1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Identification of the substance or preparation: Processed Fuel Oil (PFO) / Used Lubricating Oil

Identification on the label / trade name: Lubricating oil, used

Additional identification: CAS# 70514-12-4; EC# 274-635-9

REACH Registration No: 01-2119517646-35-0001

1.2 Use of the substance / preparation:
Combustion fuel used for heating and power at industrial and commercial facilities or as lubricant in closed systems.

1.2.1 Identified uses:
Combustion fuel used for heating and power at industrial facilities or as a lubricant in a closed system.

Uses advised against:
Any use other than as a fuel oil or lubricant in a closed system, unless an assessment is completed prior to commencement of that use, which demonstrates that the use will be controlled.

1.3 Company/undertaking identification:

Supplier (manufacturer/importer/downstream user/distributor):

Oakwood Fuels Ltd, Brailwood road, Bilsthorpe, Nottinghamshire NG22 8UA

E-Mail (competent person): m.woodhouse@oakwoodgroup.uk.com

Information contact: Mike Woodhouse

National contact: Mike Woodhouse

1.4 EMERGENCY TELEPHONE: 01623 871964

2. HAZARDS IDENTIFICATION

2.1 Hazards description:

Labelling

Signal word: Danger

2.1.1 Classification:

Chemical	Classification	Hazard Statement	Hazard Pictogram	Notes
PFO/Used Lubricant Base Oils (IP 346 <3%; >20.5 mm^2/s@40^oC)	Not classified as hazardous	NA	NA	H, L
PFO/Used Lubricant Base Oil (IP 346<3%; >7mm^2/s to <20.5 mm^2/s @40^oC)	Aspiration hazard: Asp. Tox. 1	H304: may be fatal if swallowed and enters airways		H, L
PFO / Used Lubricant Base Oil (IP 346<3%; <7mm^2/s@40^oC)	Acute toxicity	H304: may be fatal if swallowed and enters airways Xn: R65 Harmful: Harmful, may cause lung damage if swallowed		H, L

Note H: The classification and labelling shown for this substance applies to the hazardous property(ies) indicated by the hazard statements(s) in combination with the hazard class(es) and category(ies) shown. The requirements of Article 4 for manufactures, importers or downstream users of this substance apply to all other hazards classes and categories. For hazard classes where the route of exposure or the nature of the effects leads to a differentiation of the classification of the hazard class, the manufacturer, importer, or downstream user is required to consider the routes of exposure or nature of the effects not already considered.

Note L: The classification as a carcinogen need not apply where individual PAH or other aromatic constituents are <0.1% or if it can be shown that the substance contains less than 3% DMSO extract as measured by IP 346 “Determination of polycyclic aromatics in unused lubrication base oil and asphaltene free petroleum fractions – Dimethyl sulphoxide extraction refractive index method’, Institute of Petroleum, London. This note applies only to certain complex oil-derived substances in Part 3.

Oil Industry Notes:
OIN7: The EC DSD classifications as Possible risk of harm to the unborn child (R63) and Harmful: danger of serious damage to health by prolonged exposure in contact with skin (R48/21) need not apply if the substance is not classified as carcinogenic.

OIN 8: The EC CLP classifications as Suspected of damaging the unborn child (H361f) and Causes damage to organs through prolonged or repeated exposure by skin (H372) need not apply if the substance is not classified as carcinogenic.

OIN L (CLP): The classification as a carcinogen need not apply if it can be shown that the substance contains less than 3% DMSO extract as measured by IP 346 “Determination of polycyclic aromatics in unused lubrication base oil and asphaltene free petroleum fractions – Dimethyl sulphoxide extraction refractive index method’, Institute of Petroleum, London. This note applies only to certain complex oil-derived substances in Part 3.

2.1.2 Additional information:

2.2 Information pertaining to special dangers for human and environment:

Adverse physicochemical effects:

"Reason for no classification: conclusive but not sufficient for classification" for the following physicochemical effects:

Explosives, flammable gases, flammable aerosols, oxidising gases, gases under pressure, flammable liquids, flammable solids, self-reacting substances & mixtures, pyrophoric liquids, pyrophoric solids, self-heating substances & mixtures, substances and mixtures which in contact w/water emits flammable gases, oxidising liquids, oxidising solids, organic peroxides, corrosive to metals.

"Reason for no classification: conclusive but not sufficient for classification" for the following adverse human health effects and symptoms:

Acute toxicity – oral, dermal, inhalation; skin corrosion/irritation, serious damage/eye irritation, respiration sensitization, skin sensitation, aspiration hazard, reproductive toxicity and reproductive toxicity: w/effects on or via lactation, germ cell mutagenicity, specific target organ toxicity – single/repeated.

Adverse human health effects and symptoms:

Carcinogenicity:	Carc. 2 (Hazard statement: H351: Suspected of causing cancer <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.)

Reason for no classification: conclusive but not sufficient for classification" for the following adverse environmental effects:

Hazards to the aquatic environment and atmospheric environments

Other adverse hazards:
NA

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3. COMPOSITION/INFORMATION ON INGREDIENTS
3.1 Substance related information

CAS No: 70514-12-4
EC No: 274-635-9
INDEX No:
REACH Registration No: 01-2119517646-35-0001
Purity: 95-100% w/w
Synonyms:
Stabilisers:
Hazard impurities: trace metals from lubricant additives (0.1%), trace levels of halogen principally chorine (<1%), and polycyclic aromatic hydrocarbons (PCAs) and polyaromatic hydrocarbons (PAHs) (<0.1%).

3.2 Preparation / mixture related information
Description:
A saturated hydrocarbon oil having a chain length predominantly between C_{12} – C_{50}

Hazard ingredients*:

Chemical name	EC-No	REACH-No	Index-No	CAS-No	Amount (%)	Classification according Regulation (EC) No 1272/2008 [CLP]		Classification according 67/548/EEC
						Hazard Class/ Hazard Category	Hazard Symbol	
Processed Fuel Oil (PFO) / Processed Used Lubricating Oils	274-635-9			70514-12-4	>95%	GHS08: health hazard		Xn, R65 (if viscosity <7mm^2/s

3.3 Remark:
For viscosity <7mm^2/s
Xn, R65 - harmful: may cause lung damage if swallowed
S2 – Keep out of reach of children
S23 – do not breathe gas / fumes/spray
S51 – use only in well ventilated areas
S62 – If swallowed so not induce vomiting: seek medical advice immediately and show this container or label

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4. FIRST AID MEASURES

4.1 General information:

P308/P313: If exposed or concerned: get medical advice/attention
S53: Avoid exposure – obtain special instructions before use

4.2 In case of inhalation:

S23.3: Do not breathe gas/vapour/aerosol. Inhalation may cause irritation to nose or throat, or coughing. Remove to fresh air. If symptoms persist, obtain medical advice.
S51: Use only in well-ventilated areas

4.3 In case of skin contact:

Wash skin thoroughly with soap and water. Remove contaminated clothing and wash underlying skin as soon as reasonably practicable.

If in contact with hot oil, flood with cold water for at least 10 minutes. Get medical advice.

4.4 In case of eye contact:

Flush eyes immediately with copious amount of freshwater for several minutes whilst holding the eyelids open. Obtain medical advice if any pain or redness develops or persists.

