CHEMICAL SAFETY REPORT

Substance Name: Shale Oil Bitumen
EC Number: 447-780-2
CAS Number:
Registrant's Identity: VKG Oil AS

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Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

For risk management measures to control worker's and environmental exposure please refer to the exposure scenarios described in part B, chapter 9 of this document.
The above part A element applies to: Own CSR (own uses)

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

The risk management measures mentioned above are implemented by the registrant or by downstream users.
The above part A element applies to: Own CSR (own uses)

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

The risk management measures mentioned above are communicated to the downstream user via the safety data sheet.
The above part A element applies to: Own CSR (own uses)

Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1. Name and other identifiers of the substance

The substance Shale Oil Bitumen is a UVCB (kerogen) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).
The following public name is used: Shale Oil Bitumen

Table 1.1. Substance identity

EC number:	447-780-2
EC name:	
CAS number (EC inventory):	
IUPAC name:	Shale Oil Bitumen
Molecular weight range:	>300 - <1500

Other identifiers:
trade name Shale Oil Bitumen PB
Remarks:
The given molecular weight is the weight-average molecular weight

1.2. Composition of the substance

Overall information on composition:

Composition	Related composition(s)
Shale Oil Bitumen PB (legal entity composition of the substance)	

Name: Shale Oil Bitumen PB

State/form: solid: bulk
Degree of purity: 100 % (w/w)
Description: The substance is obtained by thermal, oxidative and chemical condensation of heavy fractions of shale oil from the thermal treatment of oil shale. Due to its natural origin the composition is highly complex with >1000 components. Components can be grouped into 6 blocks: 1. Asphaltenes 2. Resins (polar aromatic) 3. Aromatics 4. Saturates (the analysis (see attached document in the annex) showed that “saturates” in the shale oil bitumen are below the analytical quantification limit. Hence, this group is not listed under composition). 5. Polyaromatic hydrocarbons (PAH) 6. Volatile organic compounds (VOC) (No information has been provided for the remainder of volatiles in shale oil bitumen. As they are not contributing to the hazard profile of the substance, this information is not listed under composition). The composition is decribed below.

Table 1.2. Constituents (Shale Oil Bitumen PB)

Constituent	Typical concentration	Concentration range	Remarks
Asphaltenes EC no.:	12 % (w/w)	>5 - <15 % (w/w)	
Resins - Shale oil bitumen EC no.:	75 % (w/w)	>60 - <90 % (w/w)	
Aromates - Shale oil bitumen EC no.:	15 % (w/w)	>10 - <30 % (w/w)	
Polycyclic aromatic hydrocarbons - PAH Shale	ca.0.02 % (w/w)	>0 - <0.1 % (w/w)	

oil bitumen EC no.:			
Ash EC no.:	ca.0.5 % (w/w)	>=0 - <=1 % (w/w)	determined by GOST method 14038-78
Water EC no.: 231-791-2	ca.0.25 % (w/w)	>=0 - <=0.5 % (w/w)	determined by GOST method 2477-85
Sulphur EC no.: 231-722-6	ca.0.25 % (w/w)	>=0 - <=0.55 % (w/w)	determined by GOST Method 1437

1.3. Physicochemical properties

Table 1.3. Physicochemical properties

Property	Description of key information	Value used for CSA / Discussion
Physical state	The registered substance has been determined to be a dark brown solid block.	**Value used for CSA:** solid at 20°C and 101.3 kPa
Melting / freezing point	The registered substance has a melting range of 23 to 37 ± 0.5 °C.	**Value used for CSA:** 30°C at 101.3 kPa
Boiling point	The boiling temperature of the registered substance has been determined to be >400 ± 0.5 °C at 102.48 kPa. A calculated value of boiling temperature of the lowest molecular weight component within the test material taken from computer software gave a result of 393 °C.	**Value used for CSA:** 400°C at 101.3 kPa
Relative density	The relative density of the registered substance has been determined to be 1.08 at 20.0 ± 0.5°C.	**Value used for CSA:** 1.08 at 20°C
Granulometry	In accordance with section 2 of REACH Annex XI, the granulometry study (required in section 7.14) does not need to be conducted as it is technically not feasible to perform the study due to the substance being a solid block of material with no particulates present.	
Vapour pressure	The vapour pressure of the registered substance has been determined to be 0.0025 Pa at 25 °C.	**Value used for CSA:** 0.003Pa at 25°C
Partition coefficient n-octanol/water (log value)	The partition coefficient of the registered substance has been determined to be >1.59 x 10^6, log10 Pow >6.20.	**Value used for CSA:** Log Kow (Log Pow): 6.2 at 40°C
Water solubility	The water solubility of the registered substance has been determined to be less than 0.00115 g/l of solution at 20.0 ± 0.5°C. A calculated value of water solubility was 3.53 x 10^-7 mg/l.	**Value used for CSA:** 0.001g/L at 20°C
Surface tension	In accordance with column 2 of REACH Annex VII, the surface tension study	

	(required in section 7.6) does not need to be conducted as the water solubility of the substance is less than 1 mg/l at 20°C.	
Flash point	The registered substance has been determined not to have a flash point below 300°C.	**Value used for CSA:** 300°C at 1013 hPa
Autoflammability / self-ignition temperature	The registered substance has been determined not to have an auto-ignition temperature below 400°C.	**Value used for CSA:** 400°C at 1013 hPa
Flammability	In accordance with section 1 of REACH Annex XI, the flammability study (required in section 7.10) does not need to be conducted as it is scientifically unjustified to perform the study. Based on the known chemical and physical properties of the substance and its chemical structure, negative results are predicted for the following flammability tests, so it is considered justified to omit them; Method A12: Flammability (contact with water) Method A13: Pyrophoric properties of solids and liquids. The substance is a low-melting solid, so the tests A10 and A11 are not applicable, and it is not “extremely flammable” or “flammable”. Furthermore, since test A9 is negative, and tests A12 and A13 are predicted to be negative, the substance can be considered to be not “highly flammable”.	**Value used for CSA:** non flammable
Explosive properties	There are no chemical groups present in the registered substance that would imply explosive properties, therefore the result has been predicted negative.	**Value used for CSA:** non explosive
Oxidising properties	There are no chemical groups present in the registered substance that would imply oxidising properties, therefore the result has been predicted negative.	**Value used for CSA:** no
Stability in organic solvents and identity of relevant degradation products	A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH	

	scheme; this study does not need to be conducted and is accordingly waived.	
Dissociation constant	A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.	
Viscosity	In accordance with section 2 of REACH Annex XI, the viscosity study (required in section 7.17) does not need to be conducted as it is technically not feasible due to the substance being a solid at room temperature.	

Data waiving

Information requirement: Granulometry

Reason: study technically not feasible

Justification: see 'Remark' - In accordance with section 2 of REACH Annex XI, the granulometry study (required in section 7.14) does not need to be conducted as it is technically not feasible to perform the study due to the substance being a solid block of material with no particulates present.

Information requirement: Surface tension

Reason: study scientifically not necessary / other information available

Justification: the study does not need to be conducted because water solubility is below 1 mg/L at 20°C [study scientifically not necessary / other information available]

Information requirement: Flammability

Reason: study scientifically not necessary / other information available

Justification: see 'Remark' - In accordance with section 1 of REACH Annex XI, the flammability study (required in section 7.10) does not need to be conducted as it is scientifically unjustified to perform the study. Based on the known chemical and physical properties of the substance and its chemical structure, negative results are predicted for the following flammability tests, so it is considered justified to omit them; Method A12: Flammability (contact with water) Method A13: Pyrophoric properties of solids and liquids. The substance is a low-melting solid, so the tests A10 and A11 are not applicable, and it is not "extremely flammable" or "flammable". Furthermore, since test A9 is negative, and tests A12 and A13 are predicted to be negative, the substance can be considered to be not "highly flammable".

Information requirement: Stability in organic solvents and identity of relevant degradation products

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Information requirement: Dissociation constant

Reason: other justification

Justification: see ‘Remark’ - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Information requirement: Viscosity

Reason: study technically not feasible

Justification: the study does not need to be conducted because the substance is a solid [study technically not feasible]

2. MANUFACTURE AND USES

Table 2.1. Quantities (in tonnes/year)

Year	Tonnages (tonnes per year)
2012	Manufactured: 3721
2013	Manufactured: 3113
2014	Manufactured: 3721
2015	Manufactured: 3360
2016	Manufactured: 538
2017	Manufactured: 805

Cumulative tonnages:

- Cumulative tonnage for uses at industrial sites: <=2100 tonnes/year
- Cumulative tonnage for widespread uses by professional workers: <=0 tonnes/year
- Cumulative tonnage for consumer uses: <=0 tonnes/year
- Cumulative tonnage for service life: <=600 tonnes/year

2.1. Manufacture

The substance is obtained by thermal, oxidative and chemical condensation of heavy fractions of shale oil from the thermal treatment of oil shale.

The liquid shale oil bitumen is obtained by oxidation of distillation residue of heavy shale oil with oxygen in the liquid phase at a temperature of 170-200 0C. The whole process is closed.

The distillation residue with temperature of 300 0C is cooled to temperature 170-200 0C in coke cubes. When the temperature is 170-200 0C the compressed air is routed through a bubbler to coke cubes. At the end of oxidation the shale oil bitumen is cooled down in the cubes to a temperature of 130-150 oC and passed to the loading platform through pumps. From loading platform the substance is loaded to car tanks.

The solid shale oil bitumen is obtained by oxidation of distillation residue of heavy shale oil with oxygen in the liquid phase at a temperature of 320-360 0C. The distillation residue is heated to temperature 320-360 0C in coke cubes. When the temperature is 320-360 0C the compressed air is routed through a bubbler to coke cubes. At the end of oxidation the shale oil bitumen is cooled down in the cubes to a room temperature. Finished solid shale oil bitumen is taken out from the cubes, it is crushed and packed into big-bags.

Table 2.2. Manufacture

	Manufacture
M-1	**Shale Oil Bitumen Refining** Further description of manufacturing process: The substance is obtained by thermal, oxidative and chemical condensation of heavy fractions of shale oil from the thermal treatment of oil shale. Contributing activity/technique for the environment : **- Manufacture (ERC1)** Contributing activity/technique for the workers : **- Refining from raw shale oil - hot outdoor process; including raw material filling and car tank filling with vapour return (closed systems) (PROC 3)** **- Cleaning operations (PROC 8b)** **- solid bitumen processing (PROC 14)**

	- Analytical activities (PROC 15) use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=2100 tonnes/year Related assessment: use assessed in an own CSR

2.2. Identified uses

No information available on identified uses.

Table 2.3. Uses at industrial sites

	Uses at industrial sites
IW-2	**Use in the production of firesafe materials (<15% concentration)** Further description of the use: The substance is bound into a matrix. Elevated mechanical and /or thermal energy conditions are needed to process substance as fire safe material under compression. Three sites are assumed to perform this operation in equal amounts. Contributing activity/technique for the environment : **- Use in the production of firesafe materials (ERC5)** Contributing activity/technique for the workers : **- Use in the production of firesafe materials - open hot processes (PROC 5)** **- Filling, cleaning operations of blends at elevated temperature (<40°C) (PROC 8b)** **- Extrusion and compression operations at elevated temperatures (<40°C) (PROC 14)** **Product Category used:** PC 32: Polymer preparations and compounds **Sector of end use:** SU 19: Building and construction work **Technical function of the substance:** processing aid use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=600 tonnes/year Substance supplied to that use: in a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: Use in the production of firesafe materials Related assessment: use assessed in an own CSR
IW-1	**Polymer synthesis** Further description of the use: Contributing activity/technique for the environment : **- Polymer synthesis (ERC6d)** Contributing activity/technique for the workers : **- Polymer synthesis - hot process (PROC 3)** **- Handling and cleaning - cold process (PROC 8a)** **- Crushing and packing of product (PROC 14)** **Product Category used:** PC 32: Polymer preparations and compounds **Sector of end use:** SU 12: Manufacture of plastics products, including compounding and conversion **Technical function of the substance:** Reactant use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=1500 tonnes/year Substance supplied to that use: Subsequent service life relevant for that use: no Related assessment: use assessed in an own CSR

Table 2.4. Article service life

	Article service life
SL-2	**Use in the production of firesafe materials** Further description of the use: Article used by: workers Substance intended to be released from article: no **Article category related to subsequent service life (AC):** AC10g: Other rubber articles Contributing activity/technique for the environment: **- Use in the production of firesafe materials (ERC11a)** Contributing activity/technique for consumers: Contributing activity/technique for the workers: **- Use in the production of firesafe materials (PROC 21)** **Technical function of the substance:** flame retardant use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant Tonnage of substance for that use: <=600 tonnes/year Related assessment: use assessed in an own CSR

3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

Substance: Shale Oil Bitumen
Implementation: EU
The substance is classified as follows:

Table 3.1. Classification and labelling according to CLP / GHS for physicochemical properties

Hazard class	Hazard category	Hazard statement	Reason for no classification
Explosives:			conclusive but not sufficient for classification
Desensitised explosives:			data lacking
Flammable gases and chemically unstable gases:			conclusive but not sufficient for classification
Flammable aerosols:			conclusive but not sufficient for classification
Oxidising gases:			conclusive but not sufficient for classification
Gases under pressure:			conclusive but not sufficient for classification
Flammable liquids:			conclusive but not sufficient for classification
Flammable solids:			conclusive but not sufficient for classification
Self-reactive substances and mixtures:			conclusive but not sufficient for classification
Pyrophoric liquids:			conclusive but not sufficient for classification
Pyrophoric solids:			conclusive but not sufficient for classification
Self-heating substances and mixtures:			conclusive but not sufficient for classification
Substances and mixtures which in contact with water emit flammable gases:			conclusive but not sufficient for classification
Oxidising liquids:			conclusive but not sufficient for classification
Oxidising solids:			conclusive but not sufficient for classification
Organic peroxides:			conclusive but not sufficient for classification

Corrosive to metals:			conclusive but not sufficient for classification

Table 3.2. Classification and labelling according to CLP / GHS for health hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification
Acute toxicity - oral:			conclusive but not sufficient for classification
Acute toxicity - dermal:			conclusive but not sufficient for classification
Acute toxicity - inhalation:			data lacking
Skin corrosion / irritation:			conclusive but not sufficient for classification
Serious damage / eye irritation:			conclusive but not sufficient for classification
Respiratory sensitisation:			data lacking
Skin sensitisation:	Skin Sens. 1	H317: May cause an allergic skin reaction.	
Aspiration hazard:			data lacking
Reproductive Toxicity:			conclusive but not sufficient for classification
Reproductive Toxicity: Effects on or via lactation:			data lacking
Germ cell mutagenicity:			conclusive but not sufficient for classification
Carcinogenicity:			conclusive but not sufficient for classification
Specific target organ toxicity – single exposure:			conclusive but not sufficient for classification
Specific target organ toxicity – repeated exposure:	STOT Rep. Exp. 2 Affected organs: liver Route of exposure: Oral	H373: May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.	

Table 3.3. Classification and labelling according to CLP / GHS for environmental hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification
Hazards to the aquatic environment (acute/short-term):			conclusive but not sufficient for classification
Hazards to the aquatic environment (chronic/long-term):	Aquatic Chronic 4	H413: May cause long lasting harmful effects to aquatic life.	

M-Factor acute:			
M-Factor chronic: 0			
Hazardous to the ozone layer:			data lacking

Labelling

Signal word: Warning

Hazard pictogram:

GHS07: exclamation mark

GHS08: health hazard

Hazard statements:

H317: May cause an allergic skin reaction.

H373: May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

H413: May cause long lasting harmful effects to aquatic life.

Precautionary statements:

P260: Do not breathe dust/fume/gas/mist/vapours/spray.

P272: Contaminated work clothing should not be allowed out of the workplace.

P273: Avoid release to the environment.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P314: Get medical advice/attention if you feel unwell.

P501: Dispose of contents/container to ... …in accordance with local/regional/national /international regulations (to be specified). Manufacturer/supplier or the competent authority to specify whether disposal requirements apply to contents, container or both. (licenced waste disposal sites.)

4. ENVIRONMENTAL FATE PROPERTIES

General discussion of environmental fate and pathways:

Additional information:
Summary of degradation
Abiotic degradation
No data on the hydrolysis of shale oil bitumen are available. Based on the properties of the test substance (it is a mixture of various different compounds, not chemically well defined with no main component, of low solubility) a hydrolysis study is technically not feasible.
Biotic degradation
In a ready biodegradability study to the OECD 301B guideline, at the end of the 28-day exposure period, the mean extent of biodegradation of Shale Oil Bitumen was 11%. Thus, only a small proportion of the compounds in the test item were biodegradable.
On the basis of the results of the study for the purpose of the risk assessment it is concluded that Shale Oil Bitumen is: not readily biodegradable.
Volatilisation
No data available, however a vapour pressure of 0.0025 Pa at 25 °C and the
low solubility indicates moderate volatility.
Distribution modelling
No distribution modelling data exist.
Summary of environmental distribution
An adsorption/desorption screening test is available in which a Log Koc of >5.63 was determined by HPLC. In Section 4 the solubility of Shale Oil Bitumen is reported as <0.00115 g/L, the Log Pow as >6.2 and the vapour pressure as 0.0025 Pa at 25°C. Based on these properties the substance would be expected to be primarily distributed in soil/sediments with a low association with water.
Summary and discussion of bioaccumulation
In accordance with Annex XIII to Regulation 1907/2006 the criteria for bioaccumulation are as follows:
A substance fulfils the bioaccumulation criterion (B-) when:
— the bioconcentration factor (BCF) is higher than 2 000.
A substance fulfils the bioaccumulation criterion (vB-) when:
— the bioconcentration factor (BCF) is higher than 5 000.
No experimental data on bioaccumulation are available. Shale oil bitumen is a complex mixture of a number of different compounds which are not chemically well defined with no main component; therefore the performance of a bioaccumulation study is not possible. The log Pow of >6.2 is indicative of concern with regard to bioaccumulation, although it is accepted that for log Pow values greater than 6 the relationship between Pow and BCF is not linear and at very high Pow values the bioaccumulation potential actually decreases. Nevertheless, a BCF of 25119 is predicted using the equation of Connell and Hawker (1988) listed in Chapter R7c of the ECHA REACH guidance. This equation relies solely on Pow values as the variable for predicting BCF.
regarding PBT assessment:
According to the ECHA Guidance on Information Requirements and Chemical Safety Assessment:“Chapter R.11: PBT/vPvB assessment”, the PBT assessment of UVCB substances should be carried out by first structuring the substance into several chemical blocks based on their chemical similarity.
Based on the identification data from the analysis of the shale oil bitumen (see attachment to this dossier), the bitumen can be separated into six blocks:
1. Asphaltenes
2. Resins (polar aromatic)
3. Aromatics
4. Saturates
5. Polyaromatic hydrocarbons (PAH)
6. Volatile organic compounds (VOC)

A table has been prepared as annex to this dossier that shows the relevant endpoints and individual PBT assessments of each of the blocks. The conclusions can be summarized as follows:
The available data does not allow a complete PBT assessment for the individual chemical substance blocks of shale oil bitumen. Further information is necessary to complete the fraction profiling for shale oil bitumen. Thus, the substance is handled as if it were a PBT/vPvB.
Secondary poisoning
Based on molecular weight the substance is expected not to be substantially bioacummulative and hence the possibility of secondary poisoning is moderate but not high.

