



# REGULATORY INTELLIGENCE COSMETICS

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## 1. Ingredient Name: Octocrylene

Status until Jan, 2023	Change
Used as UV filter up to 10% in finished product.	Up to 9% in propellent spray products. Up to 10% in other products.

**Impact:** Products must be checked for the composition to meet the current requirements for Octocrylene.

Reason for Change: Identification of potential endocrine disrupting properties.

**Product list:** Sunscreen (lotion, propellant spray, pump spray), Lip stick, Face cream, Hand cream - Octocrylene SCCS, 2021

#### Source

EU CosIng: Link

European Commission: Link European Commission: Link

# 2. Ingredient Name: 3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol), when used as a fragrance ingredient.

Status until Jan, 2023	Change
Not regulated by EU (under review).	PROHIBITED – Listed in Annex II (entry 439) of EU Cosmetics Regulation on January 30, 2023

**Impact:** Products must be checked for the composition containing fragrance, which must be free of this fragrance ingredient.

Reason for Change: Dermal sensitization

**Product list:** All cosmetic products.

# 3. Ingredient Name: Cells, tissues, or products of human origin

Status until Jan -2023	Change
PROHIBITED - Listed in Annex	PROHIBITED - Listed in Annex II (entry 416) of EU Cosmetics
II (entry 416) of EU Cosmetics	Regulation on January 20, 2023
Regulation on January 20, 2023	Added new ingredients/substances to this category.

**Impact:** Products must be checked for the composition to meet the current requirements.

**Reason for Change: NA** 

**Product list:** All cosmetic products.

**Source** SCCS: <u>Link</u>

# 4. Ingredient Name: Fatty acid dialkylamides and dialkanolamides

Status until Jan -2023	Change
RESTRICTED - Listed in Annex III (entry 60) of EU Cosmetics Regulation	RESTRICTED - Listed in Annex II (entry 60) of EU Cosmetics Regulation on January 20, 2023 Added new ingredients/substances to this category.
Finished products: Maximum secondary amine content: 0.5%	
Others: Do not use with nitrosating systems Maximum secondary amine content: 5% (applies to raw materials)	
Maximum nitrosamine content: 50 microgram/kg Keep in nitrite-free containers	

**Impact:** Products must be checked for the composition to meet the current requirements.

**Reason for Change: NA** 

Product list: All cosmetic products.

# 5. Ingredient Name: Alpha-Arbutin and Beta-Arbutin

Status until Jan-2023	Change
Safety data on use of Alpha- Arbutin	On 31 January 2023
and Beta-Arbutin in combination were not available, and concerns regarding the presence of hydroquinone levels (as impurity) were not clear	Face Creams: Alpha-Arbutin and Beta Arbutin can be used up to 2% and 7%, respectively, individually or in combination.
	Body lotions: Alpha-Arbutin can be used up to 0.5% individually or in combination.
	Hydroquinone should remain as low as possible in formulations containing Alpha- or Beta-arbutin and should not be higher than the unavoidable traces in both Arbutins.

**Impact:** Products must be checked for the composition to meet the current requirements for Arbutins.

**Reason for Change:** To determine the safety when used in combination and to determine the safe levels of Hydroquinone (which is a prohibited ingredient for cosmetic use).

Product list: Body Lotion, Face cream Arbutin SCCS, 2023



# 1. Ingredient Name: Aluminum

Status until Feb-2023	Change
Risk assessment was not performed due to lack of adequate data on dermal penetration.	On 1 February 2023 – SCCS published the final opinion on safety of Aluminum compounds in cosmetic products.  Safe use levels for various categories of cosmetic products were published in Tables 4 and 6 of SCCS opinions final report.

**Impact:** Products must be checked for the composition to meet the current requirements for Aluminum compounds.

**Reason for Change:** To determine the safety of Aluminum compounds in cosmetics.

**Product list:** Body Lotion, Face cream, Hand cream, Shampoo, Hair spray, Eye liner etc. <u>Aluminium SCCS</u>, <u>2023</u>



# 1. Ingredient Name: Hydroxyapatite (nano)

Status until Mar-2023	Change
Safety of Hydroxyapatite (nano) was not assessed in oral cosmetic products	On 21-22 March 2023 – SCCS published the final opinion on safety of Hydroxyapatite (nano) in oral cosmetic products. Hydroxyapatite (nano) is safe when used at concentrations up to 10% in toothpaste, and up to 0.465% in mouthwash.

**Impact:** Oral cosmetic products must be checked for the composition to meet the current requirements for Hydroxyapatite (nano).

