



# UV FILTERS



- 32 technical sheets
- The European Regulation
- All filters in Annex VI of Regulation 1223/2009
- International requirements

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# Introduction

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These are perhaps the most difficult cosmetic ingredients to master...

In addition to the subtleties (which often turn into a headache) of the formulation, which must be effective for UV protection but also photostable, easily applicable, invisible... and without any suspected health risk, it must also be ensured that the finished product containing them can be marketed and exported without any obstacles.

And this is where things get even more complicated.

This is because some UV filters are accepted there and banned elsewhere, and sometimes the maximum concentration deemed safe, or the conditions of use, vary from one country to another.

And if the whole of Europe has standardised its regulations through the Cosmetics Regulation 1223/2009, the differences appear as soon as you cross its borders!

In order to take stock of these specificities, CosmeticOBS has compiled in this ebook the technical data sheets of all the UV filters authorised in Europe, all those listed in Annex VI of the Regulation.

For each one, the chemical identity, the toxicological profile, the conditions of use in Europe and internationally, the history of the regulations, the sources of reference...

A checklist that every sunscreen product formulator and every regulatory officer should have in hand before even starting to work on a new product!

# CAMPHOR BENZALKONIUM METHOSULFATE

**INCI Name**

Camphor benzalkonium methosulfate

**CAS No.**

52793-97-2

**English name**

Mexoryl SO

**CE No.**

258-190-8

## Origins

- Synthetic

## CosIng functions

1. Antimicrobial Agent
2. Antistatic
3. UV Absorber
4. UV Filter

## Regulation

European Cosmetics Regulation 1223/2009, Annex VI/2 (UV Filters)

### Substance Identification

**• Chemical name/INN/XAN**

N,N,N-Trimethyl-4-(2-oxoborn-3-ylidenemethyl) anilinium methyl sulfate

**• Name of Common Ingredients Glossary**

Camphor Benzalkonium Methosulfate

**• CAS number**

52793-97-2

**• EC number**

258-190-8

### Conditions

**• Product type, Body parts**

/

**• Maximum concentration in ready for use preparation (finished cosmetic product)**

6%

**• Other**

/

### International

**ASEAN**

- Authorised up to 6%

**Australia**

- Authorised up to 6%

**Brazil**

- Authorised up to 6%

**Canada**

- Non-approved filter

**China**

- Authorised up to 6%

### **Great Britain**

- Authorised up to 6%

### **India**

- Authorised up to 6%

### **Japan**

- Non-authorised filter

### **Mexico**

- Authorised up to 6%

### **New-Zealand**

- Authorised up to 6%

### **Saudi Arabia**

- Authorised up to 6%

### **South Korea:**

- -

### **Taiwan**

- Authorised up to 6%

### **United Arab Emirates**

- Authorised up to 6%

### **United States**

- Non-approved filter

## **Knowledge to date**

### **Substance**

- N,N,N-Trimethyl-4-(2-oxoborn-3-ylidenemethyl) anilinium methyl sulfate
- Patented filter of the L'Oréal group (Mexoryl SO)

### **Profile**

- Anti-UVA and anti-UVB protection
- According to the classification provided by companies to ECHA in REACH registrations this substance causes serious eye irritation and causes skin irritation

## **References**

- **Regulation (EC) No.1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products**, Annex VI/4
- **Primary Sunscreen Monograph**, Health Canada, 7 December 2018
- **21 CFR part 352.10 - Sunscreen active ingredients, Electronic Code of Federal Regulations**, FDA, 15 August 2019
- **Ingredient Camphor benzalkonium methosulfate**, CosIng
- **Information on Chemicals - Methyl N,N,N-trimethyl-4-((4,7,7-trimethyl-3-oxobicyclo(2.2.1)hept-2-ylidene)methyl)anilinium sulphate**, ECHA website

# HOMOSALATE

**INCI Name**

Homosalate

**CAS No.**

118-56-9

**English name**

Homosalate

**CE No.**

204-260-8

## Origins

- Synthetic

## CosIng functions

1. Fragrance
2. UV Absorber
3. UV Filter

## Regulation

European Cosmetics Regulation 1223/2009, Annex VI/3 (UV Filters)