4.1. Degradation

4.1.1. Abiotic degradation

4.1.1.1. Hydrolysis

No relevant information available.

Data waiving

Information requirement: Hydrolysis

Reason: study technically not feasible

Justification: the study does not need to be conducted because the substance is highly insoluble in water [study technically not feasible] - In accordance with column 2 of REACH Annex VIII, the hydrolysis as a function of pH study (required in section 9.2.2.1) does not need to be conducted as it is scientifically unjustified to perform the study due to the substance being highly insoluble in water.
The substance is predicted not to hydrolyse. The non-extractable hydrocarbon components of the substance are not susceptible to hydrolysis under environmentally relevant conditions.
It is not possible to conduct the study on this substance due to its complex nature and low water solubility.

4.1.1.2. Phototransformation/photolysis

4.1.1.2.1. Phototransformation in air

No relevant information available.

4.1.1.2.2. Phototransformation in water

No relevant information available.

4.1.1.2.3. Phototransformation in soil

No relevant information available.

4.1.2. Biodegradation

4.1.2.1. Biodegradation in water

4.1.2.1.1. Screening tests

The studies on biodegradation in water (screening tests) are summarised in the following table:

Table 4.1. Screening tests for biodegradation in water

Method	Results	Remarks
biodegradation in water: ready biodegradability: activated sludge, domestic (adaptation not specified) (aerobic) according to OECD Guideline 301 B (Ready Biodegradability: CO2 Evolution Test) ; according to EU Method C.4-C (Determination of the “Ready” Biodegradability - Carbon Dioxide Evolution Test) ; according to EPA OPPTS 835.3110 (Ready Biodegradability)	not readily biodegradable % Degradation of test substance: 11 after 28d (% degradation (CO2 evolution)) 12 after 29d (% degradation (CO2 evolution)) (Day 29 value corrected to include any carry-over of CO2 detected in Absorber 2)	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference**

		N. Clarke 2004 [95]

4.1.2.1.2. Simulation tests (water and sediments)

No relevant information available.

Data waiving

Information requirement: Simulation testing for biodegradation in water and sediment

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

4.1.2.1.3. Summary and discussion of biodegradation in water and sediment

Discussion (screening testing)

The following information is taken into account for any hazard / risk / persistency assessment:
The registered substance attained 11% degradation after 28 days and therefore cannot be considered to be readily biodegradable under the strict terms and conditions of OECD Guideline No 301B.

Value used for CSA:
Biodegradation in water: under test conditions no biodegradation observed

Discussion (simulation testing)

The following information is taken into account for any hazard / risk / persistency assessment:
A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Value used for CSA:

4.1.2.2. Biodegradation in soil

No relevant information available.

Data waiving

Information requirement: Soil simulation testing

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Discussion

The following information is taken into account for any hazard / risk / persistency assessment:
A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State

Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

4.2. Environmental distribution

4.2.1. Adsorption/desorption

The studies on adsorption/desorption are summarised in the following table:

Table 4.2. Studies on adsorption/desorption

Method	Results	Remarks
adsorption / desorption: screening HPLC estimation method according to EU Method C.19 (Estimation of the Adsorption Coefficient (KOC) on Soil and Sewage Sludge Using High Performance Liquid Chromatography (HPLC))	Adsorption coefficient: Koc: >427000 at 40°C log Koc: >5.63 at 40°C Partition coefficients: Mass balance (in %) at end of adsorption phase: Mass balance (in %) at end of desorption phase: Transformation products:	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** D.F. White; D.M. Mullee 2004 [95]

Discussion

The following information is taken into account for any environmental exposure assessment:
The adsorption coefficient (Koc) of the registered substance has been determined to be >4.27 x 10^5, Iog10 Koc >5.63.

Value used for CSA:
Koc at 20°C: 426580

Additional information:
[LogKoc: 5.63]

4.2.2. Volatilisation

No relevant information available.

4.2.3. Distribution modelling

No relevant information available.

4.3. Bioaccumulation

4.3.1. Aquatic bioaccumulation

No relevant information available.

Data waiving

Information requirement: Aquatic bioaccumulation

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived. In practice, a bioaccumulation study would not be possible to conduct due to the extremely complex nature of the substance.

4.3.2. Terrestrial bioaccumulation

No relevant information available.

4.4. Secondary poisoning

Based on the available information the bioaccumulation potential cannot be judged (see CSR chapter 7.5 "PNEC derivation and other hazard conclusions").

5. HUMAN HEALTH HAZARD ASSESSMENT

5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

5.1.1. Non-human information

No relevant information available.

5.1.2. Human information

No relevant information available.

5.1.3. Summary and discussion of toxicokinetics

Additional information:
Shale oil bitumen PB is defined as 'Complex hydrocarbons and organic oxygenated compounds produced by thermal, oxidative and chemical condensation of heavy fractions of shale oil'. It is a UVCB substance and in addition to the complex hydrocarbons other identified components are ash, water and sulphur. Considering the complex nature of Shale oil bitumen PB, standard toxicokinetic studies are not appropriate because toxicokinetic behaviours will vary depending upon the properties and interactions of the individual constituents. Single dose studies by the oral and dermal route showed low acute toxicity with no mortalities and no signs of systemic toxicity at the limit dose of 2000 mg/kg bw, thus suggesting limited, if any, absorption. Results obtained in a Mouse Local Lymph Node Assay and in a repeat-dose (28-day) oral gavage study, however, indicate a degree of absorption both for the dermal and oral route of exposure. The positive result of the LLNA indicates that Shale oil bitumen PB, or at least some of its components (likely the alkylresorcinols), can penetrate through the skin and bind to proteins thereafter. In the 28-day oral study, systemic exposure and distribution within the body was demonstrated by changes in haematological and clinical chemistry parameters, as well as in variations of organ weights and microscopic findings, mainly at the higher doses. The high Pow value suggests ready passage across cell membranes, indicating these effects could be possibly related to bioaccumulation following repeated administration of high doses. The increased liver weight, together with microscopic findings of centrilobular/generalised hepatocyte hypertrophy, is consistent with an active metabolisation of Shale oil bitumen PB by the liver, likely resulting in induction of enzymes located in the relevant zones for which hypertrophy was microscopically observed. Some damage to this organ was noted, especially at the highest dose level of 1000 mg/kg bw/day, because the hepatocyte hypertrophy, generally considered an adaptive response to the constant load from a xenobiotic, was accompanied by increases in transaminases and plasma bilirubin levels. The increases in relative kidney weight, creatinine and urea concentrations, limited to the highest dose level of 1000 mg/kg bw/day, also suggest that renal excretion capability could have been exceeded at this dose level.
As shale oil bitumen PB is of low volatility (vapour pressure 0.0025 Pa @ 25 °C), inhalation exposure is not likely to occur at ambient temperature and pressure however, all uses of shale oil bitumen PB foresee heating of the substance, and there is general scientific agreement that the human health hazards arising from bitumens, either derived from shale oil or petroleum, are hazards arising from dermal application of the substance and inhalation of the fume.Thus studies using the oral route and administration of the substance in polyethylene glycol 400 (as undertaken for the repeated dose study at base set) are probably inappropriate in terms of the likely human health hazards characterization. The exposure scenarios for shale oil bitumen PB should be very similar to those for petroleum derived bitumen, as they are intended for use in the same roles. Extensive human exposure data for users of bitumen have been shown that in Europe exposure to total vapour and aerosol does not exceed 10 mg/m3for most uses. Because of the complex nature of bitumens, characterization of the substance is the key point for conducting any appropriate testing in experimental animal models. A bitumen fume condensate (petroleum-derived) from paving bitumen was very carefully compared with that inhaled by paving workers and found similar, and tested for carcinogenicity in a recent fully compliant inhalation carcinogenicity study in rat. The bitumen fume condensate is not considered carcinogenic when administered by inhalation up to a nominal concentration of 100 mg/m3 for 2 years to rats. Additional recent data for bitumen also indicates that it depends on the test material tested as to whether it is carcinogenic following skin painting in mice. These data, together with

the completely negative results obtained with shale oil bitumen PB for all in vitro genotoxic endpoints, are reassuring.

5.2. Acute toxicity

5.2.1. Non-human information

5.2.1.1. Acute toxicity: oral

The results of studies on acute toxicity after oral administration are summarised in the following table:

Table 5.1. Studies on acute toxicity after oral administration

Method	Results	Remarks
rat [common species] (Sprague-Dawley [rat]) female oral: gavage according to OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method)	LD50: >2500 mg/kg bw (female) based on: (test mat.)	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** Sanders, A. 2004 [95]

5.2.1.2. Acute toxicity: inhalation

No relevant information available.

Data waiving

Information requirement: Acute toxicity after inhalation exposure

Reason: study scientifically not necessary / other information available

Justification: see 'Remark' - In accordance with REACH Annex XI, the acute inhalation toxicity study (required in section 8.5.2) does not need to be conducted on the basis that the study is scientifically unnecessary. Adequate data is available on exposure by the inhalation route from the repeated dose study (see section 5.6).

5.2.1.3. Acute toxicity: dermal

The results of studies on acute toxicity after dermal administration are summarised in the following table:

Table 5.2. Studies on acute toxicity after dermal administration

Method	Results	Remarks
rat [common species] (Sprague-Dawley [rat]) male/female Coverage: semiocclusive Vehicle: unchanged (no vehicle) according to OECD Guideline 402 (Acute Dermal Toxicity) ; according to EU Method B.3 (Acute Toxicity (Dermal))	LD50: >2000 mg/kg bw (male/female) based on: (test mat.)	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]).

		Reference Sanders, A. 2004 [95]

5.2.1.4. Acute toxicity: other routes

No relevant information available.

5.2.2. Human information

No relevant information available.

5.2.3. Summary and discussion of acute toxicity

The following information is taken into account for any hazard / risk assessment:

The acute oral median lethal dose (LD50) of the registered substance in the female Sprague-Dawley CD strain rat was estimated as being greater than 2500 mg/kg bodyweight.

The acute dermal median lethal dose (LD50) of the registered substance in the Sprague-Dawley CD strain rat was found to be greater than 2000 mg/kg bodyweight.

In accordance with REACH Annex XI, the acute inhalation toxicity study (required in section 8.5.2) does not need to be conducted on the basis that the study is scientifically unnecessary. Adequate data is available on exposure by the inhalation route from the repeated dose study (see section 7.5.2).

Value used for CSA:
Acute oral toxicity:
no adverse effect observed
(LD50) 2500mg/kg bw
Acute dermal toxicity:
no adverse effect observed
(LD50) 2000mg/kg bw
Acute inhalation toxicity:

Justification for classification or non classification:
Based upon the high LD50 values for oral and dermal exposure, and the absence of other major significant effects, the registered substance does not need to be classified for acute toxicity according to Regulation (EC) No 1272/2008.

5.3. Irritation

5.3.1. Skin

5.3.1.1. Non-human information

The results of studies on skin irritation are summarised in the following table:

Table 5.3. Studies on skin irritation

Method	Results	Remarks
rabbit [common species] (New Zealand White [rabbit]) Coverage: semiocclusive (shaved)	GHS criteria not met erythema score	1 (reliable without restriction) key study

Vehicle: unchanged (no vehicle) according to OECD Guideline 404 (Acute Dermal Irritation / Corrosion) ; according to EU Method B.4 (Acute Toxicity: Dermal Irritation / Corrosion)	1.67 of max. 2 (Time point: Mean score of 24, 48 and 72 hour readings) Reversibility: fully reversible within: 14 days 1.67 of max. 2 (Time point: Mean score of 24, 48 and 72 hour readings) Reversibility: fully reversible within: 7 days 0.67 of max. 1 (Time point: Mean score of 24, 48 and 72 hour readings) Reversibility: fully reversible within: 72 hours edema score 1 of max. 1 (Time point: Mean score of 24, 48 and 72 hour readings) Reversibility: fully reversible within: 7 days 0.67 of max. 1 (Time point: Mean score of 24, 48 and 72 hour readings) Reversibility: fully reversible within: 72 hours 0.33 of max. 1 (Time point: Mean score of 24, 48 and 72 hour readings) Reversibility: fully reversible within: 48 hours	experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** Sanders, A. 2004 [95]

Studies with results indicating corrosivity to the skin are summarised in section 5.4 Corrosivity.

5.3.1.2. Human information

No relevant information available.

5.3.2. Eye

5.3.2.1. Non-human information

The results of studies on eye irritation are summarised in the following table:

Table 5.4. Studies on eye irritation

Method	Results	Remarks
rabbit (New Zealand White [rabbit]) Vehicle: unchanged (no vehicle) according to OECD Guideline 405 (Acute Eye Irritation / Corrosion) ; according to EU Method B.5 (Acute Toxicity: Eye Irritation / Corrosion)	GHS criteria not met cornea opacity score (animal #1) 0 of max. 0 (Time point: Mean score of 24, 48 and 72 hour readings) not applicable cornea opacity score (animal #2) 0 of max. 0 (Time point: Mean score of 24, 48 and 72 hour readings) not applicable cornea opacity score (animal #3) 0 of max. 0 (Time point: Mean score of 24, 48 and 72 hour readings)	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** Sanders, A. 2004 [95]

	not applicable iris score (animal #1) 0 of max. 0 (Time point: Mean score of 24, 48 and 72 hour readings) not applicable iris score (animal #2) 0 of max. 0 (Time point: Mean score of 24, 48 and 72 hour readings) not applicable iris score (animal #3) 0 of max. 0 (Time point: Mean score of 24, 48 and 72 hour readings) not applicable conjunctivae score - redness (animal #1) 1.67 of max. 2 (Time point: Mean score of 24, 48 and 72 hour readings) fully reversible within: 7 days conjunctivae score - redness (animal #2) 0.33 of max. 2 (Time point: Mean score of 24, 48 and 72 hour readings) fully reversible within: 48 hours conjunctivae score - redness (animal #3) 0.67 of max. 2 (Time point: Mean score of 24, 48 and 72 hour readings) fully reversible within: 72 hours chemosis score (animal #1) 1 of max. 1 (Time point: Mean score of 24, 48 and 72 hour readings) fully reversible within: 7 days chemosis score (animal #2) 0 of max. 1 (Time point: Mean score of 24, 48 and 72 hour readings) fully reversible within: 24 hours chemosis score (animal #3) 0.33 of max. 1 (Time point: Mean score of 24, 48 and 72 hour readings) fully reversible within: 48 hours conjunctivae score - discharge (animal #1) 0.33 of max. 2 (Time point: Mean score of 24, 48 and 72 hour readings) fully reversible within: 48 hours conjunctivae score - discharge (animal #2) 0 of max. 1 (Time point: Mean score of 24, 48 and 72 hour readings) fully reversible within: 24 hours	

	conjunctivae score - discharge (animal #3) 0.33 of max. 1 (Time point: Mean score of 24, 48 and 72 hour readings) fully reversible within: 48 hours	

Data waiving

Information requirement: Eye Irritation

Reason: study scientifically not necessary / other information available

Justification: an in vitro eye irritation study does not need to be conducted because adequate data from an in vivo eye irritation study are available [study scientifically not necessary / other information available]

5.3.2.2. Human information

No relevant information available.

5.3.3. Respiratory tract

5.3.3.1. Non-human information

No relevant information available

5.3.3.2. Human information

No relevant information available.

5.3.4. Summary and discussion of irritation

The following information is taken into account for any hazard / risk assessment:

The registered substance produced a primary irritation index of 1.8 and was classified as a mild irritant to rabbit skin according to the Draize classification scheme. No corrosive effects were noted.

The registered substance does not require classification as a skin irritant according to Regulation (EC) No 1272/2008.

The registered substance produced a maximum group mean score of 8.7 and was classified as a mild irritant (Class 4 on a 1 to 8 scale) to the rabbit eye according to a modified Kay and Calandra classification system.

The registered substance does not require classification as an eye irritant according to Regulation (EC) No 1272/2008.

Value used for CSA:
Skin irritation / corrosion: no adverse effect observed (not irritating) Eye irritation: no adverse effect observed (not irritating) Respiratory irritation:

Justification for classification or non classification:
By reference to the data summarised within this dataset, the registered substance does not meet the criteria for classification for irritation according to Directive 67/548/EEC and the EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008.

5.4. Corrosivity

5.4.1. Non-human information

No relevant information available.

5.4.2. Human information

No relevant information available.

5.4.3. Summary and discussion of corrosion

The studies with results indicating corrosivity are discussed in section 5.3.4 Summary and discussion of irritation.

5.5. Sensitisation

5.5.1. Skin

5.5.1.1. Non-human information

The results of studies on skin sensitisation are summarised in the following table:

Table 5.5. Studies on skin sensitisation

Method	Results	Remarks
mouse (CBA [mouse]) female skin sensitisation: in vivo (LLNA) according to OECD Guideline 429 (Skin Sensitisation: Local Lymph Node Assay)	Category 1 (skin sensitising) based on GHS criteria Stimulation index: (See below) disintegrations per minute (DPM): (See below)	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** Sanders, A. 2004 [95]

Data waiving

Information requirement: Skin Sensitisation

Reason: study scientifically not necessary / other information available

Justification: An in vitro skin sensitisation study does not need to be conducted because adequate data from an in vivo skin sensitisation study is available

5.5.1.2. Human information

No relevant information available.

5.5.2. Respiratory system

5.5.2.1. Non-human information

No relevant information available.

5.5.2.2. Human information

No relevant information available.

5.5.3. Summary and discussion of sensitisation

The following information is taken into account for any hazard / risk assessment:

Skin sensitisation

The substance was considered to be a sensitiser under the conditions of a test conducted to OECD Test Method 429.

Value used for CSA: adverse effect observed (sensitising)
Additional information:
A study was performed to assess the skin sensitisation potential of the registered substance in the CBA/Ca strain mouse following topical application to the dorsal surface of the ear according to OECD Test Method 429.
Following a preliminary screening test, three groups, each of four animals, were treated with 50 µl (25 µl per ear) of the registered substance as a solution in acetone at concentrations of 2.5%, 5% or 10% w/w. A further group of four animals was treated with acetone alone.
The Stimulation Index (SI) expressed as the mean radioactive incorporation for each treatment group divided by the mean radioactive incorporation of the vehicle control group are as follows:

Concentration (% w/w) in acetone	Stimulation Index (SI)	Result
Vehicle	N/A	N/A
2.5	6.65	Positive
5	5.7	Positive
10	17.25	Positive

The registered substance was considered to be a sensitiser under the conditions of the test.