**Reason for Change:** To determine the safety of Hydroxyapatite (nano) in oral cosmetic products.

**Product list:** Toothpaste, Mouth wash – <u>Hydroxyapatite SCCS, 2023</u>

**Source** SCCS: <u>Link</u>

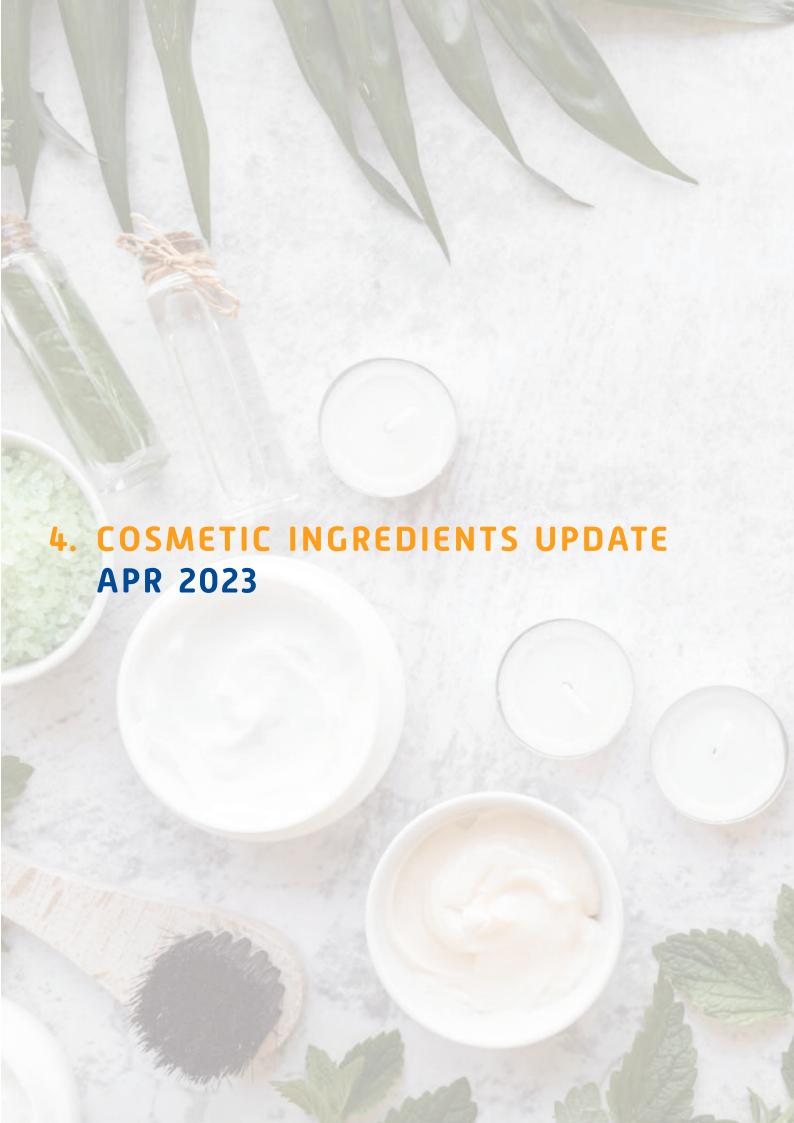
#### 2. Ingredient Name: Sodium bromothymol blue (C186)

Status until Mar-2023	Change
Safety of Sodium bromothymol blue when used in non-oxidative hair color for head at a maximum concentration of 0.5% was not assessed.	On 21-22 March 2023 – SCCS published the final opinion on Sodium bromothymol blue. The applicant used TTC approach to determine the safety of the ingredient, but SCCS concluded that TTC approach cannot be used for restricted ingredients and requires further <i>invivo</i> systemic toxicity test data to determine safety.

**Impact:** NA as of now as there are comments from SCCS for the applicant.

Reason for Change: To determine the safety of Sodium bromothymol blue.

**Product list:** Not applicable as it was not finalised.



#### 1. Silver Zinc Zeolite (SZZ)

Status until Apr-2023	Change
SZZ was a prohibited substance in cosmetic products.	On 4 April 2023 – SCCS published a preliminary opinion open for comments on Silver Zinc Zeolite - deadline for comments: 5 June 2023

**Impact:** Cosmetic products must be checked for the composition to meet the current requirements for SZZ.

**Reason for Change:** In May 2019, SZZ was added in entry 1597 of Annex II of Regulation (EC) No. 1223/2009 as a prohibited substance in cosmetic products. In August 2020, the Commission services received a dossier submission by industry to support the safety assessment of SZZ as a preservative in cosmetic products, in spray deodorant and powder foundation. A positive outcome of this assessment may support the delisting of SZZ from Annex II and its inclusion under Annex V in the Cosmetics Regulation as an authorized preservative.

**Product list:** Spray deodorant, Powder foundation – SZZ - SCCS, 2023

**Source** SCCS: <u>Link</u>

# 2. Fullerenes, Hydroxylated Fullerenes, and hydrated forms of Hydroxylated Fullerenes (nano)

Status until Apr-2023	Change
The safety of fullerenes, hydroxylated fullerenes and hydrated forms of hydroxylated fullerenes in cosmetic products was not previously assessed by SCCS.	On 24 April 2023 – SCCS published a preliminary opinion open for comments on fullerenes, hydroxylated fullerenes, and hydrated forms of hydroxylated fullerenes (nano) - deadline for comments: 12/06/23

**Impact:** The available evidence indicates that hydrated forms of hydroxylated fullerenes are genotoxic and hence, SCCS considers them as not safe for use in cosmetic products. The same concerns over genotoxicity potential apply to Hydroxylated fullerenes.

**Reason for Change:** To address the safety of Fullerenes, Hydroxylated Fullerenes, and hydrated forms of Hydroxylated Fullerenes (nano) in cosmetics.

**Product list:** Spray deodorant, Powder foundation – Fullerenes SCCS, 2023



#### 1. Methyl salicylate

Status until May-2023	Change
Methyl salicylate is currently listed in entry 324 of annex iii to the cosmetic regulation (EC) no. 1223/2009, with specific concentration limits for various product types and age groups.	On 16 May 2023 – Preliminary opinion open for comments on children exposure to methyl salicylate (methyl 2- hydroxybenzoate) - deadline: 19 June 2023

**Impact:** SCCS considers the use of methyl salicylate as safe in cosmetic products intended for children of age 0.5-3 years when used up to a maximum concentration of 0.02% in shower gel, hand soap, shampoo, body lotion, face cream, hand cream and lip products. For toothpaste, up to a maximum concentration of 2.52% methyl salicylate is considered safe.

SCCS considers the use of methyl salicylate as safe in cosmetic products intended for children of age 3-6 years at the following concentrations:

- Shower gel, hand soap, shampoo, body lotion, face cream, hand cream, hair conditioner- 0.06%
- Lip products- 0.03%
- Toothpaste- 2.52%

**Reason for Change:** The combined exposure to methyl salicylate from oral and non-oral products is above the Margin of Safety (MoS).

**Product list:** Shower gel, hand soap, shampoo, body lotion, face cream, hand cream, lip products, hair conditioner, and toothpaste.

