



Scientific Committee on Consumer Safety

SCCS

## **OPINION ON**

# **Oxidative hair dye substances and hydrogen peroxide used in products to colour eyelashes**

The SCCS adopted this opinion by written procedure on 12 October 2012

### About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

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).

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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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This opinion has been subject to a commenting period of four weeks after its initial publication. Comments received during this time have been considered by the SCCS and discussed in the subsequent plenary meeting. Where appropriate, the text of the relevant sections of the opinion has been modified or explanations have been added. In the cases where the SCCS after consideration and discussion of the comments, has decided to maintain its initial views, the opinion (or the section concerned) has remained unchanged.

Revised opinions carry the date of revision.

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## 1. BACKGROUND

The professional use of oxidative hair dyes to colour eyelashes is widespread in the EU. For example, it is currently estimated that there are over 10 million applications in Germany and Austria of such substances for this purpose per year. The products are sold exclusively for professional use at a hairdresser's studio or beauty salon. They are used subject to special protective measures (eyes closed, eyelids covered by special protective shields), have been on the market for many years and do not seem to raise concerns in terms of compatibility.

The current EU Cosmetics Directive does not contain any basic definition of "hair" or "hair product", and therefore does not contain any specific requirements for the application of hair (care) products to eyelashes, apart in a number of provisions relating to some specific substances. Hair dye products containing these substances must be labelled "Do not use to dye eyelashes and eyebrows" unless intended for professional use.

Up to date, there is only one substance, namely silver nitrate listed in entry 48 in Annex III, Part 1 to Cosmetics Directive, which is specifically authorized for colouring eyelashes in a concentration of up to 4%.

The definition of the term "hair product" was introduced in the preamble to Annexes II to VI of the EC Cosmetics Regulation. This means that, a "hair product" is defined as a cosmetic product which is intended to be applied on the hair of head or face, except eyelashes.

The application of the newly defined term "hair product" in conjunction with provisions relating to specific substances in the new Annex III to the EU Cosmetics Regulation will restrict the use of relevant substances, as is clearly shown in the case of hydrogen peroxide (Annex III, entry 12): according to the above definition, hydrogen peroxide can therefore no longer be applied to eyelashes, even though it can still be used in "hair products" (The previous reference in the Cosmetics Directive is to "hair-care mixtures", although this term was not expressly defined in the Directive). Moreover, it will no longer be legally possible to market oxidative colouring agents for application to eyelashes in the EU from July 2013.

Like conventional dyes for hair on the scalp, oxidative hair dyes for use on the eyelashes consist of two components, with a hydrogen peroxide preparation being used as a developer, but normally containing only up to 4% hydrogen peroxide (conventional hair dyes contain up to 12%), corresponding to a concentration applied on the eyelashes (in the mixture to be used) of up to 2%. The colouring components are the same as are used in conventional hair dye products and have already been (and some of them are still being) comprehensively assessed for their safety by the SCCS in the framework of the hair dye strategy.

### *Oxidative hair dye substances currently used in products to colour eyelashes*

The following hair dyes that are authorised in the EU Cosmetics Directive - or which authorisation is in the course of being obtained - are currently used in oxidative eyelash dyes up to the maximum permitted concentrations:

Table 1: Oxidative hair dye substances currently used in products to colour eyelashes

<b>INCI-name</b>	<b>Colipa No.</b>	<b>Regulatory status in Cosmetics Directive</b>
Toluene-2,5-diamine sulfate	A005	III,1/9a (under assessment)
<i>p</i> -Phenylenediamine	A007	III,1/8a (under assessment)
2-Chloro- <i>p</i> -phenylenediamine sulfate	A008	under assessment
N-Phenyl- <i>p</i> -phenylenediamine	A009	III,1/8

