Hydrocarbon, paraffin and slack waxes: Human health tier II assessment

27 November 2014

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Petrolatum	8009-03-8
Paraffin waxes and hydrocarbon waxes, microcrystalline	63231-60-7
Hydrocarbon waxes, petroleum, acid treated	64742-26-3
Hydrocarbon waxes, petroleum, chemically neutralized	64742-33-2
Hydrocarbon waxes, petroleum, clay treated microcrystaline	64742-42-3
Paraffin waxes, petroleum, clay treated	64742-43-4
Paraffin waxes, petroleum, hydrotreated	64742-51-4
Hydrocarbon waxes, petroleum, hydrotreated microcrystalline	64742-60-5
Slack wax, petroleum	64742-61-6

Chemical Name in the Inventory	CAS Number
Petrolatum, petroleum, oxidized	64743-01-7
Slack wax, petroleum, hydrotreated	92062-09-4
Paraffin waxes and hydrocarbon waxes, C19-38	97489-05-9

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

Grouping Rationale

The chemicals in this group are hydrocarbon, paraffin and slack waxes that are derived from lubricating oil basestocks (also known as base oils). The chemical composition depends on both the original crude oil and on the processes used during refining. The chemicals are UVCBs (unknown or variable composition, complex reaction products and biological materials) containing variable amounts of straight and branched chain saturated hydrocarbons. The chemical components have a wide range of molecular weights (from 290–630 Da), with carbon numbers usually between C12 to C85, with the majority exceeding C20, and boiling points between 300 and 600 °C.

The chemicals in this group are usually not defined by detailed chemical composition but by process history, physical properties and product specifications. Each chemical can also differ in the proportion and identity of the various chemical components depending upon the source of the chemical and process history.

Waxes are predominantly saturated paraffins; solid or semi-solid at room temperature, and are classed according to their oil content and melting point. Waxes are separated from the lubricating oil basestocks by chilling or solvent extraction (dewaxing). Slack waxes can be further de-oiled to produce refined waxes (paraffin or microcrystalline) with a lower oil content. Petrolatum can refer to crude petrolatum (which is primarily slack waxes and may contain polyaromatic compounds (PACs) or other contaminants) or food-grade petrolatum (highly refined). The food grade petrolatum is often produced by including food-grade white mineral oil (CAS No. 8042-47-5).

At each process step in the production of waxes, the oil and impurities content is lowered. Slack wax and crude petrolatum are the least refined chemicals in this category and usually contain from 5 to 20 % oil. The composition of this oil, including the levels of PACs, varies depending on the other processes that have been used in the previous refining steps. The removal of impurities in the production of refined/finished waxes and petrolatum from slack wax also removes aromatics and PACs.

Whilst other compositional characteristics may influence toxicity, the systemic toxicity of high-boiling petroleum substances (HBPS), such as the chemicals in this group, may be correlated with concentrations of PACs, particularly those composed of 3,4,5,6 and/or 7 fused aromatic rings (Feuston et al. 1994).

Import, Manufacture and Use

Australian

The following Australian industrial uses were reported under previous mandatory and/or voluntary calls for information:

- microcrystalline paraffin and hydrocarbon waxes (CAS No. 63231-60-7) with a reported site-limited use in explosives;
- hydrotreated paraffin waxes (CAS No. 64742-51-4) with a reported use as 'other' (substances whose technical functions are not described elsewhere);
- hydrotreated microcrystalline hydrocarbon waxes (CAS No. 64742-60-5) with a reported domestic use in adhesives;
- slack wax (CAS No. 64742-61-6) with a reported commercial use in lubricants and additives; and
- petrolatum (CAS No. 8009-03-8) with reported use as a cosmetic.

The following chemicals are listed on the 2006 High Volume Industrial Chemicals List (HVICL):

- hydrotreated paraffin waxes (CAS No. 64742-51-4) with a total reported volume of 1000–9999 tonnes; and
- slack wax (CAS No. 64742-61-6) with a total reported volume of 1000–9999 tonnes.

