

BITUMEN (all types)

REV.: B

DATE: 21/12/2015

PREPARED BY: ICARO S.r.l

FOR: ALMA PETROLI S.p.A.

1. IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND COMPANY/ORGANIZATION

1.1 Product identification

Substance name:	Bitumen, Asphalt
Synonyms	Bitumen all types, Paving bitumen
CAS number	8052-42-4
EC number	232-490-9
Index number	n.a.
Registration number	01-2119480172-44-0059
Chemical formula	The substance is an UVCB complex (prC3), and thus it is not possible to provide a molecular formula.
Molecular weight	The substance is an UVCB complex (prC3), and thus it is not possible to provide a molecular formula.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Common uses Road paving, diaphragms, sheaths, protections, water-proofing, sealants

Uses identified in the chemical safety report: general list of applications:

<i>Industrial use (G26):</i>	manufacture of substance (GEST1_I), use as an intermediate (GEST1B_I), distribution of substance (GEST1A_I) formulation & (re)packing of substances and mixtures (GEST2_I), uses in coatings (GEST3_I)
<i>Professional use (G27):</i>	use in coatings (GEST1_P), road and construction applications (GEST15_P);
<i>Consumer (G28):</i>	use in coatings (GEST3_I)

1.3 Information on the supplier of the safety data sheet:

Company name	ALMA PETROLI S.p.A.
Address	Via di Roma 67 - Via Baiona 195
City / Country	Ravenna Italy
Telephone	0039-0544-34317- 0039-0544-696411
E-mail of competent technician	info@almapetroli.com

1.4 Emergency telephone number:

Poison centre - Telephone consultation operative (24/7):

Niguarda Hospital Milan Tel: 0039-02-66101029,

Poison centre Pavia: Tel. 0039-0382-24444, Poison centre Bergamo: Tel: 0039 800 883300,

Poison centre Foggia: Tel 0039-0881-732326,

Poison centre Florence: Tel 0039-055-7947819,

Poison centre Policlinico Umberto I Rome: Tel 0039-06-490663,

Poison centre Policlinico "A.Gemelli": Tel 0039-06-3054343,

Poison centre Cardarelli Naples: Tel: 0039-081-5453333/747287

Alma Petroli - Sciascia Antonino (Employer) - Mob. 0039-3461305790 (24/7)

Alma Petroli - Fabbri Maurizio (RSPP) - Mob. 0039-3461321422 (24/7)

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2. IDENTIFICATION OF THE HAZARDS

Physical-chemical hazards: no hazard according to the classification criteria as per attachment I, part 2 of Regulation 1272/2008;

Health hazards: no hazard according to the classification criteria as per attachment I, part 3 of Regulation 1272/2008;

Environmental hazards: no hazard according to the classification criteria as per attachment I, part 4 of Regulation 1272/2008;

2.1 Classification of the substance or mixture

Not classified

2.2 Elements in the label

n.a.

2.3 Other hazards

Given that the product is used hot, the main hazard for users is the possibility of burns upon contact with the molten product or its fumes. Heated bitumen will give off fumes. Even if it is assumed that these fumes do not constitute a serious health hazard, normal prudence recommends limiting exposure to the barest minimum, using correct work procedures and ensuring good ventilation of the work environment. Prolonged inhalation of the fumes produced by the hot product can irritate the respiratory tract. The fumes can contain hydrogen sulphide (a toxic, flammable gas), which can accumulate until hazardous concentrations are reached in the storage tanks.

The product does not meet the PBT or vPvB classification criteria as per REACH annex XIII.

3. COMPOSITION / INFORMATION ON THE INGREDIENTS

3.1 Substances

The substance is an UVCB complex (PrC3); Asphalt ("Very complex combination of high molecular weight organic hydrocarbons containing a relatively high proportion of hydrocarbons having carbon numbers predominantly greater than C25 with high carbon to hydrogen ratios. It also contains small amounts of various metals such as nickel, iron or vanadium. It is obtained as the non-volatile residue from distillation of crude oil or by separation as the raffinate from a residual oil in a deasphalting or decarbonisation process")

Name	EC no.	CAS no.	Index no.	Registration no.
Bitumen (all types)	232-490-9	8052-42-4	n.d.	01-2119480172-44-0059

3.2 Mixtures

n.a.

