Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	2-ethylhexyl acetate
Chemical Group:	-
EC Number:	203-079-1
CAS Number:	103-09-3
Submitted by:	BE CA
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ΝΟΤΕ

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 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	2-ethylhexyl acetate		
EC number:	203-079-1		
EC name:	2-ethylhexyl acetate		
CAS number (in the EC inventory):	103-09-3		
CAS number:	103-09-3		
CAS name:	Acetic acid, 2-ethylhexyl ester		
IUPAC name:	e: 2-ethylhexyl acetate		
Index number in Annex VI of the CLP Regulation	NA		
Molecular formula:	C ₁₀ H ₂₀ O ₂		
Molecular weight or molecular weight range:	172.2646		
Synonyms:	Trade names on dissemination website : Acetic acid, 2-ethylhexyl ester (7CI, 8CI, 9CI) 1-Hexanol, 2-ethyl-, acetate (6CI) .betaEthylhexyl acetate 2-Ethyl-1-hexanol acetate 2-Ethyl-1-hexyl acetate 2-Ethylhexyl acetate Octyl acetate		

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not applicable

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable

2.3 Self classification

The registration data includes the following self classification:

According to CLP criteria:

• Skin Irrit. 2 ; H315 : Causes skin irritation.

According to DSD criteria:

• Xi; R38 Irritation: Irritating to skin.

In addition are the following classification(s) included in the Classification and labeling inventory:

- Eye Irrit. 2; H319: Causes serious eye irritation.
- STOT SE 3; H335: May cause respiratory irritation.
- Aquatic Chronic 2; H411: Toxic to aquatic life with long lasting effects.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE

3.1 Legal basis for the proposal

 \boxtimes Article 44(1) (refined prioritisation criteria for substance evaluation)

Article 45(5) (Member State priority)

3.2 Grounds for concern

☐ (Suspected) CMR	$oxed{imediate}$ Wide dispersive use	Cumulative exposure
(Suspected) Sensitiser	spected) Sensitiser 🛛 Consumer use	
(Suspected) PBT	Exposure of sensitive populations	Aggregated tonnage
Suspected endocrine disruptor	Other (provide further details below)	

The substance is used by professionals and by consumers. The CSR however doesn't contain any calculated RCR values.

The registration data shows a potential concern for developmental toxicity, which should be further clarified.

There are no tests on reproductive toxicity available in the dossier with the registered substance. Read-across results with 2-ethylhexan-1-ol were used as key studies.

3.3 Information on aggregated tonnage and uses

🗌 1 – 10 tpa		🗌 10 – 100 tpa		🗌 100 – 1000 tpa	
🗌 1000 – 10,000 tpa		🗌 10,000 – 100,000 tpa			
🗌 100,000 - 1000,000 tp	а	□ > 1000,000 tpa			
🛛 Industrial use	🛛 Profe	essional use	Consumer use	2	Closed System
<u>Industrial use:</u> PROC: 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 15, 17 <u>Uses by professional workers:</u> PROC: 1, 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 17 <u>Uses by consumers:</u> Use in coatings, cleaning agents, lubricants, consumer care products, co-formulant in plant production products					

3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

Dangerous substances Directive 67/548/EEC				
Existing Substances Regulation 793/93/EEC				
Plant Protection Products Regulation 91/414/EEC				
Biocidal Products Directive 98/8/EEC				
Other (provide further details below)				
Annex XVII (Restriction)				
Information on other completed/ongoing regulatory processes was not found.				

3.5 Information to be requested to clarify the suspected risk

Information on toxicological properties	Information on physico-chemical properties			
Information on fate and behaviour	Information on exposure			
☐ Information on ecotoxicological properties	Information on uses			
Other (provide further details below)				

The potential concern for developmental toxicity should be further clarified. Further information on uses and exposure might be needed to clarify the concern.

When going through the registration data more in detail other items might come up that need clarification. The above only reflects the most probable information to be requested to clarify the suspected risk, other options are however still open.

3.6 Potential follow-up and link to risk management

Restriction	Harmonised C&L	Authorisation	igvee Other (provide further details)
Depending on the o		ation however other/f	abeling for 2-ethylhexyl acetate. urther RMMs (any of the above