EUROPEAN COMMISSION

Directorate-General for Health & Consumers

Scientific Committee on Consumer Safety

SCCS

OPINION ON

Sodium perborate and perboric acid

Scientific Committees
on consumer safety
on emerging and newly identified health risks
on health and environmental risks

The SCCS adopted this opinion at its 7th plenary meeting

of 22 June 2010

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 Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCCS

The Committee shall provide opinions on questions concerning all types of health and safety risks (notably chemical, biological, mechanical and other physical risks) of non-food consumer products (for example: cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.).

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1. BACKGROUND

New classification of sodium perborate and perboric acid as toxic to reproduction according to the Commission Regulation 790/2009[1]

The Cosmetics Directive as modified by the Council and the European Parliament (2003/15/EC[2]), which is based on an opinion of the SCCNFP of September 2001 (SCCNFP/0474/01, final), stipulates that *"the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC shall be prohibited. To that end the Commission shall adopt the necessary measures in accordance with the procedure referred to in Article 10(2). A substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products."*

On 21 August 2008 and on 15 January 2009 the Commission adopted respectively Directives 2008/58/EC[3] and 2009/2/EC[4] amending Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances providing new classifications for some boron compounds[5]. On this occasion sodium perborate and perboric acid have been classified as toxic to reproduction in category 2 and 3 with specific concentration limits. These specific concentration limits indicate that a threshold for reproductive toxicity could be established.

Sodium perborate and perboric acid are covered by the following CAS nos 15120-21-5; 11138-47-9; 12040-75-1; 7632-04-4; 10332-33-9; 13517-20-9; 37244-98-7 and 10486-00-7 (see the annex I).

Sodium perborate and perboric acid might be covered by the restrictions laid down in Annex III entries 1a and 1b of the Cosmetics Directive 76/768/EEC "Boric acid, borates and tetraborates" (this question is addressed in the mandate on some boron compounds with a new classification as mutagenic and/or toxic to reproduction issued in parallel).

Sodium perborate and perboric acid might also be covered by entry 12 of Annex III of the Cosmetic Directive, "Hydrogen peroxide, and other compound or mixtures that release hydrogen peroxide…" (attached Annex II).

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[1] OJ L 235, 5.9.2009, p. 1. Commission Regulation 790/2009, amending for technical purposes the EC Regulation 1272/2008 which deleted Annex I of Council Directive 67/548/EEC as from 20 January 2009 (Article 55(11)), took over the classification provided by the Directives 2008/58/EC and 2009/2/EC, implementing the 30 and 31 ATP, respectively, to the Directive 67/548/EEC

[2] OJ L 66, 11.03.2003, p. 26. See recital (12)
(12) "The SCCNFP stated in its opinion of 25 September 2001 that substances classified pursuant to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances(2) as carcinogenic (except substances only carcinogenic by inhalation), mutagenic or toxic for reproduction, of category 1 or 2, and substances with similar potential, must not be intentionally added to cosmetic products, and that substances classified pursuant to Directive 67/548/EEC as carcinogenic, mutagenic or toxic for reproduction, of category 3, and substances with similar potential, must not be intentionally added to cosmetic products unless it can be demonstrated that their levels do not pose a threat to the health of the consumer."
(2) OJ 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2001/59/EC (OJ L 225, 21.8.2001, p. 1)

[3] OJ L 246, 15.09.2008, p. 1

[4] OJ L 11, 16.01.2009, p. 6

[5] As indicated above, the classification provided by these two Directives has been taken over by Commission Regulation 790/2009 amending EC Regulation 1272/2008

An applicant has applied for the continued use of sodium perborate in powdered, oxidative hair dye formulations up to a maximum concentration applied to the hair of 3.0% (calculated as boric acid).

In light of the new classification of sodium perborate and perboric acid a safety evaluation by the SCCS is necessary, taking into account the scientific data on which the classification has been based and the data provided by the applicant for sodium perborate.

2. TERMS OF REFERENCE

In addition to any answers provided to questions 1 and 2 in the mandate on some boron compounds with a new classification as mutagenic and/or toxic to reproduction issued in parallel, the SCCS is asked to address the following questions:

(1) Based on the current knowledge on the chemistry, biology and toxicology of sodium perborate and perboric acid, does the SCCS consider that sodium perborate and perboric acid can be considered as "hydrogen peroxide" releasing substances in the sense as the already regulated substances in Annex III, entry 12 of the Cosmetics Directive 76/768/EEC?

(2) If the answer to question 1 is yes, does the SCCS consider that the general restrictions applicable to hydrogen peroxide releasing substances should apply to sodium perborate and perboric acid?

(3) Furthermore, does the SCCS consider with the provided scientific data that sodium perborate is safe, when used in (powdered), oxidative hair dye formulations up to a maximum concentration on the head of max.3.0% calculated as boric acid corresponding to a release of x volume percentage hydrogen peroxide?

(4) Sodium perborate and perboric acid have different classifications depending on the percentage content of particles with an aerodynamic diameter below 50 µm. Does the SCCS consider that this has an impact on their safe use in cosmetic products?

Annex I

List of sodium perborate and perboric acid compounds newly classified as CMR 2 (Commission Regulation 790/2009)

Chemical name	EC No	CAS No	Classification	Concentration Limits of Regulation 790/2009
sodium perborate; [1] perboric acid, sodium salt; [2] perboric acid, sodium salt, monohydrate; [3] sodium peroxometaborate; [4] perboric acid (HBO(O2)), sodium salt, monohydrate; [5] sodium peroxoborate;	239-172-9 [1] 234-390-0 [2] - [3] 231-556-4 [4] - [5]	15120-21-5 [1] 11138-47-9 [2] 12040-72-1 [3] 7632-04-4 [4] 10332-33-9 [5]	O; R8 Repr. Cat. 2; R61 Repr. Cat. 3; R62 Xn; R22 Xi; R37-41	C ≥ 25 %: T; R61-22-37-41-62 22 % ≤ C < 25 %: T; R61-37-41-62 20 % ≤ C < 22 %: T; R61-36/37-62 14 % ≤ C < 20 %: T; R61-36-62 9 % ≤ C < 14 %: T; R61-62 6,5 % ≤ C < 9 %: T; R61