The total volume introduced into Australia, reported under previous mandatory and/or voluntary calls for information, for microcrystalline paraffin and hydrocarbon waxes (CAS No. 63231-60-7) and petrolatum (CAS No. 8009-03-8) was <1000

tonnes.

International

The following international uses have been identified through the European Union (EU) Registration, Evaluation and Authorisation of Chemicals (REACH) dossiers; Galleria Chemica; the Substances and Preparations in the Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; the United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; the OECD High Production Volume chemical program (OECD HPV).

The chemicals with CAS Nos 63231-60-7, 64742-33-2, 64742-42-3, 64742-51-4 and 64742-60-5 are included in the CosIng database and US INCI dictionary with the identified cosmetic functions of binding, emulsion stabilising, and viscosity controlling. Petrolatum (CAS No. 8009-03-8) has the identified cosmetic functions as an antistatic and emollient agent.

With the exception of petrolatum (CAS No. 8009-03-8), microcrystalline wax (CAS No. 63231-60-7) and hydrogenated microcrystalline wax (CAS No. 64742-60-5), there is currently no documented use of these chemicals in cosmetic products in the United States of America (USA). Petrolatum (CAS No. 8009-03-8) and microcrystalline wax (CAS No. 63231-60-7) had a high reported frequency of use (2307 and 1447 respectively) (ed. Bailey 2011). Hydrogenated microcrystalline wax (CAS No. 64742-60-5) was also reported but with a low frequency of use (5).

Most of the chemicals have reported domestic use including:

- in adhesives and binding agents;
- in cleaning/washing agents;
- in corrosion inhibitors;
- in paints, lacquers and varnishes; and
- in surface treatment.

In the USA, there are documented domestic uses including:

- as candles (10–100 % concentration) (CAS Nos 63231-60-7, 64742-43-4, 64742-51-4);and
- in domestic cleaning products (up to 1.5 % concentration) (CAS No. 64742-43-4).

Most of the chemicals have reported commercial use including:

- in anti-set-off and anti-adhesive agents;
- in impregnation materials; and
- as lubricants and additives.

In the USA, there are documented commercial uses including:

- in flux, welding and soldering agents (40–70 % concentration) (CAS No. 8009-03-8); and
- in commercial cleaning products (CAS No. 64742-51-4).

The following chemicals have reported site-limited use including:

- in intermediates (CAS No. 63231-60-7);
- in stabilisers (CAS No. 64742-51-4); and
- in vulcanising agents (CAS No. 64742-43-4).

The chemicals with CAS Nos 64742-51-4, 64742-60-5 and 8009-03-8 have reported non-industrial use including:

- in food/feedstuff, flavourings and nutrients;
- in non-agricultural pesticides and preservatives;
- in agricultural pesticides; and
- in pharmaceuticals.

Restrictions

Australian

No known restrictions have been identified.

International

The chemicals with CAS Nos 8009-03-8 and 64742-61-6, 64743-01-7 and 92062-09-4 are listed on the following, except if the full refining history is known, and it can be shown that the substance from which it is produced is not a carcinogen (Galleria Chemica):

- EU Cosmetics Regulation 1223/2009 Annex II—List of substances prohibited in cosmetic products; and
- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain;
- Association of South East Asian Nations (ASEAN) Cosmetic Directive Annex II Part 1: List of substances which must not form part of the composition of cosmetic products.

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals with CAS Nos 8009-03-8, 64743-01-7, 64742-61-6 and 92062-09-4 are classified as hazardous, with the following risk phrase for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

- Carc. Cat 2; R45—May cause cancer

This classification is subject to notes H and N.

