



Committee for Risk Assessment (RAC)
Committee for Socio-economic Analysis (SEAC)

Opinion
on an Annex XV dossier proposing restrictions on
octocrilene

ECHA/RAC/RES-O-0000007637-64-01/F
ECHA/SEAC/[reference code to be added after the adoption of the SEAC
opinion]

Adopted
4 June 2026



OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
octocrilene

4 June 2026

RES-O-0000007637-64-01/F

11 June 2026

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

**Opinion of the Committee for Risk Assessment
and**

Opinion of the Committee for Socio-economic Analysis

**on an Annex XV dossier proposing restrictions of the manufacture, placing on the
market or use of a substance within the EU**

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name: octocrilene

EC No.: 228-250-8

CAS No.: 6197-30-4

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitter's proposal amended for further information obtained during the consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

France has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV dossier conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at <https://echa.europa.eu/restrictions-under-consideration> on **24 September 2025**. Interested parties were invited to submit comments and contributions by **24 March 2026**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: Bert-Ove LUND

Co-rapporteur, appointed by RAC: Patrick MORGAN

Supporting the rapporteurs: Mike BRODERICK

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **4 June 2026**.

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The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by consensus**.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: Silke GABBERT

Co-rapporteur, appointed by SEAC: Ignacio GRACIA FERNANDEZ

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **11 June 2026**.

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The draft opinion was published at <https://echa.europa.eu/restrictions-under-consideration> on **17 June 2026**. Interested parties were invited to submit comments on the draft opinion by **17 August 2026**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **[date of adoption of the opinion]**. [The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]]**².

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and] 71(1) of the REACH Regulation.] [No comments were received from interested parties during the consultation in accordance with Article[s 69(6) and] 71(1)]².

The opinion of SEAC was adopted **by [consensus.]**[**a simple majority**]³ of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion.]².

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1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Table 1: Proposed restriction

Substance Identity (or group identity)	Conditions of the restriction
Octocrilene EC No.: 228-250-8 CAS No.: 6197-30-4	1. Shall not be placed on the market in finished cosmetic products in a concentration equal to or greater than 0.001% w/w. 2. The restriction shall apply 24 months after its entry into force. 3. 'Finished cosmetic product' is a cosmetic product as defined by Regulation (EC) No 1223/2009.

1.1 THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the restriction proposed by the Dossier Submitter on **octocrilene** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion.

1.2 THE OPINION OF SEAC

See SEAC opinion

2 SUMMARY OF PROPOSAL AND OPINION

2.1 Summary of proposal

Octocrilene is a substance widely used in several applications in the European Union (EU) and the rest of the world, especially for its ultraviolet (UV) filter properties. Octocrilene absorbs UV radiation and is therefore used as a UV (mainly UVB) filter in finished cosmetic products that offer sun protection, including primary sunscreens, secondary photo-protection products, and other cosmetic products. Octocrilene also acts as a general photo-stabiliser, protecting ingredients that have a lower photostability and the formula as a whole. In addition, octocrilene is used as a solvent for other crystalline and oil soluble UV filters. Within cosmetic uses, octocrilene can be used as a UVB filter at a concentration up to 10%.¹ The Dossier Submitter estimated that 1,752 tonnes of octocrilene is placed on the market annually in finished cosmetics products in the EEA. This use of octocrilene in cosmetics represents 40-45% of the total manufactured and imported volume of octocrilene, and the share can potentially be even larger.

Octocrilene is hazardous to aquatic species (and associated sediments) and soil organisms. Aquatic species (invertebrates) have been demonstrated as being the most sensitive, with a no-observed-effect-concentration (NOEC) of 2.66 µg/L for *Daphnia magna*. Moreover, the Dossier Submitter considers that octocrilene meets the criteria set out in Annex XIII of REACH regulation for persistent (P), very persistent (vP) and toxic (T) substances for the environment but not the criteria for bioaccumulation (B), although the Dossier Submitter concludes that the available in-situ monitoring studies demonstrate the potential for octocrilene to accumulate in different organisms.

This Annex XV report seeks to address the risks to the environment from the placing on the market of octocrilene in finished cosmetic products. According to the Dossier Submitter, the main driver of the environmental exposure and risks is the wide dispersive use of octocrilene in finished cosmetic products. The manufacture of octocrilene and other uses of octocrilene are outside the scope of the restriction proposal, as the Dossier Submitter considers that they either do not pose a risk to the environment (i.e. risk characterisation ratios are below 1) or the potential risks could be managed by applying appropriate risk management measures (RMMs).

The Dossier Submitter applied two approaches to estimate the exposure of octocrilene in different environmental compartments, tonnage approach and consumer approach. By comparing the estimated exposures to corresponding predicted no-effect concentrations (PNEC) for a given environmental compartment, the Dossier Submitter concludes that there are risks to fresh and marine waters, associated sediments and agricultural soil.

The Annex XV restriction report evaluates different regulatory risk management options and concludes that a REACH restriction would be the most appropriate EU-wide measure to address the risk for the environment arising from the wide dispersive use of octocrilene in finished cosmetic products.

The Dossier Submitter considers that an action on a Union-wide basis is warranted to effectively reduce the environmental exposure to octocrilene in the EU, especially as

¹ Maximum concentration in ready-use preparations: Propellant spray products up to 9% and other products up to 10% (Commission Regulation (EU) 2022/1176 of 7 July 2022 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of certain UV filters in cosmetic products).

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octocrilene is used in dispersive applications in cosmetics, and the wide-dispersive use in combination with the hazards of octocrilene lead to cross-border pollution that cannot be adequately managed by national regulatory actions. A Union-wide action would also avoid trade and competition distortions, thereby ensuring a level playing field in the internal EU market as compared to action undertaken by individual Member States.

The Annex XV restriction report proposes that octocrilene shall not be placed on the market in finished cosmetic products in a concentration equal to or greater than 0.001% w/w. At such a low concentration, octocrilene would no longer perform its intended functions, effectively resulting in the discontinuation of its use in cosmetic products.

The Dossier Submitter performed an impact assessment for two restriction options (ROs) that differ in terms of the transitional period (RO1: 2 years, RO2: 5 years). The choice of two ROs with different transition periods was motivated by the uncertainty surrounding the ability of the cosmetics industry to anticipate the changes required by the restriction.

Compared to the baseline, RO1 and RO2 are expected to reduce releases of octocrilene into the environment by about 13,300 tonnes (10,800 tonnes to soil and 2,500 tonnes to water) and 8,300 tonnes (6,800 tonnes to soil and 1,600 tonnes to water), respectively, over the 10-year assessment period (2027-2036).

The Annex XV restriction report indicates that no single drop-in alternative for octocrilene is available on the market which covers all of its functionalities, as octocrilene plays multiple roles in cosmetics. Nevertheless, alternatives that have one (or more) of octocrilene's different functions are available and already used in cosmetic products on the market.

The impact assessment includes a cost-benefit analysis (CBA), cost-effectiveness analysis (CEA) and break-even analysis (BEA).

The quantitative cost analysis in the Annex XV restriction report included reformulation and raw material costs to the manufacturers of cosmetic products, control and enforcement costs to the public authorities, and impacts on the consumers of cosmetic products. Impacts on manufacturers and importers of cosmetic ingredients, as well as importers and retailers of cosmetic products were assessed qualitatively.

The Annex XV restriction report estimated that the costs from the proposed restriction are around 354 million euros for the 10-year assessment period (annualised cost of 39 million euros) for RO1, and around 166 million euros (annualised cost of 18 million euros) for RO2. The annualised cost represents 0.04% (RO1) and 0.02% (RO2) of the total sales value of cosmetic products in 2023 in Europe.

The Dossier Submitter estimated the benefits of the proposed restriction based on a stated preference valuation study, eliciting households' willingness to pay (WTP) for improving the state of aquatic ecosystems. The WTP estimates were transferred from the six study countries within the EEA to the rest of the EEA to obtain an EEA-wide estimate of the total benefits. The benefits to the whole EEA population (in total around 203 million households) amount to €49 billion for RO1 and €44 billion for RO2, for immediate realisation of environmental improvements.

Based on the CEA, CBA and BEA, the Dossier Submitter considers both restriction options to be proportionate.

The Dossier Submitter regards that both ROs would address the identified risk and fulfil the REACH Annex XV criteria for a restriction in terms of effectiveness, practicability (including

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enforceability) and monitorability. Based on sensitivity analysis, the conclusions on the effectiveness and proportionality of both ROs are robust to alternative assumptions. Due to the better cost-benefit-ratio, the Dossier Submitter recommends implementing RO1 rather than RO2.

2.2 Summary of opinion

2.2.1 RAC opinion summary

RAC is of the view that octocrilene does not meet the criteria to be considered bioaccumulative. RAC did not conclude on persistence, however RAC notes that considering the low ultimate degradability observed in the available studies, it is likely that transformation products with persistent and very persistent properties are formed.

RAC supports using the long-term daphnia study, giving an EC10 of 4.6 µg/L and a NOEC of 2.7 µg /L as the lowest and most robust basis for the aquatic assessment. The registrants and the Dossier Submitter have used a NOEC, but RAC considers the EC10 is more relevant. Due to the lack of reliable data for different aquatic organisms, RAC is of the opinion that higher assessment factors, as proposed in the Background Document by the Dossier Submitter, should have been used in for the derivation of PNECs for fresh and marine water. RAC agrees with a NOEC of 46.3 mg/kg dry weight for *Lumbriculus variegatus* in a 28-day sediment tests and a NOEC of 19.5 mg/kg dw based on a decrease mung bean shoot weight in a short-term test.

RAC agrees with the assessment of emissions and exposure. It is clear that the use of octocrilene in cosmetics and particularly sunscreens is a significant source of emissions to the environment, with an estimated total annual volume of 1752 tonnes of octocrilene placed on the EU market in cosmetics. Correspondingly, the proposal focusses on the use of octocrilene in cosmetics, of which most products (77-93%) being sunscreens. It was assumed that octocrilene in sunscreens is 100% released, either to water and beaches (20%), or via water to wastewater treatment plants from showering and bathing (80%; WWTP). Leave-on products (e.g. lipstick, face-care products) contribute further to release. The assessment (by EUSES) resulted in 1,473-1,665 t/y entering WWTP.

Based on the refined tonnage approach on cosmetic products, the predicted environmental local concentrations were 1.4-1.6 µg /L in fresh and marine water. The predicted concentrations in fresh and marine water sediment were 1.5-1.7 mg/kg wet weight (ww) and in soil (assuming that all sludge is added to agricultural soil) 2.4-2.7 mg/kg ww.

In a consumer scenario, taking into account the emission via the rinse-off during swimming (swimming scenario), the predicted concentration in water after 1 day was 2.9E-4 in fresh water and 5.6E-2 mg/L in marine water. After a full season (91 days), the concentrations were higher even when considering degradation, i.e. 1.4E-2 and 2.8 mg/L, respectively.

RAC supports this scenario, as it is similar magnitude to the primary degradation half-life calculated by RAC for octocrilene at 53.8 days. RAC considers that the degradation study in marine water-sediment study is unreliable due to loss of microbial viability therefore, the degradation parameters from the freshwater water-sediment study should be considered for the marine water-sediment system.

In the (best case) risk assessment, based on local exposures as recorded in the respective

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registration dossiers, risk was calculated for plastisol production (RCRs just above one) as well as for wide dispersive use of cosmetics (RCRs 2-9). RAC agrees with these calculations, but notes it may lead to underestimating the risks. Based on the refined tonnage scenario for cosmetic products, the RCRs indicated risk for surface water (RCR 5-6), sediment (RCR 7-8) and soil (RCR 1-2), even when regional emissions were not included.

Risks from sunscreens were also assessed based on a consumer approach. In the swimming scenario (emission via rinse-off during swimming), risk was shown both for inland and marine water and sediment after 1 day (RCR 1 and 2,072 for water and 2 and 2,975 for sediment in fresh- and marine environment, respectively) and after a whole season (91 days), even when considering the degradation (RCR 54 and 104,544 for water and 76 and 150,137 for sediment in fresh- and marine environment, respectively). And in the showering scenario (emission via rinse-off during showering/bathing), risks were shown for surface water (RCR 30), sediment (RCR 42), and soil (RCR 8).

RAC is of the opinion that the risk characterisation shows clear risks from placing on the market of octocrilene in cosmetic product in EU Member States. One of the primary reasons to act on a Union-wide basis is the cross-boundary trade and use among EU Member States leading to risk for the environment. However, environmental transport between EU Member States may also occur. Individual national regulatory actions are not sufficient to manage the risks.

Most sunscreen products do not contain octocrilene, which shows that alternative approaches with use of other substances are available on the market. The Cosmetic Products Regulation (EC) No 1223/2009 lists 32 potential alternative substances (including nano-forms) authorised for use as a UV filter. Of the alternative substances assessed in the Background Document many of them either have properties of equivalent or greater concern than octocrilene or have insufficient environmental data, preventing appropriate assessment and causing uncertainty. Five substances are identified as having likely lower concern than octocrilene based on available data. Industry highlighted four substances as being the most relevant alternatives to octocrilene, where three of these substances are considered by RAC to be likely lower level of concern as octocrilene, and one has insufficient data to determine environmental hazard. RAC concludes that alternatives to octocrilene with lower hazards are on the market and that substitution with alternatives will reduce risks.

The ability of numerous alternative regulations and directives to address the identified risks are described in the Background Document, but RAC concludes that a REACH restriction is the best measure to regulate the use of octocrilene in a harmonised way all over the union while covering all emissions (e.g. after swimming) caused by the wide dispersive use of octocrilene in cosmetics.

RAC agrees that a limitation of the allowed concentration to 0.001% w/w in cosmetics would stop the use in cosmetics and result in significant reductions of environmental emission (estimated at 13,300 tonnes over the 10-year assessment period).

Most of total regional releases of octocrilene to water comes from wide dispersive use of cosmetic products. Regulating the use of octocrilene in cosmetics will therefore lead to significant reductions in overall environmental emissions and thus risk, with a 2-years transition period clearly leading to a greater release reduction (approximately 80%) than with a 5-years transition period (approximately 50%).

The scope and conditions of the restriction are clear. However, RAC notes that export and those scenarios that give raise to concern (e.g., plastisol and manufacturing) are not included

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in the proposal, and this may impact the effectiveness of the proposed restriction in minimizing release of octocrilene into the environment.

Regarding enforcement RAC considers that as a first step, the ingredient list can be checked for the presence of octocrilene. Analytical testing methodologies are being developed to detect octocrilene in cosmetic formulations and environmental matrixes at concentrations below the 0.001% w/w concentration limit value. While these methods are not yet accredited or validated, they are being conducted using standard laboratory equipment.

The implementation of the proposed restriction can be monitored by many different methods, including environmental monitoring, to follow the number of sunscreens/cosmetic products that contain octocrilene (currently 37% of the sunscreens on the market) and checking registration dossiers.

Concerning uncertainties, RAC agrees with the Dossier Submitter that the uncertainties identified by the Dossier Submitter underestimate the risk of octocrilene. Many uncertainties specifically concern the swimming scenario, but the scenario still supports a restriction. The identified uncertainties do not impact the effectiveness and enforceability of the restriction.

Overall, RAC concludes that the restriction proposed by the Dossier Submitter (with 2-year transitional period) is the most appropriate EU-wide measure to address the identified risk in terms of the effectiveness in reducing the risk, practicality and monitorability.

