



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

Final Opinion on Resorcinol in Cosmetic Products.

1. Introduction

1.1 Resorcinol (1,3-dihydroxybenzene; CAS No. 108-46-3; Figure 1) when used as a hair dye substance in oxidative hair dye products has a maximum use concentration of 1.25% (w/w) after mixing under oxidative conditions and then applying to the hair or eyelashes. The starting (in product) concentration for resorcinol as a hair dye coupler can therefore be a maximum of 2.5% (w/w) when mixing in a 1:1 ratio with a developer, but the final (on head) concentration must not exceed 1.25% (w/w). Several conditions of use should be printed on the labels of resorcinol-containing hair dye products, including that they are not intended for persons under the age of 16. Products intended for colouring eyelashes are for professional use only. For use in hair lotions and shampoos, resorcinol has a maximum use concentration of 0.5%. This is as stipulated in Annex III of the Cosmetic Products Regulation UK No 1223/2009¹.

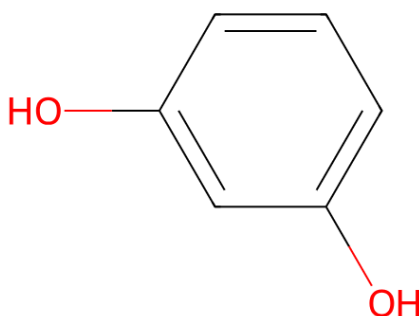


Figure 1: Structure of resorcinol (1,3-dihydroxybenzene)
(Source: ChemSpider)

¹ The Cosmetic Products (safety) 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 in due course.



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- 1.1 Resorcinol has the following classifications under the GB Classification: Labelling and Packaging regulation No 1272/2008 (as amended)²: acute toxicity category 4 (H302), eye irritation category 2 (H319), skin irritation category 2 (H315) and acute aquatic toxicity category 1 (H400) and is therefore included in the GB Mandatory Classification and Labelling (MCL) list³.
- 1.2 OPSS issued a call for data for cosmetic ingredients with suspected endocrine disrupting properties. Resorcinol was included in this call and a dossier from industry containing relevant safety studies was submitted to the OPSS.
- 1.3 OPSS requested that the SAG-CS assess the safety of resorcinol intended to be used within cosmetic products at a maximum concentration of 1.25% (w/w).
- 1.4 A summary of the key physicochemical, toxicological, and pharmacokinetic information from the submitted dossier have been provided to the committee in Annex 1.

2. Background

Intended function and uses of resorcinol.

- 2.1 Resorcinol, or its derivatives, are found widely in nature, for example, in the broad bean (*Vicia faba*) and in extracts from tobacco leaves. Resorcinol may also be produced synthetically. As a simple organic chemical intermediate, resorcinol has a variety of functions and uses (Dressler, 1994).
- 2.2 Resorcinol is used as a hair dye coupler in oxidative hair colouring products and is mixed in a 1:1 ratio, normally with hydrogen peroxide, just prior to use. This bonds the dye permanently to the hairs ([SCCS, 2010](#)).
- 2.3 Resorcinol may be found in topical medications such as those used to treat skin disorders including acne, seborrheic dermatitis, eczema and psoriasis, as well as corns, calluses and warts. Its use in GB, however, appears to be limited ([Mayo clinic, 2024](#); [SCCS, 2021](#)).

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 soon.

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



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2.4 Other uses of resorcinol include in the manufacture of rubber compounds, resins, coatings, dye products, flame retardants, biocidal products and agricultural chemicals (Dressler, 1994).

3. Previous Scientific Opinions on Resorcinol

3.1 The safety of resorcinol has been evaluated by several committees, on multiple occasions, since 1986.

3.2 In 1986, a Cosmetics Ingredient Review (CIR) Expert Panel concluded that both 2-methylresorcinol and resorcinol were safe as cosmetic ingredients when considering the practices of use and concentrations used at the time of the assessment. The panel noted that clinical testing data indicated that resorcinol is a mild skin irritant and a rare sensitizer. However, when tested on human volunteers at the concentrations used in cosmetic products, no irritation at the site of application, sensitisation or photosensitisation was observed ([CIR, 1986](#)). In 2005/2006, the CIR Expert Panel looked at newly available studies for 2-methylresorcinol and resorcinol, as well as updated information on type and concentration of use. The conclusions of the [CIR, 1986](#) paper were confirmed and therefore the CIR determined there was no need to reopen the safety assessment ([CIR, 2008](#)).