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4. FIRST AID MEASURES

4.1 Description of first aid measures

- Eye contact:** Cool the part with copious amounts of water for at least 5 minutes. Continue rinsing (670). Do not attempt to remove the bitumen. Seek immediate medical attention if irritation, blurred vision or swelling develop and persist (817).
Immediately cool the part under running water for at least five minutes; do not attempt to remove the bitumen. Take immediately the injured person to hospital.
- Skin contact:** In the event of accidental skin contact with hot product, the injured part should be immediately plunged under cold running water for at least 10 minutes (752). After cooling, do not attempt to remove the layer of bitumen from the skin as this constitutes a sterile protection over the burnt part. The layer will fall off spontaneously after some time, as the skin recovers. If necessary, the bitumen can be softened and then removed with swabs soaked in vegetable oil or Vaseline oil. No attempt must be made to remove the bitumen adherent to the skin at the worksite (787). In the case of a circumferential burn with adhesion of the bitumen, the adhering material should be split to prevent a tourniquet effect as it cools (748). Seek medical assistance (816).
For minor thermal burns, cool the burn (705). Hold the burned area under cold running water for at least five minutes, or until the pain subsides (709). Body hypothermia must be avoided (659). Do not put ice on the burn (684). DO NOT attempt to remove portions of clothing glued to burnt skin but cut round them (677). First aiders should never use gasoline, kerosene or other solvents for washing of contaminated skin (702). Seek medical attention in all cases of serious burns (818).
- Ingestion/aspiration:** This means of exposure is highly unlikely.
- Inhalation:** In case of irritation due to exposure to high concentrations of fumes, take the injured person to a non polluted area. Obtain medical advice for further treatment (792). Send the casualty immediately to hospital (822). In the event of malaise due to exposure to hydrogen sulphide, immediately take the person outdoors taking all appropriate safety precautions to protect the rescuers and immediately seek medical attention. Immediately begin artificial respiration if breathing has ceased (731). Administer oxygen if necessary (651). Monitor breathing and pulse rate (783). If the casualty is unconscious and (716) and not breathing (790), place the person in the recovery position (724). Administer oxygen if necessary (649).

4.2 Primary symptoms and effects, both acute and delayed

No symptom in case of contact with product at ambient temperature. Slight eye irritation (826). Contact with hot product may cause severe thermal burns (666).

4.3 Indication of any immediate medical attention and special treatment needed

Seek medical attention in all cases of serious burns (818).

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5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Small scale fires: earth or sand, carbon dioxide, foam, dry chemical powder. Large scale fires: foam, water fog. Note: sprayed water can only be used by specially trained personnel. Other inert gases (subject to regulations) (870)

Unsuitable extinguishing media: Do not use direct water jets on the burning product (855), they could cause splattering and spread the fire (881). Simultaneous use of foam and water on the same surface is to be avoided as water destroys the foam (873).

5.2 Special hazards arising from the substance or mixture

Contact of hot product with water will result in a violent expansion as the water turns to steam (664), this may cause splashing of hot product, or damage to, or complete loss of the tank roof (841). Respiratory problems or nausea by excessive exposure to hot product fumes (871).

Incomplete combustion is likely to give rise to a complex mixture of airborne solid and liquid particulates, gases, including carbon monoxide (867), H₂S (Hydrogen sulphide), SO_x (sulphur oxides) or H₂SO₄ (sulphuric acid) (861) unidentified organic and inorganic compounds (886).

5.3 Recommendations for fire-fighting personnel

In case of a large fire or in confined or poorly ventilated spaces, wear full fire resistant protective clothing and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode (864).

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Stop or contain leak at the source, if safe to do so (1006). Avoid direct contact with released material (903). Stay upwind (1003). In case of large spillages, alert occupants in downwind areas (956). Keep non-involved personnel away from the area of spillage. Alert emergency personnel (968). Except in case of small spillages (925), the feasibility of any actions should always be assessed and advised, if possible, by a trained, competent person in charge of managing the emergency (1007). Eliminate all ignition sources if safe to do so (e.g. electricity, sparks, fires, flares) (920). When the presence of dangerous amounts of H₂S around the leaked/spilled product is suspected or proved, additional or special actions may be warranted, including access restrictions, use of special personal protection equipment, procedures and personnel training (963). If required, notify relevant authorities according to all applicable regulations (949).

Large spillages: full body suit of chemically resistant and antistatic material (973). If necessary heat resistant and insulated (941). Work gloves (preferably gauntlets) providing adequate chemical resistance (1027). Gloves made of PVA (Polyvinyl alcohol) are not water-resistant and are not suitable for emergency use (933). If contact with hot product is possible or anticipated, gloves should be heat-resistant and thermally insulated (936). Work helmet (1030). Antistatic non-skid safety shoes or boots (899). Chemically resistant. Goggles or face shield, if splashes or contact with eyes is possible or anticipated (934). Respiratory protection: a half or full-face respirator with filter(s) for organic vapours (and when applicable for H₂S) (892) or a Self-Contained Breathing Apparatus (SCBA) can be used according to the extent of spill and predictable amount of exposure (895). If the situation cannot be completely assessed, or if an oxygen deficiency is possible, only SCBA's should be used (951).

6.2 Environmental precautions

Prevent product from entering sewers, rivers or other bodies of water (985).

6.3 Methods and materials for containment and cleaning

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Leaks and spillages will consist of molten hot material with risk of severe burns (975): solidified product may clog drains and sewers (997).