INCI-name	Colipa No.	Regulatory status in Cosmetics Directive
Resorcinol	A011	III,1/22
4-Chlororesorcinol	A012	new draft directive
<i>m</i> -Aminophenol	A015	III,1/217
<i>p</i> -Aminophenol	A016	under assessment
1-Naphthol	A017	III,1/16
4-Amino-2-hydroxytoluene	A027	III,1/243
2-Methyl-5-hydroxyethylaminophenol	A031	III,1/232
2,4-Diaminophenoxyethanol HCl	A042	III,1/244
2,4-Diaminophenoxyethanol sulfate	A042	III,1/244
2-Methylresorcinol	A044	III,1/245
Tetraaminopyrimidine sulfate	A053	new draft directive
4-Amino- <i>m</i> -cresol	A074	III,1/246
1,3-Bis-(2,4-diaminophenoxy)propane HCl	A079	III,1/202
Hydroxyethyl- <i>p</i> -phenylenediamine sulfate	A080	new draft directive
2-Amino-4-hydroxyethylaminoanisole sulfate	A084	III,1/248
5-Amino-6-chloro- <i>o</i> -cresol	A094	under assessment
6-Methoxy-2-methylamino-3-aminopyridine HCl	A130	III, 1/203
2-Amino-3-hydroxypyridine	A132	new draft directive
2,6-Diaminopyridine	A136	under assessment

### Assessment strategy for hair dye substances

The safety data on each hair dye substance submitted for risk assessment by the SCCS in the framework of the assessment strategy contain mandatory data on eye irritation. Therefore, the safety of these substances with regard to the application in the eye area was or will be assessed in the overall evaluation of each individual hair dye substance.

## 2. TERMS OF REFERENCE

1. *Does SCCS consider the safety data, in particular the data provided on eye irritation, sufficient to conclude that oxidative hair dyes which were found safe for use in hair dye products can be safely used in products to colour eyelashes? If not, which data would be required by SCCS in order to carry out safety assessment for this specific field of application?*
2. *Taking into account the scientific data available for the assessment of hydrogen peroxide used in oral hygiene products and tooth whitening products, does SCCS consider hydrogen peroxide safe for use in products to colour eyelashes (after mixing with oxidative hair dyes found safe for use in hair dye products) in concentrations up to 2% applied on eyelashes?*

### 3. OPINION

No comprehensive information on the composition of products for the dyeing of eye lashes has been available for this assessment. The opinion is based on information obtained from:

- EU member states (list of substances in use for eye lash dyeing),
- A public call for information launched by the European Commission, during which information on some individual products (composition, application procedure) was obtained from manufacturers. It is unknown whether these products are representative for the different eye lash dyeing products on the European market.

#### 3.1. Chemical and Physical Specifications

The table below shows the dyes used and their content (rounded to 1 decimal place) for four eyelash dyes from a single European manufacturer. The extent to which these formulations are representative is unknown.

##### Eyelash Dye composition

Black	Blue	Brown	Light Brown
040109	040106	040108	040107
<i>p</i> -phenylenediamine, 2.0%  2,6-diaminopyridine sulphate, 1.7%	2,4-diaminophenoxyethanol HCl, 1.3%  Toluene-2,5-diamine, 0.6%	Toluene-2,5-diamine sulphate, 2.1%  2-methylresorcinol, 0.8%  2,4-diaminophenoxy ethanol HCl, 0.1%	2-methylresorcinol, 0.4%

Ref.: 5, 6, 8, 9

These dyes require mixing with an oxidising preparation, which, in the case of the above, contains 3% hydrogen peroxide.

Ref.: 10

The same manufacturer also recommends the use of a perming gel (to curl the eyelashes) before dyeing. This gel contains (amongst other ingredients) ammonium thioglycolate (10.7%), ammonia (0.9%) and ethylenediamine (0.9%).

Ref.: 7

The SCCS is aware of an example where 2-chloro-*p*-phenylenediamine is used in a self-use product.

#### 3.2. Function and uses

The hair dyes listed in the background are used in oxidative hair dye formulations for the colouring of eye lashes at the maximum on-head concentrations which are stated in annex III of the Directive or as assessed in the respective SCCS Opinions. For the colouring of eyelashes, these hair dyes are used in combination with a hydrogen peroxide developer preparation, normally containing up to 4% hydrogen peroxide, corresponding to a concentration applied on the eyelashes (in the mixture to be used) of up to 2%.

The procedure of application of the dye mixture to eyelashes may vary. For one product on which information was received, the following method is given (ref 28):

Immediately prior to application, the dye and hydrogen peroxide are mixed using an application stick in the proportions prescribed by the producer. Once the customer has closed her eyes, the mixture is applied to the eyelashes with the application stick until they are entirely covered. The application time is up to 10 minutes. At the end of the application time, most of the dye is removed with a cotton bud.