2.2.2 SEAC opinion summary

See SEAC opinion

3 JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1 RISK ASSESSMENT

3.1.1 Hazard(s)

Relevant sections of the Background Document:

- Sections 1.4.1 to 1.4.2
- Appendices B.3 to B.7

RAC conclusion(s):

- RAC notes that a formal conclusion on the persistence criterion is not required for the purpose of the risk assessment on octocrilene. The Dossier Submitter has used DegT50 = 45 days to refine the exposure assessment.
- RAC calculated a SFO DegT50 (12 °C) of 53.8 days for the primary degradation of combined parent compound and non-extractable residues (NER). RAC notes the lack of ultimate degradation and low mineralisation (3.3% AR). RAC further recognises that some of the transformation products formed have persistent or very persistent properties, but did not conclude on this.
- RAC did not conclude on the P/vP assessment of octocrilene or any of its transformation products.
- RAC considers that the degradation study in marine water-sediment study is unreliable due to loss of microbial viability over the course of the study (> 85% reduction in microbial biomass by day 100). Therefore, this study cannot be used to form the RAC opinion.
- RAC agrees with the Dossier Submitter that octocrilene does not meet the criteria to be considered bioaccumulative, however octocrilene does present moderate bioaccumulation potential.
- RAC is of the opinion that the descriptions and assessments of the identified environmental hazard(s) are appropriate.
- RAC agrees with the assessment of long-term toxicity to *Daphnia magna*, being the most sensitive species giving an EC10 of 4.6 µg /L and a NOEC of 2.7 µg/L.
- RAC only considers a single fresh water chronic invertebrate study as reliable and all other invertebrate, fish and algae studies are not considered suitable for concluding on the potential hazardous effects of octocrilene on aquatic species, preventing conclusions to be drawn and preventing their use in a weight-of-evidence approach. A valid marine invertebrate study was used in relation to the marine AF.
- There are no reliable aquatic acute studies and there is only one reliable fresh water chronic study and for this reason RAC considers that higher AFs need to be used, instead of 10 (for fresh water) and 100 (for marine water) as used by the Dossier Submitter for the calculation of risks.
- RAC agrees with a NOEC of 19.5 mg/kg dw based on a 20% decrease in mung bean shoot weight at the LOAEL and with the corresponding a PNEC_{soil} of 1.95 mg /kg dw.
- RAC agrees with a NOEC of 46.3 mg/kg dry weight for *Lumbriculus variegatus* in a 28-days sediment test and with the corresponding PNEC_{sediment} of 0.926 and 0.0926 mg/kg dw sediment (for freshwater and marine water respectively).

Key elements underpinning the RAC conclusions:

The text below focuses on environmental hazards as human health hazards (such as carcinogenicity of the transformation product benzophenone) of cosmetic products are assessed under the Cosmetic Products Regulation (CPR).

Persistence

There are two ready biodegradability tests available, both showing that octocrilene is not readily biodegradable. One test is performed according to EU Method C.4-D (Unpublished, 1995a) and one according to OECD TG 301F (Unpublished, 1991a), both using non-adapted activated sludge. Biodegradation of 0-10% led to the conclusion that the substance is not readily biodegradable.

Four additional studies were provided on ready biodegradation and two additional studies were provided on inherent biodegradability of octocrilene were identified following the third-party consultation (comment # 9855), however no study reports for these studies were available for RAC to assess their reliability. Additionally, ECHA R11 guidance states "*The outcomes of a reliable and relevant higher tier study, supersede the screening tests*". As higher tier simulation studies are available, these screening level studies were not assessed further.

Two OECD TG 308 water-sediment simulation studies investigated the degradation of [¹⁴C]Octocrilene in water-sediment systems under aerobic conditions. One in a freshwater sediment (*Unpublished, 2024a*) and one in a marine sediment (*Unpublished, 2024b*), even though the latter was sampled in an estuarine rather than in a marine location. The tests were performed according to OECD TG 308. Clear deviations from the TG were that only one sediment type was used in each study.

In the OECD TG 308 freshwater-sediment study, total recovery of applied radioactivity (AR) from octocrilene was 96.7% AR at the end of incubation period (100 days), with most radioactivity present in the sediment phase and almost no mineralisation (3.3% AR). The rate of degradation of octocrilene was estimated with Cake 4.0. The single first order (SFO) kinetics model is generally the preferred model according to the FOCUS guidance (2014). This model was used by the registrant resulting in $DT_{50}=45.5$ days with a $\chi^2 = 7.48$, in the freshwater study. The Dossier Submitter does not consider the SFO kinetic model to be the most acceptable model as the hockey-stick (HS) kinetic model has a better visual and statistical fit, resulting in a $DT_{50 \text{ slow phase}}=7030$ days with a $\chi^2 = 3.35$. Nevertheless, the Dossier Submitter did not consider the HS kinetic model to be robust, due to variability in the data set between replicates for day 64 and 100.

Instead, the Dossier Submitter derived a $DT_{50 \text{ mineralisation}} = 1,810$ days for the freshwater system and concluded that it represents the most conservative and robust value of persistence. A mineralisation of 3.3% AR provides evidence of low ultimate degradability of the system, including parent compound and any transformation/degradation/metabolite products. RAC agrees with the Dossier Submitter that the use of mineralisation represents a conservative estimate of ultimate degradation. The ECHA R11 Guidance states; "*When the mineralisation half -life for the whole system is above the P criterion, further analysis of the data is needed. A full mass balance of the substance and any transformation/degradation products should be determined and a determination of the level of non-extractable residues should be included.*" This has been conducted by the Dossier Submitter. RAC notes one

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comment (#9765) that questioned the appropriateness of the use of degradation half-life based on mineralisation to compare against the persistence criteria. RAC has taken this comment into account. RAC considers that the mineralisation half-life is overly conservative as primary degradation of octocrilene (69.1 % AR) was observed. Mineralisation half-life represents an absolute worst-case scenario and should not be used to determine the degradation half-life and compared against the persistence criteria.

RAC notes that as non-extractable residues (NERs) were not characterised, according the ECHA R11 guidance, *"the Total NER is considered as a non-degraded parent substance unless further characterisation of the Total NER is performed."* Therefore, total NERs must be considered as non-degraded parent substance in the kinetic analysis.

Statistical analysis conducted by RAC found the data point for replicate A for day 64 and 100 to be statistically significant outliers, requiring omission from the data set. Further details can be found in the RAC box in the section B.4.1.2.1.2.1.3 of the Appendix to the Background Document. With the statistically significant outliers removed, the SFO model is determined to provide the best visual and statistical fit. This results in a SFO DegT_{50 octocrilene+NERs (12 °C)} = 53.8 days with a $\chi^2 = 3.19$ (Figure 1a). In comparison the SFO kinetic model with the outliers included results in a DegT_{50 octocrilene+NERs (12 °C)} = 53.1 days with a $\chi^2 = 7.48$ (Figure 1b). The SFO model fit is improved following exclusion of the outlier data points, resulting in a small change in DegT₅₀.

Four relevant transformation products (described as metabolites in Background Document; > 5% AR) were identified during the course of the study; M1, M2, M3 and M6. M2, M3 and M6 accumulated over the course of the study, with negligible degradation observed by day 100. A DT₅₀ > 1,000 days was set by the Dossier Submitter for these transformation products. RAC notes that as measured radioactivity remained steady/decreased slightly for M2 and M3 during the last sampling points and measured radioactivity increased/remained steady for M6 over the last three sampling points, a numerical DegT₅₀ could not be estimated for these transformation products. The degradation rate constant for M6 is not significantly different from zero. While low ultimate degradation and a degradation rate constant not significantly different from zero can provide evidence for a conclusion of persistence, no follow-up persistence studies were reported by the Dossier Submitter for these transformation products to conclude on persistence. Further details on the degradation of the transformation products can be found in the RAC box (in the section B.4.1.2.1.2.1.3 of the Appendix to the Background Document).

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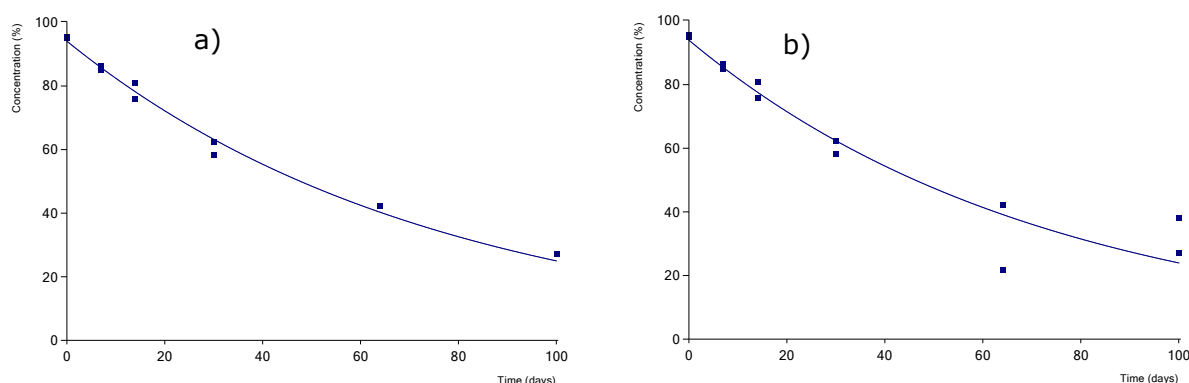


Figure 1 a) SFO degradation plot for octocrilene + NERs, with statistically significant outliers omitted, resulting in a $\text{DegT}_{50} = 53.8$ days. b) SFO degradation plot for octocrilene + NERs, with statistically significant outliers included, resulting in a $\text{DegT}_{50} = 53.1$ days.

RAC did not conclude on the P/vP assessment of octocrilene or its transformation products. However, RAC notes that the SFO DegT_{50} octocrilene+NERs (12 °C) = 53.8 days was calculated for the primary degradation of octocrilene and non-extractable residues, low ultimate degradation was observed in the system and transformation products with persistent or very persistent properties are formed during the degradation of octocrilene.

Bioaccumulation

Two bioconcentration tests were conducted, both following OECD 305 guidelines, one using flow-through conditions in *Danio rerio* (Unpublished study report (2008)) and one via diet in *Oncorhynchus mykiss* (Unpublished study report (2018d)). The *Danio rerio* study is considered as supporting by the Dossier Submitter and gave a BCF of about 850. RAC considers this study to be reliable with restrictions. All validity criteria are met, including temperature variation, dissolved oxygen concentration, feeding rate, analytical testing of substrate, water conditions and limited observed mortality/adverse effects. However, the experiment was conducted at 23 °C, whereas it is recommended studies are conducted at the standard European water temperature of 12 °C. The *Oncorhynchus mykiss* study is considered the key study by the Dossier Submitter and gave a BMF of 0.034. RAC calculated an estimated BCF of 792 (calculated using the OECD bioconcentration conversion tool). RAC considers this study reliable without restriction. All validity criteria have been met. RAC does not consider that octocrilene is bioaccumulative according to criteria for PBT or vPvB. The ECHA PBT expert group has previously concluded that octocrilene is not bioaccumulative.

Still, the Dossier Submitter considers octocrilene potentially bioaccumulative, given the moderate bioaccumulation potential from the OECD TG 305 studies and based on available environmental biomonitoring data. The field BCF reported for a range of species varies, with studies reporting field BCF for bivalve species > 2,000 L/kg (Vidal-Liñán *et al.*, 2018, Pintado-Herrera *et al.*, 2024). However, RAC notes that this was calculated from dry weight, not wet weight as recommended by ECHA R11 guidance. When wet weight conversion is conducted the estimated BCF_{ww} is < 2,000 L/kg. Two coral species monitored showed elevated levels of octocrilene (up to 102 ng/g), with a 100% detection frequency (Tovar-Salvador *et al.*, 2025) with field BAF of up to 19,950 L/kg. The study does not indicate if the samples were analysed as wet weight or dry weight. Higher field BAF would be recorded for dry weight samples and BAF values should be reported on a wet weight basis, according to ECHA R11 guidance.

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Monitoring from the Gulf of Cadiz identified elevated levels of octocrilene (up to 471 ng/g), in Bonito tuna, bluefin tuna and skipjack tuna (*Pintado-Herrera et al., 2024*). While no value for bioaccumulation was determined, the detection frequency of octocrilene in blue fin tuna was 86%, compared to 50% in the faster growing skipjack tuna. A higher detection frequency in the slower growing bluefin tuna is indicative of bioaccumulative substances. Detection frequency should not be used as a proxy for bioaccumulation, but supports the weight of evidence for bioaccumulation potential. None of the environmental studies reported in the Background Document or analysed separately by RAC provide data on octocrilene concentrations in the surrounding environment limiting the ability to interpret the bioaccumulation potential of the elevated levels of octocrilene in these studies. Further field bioaccumulation studies were provided in comment #9870. Overall, these monitoring studies indicate that octocrilene to some degree bioaccumulates in the environment, however RAC does not consider that these studies can be used to fulfil the B criteria due to methodological shortcomings outlined above.

RAC concludes that the bioaccumulation criteria are not met. However, RAC acknowledges that some degree of bioaccumulation may occur considering the moderate BCF in the OECD TG 305 studies and the results of the environmental monitoring studies.

Environmental toxicity assessment

Octocrilene is highly lipophilic (log Kow 6.1 Unpublished study report (2001f)) and poorly water soluble (9-153 µg/L to water; Unpublished study report (2017a)) which makes all aquatic tests difficult to perform. OECD guidance document 23 should therefore be consulted, there it is stated that "*the stability of the test chemical in the test solution under test conditions should be investigated in a preliminary stability study*" and that "*a number of physical, chemical, and biological processes can result in significant declines in actual exposure concentrations of a test chemical*".

For most studies below, it is not clear if any preliminary study has been conducted, and as most studies are based only on nominal concentrations and are lacking analytical monitoring, they are not considered adequate for establishing NOECs.

Fish

In total 7 short term toxicity studies on fish are available, all given a Klimisch score of 2 (reliable with restrictions) by the Dossier Submitter because of shortcomings, such as lack of analytical monitoring, lack of positive/solvent control or deviations to recommended test conditions. Only one is performed according both to Guidelines (EU method C1) and GLP, but the purity was not reported. One study was performed in *Leuciscus idus*, one in *Brachydanio rerio* and the rest in *Danio rerio* (some via spiked sediment to embryo-larval zebrafish), but none indicated any mortality. Only *Gayathri et al., (2023)*, found effects, in contrast to the other studies. The study was claimed to follow OECD TG236, but numerous deviations were noted, e.g. it is not known if the validity criteria are fulfilled. In this study zebrafish embryo/larval were exposed for 96 hours to 5, 50 and 500 µg/L (nominal) of octocrilene resulting in (at the nominal concentrations of 50 and 500) decreased hatching rate, heartbeat rate (72 hpf), and various developmental deformities (elongated yolk sac, swim bladder inflammation, muscle cell degeneration, retinal damage and pyknotic cells). However, no quantitative data was presented. Octocrilene also inhibited the activity of AchE at the nominal concentrations of 50 and 500 µg/L. A major shortcoming of the study is that no measurements of concentrations were done.

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RAC concludes that as all short-term fish studies have shortcomings, the requirements for acute fish studies are not met, and these studies should not be considered in the weight of evidence.