4.5 In case of ingestion:

If swallowed and person is conscious, give water or milk. Never give anything by mouth to an unconscious person.
S62: If swallowed, do not induce vomiting because of danger of aspiration. Seek medical advice immediately and show the container or label
P301/310: If swallowed: Immediately call a POISON CENTER or doctor/physician
P331: Do NOT induce vomiting

4.6 Self-protection of the first aider:

Eyes: Although no special eye protection is usually necessary, goggles or visor use is recommended.

Skin: Exposed employees should exercise reasonable personal cleanliness; this includes cleansing exposed skin several times daily with soap and water and laundering or dry cleaning soiled work clothing at least weekly.
Inhalation: Respiratory protection is normally not required. However, if operating conditions create airborne concentrations which exceed the recommended exposure standards(s), the use of an approved respirator is recommended.
Ventilation: Use adequate ventilation to keep the airborne concentrations of this material. Local exhausts ventilation and/or enclosure of the process is preferred in these cases.
Exposure Limits: None established for this product.

4.7 Information to physician:

Symptoms:
Ingestion: The swallowing of small amounts is unlikely to have adverse effects; larger amount may cause irritation with diarrhoea and vomiting.

Skin: Unlikely to cause irritation on single contact. Prolonged or repeated contact may cause dermatitis which could eventually lead to irreversible skin disorders.

Injection of oil under the skin may have serious effect which at first may not seem serious but, within hours, may become painful.

Contact with hot oil may cause thermal burns.

Eyes: May cause short-term irritation with redness and stinging.

Inhalation: fumes or vapour may cause irritation to eyes and mucous membranes, headache, nausea, vomiting, dizziness, drowsiness, euphoria, loss of coordination, and disorientation leading to loss of consciousness.

Treatment:
Ingestion: Wash out mouth and give water to drink. Do not induce vomiting because of danger of aspiration.
Skin: Wash skin as soon as possible with soap and water. If exposed to hot oil, flood with cold water for at least 10 minutes.
Eyes: Wash out immediately with large amounts of water.
Inhalation: Move victim immediately to fresh air.

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5. FIRE-FIGHTING MEASURES

5.1 Suitable extinguishing media:

Extinguish using foam, dry powder or carbon dioxide. Use water to cool fire-exposed containers. If a leak or spill has not ignited, use water fog to disperse the vapours and to provide protection for personnel attempting to stop the leak. Avoid spraying directly into storage containers because of the danger of boil-overs.

5.2 Extinguishing media which must not be used for safety reasons:

DO NOT USE WATER JETS.

5.3 Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases:

For fires involving this material, do not enter any enclosed or confined space without self-contained breathing apparatus to protect against the hazardous effects of combustion products or oxygen deficiency.

Large surface areas exposed to air/oxygen (e.g., oil-soaked rags, paper or absorbents spillages) may be easily ignited and should be cleared up at once.

Avoid conditions with strong oxidising agents such as chlorates, nitrates, peroxides, etc.

Dangerous decomposition products include carbon, nitrogen, sulphur, carbon monoxide, carbon dioxide, aldehydes, ketones, soot.

5.4 Special protective equipment for fire-fighters:

FIRES IN CONFINED SPACES SHOULD BE DEALT WITH BY TRAINED PERSONELL WEARING APPROVED BREATHING APPARATUS. Full fireproof clothing is recommended for large fires involving this product. Water may be used to cool nearby heat exposed areas/objects packages.

5.5 Additional information:

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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions:

P260: Do not breathe dust/fume/gas/mist/vapours/spray
P281: Use personal protective equipment as required
P308/P313: If exposed or concerned: get medical advice/attention
S45: In case of accident or if you feel unwell, see medical advice immediately (show the label where possible)
S24: Avoid contact with skin
Ventilate area.

6.2 Environmental precautions:

Protect drains from potential spills to minimize contamination. Do not wash product into drainage system. Contact the appropriate authorities in all cases where the consequences cannot be quickly and effectively controlled.

6.3 Methods for cleaning up:

Contain and recover spilled material using sand or other suitable inert absorbent material.

Precautions: It is advised that stocks of suitable absorbent material should be held in quantities sufficient to deal with any spillage which may be reasonably anticipated. Spilled material may make surfaces slipper.

In the case of spillage on water, prevent the spread of product by the use of suitable barrier equipment. Recover product from the surface. Protect environmentally sensitive areas and water supplies.

In case of spillage at sea, approved dispersants may be sued where authorized by appropriate government/regulatory authorities. Regular surveillance on the location of the spillage should be maintained.

In case of spill, stop the source of the leak or release and contain spill if possible. Ventilate area. Avoid breathing vapour. Use respirator and protective clothing. Cover spill with a generous amount of inert absorbent. Use a stiff broom to mix thoroughly.

Seep u and place in a disposable container. Scrub contaminated area with detergent and water, using a stiff broom. Pick a liquid with additional absorbent and place in a disposable container. Prevent contamination of groundwater or surface water.

6.4 Additional information:

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7. HANDLING AND STORAGE

7.1 Handling

This product must be considered as posing potential flammability hazards, capable of producing light hydrocarbons, which could result in the headspace atmosphere being flammable at temperatures below the flashpoint of the liquid.

Advices on safe handling:

Protective measures:

Avoid contact with eyes. If splashing is likely to occur wear a full face visor or chemical goggles as appropriate.
If skin contact is likely, wear impervious protective clothing and/or gloves.
High standards of personal hygiene and plant cleanliness must be maintained.
Wash hands thoroughly after use, and always wash hands before eating, drinking and smoking and before and after using the toilet.

Change heavily contaminated clothing as soon as reasonably practicable and launder before re-use. Wash any contaminated underlying skin with soap and water.

The use of a barrier cream on the hands before commencing work maybe helpful. After washing the application of a suitable conditional cream may help to prevent cracking, fissuring, or dryness of the skin.

Technical measures:

Measures to prevent aerosol and dust generation:
Local exhaust ventilation recommended if generating vapour, dust or mist.

Measures required to protect the environment:

The design, construction and maintenance of bulk storage and handling facilities are covered by codes of the practice published by the Energy institute (Institute of Petroleum), Health and Safety Executive and the Environment Agency.

Specific requirements or handling rules:

Minimum feasible handling temperatures should be maintained. Periods of exposure to high temperatures should be minimized. Water contamination should be avoided.

Precautions against fire and explosion:

Misuse of empty containers can be hazardous.
Do not cut, weld, heat or drill container.
Residue may ignite with explosive violence if heated sufficiently.
Do not pressurize or expose to open flames or heat. Keep container closed and drum bungs in place.

Further information:

7.2 Storage

Keep out of reach of children.
Store undercover away from heat and sources of ignition.
Store substance in closed system.

Technical measures and storage conditions:

RFO should be stored in accordance with local regulations and should be separated from other waste streams such as coolants, brake fluids, degreasers, and solvents.

Packaging materials:

Store in accordance with applicable local regulations and only labelled containers designed for this product.
Storage containers must be impermeable and not weakened or otherwise affected by the product.

Requirements for storage rooms and vessels:

The design, construction and maintenance of bulk storage and handling facilities are covered by codes of the practice published by the Energy institute (Institute of Petroleum), Health and Safety Executive and the Environment Agency.

Ground and bond shipping container, transfer line, and receiving container. Keep away from sparks, flame, and other sources of ignition. Protect containers against static electricity, lightning, and physical damage. Hot work (e.g., cutting/welding) must not be carried out on or near any container used for storage of this product unless has been made safe by purging or other suitable means.

