Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): [3R-(3α,3aβ,7β,8aα)]-1-(2,3,4,7,8,8a-hexahydro-3,6,8,8-tetramethyl-1H-3a,7-methanoazulen-5-yl) ethan-1-one

EC Number:	251-020-3
CAS Number:	32388-55-9
Authority:	NL
Date:	22/03/2016

Note

This document has been prepared by the evaluating Member State given in the CoRAP update

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1 IDENTITY OF THE SUBSTANCE

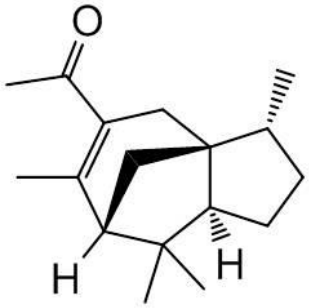
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	[3R-(3α,3aβ,7β,8aα)]-1-(2,3,4,7,8,8a-hexahydro-3,6,8,8-tetramethyl-1H-3a,7-methanoazulen-5-yl)ethan-1-one
IUPAC name (public):	1-((3R,3aR,7R,8aS)-3,6,8,8-tetramethyl-2,3,4,7,8,8a-hexahydro-1H-3a,7-met hanoazulen-5-yl)ethanone
Index number in Annex VI of the CLP Regulation:	none
Molecular formula:	C17H26O
Molecular weight or molecular weight range:	246
Synonyms:	methyl cedryl ketone (MCK)

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

None

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (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)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ 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)	

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

None

3.1.2 Self classification

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

  Skin Sens. 1B, H317: May cause an allergic skin reaction.

  Aquatic Acute 1, H400: Very toxic to aquatic life.

  Aquatic Chronic 1, H410: Very toxic to aquatic life with long lasting effects.

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Not relevant

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☒ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential
Joint submission		

4.2 Overview of uses

Part 1:

☐ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Article service life	☐ Closed system

Part 2:

	Use(s)
Formulation	Formulation of fragranced end-products Formulation of fragrance compounds
Uses at industrial sites	Industrial end-use of washing & cleaning products
Uses by professional workers	Professional end-use of washing & cleaning products Professional end-use of polishes and wax blends
Consumer Uses	Consumer end-use of washing and cleaning products Consumer end-use of air care products Consumer (and professional) end-use of cosmetics Consumer end-use of biocides Consumer end-use of polishes and wax blends

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

☒ Article 44(2) (refined prioritisation criteria for substance evaluation)

5.2. Selection criteria met (why the substance qualifies for being in CoRAP)

☐ Fulfils criteria as CMR/ Suspected CMR

☐ Fulfils criteria as Sensitiser/ Suspected sensitiser

☒ Fulfils criteria as potential endocrine disrupter

☒ Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB

☐ Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)

☒ Fulfils exposure criteria

☐ Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☐ C ☐ M ☐ R	Suspected CMR[1] ☐ C ☐ M ☐ R	☒ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[1]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[1]	☐ Other (please specify below)
Exposure/risk based concerns		
☐ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☐ Exposure of environment	☐ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☐ High (aggregated) tonnage	☐ Other (please specify below)

[1] CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

MCK is initially considered as a potential endocrine disruptor. However, the concern is not confirmed, nor put aside, by the (eco)toxicological information available. The details are as follows.

Toxicological studies
Only two valid studies were available. One was a 90d rat dermal repeated dose study. The doses used were 0, 50, 150, 300 mg/kg bw/day. Except the local dermal toxicity observed, there was no systematic toxicity in rats and the NOAEL was considered to be 300 mg/kg bw/day. Another valid study was a developmental toxicity test (TG 414) in rats exposed to MCK of 0, 25, 50, or l00 mg/kg bw/day (nominal conc., gavage). Significant reduction in body weight gain and feed consumption at 100 mg/kg bw/day. The NOAEL for maternal toxicity is 50 mg/kg bw/day. The NOAEL for developmental toxicity is 100 mg/kg bw/day because no effects were observed at the highest dosage tested. No information is available for reproductive toxicity and for the mechanism of action.

Ecotoxicological studies

Only one valid chronic Daphnia 21d toxicity test was available, with NOEC of 0.087 mg/L for reproduction and growth. No long term fish toxicity data were available.

Based on the limited information, it is impossible to conclude that MCK has or has not endocrine disrupting properties.

It is noted that the MCK is not readily biodegradable, has a logKow of 5.9 and a BCF of 3920 was determined according to OECD 305. It can be concluded that the B and T criteria are probably met, and further elucidation of the P and T properties is needed. **MCK may be a potential PBT.**

5.4 Preliminary indication of information that may need to be requested t clarify the concern

☒ Information on toxicological properties	☐ Information on physico-chemical properties
☒ Information on fate and behaviour	☐ Information on exposure
☒ Information on ecotoxicological properties	☐ Information on uses
☒ Information ED potential	☐ Other (provide further details below)
The initial concern on potential endocrine disruptor could not be removed because of the deficiency in both toxicological and ecotoxicological data as well as mode/mechanism of action (MOAs) data. If the ED properties need to be addressed, one may consider to perform an oral 90d repeated dose toxicity test and possibly a reproductive toxicity test. Based on the outcome, further elucidation of MOAs may be needed. For ecotoxicity testing, long-term fish toxicity test data are missing. Considering the potential ED concern, the fish tests suggested may be fish partial life cycle toxicity test, fish life cycle toxicity test or OECD TG 229 or 234 test. The test design may take into account both MOAs and the NOEC for deriving a PNEC. It is noted that MCK may have PBT properties. A simulation test is suggested to elucidate the P properties. T properties will be based on the outcome of (eco)toxicity tests.	

5.5 Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☒ Authorisation	☐ Other (provide further details)
Both PBT and ED properties fall into the category of authorization. In addition, classification for Skin Sens 1B could be harmonized.			