

## SCREENING-LEVEL HAZARD CHARACTERIZATION

### Waxes and Related Materials Category

#### SUBCATEGORY I: SLACK WAXES

##### SPONSORED CHEMICALS

**Slack wax (petroleum)** CASRN 64742-61-6  
[CA Name: Slack wax, petroleum]

##### SUPPORTING CHEMICALS

**Slack wax, hydrotreated** CASRN 92062-09-4  
[CA Name: Slack wax (petroleum), hydrotreated]

**White and technical mineral oil** CASRN 8042-47-5  
[CA Name: White mineral oil, petroleum]

**Solvent refined light naphthenic distillate** CASRN 64741-97-5  
[CA Name: Distillates (petroleum), solvent-refined light naphthenic]

**Solvent refined light paraffinic distillate** CASRN 64741-89-5  
[CA Name: Distillates (petroleum), solvent-refined light paraffinic]

**Solvent refined residual oil** CASRN 64742-01-4  
[CA Name: Residual oils (petroleum), solvent-refined]

**Solvent refined heavy paraffinic distillate** CASRN 64741-88-4  
[CA Name: Distillates (petroleum), solvent-refined heavy paraffinic]

**Hydrotreated light naphthenic distillate** CASRN 64742-53-6  
[CA Name: Distillates (petroleum), hydrotreated light naphthenic]

#### SUBCATEGORY II: REFINED/FINISHED WAXES (PARAFFIN)

##### SPONSORED CHEMICALS

**Paraffin waxes and hydrocarbon waxes** CASRN 8002-74-2  
[CA Name: Paraffin waxes and hydrocarbon waxes]

**Paraffin waxes (petroleum), clay treated** CASRN 64742-43-4  
[CA Name: Paraffin waxes (petroleum), clay-treated]

**Paraffin waxes (petroleum), hydrotreated** CASRN 64742-51-4  
[CA Name: Paraffin waxes (petroleum), hydrotreated]

**SUBCATEGORY III: REFINED/FINISHED WAXES (MICROCRYSTALLINE)**

**SPONSORED CHEMICALS**

**Paraffin waxes and hydrocarbon waxes, microcrystalline** CASRN 63231-60-7  
[CA Name: Paraffin waxes and hydrocarbon waxes, microcryst.]

**Hydrocarbon waxes (petroleum), clay treated,  
microcrystalline** CASRN 64742-42-3  
[CA Name: Hydrocarbon waxes (petroleum), clay-treated microcryst.]

**Hydrocarbon waxes (petroleum), hydrotreated,  
microcrystalline** CASRN 64742-60-5  
[CA Name: Hydrocarbon waxes (petroleum), hydrotreated microcryst.]

**SUBCATEGORY IV: PETROLATUM**

**SPONSORED CHEMICAL**

**Petrolatum (petroleum jelly)** CASRN 8009-03-8  
[CA Name: Petrolatum]

**SUPPORTING CHEMICAL**

**White and technical mineral oil** CASRN 8042-47-5  
[CA Name: White mineral oil, petroleum]

The High Production Volume (HPV) Challenge Program<sup>1</sup> was conceived as a voluntary initiative aimed at developing and making publicly available screening-level health and environmental effects information on chemicals manufactured in or imported into the United States in quantities greater than one million pounds per year. In the Challenge Program, producers and importers of HPV chemicals voluntarily sponsored chemicals; sponsorship entailed the identification and initial assessment of the adequacy of existing toxicity data/information, conducting new testing if adequate data did not exist, and making both new and existing data and information available to the public. Each complete data submission contains data on 18 internationally agreed to “SIDS” (Screening Information Data Set<sup>1,2</sup>) endpoints that are screening-level indicators of potential hazards (toxicity) for humans or the environment.

The Environmental Protection Agency’s Office of Pollution Prevention and Toxics (OPPT) is evaluating the data submitted in the HPV Challenge Program on approximately 1400 sponsored chemicals by developing hazard characterizations (HCs). These HCs consist of an evaluation of the quality and completeness of the data set provided in the Challenge Program submissions. They are not intended to be definitive statements regarding the possibility of unreasonable risk of injury to health or the environment.

The evaluation is performed according to established EPA guidance<sup>2,3</sup> and is based primarily on hazard data provided by sponsors; however, in preparing the hazard characterization, EPA considered its own comments and public comments on the original submission as well as the sponsor’s responses to comments and revisions made to the submission. In order to determine whether any new hazard information was developed since the time of the HPV submission, a search of the following databases was made from one year prior to the date of the HPV Challenge submission to the present: (ChemID to locate available data sources including Medline/PubMed, Toxline, HSDB, IRIS, NTP, ATSDR, IARC, EXTOXNET, EPA SRS, etc.), STN/CAS online databases (Registry file for locators, ChemAbs for toxicology data, RTECS, Merck, etc.) and Science Direct. OPPT’s focus on these specific sources is based on their being of high quality, highly relevant to hazard characterization, and publicly available.

OPPT does not develop HCs for those HPV chemicals which have already been assessed internationally through the HPV program of the Organization for Economic Cooperation and Development (OECD) and for which Screening Initial Data Set (SIDS) Initial Assessment Reports (SIAR) and SIDS Initial Assessment Profiles (SIAP) are available. These documents are presented in an international forum that involves review and endorsement by governmental authorities around the world. OPPT is an active participant in these meetings and accepts these documents as reliable screening-level hazard assessments.

These hazard characterizations are technical documents intended to inform subsequent decisions and actions by OPPT. Accordingly, the documents are not written with the goal of informing the general public. However, they do provide a vehicle for public access to a concise assessment of the raw technical data on HPV chemicals and provide information previously not readily available to the public.

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<sup>1</sup> U.S. EPA. High Production Volume (HPV) Challenge Program; <http://www.epa.gov/chemrtk/index.htm>.

<sup>2</sup> U.S. EPA. HPV Challenge Program – Information Sources; <http://www.epa.gov/chemrtk/pubs/general/guidocs.htm>.

<sup>3</sup> U.S. EPA. Risk Assessment Guidelines; <http://cfpub.epa.gov/ncea/raf/rafguid.cfm>.

<p><b>Chemical Abstract Service  Registry Number  (CASRN)</b></p>	<p><b>Subcategory I</b></p> <p><b><u>Sponsored Chemical</u></b>  64742-61-6</p> <p><b><u>Supporting Chemicals</u></b>  92062-09-4  8042-47-5  64741-97-5  64741-89-5  64742-01-4  64741-88-4  64742-53-6</p> <p><b>Subcategory II</b></p> <p><b><u>Sponsored Chemicals</u></b>  8002-74-2  64742-43-4  64742-51-4</p> <p><b>Subcategory III</b></p> <p><b><u>Sponsored Chemicals</u></b>  63231-60-7  64742-42-3  64742-60-5</p> <p><b>Subcategory IV</b></p> <p><b><u>Sponsored Chemical</u></b>  8009-03-8</p> <p><b><u>Supporting Chemical</u></b>  8042-47-5</p>
<p><b>Chemical Abstract Index  Name</b></p>	<p><b>Subcategory I</b></p> <p><b><u>Sponsored Chemical</u></b></p> <p><b>Slack wax (petroleum)</b></p> <p><b><u>Supporting Chemicals</u></b></p> <p><b>Slack wax, hydrotreated  White and technical mineral oil</b></p>

	<p><b>Solvent refined light naphthenic distillate</b>  <b>Solvent refined light paraffinic distillate</b>  <b>Solvent refined residual oil</b>  <b>Solvent refined heavy paraffinic distillate</b>  <b>Hydrotreated light naphthenic distillate</b></p> <p><b>Subcategory II</b></p> <p><b><u>Sponsored Chemicals</u></b>  <b>Paraffin waxes and hydrocarbon waxes</b>  <b>Paraffin waxes (petroleum), clay treated</b>  <b>Paraffin waxes (petroleum), hydrotreated</b></p> <p><b>Subcategory III</b></p> <p><b><u>Sponsored Chemicals</u></b>  <b>Paraffin waxes and hydrocarbon waxes, microcrystalline</b>  <b>Hydrocarbon waxes (petroleum), clay treated,</b>  <b>microcrystalline</b>  <b>Hydrocarbon waxes (petroleum), hydrotreated,</b>  <b>microcrystalline</b></p> <p><b>Subcategory IV</b></p> <p><b><u>Sponsored Chemicals</u></b>  <b>Petrolatum (petroleum jelly)</b></p> <p><b><u>Supporting Chemical</u></b>  <b>White and technical mineral oil</b></p>
<b>Structural Formula</b>	<b>See Appendix</b>

**Summary**

The members of the Waxes and Related Materials (WRM) category are solid or semi-solid substances at room temperature possessing negligible water solubility and negligible to low vapor pressure. All the substances in this category are expected to possess low mobility in soil. Volatilization from water could occur for some members based upon their Henry's Law constants; however, volatilization is expected to be attenuated as the molecular weight of the members increases and due to adsorption to sediment. The rate of hydrolysis is expected to be negligible since the substances in this category do not possess functional groups that hydrolyze under environmental conditions. The rate of atmospheric photooxidation is considered moderate to rapid for members of the category; however, this is not expected to be an important environmental fate process for most category members, since these are not expected to exist in

the vapor phase in the atmosphere. The overall weight of experimental evidence and read across from structurally similar compounds suggest that most of the category members are expected to possess low persistence (P1), with the exception of those that are highly branched or internal branched alkenes, which are expected to have moderate persistence (P2). The members of the Waxes and Related Materials category are expected to possess low to high (B1-B3) bioaccumulation potential.

### **Human Health Hazard**

The WRM category was divided into four sub-categories for the human health effects characterization.

#### ***Subcategory I: Slack Waxes***

No data were available for any of the health effects endpoints.

Data gaps for the acute, repeated-dose, reproductive, developmental and genetic toxicity endpoints were identified under the HPV Challenge Program.

#### ***Subcategory II : Refined/Finished Waxes (Paraffin)***

A paraffin wax (exact identity unknown) had low acute toxicity via the oral route in rats. Following repeated oral exposure of a hydrotreated paraffin wax via diet to rats for 90 days, increased organ weights (spleen, liver and lymph nodes) and effects on hematology, clinical chemistry, and histopathology (granulomas and centrilobular vacuolation in the liver, lesions in the lymph nodes, macrophage accumulation and infiltration in the ileum and jejunum and focal inflammatory lesions in the heart) were observed at an estimated dose of 110 mg/kg-bw/day. The NOAEL for these effects is 11 mg/kg-bw/day. In a recent (2010) study designed to evaluate differences in rat strain responses to exposure to paraffin wax, two strains of rats were exposed via the diet for 90 days. Results showed F-344 to be more sensitive than Sprague-Dawley with the following effects observed at the lowest tested dose of approximately 160 mg/kg-bw/day (changes in hematology, clinical chemistry, organ weight changes (liver, spleen, mesenteric lymph nodes and ovaries; and histopathology (liver, spleen, mesenteric lymph nodes and heart); the NOAEL for this study could not be established.

Data gaps for the reproductive, developmental and genetic toxicity (gene mutation and chromosomal aberrations) endpoints were identified under the HPV Challenge Program.

#### ***Subcategory III: Refined/Finished Waxes (Microcrystalline)***

A microcrystalline wax (exact identity unknown) had low acute toxicity via the oral route in rats. In a 90-day repeated dose oral exposure study in rats via diet, two different microcrystalline waxes (one clay-treated and one hydrotreated) were tested at doses up to approximately 1100 mg/kg-bw/day. No significant effects were observed, resulting in a NOAEL of 1100 mg/kg-bw/day.

Data gaps for the reproductive, developmental and genetic toxicity (gene mutation and chromosomal aberrations) endpoints were identified under the HPV Challenge Program.

***Subcategory IV: Petrolatum***

Following repeated oral dosing of rats with petrolatum for two years at a single dose of 5% in the diet (approximately 2500 mg/kg-bw/day), no treatment-related effects were observed. No evidence of carcinogenicity was observed.

Data gaps for the reproductive, developmental and genetic toxicity (gene mutation and chromosomal aberrations) endpoints were identified under the HPV Challenge Program.

**Hazard to the Environment**

Based on the supporting chemical CASRN 1120-36-4, the acute toxicity to fish and aquatic invertebrates, and the toxicity to aquatic plants of the WRM category chemicals are considered to be “no effects at saturation” (NES). Also, based on the supporting chemical 1120-36-4, the chronic toxicity to aquatic invertebrates is NES.

No data gaps were identified in the HPV Challenge Program.

The sponsor, American Petroleum Institute (API) Petroleum HPV Testing Group, submitted a Test Plan and Robust Summaries to EPA for the waxes and related materials category on August 5, 2002. EPA posted the submission on the ChemRTK HPV Challenge website on August 22, 2002 (<http://www.epa.gov/chemrtk/pubs/summaries/wxrelmat/c13902tc.htm>). EPA comments on the original submission were posted to the website on January 15, 2003. Public comments were also received and posted to the website. The sponsor submitted updated/revised documents on June 18, 2003, (posted to the ChemRTK website on July 18, 2003) and on January 21, 2011 (posted to the ChemRTK website on February 4, 2011).

### **Category Justification**

The Waxes and Related Materials (WRM) category consists of eight substances defined by their physicochemical properties and the degree of processing and corresponding reduction in oil content and impurities. Figure 1 in the Appendix is a schematic showing the process for the derivation of the category members (taken from p. 9 of the Category Assessment Analysis and Hazard Characterization document in the January 21, 2011 submission). The figure shows that a common starting material is used to generate three US HPV categories: (1) Lubricating Base Stocks (see <http://www.epa.gov/chemrtk/pubs/summaries/lubolbse/c14364tc.htm>); (2) Aromatic Extracts (<http://www.epa.gov/chemrtk/pubs/summaries/aroexcat/c14900tc.htm>); and (3) the WRM category chemicals that is the subject of this hazard characterization.