### **3.3. Toxicological Evaluation**

This Opinion deals with the assessment of oxidative hair dyes for the specific use to colour eye lashes. There is an on-going review of the safety of these substances, when used to dye hair on the scalp, to all relevant toxicological endpoints. Whilst the reviews are complete for some of the dyes, other dyes are yet to be assessed or the assessments are partial.

Potential exposure (dose) of hair dye chemicals is enormously lower when used on eyelashes. Therefore, the toxicological endpoints of concern are skin and eye irritation and skin sensitisation.



## OXIDATIVE HAIR DYE PRECURSORS

Table 2 below is a summary of the eye irritation results and skin sensitisation potential of the oxidative hair dyes listed in Table 1 (Background) for use on eyelashes:

Table 2: Oxidative hair dye substances currently used in products to colour eyelashes

COLIPA n°	INCI name (CAS n°)	Eye irritation potential	Sensitising potency category, based on results from LLNA or guinea pig assays	LLNA EC3 value (%)	Guinea pig assay  GPMT: i.d. induction conc (%)/incidence of sens (%)  Buehler test: topical induction conc (%)/incidence of sens (%)	References
A5	Toluene-2,5-diamine (95-70-5)  Use concentration: 2.0% (free base), 3.6% (sulfate)	Eye irritation studies have demonstrated that 50.6% toluene-2,5-diamine is irritant to the rabbit eye. Some irritant effects were also seen with 2.5% toluene-2,5-diamine.	Extreme	0.31	GPMT 0.1/100 (modified method)	SCCS/1479/12
A7	<i>p</i> -Phenylenediamine (106-50-3)  Use concentration: 2.0%	PPD was not irritant or corrosive for the skin and the eye when applied in a 2.5% aqueous solution.	Extreme	0.06		SCCS/1443/11

## Opinion on oxidative hair dye substances and hydrogen peroxide used in products to colour eyelashes

COLIPA n°	INCI name (CAS n°)	Eye irritation potential	Sensitising potency category, based on results from LLNA or guinea pig assays	LLNA EC3 value (%)	Guinea pig assay GPMT: i.d. induction conc (%) / incidence of sens (%)  Buehler test: topical induction conc (%) / incidence of sens (%)	References
A8	2-Chloro- <i>p</i> -phenylenediamine (615-66-7)  Use concentration: 2.5%	The compound (2.5% aqueous solution in distilled water with 0.05% sodium sulphite, pH 7) instilled into one eye of 3 rabbits produced no signs of irritation after 1, 2, 3, 4 and 7 days of observation period; in this study, the treated eye was irrigated with distilled water 10 seconds after treatment.	Moderate			4 October 1991
A9	N-Phenyl- <i>p</i> -phenylenediamine (101-54-2; 2198-59-6, hydrochloride; 4698-29-7, sulfate)  Use concentration: 0.2%	No data submitted	Extreme	0.02	-	SCCP/0991/06
A11	Resorcinol (108-46-3)  Use concentration: 1.25%	A 2.5% concentration of resorcinol caused mild conjunctival irritation to the rabbit eye.	Strong	1.4	-	SCCS/1270/09
A12	4-Chlororesorcinol (95-88-5)  Use concentration: 2.5%	Neat 4-chlororesorcinol is corrosive to the eyes.	Moderate	5.8	-	SCCS/1224/09

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COLIPA n°	INCI name (CAS n°)	Eye irritation potential	Sensitising potency category, based on results from LLNA or guinea pig assays	LLNA EC3 value (%)	Guinea pig assay GPMT: i.d. induction conc (%) / incidence of sens (%)  Buehler test: topical induction conc (%) / incidence of sens (%)	References
A15	<i>m</i> -Aminophenol (591-27-5; 51-81-0, hydrochloride; 68239-81-6, sulfate; 38171-54-9, sodium salt)  Use concentration: 1.2%	<i>m</i> -Aminophenol at 2% was non-irritating to rabbit eyes.	Strong	0.24	-	SCCP/0978/06
A16	<i>p</i> -Aminophenol (123-30-8, free base) (51-78-5, HCl)  Use concentration: 0.9%	<i>p</i> -Aminophenol was irritant on mucous membranes at 2.5% aqueous solution and when applied neat to rabbit eye.	Strong	-	Non-guideline tests indicating strong sensitising potency	SCCS/1409/11
A17	1-Naphthol (90-15-3)  Use concentration: 2.0%	Although all effects were transient, aqueous dilutions of 1-naphthol of 0.5 to 2.5% caused eye irritation to rabbits with irritant effects increasing with increasing dose.	Strong	1.3	Non-guideline tests, not conclusive	SCCP/1123/07
A27	4-Amino-2-hydroxytoluene (2835-95-2)  Use concentration: 1.5%	Under the described test conditions, a 2.5% aqueous solution of 4-amino-2-hydroxy toluene showed transient irritation to the conjunctivae.	Strong	0.44	-	SCCP/1001/06