# 2. Draft amendment to EC No.1233/2009

Status until May-2023	Change
Draft amendment to EC No.1233/2009. Additionally, 56 more allergens were added to the existing list.	According to the amendment draft, fragrance allergens must be individually labelled on cosmetic products, in addition to the use of the terms "parfum" or "aroma," if their concentration exceeds 0.001% in leave-on products and 0.01% in rinse-off products.
Previously, there were 25 labelled allergens listed and now they are more than 80	

**Impact:** Retailers should remove/withdraw all non-compliant products from the shelves of stores in EU member countries by 2028.

**Except from regulation/Duration:** Manufacturers will have a 3-year transition period to comply with the new regulation, including updating product labelling and revising all necessary documentation.

**Reason for Change:** This amendment will protect consumers from acquiring fragrance allergies and will additionally protect sensitized individuals from developing allergy symptoms.

**Product list:** All cosmetic products

Source

SCCS: Link; Link

# 3. THE SCCS NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION - 12TH REVISION

Status until May-2023	Change
11 <sup>th</sup> revision was effective which was published in October 2021	SCCS 12 <sup>th</sup> revision was published in May 2023

#### **Impact:** Main changes in 12th revision were:

- Importance of systematic literature review.
- Updating of animal-free alternative methods: New Approach Methodology (NAM), changes
  introduced for acute inhalation, skin irritation testing, eye irritation testing with Defined Approach for
  eye irritation, Liquid (DAL), Defined Approaches for Skin Sensitisation (DASS), new in vitro methods
  for genotoxicity testing (3D skin Comet; in vitro micronucleus).
- Importance of adverse outcome pathway (AOP), defined approaches (DAs), integrated approaches to testing and assessment (IATA), next generation risk assessment (NGRA) with definition of bioactivity/exposure ratio (BER), threshold of toxicological concern (TTC), internal TTC (iTTC).
- Updating of in silico prediction possibilities.
- Exposure data reviewed (models, parameters specific for inhalation, aggregate exposure).
- Exposure of children to different cosmetic product categories according to age.
- Sun protection by sunscreen products: rationale behind exposure data.
- Human biomonitoring (HBM) and differences with SCCS approach for risk assessment.
- CMRs reporting requirements.
- Endocrine active substances, introduction of non-monotonic dose response, reporting requirements.
- Templates for physiologically based toxicokinetics (PBTK) model description and parameter verification and analysis.

**Product list**: Not applicable as this is an update on the SCCS guideline.

Source SCCS: Link



# 1. Butyl paraben

Status until Jun-2023	Change
Allowed up to a maximum concentration of 0.14% (as acid) when used alone or for the sum of its combined use with other parabens or its salts in all cosmetic product types, except leave-on products.	On 06-07 June 2023 – Preliminary opinion open for comments on butylparaben - deadline: 21 August 2023

**Impact:** SCCS concluded that the use of butylparaben as a preservative in cosmetics is safe up to 0.14% (as acid).

**Reason for Change:** Submission of new toxicological data by stakeholders led to further assessment.

**Product list:** All Cosmetic products

**Source** SCCS: <u>Link</u>

# 2. Methyl paraben

Status until Jun-2023	Change
Allowed up to a maximum concentration of 0.4% (as acid) when used alone, up to 0.8% for mixtures of esters.	On 06-07 June 2023 – Preliminary opinion open for comments on methylparaben - deadline: 21 August 2023

**Impact:** Allowed up to a maximum concentration of 0.4% (as acid) when used alone, up to 0.8% for mixtures of esters.

**Reason for Change:** Submission of new toxicological data by stakeholders led to further assessment.

**Product list:** All Cosmetic products

#### 3. Salicylic acid

Status until Jun-2023	Change
Annex III:	On 06-07 June 2023 – Final opinion on Salicylic acid was released.
Not to be used in preparations for children under 3 years of age.	
Not to be used in applications that may lead to exposure of the enduser's lungs by inhalation. Not to be used in oral products for purposes other than inhibiting the development of micro-organisms in the product, the purpose has to be apparent from the presentation of the product.	
Annex V:	
Not to be used in products for children under 3 years of age.	
Not to be used in oral products.	
Not to be used in applications that may lead to exposure of the enduser's lungs by inhalation. Salicylic acid salts.	
Not to be used in products for children under 3 years of age, except for shampoos.	

**Impact:** Safe when used as preservative at a concentration of 0.5% in cosmetic products, considering its current restrictions in place. The provided information shows that salicylic acid is an eye irritant with the potential to cause serious damage to the eye.

Safe when as a restricted ingredient for purposes other than inhibiting the development of micro-organisms:

- Up to 3.0% for the cosmetic rinse-off hair products
- Up to 2.0% for other products except body lotion, eye shadow, mascara, eyeliner, lipstick, non-spray deodorant, and
- Up to 0.5% for body lotion, eye shadow, mascara, eyeliner, lipstick, oral products and non-spray deodorant (not applicable to any sprayable product (including mouth spray) that may lead to exposure of end-user's lungs by inhalation)

Not allowed to use in cosmetic products for children under 3 years of age.

Reason for Change: Submission of new toxicological data by stakeholders led to further assessment.

**Product list:** Rinse off hair products, body lotion, eye shadow, mascara, eyeliner, lipstick, non-spray deodorant

# 4. Benzyl salicylate

Status until Jun-2023	Change
The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products – 0.01% in rinse-off products	On 06-07 June 2023 – Preliminary Opinion open for comments on benzyl salicylate – deadline: 24 August 2023

**Impact:** Considered as safe when used at concentrations as mentioned below.

Type of cosmetic product exposure	Maximum % concentration used
Hydroalcoholic-based fragrances (spray and non-spray)	4
Rinse-off skin & hair products (except rinse off body products)	0.5
Rinse off body products	1.3
Leave on skin & hair products (non-spray/non-aerosol)(except body lotion)	0.5
Leave on hair products (spray/aerosol)	0.5
Leave on body products (non-spray/spray/aerosol)	0.7
Face make-up products and make-up remover	0.2
Oral care	0.004
Deodorant products (spray/aerosol)	0.91

**Reason for Change:** Submission of new toxicological data by stakeholders led to further assessment.

**Product list:** Fragrances, skin & hair care products, rinse off body products, leave on skin & hair care products, face make up & make up remover, oral care, and deodorant products.