### *Oil Content*

The substances in the WRM category are complex petroleum mixtures composed of hydrocarbons with carbon numbers ranging from C12 to C85, with the majority exceeding C20. All of the materials in the category are solid or semi-solid at room temperature. The physical state (semi-solid to solid) and the number of carbon atoms in the petroleum waxes severely limit their bioavailability and their environmental distribution, breakdown or conversion. In EPA's 2002 comments on the original submission, EPA expressed concern about the oil content of the category members, because the oil content is toxicologically the important component of the different waxes. In its 2011 Category Assessment Document, the Sponsor specified that the concern for potential health and environmental effects was due to the presence of polyaromatic compounds (PACs)<sup>4</sup>. In that same document, the Sponsor presented PAC profile analytical results from eight samples representing five out of eight sponsored substances and no PACs were found in any of the samples (see Table 3 in <http://www.epa.gov/chemrtk/pubs/summaries/wxrelmat/c13902ca2.pdf>). These samples were all taken from US manufacturers and the sponsor noted that...“(I)mported slack waxes from other sources could contain significant levels of PAC, depending on the severity of the refining applied to them; however, whether such substances enter commerce in the US is unknown.” (p. 12 in <http://www.epa.gov/chemrtk/pubs/summaries/wxrelmat/c13902ca2.pdf>).

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<sup>4</sup> As defined in a footnote on p. 5 in 2011 document identified as Category Assessment Document at <http://www.epa.gov/chemrtk/pubs/summaries/wxrelmat/c13902tc.htm>: Polycyclic Aromatic Hydrocarbons (PAH) refers to compounds of two or more fused-aromatic rings consisting of carbon and hydrogen only. Polycyclic Aromatic Compounds (PACs) is a more inclusive term than PAH since in addition to the PAHs it also includes molecules in which one or more atoms of nitrogen, oxygen or sulfur (a heteroatom) replaces one of the carbon atoms in a ring system. See Appendix 1 of Volume 2 of this report series for additional nomenclature details.

In its original 2002 submission, the sponsor proposed to use slack wax as a representative category member for further human health-related testing because it was expected to have a higher proportion of impurities and potentially toxic materials (i.e., PACs) compared with the other category members (refined/finished waxes and petrolatum). This is due to slack wax being the first product in the process stream shown in Figure 1 (Appendix). Further, as noted in Table 2 in the original submission and in the 2011 submission (same Table number in both), slack wax contains between 5-20% oil content (compared with a range of <2.5 to 10% for the remaining category members). However, based on the analysis of samples for PAC content as reported above (which showed no PAC content in eight samples; four of which were slack waxes), the sponsor decided not to perform the testing they proposed to do in 2002.

Although this logic seems reasonable, it is predicated on the assumption that any or all toxicity of the category members is based solely on PAC content; which presumably may be a large percentage of the oil content. The PAC modeling approach had received a Toxicology Excellence for Risk Assessment (TERA) Peer Consultation, which issued a report on January 28, 2008 (<http://www.tera.org/peer/API/PAC%20MEETING%20REPORT%20Final.pdf>, accessed 6/15/2011). The Panelists raised a number of questions, strongly suggesting that more work and greater input were needed. The revised submission (January 2, 2011) does not indicate that the Sponsor has performed additional work to address comments made in the Peer Consultation report. EPA believes that without additional information/documentation of model's performance, these models cannot be evaluations for accuracy. Therefore, at this time, the modeling approach is not acceptable. When all pertinent information is available, this modeling approach can be revisited in the future.

In EPA's 2002 comments, EPA stated that the sponsor needs to discuss whether the oil components of the category members will also have low water solubilities and vapor pressures, limited bioavailability, environmental distribution and degradation; whether the carbon number range given for the wax components also includes the range for the oil components, and whether these non-wax hydrocarbons will have similar physicochemical and environmental properties. In response, the sponsor stated that these questions, and the toxicological properties of the oil components, will be addressed in the Lubricating Oil Basestocks HPV submission. This final submission was only recently submitted to EPA and it was posted on our website on May 3, 2011 - <http://www.epa.gov/chemrtk/pubs/summaries/lubolbse/c14364tc.htm>. The Lubricating Oil Basestocks category has 36 members and it is difficult to determine which one(s) may apply to the WRM category. As such, data from this separate submission were not included in this hazard characterization.

### *Subcategorization*

For human health endpoints, EPA agrees with the overall grouping of category members. However, EPA noted in its 2003 comments that the toxicological data do not support the sponsor's inclusion of paraffin (low melting point) and microcrystalline wax (high melting point) in a single subgroup of refined/finished waxes. The two types of finished waxes would be more appropriately assigned to separate subgroups. In response, the sponsor stated that given their process history and levels of residual oil and impurities, the two types of waxes are appropriately grouped into a single sub-category. For the purposes of this hazard characterization, the two

sub-categories are considered separately. Thus, for human health, the following subcategories are used in this hazard characterization:

Subcategory I (Slack Waxes)

- Slack wax (petroleum) – CASRN 64742-61-6

Subcategory II (Refined/finished Waxes, Paraffin)

- Paraffin waxes and hydrocarbon waxes – CASRN 8002-74-2
- Paraffin waxes (petroleum), clay-treated – CASRN 64742-43-4
- Paraffin waxes (petroleum), hydrotreated – CASRN 64742-51-4

Subcategory III (Refined/finished Waxes, Microcrystalline)

- Paraffin waxes and hydrocarbon waxes, microcrystalline – CASRN 63231-60-7
- Hydrocarbon waxes (petroleum), clay-treated, microcrystalline – CASRN 64742-42-3
- Hydrocarbon waxes (petroleum), hydrotreated, microcrystalline – CASRN 64742-60-5

Subcategory IV (Petrolatum)

- Petrolatum (petroleum jelly) – CASRN 8009-03-8

For ecotoxicity, the WRM category chemicals were not subcategorized, but kept as a single category of eight substances because the C13-C85 hydrocarbons (predominantly C20-C85) are expected to result in similar ecotoxicity based on physico-chemical properties (water solubility < 0.0001 ppm and log K<sub>ow</sub> of 6.4 to 24.3).

### **Justification for Supporting Chemicals**

#### *Environmental Fate Endpoints*

The sponsor included biodegradation data for seven different supporting chemicals (all part of the lubricating oil basestock HPV category): CASRNs 92062-09-4, 8042-47-5, 64741-97-5, 64741-89-5, 64742-01-4, 64741-88-4, and 64742-53-6. The EPA accepts these supporting chemicals as useful for read-across to the sponsored members of the WRM category for this biodegradation endpoint.

#### *Human Health Endpoints*

The revised WRM category submission includes a robust summary for a dermal developmental toxicity study for CASRN 64742-04-7, a member of the Aromatic Extracts HPV Category identified above. Because this substance is not related to any of the WRM category members (due to high aromatic ring content), it is not considered a reasonable supporting chemical for any of the four WRM Subcategories chemicals.

#### *Ecotoxicity Endpoints*

The sponsor included environmental effects data for several lubricating base oils to supplement a technical discussion to satisfy the environmental effects endpoints. The supporting chemicals included solvent refined light naphthenic distillate (CASRN 64741-97-5), solvent-refined light paraffinic distillate (CASRN 64741-89-5), solvent-refined heavy paraffinic distillate (CASRN 64741-88-4), solvent refined residual oil (CASRN 64741-01-4) and hydrotreated light

naphthenic distillate (CASRN 64742-53-6). Lubricant base oils contain similar hydrocarbon ranges and structures common to materials in the waxes and related materials category. EPA initially agreed with the use of these chemicals to support the technical discussion and fulfill the environmental effects endpoints for the WRMI category. Upon further review, EPA found the data for CASRNS 64742-04-7, 64741-89-5, 64742-01-4, and 64741-88-4 to be inadequate to address the toxicity to aquatic organisms because these data were tested above the water solubility limit for the respective compounds. In addition, these studies are unacceptable due to the fact that they are derived from WAF (water accommodated fraction) preparation methods without the analytical monitoring to accompany the values for loading rates, which makes calculating an LC<sub>50</sub> or EC<sub>50</sub> value impossible.

Therefore, for the ecotoxicity endpoints, EPA determined that the measured data from 1-tetradecene (CASRN 1120-36-1) is appropriate to support the WRM category based on similar physico-chemical properties, environmental fate and mode of toxic action (narcosis). The supporting chemical, 1-tetradecene (CASRN 1120-36-1: SIAM 11), has been assessed in the OECD HPV program as a member of the alpha olefins category (<http://www.chem.unep.ch/irptc/sids/OECDSEIDS/AOalphaolefins.pdf>).

## 1. Chemical Identity

### 1.1 Identification and Purity

Table 1 is a listing of the category members and supporting substances. Each of the substances is a complex mixture. Representative structures and are provided in the Appendix.

<b>Table 1: Waxes and Related Materials</b>		
<b>CASRN</b>	<b>Chemical Name</b>	<b>Chemical Structure Description</b>
Subcategory I: Slack Waxes		
Sponsored Chemicals		
64742-61-6	Slack wax (petroleum)	Predominantly saturated straight and branched chain hydrocarbons having carbon numbers predominantly greater than C20.
Supporting Chemicals		
92062-09-4	Slack wax, hydrotreated	Predominantly saturated straight and branched chain hydrocarbons having carbon numbers largely greater than C20.
8042-47-5	White and technical mineral oil	Consists of saturated hydrocarbons having carbon numbers predominantly in the range of C15 through C50.
64741-97-5	Distillates (petroleum), solvent-refined light naphthenic	Consists of hydrocarbons having carbon numbers predominantly in the range of C15 through C30; contains relatively few normal paraffins.
64741-89-5	Distillates (petroleum), solvent-refined light paraffinic	Predominantly saturated hydrocarbons having carbon numbers predominantly in the range of C15 through C30.
64742-01-4	Residual oils (petroleum),	Consists of hydrocarbons having carbon numbers

<b>Table 1: Waxes and Related Materials</b>		
<b>CASRN</b>	<b>Chemical Name</b>	<b>Chemical Structure Description</b>
	solvent-refined	predominantly higher than C25 and boiling above approximately 400 °C (725 °F).
64741-88-4	Distillates (petroleum), solvent-refined heavy paraffinic	Predominantly saturated hydrocarbons having carbon numbers largely in the range of C20 through C50.
64742-53-6	Distillates (petroleum), hydrotreated light naphthenic	Consists of hydrocarbons having carbon numbers largely in the range of C15 through C30; contains relatively few normal paraffins.
Subcategory II: Refined/Finished Waxes (Paraffin)		
Sponsored Chemicals		
8002-74-2	Paraffin waxes and hydrocarbon waxes	Predominantly straight chain hydrocarbons having carbon numbers predominantly greater than C20.
64742-43-4	Paraffin waxes (petroleum), clay treated	Predominantly straight chain saturated hydrocarbons having carbon numbers in the range of C20 through C50.
64742-51-4	Paraffin waxes (petroleum), hydrotreated	Predominantly straight chain paraffinic hydrocarbons having carbon numbers predominantly in the range of about C20 through C50.
Subcategory II: Refined/Finished Waxes (Microcrystalline)		
Sponsored Chemicals		
63231-60-7	Paraffin waxes and hydrocarbon waxes, microcrystalline	Predominantly saturated straight and branched chain hydrocarbons predominantly greater than C35.
64742-42-3	Hydrocarbon waxes (petroleum), clay treated microcrystalline	Predominantly long branched chain hydrocarbons having carbon numbers largely in the range of C25 through C50.
64742-60-5	Hydrocarbon waxes (petroleum), hydrotreated microcrystalline	
Subcategory IV: Petrolatum		
Sponsored Chemicals		
8009-03-8	Petrolatum (petroleum jelly)	Predominantly saturated crystalline and liquid hydrocarbons having carbon numbers largely greater than C25.
Supporting Chemical		
8042-47-5	White and technical mineral oil	Saturated hydrocarbons having carbon numbers predominantly in the range of C15 through C50.

## 1.2 Physical-Chemical Properties

The physical-chemical properties of the sponsored substances and supporting chemicals in the Waxes and Related Materials category are summarized in Tables 2a and 2b. The members of this category are solid or semi-solid substances that possess negligible to low vapor pressure and negligible water solubility. The category members are generally complex mixtures of saturated hydrocarbons with carbon range of approximately C20 to C85.

**Table 2a. Physical-Chemical Properties of the Waxes and Related Materials Category<sup>1</sup>**

<b>Subcategory I: Slack Waxes</b>								
<b>Property</b>	<b>Slack Wax (petroleum)</b>	<b>Slack wax, hydrotreated (supporting chemical)</b>	<b>White and technical mineral oil (supporting chemical)</b>	<b>Solvent refined light naphthenic distillate (supporting chemical)</b>	<b>Solvent refined light paraffinic distillate (supporting chemical)</b>	<b>Solvent refined residual oil (supporting chemical)</b>	<b>Solvent refined heavy paraffinic distillate (supporting chemical)</b>	<b>Hydrotreated light naphthenic distillate (supporting chemical)</b>
CASRN	64742-61-6	92062-09-4	8042-47-5	64741-97-5	64741-89-5	64742-01-4	64741-88-4	64742-53-6
Molecular Weight	350 – 600 (average molecular weight) <sup>2</sup>	350 – 600 (average molecular weight) <sup>2</sup>	400 (average molecular weight) <sup>3</sup>	320 (average molecular weight for severely refined distillate oil) <sup>3</sup>	320 (average molecular weight for severely refined distillate oil) <sup>3</sup>	320 (average molecular weight for severely refined distillate oil) <sup>3</sup>	320 (average molecular weight for severely refined distillate oil) <sup>3</sup>	290 (average molecular weight) <sup>3</sup>
Physical State	Solid or semisolid	Solid or semisolid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid
Melting Point	43 – 63 °C (measured)	43 – 63 °C (measured)	-15 °C (measured pour point) <sup>2</sup>	-32.8 (measured pour point for severely refined distillate oil) <sup>2</sup>	32.8 (measured pour point for severely refined distillate oil) <sup>2</sup>	32.8 (measured pour point for severely refined distillate oil) <sup>2</sup>	32.8 (measured pour point for severely refined distillate oil) <sup>2</sup>	-60 (measured pour point) <sup>2</sup>
Boiling Point	>485 °C with decomposition (measured)	>485 °C with decomposition (measured)	300 – 600 °C (measured boiling range of hydrocarbons of oils produced from vacuum distillation) <sup>3</sup>	300 – 600 °C (measured boiling range of hydrocarbons of oils produced from vacuum distillation) <sup>3</sup>	300 – 600 °C (measured boiling range of hydrocarbons of oils produced from vacuum distillation) <sup>3</sup>	300 – 600 °C (measured boiling range of hydrocarbons of oils produced from vacuum distillation) <sup>3</sup>	300 – 600 °C (measured boiling range of hydrocarbons of oils produced from vacuum distillation) <sup>3</sup>	232 - 418 °C (measured) <sup>3</sup>
Vapor Pressure	<1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>	<1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>	0.0023 to <1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>	0.0023 to <1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>	0.0023 to <1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>	0.0023 to <1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>	0.0023 to <1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>	0.098 to 9.9×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>
Dissociation Constant (pK <sub>a</sub> )	Not applicable							
Henry's Law Constant	7.9 – 4.4×10 <sup>5</sup> atm·m <sup>3</sup> /mol (estimated) <sup>5,6</sup>	7.9 – 4.4×10 <sup>5</sup> atm·m <sup>3</sup> /mol (estimated) <sup>5,6</sup>	7.9 – 4.4×10 <sup>5</sup> atm·m <sup>3</sup> /mol (estimated) <sup>5,6</sup>	1.44 – 1.5×10 <sup>3</sup> atm·m <sup>3</sup> /mol (estimated) <sup>5,6</sup>	1.44 – 1.5×10 <sup>3</sup> atm·m <sup>3</sup> /mol (estimated) <sup>5,6</sup>	32.5 – 4.4×10 <sup>5</sup> atm·m <sup>3</sup> /mol (estimated) <sup>5,6</sup>	7.9 – 4.4×10 <sup>5</sup> atm·m <sup>3</sup> /mol (estimated) <sup>5,6</sup>	1.44 – 1.5×10 <sup>3</sup> atm·m <sup>3</sup> /mol (estimated) <sup>5,6</sup>
Water Solubility	4.5×10 <sup>-5</sup> to <1×10 <sup>-10</sup> mg/L at 25°C (estimated) <sup>5,6</sup>	4.5×10 <sup>-5</sup> to <1×10 <sup>-10</sup> mg/L at 25°C (estimated) <sup>5,6</sup>	0.0029 to <1×10 <sup>-10</sup> mg/L at 25°C (estimated) <sup>5,6</sup>	0.04 to <1×10 <sup>-10</sup> mg/L at 25°C (estimated) <sup>5,6</sup>	0.04 to <1×10 <sup>-10</sup> mg/L at 25°C (estimated) <sup>5,6</sup>	1.6×10 <sup>-7</sup> to <1×10 <sup>-10</sup> mg/L at 25°C (estimated) <sup>5,6</sup>	4.5×10 <sup>-5</sup> to <1×10 <sup>-10</sup> mg/L at 25°C (estimated) <sup>5,6</sup>	0.04 to <1×10 <sup>-10</sup> mg/L at 25°C (estimated) <sup>5,6</sup>