'Note H: The classification and label shown for this substance applies to the dangerous property(ies) indicated by the Risk Phrase(s) in combination with the category(ies) of danger shown. The manufacturers, distributors and importers of this substance shall be obliged to carry out an investigation to make themselves aware of the relevant and accessible data which exists for all other properties to classify and label the substance.' (Safe Work Australia)

'Note N: The classification as a carcinogen need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen. This note only applies to certain complex oil-derived substances in Annex I.' (Safe Work Australia)

Exposure Standards

Australian

No specific exposure standards are available.

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 standard is identified (Galleria Chemica):

- A Temporary Emergency Exposure Limit (TEEL) of up to 11000 mg/m3 (TEEL-3) has been stated for petrolatum (CAS No. 8009-03-8) by the US Department of Energy (DOE).

Health Hazard Information

The toxicity profile of the chemicals in this group is expected to be correlated to the levels of PACs. Slack waxes and crude petrolatum are the least refined chemicals in this group and are expected to contain the highest levels of PACs; however, levels will depend on the process history. Whilst several studies are available for slack wax (CAS No. 64742-61-6), which may be expected to represent the reasonable worst-case toxicity for the chemicals in this group, the samples of slack wax that were submitted for testing (repeat dose and developmental/reproductive toxicity) did not contain detectable levels of PACs and were, therefore, not tested.

Toxicological data have been reported for chemicals belonging to the lubricating oil basetock (base oils) groups. The saturated hydrocarbons present in these basestocks are similar to those in the chemicals in the wax group, and are derived from the same petroleum process streams. Therefore, they are expected to represent the reasonable worst-case toxicity for the chemicals in this group. The analogue chemicals for which hazard data have been used to infer effects in the absence of specific data, according to the principles of 'read-across' (OECD 2014), include:

- selected unrefined or mildly refined base oils (CAS Nos 64741-50-0, 64741-51-1, 64741-52-2, and 64741-53-3) (NICNAS b); and
- selected refined base oils include CAS Nos 64741-96-4, 64741-97-5, 64742-52-5, 64742-53-6, 64742-54-7, 64742-55-8, 64742-56-9 and 64742-65-0) (NICNAS c).

Data have also been included for paraffin waxes and hydrocarbon waxes (CAS No. 8002-74-2). This is considered a valid member of this group, with low PAC content, but has already been published as a Tier I assessment as it was considered to pose no unreasonable risk to public health by application of expert validation rules (NICNAS a).

Acute Toxicity

Oral

No data are available for the chemicals. Based on the available analogue data, the chemicals in this group are considered to have low acute toxicity following oral exposure.

The analogue chemicals, unrefined and refined base oils, have low acute toxicity based on results from animal tests following oral exposure. The median lethal dose (LD50) in rats is >5000 mg/kg bw (NICNAS b,c). Observed sub-lethal effects included hypoactivity, diarrhoea, and yellow-stained anal area.

Dermal

No data are available for the chemicals. Based on the available data, the chemicals in this group are considered to have low acute toxicity following dermal exposure.

Paraffin waxes and hydrocarbon waxes (CAS No. 8002-74-2), had low acute toxicity following dermal exposure in tests conducted in accordance with OECD Test Guideline (TG) 402. The LD50 in rats is >2000 mg/kg bw. Observed sub-lethal effects included dermal irritation and red staining around the nose and eyes.

The analogue chemicals, refined base oils, had low acute toxicity based on results from animal tests following dermal exposure, in tests conducted in accordance with OECD TG 402. The LD50 in rats is >2000 mg/kg bw. Observed sub-lethal effects included signs of dermal irritation including erythema and oedema, fissuring and desquamation (NICNAS c).

Inhalation

No data are available. However, due to the physical characteristics of the chemicals (low vapour pressure and waxy nature) there is a low potential for inhalation exposure.

Corrosion / Irritation

Skin Irritation

No data are available for the chemicals. Based on the data available, the chemicals in this group could cause irritation to the skin, particularly following prolonged or repeated exposure (see **Repeat dose toxicity** and **Reproductive toxicity** sections). Data are not sufficient to warrant classification.

