Italiana Energia e Servizi S.p.A

SAFETY DATA SHEET
BITUMEN

DATE REVISED: 30/11/2010

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

1.1 Product identity

Substance name:	Bitumen
Synonyms	Bitumen of all types
CAS number	92062-05-0
Index number	295-518-9
Registration number	01-2119498290-34-XXXX
Chemical formula	This substance is a UVCB complex, and so a molecular formula cannot be given.
Molecular weight	This substance is a UVCB complex, and so a molecular formula cannot be given.

1.2 Pertinent uses identified for the substance or mixture and uses advised against

COMMON USES: Road paving, membranes, sheaths, protective coatings, waterproofing, sealants.
USES IDENTIFIED IN THE CHEMICAL SAFETY REPORT: General list of applications:

- *Industrial use*: production of the substance, use as intermediate, distribution of the substance, formulation and (re)packaging of the substances and mixtures, use in coatings, use in drilling and forming of wells to be used to extract petroleum and natural gas, production and working of rubber;
- *Professional use*: use in coatings, use in drilling and forming of wells to be used to extract petroleum and natural gas, road and building applications, lubricants;
- *Consumers*: Use in coatings.

See Appendix 1 in section 16 for further information on the uses identified.

USES ADVISED AGAINST: The pertinent uses are listed above. Other uses are advised against unless the use is evaluated before being implemented, and it is shown that the risks connected with that use are controlled.

1.3 Information on the safety data sheet provider:

Company name	IES - ITALIANA ENERGIA E SERVIZI S.p.A.
Address	Strada Cipata, 79 (Loc. Frassino)
City / Country	46100 Mantua (Italy)
Telephone	+39.0376.3781 (24 h)
E-mail Competent technician	segreteria.direz@iesitaliana.it

1.4 Emergency telephone number:

+39.0376.3781 (24 h)

2. IDENTIFICATION OF DANGERS

Physical-chemical dangers:	No danger in terms of the classification criteria laid down in appendix I to part 2 of Regulation 1272/2008 and appendix VI of Directive 67/548/CEE, amended by Directive 2006/121/CE.
Health hazards:	No danger in terms of the classification criteria laid down in appendix I to part 3 of Regulation 1272/2008 and appendix VI of Directive 67/548/CEE, amended by Directive 2006/121/CE.
Dangers to the environment:	No danger in terms of the classification criteria laid down in appendix I to part 4 of Regulation 1272/2008 and appendix VI of Directive 67/548/CEE, amended by Directive 2006/121/CE.

2.1 Classification of the substance or mixture

Not classified

2.2 Elements of labelling

n.a.

2.3 Other dangers

Due to the product being used hot, the major danger for users is possible scalding due to contact with the molten product or its fumes. Heated bitumen gives off fumes. Even if these fumes do not present significant health dangers, normal prudence indicates limiting exposure as much as possible, using correct working procedures, and ensuring good ventilation in working spaces. Prolonged inhalation of the hot product's fumes can cause irritation of the respiratory tract. The fumes may contain hydrogen sulphide (a toxic, inflammable gas) that can accumulate to the point of reaching dangerous concentrations in storage tanks.
The product does not satisfy the criteria for PBT or vPvB classification according to appendix XIII of REACH.

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

This substance is a UVCB complex with CAS 92062-05-0/EINECS 295-518 ("Complex combination of hydrocarbons obtained by distilling the products of a thermal cracking process. It is made up mainly of hydrocarbons with a number of carbon atoms prevalently greater than C34 and an upper boiling point of approx 495°C): 100% by weight

3.2 Mixtures

n.a.

4. FIRST AID MEASURES

4.1 Description of first aid measures

Contact with the eyes: Cool the affected part with copious amounts of water for at least 5 minutes, and continue to rinse. Do not make any attempt to remove the bitumen. Seek medical attention if eye irritation, blurred sight or swelling develops and persists.
Immediately cool the affected part with running water for at least five minutes. Do not make any attempt to remove the bitumen. Transport the victim to hospital urgently.