## Opinion on oxidative hair dye substances and hydrogen peroxide used in products to colour eyelashes

COLIPA n°	INCI name (CAS n°)	Eye irritation potential	Sensitising potency category, based on results from LLNA or guinea pig assays	LLNA EC3 value (%)	Guinea pig assay GPMT: i.d. induction conc (%) / incidence of sens (%)  Buehler test: topical induction conc (%) / incidence of sens (%)	References
A31	2-Methyl-5-hydroxyethylaminophenol (55302-96-0)  Use concentration: 1.5%	2-Methyl-5-hydroxyethylaminophenol is an irritant to rabbit eyes when tested undiluted. The single instillation of 0.1 ml of 2% 2-methyl-5-hydroxyethylaminophenol in a 0.5% carboxymethylcellulose suspension was non-irritating to rabbit eyes.	Not classifiable	no value	-	SCCP/0957/05
A42	2,4-Diaminophenoxyethanol HCl (66422-95-5)  Use concentration: 2.0%	2,4-Diaminophenoxyethanol was slightly irritant to rabbit eyes when tested undiluted or at 4% in water.	Moderate	3.2	Buehler 100/10	SCCS/1367/10
A44	2-Methylresorcinol (608-25-3)  Use concentration: 1.8%	Undiluted 2-methylresorcinol was severely irritant to the rabbit eye.	Moderate	50	A 5% (w/v) aqueous solution did not produce dermal sensitisation on Guinea pigs.	SCCP/1206/08
A53	Tetraaminopyrimidine (5392-28-9, sulfate)  Use concentration: 2.0% (free base); 3.4% (sulfate)	Undiluted tetraaminopyrimidine was irritant to the eye.	Insufficient testing	No value. Should have been tested at higher conc. or in other vehicle	A test formulation containing 4.2% A53 did not cause sensitisation.	SCCP/1118/07
A74	4-Amino- <i>m</i> -cresol (2835-99-6)  Use concentration: 1.5%	At 1.5%, 4-amino- <i>m</i> -cresol may have minimal ocular irritant potential.	Strong	1.45	-	SCCP/0895/05

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COLIPA n°	INCI name (CAS n°)	Eye irritation potential	Sensitising potency category, based on results from LLNA or guinea pig assays	LLNA EC3 value (%)	Guinea pig assay GPMT: i.d. induction conc (%) / incidence of sens (%)  Buehler test: topical induction conc (%) / incidence of sens (%)	References
A79	1,3-Bis-(2,4-diamino-phenoxy)-propane HCl (81892-72-0, free base; 74918-21-1, HCl)  Use concentration: 1.2% (free base); 1.8% (tetrahydrochloride)	Undiluted 1,3-bis-(2,4-diaminophenoxy)propane was irritating to mucous membranes.	Moderate	14.7	The formulation containing the compound (5%) was considered a non-sensitiser in Guinea pigs.	SCCP/1098/07
A80	Hydroxyethyl-p-phenylenediamine sulphate (93841-25-9)  Use concentration: 2.0%	Under the conditions of the test, undiluted hydroxyethyl-p-phenylenediamine sulfate was irritant to rabbit eyes.	Strong	0.57	-	SCCS/1310/10
A84	2-Amino-4-hydroxyethylaminoanisole (83763-47-7)  Use concentration: 1.5%	Under the conditions of the test, 1% aqueous solution of 2-Amino-4-hydroxyethylaminoanisole sulphate caused transient conjunctival irritation to the eyes of guinea pigs.	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS/1250/09
A94	5-Amino-6-chloro-o-cresol  Use concentration: 2.0% (free base)	Under the conditions of the study, undiluted 5-amino-6-chloro-o-cresol was irritating to the rabbit eye.	Not classifiable	No value	The GPMT was considered inadequate	SCCS/1225/09
A130	6-Methoxy-2-methylamino-3-aminopyridine HCl (83732-72-3, 2HCl; 90817-34-8, HCl)  Use concentration: 0.68% (free base); 1.0% (hydrochloride)	A 5% solution of 6-methoxy-2-methylamino-3-aminopyridine HCl was not irritating to the rabbit eye.	Moderate	5.6	The Magnusson & Kligman test showed no evidence of sensitisation (5% in propylene glycol and in FCA (1:1)) .	SCCP/1121/07

