



SCIENTIFIC ADVISORY GROUP ON CHEMICAL SAFETY OF NON-FOOD AND NON-MEDICINAL CONSUMER PRODUCTS (SAG-CS)

Final Opinion on Sodium Orthophenylphenate (SOPP) in Cosmetic Products.

1. Introduction

- 1.1 Sodium o-phenylphenate, or SOPP (sodium 2-biphenylolate; CAS No. 132-27-4) is not listed in annex V of the UK Cosmetics Regulation No. 1223/2009¹ and is therefore not currently permitted for use as a preservative in cosmetic products.

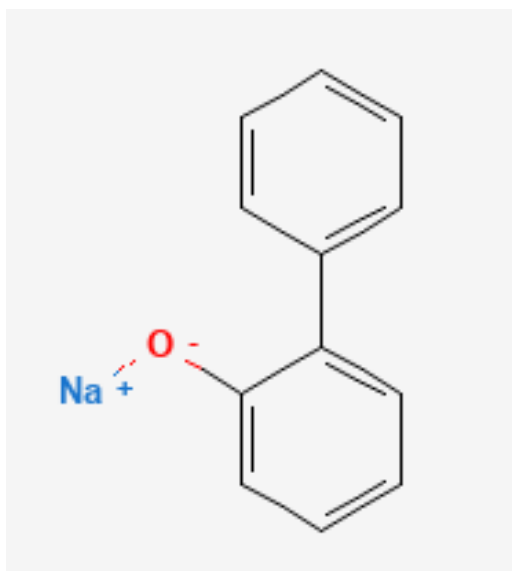


Figure 1) Structure of Sodium o-phenylphenate (SOPP) (Source: PubChem)

¹ Cosmetics product (safety) Regulations currently consists of the Regulation UK No 1223/2009 as amended by [SI 696/2019 Product Safety and Metrology \(EU Exit\) Regulations](#). The full consolidated UK text will be available in due course.



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- 1.2 Under the GB Classification, Labelling and Packaging regulation No. 1272/2008 (as amended)², SOPP has classifications for Acute Toxicity category 4, Specific Target Organ Toxicity (single exposure) category 3, Skin irritation category 2, Eye damage category 1 and Aquatic Acute Toxicity category 1. SOPP is therefore included in the GB Mandatory Classification and Labelling (MCL) list³.
- 1.3 Approval is being sought for SOPP to be added to Annex V of the UK Cosmetics Regulation No. 1223/2009 as a permitted preservative.
- 1.4 OPSS requested that the members of the SAG-CS assess the safety of SOPP intended to be used within cosmetic products at a maximum concentration of 0.2% in all rinse off products and 0.15% in all leave on products.
- 1.5 A summary of the key physicochemical, toxicological, and pharmacokinetic information from the industry-submitted dossier was provided to the members of the SAG-CS.

2. Background

Intended function and uses of SOPP

- 2.1 SOPP has a preservative function in cosmetic products however is not currently permitted for use under the UK Cosmetics Regulation No. 1223/2009.
- 2.2 SOPP is an active ingredient in broad-spectrum biocidal products such as fungicides and antibacterial agents ([Bomhard et al., 2002](#)). SOPP is included on the GB biocidal active substance list under the GB Biocidal Products Regulation (GB BPR)⁴, however is not approved for any product types⁵.
- 2.3 According to the [GB Approvals Register](#), SOPP was approved for use as a pesticide (fungicide) in 2010, but this approval expired in December 2024. In the EU, SOPP is still permitted for use as a pesticide under [Regulation \(EC\) No 1107/2009](#).

² The GB CLP Regulation No 1272/2008 as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019. The full consolidated UK text will be available in due course.