*Applicable from 1 January 2025 for products placed on the market and from 1 July 2025 for products made available on the market*

### Substance Identification

**• Chemical name/INN/XAN**

Benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester / Homosalate

**• Name of Common Ingredients Glossary**

Homosalate

**• CAS number**

118-56-9

**• EC number**

204-260-8

### Conditions

**• Product type, Body parts**

Face products with the exception of propellant spray products

**• Maximum concentration in ready use preparation**

7.34%

**• Other**

/

### International

**ASEAN**

- Authorised up to 10%

**Australia**

- Authorised up to 15%

**Brazil**

- Authorised up to 15%

**Canada**

- Authorised up to 15%

### **China**

- Authorised up to 10%

### **Great Britain**

- Authorised up to 10%

### **India**

- Authorised up to 10%

### **Japan**

- Authorised up to 10% (Quasi-Drugs: 10%, except in Bath products, Permanent wave products, and Hair coloring products: Prohibited)

### **Mexico**

- Authorised up to 10%

### **New-Zealand**

- Authorised up to 10%

### **Saudi Arabia**

- Authorised up to 10%

### **South Korea**

- Authorised up to 10%

### **Taiwan**

- Authorised up to 10%

### **United Arab Emirates**

- Authorised only in face products, except aerosol spray products, up to 7.34%

### **United States**

- Authorised up to 15%

## **Knowledge to date**

### **Substance**

- Benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester / Homosalate

### **Profile**

- Anti-UVB protection
- Potential endocrine disruptor

### **History**

- 2001: A scientific publication (Margret Schlumpf et al.) tends to show the estrogenic effect of several UV filters, including Homosalate.
- 2001: The SCCNFP comes to the conclusion that a number of important technical and scientific shortcomings are present in the study of M. Schlumpf et al. The Scientific Committee is of the opinion that the organic UV-filters used in cosmetic sunscreen products have no estrogenic effects that could potentially affect human health.
- 2019: The American FDA presents its project to revise the monograph on sunscreen filters authorized in the United States. Of the 16 currently listed, the Administration is requesting more data on 12 substances, including Homosalate, in order to assess whether they are GRASE ((Generally Recognized As Safe and Effective) or not.
- 2019: The European Commission has launched a call for data on 14 substances suspected of having endocrine disrupting properties to be assessed as a matter of priority by the SCCS. Homosalate is part of this list.
- 2020: Following the European Commission's call for data, the industry has sent a dossier to demonstrate the safety of Homosalate. Mandate is given to the SCCS to evaluate it.

- 2020: The SCCS publishes its preliminary Opinion and concludes that Homosalate is not safe when used as a UV-filter in cosmetic products at concentrations of up to 10%. The Committee recommends a maximum concentration of 1.4%.
- 2021: The SCCS publishes its final Opinion. Instead of the 1.4% recommended in its preliminary Opinion, it sets the maximum safe concentration at 0.5%. It acknowledges that the use of Homosalate at lower concentrations may affect the efficacy of the UV filter, but states that it is not within the competence of the SCCS to assess the efficacy of cosmetic ingredients.
- 2021: As the industry has submitted a new calculation of the margin of safety (MoS) based only on the use of Homosalate in face products (face creams and pump-sprays), the European Commission is again requesting the SCCS Opinion on this issue.
- 2021: The SCCS publishes a Scientific advice in which it concludes that Homosalate is safe as a UV-filter at concentrations up to 7.34% in face cream and pump spray.
- 2022: The Office for Product Safety and Standards (OPSS), which regulates cosmetic products in the UK, is calling for data on five ingredients with endocrine disrupting properties, including Homosalate, to assess their safety.
- 2022: The European Commission notifies the WTO of a draft Regulation that would tighten the conditions of use of Homosalate, allowing it only in face products, with the exception of propellant spray products, at a maximum concentration of 7.34%.
- 2022: Regulation 2022/2195 is published and confirms the planned provisions for Homosalate. It is applicable from 1 July 2025.