Contact with the skin: 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. After cooling do not attempt to remove the layer of bitumen from the skin as it provides sterile protection of the scalded part. The layer will come away spontaneously when the skin heals after some time. If necessary, the bitumen can be softened and them removed using swabs soaked in vegetable oil and vaseline. No attempt must be made to remove the bitumen adhering to the skin at the worksite. 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. Immediately call in a medical physician.
For minor burns, cool the affected part. Hold the burnt area under cold running water for at least five minutes, or until the pain subsides. Body hypothermia must be avoided. Do not put ice on the burn. Do not attempt to remove portions of clothing attached to burnt skin but cut round them. First aiders should never use petrol, kerosene or other solvents for washing of contaminated skin. Seek medical attention in all cases of serious burns.

Ingestion/aspiration: Improbable means of exposure.

Inhalation: In case of irritation due to exposure to high concentrations of fumes, take the victim to a non-polluted environment. Obtain medical advice. immediately transfer the victim to hospital. In case of illness due to exposure to sulphurated hydrogen, immediately take the victim out into open air, using suitable safety measures for the rescuers, and urgently seek medical assistance. Immediately begin artificial respiration if breathing has stopped. Administer oxygen if necessary. Monitor breathing and pulse rate. If the victim is unconscious and is not breathing keep them in a safe position on their side. Administer oxygen if necessary.

4.2 Principal symptoms and effects, both acute and delayed

No symptoms in case of contact with the product at ambient temperature. Slight eye irritation. Contact with hot product may cause severe thermal burns.

4.3 Indication of possible need to immediately consult a physician and special treatment

Seek medical attention in all cases of serious burns.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing means

Small size fires: earth or sand, carbon dioxide, foam, or dry chemical powder. Large size fires: foam, atomised water. Note: the use of a diffused water jet (atomised water) is reserved to specifically trained personnel. Other inert gases (subject to regulations).
Unsuitable extinguishing means Do not use water jets aimed at the product that is burning, as this may cause splashing and spread the fire. Simultaneous use of foam and water on the same surface is to be avoided as water destroys the foam.

5.2 Special dangers arising from the substance or mixture

Contact between the hot product and water generates violent expansion as the water is turned into steam, This can cause splashing of hot product or damage to or complete loss of the the roof of the tank. Respiratory problems or nausea are caused by excessive

exposure to the fumes generated by the hot product.
Incomplete combustion could generate a complex mixture of solid and liquid particles dispersed in the air and gas, including CO (carbon monoxide), H2S (hydrogen sulphide), SOx (sulphur oxides), or H2SO4 (sulphuric acid), and unidentified organic and inorganic compounds.

5.3 Recommendations for those extinguishing the fires

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.

6. MEASURES IN CASE OF ACCIDENTAL RELEASE

6.1 Personal precautions, protective equipment, and procedures in case of emergency

Stop or contain leak at the source, if safe to do so. Avoid direct contact with released material. Stay upwind. In case of large spillages, alert occupants in downwind areas. Keep non-involved personnel away from the area of spillage. Alert emergency personnel. Excepting for cases of small spillages, the feasibility of any actions should always be assessed and advised, if possible, by a trained, competent person in charge of managing the emergency. Eliminate all ignition sources if safe to do so (e.g. electricity, sparks, fires, flares). When the presence of dangerous amounts of H2S around the spilled/leaked product is suspected or proved, additional or special actions may be warranted, including access restrictions, use of special protection equipment, procedures and personnel training. If required, notify relevant authorities according to all applicable regulations.
Large spillages: full body suit of chemically resistant and antistatic material. If necessary heat resistant and insulated. Work gloves (preferably gauntlets) providing adequate chemical resistance. Gloves made of PVA (polyvinyl alcohol) are not water-resistant, and are not suitable for emergency use. If contact with hot product is possible or anticipated, gloves should be heat-resistant and thermally insulated. Work helmet. Anti-static and non-slip safety shoes or boots that are resistant to the chemical agents. Goggles and /or face shield, if splashes or contact with eyes is possible or anticipated. Respiratory protection: A half or full-face respirator with an organic vapour (and H2S where applicable) filter(s), or a Self-Contained Breathing Apparatus (SCBA) can be used according to the extent of spill and foreseeable amount of exposure. If the situation cannot be completely assessed, or if an oxygen deficiency is possible, only SCBA's should be used.