Chemical name	EC No	CAS No	Classification	Concentration Limits of Regulation 790/2009
[containing < 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]				
sodium perborate; [1] perboric acid, sodium salt; [2] perboric acid, sodium salt, monohydrate; [3] sodium peroxometaborate; [4] perboric acid (HBO(O2)), sodium salt, monohydrate; [5] sodium peroxoborate; [containing ≥ 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	239-172-9 [1] 234-390-0 [2] - [3] 231-556-4 [4] - [5]	15120-21-5 [1] 11138-47-9 [2] 12040-72-1 [3] 7632-04-4 [4] 10332-33-9 [5]	O; R8 Repr. Cat. 2; R61 Repr. Cat. 3; R62 T; R23 Xn; R22 Xi; R37-41	C ≥ 25 %: T; R61-22-23-37-41-62 22 % ≤ C < 25 %: T; R61-20-37-41-62 20 % ≤ C < 22 %: T ; R61-20-36/37-62 14 % ≤ C < 20 %: T; R61-20-36-62 9 % ≤ C < 14 %: T; R61-20-62 6,5 % ≤ C < 9 %: T; R61-20 3 % ≤ C < 6,5 %: Xn; R20
perboric acid (H3BO2(O2)), monosodium salt trihydrate; [1] perboric acid, sodium salt, tetrahydrate; [2] perboric acid (HBO(O2)), sodium salt, tetrahydrate; [3] sodium peroxoborate hexahydrate; [containing < 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	- [1] - [2] - [3]	13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3]	Repr. Cat. 2; R61 Repr. Cat. 3; R62 Xi; R37-41	C ≥ 36 %: T; R61-37-41-62 22 % ≤ C < 36 %: T; R61-36/37-62 20 % ≤ C < 22 %: T; R61-37-62 14 % ≤ C < 20 %: T; R61-62 10 % ≤ C < 14 %: T; R61
perboric acid (H3BO2(O2)), monosodium salt, trihydrate; [1] perboric acid, sodium salt, tetrahydrate; [2] perboric acid (HBO(O2)), sodium salt, tetrahydrate; [3] sodium peroxoborate hexahydrate; [containing ≥ 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	- [1] - [2] - [3]	13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3]	Repr. Cat. 2; R61 Repr. Cat. 3; R62 Xn; R20 Xi; R37-41	C ≥ 36 %: T; R61-20-37-41-62 25 % ≤ C < 36 %: T; R61-20-36/37-62 22 % ≤ C < 25 %: T; R61-36/37-62 20 % ≤ C < 22 %: T; R61-37-62 14 % ≤ C < 20 %: T; R61-62 10 % ≤ C < 14 %: T; R61

Annex II

Entry 12 of Annex III of the Cosmetics Directive - Annex III (Part 1)
List of substances which cosmetic products must not contain except subject to the restriction and conditions laid down

12	Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	(a) Hair-care preparations (b) Skin-care preparations (c) Nail hardening preparations (d) Oral hygiene products	(a) 12% of H2O2 (40 volumes), present or released (b) 4% of H2O2, present or released (c) 2% of H2O2, present or released (d) 0.1% of H2O2, present or released	(a) Wear suitable gloves (a) (b) (c) Contains hydrogen peroxide Avoid contact with eyes Rinse immediately if product comes into contact with them

3. OPINION

The information used in this opinion is primarily taken from the European Union Risk Assessment Report on Perboric acid, sodium salt (EU, 2007) and publications from Meetings of the Commission Working Group on the Classification and Labelling of Dangerous Substances (ECB, 2004, 2006). Unless explicitly stated otherwise, the SCCS endorses the conclusions drawn in the cited parts of the assessments.

3.1. Chemical and Physical Specifications

3.1.1. Chemical identity

Table 1: Substances considered in the opinion (see annex I)

Chemical name	EC No	CAS No	CMR Classification	Concentration Limits
Sodium perborate; [1] Perboric acid, sodium salt; [2] Perboric acid, sodium salt, monohydrate; [3] Sodium peroxometaborate; [4] Perboric acid (HBO(O2)), sodium salt, monohydrate; [5]	239-172-9 [1] 234-390-0 [2] - [3] 231-556-4 [4] - [5]	15120-21-5 [1] 11138-47-9 [2] 12040-72-1 [3] 7632-04-4 [4] 10332-33-9 [5]	Repr. Cat. 2; R61 Repr. Cat. 3; R62	C ≥6,5 % T; R61
Perboric acid (H3BO2(O2)), monosodium salt trihydrate; [1] Perboric acid, sodium salt, tetrahydrate; [2] Perboric acid (HBO(O2)), sodium salt, tetrahydrate; [3]	- [1] - [2] - [3]	13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3]	Repr. Cat. 2; R61 Repr. Cat. 3; R62	C ≥ 10 %: T; R61

3.1.2. Chemical and Physical Properties

Table 2: Chemical and physical properties of selected perborate compounds (modified from EU, 2007)

	Perboric acid, sodium salt	Sodium peroxometa-borate, anhydrous	Perboric acid (HBO(O2)), sodium salt, monohydrate; Sodium perborate	Perboric acid, sodium salt, trihydrate	Perboric acid (HBO(O2)), sodium salt, tetrahydrate
CAS Registry Number	11138-47-9	7632-04-4	10332-33-9 15120-21-5 12040-72-1	13517-20-9	10486-00-7 37244-98-7
EC Number	234-390-0	231-556-4	239-172-9	-	-
Molecular Formula		$NaBO_3$	$NaB0_3 \times H_2O$	$NaB0_3 \times 3H_2O$	$NaB0_3 \times 4H_2O$
Molecular Weight		81.80	99.8		153.8
Boron Content (%)		13.2	10.8		7.0
Boron Equivalent of 1 mg		7.6	9.3		14.3
Theoretical Content of Hydrogen peroxide (%)			34		22
Physical Form		White, amorphous powder	White crystal,no odour		White crystal, no odour

	Perboric acid, sodium salt	Sodium peroxometa -borate, anhydrous	Perboric acid (HBO(O2)), sodium salt, monohydrate; Sodium perborate	Perboric acid, sodium salt, trihydrate	Perboric acid (HBO(O2)), sodium salt, tetrahydrate
Specific Gravity (20°C)			0.4-0.65		0.65-0.9
Melting Point (°C)		63	Decompose >50->180		Ca 60-65.5
Water Solubility		21.5 g/l	15-16 g/l		23 g/l
Comment	Collective CAS/EINECS number for the mono- and the tetrahydrate of sodium perborate.	Gives a solution of hydrogen peroxide and sodium borate			Dehydrates at elevated temperatures (starting at about 50°C) via the trihydrate towards the monohydrate which then decomposes to the metaborate.