3.3 The first opinion on resorcinol published by the SCC (Scientific Committee on Cosmetology) in 1988 concluded that “The SCC does not consider the use of Resorcinol in the hair dyes to be linked to any particular toxic risk for consumers” and stated that this may be confirmed by the results of the National Toxicology Program ([SCC, 1988](#)). This conclusion was confirmed again in a later meeting of the SCC in 1993 ([SCC, 1993](#)).

3.4 The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated resorcinol in 2000 and concluded that there was no safety concern at the then current levels of intake when used as a flavouring agent ([JECFA, 2000](#)).

3.5 In 2008, the Scientific Committee on Consumer Products (SCCP) published an opinion on resorcinol. The SCCP concluded that the information submitted was insufficient to allow a final risk assessment to be carried out and recommended that before any further consideration an *in vivo* Comet assay on stomach, liver and bladder cells should be performed. This was because the mutagenic potential of resorcinol seen *in vitro* (Sire, 2004) could not be excluded in the *in vivo* study (Erexson, 2005). The SCCP also requested that studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken in accordance with the Notes of Guidance of the SCCNFP/SCCP ([SCCP, 2008](#)).



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- 3.6 Following the submission of more data, including an *in vitro* Mouse Lymphoma Assay (*hprt* assay), the SCCS published an opinion on resorcinol in 2010. It was concluded that resorcinol is a strong sensitiser. The SCCS also concluded that the “use of resorcinol as an ingredient in oxidative hair dye formulations with a maximum on-head concentration of 1.25% will not pose a risk to the health of the consumer, apart from its sensitising potential”. As in the [SCCP, 2008](#) opinion, the SCCS also recommended that studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken in accordance with the Notes of Guidance ([SCCS, 2010](#)).
- 3.7 In 2010, the European Food Safety Authority (EFSA) Panel on Food Additives and Nutrient sources added to Food (ANS) published an opinion on the use of resorcinol as a food additive (as an antioxidant in crustaceans). Based on a NOAEL of 36 mg/kg bw/day, derived from a carcinogenicity study in rats, and applying an uncertainty factor of 300, an Acceptable Daily Intake (ADI) of 0.12 mg/kg bw/day was established for resorcinol ([EFSA, 2010](#)).
- 3.8 An opinion published by the SCCS in 2012 on oxidative hair dye substances used in products to colour eyelashes concluded that resorcinol is safe up to a concentration of 1.25% and is not an eye irritant ([SCCS, 2012](#)).
- 3.9 The latest opinion by the SCCS on resorcinol was adopted in 2021. The SCCS concluded that resorcinol is safe when used as an oxidative hair dye in products intended for hair and eyelashes up to 1.25% and up to 0.5% in hair lotions and shampoos. The SCCS noted some concerns that resorcinol is a moderate skin sensitiser (based on animal study data), however clinical studies showed that the frequency of contact sensitisation in humans is low ([SCCS, 2021](#)).

The SCCS used a Point of Departure (PoD) of 80 mg/kg bw/day in their safety assessment, which was derived from a prenatal developmental toxicity study by gavage by Foulon, (2005a) (cited by the SCCS as USR, (2005b)) and a 13-week toxicity study by Foulon, (2005b) (cited by the SCCS as USR (2004)). The prenatal developmental toxicity study was OECD test guideline 414 compliant. Resorcinol was administered to four groups of 24 pregnant Sprague-Dawley rats at doses of 0, 40, 80 or 250 mg/kg bw/day from day 6 to day 19 of gestation, before being sacrificed on day 20 and subjected to macroscopic examination. The net bodyweight change was significantly reduced (compared to controls) in the 250 mg/kg bw/day group, but no other maternal effects were observed. No treatment related effects were observed on foetal data or foetal abnormalities (USR, 2005, (also cited as an unpublished report by Foulon, 2005)). The SCCS therefore derived a maternal NOAEL of resorcinol administered by gavage



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to pregnant female rats of 80 mg/kg bw/day and a developmental NOAEL of 250 mg/kg bw/day ([SCCS, 2021](#)).