Whilst unrefined base oils are considered to be skin irritants (NICNAS b), only slight skin irritant effects were observed with several highly or severely refined oils containing <3 % w/w DMSO extractables (NICNAS c). Paraffin waxes and hydrocarbon waxes (CAS No. 8002-74-2) produced no skin irritation in studies that were performed in accordance with OECD TG 404 (REACH a).

Eye Irritation

No data are available for the chemicals. Based on the data available, the chemicals in this group are considered to be, at most, slightly irritating to the eyes. The effects were not sufficient to warrant a hazard classification.

Paraffin waxes and hydrocarbon waxes (CAS No. 8002-74-2), microcrystalline wax (CAS No. 63231-60-7) and a chemical identified as 50 % paraffin in petrolatum (CAS No. not stated) were reported to, at most, slightly irritate the eyes when tested in accordance with OECD TG 405. Slight transient irritation of the conjunctivae was observed in some studies. The effects were reversible within 72 hours after application (REACH a,b).

The analogue chemicals, unrefined and refined base oils, were considered to, at most, slightly irritate the eyes when tested in accordance with OECD TG 405 (NICNAS b,c).

Sensitisation

Skin Sensitisation

There are limited data available. Based on the data available, the chemicals in this group are not considered to be skin sensitisers.

Petrolatum (CAS No. 8009-03-8) was not a dermal sensitiser in guinea pigs when tested using a modified Buehler method (REACH a,b).

Paraffin waxes and hydrocarbon waxes (CAS No. 8002-74-2), was not a dermal sensitiser in the guinea pig maximisation test (REACH a,b).

The data for refined base oils do not indicate a potential for skin sensitisation (NICNAS c).

Observation in humans

Petrolatum (CAS No. 8009-03-8) is commonly used by dermatologists as a vehicle in human patch testing (US EPA 2011).

Repeated Dose Toxicity

Oral

No data are available for the chemicals. A number of studies on analogue chemicals including petroleum waxes, petrolatums, lubricating oil basestocks and white mineral oils, have been reported. The available studies, which included two paraffin waxes (one hydrotreated) and two microcrystalline waxes (one clay treated and one hydrotreated) are considered representative. Observed effects are consistent with those observed in dermal studies with HBPS (see **Dermal** section below), and occur at levels at which effects are not sufficient for classification.

In two separate 90 day studies in Fischer 344 (F334) rats, exposure to different paraffin waxes in the diet at 0, 0.002, 0.02, 0.2 or 2.0 % concentration, led to increased organ weights (spleen, liver and lymph nodes) and effects on haematology (including decreased haemoglobin and decreased platelet count). Histopathological evaluation showed inflammatory changes in the liver, mesenteric lymph nodes, ileum and jejunum. Liver effects included hepatocellular vacuolation and granulomas. Mesenteric lymph node effects included histiocytosis and microgranulomas. There was also an increase in weight of mesenteric lymph nodes in the 2.0 % (high dose) group (data only available at this dose). The studies included a high dose recovery group; only partial reversal of the effects in the mesenteric lymph nodes was reported in the high dose group after the recovery period. The ileum and jejunum had an increased incidence of macrophage accumulation. Female F344 rats were more sensitive than males. The lowest observed adverse effect levels (LOAELs) for these studies was 0.2 % (equivalent to 110 and 160 mg/kg bw/day). Comparative toxicity, pharmacokinetic and pathology studies indicate that the response seen in F344 rats is not applicable to human health (see **Observation in humans**).