Dehydrated sodium perborate (CAS No. 7632-04-4) and sodium perborate trihydrate (13517-20-9) are described in the literature. Dehydrated sodium perborate is a not well defined compound deliberating the releasable oxygen spontaneously as elemental oxygen when coming into contact with water. It is supposed to consist of sodium borate and a boron oxygen radical (Kleinschmidt et al., 1991). The spontaneous decomposition of the substance is the reason for its use in denture cleanser tablets. The trihydrate is not of commercial importance (Kleinschmidt et al., 1991).

Table 3: Purity, impurities and additives of sodium perborate monohydrate / tetrahydrate

Parameter	CAS-No	Name	Value	Comment
Purity	10332-33-9	Sodium perborate monohydrate	≥ 94%	-
	10486-00-7	Sodium perborate Tetrahydrate	≥ 96%	-
Impurities	1303-96-4 1330-43-4	Borax	< 2%	-
	7732-18-5	Water	≤ 1%	-
		several metals	< 200 ppm total metal content	-
Additives	7487-88-9	MgSO4	≤ 1.2%	Stabilizer The concentrations in the monohydrate are somewhat higher than in the tetrahydrate

In the scientific literature, the addition of silicates or other magnesium salts in a concentration range of 0.1 to 10% is described to avoid the decomposition of the technical product (Jakobi et al., 1987; Büchel et al., 1999)

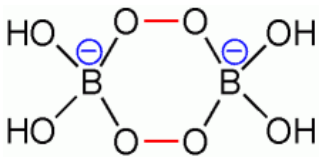
Sodium perborate hydrates are solid salts available either as tetrahydrate or monohydrate form. The particle sizes of a typical product have been determined by sieve analysis and are identical for the two hydrates: >20 mesh (0.83mm DIN): 0-5%; >35 mesh (0.42mm DIN): 30-80%; >100 mesh (0.15mm DIN): 90-100% (Degussa AG, 1997). The substance itself consists of coarse crystals > 100 µm (HERA, 2002).

3.2. Function and uses

The generation of active oxygen in aqueous solutions is the basis for the use of sodium

perborate as bleaching component in detergent products and bleaching agents. The purity of the technical products is characterized by their active oxygen content.

The crystalline reagent is available as a hydrate with the general formula $NaBO_3 \bullet n\ H_2O$ (n: 1 or 4). The compound itself is a dimer:



$2Na^+$

Sodium perborate is soluble in water and releases hydrogen peroxide. Unlike percarbonate, perborate is not just an addition compound of peroxide, but contains true peroxygen bonds. In dilute solution, an equilibrium exists that still contains peroxoborate anions. These peroxoborate species are able to deliver the hydroperoxide anion at a lower pH than when H_2O_2 is used. Sodium perborate monohydrate and tetrahydrate contain theoretically about 34% and 22% hydrogen peroxide, respectively.

In aqueous solutions at room temperature, an equilibrium between sodium perborate and hydrogen peroxide/sodium metaborate is instantly established:

$[NaBO_2(OH)_2 \times 3\ H_2O]_2$	⇆	$2NaBO_2$	+	$2H_2O_2$	+	$6\ H_2O$
Sodium perborate tetrahydrate		Sodium metaborate		Hydrogen peroxide		Water

At low concentrations (about ≤ 2 g/l) the equilibrium is largely on the side of the hydrolysis products whereas at higher concentrations (about ≥ 12 g/l) the undissociated molecule is present in aqueous solutions. Via degradation to (active) oxygen and water the hydrogen peroxide can be removed from the equilibrium leading to an irreversible shift of the equilibrium (equation above) to the degradation products sodium metaborate and water:

$2\ H_2O_2 \rightarrow 2\ H_2O + 2O\cdot$

This reaction is the basis of the bleaching effect of the sodium perborate in the washing process (ECB, 2007).

Sodium perborate mono- and tetrahydrate are used as oxidising and bleaching agents mainly in detergents (approximately 96%; household detergents as well as detergents for institutional uses) and also in cleaning (e.g. automatic dishwashers, stain removers in form of bleach booster tablets) and cosmetic preparations (denture cleansers) (approximately 4%).

The applicant applies for the use of sodium perborate monohydrate in powdered oxidative hair colouring products at a maximum concentration of 3.0 % after mixing with water just prior to use. Sodium perborate has also been used in vital tooth bleaching systems. The concentrations of sodium perborate in the different products are not available.

3.3. Toxicological Evaluation

3.3.1. Acute toxicity

3.3.1.1. Acute oral toxicity

LD50
Sodium perborate (not specified)
Mice: female, 3250 mg/kg bw, male, 3600 mg/kg bw (ECB, 2007)

Sodium perborate monohydrate
Rat: 1800 mg/kg bw (Interox, 1987a)

Sodium perborate tetrahydrate
Rat: 2567 mg/kg bw (Degussa, 1987)

The fatal dose of boric acid, sodium borate, or sodium perborate is 100 – 500 mg/kg bw in humans (Dreisbach, 1987).

3.3.1.2. Acute dermal toxicity

Sodium perborate monohydrate
Rabbit: 2000 mg/kg bw 9/10 survived, 1 male died after 13days (Interox, 1987b)

3.3.1.3. Acute inhalation toxicity

Sodium perborate tetrahydrate
Rat: 1164 mg/m^3, 4 hours. (Asta Medica, 2001)

3.3.2. Irritation and corrosivity

3.3.2.1. Skin irritation

A patch test was conducted in 26 volunteers (healthy humans aged 18 to 65). A sequential single patch test procedure was used applying 0.2 g sodium perborate monohydrate on to a 25 mm plain hill top chamber containing a moisture Webril pad to the upper outer arm progressively from 15 min to 4 h. Treatment sites were assessed for the presence of irritation using a 4-point scale. A positive skin reaction included irritation of all grades at any time point. 1 of 26 test persons showed a positive skin reaction while 21 of the 26 reacted to the positive control (SDS). The material was evaluated as non-irritant to human skin (York *et al.,* 1996).