Store between 0°C and 40°C.

Hints on storage assembly:
Storage class: NA

Further information on storage conditions:

7.3 Specific uses:
Recommendations: NA
Industrial sector specific solutions: NA

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limit values:

8.1.1 Components with occupational exposure limits rsp. biological occupational exposure limits requiring monitoring:

Occupational exposure limits:
Air limit values:

Limit value type (country of origin)	Substance name	EC-No.	CAS -No.	Occupational exposure limit value (mg/m$^{3)}$		Recommended monitoring procedures	Peak limitation	Source
				Long term	Short term			
OEL (EU)	Processed Fuel Oil			5				
EH40(?) ACGIH-TLV (USA)	Oil mist			5	10			

Biological limit values:

Limit value type (country of origin)	Substance name	EC-No.	CAS-No.	Limit Value	Investigation parameter	Source	Remark
NA							

8.1.1.2 Additional exposure limits under the conditions of use:
N/A

8.1.1.3 DNEL/DMEL and PNEC-values:

DNEL/DMEL			Exposure route	Exposure frequency	Critical component	Remark
Worker		Consumer				
Industry	Professional					
No hazard identified for this route (data available)	NA	0.692 mg/kg-day	oral	short term (acute) long term (repeated)		
		0.692 mg/kg-day				
5.4 mg/m^3		No hazard identified for this route (data	dermal	short term (acute) long term		Value derived by CONCOWE using block hydrocarbon method within PETRORISK
5.4 mg/m^3						
5.4 mg/m^3		1.2 mg/m^3	inhalation	short term (acute) long term (repeated)		
5.4 mg/m^3		1.2 mg/m^3				Based on aerosol. AF based on inter- and intraspecies differences as well as for duration
PNEC			**Exposure route**		**Critical component**	**Remark**
Worker		**Consumer**				
Industry	**Professional**					
	NA	0.692 mg/kg	Water	Short Term (single use)		PNEC represents exposure to food (see CSR chapter 7.5.3 "Calculation of PNEC oral (secondary poisoning) "
			Soil	Short Term (single use)		
			Air	Short Term (single use) Long Term (continuous)		

8.2 Exposure controls

Occupational exposure controls:
Where there is potential for exposure: Restrict access to authorised staff; wear suitable gloves (tested to EN374) and coveralls to prevent skin contamination; wear respiratory protection when its use is identified for certain contributing scenarios. Consider the need for risk-based health surveillance.

Product related measures to prevent exposure:

Instructional measures to prevent exposure:
Where there is potential for exposure: provide specific activity training to operators to minimise exposures;

Organisational measures to prevent exposure:
Regularly inspect, test and maintain all control measures.

Technical measures to prevent exposure:
Consider technical advances and process upgrades (including automation) for the elimination of releases. Minimise exposure using measures such as closed systems, dedicated facilities and suitable general/local exhaust ventilation. Drain down systems and clear transfer lines prior to breaking containment. Clean/flush equipment, where possible, prior to maintenance. Clear up spills immediately and dispose of wastes safely.

Personal protection equipment:

Respiratory protection: Filtering half-mask (disposable) respirator (A1P1 filter)
Hand protection: PVC or synthetic rubber gloves (e.g., nitrile, Viton), preferably gauntlet type.
Eye protection: Chemical resistant goggles and full face shield
Body protection: Overalls and appropriate footwear should also be worn.

8.2.2 Environmental exposure controls:

Product related measures to prevent exposure:

Instructional measures to prevent exposure:

Organisational measures to prevent exposure:

Technical measures to prevent exposure:

Consider technical advances and process upgrades (including automation) for the elimination of releases.

8.2.3 Consumer exposure control

Measures related to consumer uses of the substance (as such or in preparations):

Measures related to the service life of the substance in articles:

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Appearance

Physical state: liquid **Colour:** dark brown/black **Odour:** oily

9.2 Important health, safety and environmental information

9.2.1 Safety relevant basic data

	Units	Lubricating Oil, Used/RFO	Comments
		EC 274-635-9	
Appearance/Physical State		Liquid	Liquids of low volatility
Appearance/Colour		Dark brown - black	
Melting/freezing point		Not applicable	Single values for UVCB are not applicable, pour point is routinely used to better describe physical state phase. Pour point is lowest temperature at which movement of specimen is observed. Pour point temperature falls as an oil's viscosity increases.
Pour point	°C	<-25	
Boiling point	°C	200 - 385	It is not possible to define a single boiling point for a UVCB substance. Boiling point range is consistent with other oil categories such as lubricating oils (200 – 800°C) and VHGO (141 – 500°C)
Particle size distribution		Not applicable	The substance is a liquid
Density (at 15°C)	g/cm^3	0.86 - 0.92	Single values for a UVCB are not applicable. Values range from 0.86 – 0.92g/cm^3, consistent with VHGO category oils
Vapour pressure	kPa	<0.1	Low volatility consistent with lubricating oils (<0.01kPa) and

	Units	Lubricating Oil, Used/RFO	Comments
		EC 274-635-9	
			below that of VHGO (~0.4kPa)
Partition coefficient		Not applicable	
Water solubility		Immiscible, very low	(a)
Solubility in organic solvents/fat solubility		Highly soluble	(a)
Surface tension		Not applicable	In line with REACH Annex VII, data on surface tension are not required as, based on structural considerations, surface activity is not expected or predicted, and surface activity is not a desired property of the material.
Flash point	°C	>66	Typical flash point for other lubricant base oils is >98°C. Flash point range of 98°C - 344°C (CONCAWE 2010a), determined using the EN ISO 2719, D93 guidelines. Reported values for flash points range from >115 up to 268°C following ASTM D93 open cup guidelines (CONCAWE, 1997). Testing of PFO (method unconfirmed) demonstrates flashpoint >66°C.
Auto flammability	°C	Non flammable	Study does not need to be conducted because substance is non flammable in air (Column 2- REACH Annex VII).
Flammability	% in air	Non flammable	Since other lubricant base oils typically have flash points >66°C, substances are not classified as flammable. No measured flammability data were identified.
Explosiveness		Not applicable	Study does not need to be conducted if no chemical groups associated with explosive properties in molecule (Column 2- REACH Annex VII).
Oxidising properties		Not applicable	Oxidising properties studies do not need to be conducted as chemical structure is incapable of reacting exothermically with combustible materials (Column 2- REACH Annex VII).
Oxidation reduction potential		Not applicable	No oxidisable functional groups present
Stability in organic solvents and identity of relevant degradation products		Stable	Organic solvents study not necessary as stability of substance is not critical (Column 1 of Annex IX stability).
Storage stability and reactivity towards container material		May soften some rubbers, stable in metallic containers	
Stability: thermal, sunlight, metals		Stable to metals and under sunlight	
pH		Not applicable	Substance is immiscible
Dissociation constant		Not applicable	Molecules will not dissociate due to

	Units	Lubricating Oil, Used/RFO	Comments
		EC 274-635-9	
			non-polar character in hydrocarbon constituents in other lubricant base oils; therefore, ionized species of constituents are not expected to form. Dissociation constant is irrelevant if substance cannot dissociate due to lack of relevant functional groups (ECHA guidance Chapter R.7a).
Viscosity at 40°C	cSt	Typically >20 - 60	Other lubricant base oil viscosity is >2 mm^2/s at 40°C. Viscosity range of 1.99 - 847 mm^2/s at 40°C (CONCAWE 2010a). Viscosity determined using EN ISO 3104/ASTM D 445 test method. Other lubricant base oil viscosities may also be characterised by measured values for several lubricant base oil samples, which range from 4.48 - 1300 mm^2/s at 40°C (CONCAWE, 1984; 1997). These studies received Klimisch scores of 2 and are classified as reliable with restrictions

NOTES: (a) - Substance is a hydrocarbon UVCB. Standard tests for the partition coefficient are intended for single substances and are not appropriate for this complex substance.