³ Available at: <https://www.hse.gov.uk/chemical-classification/classification/harmonised-classification-self-classification.htm>

⁴ The Biocidal Products Regulations 2001 [The Biocidal Products Regulations 2001](#)

⁵ BPR active substance lists for GB and NI [BPR active substance lists for GB and NI - Biocides - HSE](#)



3. Previous Scientific Opinions on sodium o-phenylphenate

- 3.1 In 1999, the International Agency for Research on Cancer (IARC) evaluated SOPP as possibly carcinogenic to humans (Group 2B) because of sufficient evidence of carcinogenicity in experimental animals ([IARC, 1999](#)).
- 3.2 In 2006, the US Environmental Protection Agency (US-EPA) published a human health and environmental risk assessment for OPP⁶ and its salts (including SOPP), to determine their eligibility for re-registration for use as pesticides. For short-term oral exposure, a NOAEL (maternal) of 100 mg/kg bw/day was established for use in the risk assessment, based on two oral development toxicity studies, one in rats and one in rabbits (John et al., 1978, reformatted 1990; Zablotny et al., 1991). For intermediate-term and chronic oral exposure, a NOAEL of 39 mg/kg bw/day was established from a combined oral toxicity and carcinogenicity study in rats (Wahle and Christenson, 1996). This NOAEL was also used for the dermal route, with a dermal absorption value of 43% applied from a study by Timchalk, 1996. OPP was classified as 'Not likely to be carcinogenic below a specific dose range' and the risk was, therefore, not quantified. Several exposure scenarios were considered to calculate Margin of Exposure (MoE) values, covering the oral, dermal and inhalation routes. An aggregate scenario for the intermediate-term exposure of OPP to children was calculated with an MoE of 130, which was greater than the acceptable target of 100, below which would be considered a concern for health. A chronic aggregate risk assessment including chronic dietary exposure and inert uses from OPP, estimated risk for OPP and its salts to be well below the US-EPA's level of concern. Overall, OPP and its salts were eligible for re-registration, with some risk mitigations to be put in place as outlined in the document ([US-EPA, 2006](#)).
- 3.3 A preliminary workplan by the US EPA was published in 2013 ([US EPA, 2013](#)). Since then, a draft human health and ecological risk assessment for OPP and its salts has been published. This includes updated toxicity endpoints and Points of Departure (PoDs) following the re-registration eligibility decision document from 2006 ([US-EPA, 2006](#)). For the non-dietary risk assessment of antimicrobial uses of OPP, several PoDs have been established for different exposure routes. For incidental, oral exposure (short and intermediate term) a NOAEL (parental) of 100 mg/kg bw/day was derived from a two-

⁶ o-phenylphenol (SOPP is the sodium salt of OPP)



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generation dietary reproductive toxicity study in rats (Eigenberg and Lake, 1995). For short, intermediate and long-term dermal exposure, a NOAEL (dermal) of 100 mg/kg bw/day was derived from a 21-day dermal toxicity study in rats (Zempel and Szabo, 1993). Quantification of cancer risk was performed using the chronic Reference Dose of 1.0 mg/kg/day. Margins of Exposure were calculated for multiple exposure scenarios for different population subgroups, some of which were below the target value (US EPA, 2019).

3.4 A dietary risk assessment evaluating the potential health hazards caused by OPP and SOPP in food residues was published by the Department of Pesticide Regulation, of the California Environmental Protection Agency (Cal EPA), in 2007. Both OPP and SOPP may be used as fungicides in the post-harvest treatment of fruit and vegetables, therefore their residues may be ingested by consumers. For acute exposure, a critical NOAEL of 25 mg/kg bw/day was established for women in their child-bearing years, and a NOAEL of 150 mg/kg bw/day was established for the general population, including children (Zablotny et al., 1991; Kaneda et al., 1978). For chronic exposure, critical NOAELs of 39 mg/kg bw/day were established for males, and 49 mg/kg bw/day for females (Wahle and Christenson, 1996). Taking into account dietary exposure estimates covering the average US population and 15 selected population subgroups, Margin of Safety (MoS) calculations for both acute and chronic exposures resulted in values greater than 100, which was sufficient for non-carcinogenic effects. Because OPP showed carcinogenic activity in experimental animals, the risk calculation undertaken for humans included excess cancer risk due to the lifetime exposure. The estimated lifetime risk of the average US population was calculated to be 2.4×10^{-7} . This risk was considered to be negligible for cancer risk and therefore, lifetime dietary exposure to foods with legally allowed residues of OPP was not thought to pose a significant carcinogenic concern. Overall, it was concluded that, based on the total weight-of-evidence, there were no appreciable health concerns, including for cancer, resulting from exposure to food with legally allowed residues of OPP under acute and chronic conditions (Cal EPA, 2007).