#### 5. Nanomaterials

Status until Jun-2023	Change
1 <sup>st</sup> revision was published in October 2019	Guidance on the safety assessment of nanomaterials for cosmetics (2 <sup>nd</sup> revision) was published on 06-June 2023

**Impact:** Main changes in this revision were:

- New sections have been introduced (solubility and dissolution rate, solubility in non- aqueous media, evidence for the absence of nanoparticles, dispersion, aspect ratio, uptake into blood cells, reproductive toxicity, endocrine disruption).
- The new European Commission recommendation for a definition of nanomaterials published in 2022 has been introduced.
- Key aspects triggering safety concerns over a nanomaterial based on SCCS/1618/2020 have been introduced.
- Other sections and Annex 1 have been updated based on literature that has been published since the last update.
- Section on read-across and grouping has been revised.
- A text explaining when historical/existing data can be used has been included.

**Reason for Change:** In view of SCCS 12th revision, certain changes were made in the assessment of nanomaterials in cosmetics.

**Product list:** Not applicable as this update on the guideline.



Status until Jul-2023	Change
26 allergens were part of EC	56 additional fragrance allergens were added.
1223/2009	According to the amendment draft, fragrance allergens must be individually labelled on cosmetic products, in addition to the use of the terms "parfum" or "aroma," if their concentration exceeds 0.001% in leave-on products and 0.01% in rinse-off products.
	Fragrance substances, such as prehaptens and prohaptens, that can be transformed to known contact allergens via air oxidation or bioactivation should be treated as equivalent to fragrance allergens and subject to the same restrictions and other regulatory requirements.

**Impact:** A transition period of 3 and 5 years was provided for new product formulations and containers to be placed on the market and to withdraw cosmetic products from the market, respectively.

**Reason for Change:** In response to the request of the Commission for an update of the list of individually labelled fragrance allergens, the Scientific Committee on Consumer Safety (SCCS) adopted an opinion at its plenary meeting of 26-27 June 2012.

It confirmed that the fragrance allergens listed in entries 45 and 67–92 of Annex III to Regulation (EC) No 1223/2009 are still relevant. Furthermore, it identified 56 additional fragrance allergens, which have clearly caused allergies in humans, and which currently have no requirement of individual labelling.

Product list: All cosmetic products.

**Source** 

**Primary source:** (Link)

**List of additional 56 fragrance allergens:** (Link)

#### 2. Water soluble Zinc salts

Status until Jul-2023	Change
SCCS published an opinion on water-soluble zinc salts used in oral hygiene products - submission I (Link) in June 2018 concluding that the use of zinc in toothpaste and mouthwash at 1 and 0.1%, respectively, is safe for adults and children aged 6-17 years.	On 4 July 2023 – SCCS published a preliminary opinion open for comments on water-soluble zinc salts used in oral hygiene products - submission II (deadline: 8 September 2023)

**Impact:** SCCS has calculated aggregate exposure to water-soluble zinc salts via toothpaste at the concentrations of 1% and from diet and concluded that the use of zinc in toothpaste is safe per se except for children under the age of 1 year because the intake exceeds the upper limit level.

The inclusion of zinc in mouthwash at 0.1% Zn is considered safe across all age groups. Products should be assessed for levels of Zinc.

**Reason for Change:** Daily dietary intake of zinc was not considered in Submission I. Submission II includes considerations of the reported dietary exposures, absorption kinetics, and the age- dependent usage of oral care products by consumers.

**Product list:** Oral hygiene products.



#### 1. Methyl salicylate

Status until Sep-2023	Change

On 27 October 2021, the SCCS concluded on the safety of methyl salicylate and Regulation (EU) 2022/1531 restricted its use in cosmetic products. Methyl salicylate is currently listed in entry 324 of Annex III to the Cosmetic Regulation (EC) No. 1223/2009, with specific concentration limits for various product types and age groups.

On 16<sup>th</sup> May 2023 – Preliminary Opinion open for comments on children exposure to methyl salicylate (methyl 2- hydroxybenzoate) - deadline: 19<sup>th</sup> June 2023

On 14<sup>th</sup> September 2023 - SCIENTIFIC ADVICE – children exposure to methyl salicylate (methyl 2-hydroxybenzoate) was published.

**Impact:** In view of the conclusions of SCCS/1633/21 and the aggregate exposure, the SCCS considers the use of methyl salicylate as safe in cosmetic products intended for children of age 0.5-3 years when used up to a maximum concentration of 0.02% in shower gel, hand soap, shampoo, body lotion, face cream, hand cream, and lip products. For toothpaste, up to a maximum concentration of 2.52% methyl salicylate is considered safe.

The SCCS considers the use of methyl salicylate as safe in cosmetic products intended for children of age 3-6 years in shower gel, hand soap, shampoo, body lotion, face cream, hand cream, lip products, and hair conditioner up to the allowed maximum concentrations indicated in the Table.

Product type, Body parts	Maximum concentration in ready for use preparation	Other
(a) Leave-on skin products (except face makeup, spray/aerosol body lotion, spray/aerosol deodorant and hydroalcoholic-based fragrances) and leave on hair products (except spray/aerosol products)	(a) 0.06 %	
(b) Face makeup (except lip products, eye makeup and makeup remover)	(b) 0.05 %	
(c) Eye makeup and makeup remover	(c) 0.002 %	Not to be used in preparations for children under 6 years of age, with the exception of (k) "Toothpaste"
(d) Leave-on hair products (spray/aerosol)	(d) 0.009 %	
(e) Deodorant spray/aerosol	(e) 0.003 %	
(f) Body lotion spray/aerosol	(f) 0.04 %	
(g) Rinse-off skin products (except hand wash) and rinse-off hair products	(g) 0.06 %	
(h) Hand wash	(h) 0.6 %	
(i) Hydroalcoholic-based fragrances	(i) 0.6 %	
(j) Lip products	(j) 0.03 %	
(k) Toothpaste	(k) 2.52 %	
(I) Mouthwash intended for children aged 6–10 years	(I) 0.1 %	
(m) Mouthwash intended for children above 10 years of age and adults	(m) 0.6 %	
(n) Mouth spray	(n) 0.65 %	

For toothpaste, up to a maximum concentration of 2.52% methyl salicylate is considered safe.