The following information is taken into account for any hazard / risk assessment:

Respiratory sensitisation

Value used for CSA: no study available
Additional information:
No data available.

Justification for classification or non classification:
Based upon the above results, the substance should be classified as Skin Sensitiser Category 1 according to the EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008.

5.6. Repeated dose toxicity

5.6.1. Non-human information

5.6.1.1. Repeated dose toxicity: oral

The results of studies are summarised in the following table:

Table 5.6. Studies on repeated dose toxicity after oral administration

Method	Results	Remarks

rat [common rodent species] (Sprague-Dawley [rat]) male/female short-term repeated dose toxicity: oral (oral: gavage) Vehicle: polyethylene glycol Exposure: 28 days (Once daily) according to EU Method B.7 (Repeated Dose (28 Days) Toxicity (Oral)) ; according to OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents)	LOAEL: 15 mg/kg bw/day (actual dose received) (male/female) based on: (test mat.) see 'Remark' - Treatment-related adverse effects were observed at all dose levels. A minimal response was also seen in single females at dose levels of 15 mg/kg/day and 150 mg/kg/day and slight response in 2 males at the 1000 mg/kg/day. A "No Observed Adverse Effect Level" could not, therefore, be established. The "Lowest Observed Adverse Effect Level" is therefore set at 15 mg/kg/day.	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** Dhinsa, N. K., McKenzie, J. and Brooks, P. N. 2004 [95]

5.6.1.2. Repeated dose toxicity: inhalation

The results of studies are summarised in the following table:

Table 5.7. Studies on repeated dose toxicity after inhalation exposure

Method	Results	Remarks
rat [common rodent species] (Wistar [rat]) male/female short-term repeated dose toxicity: inhalation (inhalation) Vehicle: air Exposure: 28 days (6 hours/day, 7 days a week) according to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test) ; according to EPA OPPTS 870.3650 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	NOAEC: 100.1 mg/m³ air (analytical) (male) based on: (test mat.) Based on decreased body weight gain, food consumption and increased absolute and relative lung weight correlated with slight respiratory system changes primarily adaptive in nature at 297.3 mg/m3 NOAEC: 30 mg/m³ air (analytical) (female) based on: (test mat.) Based on statistically significant increase in relative lung weight at 100.1 and 297.3 mg/m3 correlated with slight histopathologic effects in the lungs at 297.3 mg/m3	2 (reliable with restrictions) key study experimental study **Test material** Asphalt, oxidized, (full information in Appendix [97]). **Reference** Parker, C. M., Schreiner, C.A., Hallmark, N., Kriech, A. J., Osborn, L. V., Fuhst, R., Buschmann, J., Ernst, H., Hansen, T., Pohlmann, G., Preiss, A. and Ziemann, Ch. 2011 [95]

5.6.1.3. Repeated dose toxicity: dermal

No relevant information available.

Data waiving

Information requirement: sub-chronic toxicity: dermal - all

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

5.6.1.4. Repeated dose toxicity: other routes

No relevant information available.

5.6.2. Human information

No relevant information available.

5.6.3. Summary and discussion of repeated dose toxicity

The following information is taken into account for any hazard / risk assessment:

Key Information:
Oral: LOAEL 15 mg/kg bw/day for rats. Target organ is liver. OECD 407.

Inhalation: NOAEL 30 mg/m^3 for rats. Target organ is lungs. (Read across from Built-Up type III Roofing asphalt fume condensate) OECD 422.

Value used for CSA (via oral route - systemic effects):
adverse effect observed
(LOAEL): (15mg/kg bw/day) (subacute); (rat [common rodent species])
Target organs: liver

Value used for CSA (inhalation - systemic effects):
adverse effect observed
(NOAEC): (30mg/m³) (subacute); (rat [common rodent species])
Target organs: lungs

Additional information:
Oral: treatment-related effects were observed at all dose levels in a 28-day sub-acute test in rats, and a "No Observed Effect Level" (NOEL) could not, therefore, be established.
Inhalation: Built-Up type III Roofing asphalt fume condensate and read across. A detailed read across justification is attached to the dossier.
Based on decreased body weight gain, food consumption and increased absolute and relative lung weight correlated with slight respiratory system changes (primarily adaptive in nature) the test material was determined to have a NOAEC of 100.1 mg/m3 for males and 30.0 mg/m3 for females.
Dermal: A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.
Although the oral study was conducted on the test material, is a reliable GLP study conducted to an approved OECD method and should be considered as the key repeat dose study, this route of exposure is not considered the most relevant for human health hazard characterization. The inhalation OECD 422 study, reading across from Built-Up type III Roofing asphalt fume, is also conducted to GLP standard and following an approved OECD guideline and used a more relevant route of exposure. In addition to this short-term study, a fully compliant 2 -year carcinogenicity study is also available, and reported in section 5.8.

Repeated dose toxicity: via oral route - systemic effects (target organ) digestive: liver

Repeated dose toxicity: inhalation - systemic effects (target organ) respiratory: lung

Justification for classification or non classification:
Treatment-related effects were observed at all dose levels in a 28-day oral toxicity study in rats, and a NOEL (No Observed Effect level) was not established in this study. The effects observed at a dose level of 150 mg/kg/day are considered to be of toxicological significance and the substance is therefore classified under CLP as STOT Rep. Exp. 2, H373.
The sub-acute (28-day) inhalation NOAEC of 30 mg/m3 would roughly correspond to a chronic (2 -year) inhalation NOAEC of 5 mg fume/m3. A long-term (2 -year) inhalation study with LOAEC of 6.8 mg fume/m3 is available from asphalt fume condensates (see section 5.8), based mainly on adaptive changes. On this basis no classification is considered necessary for repeated inhalation exposure.

Detailed information on the Mode of Action is available in Annex III: [99]

5.7. Mutagenicity

5.7.1. Non-human information

5.7.1.1. In vitro data

The results of in vitro genotoxicity studies are summarised in the following table:

Table 5.8. The results of in vitro genotoxicity studies are summarised in the following table:

Method	Results	Remarks
in vitro mammalian chromosome aberration test [chromosome aberration] (in vitro cytogenicity / chromosome aberration study in mammalian cells - Type of genotoxicity: chromosome aberration) lymphocytes: [primary culture] (Met. act.: with and without) Test concentrations: Experiment 1 4(20)-hour without S9: 0*, 39.07*, 78.13*, 156.25*, 312.5, 468.75 and 625 µg/ml 4(20)-hour with S9: 0*, 39.07, 78.13*, 156.25*, 312.5*, 625 and 937.5 µg/ml Experiment 2 24-hour without S9: 0*, 9.77, 19.53, 39.06, 78.13*, 156.25* and 234.38* µg/ml 4(20)-hour with S9: 0*, 19.53, 39.06, 78.33*, 156.25*, 234.38* and 312.5 µg/ml * Dose levels selected for metaphase analysis Positive control substance(s): see details on test system and conditions according to EU Method B.10 (Mutagenicity - In Vitro Mammalian Chromosome Aberration Test) [in vitro cytogenicity / chromosome aberration study in mammalian cells] ; according to OECD Guideline 473 (In Vitro Mammalian Chromosome Aberration Test) [in vitro cytogenicity / chromosome aberration study in mammalian cells]	Test results: negative for lymphocytes: human [primary culture]; met. act.: with and without genotoxicity: negative cytotoxicity: yes vehicle controls valid: yes negative controls valid: yes positive controls valid: yes Remark: all strains/cell types tested - Migrated from field 'Test system'.	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** Wright, N. and Jenkinson, P. 2004 [95]
mammalian cell gene mutation assay [gene mutation] (in vitro gene mutation study in mammalian cells - Type of genotoxicity:	Test results: negative for Chinese hamster lung fibroblasts (V79) [mammalian cell line];	1 (reliable without restriction) key study

gene mutation) Chinese hamster lung fibroblasts (V79) [mammalian cell line] (Met. act.: with and without) Test concentrations: 5.0, 10.0, 20.0, 40.0 and 80.0 µg/ml Positive control substance(s): ethylmethanesulphonate Positive control substance(s): 7,12-dimethylbenzanthracene according to OECD Guideline 476 (In Vitro Mammalian Cell Gene Mutation Test) [in vitro gene mutation study in mammalian cells]	met. act.: with and without genotoxicity: negative cytotoxicity: yes vehicle controls valid: yes negative controls valid: yes positive controls valid: yes Remark: all strains/cell types tested - Migrated from field 'Test system'.	experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** Bednáriková, M. 2010 [95]
bacterial reverse mutation assay [in vitro gene mutation study in bacteria] (in vitro gene mutation study in bacteria - Type of genotoxicity: gene mutation) S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and TA 102 [bacteria] (Met. act.: with and without) Test concentrations: 50, 150, 500, 1500 and 5000 µg/plate Positive control substance(s): See any othersee information on materials and methods section according to EU Method B.13/14 (Mutagenicity - Reverse Mutation Test Using Bacteria) [in vitro gene mutation study in bacteria] ; according to OECD Guideline 471 (Bacterial Reverse Mutation Assay) [in vitro gene mutation study in bacteria]	Test results: negative for S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and TA 102 [bacteria]; met. act.: with and without genotoxicity: negative cytotoxicity: no, but tested up to limit concentrations vehicle controls valid: yes negative controls valid: yes positive controls valid: yes Remark: all strains/cell types tested - Migrated from field 'Test system'.	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** Thompson, P. W. 2004 [95]

5.7.1.2. In vivo data

The results of in vivo genotoxicity studies are summarised in the following table:

Table 5.9. In vivo genotoxicity studies

Method	Results	Remarks
micronucleus assay [chromosome aberration] (in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus - Type of genotoxicity: chromosome aberration) rat (Wistar [rat]) male/female inhalation cyclophosphamide 60mg/kg in water was administered by oral gavage to 10 additional rats [5/sex/group] 24 hours prior to sacrifice. according to OECD Guideline 474	Genotoxicity: negative (male/female) toxicity: no effects vehicle controls valid: yes negative controls valid: yes positive controls valid: yes Remark:	2 (reliable with restrictions) key study experimental study **Test material** Asphalt, oxidized, (full information in Appendix [97]). **Reference** Parker, C. M., Schreiner, C.A., Hallmark, N.,

(Mammalian Erythrocyte Micronucleus Test) [in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus] ; according to EPA OPPTS 870.5395 (In Vivo Mammalian Cytogenetics Tests: Erythrocyte Micronucleus Assay) [in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus]		Kriech, A. J., Osborn, L. V., Fuhst, R., Buschmann, J., Ernst, H., Hansen, T., Pohlmann, G., Preiss, A. and Ziemann, Ch. 2011 [95]

5.7.2. Human information

No relevant information available.

5.7.3. Summary and discussion of mutagenicity

Value used for CSA (genetic toxicity in vitro): Genetic toxicity: no adverse effect observed (negative)

Value used for CSA (genetic toxicity in vivo): Genetic toxicity: no adverse effect observed (negative)

Justification for classification or non classification
Based on the available data, the substance should not be classified for genetic toxicity under the CLP regulation (1272/2008), or the DSD (67/548/EEC).
Additional information:
AMES
In a study conducted in accordance with EU Test Method B13/14 (1974/046), Salmonella typhimurium strains TA1535, TA1537, TA102, TA98 and TA100 were treated with the test material using the Ames plate incorporation method at five dose levels, in triplicate, both with and without the addition of a rat liver homogenate metabolising system (10% liver S9 in standard co-factors). The dose range was determined in a preliminary toxicity assay and was 50 to 5000 µg/plate in the first experiment. The experiment was repeated on a separate day using the same dose range as Experiment 1, fresh cultures of the bacterial strains and fresh test material formulations.
The vehicle (dimethyl formamide) control plates gave counts of revertant colonies within the normal range. All of the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies, both with or without metabolic activation. Thus, the sensitivity of the assay and the efficacy of the S9-mix were validated.
The test material caused no visible reduction in the growth of the bacterial background lawn at any dose level, although a slight reduction in revertant colony frequency was noted in several strains at 5000 µg/plate. The test material was, therefore, tested up to the maximum recommended dose level of 5000 µg/plate, A beige, opaque film was noted from 1500 µg/plate with an associated precipitate observed at 5000 µg/plate. Neither of these observations prevented the scoring of revertant colonies.
No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation.
The test material was considered to be non-mutagenic under the conditions of this test.
Chromosomal aberration
In a chromosome aberration study (1974/047) conducted in accordance with EU Test Method B10, duplicate cultures of human lymphocytes, treated with the test material, were evaluated for chromosome aberrations at up to three dose levels, together with vehicle and positive controls. In Experiment 1, treatment lasted 4 hours in the presence of an induced rat liver homogenate metabolising system (S9) at a 2% final concentration, with cell harvest after a 20-hour expression period and 4 hours in the absence of metabolic activation, with a 20-hour expression period. In Experiment 2, the 4 hours exposure with addition of S9 was repealed (using a 1% final S9 concentration), whilst in the absence of metabolic activation the exposure time was increased to 24 hours.
All vehicle (solvent) controls had frequencies of cells with aberrations within the range expected for normal human lymphocytes.
All the positive control materials induced statistically significant increases in the frequency of cells with aberrations indicating the satisfactory performance of the test and of the activity of the metabolising system.
The test material was toxic but did not induce any statistically significant increases in the frequency of cells with

aberrations, in either of two separate experiments, using a dose range that included a dose level that induced approximately 50% mitotic inhibition.
The test material was considered to be non-clastogenic to human lymphocytes in vitro.
Gene mutation
The test material was examined for induction gene mutation in Chinese hamster V79 cells at concentrations from 5 to 80 µg/ml in the absence and in the presence of methylcholanthrene-induced rat liver S9, with cofactors for NADP generation. Cells were treated with test article during a 3 hours incubation period in both test systems. The protocol examined the induction of hypoxantine-phosphoribosyl transferase HPRT - deficient mutants and the mutagenicity was measured as 6-tioguanine (TG) resistance.
In the absence of exogenous activation the test material induced statistically significant increase in the frequency of mutation at concentration of' 20 µg/ml in the first experiment. The mutation frequency in cells V79 was 3.01 higher than the negative control value at this concentration. There was no evidence of relationship between dose and mutant frequency. Reproducible increase in mutation frequencies was not observed in the second confirmation experiment.
The test material in the mammalian cell gene mutation (V79/HPRT) test did not induce statistically significant increase in the mutation frequency at concentration ranging from 5 to 80 µg/ml in Chinese hamster lung cells V79 in the presence of metabolic system.
The results showed that the test material did not induce a concentration-related increase in mutation frequency at the HPRT locus in V79 cells, both in the absence and presence of metabolic activation and under the test conditions the test product is not mutagenic in the cultured mammalian cells used.
Mammalian Erythrocyte Micronucleus (In Vivo)
The study was conducted on asphalt bitumen fume. The similarity of the composition of this material to that of Shale Oil Bitumen, justifies the use of read-across.
In an assessment of clastogenic action on bone marrow erythrocytes in the micronucleus test the test material showed no evidence of inducing chromosomal or other damage leading to micronucleus formation in polychromatic erythrocytes of rats treated by nose-only inhalation at 30, 100 or 300 mg/m3 for 28 consecutive days.
No significantly enhanced mean frequency of micronucleated polychromatic erythrocytes (MN per 2000 PCE) was seen in bone marrow of animals in any test material exposed groups.

Short description of key information:
In Vitro
AMES (bacterial reverse mutation assay): Negative without and with metabolic activation. According to OECD 471 and to GLP standard.
Chromosomal aberration: Negative without and with metabolic activation. According to OECD 473 and to GLP standard.
Mammalian cell gene mutation: Negative without and with metabolic activation. According to OECD 476 and to GLP standard.

In Vivo
Mammalian Erythrocyte Micronucleus Test: Negative to rats. According to OECD 474 and to GLP standard (read across from Built-Up type III Roofing asphalt fume condensate).

Endpoint Conclusion: No adverse effect observed (negative)
Detailed information on the Mode of Action is available in Annex III: [99]

5.8. Carcinogenicity

5.8.1. Non-human information

5.8.1.1. Carcinogenicity: oral

No relevant information available.

5.8.1.2. Carcinogenicity: inhalation

The results of studies on carcinogenicity after inhalation exposure are summarised in the following table:

Table 5.10. Studies on carcinogenicity after inhalation exposure

Method	Results	Remarks
rat (Wistar [rat]) male/female inhalation (nose only) Doses / Concentrations: 6.8 mg/m3 Basis: other: Taking into account the conversion factor (1.66) between the absolute bitumen fume concentration and the bitumen fume concentration determined using the BIA method Doses / Concentrations: 34.4 mg/m3 Basis: other: Taking into account the conversion factor (1.66) between the absolute bitumen fume concentration and the bitumen fume concentration determined using the BIA method Doses / Concentrations: 172.5 mg/m3 Basis: other: Taking into account the conversion factor (1.66) between the absolute bitumen fume concentration and the bitumen fume concentration determined using the BIA method Vehicle: air Exposure: 6 hours per day, for 24 months. (daily, 5 days per week) according to OECD Guideline 451 (Carcinogenicity Studies)	NOEC: 172.5 mg/m³ air (male/female) based on: (Taking into account the conversion factor (1.66) between the absolute bitumen fume concentration and the bitumen fume concentration determined using the BIA method) (Effect type: carcinogenicity (migrated information)) LOAEC: 6.8 mg/m³ air (male) based on: (Taking into account the conversion factor (1.66) between the absolute bitumen fume concentration and the bitumen fume concentration determined using the BIA method) non-neoplastic lesions, likely of adaptive nature (i.e. mucous (goblet) cell hyperplasia of the nasal/paranasal cavities and eosinophilic cytoplasmatic inclusions in the olfactory epithelium) (Effect type: toxicity (migrated information))	2 (reliable with restrictions) key study experimental study **Test material** Bitumen fume condensate, (full information in Appendix [97]). **Reference** Fuhst, R., Creutzenberg, O., Ernst, H., Hansen, T., Pohlmann, G., Preiss, A., and Rittinghausen, S. 2007 [96]

5.8.1.3. Carcinogenicity: dermal

The results of studies on carcinogenicity after dermal administration are summarised in the following table:

Table 5.11. Studies on carcinogenicity after dermal administration

Method	Results	Remarks
mouse (Crl:CD1) male Doses / Concentrations: Basis: other: see table 1 Vehicle: mineral oil Exposure: 28 weeks (Twice weekly) no guideline followed Clark et al. reported that a sample of field-matched fume condensate from a Type III built-up roofing asphalt (BURA) resulted in a carcinogenic response in a mouse skin bioassay, with relatively few tumor-bearing animals, long tumor latency and chronic skin irritation (see Carcinogenicity, Clark et al, dermal). This mouse skin initiation/promotion study was conducted to assess possible mechanisms, i.e., genotoxic initiation vs. tumor promotion subsequent to repeated skin injury and repair. The same Type III	(The results of the current study indicate that a field-matched fume condensate of Type III BURA was a tumor initiator in mouse skin.)	2 (reliable with restrictions) supporting study experimental study **Test material** BURA fume condensate, (full information in Appendix [97]). **Reference** Freeman. J.J, et. al 2011 [96]

BURA fume condensate sample was evaluated in groups of 30 male Crl:CD1 mice by skin application twice per week (total dose of 50 mg/week) for 2 weeks during the initiation phase and for 26 weeks during the promotion phase. Positive control substances were 7,12-dimethylbenz(a)anthracene (DMBA, 50 µg applied once) as an initiator and 12-O-tetradecanoyl-13-acetate (TPA, 5 µg, applied twice weekly) during the promotion phase.		
mouse (C3H/HeNCrl) male Doses / Concentrations: total weekly dose of 50 mg Basis: Vehicle: mineral oil Exposure: 104 weeks (The two-year studies were conducted using different application frequencies to avoid the potential for irritation to confound interpretation of the results. The least irritating dosing regimen was seven times per week for the paving sample and twice per week for the BURA samples, both diluted in mineral oil, which has been used widely as a diluent for evaluating the skin carcinogenicity of petroleum derived materials.) no guideline followed Asphalt (bitumen) fume condensates collected from the headspace above paving and Type III built up roofing asphalt (BURA) tanks were evaluated in two-year dermal carcinogenicity assays in male C3H/HeNCrl mice. A third sample was generated from the BURA using a NIOSH laboratory generation method. Similar to earlier NIOSH studies, the BURA fume condensates were applied dermally in mineral oil twice per week; the paving sample was applied 7 days/week for a total weekly dose of 50 mg/wk in both studies.	(A single benign papilloma was observed in a group of 80 mice exposed to paving fume condensate at the end of the two-year study and only mild skin irritation was observed.) (The lab generated BURA fume condensate resulted in statistically significant ($P < 0.0001$) increases in squamous cell carcinomas (35 animals or 55% of animals at risk).) (The field-matched BURA condensate showed a weaker but significant ($P = 0.0063$) increase (8 carcinomas or 13% of animals) and a longer average latency (90 weeks vs. 76 for the lab fume).) (Significant irritation was observed in both BURA condensates.) (It is concluded that the paving fume condensate was not carcinogenic under the test conditions and that the field-matched BURA fume condensate produced a weak tumor response compared to the lab generated sample.)	2 (reliable with restrictions) supporting study experimental study **Test material** BURA fume condensate, (full information in Appendix [97]). **Reference** Clark. CR et. al. 2010 [96]

5.8.1.4. Carcinogenicity: other routes

No relevant information available.