3.5 A proposed re-evaluation decision for OPP and its salts, for use only in the post-harvest treatment of pears and as a material preservative for a range of non-cosmetic consumer goods, was published by the Health Canada Pest Management Regulatory Agency in 2008. The available scientific information was evaluated, and it was concluded that



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products containing OPP and its salts do not present unacceptable risks to human health or the environment when used according to label directions. Therefore, the proposal was for continued registration, with implementation of risk-reduction methods ([Health Canada, 2008](#)).

3.6 In 2022, Environment and Climate Change Canada and Health Canada, published a joint screening assessment for SOPP in accordance with the Canadian Environmental Protection Act, 1999. Whilst the report focused on the potential risk of harm to the environment by SOPP, human health has also been considered in relation to environmental exposure. Two dermal exposure scenarios were considered for SOPP. The first was exposure from bar soap (ages 0-5 months) with an SOPP concentration of 0.1%. Systemic exposure was estimated to be 0.00031 mg/kg bw/day and the oral PoD was set at 39 mg/kg bw/day from a 2-year chronic toxicity/carcinogenicity study in rats (Wahle and Christenson, 1996). The Margin of Safety (MoS) was calculated to be 126,000. The second exposure scenario was from tyre and rubber lubricant for the 19 years + age group. A systemic exposure, per event, of 0.02 mg/kg bw was calculated, assuming that absorption was 100% via the oral and dermal routes. Read-across from OPP derived a maternal NOAEL of 100 mg/kg bw/day as the critical health effect endpoint. This was based on decreased body weight gain, food consumption and food efficiency seen at 300 mg/kg bw/day in rats and kidney effects at 250 mg/kg bw/day seen in rabbits in developmental toxicity studies as referred to in [Health Canada, 2008](#), [US-EPA, 2006](#) and [Cal EPA, 2007](#). The MoS was calculated to be 5000. Overall, it was concluded that SOPP does not enter the environment in a quantity or concentration that has an effect on the environment or which constitutes a danger in Canada to human life or health ([Health Canada, 2022](#)).

3.7 In 2013, a re-evaluation of the developmental and reproductive toxicity of OPP and SOPP was published by [Kwok and Silva, 2013](#) of the Cal-EPA. In this re-analysis of published studies, a pattern for developmental effects, due to OPP and SOPP treatment, was determined in rats, mice and rabbits. Foetal effects were observed in the absence of maternal toxicity which contradicted previously published reviews stating that developmental effects would only be induced at doses where maternal effects were also observed ([FAO, 2000](#); [US-EPA, 2006](#); [Bomhard et al., 2002](#)). It was recommended that the effects identified in this re-evaluation be considered in regulatory strategy for public health protection.



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3.8 A human health assessment for OPP and SOPP was carried out by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) of Australia in 2015. Systemic acute effects following oral exposure to SOPP, local effects of corrosivity, potential to be carcinogenic at high doses following long-term repeated exposure, potential for a genotoxic mode of action and potential to cause respiratory irritation were noted as critical health effects. The NICNAS recommended additional classifications for both OPP and SOPP for mutagenicity category 3 (possible risk of irreversible effects) and carcinogenicity category 3 (limited evidence of carcinogenic effect) in accordance with the Approved Criteria for Classifying Hazardous Substances (Safe Work Australia) ([NICNAS, 2015](#)).