**Reason for Change:** The combined exposure to methyl salicylate from oral and non-oral products is above the Margin of Safety (MoS), when used:

- for children of age 0-3 years, up to a maximum concentration of 0.02% in all the currently regulated cosmetic products included in the above table.
- for children of age 3-6 years, up to the allowed maximum concentrations for each of the currently regulated cosmetic products included in the above table.

Product list: All cosmetic products.

**Source:** <u>SCCS</u>

Status until Sep-2023	Change
Annex II to Regulation (EC) No 1223/2009 was amended- 19th July 2023. The annex II was updated on 14 September 2023.	According to the amendment draft (COMMISSION REGULATION (EU) 2023/1490), 30 CMR (carcinogenic, mutagenic, and toxic for reproduction) were added to annex II to Regulation (EC) No 1223/2009.

**Impact:** This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. It shall apply from 1 December 2023.

Reason for Change: To uniformly implement the prohibition of CMR substances within the internal market, to ensure legal certainty, for economic operators and national competent authorities, and to ensure a high level of protection of human health, all CMR substances should be included in the list of prohibited substances in Annex II to Regulation (EC) No 1223/2009 and, where relevant, deleted from the lists of restricted or allowed substances in Annexes III to VI to that Regulation. Where the conditions laid down in Article 15(1), second sentence, of Regulation (EC) No 1223/2009 or in Article 15(2), second subparagraph of that Regulation are fulfilled, the lists of restricted or allowed substances in Annexes III to VI to that Regulation should be amended accordingly.

Product list: All cosmetic products.

Source:

(EU) 2023/1490: (Link)

Cosing: (Link)

Status until Sep-2023	Change
Annex III to Regulation (EC) No 1223/2009 was amended- 26th July 2023.	According to the amendment draft (COMMISSION REGULATION (EU)
The annex III was updated on 14th September 2023.	2023/1545), fragrance allergens must be individually labelled on cosmetic products, in addition to the use of the terms "parfum" or "aroma," if their concentration exceeds 0.001% in leave- on products and 0.01% in rinse-off products.
	Fragrance substances, such as prehaptens and prohaptens, that can be transformed to known contact allergens via air oxidation or bioactivation should be treated as equivalent to fragrance allergens and be subject to the same restrictions and other regulatory requirements.
	The list of fragrance allergens previously had 24 entries. Following this amendment, the list now has 80 entries (56 new entries).

**Impact:** A transition period of 3 and 5 years was provided for new product formulations and containers to be placed in the market and to withdraw cosmetic products from the market, respectively.

**Reason for Change:** In response to the request of the Commission for an update of the list of individually labelled fragrance allergens, the Scientific Committee on Consumer Safety (SCCS) adopted an opinion at its plenary meeting of 26-27 June 2012.

It confirmed that the fragrance allergens listed in entries 45 and 67–92 of Annex III to Regulation (EC) No 1223/2009 are still relevant. Furthermore, it identified 56 additional fragrance allergens, which have clearly caused allergies in humans, and which have currently no requirement of individual labelling.

Product list: All cosmetic products.

Source:

(EU) 2023/1545: (Link)

Cosing: (Link)



#### Status until Oct-2023

Annex III to Regulation (EC) No 1223/2009 was updated on 24 October 2023.

- 1. Hydroxy-3-nitro-4-(3-hydroxypropylamino)benzene and its salts were prohibited for use after 2009. Status up to 2009 was as below:
  - (a) Hair dye substance in oxidative hair dye products (5.2%)
  - (b) Hair dye substance in non-oxidative hair dye products (2.6%)

#### Change

The free base and salts of this hair coloring ingredient unless prohibited under Annex II are permitted for use. Maximum concentration in ready for use preparation was 2.6%.

(a) After mixing under oxidative conditions, the maximum use concentration applied to hair must not exceed 2.6% calculated as free base.

#### For (a) and (b):

- Do not use with nitrosating systems.
- Maximum nitrosamine content: 50 microgram/kg.
  - Keep in nitrite-free containers. To be printed on the label:
- The mixing ratio.
- Hair colorants can cause severe allergic reactions.

Read and follow instructions.

- This product is not intended for use on persons under the age of 16.
- Temporary "black henna" tattoos may increase your risk of allergy.
- Do not colour your hair if:
- you have a rash on your face or sensitive, irritated and damaged scalp,
- you have ever experienced any reaction after coloring your hair.
- you have experienced a reaction to a temporary "black henna" tattoo in the past.

**Impact:** The above compliance must be followed for cosmetic ingredients with 1-hydroxy-3- nitro-4-(3-hydroxypropylamino)benzene and its salts.

**Reason for Change:** The use of this substance in cosmetic products in the European Union is banned, except under certain conditions as indicated in Annex III (details as provided in the above table).

