MINISTÈRE
DE LA TRANSITION
ÉCOLOGIQUE
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Regulatory Management Option Analysis Conclusion Document

Substance Name: Octocrilene

EC Number: 228-250-8

CAS Number: 6197-30-4

Authority: France

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FOREWORD

The purpose of Regulatory Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

A RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: https://echa.europa.eu/en/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Substance Evaluation

France is performing a substance evaluation on octocrilene since 2012 under the REACH regulation.

Octocrilene was originally included in the Community rolling action plan (CoRAP) in order to clarify concerns about suspected PBT/vPvB[2], wide dispersive use and high tonnage. During the evaluation, other concerns have been identified, regarding human health: potential thyroid toxicity and suspected toxicity to reproduction and regarding environment: suspected endocrine activity and exposure of the aquatic environment. A decision on substance evaluation was therefore published in 2014 requiring further information to clarify these concerns. The results of the tests required were received in 2019. The concerns for the environment were not totally solved and led France to request an additional test LAGDA[3] that is still ongoing in order to clear the potential concern related to endocrine disruption.

Hazard Classification

Octocrilene has no harmonised classification under CLP regulation (Annex VI) but is classified as aquatic chronic 1 in REACH registrations (very toxic to aquatic life with long lasting effects).

Table: Completed or ongoing processes

RMOA	☐ Regulatory Management Option Analysis (RMOA) other than this RMOA	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☒ Testing proposal
		☒ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII
Harmonised C&L	☐ Annex VI (CLP) (see section 3.1)	
Proc esse s unde r othe	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	

[2] PBT/vPvB : Persistent, bioaccumulative and toxic/Very Persistent and very bioaccumulative
[3] LAGDA : Larval Amphibian Growth and Development Assay

	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment
	☐ In relevant Annex
Other processes / EU legislation	☒ Other (provide further details below)

Octocrilene is regulated by the two following EU regulations:

- Regulation (EU) 1223/2009 on cosmetic products

According to Annex VI of this regulation, octocrilene is allowed in all cosmetic products as UV Filter with a maximum threshold of 10%.

According to the SCCS[4] opinion 1627/21, octocrilene is safe to be used individually in cosmetic products up to 10%. Octocrilene is also considered safe for a combined use if sunscreen cream/lotion, sunscreen pump spray face cream, hand cream and lipstick at a concentration up to 10%. SCCS indicates that the use of octocrilene in sunscreen propellant spray is considered safe when its concentration does not exceed 9% when used together with face cream, hand cream, and lipstick containing 10% of octocrilene.

- Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food

According to Annex I of this regulation, octocrilene can be used as an additive or polymer production aid but is not authorized to be used as monomer or other starting substance or macromolecule obtained from microbial fermentation. Annex I specifies that the specific migration limit applicable for the substance is 0.05mg/kg of food.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	

[4] SCCS : Scientific Committee on Consumer Safety

Restriction under REACH	X
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

Hazard Information

- Human health

As regards toxicity for reproduction, a classification of octocrilene for sexual function and fertility with category 2 is warranted according to the criteria of CLP Regulation. No final conclusion could be set for developmental toxicity and no classification for effects on or via lactations seems warranted.

No classification seems warranted for thyroid toxicity (specific target organ toxicity - repeated exposure).

Octocrilene does not meet the endocrine disruptor criteria for human health regarding the EAS-modalities and no final conclusion could be set on endocrine disruptor potential regarding T-modality for human health.

The evaluation of the reliability of the available DNEL[5] was not performed. **Nevertheless, the French authorities recommends that the registrants:**

- ✓ **Update the registration dossier, taking into account the NOAEL[6] of 750 ppm in the EOGRTS[7] based on increased incidence of follicular epithelial cells hyperplasia and loss of colloid observed in males from 2100 ppm that would justify a lower DNEL;**
- ✓ **Make a reassessment of the appropriateness of the relevant risk management measures (RMM) to ensure that the RMMs currently in place adequately control worker exposure to octocrilene and for uses not covered by a specific regulation (e.g. the cosmetic uses).**

- Environment

The available information on aquatic organisms confirms the self-classification of octocrilene as very toxic to aquatic life with long lasting effects.

Regarding the PBT/vPvB assessment, octocrilene is considered toxic for the environment and potentially persistent but not bioaccumulative.

Uncertainty persists regarding endocrine disruptor property of octocrilene, the results of the LAGDA test will be taken into account for further regulatory actions if necessary.

Environmental Risk Assessment

The risk assessment demonstrates unacceptable environmental risks for non-target organisms being in the aquatic compartment including sediment and groundwater contamination. The uses involved are the formulation of plastisol and the specific use of octocrilene as UV filter in cosmetic

[5] DNEL : Derived No Effect Level
[6] NOAEL : Non Observed Adverse Effect Level
[7] EOGRTS : Extended One Generation Reproductive Toxicity Study

ingredients covering releases from bathing and washing of people wearing suncreams.

Regulatory risk management measures

Considering the unacceptable risk identified, the French authorities concludes that the most appropriate risk management option for octocrilene is a REACH restriction dossier.

Harmonised classification under CLP is not considered appropriate to manage the risks identified as octocrilene cannot be classified for the PBT/vPvB or endocrine disruptor hazard classes and the classification as reprotoxic category 2 would not prevent the use of the substance in cosmetic products according to the cosmetic regulation.

Regarding the identification as substance of very high concern, octocrilene does not fulfill the criteria defined in article 57 of REACH.

Other regulations outside REACH and CLP have also been analysed, the Water Framework Directive (2000/60/EC) and the Industrial Emissions Directive (2010/75/EU) but these regulations do not appear as the main relevant regulatory instruments for managing the risks identified in the short term. However on the basis of the findings reported in the RMOA, and depending on the outcome of the restriction procedure, the French authorities would recommend that the authorities in charge of these legislations at EU level examine the relevance of setting an environmental quality standard and/or regulating releases from industrial activities using octocrilene through a concentration limit value.

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

No need for action other than EU regulatory action.

5. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for follow-up	Actor
Restriction dossier	2025	France

The French authorities have submitted an intention for restriction on 4 October 2023. The dossier is expected to be submitted in early 2025.