Spills on the ground: If necessary dike the product with dry earth, sand or similar non-combustible materials (940). Let hot product cool down naturally (976). If necessary, cautiously use water fog to help the cooling (943). Do not play direct jets of foam or water on the spilled molten product, as this may cause splattering (917). When inside buildings or confined spaces, ensure adequate ventilation (1022). Collect solidified product with suitable means (909) (e.g.: shovels) (888).

Collect recovered product and other materials in suitable tanks or containers for recovery or safe disposal (908). Transfer collected product and other contaminated materials to suitable tanks or containers for recovery or safe disposal (1015).

Spills into water: the product will cool down rapidly and become solid (1010). The solid product is denser than water and will slowly sink to the bottom, and usually no intervention will be feasible (1011). If possible, contain the product (946). Contain the product and contaminated materials with mechanical means (915).

Recommended measures are based on the most likely spillage scenarios for this material. Local conditions (wind, air temperature, wave/current direction and speed) may significantly influence the choice of appropriate actions (990). For this reason, local experts should be consulted when necessary (928).

6.4 Reference to other sections

For more information regarding personal protective equipment see section "Exposure control/personal protection" (1086).

6.5 Additional information

Concentration of H₂S (hydrogen sulphide) in the head space of the tank may reach hazardous values, especially in case of prolonged storage (912). This situation is especially relevant for those operations which involve direct exposure to the vapours in the tank. (1014)

Spillages of limited amounts of product, especially in the open air when vapours will be usually quickly dispersed, are dynamic situations, which will presumably limit the exposure to dangerous concentrations (999). As H₂S has a density greater than ambient air, a possible exception may regard the build-up of dangerous concentrations in specific spots, like trenches, depressions or confined spaces (902). In all these circumstances, however, the correct actions should be assessed on a case-by-case basis (954).

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

7.1.1 Protective measures

Ensure that all relevant regulations regarding product handling and storage facilities are followed. Avoid contact of hot product with water (1040). Risk of splashing of hot material (1121).

Product may release H₂S (Hydrogen Sulphide): a specific assessment of inhalation risks from the presence of hydrogen sulphide in tank headspaces, confined spaces, product residue, tank waste and waste water, and unintentional releases should be made to help determine controls appropriate to local circumstances (E500).

Ground/bond container and receiving equipment (1086). Do not breathe fumes from hot product (1069). Use adequate personal protective equipment as needed (1146). Do not use compressed air for filling, discharging or handling operations (1073). Prevent the risk of slipping (1111).

7.1.2 Indications regarding hygiene in the workplace

Ensure that proper housekeeping measures are in place (1081). Contaminated material should not be allowed to accumulate in the workplaces and should never be kept inside the pockets (1061). Keep away from food and beverages (1096). Do not

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eat, drink or smoke when using this product (1071). Wash the hands thoroughly after handling (1156). Do not reuse contaminated clothing. Do not use solvents or other products with a defatting effect on the skin (1074).

7.2 Conditions for safe storage, including any incompatibilities

Storage area layout, tank design, equipment and operating procedures must comply with the relevant European, national or local legislation (1127). Storage installations should be designed with adequate bunds so as to prevent ground and water pollution in case of leaks or spills (1129). Cleaning, inspection and maintenance of internal structure of storage tanks must be done only by properly equipped and qualified personnel as defined by national, local or company regulations (1054). Before entering storage tanks and commencing any operation in a confined area, check the atmosphere for oxygen content, hydrogen sulphide (H₂S) and flammability (1050).

Store separately from oxidising agents (1133).

Recommended materials for containers or container linings are mild steel or stainless steel (1116). Most synthetic materials are unsuitable for containers or container linings, due to low heat resistance (1104).

If the product is supplied in containers (1094) keep it only in the original container or in a suitable container for this kind of product (1099). Hot product must never be filled into containers without first checking that the container is completely dry (1091). Empty containers may contain combustible product residues (1077). Do not weld, solder, drill, cut or incinerate empty containers, unless they have been properly cleaned (1075).

7.3 Specific final uses

Non envisaged.

8. EXPOSURE CONTROL / PERSONAL PROTECTION

8.1 Control parameters

Exposure limit values (substance):

Asphalt (Bitumen fumes-sprays soluble in benzene)

ACGIH 2014:

TLV®-TWA: 0.5 mg/m³

BEI (See BEI for PAH): 1-hydroxypyrene-(1-HP) in the urine - end of shift at end of workweek: Not quantitative

Hydrogen sulphide

It. legislative decree no. 81/08:

Limit values (8 hours): 5 ppm; 7 mg/m³

Limit values (short term): 10 ppm; 14 mg/m³

ACGIH 2014:

TLV®-TWA: 1 ppm; 1.4 mg/m³

TLV®-STEL: 5 ppm; 7 mg/m³

Monitoring procedure: see It. Leg. Dec. 81/2008 and subsequent amendments and integrations or to good industrial hygiene practices.