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<b>COLIPA n°</b>	<b>INCI name (CAS n°)</b>	<b>Eye irritation potential</b>	<b>Sensitising potency category, based on results from LLNA or guinea pig assays</b>	<b>LLNA EC3 value (%)</b>	<b>Guinea pig assay</b>  GPMT: i.d. induction conc (%)/incidence of sens (%)  Buehler test: topical induction conc (%)/incidence of sens (%)	<b>References</b>
A132	2-Amino-3-hydroxypyridine (16867-03-1)  Use concentration: 1.0%	Undiluted 2-Amino-3-hydroxypyridine was irritating to the rabbit eye.	Not classifiable	no value	-	SCCP/1126/07
A136	2,6-Diaminopyridine (141-86-6)  Use concentration: 0.15%	A 3% 2,6-diaminopyridine in water solution was slightly irritant to the eye of the rabbits under the conditions in the study.	Strong	-	-	SCCS/1450/11

Three of the oxidative dyes are classified as extreme sensitisers. 9 as strong sensitisers, 5 as moderate sensitisers and 5 are unclassifiable.

Information of eye irritation at anticipated use dilutions in products intended for eyelashes is available for only some of the dyes. For those tested near anticipated use dilutions there was either no or only slight irritant potential. The irritant potential of those which have not been tested at use dilutions but which are irritant at the concentrations tested, is unknown.

## **HYDROGEN PEROXIDE**

The safety of hydrogen peroxide in relation to its use in oral hygiene products was assessed by the SCCP in SCCP/1129/07.

In the opinion it was stated that 4 hours exposure to 10% hydrogen peroxide caused slight skin irritation to the rabbit. A 5% solution of hydrogen peroxide was slightly irritating to the rabbit eye whilst 10% was highly irritating. The threshold of detection of hydrogen peroxide when instilled onto the human eye is 0.1%.

Hydrogen peroxide has been shown to cause toxicity to corneal epithelial cells *in vitro* at concentrations as low as 30 ppm. The effects of ocular exposure in humans have been reviewed. Exposure to 3% solutions may cause immediate stinging, irritation, lacrimation and blurred vision and sub-epithelial corneal and conjunctival bubbles may be observed. Corneal opacity has been reported following the use of hydrogen peroxide-soaked tonometer tips. Insertion (without neutralisation) of a soft contact lens that had been stored for 1 week in 3% hydrogen peroxide caused an almost immediate central white corneal opacity. There was no discomfort or reflex tearing and the lesion resolved over several days.

Ref.: 32

Hydrogen peroxide is not considered a skin sensitiser.

### **Comment**

Based on the SCCP Opinion (SCCP/1129/07), it could be extrapolated that transient exposure to 2% hydrogen peroxide may be slightly irritant to the eye.

## **COMMERCIAL EYELASH DYE PRODUCTS**

### **Skin irritation**

The irritation potential of several eyelash dyes was tested on rabbit skin.

