SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Name	Modified bitumen
Trading name	Fast Draining
Synonyms	PmB
CAS Number	Not applicable (mixture)
EC Number	232-490-9 Not applicable (mixture)
IndexNumber	Not applicable (mixture)
Regestration Number	Not applicable (mixture)
UFI	Not applicable

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

Relevant identified uses: Road pavement, membranes, sheaths, protective, waterproofing, sealants.

Uses identified in the Chemical Safety Report of Bitumen: Generic list of applications:

Life Cycle:

Production: Production of the substance.

Formulation: Formulation and (re)packaging of substances and mixtures.

Use at industrial sites: Use of the substance as an intermediate, use in coatings, use in Oil and Gas field drilling and production operations onshore/offshyore, production and processing of rubber, use in fuels, use in lubricants.

Generalized use by professional operators: Use in coatings, use in Oil and Gas field drilling and production operations onshore/offshyore, road and construction applications, use in lubrificants (low environmental release and high environmental release), use in agrochemical products.

Consumer use: Use in coatings, Use in road and construction applications

Service life: Use in road and construction applications (professional and consumer).

See Annex for full list of uses.

Uses advised against: The relevant uses are listed above. No other uses are recommended.

Reasons for uses advised against: Uses other than those identified as relevant are not recommended unless an assessment has been carried out prior to the start of such use indicating that the risks associated with such use are safe.

1.3 Details of 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
Phone0	039054434317-00390544696411
Competent technician E-mail	info@almapetroli.com

1.4 Emergency telephone number

For Appropriate National Emergency Information Services see the following link:

https://echa.europa.eu/support/helpdesks

Other useful numbers

Alma Petroli - Pietro Scala (Employer) - Mob. 3442402229 (24 hours)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

The substance is not classified as hazardous under Regulation (EC) No 1272/2008 (CLP).

2.2 Label elements

Signal word: -

Hazards identification: -

Safety advise: -

Supplemental hazard information:

Authorization numebr: n.a.

2.2 Label elements

None.

2.3 Other hazards

Given the hot use of the product, the greatest danger for users is the possibility of burns from contact with the molten product or its fumes. Heated bitumen emits fumes. Although it is assumed that such fumes do not present significant dangers to health, normal caution advises to limit exposure as much as possible, using correct working procedures and ensuring good ventilation of the working environments. Prolonged inhalation of the fumes of the hot product can cause irritation of the respiratory tract. Hydrogen sulfide (toxic and flammable gas) may be present in the fumes, which can accumulate until dangerous concentrations are reached in storage tanks.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

The mixture consists of Bitumen, Polymer (10%) and Cross-linking (0.3%).

Below is the information relating to the main component Bitumen.

The Bitumen is a UVCB complex, a very complex combination of organic hydrocarbons with high molecular weight, containing a relatively high amount of hydrocarbons with carbon numbers predominantly higher than C25 and high carbon-hydrogen ratios. It also contains small amounts of metals such as nickel, iron or vanadium. It is obtained as a non-volatile residue of the distillation of crude oil, or by separation in refined form from a residual oil, in a process of deasphaltation or decarbonization.

Denomination	EC	CAS	n.Index	n.Registration	Classification
Bitumen	232-490-9	8052-42-4	n.a.	01-2119480172-44-0059	Not classified

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

Warning before intervention: Contact with the hot product can cause severe thermal burns. Hydrogen sulfide (H2S) can accumulate in the headspace of storage tanks and reach potentially dangerous concentrations.

Eye contact: Remove contact lenses. Irrigate the eyes with 0.9% saline, if available, or water for at least 15 minutes. Irrigate before and after removing the lenses to avoid dragging substances into the shielded area of the lenses. Continue to rinse. Do not make any attempt to remove the bitumen. See a doctor immediately in case irritation, blurred vision or swelling develop and persist.

Immediately cool the part with running water for at least five minutes; do not make any attempt to remove the bitumen. Urgently transport the affected person to the hospital.

Skin contact: In case the hot product accidentally comes into contact with the skin, soak the exposed part in cold water for 10-15 min. After cooling do not attempt to remove the bitumen layer from the skin as it constitutes a sterile protection of the burned part. The layer spontaneously removes at the mimento of skin healing after some time. If necessary, the bitumen can be softened and then removed with swabs soaked in vegetable oil and petroleum jelly oil. Do not attempt to remove bitumen that adheres to the skin or contaminated clothing at the workplace. In case of circumferential burns with bitumen adhesion, etch the material to prevent a "tourniquet" effect during cooling. Seek immediate medical attention. For minor thermal burns, cool the injured part. Keep the burned part under cold running water for at least five minutes, or until the pain disappears. Avoid general hypothermia. Do not apply ice on the burn. DO NOT attempt to remove the portions of clothing attached to the burnt skin but cut its contours. First aid workers should never use gasoline, kerosene or other solvent to clean contaminated skin. Consult a doctor in all cases of severe burns.

Ingestion/aspiration: Unlikely route of exposure. it happens, mild nausea may occur. Do not induce vomiting. Consult a physician. Aspiration not applicable.

Inhalation: In case of irritation due to exposure to high concentrations of fumes, transport the affected person into an unpolluted atmosphere. Consult a doctor. Immediately transfer the injured person to the hospital. In case of discomfort due to exposure to hydrogen sulfide immediately take to the fresh air using the appropriate safety measures for rescuers and urgently request medical assistance. Start artificial respiration immediately if breathing has stopped. Administer oxygen if necessary. Keep your breathing and heartbeat under control. If the injured person is unconscious and does not breathe, keep him in a safe lateral position. Administer oxygen if necessary.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms following inhalation: Exposure to hot fumes can cause: eye irritation, nasal irritation, throat irritation, irritation of the respiratory tract, headache, nausea, nervousness. Following contact with the skin: Exposure to the hot product can cause thermal burns. Eye contact symptoms: Exposure to hot fumes can cause: severe irritation of the eyes and mucous membranes

4.3 Indication of any immediate medical attention and special treatment needed

Consult a doctor in all cases of severe burns.

