

ENDOCRINE DISRUPTORS INGREDIENTS



- 37 TECHNICAL DATA SHEETS
- CURRENT REGULATIONS
- ONGOING EVALUATIONS
- OUTLOOK FOR THE FUTURE

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Introduction

In its Article 15 dedicated to CMRs, Cosmetics Regulation 1223/2009 devotes a paragraph to endocrine disruptors, which provides that: *“When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties.”*

The criteria for identifying endocrine disruptors were defined far after the 2015 deadline, exactly in November 2017 for biocides and in April 2018 for plant protection products.

Even if they do not apply specifically to cosmetic products, these criteria are still “criteria agreed by the Community for the identification of substances with endocrine disrupting properties”, and according to Article 15, the Commission should have revised the Cosmetics Regulation on this basis.

Instead, the Commission has reviewed how substances considered as potential endocrine disruptors have so far been treated under the Regulation, i.e. either banned or limited on a case-by-case basis after their safety assessment by the SCCS, or covered by the REACH Regulation or the provisions of Article 15 of the Cosmetic Regulation on CMRs. And concluded, in a report published on 7 November 2018, that *“the cosmetic regulation provides the adequate tools to regulate the use of cosmetic substances that present a potential risk for human health.”*

However, the Commission also undertook to establish a priority list of potential endocrine disruptors that were not already covered by the prohibitions provided for in the Cosmetics Regulation for the assessment of their risks.

A list of 28 substances was established and divided into two groups:

- Group A consists of 14 substances that should be treated with higher priority for assessment as they are undergoing substance evaluation (SEV) under REACH for ED concerns or the SEV has already confirmed ED concerns
- Group B consists of 14 substances where either no SEV has been initiated or the outcome of the SEV is of an environmental ED concern and not a human health one, or that have recently been evaluated by the SCCS

Group A substances were the subject of a call for data launched on 16 May 2019 by the Commission, with the aim of gathering sufficient information before their evaluation by the SCCS. A second call for data was launched on 15 February 2021 for Group B substances.

This means that 28 cosmetic ingredients are already in regulatory status pending an ongoing or future assessment.

And substances that have been included in the CoRAP (Community Rolling Action Plan), the chemical evaluation programme under the REACH Regulation, for their potential as endocrine disruptors, should be added.

As well as **those listed by the work of IPCP** (International Expert Group on Chemical Pollution) initiated by the UN.

And very recently, those listed by five European Union Member States (France, Belgium, the Netherlands, Sweden and Denmark) on a dedicated website: **Endocrine Disruptor Lists**.

All these sources were the basis for the selection of ingredients in this ebook. They have been arranged here in alphabetical order.

For each of them, CosmeticOBs presents the reasons why they are targeted, the current regulations applicable to them, the timetable for their evaluation.... In a way, the essential points to know before deciding whether or not to use and/or substitute them in the formulation of a product.

To be read in addition to the **Databook Endocrine Disruptors** for a comprehensive overview of everything we know today about these types of substances, their identification, the assessment of their safety and the debates they give rise to.



ACETYL CEDRENE

INCI Name

Acetyl Cedrene

tetramethyl1H-3a,7-methanoazulen-5-yl)ethan1-one

English name

[3R-(3 α ,3a β ,7 β ,8a α)]-(2,3,4,7,8,8ahexahydro-3,6,8,8-

CAS No.

1- 32388-55-9

CE No.

251-020-3

Origins

- Synthetic

CosIng functions

1. Fragrance

Regulation

European Cosmetics Regulation 1223/2009

Not regulated

European Cosmetics Regulation 1223/2009, Annex III/327 (Restricted substances)

Applicable from 31 July 2026 for products placed on the market and from 31 July 2028 for products made available on the market

Substance Identification

• Chemical name/INN

[3R-(3 α ,3a β ,7 β ,8a α)]-1-(2,3,4,7,8,8ahexahydro-3,6,8,8-tetramethyl1H-3a,7-methanoazulen-5-yl)ethan1-one

• Name of Common Ingredients Glossary

Acetyl Cedrene

• CAS number

32388-55-9

• EC number

251-020-3

Restrictions

• Product type, Body part

/

• Maximum concentration in ready use preparation

/

• Other

The presence of the substance shall be indicated in the list of ingredients when its concentration exceeds:

> 0.001% in leave-on products

> 0.01% in rinse-off products

International

ASEAN

- Not regulated

Australia

- OTC: If used in a fragrance the total fragrance concentration must be no more than 1%