Five long-term studies in fish are reported by the Dossier Submitter. However, none of them is conducted following relevant OECD guidelines. One study was performed in female *Gasterosteus aculeatus*, three in *Danio rerio* and one in Japanese medaka (*Oryzias latipes*). One study on the analogue etocrilene was mentioned in a REACH registration dossier, but as the read across was rejected by the Dossier Submitter, it is not considered further. Only the study in Japanese medaka indicated effects in F1 embryos exposed for 14 days (Yan et al., 2020). This study was designed to measure hormonal effects of octocrilene. The Dossier Submitter reports increased time to hatching, morphological abnormalities, accumulative mortality, and decreased body length in exposed embryos. For the latter three endpoints, effects were noted at all exposure levels (nominal: 5, 50, 500 µg/L; measured: 2.71, 14.29, 232.62 µg/L but it is not completely clear if the measured data represents concentrations at the beginning or prior to water renewal). A speculation by the RAC rapporteurs is that the measured data represents concentrations at the beginning of exposure, since it is reported that concentrations decreased much further during the experiments (to 29-54% of concentrations at start of the experiments (54% at the low dose, 29% at mid dose, and 47% at the high dose). Each group contained 20 breeding pairs of mature Medaka but water was presumably only analysed in three out of them (the paper states "Three water sample replications from each group were made."). RAC notes that the study reports significant decreases in fecundity in adult Japanese Medaka but no effects on fertility, and without mentioning how fecundity and fertility were measured. The age of the fish at start was approximately 3-4 months old. The Dossier Submitter concluded that octocrilene can affect fish species at doses as low as 2.7 µg/L (51% mortality compared to 15% in the control group). Based on RAC's own evaluation, only the vitellogenin induction was clearly dose-related over all doses in males, indicating an estrogenic effect. In females the dose-related increase concerned 50 and 500 µg/L. For other effects, almost identical effects were seen at 50 and 500 µg/L. When both parents and F1 embryos were exposed to 5 µg/L, Table 1 of the study report indicates increases in morphological abnormality rates (but without presenting any data) and accumulative death rates. The body length was decreased on day 14, but according to the study report only the death rates and decreased body length were statistically significant. The report does not differentiate between effects noted with and without exposure of F1-generation. Table 1 of the study report indicates that no effects were noted if only the parents (F0) were exposed, except that death rates were statistically increased in embryos at the top dose (nominally 500 µg /L), which is much higher than the water solubility (40+/-44 µg /L according to the registrations). Furthermore, decreases in fecundity were not dose-dependent. RAC concludes that despite many shortcomings, e.g. contradictory and poor reporting, lack of information on when the concentrations were measured and on the results of negative and positive controls, that this study indeed indicates some effects in medaka embryos at low exposure levels. RAC is of the view that differences in sensitivity between species are possible, such as a very high sensitivity of Japanese medaka, considering that no effects were observed in zebra fish (*Danio rerio*). Except Unpublished study report (2018b), the studies are research studies. The effects noted in these studies indicate potential toxicity in embryos of Japanese Medaka, but the shortcoming on reporting are so severe that RAC considers that the effects identified in these studies cannot be relied upon to support long term toxicity and no NOEC or EC10 value can be derived for PNECaquatic.

Thus, neither short-term nor long-term toxicity to fish is adequately studied.

Aquatic invertebrates

In total, 9 studies are reported for short-term toxicity in aquatic invertebrates. Three of them (unpublished reports 1995d, 2001b, and 2000) are performed on *Daphnia magna* according to OECD Guideline 202 (1984) / EU C.2 and GLP. The guideline studies report EC50 (48 hours) of 3.6, > 0.023 and > 100 mg/L based on immobilization. The 'higher than' values represent nominal concentrations (not measured). RAC concludes that all studies suffer from either using too high concentrations (well above water solubility) and/or using nominal concentrations. The Dossier Submitter has interpreted Boyd et al (2020), in which EC50 (48 hours) was 0.03 mg/L based on immobilization and nominal concentrations in an OECD TG202 study on juvenile *Daphnia magna*, to indicate that octocrilene has toxicologically relevant effects at environmentally relevant concentrations. The Dossier Submitter also considered acute invertebrates toxicity endpoints as supportive data, due to methodological limitations, including high test concentrations above water solubility and no analytical measurements. RAC notes a concentration of 2.3% for the solvent (DMSO), but the paper states that a solvent concentration of 0.1% v/v was used for all test exposures. Given the significant limitations, (notably not sufficient test concentrations, photoperiod not recorded, lack of analytical measurements/measured analyte concentration), the OECD 202 test guidelines have not been met. RAC does not consider the requirements for acute aquatic invertebrate studies to have been fulfilled. As a result, these studies are not reliable and cannot be used for hazard assessment, although effects were noted in the study by Boyd et al (2020).

There are four long-term studies on aquatic invertebrates (*Daphnia magna*) reported in the dossier, but only one of them is following OECD TG 211 and GLP and is considered by the Dossier Submitter to be the key study (Unpublished study report (2018c)). In this study, *Daphnia magna* were exposed for 22 days, with daily renewal of octocrilene and water. The concentration of octocrilene was measured and deviated from nominal concentrations (nominal concentrations were 3.1, 6.3, 12.5, 25 and 50 µg/L and measured concentrations were 2.66, 5.25, 9.62, 19.2, and 40.6 µg/L). Information provided in the Appendix indicated 100% mortality of parents at the top dose (40.6 µg/L) and that mortality increased dose-dependently (living offspring per surviving adult were decreased by 16%, 30%, 66% and 100% at measured concentrations of 5.25, 9.62, 19.2, 40.6 µg/L, respectively). EC10, LOEC, and NOEC were 4.58, 5.25, and 2.66 µg/L, respectively, based on living offspring per surviving adult. As this study is considered robust by RAC, the others are not considered further. RAC considers this to be the key study determining toxicity. The NOEC value is used by the Dossier Submitter as it was used by the registrants although page 136 in 'Chapter R.7b of the Guidance on Information Requirement and Chemical Safety Assessment - Endpoint Specific Guidance' advocates the use of EC10-values.

In response to comments received in the third-party consultation (#9857, #9860, #9869), the Dossier Submitter included additional studies in the Background Document. A study in Sea Urchin (*Arbacia punctulata*) was conducted by Burns et al (2025). The study assessed fertilization and followed Test Method 1008.0 (USEPA, 2002), but GLP was not followed. The chosen nominal test concentrations were 0, 18, 36, 54, 72, 90, 108, and 120 µg/L, analytically determined to be 0.5, 14.9, 30.2, 48.3, 71.9, 88.2, 111.1, 103.0 µg/L, thus > 82% of nominal concentrations. Some octocrilene was found also in the control, but the concentration was low. Exposure time was 80 minutes but the urchins were followed for 21 days. The test fulfilled validity criteria, e.g. with respect to the fertilization rate. A dose-response was observed for

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fertilization, but concentrations well above water solubility (≥ 90 µg/L) gave almost identical results. The supplementary data state that pooled sperm and eggs from 4 males and 5 females were used, whereas the publication state that 6 urchins of each sex were used. An EC₁₀ of 41.5 µg/L was calculated. The Dossier Submitter considers this study reliable and relevant for marine environmental risk assessment. RAC is of the opinion that the test is well performed, but is of the view that the study on *Daphnia magna* is more relevant as *Daphnia magna* is more sensitive.

Carvalho et al., (2025) studied embryotoxic effects of octocrilene and its degradation product benzophenone on early life stages of the Pacific oyster (*Magallana gigas*) at concentrations (1, 10 and 100 µg/L) over a 24-hour exposure period. Developmental abnormalities were observed at all tested concentrations. The Dossier Submitter concluded that although the study is not sufficiently reliable for quantitative endpoint derivation, it provides qualitative evidence of developmental effects in marine bivalve larvae at concentrations as low as 1 µg/L. RAC considers the shortcomings (e.g. no raw data and no analytical verification of concentrations) so severe, that this study has not been considered further.

Picone et al. (2025) studied the effects of octocrilene on the reproduction and feeding of the marine calanoid copepod *Acartia tonsa* through a full life-cycle exposure. Measured concentrations were 0.07, 0.19, 0.67 and 4.36 µg/L and significant effect on egg production and pellet productions were observed at 4.36 µg/L, resulting in a NOEC = 0.67 µg/L. The Dossier Submitter considered this study reliable and relevant for marine environmental risk assessment. An ISO standard method for testing with the marine copepod *Acartia tonsa* (ISO, 2015) is mentioned by Picone et al (2025), but the standard seemed not be followed and GLP was clearly not followed. The standard errors of the mean varied significantly and were up to 100% of a given mean value. Therefore, RAC does not agree with the Dossier Submitter that the study is reliable.

Algae and aquatic plants

For algae and aquatic plants, one guideline/GLP study is available on *Desmodesmus subspicatus* (algae) (unpublished study report 2010) and in addition the Annex XV report contains four research studies on a fresh water green algae (*Chlorella vulgaris*) (Pablos et al. 2015), a marine green algae (*Tetraselmis* sp) (Thorel et al. 2020), a freshwater green algae (*Desmodesmus subspicatus*) (De C S de Paula et al., 2022), and the freshwater plant *Lemna minor* (Marcin et Aleksander., 2023). In none of these studies concentrations were measured, which makes them unreliable. Unpublished study report 2010 gave a NOEC (72 h) of 100 mg/L test material (nominal) based on growth rate. The lowest endpoint (EC₅₀ = 1.54 mg/L based on growth inhibition) was reported for (*Desmodesmus subspicatus*) (De C S de Paula et al., 2022). RAC concludes that the testing requirements are not fulfilled. No chronic studies are noted for aquatic plants.

Toxicity tests were also conducted in other aquatic organisms (Gao et al. 2013, Giraldo et al. 2017, Stien et al. 2018, He et al. 2018b, Thorel et al. 2022, and Marcin and Aleksander 2023) but generally reporting nominal concentrations or when having measured concentrations they were only measured at the end of the studies. Nevertheless, the studies indicated (based on nominal concentrations) that corals might be sensitive species, with the lowest nominal NOEC = 5 µg/L in *Pocillopora damicornis*, based on effects on fatty acids metabolism (Stien et al., 2018). RAC has not considered these studies further due to shortcomings in the studies and

absence of relevant information.

RAC conclusions on aquatic organism toxicity

RAC concludes that octocrilene has long-term effects on *Daphnia magna* (NOEC 2.66 µg/L, EC₁₀ 4.58 µg/L). The short-term data (e.g., Boyd et al. 2020) suffer from only representing nominal concentrations. As a result of shortcomings in the studies in fish, invertebrates, algae and aquatic plants, RAC considers that these studies should not be considered in the overall weight of evidence (see RAC box in Appendix B.7.1. of the Background Document for RAC's assignment of Klimisch Scores for aquatic studies). As no reliable studies are available for a number of trophic levels, RAC is of the opinion that a more conservative assessment factor should be used than the AF 10/100 used for calculation of RCRs. AFs of 10 for fresh and 100 for marine water should be used when valid (long term) data is available for at least three species representing three trophic levels, which is not the case here. A higher assessment factor of 100 for freshwater and 1,000 for marine water should be considered according to Chapter R10 (in REACH Guidance on information requirements and chemical safety assessment) given that data for only one species (*Daphnia magna*) is considered robust and reliable. R10 states *"An assessment factor of 100 applies to a single long-term result (e.g. EC10 or NOECs) (fish or Daphnia) if this result was generated for the trophic level showing the lowest L(E)C50 in the short-term tests. If the only available long-term result (e.g. EC10 or NOECs) is from a species (standard or non-standard organism) **which does not have the lowest L(E)C50 from the short-term tests**, it cannot be regarded as protective of other more sensitive species using the assessment factors available. Thus the hazard assessment is based on the short-term data with an assessment factor of 1,000. However, the resulting PNEC based on short-term data may not be higher than the PNEC based on the long-term result available."* and for saltwater *"if the only available long-term result (e.g. EC10 or NOEC) is from a species which does not have the lowest L(E)C50 in the short-term tests, it cannot be regarded as protective of other more sensitive species using the assessment factors available. Thus, the hazard assessment is based on the short-term data with an assessment factor of 10,000"*.

As there is no reliable short-term data for octocrilene, RAC does not know if an AF of 100 is sufficiently protective for freshwater scenarios. The Dossier Submitter discusses AF of 100 both for fresh- and marine water, based on the new studies provided for marine water species in the consultation and described above, but concludes that as a risk was already demonstrated with AF 10/100, the question of increasing the AF does not need to be elaborated further. RAC has not changed any risk calculations, but is of the view that the AF should be higher than 10 for fresh water and 100 for marine water. Assuming an AF of 100 is sufficiently protective for fresh water, an AF of 1,000 could be used for marine scenarios. However, considering the availability of the Burns et al. (2025) study, the uncertainty related to the marine water decreases and 1,000 seems too high. Thus, a combination of lack of data, especially regarding the short-term data, and the guidance not being fully explicit on how to set the AFs in this case (the R10 guidance does not discuss situations where only valid long-term data is available, leading to uncertainty as to what AF should be used), RAC concludes that the AFs should be higher than 100 for the marine scenario. Another uncertainty is that no reliable data is available for corals. Concerning the uncertainty of which AF to use, RAC has not recalculated the RCRs but just states that they should be higher as there is a risk already with the AFs of 10/100 used by the Dossier Submitter.

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Sediment organisms

Three OECD guideline GLP studies are available on *Chironomus riparius* (Unpublished study report, 2023a), *Myriophyllum spicatum* (Unpublished study report, 2023b), and *Lumbriculus variegatus* (Unpublished study report, 2023c). No effects were observed in the *Chironomus* study (2023a) and in the *Myriophyllum* study (2023b). However, concerning the study on *Chironomus riparius*, the Dossier Submitter notes that the toxicity was probably underestimated since the food in the study was not treated with octocrilene.

Octocrilene was added directly to the sediment in a study on the sediment-endobenthic dwelling worm *Lumbriculus variegatus* (2023c). Synchronized worms were exposed during 28 days to octocrilene spiked into the artificial sediment at doses of 9.7, 21, 47, 103, 227, and 500 mg/kg dw. Food was also spiked into the sediment. A statistically significant and dose-dependent reduction in worm reproduction and biomass was found at day 28 at the three highest dose levels. The NOEC was determined to be at 47 mg/kg dw, and the EC₁₀ 46.3 mg/kg dw.

Five further research studies were available, but the studies were not performed according to GLP and generally using very low concentrations of octocrilene (up to 50 mg/kg dw in sediment or up to 100 mg/L in water when studying *Chironomus riparius*). Only nominal concentrations were reported, and when concentrations were measured they were not available at the end of the studies. Considering these shortcomings and the availability of three studies performed according to guidelines and GLP, RAC has not assessed these research studies further.

Test results show that ***Lumbriculus variegatus* is the most sensitive species in the 28-day sediment tests performed (unpublished report 2023c), with the NOEC at 47 and EC₁₀ for biomass at 46.3 mg/kg dry weight.** An assessment factor of 50 for the freshwater environment and 500 for the marine environment was applied by the Dossier Submitter, which RAC agrees with. A PNEC_{sediment} of 0.926 and 0.0926 mg/kg dw sediment (for freshwater and marine water respectively) have been used in the risk characterisation. RAC agrees with the derived PNEC for the freshwater and marine water environments for sediment dwelling organisms.