5.8.2. Human information

No relevant information available.

5.8.3. Summary and discussion of carcinogenicity

The following information is taken into account for any hazard / risk assessment:

No evidence of carcinogenicity in rats at any of the tested dose levels. NOAEC of 172.5 mg/m3. Conducted accrding to OECD 451.

Value used for CSA (route: inhalation):
no adverse effect observed
(NOAEC) 172.5mg/m³ (chronic); (rat [common rodent species])

Additional information:
All of the studies were conducted on asphalt bitumen fume. The similarity of the composition of asphalt bitumen fumes used in this study to fumes generated by Shale Oil Bitumen has been demonstrated, see "Analytics Summary" report, as attached to this dossier. A detailed read across justification for this endpoint is attached to the dossier (Expert report Read Across, PICS 2011).
PAH concentrations in shale oil bitumen are in the 100 -300ppm range and therefore substantially lower that in other asphalt samples that were tested in the literature (see "Analytics Report" attached). One of three shale oil bitumen samples showed detectable concentrations of Crysene and Benzo-anthracene but otherwise carcinogenic PAHs such as benzo(a,e)pyrene were below the detection limit. Read across of carcinogenicity from other bitumen species is considered justified for the shale oil bitumen.
The paper by Fuhst et al was chosen as the key study on the basis that it is a well written and detailed report, the study was conducted according to the OECD 451 guideline and to GLP standard. Based on the results of a 13-Week Study 4, 20, and 100 mg/m3THC (Total Hydrocarbons) were chosen as the concentrations for the low, medium, and high dose groups.
Exposure of Wistar (WU) rats to Bitumen fume for 2 years under the experimental conditions described did not result in any statistically significant increase in total and organ-specific tumor incidence, between the clean air control and the Bitumen exposure groups. Based on these results Bitumen fume is not considered to be tumorigenic to rats up to and including 172.5 mg/m3. Bitumen-related irritant effects were observed in the nasal passages and in the lungs and therefore 6.8 mg/m3 was considered the LOAEC for lifespan exposure.
Neither of the supporting papers by Clark et al or Freeman et al indicate that the substance should be considered a carcinogen.
Three in vitro and one in vivo mutagenicity studies all showed negative results and suport the conclusion for the shale oil bitumen to be non-carcinogenic.

Justification for classification or non classification:
Based on the available data, the substance should not be classified as a carcinogen under the CLP regulation (1272/2008).

Detailed information on the Mode of Action is available in Annex III: [99]

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

The results of studies on fertility are summarised in the following table:

Table 5.12. Studies on fertility

Method	Results	Remarks
rat (Wistar [rat]) male/female two-generation reproductive toxicity inhalation (nose only) Doses / Concentrations: 30.0 mg/m3 Basis: analytical conc. Doses / Concentrations: 100.1 mg/m3 Basis: analytical conc. Doses / Concentrations: 297.3 mg/m3	**First parental generation (P0)** NOAEC - reproductive toxicity (PO) >=297.3 mg/m³ air (analytical)) (male/female) based on: clinical signs [general toxicity] ; body weight and weight gain [general toxicity] ; food consumption and compound intake [general toxicity] ; water consumption and compound intake [general toxicity] NOAEC - systemic - maternal (PO) 100.1	2 (reliable with restrictions) key study experimental study **Test material** Asphalt, oxidized, (full information in Appendix [97]).

Basis: analytical conc. Vehicle: air Exposure: 28 days for subchronic males; approximately 35-48 days for pregnant satellite females based on 14 days pre-mating, up to 14 days mating and Gestation days 0-20; and 54 days [26 days after end of cohabitation] for females with no evidence of copulation (6 hours/day. 7 days/week) according to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test) ; according to EPA OPPTS 870.3650 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	mg/m³ air (analytical)) (female) based on: see 'Remark' - Increased absolute and relative lung weight, accompanied by a slight increase of alveolar macrophage accumulation in combination with minimal mononuclear/inflammatory cell infiltration and minimal to slight (adaptive) alveolar hyperplasia of the bronchiolar type (alveolar bronchiolization) at 300 mg/m3. **F1 generation** NOAEC - developmental toxicity (PO): >=297.3 mg/m³ air (analytical) (male/female) based on: viability ; mortality ; body weight and weight gain **Overall reproductive toxicity** not specified Lowest effective dose / concentration Relation to other toxic effects:	**Reference** Parker, C. M., Schreiner, C.A., Hallmark, N., Kriech, A. J., Osborn, L. V., Fuhst, R., Buschmann, J., Ernst, H., Hansen, T., Pohlmann, G., Preiss, A. and Ziemann, Ch. 2011 [95]

5.9.1.2. Human information

No relevant information available.

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

No relevant information available.

Data waiving

Information requirement: Developmental Toxicity / teratogenicity

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Information requirement: Developmental Toxicity / teratogenicity

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

5.9.2.2. Human information

No relevant information available.

5.9.3. Summary and discussion of reproductive toxicity

Effects on fertility

Value used for CSA (route: inhalation):
(NOAEC) 297.3mg/m³

Additional information:
The study was conducted on asphalt bitumen fume. The similarity of the composition of asphalt bitumen fumes used in this study to fumes generated by Shale Oil Bitumen has been demonstrated, see "Analytics Summary" report, as attached to this dossier. A detailed read across justification for this endpoint is attached to the dossier (Expert report Read Across, PICS 2011).
The administration of the test material to rats by nose-only inhalation at dose levels of 30, 100 and 300 mg/m3 (30, 100.1 and 297.3 mg/m3 THC, analytically determined) did not cause significant adverse effects in any reproductive parameters [mean number of pregnant animals, number of animals delivering, mating index, fertility index, gestation length, number of corpora lutea, number of implantation sites or percent of post implantation loss] for any exposure group. Systemic effects in maternal animals demonstrated that treatment at concentrations up to 297.3mg/m3 was sufficient to induce some level of toxicity. The "No Observed Adverse Effect Concentration" (NOAEC) for reproductive and developmental toxicity was therefore 297.3 mg/m3, the highest concentration tested.

Short description of key information:
NOAEC fertility effects = 297.3 mg/m3 (analytical) in rats. Test performed according to OECD 422 and to GLP standard.

Developmental toxicity

The following information is taken into account for any hazard / risk assessment:

NOAEC developmental effects = 297.3 mg/m3 (analytical) in rats. Test performed according to OECD 422 and to GLP standard.

Value used for CSA (route: inhalation):
(NOAEC) 297.3mg/m³

Additional information:
The study was conducted on asphalt bitumen fume. The similarity of the composition of this material to that of Shale Oil Bitumen, justifies the use of read-across. A detailed read across justification is attached to the dossier. The administration of the test material to rats by nose-only inhalation at dose levels of 30, 100 and 300 mg/m3 (30, 100.1 and 297.3 mg/m3 THC, analytically determined) did not cause significant adverse effects in any reproductive parameters [mean number of pregnant animals, number of animals delivering, mating index, fertility index, gestation length, number of corpora lutea, number of implantation sites or percent of post implantation loss] for any exposure group. Systemic effects in maternal animals demonstrated that treatment at concentrations up to 297.3mg/m3 was sufficient to induce some level of toxicity. The "No Observed Adverse Effect Concentration" (NOAEC) for reproductive and developmental toxicity was therefore 297.3 mg/m3, the highest concentration tested.

Justification for classification or non classification:
Based on the available data, the substance should not be classified for reproductive or developmental toxicity under the CLP regulation (1272/2008).

Detailed information on the Mode of Action is available in Annex III: [99]

5.10. Other effects

5.10.1. Non-human information

5.10.1.1. Neurotoxicity

No relevant information available.

5.10.1.2. Immunotoxicity

No relevant information available.

5.10.1.3. Specific investigations: other studies

No relevant information available.

5.10.1.4. Additional toxicological effects

No relevant information available.

5.10.2. Human information

No relevant information available.

5.11. Derivation of DNEL(s) and other hazard conclusions

5.11.1. Overview of typical dose descriptors for all endpoints

Table 5.13. Available dose-descriptor(s) per endpoint as a result of its hazard assessment

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type
Acute toxicity	oral	no adverse effect observed (LD50): 2500mg/kg bw
Acute toxicity	dermal	no adverse effect observed (LD50): 2000mg/kg bw
Irritation / Corrosivity	skin	no adverse effect observed (not irritating)
Irritation / Corrosivity	eye	no adverse effect observed (not irritating)
Sensitisation	skin	adverse effect observed (sensitising)
Sensitisation	resp. tract	no study available
Repeated dose toxicity	oral	adverse effect observed (LOAEL): 15mg/kg bw/day (subacute; rat [common rodent species]) Target system/organs: liver
Repeated dose toxicity	inhalation (systemic effects)	adverse effect observed (NOAEC): 30mg/m³ (subacute; rat [common rodent species]) Target system/organs: lungs
Mutagenicity	in vitro / in vivo	In vitro: no adverse effect observed (negative) In vivo: no adverse effect observed (negative)
Carcinogenicity	inhalation	no adverse effect observed (NOAEC): 172.5mg/m³ (chronic; rat [common rodent species])

Reproductive toxicity: effects on fertility	inhalation	(NOAEC): 297.3mg/m³
Reproductive toxicity: developmental toxicity	inhalation	(NOAEC): 297.3mg/m³

5.11.2. Selection of the DNEL(s) or other hazard conclusions for critical health effects

Table 5.14. Hazard conclusions for workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.4mg/m³	repeated dose toxicity (By inhalation)
Inhalation	Systemic effects - Acute	no hazard identified	acute toxicity (Oral)
Inhalation	Local effects - Long-term	DNEL (Derived No Effect Level) 0.45mg/m³	carcinogenicity
Inhalation	Local effects - Acute	no hazard identified	acute toxicity
Dermal	Systemic effects - Long-term	high hazard (no threshold derived)	sensitisation (skin) (Dermal)
Dermal	Systemic effects - Acute	no hazard identified	acute toxicity (Dermal)
Dermal	Local effects - Long-term	high hazard (no threshold derived)	sensitisation (skin)
Dermal	Local effects - Acute	no hazard identified	skin irritation/corrosion
Eyes	Local effects	no hazard identified	

Inhalation Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEC

Modified dose descriptor starting point: NOAEC

Overall Assessment Factor: 75

AF for dose response relationship: 1 (ECHA guidance default)

AF for difference in duration of exposure: 6 (ECHA guidance default)

AF for interspecies differences (allometric scaling): 1 (inhalation to inhalation)

AF for other interspecies differences: 2.5 (ECHA guidance default)

AF for intraspecies differences: 5 (ECHA guidance default)

Further explanation on hazard conclusions:

AF = 75 [2.5 (remaining differences) x 5 (intraspecies – workers) x 6 (duration of exposure subacute to

chronic) x 1 (dose-response) x 1 (quality of data base)]

Inhalation Systemic effects - Acute

Further explanation on hazard conclusions:

The substance is not acutely toxic following oral administration or dermal application. No DNEL required.

Inhalation Local effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: LOAEC

Overall Assessment Factor: 15

AF for dose response relationship: 3 (extrapolation from LOAEL to NOAEL; LOAEC from chronic carcinogenicity study for nasal effects)

AF for difference in duration of exposure: 1 (ECHA REACH Guidance)

AF for interspecies differences (allometric scaling): 1 (ECHA REACH Guidance)

AF for other interspecies differences: 5 (ECHA REACH Guidance)

Further explanation on hazard conclusions:

AF = 15 [1 (interspecies differences) x 5 (intraspecies – workers) x 1 (duration of exposure – chronic) x 3 (dose-response – extrapolation from LOAEL to NOAEL) x 1 (quality of data base)]

Inhalation Local effects - Acute

Further explanation on hazard conclusions:

No indication of short term effects from inhalatation studies

Dermal Systemic effects - Long-term

Dermal Systemic effects - Acute

Further explanation on hazard conclusions:

The substance is not acutely toxic following dermal application. No DNEL required.

Dermal Local effects - Long-term

Dermal Local effects - Acute

Further explanation on hazard conclusions:

not classified for skin irritation

Discussion:

The substance is of low acute toxicity following oral and dermal exposure. The substance is not classifiable for skin and eye irritating properties, but was found to be a skin sensitizer in a LLNA which did not give information on dose-response. On these bases no acute DNELs are required and it is not possible to derive a dermal DNEL for local effects based on skin sensitisation.
The genotoxic potential of the substance was evaluated in-vitro, with all endpoints resulting negative. On this basis the substance is considered to not possess genotoxic potential.

Although historically considered a potential human carcinogen because of positive results in dermal non-guideline animal studies, a more recent and fully compliant inhalation study in rats with an analogous substance, appropriately characterized, showed no carcinogenic potential by this route of exposure which is more relevant to the actual workers' exposure. The study, however, revealed non-neoplastic lesions as a result of repeated local irritation in male rats exposed for 2 years to 6.8 mg/m3. These changes were of adaptive nature and consisted mainly of mucous (goblet) cell hyperplasia of the nasal/paranasal cavities and eosinophilic cytoplasmatic inclusions (hylinosis) in the olfactory epithelium. Therefore, the concentration of 6.8 mg/ m3is

considered to be a local inhalation LOAEC for lifespan exposure and this endpoint has been chosen as the more appropriate for long-term local effects inhalation DNEL setting for workers. As the performing laboratory previously demonstrated that the rat model is sufficiently sensitive for testing a complex PAH containing fume, an assessment factor of 1 was applied for interspecies differences.
An inhalation OECD 422 study is also available, performed with an analogous well characterized substance, with daily 6 hrs exposures on each day of the week. The study did not reveal any reproductive and/or developmental effects up to the highest concentration tested (nominal 300 mg/m3, actual 297.2 mg/m3) but the systemic NOAEC for female rats was set at 30 mg/m3, based on a statistically significant increase in relative wet lung weight, which correlated with slight histopathologic effects in the lungs at the highest dose level of 297.2 mg/m3only. This NOAEC has been chosen as the more appropriate for setting the long-term inhalation DNEL for systemic effects.
No DNEL was derived for dermal systemic long term effects. The substance is a skin sensitizer and also classified as STOT RE 2 due to effects seen in a oral 28 day study with rats (minimal anaemic response, adaptive microscopic liver changes and isolated increased bilirubin levels). A high hazard was concluded for dermal local and systemic effects and risk management measures must be implemented accordingly.
An additional assessment factor of 3 was used to extrapolate from the LOAEL/NOAEC obtained in the studies to a NOAEL/NOAEC, when appropriate.

Table 5.15. Hazard conclusions for the general population

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	DNEL (Derived No Effect Level) 0.2mg/m³	repeated dose toxicity (By inhalation)
Inhalation	Systemic effects - Acute	no hazard identified	acute toxicity (Oral)
Inhalation	Local effects - Long-term	high hazard (no threshold derived)	sensitisation (skin)
Inhalation	Local effects - Acute	no hazard identified	sensitisation (skin)
Dermal	Systemic effects - Long-term	high hazard (no threshold derived)	sensitisation (skin)
Dermal	Systemic effects - Acute	no hazard identified	acute toxicity (Dermal)
Dermal	Local effects - Long-term	high hazard (no threshold derived)	sensitisation (skin)
Dermal	Local effects - Acute	no hazard identified	skin irritation/corrosion
Oral	Systemic effects - Long-term	high hazard (no threshold derived)	repeated dose toxicity (Oral)
Oral	Systemic effects - Acute	no hazard identified	acute toxicity (Oral)
Eyes	Local effects	no hazard identified	

Inhalation Systemic effects - Long-term

DNEL derivation method: ECHA REACH Guidance

Dose descriptor starting point: NOAEC

Modified dose descriptor starting point: NOAEC

see under workers

Overall Assessment Factor: 150

AF for difference in duration of exposure: 6 (ECHA REACH Guidance)

AF for other interspecies differences: 2.5 (ECHA REACH Guidance)

AF for intraspecies differences: 10 (ECHA REACH Guidance)

Further explanation on hazard conclusions:

see under workers

Inhalation Systemic effects - Acute

Inhalation Local effects - Long-term

Inhalation Local effects - Acute

Dermal Systemic effects - Long-term

Further explanation on hazard conclusions:

No DNEL is derived for dermal systemic long term effects. The substance is a skin sensitizer and also classified as STOT RE 2 due to effects seen in a oral 28 day study with rats (minimal anaemic response, adaptive microscopic liver changes and isolated increased bilirubin levels). A high hazard without threshold is concluded for the substance.