**Product list:** All cosmetic products.

**Source:** 

EU CosIng: Annex III (Link)

Cosing: 1-Hydroxy-3-nitro-4-(3-hydroxypropylamino)benzene (Link)

#### Status until Oct-2023 Change Annex III to Regulation (EC) No The free base and salts of this hair coloring ingredient unless pro-1223/2009 was updated on 24 hibited under Annex II are permitted for use. Maximum concen-October 2023. tration in ready for use preparation was 2% in non-oxidative hair 1-[(2'-Methoxyethyl)amino]-2-nidye products. tro-4-[di-(2'- hydroxyethyl)amino] Do not use with nitrosating agents benzene and its salts were prohib-Maximum nitrosamine content: 50 μg/kg ited for use after 2009. Status up to Keep in nitrite-free containers 2009 was as below: (a) Hair dye substance in oxidative hair dye products (3%)(b) Hair dye substance in non-oxidative hair dye products (2%)

**Impact:** The above compliance must be followed for cosmetic ingredients with 1-[(2'- methoxyethyl)amino]-2-nitro-4-[di-(2'-hydroxyethyl)amino]benzene and its salts.

**Reason for Change:** The use of this substance in cosmetic products in the European Union is banned, except under certain conditions as indicated in Annex III (details as provided in the above table).

Product list: All cosmetic products.

#### **Source:**

EU CosIng: Annex III (Link)

Cosing: 1-[(2'-Methoxyethyl)amino]-2-nitro-4-[di-(2'-hydroxyethyl)amino]benzene (Link)

Status until Oct-2023	Change
Annex III to Regulation (EC) No 1223/2009 was updated on 24 October 2023.	The free base and salts of this hair coloring ingredient unless prohibited under Annex II are permitted for use. 1-Propanol, 3-[[4-[bis(2- hydroxyethyl)amino]-2-
1-(3-Hydroxypropyl- amino)-2- nitro-4-bis(2- hydroxyethyl)amino)	nitrophenyl]amino] (HC Violet No 2) was allowed with a maximum concentration of 2% in ready for use preparation in non- oxidative hair dye products.
it salts (HC Violet No 2) were prohibited for use after 2009.	<ul> <li>Do not use with nitrosating agents</li> <li>Maximum nitrosamine content: 50 μg/kg</li> <li>Keep in nitrite-free containers</li> </ul>

**Impact:** The above compliance must be followed for cosmetic ingredients with HC Violet No 2.

**Reason for Change:** The use of this substance in cosmetic products in the European Union is banned, except under certain conditions as indicated in Annex III (details as provided in the above table).

Product list: All cosmetic products.

#### Source:

EU CosIng: Annex III (Link)

Cosing: 1-Propanol, 3-[[4-[bis(2-hydroxyethyl)amino]-2-nitrophenyl]amino] (Link)

Status until Oct-2023	Change
Annex III to Regulation (EC) No 1223/2009 was updated on 24 October 2023.	4,4'-[1,3-Propanediylbis(oxy)]bisbenzene- 1,3-diamine and its tetra- hydrochloride salt were allowed up to a maximum concentration of 1.2 and 1.8% (calculated as free base and as tetrahydrochloride
4,4'-[1,3-Propanediylbis(oxy)]bis-,	salt, respectively) after mixing under oxidative conditions.
benzene-1,3-diamine and its salts	To be printed on the label:
were prohibited for use after 2009.	The mixing ratio.
	Hair colorants can cause severe allergic reactions.
	Read and follow instructions.
	This product is not intended for use on persons under the age of 16 years.
	Temporary "black henna" tattoos may increase your risk of allergy.  Do not colour your hair if:
	<ul> <li>you have a rash on your face or sensitive, irritated and damaged scalp,</li> </ul>
	<ul> <li>you have ever experienced any reaction after coloring your hair,</li> </ul>
	<ul> <li>you have experienced a reaction to a temporary "black henna" tattoo in the past.</li> </ul>
	Can cause allergic reaction.

**Impact:** The above compliance must be followed for cosmetic ingredients with 4,4'-[1,3-propanediylbis(oxy)]bisbenzene-1,3-diamine and its tetrahydrochloride salt.

**Reason for Change:** The use of this substance in cosmetic products in the European Union is banned, except under certain conditions as indicated in Annex III (details as provided in the above table).

**Product list:** All cosmetic products.

#### Source:

EU CosIng: Annex III (Link)

Cosing: 4,4'-[1,3-Propanediylbis(oxy)]bisbenzene-1,3-diamine and its tetrahydrochloride salt (Link)



#### 1. Water soluble zinc salts

Status until Nov-2023	Change
SCCS published an opinion on water-soluble zinc salts used in oral hygiene products - submission I (Link) in June 2018 concluding that the use of zinc in toothpaste and mouthwash at 1 and 0.1%, respectively, is safe for adults and children aged 6-17 years.	On 6 <sup>th</sup> November 2023 – SCCS published a final opinion on water-soluble zinc salts used in oral hygiene products - Submission II.

**Impact:** SCCS has calculated aggregate exposure to water-soluble zinc salts via toothpaste at the concentrations of 1% and from diet and concluded that the use of zinc in toothpaste is safe per se except for children under the age of 1 year because the intake exceeds the upper limit level. For children up to 1 year of age, the SCCS recommends a safe concentration of 0.72% for soluble zinc salts (as zinc) in toothpaste.

The inclusion of zinc in mouthwash at 0.1% Zn is considered safe across all age groups.

Reason for Change: Daily dietary intake of zinc was not considered in Submission I.

Submission II includes considerations of the reported dietary exposures, absorption kinetics, and the age dependent usage of oral care products by consumers.

Product list: All cosmetic products.

# 2. Fullerenes, hydroxylated fullerenes and hydrated forms of hydroxylated fullerenes (nano)

Status until Nov-2023	Change
The safety of fullerenes, hydroxylated fullerenes and hydrated forms of hydroxylated fullerenes in cosmetic products was not previously assessed by SCCS.	On 3 <sup>rd</sup> November 2023 – SCCS published a final opinion on fullerenes, hydroxylated fullerenes and hydrated forms of hydroxylated fullerenes (nano).

**Impact:** The available evidence indicates that hydrated forms of hydroxylated fullerenes are genotoxic and hence, SCCS considers them as not safe for use in cosmetic products. The same concerns over genotoxicity potential apply to hydroxylated fullerenes.