9.2.2 Substance group relevant properties:

Explosives	NA
Flammable gases	NA
Flammable aerosols	NA
Oxidising gases	NA
Gases under pressure	NA
Flammable liquids	NA
Flammable solids	NA
Self-reactive substances and mixtures	NA
Pyrophoric liquids	NA
Pyrophoric solids	NA
Self-heating substances and mixtures	NA
Substances or mixtures which, in contact with water emit flammable gases	NA
Oxidising liquids	NA
Oxidising solids	NA
Organic peroxides	NA
Metal corrosion	NA

9.3 Other information:

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10. STABILITY AND REACTIVITY

10.1 Conditions to avoid:

Elevated temperatures; sources of ignition

10.2 Materials to avoid:

Strong oxidisers (chlorates, nitrates, peroxides)

10.3 Hazardous decomposition products:

Carbon dioxide, carbon monoxide, oxides of nitrogen, sulphur and phosphorus; unburned organic compounds including aldehydes, ketones

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11. TOXICOLOGICAL INFORMATION

Toxicokinetics, metabolism and distribution

Non-human toxicological data

See Attachment A

Human toxicological data:

NA

Toxicological Summary:

Although other lubricant base oils (OLBOs) have not been assessed in toxicokinetic studies, they are similar in composition to highly refined mineral oils (white oils), so similar toxicokinetic properties would also be expected. Mineral hydrocarbons (including other lubricant base oils) are chemically inert and, when ingested, most of the mineral oil (98%) remains unabsorbed in the faeces. Data from studies of "Highly Refined Mineral Oil" (white oil) suggests that small amounts of mineral oil (~2%) are absorbed as such by the animal or human intestinal mucosa and further distributed throughout the body. A very small fraction may undergo further biochemical transformation.

"Sufficiently Refined" Other Lubricant Base Oils (IP 346 <3%)

In a basic toxicokinetic study performed by Baldwin et al., hydrotreated white oil was mixed with the diet of male and female rats in concentrations of 0, 10, 100, 500, 1000, 5000, 10000, and 20000 ppm for a period of 13 weeks. After sacrifice, haematological, clinical chemistry, gross necropsy, tissue residue, and histopathological examinations were preformed. There were no mortalities or adverse effects associated with feeding the rats oleum-treated white oil. Treatment related effects were generally dose-related and more marked in females than in males. After 90 days of treatment, moderate multifocal granulomatous changes in mesenteric lymph nodes and liver were observed. Oleum-treated oil caused a greater pathological response then hydrotreated white oil. The hydrotreated white oil (applicable to sufficiently refined hydrocarbons, IP 346 < 3%) is metabolized to the corresponding fatty acids of the same carbon chain length as the parent carbons, suggesting omega oxidation.

A toxicokinetics study performed by Albro et al. evaluated absorption of hydrocarbon mixtures (IP 346 <3%). Simple mixtures of aliphatic hydrocarbons were administered to rats by gastric intubation at dose levels of up to 500 mg/kg bw. The percentage retention of the aliphatic hydrocarbons was inversely proportional to the number of carbon atoms and ranged from 60% for C_{14} to 5% for C_{28}compounds. The major site of absorption was found to be the small intestine.

A toxicokinetics study performed by Ebert et al. evaluated distribution of tritiated mineral oil (IP 346 <3%) administered orally and via ip injections. Male and female rats were dosed with 0.66 mL of radiolabeled mineral oil for 31 consecutive days. Radioactivity was measured in extracted tissues after sacrifice. Results indicate that radioactivity is primarily found in liver, fat, kidney, brain, and spleen. Both oral and ip routes of administration exhibited the same characteristics of absorption.

A toxicokinetics study performed by Ebert evaluated excretion of tritiated mineral oil (IP 346 <3%) administered orally and via ip injections. Male and female rats were dosed with 0.66 mL of radiolabeled mineral oil for 31 consecutive days. Urine and faeces were collected and stored daily for radioactivity analysis. Eighty percent of the tritiated mineral oil administered orally was not absorbed but rather excreted in the faeces 2 days after treatment. Only 11% of the total dose administered by ip injection was excreted in the faeces during the first 8 days of the study. About 8% of the radioactivity administered orally and via ip injection was excreted in the urine during the week following drug administration.

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

Toxicokinetics of other lubricant base oils has been examined in rodents. Absorption of other lubricant base oils across the small intestine is related to carbon chain length; hydrocarbons with smaller chain length are more readily absorbed than hydrocarbons with a longer chain length. The majority of an oral dose of mineral hydrocarbon is not absorbed and is excreted unchanged in the faeces. Distribution of mineral hydrocarbons following absorption has been observed in liver, fat, kidney, brain and spleen. Excretion of absorbed mineral hydrocarbons occurs via the faeces and urine. Based on the pharmacokinetic parameters and disposition profiles, the data indicate inherent

strain differences in the total systemic exposure (~3 fold greater systemic dose in F344 vs SD rats), rate of metabolism, and hepatic and lymph node retention of $C_{26}H_{52}$, which may be associated with the different strain sensitivities to the formation of liver granulomas and MLN histiocytosis.

Value used for CSA: no bioaccumulation potential

11.2 Acute effects (toxicity tests)

	Effect dose	Species	Method	Remark
Acute oral toxicity	LD_{50}= 5000 mg/kg bw	See Attachment A		
Acute dermal toxicity	LD_{50}= 5000 mg/kg bw	See Attachment A		

Specific Target Organ Toxicity (STOT)

Single exposure	Specific effects	Affected organs	Remark
Acute oral toxicity	Granulomatous changes	Lymph nodes	Baldwin et al.1992
Acute dermal toxicity	None found		API, 1982a, 1986a
Acute inhalative toxicity	None found		API 1987; ExxonMobil Biomedical, 1988

Irritant and corrosive effects:

	Exposure time	Species	Evaluation	Method	Remark
Primary irritation to the skin:			Not irritating		See Attachment A
Irritation to eyes			Not irritating		See Attachment A

Specific target organ toxicity (STOT)

Repeated exposure	Specific effects	Affected organs	Remark
Sub-acute oral			See Attachment A
Sub-acute dermal			
Sub-acute inhalative			
Sub-chronic oral			
Sub-chronic dermal			
Sub-chronic inhalative			
Chronic oral			
Chronic dermal			
Chronic inhalative			

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

Sufficiently refined other lubricant base oils with IP 346 < 3% are not carcinogenic in dermal application studies. Similarly, no tumours were noted in chronic repeat dose inhalation toxicity studies of lubricant base oils conducted in a number of species of laboratory animals (see Attachment A for details of the toxicological studies.)