Waste-water treatment plants

The effect of octocrilene on activated sludge was assessed in two studies according to ISO 8192 (similar to OECD TG 209) (Unpublished study Report (1995b)) or OECD TG209 (Unpublished study Report (1991a)). Both studies showed no effects at concentrations much higher than water solubility (EC₅₀ (30 min): > 1,000 mg/L). Very little information was provided by the Dossier Submitter for the activated sludge studies, but RAC notes that no effects were observed.

Based on the tests with activated sludge, RAC agrees to use > 1,000 mg/L as the most relevant IC₅₀ for assessing effects on waste-water treatment plants.

Soil

Octocrilene did not induce significant toxicity on the soil microbial activity (OECD TG 216; unpublished study report, 2023d).

OECD TG 222 was used to study the earthworm species *Eisenia fetida* for 28 days (Unpublished study report, 2017b), and no adverse effects were observed. After additional

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four weeks, the earthworm reproduction was significantly reduced giving a NOEC (reproduction) of 125 mg/kg dw.

OECD TG 208 was used to study seedling emergence and early growth of six terrestrial plants (Unpublished study report, 2024d). No effect was shown on emergence and mortality of emerged plants. However, the lowest significant effect was observed at the lowest concentration tested of 12.3 mg/kg dw (mung bean (*Vigna radiata*) shoot weight was decreased by 20%). As this finding was not reproduced in a second test, the study author ignored the data from test 1 and instead suggested a NOEC of 12.3 mg/kg dry soil based on phytotoxic symptoms in buckwheat. The Dossier Submitter has anyway used the LOEC from mung bean) and calculated a NOEC of 6.15 mg/kg (NOEC=LOEC/2; according to the ECHA, 2008c). RAC agrees to the calculated NOEC based on the flat dose-response. Then, the NOEC of 6.15 mg/kg dw was normalized to a standard soil at 2% organic carbon, resulting in a NOEC of 19.5 mg/kg dw. RAC notes a high biological variability was observed in this study for all plant species making the NOEC somewhat uncertain.

Additional 48 hour at the concentrations of 0.1 and 1 mg/L caused lipid peroxidation in *Eisenia fetida* and *Allium cepa*, when the test solution was applied on artificial soil or filter paper, respectively. In *A. cepa*, additional cellular effects were observed and in *E. fetida*, the avoidance of earthworms from the contaminated soil increased to 20% and 80% at 0.1 and 1 mg/l respectively (Santo et al., 2022). In Gautam et al. (2023), reduction in body weight of *E. fetida* were observed at 1500 and 2000 mg/kg dw.

RAC conclusions on terrestrial species toxicity

Experimental data on the toxicity of octocrilene are available for three different terrestrial species: soil microorganisms, terrestrial worm and terrestrial plants, with plants being most sensitive, in contrast to the situation for aquatic plants. A corrected NOEC of 19.52 mg/kg dw has been determined. A PNEC of 1.95 mg/kg dw is used in the terrestrial risk characterization, based on an AF of 10.

A summary of all PNECs proposed by the Dossier Submitter to be used in the risk characterisation of octocrilene is presented in Table 2.

Table 2 summary of PNECs proposed by the Dossier Submitter

Environment compartment	Hazard conclusion as proposed by the Dossier Submitter
Freshwater	PNEC _{aquatic} (freshwater): 0.27 µg/l
Marine water	PNEC _{aquatic} (marine water): 0.027 µg/l
Sediments (freshwater)	PNEC _{sediment} (freshwater): 0.926 mg/kg dw
Sediments (marine water)	PNEC _{sediment} (marine water): 0.0926 mg/kg dw
Wastewater treatment plant	PNEC WWTP: > 10 mg/L

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Environment compartment	Hazard conclusion as proposed by the Dossier Submitter
Soil	PNEC soil: 1.95 mg/kg dw considering the organic carbon normalisation (2%)

RAC agrees with the PNECs derived by the Dossier Submitter, with the exception, that due to a shortage of reliable data for many aquatic species, a higher AF should have been used to derive PNECs for fresh- and marine water. If a higher AF had been used, the PNEC_{water} would become lower.

3.1.2 Emissions and exposures

Relevant sections of the Background Document:

- Sections 1.3, 1.4.3, 1.4.4, 3.2.1 (baseline)
- Appendices A.1, A.2, B.8

RAC conclusion(s):

- RAC agrees with the assessment of emissions and exposure, and the conclusion that the use of finished cosmetic products is the most relevant use in terms of environmental emissions. Based on an assumed release factor of almost 100%, a predicted environmental local concentration of 0.0017 mg/L was calculated for freshwater. The corresponding concentration in sediment was 1.8 mg/kg wet weight (ww) and in soil (after application of sludge) 2.9 mg/kg ww. Local PECs outside wastewater treatment plants (WWTPs) were calculated for cosmetic products in a refined scenario based on the estimated 1,752 tonnes of octocrilene placed on the EU market in cosmetics yearly, of which 1,473-1,665 tonnes octocrilene/year entering WWTPs, 10,000 persons connected per WWTP, and 20% of applied octocrilene released, resulting in slightly lower values than above (1.4-1.6 µg /L in fresh and marine water, 1.5-1.7 mg/kg wet weight (ww) in fresh and marine water sediment and 2.4-2.7 mg/kg ww in soil.
- A consumer scenario (after swimming) led to local concentrations of 2.9E-4 in fresh water and 5.6E-2 mg/L in marine water after 1 day. After 91 days, the corresponding concentrations were 2.6E-2 and 5.1 mg/L, respectively. If considering degradation (as suggested by the registrations, i.e., a half-life of 45-47 days) in the model, the concentrations after 91 days were 1.4E-2 and 2.8 mg/L, respectively. RAC supports this scenario, as it is similar magnitude to the primary degradation half-life calculated by RAC at 53.8 days. Additionally, in the showering scenario (rinse-off during showering/bathing) estimated concentrations were 7.9E-3 mg/L in freshwater, 8.4 mg/kg (ww) in freshwater sediment and 13.7 mg/kg (ww) in agricultural soil.
- As concluded in section 3.1.1. of this opinion, RAC considers that the degradation study in marine water-sediment study is unreliable due to loss of microbial viability over the course of the study (> 85% reduction in microbial biomass by day 100). Therefore, the degradation parameters from the freshwater water-sediment study should be considered for the marine system.

Key elements underpinning the RAC conclusion(s):

Octocrilene used in cosmetics may end up in surface waters (fresh and marine) directly from

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swimmers (especially from use of sunscreens) or via wastewater treatment plants (WWTP) effluents. Since octocrilene preferentially distributes to sludge, and sludge may be used as fertilizer on agricultural soil, octocrilene may end up in soil. The assessment of emissions and exposure has been done for a local and a regional scenario based on modelling using a tonnage approach and refined for the consumer use of sunscreens in a swimming and showering scenario. Input variables and exposure are described in Appendix B.8 of the Background Document. **With one exception, all input variables used in the tonnage approach were adopted from different REACH registrations.** The exception was that application of sludge to soil was assumed as a default, instead of assuming incineration, because the way sludge is handled in the EU varies and often, but certainly not always, involves application to soil. Assuming no application to soil would be an underestimation, just as assuming that all sludge is applied to soil overestimates the emissions. Concerning the PECsoil, it is not clear if it also takes into account the input from air deposition (some cosmetics are used as spray). Concerning sludge applied to soil, beside contamination of soil, there is a risk for runoff of octocrilene to surface water, as have been shown for other substances by Ghirardini and Verlicchi (2019). However, it is not known if such runoff occurs for octocrilene.

RAC considers the input variables generally acceptable, but considers the $\text{DegT}_{50} = 53.8$ days for degradation more appropriate than 45-47 days used by the Dossier Submitter.

Use at industrial sites was assumed for manufacture and formulation, whereas a wide dispersive use was assumed for professional workers, consumers, and for service life. Exposure assessment was performed using EUSES, both for a local and a regional scale.

Local PECs were calculated for 2 manufacturers, one formulator (production of plastisol), one formulator (preparing pre-mixture for finished cosmetic products), one formulator (for finished cosmetic products), one industrial use (production of plastic articles), and in total 12 scenarios for wide dispersive use (finished cosmetic articles)/service life (plastic articles/articles including plastic articles). For 8 scenarios no calculations were made based on assumed no emissions. Local concentrations for production of plastisol (one registrant) were predicted to be $3.82\text{E-}4$ mg/L in fresh water, $4.07\text{E-}1$ mg/kg ww in sediment, and $6.63\text{E-}1$ mg/kg ww in soil, whereas the other registrant considered all washing liquid to be incinerated and that there was no releases to wastewater. Local concentrations for one manufacturer were $2.2\text{E-}2$ mg/L in fresh water and $2.3\text{E+}1$ mg/kg ww in fresh water sediment based on an assumed 2% release to water, as given in the Technical Guidance Document on Risk Assessment Part II (2003), whereas the other manufacturer refined the release rate to water to 0.01% because of the low solubility of octocrilene ($40\mu\text{g/L} \pm 44\mu\text{g/L}$ at 20°C). RAC does not know whether 2 or 0.01% is more correct, but octocrilene is indeed highly lipophilic ($\log K_{ow}$ 6.1 (Unpublished study report (2001f))). RAC also notes that the Dossier Submitter has not assessed the RMM used by the registrants and that a first-tier risk assessment, as reported by the Dossier Submitter, is generally conservative. Furthermore, RAC notes that manufacture and plastisol production are not included in the restriction proposal and that further assessment of manufacture and plastisol production is required in order to conclude on their risks.

Table 3 presents two regional PECs that were calculated (for fresh and marine water environments), assumed to represent long-term average exposure levels. The table also shows calculated regional PECs for the dispersive use of cosmetic products.

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Table 3 Regional PECs

Protection target	Regional PEC all uses	Regional PEC Dispersive uses of cosmetic products
Surface water		
Freshwater (dissolved)	1.15E-04 mg/L	9.39E-05 mg/L
Marine water (dissolved)	6.86E-06 mg/L	5.61E-06 mg/L
Sediment		
Freshwater sediment (total)	2.11E-01 mg/kg ww	1.73E-01 mg/kg ww
Marine water sediment (total)	7.91E-03 mg/kg ww	6.47E-03 mg/kg ww
Soil		
Natural soil	1.80E-02 mg/kg ww	1.40E-02 mg/kg ww

One regional PEC summed all regional emissions from all uses, and as a refinement one regional PEC was calculated for uses related to cosmetics only, stated by the Dossier Submitter to represent 82% of the total regional release to wastewater and surface water. However, RAC focuses more on the further local assessment of use of octocrilene in cosmetics/sunscreens, which is the basis for this restriction proposal.

Because of the magnitude of emissions from cosmetic uses, based on an estimated total annual volume of 1,752 tonnes of octocrilene placed on the EU market in cosmetics, the further assessment was focused on cosmetic use. It was estimated that most of octocrilene used in cosmetics will reach WWTPs, e.g., via sewage water from showering while wearing cosmetic products that are released while showering (this concerns both leave on products and sunscreens) or from washing nearly empty packages. A small exception concerns some leave-on cosmetics that end up in the garbage bins after removal. As risk was observed with a generic method, the approach was refined by using (i) an evaluation model (refined tonnage approach) used in restrictions of other cosmetic ingredients and (ii) an approach based on consumer behavior in relation to swimming and use of sunscreen. The approach based on consumer behavior was further divided into two scenarios, i.e. emission via rinse-off during swimming (swimming scenario) and emission via municipal wastewater due to the rinse-off during showering/bathing (shower scenario).

Briefly, the evaluation model used the annual quantity of octocrilene placed on the EU market in cosmetics (i.e. 1,752 tonnes), consumer behavior (type of products and disposal route), and wastewater treatment plant connection rate. Depending on type of product (7-23% leave on products such as lipstick, face-care products, body-cream, nail-care products, etc. and 77-93% sunscreens), emissions were estimated to wastewater treatment plants (WWTP), recycling facilities, landfill or incineration facilities for leave on products and for sunscreens to water or surrounding area (beaches) or finally via water to WWTP. It was assumed that 10% of the cosmetic packaging was recycled, with washing of plastic materials leading to discharge to water/WWTP. The assessment resulted in 1,473-1,665 t/y entering WWTP. The corresponding PEC-values were calculated using minimum and maximum values of this range, "low value" and "high value", respectively. RAC agrees with the selection of parameters. Table 4 shows local predicted concentrations of octocrilene based on 1,473-1,665 tonnes of octocrilene/year entering WWTPs from the use of cosmetics.

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Table 4 Local PECs based on the range of releases of octocrilene to WWTP (Low value: 1473 tonnes/y; high value 1665 tonnes/y)

Protection target	Local PEC
WWTP	
Low value	1.50E-02 mg/L
High value	1.69E-02 mg/L
Freshwater (covering marine water)*	
Low value	1.39E-03 mg/L
High value	1.58E-03 mg/L
Freshwater sediment (covering marine sediment) *	
Low value	1.48 mg/kg ww 1.68 mg/kg ww
High value	
Agricultural soil	
Low value	2.42 mg/kg ww 2.73 mg/kg ww
High value	

A consumer approach was also performed according to Emission Scenario Document PT19: Emission scenarios for repellents and attractants (ECHA, 2015). In the "swimming scenario" 1,500 swimmers daily and a total volume of 435,000 m³ (total volume of lake) was assumed for inland water bodies (ponds and lakes), and 3,000 swimmers daily and a total volume of 4,530 m³ for marine waters (only beach considered). It is not clear if the number of swimmers has been corrected to the size of the beach, but as these numbers of swimmers are justified (Biocide ESD PT 19, and Labille et al 2020), RAC accepts them. Assumption common for both water types are 10% octocrilene in sunscreens, 18 grams applied daily, 70% of swimmers using sunscreen, 36% of the sunscreens containing octocrilene and a release of 20% of the applied amount. Concerning the amount applied per day, it is quite clear that different studies have generated very varying values (see Table 36 of the Appendix of the Background Document). As concluded in the appendix, *"How much sunscreen is applied to the skin and how often will vary based on: habits, climate, time spent outside vs indoors (due to occupation or recreation), cost of sunscreens, socioeconomic factors, organisational, perception of skin cancer risk, susceptibility to sunburn and whether sunscreen is available when needed."* More recently a high value has been introduced in the ConsExpo model (34 g/application) (Cosmetics Fact Sheet, Default parameters for estimating consumer exposure, 2025). However, as the value chosen by the Dossier Submitter is also used by the Scientific Committee on Consumer Safety, which determines allowed concentrations in cosmetics, RAC accepts this value (18 g/day, representing 2 applications).

Concerning the concentration of octocrilene in sunscreens, RAC notes that 10% is the maximum allowed content, and that the median content is lower than 10% and not known. In the third-party consultation, an industry representative proposed (#9766, #9860) to use 6.5% as the average content based on a study by Gouin et al. (2022). The 10% value is thus a conservative value, but RAC accepts the value as a reasonable worst-case value as octocrilene is allowed to be used up to this concentration. Table 5 below shows the predicted concentrations of octocrilene in inland and marine waters in the "swimming scenario" based on the assumptions made by the Dossier Submitter.