6.2 Environmental precautions

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

6.3 Methods and materials for containment and cleaning up

Leaks and spillages will consist of molten hot material with risk of severe burns. Solidified product may clog drains and sewers.
Spilling on the ground: If necessary contain the product with dry earth, sand or similar non-combustible materials. Let hot product cool down naturally. If necessary, cautiously use water mist to help the cooling. Do not direct jets of foam or water on the spilled molten product, as this may cause splattering. When inside buildings or closed spaces, ensure adequate ventilation. Gather the solidified product using suitable means (e.g. shovels).
Collect recovered product and other materials in suitable tanks or containers for recovery or safe disposal. Transfer collected product and other contaminated materials to suitable containers for recovery or safe disposal.
Spilling in water: the product cools quickly and becomes solid. The solid product is denser than water and will slowly sink to the bottom, and usually no intervention will be feasible. If possible, contain the product. Contain the product and contaminated materials with mechanical means.
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. For this reason, local experts should be consulted when necessary.

6.4 Reference to other sections

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

6.5 Other information

Concentration of H2S (hydrogen sulphide) 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.
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. 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. In all these circumstances, however, the correct actions should be assessed on a case-by-case basis.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

7.1.1 Protective measures

Ensure that all relevant regulations regarding handling and storage facilities for the product are respected correctly. Avoid contact between the hot product and water. Risk of splashing of hot material.
The 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.
Check that the container and receiving equipment are earthed. Do not inhale the fumes generated by the hot product. Use appropriate personal protective equipment if necessary. Do not use compressed air for filling, discharging, or handling operations. Prevent the risk of slipping.

7.1.2 Indications regarding health in the workplace

Ensure that proper housekeeping measures are in place. Contaminated materials should not be allowed to accumulate in the workplaces and should never be kept inside the pockets. Keep away from food and beverages. Do not eat, drink or smoke when using this product. Wash the hands thoroughly after handling. Do not use contaminated clothing again. Do not use solvents or other products with a defatting effect on the skin. Contaminated materials should not be allowed to accumulate in the workplaces and should never be kept inside the pockets. Ensure that proper housekeeping measures are in place.

7.2 Conditions for safe storage, including any incompatibility

Storage area layout, tank design, equipment and operating procedures must comply with the relevant European, national or local legislation. Storage installations should be designed with adequate means to prevent ground and water pollution in case of leaks or spills. 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. Before entering storage tanks and commencing any operation in a confined area, check the atmosphere for oxygen content, hydrogen sulphide (H2S) and flammability.
Store separately from oxidising agents.
Use mild or stainless steel for containers and linings. Most synthetic materials are unsuitable for containers or container linings, due to low heat resistance.
If the product is supplied in containers, only store it in the original container or a container that is suitable for the type of product. Hot product must never be filled into containers without first checking that the container is completely dry. 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 uses

No information in addition to that provided above is necessary.

8. CHECKING EXPOSURE / PERSONAL PROTECTION

8.1 Checking parameters

Exposure limit values (substance):
None

Exposure limit values (atmospheric pollutants)
Sulphurated hydrogen:
Directive 2009/161/EU:
Limit values (8 hours): 5 ppm; 7 mg/m3
Limit values (short-term): 10 ppm; 14 mg/m3
ACGIH 2010:
TLV®-TWA: 1 ppm
TLV®-STEL: 5 ppm
Monitoring procedures: see Legislative Decree 81/2008 and subsequent amendments and additions or good practice for industrial hygiene.

DNEL (Derived Non-Effect Level) and DMEL (Derived Minimum Effect Level)
Not derived since the substance is not a danger to health.

PNEC(S) (Predicted Non Effect Concentration)
Not derived since the substance is not a danger to the environment.

Biological limit values (substance):
n.d.

8.2 Exposure checks

8.2.1 Suitable technical checks

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

8.2.2 Personal protection measures

(a) Eye / face protection:

Protective shields are advisable for operations that cause splashing.
Hardhat with protection for the back of the neck. Wea protective glasses (UNI EN 166).