DNEL (Derived No-Effect Level)

Workers

DNEL long-term inhalation (local effects): 2.9 mg/m³/8h

General population

DNEL long-term inhalation (local effects): 0.6 mg/m³/24h

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8.2 Exposure control

8.2.1 Suitable technical checks

Minimise exposure to mist/ vapours/sprays. Where hot product is handled in confined spaces, effective local ventilation must be provided (1217). Before entering storage tanks and commencing any operation in a confined area, check the atmosphere for oxygen content, hydrogen sulphide (H₂S) and flammability (1050).

8.2.2 Personal protection measures

(a) Eye/face protection:

Protective shields are recommended for operations that cause splashing. Helmet with neck protection. Wear protective goggles (UNI EN 166).

(b) Skin protection:

i) Hand protection

In the absence of containment systems, and if contact with the skin is possible, use hydrocarbon-resistant gloves with long cuffs that are plush lined and, if necessary, thermally insulated. Materials assumed to be adequate: nitril, PVC or PVA (polyvinyl alcohol) with index of protection against chemical agents of at least 5 (permeation time > 240 minutes). Use gloves under the conditions and respecting the limits set by the manufacturer. If necessary, see UNI EN 374. Gloves must be periodically inspected and changed in case of wear, perforations or contaminations (1174).

ii) Other

Wear protective clothing for operations with hot material: heat resistant coveralls (with trousers legs over boots and sleeves over cuffs of gloves), heat resistant heavy duty antiskid boots (e. g. leather). (EN 943-13034-14605) (1216) Chemically resistant. If the clothing becomes contaminated, replace and clean immediately.

(c) Respiratory protection:

If worker exposure is, or may be greater than the exposure levels established for the position, wear breathing apparatus compliant with EN 140 with A/P2 filter or higher.

Approved respiratory protection equipment shall be used in spaces where hydrogen sulphide may accumulate: full face mask with type "B" filter cartridge (grey for inorganic vapours including H₂S) or self-contained breathing apparatus (EN 529)(1163). If exposure levels cannot be determined or estimated with adequate confidence, or an oxygen deficiency is possible, only SCBA's should be used (1183).

(d) Thermal hazards: see letter b above



8.2.3 Environmental exposure control

Avoid release to the environment (1046) Storage installations should be designed with adequate bunds so as to prevent ground and water pollution in case of leaks or spills (1129).

8.3 Other

No additional information

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on the essential physical and chemical properties

a) Appearance	Blackish solid
b) Odour	characteristic when hot, odourless when cold
c) Olfactory threshold	n.d.
d) pH	n.a.
e) Melting/freezing point	> 25°C (EN 1427)
f) Initial boiling point and boiling range	389.9°C Boiling interval at 5% and 40%: 425.8-559.3°C ASTM1160 Test report no.: GE10-01308.001
g) Flash point	> 180°C ASTM D 92/EN ISO 2592
h) Evaporation rate	n.a.
i) Flammability (solids, gases)	not flammable
j) Upper/lower flammability or explosive limits	n.a.
k) Vapour pressure	<< 0.1 kPa at 20°C
l) Vapour density	n.a.
m) Density	from 0.925 to 1.150 at 15°C EN ISO 12185/EN ISO 3838/EN
n) Solubility	Solubility in water not applicable since it is an UVCB substance
o) Partition coefficient (n-octanol/water)	Not applicable since it is an UVCB substance
p) Self-ignition temperature	> 400°C ASTM 659
q) Decomposition temperature	n.a.
r) Kinematic viscosity	> 130 mm ² /s at 135°C EN 12595
s) Explosive properties	Not explosive
t) Oxidising properties	The substance does not react exothermally with combustible materials

9.2 Additional information

The characteristic analysis methods are the nationally and internationally recognized methods reported, for the most part, in the product commercial specifications.

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10. STABILITY AND REACTIVITY

10.1 Reactivity

The substance does not present any further hazard related to reactivity, above and beyond those reported in the following subsections

10.2 Chemical stability

Bitumen is normally stored and handled at temperatures above 100°C, and contact with water will result in a violent expansion which may cause splashing and boiling over.

10.3 Possibility of dangerous reactions

A mixture with nitrates or other strong oxidisers (e.g. chlorates, perchlorates, liquid oxygen) may create an explosive mass (611). Sensitivity to heat, friction or shock cannot be assessed in advance (618).

10.4 Conditions to be avoided

Excessive heating above the recommended temperature may cause degradation of the product and evolution of flammable fumes.

10.5 Non-compatible materials

Avoid contact of molten product with water or other liquids. Avoid contact with oxidizing substances. Avoid contact of hot bitumen products with water (1039). Oil and bitumen contamination of thermal insulation materials and the accumulation of oily rags or similar material near hot surfaces should be avoided, and lagging should be replaced where necessary by a non-absorbent type of insulation (1106). Self-heating leading to auto ignition at the surfaces of porous or fibrous materials impregnated with oils or bitumen, can occur at temperatures as low as 100°C (1122).