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Table 5 PECs for one and 91 days of emissions to inland and marine water

<i>Variable</i>	<i>Symbol</i>	<i>Inland water</i>	<i>Marine water</i>
Local emission rate to water (kg/d)	$E_{\text{local,water}}$	1.36E-01	2.72E-01
Local concentration in water body after one day (mg/L)	$C_{\text{local,water,1d}}$	2.91E-04	5.59E-02
Local concentration in water body over 91 days (mg/L)	$C_{\text{local,water,91d}}$	2.65E-02	5.09E+00
Refined local concentration in water body over 91 days (including degradation) (mg/L)	$C_{\text{local,water,91d-ref}}$	1.44E-02	2.82E+00

For the whole swimming season (91 days assumed), degradation rates based on single first-order (SFO) degradation determined by the registrant were applied (DT50 of 45.5d and 47.2d for freshwater and estuarine systems, respectively). RAC agrees in general with the parameters used by the Dossier Submitter, noting that degradation half-life for octocrilene determined by RAC is 53.8 days, contrary to 45-47 days used by the Dossier Submitter. Furthermore, as concluded in section 3.1.1. of this opinion, RAC considers that the degradation study in marine water-sediment study is unreliable. Therefore, the degradation parameters from the freshwater water-sediment study should be considered for the marine water-sediment system. The Dossier Submitter has assumed a tidal cycle (12h) and 50% dilution in a refined swimming scenario, but RAC notes that it is not very often that inland waters are affected by tide and that the conclusions for inland waters affected by tide are rather unusual. However, RAC notes that no values for the marine environment were presented in the Emission Scenario Document for Product Type 19 (Repellents and attractants) because of dilution. In the study by Labille et al (2020) a dilution of 29% during 7 hours of recreation time was considered increasing the total water column volume from 4,530 m³ to 5,850 m³. RAC notes that this value is only based on data for one single beach (Prophète Beach in Marseille, with dilution limited by a dike) and would rather use a value from a marine scenario where the dilution is not limited. Whether a 29% or 50% dilution is sufficient can be discussed. However, emissions leading to risks were calculated by the Dossier Submitter also with a 50% dilution. A similar dilution was assumed for the fresh water and marine scenarios, but it is not clear how dilution of a freshwater scenario can occur, especially considering that the whole water volume of a lake (or pond) is considered. The Background Document also states that water bodies with a minimal water exchange were excluded, but it is not clear how that was done. The Dossier Submitter acknowledges that the marine coastal water scenario cannot be considered as a realistic worst-case scenario in the absence of more robust data on the volume of water bodies related to a number of swimmers, and RAC agrees. RAC is of the opinion that there is an unfortunate discrepancy in volume of water between the freshwater scenario (whole volume of lake considered) and the marine scenario (only the beach considered).

In the "showering scenario" the emissions were estimated arising through the release to the municipal wastewaters due to the sunscreen rinse-off during showering/bathing. The only additional assumptions, compared to the "swimming scenario", were that 10,000 persons are connected per WWTP, and that the fraction of octocrilene released into wastewater was 20%. Showering scenario resulted in estimated concentrations of 7.9E-3 mg/L in freshwater, 8.4

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mg/kg (ww) in freshwater sediment and 13.7 mg/kg (ww) in agricultural soil. RAC notes that the fraction of octocrilene released into wastewater probably varies, but as this modelled value has been proposed by the cosmetic industry in a poster (SETAC, 2024 Models to Evaluate direct Release of Cosmetic Ingredients into natural waters (MERCi) Framework with BASF, DSM-Firmenich, and Symrise), RAC can agree with this assumption. An industry representative has proposed a lower value (5%) in the third-party consultation (#9766, #9860) based on a study by Saxe et al (2021). Saxe et al studied release of some organic UV-filters (including octocrilene) from porcine abdominal skin (stored overnight in coolers with wet ice) after washing the skin in artificial sea water 4 times (in total 40 minutes in 1 liter sea water at 28°C). Whether porcine skin is a good model is not known. They found that release varied depending on formulation and application rate and the spray could not even be studied. RAC continues to support 20% as a reasonable worst-case value, as this value is in between other values proposed, but acknowledges that it may be a conservative value (see uncertainties in section 3.5.1).

RAC notes that many modelled data exceed the water solubility of octocrilene in clean water. However, as shown by e.g., Biel-maeso et al. (2019) octocrilene preferentially binds to particles in the water so the actual concentration in water depends on amount of particles in the water. The modelling shows that octocrilene is very likely to end up in water, and in this case local monitoring is supported by consumer scenarios and by monitoring.

Many environmental monitoring studies (see B.8.5 in the Appendix of the Background Document) confirm the presence of octocrilene in WWTP effluents (in particular in the particulate fraction (Biel-maeso et al. (2019)). Industry provided in the third-party consultation (#9766, #9857, #9860) a review of monitoring data found in the scientific literature (Gouin 2025, financed by Industry) and not surprisingly (considering that no standard methods for sampling and analysis are available) found highly varying methods and results. Other reasons for highly varying results are the dependence on how, where, and when measurements are conducted. Industry suggested to give priority to monitoring, since the modelled exposure estimates were much higher than the measured concentrations. Gouin ranked the monitoring data based on reliability and relevance using the Creed scoring tool (Di Paolo et al., 2024). In the recommendation, Gouin noted that *"there is a general tendency in the peer-reviewed literature to report concentrations of OCR [octocrilene] in systems that are directly affected by its release"* and suggested much larger studies. RAC notes that Gouin (2025) report the existence of octocrilene also in background areas, and that the most reliable studies in marine areas report mean values exceeding the PNEC_{marine} calculated by the Dossier Submitter. If using a higher AF, as suggested by RAC, the PNEC would be lower, and maybe also there would be concern for freshwater based on the Gouin data.

In the studies noted in the Background Document, octocrilene was found in freshwater lakes and rivers, but only some occurrences were above the PNEC derived by the Dossier Submitter. It seemed that octocrilene was preferentially looked for and found in southern Europe. Octocrilene was also often found in marine water, especially in semi-closed areas, in areas near WWTPs, and with high tourism. The recent review by Gouin (2025) confirms exposure of marine water. The concentration of octocrilene in sediment (fresh and marine water) seemed to generally be low, except in the study by Agawin et al., 2024. Labille et al (2020) estimated PECs in marine water (using site-specific data on e.g., sunscreen use) but could only measure a few percent of estimated PECs, but they did not analyse sediment samples. Thus, the modelled local concentrations are to some extent supported by monitoring, although the monitored concentrations vary too much (e.g., with geography and time of year) to allow

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a direct comparison with EUSES-modelled PECs. Only the study by Labille et al. (2020) allows a comparison of estimated (based on their information on applied amount of sunscreen during tanning/bathing) and measured marine water concentrations at beaches. However, RAC has not analysed the study in detail. Fewer studies are available for the terrestrial compartment, but some studies suggest the presence of octocrilene also in soil and biota.

3.1.3 Risk characterisation

Relevant sections of the Background Document:

- Sections 1.4.3
- Appendix B.8

RAC conclusion(s):

- In the (best-case) risk assessment based on registration reports, risk was calculated for plastisol production (RCRs just above one) as well as for wide dispersive use of cosmetics (RCRs 2-9), and RAC agrees with those conclusions. Thus, RAC agrees to the risk for cosmetic products but is of the opinion that the risk is underestimated in this best-case risk assessment because of using too low AFs of 10 and 100 for fresh and marine water respectively in deriving the PNECs used for calculating the RCRs. The Dossier Submitter has chosen this approach (10/100) since it anyway shows environmental risks from the use of octocrilene in cosmetic products but acknowledges that higher AFs could be warranted for water PNECs (freshwater and marine). In the Background Document they are discussing 100 for both PNECs.
- RAC agrees that cosmetic products, and especially sunscreens, are the main source of octocrilene released to the environment and for environmental risks.
- For cosmetic products, the refined assessment (of showering and disposal of cosmetic products by EUSES) resulted in 1,473-1,665 t/y entering WWTP. The resulting RCRs indicated risks for all surface water (RCRs 5-6), sediment (RCRs 7-8), and soil (RCRs 1-2), even when regional emissions were not included.
- A consumer approach for the use of sunscreens when swimming indicated risk both for inland and marine water and sediment after 1 day (RCR 1 and 2072 for water and 2 and 2975 for sediment in fresh- and marine environment, respectively) and after a whole season (91 days), even when considering degradation in surface water determined by the registrant (45-47 days; RCR 54 and 104,544 for water and 76 and 150,137 for sediment in fresh- and marine environment, respectively). And in the showering scenario (emission via rinse-off during showering/bathing), risks were shown for surface water (RCR 30), sediment (RCR 42), and soil (RCR 8) RAC considers that the risk may be underestimated as RAC would rather use a higher AF for water.
- Risk (RCR > 1) was shown for the use of octocrilene in cosmetics by modelled general local scenarios and a modelled showering scenario, for the use of octocrilene in sunscreens in a bathing scenario, and by some monitoring data. RAC considers that the risk may be underestimated as RAC would rather use a higher AF for water.

Key elements underpinning the RAC conclusion(s):

Local RCR-values (PEC/PNEC quotas) were calculated for the scenarios with emissions. Values above 1, indicating a potential risk, were reported for one manufacturing site, one formulating site (plastisol production) (just above one both for fresh water and sediment) and for the wide dispersive use of finished cosmetic products based on the aggregated tonnage for all cosmetic

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use (6 for fresh water, 9 for sediment and 2 for agricultural soil). RAC agrees with these conclusions.

Table 6 below presents the RCRs in more detail. The concern for manufacturing was downplayed by the Dossier Submitter because the risk calculations were based on a too high fraction (2%) used for release to water of this highly lipophilic substance (even though 2% was proposed by Technical Guidance Document on Risk Assessment, Part II (2003)). The concern for plastisol production was downplayed because risk management measures are available (as indicated by one of the sites incinerating washing liquid and excluding release to wastewater). The concern for cosmetic uses was the basis for the present restriction proposal, and RAC agrees that cosmetic products, and especially sunscreens, are the main source of octocrilene released to the environment.

Table 6 Local risk characterisation ratios (RCRs), Numbers in red indicate risk (RCR > 1)

MANUFACTURE					
	ES1		ES2		
RCR _{WWTP} (-)	2.43E-02		8.53E-04		
RCR _{freshwater} (-)	8.19E+01		9.38E-02		
RCR _{freshwater sediment} (-)	1.16E+02		1.33E-01		
RCR _{agricultural soil} (-)	NR		NR		
FORMULATION: production of plastisol					
	ES3		ES4		
RCR _{WWTP} (-)	4.11E-04		No emission*		
RCR _{freshwater} (-)	1.44E+00				
RCR _{freshwater sediment} (-)	2.03E+00				
RCR _{agricultural soil} (-)	3.85E-01				
FORMULATION: preparations containing additives					
	ES5				
RCR _{WWTP} (-)	No emission*				
RCR _{freshwater} (-)					
RCR _{freshwater sediment} (-)					
RCR _{agricultural soil} (-)					
FORMULATION: pre-mixture for finished cosmetic products					
	ES6				
RCR _{WWTP} (-)	2.48E-04				
RCR _{freshwater} (-)	2.72E-02				
RCR _{freshwater sediment} (-)	3.85E-02				
RCR _{agricultural soil} (-)	NR				
FORMULATION: finished cosmetic products					
	ES7	ES8	ES9	ES10	ES11
RCR _{WWTP} (-)	No emission*		1.84E-04	No emission*	
RCR _{freshwater} (-)			6.46E-01		
RCR _{freshwater sediment} (-)			9.14E-01		
RCR _{agricultural soil} (-)			1.73E-01		
INDUSTRIAL USE: production of Plastic Articles					
	ES12		ES13		
RCR _{WWTP} (-)	3.73E-05		No emission*		

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RCR _{freshwater} (-)	1.31E-01	
RCR _{freshwater sediment} (-)	1.85E-01	
RCR _{agricultural soil} (-)	3.51E-02	
INDUSTRIAL USE: additives resulting in inclusion into a matrix, including application in coatings, adhesives and plastics		
	ES14	
RCR _{WWTP} (-)	No emission*	
RCR _{freshwater} (-)		
RCR _{freshwater sediment} (-)		
RCR _{agricultural soil} (-)		
WIDE DISPERSIVE USE: additives resulting in inclusion into a matrix, including application in coatings, adhesives and plastics**		
	Sum of ES15 to ES18	
RCR _{WWTP} (-)	No emission*	
RCR _{freshwater} (-)		
RCR _{freshwater sediment} (-)		
RCR _{agricultural soil} (-)		
WIDE DISPERSIVE USE: finished cosmetic products**		
	Sum of ES19 to ES 23	
RCR _{WWTP} (-)	1.78E-03	
RCR _{freshwater} (-)	6.14E+00	
RCR _{freshwater sediment} (-)	8.83E+00	
RCR _{agricultural soil} (-)	1.67E+00	
SERVICE LIFE: plastic articles**		
	Sum of ES24 to ES 27	
RCR _{WWTP} (-)	8.82E-06	
RCR _{freshwater} (-)	3.08E-02	
RCR _{freshwater sediment} (-)	4.37E-02	
RCR _{agricultural soil} (-)	8.28E-03	
SERVICE LIFE: articles including plastic articles**		
	Sum of ES28 to ES31	
RCR _{WWTP} (-)	1.67E-05	
RCR _{freshwater} (-)	5.82E-02	
RCR _{freshwater sediment} (-)	8.24E-02	
RCR _{agricultural soil} (-)	1.56E-02	

NR means Not Relevant

Regional RCRs were calculated from the sum of the regional total release of all environmental emission scenarios and all CSRs and were slightly above one for freshwater sediment but clearly below one for the other compartments when using the (low) AF proposed by the Dossier Submitter. However, as mentioned above, RAC will focus on the local assessments.

Because of the magnitude of emissions from cosmetic uses, the refined regional assessment was focused on cosmetic use. The regional RCR-values were below one for all compartments. The regional RCRs from cosmetics were added to local RCRs, and the resulting local RCRs indicated risk for all compartments from wide dispersive use of cosmetic products by consumers.

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In the refined tonnage approach conducted for cosmetic products (including disposal/recycling; see evaluation model (i) above), RCRs above one were calculated for surface water (RCRs 5-6), sediment (RCRs 7-8), and soil (RCRs 1-2), even when regional emissions were not included. RAC agrees to the risk for cosmetic products but is of the opinion that the risk is underestimated because of using a too low AF used by the Dossier Submitter. Another potential cause for underestimation is that the Dossier Submitter has calculated the releases assuming 20% release of sunscreens separately during swimming (swimming in pools is not considered) and during subsequent showering.

In the consumer showering scenario, local RCRs were modelled based on sunscreen consumption (Table 7).

Table 7 RCRs after sunscreen rinse-off from showering/bathing in the consumer approach.

RCR freshwater	30
RCR freshwater sediment	42
RCR agricultural soil	8

In the “swimming scenario”, RCRs above one were calculated both for inland and marine water and sediment after 1 day and a whole season (91 days), even when considering degradation determined by the registrant in surface water (45-47 days). Table 8 presents risk characterization ratios in fresh and marine water after direct release of octocrilene during swimming (see evaluation of model (ii) above).