Direct comparison studies were performed with F344 and Sprague Dawley (SD) rats in 90-day feeding studies with low-viscosity and low molecular weight white mineral oils at dosages of 0.2 or 2.0 % (HPV Testing Group 2011). In F344 rats, there were similar changes to those observed in the previous studies. However, in SD rats, there was no formation of microgranulomas and there was only a slight increase in inflammatory cells in the liver at the highest dose. The mineral hydrocarbon concentrations in the mesenteric lymph nodes in both strains were similar, but the F344 rats were reported to have a 3- to 4-fold greater liver burden than SD rats at the same doses. The F344 rats also accumulated more mineral hydrocarbons in the liver and lymph nodes than SD rats and had a much greater inflammatory response. In one study, Kupffer cells were also isolated from the liver for evaluation, as these cells can be involved in the formation of granulomas. The electron microscopy evaluation of Kupffer cells from F344 rats reported large, irregularly shaped, membrane associated vacuoles in over half the cells, and decreased production of tumour necrosis factor-a and leukotrine B4. The effects in the lymphoid and Kupffer cells were not observed, or only rarely observed, in SD rats. An overall NOAEL of 2.0 % (about 1600 mg/kg bw/day) for the white mineral oil was reported in SD rats.

In the rats administered microcrystalline waxes, there were no significant changes in growth rates, food intake, clinical condition, organ weights, or histopathological examinations. There was a slight increase in haemoglobin concentration in high-dose males. An overall NOAEL of 2.0 % (about 1100 mg/kg bw/day) for the microcrystalline waxes was reported.

Dermal

No data are available for the chemicals.

The systemic toxicity of high-boiling petroleum substances (HBPS), such as the chemicals in this group, may be correlated with concentrations of PACs, particularly those composed of 3,4,5,6 and/or 7 fused aromatic rings. Although other compositional characteristics may influence toxicity (TERA 2008), the systemic toxicity of the chemicals is expected to be correlated with the level of refinement of the chemicals. An analysis of several dermal toxicity studies for HBPS indicate that the sensitive endpoints

for repeated dose toxicity include changes in organ weight (decreased thymus weight and increased liver weights) and changes in haematological parameters (decreased haemoglobin concentrations and decreased platelet count) (Feuston et al. 1994; Simpson et al. 2008).

Minimal systemic effects have been observed for the analogue chemicals, unrefined and refined base oils, that have been tested (NICNAS b,c). The analogue chemicals (with CAS Nos 64741-50-0, 64741-96-4, 64741-97-5 and 64742-65-0) were applied dermally to New Zealand White rabbits. Skin irritation was consistently reported in the studies. There were slightly increased liver weights reported in some studies but they were not statistically significant. There were no other significant histopathological changes reported. The NOAEL for systemic toxicity ranged from 1000 to 5000 mg/kg bw/day.

Inhalation

No data are available. Due to the low vapour pressure and waxy nature of these chemicals, inhalation exposure is not expected, with the most likely routes of human exposure to the chemicals in this group being oral and/or dermal.

Observation in humans

There are limited data available.

The HPV Testing Group (2011) summarised studies examining the absorption and metabolism of mineral hydrocarbons, and reported that there is limited absorption (2–20 %) following ingestion for mammalian species, including humans. Human lipogranulomas in the liver, lymph nodes and spleen are reported to occur in a high percentage of the population; however, they do not progress to clinically significant lesions. In contrast to observations in F344 rats, humans have been reported to show small histiocytic collections with minimal inflammation.

Genotoxicity

Based on the weight of evidence from the available in vitro and in vivo genotoxicity studies, the chemicals in this group are not considered to be genotoxic. Chemicals in this group were negative in several in vitro (bacterial gene mutation, mouse lymphoma assay) and in vivo (chromosomal aberration, bone marrow micronucleus) tests for gene mutation and clastogenicity (HPV Testing Group 2011). However, the genetic toxicity of the chemicals is expected to be related to the level of refinement and associated removal of PACs. The genotoxicity of the base oil that that chemicals are derived from can be verified with screening tests such as the optimised Ames test and/or the IP346 test. 'The modified Ames test measures the amount of extractable mutagenic activity in a mineral-oil sample; mineral oils with a mutagenicity index = 1.0 in this assay are considered highly or severely refined. The IP346 assay measures the amount of material extractable in dimethyl sulfoxide (DMSO)-mineral oils with a DMSO-extractable content < 3 % in the IP346 assay are considered highly or severely refined.' (IARC 2012).