Conclusion by ECB (2007)
Both, sodium perborate monohydrate and tetrahydrate tested in rabbits as a solid substance according to the criteria for classification should not be classified as skin irritants. However, in some studies with the monohydrate after prolonged exposure very mild irritating effects were observed which were not completely reversible in some cases. Solutions of 10% sodium perborate tetrahydrate are mildly irritating.

3.3.2.2. Eye irritation

In all studies according to standard protocols, sodium perborate showed severe eye irritating effects, when applied as solid substance to the eyes (Bagley *et al*., 1994; ICI, 1986a,b; Interox, 1987c; Momma *et al*., 1986). Moderate corneal opacity, severe iritis and

conjunctival effects which consisted of severe redness, moderate chemosis and severe discharge were recorded. The effects were not completely reversible. Rinsing within 30 seconds after application reduced the severity of the effect considerably (Momma *et al.*, 1986). Also with lower concentrations than in standard protocols the effect was weaker (Procter & Gamble, 1965, 1973). The irritating potential of sodium perborate tetrahydrate seems to be lower than for the monohydrate, being consistent with its higher water content (ICI, 1986 a, b).

Conclusion by ECB (2007)
Sodium perborate caused strong eye irritation in animal studies, the effects being not reversible in most of the animals tested. Although the scores for irritation are not sufficient for classification with R41, due to the irreversible effect, both sodium perborate monohydrate and sodium perborate tetrahydrate are proposed to be classified with R41, "Risk of serious damage to eyes".

3.3.3. Skin sensitisation

Sodium perborate monohydrate was tested in a Bühler test according to OECD guideline 405 test in 10 guinea pigs (5 males, 5 females) applying 0.5 ml/animal (not further specified, probably powder as it is, 6 h/d, occlusive) once every seven days for a total of three applications. 14 days after the last induction the animals were challenged with 0.5ml of a 5% solution in distilled water (maximum non-irritant concentration). 10 untreated animals served as controls. One of 10 test group animals as well as one of 10 control group animals showed a very slight erythema after 24 h. The test substance was regarded to be not skin sensitising in this test (Interox, 1987c).

Conclusion by ECB (2007)
Sodium perborate is not to be regarded as a skin sensitising substance. Furthermore, there is no concern for respiratory sensitisation.

3.3.4. Absorption

3.3.4.1. Dermal / percutaneous

Conclusion by ECB (2007)
There are no valid quantitative data on the absorption of sodium perborate following dermal exposure. Absorption from the mucous membranes of the mouth seems to be low. Dermal absorption of H_2O_2 is negligible. A thorough investigation showed that dermal absorption of other boron compounds is very low. Therefore for the risk assessment dermal absorption of 1% was assumed. (The study described below was not available at the time of this assessment).

Guideline:	OECD 428
Tissue:	Porcine ears (for meat) from 10 pigs.
Group size:	Skins of 6 pigs were used for skin permeation tests, selected according to the results of integrity checks (n=10)
Diffusion cells:	Franz diffusion cell. 6 chambers were analysed. Membrane surface 1.77 cm^2
Skin integrity:	Permeability coefficient for tritiated water (< $4.5x10^{-3}$ cm/h for all selected membranes)
Test substance:	1) Powder Hair Dye A (composition given in Table 5) containing 30% sodium perborate 2) Powder Hair Dye A without sodium perborate
Component:	$NaBO_3xH_2O$, 30%
Batch:	15504

Purity:	95.9%
Test item:	1) Hair colouring powder formulation containing 30% sodium perborate diluted 10 times to give a final concentration of 3% sodium perborate 2) Hair colouring powder formulation without sodium perborate diluted 10 times.
Doses:	1) 113 mg/cm^2 with Hair Dye A, corresponding to 2.98 mg/cm^2 with sodium perborate 1) 113 mg/cm^2 with Hair Dye A, without sodium perborate
Receptor fluid:	Saline
Solubility receptor fluid:	>15 g/l in water
Stability:	/
Method of Analysis:	ICP-MS with beryllium and sodium perborate as standards
GLP:	In compliance
Date:	7 August – 21 October 2009

Sodium perborate could not be distinguished from naturally occurring boron using the analytical methods of the study. As boron widely exists in nature, it was expected that boron also exists in the skin, and a blank boron value was confirmed by measuring the concentration of boron derived from the skin after application of the formulation not containing sodium perborate. As a consequence, two experiments were performed with Hair Dye A, one with normal content of sodium perborate (30%) and one with without sodium perborate. The absorbance was calculated from the difference in boron in the receptor fluid in the two experiments.

Each of the permeability coefficient (Kp) values of ^3H_2O in pig skin (n=6) used in the study was less than the adapted criteria value of $4.5x10^{-3}$ cm/h.

200 mg of formulation 1 (113 mg/cm^2 Powder Hair Dye A (content shown in Table 4), 2.98 mg/cm^2 sodium perborate) or formulation 2 (113 mg/cm^2 Powder Hair Dye A, no sodium perborate) was applied to the skin (n=6 for each formulation). After a 30-minute application, the formulation on skin surface was wiped with surgical cotton containing lukewarm water and then the skin surface was rinsed with 1ml of purified water.

Table 4: *Contents of Powder Hair Dye A*

Ingredient Name	**Content (%)**
Sodium perborate monohydrate	30.0
Carboxymethylcellulose sodium	27.5
Disodium lauryl sulfosuccinate	2.0
Sodium carbonate	2.5
Magnesium stearate	0.5
Perfume	0.5
Sapindus mukurossi peel extract	0.01
Sodium alginate	0.01
p-Phenylenediamine sulfate	30.0
m-Aminophenol	6.5
p-Aminophenol	0.5
Total	100.0

At 0 (immediately after application), 0.5 (before wiping the formulation), 1, 2, 4, 6, and 8 h after application, the receptor fluid (200 µl) was collected, and the receptor chamber was refilled with 200 µl of receptor fluid after sampling. At 24 h after application, 4 ml of receptor fluid were collected -. The skin sample was discarded. The receptor fluid was analyzed for boron (the results after 24 h expressed as sodium perborate are shown in Table 5).