**Table 2a. Physical-Chemical Properties of the Waxes and Related Materials Category<sup>1</sup>**

<b>Subcategory I: Slack Waxes</b>								
<b>Property</b>	<b>Slack Wax (petroleum)</b>	<b>Slack wax, hydrotreated (supporting chemical)</b>	<b>White and technical mineral oil (supporting chemical)</b>	<b>Solvent refined light naphthenic distillate (supporting chemical)</b>	<b>Solvent refined light paraffinic distillate (supporting chemical)</b>	<b>Solvent refined residual oil (supporting chemical)</b>	<b>Solvent refined heavy paraffinic distillate (supporting chemical)</b>	<b>Hydrotreated light naphthenic distillate (supporting chemical)</b>
Log K <sub>ow</sub>	9.3 – 24.3 (estimated) <sup>5,6</sup>	9.3 – 24.3 (estimated) <sup>5,6</sup>	7.7 – 24.2 (estimated) <sup>5,6</sup>	6.4 – 14.7 (estimated) <sup>5,6</sup>	6.4 – 14.7 (estimated) <sup>5,6</sup>	11.7 – 24.3 (estimated) <sup>5,6</sup>	9.3 – 24.3 (estimated) <sup>5,6</sup>	6.4 – 14.7 (estimated) <sup>5,6</sup>

<sup>1</sup> The Petroleum HPV Testing Group. Revised Test Plan and Robust Summary for Waxes and Related Materials. January 21, 2011. Available at: <http://www.epa.gov/chemrtk/pubs/summaries/wxrelmat/c13902tc.htm> as of February 28, 2011.

<sup>2</sup> Imperial Oil. Product Data Sheet for Slack Wax. August 2002. Available at: [http://www.imperialoil.ca/Canada-English/Files/Products\\_Lubes/IOCAENWPOESSlack\\_wax.pdf](http://www.imperialoil.ca/Canada-English/Files/Products_Lubes/IOCAENWPOESSlack_wax.pdf) as of February 28, 2011.

<sup>3</sup> The Petroleum HPV Testing Group. Revised Test Plan and Robust Summary for Lubricating Oil Basestock Category. March 2, 2004. Available at: <http://www.epa.gov/chemrtk/pubs/summaries/lubolbse/c14364tc.htm> as of February 28, 2011.

<sup>4</sup> NOMO5. 1987. Programs to Enhance PC-Gems Estimates of Physical Properties for Organic Compounds. The Mitre Corp.

<sup>5</sup> U.S. EPA. 2011. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online at <http://www.epa.gov/opptintr/exposure/pubs/episuitedi.htm> as of February 28, 2011.

<sup>6</sup> Data range is based upon the representative structures; see Appendix for detailed information on the structures.

**Table 2b. Physical-Chemical Properties of the Waxes and Related Materials Category (continued)**

Property	Subcategory II: Refined/Finished Waxes (Paraffin)			Subcategory III: Refined/Finished Waxes (Microcrystalline)			Subcategory IV: Petrolatum	
	Paraffin waxes and hydrocarbon waxes	Paraffin waxes (petroleum), clay treated	Paraffin waxes (petroleum), hydrotreated	Paraffin waxes and Hydrocarbon waxes, microcrystalline	Hydrocarbon waxes (petroleum), clay treated, microcrystalline	Hydrocarbon waxes (petroleum), hydrotreated, microcrystalline	Petrolatum (petroleum jelly)	White and technical mineral oil (supporting chemical)
CASRN	8002-74-2	64742-43-4	64742-51-4	63231-60-7	64742-42-3	64742-60-5	8009-03-8	8042-47-5
Molecular Weight	405 – 450 (average molecular weight for three paraffin waxes)	405 – 450 (average molecular weight for three paraffin waxes)	405 – 450 (average molecular weight for three paraffin waxes)	600 – 630 (average molecular weight for two microcrystalline waxes)	600 – 630 (average molecular weight for two microcrystalline waxes)	600 – 630 (average molecular weight for two microcrystalline waxes)	No data	400 (average molecular weight) <sup>2</sup>
Physical State	Solid or semisolid							
Melting Point	43 – 68 °C (measured)	43 – 68 °C (measured)	43 – 68 °C (measured)	60 – 95 °C (measured)	60 – 95 °C (measured)	60 – 95 °C (measured)	36 – 60 °C (measured)	-15 °C (measured pour point) <sup>2</sup>
Boiling Point	350 – 485 °C (measured)	350 – 485 °C (measured)	350 – 485 °C (measured)	>500 °C (measured)	>500 °C (measured)	>500 °C (measured)	>485 °C with decomposition (measured)	300 – 600 °C (measured boiling range of hydrocarbons of oils produced from vacuum distillation) <sup>3</sup>
Vapor Pressure	0.00010 to <1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>	0.00010 to <1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>	0.00010 to <1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>	<1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>	<1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>	<1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>	<1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>	0.0023 to <1×10 <sup>-7</sup> mm Hg at 25°C (estimated) <sup>4</sup>
Dissociation Constant (pK <sub>a</sub> )	Not applicable							
Henry's Law Constant	120 – 372 atm-m <sup>3</sup> /mol (estimated) <sup>5,6</sup>	90.2– 4.4×10 <sup>5</sup> atm-m <sup>3</sup> /mol (estimated) <sup>5,6</sup>	90.2– 4.4×10 <sup>5</sup> atm-m <sup>3</sup> /mol (estimated) <sup>5,6</sup>	8.4×10 <sup>3</sup> atm-m <sup>3</sup> /mol (estimated) <sup>5,6</sup>	372 - 4.4×10 <sup>5</sup> atm-m <sup>3</sup> /mol (estimated) <sup>5,6</sup>	372 – 4.4×10 <sup>5</sup> atm-m <sup>3</sup> /mol (estimated) <sup>5,6</sup>	280 – 494 m <sup>3</sup> /mol (estimated) <sup>5,6</sup>	7.9 – 4.4×10 <sup>5</sup> atm-m <sup>3</sup> /mol (estimated) <sup>5,6</sup>
Water Solubility	2.9 ×10 <sup>-8</sup> to	9.4×10 <sup>-6</sup> to	9.4×10 <sup>-6</sup> to <1×10 <sup>-7</sup>	<1×10 <sup>-10</sup> mg/L at	2.9 ×10 <sup>-8</sup> to<1×10 <sup>-7</sup>	2.9 ×10 <sup>-8</sup> to<1×10 <sup>-7</sup>	1.1 ×10 <sup>-7</sup> to	0.0029 to

**Table 2b. Physical-Chemical Properties of the Waxes and Related Materials Category (continued)**

Property	Subcategory II: Refined/Finished Waxes (Paraffin)			Subcategory III: Refined/Finished Waxes (Microcrystalline)			Subcategory IV: Petrolatum	
	Paraffin waxes and hydrocarbon waxes	Paraffin waxes (petroleum), clay treated	Paraffin waxes (petroleum), hydrotreated	Paraffin waxes and Hydrocarbon waxes, microcrystalline	Hydrocarbon waxes (petroleum), clay treated, microcrystalline	Hydrocarbon waxes (petroleum), hydrotreated, microcrystalline	Petrolatum (petroleum jelly)	White and technical mineral oil (supporting chemical)
	2.9×10 <sup>-6</sup> mg/L at 25°C (estimated) <sup>5,6</sup>	<1×10 <sup>-10</sup> mg/L at 25°C (estimated) <sup>5,6</sup>	<sup>10</sup> mg/L at 25°C (estimated) <sup>5,6</sup>	25°C (estimated) <sup>5,6</sup>	<sup>10</sup> mg/L at 25°C (estimated) <sup>5,6</sup>	<sup>10</sup> mg/L at 25°C (estimated) <sup>5,6</sup>	9.1×10 <sup>-9</sup> mg/L at 25°C (estimated) <sup>5,6</sup>	<1×10 <sup>-10</sup> mg/L at 25°C (estimated) <sup>5,6</sup>
Log K <sub>ow</sub>	10.6 – 12.6 (estimated) <sup>5,6</sup>	10.2 – 24.9 (estimated) <sup>5,6</sup>	10.2 – 24.9 (estimated) <sup>5,6</sup>	17.8 – 18.0 (estimated) <sup>5,6</sup>	12.2 – 24.2 (estimated) <sup>5,6</sup>	12.2 – 24.2 (estimated) <sup>5,6</sup>	12.0 – 13.1 (estimated) <sup>5,6</sup>	7.7 – 24.2 (estimated) <sup>5,6</sup>

<sup>1</sup> The Petroleum HPV Testing Group. Revised Test Plan and Robust Summary for Waxes and Related Materials. January 21, 2011. Available at: <http://www.epa.gov/chemrtk/pubs/summaries/wxrelmat/c13902tc.htm> as of February 28, 2011.

<sup>2</sup> Imperial Oil. Product Data Sheet for Slack Wax. August 2002. Available at: [http://www.imperialoil.ca/Canada-English/Files/Products\\_Lubes/IOCAENWPOESSlack\\_wax.pdf](http://www.imperialoil.ca/Canada-English/Files/Products_Lubes/IOCAENWPOESSlack_wax.pdf) as of February 28, 2011.

<sup>3</sup> The Petroleum HPV Testing Group. Revised Test Plan and Robust Summary for Lubricating Oil Basestock Category. March 2, 2004. Available at: <http://www.epa.gov/chemrtk/pubs/summaries/lubolbse/c14364tc.htm> as of February 28, 2011.

<sup>4</sup> NOMO5. 1987. Programs to Enhance PC-Gems Estimates of Physical Properties for Organic Compounds. The Mitre Corp.

<sup>5</sup> U.S. EPA. 2011. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online at <http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm> as of February 28, 2011.

<sup>6</sup> Data range is based upon the representative structures; see Appendix for detailed information on the structures.

## 2. General Information on Exposure

### 2.1 Production Volume and Use Pattern

The C Waxes and related materials category chemicals had an aggregated production and/or import volume in the United States greater than two billion 761 million pounds in calendar year 2005

- CASRN 64742-61-6: 1 billion pounds and greater;
- CASRN 8002-74-2: 1 billion pounds and greater;
- CASRN 64742-43-4: 100 to <500 million pounds;
- CASRN 64742-51-4: 500 million to <1 billion pounds;
- CASRN 63231-60-7: 50 million to <100 million pounds
- CASRN 64742-42-3: 1 million to <10 million pounds
- CASRN 64742-60-5: 10 million to <50 million pounds
- CASRN 8009-03-8: 100 to <500 million pounds;

CASRN 64742-61-6 and 64742-42-3:

Industrial processing and uses, and commercial and consumer uses of these chemicals are claimed confidential.

CASRN 8002-74-2:

Non-confidential information in the IUR indicated that the industrial processing and uses for the chemical include adhesive manufacturing as adhesives and binding agents. Non-confidential commercial and consumer uses of this chemical include adhesives and sealants.

CASRN 64742-43-4:

Non-confidential information in the IUR indicated that the industrial processing and uses for the chemical include all other chemical product and preparation manufacturing as adhesives and binding agents. Non-confidential commercial and consumer uses of this chemical include adhesives and sealants.

CASRN 64742-51-4, 63231-60-7, 64742-60-5 and 8009-03-8:

No industrial processing and uses, and commercial and consumer uses were reported for these chemicals.