Table 8 RCRs after one day and one season (91 days) of swimming in fresh and marine water

		Fresh water	Marine water
Risk characterisation water	RCR 1 day	1.10	2,072
Risk characterisation water	RCR 91 days	54	104,544
Risk characterisation sediment	RCR 1 day	1.55	2,975
Risk characterisation sediment	RCR 91 days	76.4	150,137

Environmental monitoring studies are presented in section B.8.5 of the appendix. The data confirms the presence of octocrilene in WWTP, but not at levels affecting the functioning of the sewage treatment plants. Octocrilene was also found in freshwater lakes with 1 out of 5 studies reporting concentrations above the PNEC proposed by the Dossier Submitter, therefore resulting in RCR > 1. In rivers, 2 out of 6 studies reported concentrations above the PNEC, in at least one sample. In marine environments, concentrations resulting in RCRs > 1 were reported in several studies from different European countries, sometimes based on the mean value and sometimes based on the maximum concentration found. A recent review of octocrilene monitoring data by Gouin (2025), where data had been ranked based on reliability and relevance, confirm exposure of marine water in the studies with highest reliability. The concentration of octocrilene in sediment (fresh and marine water) seemed to generally be low, except in the study by Agawin et al., 2024 in Spain. Thus, the calculated local concentrations (by modelling) are supported especially in the marine environment by

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monitoring, although only the study by Labille et al. (2020) allow a comparison of estimated (based on their information on applied amount of sunscreen during tanning/bathing and assuming a 100% release factor from skin) and measured marine water concentrations at beaches. For octocrilene, only a few percent of applied sunscreen was found in water when measured, and the authors speculate that the low recovery was caused by octocrilene being trapped in the skin and thus in reality having a lower release factor than 100%. However, RAC has not analysed how and what information Labille et al (2020) collected regarding the use of octocrilene-based sunscreens on three beaches in Marseille in detail.

To summarize the risk characterisation, risk was shown for the use of octocrilene in cosmetics by modelled general local scenarios and a modelled showering scenario, for the use of octocrilene in sunscreens in a bathing scenario, and by some monitoring data (especially in marine environments). Concerning monitoring, it has to be acknowledged that the source of octocrilene in the environment is not known, and that the results are dependent on how matrices are being monitored and reported.

3.2 JUSTIFICATION THAT ACTION IS REQUIRED ON A UNION WIDE BASIS

Relevant sections of the Background Document:

- Section 1.5

RAC conclusion(s):

- Based on the key principle of ensuring a high level of protection across the Union, RAC concludes that any necessary action to address the risk(s) associated with use of octocrilene should be implemented in all Member States.

Key elements underpinning the RAC conclusion(s):

Octocrilene is a substance with toxic properties for the environment for which risks are not adequately controlled. RAC considers that measures are required to reduce ongoing emissions and exposure of the environment. The risk characterisation conducted by the Dossier Submitter showed clear risk associated with the use of octocrilene in finished cosmetic products. These products are manufactured/imported into the EU and placed on the market in EU Member States. One of the primary reasons to act on a Union-wide basis is the cross-boundary trade and use among EU Member States leading to risk for the environment, that cannot be adequately managed separately by Member States. In addition, travel between Member States of individuals with cosmetics containing octocrilene represents another pathway of emissions and cannot be controlled by individual Member States. Individual national regulatory actions are not considered appropriate to manage the risks. Any EU-wide action would ensure a high level of protection across the Union, as compared to action undertaken by individual Member States.

RAC agrees that EU-wide measures are needed to minimise the release of octocrilene into the environment from the use in finished cosmetic products. Release from these cosmetic products occurs primarily from the use phase, where direct emissions to the environment or indirect emissions from WWTPs from application of the cosmetic product occur. Monitoring studies across the EU highlight the wide dispersive and ubiquitous nature of octocrilene in freshwater and marine water, particularly during the bathing season.

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The risk assessment shows that even with best case assumptions there is concern for plastisol production that needs to be managed. Based on the assessment by the Dossier Submitter, when appropriate RMMs are implemented (i.e., incineration of waste) the risks associated with the use of octocrilene in the manufacture of plastisol are managed. Therefore, if these RMMs were enforced, the risk of octocrilene in these cases would be reduced and considered acceptable. RAC is of the opinion that no mechanism exists to enforce these voluntary measures. Without implementation the risk would remain uncontrolled.

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.3 ANALYSIS OF ALTERNATIVES

3.3.1 Availability and technical and economic feasibility of alternatives

Relevant sections of the Background Document:

- Section 3.2.4
- Appendix E.2

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.3.2 Risk of alternatives

Relevant sections of the Background Document:

- Section 3.2.4
- Appendix E.2

RAC conclusion(s):

- RAC concludes that the Dossier Submitter's assessment of risks of alternatives, based on their environmental concerns, poses no major shortcomings or uncertainties related to the methodology used. However, RAC acknowledges the lack of available environmental hazard data for the majority of substances.
- The Dossier Submitter has assessed a number of substances which are approved in the Cosmetic Products Regulation and could be used as alternatives to octocrilene. RAC concludes that nine of these substances have potential equivalent or greater level of environmental concern as octocrilene, five have likely lower environmental concern and 15 have insufficient data. Nine substances are undergoing additional data generation.
- The Dossier Submitter has identified four substances as the most suitable alternatives to octocrilene, as provided through a Call-for-Evidence organised by the Dossier Submitter. As these substances are the leading candidates identified by stakeholders

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to replace octocrilene in sunscreens. RAC has evaluated the data available for these substances, in addition to those substances screened by RAC as presenting likely lower concern compared to octocrilene.

- Based on the available information provided by the Dossier Submitter and the third-party consultation, RAC concludes that three of the four shortlisted alternatives from the Call-for-Evidence (ethylhexyltriazone, bisethylhexyloxyphenolmethoxyphenyl triazine and diethylamino hydroxybenzoylhexylbenzoate) pose lower environmental concern compared to octocrilene. There is insufficient data available for diethylhexyl butamido triazine to assess its potential hazard.

Key elements underpinning the RAC conclusion(s):

RAC's analysis of alternatives is based on the data provided by the Dossier Submitter and supplemented by information available to RAC and additional information available from the third-party consultation comments. The Dossier Submitter has identified a list of substances, which are included in Annex VI of the Cosmetic Products Regulation and could be used as alternatives to octocrilene. The Dossier Submitter's approach to assessing the risk of alternatives is primarily based on an evaluation of the hazard properties of the alternatives. A more detailed risk evaluation is not possible as this would require specific use, emission and exposure data. RAC agrees with the Dossier Submitter's approach as insufficient data is available for the majority of identified alternatives to conduct an environmental risk assessment, therefore an evaluation of the hazardous properties can be used in lieu of sufficient data to conclude on likely risk of identified alternatives, where appropriate hazard data is available. In comment #9857, provided during the third-party consultation, it is emphasised that an environmental risk assessment of shortlisted alternatives should be conducted. RAC agree that an environmental risk assessment of potential alternatives would result in a more robust assessment of alternatives. However, RAC notes that the development of a full quantitative risk assessment would not be proportionate.

The Dossier Submitter has outlined currently available hazard information and any suspected hazard in the Appendix E.2. of the Background Document.

Due to the use of these substances as UV filters in cosmetics, and their inclusion in the Positive List of the Cosmetic Products Regulation, RAC has focussed on environmental hazards of the identified alternatives. RAC categorised the identified alternatives when compared to octocrilene as;

1. Likely lower concern
2. Equivalent or greater concern
3. Insufficient data

Alternatives of likely lower concern are substances which are sufficiently characterised and are not known to exert a severe environmental hazard (e.g. SVHC properties, EDCs, Aquatic Acute 1, Aquatic Chronic 1 or PBT/vPvB or PMT/vPvM). However, RAC would emphasise that there might be some uncertainties related to the fact that the assessment is limited to hazard assessment of the alternatives, and RAC have not independently assessed the reliability of the available data as the background studies were not available. Only environmental hazard data available was taken into account for this assessment as human health hazards are addressed by the Cosmetic Products Regulation and the positive listing.

Alternatives of equivalent or greater concern are substances with known severe environmental hazard (e.g. SVHC properties, EDCs, Aquatic Acute 1, Aquatic Chronic 1 or

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PBT/vPvB or PMT/vPvM)

Alternatives with insufficient data are substances where suitable information on the hazard properties of the identified alternative are not available to conduct a detailed assessment of the environmental concern. In these cases no conclusion can be provided by RAC.

RAC conducted a screening activity of the identified alternatives using information in the Background Document, ECHA's dissemination website and comment #9861. Following this screening all substances identified as likely lower concern and the four substances identified in the Call-for-Evidence organised by the Dossier Submitter and being the most suitable substances to replace octocrilene underwent further assessment using all data available to RAC.

RAC concluded that nine substances on the list have potential equivalent or greater level of concern as octocrilene, five have likely lower concern and 15 have insufficient data available to assess potential hazard (Table 9). Nine substances are undergoing additional data generation, however this includes data generation for both human health and environmental hazard endpoints.

Table 9 Overview of identified alternatives to octocrilene including the criteria of concern as identified by RAC.

Reference number	Substances information			
	Name of Common Ingredients Glossary	CAS number	EC number	Level of Concern
2	Camphor Benzalkonium Methosulfate	52793-97-2	258-190-8	Insufficient data
3	Homosalate	118-56-9	204-260-8	Equivalent or greater concern
4	Benzophenone-3	131-57-7	205-031-5	Equivalent or greater concern
6	Phenylbenzimidazole Sulfonic Acid	27503-81-7	248-502-0	Insufficient data
7	Terephthalylidene Dicamphor Sulfonic Acid	92761-26-7, 90457-82-2	410-960-6	Insufficient data
8	Butyl Methoxydibenzoylmethane	70356-09-1	274-581-6	Equivalent or greater concern
9	Benzylidene Camphor Sulfonic Acid	56039-58-8	809-459-9	Insufficient data
10	Octocrilene	6197-30-4	228-250-8	N/A
11	Polyacrylamidomethyl Benzylidene Camphor	113783-61-2		Insufficient data

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12	Ethylhexyl Methoxycinnamate	5466-77-3	226-775-7	Insufficient data
13	PEG-25 PABA	116242-27-4		Insufficient data
14	Isoamyl p-Methoxycinnamate	71617-10-2	275-702-5	Equivalent or greater concern
15	Ethylhexyl Triazone	88122-99-0	402-070-1	Likely lower concern
16	Drometrizole Trisiloxane	155633-54-8	423-660-5	Insufficient data
17	Diethylhexyl Butamido Triazone	154702-15-5	421-450-8	Insufficient data
18	4-Methylbenzylidene Camphor	38102-62-4/36861-47-9	- / 253-242-6	Equivalent or greater concern
20	Ethylhexyl Salicylate	118-60-5	204-263-4	Equivalent or greater concern
21	Ethylhexyl Dimethyl PABA	21245-02-3	244-289-3	Insufficient data
22	Benzophenone-4, Benzophenone-5	4065-45-6 6628-37-1	223-772-2 613-918-7	Insufficient data
23	Methylene Bis-Benzotriazolyl Tetramethylbutylphenol Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (nano)	103597-45-1	403-800-1	Equivalent or greater concern
24	Disodium Phenyl Dibenzimidazole Tetrasulfonate	180898-37-7	429-750-0	Insufficient data
25	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	187393-00-6	425-950-7	Likely lower concern
26	Polysilicone-15	207574-74-1	426-000-4	Insufficient data
27	Titanium dioxide Titanium dioxide (nano)	13463-67-7/1317-70-0/1317-80-2	236-675-5/215-280-1/215-282-2	Likely lower concern
28	Diethylamino Hydroxy benzoyl Hexyl Benzoate	302776-68-7	443-860-6	Likely lower concern
29	Tris-biphenyl triazine Tris-biphenyl triazine (nano)	31274-51-8	479-950-7	Likely lower concern

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30	Zinc oxide	1314-13-2	215-222-5	Equivalent or greater concern
31	Phenylene Bis-Diphenyltriazine	55514-22-2	700-823-1	Equivalent or greater concern
32	Methoxypropylamino Cyclohexenylidene Ethoxyethylcyanoacetate	1419401-88-9	700-860-3	Insufficient data
33	Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine (nano)	919803-06-8	485-100-6	Insufficient data

In the Call-for-Evidence organised by the Dossier Submitter, stakeholders identified four substances as the most suitable alternatives to octocrilene; ethylhexyltriazone, diethylhexyl butamido triazone, bis-ethylhexyloxyphenolmethoxy phenyl triazine, diethylaminohydroxybenzoyl hexylbenzoate. As these substances are the leading candidates identified by stakeholders to replace octocrilene in sun protection cosmetic formulations RAC has conducted a further assessment of these substances.

Ethylhexyltriazone is used as a UV filter in cosmetic formulations. It is manufactured or imported into the EU at > 1,000 tonnes/year. The substance is not readily biodegradable and potentially persistent (OECD 301C). The Dossier Submitter provided a PNEC for ethylhexyltriazone of 0.08 mg/L in freshwater and 0.008 mg/L in marine water, indicating potential toxicity. The substance has no harmonised classification but has a self-classification as Aquatic Chronic 4. However, a RAC opinion from 2016 found no aquatic toxicity concerns and removed the Aquatic Chronic 4 entry.² RAC concludes, based on the available information, that the environmental hazards of ethylhexyltriazole are likely of lower concern compared to octocrilene.

Diethylhexyl butamido triazone is used as a UV filter in cosmetic formulations. It is manufactured or imported into the EU at > 100 tonnes/year. The substance has been identified by the Dossier Submitter as a potential regrettable substitute to octocrilene, where they noted that the substance is considered to be very persistent, with a PNEC value in the same magnitude as octocrilene. Diethylhexyl butamido triazone does not meet the criteria to be classified as PBT/vPvB. The substance has self-classification ranging from Aquatic Chronic 2 to Aquatic Chronic 4, however RAC notes that no long-term toxicity data for fish and invertebrates is presented in the available data. RAC concludes, based on the available information that there is insufficient data available to appropriately assess the hazard for diethylhexyl butamido triazone.

Bis-ethylhexyloxyphenolmethoxyphenyl triazine is used as a UV filter in cosmetic formulations. It is manufactured or imported into the EU at > 1,000 tonnes/year. The substance is considered to be very persistent and not bioaccumulative. No harmonised or self-classification for the substance is available. The substance does not meet the criteria to be considered as PBT/vPvB and based on the available information provided by the Dossier

² [Opinion proposing harmonised classification and labelling at EU level of tris\(2-ethylhexyl\) 4,4',4''-\(1,3,5-triazine-2,4,6-triyltriimino\)tribenzoate](#)

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Submitter, RAC concludes that the environmental hazards of bis-ethylhexyloxyphenolmethoxyphenyl triazine are likely of lower concern compared to octocrilene.

Diethylaminohydroxybenzoylhexylbenzoate is used as a UV filter in cosmetic formulations. It is manufactured or imported into the EU at > 1,000 tonnes/year. The substance is not readily biodegradable and potentially persistent (OECD 301F). Diethylaminohydroxybenzoyl hexylbenzoate is not bioaccumulative. The substance does not meet the criteria to be considered PBT/vPvB. The substance has a self-classification as Aquatic Chronic 4. Based on the available information provided by the Dossier Submitter, diethylaminohydroxybenzoyl hexylbenzoate would not classify as toxic to the aquatic environment as test results showed no toxicity up to limit of solubility. A RAC opinion from 2018 supports the opinion that no acute or chronic aquatic toxicity concerns have been demonstrated.³ RAC concludes that the environmental hazards of diethylaminohydroxybenzoylhexylbenzoate are likely of lower concern compared to octocrilene.

Two additional substances, tris-biphenyl triazine and titanium dioxide were assessed as possessing likely lower environmental concern compared to octocrilene, based on the information available to RAC. Titanium dioxide is listed in the Background Document as a potential carcinogen. However, RAC notes that the classification of titanium dioxide as carcinogen was annulled by the General Court of the European Union in 2022. This decision was appealed by France and the Commission to the Court of Justice, which dismissed the appeal on 1 August 2025.