In a modified bacterial reverse mutation test, DMSO-extracts of oxidised petrolatum (CAS No. 64743-01-7) and slack wax (CAS No. 64742-61-6) (4 samples) were negative in *Salmonella typhimurium* strain TA 98 in the presence of metabolic activation. In the same study, the unrefined base oils (CAS Nos 64741-50-0, 64741-51-1 and 64741-53-3) were positive in *S. typhimurium* strain TA 98 in the presence of metabolic activation.

In a modified bacterial reverse mutation test, a DMSO-extract of the analogue paraffin waxes and hydrocarbon waxes (CAS No. 8002-74-2), was not mutagenic to *S. typhimurium* (strains TA98, 100, 1535, and 1537) and *Escherichia coli* (strain WP2uvrA) with and without metabolic activation.

In a cell gene mutation test in mouse lymphoma L5178Y cells conducted similarly to OECD TG 476, with the analogue paraffin waxes and hydrocarbon waxes (CAS No. 8002-74-2) negative results were reported with metabolic activation. An increased mutant frequency was observed at a single dose level of 2.4 mmol/L without metabolic activation. The authors stated that this was caused by a low value of the cloning efficiency and was not due to mutagenicity.

In a chromosome aberration test conducted similarly to OECD TG 473, with CAS Nos 8002-74-2, negative results were reported in Chinese hamster ovary cells, with and without metabolic activation.

Mixed results from genotoxicity studies (mouse micronucleus tests conducted in accordance with OECD TG 473) are available for analogue chemicals from the refined base oils (NICNAS c).

Carcinogenicity

The slack waxes and petrolatums are currently classified as hazardous as a Category 2 carcinogen with the risk phrase 'May cause cancer' (T; R45) in HSIS (Safe Work Australia). This is subject to the note that the classification as a carcinogen need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen. Paraffin and microcrystalline waxes are not currently classified for their carcinogenicity; this is considered appropriate as the removal of impurities in the production of refined/finished waxes and petrolatum from slack wax is reported to also removes aromatics and PACs (HPV Testing Group 2011).

In skin painting studies reported with slack wax (CAS No. 64742-61-6), that were produced using a modern refining method, and petrolatum (CAS No. not identified), the backs of male mice were painted at doses of 25 or 50 mg of the chemical for 2 days/week for 80 weeks. There was no significant increase in the incidence of skin tumours (HPV Testing Group 2011).

In a lifetime skin-painting study reported with eight slack wax (CAS No. 64742-61-6) samples, that were produced using older 'pressing' refining methods, the backs of male mice were painted at doses of 15 mg of the chemical for 3 days/week. At 450 days benign skin tumours had developed in all groups and malignant skin tumours in five of the eight groups. The study authors concluded that the carcinogenicity was caused by the aromatic content of the chemicals (Petroleum HPV Testing Group 2011).

In a two year oral repeated dose toxicity study in which rats were exposed to high doses of petrolatum (approximately 2500 mg/kg bw/day) there was no evidence of carcinogenicity (US EPA, 2011).

Petroleum substances containing <3% w/w DMSO extractables (as measured by the IP346 assay) are not carcinogenic to skin (IPIECA 2010). For the chemicals in this group, an unrefined process stream chemical which contains significant DMSO extractables (i.e. PAC), and a refined process stream chemical which does not, can be listed under the same CAS No. Therefore, the classification of the chemicals in this group is dependent on knowledge of the process history of each chemical.

Reproductive and Developmental Toxicity

No data are available for the chemicals.