3.9 The Scientific Committee on Consumer Safety (SCCS) first published an opinion on OPP and SOPP in 2015. This opinion also looked at the potassium salt of OPP (potassium o-phenylphenate, or POPP). The SCCS concluded that OPP was not safe in leave-on products at a maximum concentration of 0.2% and recommended a lower level of 0.15% when considering further exposures from non-cosmetic uses in relation to a report by [ANSES, 2014](#)⁷. In rinse-off products, a maximum concentration of 0.2% was considered to be safe. No conclusions were able to be made for SOPP or POPP due to a lack of specific information ([SCCS, 2015](#)). An addendum to this opinion was published in 2018 which looked specifically at SOPP, POPP and MEA o-phenylphenate. This addendum stated that in the view of the SCCS, a direct comparison was unable to be made between the safety of OPP and the three of its salts mentioned and therefore, due to a lack of relevant information for the salts, the SCCS could not conclude on their safe use ([SCCS, 2018](#)).

3.10 The most recent opinion on OPP and SOPP by the SCCS was published in 2024 ([SCCS, 2024](#)). The SCCS used a dermal absorption value of 45% in their safety assessment based on a study by Selim, 1996 using OPP as the test substance. It was noted by the SCCS that based on water solubility and flux, this value should be lower for SOPP, however, as a worst-case estimate, and considering the lack of specific dermal absorption data for SOPP, this value was used for both OPP and SOPP. A Point of Departure (PoD) of 25 mg/kg bw/day was used in the safety assessment for both OPP and SOPP, based on an oral developmental toxicity study in rabbits which derived the lowest

⁷ Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (French Agency for Food, Environmental and Occupational Health and Safety)



NOAEL value out of all the repeated dose/long-term toxicity studies considered in the opinion (Zablotny et al., 1991; re-analysis by [Kwok and Silva, 2013](#)). Although SOPP was not tested in this study, this was still considered as a conservative value by the SCCS given information which suggests that SOPP will not be absorbed into the cells any more than OPP when entering systemic circulation and will be cleared more quickly via the urine. The SCCS did not agree with the applicant to derive a PoD of 22.4 mg/kg bw/day specifically for SOPP from a 104-week carcinogenicity study in rats, by Hiraga et al., 1983. This was because the study was not performed to currently accepted standards and was incomplete in certain aspects ([SCCS, 2015](#)). Overall, the SCCS concluded that both OPP and SOPP are safe at a maximum concentration of 0.15% in leave-on products and 0.2% in rinse-off products dermally applied as the SCCS did not consider oral or inhalation routes of exposure. However, when the SCCS did include oral care products, the Margin of Safety (MoS) values for both OPP and SOPP were above the acceptable MoS of 100. The SCCS also concluded that when OPP and SOPP are used together, the total concentration must not exceed the maximum concentrations of 0.15% in leave-on products and 0.2% in rinse-off products ([SCCS, 2024](#)).

4. Discussion by the Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products (SAG-CS)

- 4.1 At their April 2025 meeting, the members of the SAG-CS discussed a paper which focused on the risks posed to human health by sodium o-phenylphenate (SOPP) when used as a preservative in cosmetic products.
- 4.2 Members discussed the analytical methods available for the detection and quantification of SOPP in cosmetic products. No information could be found on the detection or quantification of SOPP. It is possible, however, for SOPP to become OPP (o-phenylphenol) by proton exchange, potentially during the preparation phase before analysis or during analysis. For OPP, methods were not readily available in the literature however members were content that analytical methods could be developed for routine application following appropriate validation. Published LC and LC-MS methods for OPP in food matrices (e.g., citrus fruit peel) of low or medium (e.g., human breast milk, pollen) analytical difficulty, respectively, may be capable of adaptation for cosmetic products (Saad et al., 2004; Ye et al., 2008; Parrilla Vázquez et al., 2015). This would require suitable method development paying



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attention to equilibration between SOPP and OPP as a function of pH, phase partitioning and extraction clean up.