### 2.2 Environmental Exposure and Fate

The environmental fate properties are provided in Tables 3a and 3b. The substances in the Waxes and Related Substances category are expected to possess low mobility in soil. Biodegradation data exists for several sponsored substances and supporting chemicals. A sample of slack wax was degraded 40% over the course of a 28 days incubation period using the Manometric respirometry (OECD 301F) test. Three samples of hydrotreated slack wax of differing viscosities, achieved 26%, 41%, and 48% mineralization using a modified Sturm procedure (OECD 301B). Paraffin waxes and hydrocarbon waxes (CASRN 8002-74-2), a mixture consisting predominantly of straight chain saturated hydrocarbons, achieved 80% of its theoretical CO<sub>2</sub> production using the modified Sturm procedure and was classified as readily

biodegradable. Paraffin waxes and Hydrocarbon waxes, microcrystalline (CASRN 63231-60-7), which consists of saturated straight and branched chain hydrocarbons predominantly greater than C35, achieved 27% of its theoretical CO<sub>2</sub> production using a method similar to the modified Sturm procedure during a 31 day incubation period and greater than 67% of its theoretical CO<sub>2</sub> production after 137 days. Volatilization from water could occur for some members based on the Henry's Law constants for the sponsored and supporting chemicals; however, the increasing molecular weights and tendency for those category members to adsorb to sediment will attenuate volatilization. The rate of hydrolysis is expected to be negligible since the substances in this category do not possess functional groups that hydrolyze under environmental conditions. The overall weight of experimental evidence and read across from structurally similar compounds suggest that most of the category members are expected to possess low persistence (P1), with the exception of those that are highly branched, which are expected to have moderate persistence (P2). The members of this category are expected to possess low (B1) to high (B3) bioaccumulation potential.

**Table 3a. Environmental Fate Characteristics of the Waxes and Related Materials Category**

Subcategory I: Slack Waxes								
Property	Slack Wax (petroleum)	Slack wax, hydrotreated (supporting chemical)	White and technical mineral oil (supporting chemical)	Solvent refined light naphthenic distillate (supporting chemical)	Solvent refined light paraffinic distillate (supporting chemical)	Solvent refined residual oil (supporting chemical)	Solvent refined heavy paraffinic distillate (supporting chemical)	Hydrotreated light naphthenic distillate (supporting chemical)
CASRN	64742-61-6	92062-09-4	8042-47-5	64741-97-5	64741-89-5	64742-01-4	64741-88-4	64742-53-6
Photodegradation Half-life	1.8 – 4.8 hours (estimated) <sup>2,3</sup>	1.8 – 4.8 hours (estimated) <sup>2,3</sup>	1.8 – 7.1 hours (estimated) <sup>2,3</sup>	3.1 – 4.7 hours (estimated) <sup>2,3</sup>	3.2 – 4.7 hours (estimated) <sup>2,3</sup>	1.8 – 3.8 hours (estimated) <sup>2,3</sup>	1.8 – 5.1 hours (estimated) <sup>2,3</sup>	3.1 – 4.7 hours (estimated) <sup>2,3</sup>
Hydrolysis Half-life	Stable							
Biodegradation	No data	40% after 28 days (not readily biodegradable); 26 – 48 % after 28 days (not readily biodegradable)	0 – 24% after 28 days (not readily biodegradable)	1.5% after an unspecified time frame <sup>4</sup>	22 – 29% after 28 days (not readily biodegradable) <sup>4</sup> ; 61 – 63 % after 21 days (readily biodegradable) <sup>4</sup>	2 – 45 % after an unspecified time frame <sup>4</sup>	3 – 22% after 28 days (not readily biodegradable) <sup>4</sup>	23 – 50% after 28 days (not readily biodegradable) <sup>4</sup>
Bioaccumulation Factor	BAF = 0.9 – 7.3×10 <sup>5</sup> (estimated) <sup>2,3</sup>	BAF = 0.9 – 7.3×10 <sup>5</sup> (estimated) <sup>2,3</sup>	BAF = 0.9 – 7.3×10 <sup>5</sup> (estimated) <sup>2,3</sup>	BAF = 6.8 – 1.5×10 <sup>6</sup> (estimated) <sup>2,3</sup>	BAF = 6.8 – 1.5×10 <sup>6</sup> (estimated) <sup>2,3</sup>	BAF = 0.9 – 7,361 (estimated) <sup>2,3</sup>	BAF = 0.9 – 7.3×10 <sup>5</sup> (estimated) <sup>2,3</sup>	BAF = 6.8 – 1.5×10 <sup>6</sup> (estimated) <sup>2,3</sup>
Log K <sub>oc</sub>	5.9 – 13.1 (estimated) <sup>2,3</sup>	5.9 – 13.1 (estimated) <sup>2,3</sup>	4.5 – 13.1 (estimated) <sup>2,3</sup>	4.5 – 13.1 (estimated) <sup>2,3</sup>	4.3 – 8.1 (estimated) <sup>2,3</sup>	7.1 – 13.1 (estimated) <sup>2,3</sup>	5.8 – 13.1 (estimated) <sup>2,3</sup>	4.5 – 13.1 (estimated) <sup>2,3</sup>
Fugacity (Level III Model) <sup>2,3</sup>								
Air (%)	1.1 – 7.6	1.1 – 7.6	1.1 – 11.1	1.1 – 11.1	1.5 – 11.1	0.6 – 3.1	1.1 – 6.1	1.1 – 11.1
Water (%)	43.2 – 80.9	43.2 – 80.9	43.2 – 79.9	43.2 – 79.9	39.0 – 77.2	30.0 – 79.9	41.1 – 82.5	43.2 – 79.9
Soil (%)	12.3 – 36.5	12.3 – 36.5	5.6 – 36.5	5.6 – 36.5	5.6 – 42.1	19.0 – 68.3	9.4 – 57.4	5.6 – 36.5
Sediment (%)	<0.1 – 18.9	<0.1 – 18.9	<0.1 – 18.9	<0.1 – 18.9	<0.1 – 42.7	<0.1 – 1.0	<0.1 – 18.9	<0.1 – 18.9
Persistence <sup>5</sup>	P1 (low) – P2 (moderate)	P1 (low) – P2 (moderate)	P1 (low) – P2 (moderate)	P1 (low) – P2 (moderate)	P1 (low) – P2 (moderate)	P1 (low) – P2 (moderate)	P1 (low) – P2 (moderate)	P1 (low) – P2 (moderate)
Bioaccumulation <sup>5</sup>	B1 (low) – B3 (high)	B1 (low) – B3 (high)	B1 (low) – B3 (high)	B1 (low) – B3 (high)	B1 (low) – B3 (high)	B1 (low) – B3 (high)	B1 (low) – B3 (high)	B1 (low) – B3 (high)

<sup>1</sup> The Petroleum HPV Testing Group. Revised Test Plan and Robust Summary for Waxes and Related Materials. January 21, 2011. Available at: <http://www.epa.gov/chemrtk/pubs/summaries/wxrelmat/c13902tc.htm> as of February 28, 2011.

<sup>2</sup> U.S. EPA. 2011. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online at <http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm> as of February 28, 2011.

<sup>3</sup> Data range is based upon the representative structures; see Appendix for detailed information on the structures.

<sup>4</sup> The Petroleum HPV Testing Group. Revised Test Plan and Robust Summary for Lubricating Oil Basestock Category. March 2, 2004. Available at: <http://www.epa.gov/chemrtk/pubs/summaries/lubolbse/c14364tc.htm> as of February 28, 2011.

<sup>5</sup> Federal Register. 1999. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register* 64, Number 213 (November 4, 1999) pp. 60194–60204.

**Table 3b. Environmental Fate Characteristics of the Waxes and Related Materials Category (continued)<sup>1</sup>**

Property	Subcategory II: Refined/Finished Waxes (Paraffin)			Subcategory III: Refined/Finished Waxes (Microcrystalline)			Subcategory IV: Petrolatum	
	Paraffin waxes and hydrocarbon waxes	Paraffin waxes (petroleum), clay treated	Paraffin waxes (petroleum), hydrotreated	Paraffin waxes and Hydrocarbon waxes, microcrystalline	Hydrocarbon waxes (petroleum), clay treated, microcrystalline	Hydrocarbon waxes (petroleum), hydrotreated, microcrystalline	Petrolatum (petroleum jelly)	White and technical mineral oil (supporting chemical)
CASRN	8002-74-2	64742-43-4	64742-51-4	63231-60-7	64742-42-3	64742-60-5	8009-03-8	8042-47-5
Photodegradation Half-life	4.0 – 4.8 hours (estimated) <sup>2,3</sup>	1.9 – 5.1 hours (estimated) <sup>2,3</sup>	1.9 – 5.1 hours (estimated) <sup>2,3</sup>	2.7 hours (estimated) <sup>2,3</sup>	1.8 – 3.8 hours (estimated) <sup>2,3</sup>	1.8 – 3.8 hours (estimated) <sup>2,3</sup>	3.8 – 4.1 hours (estimated) <sup>2,3</sup>	1.8 – 7.1 hours (estimated) <sup>2,3</sup>
Hydrolysis Half-life	Stable							
Biodegradation	80% after 28 days (readily biodegradable)	No data	No data	21% after 28 days (not readily biodegradable)	No data	No data	No data	0 – 24% after 28 days (not readily biodegradable)
Bioaccumulation Factor	BAF = 369 – 8,180 (estimated) <sup>2,3</sup>	BAF = 0.9 – 1.5×10 <sup>4</sup> (estimated) <sup>2,3</sup>	BAF = 0.9 – 1.5×10 <sup>4</sup> (estimated) <sup>2,3</sup>	BAF = 0.9 (estimated) <sup>2,3</sup>	BAF = 0.9 – 680 (estimated) <sup>2,3</sup>	BAF = 0.9 – 680 (estimated) <sup>2,3</sup>	BAF = 150 – 1,064	BAF = 0.9 – 7.3×10 <sup>5</sup> (estimated) <sup>2,3</sup>
Log K <sub>oc</sub>	6.0 – 7.1 (estimated) <sup>2,3</sup>	5.8 – 13.6 (estimated) <sup>2,3</sup>	5.8 – 13.6 (estimated) <sup>2,3</sup>	9.8 – 10.0 (estimated) <sup>2,3</sup>	6.8 – 13.1 (estimated) <sup>2,3</sup>	6.8 – 13.1 (estimated) <sup>2,3</sup>	6.8 – 7.3 (estimated) <sup>2,3</sup>	4.5 – 13.1 (estimated) <sup>2,3</sup>
Fugacity (Level III Model) <sup>2,3</sup>								
Air (%)	3.6 – 5.6	1.2 – 6.1	1.2 – 6.1	0.3	1.1 – 2.8	1.1 – 2.8	3.1 – 5.4	1.1 – 11.1
Water (%)	65.5 – 80.9	81.1 – 82.5	81.1 – 82.5	21.6 – 22.9	59.0 – 82.6	59.0 – 82.6	60.1 – 64.8	43.2 – 79.9
Soil (%)	12.3 – 30.8	9.4 – 17.7	9.4 – 17.7	76.8 – 78.1	14.2 – 38.2	14.2 – 38.2	29.7 – 36.7	5.6 – 36.5
Sediment (%)	0.1 – 1.1	<0.1 – 2.0	<0.1 – 2.0	<0.1	<0.1 – 0.3	<0.1 – 0.3	<0.1 – 0.1	<0.1 – 18.9
Persistence <sup>4</sup>	P1 (low)	P1 (low)	P1 (low)	P1 (low) – P2 (moderate)	P1 (low) – P2 (moderate)	P1 (low) – P2 (moderate)	P1 (low) – P2 (moderate)	P1 (low) – P2 (moderate)
Bioaccumulation <sup>4</sup>	B1 (low) – B3 (high)	B1 (low) – B3 (high)	B1 (low) – B3 (high)	B1 (low)	B1 (low)	B1 (low)	B1 (low) – B2 (moderate)	B1 (low) – B3 (high)

<sup>1</sup> The Petroleum HPV Testing Group. Revised Test Plan and Robust Summary for Waxes and Related Materials. January 21, 2011. Available at: <http://www.epa.gov/chemrtk/pubs/summaries/wxrelmat/c13902tc.htm> as of February 28, 2011.

<sup>2</sup> U.S. EPA. 2011. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online at <http://www.epa.gov/opptintr/exposure/pubs/episuitedi.htm> as of February 28, 2011.

<sup>3</sup> Data range is based upon the representative structures; see Appendix for detailed information on the structures.

<sup>4</sup> Federal Register. 1999. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register* 64, Number 213 (November 4, 1999) pp. 60194–60204.

### **3. Human Health Hazard**

A summary of health effects data submitted for SIDS endpoints is provided in Table 4. The table also indicates where data for tested category members are read-across (RA) to untested members of the category.

#### ***Acute Oral Toxicity***

##### ***Subcategory I: Slack Waxes***

No data were provided for this endpoint. The sponsor stated that the toxicity of the slack waxes would result from the combined effects of the component waxes and oils, which could be extrapolated from the data submitted for the refined/finished waxes and data from the Lubricating Oil Basestocks and Aromatic Extracts HPV submissions. The sponsor did not provide data from those submissions.

##### ***Subcategory II: Refined/Finished Waxes (Paraffin)***

A paraffin wax (described as R 9071, dissolved in arachis oil) was administered as a single oral dose to rats (5/sex/dose, species not specified) at doses of 1000 and 5000 mg/kg. Animals were observed for seven days. There were no mortalities.

**LD<sub>50</sub> > ~ 5000 mg/kg**

##### ***Subcategory III: Refined/Finished Waxes (Microcrystalline)***

A microcrystalline wax (described as R 9269, dissolved in arachis oil) was administered as a single oral dose to rats (5/sex/dose, species not specified) at doses of 1000 and 5000 mg/kg. Animals were observed for seven days. There were no mortalities.

**LD<sub>50</sub> > ~ 5000 mg/kg**

##### ***Subcategory IV: Petrolatum***

No data were provided for this endpoint.

#### ***Repeated-Dose Toxicity***

##### ***Subcategory I: Slack Waxes***

No adequate data were submitted for this endpoint.

##### ***Subcategory II: Refined/Finished Waxes (Paraffin)***

###### ***Paraffin waxes (petroleum), hydrotreated (CASRN 64742-51-4)***

In a 90day study, Fischer 344 rats (20/sex/dose, 60/sex for control) were administered a hydrotreated paraffin wax (identified as LMPW for low melting point paraffin wax) in the diet at 0, 0.002, 0.02, 0.2 or 2.0% (calculated by EPA to be ~0, 1.1, 11, 110 or 1100 mg/kg-bw/day) (“main study”). Additional groups of rats (10/sex for dosed, 30/sex for control) were administered LMPW in the diet at 0 or 2.0% (~ 0 or 1100 mg/kg-bw/day) for 90 days followed by a 28-day recovery period (“reversal study”). A third set of Fischer 344 rats (10/sex/dose) were administered LMPW in the diet at 0 or 2.0% (~ 0 or 1100 mg/kg-bw/day) for 90 days; after which five animals/sex/dose were sacrificed and five animals/sex/dose were allowed a 28-day recovery period before undergoing tissue level studies (“tissue level and reversal study”).

