



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

Final Opinion on Hexyl Salicylate in Cosmetic Products

1. Introduction

- 1.1 Hexyl salicylate (hexyl 2-hydroxybenzoate; CAS No. 6259-76-3), Figure 1, is classified as a category 1 skin sensitiser and a category 2 reproductive toxicant under the GB Classification, Labelling and Packaging (CLP) regulation No 1272/2008 (as amended)¹ and is included in the GB Mandatory Classification and Labelling (MCL) list² as it may cause allergic skin reactions (CLP code H317) and is suspected of damaging the unborn child (CLP code H361d).
- 1.2 Hexyl salicylate is classified as a Carcinogenic, Mutagenic, or Reprotoxic (CMR) category 2 substance under the GB Classification, Labelling and Packaging (CLP) regulation No 1272/2008 (as amended), and it is not currently listed in the Annexes III – VI of the Cosmetic Products Regulation UK No 1223/2009 (as amended)³. As a result of the CMR classification, the use of hexyl salicylate in cosmetic products would have been prohibited when the CMR classification becomes legally binding. As a consequence, industry have provided a safety dossier to OPSS in support of continued use of hexyl salicylate as per the requirements in the UK cosmetics regulations. The SAG-CS were asked to review this dossier and offer an opinion on the exemption requested by the industry.

¹ 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.

² Available at: <https://www.hse.gov.uk/chemical-classification/classification/harmonised-classification-self-classification.htm>

³ The UK Regulation 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 soon.



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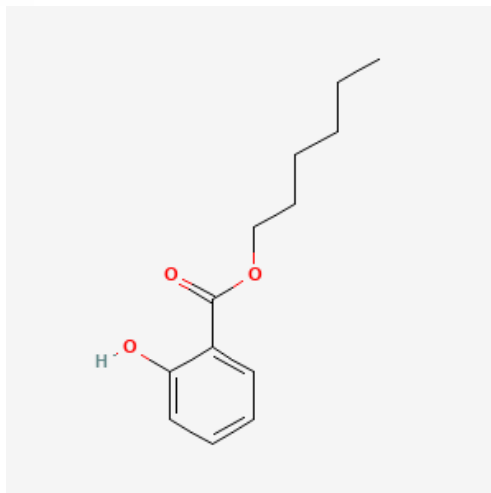


Figure 1: Structure of Hexyl salicylate (hexyl 2-hydroxybenzoate) Source: PubChem.

1.3.

1.4 The SAG-CS assessed the safety of hexyl salicylate intended to be used within cosmetic products at the concentrations listed in Table 1.

Type of cosmetic product	Maximum concentration (%)
<i>Hydroalcoholic-based fragrances</i>	2
<i>All rinse-off products</i>	0.5
<i>All leave on products</i>	0.3
<i>Oral care (toothpaste and mouthwash)</i>	0.001

Table 1: Industry-proposed UK use levels for hexyl salicylate in cosmetic products

2. Background

Intended function and uses of hexyl salicylate.

2.1 Hexyl salicylate is used as a fragrance ingredient as it has a sweet, floral and fruity odour. It can be synthesised for use in a range of manufactured goods including cosmetic products, household cleaning products, detergents and home fragrance products ([CIR, 2019](#); [PubChem, 2025](#)).



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3. Previous Scientific Opinions on Hexyl Salicylate