SECTION 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Small fires: earth or sand, carbon dioxide, foam, dry chemical powder. Large fires: foam, water spray. Note: The use of fractional jet water (spray water) is reserved for specially trained personnel. Other inert gases (as permitted by law).

NOT suitable extinguishing media: Do not use direct water jets on the burning product, they can cause splashes and spread the fire. Avoid using foam and water simultaneously on the same surface as water destroys the foam.

5.2 Special hazards arising from the substance or mixture

The contact of the hot product with water generates a violent expansion since the water turns into steam, this can generate splashes of hot product, or damage or complete loss of the roof of the tank. Breathing problems or nausea caused by excessive exposure of the fumes generated by the hot product.

Incomplete combustion could generate a complex mixture of airborne solid and liquid particles and gases, including carbon monoxide, H2S (hydrogen sulfide), SOx (sulfur oxides), H2SO4 (sulfuric acid), and other unidentified organic and inorganic compounds.

5.3 Advice for firefighters

In the event of a large fire or in confined or poorly ventilated spaces, wear a garment complete with fireproof protection and a stand-alone respirator equipped with a complete mask working under positive pressure.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

If safety conditions permit, stop or contain the leak at source. Avoid direct contact with the released material. Stay windward. In the event of large spills, warn residents of leeward areas. Remove uninvolved personnel from the spill area. Warn emergency teams. Except in the case of small payments, the feasibility of the interventions must always be evaluated and approved, if possible, by qualified and competent personnel in charge of managing the emergency. Eliminate all sources of ignition if safety conditions allow (e.g. electricity, sparks, fires, torches).

When the presence of dangerous amounts of H2S in the spilled/spilled product is suspected or ascertained, additional or special actions may be indicated, such as the limitation of access, the use of special personal protective equipment, the adoption of specific procedures and the training of personnel. If required, communicate the event to the competent authorities in accordance with the applicable legislation, particularly in the case of prolonged storage. This situation is particularly relevant for operations involving direct exposure to vapors in the tank.

The spillage of a limited quantity of product, particularly in the open air where the vapours disperse faster, is a dynamic situation that is likely to limit exposure to dangerous concentrations. Since H2S has a higher density than ambient air, a possible exception may be the accumulation of dangerous concentrations in specific places such as ditches, depressions or enclosed spaces. In all these circumstances, however, the assessment of the correct intervention to be taken must be carried out on a case-by-case basis.

6.1.2 For emergency personnel

Large spills: total protection garment resistant to chemical agents and made of antistatic material. If necessary, heat-resistant and heat insulated. Full-length, fireproof, and heat-resistant suit, compliant with EN ISO 11612 and EN 1149-5 standards. Heat-resistant gloves with long sleeves, compliant with EN 388, EN 407, or applicable standards. Work gloves (preferably half-arm gloves) that provide adequate resistance to chemical agents. Gloves made of PVA (polyvinyl alcohol) are not water resistant and are not suitable for emergency use. If contact with the hot product is possible or foreseeable, the gloves must be heat resistant and thermally insulated. Protective helmet. Antistatic and non-slip safety shoes or boots resistant to chemical agents. Goggles or face protection equipment if splashes or contact with eyes are possible or foreseeable.

Respiratory protection: A half-mask or a whole mask equipped with an organic vapour filter(s) (and H2S, where applicable) or a stand-alone respirator may be used depending on the extent of the spillage and the foreseeable level of exposure. In the event that the situation cannot be fully assessed or if there is a risk of oxygen starvation, use only an autonomous respirator.

When the presence of dangerous amounts of H2S in the spilled/spilled product is suspected or ascertained, additional or special actions may be indicated, such as the limitation of access, the use of special personal protective equipment, the adoption of specific procedures and the training of personnel. If required, communicate the event to the competent authorities in accordance with the applicable legislation, particularly in the case of prolonged storage. This situation is particularly relevant for operations involving direct exposure to vapors in the tank. The spillage of a limited quantity of product, particularly in the open air where the vapours disperse faster, is a dynamic situation that is likely to limit exposure to dangerous concentrations. Since H2S has a higher density than ambient air, a possible exception may be the accumulation of dangerous concentrations in specific places such as ditches, depressions or enclosed spaces. In all these circumstances, however, the assessment of the correct intervention to be taken must be carried out on a case-by-case basis.

6.2 Environmental precautions

Prevent the product from ending up in sewers, rivers or other bodies of water.

6.3 Methods and material for containment and cleaning up

Leaks and spills are formed from hot liquefied material, with the risk of severe burns; Solidified product can clog manholes and sewers.

Spreading on the ground: If necessary, stem the product with dry earth, sand or other non-flammable material. Let the hot product cool naturally. If necessary, use nebulized water with caution to help cooling. Do not direct jets of foam or water on the spill of molten product to avoid splashing. Inside buildings or enclosed spaces, ensure appropriate ventilation. Collect the solidified product by appropriate means (e.g. shovels).

Collect the recovered product and other materials in appropriate tanks or containers, for recycling or safe disposal. Transfer the product and other contaminated materials collected into appropriate tanks or containers for recycling or safe disposal.

Spreading in water: the product cools quickly, becoming solid. The product in the solid state is denser than water, sinks slowly and lies on the bottom, making any type of intervention normally impractical. If possible, contain the product. Contain the contaminated product and materials using mechanical means.

The recommended measures are based on the most likely spill scenarios for this product. Local conditions (wind, air temperature, direction and speed of waves and currents) can, however, significantly influence the choice of action to be taken. Consult, therefore, local experts if necessary.