(b) Skin protection:

i) Hand protection

In the absence of containment systems and where there is a danger of contact with the skin, use gloves with wrist bands that are highly resistance to hydrocarbons and have felt on the inside, and heat insulated if necessary. Presumably adequate materials: nitrile, PVC or PVA (polyvinyl alcohol) with a protective index for chemical agents of at least 5 (permeation time > 240 minutes). Use the gloves according to the conditions and within the limits set by the manufacturer. If necessary, refer to the UNI EN 374 standard. Gloves must be periodically inspected and changed in case of wear, perforations or contaminations.

ii) Other

Wear protective clothing during operations involving hot material, clothing that is heat resistant (with trousers over the boots and sleeves over the wristband on gloves), heavy boots that are heat resistant and non-slip (e.g. leather) (EN 943-13034-14605) (1216) Resistant to chemical agents. If clothing gets contaminated change it and clean it immediately.

(c) Respiratory protection:

In places in which hydrogen sulphide can accumulate, use appropriate devices to protect the respiratory tract - full-face masks with a B type 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.

(d) Thermal dangers: See letter b above.



8.2.3 Environmental exposure checks

Avoid releasing into the environment. Storage installations should be designed with adequate means to prevent ground and water pollution in case of leaks or spills.

8.3 Other

No information in addition to that provided above is necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on fundamental physical and chemical properties

a)	*Appearance:*	Solid and blackish at ambient temperature
b)	*Odour:*	Characteristic when hot, odourless when cold
c)	Olfactory threshold:	n.d.
d)	*pH:*	*n.a.*
e)	*Melting point / freezing point:*	> 25°C (EN 1427)
f)	*Initial boiling point and boiling interval:*	
	:	approximately >= 495°C (IP480).
g)	*Flash point:*	>180°C (ASTM D 92/EN ISO 2592)
h)	*Evaporation rate:*	n.a.
i)	*Inflammability (solids, gases):*	not inflammable
j)	*Upper / lower limits of*	

	inflammability or explosiveness:	n.a.
k)	*Vapour tension:*	<< 0,1 kPa a 20°C
l)	*Vapour density:*	n.a.
m)	*Relative density:*	from 1,000 to 1,070 at 15°C (ASTM D70)
n)	*Solubility:*	Solubility in water not applicable as this is a UVCB substance.
o)	*Coefficient of n-octanol/water breakdown:*	not applicable as this is a UVCB substance.
p)	*Spontaneous combustion temperature*	> 400 °C ASTM 659
q)	*Decomposition temperature:*	n.a.
r)	*Viscosity:*	from 80 to 3210 mm^2/s at 135°C (ISO 3104)
s)	*Explosive properties:*	not explosive
t)	*Oxidant properties:*	The substance does not react exothermically with combustible materials.

9.2 Other information

Not included.

10. STABILITY AND REACTIVITY

10.1 Reactivity

The substance does not present further dangers related to reactivity other than those indicated in the sub-sections that follow.

10.2 Chemical stability

Bitumen is normally stored and handled at temperatures exceeding 100°C and contact with water causes violent expansion with the danger of splashing and bubbling.

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. Sensitivity to heat, friction or shock cannot be assessed in advance.

10.4 Conditions to be avoided

Excessive heating to temperatures higher than those recommended may cause alterations to the product and the development of inflammable fumes.

10.5 Incompatible materials

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

10.6 Dangerous products of decomposition

Confined spaces: 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.

11. TOXICOLOGICAL INFORMATION

11.1 Toxicokinetics, metabolism and distribution

Complex substances such as bitumen are not suitable for toxico-kinetic analysis. However the toxico-kinetic properties of some individual components, such as polycyclic aromatic hydrocarbons (IPA) were studied in detail. For human beings the main ways of exposure to bitumen are inhalation and via the skin. The principal sites for potential absorption of IPA from bitumen in humans is the lungs and respiratory system following exposure due to inhalation of bitumen fumes, and the skin due to contact with pure bitumen or condensed bitumen fumes.
In general, the individual constituents of bitumen and bitumen fumes undergo oxidising metabolism, which may result in bioactivation.
The distribution of the IPAs throughout the body was studied in rodents. These studies showed that a low level of IPA can be found in internal organs, especially the adipose tissue.
In general, the IPAs are eliminated in the form of urine or bile.

11.2 Toxicological information

a) Acute toxicity:

By mouth

Acute toxicity by mouth for bitumen was evaluated in some studies carried out on rats. These studies showed an acute oral DL50 exceeding 5 g/kg that does not imply any classification in terms of the regulations for hazardous substances.