- 3.1 In 2019, the Cosmetic Ingredient Review Expert Panel (CIR) conducted an amended safety assessment of salicylic acid and salicylates as used in cosmetics following an exhaustive literature search. This was the first time a CIR assessment of salicylates included hexyl salicylate had been undertaken. The CIR Panel concluded that hexyl salicylate is safe to use at the concentration levels established by the International Fragrance Association (IFRA) when formulated to be non-irritating and non-sensitising ([CIR, 2019](#)).
- 3.2 In 2020, IFRA published maximum acceptable concentrations in finished cosmetic products for hexyl salicylate following a comprehensive safety assessment. These included 6.5% for fragrances, 0.38 – 1.2 % for rinse-off products, 0.092 – 6.5% for leave-on products and 0.0092% for oral care products. The intrinsic properties driving the risk assessment and management were dermal sensitisation and systemic toxicity ([IFRA, 2020](#)).
- 3.3 In 2023, the Research Institute for Fragrance Materials (RIFM) conducted a safety assessment of hexyl salicylate, producing a number of maximum acceptable concentrations for IFRA's product categories. The concentrations established were 15% for products related to fine fragrance, 6.2 – 29% for rinse-off products, 0.8 – 37% for leave-on products and 0.15% for products with oral and lip exposure. These are considerably higher than the maximum acceptable concentrations established by IFRA. RIFM's safety assessment includes the use of *in silico* predictions and read-across using data from isoamyl salicylate (CAS 87-20-7) as both compounds are salicylate esters. No data from salicylic acid was used in the assessment ([Api et al, 2024](#), IFRA, 2025).
- 3.4 In 2022 the European Chemicals Agency's (ECHA) Committee for Risk Assessment (RAC) published an opinion proposing harmonised classification and labelling at EU level of hexyl salicylate. The RAC classed hexyl salicylate as a category 1 skin sensitizer based on a GLP compliant LLNA study conducted to OECD Guidelines that showed a positive result for skin sensitisation. There were no studies available to evaluate the reproductive toxicity of hexyl salicylate so the compound was classified as a category 2 reproductive toxicant (suspected human reproductive toxicant) based on a read-across approach using data on methyl and ethylhexyl salicylates and their common metabolite salicylic acid ([RAC, 2022](#)).
- 3.5 The Scientific Committee on Consumer Safety (SCCS) published a scientific opinion in 2024 based on a dossier submitted by stakeholders to support the safe use of hexyl salicylate according to article 15(1)



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Reg. 1223/2009 with specific concentration limits for various product types. These are the same concentration limits listed in Table 1.

- 3.6 ADME data on hexyl salicylate indicate that the compound is expected to be extensively metabolised in both the gut and liver tissue by first pass metabolism, to salicylic acid and 1-hexanol following oral exposure in both rats and humans. An *in vitro* study using human skin shows almost complete metabolism to salicylic acid by skin esterases ([SCCS, 2024a](#)). Salicylic acid was reviewed in the SCCS opinion in 2018 and 2023 ([SCCS, 2018](#), [SCCS, 2023a](#)). The SCCS considers salicylic acid safe up to a concentration of 0.5% in cosmetic products when used as a preservative. For other purposes, salicylic acid is considered safe when used at concentrations up to 3.0% for rinse-off hair products and up to 2.0% for products as listed in Annex III (entry 98) of the Cosmetics Regulation. In body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant, salicylic acid is considered safe up to concentrations of 0.5%. These concentrations should not be exceeded by the additional use as a preservative.
- 3.7 The SCCS acknowledges that available human, animal and NAMs data are contradictory with only the LLNA assay providing a positive result. It was concluded that although hexyl salicylate is classed as a skin sensitiser, based on clinical evidence, the risk of skin sensitisation in humans from the use of cosmetic products can be considered negligible ([SCCS, 2024a](#)).
- 3.8 Reproductive toxicity was evaluated by read across to salicylic acid due to lack of data for hexyl salicylate and the rapid and complete metabolism of hexyl salicylate to salicylic acid. Salicylic acid has demonstrated teratogenicity in rats ([SCCS, 2018](#); [SCCS, 2024a](#)).
- 3.9 The SCCS ([SCCS, 2024a](#)) evaluated the potential for teratogenicity to be due to endocrine disruption based on a Danish review ([Hass et al., 2018](#)). The SCCS concluded that there was no evidence from available data of an adverse effect of hexyl salicylate and salicylic acid resulting from an endocrine mechanism. Under the OECD Endocrine Disruption Framework, data are available under levels 1 and 2 for salicylic acid but not for the other levels. In a suite of *in vitro* assays looking at endocrine related effects (Endocrine Disruptor Screening Program within US EPS Tox21 program, including 18 oestrogen receptor assays, 9 thyroid receptor assays, 2 steroidogenic assays and 15 androgen receptor assays) only one weakly positive result was seen in an androgenic receptor assay. Read across from data on acetylsalicylic acid (aspirin) was used by [Hass et al., 2018](#) who reviewed several studies. All of these studies showed potential effects but deficiencies or uncertainties in all three studies meant that identification of an



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endocrine mode of action is not possible. Under the OECD Endocrine Disruption framework this remains at level one as the data used does not relate to the substance of interest. After reviewing the data within the dossier, and considering the concerns related to potential endocrine disrupting properties, the SCCS considered hexyl salicylate to be safe when used up to the maximum concentrations as listed in Table 1 ([SCCS, 2024a](#)).

