Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	methyl salicylate
Chemical Group:	
EC Number:	204-317-7
CAS Number:	119-36-8
Submitted by:	FRANCE
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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

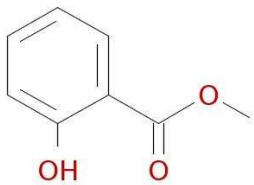
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	methyl salicylate
EC number:	204-317-7
EC name:	methyl salicylate
CAS number (in the EC inventory):	119-36-8
CAS number:	119-36-8
CAS name:	Benzoic acid, 2-hydroxy-, methyl ester
IUPAC name:	Methyl 2-hydroxybenzoate
Index number in Annex VI of the CLP Regulation	
Molecular formula:	C8H8O3
Molecular weight or molecular weight range:	152.1473 g/mol
Synonyms:	

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 listed in Annex VI

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None

2.3 Self classification

The registration data includes the following self classification:

<u>According to CLP criteria</u>:

- Acute Tox. 4, H302: Harmful if swallowed.

<u>According to DSD criteria</u>:

- Xn; R22 Harmful; Harmful if swallowed.

In addition are the following classification(s) included in the Classification and Labelling Inventory:

- Eye Irrit. 2, H319: Causes serious eye irritation
- Skin Irrit. 2, H315: Causes skin irritation
- Repr. 2, H361: Suspected of damaging fertility or the unborn child
- STOT SE 3, H335: May cause respiratory irritation
- Repr. 1B, H360: May damage fertility or the unborn child
- Lact., H362: May cause harm to breast-fed children
- Eye Irrit. 2A, H319: Causes serious eye irritation

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

◉ Article 44(1) (refined prioritisation criteria for substance evaluation)

○ Article 45(5) (Member State priority)

3.2 Grounds for concern

☒ (Suspected) CMR	☐ Wide dispersive use	☐ Cumulative exposure
☐ (Suspected) Sensitiser	☑ Consumer use	☐ High RCR
☐ (Suspected) PBT	☐ Exposure of sensitive populations	☑ Aggregated tonnage
☐ Suspected endocrine disruptor	☐ Other (provide further details below)	

Available data with MeS give hint that it could be embryofoetotoxic. From the tremendous amount of data presented for read-across from aspirin and salicylic acid, the results of the key and supporting studies suggests that salicylic acid has embryofoetotoxic effect in rats at doses not causing clear maternal toxicity, with evidence of malformations at maternally toxic doses (registration data).
Therefore this point deserves to be evaluated.

3.3 Information on aggregated tonnage and uses

☐ 1 - 10 t	☐ 10 - 100 t	☐ 100 - 1000 t	☑ 1000 - 10,000 t	
☐ 10,000 - 100,000 t	☐ 100,000 - 1000,000 t	☐ > 1000,000 t	☐ Confidential	

☑ Industrial Use	☑ Professional Use	☑ Consumer Use	☐ Closed System

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

☐ Compliance Check	☐ Annex VI (CLP)
☐ Testing Proposal(s)	☐ Annex XIV (Authorisation)
☐ Substance Identification Issues	☐ Annex XVII (Restriction)
☐ ESR Programme	☐ Other (provide further details below)

3.5 Information to be requested to clarify the suspected risk

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

Substance evaluation (targeted to reprotoxicity) would allow evaluating the tremendous amount of data available by read across with acetylsalicylic acid regarding the potential reproductive (developmental in particular) toxicity of MeS. Would those data be sufficient to clarify the concern (no need for classification or CLH report), the substance evaluation will end-up with no additional data requirement.

3.6 Potential follow-up and link to risk management

☐ Restriction	☐ Harmonised C&L
☐ Authorisation	☐ Other (provide further details below)

To be determined following substance evaluation