Dermal Systemic effects - Acute

Dermal Local effects - Long-term

Dermal Local effects - Acute

Further explanation on hazard conclusions:

No DNEL could be derived (sensitisation). No DNEL required (irritation).

Oral Systemic effects - Long-term

Further explanation on hazard conclusions:

No DNEL is derived for dermal systemic long term effects. The substance is a skin sensitizer and also classified as STOT RE 2 due to effects seen in a oral 28 day study with rats (minimal anaemic response, adaptive microscopic liver changes and isolated increased bilirubin levels). A high hazard without threshold is concluded for the substance.
No DNEL is derived for dermal systemic long term effects. The substance is a skin sensitizer and also classified as STOT RE 2 due to effects seen in a oral 28 day study with rats (minimal anaemic response, adaptive microscopic liver changes and isolated increased bilirubin levels). A high hazard without threshold is concluded for the substance.
No DNEL is derived for dermal systemic long term effects. The substance is a skin sensitizer and also classified as STOT RE 2 due to effects seen in a oral 28 day study with rats (minimal anaemic response, adaptive microscopic liver changes and isolated increased bilirubin levels). A high hazard without threshold is concluded for the substance.

Oral Systemic effects - Acute

Discussion:

The substance is of low acute toxicity following oral and dermal exposure and therefore no DNELs for acute systemic effects are derived.
No DNEL is derived for dermal systemic long term effects. The substance is a skin sensitizer and also classified as STOT RE 2 due to effects seen in a oral 28 day study with rats (minimal anaemic response, adaptive microscopic liver changes and isolated increased bilirubin levels). A high hazard without threshold is concluded for the substance.
For the general population, long-term (repeat) exposure is not expected to occur. Whilst the air concentration of bitumen fumes emitted from the road surface is expected to decline quickly once the treatment has been applied, persons living near to a section of road being resurfaced could be exposed to airborne concentrations over a 24 hour period, for one or two days, i.e. as the section of road near to their dwelling is re-surfaced. This does not represent a long-term (repeat) exposure scenario.

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

6.1. Explosivity

The available information on explosivity is summarised in the following table:

Table 6.1. Information on explosivity

Method	Results	Remarks
explosiveness [deactivated phrase] according to EU Method A.14 (Explosive properties)	Evaluation of results: non explosive - Migrated information Study results: Small-scale preliminary tests: More sensitive to shock than m-dinitrobenzene - migrated information: (not measured/tested) More sensitive to friction than m-dinitrobenzene - migrated information: (not measured/tested) Explosive under influence of flame - migrated information: (not measured/tested) Explosive (not specified) - migrated information: (negative (not further specified))	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** S.P. Tremain 2004 [96]

Discussion

The following information is taken into account for any hazard / risk assessment:
There are no chemical groups present in the registered substance that would imply explosive properties, therefore the result has been predicted negative.

Value used for CSA:
Explosiveness: non explosive

Justification for classification or non-classification:

No explosive properties can be predicted on the basis of chemical structure. On this basis, no classification with regards to explosive properties is required according to Directive 67/548/EEC or Regulation (EC) No 1272/2008.

6.2. Flammability

Flammability

No relevant information available.
Data waiving: see CSR section 1.3 Physicochemical properties.

Discussion

The following information is taken into account for any hazard / risk assessment:
Flammability
Key value for chemical safety assessment: Flammability: non flammable

In accordance with section 1 of REACH Annex XI, the flammability study (required in section 7.10) does not need to be conducted as it is scientifically unjustified to perform the study.

Based on the known chemical and physical properties of the substance and its chemical structure, negative results are predicted for the following flammability tests, so it is considered justified to omit them;

Method A12: Flammability (contact with water)

Method A13: Pyrophoric properties of solids and liquids.

The substance is a low-melting solid, so the tests A10 and A11 are not applicable, and it is not “extremely flammable” or “flammable”. Furthermore, since test A9 is negative, and tests A12 and A13 are predicted to be negative, the substance can be considered to be not “highly flammable”.

Flash Point

The available information on flash point is summarised in the following table:

Table 6.2. Information on flash point

<table>
<tr><th>Method</th><th>Results</th><th>Remarks</th></tr>
<tr><td>Determination of flash point equilibrium method closed cup according to EU Method A.9 (Flash-Point)</td><td>Flash point:
>300 °C (No pressure at which study conducted reported; however reasonable to assume test conducted at ambient pressure.)
Remarks:
Results
<table>
<tr><td>Temperature (°C)</td><td>Observations</td></tr>
<tr><td>20</td><td>No flash.</td></tr>
<tr><td>25</td><td>No flash.</td></tr>
<tr><td>30</td><td>No flash.</td></tr>
<tr><td>35</td><td>No flash.</td></tr>
<tr><td>40</td><td>No flash.</td></tr>
<tr><td>45</td><td>No flash.</td></tr>
<tr><td>50</td><td>No flash.</td></tr>
<tr><td>55</td><td>No flash.</td></tr>
<tr><td>60</td><td>No flash.</td></tr>
<tr><td>65</td><td>No flash.</td></tr>
<tr><td>70</td><td>No flash.</td></tr>
<tr><td>70 (fresh sample)</td><td>No flash.</td></tr>
<tr><td>75</td><td>No flash.</td></tr>
<tr><td>80</td><td>No flash.</td></tr>
<tr><td>85</td><td>No flash.</td></tr>
<tr><td>90</td><td>No flash.</td></tr>
<tr><td>95</td><td>No flash.</td></tr>
<tr><td>100</td><td>No flash.</td></tr>
<tr><td>105</td><td>No flash.</td></tr>
<tr><td>110</td><td>No flash.</td></tr>
<tr><td>110 (fresh sample)</td><td>No flash.</td></tr>
<tr><td>120</td><td>No flash.</td></tr>
</table></td><td>1 (reliable without restriction)
key study
experimental study

Test material
Shale Oil Bitumen, (full information in Appendix [97]).

Reference
S.P. Tremain 2004 [96]</td></tr>
</table>

125	No flash.	
130	No flash.	
135	No flash.	
140	No flash.	
145	No flash.	
150	No flash.	
155	No flash.	
160	No flash.	
160 (fresh sample)	No flash.	
165	No flash.	
170	No flash.	
175	No flash.	
180	No flash.	
185	No flash.	
190	No flash.	
195	No flash.	
200	No flash.	
205	No flash.	
210	No flash.	
210 (fresh sample)	No flash.	
215	No flash.	
220	No flash.	
225	No flash.	
230	No flash.	
235	No flash.	
240	No flash.	
245	No flash.	
250	No flash.	
255	No flash.	
260	No flash.	
260 (fresh sample)	No flash.	
265	No flash.	
270	No flash.	
275	No flash.	
280	No flash.	
285	No flash.	
290	No flash.	
295	No flash.	
300	No flash.	
300 (fresh sample)	No flash.	

Discussion

The following information is taken into account for any hazard / risk assessment:
The registered substance has been determined not to have a flash point below 300°C.

Justification for classification or non-classification:

No flammable results have been observed for any of the studies performed on the registered substance. On this basis, no classification with regards to flammability is required according to Directive 67/548/EEC or Regulation (EC) No 1272/2008.

6.3. Oxidising potential

The available information on the oxidising potential is summarised in the following table:

Table 6.3. Information on oxidising potential

Method	Results	Remarks
oxidising solids according to EU Method A.17 (Oxidising Properties (Solids))	Evaluation of results: GHS criteria not met Test results: Oxidising solids: test mixture as specified: Expert Opinion: (There are no chemical groups that would imply oxidising properties, therefore the result has been predicted negative) Remarks: There are no chemical groups that would imply oxidising properties, therefore the result has been predicted negative.	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** S.P. Tremain 2004 [96]

Discussion

The following information is taken into account for any hazard / risk assessment:
There are no chemical groups present in the registered substance that would imply oxidising properties, therefore the result has been predicted negative.

Value used for CSA:
Oxidising properties: no

Justification for classification or non-classification:

No oxidising properties can be predicted on the basis of chemical structure. On this basis, no classification with regards to oxidising properties is required according to Directive 67/548/EEC or Regulation (EC) No 1272/2008.

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

7.1.1. Fish

7.1.1.1. Short-term toxicity to fish

The results are summarised in the following table:

Table 7.1. Short-term effects on fish

Method	Results	Remarks
Oncorhynchus mykiss (previous name: Salmo gairdneri) freshwater short-term toxicity to fish according to OECD Guideline 203 (Fish, Acute Toxicity Test) ; according to EU Method C.1 (Acute Toxicity for Fish) In view of the difficulties associated with the evaluation of aquatic toxicity of poorly water soluble test materials, a modification of the standard method for the preparation of aqueous media was performed. An approach endorsed by several important regulatory authorities in the EU and elsewhere (ECETOC 1996, OECD 2000 and Singer et al 2000), is to expose organisms to a Water Accommodated Fraction (WAF) of the test material in cases where the test material is a complex mixture and is poorly soluble in water and in the permitted auxiliary solvents and surfactants. Using this approach, aqueous media are prepared by mixing the test material with water for a prolonged period. Pre-study work showed that a preparation period of 23 hours was sufficient to ensure equilibration between the test material and water phase. At the completion of mixing, the test material phase is separated by siphon and the test organisms exposed to the aqueous phase or WAF (which may contain dissolved test material and/or leachates from the test material). Exposures are expressed in terms of the original concentration of test material in water at the start of the mixing period (loading rate) irrespective of the actual concentration of test material in the WAF.	LL50 (96h): >1000 mg/L test mat. (nominal) based on: mortality (nominal loading rate WAF) NOEC (96h): 1000 mg/L test mat. (nominal) based on: mortality (nominal loading rate WAF)	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** P.M. Wetton; J. McKenzie 2004 [96]

Discussion

The following information is taken into account for acute fish toxicity for the derivation of PNEC:

The acute toxicity of the test material to the freshwater fish rainbow trout (Oncorhynchus mykiss) has been

investigated and gave a 96-Hour LL50* value of greater than 1000 mg/l loading rate WAF. Correspondingly the No Observed Effect Loading rate was 1000 mg/l loading rate WAF.

* LL - Lethal Loading rate

Value used for CSA:
Oxidising properties: no

7.1.1.2. Long-term toxicity to fish

No relevant information available.

Data waiving

Information requirement: Long-term toxicity testing to aquatic vertebrates

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Discussion

The following information is taken into account for long-term fish toxicity for the derivation of PNEC:

A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Value used for CSA:
Oxidising properties: no

7.1.2. Aquatic invertebrates

7.1.2.1. Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 7.2. Short-term effects on aquatic invertebrates

Method	Results	Remarks
Daphnia magna freshwater static according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) ; according to EU Method C.2 (Acute Toxicity for Daphnia) In view of the difficulties associated with the evaluation of aquatic toxicity of poorly water soluble test materials, a modification of the standard method for the preparation of aqueous media was performed. An approach endorsed by several important regulatory authorities in the EU and elsewhere (ECETOC 1996, OECD 2000 and Singer et al 2000), is to expose	EL50 (48h): 140 mg/L test mat. (nominal) based on: mobility (95% CL: 120 - 160 mg/l nominal loading rate WAF) NOELR (48h): 56 mg/L test mat. (nominal) based on: mobility (nominal loading rate WAF)	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** T.J. Goodband; J. McKenzie 2004 [96]

organisms to a Water Accommodated Fraction (WAF) of the test material in cases where the test material is a complex mixture and is poorly soluble in water and in the permitted auxiliary solvents and surfactants. Using this approach, aqueous media are prepared by mixing the test material with water for a prolonged period. Pre-study work showed that a preparation period of 24 hours was sufficient to ensure equilibration between the test material and water phase. At the completion of mixing, the test material phase is separated by siphon and the test organisms exposed to the aqueous phase or WAF (which may contain dissolved test material and/or leachates from the test material). Exposures are expressed in terms of the original concentration of test material in water at the start of the mixing period (loading rate) irrespective of the actual concentration of test material in the WAF.		

Discussion

The following information is taken into account for short-term toxicity to aquatic invertebrates for the derivation of PNEC:

The acute toxicity of the registered substance to the freshwater invertebrate Daphnia magna has been investigated and gave a 48-Hour EL*50 value of 140 mg/l loading rate WAF with 95% confidence limits of 120 - 160 mg/l loading rate WAF. The No Observed Effect Loading rate at 48 hours was 56 mg/I loading rate WAF.

Value used for CSA:
Oxidising properties: no

7.1.2.2. Long-term toxicity to aquatic invertebrates

No relevant information available.

Data waiving

Information requirement: Long-term toxicity testing on aquatic invertebrates

Reason: other justification

Justification: see ‘Remark’ - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Discussion

The following information is taken into account for long-term toxicity to aquatic invertebrates for the derivation of PNEC

A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Value used for CSA:
Oxidising properties: no

7.1.3. Algae and aquatic plants

The results are summarised in the following table:

Table 7.3. Effects on algae and aquatic plants

Method	Results	Remarks
Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to OECD Guideline 201 (Alga, Growth Inhibition Test) [before 23 March 2006] ; according to EU Method C.3 (Algal Inhibition test) In view of the difficulties associated with the evaluation of aquatic toxicity of poorly water soluble test materials, a modification of the standard method for the preparation of aqueous media was performed. An approach endorsed by several important regulatory authorities in the EU and elsewhere (ECETOC 1996, OECD 2000 and Singer et al 2000), is to expose organisms to a Water Accommodated Fraction (WAF) of the test material in cases where the test material is a complex mixture and is poorly soluble in water and in the permitted auxiliary solvents and surfactants. Using this approach, aqueous media are prepared by mixing the test material with water for a prolonged period. Previous experience gained from studies conducted on poorly water soluble test materials has shown that a mixing period of 24 - 48 hours is sufficient to ensure equilibration between the test material and water phase. At the completion of mixing, the test material phase is separated by siphon and the test organisms exposed to the aqueous phase or WAF (which may contain dissolved test material and/or Ieachates from the test material). Exposures are expressed in terms of the original concentration of test material in water at the start of the mixing period (loading rate) irrespective of the actual concentration of test material in the WAF.	EL50 (72h): >1000 mg/L test mat. (nominal) based on: growth rate (nominal loading rate WAF) NOELR (72h): 1000 mg/L test mat. (nominal) based on: growth rate (nominal loading rate WAF) EL50 (72h): >1000 mg/L test mat. (nominal) based on: biomass (nominal loading rate WAF) NOELR (72h): 1000 mg/L test mat. (nominal) based on: biomass (nominal loading rate WAF)	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** H. Vryenhoef; J. McKenzie 2004 [96]

Discussion

Effects on algae / cyanobacteria

The following information is taken into account for effects on algae / cyanobacteria for the derivation of PNEC:

The effect of the registered substance on the growth of Scenedesmus subspicatus has been investigated and gave EL*50 values of greater than 1000 mg/l loading rate WAF. Correspondingly the No Observed Effect Loading rate was 1000 mg/l loading rate WAF.

* EL = Effective Loading Rate

Value used for CSA:
Oxidising properties: no

7.1.4. Sediment organisms

No relevant information available.

Data waiving

Information requirement: Effects on sediment organisms

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Discussion

The following information is taken into account for sediment toxicity for the derivation of PNEC:

A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Value used for CSA:
Oxidising properties: no

7.1.5. Other aquatic organisms

No relevant information available.

7.2. Terrestrial compartment

7.2.1. Toxicity to soil macro-organisms

No relevant information available.

Data waiving

Information requirement: Toxicity to soil macro-organisms except arthropods

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Information requirement: Toxicity to soil arthropods

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Discussion of effects on soil macro-organisms except arthropods

The following information is taken into account for effects on soil macro-organisms except arthropods for the derivation of PNEC:

A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Value used for CSA:
Oxidising properties: no

Discussion of effects on soil dwelling arthropods

The following information is taken into account for effects on soil dwelling arthropods for the derivation of PNEC:

A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Value used for CSA:
Oxidising properties: no

7.2.2. Toxicity to terrestrial plants

No relevant information available.

Data waiving

Information requirement: Effects on terrestrial plants

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Discussion

The following information is taken into account for toxicity on terrestrial plants for the derivation of PNEC:

A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Value used for CSA:
Oxidising properties: no

7.2.3. Toxicity to soil micro-organisms

No relevant information available.

Data waiving

Information requirement: Effects on soil micro-organisms

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Discussion

The following information is taken into account for toxicity on soil micro-organisms for the derivation of PNEC:

A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Value used for CSA:
Oxidising properties: no

7.2.4. Toxicity to other terrestrial organisms

No relevant information available.

Data waiving

Information requirement: Toxicity to terrestrial arthropods other than soil macro-organisms

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Discussion

The following information is taken into account for any hazard / risk assessment:

A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

7.3. Atmospheric compartment

No relevant information available.

7.4. Microbiological activity in sewage treatment systems

The results are summarised in the following table:

Table 7.4. Effects on micro-organisms

Method	Results	Remarks

activated sludge of a predominantly domestic sewage freshwater static according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010] ; according to EPA OPPTS 850.6800 (Modified Activated Sludge, Respiration Inhibition Test for Sparingly Soluble Chemicals)	NOEC (3h): 1000 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate EC50 (3h): >1000 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate	1 (reliable without restriction) key study experimental study **Test material** Shale Oil Bitumen, (full information in Appendix [97]). **Reference** N. Clarke 2004 [96]

Discussion

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:

The effect of the test material on the respiration of activated sewage sludge micro-organisms gave a 3-Hour EC50 of greater than 1000 mg/I. The No Observed Effect Concentration (NOEC) after 3 hours exposure was 1000 mg/l.

Value used for CSA:
EC50/LC50 for aquatic micro-organisms: 1000mg/L EC10/LC10 or NOEC for aquatic micro-organisms:

7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

7.5.1. Toxicity to birds

No relevant information available.

Data waiving

Information requirement: Toxicity to birds

Reason: other justification

Justification: see 'Remark' - A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Discussion

The following information is taken into account for effects on birds for the derivation of PNEC:

A final decision regarding the testing required for the >1000 tonnes supply level was made by the Member State Competent Authority (MSCA) prior to 1st June 2008. This study was not requested by the MSCA for this supply level. Therefore in accordance with Article 135, this decision made under the previous NONS scheme should be upheld under the new REACH scheme; this study does not need to be conducted and is accordingly waived.

Value used for CSA:
EC50/LC50 for aquatic micro-organisms: 1000mg/L EC10/LC10 or NOEC for aquatic micro-organisms:

7.5.2. Toxicity to mammals

No relevant information available.