3.10 The SCCS ([SCCS 2024b](#)) also released an addendum to their opinion reviewing the use of hexyl salicylate in products intended for children between the ages of 0-3 years old. The SCCS stated that hexyl salicylate was safe for use in cosmetic products for children under 3 years old when used at specific maximum concentrations. The safe maximum levels were 0.1% (w/w) for shower gel, hand soap, shampoo, hair conditioner, body lotion, face cream, hand cream, lipstick/lip balm and fragrance products, and 0.001% (w/w) for toothpaste. Margins of safety were found to be acceptable using these concentrations and in this age group ([SCCS, 2024b](#)).

3.11 Cosmetics Europe have commissioned a study entitled an "Exposure Study in European Infants & Children" using probabilistic modelling to assess the exposure of children aged 0–3 years to cosmetic products. The purpose of this study was to provide sufficient exposure data to evaluate potential risks from cosmetic ingredients to children aged 0–3 years. Cosmetics Europe attended the SAG-CS meeting in September and gave an update to the group on the study and its findings. The study is not yet published, but an abstract is available ([Kirsch et al 2023](#)).

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

4.1 In their April 2025 meeting, the SAG-CS discussed a paper and an associated industry-prepared dossier which focused on the available safety data for hexyl salicylate when used in cosmetic products at the concentrations listed in Table 1. Safety data were presented for adults and infants/toddlers in the 0 – 3 age range (see Appendix).

4.2 Examples of relevant analytical methods developed for cosmetics and personal care products are available in the literature (for example Abedi et al., 2018; Liu and Wu, 2011; Pafili et al., 2021; Fardin-Kia and Zhou, 2020; Vecchiato et al., 2016; Mei and Huang, 2017). These rely mainly on gas or liquid chromatographic separation coupled with either UV-Vis or mass spectrometry quantification. Acceptable performance is available for the determination of salicylic acid and various salicylates,



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however publications on methods for hexyl salicylate itself are sparse. Members were thus content that analytical methods could be developed for routine application following appropriate validation.

- 4.3 Members noted the ADME data which indicated that hexyl salicylate is extensively and rapidly metabolised to salicylic acid and 1-hexanol through all routes of exposure.
- 4.4 Hexyl salicylate itself is not considered to be genotoxic, mutagenic or carcinogenic.
- 4.5 The Point of Departure (PoD) of 75 mg/kg bw/day selected for the safety assessment was the same PoD used in the previous SCCS opinion on salicylic acid ([SCCS, 2018](#)), which was the NOAEL derived from an oral exposure study by Tanaka et al., 1973 which observed fetal mortality, reproductive effects, growth retardation and skeletal abnormalities following dosage with salicylic acid at levels higher than 75mg/kg bw/day. Given the ADME data, members were content to use this PoD in their safety assessment.
- 4.6 Members were satisfied with the dermal absorption value of 13.4% applied in the dermal exposure assessment, which was derived from an 8-hour occupational exposure study (Maas, 2016) adjusted for a 24-hour exposure, using a mean of $(3.04\% + 1SD) \times 3$ (correction factor).
- 4.7 Members discussed the skin sensitisation data due to the categorisation of hexyl salicylate as a category 1 skin sensitiser. It was agreed that there was no concern of skin sensitisation stemming from the use of hexyl salicylate in cosmetic products at the concentrations proposed by industry as the human data confirms that there are only rare cases where sensitisation is observed, and only at excessive concentrations.
- 4.8 Although hexyl salicylate is not classed as an endocrine disruptor its primary metabolite, salicylic acid, has been classified as a suspected endocrine disruptor. Therefore, members considered the endocrine-disrupting potential of hexyl salicylate. It was agreed that the available data indicate that hexyl salicylate itself is not an endocrine disruptor.
- 4.9 In April 2025, members considered a safety assessment provided in the industry-supplied dossier which specifically considered children aged 0 – 3 years due to the current restrictions on salicylic acid in products intended for use by children of this age group. These data are presented in Table 5 and exposures were based on the study carried out by Cosmetics Europe entitled “Exposure Study in European Infants & Children”.