**Reason for Change:** To address the safety of fullerenes, hydroxylated fullerenes and hydrated forms of hydroxylated fullerenes (nano) in cosmetics.

**Product list:** Oral care products.

# 3. Benzyl salicylate

Status until Nov-2023	Change
The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products.	On 6 <sup>th</sup> November 2023 – SSCS published a final opinion on benzyl salicylate (CAS No. 118-58-1, EC No. 204-262-9).

**Impact:** The finished product containing benzyl salicylate must comply with the details mentioned in the below table.

Type of cosmetic product exposure	Maximum % concentration used
Hydroalcoholic-based fragrances (spray and non-spray)	4
Rinse-off skin & hair products (except rinse off body products)	0.5
Rinse off body products	1.3
Leave on skin & hair products (non-spray/non-aerosol)(except body lotion)	0.5
Leave on hair products (spray/aerosol)	0.5
Leave on body products (non-spray/spray/aerosol)	0.7
Face make-up products and make-up remover	0.2
Oral care	0.004
Deodorant products (spray/aerosol)	0.91

**Reason for Change:** Submission of new toxicological data by stakeholders led to further assessment.

**Product list:** All cosmetic products.

# 4. Butylparaben

Status until Nov-2023	Change
Allowed up to a maximum concentration of	On 6 <sup>th</sup> November 2023 – SCCS published a final opinion on butylparaben (CAS No.
0.14 % (as acid) when used alone or for the sum of its combined use with other parabens or its salts in all cosmetic product types, except leave-on products.	94-26-8, EC No. 202-318-7).
Not to be used in leave-on products designed for application on the nappy area of children under three years of age.	

**Impact:** SCCS concluded that the use of butylparaben as a preservative in cosmetics is safe up to 0.14% (as acid).

**Reason for Change:** Submission of new toxicological data by stakeholders led to further assessment.

**Product list:** All cosmetic products.

# 5. Hydroxypropyl p-phenylenediamine and its dihydrochloride salt (A165)

Status until Nov-2023	Change
In its first opinion (Link), SCCS has reported that hydroxypropyl p-phenylenediamine and its dihydrochloride salt were not safe when used in oxidative hair coloring products due to potential genotoxicity.	On 6 <sup>th</sup> November 2023 – SCCS published a preliminary opinion open for comments on hydroxypropyl p-phenylenediamine and its dihydrochloride salt (A165) - deadline: 8 January 2024.

**Impact:** SCCS considers that hydroxypropyl p-phenylenediamine and its dihydrochloride salt are safe when used in oxidative hair coloring products up to a maximum on-head concentration of 2%.

A mild to moderate eye irritation potential of the test item cannot be excluded. Hydroxypropyl p-phenylenediamine and its dihydrochloride salt are moderate skin sensitisers based on animal data.

**Reason for Change:** Submission of new toxicological data by stakeholders led to further assessment.

**Product list:** All cosmetic products.

# 6. Hexyl salicylate

Status until Nov-2023	Change
The safety of hexyl salicylate in cosmetic products was not previously assessed by SCCS.	On 9 <sup>th</sup> November 2023 – SCCS published a preliminary opinion open for comments on hexyl salicylate – deadline: 12 January 2024.

**Impact:** SCCS considers hexyl salicylate safe when used up to the maximum concentrations as provided in the table.

Product type, Body parts	Maximum concentration
Hydroalcoholic-based fragrances	2
All Rinse-off products	0.5
All Leave on products	0.3
Oral care (toothpaste and mouthwash)	0.001

**Reason for Change:** To address the safety of hexyl salicylate in cosmetics.

**Product list:** All cosmetic products.



#### 1. Aluminum

Status until Dec-2023	Change
A submission III on aluminum was published by the SCCS in February 2023, where it concluded that aluminum compounds are safe when used in non-sprayable product categories at the maximum levels indicated in Tables 4 and 6; and in sprayable products, at the maximum levels indicated in table 4, provided that the percentage of particles/droplets with a diameter of less than 10 µm does not exceed 20% of the total aerosolized particles/droplets (Link).	On 15 <sup>th</sup> December 2023-SCCS published a preliminary opinion open for comments on the safety of aluminum in cosmetic products - Submission IV (Deadline for comments: 16 February 2024).

**Impact:** The SCCS considers that aluminum compounds are safe when used :

- in non-sprayable product categories at the maximum levels indicated in the table below
- in sprayable products, at the maximum levels indicated in the table below, provided that the percentage of particles/droplets with a diameter of less than 10 µm does not exceed 20% of the total aerosolized particles/droplets. Since the applicant's data submission indicated that aluminum is not used in sunscreen aerosol sprays, this opinion does not cover sunscreen aerosol sprays.
- in talc because aluminum is not bioavailable from talc up to a level of 2%.

	Product as labelled in the model	Aluminium concentrations (%) in products in Scenario 1b
1	AfterShave	2.15%
2	BarSoap	4%
3	BodyLotion	3.81%
4	BodySpray	1.18%
5	DeoRollOn – Gel	6.18%
6	DeoRollOn - RollOn	5.63%
7	DeoRollOn - Stick	7.73%
8	DeoRollOn – Wipes	0%
9	DeoSpray - Anti-Perspirant	3.24%
10	DeoSpray - Pump	4.88%
11	EaudeParfum, EaudeToilette	0.05%
12	EyeShadow	43.31%
13	EyeLiner	15.76%
14	FaceMoisturizer	10.59%
15	HairSpray	0.15%
16	HairStyling	6.7%
17	HandCream	0.86%
18	Lipstick	14.62%
19	LiquidHandSoap	0.89%
20	LiquMakeupFoundation	23%
21	MakeupRemover	10.59%
22	Mascara	3.13%
23	Mouthwash	0%
24	RinseoffConditioner	7.14%
25	Shampoo	7.14%
26	Showergel	0.89%
27	Toothpaste	3.18%

**Reason for Change:** Updated use concentrations.

This opinion specifically covers the risk to consumers from exposure to aluminum from cosmetic products. As such, this opinion does not address the safety of the use of talc in cosmetic products beyond the safety of the aluminum content in talc.