There were no treatment-related effects on growth rate, food intake or clinical conditions. Effects on organ weight included increased absolute and relative spleen and liver weights in animals at the two highest dose levels and increased mesenteric lymph node weight in high-dose animals. Following the recovery period, these effects had reduced, but were still present (there was only one treated group in the reversal study, at 1100 mg/kg-bw/day). The statistical significance of the organ weight changes was not reported.

There were a variety of hematological effects observed at the highest dose level (1100 mg/kg/bw-day), primarily in females. All the effects noted here were statistically significant at a level of  $p < 0.05$  or lower. Effects in males at the two highest doses included decreased hemoglobin, mean corpuscular hemoglobin (MCH) and platelets and increased neutrophils. Effects in females included increased lymphocytes at the three highest dose levels, increased white blood cells (WBCs), neutrophils, monocytes and basophils, and decreased platelets at the two highest doses and decreased red blood cells (RBCs), hemoglobin content, hematocrit and MCH and increased reticulocytes and eosinophils at the high-dose level. Effects on clinical chemistry were observed in males (highest dose) and females (two highest doses) and included elevated serum liver enzyme activity (alanine, alanine aminotransferase [ALT], aspartate aminotransferase [AST] and gamma-glutamyltransferase [GGT]) and decreased albumin/globulin ratios. Elevated serum bilirubin was also observed in high dose females. Statistical significance for these clinical chemistry effects was not reported.

Histopathology revealed treatment-related effects on the liver (granulomas in males and females at the two highest doses and centrilobular vacuolation in high-dose animals), mesenteric lymph node (lesions comprised of focal collections of slightly vacuolated macrophages to varying degrees in animals at all dose levels), ileum and jejunum (increased incidence in macrophage accumulation in animals at the highest two doses and increased macrophage infiltration of the lamina propria in high-dose females) and heart (focal inflammatory lesion in high-dose males [11/20] and females at the two highest doses; 11/20 for high dose and 5/20 for next highest). Lesions in the liver, lymph nodes, and heart persisted following recovery (although they did reduce in severity). Details of these effects (e.g., tables with incidence, statistical significance, quantification of severity) were not reported with the exception of the incidence for the heart effect. As noted in the protocol above, a third group of animals had certain tissues analyzed for the presence of mineral hydrocarbons. Results showed no hydrocarbons in the kidney, but they were seen in the perirenal fat, liver and lymph nodes (only high dose animals were evaluated and no other information was reported). Mineral hydrocarbon was still found in these tissues after the reversal period, but at lower concentrations.

**LOAEL ~ 110 mg/kg-bw/day** (based on changes in hematological parameters and histopathological lesions [liver, mesenteric lymph node, ileum and jejunum, and heart [only females at the 110 mg/kg-bw/day level]])

**NOAEL ~ 11 mg/kg-bw/day**

#### ***Paraffin and hydrocarbon waxes (CASRN 8002-74-2)***

In a recent 90-day study published in the open literature to compare rat strain response to LMPW exposure, female F-344 and Sprague-Dawley rats were administered CASRN 8002-74-2 in the diet at 0, 0.2% or 2% (approximately 160 and 1600 mg/kg-bw/day) (Griffis et al., 2010). The test material was characterized as: melting point of 55 °C; oil content of 0.1%, sulfur content of < 5 ppm; and carbon number of *n*-alkanes from C<sub>19</sub>-C<sub>42</sub>. The study design included interim

sacrifices. Ten control and high-dose rats of each strain were euthanized and necropsied after 30 and 60 days of treatment. Ten control, low- and high-dose rats of each strain were necropsied after 90 days. Additional rats (5/dose) were used to analyze mineral hydrocarbon contents in certain tissues after 30, 60 and 90 days of treatment. Thus the total number of rats used were 45 in control group, 25 in mid-dose group and 45 in the high-dose group for each strain. Normal repeated-dose toxicity parameters were evaluated in the main study group (clinical signs, hematology, clinical chemistry, organ weight and histopathology). Given knowledge from previous studies (including the one summarized above), there was focus on mesenteric lymph nodes and the liver by use of immunohistochemical analyses. In the additional animal group, the liver, kidney, heart, spleen and mesenteric lymph nodes were analyzed for mineral hydrocarbon content.

There were no effects in either strain at either dose on mortality, clinical signs, body weight gain (there is no mention of effects on body weight) and food consumption. The following effects (hematology and clinical chemistry) were seen in F-344 rats but not in the Sprague-Dawley strain of rats (only those labeled as statistically significant and that are dose-related are reported here): increased neutrophils (both doses); decreased hemoglobin (both doses); elevated liver enzymes (both doses for AST, ALT, GGT, high dose only for alkaline phosphatase (ALP)); and decreased serum albumin levels (both doses).

The organ weight data (both absolute and relative to body weight) showed statistical increases in liver, spleen, and mesenteric lymph nodes (all at 30, 60 and 90 days) and ovaries (90 days only) at both doses in F-344 rats. Histopathological changes were noted in the liver (microgranulomas), spleen (extramedullary hematopoiesis) and mesenteric (and cervical) lymph nodes (microgranulomas) and heart (mitral valve-based lymphoid cell infiltrate) - but not the ovaries. In Sprague-Dawley rats, the only organ weight changes noted were increases in the absolute and relative mesenteric lymph nodes (at 30, 60 and 90 days), some of which were statistically significant for the 30 and 60 day time periods, but specifics were not provided in Griffis et al., 2010. The report further indicated that some histopathological changes in the mesenteric lymph nodes (again, microgranulomas) were in the Sprague-Dawley rats. There was also reticuloendothelial cell hyperplasia observed in both rat strains at both doses. Documentation of histopathological changes was reported on a severity scale and there did not appear to be a statistical analysis of these data.

In addition to the organ weight data above, results from the immuno-histochemical and tissue mineral hydrocarbon analyses confirmed that the liver and mesenteric lymph nodes were target organs in rats exposed to CASRN 8002-74-2, but that F-344 rats were more sensitive in terms of both dose and magnitude of response.

**LOAEL ~ 160 mg/kg-bw/day** (based on changes in hematology, clinical chemistry, organ weight changes (liver, spleen, mesenteric lymph nodes and ovaries; and histopathology (liver, spleen, mesenteric lymph nodes and heart))

**NOAEL = Not established**

### ***Subcategory III: Refined/Finished Waxes (Microcrystalline)***

#### ***Hydrocarbon waxes (petroleum), clay treated, microcrystalline (CASRN 64742-42-3)***

Fischer 344 rats (20/sex/dose, 60/sex for control) were administered clay treated microcrystalline hydrocarbon wax (identified as HSW, or high sulfur wax) following the same protocol identified

above for Subcategory II chemical, CASRN 64742-51-4 (three different study groups, same dose levels). There were no effects on growth rates, food intakes, clinical conditions or histology. Slightly increased relative male liver weight was observed in the two middle dose groups, but not the high dose group. A slight increase (2% above control, statistical significance not reported) in hemoglobin was seen in high-dose males and increased serum glucose activity (magnitude and statistical significance not reported) was observed in all but the highest dose group of animals. There were no mineral hydrocarbons seen in any of the animals fed the HSW during the tissue level and reversibility study test.

**NOAEL ~ 1100 mg/kg-bw/day** (based on no effects at the highest dose tested)

***Hydrocarbon waxes (petroleum), hydrotreated, microcrystalline (CASRN 64742-60-5)***

Fischer 344 rats (20/sex/dose, 60/sex for control) were administered a hydrotreated microcrystalline hydrocarbon wax (identified as HMPW for high melting point wax) following the same protocol identified above for Subcategory II chemical CASRN 64742-51-4 (three different study groups, same dose levels). There were no effects on growth rates, food intakes, clinical conditions, organ weights, necropsy or histology. A minor increase in hemoglobin (2% above control, statistical significance not reported) was observed in high-dose males and a non-dose-related increase in serum glucose activity was observed in all dosed animals. There were no mineral hydrocarbons seen in any of the animals fed the HMPW during the tissue level and reversibility study test.

**NOAEL ~ 1100 mg/kg-bw/day** (based on no effects at the highest dose tested)

***Subcategory IV: Petrolatum***

In the carcinogenicity study described below, FDRL rats (50/sex/dose) were administered three blends of petrolatum at 5% in the diet (calculated by EPA to be ~ 2500 mg/kg-bw/day) for two years (there was a control group of 100 animals/sex). No treatment-related effects were noted for daily appearance, behavior, survival, body weight, hematology, clinical chemistry or histology of multiple organs, including the reproductive organs.

**NOAEL ~ 2500 mg/kg-bw/day** (based on no effects at the highest dose tested)

***Reproductive/Developmental Toxicity***

***Subcategory I: Slack Waxes***

No data.

***Subcategory II: Refined/Finished Waxes (Paraffin)***

No data.

***Subcategory III: Refined/Finished Waxes (Microcrystalline)***

No data.

***Subcategory IV: Petrolatum***

No data.

***Genetic Toxicity***

There were no robust summaries provided for this endpoint (either in vitro or in vivo). In fact, the robust summary document states “no data available” on p. 31 in <http://www.epa.gov/chemrtk/pubs/summaries/wxrelmat/c13902rr2.pdf> . However, in the submitter’s 2011 Category Assessment Document (<http://www.epa.gov/chemrtk/pubs/summaries/wxrelmat/c13902ca2.pdf>), information is provided on pp. 35-37 and Appendix 2 describing modified Ames tests that were performed on slack wax samples. No details are provided and the reference (Petrolabs, 2004) is unpublished. Thus, this information could not be used in this hazard characterization.

### ***Additional Information***

#### ***Carcinogenicity***

The sponsor included a number of lifetime/carcinogenicity animal studies in their submission (see pp. 32-44 of revised robust summaries at <http://www.epa.gov/chemrtk/pubs/summaries/wxrelmat/c13902tc.htm>). However, conclusions could not be drawn from most of them.

#### ***Subcategory IV: Petrolatum***

##### ***Petrolatum (petroleum jelly) (CASRN 8009-03-8)***

(1) Swiss mice (30 males/40 females per treatment group and 50/sex/control group; species/strain not specified) were administered a 15% solution of “amber petrolatum” (NF grade) in isooctane twice weekly via the dermal route. Three drops (approximately 60 microliters) per application was applied to the shaved skin (location not reported) twice a week for their lifetime. Controls received 60 microliters of isooctane. The treated group had moderate epidermal hyperplasia (specifics not reported) and there was no apparent effect on survival (data presented). Skin tumor incidence data were provided: tumor-bearing animals - two males from control group and two males/one female in the treated group; total number of tumors – two in controls and five in treated group; the only carcinoma was seen in the controls, all others were listed only as tumors. The robust summary states that “(N)o data are included here for the various extracts of petrolatum that were tested, even though such data were given in the publication reviewed.”. Upon retrieval of the publication (Lijinsky et al., 1966), five different extracts of petrolatum were tested with the same protocol: petrolatum, aromatic-free fraction, aromatic fraction, aromatic subfraction (nitromethane extract), and another aromatic subfraction (cyclohexane subfraction). The data show that the three aromatic fractions caused tumors whereas the petrolatum and aromatic-free fraction did not (Table 1 in Lijinsky et al., 1966). (Ref. 39 and pp. 33-34 of robust summaries).

**The aromatic fractions increased the incidence of tumors whereas the petrolatum and aromatic-free fractions did not.**

(2) FDRL rats (50/sex/dose) were administered three blends of petrolatum at concentrations of 5% in the diet (~ 2500 mg/kg-bw/day) for two years. Each blend was a mixture of 5-6 commercially available materials. The control group consisted of 100 rats/sex. No treatment-related effects were noted for daily appearance, behavior, survival, body weight, hematology, clinical chemistry, histology or tumor incidence. (Ref. 46 and pp. 39-40 of the robust summaries).

**Petrolatum did not increase the incidence of tumors in rats in this study.**

**Conclusion:** The waxes and related materials (WRM) category was divided into four sub-categories for the human health effects characterization.

***Subcategory I: Slack Waxes***

No data were available for any of the health effects endpoints.

***Subcategory II: Refined/Finished Waxes (Paraffin)***

A paraffin wax (exact identity unknown) had low acute toxicity via the oral route in rats. Following repeated oral exposure of a hydrotreated paraffin wax to rats for 90 days, increased organ weights (spleen, liver and lymph nodes) and effects on hematology, clinical chemistry, and histology (granulomas and centrilobular vacuolation in the liver, lesions in the lymph nodes, macrophage accumulation and infiltration in the ileum and jejunum and focal inflammatory lesions in the heart) were observed at an estimated dose of 110 mg/kg-bw/d. The NOAEL for these effects was 11 mg/kg-bw/d. In a recent (2010) study designed to evaluate differences in rat strain responses to exposure to paraffin wax, two strains of rats were exposed via the diet for 90 days. Results showed F-344 to be more sensitive than Sprague-Dawley with the following effects observed at the lowest tested dose of approximately 160 mg/kg-bw/d (changes in hematology, clinical chemistry, organ weight changes (liver, spleen, mesenteric lymph nodes and ovaries; and histopathology (liver, spleen, mesenteric lymph nodes and heart); the NOAEL for this study could not be established.

***Subcategory III: Refined/Finished Waxes (Microcrystalline)***

A microcrystalline wax (exact identity unknown) had low acute toxicity via the oral route in rats. In a 90-day repeated dose oral exposure study in rats, two different microcrystalline waxes (one clay treated and one hydrotreated) were tested at doses up to approximately 1100 mg/kg-bw/d. No significant effects were observed, resulting in a NOAEL of 1100 mg/kg-bw/d.

***Subcategory IV: Petrolatum***

Following repeated oral dosing of rats with petrolatum for two years at a single dose of 5% in the diet (approximately 2500 mg/kg/day) and no treatment-related effects were observed. CASRN 8009-03-8 did not increase the incidence of tumors in rats.