A summary of the most representative studies in the registration dossier is given below.

Method	Result	Comments	Source
RAT (M/F) Administration: gavage OECD Guideline 401	DL50:>5000 mg/kg (M/F)	Key study CAS 64741-56-6	American Petroleum Institute (API) 1982a

By inhalation

To evaluate acute toxicity doe to inhalation of bitumen, some studies on rats are available.

These studies showed an acute inhalation DL50 that does not imply any classification in terms of the regulations for hazardous substances.

A summary of the most representative studies in the registration dossier is given below.

Method	Result	Comments	Source
RAT (M/F) Vapours (nose only) OECD Guideline 403	CL50: > 94,4 mg/m³ (M/F)	Key study Read-across Aerosol of condensed oxidised bitumen fumes	Fraunhofer Institute of Toxicology and Aerosol Research (2000)

Via the skin

Acute toxicity via the skin for bitumen was evaluated in some studies carried out on rabbits. These studies showed an acute skin DL50 exceeding 2 g/kg that does not imply any classification in terms of the regulations for hazardous substances.

A summary of the most representative studies in the registration dossier is given below.

Method	Result	Comments	Source
RABBIT (male/female) Occlusive bandage OECD Guideline 402 (Acute Dermal Toxicity)	DL50>2000 mg/kg (male/female)	Key study CAS 64741-56-6	Study by the American Petroleum Institute (API) 1982a

b) Corrosion / skin irritation

The potential for skin irritation by bitumen was tested in some studies done on rabbits. The conclusions of these studies indicate an absence of skin irritation.

These results do not point to any classification in terms of the standard on hazardous substances.

A summary of the most representative studies in the registration dossier is given below.

Method	Result	Comments	Source
RABBIT Occlusive bandage OECD Guideline 404	Non irritant Average erythema score 0,1 of max. 4 (skin intact) Oedema index: 0,1 of max. 4 (skin intact)	Key study CAS 64741-56-6	American Petroleum Institute (API) 1982a

c) Serious eye injury / serious eye irritation

The potential for eye irritation by bitumen was tested in some studies done on rabbits.

All these studies showed an absence of eye irritation, and so no classification of the substance is necessary.

A summary of the most representative studies in the registration dossier is given below.

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

d) Respiratory or skin sensitisation

Respiratory sensitisation

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

Skin sensitisation

Some studies are available that were carried out to test the potential of sensirtisation due to bitumen.

The results obtained from these studies indicate the absence of potential skin sensitisation and so no classification of the substance is necessary.

A summary of the most representative studies in the registration dossier is given below.

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

e) Mutagenicity of germinal cells

The mutagen potential of bitumen has been amply studied in a series of live and in vitro tests. Most of the studies dod not show coherent proof of mutagen activity, and so no classification is required in terms of the standard for hazardous substances.
A summary of the most representative studies in the registration dossier is given below.

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 without metabolic activation Positive with metabolic activation	Key study Condensates of bitumen fumes	De Meo, M., Genevois, C., Brandt, H, Laget, M., Bartsch, H., Castegnaro, M. (1996)

Live studies:

Method	Result	Comments	Source
Transgenic mutagenicity test in animals RAT (males) Means of administration: inhalation of vapours Doses: 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 (2006)
Micronucleus test (gene mutation) RAT (M/F) Means of administration: inhalation of vapours Doses: 0, 30, 100, mg/m3 (total hydrocarbons) OECD Guideline 474	Negative	Key study Read-across With condensates of oxidised asphalt fumes (CAS 64742-93-4)	Fraunhofer (2009a)

f) Cancerogenicity

Some cancerogenicity studies are available for inhalation or skin exposure.
By inhalation the study available did not find any carcinogenic effect.
For skin exposure some studies on animals indicate weak activity. We wish to point out that the presence of solvents used for administering bitumen clearly increase 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 cancer of the lungs.
Based on an overall evaluation of the results of the studies on key and support animals, and the two key epidemiological studies, it was concluded that there is no proof that via the skin or inhalation bitumen presents a carcinogenic risk under normal usage conditions.
A summary of the most representative studies on animals in the registration dossier is given below.

