Distillates, petroleum, hydrofined lubricating oil: Human health tier II assessment

12 December 2019

CAS Number: 68782-97-8

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted

and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:www.nicnas.gov.au

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	hydrofined lube oil overhead, petroleum DHLO
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight (g/mol)	N/A

Import, Manufacture and Use

Australian

Distillates (petroleum), hydrofined lubricating-oil (DHLO; CAS No. 68782-97-8) is a refined mineral oil. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) has previously conducted a Human Health Tier II assessment of selected refined base oils under the Inventory Multi-Tiered Assessment and Prioritisation (IMAP) framework. This assessment will form the basis of the assessment of Distillates (petroleum), hydrofined lubricating-oil, and is available at www.nicnas.gov.au. This report should be read in conjunction with the Human Health Tier II assessment of selected refined base oils.

No specific Australian use, import or manufacturing information has been identified for the chemical.

Similar refined base oils have reported commercial uses in Australia, including as:

- surface active agents;
- heat transferring agents;
- hydraulic fluids and agents;
- fuel additives; and
- viscosity adjusters.

International

The following industrial uses have been identified for DHLO and refined base oils through: Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN) database; and the US Environmental Protection Agency's Aggregated Computational Toxicology Resource (ACToR).

The chemical (DHLO) has reported commercial uses in:

- autocare products;
- wood, textile and leather treatments;
- lubricants;
- protective coatings;
- paints, lacquers and varnishes; and
- adhesives.

Based on a Canadian survey, DHLO is unlikely to be in use in Canada (Government of Canada, 2018).

In general, the selected refined base oils have reported commercial and site-limited uses including:

- as solvents
- as industrial lubricants including engine oils, transmission fluids, ear oils, hydraulic fluids, fuel additives, metalworking oils, greases, heat transfer oils, machine oils, spray oils, tyre oils, and general purpose oils; and
- in printing inks (US EPA, 2011; IARC, 2012)

Some of the selected base oils have additional reported uses, up to a concentration of 100 %, as grease/lubricants, oils and oil additives, e.g. motor oil; and in power steering fluid and transmission fluids (US Department of Health and Human Services, Household Products Database (HHPD). These products may be used by members of the public for car maintenance activities. As the chemical of this assessment is a lubricating oil it is expected to have the same reported uses.

Restrictions

Australian

No known restrictions have been identified for the chemical or the group of selected refined base oils.

International

Generally, selected refined base oils are listed on the following (Galleria Chemica):

- ASEAN Cosmetic Directive Annex II Part 1: List of substances which must not form part of the composition of cosmetic products;
- EU Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products—Annex II—List of substances prohibited in cosmetic products;
- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain—Table 1.
- Annex XVII to REACH Regulation as follows:

'Shall not be used in substances and preparations placed on the market for sale to the general public in individual concentration equal to or greater than: either the relevant concentration specified in Annex I to Directive 67/548/EEC, or the relevant concentration specified in Directive 1999/45/EC.'

Existing Work Health and Safety Controls

Hazard Classification

The chemical is not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

As a result of NICNAS recommendation from the selected refined base oils assessment (July 2014), the chemicals in the selected refined base oils assessment are classified as hazardous, with the following risk hazard categories and hazard statements for human health (depending on the degree of refinement) in the HCIS:

Acute Toxicity – Category 4; H332 (Harmful if inhaled)

Skin Irritation – Category 2; H315 (Causes skin irritation)

Carcinogenicity – Category 1B; H350 (May cause cancer)

Reproductive Toxicity – Category 2; H361d (Suspected of damaging the unborn child)

Exposure Standards

Australian

No specific exposure standards are available for the specific chemical. The exposure standard for oil mist, refined mineral is 5 mg/m^3 time weighted average (TWA).

Guidance on the interpretation of workplace exposure standards for airborne contaminants provides advice that exposure to carcinogens should be eliminated or minimised so far as is reasonably practicable (Safe Work Australia, 2013).

International

The following exposure standards are identified (Galleria Chemica):

A number of countries have exposure standards for oil mist mineral including an exposure limit of 0.2–5 mg/m^3 (TWA) in different countries such as the United Arab Emirates, Japan, Austria, United States of America (USA) and Canada; and a short-term exposure limit (STEL) of 3–10 mg/m^3 in countries such as Sweden, Egypt, the USA, Canada, Singapore and Poland.