**Table 4. Summary of Screening Information Data Set Under the U.S. HPV Challenge Program - Human Health Data**

Sub-Category	I	II			III			IV
<b>Endpoints</b>	<b>Slack Wax (Petroleum)</b>  (64742-61-6)	<b>Paraffin waxes (petroleum), hydrotreated</b>  (64742-51-4)	<b>Paraffin waxes (petroleum), clay treated</b>  (64742-43-4)	<b>Paraffin waxes and hydrocarbon waxes</b>  (8002-74-2)	<b>Hydrocarbon waxes (petroleum), clay treated, microcrystalline</b>  (64742-42-3)	<b>Hydrocarbon waxes (petroleum), hydrotreated, microcrystalline</b>  (64742-60-5)	<b>Paraffin waxes and hydrocarbon waxes, microcrystalline</b>  (63231-60-7)	<b>Petrolatum (petroleum jelly)</b>  (8009-03-8)
<b>Acute Oral Toxicity LD<sub>50</sub> (mg/kg)</b>	No data	>5000 mg/kg			>5000 mg/kg			No data
<b>Repeated-Dose Toxicity NOAEL/LOAEL Oral (Diet) (mg/kg-bw/day)</b>	No data	<b>NOAEL ~ 11 LOAEL ~ 110</b>	No Data NOAEL ~ 11 LOAEL ~ 110 (RA)	<b>NOAEL = NE LOAEL = 160</b>	<b>NOAEL ~ 1100 (highest dose tested)</b>	No Data NOAEL ~ 1100 (RA)	No Data NOAEL ~ 1100 (RA)	<b>NOAEL ~ 2500 (2-yr, highest dose tested)</b>
<b>Reproductive/ Developmental Toxicity NOAEL/LOAEL Oral (mg/kg-bw/day)</b>	No data	No data			No data			No data
<b>Genetic Toxicity – Gene Mutation <i>In vitro</i></b>	No data	No data			No data			No data
<b>Genetic Toxicity – Chromosomal Aberrations <i>In vivo</i></b>	No data	No data			No data			No data
<b>Additional Information Carcinogenicity</b>	–	–	–	–	–	–	–	<b>Negative</b>

Measured data in bold text; (RA) = Read Across; – indicates that endpoint was not addressed for this substance. NE = not established

#### **4. Hazard to the Environment**

A summary of aquatic toxicity data for SIDS endpoints is provided in Table 5. The table also indicates where data are read-across (RA) to sponsored members of the WRM category.

##### *Acute Toxicity to Fish*

*1-Tetradecene (CASRN 1120-36-1, supporting chemical)*

<http://www.chem.unep.ch/irptc/sids/OECDSIDS/AOalfaolefins.pdf>

**96-h LC<sub>50</sub> = No effects at saturation.**

##### *Acute Toxicity to Aquatic Invertebrates*

*1-Tetradecene (CASRN 1120-36-1, supporting chemical)*

<http://www.chem.unep.ch/irptc/sids/OECDSIDS/AOalfaolefins.pdf>

**48-h EC<sub>50</sub> = No effects at saturation.**

##### *Toxicity to Aquatic Plants*

*1-Tetradecene (CASRN 1120-36-1, supporting chemical)*

<http://www.chem.unep.ch/irptc/sids/OECDSIDS/AOalfaolefins.pdf>

**96-hEC<sub>50</sub> = No effects at saturation.**

##### *Chronic Toxicity to Aquatic Invertebrates*

*1-Tetradecene (CASRN 1120-36-1, supporting chemical)*

<http://www.chem.unep.ch/irptc/sids/OECDSIDS/AOalfaolefins.pdf>

**ChV = No effects at saturation**

#### **Conclusion**

Based on the supporting chemical CASRN 1120-36-4, the acute toxicity to fish and aquatic invertebrates, and the toxicity to aquatic plants of the WRM category chemicals are considered to be “no effects at saturation” (NES). Also, based on the supporting chemical 1120-36-4, the chronic toxicity to aquatic invertebrates is NES.

<b>Table 5. Summary of Environmental Effects – Aquatic Toxicity Data</b>				
<b>Test Substance (CASRN)</b>	<b>Fish 96-h LC<sub>50</sub> (mg/L)</b>	<b>Aquatic Invertebrates 48-h EC<sub>50</sub> (mg/L)</b>	<b>Aquatic Plants 72/96-h EC<sub>50</sub> (mg/L) Biomass Growth Rate</b>	<b>Chronic Toxicity to Aquatic Invertebrates ChV (mg/L)</b>
<b>SUPPORTING CHEMICAL 1-Tetradecene (1120-36-1)</b>	<b>NES</b>	<b>NES</b>	<b>NES</b>	<b>NES</b>
<b>SPONSORED CHEMICAL Slack wax (petroleum) (64742-61-6)</b>	No Data NES (RA)			
<b>SPONSORED CHEMICAL Petrolatum (petroleum jelly) (8009-03-8)</b>	No Data NES (RA)			
<b>SPONSORED CHEMICAL Paraffin waxes and hydrocarbon waxes (8002-74-2)</b>	No Data NES (RA)			
<b>SPONSORED CHEMICAL Paraffin waxes (petroleum), clay treated (64742-43-4)</b>	No Data NES (RA)			
<b>SPONSORED CHEMICAL Paraffin waxes (petroleum), hydrotreated (64742-51-4)</b>	No Data NES (RA)			
<b>SPONSORED CHEMICAL Paraffin waxes and hydrocarbon waxes, microcrystalline (63231-60-7)</b>	No Data NES (RA)			
<b>SPONSORED CHEMICAL Hydrocarbon waxes (petroleum), clay treated, microcrystalline (64742-42-3)</b>	No Data NES (RA)			
<b>SPONSORED CHEMICAL Hydrocarbon waxes (petroleum), hydrotreated, microcrystalline (64742-60-5)</b>	No Data NES (RA)			

**Bold = measured data (i.e., derived from experiment); NES = no effects at saturation (water solubility limit); (RA) = Read Across; – indicates that endpoint was not addressed for this substance.**

## REFERENCES

Griffis, LC, LE Twerdok, S Francke-Carroll, RW Biles, RE Schroeder, H Bolte, H Faust, WC Hall and J Rojko. 2010. Comparative 90-day dietary study of paraffin wax in Fischer-344 and Sprague-Dawley rats. *Food Chem Tox* (48): 363-372.

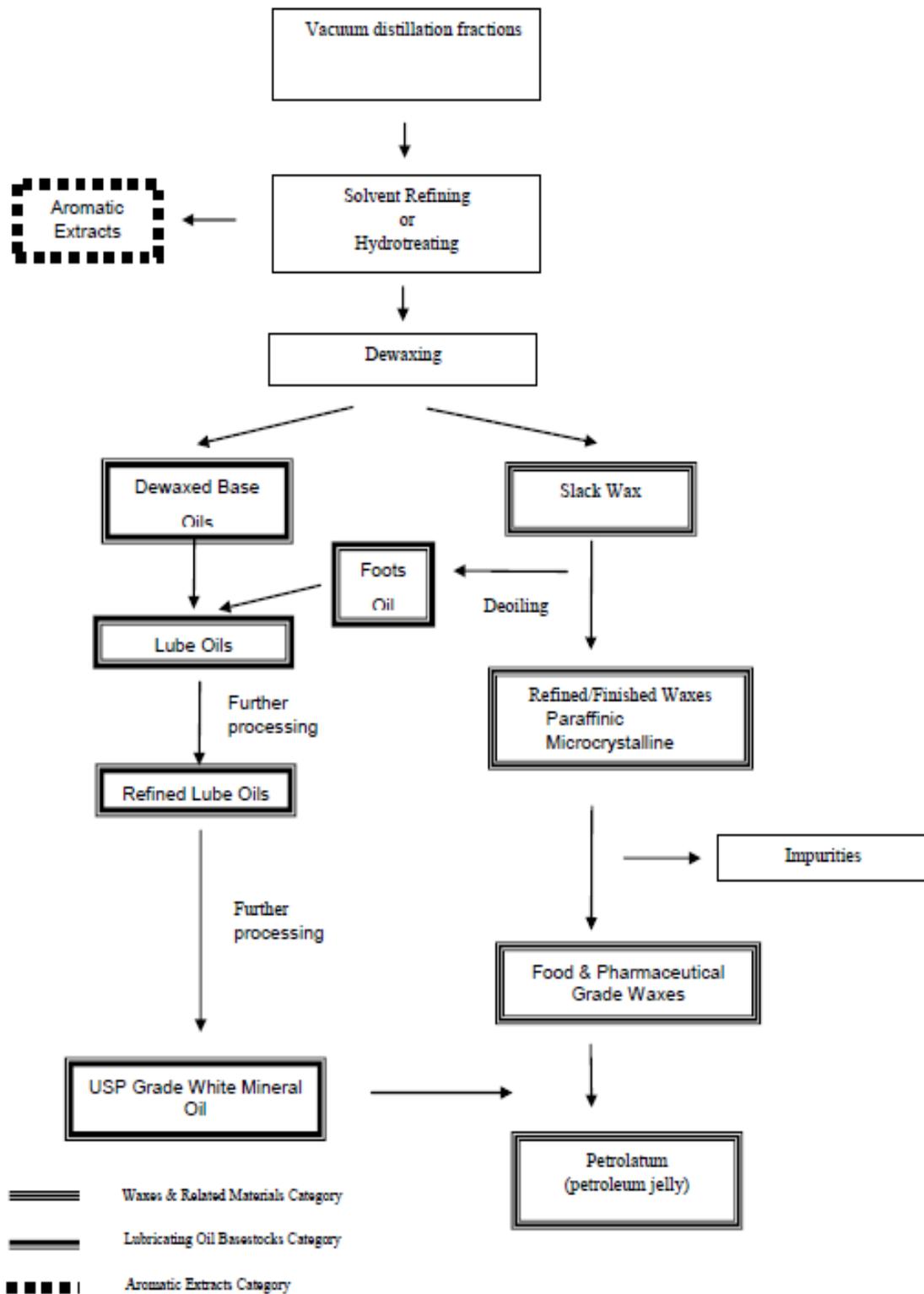
Lijinsky, W., U Saffiotti and P Shubik. 1966. Skin tumorigenesis by an extract of amber petrolatum. *Tox Appl Pharm* (8): 113-117.

The following pages show:

- Appendix A: Schematic of the Production Process for Waxes and Related Materials
- Appendix B: Short description of the category members and the representative structures

APPENDIX A

Figure 1. Schematic of the Production Process for Waxes and Related Materials



## Appendix B

Notes on representative structures: Limited compositional data was provided for the majority of category members. Hence, the structures chosen in the table below were based on the partial information provided by the CAS names and CAS definitions, as well as the description of the category members in the test plan.

Slack wax may contain 5% to 20% of lubricating oils which contain paraffins, naphthenes and possibly polycyclic aromatic compounds and alkyl aromatics. Refined/finished waxes and petrolatum are produced from slack waxes by removing some of the impurities and base oils. The refined/finished waxes subcategory itself is further divided into paraffinic waxes (lower melting paraffin waxes) and microcrystalline waxes (high melt waxes). Paraffin waxes contain mainly normal alkanes, varying amounts of isoalkanes, cycloalkanes, and a very low concentration of alkylated aromatic hydrocarbons (average molecular weight of 350-420), while the microcrystalline waxes consist mainly of iso- and cycloalkanes with a lesser amount of normal alkanes and only trace amounts of alkylated aromatic hydrocarbons. Petrolatum is a complex mixture of highly refined higher-melting paraffin wax and >10% USP-grade white mineral oil and mainly consists of branched and straight chain alkanes (generally >C25).

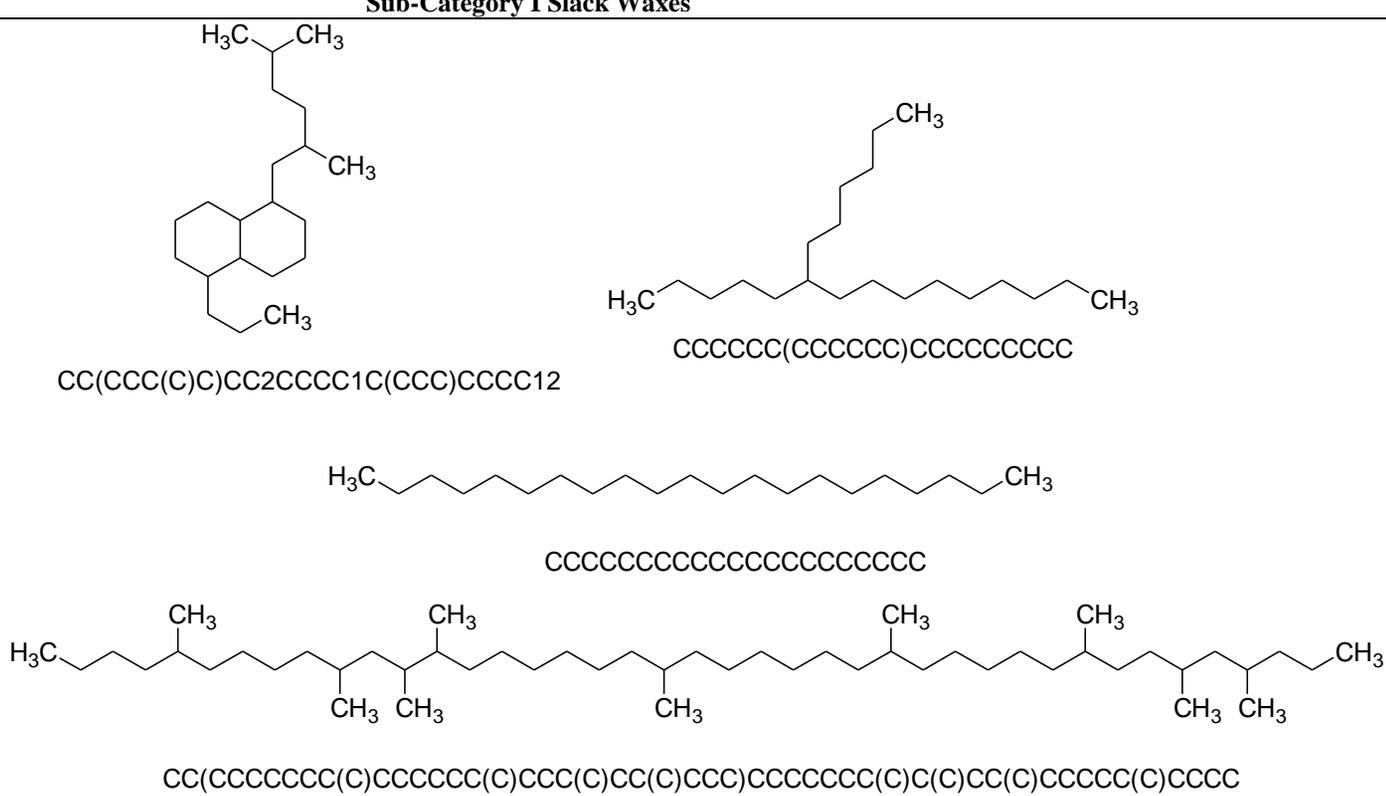
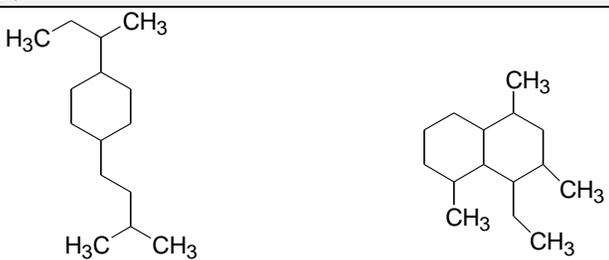
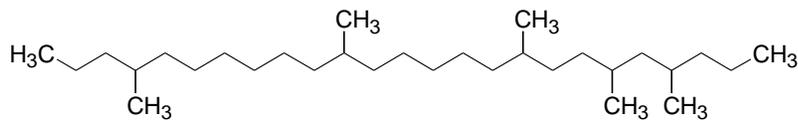
Table A-1. Chemical Name, CASRN and Chemical Structures for Waxes and Related Materials		
Name	CASRN	Structure
<b>Sub-Category I Slack Waxes</b>		
Slack wax (petroleum)	64742-61-6	 <p> <chem>CC(CCC(C)C)CC2CCCC1C(CCC)CCCC12</chem>  <chem>CCCCC(CCCCC)CCCCCCCC</chem>  <chem>CCCCCCCCCCCCCCCCCCCC</chem>  <chem>CC(CCCCCC(C)CCCCC(C)CCC(C)CC(C)CCC)CCCCC(C)C(C)CC(C)CCCC(C)CCCC</chem> </p> <p>Complex combination of hydrocarbons obtained from a petroleum fraction by solvent crystallization (solvent dewaxing) or as a distillation fraction from a very waxy crude. It consists predominantly of saturated straight and branched chain hydrocarbons having carbon numbers predominantly greater than C20.</p>
<b>Supporting Chemicals</b>		