4.3 Members discussed the study by Timchalk et al., (1998) as the key study submitted to derive the dermal absorption of SOPP. This study was carried out with o-phenylphenol (OPP) as the test substance and SOPP is the sodium salt of OPP. Since the dermal absorption of SOPP is expected to be lower than for OPP, because of differences in water solubility (higher for OPP) and flux values, members agreed this study would be appropriately conservative, in the absence of specific data for SOPP. In this study, a single 8-hour dermal dose of approximately 6 µg radioactive OPP/kg bodyweight was applied to the forearm of 6 healthy male volunteers. A one-compartment pharmacokinetic model was used to describe the time-course of OPP absorption and clearance. OPP was rapidly eliminated via the urine following absorption through the skin. An approximate average of 43% of the applied dose was calculated as being absorbed by comparing the amount of radioactivity in the urine and faeces versus swabs, skin rinses, and protective enclosures. Members agreed, based on this study, that a dermal absorption of 45% will be taken forward for the safety assessment, caveating that this study has used a pharmacokinetic model of which not all the details have been made available.

4.4 Members noted that the data package for the genotoxicity and mutagenicity of SOPP is large, exhibiting mixed results both *in vitro* and *in vivo*. The metabolites phenylhydroquinone (PHQ) and phenylbenzoquinone (PBQ) showed clear genotoxic potential *in vitro*. Based on the available data, members also agreed that SOPP has genotoxic potential *in vitro*. *In vivo*, DNA damage was observed for SOPP, PHQ and PBQ in unscheduled DNA synthesis/damage assays. A comet assay by De Boeck et al., 2015, however, produced a negative result for SOPP because it did not induce DNA strand breaks in liver or stomach cells. This study was carried out post the 2013 animal testing ban but may be included in the assessment as it was conducted for purposes other than for cosmetics⁸. Based on the evidence presented, members agreed that SOPP has genotoxic potential *in vivo* but is unlikely to pose a genotoxic risk at the maximum concentrations to be used on cosmetic products.

4.5 A number of studies indicated that SOPP is carcinogenic in mice and rats via the oral route, with the bladder and kidneys as the primary

⁸ [Regulation \(EC\) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products \(recast\) \(Text with EEA relevance\)](#)



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targets. A dietary study by Hiraga et al., (1983), summarised in Cal EPA, (2007), investigated the carcinogenicity of SOPP after 104 weeks of dosing. Overall, SOPP was carcinogenic in rats, specifically affecting the kidneys, urinary bladder and the pancreas. A LOAEL for systemic toxicity and carcinogenicity was established at 270 and 224 mg/kg bw/day in males and females, respectively. Studies by Hiraga et al., (1981), Fukushima et al., (1982) and Niho et al., (2002) also indicated that SOPP is carcinogenic via the oral route, with NOAEL values for carcinogenicity reported between 125 mg/kg bw/day and 1000 mg/kg bw/day. In a 52-week dermal two-stage mouse skin carcinogenesis study in female mice, SOPP was found to be an ulcerogenic agent which induces epidermal proliferation and can act as a promoter, but not an initiator or a complete carcinogen (Takahashi et al., 1989).

4.6 It was noted that SOPP is a more potent carcinogen than OPP, which has also been considered by the SAG-CS. Members discussed the potential mode of action of the carcinogenicity of SOPP, taking into account the increased potency in comparison with OPP. Urine pH has been identified as a key factor in the development of bladder tumours, with alkaline conditions promoting tumour formation (Balakrishnan et al., 2016). The sodium in SOPP may contribute to urinary sodium levels, increasing urine alkalinity and thus promoting tumour formation. This may explain the increased potency of SOPP compared to OPP which lacks the sodium. The study by Balakrishnan et al., (2016), an *in vivo* micronucleus assay in male rats with OPP as the test substance, linked positive results seen at high doses and under alkaline conditions with the induction of cytotoxicity by the OPP metabolites PHQ and PBQ, along with the generation of reactive oxygen species (ROS) from the pH-dependent autoxidation of PHQ in the urine. This plays a key role in the development of bladder lesions.

4.7 Members recognised that SOPP is carcinogenic in rats and mice via the oral route. However, when considering the mode of action of carcinogenicity, the unlikely potential of posing a genotoxic risk at concentrations relevant to cosmetic usage, and the expected low exposure from dermally applied cosmetic products, members were content that the carcinogenic risk is negligible. The Point of Departure selected for the safety assessment will be sufficiently protective of any carcinogenic effects.

