP induced toxicity. The currently available data are also not sufficient to exclude such a possibility for the other two compounds (potassium-OPP and MEA-OPP). Long-term repeat dose studies have pointed out to a threshold between 35 and 40 mg/kg bw/d for OPP, but due to the lack of dose-response data, a threshold for sodium-OPP, potassium-OPP or MEA-OPP cannot be derived.

2. Does the SCCS consider that the same conclusion for OPP, as reported in SCCS/1555/15, may also be applied to Sodium o-phenylphenate, Potassium o-phenylphenate and MEA o-Phenylphenate concerning the proposed maximum use concentration (i.e. 0.15% in leave-on and 0.2% in rinse-off cosmetic products as preservatives)?

For the reasons given above, the SCCS considers that the same conclusions on the safe use levels of OPP cannot be applied as such to sodium-OPP, potassium-OPP or MEA-OPP for use in rinse-off and leave-on cosmetic products.

Based on the available information, the SCCS is of the opinion that a potential risk to human health from the use of sodium-OPP and potassium-OPP as preservatives in cosmetic products cannot be excluded.

Although the safety of MEA-OPP was not evaluated in the Opinion SCCS/1555/15, the SCCS has a similar view that a potential risk from its use as preservative in cosmetic products cannot be excluded in the absence of relevant data.

4. MINORITY OPINION

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6. GLOSSARY OF TERMS

See SCCS/1564/15, 9th Revision of the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation – from page 144

7. LIST OF ABBREVIATIONS

See SCCS/1564/15, 9th Revision of the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation – from page 144