In the Foulon, (2005b) (also cited by the SCCS as USR, 2004) study, four groups of 10 female and 10 male Sprague-Dawley rats were administered resorcinol daily by gavage at 0, 40, 80, or 250 mg/kg bw/day for at least 13 weeks. In the 250 mg/kg bw/day group, a decrease in the absolute (-19%) and relative (-13%) thyroid gland weight was observed. The study authors considered these effects to have no toxicological importance, however the SCCS did not concur with this as in the reproductive study effects on the thyroid were also observed. Overall, the NOAEL was determined to be 80 mg/kg bw/day where no clinical observations were recorded ([SCCS, 2021](#)).

The SCCS used a dermal absorption value of 2.06 $\mu\text{g}/\text{cm}^2$ in their safety assessment, based on an *in vitro* percutaneous absorption study by Toner and Roper (2005) using radiolabelled resorcinol in a typical oxidative hair dye formulation (final resorcinol concentration 1.25% w/w). The study was OECD test guideline 428 compliant and was carried out to GLP. Resorcinol was formulated in oxidative and non-oxidative hair dye test preparations to reflect the actual hair dying process and was washed off after 30 minutes. Ten skin samples of human breast and abdomen skin from 5 female donors were used in the oxidative hair dye test preparation and 12 samples from 4 donors were used in the non-oxidative test preparation. Under oxidative conditions, total absorption (dermal delivery) was $1.04 \pm 0.51 \mu\text{g}/\text{cm}^2$ ($1.55 \mu\text{g}/\text{cm}^2$) or $0.40 \pm 0.18 \%$ of applied dose (0.58% of applied dose). The SCCS considered that results from only four chambers were usable and therefore used the mean plus two standard deviations to give a final value of 2.06 $\mu\text{g}/\text{cm}^2$ to be used in the safety assessment.

Overall, the SCCS calculated a Margin of Safety of 4000 for resorcinol in oxidative hair dye products for hair and eyelashes up to 1.25% and in hair lotions and shampoos up to 0.5%



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

- 4.1 At their July 2024 meeting, the SAG-CS discussed a paper which focused on the safety of resorcinol when used as a hair dye substance in oxidative hair dye products, and in hair lotions and shampoos.
- 4.2 Members discussed the analytical methods available for the detection and quantification of resorcinol. Supported by a literature review carried out by OPSS, members were content that appropriate analytical methods could be applied routinely following appropriate validation (for example Long et al., 2022; Narita et al., 2007; Penner and Nesterenko, 2000; Kumar de et al., 2014, 2016).
- 4.3 Members were content with the dermal absorption study by Toner and Roper (2005) described above in paragraph 3.9, in which the *in vitro* percutaneous absorption of radiolabelled resorcinol was measured in human skin in accordance with OECD test guideline 428 and carried out to GLP. Members concurred with the decision of the SCCS to use the mean plus two standard deviations to give a final value of 2.06 µg/cm² to be used in the safety assessment. As per the OECD test guidelines, this study was carried out with intact skin and therefore does not account for use on broken skin which would result in an increased dermal absorption of resorcinol. As listed in Annex III of the Cosmetic Products Regulation UK No 1223/2009 (as amended), the label of hair dye products containing resorcinol must state, amongst others, the following condition of use 'Do not colour your hair if: you have a rash on your face or sensitive, irritated and damaged scalp'.
- 4.4 Members discussed the applicability of this dermal absorption value to the exposure scenario for hair dye products, considering the hair dying process and that the scalp contains multiple hair follicles. Hair dye is rinsed off after approximately 30 minutes which is accounted for in the dermal penetration study by Toner and Roper (2005). The skin samples used in the study were, however, from female breast and abdomen skin which contain hair follicles at a lower density than the scalp. There have been limited studies on the contribution of the follicular route to dermal absorption, with no data available specifically for resorcinol. A study by Sebastia-Saez et al., (2024) investigated the contribution of hair follicles to the overall dermal permeability of small molecules using *in silico* methods. The study results indicated that this depends on the combination of lipophilicity/hydrophilicity of the substance filling the follicular route, and the permeant. Studies looking at the role of hair follicles in percutaneous absorption and the development of mechanistic



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models of the follicular pathway have also been identified using caffeine as the test compound (Otberg et al., 2007; Kattou et al., 2017). In the absence of specific data, members noted that follicular absorption can contribute at early time points for non-lipophilic molecules however this is not likely to be significant for resorcinol.

