baua:
Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	2-ethylhexyl salicylate
EC Number:	204-263-4
CAS Number:	118-60-5
Authority:	German CA
Date:	20/03/2018

Cover 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

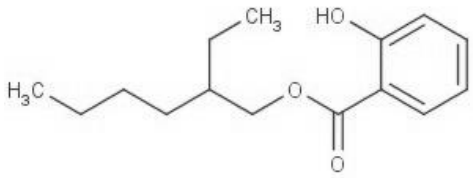
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	2-ethylhexyl salicylate
IUPAC name (public):	2-ethylhexyl salicylate
Index number in Annex VI of the CLP Regulation:	N/A
Molecular formula:	$C_{15}H_{22}O_3$
Molecular weight or molecular weight range:	250.33 g/mol
Synonyms:	*2-ethylhexyl 2-hydroxybenzoate* *2-Ethylhexylsalicylate* *Ethylhexyl Salicylate* *p-menth-1-en-8-ol* *SOCT* *Sunobel® OS*

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

Structural formula:



1.2 Similar substances/grouping possibilities

The group of salicylates (i.e. esters of 2-hydroxysalicylate as indicated below) can be considered as similar.

Structural formula:

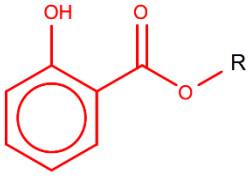
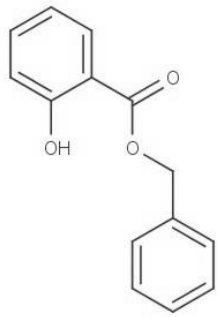


Table 2: Similar substance

EC number:	204-262-9
EC name (public):	benzyl salicylate
CAS number:	118-60-1
IUPAC name (public):	benzyl salicylate
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	$C_{14}H_{12}O_3$
Molecular weight or molecular weight range:	228.24 g/mol
Synonyms:	*2-hydroxybenzoic acid phenylmethyl ester* *Benzoic acid, 2-hydroxy-, phenylmethyl ester* *Benzyl 2-hydroxybenzoate* *Benzyl-2 hydroxibensoate* *Benzylsalicylat* *Phenylmethyl 2-hydroxybenzoate* *Salicylic acid, benzylester* *Benzyl o-hydroxybenzoate* *Phenylmethyl 2-hydroxybenzoate* *Salicylic acid, benzyl ester*

Structural formula:

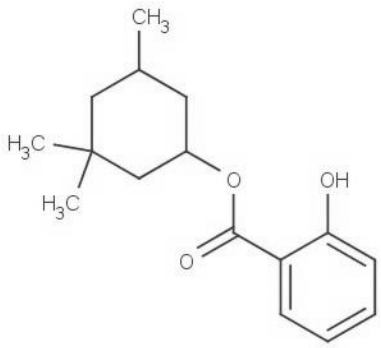


Benzyl salicylate is proposed for substance evaluation in parallel to 2-ethylhexyl salicylate due to their structural similarity.

Table 3: Similar substance

EC number:	204-260-8
EC name (public):	Homosalate
CAS number:	118-56-9
IUPAC name (public):	3,3,5-trimethylcyclohexyl salicylate
Index number in Annex VI of the CLP Regulation:	n.a.
Molecular formula:	$C_{16}H_{22}O_3$
Molecular weight or molecular weight range:	262,34 g/mol
Synonyms:	*(3,3,5-trimethylcyclohexyl) 2-hydroxybenzoate* *Homomenthylsalicylate* *Sunobel®HMS*

Structural formula:



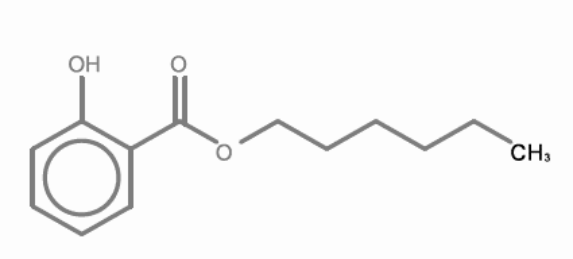
The substance has been included in the Public Activity Coordination Tool (PACT) due to an RMOA process initiated by France.[1]

[1] PACT section on homosalate: https://echa.europa.eu/de/addressing-chemicals-of-concern/substances-of-potential-concern/pact/-/substance-rev/12933/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=204-260-8

Table 4: Similar substance

EC number:	228-408-6
EC name (public):	hexyl salicylate
CAS number:	6259-76-3
IUPAC name (public):	hexyl salicylate
Index number in Annex VI of the CLP Regulation:	n.a.
Molecular formula:	$C_{13}H_{18}O_3$
Molecular weight or molecular weight range:	222.282 g/mol
Synonyms:	*Benzoic acid, 2-hydroxy-, hexyl ester* *Hexyl Salicylate* *Hexyl o-hydroxybenzoaten-Hexyl Salicylate*