Table A-1. Chemical Name, CASRN and Chemical Structures for Waxes and Related Materials		
Name	CASRN	Structure
Slack wax (petroleum), hydrotreated	92062-09-4	<p> <chem>CC(CCC(C)C)CC2CCCC1C(CCC)CCCC12</chem> </p> <p> <chem>CCCCC(CCCCC)CCCCCCCC</chem> </p> <p> <chem>CCCCCCCCCCCCCCCCCCCC</chem> </p> <p> <chem>CC(CCCCCC(C)CCCCC(C)CCC(C)CC(C)CCC)CCCCC(C)C(C)CC(C)CCCC(C)CCCC</chem> </p>
<p>A complex combination of hydrocarbons obtained by treating slack wax with hydrogen in the presence of a catalyst. It consists predominantly of saturated straight and branched chain hydrocarbons having carbon numbers predominantly greater than C20.</p>		

Table A-1. Chemical Name, CASRN and Chemical Structures for Waxes and Related Materials		
Name	CASRN	Structure
White mineral oil (petroleum)	8042-47-5	<p> <chem>CC(CCC(C)C)CC2CCCC1C(CCC)CCCC12</chem>  <chem>CCCCCCCCCCCCCCCCCCCC</chem>  <chem>CC(CCCCCC(C)CCCCC(C)CCC(C)CC(C)CCC)CCCCCCC(C)C(C)CC(C)CCCC(C)CCCC</chem> </p> <p>A highly refined petroleum mineral oil consisting of a complex combination of hydrocarbons obtained from the intensive treatment of a petroleum fraction with sulfuric acid and oleum, or by hydrogenation, or by a combination of hydrogenation and acid treatment. Additional washing and treating steps may be included in the processing operation. It consists of saturated hydrocarbons having carbon numbers predominantly in the range of C15 through C50.</p>
Distillates (petroleum), solvent-refined light naphthenic	64741-97-5	

Table A-1. Chemical Name, CASRN and Chemical Structures for Waxes and Related Materials		
Name	CASRN	Structure
		 <chem>CC(C)CCC1CCC(C(C)CC)CC1</chem> <chem>CC2CC(C)C(CC)C1C(C)CCCC12</chem>
		 <chem>CCCC(C)CCCCCCC(C)CCCCC(C)CCC(C)CC(C)CCC</chem> <p>A complex combination of hydrocarbons obtained as the raffinate from a solvent extraction process. It consists of hydrocarbons having carbon numbers predominantly in the range of C15 through C30 and produces finished oil with a viscosity of less than 100 SUS at 100.degree.F (19 cSt at 40.degree.C). It contains relatively few normal paraffins.</p>
Distillates (petroleum), solvent-refined light paraffinic	64741-89-5	

**Table A-1. Chemical Name, CASRN and Chemical Structures for Waxes and Related Materials**

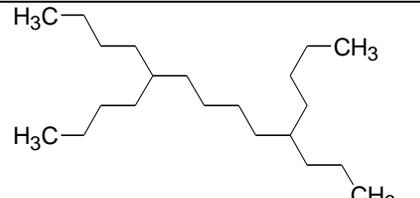
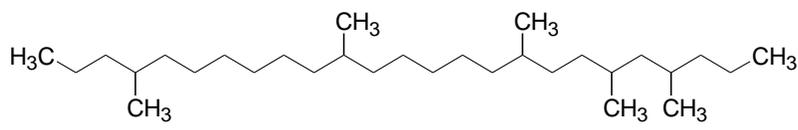
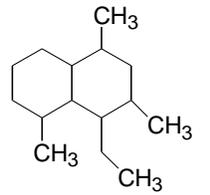
Name	CASRN	Structure
		<div style="text-align: center;">  <p>CCCCC(CCCC)CCCC(CCC)CCCC</p> </div> <div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;">  <p>CCCC(C)CCCCCCC(C)CCCCC(C)CCC(C)CC(C)CCC</p> </div> <div style="text-align: center;">  <p>CC2CC(C)C(CC)C1C(C)CCCC 12</p> </div> </div> <p>A complex combination of hydrocarbons obtained as the raffinate from a solvent extraction process. It consists predominantly of saturated hydrocarbons having carbon numbers predominantly in the range of C15 through C30 and produces finished oil with a viscosity of less than 100 SUS at 100.degree.F (19cSt at 40.degree.C).</p>

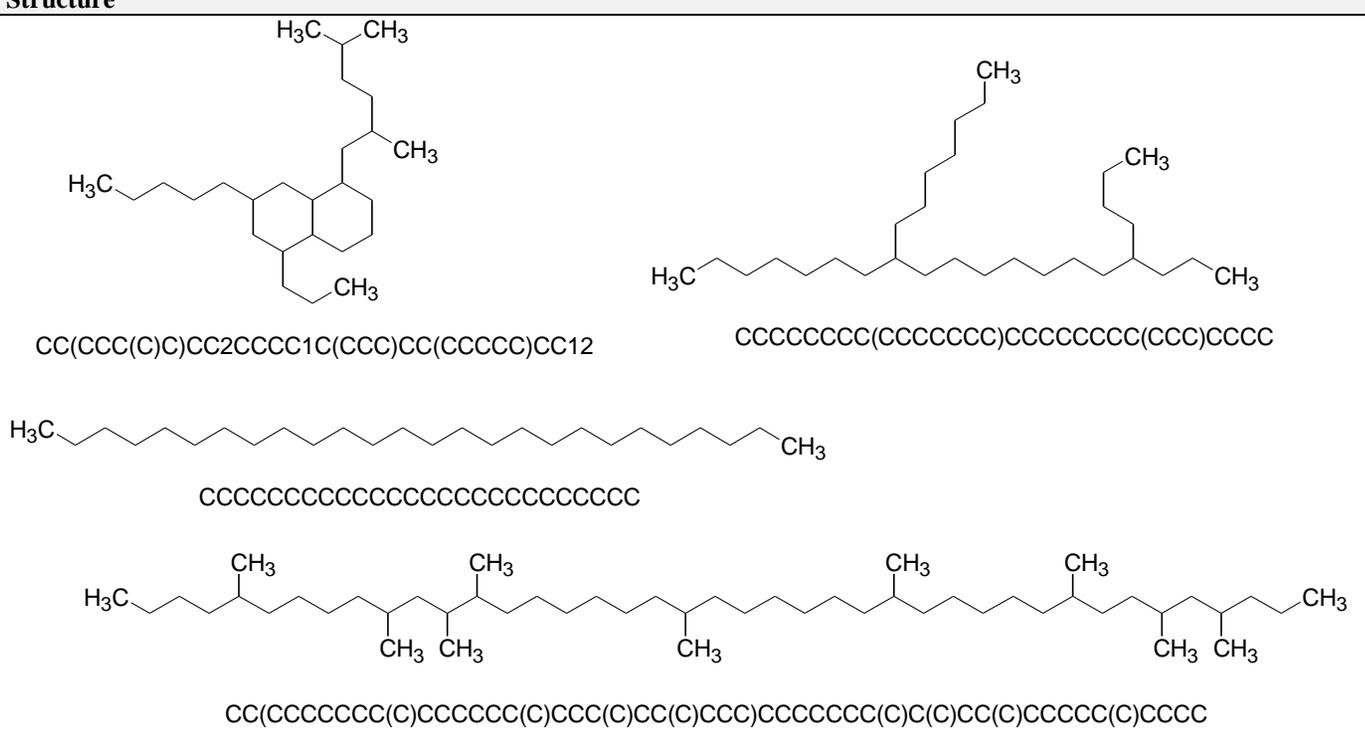
Table A-1. Chemical Name, CASRN and Chemical Structures for Waxes and Related Materials		
Name	CASRN	Structure
Residual oils (petroleum), solvent-refined	64742-01-4	 <p> <chem>CC(CCC(C)C)CC2CCCC1C(CCC)CC(CCCCC)CC12</chem> <chem>CCCCCCCC(CCCCCC)CCCCCCCC(CCC)CCCC</chem> <chem>CCCCCCCCCCCCCCCCCCCCCCCCCCCC</chem> <chem>CC(CCCCCC(C)CCCCC(C)CCC(C)CC(C)CCC)CCCCCCC(C)C(C)CC(C)CCCC(C)CCCC</chem> </p> <p>A complex combination of hydrocarbons obtained as the solvent insoluble fraction from solvent refining of a residuum using a polar organic solvent such as phenol or furfural. It consists of hydrocarbons having carbon numbers predominantly higher than C25 and boiling above approximately 400.degree.C (752.degree.F).</p>

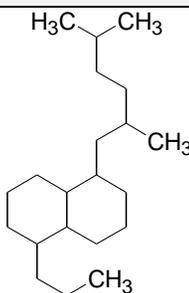
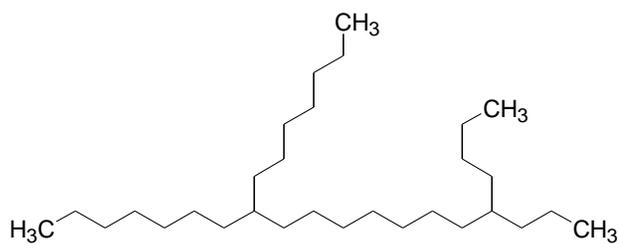
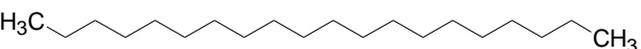
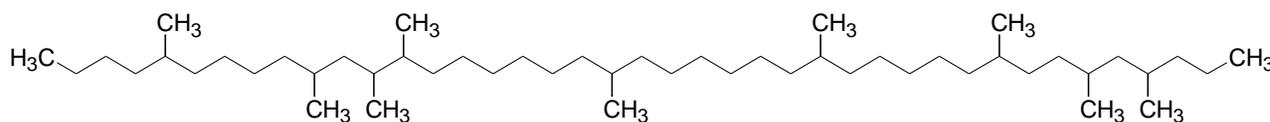
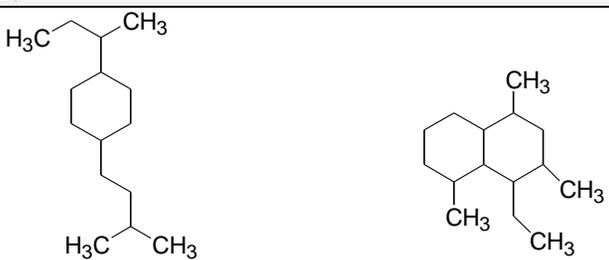
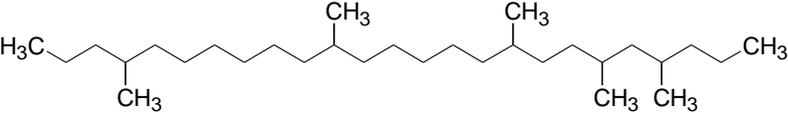
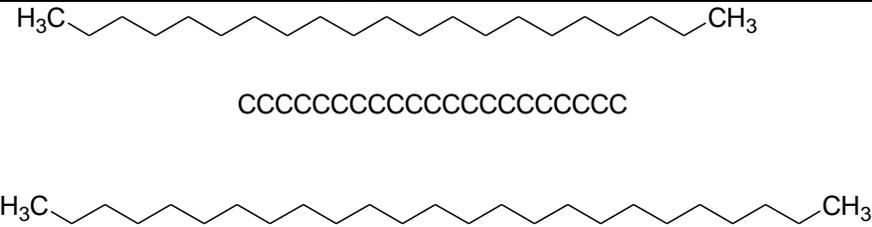
Table A-1. Chemical Name, CASRN and Chemical Structures for Waxes and Related Materials		
Name	CASRN	Structure
Distillates (petroleum), solvent-refined heavy paraffinic	64741-88-4	 <chem>CC(CCC(C)C)CC2CCCC1C(CCC)CCCC12</chem>
		 <chem>CCCCCCCC(CCCCCC)CCCCCCCC(CCC)CCCC</chem>
		 <chem>CCCCCCCCCCCCCCCCCCCC</chem>
		 <chem>CC(CCCCCC(C)CCCCC(C)CCC(C)CC(C)CCC)CCCCC(C)C(C)CC(C)CCCC(C)CCCC</chem>
		<p>A complex combination of hydrocarbons obtained as the raffinate from a solvent extraction process. It consists predominantly of saturated hydrocarbons having carbon numbers predominantly in the range of C20 through C50 and produces a finish oil with a viscosity of at least 100 SUS at 100.degree.F (19cSt at 40.degree.C).</p>