The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a threshold limit value (TLV) of 5 mg/m^3 (TWA) for pure, highly and severely refined mineral oils. The ACGIH does not recommend application of this TLV to poorly- and mildly-refined mineral oils. No TLV is assigned for these based on insufficient data, although an A2 suspected human carcinogen classification is assigned (ACGIH, 2011).

Health Hazard Information

Distillates, petroleum, hydrofined lubricating oil (CAS No. 68782-97-8) is a type of refined distillate base oil from crude oil, consisting of 50 % lubricating oil and the remainder being lighter hydrocarbons resulting from condensation of the stripper overheads from a hydrofining process for lube oil. The refining process aims to reduce the sulfur content of crude oil through reaction in the presence of a catalyst and hydrogen (hydrofining). For lubrication oil hydrofining, the crude mixture enters a furnace and is heated, then pushed through a stripper tower where sulfur is removed in the form of hydrogen sulfide. This stripper tower contains the overheads, from which lighter hydrocarbons condense onto, and mix with hydrofined oil to generate the hydrofined lube oil overhead mixture comprising DHLO (Speight, 2011a).

The 50 % lubricating oil is consistent with the types of ‘lubricating oils’ in the selected refined base oils assessment. The remainder of the mixture consists of shorter chain hydrocarbons from the condensate, these are known to have boiling points approximately between 21°C and 482°C (SciFinder). These boiling points indicate that carbon chains between C5 and C35 are present. The C15-50 carbon chains are found in multiple chemicals within the selected refined base oils assessment. The properties of C5-C15 carbon chains are not assessed in this report (Speight, 2011b).

The toxicity of the shorter carbon chains present is not expected to be greater than the toxicity of the longer length chains. However, the lower boiling point of the shorter chain oils will result in more vapour being present, leading to higher chance of inhalation or ignition. A review of the physical hazards of the chemical has not been undertaken as part of this assessment, as such these properties are not considered.

On the basis of the chemical composition and the processing to generate hydrofined lube oil overhead, it can be defined as a refined base oil.

The NICNAS Human Health Tier II assessment of selected refined base oils will form the basis of the assessment of hydrofined lube oil overhead, and is available at www.nicnas.gov.au. This report should be read in conjunction with the Human Health Tier II assessment of selected refined base oils.

Toxicological profile

The toxicological profile of HDLO is expected to be closely related to that of the selected refined base oils. Given the similar use profiles and generally similar physicochemical properties, toxicological data for selected refined base oils can be read across to the chemical hydrofined lube oil overhead.

In general, it can be assumed that the toxicity of base oils increases with the polycyclic aromatic hydrocarbon (PAH) content (Government of Canada, 2018).

Following oral exposure, refined base oils are expected to have low oral acute toxicity, with median lethal dose (LD50) values reported to be >5000 mg/kg body weight (bw). Refined base oils are expected to have low acute toxicity following dermal exposure, with the available data for several of these chemicals indicating acute dermal LD50 values >2000 mg/kg bw (NICNASa).

The level of acute toxicity after inhalation exposure is expected to depend on the degree to which the oil has been refined. Insufficiently refined oil warrant hazard classification for acute inhalation toxicity (see **Recommendations**). (Does not apply to highly or severely refined oils, containing <3 % w/w dimethylsulfoxide (DMSO) extractables (as measured by the IP346 assay) (US EPA, 2011; NICNASa; REACH).

Based on the available data for an insufficiently refined oil, hazard classification is warranted for skin irritation (NICNASa) (see **Recommendations**). This does not apply to highly or severely refined oils with <3 % DMSO extractable content (NICNASa).

Based on the data available for refined base oils, the chemical may be slightly irritating to eyes.

The limited available data for refined base oils do not indicate a potential for skin sensitisation.

The systemic toxicity of the chemical and the chemicals in the read-across group of selected refined base oils are dictated by the systemic toxicity of high-boiling petroleum substances. The level of toxicity is correlated with the concentration of PAHs, which is linked with the level of refinement. Minimal systemic effects were observed for highly refined chemicals in the selected refined base oils group.

The genetic toxicity of the chemical is expected to be related to the level of refinement and associated removal of PAHs. The data available on selected refined base oils gave mixed results for genotoxicity studies.