4.5 Members discussed the potential for resorcinol or its derivatives to persist in the hair shafts and agreed that this is unlikely given the role of resorcinol as a hair dye coupler. Resorcinol reacts with other dye precursors to form the final hair colour, and it is these hair dye oligomers which are locked in the hair shaft. Any residual resorcinol will be rinsed off during the hair washing process. Members were therefore content that the dermal absorption value of $2.06 \mu\text{g}/\text{cm}^2$ is applicable to the hair dye exposure scenario and is appropriate to be used in the safety assessment.

4.6 Based on the data available to the SAG-CS, members were of the opinion that resorcinol is not an endocrine disruptor but may be considered endocrine active, as according to the WHO/IPCS definition⁴ (WHO/IPCS, 2002). The limited data presented in the [SCCS, \(2021\)](#) opinion had mixed results but indicated some evidence of thyroid disruption. Members discussed a paper by Pasquier et al., (2023) in relation to the potential thyroid disrupting effects of resorcinol. There is a current CLH report which has been submitted to ECHA, proposing that resorcinol is classified as a category 1 endocrine disruptor for human health (ED HH 1) based on its potential effects on the thyroid. Depending on the outcome of this report, members may wish to review the endocrine disrupting potential of resorcinol again in the future. Members noted that the NOAEL used as the Point of Departure in the safety assessment would likely be protective of any potential endocrine effects.

4.7 The available mutagenicity and genotoxicity data for resorcinol were reviewed by members. Several *in vitro* studies were submitted. Resorcinol was not mutagenic in the Ames test (Williams, 2005). In a mammalian cell gene mutation test in mouse lymphoma cells at the *hprt* locus, resorcinol did not induce gene mutations (Lloyd, 2009). Members noted that the *hprt* locus is generally considered a less sensitive target for some mutagens, compared with the *tk* locus, with a lower spontaneous mutation frequency, requiring more cells for effective testing (Liber et al., 1989). In the more sensitive mouse lymphoma assay using the *tk* locus, resorcinol induced mutagenic activity in the absence of metabolic activation and there was evidence of clastogenicity (Sire, 2004). Resorcinol was tested in the absence and

⁴ “An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.”



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presence of metabolic activation (S9 mix) in an *in vitro* micronucleus assay in human peripheral blood lymphocytes in two independent experiments. Resorcinol was clastogenic in the absence of S9 mix in both experiments. The results in the presence of S9 mix are mixed. The first experiment showed a concentration-related increase in micronucleus frequency when assessed up to the limit of cytotoxicity (94.49 µg/mL), but this effect was not replicated in the second experiment when assessed up to a notably higher limit of cytotoxicity (704 µg/mL) (Whitwell, 2004). Members agreed there was sufficient evidence that resorcinol is clastogenic *in vitro*, however comprehensive *in vivo* data are lacking. One *in vivo* study, a rat bone marrow micronucleus assay, was submitted, which was negative for clastogenicity up to the maximum tolerated dose of 500 mg/kg (Erexson, 2005). Additionally, in a 2-year carcinogenicity study, there was no evidence of carcinogenic activity of resorcinol in rats or mice at doses up to 225 mg/kg (NTP, 1992). Based on the weight of available evidence, together with the fact that the mutagenicity and clastogenicity observed *in vitro* was not observed in the limited *in vivo* data, members were content that resorcinol does not have genotoxic potential *in vivo* at concentrations relevant to cosmetic use.

4.8 Members agreed to use a Point of Departure (PoD) of 80 mg/kg bw/day in the safety assessment. This has been derived from two studies by Foulon, (2005a) and Foulon, (2005b), which are a prenatal developmental toxicity study and a 13-week toxicity study, respectively.

4.9 Members noted that there may be additional safety concerns for resorcinol in eyelash dyes, given the category 2 classification for eye irritation. However, at the low concentration proposed there should be limited risk. Members also queried whether absorption through the mucous membrane of the eye, which is highly permeable, might occur. No specific data on this could be identified, but with correct use by the consumer, as already stipulated in the cosmetic products regulation there should be no or very minimal contact with the mucous membrane. Overall, there was no concern for systemic toxicity resulting from the use of resorcinol in eyelash products due to the low systemic exposure with correct use.



5. Conclusions

Members were content that appropriate analytical methods are available for resorcinol and could be applied routinely following appropriate validation.

Members considered that resorcinol is endocrine active in vitro but based on the currently available evidence does not meet the WHO definition of an endocrine disruptor.