6.4 Reference to other sections

For more information about personal protective equipment, please refer to the section 8 "Exposure control and personal protection".

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

7.1.1 Protective measures (containment and preventive measures)

Ensure that all provisions regarding product management and storage facilities are properly complied with. Avoid contact of the hot product with water: risk of splashes generated by the hot material.

The product may release H2S (hydrogen sulfide): carry out a specific assessment of the inhalation risks arising from the presence of hydrogen sulfide in the free spaces of tanks, in confined spaces, in product residues and surpluses, in tank waste and waste water, and in all situations of unintentional release, to determine the best means of control according to local conditions.

Before entering storage tanks and commencing any operation in a confined area, like opening truck tanks, check the atmosphere for oxygen content, hydrogen sulphide (H2S) and flammability. H2S has a density greater than air, therefore H2S will concentrate in low points (especially when poorly ventilated) and concentration is likely to increase towards the bottom of the space. Bitumen truck tank´s atmosphere should be checked carefully from manhole down to the bottom, for example using an H2S detector attached by a wire before entering, even after careful ventilation. Use adequate personal protective equipment as needed.

Ensure the grounding of the container and receiving equipment. Do not breathe the fumes generated by the hot product. Use appropriate personal protective equipment if necessary. Do not use compressed air during filling, unloading or handling operations. Prevent the risk of slipping.

7.1.2 General recommendations on occupational hygiene

Make sure that adequate cleaning measures are taken (housekeeping). Contaminated material must not accumulate in the workplace and should never be stored in your pocket. Keep away from food and drink. Do not eat, drink or smoke while using the product. Wash your hands thoroughly after handling. Do not reuse contaminated clothing. Do not use solvents or other products with a degreasing effect on the skin.

7.2 Conditions for safe storage, including any incompatibilities

The structure of the storage area, the characteristics of the tanks, the equipment and the operating procedures must comply with the relevant legislation at European, national or local level. Storage facilities must be equipped with appropriate systems to prevent contamination of soil and water in the event of leaks or spills. Store and handle at the lowest possible temperature to avoid the formation and exposure to fumes. The activities of cleaning, inspection and maintenance of the internal structure of the storage tanks must be carried out by qualified and properly equipped personnel, as established by national, local, or company regulations. Before entering the storage tanks and starting any type of intervention in a confined space, check the atmosphere and check the oxygen content, the presence of hydrogen sulfide (H2S) and the degree of flammability.

Store separately from oxidizing agents. Store in a well-ventilated place.

Use mild steel or stainless steel for containers and coatings. most synthetic materials are not suitable for containers or coatings due to the low degree of heat resistance.

If the product is supplied in containers, store only in the original containers or in containers suitable for the type of product. The hot product should never be transferred to the containers without first checking that the container is completely dry. Empty containers may contain combustible product residues. Do not weld, braze, drill, cut or incinerate empty containers unless they have been properly reclaimed.

Do not exceed maximum handling and storage temperatures, refer to attachment in this section “Updated Eurobitume Technical Guidance on Maximum Safe Handling Temperatures for Bitumen (Paving and Industrial)”. The current recommended maximum temperatures for bitumen & Air-Rectified bitumen are 200°C and for Severely Oxidised bitumen 230°C, respectively. Use above these temperatures is advised against.

H_2S in tank headspaces may reach hazardous values, especially in case of prolonged storage. This situation is especially relevant for those operations which involve direct exposure to the vapours in the tank. Empty containers may contain combustible product residues. Do not weld, solder, drill, cut or incinerate empty containers, unless they have been properly cleaned.

7.3 Specific end use(s)

Road pavement, membranes, sheaths, protective, waterproofing, sealants.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure limit values Asphalt (Bitumen fumes):

ACGIH 2025

TLV-TWA®: 0.5 mg/m^3

BEI (Refer to PAH BEI): 1-Hydroxypyrene-(1-HP) in urine f.t.f.s.l (end of shift working weekend): 2.5µg/l;

3-Hydroxybenzo(a)pyrene in urine f.t.f.s.l (end of shift working weekend): non-quantitative.

Limit values for hydrogen sulphide exposure:

ACGIH 2025:

TLV®-TWA: 1 ppm; 1,4 mg/m^3

TLV®-STEL: 5 ppm; 7 mg/m^3

Dir 98/24/EC and further amendments

8 hours: 7 mg/m^3; 5 ppm

Short term: (4 hours): 14 mg/m^3; 10 ppm

Monitoring procedures: refer to national regulations or good industrial hygiene practices.

DNEL (Derived No-Effect Level) of Bitumen

Workers

DNEL long-term inhalation (local effects): 2.88 mg/m^3/8h (repeated dose toxicity)

General population

DNEL long-term inhalation (local effects): 0.61 mg/m^3/24h (repeated dose toxicity)

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Minimize exposure to mists/vapours/aerosols. When handling the hot product in confined spaces, ensure effective ventilation. Before entering the storage tanks and starting any type of intervention in a confined space, check the atmosphere and check the oxygen content, the presence of hydrogen sulfide (H2S) and the degree of flammability.

Provide emergency showers and eye wash stations.

8.2.2 Individual protection measures, such as personal protective equipment

a) Eye/face protection:

Protective screens are advisable for operations that provoke splashes. Helmet with nape protection. Wear goggles (UNI EN 166).

b) Skin protection:

(i) Hand protection

In the absence of containment systems and in case of possibility of contact with the skin, use gloves with high cuffs resistant to hydrocarbons, internally plush and thermally insulated if necessary. Materials presumably suitable: nitrile, PVC or PVA (polyvinyl alcohol) with a chemical protection index of at least 5 (permeation time > of 240 minutes). Use gloves in accordance with the conditions and limits set by the manufacturer. In the case, refer to the UNI EN 374 standard. Gloves must be periodically inspected and replaced in case of wear, perforation or contamination.