10.6 Hazardous decomposition products

Confined spaces (1057): as hydrogen sulphide (H₂S) has a density greater than ambient air, a possible exception may regard the build-up of dangerous concentrations in specific spots, like trenches, depressions or confined spaces (902)

11. TOXICOLOGICAL INFORMATION

11.1 Toxicokinetics, metabolism and distribution

Complex substances such as bitumen do not lend themselves to toxicokinetic analysis. Nevertheless, the toxicokinetics of some of the individual components — e.g. polycyclical aromatic hydrocarbons (PAH) — has been studied in detail. For humans, the main means of exposure to bitumen are inhalation and contact with skin. In humans, the main sites of potential absorption of PAH from bitumen are the lungs and respiratory tract, upon inhalation of bitumen fumes, and the skin, following contact with pure bitumen or bitumen fume condensates.

In general, the individual components in bitumen and the bitumen fumes undergo oxidative metabolism which can lead to bioactivation.

Distribution of the PAHs throughout the body has been studied in rodents. These studies have shown that a low level of PAHs can be found in the internal organs, particular in fatty tissues.

In general, PAHs are eliminated through the urine and bile.

11.2 Toxicological information

a) Acute toxicity

Oral route

Acute toxicity from oral intake of bitumen has been assessed in some studies performed in rats. These studies have shown acute oral LD50 greater than 5 g/kg and thus the standards on hazardous substances do not require any classification.

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Below is a summary of the most representative studies found in the registration file.

Method	Result	Comments	Source
RAT M/F Administration: force feeding OECD Guideline 401	LD50:>5000 mg/kg (M/F)	Key study CAS 64741-56-6	American Petroleum Institute (API) 1982a

Inhalation route

Acute toxicity of bitumen through inhalation was assessed in some studies performed on the rat.

These studies have shown high acute inhalatory LC50 for which the standards on hazardous substances do not require any classification.

Below is a summary of the most representative studies found in the registration file.

Method	Result	Comments	Source
RAT M/F Vapours (nose only) OECD Guideline 403	LC50: > 94.4 mg/m ³ (M/F)	Key study Read-across Aerosol from oxidized bitumen fume condensates	Fraunhofer Institute of Toxicology and Aerosol Research (2000)

Cutaneous route

Acute toxicity of bitumen through the skin was assessed in some studies performed on rabbits. These studies have shown acute cutaneous LD50 higher than 2 g/kg and thus the standards on hazardous substances do not require any classification.

Below is a summary of the most representative studies found in the registration file.

Method	Result	Comments	Source
RABBIT (male/female) Occlusive bandage OECD Guideline 402 (Acute Dermal Toxicity)	LD50>2000 mg/kg (male/female)	Key study CAS 64741-56-6	Study performed by the American Petroleum Institute

b) Corrosion/skin irritation

The skin irritation potential of bitumen has been tested in some studies performed on the rabbit. The relevant conclusions have shown that it is not a skin irritant.

Given these results, the standards on hazardous substances do not require any classification.

Below is a summary of the most representative studies found in the registration file.

Method	Result	Comments	Source
RABBIT Occlusive bandage OECD Guideline 404	Non irritant Average erythema score: 0.1 of max. 4 (intact skin) Edema Index: 0.1 of max. 4 (intact skin)	Key study CAS 64741-56-6	American Petroleum Institute (API) 1982a

c) Severe eye lesions/severe eye irritation

The potential of bitumen to irritate the eyes has been tested in some studies performed on the rabbit.

All the studies have shown that the substance does not irritate the eyes and thus no substance classification is required.

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Below is a summary of the most representative studies found in the registration file.

Method	Result	Comments	Source
RABBIT OECD Guideline 405	Non irritant	Key study CAS 64741-56-6	American Petroleum Institute (API) 1982a

d) Sensitization of respiratory tract and skin

Sensitization of respiratory tract

This endpoint is not a REACH requirement and no data are available for this endpoint.

Sensitization of skin

Some studies have been conducted to test the sensitization potential of bitumen.

The results obtained from these studies indicate that there is no potential for skin sensitization and thus no substance classification is required.

Below is a summary of the most representative studies found in the registration file.

Method	Result	Comments	Source
GUINEA PIG OECD Guideline 406	Non sensitizing	Key study CAS 64741-56-6	American Petroleum Institute (API) 1983a

e) Germ cell mutagenicity

The mutagenic potential of bitumen has been widely studied in a series of in vivo and in vitro tests. Most of these studies have not shown any coherent proof of mutagenic activity, and thus the standards on hazardous substances do not require any classification.

Below is a summary of the most representative studies found in the registration file.