Guideline:	Journal Officiel République Française 21/2/82
Species:	Rabbit; 3 white male New Zealand
Dose:	0.5ml
Material ID:	/
Batch:	/
Area of application:	/
Application:	non-abraded and abraded skin
Duration of application:	/
Readings:	1 day 3 days (erythema, oedema)
GLP:	/
Date:	2003

colour	24 hours Erythema	72 hours Erythema
Black (Ref 18)	Non-abraded 3/3 Abraded 3/3	Non-abraded 3/3 Abraded 3/3
Blue (Ref 15)	Non-abraded 3/3 Abraded 3/3	Non-abraded 2/3 Abraded 3/3
Brown (Ref 17)	Non-abraded 3/3 Abraded 3/3	Non-abraded 0/3 Abraded 3/3
Light Brown (Ref 16)	Non-abraded 3/3 Abraded 3/3	Non-abraded 2/3 Abraded 2/3

Ref.: 15, 16, 17, 18

#### Results

The results indicate that the tested products have irritant potential to the rabbit skin. Erythema was seen in all animals at the 1 day reading.

#### Comment

It is unknown whether the experiments were conducted with the indicative dye formulations listed in section 3.1. No batch identifications or formulation details were given. Additionally, it is not stated whether they were mixed with oxidiser. It is also unknown how these four colours are representative of dye formulations for eyelash colouring in the EU market. The study was not performed under GLP.

Additional studies (Refs 26 and 25) cannot be assessed as no information on the composition of the test substance ('Permanent Gel' and 'Special Dye Solution' respectively) was provided.

#### Eye Irritation

The irritation potential of several eyelash dyes was tested on the rabbit eye.

Guideline: Journal Officiel République Française 10/7/92  
 Species: Rabbit; 3 white male New Zealand  
 Dose: 0.1ml  
 Material ID: /  
 Batch: /  
 Readings: 1 hour and at days 1, 2, 3, 4 and 7  
 GLP: /  
 Date: 2003

colour	1 hour	Day 1	Day 2
Black (Ref 22)	Conjunctival oedema and redness 3/3	Conjunctival redness 3/3 Corneal opacity 1/3	nil



	Corneal opacity 2/3		
Blue (Ref 19)	Conjunctival oedema and redness 3/3 Corneal opacity 0/3	nil	nil
Brown (Ref 21)	Conjunctival oedema and redness 3/3 Corneal opacity 2/3	Conjunctival redness 1/3	nil
Light Brown (Ref 20)	Conjunctival oedema and redness 3/3 Corneal opacity 0/3	Nil	nil

Ref.: 19, 20, 21, 22

**Results**

The results indicate that the tested materials can cause transient irritation to rabbit eyes. Any reactions had largely settled by day.

**Comment**

It is unknown whether the experiments were conducted with the indicative dye formulations listed in section 3.1. No batch identifications or formulation details were given. Additionally, it is not stated whether they were mixed with oxidiser. It is also unknown how these four colours are representative of dye formulations for eyelash colouring in the EU market. The study was not performed under GLP.

Additional studies (Refs 24 and 23) cannot be assessed as no information on the composition of the test substances ('Permanent Gel' and 'Special Dye Solution' respectively) was provided.

**Human Data**Use tests

Two series of experiments in which commercial eyelash dye products were used on 10 volunteers in each experiment showed good tolerance with no side effects experienced by the subjects. In each experiment the eyelashes were first curled using an eyelash perming gel before application of the oxidative dye.

Several colours appear to have been used but formulation details and characteristics are not disclosed in the reports.

Ref.: 13, 14

Cosmetovigilance

From one producer, a few reports of adverse reactions to their eyelash dyes are available (2010-2011). Of the 5 cases, none were investigated and ranged from 'stinging' to 'allergic'.

Ref.: 28

Another manufacturer reported that, out of 800 000 units sold, only a single case of eye irritation was reported (2011-2012) and this was caused by incorrect application of the product.

Ref.: 29

Three reports from direct consumer complaints are provided by a supplier. Two were dismissed as instructions had not been followed and the other was described as that expected from an allergic reaction.

Refs 2, 3, 4

### Case Reports

Case reports of allergic contact dermatitis to 2-chloro-*p*-phenylenediamine, *p*-phenylenediamine, toluene-2,5-diamine and *m*-aminophenol in eyelash dyes have been described.

Ref.: 31, 34, 35

### Comment

The use tests were performed under laboratory conditions where attention to application is expected.

It is unknown how representative the cosmetovigilance reports are of the true incidence of adverse reactions, but they may be indicative.

## **Discussion**

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The critical toxicological endpoints considered of relevance to the use of oxidative dyes on eyelashes are skin and eye irritation and skin sensitisation, either by the dye substance or hydrogen peroxide used as oxidant.