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- 4.10 In September 2025, Cosmetics Europe presented the results from this study ([Kirsch et al, 2023](#), abstract only, awaiting full study publication) to the SAG-CS.
- 4.11 Given the methodology presented and the margins of safety in this age group, members were content that a safe level of 0.1% for use in shower gel, hand soap, shampoo, hair conditioner, body lotion, face cream, hand cream, lipstick/lip balm, fragrance products and 0.001% in toothpaste for children under 3 years old could be established for hexyl salicylate.
- 4.12 In light of the large margins of safety for adults and the smaller range of products used by children, the SAG-CS concluded that the use of hexyl salicylate at 2% in hydroalcoholic-based fragrances (spray and non-spray); 0.5% in all rinse-off products; 0.3% in all leave-on product and 0.001% in all oral care products, were likely to be safe in children aged 3 years and above.
- 4.13 Whilst these data did not raise immediate concerns, the Committee were of the opinion that a full risk assessment in children aged 3 years of age and above should be conducted when adequate data and an adequate methodology become available.

5. Conclusions

Based on the evidence available to the SAG-CS, members agreed that hexyl salicylate is acceptable for use in cosmetic products intended for use by adults and children aged 3 years and above at the stated concentrations:

- *Hydroalcoholic-based fragrances (spray and non-spray): 2%*
- *All rinse-off products: 0.5%*
- *All leave-on products: 0.3%*
- *All oral care products: 0.001%*

However, the data were limited in children aged 3 years of age and above and the SAG-CS recommended that a full risk assessment should be conducted when an adequate methodology and data become available in order to fully assess the use of hexyl salicylate in products intended for children.

Based on the evidence available to the SAG-CS, members agreed that hexyl salicylate is acceptable for use in cosmetic products intended for use by children aged 0-3 at the stated concentrations: 0.1% for use in shower gel, hand soap, shampoo, hair conditioner, body lotion, face cream, hand cream, lipstick/lip balm, fragrance products and 0.001% in toothpaste.

The SAG-CS based these conclusions on the exposures derived from the new baby study by Cosmetics Europe using P95 aggregate exposures. In coming to their conclusions, the SAG-CS were further reassured by the high MoS in this age group (Table 5).



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Consideration of the environmental safety of chemicals does not fall within the remit of the SAG-CS.

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

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Safety Assessment

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

Using the proposed use levels from Table 1 in the main paper, the following exposure and Margin of Safety calculations have been performed. Exposure assessments have used the default values for product use amounts as defined in the [SCCS Notes of Guidance \(12th revision\)](#) unless data was unavailable. In this case, an alternative method to estimate daily use amounts is used and will be indicated in the table footnotes.

A dermal absorption value of 13.4% has been applied to all dermally applied products, excluding oral care products, based on the study by Maas et al. (2016). For oral care products, a dermal absorption value of 100% has been used as the most conservative value. Oral absorption is assumed to be 100%.

For dermally applied and oral products, a point of departure of 75 mg/kg bw/day is used based on the NOAEL for salicylic acid observed in a study by Tanaka et al., (1973). Hexyl salicylate is expected to undergo rapid and extensive metabolism to salicylic acid through both the dermal and oral route. The Margin of Safety (MoS) is based on the SED_{dermal} for salicylic acid, which is calculated by molecular weight conversion from the SED_{dermal} for hexyl salicylate.

The MoS is 100 (default).



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Dermal

Table 2: Worst case deterministic aggregate Tier 1 exposure assessment ([SCCS, 2023b](#)) for all dermally applied products and oral hygiene products to calculate SED_{dermal} and Margin of Safety (MoS) in adults.

Product category	Individual products	Concentration of hexyl salicylate (%)	E _{product/bw} (mg/kg bw/day) ¹	Dermal absorption (%) ²	SED _{dermal} hexyl Sal (mg/kg bw/day)	SED _{dermal} Sal Acid ³ (mg/kg bw/day)	MoS ⁴
Hydroalcoholic-based fragrances (non-spray)		2.000	4.67*	13.4	0.01252	0.00778	9640
Rinse-off skin and hair products	Shower gel	0.500	2.79	13.4	0.00187	0.00116	64544
	Hair conditioner	0.500	0.67	13.4	0.00223	0.00139	54077
	Shampoo	0.500	1.51	13.4	0.00101	0.00063	119257
	Hand wash soap	0.500	3.33	13.4	0.00045	0.00028	268773
Leave-on skin and hair products	Body lotion	0.300	123.20	13.4	0.04953	0.03079	2436
	Face cream	0.300	24.14	13.4	0.00970	0.00603	12433
	Hand cream	0.300	32.70	13.4	0.01290	0.00802	9350
	Deodorant, non-spray	0.300	22.08	13.4	0.00888	0.00552	13593
	Hair styling products	0.300	5.74	13.4	0.00231	0.00143	52287
Face make-up products	Liquid foundation	0.300	7.90	13.4	0.00318	0.00197	37991
	Lipstick, lip salve	0.300	0.90	100	0.00335	0.00208	36030
	Make-up remover	0.300	8.33	13.4	0.00013	0.00008	909484
	Eyeshadow	0.300	0.33	13.4	0.00017	0.00010	714595
	Mascara	0.300	0.42	13.4	0.00003	0.00002	3751622
	Eyeliners	0.300	0.08	13.4	0.00270	0.00168	7321429
Oral care products	Toothpaste	0.001	2.17	100	0.00002	0.00001	5585749
	Mouthwash	0.001	32.54	100	0.00033	0.00020	370781
Aggregate					0.11130	0.06919	1084⁴