Method	Result	Comments	Source
RAT (M/F) Inhalation (nose only) Exposure: 104 weeks (6 hours a day for 5 days a week) Doses: 0, 4, 20, or 100 mg/m3 OECD Guideline 451	NOAEC (carcinogenicity): 103,9 mg/m³ air (analytical) (value adjusted for neoplastic histopathologies: 172,5 mg/m3) Neoplastic effects: no effect	Key study Read-across Condensates of oxidised bitumen fumes	Fraunhofer (2006)
RAT (M/F) Via the skin (acetone carrier) Doses: 1 drop Exposure: twice a week for two years	Incidence of skin tumour: 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 for reproduction (summarised in the table below) that relates to the effects on fertility and development. This study did not show any effect for this endpoint by bitumen, and so the substance is not classified hazardous in terms of the European standards.

Method	Result	Comments	Source
RAT (M/F) Repeated combined toxicity study for reproduction / development Doses: 30, 100, or 300 mg/m3.	NOAEC (P): 30 mg/m³ air (weight of the organs) (NOAEC (P): 300 mg/m³ air (specific parameters of	Key study Read-across With condensates of asphalt fumes (CAS 64742-93-4)	Fraunhofer (2009a)

Administration by inhalation (nose only) Exposure: males: 28 days females: 50 days 6 hours a day for 7 days a week OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	reproduction) NOAEC (F1): 300 mg/m³ air (nominal) (all the effects)		

h) Specific toxicity for target organs (STOT) - single exposure:

Studies on rats show that exposure to condensates of bitumen fumes does not induce pulmonary inflammation.
In a study on 170 workers exposed to bitumen fumes (with concentrations up to 1,3 mg/m3) no association was found between acute effects on pulmonary functionality, respiratory irritation, or other symptoms, and exposure to bitumen fumes.

i) Specific toxicity for target organs (STOT) - repeated exposure:

Repeated toxicity studies for oral means for bitumen are not appropriate as the main means of exposure for man in inhalation and via the skin. In all the inhalation and dermal studies carried out an absence of adverse systemic effects was found, even at the highest doses administered, and so bitumen is not classified hazardous for this endpoint in terms of the standards for hazardous substances.
A summary of the most representative studies in the registration dossier is given below.

Method	Result	Comments	Source
Inhalation			
RAT (M/F) Combined repeated (chronic) toxicity and carcinogenicity study Doses: 4, 20, or 100 mg/m3. Exposure: 2 years (6 hours a day for 5 days a week - except during holidays) OECD 451	NOAEC (local effects): 10,4 mg/m³ air (analytical) (Value adjusted on the basis of the histopathology 17,2 mg/m^3) NOAEC (systemic effects): 103,9 mg/lit air (analytical) (adjusted value 172,5 mg/m³) LOAEC (local effects): 20,7 mg/m³ air (analytical) (Value adjusted on the basis of the histopathology 34,4 mg/m^3)	Key study Read-across Aerosol of condensed oxidised bitumen fumes	Fraunhofer (2006)
Cutaneous			
RAT (Males/females) Subacute 28 days (3 times a week for 6 hours at a time) Doses: 200, 1000, or 2000 mg/kg/day OECD Guideline 410	NOAEL (topical effects): 200 mg/kg/day (on the basis of an absence of significant histopathological results) NOAEL (systemic effects): 2000 mg/kg/day (on the basis of data on body weight in the absence of significant histopathological results)	Key study CAS 64741-56-6	American Petroleum Institute (API) 1983a

j) Aspiration danger

Given the estimated or measured viscosity value for bitumen, the substance is not classified for the pulmonary aspiration danger.

k) Other information

No information in this regard is available.

12. ECOLOGICAL INFORMATION

Based on the ecological information given below and the criteria indicated in the standards for hazardous substances, bitumen is not classified as dangerous for the environment.

12.1 Toxicity

A summary of the most representative studies in the registration dossier is given below.