In vitro studies:

Method	Result	Comments	Source
Ames test with and without metabolic activation S. typhimurium TA98, T100, YG 1041, YG 1042 Doses: ≤ 10 µL and 0.1 mL (OECD Guideline 471 (Bacterial Reverse Mutation Assay))	Negative - no metabolic activation Positive - metabolic activation found	Key study Bitumen fume condensates	De Meo, M., Genevois, C., Brandt, H, Laget, M., Bartsch, H., Castegnaro, M. (1996)

In vivo studies:

Method	Result	Comments	Source
Assay of transgenic mutagenicity in animals RAT (male) Means of administration: vapour inhalation Doses: 100, mg/m ³ (total hydrocarbons)	Negative	Key study CAS 8052-42-4	Bottin, M.C., Gate, L., Rihn, B., Micillino, J.C., Nathalie, M., Martin (2006)

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f) Carcinogenicity

Some studies are available on the carcinogenicity of the substance when exposure occurs by inhalation or contact with the skin.

For the inhalation route, the available study has not revealed any carcinogenic effect.

For contact with skin, some studies in animals have reported weak activity. It must be pointed out that the solvents used in administering the bitumen clearly enhance the bioavailability and/or skin absorption.

In two epidemiological studies on workers exposed to asphalt, no cause-effect relationship was found between exposure to bitumen fumes and risk of lung cancer.

On the basis of a complex evaluation of the results of key and support studies in animals, and of the two key epidemiological studies, it was concluded that there is no proof supporting a carcinogenic risk of bitumen through the cutaneous or inhalation routes under normal operating conditions.

Below is a summary of the most representative animal studies present in the registration file.

Method	Result	Comments	Source
RAT - (M/F) Inhalation (nose only) Exposure: 104 weeks (6 hours a day, 5 days a week) Doses: 0, 4, 20, or 100 mg/m ³ OECD Guideline 451	NOAEC (carcinogenicity): 103.9 mg/m ³ air (analytical) (value adjusted for neoplastic histopathology: 172.5 mg/m ³) Neoplastic effects: no effect	Key study Read-across With oxidized bitumen fume condensates	Fraunhofer (2006). Fuhst et al. (2007)
MOUSE - (M/F) dermal route (acetone carrier) Doses 1 drop Exposure: twice a week for two years	Incidence of skin tumours: 0 % for the first two types of bitumen 4 % for the third type of bitumen 2 % for the fourth type of bitumen 2 % for the fifth type of bitumen	Key study (5 types of bitumen)	Hueper, W.C., Payne, W.W. (1960)

g) Toxicity for reproduction

A single study is available on toxicity to reproduction (summarized in the table below) covering the effects both on fertility and development. This study did not reveal that bitumen presented any effects for this end-point and thus it is not classified as hazardous according to the European standards on hazardous substances.

Method	Result	Comments	Source
RAT - M/F Combined repeated dose toxicity study with the reproduction/developmental toxicity Doses: 30, 100 or 300 mg/m ³ Administered by inhalation (nose only) Exposure: males: 28 days females: 50 days 6 hours a day, 7 days a week OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	NOAEC (P): 30 mg/m ³ air (weight of the organs) (NOAEC (P): 300 mg/m ³ air (specific reproduction parameters) NOAEC (F1): 300 mg/m ³ air (nominal) (all effects)	Key study Read-across With asphalt fume condensates (CAS 64742-93-4)	Fraunhofer (2009) Parker et al. (2011)

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h) Specific target organ toxicity (STOT) - single exposure:

Studies in rats have shown that exposure to bitumen fume condensates does not induce pulmonary inflammation.

In a study on 170 workers exposed to bitumen fumes (with concentrates of up to 1.3 mg/m³), no association was found between the acute effects on pulmonary function, irritation of the respiratory tract or other symptoms and exposure to bitumen fumes.

i) Specific target organ toxicity (STOT) - repeated exposure:

Studies on the toxicity due to repeated oral exposure to bitumen are not appropriate since the main routes of exposure in humans are inhalation and contact with the skin. None of the studies performed on inhalation and skin exposure have revealed any adverse systemic effects, even at the highest doses administered and thus the bitumen is not classified as hazardous for this end-point under the standards on hazardous substances.

Below is a summary of the most representative studies found in the registration file.