SED – Systemic exposure dose

MoS – Margin of safety



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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](#).

2 – A dermal absorption factor of 13.4% is applied in the calculation of SED_{dermal} . For lip products and oral care products, this value is 100%.

3 – 1 mole of Hexyl salicylate (MW = 222 g/mole) is assumed to be 100% metabolised to 1 mole of salicylic acid (MW = 138 g/mole), therefore a conversion factor can be applied to account for this, using % metabolised and using relative molecular weight conversion this leads to the calculation of salicylic acid equivalents in mg/kg/day. (SED Parent $\times$ 100% $\times$ 138 (MW metabolite) / 222 (MW parent) = SED metabolite equivalent).

4 – Margin of Safety was calculated by dividing the PoD (75 mg/kg/day) by the SED_{dermal} .

*Data from Ficheux and Roudot, 2017.

Overall: Margin of Safety is 1084 for aggregate exposure to dermally applied products. This is > 100 and therefore, **acceptable**.

Inhalation

Table 3: Parameters for the two-box inhalation model

Parameter	Unit	Reference(s)
Proportion of non-propellant in formulation	Default: • Propellant spray= 0.6 • Pump spray= 1	Bremmer <i>et al</i> , 2006
Airbourne fraction	• Propellant spray= 1 • Pump spray=0.2	Bremmer <i>et al</i> , 2006
Box 1 volume	1000L (1m ³)	SCCS, 2023b
Box 2 volume	10,000L (10m ³)	SCCS, 2023b
Duration in box 1	2 minutes	SCCS, 2023b
Duration in box 2	20 minutes	SCCS, 2023b
Inhalation rate	13 L/min	US-EPA, 2011
Retention fraction in lungs	0.75 (default)	Rothe et al., 2011
Respirable fraction	• Propellant spray= 0.2 • Pump spray= 0.01	Delmaar and Bremmer, 2009 (all products excluding body lotion) and SCCS, 2023b (for body lotion, assumed similar to sunscreen lotion)



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Table 4: Two-box inhalation model to calculate $SED_{inhalation}$ and MoS for sprayed products.

	Hydroalcoholic fragrance spray	Deodorant spray	Hair leave- on pump spray	Hair leave-on propellant spray	Body lotion pump spray	Body lotion propellant spray
Amount per application (mg/application)¹	280	3050	3158	5965	3430	5720
Hexyl salicylate concentration (%)	2	0.3	0.3	0.3	0.3	0.3
Proportion of non-propellant in formulation	1	0.6	1	0.6	1	0.6
Airbourne fraction	0.2	0.886	0.2	1	0.2	1
Potential amount inhaled (mg)²	1.12	4.86414	1.8948	10.737	2.058	10.296
Box 1 Volume (L)	1000	1000	1000	1000	1000	1000
Duration in box 1 (min)	2	2	2	2	2	2
Inhalation rate (L/min)	13	13	13	13	13	13
Potential amount inhaled in Box 1³	0.02912	0.12646764	0.0492648	0.279162	0.053508	0.267696
Box 2 volume (L)	10000	10000	10000	10000	10000	10000
Duration in box 2 (min)	20	20	20	20	20	20
Inhalation rate (L/min)	13	13	13	13	13	13
Potential amount inhaled in Box 2³	0.02912	0.12646764	0.0492648	0.279162	0.053508	0.267696
Retention fraction in lungs	0.75	0.75	0.75	0.75	0.75	0.75
Respirable fraction	0.01	0.2	0.01	0.2	0.01	0.2
Frequency of application⁴	1	2	1.14	1.14	2.28	2.28