Information of eye irritation at or near anticipated use concentrations intended for eyelashes is available for only some of the dye substances indicated to be used in eyelash colouring products. For those tested at such concentrations there was either no or slight irritant potential. It is unknown what the irritant potential is of those dyes which have not been tested at use concentrations but which are irritant at the concentrations tested.

Based on a previous SCCP Opinion (SCCP/1129/07), it could be extrapolated that transient exposure to 2% hydrogen peroxide may be slightly irritant to the eye.

Accidental introduction of an oxidative dye or hydrogen peroxide onto the eye would cause rapid elimination by lachrymation. Only mild and transient irritation is expected from those substances for which information is available.

There is no detailed information on what the ocular irritant properties are of mixtures of dyes in actual formulations intended for application to eyelashes. Some indicative experiments (probably performed without addition of oxidiser) suggest transient irritant potential.

Four of the oxidative dyes listed as being used in permanent eyelash dyes (Table 1) are classified as extreme sensitisers. 8 as strong sensitisers, 5 as moderate sensitisers and 4 are unclassifiable. There is potential for an allergic contact reaction to occur if the eyelid margin is exposed to dyes which are sensitizers or if there is greater (accidental) exposure to the eyelid skin. Individuals with a history of an allergic reaction to hair dyes are at particular risk.

The available cosmetovigilance data indicates few reported adverse reactions to permanent eyelash dyes but it is unknown how representative the cosmetovigilance reports are.

Although the Background information states that the permanent eyelash dyes are for professional use only, products are known to be available for 'home use'.

#### 4. CONCLUSION

1. *Does SCCS consider the safety data, in particular the data provided on eye irritation, sufficient to conclude that oxidative hair dyes which were found safe for use in hair dye products can be safely used in products to colour eyelashes? If not, which data would be required by SCCS in order to carry out safety assessment for this specific field of application?*

Information of eye irritation of oxidative dyes at or near anticipated use concentrations intended for eyelashes is available for only some of the dyes. For those tested at such concentrations there was either no or slight irritant potential and their use is considered safe in permanent eyelash dye formulations intended for the consumer. Dyes tested at higher concentration which were found to be not or slightly irritant can be considered safe.

It is unknown what the irritant potential is of those dyes which have not been tested at use concentrations but which are irritant at the concentrations tested. For these substances appropriate information is required before they can be assessed.

	<b>Not or slightly irritant</b>	<b>irritant</b>
oxidative dyes tested at or near anticipated use concentrations	A8, A11, A15, A27, A31, A33, A42, A74, A84	/
Oxidative hair dyes tested at higher concentration than use concentration	A7, A130, A136	A5, A12, A16, A17, A44, A53, A79, A80, A94, A132

For those hair dyes substances for which there is information on eye irritation at anticipated dilutions and were found to have no or slight effects, there is no concern about eye irritation in the consumer.

For those hair dyes substances for which there is no information on eye irritant potential at anticipated dilutions, it is not possible to draw a conclusion without additional information on eye irritant potential at anticipated use concentrations.

For those dyes which are skin sensitizers, there is a risk of allergic contact dermatitis developing in previously sensitised individuals.

No detailed information is available on the ocular irritant properties of permanent eyelash dyes formulations intended for the consumer and these formulations need to be assessed on a case by case basis by the supplier.

2. *Taking into account the scientific data available for the assessment of hydrogen peroxide used in oral hygiene products and tooth whitening products, does SCCS consider hydrogen peroxide safe for use in products to colour eyelashes (after mixing with oxidative hair dyes found safe for use in hair dye products) in concentrations up to 2% applied on eyelashes?*

Based on the SCCP Opinion, SCCP/1129/07 and other information it could be extrapolated that transient exposure to 2% hydrogen peroxide may be slightly irritant to the eye. Therefore, up to 2% hydrogen peroxide is considered safe for the consumer when applied on eyelashes.

The background to the mandate refers to the exclusively professional use of oxidative hair dye products for use to colour eye lashes. However, the SCCS is aware that these products are available directly to consumers from the regular retail outlets.

The SCCS considers that the potential risk to the consumer from the use of these products is greater from non-professional use compared with professional use of the same products as there may be increased eye and eyelid contamination.

## 5. MINORITY OPINION

Not applicable

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