4.8 Members discussed the Point of Departure (PoD) to be used for SOPP in the safety assessment. The SCCS used the same PoD value for both OPP and SOPP of 25 mg/kg bw/day, derived from an oral



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developmental toxicity study in rabbits by Zablony et al., 1991, which was re-analysed by Kwok and Silva, 2013. In the industry dossier submission, however, a PoD of 22.4 mg/kg bw/day derived from a 104-week carcinogenicity study in rats by Hiraga et al., (1983) was proposed for SOPP. In this study, a LOAEL for systemic toxicity and carcinogenicity was determined via the oral route to be 224 mg/kg bw/day based on increased incidences of focal atrophy of pancreatic acinar cells and interstitial nephritis in female rats. A composite uncertainty factor of 10 was applied to this value to extrapolate from LOAEL to NOAEL and to account for the quality of the study data. Members decided to use this PoD in their safety assessment as the most sensitive carcinogenicity study and the most sensitive toxicity endpoint identified for SOPP. Members recognised several limitations to this study including incomplete haematology and ophthalmology data and that the study has not been carried out to currently accepted standards, however these limitations are covered by the conservative uncertainty factor of 10 applied to the LOAEL.

- 4.9 Overall, an acceptable Margin of Safety (MoS) of 139 has been achieved when considering the aggregate dermal exposure to SOPP in cosmetic products at maximum concentrations of 0.2% in rinse-off products and 0.15% in leave-on products. Oral care products and products which lead to exposure by inhalation are excluded. The full safety assessment calculations can be found in the Appendix.
- 4.10 No children-specific safety assessment has been submitted by industry at this time. Members were of the opinion that a full risk assessment should be conducted for children and adolescents when adequate data becomes available, and an appropriate methodology has been subsequently agreed.
- 4.11 The members of the SAG-CS have separately reviewed the safety of OPP in cosmetic products. Although the combined use of SOPP and OPP was not considered, members agreed with the advice of the SCCS that when SOPP and OPP are used together, the total combined concentrations should not exceed the maximum concentrations of 0.15% in leave-on products and 0.2% in rinse-off products.



5. Conclusions

Members were content that a reasonable analytical method could be developed for sodium o-phenylphenate, subject to matrix specific validation.

Members agreed that sodium o-phenylphenate has genotoxic potential, however when considering the mechanisms by which genotoxicity occurs and the low concentrations found in cosmetic products, sodium o-phenylphenate is unlikely to pose a genotoxic risk.

Members recognised the carcinogenic potential of sodium o-phenylphenate as observed in rodents. However, considering the likely mechanisms by which carcinogenicity arises, the unlikely potential to pose a genotoxic risk, and the low exposure to sodium o-phenylphenate from cosmetic products via the dermal route only, members agreed that sodium o-phenylphenate is unlikely to pose a carcinogenic risk when used in cosmetic products at the proposed concentrations and conditions of use.

Overall, members concluded that sodium o-phenylphenate is acceptable for use in the following cosmetic product types (excluding oral care and spray products) and at the following concentrations:

- *Rinse-off products- 0.2%*
- *Leave-on products- 0.15%*

Members have separately considered the safety of o-phenylphenol, of which sodium o-phenylphenate is the sodium salt of, in cosmetic products. When used together, the concentration of sodium o-phenylphenate and o-phenylphenol should not exceed the maximum concentrations of:

- *0.2%- all rinse off products*
- *0.15%-all leave on products*

Oral care products and spray products are excluded from this safety assessment.

Members were of the opinion that a full risk assessment should be conducted for children and adolescents when adequate data becomes available, and an appropriate methodology has been agreed.

Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products

March 2026



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Abbreviations

BPR	Biocidal Products Regulation
Cal EPA	California Environmental Protection Agency
CLH	Harmonised classification and labelling (ECHA)
CLP	Classification, Labelling and Packaging
EC	European Commission
IARC	International Agency for Research on Cancer
LC-MS	Liquid Chromatography Mass Spectrometry
LOAEL	Lowest Observed Adverse Effect Level
MCL	Mandatory Classification and Labelling
MoE	Margin of Exposure
MoS	Margin of Safety
NOAEL	No Observed Adverse Effect Level
OPP	Ortho-phenylphenol
PoD	Point of Departure
RAC	The Committee for Risk Assessment of ECHA
ROS	Reactive oxygen species
SCCS	Scientific Committee on Consumer Safety
SED	Systemic Exposure Dose
SOPP	Sodium ortho-phenylphenate
US EPA	United States Environmental Protection Agency



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Safety Assessment

The full industry dossier, key unpublished studies and other references have been supplied to the committee.

An estimate of exposure and calculations of Margin of Safety (MoS) have been undertaken using the maximum use levels for SOPP in dermally applied products of:

- 0.2% for all rinse-off products
- 0.15% for all leave-on products

Exposure has been estimated using the default values for product use amounts, and the methodology, as defined in the [SCCS Notes of Guidance \(2023\)](#).

A dermal absorption value of 45% has been applied based on the key human volunteer pharmacokinetic study by Timchalk et al., 1998.

A Point of Departure (PoD) of 22.4 mg/kg bw/day has been derived from a 104-week carcinogenicity study in rats (Hiraga et al., 1983). This study derived a LOAEL of 224 mg/kg bw/day. A composite uncertainty factor of 10 is applied to account for extrapolation from LOAEL to NOAEL and to take into account limitations in the study data.

No bioavailability adjustments have been made to the PoD values as oral absorption is rapid and complete.

Data was not presented for children's exposure, therefore no safety assessment in children has been carried out.

The required Margin of Safety (MoS) is 100 (default).



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Table 1) Worst case deterministic aggregate Tier 1 exposure assessment (SCCS) for all dermally applied products to calculate SED_{dermal} and Margin of Safety (MoS) for SOPP.

Product category	Individual products	Relative daily exposure (mg/kg bw/day) ¹	SOPP concentration (%)	Dermal absorption (%) ²	SED (mg/kg bw/day) ³	MoS ⁴
Rinse off skin and hair cleansing products	Shower gel	2.79	0.2	45	0.00251	8921
	Hand wash soap	3.33	0.2	45	0.00300	7474
	Shampoo	1.51	0.2	45	0.00136	16483
	Hair conditioner	0.67	0.2	45	0.00060	37148
Leave on skin and hair cleansing products	Body lotion	123.2	0.15	45	0.08316	269
	Face cream	24.14	0.15	45	0.01629	1375
	Hand cream	32.7	0.15	45	0.02207	1015
	Deodorant (non-spray)	22.08	0.15	45	0.01490	1503
	Hair styling products	5.74	0.15	45	0.00387	5781
Make-up products	Liquid foundation	7.9	0.15	45	0.00533	4201
	Make-up remover	8.33	0.15	45	0.00562	3984
	Eyeshadow	0.33	0.15	45	0.00022	100561
	Mascara	0.42	0.15	45	0.00028	79012
	Eyeliners	0.08	0.15	45	0.00005	414815
	Lipstick/lip salve	0.9	0.15	100	0.00135	16593
				Aggregate	0.16064	139

SED – Systemic exposure dose

MoS – Margin of safety

1 – The effective exposure to a product category calculated by dividing the calculated daily exposure by the specific body weight of the persons in the study and taking into account the product specific retention factor as in the [SCCS Notes of Guidance \(2023\)](#).

2- A dermal absorption factor of 45% is applied in the calculation of SED. As a conservative approach, 100% has been applied for lip products.

3- SED= Relative daily exposure x Concentration (%) x Dermal absorption (%)

4- MoS is calculated by dividing the PoD (22.4 mg/kg bw/day) by the SED

Overall: Margin of Safety (MoS) is 139 for aggregate exposure to dermally applied products. This is > 100 and therefore is acceptable.