Table A-1. Chemical Name, CASRN and Chemical Structures for Waxes and Related Materials		
Name	CASRN	Structure
Distillates (petroleum), hydrotreated light naphthenic	64742-53-6	 <chem>CC(C)CCC1CCC(C(C)CC)CC1</chem> <chem>CC2CC(C)C(CC)C1C(C)CCCC12</chem>  <chem>CCCC(C)CCCCCCC(C)CCCCCC(C)CCC(C)CC(C)CCC</chem> <p>A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C15 through C30 and produces a finished oil with a viscosity of less than 100 SUS at 100.degree.F (19cSt at 40.degree.C). It contains relatively few normal paraffins.</p>
<b>Sub-Category II Refined/Finished Waxes (Paraffin)</b>		
Paraffin waxes and Hydrocarbon waxes	8002-74-2	 <chem>CCCCCCCCCCCCCCCCCCCC</chem> <chem>CCCCCCCCCCCCCCCCCCCC</chem> <p>A complex combination of hydrocarbons obtained from petroleum fractions (by solvent crystallization or the sweating process) or from the catalytic hydrogenation of carbon monoxide (the Fischer-Tropsch Process). It consists predominantly of straight chain hydrocarbons having carbon numbers predominantly greater than C20.</p>

<b>Table A-1. Chemical Name, CASRN and Chemical Structures for Waxes and Related Materials</b>		
<b>Name</b>	<b>CASRN</b>	<b>Structure</b>
Paraffin waxes (petroleum), clay-treated	64742-43-4	<p>A complex combination of hydrocarbons obtained by treatment of a petroleum wax fraction with natural or modified clay in either a contacting or percolation process to remove the trace amounts of polar compounds and impurities present. It consists predominantly of straight chain saturated hydrocarbons having carbon numbers in the range of C20 through C50.</p>
Paraffin waxes (petroleum), hydrotreated	64742-51-4	<p>A complex combination of hydrocarbons obtained by treating a petroleum wax with hydrogen in the presence of a catalyst. It consists predominantly of straight chain paraffinic hydrocarbons having carbon numbers predominantly in the range of about C20 through C50.</p>
<b>Sub-Category III Refined/Finished Waxes (Microcrystalline)</b>		

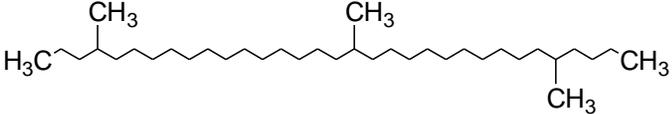
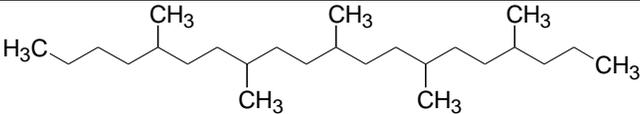
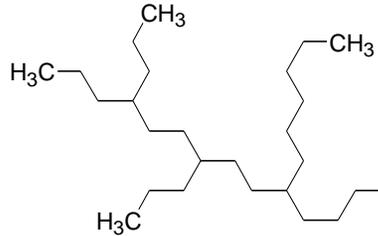
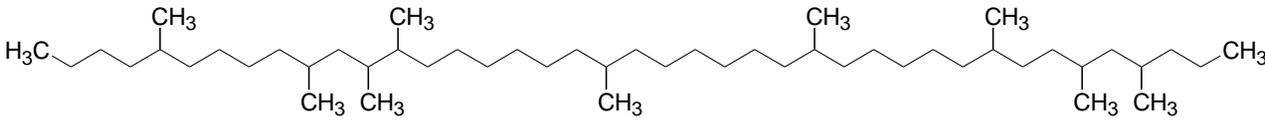
Table A-1. Chemical Name, CASRN and Chemical Structures for Waxes and Related Materials		
Name	CASRN	Structure
Paraffin waxes and Hydrocarbon waxes, microcryst.	63231-60-7	<p> <math>\text{H}_3\text{C}</math>~~~~~~<math>\text{CH}_3</math>            CC              CCCC(C)CCCCCCCCCCCCC(C)CCCCCCCCC(C)CCCC         </p> <p>A complex combination of long, branched chain hydrocarbons obtained from residual oils by solvent crystallization. It consists predominantly of saturated straight and branched chain hydrocarbons predominantly greater than C35.</p>
Hydrocarbon waxes (petroleum), clay-treated microcryst.	64742-42-3	<p>             CCCCC(C)CCC(C)CCC(C)CCC(C)CCC(C)CCC              CCCC(CCC)CCC(CCC)CCC(CCCCC)CCCCC              CC(CCCCCC(C)CCCCC(C)CCC(C)CC(C)CCC)CCCCC(C)C(C)CC(C)CCCC(C)CCCC         </p>

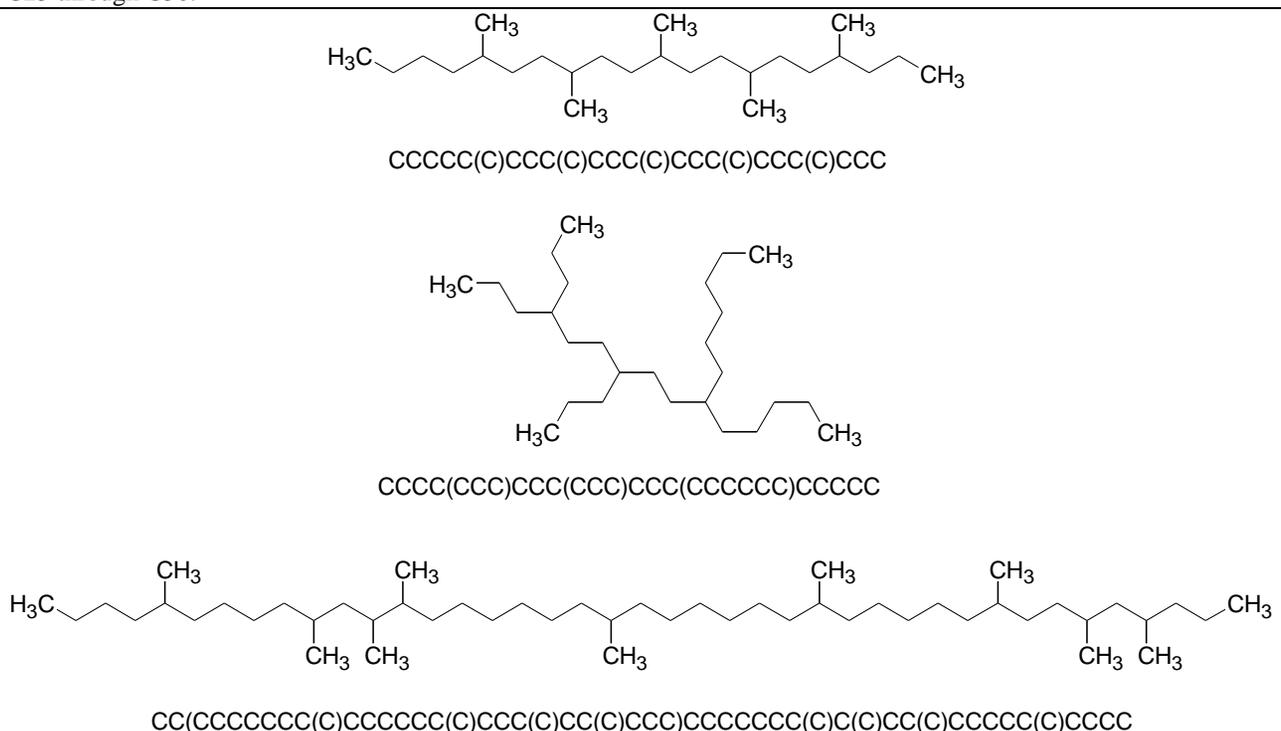
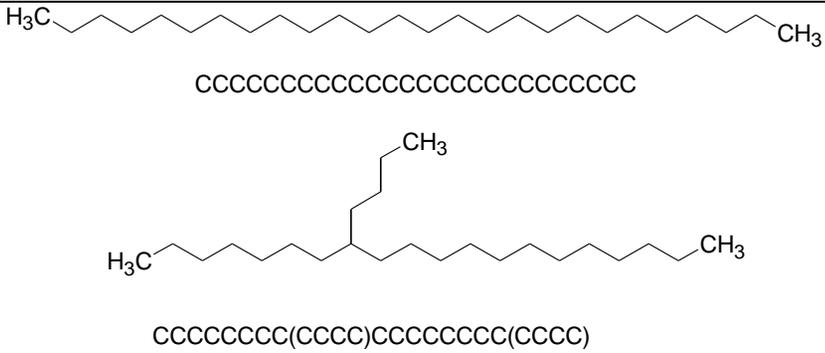
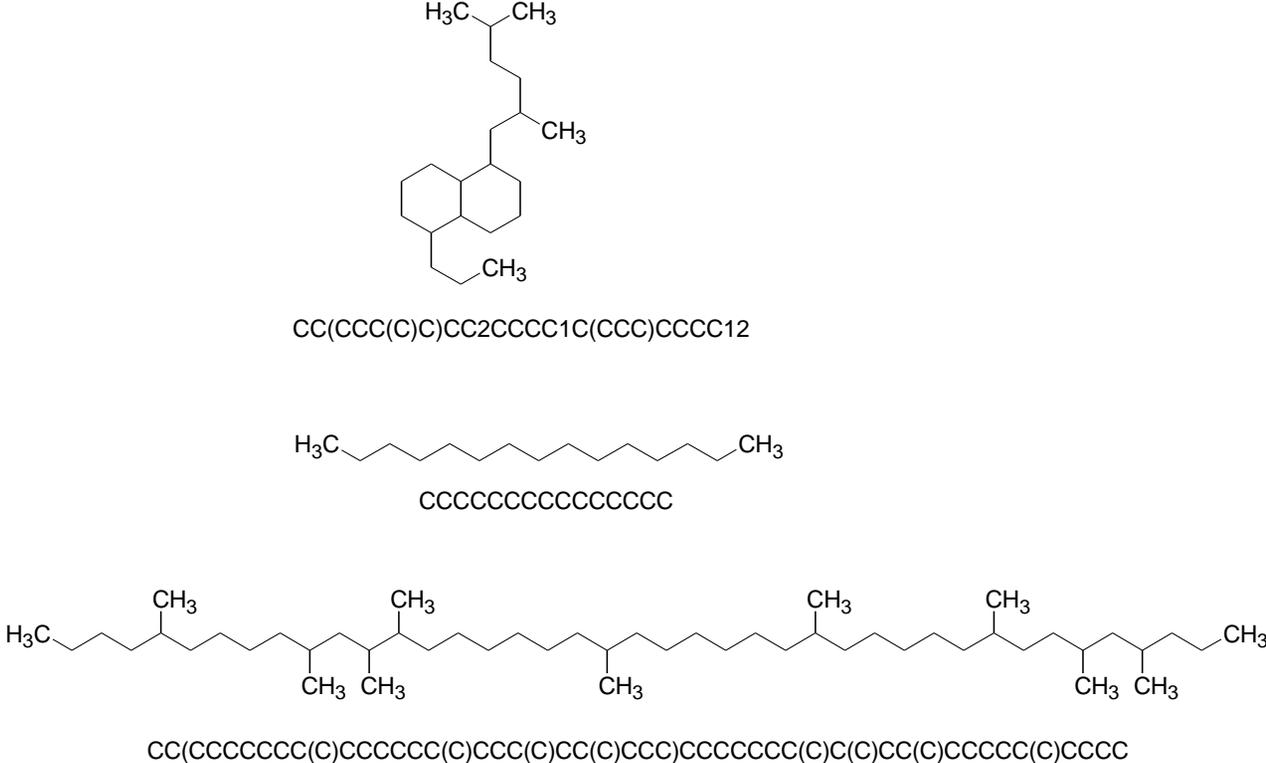
Table A-1. Chemical Name, CASRN and Chemical Structures for Waxes and Related Materials		
Name	CASRN	Structure
		<p>A complex combination of hydrocarbons obtained by treatment of a petroleum microcrystalline wax fraction with natural or modified clay in either a contacting or percolation process to remove the trace amounts of polar compounds and impurities present. It consists predominantly of long branched chain hydrocarbons having carbon numbers predominantly in the range of C25 through C50.</p>
Hydrocarbon waxes (petroleum), hydrotreated microcryst.	64742-60-5	 <p> <chem>CCCCC(C)CCC(C)CCC(C)CCC(C)CCC(C)CCC</chem>  <chem>CCCC(CCC)CCC(CCC)CCC(CCCCC)CCCC</chem>  <chem>CC(CCCCCC(C)CCCCC(C)CCC(C)CC(C)CCC)CCCCC(C)C(C)CC(C)CCCC(C)CCCC</chem> </p> <p>A complex combination of hydrocarbons obtained by treating a petroleum microcrystalline wax with hydrogen in the presence of a catalyst. It consists predominantly of long, branched chain hydrocarbons having carbon numbers predominantly in the range of C25 through C50.</p>
<b>Sub-Category IV Petrolatum</b>		

Table A-1. Chemical Name, CASRN and Chemical Structures for Waxes and Related Materials		
Name	CASRN	Structure
Petrolatum	8009-03-8	 <p>A complex combination of hydrocarbons obtained as a semi-solid from dewaxing paraffinic residual oil. It consists predominantly of saturated crystalline and liquid hydrocarbons having carbon numbers predominantly greater than C25.</p>
White mineral oil (petroleum)	8042-47-5	

<b>Table A-1. Chemical Name, CASRN and Chemical Structures for Waxes and Related Materials</b>		
<b>Name</b>	<b>CASRN</b>	<b>Structure</b>
		A highly refined petroleum mineral oil consisting of a complex combination of hydrocarbons obtained from the intensive treatment of a petroleum fraction with sulfuric acid and oleum, or by hydrogenation, or by a combination of hydrogenation and acid treatment. Additional washing and treating steps may be included in the processing operation. It consists of saturated hydrocarbons having carbon numbers predominantly in the range of C15 through C50.