Brazil

- Not regulated

Canada

- Not regulated

China

- -

India

- Not regulated

Japan

- Not regulated

Mexico

- Not regulated

New Zealand

- Not regulated

Russia

- Not regulated

Saudi Arabia

- Not regulated

South Korea

- Not regulated

Taiwan

- Not regulated

United Arab Emirates

- Not regulated

United Kingdom

- Not regulated

United States

- Not regulated

Knowledge to date

Substance

- (3R-(3a,3ab,7b,8aa))-1-(2,3,4,7,8,8a-Hexahydro-3,6,8,8-tetramethyl-1H-3a,7-methanoazulen-5-yl)ethan-1-one

Profile

- Aromatic molecule classified as an allergenic fragrance compound for which declaration is mandatory in Europe when the next “Allergens” Regulation comes into force
- According to the self-classification provided by companies to ECHA in REACH registrations this substance is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects and may cause an allergic skin reaction
- Potential endocrine disruptor

History

- 2012: The SCCS (European Scientific Committee on Consumer Safety) publishes an Opinion in which it confirms that the labelling obligation for fragrance allergens subject to it is still relevant, and identifies 56 additional fragrance allergens, including Acetyl Cedrene, to be labelled.
- 2017: The substance appears in the CoRAP (Community Rolling Action Plan), the programme for the evaluation of chemical substances under the REACH Regulation. It is to be evaluated in 2019 by the Netherlands for its potential as an endocrine disruptor and PBT/vPvB (Persistent, Bioaccumulative, Toxic / very Persistent / very Bioaccumulative).
- 2019: The assessment of the substance is postponed to 2021.
- 2019: The assessment of the substance is again postponed, to 2022.
- 2022: The substance, whose evaluation had already been postponed, is removed from the CoRAP list of substances to be evaluated under the REACH Regulation. ECHA states that it may be placed on the list again *“if, after conclusion of the dossier evaluation process, concerns would remain”*.
- 2022: The substance is now one of the new labellable allergens included in the draft “Allergens” Regulation notified by the European Commission to the WTO.
- 2023: The Regulation 2023/1545 is published. It is applicable from 31 July 2026 for products placed on the market and from 31 July 2028 for products made available on the market.

References

- **Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast)**, *Official Journal of the European Union*, L 342/59, 22 December 2009
- **Allergens: more substances, more limitations**, CosmeticOBS, 1st August 2012
- **SCCS (Scientific Committee on Consumer Safety), Opinion on fragrance allergens in cosmetic products**, SCCS/1459/11, 26-27 June 2012
- **Ingredient Acetyldedrene**, CosIng
- **Information on Chemicals - (3R-(3 α ,3 β ,7 β ,8 α))-1-(2,3,4,7,8,8a-hexahydro-3,6,8,8-tetramethyl-1H-3a,7-methanoazulen-5-yl)ethan-1-one)**, ECHA website
- **Justification Document for the Selection of a CoRAP Substance - Substance Name (public name): [3R-(3 α ,3 β ,7 β ,8 α))-1-(2,3,4,7,8,8ahexahydro-3,6,8,8-tetramethyl-1H-3a,7-methanoazulen-5-yl)ethan-1-one**, 22 mars 2016
- **CoRAP 2017-2019 adopted**, CosmeticOBS, 29 March 2017
- **CoRAP 2019-2021: 100 substances to be evaluated**, CosmeticOBS, 3 avril 2019
- **CoRAP: ECHA’s proposal for 2020-2022**, CosmeticOBS, 28 October 2019
- **Draft Community Rolling Action Plan (CoRAP) update for years 2020-2022**, ECHA, 23 October 2019
- **The CoRAP 2022-2024 in lean mode**, CosmeticOBS, 29 March 2022
- **Community rolling action plan update covering the years 2022, 2023 and 2024**, ECHA, 22 March 2022
- **Draft EU Allergen Regulation notified to the WTO**, CosmeticOBS, 26 September 2022
- **Committee on Technical Barriers to Trade, Notification, G/TBT/N/EU/924**, World Trade Organization, 15 September 2022
- **Draft Commission Regulation (EU) .../... of XXX amending Regulation (EC) No.1223/2009 of the European Parliament and of the Council as regards labelling of fragrance allergens in cosmetic products**, European Commission, 15 September 2022
- **Annexes to the Draft Commission Regulation (EU) .../... of XXX amending Regulation (EC) No.1223/2009 of the European Parliament and of the Council as regards labelling of fragrance allergens in cosmetic products**, European Commission, 15 September 2022
- **The European “New Allergens” Regulation has been published!**

CosmeticOBS, 31 July 2023

• **Commission Regulation (EU) 2023/1545 of 26 July 2023 amending Regulation (EC) No.1223/2009 of the European Parliament and of the Council as regards labelling of fragrance allergens in cosmetic products**, *Official Journal of the European Union*, L 188/1, 27 July 2023