Endpoint	Result	Comments
Aquatic toxicity		
Invertebrates Daphnia magna Short-term	LL50 48/hours: >1000 mg/lit	Key study Redman Et al (2010b) QSAR
Invertebrates	NOAEL 21/days: >=1000 mg/lit	Key study

Endpoint	Result	Comments
Daphnia magna Long-term		Redman Et al (2010b) QSAR Read/Across
Algae Selenastrum capricornutum	EL50 72/hours: >=1000 mg/lit	Key study Redman Et al (2010b) QSAR
Fish Short-term Oncorhynchus mykiss	LL50 96/hours: >1000 mg/lit	Key study Redman Et al (2010b) QSAR
Fish Long-term Oncorhynchus mykiss	LL50 28/days: >1000 mg/lit NOEL: 28/ days >=1000 mg/lit	Key study Redman Et al (2010b) QSAR

12.2 Persistence and degradability

Abiotic degradability
Hydrolysis: the components of bitumen are resistant to hydrolysis due to a lack of a functional group that is hydrolytically active. Therefore, this process will not contribute to a measurable loss of degradation of the substance 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 ground

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 laid down in appendix XIII of the REACH Regulation.
Persistence evaluation: some hydrocarbon structures included in this category present P (persistent) or vP (very Persistent) characteristics.
Evaluation of bioaccumulation potential: the structure of most of the hydrocarbons included in this category DO NOT present vB (very Bioaccumulative) characteristics, although some components do present B (Bioaccumulative) characteristics.
Evaluation of toxicity: for the structures that showed P and B characteristics, the toxicity was evaluated but no relevant component satisfies the toxicity criteria with the exception of antracene which was confirmed to be a PBT. Since the antracene is included in concentrations < 0,1% the product is not PBT/vPvB.

12.6 Other harmful effects

Not included.

13. COMMENTS ON DISPOSAL

13.1 Waste treatment methods

Do not discharge onto the ground, into sewers, culverts, or water courses.
For disposal of the waste derived from this product, including non depolluted empty containers, comply with Legislative Decree 152/06 and subsequent amendments and additions
European Waste Catalogue Code: 05 01 17 (Ref: 2001/118/CE and Dir. of the Min. of the Environment 9/04/2002) (The code indicated only provides a general indication based in the original composition of the product and the intended uses).
The user (waste producer) is responsible for choosing the most adequate code on the basis of the effective use of the product, any alterations, and pollution. The product as is does not contain halogenated compounds.
Disposal of containers: Do not throw the containers away in the environment. Dispose of them according to local regulations.
Do not puncture, grond, weld, braze, burn, or incinerate the containers or empty drums that have not bee depolluted.

14. INFORMATION ON TRANSPORTATION

14.1 UNO Number

Note: The product is classified as hazardous goods only if transported molten at a temperature > 100 °C
3257
We wish to point out that the product is classified as hazardous goods only if transported molten at a temperature > 100 °C

14.2 UNO transportation name

LIQUID TRANSPORTED HOT, N.A.S. (molten bitumen)

14.3 Danger classes connected with transportation

Road / rail transport (ADR/RID): Class 9, M9
Sea transport (IMDG): Class 9
Air transport (IATA): Class 9
Transportation is forbidden on cargo and passenger flights.

14.4 Packaging groups

III; Label 9 + "High temperature" indication

14.5 Danger to the environment

Substance NOT dangerous to the environment in terms of codes ADR, RID, ADN and IMDG.

14.6 Special precautions for users (transport operations)

Wear protective gloves against chemical agents (that conform to the EN374 standard) and undergo a basic training course (PPE16).

14.7 Bulk transportation according to appendix II of MARPOL 73/78 and the IBC code

If you intend effecting bulk transportation, comply with appendix II of MARPOL 73/78 and the IBC code, where applicable.

14.8 Other

Tunnel restriction code (ADR): D

15. INFORMATION ON REGULATION

15.1 Specific health, safety, and environmental regulations and legislation for the substance or mixture

Authorisation in terms of the REACH Regulation (CE Regulation n° 1907/2006 and subsequent amendments and additions): product not included in the list of extremely worrying substances (SVHC) that require authorisation.
Restrictions in terms of the REACH Regulation (CE Regulation n° 1907/2006 and subsequent amendments and additions): Substance not subject to Restrictions in terms of Heading VIII
Other EU norms and national implementations:
Seveso Category (Dir 96/82/CE and Dir 105/2003/CE, as well as Legislative Decree 334/99 and subsequent amendments and additions): n.a.
Dangerous chemical agent in terms of Heading IX (implementation of Dir 98/24/CE) of Legislative Decree 81/08.
For waste disposal see Legislative Decree 152/06 and subsequent amendments and additions.