Justification for classification or non classification

Some mildly or poorly refined other lubricant base oils are Carcinogenic: Category 2 (EU). Lubricant base oils are non-carcinogenic if DMSO extract as measured by IP346 is less than 3% and are considered sufficiently refined. Results are based on 37 negative cancer (dermal) studies available where the negative results have been compared to IP346 (DMSO extract <3%, sufficiently refined) and 4 positive cancer (dermal) studies available where the positive results have been compared to IP346 (DMSO extract >3%, insufficiently refined).

MUTAGENICITY

Value used for CSA: Genetic toxicity: negative

Justification for classification or non classification

Based on the IP < 3% and the poor bioavailability, this chemical does not demonstrate inherent genotoxicity in either in vivo or in vitro tests (See Attachment A).

TOXICITY FOR REPRODUCTION

Data waiving

Reason: other justification

Justification: In accordance with Section 1 of REACH Annex XI, additional reproductive toxicity studies do not appear to be scientifically necessary, as two developmental/reproductive toxicity studies conducted under internationally agreed validation principles provided no indication that sufficiently refined lubricant base oils (IP 346< 3 wt%) have adverse reproductive effects. Further no adverse effects on reproductive organs have been noted in multiple dermal or inhalation repeat dose studies (28-day) or carcinogenesis bioassays: for the other repro endpoint (See Attachment A for reproduction toxicity studies).

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

Two key screening reproductive/developmental studies (OECD 421) were identified. No reproductive or developmental effects were observed in Sprague-Dawley rats.

Value used for CSA (route: oral): NOAEL: 1000 mg/kg bw/day

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

For sufficiently refined other lubricant base oils (IP 346 < 3%), one key developmental study (OECD 414) was identified. The study was conducted dermally with Sprague-Dawley rats where a maternal LOAEL was not reported but can be referenced to be 125 mg/kg/day based on skin irritation. A developmental/teratogenic NOAEL was not reported; however, it can be inferred that this value is 2000 mg/kg/day.

Value used for CSA (route: dermal): NOAEL: 2000 mg/kg bw/day

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

In accordance with Section 1 of REACH Annex XI, additional reproductive toxicity studies do not appear to be scientifically necessary, as two developmental/reproductive toxicity studies conducted under internationally agreed validation principles provided no indication that sufficiently refined lubricant base oils (IP 346< 3 wt%) have adverse reproductive effects. Further, no adverse effects on reproductive organs have been noted in multiple dermal or inhalation repeat dose studies (28-day) or carcinogenesis bioassays.

Justification for classification or non classification

A key screening reproductive/developmental toxicity study on sufficiently refined other lubricant base oils showed no effects on reproductive parameters. Sufficiently refined other lubricant base oils do not meet the EU criteria for reproductive toxicity and are not classified under Annex VI of EU Dangerous Substances Directive 67/584/EEC.

Developmental toxicity studies conducted using sufficiently refined other lubricant base oils (IP 346 < 3%) did not reveal any treatment-related teratogenic effects. Sufficiently refined other lubricant base oils do not meet the EU criteria for developmental toxicity and are not classified (See Attachment A for details of toxicological studies on genotoxicity/development toxicity.

11.3 Experiences made in practice
Observations relevant to classification: NA
Other observations: NA

11.4 General remarks: NA

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12. Ecological information

12.1 Ecotoxicity:

Short-term toxicity to fish:

In a key static 96-hour short-term fathead minnow (*Pimephales promelas*) limit test (OECD 203; KS=1), 10 animals/loading were exposed to the WAF of Basestock Solvent Neutral 600 (MRD-94 -981) at a nominal concentration of 100 mg/L. The LL_{50} was >100 mg/L and the NOEL was ≥100 mg/L (Exxon, 1995b).

Long-term toxicity to fish:

For other lubricant base oils, read across has been applied for the long-term toxicity in fish endpoint, using the results of long-term toxicity testing on invertebrates (*Daphnia magna*). Toxic effects of hydrocarbons are primarily caused by narcosis and occur in a narrow range of molar concentrations across aquatic taxa; hence, read across between species is justified.

Results of computer modelling to estimate aquatic chronic toxicity of other lubricant base oils in a 28-day freshwater fish study show no chronic toxicity to freshwater fish at or below its maximum attainable water solubility (Redman et al., 2010b). This supports the applied interspecies read across.

Short-term toxicity to aquatic invertebrates:

In a key static 48-hour short-term *Daphnia magna* toxicity test (OECD 202; KS = 2), 10 animals/loading were exposed to the WAF of another lubricant base oil, MVI(N) 40 base oil (CAS # 64742-53-6 or 64741-97-5), at nominal concentrations of 0, 10, 100, 1000, and 10,000 mg/L. The EL_{50} was >10,000 mg/L based on mobility and the NOEL was ≥1000 mg/L (Shell, 1988).

In a key semi-static 96-hour short-term freshwater shrimp (*Gammarus pulex)* toxicity test (OECD 202; KS = 2), 10 animals/loading were exposed to the WAF of another lubricant base oil, MVI(N) 40 base oil (CAS # 64742-53-6 or 64741-97-5), at nominal concentrations 0, 10, 100, 1000, and 10,000 mg/L. The LL_{50} was >10,000 mg/L and the NOEL was ≥10,000 mg/L (Shell, 1988).

Long-term toxicity to aquatic invertebrates:

In a key semi-static 21-day long-term *D. magna* toxicity test (OECD 211; KS = 2), 10 animals/loading were exposed to the WAF of other lubricant base oil LVIN 38 (CAS #64742-53-6) at nominal concentrations of 1, 10, 100 and 1000 mg/L resulting in a NOEL of 10 mg/L, based on reproduction. The loss of all daphnids in the 100 mg/L WAF was attributed to a non-treatment related effect, the cause of which was unknown. Further testing would be required to clarify the consequences of exposure to a 100 mg/L WAF of the base oil (Shell, 1995).

In a supporting semi-static 21-day long-term *D. magna* reproduction test (OECD 211; KS = 2), 10 animals/loading were exposed to the WAF of solvent-refined heavy paraffinic distillate (PSG 1860; CAS # 64742-04-7) at nominal concentrations of 0, 10, and 1000 mg/L. The EL_{50} was >1000 mg/L and the NOEL was ≥1000 mg/L based on the lack of mortality or reproduction impairment (BP Oil Europe, 1995).

In supporting semi-static 21-day long-term *D. magna* reproduction test (OECD 211; KS = 2), 10 animals/loading were exposed to the WAFs of other lubricant base oils HVI 60, XHVI 4.0, HVI 65, and LVIN 38 (CAS #64742-53-6) at nominal concentrations of 1 and 1000 mg/L. The NOELs for other lubricant base oils HVI 60, XHVI 4.0, and HVI 65 were ≥1000 mg/L based on reproduction. The NOEL for LVIN 38 was ≥1 mg/L based on reproduction (Shell, 1994); this substance was retested across a wider range of nominal concentrations and a NOEL of 10 mg/L was determined (as described above in Shell, 1995).

Discussion

In a key semi-static 21 -day long-term *D. magna* toxicity test (OECD 211; KS = 2), 10 animals/loading were exposed to the Water Accommodated Fraction (WAF) of other lubricant base oil LVIN 38 (CAS #64742-53-6) at nominal concentrations of 1, 10, 100 and 1000 mg/L resulting in a NOEL of 10 mg/L, based on reproduction. The loss of all daphnids in the 100 mg/L WAF was attributed to a non-treatment related effect, the cause of which was unknown. Further testing would be required to clarify the consequences of exposure to a 100 mg/L WAF of the base oil (Shell, 1995).