Certain petroleum stream chemicals have been shown to be developmentally toxic by the dermal route of exposure. Effects include increased incidence of early and total resorptions and decrease in foetal body weight (IPIECA 2010; Murray et al. 2013). Similar embryotoxic effects have been described in laboratory animals exposed to PACs such as benz[a]anthracene, benzo [a]pyrene, and naphthalene (EHC 1998). The chemical in this category which might contain significant concentrations of PACs is slack wax (CAS No. 64742-61-1); however, none of the samples submitted for testing contained detectable concentrations of PAC and were, therefore, predicted to be non-hazardous and not tested (HPV Testing Group 2011).

Based on the weight of evidence from developmental toxicity studies the analogues, unrefined and refined base oils, were recommended for classification for developmental effects, although it was acknowledged that this need not apply for highly or severely refined oils (NICNAS b,c).

The developmental toxicity of HBPS, such as the chemicals in this group, may be correlated with concentrations of PACs, particularly those composed on 3,4,5,6 and/or 7 fused aromatic rings (Feuston et al. 1994; Murray et al. 2013). Although other compositional characteristics may influence toxicity (TERA 2008), the developmental toxicity of the chemicals is expected to be correlated with the level of refinement of the chemicals. In the absence of further information, classification for developmental toxicity is considered appropriate for those chemicals classified for carcinogenicity.

Whilst a predictive test for the developmental effects of HBPS has not been developed (IPIECA 2010), the associated developmental effects (increased incidence of resorptions and decrease in foetal body weight) have been shown to be significantly correlated with the mutagenicity index (Feuston et al. 1994). Therefore, in the absence of more information, the current note N that applies to the carcinogenicity classification is also considered appropriate for the developmental classification.

Paraffin and microcrystalline waxes are not currently classified for their developmental toxicity; this is considered appropriate as the removal of impurities in the production of refined/finished waxes and petrolatum from slack wax is reported to also remove aromatics and PACs (HPV Testing Group 2011).

Risk Characterisation

Critical Health Effects

The critical health effects for chemicals in this group are dependent upon the level of refinement. For chemicals which have been highly refined such that there are no detectable concentrations of PACs, there are no critical health effects.

For less refined hydrocarbon waxes such as slack wax and crude petrolatums with detectable concentrations of PACs, the critical health effects are carcinogenicity and developmental toxicity.

Public Risk Characterisation

There is widespread exposure of the refined and finished wax chemicals in this group to the public through cosmetic and domestic uses. However, given the low hazard of the chemicals when highly refined, the chemicals are not considered to pose an unreasonable risk to public health. Based on international use information, widespread public exposure to less refined waxes such as slack waxes and crude petrolatum is not expected.

Occupational Risk Characterisation

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

Given the critical systemic long-term health effects for unrefined chemicals, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise dermal and ocular exposure are implemented. The chemicals 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 the appropriate controls.

The data available support an amendment to the hazard classification in the HSIS (Safe Work Australia) (refer to **Recommendation** section).

NICNAS Recommendation

Assessment of these chemicals is considered to be sufficient, provided that the recommended amendment to the classification is 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 chemicals CAS Nos 8009-03-8, 64743-01-7, 64742-61-6 and 92062-09-4 are recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical hazards and environmental hazards.

The current HSIS classification for carcinogenicity of these chemicals indicates notes N and H. Based on this assessment, all of the classifications provided below should be subject to note N. Therefore, note N should be slightly modified as follows:

'Note N: The classifications need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen. This note only applies to certain complex oil-derived substances in Annex I.'

The current HSIS classification for carcinogenicity of these chemicals indicates note H. Note H is no longer considered relevant for these chemicals.