Method	Result	Comments	Source
Inhalation			
RAT - (M/F) Combined Repeated Dose Toxicity (chronic) and carcinogenicity study Doses: 4, 20, or 100 mg/m ³ Exposure: 2 years (6 hours a day, 5 days a week (except during holidays)) OECD 451	NOAEC (local effects): 10.4 mg/m ³ air (analytical) (Value adjusted according to histopathology 17.2 mg/m ³) NOAEC (systemic effects): 103.9 mg/L air (analytical) (adjusted value 172.5 mg/m ³) LOAEC (local effects): 20.7 mg/m ³ air (analytical) (Value adjusted according to histopathology 34.4 mg/m ³)	Key study Read-across Aerosol from oxidized bitumen fume condensates	Fraunhofer (2006)
Skin			
RAT (male/female) Subacute 28 days (3 times a week, 6 hours at a time) Doses: 200, 1000, or 2000 mg/kg/day OECD Guideline 410	NOAEL (topical effects): 200 mg/kg/day (based on the lack of any significant histopathological results) NOAEL (systemic effects): 2000 mg/kg/day (on the basis of body weight data in the absence of any significant histopathological results)	Key study CAS 64741-56-6	American Petroleum Institute (API) 1983a

j) Aspiration hazard:

Considering the estimated, or measured, viscosity of the bitumen, the substance is not classified in terms of danger of aspiration into the lungs.

Additional information

No additional information is available in this regard

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12. ECOLOGICAL INFORMATION

On the basis of the ecological information reported, and on the basis of the criteria indicated in the standards on hazardous substances, bitumen is NOT classified as hazardous for the environment.

12.1 Toxicity

Below is a summary of the most representative studies found in the registration file.

Endpoint	Result	Comments
Aquatic toxicity		
Invertebrates Daphnia magna Short term	LL50 48/hours > 1000 mg/l	Key study Redman Et al (2010b) QSAR
Invertebrates Daphnia magna Long term	NOAEL 21/days: ≥ 1000 mg/l	Key study Redman Et al (2010b) QSAR
Algae Selenastrum capricornutum	EL50 72/hours: ≥ 1000 mg/l	Key study Redman Et al (2010b) QSAR
Fish Short term Oncorhynchus mykiss	LL50 96/hours: > 1000 mg/l	Key study Redman Et al (2010b) QSAR
Fish Long term Oncorhynchus mykiss	LL50 28 /days: > 1000 mg/l NOEL 28/days ≥ 1000 mg/l	Key study Redman Et al (2010b) QSAR

12.2 Persistence and degradability

Abiotic degradability

Hydrolysis: the components in bitumen are resistant to hydrolysis because they lack a hydrolytically reactive functional group. Therefore, this process does not lead to any measurable degradation substance losses in the environment.

Photolysis in air: this endpoint is not required by REACH.

Photolysis in water and soil: this endpoint is not required by REACH.

Biotic degradability:

Water/sediments/soil: the standard tests for this endpoint are not applicable to UVCB substances

12.3 Bioaccumulation potential

The standard tests for this endpoint are not applicable to UVCB substances

12.4 Mobility in the soil

Koc absorption: the standard tests for this endpoint are not applicable to UVCB substances

12.5 Results of PBT and vPvB evaluation

Comparison with the criteria established in annex XIII of REACH regulation

Persistence evaluation: some hydrocarbon structures contained in this category show characteristics deemed P (Persistent) or vP (very Persistent).

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Bioaccumulation potential evaluation: the structure of most hydrocarbons contained in this category do NOT present characteristics deemed vB (very Bioaccumulative) although some components do present characteristics deemed B (Bioaccumulative).

Toxicity evaluation: for the structures with characteristics of P and B, toxicity was evaluated although none of the main components met the toxicity criteria except anthracene which has been confirmed to be PBT. Since anthracene is present in concentrations < 0.1%, the product is not deemed PBT/vPvB.

12.6 Other adverse effects

None.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Do not discharge on the ground or in sewers, tunnels or waterways.

To dispose of waste derived from this product, including empty uncleaned containers, comply with It. Leg. Dec. 152/06 and subsequent amendments and integrations

European Waste Catalogue Code: 05 01 17 (It. legislative decree no. 152/06 and subsequent amendments and integrations), the code indicated provides only general indication, based on the original composition of the product and the envisaged uses thereof.

The user (producer of the wastes) is responsible for choosing the most appropriate code to apply according to the real use of the product, any alterations and contaminations. The product 'as is' does not contain halogenated compounds.

Disposal of containers: Do not dispose of the containers in the environment. Dispose of them in compliance with current local standards.

Do not drill, cut, grind, weld, solder, burn or incinerate empty containers or drums, unless they have been drained and cleaned.

14. TRANSPORT INFORMATION

14.1 UN number:

3257

Note: the product is classified as hazardous goods only if transported in molten form at temperatures > 100 °C

14.2 UN shipping name

ELEVATED TEMPERATURE LIQUID, N.O.S. (molten bitumen)

14.3 Hazard classes related to transport

Land/rail transport (ADR/RID) Class:9, M9

Maritime transport (IMDG) Class 9

Air transport (IATA) Class 9

Transport is forbidden for both cargo and passenger flights

Note: bitumen transported cold, in solid state, is not classified

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14.4 Packaging groups

III; Labelled 9 + indication "High temperature"

14.5 Environmental hazard

The substance is NOT dangerous for the environment as per ADR, RID, ADN and IMDG codes

14.6 Special precautions for users (transport operations):

Wear chemically resistant gloves (tested to EN374) in combination with basic employee training (PPE16).