(ii) Other

Wear protective clothing during operations involving hot material, heat-resistant clothing (with trousers over boots and sleeves over the cuff of gloves), heat-resistant and non-slip heavy boots (e.g., leather) (EN 943-13034-14605) based on chemical agents. In case of counting of clothing, replace and clean them immediately.

c) Respiratory protection:

If the exposure of workers is, or may be, higher than the exposure levels established for the working position, wear respirator in accordance with UNI EN14387: 2021 with filter type A (organic vapors)/P2 or higher.

Alarmed monitors for H2S are recommended.

In the absence of containment systems:

In places where hydrogen sulfide can accumulate, use approved respiratory protection devices: whole masks equipped with a type B filter cartridge (gray for inorganic vapors, H2S included), or autonomous respirators (UNI EN 11719: 2025).

If it is not possible to determine or estimate exposure levels with good certainty or if it is possible that oxygen deficiency may occur, use only a stand-alone respirator.

d) Thermal hazards: see point b above**.**

e)

8.2.3 Environmental exposure controls

Do not release into the environment. Storage facilities must be equipped with appropriate systems to prevent contamination of soil and water in the event of leaks or spills.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Data refers to the component Bitumen (EC: 232-490-9; CAS: 8052-42-4)

(a)physical state	Solid
b)color	blackish
c)odour	characteristic hot, cold odorless
(d) melting point/freezing point	For complex hydrocarbon substances like bitumen, a melting point is not a meaningful parameter, since they become gradually softer as the temperature rises. ≥ 30 °C and ≤ 128 °C (EN 1427) (ASTM D36, Concawe)
(e) boiling point or boiling starting point and boiling range	406.2 °C 406.2 - 542.8 °C (Test Report N°: GE10-01308.001)
(f) Flammability	Non-flammable
(g) lower and upper explosive limit	Data not available
(h) flash point	>150°C based on registrant data
(i) auto-ignition temperature	>400 °C (ASTM 659 TOTAL, 1979; Shell 2003).
(j) decomposition temperature	Data not available
(k) pH	Data not available
(l) kinematic viscosity	> 1000 mm2/s a 60°C (EN 12595 Concawe 2010a)
(m) solubility	2.69E-12 – 1.99 mg/l (calculated range-QSAR)
(n) partition coefficient n-octanol/water (logarithmic value):	5.4-18.2 (calculated range-QSAR for Bitumen)
(o) vapour pressure	<< 0.1 kPa at 20°C
(p) density and/or relative density	0.990 to 1.100 at 25 °C (EN ISO 12185/EN ISO 3838/EN 15326)
(q) relative vapour density	Data not available
(r) particle characteristics	Not applicable

9.2 Other information

9.2.1. Information with regard to physical hazard classes

No chemical group associated with the molecules contained with oxidizing properties. Based on the chemical structure, the mixture is not able to react exothermically with combustible materials.

9.2.2.Other security features

The product does not possess dangerous properties that require mention.

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

The mixture has no additional reactivity hazards than those listed in the following subtitles

10.2 Chemical stability

The asphalt is normally stored and manipulated at temperatures above 100 ° C, and contact with water causes a violent expansion with the danger of splashing and boiling.

10.3 Possibility of hazardous reactions

A mixture with nitrates or other strong oxidants (such as chlorates, perchlorates and liquid oxygen) can generate an explosive mass. Sensitivity to heat, friction and shock cannot be assessed in advance.

10.4 Conditions to avoid

Excessive heating to a temperature above the recommended temperature causes alterations of the product and the development of flammable fumes. Do not use above the maximum recommended temperatures (200 °C).

10.5 Incompatible materials

Avoid contact of the molten product with water or other liquids. Avoid contact with oxidizing substances. Avoid contact of hot bitumen with water. Avoid oil and bitumen contamination of thermal insulation materials and the accumulation of oily residues or similar material near hot surfaces and replace the thermal insulation coating, where necessary, with a non-absorbent insulator. The phenomenon of self-heating and subsequent self-ignition of surfaces of porous or fibrous material impregnated with oil or bitumen, can also occur at a temperature of only 100 ° C.

10.6 Hazardous decomposition products

Confined spaces: Since hydrogen sulfide (H2S) has a higher density than ambient air, a possible exception may be the accumulation of dangerous concentrations in specific places such as ditches, depressions or enclosed spaces.

Incomplete combustion could generate a complex mixture of airborne solid and liquid particles and gases, including carbon monoxide, H2S (hydrogen sulfide), SOx (sulfur oxides), H2SO4 (sulfuric acid), and other unidentified organic and inorganic compounds.

SECTION 11. TOXICOLOGICAL INFORMATION

There are no experimental studies of the mixture itself. Therefore, we examined the concentration of each component to assess toxicological effects resulting from exposure to the product. Data refers to the component Bitumen (EC: 232-490-9; CAS: 8052-42-4)

Complex substances such as bitumen do not lend themselves to kinetic toxic analysis. However, the toxicokinetics of some individual components, such as polycyclic aromatic hydrocarbons (PAHs) have been studied in detail. For humans, the main routes of exposure to bitumen are inhalation and the skin pathway. The main potential absorption sites of bitumen PAHs in humans are the lungs and respiratory system, after exposure by inhalation to bitumen fumes, and the skin, due to contact with pure bitumen or fumes condensed by bitumen.

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

The distribution of PAHs throughout the body has been studied in rodents. These studies have shown that a low level of PAHs can be found in internal organs, especially in adipose tissue.

In general, PAHs are eliminated by urine or biliary route.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

a) Acute toxicity

Oral

Acute oral toxicity of bitumen has been evaluated in some rat studies These studies have shown an acute oral LD50 of more than 5 g/kg which does not result in any classification under the CLP Regulation.

Below is a summary of the most representative studies of the Registration Dossier.