Based on the available information for selected refined base oils, the chemical warrants hazard classification for carcinogenicity, depending on the degree of refinement (see **Recommendations**). Several refined base oils caused skin tumours in mice.

This classification does not apply to highly or severely refined oils, containing <3 % w/w dimethylsulfoxide (DMSO) extractables (as measured by the IP346 assay) (US EPA, 2011; REACH).

No reproductive or developmental data are available for the refined base oils; however, based on developmental toxicity of unrefined base oils (NICNASb) and certain petroleum streams, classification for developmental toxicity is warranted for the chemical (see **Recommendations**).

Risk Characterisation

Critical Health Effects

The critical health effects for the chemical, as a selected refined base oil, is dependent upon the level of refinement. The critical health effects for less refined base oils (DMSO extractable content > 3 % in the IP346 assay) include carcinogenicity and developmental toxicity, acute effects (acute toxicity by the inhalation route of exposure) and local effects (skin irritation).

Exposure to mists may also cause respiratory symptoms such as cough and phlegm.

Public Risk Characterisation

No specific use information was identified for the chemical. Given the uses identified for the group of selected refined base oils, the most significant source of public exposure will be through using auto products such as motor oils during car maintenance activities. Therefore, widespread public exposure is not expected, with exposure limited to hobbyists.

The chemical is expected to be highly refined; however, verification by testing would be needed to determine the hazardous properties. Auto products available to consumers are also expected to be available in the workplace, and subject to workplace labelling. Workplace labelling will identify the hazards of any products containing chemicals with a DMSO-extractable content > 3% in the IP346 assay. Hence, the public risk from these chemicals is not considered to be unreasonable.

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation exposure of workers to the chemical may occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemical at lower concentrations may also occur while using formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical systemic long-term, systemic acute and local health effects, the chemical may pose an unreasonable risk to workers unless adequate control measures to minimise dermal and inhalation exposure to the chemical are implemented. The chemical should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine appropriate controls.

The Guidance on the interpretation of workplace exposure standards for airborne contaminants provides advice that exposure to carcinogens should be eliminated or minimised so far as is reasonably practicable (Safe Work Australia, 2013). The controls

expected to be in place due to the carcinogenicity classification are considered to be sufficient to protect workers from any potential developmental and non-cancer systemic effects.

The data available support an amendment to the hazard classification in the Hazardous Chemical Information System (HCIS) (Safe Work Australia) (refer to **Recommendation** section).

NICNAS Recommendation

Assessment of the chemical is considered to be sufficient, provided that the recommended amendments to the classification are adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Work Health and Safety

The chemical is recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This does not consider classification of physical hazards and environmental hazards. The hazard classifications in place for selected refined base oils should apply to DHLO (CAS No. 68782-97-8).

The classifications need not apply if it can be shown that the substance contains less than 3% DMSO extract as measured by the IP346 assay.

The recommended classification and labelling entry should have the following note appended 'Note 10 (The chemical is a substance of unknown or variable composition, complex reaction product, or biological material (UVCB). The hazards of the chemical may depend on the composition. For more information refer to the assessment report published on the website of the National Industrial Chemical Notification and Assessment Scheme.)'

As of 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Not Applicable	Harmful if inhaled - Cat. 4 (H332)
Irritation / Corrosivity	Not Applicable	Causes skin irritation - Cat. 2 (H315)
Carcinogenicity	Not Applicable	May cause cancer - Cat. 1A (H350)
Reproductive and Developmental Toxicity	Not Applicable	Suspected of damaging the unborn child - Cat. 2 (H361d)

[a] Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

[b] Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

[*] Existing Hazard Classification. No change recommended to this classification

Advice for industry

Control measures

Control measures to minimise the risk from dermal and inhalation exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate, or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures that could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemicals from entering the breathing zone of any worker;
- health monitoring for any worker who is at risk of exposure to the chemical, if valid techniques are available to monitor the effect on the worker's health;
- air monitoring to ensure control measures in place are working effectively and continue to do so;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemicals.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to help meet obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((M)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (M)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals—Code of practice* and *Labelling of workplace hazardous chemicals—Code of practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemical has not been undertaken as part of this assessment.

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Last update 12 December 2019

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