## References

- **Regulation (EC) No.1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products**, Annex VI/3
- **Primary Sunscreen Monograph**, Health Canada, 7 December 2018
- **21 CFR part 352.10 - Sunscreen active ingredients, Electronic Code of Federal Regulations**, FDA, 15 August 2019
- **Ingredient Homosalate**, CosIng
- **Information on Chemicals - Homosalate**, ECHA website
- **In vitro and in vivo estrogenicity of UV screens**, Schlumpf M, Cotton B, Conscience M, Haller V, Steinmann B, Lichtensteiger W, Environ Health Perspect. 2001 Mar;109(3):239-44
- **SCCNFP, Opinion on the evaluation of Potentially estrogenic effects of UV-filters**, 12 June 2001
- **SCCP (Scientific Committee on Consumer Products), Opinion on Homosalate, SCCP/1086/07**, 21 March 2007
- **Sunscreen Monograph: the FDA proposal**, CosmeticOBS, 6 March 2019
- **Endocrine disruptors: 1st call for data from the European Commission**, CosmeticOBS, 21 May 2019
- **Endocrine disruptors: 5 requests for SCCS Opinions**, CosmeticOBS, 10 February 2020
- **Scientific Committee on Consumer Safety (SCCS), Request for a scientific opinion on Homosalate (CAS No 118-56-9, EC No 204-260-8)**, European Commission, 5 February 2020
- **Propylparaben, Homosalate: Preliminary Opinions of the SCCS**, CosmeticOBS, 16 November 2020
- **SCCS (Scientific Committee on Consumer Safety), Opinion on Homosalate (CAS No.118-56-9, EC No.204-260-8), preliminary version, SCCS/1622/20**, 27-28 October 2020
- **Homosalate: Final Opinion of the SCCS**, CosmeticOBS, 5 July 2021
- **SCCS (Scientific Committee on Consumer Safety), Opinion on Homosalate (CAS No.118-56-9, EC No.204-260-8), SCCS/1622/20**, preliminary version of 27-28 October 2020, final version of 24-25 June 2021
- **Butylparaben, Homosalate: requests for SCCS Opinions**, CosmeticOBS, 18 octobre 2021



- **Scientific Committee on Consumer Safety (SCCS), Request for a scientific advice on the safety of Homosalate (CAS No.118-56-9, EC No.204-260-8) as a UV-filter in cosmetic products**, European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, 11 October 2021
- **SCCS: Scientific advice on the safety of Homosalate**, CosmeticOBS, 13 December 2021
- **SCCS (Scientific Committee on Consumer Safety), Scientific advice on the safety of Homosalate (CAS No.118-56-9, EC No.204-260-8) as a UV-filter in cosmetic products in cosmetic products, SCCS/1638/21**, final version of 2 December 2021
- **Endocrine disruptors: OPSS call for data**, CosmeticOBS, 19 April 2022
- **Safety of Cosmetic Ingredients with Suspected Endocrine Disrupting Properties: call for data**, OPSS, Department for Business, Energy & Industrial Strategy, 5 April 2022
- **Europe notifies new regulation for 4 cosmetic ingredients (EDs, colorant, UV filters)**, CosmeticOBS, 19 April 2022
- **Committee on Technical Barriers to Trade, Notification, G/TBT/N/EU/886**, World Trade Organization, 12 April 2022
- **Draft Commission Regulation (EU) .../... of XXX amending Regulation (EC) No.1223/2009 of the European Parliament and of the Council**, European Commission, 12 April 2022
- **Annex to the Draft Commission Regulation (EU) .../... of XXX amending Regulation (EC) No.1223/2009 of the European Parliament and of the Council**, European Commission, 12 April 2022
- **Regulation (EU) 2022/2195: new regulation for 4 cosmetic ingredients (EDs, colorant, UV filters)**, CosmeticOBS, 21 November 2022
- **Commission Regulation (EU) 2022/2195 of 10 November 2022 amending Regulation (EC) No.1223/2009 of the European Parliament and of the Council as regards the use of Butylated Hydroxytoluene, Acid Yellow 3, Homosalate and HAA299 in cosmetic products and correcting that Regulation as regards the use of Resorcinol in cosmetic products**, *Official Journal of the European Union*, L 292/32, 11 November 2022