15.2 Evaluation of chemical safety

Chemical safety was evaluated.

16. OTHER INFORMATION

List of pertinent phrases
These phrases are given for information and do not necessarily correspond to the classification of the product.

R phrases
Not included.

H Hazard indications
Not included.

Indications on training:

Adequately train workers that will potentially be exposed to these substances, based on the contents of this safety data sheet.

Principal biological references and data sources

Registration Dossier

Legend for abbreviations and acronyms

ACGIH = American Conference of Governmental Industrial Hygienists
CSR = Report on Chemical Safety
DNEL = Derived Non-Effect Level
DMEL = Derived Minimum Effect Level
EC50 = Mean effective concentration
IC50 = Inhibition concentration, 50%
LC50 = Lethal concentration, 50%
LD50 = Mean lethal dosage
PNEC = Envisaged Non-Effect Concentration
n.a. = not applicable
n.d. = not available
PBT = Persistent, Bioaccumulable, and Toxic Substance
SNC = Central Nervous System
STOT = Specific Toxicity for Organs Targeted
(STOT) RE = Repeated exposure
(STOT) SE = Single exposure
TLV®TWA = Threshold Limit Value – mean pondered over time
TLV®STEL = Threshold Limit Value - limit for short exposure time
UVCB = Substances of Unknown or Variable composition
vPvB = very Persistent and very Bioaccumulable

Date revised 30/11/2010

Reason for the revision: Update in terms of CE Regulation N° 1907/2006(REACH) as amended, Appendix I of EU Regulation 453/2010, and in terms of CE Regulation n° 1272/2008(CLP)

APPENDIX 1 LIST OF USES IDENTIFIED

Name of use identified	Sector	Usage sector SU	Process categories PROC	Environmental release categories ERC	Specific environmental release categories ERC
01- Production of the substance	Industrial	3, 8, 9	1, 2, 3, 4, 8a, 8b. 15	1,4	ESVOC SpERC 1.1.v1
01b- Use as intermediate	Industrial	3, 8, 9	1, 2, 3, 4, 8a, 8b. 15	6a	ESVOC SpERC 6.1a.v1
01a- Distribution of the substance	Industrial	3	1, 2, 3., 8a, 8b, 9, 15	1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7	ESVOC SpERC 1.1b.v1
02- Formulation & (re)packing of substances and mixtures	Industrial	3,10	1, 2, 3, 4, 8a, 8b. 15	2	ESVOC SpERC 2.2.v1
03a-Use in coatings	Industrial	3	1, 2, 3, 4, 8a, 8b, 15	4	ESVOC SpERC 4.3a.v1
05a - Use in Oil and Gas field drilling and production operations	Industrial	3	1, 2, 3, 4, 8a, 8b	4	Qualitative evaluation for the environment
19- Rubber production and processing	Industrial	3, 10, 11	1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 13, 14, 15, 21	1, 4, 6d	ESVOC SpERC 4.19.v1
03b- Use in coatings	Professional	22	1, 2, 3., 4, 5, 8a, 8b, 10, 11, 13, 15, 19	8a, 8d	ESVOC SpERC 8.3b.v1
05a - Use in Oil and Gas field drilling and production operations	Professional	3	1, 2, 3., 4, 8a, 8b	4	Qualitative evaluation for the environment
15 - Road and building applications (GEST15-P)	Professional	22	8a, 8b, 9, 10, 11, 13	8d, 8f	ESVOC SpERC 8.15.v1
06b - Low release lubricants	Professional	22	1, 2, 3., 4, 8a, 8b, 9 10, 11, 13, 17, 18, 20	9a, 9b	ESVOC SpERC 9.6b.v1
06c - High release lubricants	Professional	22	1, 2, 3., 4, 8a, 8b, 9 10, 11, 13, 17, 18, 20	8a, 8d	ESVOC SpERC 8.6c.v1
03c- Use in coatings	Consumer	21	n.a.	8a, 8d	ESVOC SpERC 8.3c.v1