It is also worth noting that information was provided in the Background Document regarding the use of new UV filter substances or technologies as alternatives to octocrilene. However, as these have not been authorised for use in cosmetics and added to Annex XI of Regulation (EC) No 1223/2009, these substances cannot currently be used as alternatives. These “new” alternatives or technologies include; esters of cyanodiphenyl propenoic acid (octocrilene is a member of this group), nanotechnology and nature derived substances. However, as these alternatives are not currently available/authorised for use, coupled with the lack of hazard information in many cases the potential risk of these alternatives have not been assessed by the Dossier Submitter. Comment #9857 notes that “*potential alternatives not yet authorised under Annex VI of the CPR must not be considered as viable alternatives*”. RAC does not consider these substances/technologies as suitable alternatives and has not conducted any further hazard/risk assessment.

RAC concludes that the Dossier Submitter’s assessment of risks of alternatives, based on their environmental hazards, poses no major shortcomings or uncertainties related to the methodology used. Based on the available information, which is limited in some cases, alternatives to octocrilene with likely lower concern are available. RAC notes that the assessment of risk of alternatives has been conducted using available hazard data as a proxy for risk. If new data on the hazards of the identified alternatives becomes available, appropriate assessment of this data should be conducted by the relevant parties.

³ [Opinion proposing harmonised classification and labelling at EU level of hexyl 2-\(1-\(diethylaminohydroxyphenyl\) methanoyl\)benzoate; hexyl 2-\[4-\(diethylamino\)-2-hydroxybenzoyl\]benzoate](#)

3.4 JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

3.4.1 Regulatory risk management options other than restriction

Relevant sections of the Background Document:

- Section 2.1
- Appendix E.1

RAC conclusion(s):

- The Dossier Submitter has analysed the ability of numerous alternative regulations and directives to address the identified risks, and concluded that a REACH restriction is the best measure to regulate the use of octocrilene in a harmonised way all over the union with coverage of all effects (e.g. after swimming) caused by the wide dispersive use of octocrilene in finished cosmetic products. RAC agrees with this conclusion.

Key elements underpinning the RAC conclusion(s):

The Dossier Submitter discussed many possible risk management measures, such as Council Directive 92/43C/EEC on the conservation of natural habitats and of wild fauna and flora, Directive 2008/56/EC (Marine Strategy Framework Directive), and regional conventions, such as the Mediterranean Action Plan (MAP), Ospar, Helcom, Cartagena and Nairobi conventions, and concludes that they will not minimise emissions of octocrilene because of a lack of data, risk assessment, measurement and enforcement.

Other measures within the European Economic region includes SVHC listing and subsequent authorisation under REACH. The Dossier Submitter noted the PBT expert group had assessed the data and concluded that the criteria were not fulfilled for octocrilene as a PBT substance, and other criteria are not met. RAC notes that no attempt to list octocrilene as causing an equivalent level of concern as CMR or PBT/vPvB substances has been made.

Other possible regulatory frameworks include the Water Framework Directive (Directive 2000/60/EC), but it is noted that directives may be implemented differently in different Member States.

The substance is not suitable for harmonised classification under the CLP regulation ((EC) No 1272/2008) for PBT/vPvB concerns as it does not meet the criteria defined under this regulation to be classified as PBT or vPvB. The Cosmetic Regulation (EC) No 1223/2009 only considers human health issues and is thus not an alternative for risk management of substances with environmental hazards. The POPs Regulation ((EC) No 850/2004) is not an alternative as octocrilene is not a POP.

Council Directive 91/271/EEC concerning urban waste-water treatment and Directive 2008/98/EC on waste and Directive 2010/75/EU on industrial emissions (formerly integrated pollution prevention and control) are besides being directives (not guaranteeing harmonised measures) not being able to handle all effects as they do not deal with direct emissions through recreational activities such as swimming.

The Background Document also discusses other possible regulatory measures but concludes that only a REACH restriction will cover all effects caused by the wide dispersive use of octocrilene in finished cosmetic products.

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RAC notes that the Dossier Submitter extensively assessed numerous alternative regulations and directives to identify the most appropriate regulatory risk management measure, including the possibility of managing the risks of octocrilene through two or more of the above mentioned regulatory risk management measures to regulate the use of the substance in a harmonised way throughout the Union. RAC agrees with the Dossier Submitter that the Restriction is the most appropriate measure to regulate the use and manage the risks of octocrilene across the Union.

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.4.2 Restriction options

Summary of the restriction options proposed by the Dossier Submitter

Two restriction options (ROs) were proposed by the Dossier Submitter:

- **RO1:** Restriction on placing octocrilene on the market in consumer and professional finished cosmetic products (concentration limit of 0.001% w/w). A **two-year** transitional period is implemented after the enforcement of the proposed restriction.
- **RO2:** Restriction on placing octocrilene on the market in consumer and professional finished cosmetic products (concentration limit of 0.001% w/w). A **five-year** transitional period is implemented after the enforcement of the proposed restriction.

3.4.2.1. Effectiveness in reducing the identified risk(s)

Relevant sections of the Background Document:

- Description of the restriction options: Sections 2.2, 2.3
- Risk reduction and environmental impacts: Section 3.3

RAC conclusion(s):

- RAC considers that the proposed restriction options will significantly reduce releases of octocrilene into the environment from the wide dispersive use of octocrilene containing cosmetic products.
- The 0.001% (w/w) concentration limit defined for RO1 and RO2 would result in loss of function of octocrilene in cosmetic products, which will be effective in reducing the emission and release of octocrilene into the environment from the wide dispersive use of octocrilene in cosmetic products.
- RO1 will result in greater emission reductions than RO2.

Key elements underpinning the RAC conclusion(s):

The restriction in placing on the market of octocrilene in cosmetic products to the allowed concentration of equal to or greater than 0.001% w/w, will result in significant reductions in overall environmental emissions and thus risk. The reduction in emissions can be used as a proxy for reduction in risk. However, the Dossier Submitter notes that current releases will

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not be entirely abated as the use and disposal of mixtures containing octocrilene will continue after the restriction enters into force, and after the transition periods have elapsed.

Based on the tonnage approach to the exposure assessment, 1,752 tonnes of octocrilene are placed on the market in cosmetic products annually, with 1,473-1,665 tonnes of octocrilene per year estimated to be emitted from WWTPs. RAC considers these emission figures appropriate based on the tonnage approach used by the Dossier Submitter. The Dossier Submitter concluded that compared to the baseline, RO1 and RO2 are expected to reduce releases of octocrilene into the environment by about 13,300 tonnes (10,800 tonnes to soil and 2,500 tonnes to water) and 8,300 tonnes (6,800 tonnes to soil and 1,600 tonnes to water). RAC agrees with the calculations of total reduction of releases. However, because these calculations are based on the assumption that sludge is always applied to soil, RAC considers that the proportion of releases to soil should be smaller than estimated by the Dossier Submitter. Because the practices in the use of sludge varies within the EU, the RAC cannot provide exact proportions for the releases in water and soil.

Table 10 Octocrilene release reduction in cosmetic formulations over 10-year assessment period used for the impact assessment.

Restriction option	Releases of octocrilene to the environment (tonnes)	Release reduction of octocrilene compared to baseline (tonnes)	% reduction compared to baseline
Baseline (i.e. no EU action)	16,650	-	-
RO1 (i.e. limiting concentration of octocrilene in cosmetics to 0.001% w/w with a 2-year transition period)	Not provided	13,300	80%
RO2 (i.e. limiting concentration of octocrilene in cosmetics to 0.001% w/w with a 5-year transition period)	Not provided	8,300	50%

The Dossier Submitter calculated the baseline based on the upper bound estimate of annual releases (1,665 tonnes/year) multiplied by the 10-year assessment period. The Dossier Submitter has assumed a negligible growth rate in use of octocrilene in cosmetic products based on the assumption that the expected overall growth in the market for sun protection products and cosmetic products will be counteracted by societal pressures to reduce the use of octocrilene in cosmetic products (Background Document Section 3.2.1). RAC notes that increasing awareness of the importance of sunscreen for reducing the incidence of skin cancer and impacts of climate change may increase the need for sunscreen. These additional factors may lead to an increased use of octocrilene containing finished cosmetic products, potentially increasing emissions of octocrilene over the assessment period. However, RAC considers that the Dossier Submitter's approach towards calculating emission reductions is appropriate. Despite the use of upper bound estimate for the annual emissions, RAC considers this to represent an underestimation of release, as the Dossier Submitter note

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that the annual release estimates represent an underestimation of total releases and assuming no growth in the market for octocrilene in cosmetics. Based on this approximation, RO1 would lead to an 80% reduction in release of octocrilene to the environment and RO2 would result in a 50% release reduction.

RAC is of the opinion that RO2 would lead to demonstrably lower emission reductions due to the increased transition time, resulting in higher risks over the course of the assessment period.

Voluntary substitution of octocrilene for alternative UV filters is currently ongoing, where alternatives may be introduced before the entry into force of the restriction. However, a quantitative figure on tonnage reductions is not available, therefore this uncertainty may impact baseline calculations. Additionally, consumers may continue to use octocrilene containing finished cosmetic products, purchased prior to the end of the transition period. A quantitative figure has not been included in emission reduction calculations.

Targeted scope

As mentioned above, RAC agrees that restricting the use of octocrilene in finished cosmetic products will lead to significant reduction in emissions to environment. Nevertheless, in section 1.4.3.2.3 of the Background Document the environmental risk assessment identifies a potential risk related to the production of plastisol, with an RCR > 1 in freshwater and freshwater sediment. While the Dossier Submitter notes that RMMs can be established to remove emissions of octocrilene, thereby reducing risk, the requirement of using these RMMs to remove emissions of octocrilene from the production of plastisol are not proposed by the Dossier Submitter as a formal risk option. Yet, the Dossier Submitter included in the uncertainties section that these RMM "*must be put in place*", which is supported by RAC. RAC appreciates the clear scope of the restriction proposal, solely focussing on wide dispersive uses of finished cosmetic products, but highlight that the management of the identified risk from use of octocrilene in plastisol production (without taking into account higher AF), without a formal restriction option is an uncertainty. RAC agrees that the higher risks result from the use of octocrilene in cosmetic products where a RCR above 1 is found in freshwater and above 2,000 in marine water. Over the course of the 91 day swimming season a RCR above > 100,000 are found for marine water and > 150,000 for marine sediment. RAC considers that the restriction as proposed by the Dossier is effective in limiting these risks.

Concentration limit value

A concentration limit value of 0.001% w/w of octocrilene in finished cosmetic products is proposed by the Dossier Submitter. The rationale for this value is to set the concentration at which octocrilene is permitted to be used in finished cosmetic products at such a low level as to render no positive benefit from the inclusion of the substance. The lowest concentration from intentionally added octocrilene currently used to gain photo-protection in the cosmetic product is 0.2 % w/w.

A concentration limit of 0.001% w/w allows for the potential for a small degree of unintentional contamination or impurities, for example from the production process or packaging or recycling. RAC notes that a higher concentration limit value of 0.01% may be sufficient to limit the use of intentionally added octocrilene for photo-protection purposes as this is an order of magnitude below the concentration used for intentionally added octocrilene. However, due to the insufficient information available, RAC cannot qualitatively or quantitatively assess the risk reduction capacity of the proposed restriction for unintentionally added octocrilene in finished cosmetic products between 0.01 % and 0.001 %. The proposed

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concentration limit value will in effect, ban the use of octocrilene in cosmetic products. RAC agrees that the concentration limit value of 0.001% w/w would be effective in reducing the risk, as a result of the reduction in emission of octocrilene.

The Forum⁴ notes that consulted laboratories test for concentrations of octocrilene close to the standard concentrations (0.2 – 10% octocrilene), however methods could become available that are applicable for the restriction. RAC notes that the 0.001% limit is justified by available analytical methods, which allows for LoQ at lower concentrations. However, these methods for the identification and quantification of octocrilene have not yet been validated for the use in a wide range of cosmetic products (as discussed in section 3.4.2.3 of this opinion).

Analysis of restriction options

The Dossier Submitter proposes two restriction options: RO1 and RO2. Both restriction options introduce a concentration limit value of 0.001% w/w of octocrilene in finished cosmetic products. The Dossier Submitter proposes a transition period of two years from entry into force for RO1, while a transition period of five years from entry into force is proposed for RO2.

Additionally, RAC notes a substantial difference in the emission reductions between RO1 and RO2. RO2 would result in an additional 5000 tonnes of additional emissions of octocrilene over the implementation of RO1. RAC considers that RO1 to be the most appropriate restriction option given that it would result in the highest reduction in emission of octocrilene.

3.4.2.2. Socio-economic analysis

3.4.2.2.1 Costs

Relevant sections of the Background Document:

- Sections 3.1, 3.4.1 to 3.4.5
- Appendices E.2, E.4.1 to E.4.3

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.4.2.2.2. Benefits

Relevant sections of the Background Document:

- Sections 3.1, 3.3, 3.4.6
- Appendices E.4.4 to E.4.5

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

⁴ <https://echa.europa.eu/about-us/who-we-are/enforcement-forum>

3.4.2.2.3. Other relevant impacts

Relevant sections of the Background Document:

- Section 3.5

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.4.2.2.4. Proportionality

Relevant sections of the Background Document:

- Section 3.6

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.4.2.3. Practicality, including enforceability

Relevant sections of the Background Document:

- Sections 4.1 to 4.2

RAC conclusion(s):

- RAC considers that the scope and conditions of the restriction are clear.
- RAC notes that the ingredient list of a cosmetic product containing octocrilene can be checked by enforcement authorities, as an initial process of enforcing the restriction.
- RAC notes that no validated analytical tests are currently available but testing methodologies are being developed to detect octocrilene in cosmetic formulations and environmental matrixes at concentrations below the 0.001% w/w concentration limit value outlined by the restriction proposal. While these methods are not yet accredited or validated, they are being conducted on standard laboratory equipment, without the need for extensive modification.
- RAC concludes that based on the above-mentioned points, the proposed restriction options are enforceable and implementable.

Key elements underpinning the RAC conclusion(s):

Risk of alternatives

Alternatives identified by the Dossier Submitter have potential human health and environmental concerns, including ED, CMR and PBT properties. The Dossier Submitter notes that a significant number of alternatives appear to be less hazardous than octocrilene. RAC has conducted a screening level evaluation (see 3.3.2 of this opinion) of available environmental hazard information outlined in the Background Document and the ECHA dissemination website and concludes that alternatives to octocrilene with likely lower risk to the environment exist and that the restriction proposal is practicable from a risk perspective.

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The majority of sunscreens currently on the market do not contain octocrilene. Comment #9863 noted that alternative substances to octocrilene are widely used in cosmetic and personal care products, including substances identified by the Call-for-Evidence organised by the Dossier Submitter as most likely alternatives to octocrilene.

Clarity of scope

In terms of enforcement and implementability, the scope and conditions of the restriction are clear. RAC considers that all parties associated with the formulation of cosmetics containing octocrilene, as well as enforcement authorities, will be able to unambiguously understand the scope of both RO1 and RO2. The concentration limit value proposed by the Dossier Submitter enable the restriction to be monitored and enforced.