Structural formula:



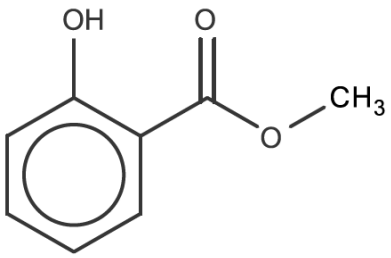
The substance has been subjected to REACH substance evaluation by the Netherlands in 2012.[2]

[2] CoRAP section on hexyl salicylate: https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e3d24

Table 5: Similar substance

EC number:	204-317-7
EC name (public):	methyl salicylate
CAS number:	119-36-8
IUPAC name (public):	methyl salicylate
Index number in Annex VI of the CLP Regulation:	n.a.
Molecular formula:	$C_8H_8O_3$
Molecular weight or molecular weight range:	152.1482 g/mol
Synonyms:	*methyl 2-hydroxybenzoate* *Methyl 2-hydroxybenzoate* *METHYL SALICYLATE* *methyl-2-hydroxybenzoate* *METHYL-SALICYLATE* *Metil szalicilát* *salicylic acid, methyl ester*

Structural formula:



The substance has been subjected to REACH substance evaluation by France in 2015.[3]

[3] CoRAP section on methyl salicylate: https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e9072

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
	Restric -tion	☐ Annex XVII[4]
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)	

[4] Please specify the relevant entry.

Further details	Regulated in cosmetic products as described in Annex VI of the Regulation (EC) No 1223/2009 on Cosmetic Products. A compliance check is in progress for the substance.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

There is no harmonised Classification for the substance in Annex VI.

3.1.2 Self classification

- In the registration:

  Not classified

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

Skin Irrit. 2	H315
Aquatic Chronic 4	H413
Eye Irrit. 2	H319

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

No Proposal for Harmonised Classification and Labeling has been submitted to the Registry of Intentions.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[5]

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

***the total tonnage band has been calculated by excluding the intermediate uses, for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11):

https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0

4.2 Overview of uses

Ethyl hexyl salicylate is used as UVA and UVB absorber in cosmetics (e.g. sun screens) and personal care products.

Part 1:

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

Part 3: There is high potential for exposure of

☐ Humans	☒ Environment

[5] *Dissemination site accessed on 20 July 2017*

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)

☐ Article 45(5) (Member State priority)

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[6]	
☐ 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)

[6] 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

In vitro studies are available that show weak estrogenic effects (Morohoshi et al. 2005; Miller et al. 2001). Also weak anti-estrogenic and androgen effects were seen (Kunz and Fent 2006). Most pronounced were anti-androgen effects also seen by Kunz and Fent (2006) in an *in vitro* assay. Ethyl hexyl salicylate is structurally related to homosalate and benzyl salicylate, another UV absorber used in cosmetics which also shows *in vitro* endocrine properties. As available data on registered uses suggest that there is relevant exposure of the environment to the substance, further tests may be required to clarify the concern of endocrine disruption to the environment.

5.4. Preliminary indication of information that may need to be requested to 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)
Based on the preliminary evaluation of the data related to endocrine disrupting properties of ethyl hexyl salicylate, *in vitro* studies and chronic studies using aquatic vertebrate (e.g. fish sexual development test) could be requested to clarify the concern on the estrogenic effects in the environment. Additionally, a detailed evaluation of the available data may lead to further information requirements.	

5.5. Potential follow-up and link to risk management

☐ Harmonised C&L	☒ Restriction	☒ Authorisation	☒ Other (provide further details)
Depending on the outcome of the substance evaluation, an analysis of Risk Management Options shall be carried out to identify appropriate risk management measures. If the substance is to be considered an Endocrine Disruptor according to WHO/IPCS definition, SVHC identification and candidate listing might be the first steps that will be further analysed in a risk management option analysis.			

References

Kunz PY., Fent K. 2006: Multiple hormonal activities of UV filters and comparison of in vivo and in vitro estrogenic activity of ethyl-4-aminobenzoate in fish. Aquat Toxicol 79(4), 305-324.

Morohoshi K., Yamamoto H., Kamata R., Shiraishi F., Koda T., Morita M. 2005: Estrogenic activity of 37 components of commercial sunscreen lotions evaluated by in vitro assays. Toxicol In Vitro 19(4), 457-469.

Miller D., Wheals bb., Beresford N., Sumpter JP. 2001: Estrogenic Activity of Phenolic Additives Determined By an In Vitro Yeast Bioassay. Environ Health Perspec 109 (2), 133-138.