In a supporting semi-static 21-day long-term *D. magna* reproduction test (OECD 211; KS = 2), 10 animals/loading were exposed to the WAF of solvent-refined heavy paraffinic distillate (PSG 1860; CAS # 64742-04-7) at nominal concentrations of 0, 10, and 1000 mg/L resulting in an EL_{50} of >1000 mg/L and a NOEL of ≥1000 mg/L, based on the lack of mortality or reproduction impairment (BP Oil Europe, 1995).

In supporting semi-static 21-day long-term *D. magna* reproduction test (OECD 211; KS = 2), 10 animals/loading were exposed to the WAFs of other lubricant base oils HVI 60, XHVI 4.0, HVI 65, and LVIN 38 (CAS #64742-53-6) at nominal concentrations of 1 and 1000 mg/L. The NOEL for other lubricant base oils HVI 60, XHVI 4.0, and HVI 65 was ≥ 1000 mg/L based on reproduction. The NOEL for LVIN 38 was ≥1 mg/L based on reproduction (Shell, 1994); this substance was retested across a wider range of nominal concentrations and a NOEL of 10 mg/L was determined (as described above in Shell, 1995).

These studies are scientifically sound and satisfy the guideline requirements for long-term toxicity to aquatic invertebrates.

Toxicity to aquatic algae:

In a key static 72-hour algal (*P. subcapitata*) limit test (OECD 201; KS = 2), the freshwater alga was exposed to the WAF of another lubricant base oil (N100DW; CAS # 72623-87-1), at a nominal concentration of 100 mg/L with a NOEL of ≥100 mg/L, based upon average specific growth rate and cell yield (Petro-Canada 2008a).

In a supporting static 72-hour algal (*P. subcapitata*) limit test (OECD 201; KS = 2), the freshwater alga was exposed to the WAF of another lubricant base oils (N65DW; CAS # 7262-386-0), at a nominal concentration of 100 mg/L resulting in a NOEL of ≥ 100 mg/L, based upon average specific growth rate and cell yield (Petro-Canada 2008b).

Discussion

Effects on algae/cyanobacteria

In a key static 72-hour algal (*P. subcapitata*) limit test (OECD 201; KS = 2), the freshwater alga was exposed to the Water Accommodated Fraction (WAF) of another lubricant base oil (N100DW; CAS # 72623-87-1), at a nominal concentration of 100 mg/L resulting in a NOEL of ≥100 mg/L, based upon average specific growth rate and cell yield (Petro-Canada 2008a).

In a supporting static 72-hour algal (*P. subcapitata*) limit test (OECD 201; KS = 2), the freshwater alga was exposed to the WAF of another lubricant base oils (N65DW; CAS # 7262-386-0), at a nominal concentration of 100

mg/L resulting in a NOEL of ≥100 mg/L, based upon average specific growth rate and cell yield (Petro-Canada 2008b).

Toxicity to microorganisms:

In a key static 4-day *Photobacterium phosphoreum* luminescence inhibition study (KS=2) using other lubricant base oils as control substances, no significant luminescence inhibition was observed for Spindle oil (BP 320-400 ºC) and Neutral oil Ro NIII (BP 400-450 ºC), as well as for the n-paraffin dodecane. The actual NOEL for Spindle oil was >1.93 mg/L and the actual NOEL for Neutral oil Ro NIII was > 2.17 mg/L (Riis et al., 1996).

Results of computer modelling to estimate aquatic toxicity of other lubricant base oil show no acute toxicity to aquatic microorganisms at or below its maximum attainable water solubility (Redman et al., 2010b). This supports the Riis et al. 1996 experimental results mentioned in the previous paragraph. Some information for this category has been generated using the models PETROTOX and/or SPARC. The QMRFs for PETROTOX and SPARC are attached in IUCLID Section 13, with the associated QPRF.

Details of ecotoxicological studies are found in Attachment A.

12.2 Mobility:

Known or predicted distribution to environmental compartments:

General discussion of environmental fate and pathways:

When a complex petroleum substance is released into the environment, the hydrocarbon constituents distribute to the different environmental compartments according to individual physico-chemical properties (e.g., volatility, water solubility, partition coefficients). Exposure concentrations are further modulated by differential degradation rates between constituents and compartments. Consequently, it is difficult to assess environmental exposure of petroleum substances from field monitoring studies because measured concentrations of constituents or total hydrocarbons detected in the environment can no longer be directly related to the original petroleum substance. A further complication is multiple hydrocarbon sources, both man-made and natural, which may contribute to concentrations observed in each environmental compartment (CONCAWE, 1999). Therefore, it is not possible to directly apply current risk assessment guidance developed for simple substances to complex petroleum substances.

To quantify environmental exposure resulting from multimedia distribution and degradation of hydrocarbon components that comprise a complex petroleum substance, the 'Hydrocarbon Block Method', has been proposed by CONCAWE (1996) and EC (2003) and subsequently implemented in REACH (ECHA, 2008). In this approach, individual hydrocarbons with different partitioning and degradation properties are used to simulate petroleum substance fate in the environment.

Degradation in the environment is a result of abiotic processes and biodegradation. The relative importance of these processes will depend upon the environmental compartment to which the individual components of the petroleum product partition. In general, abiotic processes are important in the atmosphere, whilst biodegradation is the principle mechanism of the breakdown of lower carbon chain length products in water and soil. Direct photolysis is not expected to be a major degradation pathway for many of the hydrocarbon components in petroleum substances and neither is hydrolysis, as the components of petroleum products lack hydrolysable functional groups.

The combined role of partitioning and degradation properties of constituent hydrocarbons on environmental fate and resulting exposure of complex petroleum substances at both local and regional scales has been predicted using the PETRORISK model (Redman, 2010c) based on the principles of the hydrocarbon block method and using fate factors derived from EUSES v2.

Hydrolysis:

Hydrolysis is a reaction in which a water molecule or hydroxide ion substitutes for another atom or group of atoms present in a chemical resulting in a structural change of that chemical. Potentially hydrolyzable groups include alkyl halides, amides, carbamates, carboxylic acid esters and lactones, epoxides, phosphate esters, and sulfonic acid esters (Neely and Blau, 1985). The lack of a suitable leaving group renders compounds resistant to hydrolysis.

The chemical constituents that comprise the other lubricant base oils category consist entirely of carbon and hydrogen and do not contain hydrolyzable groups resulting in a very low potential to hydrolyze. Therefore, this degradative process will not contribute to their removal from the environment.

The available data and available weight of evidence demonstrate that other lubricant base oils are resistant to hydrolysis because they lack a functional group that is hydrolytically reactive. Therefore, this fate process will not contribute to a measurable degradative loss of these substances from the environment. Further testing is not required under Annex XI, section 1.2.

Biodegradation:
Biodegradation in water, screening tests:
Substance is a hydrocarbon UVCB where test results for biodegradation in water are used for classification. For the purpose of risk assessment, this endpoint is characterized using quantitative structure property relationships for representative hydrocarbon structures that comprise the hydrocarbon blocks. The environmental risk of this substance is assessed using the PETRORISK model (see Product Library in PETRORISK spreadsheet attached to IUCLID Section 13).