Table 5: *Individual concentration of Sodium Perborate in receptor fluid after application of Powder Hair Dye A at 113 mg/cm^2 (2.98 mg/cm^2) to pig skin.*

Sample	1 (µg/ml)	2 (µg/ml)	3 (µg/ml)	4 (µg/ml)	5 (µg/ml)	6 (µg/ml)	Average (µg/ml)
With sodium perborate	8.66	9.02	6.99	7.40	6.19	7.15	7.57 ±1.07
Without sodium perborate	7.55	6.35	5.84	6.83	5.75	5.51	6.31 ± 0.77

Mean difference concentration in receptor fluid = 1.26 µg/ml (corrreponding to the mean of the experiment with sodium peroxide minus the mean of the experiment without sodium peroxide). The 95% confidence interval of the difference is 0.04 to 2.48 µg/ml.

Cumulative amount (µg/cm^2) = Concentration of Sodium Perborate × Volume of receptor chamber (4.7 ml) / Application area of skin (1.77 cm^2).

Mean difference cumulative amount = 3.35 µg/cm^2 (0.11%). The 95% confidence interval of the difference is 0.11 µg/cm^2 (0.04%) to 6.59 µg/cm^2 (0.22%).

Ref.: Hoyu Co, Ltd. (2009)

Comment
The experiment was performed with pig ear skin. Only 6 chambers were used, although skins from different pigs were used in all chambers. Moreover, only total borate was determined. Thus, in order to obtain a value for absorption of sodium perborate it was necessary to make a "blank" experiment without sodium borate and calculate the absorbance of sodium borate from the differences. The upper 95% confidence interval for absorption was calculated to be 6.59 µg/cm^2 (0.22%). The difference between the chamber with the highest value for absorbance minus the lowest value in the "blank" corresponds to 9.32 µg/cm^2 (0.31%). Since the boron content of sodium perborate monohydrate is 10.8% (see Table 2), the dermal absorption expressed as boron is: upper 95% confidence interval: 0.71 µg/cm^2 (0.22%), difference between the chamber with the highest value for absorption minus the lowest value in the "blank": 1.0 µg/cm^2 (0.31%). Amount remaining in the skin has not been taken into account for the calculation of absorption, so this result is likely to be an underestimation. On the other hand, the difference between lowest blank and highest measured value is a worst case. 1.0 µg B/cm^2 (corresponding to 0.3%) will be used in the calculation of MoS. It should be noted that a dermal absorption of 0.5% has been used for other boron compounds (SCCS, 2010).

3.3.4.2. Oral / inhalation

Conclusion by ECB (2007)
From a study with human volunteers it can be concluded that oral absorption is higher than 30 %. For the risk assessment, oral absorption and the absorption via inhalation of sodium perborate hydrates are assumed to be 100 %.

3.3.5. Repeated dose toxicity

3.3.5.1. Repeated Dose (28 days)

Oral
Experiments in rats with oral application (via gavage) of sodium perborate have been performed with the tetrahydrate (Degussa, 1989, 1000 mg/kg bw/d, 215 mg/ml, 28 days) or not further specified perborate (Dufour *et al.,* 1971, 200 mg/kg bw/d or 1000 mg/kg bw/d for 6 days). Targets for toxic effects at a dose level of 1000 mg/kg bw/d were the stomach, the haematological system and possibly the testes.

In the 28 day-study from Degussa (1989) acanthosis and hyperkeratosis in the forestomach and hyperplasia of the fundic mucosa were observed after application of 1000 mg/kg bw/d

via gavage. No effects on the stomach were found in the study of Dufour *et al.* (1971) in rats receiving the same dose. But in this study the exposure was only for 6 days to a more diluted solution and the animals were examined after a recovery period of 8 days.

Haematological effects have been observed in both studies. In the study of Degussa (1989) after application of 1000 mg/kg bw/d at the end of the study red blood cell count, haemoglobin, haematocrit and number of lymphocytes was statistically significantly decreased, the number of platelets was statistically significantly increased. The spleen size and spleenic parenchyma were reduced. In contrast in the Dufour-study, (with 8 days duration instead of 28 days in the Degussa study) no changes in blood cell parameters were observed during the study but haemoglobin and haematocrit were increased up to 15 days after the end of the application. This was explained by depression of haematopoiesis during the study and overregulation at the termination of the application. In conclusion the NOEL for these endpoints is below the dose of 1000 mg/kg bw/d tested.
Conclusion by ECB (2007)
Effects after oral application of sodium perborate can be attributed to the degradation products. From the 28-day study from Degussa (1989) a NOAEL cannot be derived, because the only dose investigated was 1000 mg/kg bw/d which showed effects on the stomach, spleen and the haematopoietic system. No effects were recorded in the study of Dufour (1971). This study was only for 6 days with 8 days of recovery and only a limited number of parameters have been investigated. Therefore also from this study a NOAEL cannot be derived. Systemic effects, which have to be considered, are the effects on the haematopoietic system. Thus the LOAEL is 1000 mg sodium perborate tetrahydrate/kg bw/d (70 mg boron/kg bw/d) and no NOAEL can be derived.

Dermal
Two dermal studies, both on sodium perborate tetrahydrate, with limited reporting of the results are available. New Zealand white rabbits received either a dermal dose of 200 mg/kg bw/d in 10% aqueous solution on the abraded skin for 3 weeks (Proctor & Gamble, 1965; 1966a) or 50 mg/kg bw/d as 2.5% solution on the intact skin for 13 weeks (Procter & Gamble, 1966b). In both studies, there were no statistically significant differences compared to controls in growth, organ/body weight ratios (liver, kidney), blood parameters (all relevant parameters investigated, figures included in the report), gross pathology, or histopathology (organs required in current guidelines investigated). Only during the application of the 10 % solution to the abraded skin, some animals showed mild irritative effects.

Conclusion by ECB (2007)
The reporting of the results of the available studies (Procter & Gamble, 1965, 1966a,b) is limited. However all relevant organs have been examined by histopathology and also haematological parameters have been investigated which have shown changes in the oral studies. Therefore the studies are considered as sufficient for the risk assessment. In comparison with the results from the oral studies and as it can be assumed that sodium perborate is not taken up by the skin very efficiently the NOAEL of this study of 200 mg/kg bw/d, which was the highest dose tested, may be too low.