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

inhalation

Rat studies are available to assess the acute inhalation toxicity of bitumen.

These studies revealed a high acute inhaled LC50 that does not involve any classification under hazardous substances regulations.

Below is a summary of the most representative studies of the Registration Dossier

Method	Result	Comments	Source
RAT M/F Vapors (nose only) OECD Guideline 403	CL50: > 94.4 mg/m³ (M/F)	Key study Read-across CAS 64742-93-4 Aerosol of condensed fumes of oxidized bitumen	Fraunhofer Institute of Toxicology and Aerosol Research (2000)

Dermal

Acute dermal toxicity of bitumen has been evaluated in studies in rabbits. These studies revealed an acute cutaneous LD50 of more than 2 g/kg which does not involve any classification under the CLP Regulation.

Below is a summary of the most representative studies of the Registration Dossier.

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 by American Petroleum Institute

Based on the available information, the classification criteria for this endpoint are not met.

b) Skin corrosion/irritation

The potential skin irritation of bitumen has been tested in some studies conducted on rabbits. The conclusions of these studies indicate the absence of skin irritation.

These results do not lead to any classification under the CLP Regulation. Based on the available data, the classification criteria for this endpoint are not met.

Below is a summary of the most representative studies of the Registration Dossier:

Method	Result	Comments	Source
RABBIT Occlusive bandage OECD Guideline 404	Non-irritating Average Erythema score: 0.2 of max. 4 (intact skin) 0 of max. 4 (intact skin)(72h) Edema Index: 0.2 of max. 4 (intact skin)	Key study CAS 64741-56-6	American Petroleum Institute (API) 1982a

Based on the available information, the classification criteria for this endpoint are not met.

c) Serious eye damage/irritation

The eye irritation potential of bitumen has been tested in some studies conducted on rabbits

All studies have shown no eye irritation, so no classification of the substance is necessary.

Below is a summary of the most representative studies of the Registration Dossier

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

Based on the available information, the classification criteria for this endpoint are not met.

d) Respiratory or skin sensitisation

Respiratory sensitization

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

Skin sensitization

Some studies are available to test the sensitization potential of bitumen.

The results obtained from these studies indicate the absence of skin sensitisation potential, therefore no classification of the substance is necessary. Based on the available data, the classification criteria for this endpoint are not met.

A summary of the most representative studies of the Registration Dossier is reported below

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

Based on the available information, the classification criteria for this endpoint are not met.

e) Germ cell mutagenicity

The potential mutagen of bitumen has been extensively studied in a series of in vivo and in vitro tests. It should be noted that for the Ames test the OECD 471 test standard is not suitable for UVCB petroleum substances, as it tends to give false negatives for these substances. For this reason, the oil industry has developed a modified Ames test. Most studies have not shown consistent evidence of mutagenic activity, so there is no classification under the CLP Regulation.

Below is a summary of the most representative studies of the Registration Dossier:

In vitro studies:

Method	Result	Comments	Source
Ames test with and without metabolic activation S. typhimurium T98, T100, YG 1041, YG 1042 OECD Guideline 471 (Bacterial Reverse Mutation Assay)	negative - with metabolic activation positive - with metabolic activation	Key study Condensates of bitumen fumes CAS 8052-42-4 / 8052-42-4	De Meo, M., Genevois, C., Brandt, H, Laget, M., Bartsch, H., Castegnaro, M. (1996)

In vivo studies:

Method	Result	Comments	Source
In vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus - Type of genotoxicity: DNA damage and/or repair RAT (M/F) Doses / Concentrations: 0, 4, 20, 100 mg/m^3 OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)	Genotoxicity: negative Toxicity: no effects	Key study Read Across	Halter R, Hansen T, Seidel A, Ziemann C, Borlak J (2007)
Transgenic mutagenicity test in animals RAT (males) Route of administration: inhalation of vapours Servings: 100, mg/^{m3} (total hydrocarbons)	Negative	Key study CAS 8052-42-4	Bottin, M.C., Gate, L., Rihn, B., Micillino, J.C., Nathalie, M., Martin, A., Hunge, H., Morel, G., Wrobel, R., Ayi-Fanou, Champmartin, C., Keith, G, and Binet s. 2006

Based on the available information, the classification criteria for this endpoint are not met.

f) Carcinogenicity

Some carcinogenicity studies are available for the inhalation and skin exposure pathways. For the inhalation route, the available study did not detect any carcinogenic effects. In a key dermal cancer study (Clark et al 2011), there was no evidence of a carcinogenic effect following daily skin application of a paving bitumen fume condensate in mice for 2 years.

For skin exposure, some animal studies report weak activity. It should be noted that the presence of solvents used in the administration of bitumen clearly increases bioavailability and/or dermal absorption.

In two epidemiological studies on workers exposed to asphalt, it was not possible to find a causal link between exposure to bitumen fumes and the risk of lung cancer.

On the basis of an overall assessment of the results of the key and supporting animal studies, and of the two key epidemiological studies, it was concluded that there is no evidence to support that bitumen presents a carcinogenic risk under normal conditions of use by skin or inhalation.

Based on the available data, the classification criteria for this endpoint are not met.