Biodegradation in water and sediment, simulation tests; biodegradation in soil:
Substance is a hydrocarbon UVCB. Given that standard tests for this endpoint are intended for single substances, they are not appropriate for this complex substance. However, this endpoint is characterized using quantitative structure property relationships for representative hydrocarbon structures that comprise the hydrocarbon blocks used to assess the environmental risk of this substance with the PETRORISK model (see Product Library in PETRORISK spreadsheet attached to IUCLID Section 13).

Bioaccumulation
Aquatic/sedimen and terrestrial bioaccumulation:
Substance is a hydrocarbon UVCB. Given that standard tests for this endpoint are intended for single substances, they are not appropriate for this complex substance. For the purposes of PBT assessment, measured bioaccumulation data for representative hydrocarbon constituents have been used as detailed in section 8 of the CSR.

Adsorption/desorption:
Substance is a hydrocarbon UVCB. Given that standard tests for this endpoint are intended for single substances, they are not appropriate for this complex substance. However, this endpoint is characterized using quantitative structure property relationships for representative hydrocarbon structures that comprise the hydrocarbon blocks used to assess the environmental risk of this substance with the PETRORISK model (see Product Library in PETRORISK spreadsheet attached to IUCLID Section 13).

Distribution modelling:
The distribution of the substance in the environmental compartments, air, water, soil, and sediment, has been calculated using the PETRORISK Model. Based on the regional scale exposure assessment, the multimedia distribution of the substance is 39.93% to air, 3.98% to water, 34.01% to sediment and 22.09% to soil. Distribution modelling results are included in the 'Multimedia distribution modelling results' tab in the PETRORISK spreadsheet attached to IUCLID Section 13 (Redman et al., 2010a).

Surface tension:

Value	°C	Concentration	Method	Remark
NA				In accordance with column 2 of REACH Annex VII, this study does not need to be conducted as, based on structure, surface activity is not expected

Adsorption/Desorption

Transport	A/D coefficient Henry constant	log Koc	Volatility rate	Method	Hysteresis	Remark
Soil-water						Substance is a hydrocarbon UVCB. Standard tests for the partition coefficient are intended for single substances and are not appropriate for this complex substances
Water-air						
Soil-air						

12.3 Persistence and degradability

Abiotic Degradation

Half-time		Method	Evaluation	Remark
Sea-water				See below, as applicable
Fresh-water				
Air				
Soil				

Physical- and photo-chemical elimination

Hydrolysis:
Hydrolysis is a reaction in which a water molecule or hydroxide ion substitutes for another atom or group of atoms present in a chemical resulting in a structural change of that chemical. Potentially hydrolyzable groups include alkyl halides, amides, carbamates, carboxylic acid esters and lactones, epoxides, phosphate esters, and sulfonic acid esters (Neely and Blau, 1985). The lack of a suitable leaving group renders compounds resistant to hydrolysis. The chemical constituents that comprise the other lubricant base oils category consist entirely of carbon and hydrogen and do not contain hydrolyzable groups. As such, they have a very low potential to hydrolyze. Therefore, this degradative process will not contribute to their removal from the environment.

The available data and available weight of evidence demonstrate that other lubricant base oils are resistant to hydrolysis because they lack a functional group that is hydrolytically reactive. Therefore, this fate process will not contribute to a measurable degradative loss of these substances from the environment. Further testing is not required under Annex XI, section 1.2.

Phototransformation in air:
Standard tests for atmospheric oxidation half-lives are intended for single substances and are not appropriate for this complex substance. However, this endpoint is characterized using quantitative structure property relationships for representative hydrocarbon structures that comprise the hydrocarbon blocks used to assess the environmental risk of this substance with the PETRORISK model (see library tab in PETRORISK spreadsheet attached to Section 13).

Phototransformation in water and soil:
The direct photolysis of an organic molecule occurs when it absorbs sufficient light energy to result in a structural transformation. The absorption of light in the ultra violet (UV) -visible range, 110-750 nm, can result in the electronic excitation of an organic molecule. The stratospheric ozone layer prevents UV light of less than 290 nm from reaching the earth's surface. Therefore, only light at wavelengths between 290 and 750 nm can result in photochemical transformations in the environment. A conservative approach to estimating a photochemical degradation rate is to assume that degradation will occur in proportion to the amount of light wavelengths >290 nm absorbed by the molecule. This substance contains hydrocarbon molecules that absorb UV light below 290 nm, a range of UV light that does not reach the earth's surface. Therefore, this substance does not have the potential to undergo photolysis in water and soil, and this fate process will not contribute to a measurable degradative loss of this substance from the environment.

Biodegradation:

Deagradation rate (%)	Time (d)	Method	Evaluation	Remark
50	64			water
50	250			sediment
31.3	28			Solvent neutral 600 base oil (ExxonMobil, 1995a)
2-4	28			Lubricant base oil (GOHC 1468)(BP Ltd. International, 1990)

Biodegradation in water: inherently biodegradable based on the following:

Method	Results	Remarks	Reference
Test type: ready biodegradability activated sludge (adaptation not specified)(c)	inherently biodegradable % Degradation of test substance: 31 after 28 d (O_2 consumption) [by day 28 of study (average of 3 replicates)]	(1a) Test material: Solvent Neutral 600 Base Oil (MRD-94-981)	Exxon (1995a)
Test type: ready biodegradability activated sludge (adaptation not specified)(d)	not inherently biodegradable % Degradation of test substance: 2-4 after 28 d (CO_2 evolution) (Determined by CONCAWE) 2-8 after 28 d (CO_2 evolution) (Determined by Study Authors)	(1a) Test material (Sponsor Code): GOHC 1468	BP International Limited (1990)
Test type: ready biodegradability activated sludge (adaptation not specified)(c)	inherently biodegradable % Degradation of test substance: 31 after 28 d (O_2 consumption) (by day 28 of study (average of 3 replicates))	(1b)	Exxon (1995a)

NOTES: Study codes: (1) studies are supporting studies that are reliable without restrictions, based on experimental results (a) or read-across (b). Studies conducted in accordance with or similar/equivalent to (c) OECD Guideline 301 F (Ready Biodegradability: Manometric Respirometry Test) or (d) OECD Guideline 301 B (Ready Biodegradability: CO_2 Evolution Test).

Substance is a hydrocarbon UVCB. Test results for biodegradation in water are used for classification. For the purpose of risk assessment, this endpoint is characterized using quantitative structure property relationships for representative hydrocarbon structures that comprise the hydrocarbon blocks. The environmental risk of this substance is assessed using the PETRORISK model (see Product Library in PETRORISK spreadsheet attached to IUCLID Section 13).

Bioaccumulative potential

Partition coefficient n-octanol /water (log $K_{O/W}$):

Value	Concen-tration	pH	°C	Method	Evaluation	Remark
8						Substance is a hydrocarbon UVCB. Standard tests for this endpoint are intended for single substances and are not appropriate for this complex substance. However, this endpoint is characterized using quantitative structure property relationships for representative hydrocarbon structures that comprise the hydrocarbon blocks used to assess the environmental risk of this substance with the PETRORISK model (see Product Library in PETRORISK spreadsheet attached to IUCLID Section 13).