3.3.5.2. Sub-chronic (90 days) oral / dermal / inhalation toxicity

No data submitted

3.3.5.3. Chronic (> 12 months) toxicity

No data submitted

3.3.6. Mutagenicity / Genotoxicity

3.3.6.1. Mutagenicity / Genotoxicity *in vitro*

Sodium perborate was able to oxidize thymidine to an appreciable extent at an incubation temperature of 80°C, but even at 40°C the oxidation was measurable.

Sodium perborate induced point mutations without metabolic activation in *Salmonella typhimurium* strains TA100 and TA102. There was no response with (TA98). The mutagenic activity was abolished completely by incubation in the presence of rat liver S9 (Seiler, 1989). Sodium perborate tetrahydrate induced mutations in *Escherichia coli* WP2 (PKM101), and *Escherichia coli* WP2 UVRA (PKM101), in the absence of metabolic activation (Watanabe *et al.,* 1998). Sodium perborate was positive in the *Escherichia coli* polA (W3119 vs P3478) rec-assay, DNA effects (bacterial DNA repair).

Chinese hamster ovary cells (strain CHO-K1) underwent extensive chromosomal damage when treated with sodium perborate. Special note was taken of the rather unusual prevalence of chromosome rearrangements (Seiler, 1989).

3.3.6.2 Mutagenicity/Genotoxicity *in vivo*

No data found.

Conclusion by ECB (2007) on mutagenicity
The mutagenic potential of sodium perborate was investigated in three different assays which included the induction of DNA damage, of point mutations, and of chromosomal aberrations. The results indicated that sodium perborate was capable of producing mutagenic changes in a number of *in vitro* test systems. In an assay for oxidative damage induced by a chemical agent, the potential of sodium perborate for inflicting damage to DNA was demonstrated.
The in vitro studies on sodium perborate show a genotoxic potential. This may be due to the generation of H2O2, as similar to investigations with H2O2 the responses observed were reduced by the presence of catalase. Therefore, analogous to H2O2, the genotoxic potential may not be relevant in vivo. Furthermore, in contrast to H2O2, due to its ionisation, sodium perborate itself should be taken up by cells less easily than H2O2.

3.3.7. Carcinogenicity

No studies have been found on perborates.

Hydrogen peroxide has been evaluated by IARC (1999). There is *inadequate evidence* in humans and *limited evidence* in experimental animals for the carcinogenicity of hydrogen peroxide.

The studies on borates available in animals were inadequate and can not be used to conclude whether boron causes cancer (SCCS, 2010).

3.3.8. Reproductive toxicity

Fertility
In the 28-day study of Degussa (1989) (see section 3.3.5.1) on sodium perborate (1000 mg/kg bw/day; 70 mg B/kg bw/day), an 18% significant decrease in absolute testicular weights was recorded with relative testes weights not reduced. By the authors of the study this was attributed to a generalised weight reduction of 15%. A histological examination of the testes revealed no adverse effects.

It should be noted that in a multigeneration study (Weir and Fisher, 1972) with rats with boric acid and disodium tetraborate decahydrate, a NOAEL for fertility of 17.5 mg B/kg bw/day were identified.

Comment
Based on the above experiment with sodium perborate and the data on borate, the Specialised Experts (ECB, 2004) recommended classification of perborates as Repr. Cat 3; R62 (Possible risk of impaired fertility). 70 mg B/kg bw/day is considered a LOAEL for fertility for perborates.

Developmental toxicity
In a developmental toxicity study according to OECD Guideline 414, groups of 25 mated Crl:Cd (SD) BR rats were dosed by gavage from day 6 to day 15 of pregnancy with 0, 100, 300 and 1000 mg/kg bw/day of sodium perborate tetrahydrate in 1% aqueous methylcellulose ((Bussi, 1995, Bussi *et al*., 1996).

Since no clinical signs of toxicity were reported, the only criteria for assessment of maternal toxicity are effects on body weight gain and food intake. Significant reductions in body weight gain were observed at the two top doses. A significant reduction in food intake was observed in the top dose group (1000 mg/kg bw/d). The reduced body weight gain of the dams is partly (in later stages of pregnancy) due to reduced weights of the litters, due to reduced foetal weights and increased number of resorptions. No significant differences for the different doses and no clear dose response are found for the weight gain of the dams from day 20 except for gravid uterine weight. As maternal toxicity was apparent also in earlier times of the pregnancy the NOAEL for maternal toxicity is 100 mg/kg bw/day (7 mg B/kg bw/d).

At 100 mg/kg bw/day six externally malformed foetuses with ablepharia, acrania, exencephaly, macroglossia, cleft palate, cleft lip and facial cleft were found. This increase compared to controls was statistically significant. The authors of the study considered this finding incidental, since these kinds of malformations were only present in 2 litters and not at the higher dosages. Historical control data for the years 1993-1999 (Instituto di Ricerche Biomediche, 2000) showed, that such malformations occurred, however extremely seldom, with an incidence of 0 - 0.12 %.

A dose related effect was found on the ossification and the bone system. At 100 mg/kg bw/day statistical significant effects were found for unossified 5th sternebra and supraoccipital incomplete ossification, both being close to the historical control data. At 300 mg/kg bw/day and above, various incomplete ossifications and wavy ribs occurred. At 1000 mg/kg bw/day malformations (fused ribs) were observed.

In addition visceral changes were found. The kidney was the main target at lower dosages. At 100 mg/kg bw/d and above, the number of variants was statistically significant increased, at 1000 mg/kg bw/day also the number of anomalies and malformations were increased. The malformation included hydroneprhrosis and hypoplasia. Other viscereal malformations were microphtalmia or anophthalmia, vascular ring, displaced or double aortic arch, displaced botallus duct. The malformations were different from those observed at 100 mg/kg bw/day. Furthermore, at 300 and 1000 mg/kg bw/day dose-related increases of post implantation losses and early resorptions and dose-related lower mean foetal and placental weights were observed. The authors of the study considered 100 mg/kg bw/day as NOAEL for foetal effects.