7.6. PNEC derivation and other hazard conclusions

7.6.1. PNEC derivation and other hazard conclusions

Table 7.5. Hazard assessment conclusion for the environment

Compartment	Hazard conclusion	Remarks/Justification
Freshwater	PNEC aqua (freshwater): 0.14mg/L Intermittent releases: 1.4mg/L	Assessment factor: 1000 Extrapolation method: assessment factor PNEC aqua (freshwater) Assessment factor of 1000 applied to the lowest of 3 acute end-points (140 mg/L - Daphnia) **PNEC intermittent release hazard assessment conclusion:** PNEC aqua (intermittent releases) **PNEC intermittent release assessment factor:** 100.0 **PNEC intermittent release extrapolation method:** assessment factor **PNEC intermittent release justification:** Assessment factor of 100 applied to the lowest of 3 acute end-points (140 mg/L - Daphnia)
Marine water	PNEC aqua (marine water): 0.014mg/L Intermittent releases:	Assessment factor: 10000 Extrapolation method: assessment factor PNEC aqua (marine water) Assessment factor of 10000 applied to the lowest of 3 acute end-points (140 mg/L - Daphnia)
Sediments (freshwater)	PNEC sediment (freshwater): 5972.6mg/kg sediment dw	Extrapolation method: equilibrium partitioning method PNEC sediment (freshwater) Calculated from the PNEC aquatic using the equilibrium partitioning method and a Koc of 426580 (Equiv to Log Koc of 5.63)
Sediments (marine water)	PNEC sediment (marine water): 597.2mg/kg sediment dw	Extrapolation method: equilibrium partitioning method PNEC sediment (marine water) Assessment factor of 10 applied to PNEC sediment
Sewage treatment plant	PNEC STP: 100mg/L	Assessment factor: 100 Extrapolation method: assessment factor PNEC STP Assessment factor of 10 applied to the NOEC of 1000 mg/l from the OECD 209 ASRI study
Soil	PNEC soil: 1194mg/kg soil dw	Extrapolation method: equilibrium partitioning method PNEC soil Calculated from the PNEC aquatic using the equilibrium partitioning method and a Koc of 426580 (Equiv to Log Koc of 5.63)
Air	no hazard identified:	
Secondary	no potential to cause toxic	Exposure to environment is strictly controlled and

poisoning	effects if accumulated (in higher organisms) via the food chain:	minimised. Thus, no potential for accumulation in the environment expected.

Conclusion on environmental classification

Classification and labelling has been based upon the key information for the ecotoxicity endpoints. The results of these studies are as follows:
96 hour LC50 (fish): >1000 mg/L
48 hour EC50 (Daphnia): 140 mg/L
72 hour EC50 (algae): >1000 mg/l
It should also be considered that the substance does not meet the definition of a readily biodegradable substance .
The lowest acute end-point is the 48 hour EC50 for Daphnia and this end-point has been used for classification and labelling and this meets the criteria under EC Regulation 1272/2008 as follows:
Hazardous to the aquatic environment, Chronic: Category 4

General discussion

Aquatic

Standard acute toxicity studies are available for three trophic levels. The LC50 to fish (OECD 203) was >1000 mg/L (nominal). The EC50 to Daphnia (OECD 202) was 140 mg/L and the EC50 to algae (OECD 201) was >1000 mg/L (NOEC 1000 mg/L).
These are all reliable studies (rated 1 according to the Klimisch (1999) scale). All end-points are significantly greater than the solubility of Shale oil bitumen.
PNEC aquatic have therefore been based on the EC50 of 140 mg/L from the Daphnia study and the standard assessment factors given in the European Chemicals Agency guidance document (R.10: Characterisation of dose [concentration]-response for environment) have been used to predict the above PNEC values from the results.

Sediment

No experimental data on the toxicity to sediment dwellers are available. PNEC sediment have therefore been calculated using the equilibrium partitioning method.

Terrestrial

No experimental data on the toxicity to terrestrial organisms are available. PNEC terrestrial have therefore been calculated using the equilibrium partitioning method.

STP

The EC50 for STP organisms (OECD 209) was >1000 mg/L (NOEC 1000 mg/L). This is a reliable study (rated 1 according to the Klimisch (1999) scale).
The PNEC STP was therefore based on the NOEC from this study and the standard assessment factors given in the European Chemicals Agency guidance document (R.10: Characterisation of dose [concentration]-response for environment) have been used to predict the above PNEC value from the results.

8. PBT AND vPvB ASSESSMENT

8.1. Assessment of PBT/vPvB Properties

8.1.1. PBT/vPvB criteria and justification

8.1.1.1. Assessed substance: substance itself

Shale Oil Bitumen
Composition of assessed substance: Shale Oil Bitumen PB
PBT status of the assessed substance: the substance is handled as if it were a PBT/vPvB
Remark for assessed substance: See PBT assessment document under section 13.

8.1.1.1.1. Persistence assessment

Evidence of P or vP properties

The substance is not classified as “readily biodegradable”. By reference to ECHA Guidance R.11.1.2.2 “Screening criteria and information for identification of PBTs and vPvBs” the substance is considered to be classed as P but insufficient data is available to justify classification as vP.

Conclusion on P / vP properties:

No conclusion can be reached based on available informationThe substance is not classified as “readily biodegradable”. By reference to ECHA Guidance R.11.1.2.2 “Screening criteria and information for identification of PBTs and vPvBs” the substance is considered to be classed as P but insufficient data is available to justify classification as vP.

8.1.1.1.2. Bioaccumulation assessment

- Remarks on criterion “2000<BCF<=5000 L/kg” See PBT assessment document under section 13.

Conclusion on B / vB properties:

No conclusion can be reached based on available informationSee PBT assessment document under section 13.

8.1.1.1.3. Toxicity assessment

Further information is necessary to conclude on the T properties in the context of the PBT assessment

It is expected that the toxic effects observed resulting in the overall “T” status of the substance are caused by low molecular weight components which are contained in the PAH and VOC fractions (blocks, see analytics). These components are not bioaccumulative. Further information is necessary to understand the origin of the “T” effect.

Evidence of T properties

Other evidence
Remark: No chronic data are available. All the acute endpoints (EC/LC50s) are >>0.1 mg/L. The lowest acute NOEC, obtained in the Daphnia study was 56 mg/L and the NOEC from the algal study was 1000 mg/L (also considered a long term end point). Based on the environmental data shale oil bitumen is not considered to satisfy the T criteria. However, shale oil bitumen is classified as STOT Rep. Exp. 2, H373 under CLP. Shale oil bitumen is therefore considered to satisfy the T criteria.

Conclusion on T properties:

TShale oil bitumen is classified as STOT Rep. Exp. 2, H373 under CLP. Shale oil bitumen is therefore considered to satisfy the T criteria.

8.1.2. Summary and overall conclusions on PBT or vPvB properties

Assessed composition: Shale Oil Bitumen PB

Overall conclusion: The submission substance is handled as if it were a PBT / vPvB substance.

Justification:
See PBT assessment document under section 13.

8.2. Emission characterisation

Operational conditions and risk management measures: The operational conditions and risk management measures put in place are reported in the exposure scenarios in section 9.

Residual releases The total release and emissions values are reported in section 9.

Likely routes by which humans and the environment are exposed:

Justification of minimisation of emission/exposure: The justification of the minimisation of emissions and (subsequent) exposures of humans and the environment is reported in sections 9 and 10.

9. EXPOSURE ASSESSMENT (and related risk characterisation)

The sections 9 and 10 of this CSR have been generated with Chesar 3.3.

9.0. Introduction

9.0.1. Overview on uses

See the description of the various uses in section 2 of the CSR.

9.0.2. Assessment entity groups

Not applicable

9.0.3. Introduction to the assessment for the environment

9.0.3.1. Tonnage

Assessed tonnage: 2.1E3 tonnes/year based on:

- 2.1E3 tonnes/year manufactured

The following table provides the tonnage per use and the local tonnages used in the assessment for each environmental contributing activity. The local tonnage corresponds to a tonnage at the site for uses taking place at industrial sites and to a tonnage assumed for a town of 10 000 inhabitants for widespread uses.

Table 9.1. Tonnage for assessment

ES#	Exposure scenario (ES) name and related environmental contributing scenarios	Tonnage per use (t/year)	Daily local tonnage (t/day)	Annual local tonnage (t/year)
ES1 (M)	Shale Oil Bitumen Refining	2.1E3		
	- Manufacture (ERC 1)		21	2.1E3
ES2 (IS)	Use in the production of firesafe materials (<15% concentration)	600		
	- Use in the production of firesafe materials (ERC 5)		1	600
ES3 (IS)	Polymer synthesis	1.5E3		
	- Polymer synthesis (ERC 6d)		7.5	1.5E3
ES4 (SL)	Service Life of firesafe materials	600		
	- Service Life of firesafe materials (ERC 11a)		3.3E-4	-

9.0.3.2. Scope and type of assessment for the environment

The substance is considered to be PBT / vPvB (see CSR section 8). Hence, a qualitative assessment has been carried out aiming to demonstrate minimisation of releases.

9.0.3.3. Fate and distribution parameters

Physicochemical properties used for exposure estimation

The following substance properties are used in the fate estimation done by EUSES. They correspond to the “value used for CSA” reported in sections 1 and 4.

Table 9.2. Substance key phys-chem and fate properties

Substance property	Value
Molecular weight	300 - 1.5E3
Molecular weight used for the assessment	625
Melting point at 101 325 Pa	30 °C
Vapour pressure	2.5E-3 Pa at 25 °C

Substance property	Value
Partition coefficient (Log Kow)	6.2 at 40 °C
Water solubility	1.15E-3 g/L at 20 °C
Biodegradation in water: screening tests	under test conditions no biodegradation observed
Adsorption/Desorption: Koc at 20 °C	4.27E5

Caution: The log Kow is above 5 and the PNEC sediment/soil have been derived on equilibrium partitioning method. Therefore the risk characterisation ratio for sediment/soil will be multiplied by a factor of 10 to account for uncertainty due to the potential for adsorption of the substance.

Fate (release percentage) in the modelled biological sewage treatment plant

In a standard (modelled) biological STP, the emissions are distributed in the following way:

Release to water	9.531%
Release to air	0.02%
Release to sludge	90.45%
Release degraded	0%

The above fractions are calculated by the SIMPLETREAT model integrated in EUSES.

9.0.3.4. Comments on assessment approach for the environment

The regional concentrations are reported in section 10.2.1.1. The local Predicted Exposure Concentrations (PECs) reported for each contributing scenario correspond to the sum of the local concentrations (Clocal) and the regional concentrations (PEC regional).

9.0.3.5. Scope and type of assessment for man via environment

The substance is considered to be PBT / vPvB (see CSR section 8). Consequently a reliable exposure assessment for man via the environment is not possible.

9.0.4. Introduction to the assessment for workers

9.0.4.1. Scope and type of assessment for workers

The scope of exposure assessment and type of risk characterisation required for workers are described in the following table based on the hazard conclusions presented in section 5.11.

Table 9.3. Type of risk characterisation required for workers

Route	Type of effect	Risk characterisation type	Hazard conclusion (see section 5.11)
Inhalation	Systemic effects - long term	Quantitative	DNEL (Derived No Effect Level) = 0.4 mg/m³
	Systemic effects - acute	Not needed	No hazard identified
	Local effects - long term	Quantitative	DNEL (Derived No Effect Level) = 0.45 mg/m³
	Local effects - acute	Not needed	No hazard identified
Dermal	Systemic effects - long term	Qualitative	High hazard (no threshold derived)
	Systemic effects - acute	Not needed	No hazard identified
	Local effects - long term	Qualitative	High hazard (no threshold derived)
	Local effects - acute	Not needed	No hazard identified
Eye	Local effects	Not needed	No hazard identified

9.0.4.2. Comments on assessment approach for workers

Assessment approach related to toxicological hazard:

The substance is solid at room temperature and a melting point of 30°C has been assumed for the risk assessment. Some uses are performed above the melting point at temperatures between 40°C and 200°C with a liquid but highly viscous shale oil bitumen. Temperatures between 170 and 200°C are employed in closed reactors and are not considered relevant for employee's exposure. Handling, sample taking, blending and application of the liquid are performed with bitumen at lower temperatures. A standard temperature of 125°C has been assumed for these uses. Due to its complex chemical nature the normal exposure models (e.g. Ecetoc TRA) for liquids are not suitable to estimate workplace air concentrations and inhalation exposure. Worker scenarios and corresponding inhalation exposure has been modeled as follows:

• For applications of the substance below a temperature of 40°C exposure calculations are modeled with EcetocTRA using the default Chesar 3.3 determinants.

• For applications above 40°C up to the standard application temperature of 125°C ART Version 1.5 has been used to calculate the inhalation exposure.

A vapor pressure value of 69 Pa has been assumed for the shale oil bitumen at this use temperature (125°C). The number is taken from information provided by the Asphalt institute for normal bitumen (http://www.asphaltinstitute.org) and used in the ART calculations.

General information on risk management related to physicochemical hazard:

In accordance with Directive 89/686/EEC on Personal Protective Equipment it is a must for products that possess unique features that PPE must provide for protection against specific hazards, in order to ensure the user's safety and health in specific circumstances. Therefore, due to the skin sensitising properties of shale oil bitumen and its classification as organ-toxic (STOT RE Cat. 2) any skin contamination must be strictly avoided. Safety shoes, clothes (Full overall - EN ISO 13688:2013) and gloves (standard EN374-3:2003 Chemical risks) are mandatory, aprons, face shields and respirators (Half mask respirator with gas filter - EN 14387:2004+A1:2008) are employed where needed.

9.0.5. Introduction to the assessment for consumers

Exposure assessment is not applicable as there are no consumer-related uses for the substance.

9.1. Exposure scenario 1: Manufacture - Shale Oil Bitumen Refining

Environment contributing scenario(s):		
CS 1	Manufacture	ERC 1
Worker contributing scenario(s):		
CS 2	Refining from raw shale oil - hot outdoor process; including raw material filling and car tank filling with vapour return (closed systems)	PROC 3
CS 3	Cleaning operations	PROC 8b
CS 4	solid bitumen processing	PROC 14
CS 5	Analytical activities	PROC 15

Further description of the use:

The substance is obtained by thermal, oxidative and chemical condensation of heavy fractions of shale oil from the thermal treatment of oil shale.

Explanation on the approach taken for the ES:

The facility has an extensive Occupational Health and Safety Program in place which ensures that the workers are fully trained in the various processes at the facility (including use of appropriate OC/RMMs). Training is fully documented and reviewed on a quarterly basis.

9.1.1. Env CS 1: Manufacture (ERC 1)

The coke cube, where bitumen is produced may burn through and there could be a leakage from the bottom, resulting that bitumen falls down into combustion chamber where it burns. The bottom of the chamber is stacked in bricks (several layers on each other). Therefore, it is almost impossible for bitumen to emit into the soil. In order to avoid it the company has an “Emergency Plan”. Most relevant measures are planned preventive repairs.
Liquid bitumen is directly loaded from production cube to car tanks. Liquid bitumen is pumped from production cube to loading ramp through pipelines. No hoses are used. Leakage in the pipeline is unlikely, but in case of emergency the best available techniques are used in the loading area, i.e the area is concrete and the leaked bitumen could be collected.
For solid bitumen production the liquid bitumen is poured into a special area (bitumen solidification area), which is covered with metal plates, thus preventing possible penetration into soil and waste water. Also workers are trained to prevent such accidents.

9.1.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 21.0 tonnes/day
• Annual use amount at site: <= 2100 tonnes/year
Conditions and measures related to biological sewage treatment plant
• Biological STP: Standard [Effectiveness Water: 90.47%]
• Discharge rate of STP: >= 2000 m3/day
• Application of the STP sludge on agricultural soil: Yes
• on-site waste water treatment: 90 [Effectiveness Water: 90%] *Two types of waste are generated from manufacture: liquid and solid waste. Waste is only emitted during cleaning of the reactors. Liquid residues are taken back to shale oil heavy fraction production; and solid waste is used in coke production. Thus, all residues/waste are used again in production processes.* Water explanation: *on-site waste water treatment*
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations
Other conditions affecting environmental exposure

• Receiving surface water flow rate: >= 18000 m3/day

9.1.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.4. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor	**Release factor before on site RMM:** 0% **Release factor after on site RMM:** 0% **Local release rate:** 0 kg/day **Explanation:** There is involvement of water in the manufacturing process. Thus no wastewater is generated. Water is used only for indirect cooling to produce solid bitumen. This water is collected and re-used as cooling water. No other water is used in bitumen process (the cleaning is done mechanically).
Air	Estimated release factor	**Release factor before on site RMM:** 1% **Release factor after on site RMM:** 1% **Local release rate:** 210 kg/day **Explanation:** Bitumen production takes place in electrocoke unit: emissions (VOC residuals) are directed to the combustion into coke ovens (thermal oxidation). Thermal oxidation of VOC residuals is done according to European Commission decision from 09.10.2014, which establishes BAT (Best Available Techniques) conclusions for refining of mineral oil and gas. One of the BAT measures is to prevent and reduce VOC emissions. VOC residuals are burnt in high temperatures in cube units, during which the pollutants are mainly oxidized to CO2 and H2O. According to the data of 2016, the total emission from the electrocoke unit totaled 30417,958 t/y (containing both organic and inorganic pollutants). 98,02% of these emissions are CO2 (29 816,684 t/y). Organic emissions from electrocoke unit make up to 1,903 t/y, which is about 0,01% of the total emissions in coke unit.
Non agricultural soil	ERC	**Release factor after on site RMM:** 0.01%

9.1.1.3. Exposure and risks for the environment and man via the environment

The substance is considered as PBT / vPvB. Consequently, the regional concentrations cannot be estimated with sufficient reliability. Exposure of man via the environment via the oral route cannot be estimated with sufficient reliability. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Risk characterisation (minimisation of emission/exposure)

The total releases are displayed in section 10.2.1.1.
Releases used in the risk assessment are worst case assumptions. Emissions in this exposure scenario are air emissions only which relate to low molecular weight VOCs. As shown in the attached document “PBT assessment_shale oil bitumen” the VOCs emitted via air are not PBT. Releases in the manufacturing step are strictly controlled and minimized.

9.1.2. Worker CS 2: Refining from raw shale oil - hot outdoor process; including raw material filling and car tank filling with vapour return

(closed systems) (PROC 3)

Condensation of heavy fractions of shale oil during the thermal treatment of oil shale. The process is carried out in closed batch reactors, outdoors, with minor manual intervention (sample taking). Refining takes place at temperatures between 170 and 200°C, however, sample taking involves bitumen at temperatures of 125°C.
Shale Oil Bitumen PB is manufactured in a closed process where the potential for exposure to the chemical is limited to QC sampling only.
The manufacturing facility operates a strictly controlled process, which conforms to various integrated management systems such as ISO 9001 (Quality), 14001 (Environment), OHSAS 18001 (Occupational Health and Safety).
The QC sampling takes place 1-2 times during the shift and the duration of a single sampling procedure is dependent upon the volume of the sample, but typically sampling takes 10 seconds to 1 minute. Samples of the shale oil bitumen PB is taken from the transfer pipes by a tap (valve). During the sampling of the shale oil, appropriate gloves are worn which have been chosen to conform to the European Standard, EN 374:2003. This standard ensures that gloves have adequately high permeation breakthrough times (determined when 1 µg/cm² x min of chemical permeates through the glove), such that no chemical permeates through the glove during the work activity.
Raw material is filled into process (cubes or reactor) through pipes. Liquid bitumen is directly loaded from production cube to car tanks. Liquid bitumen is pumped from production cube to loading ramp through pipelines. No hoses are used.