Method	Results	Remarks	Reference
Media: air - biota - sediment(s) - soil - water Calculation according to Mackay, Level III Calculation programme: PETRORISK Model	Percent distribution in media: Air (%): 39.93 Water (%): 3.98 Soil (%): 22.09 Sediment (%): 34.01 Susp. sediment (%): 0.1 Biota (%): 0.1 Aerosol (%): 0.1	2 (reliable with restrictions) key study estimated by calculation **Test material (Common name):** **Other lubricant base oils**	Redman, A. et al. (2010a)

Bioconcentration factor (BCF):

Value	Species	Method	Evaluation	Remark
Aquatic				Substance is hydrocarbon UVCB. For the purposes of PBT assessment, measured bioaccumulation data for representative hydrocarbon constituents have been used as detailed in section 8 of the CSR.
Terrestrial				Substance is a hydrocarbon UVCB.

NOTES: Standard tests for this endpoint are intended for single substances and are not appropriate for this complex substance.

Discussion

In a key semi-static 21 -day long-term *D. magna* toxicity test (OECD 211; KS = 2), 10 animals/loading were exposed to the WAF of other lubricant base oil LVIN 38 (CAS #64742-53-6) at nominal concentrations of 1, 10, 100 and 1000 mg/L resulting in a NOEL of 10 mg/L, based on reproduction. The loss of all daphnids in the 100 mg/L WAF was attributed to a non-treatment related effect, the cause of which was unknown. Further testing would be required to clarify the consequences of exposure to a 100 mg/L WAF of the base oil (Shell, 1995).

In a supporting semi-static 21-day long-term *D. magna* reproduction test (OECD 211; KS = 2), 10 animals/loading were exposed to the WAF of solvent-refined heavy paraffinic distillate (PSG 1860; CAS # 64742-04-7) at nominal concentrations of 0, 10, and 1000 mg/L resulting in a EL_{50} of >1000 mg/L and a NOEL of ≥1000 mg/L, based on the lack of mortality or reproduction impairment (BP Oil Europe, 1995).

In supporting semi-static 21-day long-term *D. magna* reproduction test (OECD 211; KS = 2), 10 animals/loading were exposed to the WAFs of other lubricant base oils HVI 60, XHVI 4.0, HVI 65, and LVIN 38 (CAS #64742-53-6) at nominal concentrations of 1 and 1000 mg/L. The NOEL for other lubricant base oils HVI 60, XHVI 4.0, and HVI 65 was ≥ 1000 mg/L based on reproduction. The NOEL for LVIN 38 was ≥1 mg/L based on reproduction (Shell, 1994); this substance was retested across a wider range of nominal concentrations and a NOEL of 10 mg/L was determined (as described above in Shell, 1995).

These studies are scientifically sound and satisfy the guideline requirements for long-term toxicity to aquatic invertebrates (See Attachment A).

12.4 Results of PBT assessment:

Overall conclusion: Based on the assessment described in the subsections below the submission substance is not considered as PBT/vPvB.

Rationale: Evaluation documented in “An Evaluation of the Persistence, Bioaccumulation and Toxicity of Petroleum Hydrocarbons” in the Assessments Section.

Persistence assessment

An evaluation of representative hydrocarbon structures indicates some structures meet the persistent (P) or very persistent (vP) criteria (see Concawe 2010b).

Bioaccumulation assessment

An evaluation of representative hydrocarbon structures indicates that none of the structures meet the bioaccumulative (B) or very Bioaccumulative (vB) criteria (see Concawe 2010b).

Toxicity assessment

For the representative structures that were found to meet the P criteria, a toxicity evaluation was performed (see Concawe 2010b). No structure that is relevant to the composition of lubrication oil; used was found to meet the toxicity criterion.

12.5 Other adverse effects:

12.6 Further ecological information:

Long-term EC_{10}/LC_{10} or NOEC for soil micro-organisms: 9.6 mg/kg soil dw

EC_{10}/LC_{10} or NOEC for aquatic micro-organisms: 2 mg/L

Information requirement: Toxicity to birds

Reason: study scientifically unjustified

Justification: In accordance with Column 2 of REACH Annex X, studies on long-term or reproductive toxicity to birds studies do not need to be conducted due to the existence of a large mammalian dataset.

Long-term EC_{10}/LC_{10}or NOEC for soil arthropods: 9.3 mg/kg soil dw. See Attachmen A for details of toxicological studies.

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13. DISPOSAL CONSIDERATIONS

13.1 Appropriate disposal / Product:

Place contaminated materials in disposable containers and dispose of in a manner consistent with applicable regulations. Contact local environmental or health authorities for approved disposal of this material.

This material may present environmental risks common to oil spills. Contact your local oil spill response group and applicable government agencies if a spill occurs.

13.2 Waste codes / waste designations according to EWC / AVV:

EWC No. 13 07 01

13.3 Appropriate packaging:

13.4 Additional information:

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14. TRANSPORT INFORMATION

14.1 Land transport (ADR/RID/GGVSE):

Official transport designation:
Class:
Classification Code: Non-hazardous
UN-No.: NA
Packing group:
Hazard label:
Tunnel restriction code:
Special provisions:

14.2 Sea transport (IMDG-Code/GGVSee):

Proper Shipping Name:

Class: Non-hazardous
UN-No.: NA
Packing group:
EmS:
Marine Pollutant:
Special provisions:

Air transport (ICAO-IATA/DGR):
Proper Shipping Name:
Class: Non-hazardous
UN-No.: NA
Packing group:
Special provisions:

15. REGULATORY INFORMATION

15.1 EU regulations

Chemical Safety Assessment:
Use within closed system for combustion or as a lubricating base oil

Labelling (Regulation (EC) No 1272/2008)

Hazard components for labelling:
Signal words: Danger
Hazard pictograms:

Hazard statements:
Xn - Harmful

Precautionary statements:
H304 – may be fatal if swallowed and enters airways

Supplemental Hazard information (EU):

Special rules for supplemental label elements for certain mixtures:
None

Labelling (67/548/EEC or 1999/45/EC)

Hazard symbols and hazard statements of dangerous substances and preparations:

Hazard components for labelling:
R-Phrases:
Xn, R65 - harmful: may cause lung damage if swallowed

S-Phrases:
S2 – keep out of reach of children
S23 – do not breathe gas / fumes/spray
S51 – use only in well ventilated areas
S62 – If swallowed so not induce vomiting: seek medical advice immediately and show this container or label

Remark:
None

Authorisations and/or restrictions on use:

Authorisations:
Restrictions on use:

Other EU regulations:

Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline):

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16. OTHER INFORMATION

16.1 Relevant R- and H-phrases (number and full text):

R65 - harmful: may cause lung damage if swallowed
H304 – may be fatal if swallowed and enters airways

16.2 Training instructions:

16.3.1 Uses- and exposure categories (overview):

Exposure	Industrial use:	Professional use:	Consumer use:
Human, oral, short term:	**0**	**0**	**0**
Human, oral, long term/repeated:	**0**	**0**	**0**
Human, dermal, short term:	**0**	**0**	**0**
Human, dermal, long term/repeated:	**0**	**0**	**0**
Human, inhalative short term:	**0**	**0**	**0**
Human, inhalative, long term/repeated:	**0**	**0**	**0**
Environment, water, short term/single:	**0**	**0**	**0**
Environment, water, continuous:	**0**	**0**	**0**
Environment, air, short term/single:	**0**	**0**	**0**
Environment, air, continuous:	**0**	**0**	**0**
Environment, soil, short term/single:	**0**	**0**	**0**
Environment, soil, continuous:	**0**	**0**	**0**

use advised (+)
use advised against (-)
not identified use (0)