Conclusion by ECB (2007)
In a study on developmental effects of sodium perborate tetrahydrate according to OECD Guideline 414, 100 mg/kg bw/d of sodium perborate tetrahydrate was regarded by the

authors of the study as the NOAEL for both maternal and developmental toxicity (Bussi, 1995, Bussi *et al*., 1996).

Although reduced maternal weight gain as measure of maternal toxicity may partly be due to an increased number of resorptions and reduced foetal weights, other toxicological studies support the view that doses above 100 mg/kg bw/day via gavage are toxic to the dams.

Critical is the evaluation of the external malformations at 100 mg/kg bw/day. They were statistically significant but considered incidental due to lack of dose response by the authors of the study and in an expert report (Giavini, 2000). This is supported by the fact that with other boron compounds which have very similar developmental effects as sodium perborate at higher dose levels, this type of effect was not found. The hypothesis of the syndromic origin of these malformations as proposed by Giavini seems therefore plausible. On the other hand, the effects occurred in two litters and the syndromic nature of the effects cannot be supported further as no information was provided on the mating males. Although there are uncertainties, due to the absence of these effects in investigations with other boron compounds, these effects are not taken into consideration for deriving the NOAEL for sodium perborate. The NOAEL therefore is 100 mg/kg bw/day.

Comment
The Specialised Experts (ECB, 2004) agreed that the developmental effects of sodium perborate in one rat study (Bussi, 1995), which are not a consequence of general systemic toxicity, warrent classification as Repr. Cat 2; R61: May cause harm to the unborn child. The majority of the Specialised Experts assessed the boric acid data supportive to this classification. 100 mg/kg bw/day (7 mg B/kg bw/day) is considered a NOAEL for developmental effects for perborates.

3.3.9. Toxicokinetics

The information is taken from EU (2007).

From a study with human volunteers using mouthwash solutions about 97% (94-101%) of the dose were spat out. The remaining 3% corresponded to 36 mg sodium perborate. The blood concentration increased from 0.04 µg/ml to a maximum of 0.14 µg/ml 2 hours after administration and returned to the initial level within 1-2 days after single mouthwash as well as after prolonged treatment. A blood half-life of 5 – 10 hours was estimated. Sodium perborate is degraded to boric acid and H_2O_2 and is excreted as boric acid via the urine.

The generation of foam and bloating of the stomach and the intestine after oral intake of perborate are presumably to the development of gas. Thus, in the stomach in the presence of HCl boric acid and H_2O_2 are generated very effectively, the latter being degraded to H_2O and O_2. It may be assumed, that several, if not all of the systemic toxic effects are caused by the degradation products.

After dermal exposure, degradation at the site of contact may be less effective. However, due to the high catalase activity in blood, degradation should then occur in the blood.

No information is available on absorption via inhalation. Since the lung is rather effective in the degradation of H_2O_2 due to the presence of catalase, the equilibrium between perborate and its degradation products is shifted towards the degradation products, leading to further degradation of sodium perborate. The absorption via inhalation of sodium perborate hydrates is assumed to be 100%.

No data are available on the metabolism and the distribution of sodium perborate within the body. From investigations with other boron compounds, it may be suspected that elevated boron concentrations are found in the bones.

3.3.10. Photo-induced toxicity

No data submitted

3.3.11. Human data

No data submitted

3.3.12. Special investigations

No data submitted

3.3.13. Safety evaluation (including calculation of the MoS)

CALCULATION OF THE MARGIN OF SAFETY

Sodium Perborate (calculated as boron)

Use in oxidative hair dye formulations

Absorption through the skin	**A (µg/cm^2)**	**=**	**1.0 µg B/cm^2**
Skin Area surface	**SAS (cm^2)**	**=**	**580 cm^2**
Dermal absorption per treatment	**SAS x A x 0.001**	**=**	**0.58 mg B**
Typical body weight of human		**=**	**60 kg**
Systemic exposure dose (SED)	**SAS x A x 0.001/60**	**=**	**0.01 mg/kg bw/d**
No observed adverse effect level (90-day study and maternal toxicity in developmental study, oral, rat)	**NOAEL**	**=**	**7 mg B/kg bw/d**

Margin of Safety	**NOAEL / SED**	**=**	**700**

Other use in cosmetic formulations

Table 6: Calculation of systemic daily dose of boron from the use of perborates in different cosmetic products. (according to Annex III/1a) A dermal absorption of 0.3% has been used for calculation of the systemic exposure dose of boron.

Field of application and/or use	Daily use of finished product (g)	Retention factor	Boric acid (%)	Boron (%)	Daily exposure calculated as boron (mg)	Systemic daily dose (mg)
Powder	18	0.1	5	0.88	15.8	0.05
Products for oral hygiene	3.48 (amount considered absorbed)	1	0.1	0.018	0.63	0.63
Other products	18	1	3	0.53	95	0.29
Total						0.97

Total daily systemic exposure dose (SED) of boron from cosmetic products containing perborates is estimated to be 0.97 mg per day corresponding to (0.97/60) 0.016 mg/kg bw/day.

SED	=	0.016 mg B/kg bw/day
NOAEL (90-day study and maternal toxicity in developmental study, oral, rat)	=	7 mg B/kg bw/day

Margin of Safety	**NOAEL / SED**	**=**	**440**

The calculation of MOS given above is based on dermal absorption of healthy skin. Skin absorption is probably higher in case of damaged skin and the MOS may be significantly lower if boron compounds are used in cosmetics applied to damaged skin.

3.3.14. Discussion

Physico-chemical properties
Sodium perborates are soluble in water and hydrolysis to sodium metaborate and hydrogen peroxide. The monohydrate and tetrahydrate contain theoretically about 34% and 22% hydrogen peroxide, respectively. Sodium perborates contain < 2% borax, < 200 ppm total metal content, and $\leq$ 1.2% $MgSO_4$ (stabilizer) as impurity. The stability of sodium perborates in products are not known.

Acute toxicity
The oral LD50 in mice and rats is > 1000 mg/kg bw. The dermal LD50 in rabbits is > 2000 mg/kg bw. The fatal dose of boric acid, sodium borate, or sodium perborate is 100 – 500 mg/kg bw in humans.

Irritation and corrosivity
Solutions of 10% sodium perborate are mildly skin irritating. Sodium perborate caused strong eye irritation in animal studies.

