

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name): Shale Oil Bitumen
Chemical Group: -
EC Number: 447-780-2
CAS Number: NS
Submitted by: Health Board, Estonia
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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 Other identifiers of the substance

Table 1: Substance identity

EC name:	Shale Oil Bitumen
EC number:	447-780-2
IUPAC name:	Not assigned
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	Not specified
Molecular weight or molecular weight range:	Not specified
Synonyms/Trade names:	Shale Oil Bitumen PB

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula: Not specified

1.2 Similar substances/grouping possibilities

EC name:	Shale oil pitch
EC number:	447-790-7
IUPAC name:	Shale oil pitch
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	-
Molecular weight or molecular weight range:	-
Synonyms/Trade names:	Shale Oil Pitch

Structural formula: -

EC name:	Asphalt, oxidized
EC number:	265-196-4
IUPAC name:	Asphalt, oxidized
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	-
Molecular weight or molecular weight range:	-
Synonyms/Trade names:	<i>Bitumen petroleum viscosus</i>

EC name:	Asphalt
EC number:	232-490-9
IUPAC name:	Asphalt
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	-
Molecular weight or molecular weight range:	-
Synonyms/Trade names:	-

Structural formula: -

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not listed.

2.2 Self classification

The registration data includes the following self-classification:

According to CLP criteria:

- Skin Sens. 1; H317: May cause an allergic skin reaction.
- Aquatic Chronic 4; H413: May cause long lasting harmful effects to aquatic life.
- STOT Rep. Exp. 2; H373: May cause damage to organs through prolonged or repeated exposure.

Affected organs: liver

Route of exposure: oral

According to DSD criteria:

- Xn; R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed
- R43 - May cause sensitisation by skin contact
- R53 - May cause long-term adverse effects in the aquatic environment

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

No other given.

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa	
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa	
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa	
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input checked="" type="checkbox"/> Confidential	
The registration is as a NONS. Tonnage is confidential.			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
No uses are disseminated.			

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

4.2 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

4.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input checked="" type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input checked="" type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p>The substance was previously notified under Directive 67/548/EEC as a new substance. The request to the notifier to provide further information was submitted in accordance with Article 16(1) of Directive 67/548/EEC. The new information was provided as a read-across from asphalt/oxidised asphalt studies. However, with the submitted new data some concerns still remain which need to be clarified.</p> <p>Summary of concerns:</p> <ul style="list-style-type: none"> • Carcinogenicity: read-across from asphalt fume to Shale Oil Bitumen is not sufficiently justified. • Combined repeated dose toxicity study with the reproductive/developmental toxicity screening test for roofing asphalt fume condensate (read-across to Shale Oil Bitumen) is not sufficient to provide evidence for definite claims of no reproduction/developmental effects. Further information is needed for reproductive and developmental toxicity endpoint. • The substance may satisfy PBT criteria. No experimental data on bioaccumulation is available since the substance is a complex mixture of a number of different compounds which are not chemically well defined (UVCB). Taking into account the P_{ow} value and predicted BCF value the substance may have bioaccumulation potential. • More detailed description of the manufacturing process and uses could give more information for better risk characterisation and exposure estimation. Concerns about worker and environmental exposure. <p>Further action is required in order to identify whether the substance constitutes a risk to human health or the environment - investigate the appropriateness of a read-across approach from similar substances that are registered in REACH, identify specific information to clarify the concerns identified above and potential exposure to environment and workers.</p>		

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

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

<input type="checkbox"/> Compliance check, Final decision	<input checked="" type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
<p>Notified substance.</p> <p>Confidentiality under Directive 67/548/EEC not yet expired.</p>	

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

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input checked="" type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input checked="" type="checkbox"/> Other (provide further details below)
<p>More detailed justification for read-across application has to be provided. The bioaccumulation potential of the substance needs to be revised. Clarification of risks might be obtained by better information on exposure potential.</p>	

4.6 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)