The classifications proposed below are based on read across principles (see **Grouping Rationale** section). It should be used as a default for all members of the group. If empirical data become available for any member of the group indicating that a lower (or higher) classification is appropriate for the specific chemical, these may be used to amend the default classification for that chemical.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Carcinogenicity	Carc. Cat 2 - May cause cancer (T; R45)	May cause cancer - Cat. 1B (H350)
Reproductive and Developmental Toxicity	Repro. Cat 3 - Possible risk of harm to the unborn child (Xn; R63)	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 consumers

Products containing the chemicals should be used according to the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from dermal or ocular exposure to the chemicals 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 chemicals are used. Examples of control measures which could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- health monitoring for any worker who is at risk of exposure to the chemicals, if valid techniques are available to monitor the effect on the worker’s health;
- 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 chemicals 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 these chemicals has not been undertaken as part of this assessment.

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Last Update 27 November 2014

Chemical Identities

Chemical Name in the Inventory and Synonyms	**Petrolatum** petrolatum petroleum jelly red petrolatum mineral jelly
CAS Number	8009-03-8
Structural Formula	**No Structural Diagram Available**

Molecular Formula	Unspecified
Molecular Weight	

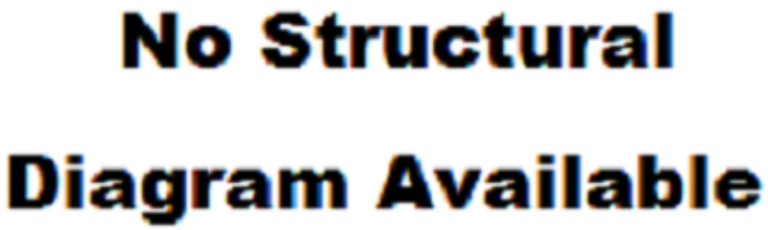
Chemical Name in the Inventory and Synonyms	**Paraffin waxes and hydrocarbon waxes, microcrystalline** cera microcristallina microcrystalline wax petroleum wax, microcrystalline
CAS Number	63231-60-7
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	

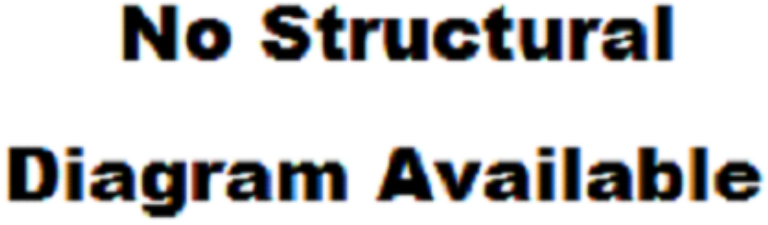
Chemical Name in the Inventory and Synonyms	**Hydrocarbon waxes, petroleum, acid treated** acid treated wax
CAS Number	64742-26-3
Structural Formula	

	
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Hydrocarbon waxes, petroleum, chemically neutralized** chemically neutralized wax ozokerite
CAS Number	64742-33-2
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Hydrocarbon waxes, petroleum, clay treated microcrystaline** clay treated microcrystalline wax cera microcrystallina

CAS Number	64742-42-3
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Paraffin waxes, petroleum, clay treated** clay treated paraffin wax
CAS Number	64742-43-4
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the	**Paraffin waxes, petroleum, hydrotreated**

Inventory and Synonyms	hydrotreated paraffin wax
CAS Number	64742-51-4
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Hydrocarbon waxes, petroleum, hydrotreated microcrystalline** hydrotreated, microcrystalline wax hydrotreated microcrystalline wax hydrogenated microcrystalline wax
CAS Number	64742-60-5
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Slack wax, petroleum** slack wax
CAS Number	64742-61-6
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Petrolatum, petroleum, oxidized** oxidized petrolatum (petroleum) petrolatum (blown)
CAS Number	64743-01-7
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Slack wax, petroleum, hydrotreated** slack wax
CAS Number	92062-09-4
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Paraffin waxes and hydrocarbon waxes, C19-38**
CAS Number	97489-05-9
Structural Formula	**No Structural Diagram Available**

Molecular Formula	Unspecified
Molecular Weight	

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