Skin sensitisation
Sodium perborates are not considered to be skin sensitising.

Dermal / percutaneous absorption
Dermal absorption of sodium perborate monohydrate has been studied *in vitro* with pig ear skin. Although the study was performed in 2009 it is not up to the modern standard as only 6 chambers were used in the experiments. Moreover, due to the occurrence of boron in the skin and the hydrolysis of perborates, only total boron was determined. Thus, in order to obtain a value for absorption of sodium perborate it was necessary to make a "blank" experiment without sodium borate and calculate the absorption of sodium borate from the differences. The upper 95% confidence interval for absorption was calculated to 6.59 µg/cm^2 (0.22%). The difference between the chamber with the highest value for absorption minus the lowest value in the "blank" corresponds to 9.32 µg/cm^2 (0.31%). Since the boron content of sodium perborate monohydrate is 10.8%), the absorption expressed as boron is: The upper 95% confidence interval for absorption was calculated to 0.71 µg/cm^2 (0.22%). The difference between the chamber with the highest value for absorption minus the lowest value in the "blank" corresponds to 1.0 µg/cm^2 (0.3%). *1.0 µg B/cm^2 was used in the*

calculation of MoS. It should be noted that a dermal absorption of 0.5% has been used for other boron compounds (SCCS, 2010).

Repeated dose toxicity
Effects after oral application of sodium perborate to rats can be attributed to the degradation products. Systemic effects, which have to be considered on the basis of a 28 day study, are the effects on the haematopoietic system. The LOAEL is 1000 mg sodium perborate tetrahydrate/kg bw/d (70 mg boron/kg bw/d) (only dose tested). The NOAEL from a 3 week skin painting study on rabbits is 200 mg/kg bw/d, which was the highest dose tested.

Mutagenicity / Genotoxicity
The in vitro studies on sodium perborate show a genotoxic potential, which may be due to the generation of H2O2. No in vivo studies are available. Analogous to H2O2, the genotoxic potential may not be relevant in vivo. Furthermore, in contrast to H2O2, due to its ionisation, sodium perborate itself should be taken up by cells less easily than H2O2.

Carcinogenicity
No data found.

Reproductive toxicity
In a study on developmental effects of sodium perborate tetrahydrate according to OECD Guideline 414, *100 mg/kg bw/day (corresponding to 7 mg B/kg bw/day) of sodium perborate tetrahydrate is regarded as the NOAEL for developmental toxicity and is used in calculation of MoS.* It should be noted that a NOAEL of 9.6 mg B/kg bw/day has been used for other boron compounds (SCCS, 2010).

Sodium perborates are classified as toxic to reproduction category 2; R61 *May cause harm to the unborn child* and category 3; R62 *Possible risk of impaired fertility.*

Toxicokinetics
From a study with human volunteers using mouthwash solutions it can be concluded that oral absorption is 100%. Sodium perborate is degraded to boric acid and H_2O_2 and is excreted as boric acid via the urine. It may be assumed, that several, if not all of the systemic toxic effects are caused by the degradation products. After dermal exposure, degradation at the site of contact may be less effective. However, due to the high catalase activity in blood, degradation should then occur in the blood. The absorption via inhalation of sodium perborate hydrates is assumed to be 100%. No data are available on the metabolism and the distribution of sodium perborate within the body. From investigations with other boron compounds, it may be suspected that elevated boron concentrations are found in the bones.

4. CONCLUSION

(1) *Based on the current knowledge on the chemistry, biology and toxicology of sodium perborate and perboric acid, does the SCCS consider that sodium perborate and perboric acid can be considered as "hydrogen peroxide" releasing substances in the sense as the already regulated substances in Annex III, entry 12 of the Cosmetics Directive 76/768/EEC?*

The SCCS is of the opinion that sodium perborate and perboric acid can be considered as "hydrogen peroxide" releasing substances and thus are covered by the entries 12 of Annex III, of the Cosmetics Directive 76/768/EEC,

(2) *If the answer to question 1 is yes, does the SCCS consider that the general restrictions applicable to hydrogen peroxide releasing substances should apply to sodium perborate and perboric acid?*

The SCCS considers that the general restrictions applicable to hydrogen peroxide releasing substances should apply to sodium perborate and perboric acid. As laid out in opinion SCCS/1249/09, the substances listed in the Annex I of this mandate are, in addition to entry 12 of Annex III, also covered by entry 1a of Annex III of the Cosmetics Directive 76/768/EEC. The more restrictive of the two entries should be applied.

(3) *Furthermore, does the SCCS consider with the provided scientific data that sodium perborate is safe, when used in (powdered), oxidative hair dye formulations up to a maximum concentration on the head of max.3.0% calculated as boric acid corresponding to a release of x volume percentage hydrogen peroxide?*

The SCCS is of the opinion that the use of sodium perborates as an ingredient in oxidative hair dye formulations with a maximum on-head concentration of 3% will not pose a risk to the health of the consumer.
Exposure to sodium perborate and boric acid from other uses, except the use in cosmetics according to Annex III, entry 1a of the Cosmetics Directive 76/768/EEC, were not taken into account for this risk assessment.
The SCCS notes, however, that the hair dye powder formulation as supplied to the consumer contains 30% sodium perborate monohydrate. It other types of consumer products this would require labelling as "Toxic" and such products would not be generally available to consumers.

(4) *Sodium perborate and perboric acid have different classifications depending on the percentage content of particles with an aerodynamic diameter below 50 µm. Does the SCCS consider that this has an impact on their safe use in cosmetic products?*

The SCCS considers that the percentage content of particles with an aerodynamic diameter below 50 µm does not have an impact on the safety of sodium perborate and perboric acid when used in a liquid cosmetic formulation. However, in connection to the use addressed in question 3, exposure of consumers to powdered formulations can occur. When using powdered formulation, exposure via inhalation can take place when particles with sizes in the inhalable range (i.e. <15um) are present. Therefore the SCCS considers that the different classification with regard to percentage content may indeed have an impact on their safe use in consumer products. However, since no information on the particle size distribution of the powder is available, the risk of inhalation of particles due to use of the powdered formulation cannot be assessed.

5. MINORITY OPINION

Nor applicable

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