Members noted there was sufficient evidence that resorcinol is clastogenic in vitro. An in vivo rat bone marrow micronucleus study with resorcinol did not show genotoxic potential in vivo. There was also no evidence of carcinogenicity of resorcinol in vivo. Members therefore concluded that resorcinol does not have genotoxic potential in vivo at concentrations relevant to cosmetic use.

Members concluded that resorcinol is acceptable for use as a cosmetic ingredient in the following product types, when adhering to the conditions of use to be printed on the label as already stipulated in the cosmetic products regulation, and at the following concentrations:

- *Oxidative hair dye products intended for the hair and to colour eyelashes- maximum on-head concentration of 1.25%*
- *Hair lotions and shampoos- 0.5%*

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January 2026



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Abbreviations

ADI	Acceptable Daily Intake
ANS	EFSA Panel on Food Additives and Nutrient Sources added to Food
CIR	Cosmetics Ingredient Review
CLH	Harmonised Classification and Labelling
CLP	Classification, Labelling and Packaging
ECHA	European Chemicals Agency
ED	Endocrine Disruptor
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
FSA	Food Standards Agency
GLP	Good Laboratory Practice
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOAEL	Low Observed Adverse Effect Level
MLC	Mandatory Classification and Labelling
MoS	Margin of Safety
NOAEL	No Observed Adverse Effect Level
NTP	National Toxicology Program (United States)
OECD	Organisation for Economic Co-operation and Development
PoD	Point of Departure
REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals
SCC	Scientific Committee on Cosmetology
SCCNFP	Scientific Committee on Cosmetic and Non-Food Products
SCCP	Scientific Committee on Consumer Products
SCCS	Scientific Committee on Consumer Safety
SED	Systemic Exposure Dose
WHO	World Health Organization



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Safety Assessment

The full industry dossier, key studies and other references have been supplied to the SAG-CS.

Using the maximum use level for resorcinol of 2.5% (1.25% on head), the following exposure and Margin of Safety calculations have been performed. As a worst-case approach, it is assumed that oxidative hair dye is applied to the head daily. Calculations have therefore not been undertaken for hair lotions/shampoos which have a lower maximum use concentration of 0.5% resorcinol. Calculations have also not been included for hair dye products intended for the eyelashes/eyebrows as exposure via this route will be low. Data on irritation (eye/skin) is evaluated in Annex 1 (provided to the SAG-CS).

A dermal absorption value of $2.06 \mu\text{g}/\text{cm}^2$ has been applied based on the study by Toner and Roper (2005).

A point of departure (PoD) of 80 mg/kg bw/day is used based on the NOAEL of 80 mg/kg bw/day derived from two key studies (described in detail in Annex 1 to this paper) by Foulon 2005a (a prenatal developmental toxicity study) and Foulon 2005b (a 13-week toxicity study). No bioavailability adjustment has been applied to the NOAEL.

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

No children's assessment has been carried out based on the age restrictions for the use of resorcinol containing hair dye products.



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Table 1) Calculation of SED and MoS for oxidative hair dye products containing resorcinol at a maximum concentration of 2.5% (final on head concentration 1.25%).

Exposure assumptions	Resorcinol in oxidative hair dye products (1.25% on head concentration)
Percutaneous absorption (ug/cm ²) ¹	2.06
Mean surface area of exposed scalp (cm ²) ²	580
Frequency of application (per day)	1
Default body weight of adult (kg) ³	70
NOAEL (mg/kg bw/day)	80
SED (mg/kg/day) ⁴	0.0171
MoS ⁵	4687
Acceptable MoS	100
Conclusion	Acceptable

SED – Systemic exposure dose

MoS – Margin of safety

1 – Derived from the *in vitro* percutaneous absorption study by Toner and Roper (2005) using a formulations containing resorcinol coupled with PPD and mixed with hydrogen peroxide for a final concentration of 1.25%.

2 – From Bremmer, (2006a; 2006b) as in the SCCS Notes of Guidance 12th revision (2023) for oxidative/permanent hair dyes.

3-Default body weight (<https://www.gov.uk/government/groups/scientific-advisory-group-on-chemical-safety-in-consumer-products>)

4-[(percutaneous absorption/1000) x surface area of exposed scalp x frequency of application per day]/default body weight as in the SCCS Notes of Guidance (2023)

5– Margin of Safety was calculated by dividing the PoD (80 mg/kg/day) by the SED