Method	Result	Comments	Source
RAT - (M/F) Inhalation (nose only) Exposure: 104 weeks (6 hours a day for 5 days a week) Servings: 0, 4, 20, or 100 mg/^{m3} OECD Guideline 451	NOAEC (carcinogenicity): 103.9 mg/m³ air (analytical) (adjusted value for neoplastic histopathologists: 172.5 mg/m3) Neoplastic effects: no effect	Key study Read-across CAS: 64742-93-4 With condensates of oxidized bitumen fumes	Fraunhofer (2006) Fuhst et al. (2007)"
MOUSE Doses / Concentrations: 37.5 µL twice weekly (weekly dose of 75 µL) Exposure: 24 months	Skin tumour incidence: No tumours were observed	Key study CAS:64741-56-6 CAS: 8052-42-4	Clark C.R et al 2011
MOUSE (M/F) Doses / Concentrations: One drop Twice weekly	Incidence of skin cancer: 0% for the first two types of asphalt 4% for the third type of asphalt 2% for the fourth type of asphalt 2% for the fifth type of asphalt	supporting study (5 types of asphalt)	Hueper, W.C., Payne, W.W. (1960)

Based on the available information, the classification criteria for this endpoint are not met.

g) Reproductive toxicity

Two reproductive toxicity studies are available, one on fertility and one on development (summarised in the following tables). The currently available data are not of concern with regard to the classification of bitumen as toxic to reproduction or development under the CLP Regulation. A repeated dose toxicity study of bitumen is also available, showing no harmful effect of the substance on the weight and morphology of the reproductive organs following dermal exposure.

Fertility toxicity study:

Method	Result	Comments	Source
RAT - M/F Reproductive toxicity study - 2 generations Doses: 50, 250, or 1000 mg/kg/day Oral administration (gavage) Vehicle: Corn oil Exhibition: males and females: for the F0 and F1 generation, daily for 70 days before mating. The evidence was administered to the selected offspring to become the F1 parental generation after weaning, starting on the postnatal day.	First parental generation (P0)/second parental generation (P1)/ F1 generation: NOAEL (P0): 1000 mg/kg body weight/day (no adverse effects) F2 generation/ General reproductive toxicity: the lowest effective dose/concentration has not been identified	Support studio Read-across With Distillates (Fischer-Tropsch), heavy, C18-50 – branched, cyclic and linear (CAS 848301-69-9)	B. Faiola (2011)

O males of generation F0 and F1 continued to receive the object of the test during mating and throughout the day before euthanasia. Generation F0 and F1 females continued to receive the substance during mating, gestation, lactation and throughout the day before euthanasia. The offspring of generations F0 and F1 (F1 and F2 litters, respectively) were potentially exposed to the test article in utero and through lactation (pre-natal day 0 to 21). F1 puppies selected as parents for the F2 generation (25 / sex / group) received the object of the test after weaning (starting from the day before Christmas 22) US EPA Health Effects Test Guideline OPPTS 870.3800 and OECD Guidelines for the Testing of Chemicals, No, 416 "Two-Generation Reproduction Toxicity Study".)			

Developmental toxicity study:

Method	Result	Comments	Source
RAT - M/F Repeated toxicity study combined with reproductive/developmental toxicity Doses: 0, 3050, 150, 500 mg/m3 Inhaled administration (nose only – rats were exposed to a mixture of bitumen fume vapors and aerosols in a direct flow nose-only inhalation exposure system) Exhibition: 6 hours a day OECD Guideline 414 (Prenatal Developmental Toxicity Study)	Maternal animals: NOAEL: 50 mg/m3 Fetuses: no effects of foetal abnormalities were observed NOAEL: 150 mg/m3 General developmental toxicity: YES Lowest effective dose/concentration: 150 mg/L in relation to maternal toxicity: reproductive effects as a non-specific secondary consequence of other toxic effects	Key study Aerosol of asphalt fumes (CAS 8052-42-4)	Fraunhofer Institute for Toxicology and Experimental Medicine (2017)

Repeated dose toxicity study for reproductive organs:

Method	Result	Comments	Source
Dermal exposure of a vacuum residue (API 81-13) on rabbit M/F DOSES: 0, 200, 1000, 2000 mg/kg, applied by gauze and kept in contact with the skin for 6 hr, 3 days/week or for 4 weeks	No effect on seminal vesicles, testicles, epididymis, prostate, ovaries, uterus and vagina	Asphalt (CAS 64741-56-6)	API 1983 a and b

Based on the available information, the classification criteria for this endpoint are not met.

h) STOT-single exposure

No information is available on specific toxic effects for particular target organs following single exposure.

Numerous occupational exposure studies have evaluated acute and chronic lung irritation and function in correlation with

exposure to bitumen fumes (EC 232-490-9).

Effects on acute and (sub)chronic respiratory inflammation and lung function in bitumen workers were conducted by Hansen, 1991; Norseth 1991; Bergdahl 2004; Randem 2004; Tepper 2006; Ulvestad 2007; Ulvestad 2017, but due to co-exposure to a variety of other chemicals (e.g. benzene, coal tar, tobacco) the symptoms cannot be directly attributed to bitumen fumes. Furthermore, a consistent association between acute and chronic clinical effects on lung or respiratory function and irritation following exposure to bitumen fumes was not observed in additional human studies conducted by Gamble 1999; Watkins 2002; Burstyn 2003; Randem 2003; Breuer 2011; Marczynski 2011; Fishing 2011; Raulf-Heimsoth 20011a, 2011b, 2011c; Rihs 2011; Spickenheuer 2011; Welge 2011). The qualitative evaluation of these epidemiological studies confirms that the substance does not meet the criteria for CLP classification.

i) STOT-repeated exposure

Oral repeated toxicity studies on bitumen are not appropriate as the main routes of exposure for humans are inhalation and cutaneous. In all inhaled and dermal studies, there were no adverse systemic effects even at the higher doses administered, so bitumen is not classified as hazardous for this end-point under hazardous substances regulations.