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Body weight (kg)⁵	70	70	70	70	70	70
SED_{inhalation} (mg/kg bw/day)⁶	0.00000624	0.001084008	1.20347E-05	0.001363906	2.6142E-05	0.00261577
Calculation of Margins of Safety						
PoD_{inhalation} (mg/kg bw/day)	75	75	75	75	75	75
Oral absorption (%)	100	100	100	100	100	100
POD_{sys} (mg/kg bw/day)	75	75	75	75	75	75
MoS⁷	12019231	69188	6231986	54989	2868894	28672
Safe MoS	100	100	100	100	100	100
Conclusion	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable
Aggregate inhalation						
Aggregate SED_{inhalation}	0.005108104					
MoS	14683	Acceptable				

SED – Systemic exposure dose

MoS – Margin of safety

1 – Hydroalcoholic fragrance spray - based on the daily use amount reported by Ficheux and Roudot (2017) Deodorant spray - based on daily use amount reported by Hall et al., (2007), Hair pump spray-from Loretz et al., (2006), Hair propellant spray-based on daily use amount reported by Steiling et al., (2014), Body lotion pump spray and body lotion propellant spray - based on [SCCS Notes of Guidance \(SCCS, 2023b\)](#)

2 – Calculated as: amount per application x hexyl salicylate concentration x proportion of non-propellant x airborne fraction

3 – Calculated as Potential amount inhaled / box volume x duration in box x inhalation rate

4 – From the SCCS Notes of Guidance (SCCS, 2023b)

5 – Default body weight for adults of 70kg

6 – $SED_{inhalation} = (\text{Box 1} + \text{Box 2}) \times \text{retention in lungs} \times \text{respirable fraction} \times \text{frequency of application} / \text{default body weight}$

7 – The MOS has been calculated by dividing the $POD_{inhalation}$ (75 mg/kg bw/day) by the $SED_{inhalation}$.

Overall: Hexyl salicylate exposure via the inhalation route is low, and all Margins of Safety are above 100. Exposure is higher for the non-spray equivalents of all dermally applied products and so Table 2 shows the final aggregate scenario for adults.



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The aggregate SED from both routes of exposure is 0.11641 mg/kg bw/day, which results in a Margin of Safety of 1036. This is greater than the standard MoS of 100, therefore the use of hexyl salicylate at the concentrations proposed by the applicant is considered safe.



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Risk assessment for use of hexyl salicylate in cosmetics products for children <3 years

The following safety assessment is included due to the restriction of salicylic acid-containing cosmetic products for children below the age of 3 years. The safety of the maximum use concentration of 0.1% is assessed, and an MoS for the aggregate SED from all cosmetic products is calculated.

Table 5: Child-specific safety assessment of hexyl salicylate in products intended for children.

Cosmetic Product	Estimated exposure to product (P95) (mg/kg bw/day)¹	Maximum use concentration (%)	Calculated HexSal SED (mg/kg bw/day)²	Calculated SalAcid SED (mg/kg bw/day)²	NOAEL for SalAcid (mg/kg bw/day)	MoS
All products	1200	0.1	0.16	0.1	75 ³ 100 ⁴	750 1000

SED – Systemic exposure dose

MoS – Margin of safety

1 – Total product exposure from the Cosmetics Europe study in European Infants & Children (0-3 years old), Crème Report, 14th October 2022.

2 – SED based on 13.4% dermal absorption from Maas et al, (2016) adjusted for 24-hour exposure

3 – NOAEL of 75 mg/kg bw/day for salicylic acid from Tanaka et al., (1973).

4 – NOAEL of 100 mg/kg bw/day considered by Health Canada (2020) assessment, based on a short-term study described in JECFA (1962). Differential PoD considered as the relevance of 75 mg/kg bw/day as a PoD for toddlers and children questioned as this is based on reproductive toxicity.



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Abbreviations

ADME	Absorption, Distribution, Metabolism and Excretion
CIR	Cosmetics Ingredient Review
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic or Reprotoxic
ECHA	European Chemicals Agency
IFRA	International Fragrances Association
LLNA	Local Lymph Node Assay
MLC	Mandatory Classification and Labelling
MoS	Margin of Safety
NAM	New Approach Methodology
NOAEL	No Observed Adverse Effect Level
OECD	The Organisation for Economic Co-Operation and Development
OPSS	Office for Product Safety and Standards
PoD	Point of Departure
RAC	European Committee for Risk Assessment
RIFM	Research Institute for Fragrance Materials
SAG-CS	Scientific Advisory Group on Chemical Safety in Consumer Products
SCCS	Scientific Committee on Consumer Safety
SED	Systemic Exposure Dose



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