**Product list:** All cosmetic products.

**Source:** <u>SCCS</u>

## 2. Benzophenone-4

Status until Dec-2023	Change
In safety evaluation by SCCNFP in 1999, it was concluded that benzophenone-4 can be used safely in cosmetic sunscreen formulations at a maximum concentration of 5%, expressed as acid and proposed no further restrictions or conditions for its use in cosmetic products (Link).	On 15th December 2023- SCCS published a preliminary opinion open for comments on benzophenone - 4 (deadline for comments: 16 February 2024).

**Impact:** Based on the safety assessment, and considering the concerns related to potential endocrine disrupting properties of benzophenone-4, the SCCS is of the opinion that benzophenone-4 is safe when used as UV filter up to a maximum concentration of 5% in sunscreen, face and hand cream, lipstick, sunscreen propellant spray and pump spray, when used separately or in combination (based on deterministic aggregated exposure).

**Reason for Change:** Benzophenone-4 was one among the priority list of potential endocrine disruptors which were not already covered by bans or restrictions in the Cosmetics Regulation for their subsequent safety assessment.

Hence, a call for data took place.

Product list: All cosmetic products.

#### 3. Silver zinc zeolite

Status until Dec-2023	Change
SZZ was a prohibited substance in cosmetic products.	On 22 <sup>nd</sup> December 2023 – SCCS published a final opinion on silver zinc zeolite.
SCCS published a preliminary opinion open for comments on silver zinc zeolite in April.	

**Impact:** The SCCS considers that SZZ incorporating a maximum silver content of 2.5% is safe in spray deodorant and powder foundation when used at the proposed concentration of 1%.

**Reason for Change:** In May 2019, SZZ was added in entry 1597 of Annex II of Regulation (EC) No. 1223/2009 as a prohibited substance in cosmetic products. In August 2020, the Commission services received a dossier submission by industry to support the safety assessment of SZZ as a preservative in cosmetic products, in spray deodorant and powder foundation. A positive outcome of this assessment may support the delisting of SZZ from Annex II and its inclusion under Annex V to the Cosmetics Regulation as an authorized preservative.

Product list: All cosmetic products.

# 4. Methyl paraben

Status until Dec-2023	Change
Preliminary opinion was published in June.	On 15 <sup>th</sup> December 2023 – SCCS published a final opinion on methylparaben.

**Impact:** Based on the safety assessment considering all available data and the concerns related to endocrine activity, the SCCS is of the opinion that the use of methylparaben as a preservative in cosmetic products at concentrations of up to 0.4% (expressed as acid) is safe.

**Reason for Change:** Methyl paraben was one among the priority list of potential endocrine disruptors which were not already covered by bans or restrictions in the Cosmetics Regulation for their subsequent safety assessment. Hence, a call for data took place.

**Product list:** All cosmetic products.

#### 5. Titanium dioxide

#### Status until Dec-2023 Change

Titanium dioxide is authorized both as a colorant under entry 143 of Annex IV and as UV-filter under entries 27 and 27a (nano form) of Annex VI to Regulation (EC) No. 1223/2009 (Cosmetics Regulation). Considering its classification as a Carcinogen Category 2 (i.e. suspected human carcinogen) by inhalation route only and its inclusion in Annex VI to Regulation (EC) No. 1272/2008 (CLP Regulation) titanium dioxide was reassessed by the SCCS. Subsequently, entry 321 in Annex III was introduced and additional provisions in the existing entries of 143 of Annexes IV and 27 and 27a of Annex VI were added that further restricted the use of titanium dioxide in cosmetic products.

On 5<sup>th</sup> December 2023- SCCS published a preliminary scientific advice on titanium dioxide open for comments – deadline: 6 February 2024.

**Impact:** The SCCS considers that the available evidence is not sufficient to exclude the genotoxicity potential of almost all the types of titanium dioxide grades (44 pigmentary and 40 nano grades) used in oral cosmetic products. The only exception are two nano grades (RM09 and RM11) for which the provided genotoxicity data indicate no genotoxicity concern. More information is, however, needed on the potential uptake and cellular effects of the nano grades in the oral mucosa to consider them safe for use in oral-care products. More experimental data are needed from studies carried out under valid protocols and appropriate testing guidelines to exclude the genotoxicity potential of the selected representatives of the other grades of titanium dioxide (both pigmentary and nano) used in oral cosmetic products.

The conclusions drawn in previous SCCS opinions on dermally applied cosmetic products (SCCS/1516/13, SCCS/1580/16) remain unchanged for the titanium dioxide grades and the coatings evaluated in those opinions. The conclusions drawn in the previous opinions (and SCCS/1583/17, SCCS/1617/20) on the safety of titanium dioxide used in specific cosmetic products that may lead to exposure by inhalation also remain unchanged. Studies have indicated that oral mucosal cells are prone to the uptake of nanoparticles (including titanium dioxide nanoparticles), as they may penetrate the mucous layer and may be internalized by the epithelial cells. Considering that some oral products containing titanium dioxide nanoparticles, such as toothpastes and mouthwashes, will be used every day and potentially more than once a day, further investigations are needed to exclude the risk to the consumer from long-term repeated exposures of the oral mucosa to titanium dioxide nanoparticles.

Reason for Change: In 2021, the EFSA panel has issued an opinion on titanium dioxide as a food additive, where it has indicated a concern for genotoxicity. They have concluded that titanium dioxide should no longer be considered as safe when used as a food additive. The commission has requested SCCS to re-assess the safety of titanium dioxide with focus on genotoxicity and exposure via the inhalation and oral route (lip care, lipstick, toothpaste, loose powder, and hair spray), since the currently available scientific evidence supports an overall lack of dermal absorption of titanium dioxide particles.

Product list: All cosmetic products.



# **About ClinChoice**

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