14.7 Bulk transport as per annex II of the MARPOL Convention 73/78 and IBC code

Not applicable.

14.8 Other

Tunnel restriction code (ADR): D

15. REGULATORY INFORMATION

15.1 Specific health, safety and environment standards and legislation for the substance or mixture

- Title VII Authorization as per REACH (Reg. EC no. 1907/2006 and subsequent amendments and integrations): not subject to authorization.
- Title VIII Restrictions as per REACH (Reg. EC no. 1907/2006 and subsequent amendments and integrations): not subject to restrictions.

Other EU regulations and national transpositions:

- Seveso category (Dir. 2012/18/EU) It. legislative decree no. 105/2015): n.a.
- Title IX (transposition of Dir. 98/24/EC) of It. Leg. Dec. 81/08: Dangerous chemical agent
- Title IX (transposition of Dir. 97/42/EC and 99/38/EC) of It. Leg. Dec 81/08: not applicable because not carcinogenic

For waste disposal, see It. leg. Dec. 152/06 and subsequent amendments and integrations

15.2 Chemical safety assessment

A chemical safety assessment has been performed.

Since the product is not classified as hazardous for the health and environment, exposure assessment and risk characterization are not required. Therefore, it is not necessary to work up exposure scenarios.

16. OTHER INFORMATION

List of pertinent hazard statements

These phrases are presented as a source of information and do not necessarily correspond to the product classification.

H Hazard indications

None

Indications for training

Provide workers who may be exposed to the substance with adequate training as outlined in this safety data sheet

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Main bibliography and sources of data

Registration file

Key to abbreviations and acronyms:

ACGIH	= American Conference of Governmental Industrial Hygienists
CSR	= Chemical Safety Report
EC50	= Effective concentration, 50%
IC50	= Inhibitory concentration, 50%
Klimisch	= Criterion for assessing reliability of method used.
LC50	= Lethal Concentration, 50%
LD50	= Average lethal Dose
n.a.	= not applicable
n.d.	= not available
PBT	= Persistent, bioaccumulative, toxic substance
CNS	= Central nervous system
STOT	= Specific target organ toxicity
(STOT) RE	= Repeated exposure
(STOT) SE	= Single exposure
Key Study	= Most pertinent study
TLV®TWA	= Threshold limit value – time weighted average
TLV®STEL	= Threshold limit value – short term exposure limit
UVCB	= substances of Unknown or Variable composition
vPvB	= very Persistent and very Bioaccumulative

Drafted on 29/11/2010

Revision date 01/12/2010

Reason for Rev00 of 01/12/2010: Update to comply with Annex I of EU Regulation 453/2010

Revision date 04/05/2015

Reason for Rev.A of 04/05/2015: Update emergency telephone numbers. Update to 5th ATP

Revision date 21/12/2015

Reason for Rev. B of 21/12/2015: Update the following sections: 2, 8, 11, 14, 15, 16 and inclusion of complete List of uses and use identifiers

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ANNEX

Complete List of uses and use identifiers

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Name of identified use	Sector	Sector of Use (SU)	Chemical Product Category (PC)	Process categories (PROC)	Environmental Release Category (ERC)	Specific Environmental Release Category (SpERC)
Manufacture of substance	Industrial	3, 8, 9	n.a.	1, 2, 3, 4, 8a, 8b, 15	1	ESVOC SpERC 1.1.v1
Use as an intermediate	Industrial	3, 8, 9	n.a.	1, 2, 3, 4, 8a, 8b, 15	6a	ESVOC SpERC 6.1a.v1
Distribution of substance	Industrial	3	n.a.	1, 2, 3, 4, 8a, 8b, 9, 15	4, 5, 6a, 6b, 6c, 6d, 7	ESVOC SpERC 1.1b.v1
Formulation & (re)packing of substances and mixtures	Industrial	3, 10	n.a.	1, 2, 3, 4, 5, 8a, 8b, 9, 14, 15	2	ESVOC SpERC 2.2.v1
Use in Coatings	Industrial	3	n.a.	1, 2, 3, 4, 5, 7, 8a, 8b, 10, 13, 15	4	ESVOC SpERC 4.3a.v1
Use in Coatings	Professional	22	n.a.	1, 2, 3, 4, 5, 8a, 8b, 10, 11, 13, 15, 19	8a, 8d	ESVOC SpERC 8.3b.v1
Road and construction applications	Professional	22	n.a.	8a, 8b, 9, 10, 11, 13	8d, 8f	ESVOC SpERC 8.15.v1
Use in Coatings	Consumer	21	1, 4, 5, 9a, 9b, 9c, 10, 15, 18, 23, 24, 31, 34	n.a.	8a, 8d	ESVOC SpERC 8.3c.v1