9.1.2.1. Conditions of use

	Method
Product (Article) characteristics	
• Percentage (w/w) of substance in mixture/article: <= 100.0 %	TRA Workers 3.0 ART 1.5
• Physical form of the used product: Liquid	TRA Workers 3.0 ART 1.5
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 1.0 h/day	TRA Workers 3.0 ART 1.5
Technical and organisational conditions and measures	
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0 ART 1.5
• Closed batch process with occasional controlled exposure	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA Workers 3.0 ART 1.5
• Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with specific activity training) and (other) appropriate dermal protection [Effectiveness Dermal: 95%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Outdoor	TRA Workers 3.0 ART 1.5
• Operating temperature: <= 125.0 °C	TRA Workers 3.0 ART 1.5
• Skin surface potentially exposed: One hand face only (240 cm2)	

9.1.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.5. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.22 mg/m³ (ART 1.5)	RCR = 0.55
Inhalation, local, long term	0.22 mg/m³ (ART 1.5) **Supportive exposure (not used for RC):** 182.3 mg/m³ (TRA Workers)	RCR = 0.489
Dermal, systemic, long term	6.9E-3 mg/kg bw/day (TRA Workers)	
Dermal, local, long term	2.01E-3 mg/cm² (TRA Workers)	
Combined routes, systemic, long-term		RCR = 0.55

Remarks on exposure dataset obtained with ECETOC TRA

The vapour pressure at operating temperature (125°C) used for the calculation is 1E4 Pa.

Remarks on exposure data from external estimation tools:

ART 1.5:
Explanation: ART REPORT – shale oil bitumen manufacturing – 31-May-17
Industrial use (PROC 3 equivalent); Condensation of heavy fractions of shale oil during the thermal treatment of oil shale. The process is carried out in closed batch reactors with minor manual intervention (sample taking).
Chemical details
Chemical shale oil bitumen
CAS No. (unknown)
Scenario details
Number of activities 1
Total duration (mins) 480
Nonexposure period (mins) 420
Details for Activity product condensation and separation in reactors
Emission sources: Duration (mins): 60
Near-field exposure
Operational Conditions
Substance emission potential
Substance product type Liquids
Process temperature 398 K
Vapour pressure 69 Pa
Liquid mole fraction 1
Activity coefficient 1
Activity emission potential
Activity class Handling of contaminated objects
Situation Activities with treated/contaminated objects (surface <0.1 m²)
Contamination level Contamination > 90 % of surface
Process fully enclosed? No
Effective housekeeping practices in place? Yes
Dispersion
Work area Outdoors
Source located close to buildings? Yes
Risk Management Measures
Localised controls
Primary No localized controls (0.00 % reduction)
Secondary No localized controls (0.00 % reduction)
Predicted exposure levels
ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.
Mechanistic model results
The predicted 90th percentile full-shift exposure is 0.22 mg/m³.
The inter-quartile confidence interval is 0.098 mg/m³ to 0.53 mg/m³.

Risk characterisation

Qualitative risk characterisation:

The substance is a skin sensitizer and labeled as organ-toxic (STOT RE Cat.2). Any skin contamination must be strictly avoided. Gloves are mandatory together with strict control of breakthrough times. Additional measures are given in section 9.0.4 of this report and must be followed.

9.1.3. Worker CS 3: Cleaning operations (PROC 8b)

Cleaning of vessels, pumps, pipes

9.1.3.1. Conditions of use

	Method
Product (Article) characteristics	
• Percentage (w/w) of substance in mixture/article: <= 100.0 %	TRA Workers 3.0
• Physical form of the used product: Solid (non or low dusty form)	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 12.0 h/day	TRA Workers 3.0
Technical and organisational conditions and measures	
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA Workers 3.0
• Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with basic employee training) and (other) appropriate dermal protection [Effectiveness Dermal: 90%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Outdoor	TRA Workers 3.0
• Operating temperature: <= 20.0 °C	TRA Workers 3.0

9.1.3.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.6. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk quantification**
Inhalation, systemic, long term	0.07 mg/m³ (TRA Workers)	RCR = 0.175
Inhalation, local, long term	0.07 mg/m³ (TRA Workers)	RCR = 0.156
Dermal, systemic, long term	1.371 mg/kg bw/day (TRA Workers)	
Dermal, local, long term	0.1 mg/cm² (TRA Workers)	
Combined routes, systemic, long-term		RCR = 0.175

Remarks on exposure dataset obtained with ECETOC TRA

The vapour pressure at operating temperature (20°C) used for the calculation is 1.77E-3 Pa.

Risk characterisation

Qualitative risk characterisation:
The substance is a skin sensitizer and labeled as organ-toxic (STOT RE Cat.2). Any skin contamination must be strictly avoided. Gloves are mandatory together with strict control of breakthrough times. Additional measures are given in section 9.0.4 of this report and must be followed.

9.1.4. Worker CS 4: solid bitumen processing (PROC 14)

Processing of solid bitumen at low temperatures (<30°C) using extrusion, granulation and bulk block forming

processes

9.1.4.1. Conditions of use

	Method
Product (Article) characteristics	
• Percentage (w/w) of substance in mixture/article: <= 100.0 %	TRA Workers 3.0
• Physical form of the used product: Solid (non or low dusty form)	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 12.0 h/day	TRA Workers 3.0
Technical and organisational conditions and measures	
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
• Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%]	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA Workers 3.0
• Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with specific activity training) and (other) appropriate dermal protection [Effectiveness Dermal: 95%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Outdoor	TRA Workers 3.0
• Operating temperature: <= 20.0 °C	TRA Workers 3.0
• Skin surface potentially exposed: Two hands face (480 cm2)	

9.1.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.7. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.07 mg/m³ (TRA Workers)	RCR = 0.175
Inhalation, local, long term	0.07 mg/m³ (TRA Workers)	RCR = 0.156
Dermal, systemic, long term	0.172 mg/kg bw/day (TRA Workers)	
Dermal, local, long term	0.025 mg/cm² (TRA Workers)	
Combined routes, systemic, long-term		RCR = 0.175

Remarks on exposure dataset obtained with ECETOC TRA

The vapour pressure at operating temperature (20°C) used for the calculation is 1.77E-3 Pa.

Risk characterisation

Qualitative risk characterisation:
The substance is a skin sensitizer and labeled as organ-toxic (STOT RE Cat.2). Any skin contamination must be strictly avoided. Gloves are mandatory together with strict control of breakthrough times. Additional measures are given in section 9.0.4 of this report and must be followed.

9.1.5. Worker CS 5: Analytical activities (PROC 15)

Laboratory activities with the substance at room temperature.

9.1.5.1. Conditions of use

	Method

	Method
Product (Article) characteristics	
• Percentage (w/w) of substance in mixture/article: <= 100.0 %	TRA Workers 3.0
• Physical form of the used product: Solid (non or low dusty form)	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8.0 h/day	TRA Workers 3.0
Technical and organisational conditions and measures	
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
• General ventilation: Enhanced general ventilation (5-10 air changes per hour) [Effectiveness Inhalation: 70%]	TRA Workers 3.0
• Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%]	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA Workers 3.0
• Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with specific activity training) and (other) appropriate dermal protection [Effectiveness Dermal: 95%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Operating temperature: <= 25.0 °C	TRA Workers 3.0
• Skin surface potentially exposed: One hand face only (240 cm2)	

9.1.5.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.8. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.03 mg/m³ (TRA Workers)	RCR = 0.075
Inhalation, local, long term	0.03 mg/m³ (TRA Workers)	RCR = 0.067
Dermal, systemic, long term	0.017 mg/kg bw/day (TRA Workers)	
Dermal, local, long term	4.96E-3 mg/cm² (TRA Workers)	
Combined routes, systemic, long-term		RCR = 0.075

Remarks on exposure dataset obtained with ECETOC TRA

The vapour pressure at operating temperature (25°C) used for the calculation is 2.5E-3 Pa.

Risk characterisation

Qualitative risk characterisation:
The substance is a skin sensitizer and labeled as organ-toxic (STOT RE Cat.2). Any skin contamination must be strictly avoided. Gloves are mandatory together with strict control of breakthrough times. Additional measures are given in section 9.0.4 of this report and must be followed.

9.2. Exposure scenario 2: Use at industrial sites - Use in the production of firesafe materials (<15% concentration)

Product category used: PC 32: Polymer Preparations and Compounds
Sector of use: SU 19: Building and construction work

Environment contributing scenario(s):		
CS 1	Use in the production of firesafe materials	ERC 5
Worker contributing scenario(s):		
CS 2	Use in the production of firesafe materials - open hot processes	PROC 5
CS 3	Filling, cleaning operations of blends (<40°C)	PROC 8b
CS 4	Extrusion and compression operations (<40°C)	PROC 14

Subsequent service life exposure scenario(s):
ES4: Service life (professional worker) - Service Life of firesafe materials

Further description of the use:

The substance is bound into a matrix. Elevated mechanical and /or thermal energy conditions are needed to process substance as fire safe material under compression. Three sites are assumed to perform this operation in equal amounts.

9.2.1. Env CS 1: Use in the production of firesafe materials (ERC 5)

9.2.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 1.0 tonnes/day
• Annual use amount at site: <= 600.0 tonnes/year
Conditions and measures related to biological sewage treatment plant
• Biological STP: Standard [Effectiveness Water: 90.47%]
• Discharge rate of STP: >= 2000 m3/day
• Application of the STP sludge on agricultural soil: Yes
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 18000 m3/day

9.2.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.9. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor	**Release factor before on site RMM:** 0.2% **Release factor after on site RMM:** 0.2% **Local release rate:** 2 kg/day **Explanation:** No water involved in the process. However, a local release rate of 2 kg/day is assumed as worst-case.
Air	ERC	**Release factor before on site RMM:** 50% **Release factor after on site RMM:** 50% **Local release rate:** 500 kg/day

Release	Release estimation method	Explanations
		Explanation: Waste air is scrubbed prior to release to the environment. Mainly aliphatic hydrocarbons are released. A loss of around 1% of the total manufactured amount of substance is anticipated in this process.
Non agricultural soil	ERC	**Release factor after on site RMM:** 1% **Explanation:** No releases to soil. No dust is created in the process. All waste streams are collected and sent to incineration.

9.2.1.3. Exposure and risks for the environment and man via the environment

The substance is considered as PBT / vPvB. Consequently the regional concentrations cannot be estimated with sufficient reliability. Exposure of man via the environment via the oral route cannot be estimated with sufficient reliability. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Risk characterisation (minimisation of emission/exposure)

The total releases are displayed in section 10.2.1.1.
Releases used in the risk assessment are worst case assumptions. Emissions to air relate to low molecular weight VOCs. As shown in the attached document “PBT assessment_shale oil bitumen” the VOCs emitted via air are not PBT. Releases in the manufacturing of firesafe materials are strictly controlled and minimized.

9.2.2. Worker CS 2: Use in the production of firesafe materials - open hot processes (PROC 5)

9.2.2.1. Conditions of use

	Method
Product (Article) characteristics	
• Percentage (w/w) of substance in mixture/article: <= 15.0 %	TRA Workers 3.0
• Physical form of the used product: Liquid	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 4.0 h/day	TRA Workers 3.0
Technical and organisational conditions and measures	
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
• General ventilation: Good general ventilation (3-5 air changes per hour) [Effectiveness Inhalation: 30%]	TRA Workers 3.0
• Local exhaust ventilation: Yes (TRA effectiveness) [Effectiveness Inhalation: 90%, Dermal: 90%]	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: Yes (Respirator with APF of 10) [Effectiveness Inhalation: 90%]	TRA Workers 3.0
• Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with specific activity training) and (other) appropriate dermal protection [Effectiveness Dermal: 95%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Operating temperature: <= 120.0 °C	TRA Workers 3.0
• Skin surface potentially exposed: Two hands face (480 cm2)	

9.2.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.10. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.11 mg/m³ (ART 1.5)	RCR = 0.275
Inhalation, local, long term	0.11 mg/m³ (ART 1.5)	RCR = 0.244
Dermal, systemic, long term	0.025 mg/kg bw/day (TRA Workers)	
Dermal, local, long term	3.6E-3 mg/cm² (TRA Workers)	
Combined routes, systemic, long-term		RCR = 0.275

Remarks on exposure dataset obtained with ECETOC TRA

The local exhaust ventilation effectiveness has been taken into account for dermal exposure as well.
The vapour pressure at operating temperature (120°C) used for the calculation is 1E4 Pa.

Remarks on exposure data from external estimation tools:

ART 1.5:
Explanation: ART REPORT – shale oil bitumen tyre manufacture – 19-May-17
Industrial Use PROC5 equivalent, exposure to vapor
Chemical details
Chemical shale oil bitumen
CAS No. (unknown)
Scenario details
Number of activities 1
Total duration (mins) 480
Nonexposure period (mins) 0
Details for Activity Tyre manufacturing workplace
Emission sources: Duration (mins): 480 Far-field exposure
Operational Conditions
Substance emission potential
Substance product type Liquids
Process temperature 293 K
Vapour pressure 69 Pa
Liquid mole fraction 0.12
Activity coefficient 1
Activity emission potential
Activity class Activities with agitated surfaces
Situation Open surface > 3 m²
Surface contamination
Process fully enclosed? No
Effective housekeeping practices in place? Yes
Dispersion
Work area Indoors
Room size 1000 m³
Risk Management Measures
Localised controls
Primary Fixed capturing hood (90.00 % reduction)
Secondary No localized controls (0.00 % reduction)
Segregation No segregation (0.00 % reduction)
Personal enclosure No personal enclosure (0.00 % reduction)
Dispersion
Ventilation rate Mechanical ventilation giving at least 1 ACH
Predicted exposure levels
ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.
Mechanistic model results
The predicted 90th percentile full-shift exposure is 1.1 mg/m³.

The inter-quartile confidence interval is 0.55 mg/m³ to 2.3 mg/m³.

Risk characterisation

Qualitative risk characterisation:
The substance is a skin sensitizer and labeled as organ-toxic (STOT RE Cat.2). Any skin contamination must be strictly avoided. Gloves are mandatory together with strict control of breakthrough times. Additional measures are given in section 9.0.4 of this report and must be followed.

9.2.3. Worker CS 3: Filling, cleaning operations of blends (<40°C) (PROC 8b)

The scenario takes into account highly viscous blends at temperatures up to 40°C. Operations indoors in well ventilated rooms but without local exhaust ventilation

9.2.3.1. Conditions of use

	Method
Product (Article) characteristics	
• Percentage (w/w) of substance in mixture/article: <= 15.0 %	TRA Workers 3.0
• Physical form of the used product: Solid (non or low dusty form)	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 1.0 h/day	TRA Workers 3.0
Technical and organisational conditions and measures	
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
• General ventilation: Enhanced general ventilation (5-10 air changes per hour) [Effectiveness Inhalation: 70%]	TRA Workers 3.0
• Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%]	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA Workers 3.0
• Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with basic employee training) and (other) appropriate dermal protection [Effectiveness Dermal: 90%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Skin surface potentially exposed: Two hands (960 cm2)	
• Operating temperature: <= 40.0 °C	TRA Workers 3.0

9.2.3.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.11. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk quantification**
Inhalation, systemic, long term	0.094 mg/m³ (TRA Workers)	RCR = 0.234
Inhalation, local, long term	0.094 mg/m³ (TRA Workers)	RCR = 0.208
Dermal, systemic, long term	0.823 mg/kg bw/day (TRA Workers)	
Dermal, local, long term	0.06 mg/cm² (TRA Workers)	
Combined routes, systemic, long-term		RCR = 0.234

Remarks on exposure dataset obtained with ECETOC TRA

The vapour pressure at operating temperature (40°C) used for the calculation is 6.57E-3 Pa.

Risk characterisation

Qualitative risk characterisation:
The substance is a skin sensitizer and labeled as organ-toxic (STOT RE Cat.2). Any skin contamination must be strictly avoided. Gloves are mandatory together with strict control of breakthrough times. Additional measures are given in section 9.0.4 of this report and must be followed.

9.2.4. Worker CS 4: Extrusion and compression operations (<40°C) (PROC 14)

The scenario assumes that a highly viscous blend with <15% of substance is processed in machines at temperatures up to 40°C. Operations indoors in ventilated rooms with local exhaust ventilation fitted to the machinery.

9.2.4.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of the used product: Solid (non or low dusty form)	TRA Workers 3.0
• Percentage (w/w) of substance in mixture/article: <= 15.0 %	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8.0 h/day	TRA Workers 3.0
Technical and organisational conditions and measures	
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
• General ventilation: Good general ventilation (3-5 air changes per hour) [Effectiveness Inhalation: 30%]	TRA Workers 3.0
• Local exhaust ventilation: Yes (TRA effectiveness) [Effectiveness Inhalation: 90%, Dermal: 90%]	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA Workers 3.0
• Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with basic employee training) and (other) appropriate dermal protection [Effectiveness Dermal: 90%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Operating temperature: <= 40.0 °C	TRA Workers 3.0
• Skin surface potentially exposed: Two hands face (480 cm2)	

9.2.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.12. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk quantification**
Inhalation, systemic, long term	0.109 mg/m³ (TRA Workers)	RCR = 0.273
Inhalation, local, long term	0.109 mg/m³ (TRA Workers)	RCR = 0.243
Dermal, systemic, long term	0.021 mg/kg bw/day (TRA Workers)	
Combined routes, systemic, long-term		RCR = 0.273

Remarks on exposure dataset obtained with ECETOC TRA

The local exhaust ventilation effectiveness has been taken into account for dermal exposure as well.
The vapour pressure at operating temperature (40°C) used for the calculation is 6.57E-3 Pa.

Risk characterisation

Qualitative risk characterisation:
The substance is a skin sensitizer and labeled as organ-toxic (STOT RE Cat.2). Any skin contamination must be strictly avoided. Gloves are mandatory together with strict control of breakthrough times. Additional measures are given in section 9.0.4 of this report and must be followed.