Below is a summary of the most representative studies of the Registration Dossier:

Method	Result	Comments	Source
Inhalation			
RAT - (M/F) Combined repeated dose (chronic) toxicity and carcinogenicity study Doses: 4, 20, or 100 mg/m3 Exposure: 2 years (6 hours per day for 5 days per week (except during holidays) according to OECD Guideline 451	NOAEC - Local effects: 17.2 mg/m3 (calculated) (male/female) Based on lack of upper respiratory tract histopathology; 17.2 mg/m³ adjusted LOAEC - Local effects: 34.4 mg/m3 (calculated) (male/female) Based on upper respiratory tract histopathology; 34.4 mg/m³ adjusted	Key study Reliable without restrictions Read across Aerosol of fume condensate	Fuhst (2006)

	NOAEC - Systemic effects: >172.5 mg/m3 (calculated) (male/female) No treatment related findings. 172.5 mg/m³ adjusted		
Cutaneous			
RAT (Male/female) Subacute 28 days (3 times a week for 6 hours at a time) Doses: 200, 1000, or 2000 mg/kg/day OECD Guideline 410	LOAEL (topical effects): 200 mg/kg/day (based on the absence of significant histopathological results) NOAEL (systemic effects): 2000 mg/kg/day (based on body weight data in the absence of significant histopathological results)	Key study CAS 64741-56-6	American Petroleum Institute (API) 1983a

Based on the available information, the classification criteria for this endpoint are not met.

j) Aspiration hazard:

Taking into account the estimated or measured viscosity value for asphalt, the substance is not classified for the danger of aspiration into the lungs.

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

The mixture is not is not classified for endocrine disruption to health due to lack of data.

11.2.2. Other information

Not available.

SECTION 12. ECOLOGICAL INFORMATION

No information is available on the mixture as such. Below is the information relating to the main component Bitumen

12.1 Toxicity

Below is a summary of the most representative studies of the Registration Dossier of the main component Bitumen:

Endpoint	Result	Comments
	Aquatic toxicity	
Invertebrates Daphnia magna Short term	LL50 48/hour > 1000 mg/l	Key study Redman Et al (2010b) QSAR
Invertebrates Daphnia magna Long term	NOAEL 21/day: ≥ 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/hour: > 1000 mg/l	Key study Redman Et al (2010b) QSAR
Fish Long term Oncorhynchus mykiss	LL50 28 /day: > 1000 mg/l NOEL 28/day ≥ 1000 mg/l	Key study Redman Et al (2010b) QSAR

Based on the available data, the classification criteria cannot be met.

12.2 Persistence and degradability

Abiotic degradability

Hydrolysis: The components of bitumen are resistant to hydrolysis due to the lack of a functional group that is hydrolytically reactive. Therefore, this process will not contribute to a measurable loss of degradation of the substance in the environment.

Photolysis in the air: This endpoint is not required by REACH.

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

Biotic degradability

Standard tests for this endpoint are not applicable to UVCB substances.

The following Biodegradation values were calculated by QSAR for UVCB constituents:

Water: range of 1.74-165496 days.

Sediments: range of 1.74 - 661986 days

Soil: range of 1.74-165496 days

12.3 Bioaccumulative potential

Standard tests for this endpoint are not applicable to UVCB substances.

A BCF for aquatic-fish species of 0.4-2472 L/Kg was calculated by QSAR for UVCB constituents.

12.4 Mobility in soil

Koc absorption: Standard tests for this endpoint are not applicable to UVCB substances.

A Log Koc of 4.47-14.70 was calculated by QSAR for the constituents of UVCB.

12.5 Results of PBT and vPvB assessment

The mixture does not meet the PBT or vPvB classification criteria set out in Annex XIII of Regulation (EC) No. 1907/2006 and s.m.i. (REACh) and Annex I of Regulation 1272/2008 and s.m.i. (CLP).

12.6. Endocrine disrupting properties

The mixture is not classified for endocrine disruption to the environment due to lack of data.

12.7 Other adverse effects

is not classified as PMT and/or vPvM due to lack of data.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

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

For the disposal of waste deriving from the product, including empty containers not reclaimed, compliant with the national regulation.

European Waste Catalogue Code: 05 01 17, the code indicated is only a general indication, based on the original composition of the product and the intended uses.

The user (producer of the waste) is responsible for choosing the most appropriate code based on the actual use of the product, any alterations and contaminations. The product as such does not contain halogenated compounds.

Disposal of containers: Do not disperse containers in the environment. Dispose of according to local regulations.

Do not drill, cut, grind, weld, braz, burn or incinerate unreclaimed empty containers or drums.

SECTION 14. TRANSPORT INFORMATION

14.1 UN number or ID number

3257

Note: The product is classified as a dangerous good only if it is transported melted at a temperature > 100 °C but below its flash point.

14.2 UN proper shipping name

ELEVATED TEMPERATURE LIQUID, N.O.S., (molten oxidized asphalt)

14.3 Transport hazard class(es)

Road/rail transport (ADR/RID)	Class: 9, M9
	Tunnel Restriction Code: D
Maritime Transport (IMDG)	Class 9
Air transport (IATA)	Class 9
	Carriage is prohibited on both cargo and passenger flights

Note : Cold transported bitumen, solid, is not classified

14.4 Packing group

ADR: III; Label 9 + indication "High temperature"

IMDG: III; Label 9

IATA: III; Label 9

14.5 Environmental hazards

Mixture NOT hazardous to the environment within the meaning of the ADR, RID, ADN and IMDG codes

14.6 Special precautions for user

Refer to Section 7 of the SDS, “Handling & Storage” for particular preventive measures users have to observe respectively have to fulfil in the context of transport regulations

Special provisions ADR/RID/ADN : 274, 643, 668

Special provisions: 232, 274

SEm: F-A, S-P

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- Title VII Authorization pursuant to reach Regulation (EC Reg. no. 1907/2006): not subject to authorization
- Title VIII Restrictions pursuant to reach Regulation (EC Reg. no. 1907/200.): not subject to restriction

Other EU legislation and national transpositions:

- Category Seveso ((Dir. 2012/18/UE): not applicable
- Dir. 98/24/EC: Non-hazardous chemical agent
- Dir. 97/42/EC and 99/38/EC: not applicable as it is not carcinogenic

15.2 Chemical safety assessment

A chemical safety assessment was carried out for the main Bitumen component

As the Bitumen is not classified as hazardous to health and the environment, no exposure assessment or risk characterisation is required. Therefore, there is no need to process exposure scenarios.

SECTION 16. OTHER INFORMATION

List of relevant hazard statements and notes :

Not present.

Advice on any training appropriate for workers:

Adequate training of workers potentially exposed to this mixture on the basis of the contents of this safety data sheet.

Main bibliographic references and data sources

Registration Dossier of Bitumen

CSR 2025 of Bitumen

Legend of abbreviations and acronyms:

ACGIH = American Conference of Governmental Industrial Hygienists

CSR = Chemical Safety Report

EC50 = Median effective concentration

IC50 = Inhibition concentration, 50%

Klimisch=Evaluation criterion for reliability of the method used.

LC50 = Lethal concentration, 50%

LD50 = Mean Lethal Dose

PBT = Persistent, Bioaccumulative and Toxic Substance

CNS=Central nervous system

STOT = Specific target organ toxicity

(STOT) RE = Repeated exposure

(STOT) SE = Single exposure

Key Study=Study of greater relevance

TLVTWA®= Threshold limit value – time-weighted average

TLVSTEL®= Threshold limit value – limit for short exposure time

UVCB=substances of Unknown or Variable composition

vPvB = very Persistent and very Bioaccumulative

Compilation date 10/07/2017

Revision date 27/09/2022

Reason for RevB of 27/09/2022: Translation of the SDS in English. Update of the SDS model according to Reg. (EU) 2020/878. Updating the content of Sections 1, 2, 3, 6, 8, 9, 11, 12, 15, 16 and preparation of the Annex.

Revision date 23/01/2023

Reason for RevC of 23/01/2023: Update of the SDS in according to Chemical Safety Report 2022, sections, 1, 8, 9, 11, 12, 16

Revision date 23/12/2025

Reason for RevD of 23/12/2025: Update of the SDS in according to Chemical Safety Report 2025, sections, 2, 6, 7, 8, 9, 11, 12, 14, 15 and 16.

ATTACHMENT

Complete list of uses of the Bitumen component

Identified use name	Life Cycle	Category of chemicals (PC)	Article Category (AC)	Process Category (PROC)	Environmental Release Category (ERC)
M1 01 – Production of the substance (not classified)	Production			1, 2, 3, 4, 8a, 8b, 9, 15, 28	1
F-4 02 - Formulation and (re)packaging of substances and mixtures (not classified)	Formulation			1, 2, 3, 4, 5, 8a, 8b, 9, 14, 15, 28	2
IW-2 01b - Use of the substance as an intermediate (not classified)	Use at industrial sites	0		1, 2, 3, 4, 8a, 8b, 9, 15, 28	6a
IW-5 03a - Use in coatings: Industrial (not classified)	Use at industrial sites	1, 9		1,2,3,4,5,7,8a,8b,9, 10,13,14,15,28	4
IW-11 19 – Rubber production and processing: Industrial (not classified)	Use at industrial sites	20, 32		1, 2, 3, 4, 5, 7, 8a, 8b, 9, 13, 14, 15, 28	4
IW-12 12a – use in fuels: Industrial (not classified)	Use at industrial sites	13		1, 2, 8a, 8b, 16, 28	7
IW-13 06a - Lubricants: Industrial (not classified)	Use at industrial sites	24		1, 2, 3, 4, 7, 8a, 8b, 9, 10, 13, 17, 18, 28	4,7
IW-18 05aON - Use in Oil and Gas field drilling and production operations: Industrial onshore (not classified)	Use at industrial sites	41		1, 2, 3, 4, 8a, 8b, 9, 28	4
IW-19 05aOFF - Use in Oil and Gas field drilling and production operations: Industrial offshore (not classified)	Use at industrial sites	41		1,2,3,4,8a,8b,9,28	4
PW-6 03b - Uses in Coatings: Professional (not classified)	Widespread use by professional operators	1, 9a		1,2,3,4,8a,8b,10,11, 13,15,19,28	8a,8d
PW-10 15 - Road and construction applications: Professional (not classified)	Widespread use by professional operators	0, 1, 9b		1,2,8a,8b,9,10,11,13,28	8f
PW-14 06b - Lubricants: Professional (low environmental release) (not classified)	Widespread use by professional operators	24		1, 2, 3, 4, 8a, 8b, 9, 10, 11, 13, 17, 18, 20, 28	9a, 9b

Identified use name	Life Cycle	Category of chemicals (PC)	Article Category (AC)	Process Category (PROC)	Environmental Release Category (ERC)
PW-15 06c - Lubricants: Professional (high environmental release) (not classified)	Widespread use by professional operators	24		1, 2, 3, 4, 8a, 8b, 9, 10, 11, 13, 17, 18, 20, 28	8a, 8d
PW-16 11a - Use in Agrochemicals: Professional (not classified)	Widespread use by professional operators	12		1, 2,4, 8a, 8b, 11, 28	8a, 8d
PW-20 05bON - Use in Oil and Gas field drilling and production operations: Professional onshore (not classified)	Widespread use by professional operators	41		1,2,3,4,8a,8b,9,28	8d
PW-21 05bOFF - Use in Oil and Gas field drilling and production operations: Professional offshore (not classified)	Widespread use by professional operators	41		1,2,3,4,8a,8b,9,28	8d
C-7 03c - Uses in Coatings: Consumer (not classified)	Consumer Use	1, 9a, 9b, 9c, 15, 18, 23, 24			8a, 8d
C-22 15c - Road and construction applications: Consumer (not classified)	Consumer Use	0, 1, 9b			8f
SL-17 A15SLb - Use in Road and construction applications: Service life (Professional) (not classified)	Service life			21	10a
SL-23 A15SLc - Use in Road and construction applications: Service life (Consumer) (not classified)	Service life		0		10a