Forum suggested that the term "finished cosmetic product" should be further defined (as in Art. 18 no. 3 (a) of Regulation (EC) 1223/2009). This has since been conducted by the Dossier Submitter in the Background Document.

Enforcement of restriction proposal

The Dossier Submitter notes that enforcement authorities can evaluate whether octocrilene is present in a cosmetic product through reading the INCI ingredient list on the cosmetic packaging. This ingredient list is not always reliable and the Dossier Submitter notes that brand owners may not respect EU regulation. RAC agrees with the Dossier Submitter that this methodology should not be used as a primary method for enforcement but could act as a preliminary check by enforcement authorities. However, while the concentration limit value of octocrilene proposed for the restriction is below the known concentration at which a positive function can be derived, octocrilene can be present in cosmetic formulations at below 0.001% w/w and be listed as an ingredient in the cosmetic product. RAC considers that the concentration limit proposed by the Dossier Submitter is appropriate as octocrilene is known to be added to cosmetic products at > 0.1%. The concentration limit of 0.001% w/w therefore represents two orders of magnitude lower limit value compared to the concentration of intentionally added octocrilene. RAC notes that a concentration limit value one order of magnitude below the concentration of intentionally added octocrilene (0.01% w/w) may be sufficient to protect the environment from intentionally added octocrilene, however RAC is unable to qualitatively or quantitatively assess the potential impacts of concentrations between 0.01% and 0.001% w/w.

Forum suggests that *"the proposed concentration limit is far below the standard concentration of octocrilene found in finished cosmetic products (0.2 – 10% w/w) and will cover intentionally added octocrilene and impurities."*

The enforcement of the restriction relies upon the existence of effective analytical methods that are available in sufficient quantities across the EU. No validated tests are currently available for testing octocrilene in a range of cosmetic matrixes at the concentration limit value proposed in RO1 and RO2, or in environmental samples. The development of such methods is necessary to support the enforcement of the restriction proposal. The development of methodologies for analysis of octocrilene in different matrixes was recommended following the inclusion of octocrilene on the 4th watch list of the Water Framework Directive. As such, a number of methodologies are under development and validation for the analysis of octocrilene in different media.

The Dossier Submitter notes a number of research publications highlighting low LoD values (> 0.1 ng/g and > 0.3 ng/L) of octocrilene in environmental samples when using GC/MS, and

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LoQ values > 5 ng/g and > 5 ng/L when using LC-MS/MS or GC-MS/MS, respectively. Additionally, the Dossier Submitter notes that the US Food and Drug Administration has proposed a HPLC-DAD methodology for the identification and quantification of UV filters, including octocrilene. However, no details of this study have been provided and no LoD or LoQ values for octocrilene are available.

Alternatively, a quadrupole ion trap LC-MS/MS methodology (QTRAP) has been identified by RAC, where octocrilene can be analysed in liquid cosmetic products with a LoQ of > 5 ng/mL. This methodology has been developed for a range of UV filters, using standard laboratory equipment, enabling identification and quantification of octocrilene at concentrations below the concentration limit value proposed in the restriction. This methodology has not been validated, and may not be appropriate for all cosmetic formulations as it has only been tested for liquid cosmetics. Comment #9858 provided additional information on accredited analytical methods available for the quantitative determination of octocrilene in cosmetic products and comment # 9870 provided information on analytical methodologies using standard laboratory equipment with detection and quantification limits below the concentration limit proposed by the restriction. Comment #9857 notes potential challenges with enforceability given the lack of currently validated methods to detect octocrilene in a range of cosmetic products at the proposed concentration limit. Forum state that *"consulted laboratories are currently not able to test for concentrations close to the restriction limit value proposed."*

Overall, RAC considers that testing methodologies are being developed to detect octocrilene in cosmetic formulations and environmental matrixes at concentrations below the 0.001% w/w concentration limit value outlined by the restriction proposal. While these methods are not yet accredited or validated, as noted in comment #9857 and by Forum, they are being conducted on standard laboratory equipment, without the need for extensive modification. These methodologies have also been shown to work for a range of UV filters, which may increase the utilisation of these methods in commercial laboratories. Regulatory pressure internationally is driving the development of appropriate methods to identify and quantify UV filters at low concentrations. Forum concludes that the restriction is enforceable. RAC considers that from a technical perspective the proposed concentration limit is enforceable and practical.

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.4.2.4. Monitorability

Relevant sections of the Background Document:

- Section 4.3

RAC conclusion(s):

- RAC concludes that the restriction can be monitored using different methods, including environmental monitoring, analytical monitoring of cosmetic samples and following the number of sunscreens containing octocrilene available on the market.

Key elements underpinning the RAC conclusion(s):

The effectiveness of the proposed restriction can be monitored by environmental monitoring, especially in surface water, wastewater or newly produced sediment. However, differentiating between new and legacy emissions can prove difficult, during the first few years of enforcement. Other approaches are chemical analysis of cosmetic products, to follow the number of sunscreens/cosmetic products that contain octocrilene (currently 37% of the sunscreens on the market), checking registration dossiers, conducting market surveys, checking information on cosmetic products packaging, or via action under the Water Framework Directive as octocrilene is registered under the watch list of this regulation. Suitable analytical methods are available for the monitoring of octocrilene in environmental and cosmetic samples, as described in Section 3.4.2.3 of this opinion. Octocrilene is also regularly monitored in environmental samples in academic literature, and some MS and EEA national monitoring therefore this can be a useful source for enforcement authorities. Therefore, RAC concludes that the restriction proposal is monitorable.

Forum is of the opinion that sampling will be simple as standard methods for cosmetics is available. Concerning analysis, they highlight two European methods for standard concentrations (EN 16344 and EN 17156:2018). These standards are not mentioned in the Background Document but it is not clear if these standards are useful for the determination of concentrations near the limit value proposed (the methods are intended for the quantitative determination of intentionally added Octocrilene (0.2 – 10% w/w)). It is possible that development and validation may be necessary to achieve 0.001%. The Background Document refers to another method, but it is not clear to Forum if that method also is suitable for solids (lip balm, lip stick).

Forum also notes that access to chemical inspectors of the EU CPNP database (Cosmetics Product Notification Portal) would be helpful as would also indicating that the substance is restricted under REACH in the CosIng database.

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.4.3 Conclusion whether the suggested restriction is the most appropriate EU-wide measure

RAC conclusion(s):

- RAC concludes that the restriction proposal is implementable, enforceable, manageable as well as monitorable.
- RAC also concludes that the proposed restriction is effective in reducing the identified risk. Therefore, RAC considered that the proposed restriction is the most appropriate EU-wide measure to control the environmental risks of octocrilene.

Key elements underpinning the RAC conclusion(s):

The restriction proposal is specifically targeted towards cosmetic products and the

environmental risk the cosmetic products cause via the content of octocrilene. If a short transition period (2 years) is agreed, the risks will be reduced within a reasonable period of time. As stated in the section 3.4.2.3 of this opinion, RAC considers the restriction proposal implementable, and as analytical methods with a low LoQ are available, RAC also finds the proposal enforceable and manageable. As concluded in section 3.4.2.4 of this opinion, it is possible to monitor the restriction using many different methods, especially including environmental monitoring, analytical monitoring of cosmetic samples and following the market and number of sunscreens containing octocrilene as the most important ones.

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.5 SUMMARY OF UNCERTAINTIES

3.5.1 Uncertainties evaluated by RAC

Relevant sections of the Background Document:

- Section 6
- Appendix F

RAC conclusion(s):

- RAC agrees that the uncertainties identified by the Dossier Submitter underestimate the risk of octocrilene.
- RAC concludes that, despite uncertainties, the risk from wide dispersive use of octocrilene is clear, and that a restriction is needed.
- RAC considers that the analysis of uncertainties provided by the Dossier Submitter in Section 6 of the Background Document is appropriate.
- The identified uncertainties do not impact the effectiveness and enforceability of the restriction.

Key elements underpinning the RAC conclusion(s):

RAC considers that the following uncertainties are important to consider.

Hazard

Statistical assessment of the degradation data performed by RAC resulted in the omission of two data points from replicate A of the OECD TG 308 freshwater sediment study. This leaves only one data point for day 64 and day 100 from replicate B resulting in an uncertainty due to loss in replicability. RAC conducted Huber regression analysis to manage this uncertainty, where replicate conforms with mean degradation following data analysis. Additionally, the degradation half-life following outlier omission is very close in value to the degradation half-life without omission, and below the P criteria in freshwater sediment system of > 120 days.

The ECHA R11 guidance states that if a potentially persistent transformation product is formed during degradation studies, "*The PBT/vPvB assessment should be performed on each relevant constituent, impurity, additive and transformation/degradation product*". Transformation product M2, M3 and M6 have persistent or very persistent properties. These transformation

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products may be more persistent, bioaccumulative and/or toxic than the parent substance. The lack of additional information on relevant transformation products is a known uncertainty. Further data on persistence, bioaccumulation and toxicity of these transformation products are relevant to the overall PBT/vPvB conclusions for octocrilene. Further information was provided for the degradation of M2 in the third-party consultation, however as no study reports were available, the degradation of all transformation products are considered to be an uncertainty.

RAC notes that no degradation data on octocrilene is available from the soil or water compartment.

RAC considers that that T criteria has been met, based on a EC₁₀ of 4.58 µg/L for long term effects on *Daphnia magna*. There is uncertainty as the reliability of data for additional species, at a range of trophic levels, in different environmental compartments is questionable. Based on this uncertainty, RAC considers that the AF for freshwater and marine environment should be higher, resulting in higher risks.

RAC notes that ED ENV data has become available during the development of the DO. This data has not yet been evaluated by the Dossier Submitter, therefore there is uncertainty whether the substance could be considered as an ED, which may impact the overall risk assessment and restriction proposal.

Another uncertainty concerns the impact of formation of (carcinogenic and suspected endocrine disruptor) benzophenone in octocrilene as sunscreens get older (Downs et al. 2021). Benzophenone has been identified as a potential transformation product of octocrilene, however the rate of formation in any octocrilene containing products has not been quantified in the Background Document. The study by Downs, et. al. 2021 quantified benzophenone concentrations from the breakdown of octocrilene in octocrilene containing products, ranging between 1.5 – 461 mg/kg (geometric mean of 37.4 mg/kg). RAC cannot conclude on the potential impacts of benzophenone formation on the restriction proposal, however RAC highlights that REACH entry 28 does not apply to cosmetics and benzophenone is banned in cosmetics through Annex II of the Cosmetic Products Regulation, where it states that "*Benzophenone as an impurity and/or degradation product of Octocrylene shall be kept at trace level.*".

Emissions

RAC notes uncertainties related to the amount of sunscreen applied by consumers, the concentration of octocrilene in products and the releases of octocrilene to the environment. RAC has estimated the uncertainties in the swimming scenario as follows (Table 11).

Table 11 Uncertainties in the swimming scenario and the direction of influence on the exposure estimates.

<u>Uncertainty</u>	<u>Direction</u>	<u>Remark</u>
<u>Amount of sunscreen applied</u>	↓	18 g daily is used. The range is 16-68 g/day.
<u>Frequency of application</u>	↑↓	Two is used. 2 is the general assumption.
<u>Release of octocrilene</u>	↑↓	20% is used. The range is 6-50%
<u>Number of swimmers</u>	↑↓	1,500 and 3,000 are assumed. Probably depends on size of the beach.

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<u>Water volume</u>	↑	Fresh water-whole lake/pond Marine- based on a small beach
<u>Dilution</u>	↓	Only for marine scenario
Fraction of sunscreen products with Octocrilene	↓	36% is used. The range is 36-70%

↑ means that emissions are overestimated, ↓ means that emissions are underestimated, ↑↓ means that the uncertainty is site-specific and can go in either direction

The Dossier Submitter has outlined specific considerations taken into account to limit the impact of the uncertainty regarding releases to the environment. RAC can agree with the approach adopted by the Dossier Submitter (different assessments led to similar conclusions) to minimise the impact of this uncertainty. However, it must be noted that the estimated release of octocrilene to the environment represents an underestimation of total releases as the restriction only considers releases from cosmetics. Based on this underestimation, risk is still identified, therefore this underestimation does not impact the outcome of the proposed restriction.

There is a big difference between volumes of fresh water (whole lake considered) and marine water (only beach considered) used in the swimming scenarios. RAC notes that the scenario for fresh water is used elsewhere (Emission Scenario Document PT19: Emission scenarios for repellents and attractants (ECHA, 2015)), but there is no accepted scenario for marine water. The small volume considered for the marine scenario seems an underestimation of volume (noting that a 50% dilution still leads to risk). On the other hand, considering dilution in the whole lake volume feels like a worst-case assumption for fresh water. Sunscreen containing octocrilene that are purchased by consumers outside the EU are brought back home and reused, representing another uncertainty and underestimation of emissions that cannot be accounted for with available data.

Risk characterisation

RAC notes that risk characterisation has been calculated from a best-case approach used for degradation, exposure, and hazards (too low AF considering the limited reliable environmental hazard data). However, a worst case or realistic risk characterisation have not been developed for RAC to assess the likelihood or potential risk of each scenario. A realistic or worst-case approach is outlined by ECHA Guidance R16 as the most appropriate approach, where there is limited knowledge of the fate and distribution of the substance, including from wide dispersive use. As risk has been identified from this best-case approach, this will not have an impact on the justification of the proposed restriction as it may in fact underestimate the risk.

Alternatives

RAC considers that there is a lack of relevant hazard data available for some of the alternatives identified by the Dossier Submitter. This impacts RACs ability to assess potential hazard of these alternatives. While the hazard criteria and high-level hazard data for the identified alternatives for octocrilene has been provided, no study reports are available for RAC to independently assess the reliability of the studies. Lack of further information of use, exposure and emissions limits RAC's ability to assess the risk of alternatives. Therefore, where hazard data is available, hazard assessment has been used to group substances as equivalent or greater level of concern, likely lower concern and insufficient data as RAC does not have the relevant data to conduct a more detailed environmental risk assessment.

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Effectiveness of reducing risks

The Dossier Submitter notes that voluntary cosmetic reformulation and octocrilene emission reductions are occurring. However, no quantitative information has been provided, leading to uncertainty in the effectiveness of voluntary measures.

Scope

The scope of the present restriction proposal is clearly focused on octocrilene in cosmetics. Additionally, no information is available on the concentrations and quantity of octocrilene entering the European environment from outside of EEA, including through consumer import (i.e. purchasing octocrilene containing sunscreen and returning from outside the EEA). Therefore, the risk associated with consumer import or other uses outside of the scope of the restriction proposal remain underestimated and unknown.

Export of octocrilene containing cosmetic products and manufacture of octocrilene and plastisol production are not in scope of the restriction proposal. A minor uncertainty is that the contribution to environmental concentrations from manufacture of octocrilene and plastisol production is not known, although EUSES indicates concerns locally at some sites.

Monitorability and Enforcement

RAC notes that the analytical methods for the analysis of octocrilene in cosmetic formulations require further development and validation to enable monitorability of the proposed restriction at an EU-wide level. Therefore, the enforcement of the restriction remains uncertain until suitable methods have been appropriately validated. However, methods are available and RAC is of the opinion that monitorability is practicable and technically feasible. Lack of currently validated or accredited analytical methods is not a suitable reason to prevent restriction.

3.5.2 Uncertainties evaluated by SEAC

Relevant sections of the Background Document:

- Section 6
- Appendices E.4.3, E.4.5.2

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

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