9.3. Exposure scenario 3: Use at industrial sites - Polymer synthesis

Product category used: PC 32: Polymer Preparations and Compounds
Sector of use: SU 12: Manufacture of plastics products, including compounding and conversion

Environment contributing scenario(s):		
CS 1	Polymer synthesis	ERC 6d
Worker contributing scenario(s):		
CS 2	Polymer synthesis - hot process	PROC 3
CS 3	Handling and cleaning - cold process	PROC 8a
CS 4	Crushing and packing of product	PROC 14

9.3.1. Env CS 1: Polymer synthesis (ERC 6d)

9.3.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 7.5 tonnes/day *200 days of operation*
• Annual use amount at site: <= 1500 tonnes/year *assuming a single use site as worst case*
Conditions and measures related to biological sewage treatment plant
• Biological STP: Site specific [Effectiveness Water: 90.48%] *default EUSES settings*
• Discharge rate of STP: >= 2000 m3/day
• Application of the STP sludge on agricultural soil: No
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: Closed system required to minimise release to the environment.
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 18000 m3/day

Fate (release percentage) in the biological sewage treatment plant

The biological STP is site specific and the releases to the various compartments have been set by the assessor They are distributed in the following way:

Release to water	9.522%
Release to air	0.047%
Release to sludge	90.43%
Release degraded	0%

Explanation: Default EUSES settings

9.3.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.13. Local releases to the environment

Release	Release estimation method	Explanations

Release	Release estimation method	Explanations
Water	ERC	**Release factor before on site RMM:** 5E-3% **Release factor after on site RMM:** 5E-3% **Local release rate:** 0.375 kg/day **Explanation:** The deafult value for release to water is used. However, no water shall be used in this exposure scenario for either synthesis or maintenance/cleaning.
Air	Estimated release factor	**Release factor before on site RMM:** 1% **Release factor after on site RMM:** 1% **Local release rate:** 75 kg/day **Explanation:** Substance is used in closed batch process. Waste air is scrubbed prior to release to the environment. Mainly aliphatic hydrocarbons are released. A loss of around 1% of the total manufactured amount of substance is anticipated in this process.
Non agricultural soil	Estimated release factor (0)	**Release factor after on site RMM:** 0% **Explanation:** No releases to soil. No dust is created in the process. All waste streams are collected and sent to incineration.

Releases to waste

Release factor to external waste: 0 %

9.3.1.3. Exposure and risks for the environment and man via the environment

The substance is considered as PBT / vPvB. Consequently the regional concentrations cannot be estimated with sufficient reliability. Exposure of man via the environment via the oral route cannot be estimated with sufficient reliability. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Risk characterisation (minimisation of emission/exposure)

The total releases are displayed in section 10.2.1.1.
Releases used in the risk assessment are worst case assumptions. Emissions to air relate to low molecular weight VOCs. As shown in the attached document “PBT assessment_shale oil bitumen” the VOCs emitted via air are not PBT. Releases in the manufacturing of polymers are strictly controlled and minimized.

9.3.2. Worker CS 2: Polymer synthesis - hot process (PROC 3)

9.3.2.1. Conditions of use

	Method
Product (Article) characteristics	
• Percentage (w/w) of substance in mixture/article: <= 100.0 %	TRA Workers 3.0 ART 1.5
• Physical form of the used product: Liquid *The substance is used as highly viscous liquid at temperatures above the melting point.*	TRA Workers 3.0 ART 1.5
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 12.0 h/day	TRA Workers 3.0 ART 1.5
Technical and organisational conditions and measures	
• Closed batch process with occasional controlled exposure	ART 1.5
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0 ART 1.5
• General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%]	TRA Workers 3.0 ART 1.5

	Method
• Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%]	TRA Workers 3.0 ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA Workers 3.0 ART 1.5
• Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with basic employee training) and (other) appropriate dermal protection [Effectiveness Dermal: 90%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0 ART 1.5
• Operating temperature: <= 180.0 °C	TRA Workers 3.0 ART 1.5
• Skin surface potentially exposed: One hand face only (240 cm2)	

9.3.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.14. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.3 mg/m³ (ART 1.5)	RCR = 0.75
Inhalation, local, long term	0.3 mg/m³ (ART 1.5) **Supportive exposure (not used for RC):** 1.3E3 mg/m³ (TRA Workers)	RCR = 0.667
Dermal, systemic, long term	0.069 mg/kg bw/day (TRA Workers)	
Dermal, local, long term	0.02 mg/cm² (TRA Workers)	
Combined routes, systemic, long-term		RCR = 0.75

Remarks on exposure dataset obtained with ECETOC TRA

The vapour pressure at operating temperature (180°C) used for the calculation is 1E4 Pa.

Remarks on exposure data from external estimation tools:

ART 1.5:
Explanation: ART REPORT – shale oil bitumen manufacturing PROC3 indoor – 30-Oct-17
Industrial use (PROC 3 equivalent); The process is carried out in closed batch reactors with minor manual intervention (sample taking).
Chemical shale oil bitumen
CAS No. (unknown)
Scenario details
Number of activities 1
Total duration (mins) 480
Nonexposure period (mins) 0
ART version 1.5
Creator eckhard.schaefer@erm.com
Date created 19-May-17
Date last edited 30-Oct-17
Details for Activity product reaction - poymerisation - separation in reactors
Emission sources: Duration (mins): 480 Far field
Substance emission potential
Substance product type Liquids
Process temperature Hot

Vapour pressure 69 Pa
Liquid mole fraction 1
Activity coefficient 1
Activity emission potential
Activity class Handling of contaminated objects
Situation Activities with treated/contaminated objects (surface <0.1 m²)
Contamination level Contamination > 90 % of surface
Surface contamination
Process fully enclosed? No
Effective housekeeping practices in place? Yes
Dispersion
Work area Indoors
Room size Large workrooms only
Risk Management Measures
Localised controls
Primary No localized controls (0.00 % reduction)
Secondary No localized controls (0.00 % reduction)
Segregation Partial segregation without ventilation (30.00 % reduction)
Personal enclosure No personal enclosure (0.00 % reduction)
Dispersion
Ventilation rate Mechanical ventilation giving at least 1 ACH
Predicted exposure levels
ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.
Mechanistic model results
The predicted 90th percentile full-shift exposure is 0.3 mg/m³.
The inter-quartile confidence interval is 0.15 mg/m³ to 0.63 mg/m³.

Risk characterisation

Qualitative risk characterisation:
The substance is a skin sensitizer and labeled as organ-toxic (STOT RE Cat.2). Any skin contamination must be strictly avoided. Gloves are mandatory together with strict control of breakthrough times. Additional measures are given in section 9.0.4 of this report and must be followed.

9.3.3. Worker CS 3: Handling and cleaning - cold process (PROC 8a)

Covers PROC 28 (manual maintenance)

9.3.3.1. Conditions of use

	Method
Product (Article) characteristics	
• Percentage (w/w) of substance in mixture/article: <= 100.0 %	TRA Workers 3.0
• Physical form of the used product: Solid (non or low dusty form)	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 12.0 h/day	TRA Workers 3.0
Technical and organisational conditions and measures	
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
• General ventilation: Enhanced general ventilation (5-10 air changes per hour) [Effectiveness Inhalation: 70%]	TRA Workers 3.0
• Local exhaust ventilation: Yes (TRA effectiveness) [Effectiveness Inhalation: 90%, Dermal: 90%]	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA Workers 3.0
• Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with basic employee training) and (other) appropriate dermal protection [Effectiveness Dermal:	TRA Workers 3.0

	Method
90%]	
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Operating temperature: <= 25.0 °C	TRA Workers 3.0
• Skin surface potentially exposed: Two hands (960 cm2)	

9.3.3.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.15. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.015 mg/m³ (TRA Workers)	RCR = 0.038
Inhalation, local, long term	0.015 mg/m³ (TRA Workers)	RCR = 0.033
Dermal, systemic, long term	0.137 mg/kg bw/day (TRA Workers)	
Dermal, local, long term	1E-2 mg/cm² (TRA Workers)	
Combined routes, systemic, long-term		RCR = 0.038

Remarks on exposure dataset obtained with ECETOC TRA

The local exhaust ventilation effectiveness has been taken into account for dermal exposure as well.
The vapour pressure at operating temperature (25°C) used for the calculation is 2.5E-3 Pa.

Risk characterisation

Qualitative risk characterisation:
The substance is a skin sensitizer and labelled as organ-toxic (STOT RE Cat.2). Any skin contamination must be strictly avoided. Gloves are mandatory together with strict control of breakthrough times. Additional measures are given in section 9.0.4 of this report and must be followed.

9.3.4. Worker CS 4: Crushing and packing of product (PROC 14)

9.3.4.1. Conditions of use

	Method
Product (Article) characteristics	
• Percentage (w/w) of substance in mixture/article: <= 100.0 %	TRA Workers 3.0
• Physical form of the used product: Solid (non or low dusty form)	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8.0 h/day	TRA Workers 3.0
Technical and organisational conditions and measures	
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
• General ventilation: Enhanced general ventilation (5-10 air changes per hour) [Effectiveness Inhalation: 70%]	TRA Workers 3.0
• Local exhaust ventilation: Yes (TRA effectiveness) [Effectiveness Inhalation: 90%, Dermal: 90%]	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA Workers 3.0
• Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with basic employee training) and (other) appropriate dermal protection [Effectiveness Dermal:	TRA Workers 3.0

	Method
90%]	
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Operating temperature: <= 25.0 °C	TRA Workers 3.0
• Skin surface potentially exposed: Two hands face (480 cm2)	

9.3.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.16. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	3E-3 mg/m³ (TRA Workers)	RCR < 0.01
Inhalation, local, long term	3E-3 mg/m³ (TRA Workers)	RCR < 0.01
Dermal, systemic, long term	0.034 mg/kg bw/day (TRA Workers)	
Dermal, local, long term	5E-3 mg/cm² (TRA Workers)	
Combined routes, systemic, long-term		RCR < 0.01

Remarks on exposure dataset obtained with ECETOC TRA

The local exhaust ventilation effectiveness has been taken into account for dermal exposure as well.
The vapour pressure at operating temperature (25°C) used for the calculation is 2.5E-3 Pa.

Risk characterisation

Qualitative risk characterisation:
The substance is a skin sensitizer and labeled as organ-toxic (STOT RE Cat.2). Any skin contamination must be strictly avoided. Gloves are mandatory together with strict control of breakthrough times. Additional measures are given in section 9.0.4 of this report and must be followed.

9.4. Exposure scenario 4: Service life (professional worker) - Service Life of firesafe materials

Article categories: AC 10g: Other rubber articles

Environment contributing scenario(s):		
CS 1	Service Life of firesafe materials	ERC 11a
Worker contributing scenario(s):		
CS 2	Service Life of firesafe materials	PROC 21

Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s):
ES2: Use at industrial sites - Use in the production of firesafe materials (<15% concentration)

9.4.1. Env CS 1: Service Life of firesafe materials (ERC 11a)

9.4.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily local widespread use amount: <= 0.00033 tonnes/day
Conditions and measures related to biological sewage treatment plant
• Biological STP: Standard [Effectiveness Water: 90.47%]
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations

9.4.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.17. Local releases to the environment

Release	Release estimation method	Explanations
Water	ERC	**Release factor before on site RMM:** 0.05% **Release factor after on site RMM:** 0.05% **Local release rate:** 1.65E-4 kg/day
Air	ERC	**Release factor before on site RMM:** 0.05% **Release factor after on site RMM:** 0.05%
Non agricultural soil	ERC	**Release factor after on site RMM:** 0%

9.4.1.3. Exposure and risks for the environment and man via the environment

The substance is considered as PBT / vPvB. Consequently the regional concentrations cannot be estimated with sufficient reliability. Exposure of man via the environment via the oral route cannot be estimated with sufficient reliability. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Risk characterisation (minimisation of emission/exposure)

The total releases are displayed in section 10.2.1.1.
Shale oil bitumen is used in firesafe articles. They are used as components in assembled articles and available to industrial and professional workers only. The purpose of the firesafe articles are to safeguard against the consequences of fires. Normally they are passive and remain unaffected until the end of their service life. The substance is contained in the matrix during its entire life cycle. It can be concluded that there is no release of substance during the service life of the articles.
At the end of life, the assembled articles are dismantled and components are recycled or sent to incineration. In particular all articles containing firesafe materials and the substance are incinerated. It can be concluded that the end of life of the articles is also the end of life of shale oil bitumen.

9.4.2. Worker CS 2: Service Life of firesafe materials (PROC 21)

9.4.2.1. Conditions of use

	Method
Product (Article) characteristics	
• Percentage (w/w) of substance in mixture/article: <= 1.0 % *It is assumed that hazardous vapors released from the bitumen component in fire safe materials is rapidly evaporated from the surface. Both inhalation and dermal contact is with a fully solidified article. To simulate the small releases, a concentration of 1% has been assumed for this scenario.*	TRA Workers 3.0
• Physical form of the used product: Solid (non or low dusty form)	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8.0 h/day	TRA Workers 3.0
Technical and organisational conditions and measures	
• Occupational Health and Safety Management System: Basic	TRA Workers 3.0
• General ventilation: Good general ventilation (3-5 air changes per hour) [Effectiveness Inhalation: 30%]	TRA Workers 3.0
• Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%]	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA Workers 3.0
• Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection [Effectiveness Dermal: 80%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Operating temperature: <= 25.0 °C	TRA Workers 3.0
• Skin surface potentially exposed: Two hands and forearms (1980 cm2)	

9.4.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9.18. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, systemic, long term	0.21 mg/m³ (TRA Workers)	RCR = 0.525
Inhalation, local, long term	0.21 mg/m³ (TRA Workers)	RCR = 0.467
Dermal, systemic, long term	0.057 mg/kg bw/day (TRA Workers)	
Dermal, local, long term	2E-3 mg/cm² (TRA Workers)	
Combined routes, systemic, long-term		RCR = 0.525

Remarks on exposure dataset obtained with ECETOC TRA

The vapour pressure at operating temperature (25°C) used for the calculation is 2.5E-3 Pa.

Risk characterisation

Qualitative risk characterisation:
The substance is bound into the matrix of the firesafe materials, which are assembled to articles.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers

Road construction workers may combine activities described in section 9.5. The normal operation is covered by the far field operation in section 9.5.6 with RCR of 0.475. It is expected that on a single workday only one of the other activities is performed, so that the overall combined RCR for the workers is kept below 1.
No combination of exposure on the same workday is foreseen for the other uses of shale oil bitumen.

10.1.2. Consumer

not relevant, as there is no consumer exposure.

10.2. Environment (combined for all emission sources)

10.2.1. All uses (regional scale)

10.2.1.1. Total releases

The total releases to the environment from all the exposure scenarios covered are presented in the table below. This is the sum of the releases to the environments from all exposure scenarios addressed.

Table 10.1. Total releases to the environment per year from all life cycle stages

Release route	Total releases per year
Water	1.58E3 kg/year
Air	3.36E5 kg/year
Soil	6.21E3 kg/year

10.2.2. Regional assessment

The substance is regarded as PBT / vPvB. Consequently the regional concentrations cannot be estimated with sufficient reliability.

10.2.3. Local exposure due to all widespread uses

Not relevant as there are not several widespread uses covered in this CSR.

Annexes

1. Annex: References

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2. Annex: Information on Test Material

Test material: **Shale Oil Bitumen**
Form:

Composition type: Constituent	**Reference substance:** Shale Oil Bitumen EC no.: 447-780-2 CAS no: IUPAC name: Shale Oil Bitumen	**Concentration range:**

Test material: **Asphalt, oxidized**
Form:

Composition type: Constituent	**Reference substance:** Asphalt, oxidized EC no.: 265-196-4 CAS no: 64742-93-4 IUPAC name:	**Concentration range:**

Details on test material: Built-Up type III Roofing asphalt fume condensate (RAFC) generated, collected and characterized by Heritage Research Group (Indianapolis). density = 0.8745g/ml, Refractive Index 1.4831 at 25C, Kinematic viscosity 8.3616 cst at 1000F. Concentration of Polycyclic Aromatic Hydrocarbon in RAFC Compound Analysis A [µg/g] Analysis B [µg/g] Naphthalene 164.0 165.0 Acenaphthylene Not determined Not determined Acenaphthene 29.2 28.8 Fluorene 254.0 253.0 Phenanthrene 248.0 250.0 Anthracene 31.9 32.0 Fluoranthene 10.5 9.97 Pyrene 48.8 47.7 Benz(a)anthracene 7.81 7.99 Triphenylene 20.7 21.6 Chrysene 19.8 19.8 Benzo(b)fluoranthene 4.80 4.70 Benzo(k)fluoranthene 1.72 1.15 Benzo(e)pyrene 7.72 7.73 Benzo(a)pyrene 4.09 4.10 Indeno(1,2,3-cd)pyrene 0.70 0.60 Dibenz(ah)anthracene 1.41 1.37 Benzo(ghi)perylene 2.93 2.76 Fraunhofer ITEM Rpt 02N07532

Test material: **Bitumen fume condensate**
Form:

Composition type: Constituent	**Reference substance:** Bitumen fume condensate EC no.: CAS no: IUPAC name: Bitumen fume condensate	**Concentration range:**

Details on test material: Sampling of the bitumen fume condensate for the 2-year study took place at an operating asphalt mixing plant, supplied directly with bitumen from a nearby refinery. It was demonstrated that the bitumen fume in the bitumen storage tank and therefore the sampled bitumen fume condensate is representative for workers exposed during road paving. The fume was collected from a hot bitumen storage tank, maintained at 175 °C and was sampled from the air space, about 10 cm above the liquid bitumen surface (Figure 1). Since the bitumen level in the tanks changes continuously during workdays, floats. The fume was sucked through a stainless steel pipe (3 m) and passed through a heated Teflon tube (5 m in length) into a tool house located near the bitumen tanks, where the sampling equipment was located. To prevent the sampling system from being blocked by liquid bitumen that may be accidentally sucked into the sampling tube, a pre-separator was installed at the entrance to the sampling system. From the insulated preseparator, the fume was conducted into four separate sampling units. Each sampling unit comprised a cooling spiral, a Peltier condenser, collection bottles, and a peristaltic pump. The fume passed through the cooling spiral into the Peltier condenser running at a temperature of about 5 °C. The condensed bitumen fume and water were collected in two 10-liter vacuum tied polyethylene collection bottles at a pressure level in the bottle of about 800 mbar. Bitumen condensate was only found in small amounts in the first bottle. This condensate was not used for the inhalation study.

Test material: **BURA fume condensate**
Form:

Composition type: Constituent	**Reference substance:** BURA fume condensate EC no.: CAS no: IUPAC name: BURA fume	**Concentration range:**

	condensate	

Details on test material: Fume condensates used in the study were generated, collected and characterized by the Heritage Research Group, Indianapolis, IN, as previously described (Kriech et al., 2007). A single paving, roofing and lab generated roofing fume condensate were selected for the two year dermal carcinogenicity bioassay from the four samples of each asphalt type that were studied (identified in the Kriech paper as samples TP-D, TR-A, and LR-A). They are referred to as the ‘‘field-matched’’ paving or BURA fume condensate and the ‘‘lab-generated’’ BURA fume condensate.

3. Annex: Mode of action / Human relevance Framework

Section 5.6.3: Repeated dose toxicity
Detailed information on mode of action / Human relevance framework:

Section 5.7.3: Genetic toxicity
Detailed information on mode of action / Human relevance framework:

Section 5.8.3: Carcinogenicity
Detailed information on mode of action / Human relevance framework:

Section 5.9.3: Toxicity to reproduction
Detailed information on mode of action / Human relevance framework: