OVERVIEW

Since our petition presentation (April 20, 2006) points out (in paragraph three) that our log-grown Shiitake "mushrooms fruit naturally on fallen logs with no amendments or inputs needed", we feel that any and all analysis of the manufacturing process of food grade cheese wax is redundant at best and uncalled for at worst. The food grade cheesewax that we use is clearly and simply NOT an input. It's not a fertilizer, it's not a conditioner and it's not an amendment. What it is, is a moisture barrier or sealant used to hold the water inside the log, curtail moisture loss and deny access to contaminates. Shiitake spawn does not grow on cheesewax and cheesewax is not an input into the growth process of either Shiitake spawn, Shiitake hyphae or Shiitake mushroom caps. On the other hand, since you have required information on our food grade cheesewax, before you further process and approve our petition, we have researched the areas you outlined in your letter of August 24, 2006 and compiled and printed the data for this addendum.

We use food grade cheesewax from two domestic suppliers: IGI and Blended Wax, Inc.. The IGI wax is called Parafflex 4669A and is FDA approved for use "in and around food". This was the wax we passed around for inspection by the members of the NOSB at their meeting April 20, 2006. Blended Wax, Inc. sells BW100F01 cheesewax which is also FDA approved and is virtually identical (See CAS numbers) to the IGI cheesewax. As you will find from an examination of the literature cited herein, cheesewaxes are put together as "blends" of three ingredients (microcrystalline wax, paraffin, and petrolatum). Different blends give different attributes for different uses. All of the three ingredients of the blend derive from fossils (decomposed aquatic plants and animals that lived in ancient seas millions of years ago) or what has come to be known as - fossil fuel. These original fossils were organic plants and animals and not synthetic nor derived from synthesized processes. Because the cheesewax is made "from a blend", we will have to supply details of the manufacturing process and chemical modes of action in triplicate for each of the three ingredients in the blend in order to have their specific histories and analytical references documented properly. Since we use more IGI cheesewax and since they have supplied more technical data, we will refer to their 4669A as our primary cheesewax (Company A) and to Blended Wax, Inc. as our secondary cheesewax (Company B) even though their CAS #'s and FDA-food-grade approval codes are the same (21CFR-172.886 and 21CFR-178.3710).

The detailed description of the manufacturing process you requested in your letter is stipulated in detail in two places: 1) for IGI on page two of Attachment I - "The Blend" under the heading 'Parafflex 4669A Wax is made up of all three categories of wax, primarily.....' And 2) for Blended Wax, Inc. on page one under the heading "Company: Blended Wax, Inc." and titled "Generic Process for Blending Cheesewaxes".

Your question number two on Chemical Mode of Action, Impacts and Effects on soil organicism, livestock, etc. is addressed in great detail for each component of the "Blend" under Attachment II (Microcrystalline Wax - CAS#64742-42-3), Attachment III

Shiitake Mushroom Center

Shirley CDC
366 Brown Rd. Shirley, AR 72153
Phone: 501-723-4443 Fax: 501-723-8441

December 27, 2006

Mr. Robert Pooler, Agricultural Marketing Specialist
USDA/NOP
1400 Independence Ave. S.W
STOP 0268-Room 4008-S
Washington, D.C. 20250-0200

Dear Mr. Pooler

Please find enclosed the supplemental information that you requested for the Petition that we submitted to both the NOP and the NOSB on April 20th at Penn. State.

We have structured the Addendum as follows: Cover Letter, Overview, Your Letter requesting supplemental information (in the three areas of Mfg. process, chemical mode of action, contrary positions), Copy of Original Petition/Presentation to NOSB, Supplemental Information requested, and finally, our comments on what this all means – from our perspective.

Because your request covered a very large range of topics, processes and modes of action, it has taken us much longer than we first expected to meet your request for additional information. Further, it has required us to take several extra months, several hundred pages of paper and several thousands of dollars in expenses to fulfill your request. We hope that NOP can appreciate this extra burden on small, organic farmers.

We now look forward to a speedy processing of this supplemental information and to complete acceptance by NOP and NOSB of the food grade microcrystalline cheesewax that we and the members of our organically certified, log-grown, Shiitake mushroom industry have been using for the past thirty years.

Sincerely,

Tom E. Kimmons,
Director, Shiitake Mushroom Center

(Paraffin Substance - CAS#8002-74-2), and Attachment IV (Petrolautum - CAS#8009-03-8).

The full spectrum of toxicity tests on mice, lab rats, rabbits, fish, etc. were included based on data reported by the European Chemical Industry following 'Council Regulation (EEC) NO. 793/93 on the Evaluation and Control Risks of Existing Substances'.

Your requirement #3 stated that "petition does not include research information about microcrystalline cheesewax" including contrasting positions. You will be able to read an abundance of research information in this Addendum. Our original petition presented contrasting positions under Item B, #12, which will be re-stated here.

There are three alternative or "contrasting" ways to seal moisture in Shiitake logs, as opposed to using food-grade cheesewax. These would be 1) logs in plastic bags, 2) Styrofoam plugs and 3) beeswax (natural wax).

1. Logs in plastic bags - This method would be similar to sawdust or substrate Shiitake, also known as bag culture or synthetic logs. The advantages of this method are that plastic bags are quicker and cheaper than cheesewax and the plastic bag holds even more moisture in the log than would cheesewax over the drilled hole. The disadvantage of the plastic bag is that the bag is a synthetic polyethylene derived from a petrol base and, unlike food-grade cheesewax, not FDA approved for use around and in foods. Another disadvantage is that much of the Shiitake spawn would fall out of the unsealed hole.

2. Styrofoam ($C_6H_5CH{:}CH_2$) is a trademark name for rigid, lightweight, cellular polystyrene. Styrene is a colorless or yellowish, easily polymerized, aromatic liquid used in manufacturing synthetic rubbers and plastics. Some Shiitake growers buy 12mm round plugs of Styrofoam and insert the plugs into the drilled holes in the Shiitake logs to seal in the moisture in the log. The advantage of using Styrofoam plugs is that they are much cheaper than food-grade cheesewax, lighter and quicker to install (no heat-up or melting as required with cheesewax). The disadvantage to using Styrofoam plugs is that they are not FDA approved for use around and in food, as is food-grade cheesewax and they are a total synthetic, petro-based and non-biodegradable. Aside from being unsightly, burning Styrofoam releases toxic fumes and should never be inhaled when cleaning up areas where the plugs have been used.

3. Beeswax is a natural wax produced on the abdomen of honey bees for beehive construction. The advantage of beeswax is that is a natural "animal" wax and is readily available. The disadvantages are that beeswaxes are not FDA "approved for use around and in food", as is food-grade cheesewax. Beeswaxes are aromatic and sought after by insects, pests and rodents - which remove them from the drilled hole in the logs. Many beehives are exposed to pesticides, either directly or indirectly. Mitacides, like Apistan strips, are used directly on and around hives to prevent trachea mites which attack, debilitate and kill bees. Indirectly, many bees are exposed to pesticides and heavy metals (paint-based) due to their wandering and uncontrolled habits. Beeswax is physically more dangerous to use than cheesewax because it has a flashpoint of only 250F while

cheesewax has a flashpoint of 450 F. Finally, organic beeswax costs approximately $6.00 - $9.00 per pound while FDA approved food-grade cheesewax costs approximately $.60 per pound. (It is our belief that due to the wandering nature of bees, it is ill-advised to label any beeswax "organic".)

United States Department of Agriculture
Agricultural Marketing Service
STOP 0268 – Room 4008-S
1400 Independence Avenue, SW.
Washington, D.C. 20250-0200

August 24, 2006

Thomas Kimmons
Shiitake Mushroom Center
366 Brown Road
Shirley, Arkansas 72153

Dear Mr. Kimmons,

Thank you for your petition of April 24, 2006, which requests the inclusion of Mycrocrystalline Cheesewax onto section 205.601 of the National Organic Program's (NOP) National List of Allowed and Prohibited Substances (National List).

We have reviewed your petition information and determined that your petition cannot move forward through the petition process at this time for the following reasons:

1. Petition does not provide a detailed description of the manufacturing process of the Mycrocrystalline Cheesewax from the basic components to the final product.
2. Petition does not provide sufficient information on the substances physical properties and chemical mode of action. Specifically, information on chemical interactions with other substances, toxicity and environmental persistence, environmental impacts from substance use or manufacture, and possible effects on soil organisms, crops or livestock.
3. Petition does not include research information about Mycrocrystalline Cheesewax including reviews that present contrasting positions to those presented in the petition.

Due to the reasons listed above, the NOP will stay your petition to include Mycrocrystalline Cheesewax onto section 205.601 of the National List until the supplemental petition information is received and evaluated. Should the supplemental information be sufficient, your petition will be forwarded through the petition process.

We apologize for the delay in our response. If you should have any questions, please contact me by phone at (202) 702-3252 or by e-mail at bob.pooler@usda.gov.

Sincerely,

Robert L Pooler

Robert L. Pooler
Agricultural Marketing Specialist
USDA National Organic Program

cc: National Organic Standards Board

Original Petition & Attached Documentation

Presentation to NOSB on April 20, 2006 with Support Letters

INFORMATION TO BE INCLUDED IN A PETITION

ITEM A

Synthetic substance's allowed for use in organic crop production.

ITEM B

1. **The substance's common name.** Mycrocrystalline Cheesewax - (Parafflex #4669A)
2. **The manufacturer's name, address and telephone number.**
   International Group, Inc., 7106 Hwy. 146 N, Baytown, TX 77520 Phone: 281-573-9280
3. **The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nanagricultural ingredient, sanitizer or disinfectant.**
   Non-agricultural ingredient/ Moisture Barrier to seal inoculation sites.
4. **A list of the crop, livestock or handling activities for which the substance will be used.** Shiitake Mushroom production on natural logs. Rate = 1 lb. of cheese wax per 10 logs (360 inoculation sites: 7/16" diameter). Wax is heated to 375 degrees F and applied with a bristled brush to each inoculation site.
5. **The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product.**
   See attachment #2. "The term wax" is applied to a large number of chemically different materials. Technological advances in the world today had led to an increasing number of commercially available substances of various chemical compositions and properties which have acquired the name "Wax". In the most general terms waxes are "naturally" or "synthetically" derived. Waxes can be further categorized by origin as follows:

   Natural Waxes -
   - Animal Waxes - Beeswax, lanolin, Tallow
   - Vegetable Waxes - Carnauba, Candelilla, Soy
   - Mineral Waxes
     - Fossil or Earth - Ceresin, Montan
     - Petroleum - Paraffin, ***Microcrystalline***

   Synthetic (man-made)
   - Ethylenic polymers e.g. ***polyethylene*** & polyol ether-esters
   - Chlorinated naphthalenes
   - Hydrocarbon type, e.g. Fischer-Tropsch

Log-grown Shiitake mushroom production incorporates the use of Microcrystalline wax - a Natural Wax. Substrate Shiitake mushroom production incorporates the use of polyethylene - a Synthetic Wax. "Microcrystalline waxes are produced from a combination of heavy lube distillates and residual oils. They differ from paraffin waxes in that they have poorly defined crystalline structure, darker color, and generally higher viscosity and melting points. Microcrystalline waxes (sometimes also called micro wax) tend to vary much more widely than

paraffin waxes with regard to physical characteristics. Microcrystalline waxes can range from being soft and tacky to being hard and brittle, depending on the compositional balance. The last category of petroleum wax is referred to as petrolatums. Petrolatums are derived from heavy residual oils and are separated by a dilution and filtering (or centrifuging) process. Petrolatums are microcrystalline in nature and semi-solid at room temperature. Other terms are also used to refer to petroleum wax,. In general these terms refer to the amount of oil contained in the product. Slack wax refers to petroleum wax containing anywhere from 3 to 50% oil content. Scale wax refers to wax containing 1 - 3% oil. Fully refined paraffin (FRP) wax is wax that has had nearly all of the oil refined out of it. Fully refined paraffins typically have less than 0.5% oil content.

6. **A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.** See Attachment #4. OCIA International Certification Standards: Approved at the AGMM 2003 (February 24th - March 1st, 2003) Page 29; 4.4 SHIITAKE AND OYSTER MUSHROOMS: Trees; "Only trees not treated with synthetic pesticides can be used in the cultivation of specialty mushrooms. Trees treated with Bacillus Thuriengensis (BY) are acceptable as are trees or limbs of trees treated with any of the pesticide alternatives acceptable by OCIA. Supplements: All supplements as synthetic fertilizers or pesticides are prohibited. Log and spawn site coatings used to prevent moisture loss must be food grade paraffin, cheese wax, mineral oil or beeswax. Recycled wax can be used as long as its origin can be ascertained. Petroleum based tree coatings, latex and oil based paints are prohibited."
7. **Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers.** FDA Status: See Attachment #3
8. **The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance.** N/A
9. **The substance's physical properties and chemical mode of action including.....** Physical Properties: See Attachment #1
10. **Safety information about the substance.....** Safety Properties: See Attachment #1
11. **Research information about the substance which includes.....** N/A

12. **A "Petition Justification Statement" which provides justification for one of the following actions requested in the petition:**
Petition Justification Statement: For Inclusion-Parafflex #4669A and/or other Crystalline Food Grade Cheese Wax

Cheesewax is a clean, stable, insoluble, high quality petroleum based product that is needed by the Shiitake "log culture" industry as a moisture barrier and used during inoculation and incubation periods of cultivation. Crystalline wax performs very well in this capacity and is less problematic than either styrofoam or beeswax. Cheese wax meets FDA requirement for in non-food article in contact with food and for use in food, making it desirable for use in organic product of log-grown shiitake mushrooms. Two other substances have been occasionally used by growers to replace food grade cheese wax. These are: Styrofoam and Beeswax. For the most part, both of these alternative products have been discarded for the following reasons.

Styrofoam is more prone to cause litter problems to the surrounding environment and is not biodegradable. Burning Styrofoam releases toxic fumes and should not be practiced when

cleaning up areas where styrofoam plugs have been used. The plugs do not seal as well as cheesewax and therefore are a poor substitute for cheesewax. From the producers stand-point, they are also more labor intensive to apply.

Beeswax has been suggested as an alternative to Cheesewax. Among the problems with Beeswax is that it is short lived as a moisture barrier because insects, pests and rodents are drawn to it's aroma. They eat, chew and steal the beeswax causing the spawn under the wax to dry and die, thus often causing crop failure. Many bee hives are exposed to pesticides - either directly or indirectly. Mitacides, like Apistan strips, are used directly on and around hives to prevent trachea mites which attack, debilitate and kill bees. Indirectly, many bees are exposed to pesticides simply because of their wandering habits. Obtaining "organically certified" bees wax is both difficult and extremely expensive. Organic beeswax costs approximately $6.00 - $9.00 per pound, while FDA approved food grade cheesewax costs about $.60.

Shiitake log-growers have been using FDA approved food grade cheesewax for many years and have passed their organic certification inspections. Please note that many substrate grown Shiitake mushrooms are certified organic but, involve the use of polyethlene in it's products. Polyethelene is a synthetic (man-made) ethylenic polymer. It is the belief of the Shiitake log-growers that the use of natural logs and FDA food grade cheesewax is a more pristine, more natural and more "organic" method of growing Shiitake mushrooms than using grain enhanced sawdust in polyethelene plastic bags. In a USDA/ARS report found in the Journal of Agricultural and Food Chemistry, Volume 50, Number 19, Pages 5333-5337 entitled "Effects of Management on the Yield and High-Molecular-Weight Polysaccharide Content of Shiitake (Lentinula edodes) Mushrooms that Shiitake grown on logs produced more polysaccharides than their substrate counterpart. (The polysaccharide - Lentinan - is the medicinal compound for which Shiitake are traditionally noted.)

Aside from considering alternative products to be considered as replacements for food grade cheese wax, which is already FDA approved, it should be stated that the cheese wax "<u>is not an input</u>"! Shiitake does not grow on or consume, digest wax! It is merely a moisture barrier, preventing moisture loss from inoculum and airborne contaminants from colonizing the inoculation sites.

The term "cheesewax" derives from the use, for centuries, of wax to coat and hold moisture in various cheeses. If the use of this product is prohibited for the production of log-grown Shiitake mushrooms, then all of the presently certified organic cheese makers, who still seal or coat their cheese with cheesewax, will also be affected by this petition.

Attachment #1

THE INTERNATIONAL GROUP, INC.

MATERIAL SAFETY DATA SHEET

SECTION 1 -- PRODUCT AND COMPANY IDENTIFICATION

Material	Revision date
4600 SERIES PRODUCTS (NOCHEK®, PARAFFLEX®) (See page 6 for a complete listing of 4600 series product numbers)	22-Sep-05

Previous revision date	File designation	Material use
21-Sep-05	Series\4600	Various

Manufacture's Name and issuing location	EMERGENCY PHONE NUMBER
THE INTERNATIONAL GROUP, INC. 50 SALOME DRIVE AGINCOURT, ONTARIO, CANADA M1S 2A8	**416 - 293 - 4151 day & night** Issuer's phone number 416 - 293 - 4151

Manufacturing sites

50 Salome Drive Agincourt, Ontario, Canada M1S 2A8	7106 Highway 146 North Baytown, TX 77520	2875 North Main St. Oshkosh, WI 54901	1140 Canal Boulevard Richmond, CA 94804

SECTION 2 -- COMPOSITION / INFORMATION ON INGREDIENTS

No hazardous ingredients as defined by the Canadian Hazardous Products Act (BILL C70) or by OSHA 29 CFR 1910.1200.

Chemical name	Chemical family	CAS No.
Not Applicable	Petroleum Hydrocarbon	Not Applicable

SECTION 3 -- HAZARDS IDENTIFICATION

Emergency Overview

The material is a solid at room temperature exhibiting elevated temperature softening characteristics. Above its softening point, the material liquefies and flows more readily as the temperature increases. The material is used as a hot liquid for application purposes and requires caution in handling. At elevated temperatures well above the softening point and in contact with air, the generation of hydrocarbon vapors including possible oxidized products may be expected.

SKIN CONTACT	Contact with molten material can result in severe burns.
EYE CONTACT	Direct contact of molten product to the eyes will cause thermal burns and eye injury.
INHALATION	Breathing fumes in confined areas can cause respiratory discomfort and possible irritation.

Potential Health Effects

(HMIS Rating)

Fire Hazard: 1	Health Hazard: 0	Reactivity: 0	Personal Protection: See Section 8

0 = MINIMAL 1 = SLIGHT HAZARD 2 = MODERATE HAZARD 3 = SERIOUS HAZARD 4 = SEVERE HAZARD

THE INTERNATIONAL GROUP, INC.
MATERIAL SAFETY DATA SHEET

Material: 4600 SERIES PRODUCTS (NOCHEK®, PARAFFLEX®) Version:2

SECTION 3 -- HAZARDS IDENTIFICATION (CONTINUED)	
EYE CONTACT	Exposure to fumes, vapors or smoke from thermally degraded product can cause irritation to eyes.
INHALATION	Exposure to vapors, fumes, or smoke from molten material handled in confined areas can produce irritation of respiratory tracts, and possible physical discomfort to sensitive individuals.
INGESTION	This material is essentially inert and non-toxic. Regardless of this the material should be handled with care and not be ingested or put in mouth.
SKIN	Skin contact with molten material can cause severe burns.

SECTION 4 -- FIRST AID MEASURES	
EYES	Exposure to fumes, vapors or smoke of over heated product can result in irritation to eyes. Direct contact of the molten material will cause eye injury and burns. When handling molten material eye shields must be worn at all times. Should an accident occur, flush eyes with generous amounts of water for at least 15 minutes. Administer prompt first aid measures. **Call a physician to attend to the injury.**
SKIN	Exposure to fumes, vapors or smoke of thermally degraded product can result in irritation to skin. Direct contact of the molten material will cause injury and burns. For burns apply running water injured area for 15 minutes. Do not attempt to remove any material bonded to skin. **Call a physician to attend to the injury.**
INHALATION	Remove individual to a well ventilated area for fresh air and **call a physician if respiratory symptoms warrant medical attention.**
INGESTION	Material is not acutely toxic by ingestion. **If material is ingested, do not induce vomiting. Call a physician.**

SECTION 5 -- FIRE FIGHTING MEASURES	
Flammability YES [X] NO [ ]	If yes, under which conditions? Will support a flame above flash point.
Means of extinction Use water fog, foam, dry chemical or CO_2 extinguisher. Do not use direct water stream.	
Special procedures Use water to keep containers cool.	

FIRE and EXPLOSION DATA			
Flash point (ASTM D92) > 190°C	Upper explosion limit (% by volume) 7.0%		Lower explosion limit (% by volume) 0.9%
Auto ignition temperature Not Available	TDG flammability classification Not Dangerous		Hazardous combustion products CO_2, CO (See Section 10)
Sensitivity to impact Not Applicable	Rate of burning Not Applicable	Explosive power Not Applicable	Sensitivity to static discharge Not Applicable

Attachment #1 (pg. 3)

SECTION 6 -- ACCIDENTAL RELEASE MEASURES

SPILLS OR LEAKS	Handle as a thermoplastic. With molten spills, allow the material to solidify and cool. Keep material out of sewers and watercourses by diking or impounding. Recover and place into appropriate containers for recycling or disposal, according to prevailing local, state and federal laws.

SECTION 7 -- HANDLING AND STORAGE

When kept in molten state, inert gas blanketing may be used to avoid material degradation. As a solid, avoid contamination by keeping in closed containers.

SECTION 8 -- EXPOSURE CONTROLS / PERSONAL PROTECTION

This material will be utilized in molten form. Proper protective splash resistant clothing, thermal gloves, splash resistant shoes, and eye shields must be worn to prevent injury. Use molten material in well ventilated areas. When working in confined areas, use of appropriate respiratory gear is recommended.

SECTION 9 -- PHYSICAL AND CHEMICAL PROPERTIES

Appearance White to dark amber	Odor None - intermediate petroleum odor	Physical state Solid @ 25°C	pH Not Applicable
Vapor pressure (mm Hg) < 0.01 @ 25°C	Vapor density (air = 1) > 5	Boiling point (IBP) > 300°C	Solubility in water (20°C) < 0.1%
Evaporation rate (Butyl acetate =1) < 0.01	Freezing point Not Applicable	Volatiles (By volume) < 1.0%	Specific gravity (25°C) 0.90-0.94
Coeff. water / oil distribution < 0.01	Melt point 46-95°C	Molecular weight Not Defined	Odor threshold (PPM) Not Available

SECTION 10 -- STABILITY AND REACTIVITY

Chemical stability YES [X] NO [ ]	If no, which conditions?
Compatibility with other substances YES [ ] NO [X]	If NO, which ones? Strong oxidizing agents, eg., peroxides, chlorine

Reactivity, and under what conditions
Stable

Hazardous decomposition products
Carbon dioxide, carbon monoxide and other products such as aldehydes and ketones depending on conditions of oxidation.

SECTION 11 -- TOXICOLOGICAL INFORMATION

Carcinogenicity Classification		Route of Entry	
IARC : Not listed	ACGIH: Not listed	Skin contact [X]	Inhalation acute [X]
OSHA: Not listed		Skin absorption [ ]	Inhalation chronic [X]
NTP : Not listed		Eye contact [ ]	Ingestion [ ]

Effects of acute exposure to material
Wax fumes have been reported to be irritating to the respiratory tract, especially to sensitized persons. Molten product could cause thermal burns on contact with the skin.

Attachment #1 (pg. 4)

Effects of chronic exposure to material
In rats, chronic ingestion has shown accumulation in target organs (liver, spleen) with associated nonspecific immune response.

LD50 of material: Specify species & route Not Available	LC50 of material: Specify species Not Available	Exposure limit of material TLV/TWA 2 mg/m^3 for paraffin wax fume (A.C.G.I.H)	Irritancy of material TLV set to prevent irritancy
Sensitizing capability of material Not known	Carcinogenicity / Mutagenicity of material Not carcinogenic by studies to date. Ames negative.	Reproductive effects of material None known.	Synergistic materials None known.

SECTION 12 -- ECOLOGICAL INFORMATION

Material is not considered harmful to the environment. Nevertheless, material from spills and other generated waste must be disposed of properly in conformance with all local, state and federal laws.

SECTION 13 -- DISPOSAL CONSIDERATIONS

This material is not a RCRA hazardous waste material. Follow local regulatory laws for proper disposal.

SECTION 14 -- TRANSPORT INFORMATION

DOT proper shipping name	Not regulated
DOT hazardous classification	Not Applicable
DOT Haz. Mat table 172.101	Not listed
DOT appendix to sec. 172.101	Not listed
DOT labels required	None
DOT placards required	None for solid product. None for molten product shipped under 212°F/100°C. Hot molten product shipped over 212°F/100°C requires a class 9 "HOT" placard Bill of lading must carry the statement: Elevated temperature material, liquid, N.O.S. 9, UN3257, III (WAX).
TDG classification	Not controlled under TDG (Canada).

SECTION 15 -- REGULATORY INFORMATION

FDA status	See product's technical information sheet.
CERCLA reportable quantity	This material is not reportable under 40 CFR Part 302.4.
OSHA hazardous chemicals	None according to 29 CFR 1910.1200.
RCRA	This material is not a RCRA hazardous waste.
SARA status	Sections 311 and 312: Not Applicable Section 313: None
TSCA status	This product, or its ingredients as a mixture, appears on the toxic substances control act inventory.
WHMIS status	This is not a controlled material as defined by the Canadian Hazardous Products Act (Bill C70).
California Proposition 65 list	Carcinogens: None. Adverse reproductive effects: None
Massachusetts Substance list	None

THE INTERNATIONAL GROUP, INC.
MATERIAL SAFETY DATA SHEET

Material: 4600 SERIES PRODUCTS (NOCHEK®, PARAFFLEX®) Version:2

New Jersey Haz. Substance list	None
Pennsylvania Haz. Substance list	None
Canadian DSL status	Listed
CONEG	In compliance

SECTION 16 -- OTHER

Source used:
A.C.G.I.H. (Documentation of threshold values), RTECS, IARC Monographs, Oxford Toxicology Forum, Special Meeting on Hydrocarbons.

Prepared by	Signature
I. Davie	Ian Davie

Disclaimer

This material safety data sheet is offered for your information only. We believe the statements, technical information and recommendations contained here in are reliable, but are given without warranty or guarantee of any kind, expressed or implied. THE INTERNATIONAL GROUP, INC. assumes no responsibility for any loss, damage or expense, direct or consequential, arising from the use of our material. It is the responsibility of the user to determine the suitability and completeness of such information for the required use or application. We do not assume any legal responsibility for nor do we give permission, inducement or recommendation to practice any patented invention without a license. Further, it is the user's obligation to utilize this material in full compliance with all health, safety and environmental regulations.

(Attachment #1 - Pg 6

THE INTERNATIONAL GROUP, INC.
MATERIAL SAFETY DATA SHEET

Material: 4600 SERIES PRODUCTS (NOCHEK®, PARAFFLEX®) Version:2

PRODUCT NUMBER	PRODUCT NUMBER	PRODUCT NUMBER
4601A	4643A	4695A
4601B	4644A	4696A
4602A	4645A	4697A
4603A	4646A	4698A
4604A	4647A	4699A
4605A	4648A	
4607.02	4649A	
4607A	4650A	
4608A	4652A	
4608B	4653A	
4608D	4654A	
4609A	4655A	
4610A	4656A	
4611A	4657A	
4612A	4660A	
4612B	4661A	
4613A	4661B	
4614A	4662A	
4615A	4663A	
4615B	4664A	
4616A	4665A	
4617A	4666A	
4618A	4667A	
4618B	4668A	
4618C	4669A	
4619A	4670A	
4620A	4671A	
4621A	4672A	
4621B	4674A	
4621C	4675A	
4622A	4676A	
4623A	4678A	
4624A	4679.01	
4625A	4679A	
4626A	4680A	
4627A	4681A	
4628A	4683A	
4629A	4684A	
4630A	4684B	
4631A	4686A	
4632A	4687A	
4633A	4688A	
4634A	4690A	
4635A	4691A	
4636A	4691B	
4637A	4692A	
4639A	4693A	
4641A	4694A	

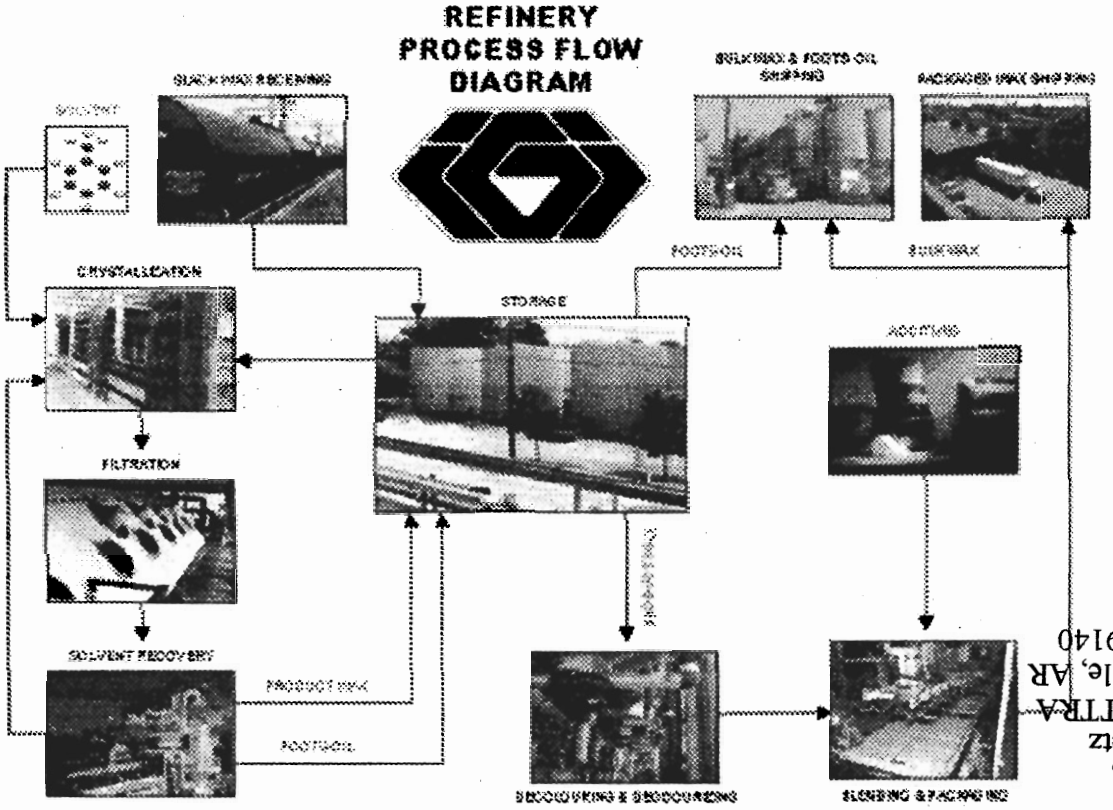
WAX OVERVIEW

AX REFINING
AX PROPERTIES
AX FAQ

WAX REFINING

attachment 2

One of the many products derived from refining is lubricating oil, from which a byproduct called slack wax is obtained. Slack wax is a mixture of oil and wax. It is the product, which serves as IGI's feedstock and that is further refined and blended to create value-added petroleum wax products.



The principal steps in IGI's refinery operation include:

Crystallization - Slack wax is heated, mixed with solvent and then cooled. As it is cooled, wax crystallizes out leaving oil in solution. Wax specifications such as melt point, penetration, and oil content are controlled primarily by the amount of solvent added, the rate of cooling and the temperature from the crystallization process.

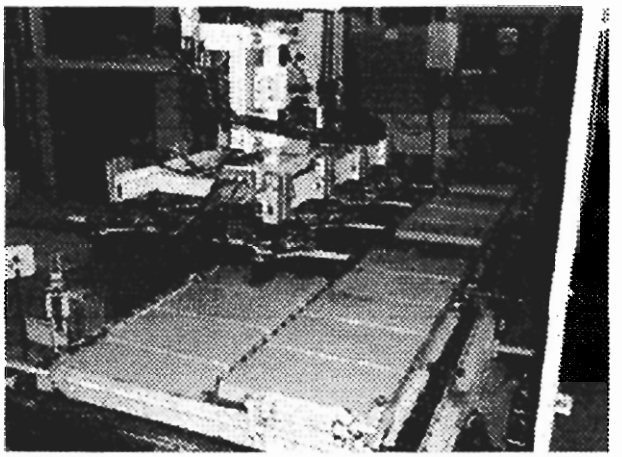
Filtration - The crystallized

from the solvent in totally enclosed, inert gas blanketed, rotary drum filters. In order to obtain the low oil content required in final wax products, two and sometimes three stages of filtration are required.

Solvent Recovery - Two streams come from each drum filter, one containing the wax and some solvent and the other containing extracted oil and solvent. These streams go to the solvent recovery plant where solvent is removed by continuous distillation in steam-heated kettle heat exchangers and stripping towers. The recovered solvent is recycled to the crystallization process and to the drum filters as a wash. The solvent-free wax and oil streams go to separate storage. At this point the wax is known as a "product wax" and the oil is called "foots oil". The product wax is usually processed further and most of the foots oil is sold as catalytic cracker feedstock.

Decoloring & Deodorizing - To produce a "fully refined" wax from a product wax requires that the wax be passed through a bed of clay to remove color and through a vacuum stripping tower for odor removal. The decoloring operation is known as "percolation" and is a batch process. The clay is regenerated before reuse by passing it through a multiple hearth furnace to remove the absorbed color bodies.

Blending and Manufacturing - Fully refined paraffin waxes are blended together to give certain desired properties such as melt point and penetration. These blended waxes are then either sold in a liquid state or converted into slabs, chicklets, pastilles or granules in one of our manufacturing plants. Blended waxes are also used for base stock for further blending with other petroleum based products such as resins and polymers to incorporate special properties such as flexibility, toughness and/or gloss.



WAX REFINING • WAX PROPERTIES • WAX FAQ

HOME • ABOUT IGI • WAX OVERVIEW • PRODUCTS • SERVICES • CUSTOMER LOGIN

Attachment #3

THE INTERNATIONAL GROUP, INC.

85 Old Eagle School Road · P.O. Box 384 · Wayne, PA 19087· (610) 687-9030 · Fax (610) 254-8548
50 Salome Drive · Agincourt, Ontario, Canada M1S 2A8 · (416) 293-4151 · Fax (416) 293-0344

PARAFFLEX® 4669A

PARAFFLEX® 4669A is a specialty blend of petroleum waxes formulated to provide a clear coating on cheese.

PHYSICAL PROPERTIES

TEST METHODS	ASTM METHOD	SPECIFICATIONS Minimum	SPECIFICATIONS Maximum	TYPICAL
Congealing Point °F (°C)	D 938	146 (63.3)	156 (68.9)	151 (66.1)
ASTM Color	D 6045	----	1.5	----
Needle Penetration, dmm @ 77°F (25°C)	D 1321	----	----	35

FDA STATUS:

This product meets the FDA requirements set forth in 21 CFR 178.3710 for use in non-food articles in contact with food and in 21 CFR 172.886 for use in food.

8/26/04

— Attachment #4 —

Organic Crop Improvement Association International, Inc.

International Certification Standards

Approved at the AGMM 2003 (February 24th – March 1st, 2003)

Effective Date: July 21, 2003

OCIA INTERNATIONAL

WORLD HEADQUARTERS
6400 CORNHUSKER, SUITE 125
LINCOLN, NE 68507-3160 USA
Phone: (402) 477-2323 • Fax: (402) 477-4325
E-Mail: info@ocia.org • Web Site: http://www.ocia.org

NOSB Meeting: 2006
Pennsylvania State University
On the Discussion of the Use of FDA Approved Cheese Wax
In the Production of Log-Grown Shiitake Mushrooms

My name is Tom Kimmons, I am here to represent myself, my organization and place on the record six proxies as samples of comments from a broad section of Shiitake farmers, USDA Shiitake specialists and Shiitake advisors.

I am the director of the Shiitake Mushroom Center in Arkansas where we grow organically certified, log-grown Shiitake Mushrooms on approximately 30,000 hardwood logs. We began this operation in 1988 and have been certified organic over the years by OSFVP, AOCIA, OCIA, ACO, ICO and for the past two years under the authority of the new NOP. During this time I have been a staunch advocate and promoter of Organic certification and, more importantly, the principles and values surrounding organic practices, processes and methods. I was a Founder and original Trustee of the Arkansas OCIA, President of Arkansas Certified Organic as well as Founder, Trustee and President of the Ozark Shiitake Growers Association, the Arkansas Shiitake Growers Assoc., among others. Over the past decade and a half my organization has trained over 600 small family farmers in the techniques and method of growing organically certifiable mushrooms.

Shiitake Mushrooms, a lignicolus fungus, have been grown and harvested from hardwood logs for over 2000 years. Because the mushrooms fruit naturally on fallen logs, with no amendments or inputs needed, they are among the easiest to inspect and certify as organically grown. In order to better manage and expedite the natural fungal colonization of the hardwood log a series of holes are drilled 1" deep into the logs sapwood. Shiitake spawn is then inserted into the hole and heated cheese wax is painted or daubed over the hole in order to hold moisture in the inoculation site and to keep contaminants and competing fungi out of the log. In past generations, mud cakes, wet vines, rags, beeswax, etc. were used to hold moisture in the logs until colonization was complete. Over the past 30 years in the USA, cheese wax has become the moisture "sealant" of choice for natural Shiitake growers because it is more efficient, more affordable, cleaner and safer than other sealants. Styrofoam plug sealants, used by some modern growers, are scoffed at by organically certified log-growers because Styrofoam is unseemly, non-biodegradable and caustic when incinerated. Beeswax presents multiple problems. First it attracts bees and other insects who steal the beeswax from the holes allowing the spawn to dry out and die. Second it has a low melting point and melts away easily in summer heat. Modern day Beeswax contains miticides sprayed to control trachea mites in bee populations, is 6 to 8 times more expensive than cheese wax and tends to shrink in extreme temperatures, thus losing effectiveness as a sealant. So, cheese wax. Cheese wax has been around for centuries either by use or by design to seal moisture in various cheeses and/or to keep undesirable molds and fungi from growing on finished cheese. The cheese wax used by modern Shiitake growers is the same cheese wax used by cheese makers and, essentially, for the same reasons. Namely, it's used to hold in moisture and keep out contaminants. Cheese wax is neither an input in cheese making nor in log grown Shiitake making. Cheese/milk doesn't grow on wax and shiitake spawn doesn't grow on wax--wax IS NOT AN INPUT in either cheese making or shiitake growing.

What I want to offer to the NOSB in this session are 5 reasons why food grade cheese wax has been, is now and should continue to be approved for use in growing organically certified log-grown Shiitake.

1) Virtually every certified log-grown shiitake producer that has grown shiitake in the USA since the early 1980's has used food grade cheese wax to seal the inoculation sites. That's 25 + years of precedence for an accepted organic practice and, as far as I know, without question. There is a legal cannon in the U.S. System of Justice known as Stare Decisis which states that traditions matter to societies and ways of doing things, over time, require respect and consideration because they become a part of the fabric of civil life. If new evidence comes forward to challenge a tradition, that shows it to be harmful or dangerous to consumers, then it can and should be challenged. In that respect if the NOP or the NOSB has analytical proof or new science that shows the tradition of using food grade cheese wax to be harmful....then it should be presented and ALL petroleum based products, be they cheese wax, plastic, or any petrol based coatings for shiitake logs, cheeses, wax coated shipping containers, poly-bag produce containers, wrappings, etc. need to be inspected, and potentially prohibited in organic production.

2) Existing rules. The most current published Organic rules that we have a record of for governing the use of cheese wax in Organic Shiitake production not only allows cheese wax but requires cheese wax for sealing inoculation sites (see attachment #1). These standards, published by OCIA, under the title "International Certification Standards-Approved at the AGMM 2003" state under section #4.4-- Shiitake and Oyster Mushrooms that "log and spawn site coatings used to prevent moisture loss must be food grade paraffin, cheese wax, mineral oil or beeswax." This is the standard that was stated from OCIA International--World Headquarters in 2003 and this is the same standard that we have operated in accordance with for 20 + years.

3) The certification of the quality of food grade cheese wax used by log-grown Shiitake growers comes from the U.S. Food and Drug Admin.(see attachment # 2). The FDA analysis states that "Parafflex 4669A is a specialty blend of petroleum waxes formulated to provide a clear coating on cheese". It goes on to say "this product meets the FDA requirements set forth in 21 CFR 178.3710 for use in non-food articles in contact with food and in 21 CFR 172.886 for use in food". The primary use for this wax other than coating cheese is for use in chewing gum.

4) Alternatives to cheese wax. As mentioned earlier Styrofoam plugs are synthetic, non-compostable, non-biodegradable, unseemly and produce toxic gases upon incineration. Styrofoam is very cheap and very ugly. Organic Beeswax is simply too expensive for small log-growers to afford at 6 to 8 times the cost of cheese wax. Because it attracts bees and other insects it has little staying power and its' low melting point makes it useless in hot summer climates. Miticide content makes it a health concern.

5) Unintended consequences. The ongoing issue of cheese wax use/prohibition arose from certifiers through OneCert in Missouri and EcoFarm in California. The charge was that since cheese wax was petro-based it was automatically prohibited. When one thinks of all the petro-based items, polyethylene bags, waxed boxes, plastic sheeting, tomato stakes, buckets, greenhouse panels etc. that could potentially be prohibited because they are petro-based, it opens up a whole universe of potentially prohibited items and de-certifiable organic growers. The large substrate (artificial log)

shiitake growers that produce the bulk of organically certified shiitake use a host of petro-based aids and tools and must be held to the same standards as others. So, too, the organic cheese producers who use cheese wax. If the NOSB wants to support the prohibition of cheese wax and all petro-based aids in all organic production then I will comply and I'm sure all log grown shiitake growers will give up certification. But the prohibition must be applied across the board without regard to the size of the industry, the nature of the industry or the commercial value of the industry. Log- grown Shiitake growers don't grow the most mushrooms. We don't grow the cheapest mushrooms. We certainly don't grow the easiest mushrooms. We grow the best, highest quality, most natural, most organic Shiitake mushrooms. When the Organic community looses sight of affirming the best...it looses its' organic vision.

Thank you,

Tom E. Kimmons

OZARK SHIITAKE GROWERS ASSOCIATION

366 Brown Rd., Shirley, AR 72153 - Phone: 870-746-4566

April 1, 2006

RE: NOP Ruling as it relates to the use of Food Grade Cheesewax in the production of Log-Grown Shiitake Mushrooms

To Whom It May Concern:

As President of the Ozark Shiitake Growers Association and on behalf of our Shiitake mushroom producers growing on real, natural logs, I would like to comment on the use of food grade cheesewax. This product meets FDA requirements for being safe and our Association has encouraged it's use among the 400+ Shiitake growers that we have trained or assisted over the past several years.

As a moisture barrier, food grade cheesewax has been our preference over other like substances because of it's stability, insolubility, and it's FDA approval for use in and around food.

Our organic growers are small family operations. It would be a real hardship for them to find a comparable product at a comparable price. These growers have been certified organic for many years using the same process and the same product (food grade cheese wax).

Though cheese wax is a petroleum-based product, it is <u>not</u> an input to the growth cycle. The wax simply serves as a moisture barrier to keep the shiitake spawn from drying out during it's spawn run. It acts much like black plastic mulch which is used to maintain moisture. One big difference - many of us chew cheese wax (chewing gum), but most of us do not chew plastic mulch! Further, many organic producers of Shiitake grow on substrate which is enhanced sawdust contained in plastic bags. The purpose of the plastic bags is both to contain the sawdust growing medium and spawn and to act as a moisture barrier. However, the plastic is an extruded chemical plastic that is not as "organic" as the cheesewax petroleum product. If cheesewax is prohibited, then too should the extruded plastic bags be prohibited. It should also be noted that most produce is delivered to market packed in "waxed boxes". This is the same wax that is used in the production of log-grown shiitake. If cheesewax is prohibited as a moisture barrier for log-grown shiitake production, then the waxed boxes used to transport produce to market must also be prohibited.

The prohibition of food grade cheese wax will have an enormous impact on all sorts of "plastic" products that all farmers use in the production, transportation and processing of foods. We hope that the NOP will not prohibit the use of food grade cheesewax or it will affect the use of so many petroleum-based products that most organic farmers have come to rely on as a part of their occupations.

Sincerely,

Mark Phillips

Mark Phillips, President

Tom Kimmons

From: "claudia bennett" <claudia2tim@yahoo.com>
To: <shirlcdc@artelco.com>
Sent: Friday, April 14, 2006 10:37 AM
Subject: Growers Statement

IM BENNETT
ED RIVER TRADITIONS
IOUNTAIN VIEW, ARK. 72560

70-269-5649

.S AN ORGANIC SHIITAKE MUSHROOM GROWER, I HAVE FOUND
HEESE WAX NOT ONLY TO BE COST EFFECTIVE, BUT ALSO
.N EXELLENT PRODUCT FOR THE USE OF SEALING LOG
PAWN. HOT CHEESE WAX IS APPLIED ON THE OUTER LOG
VHICH BURNS A THIN LAYER OF SPAWN LEAVING IT SEALED
.GAINST ANY CONTAMINATION OF THE INTERIOR OF THE LOG.
CANNOT SEE ANY REASON [ORGANICALLY SPEAKING] TO
MAKE A CHANGE.

SINCERELY, TIM BENNETT

Lost Creek Mushroom Farm

PO Box 520, Perkins, OK 74059-0520

Ph 800-792-0053 / Fax 405-547-5097 / email lcmf@cowboy.net

www.shiitakemushroomlogs.com

April 6, 2006

National Organic Standards Board

To Whom It May Concern:

We are writing to voice our concern that using cheese wax to seal inoculation holes in shiitake mushroom logs would prevent "organic" classification for all-natural, log-grown shiitakes.

We have been growing shiitakes on logs since 1986. We have tried sealing the holes with cheese wax, plastic plugs, and beeswax, the standard practices in shiitake production. We have found that food-grade FDA-approved cheese wax is the best choice because it is clean and safe, provides a good moisture barrier for the inoculation process and it is affordable.

The shiitakes don't grow on the wax nor on the bark that the wax is attached to. The wax in the inoculation holes has no effect on the mushrooms; and as an FDA food-grade product, it should be considered no more toxic or harmful than plastics or metals used as vegetable stakes or containers.

We do not use the plastic plugs because they do not provide a secure seal and they fall out and create litter as the holes expand. The material is intended for use in concrete expansion joints and, therefore, is not compatible with our concept of organic mushroom production.

The cost of beeswax is prohibitive: four times that of food-grade cheese wax, $8.00 a pound compared to $2.00. We have found that it attracts insects, rodents and other animals to the logs to eat the wax. Insects consume all the wax, clearing the hole and leaving the log open to infection and moisture loss. Some insects burrow through the wax and into the logs.

Removing cheese wax as an option for sealing the holes would significantly increase the production costs and create a financial hardship for log-growers. It is a product that organic growers can use in good conscience. Of the available sealants, it is compatible with organic production and is the highest-grade, safest product and best practice for growers to use.

Sincerely,

J. Douglass Williams Sandra Williams

USDA

Agricultural Research Service

Research, Education and Economics
United States Department of Agriculture

April 10, 2006

To Whom It May Concern:

I am Research Leader of the Dale Bumpers Small Farms Research Center (DBSFRC) located in Booneville, Arkansas. DBSFRC is one of 105 locations that comprise Agricultural Research Service. ARS is the in-house research arm of USDA. The mission of this USDA/ARS Center is to assist family farmers find new and better ways to maintain the family farm. Many small farmers prefer producing "Organically Certified" products because they often command a higher price on the market, thus increasing their farms' profitability.

I am writing on behalf of farmers that produce log-grown Shiitake mushrooms and who have had their mushrooms certified organic for many years. Log-grown Shiitake is one of the crops that we have been investigating the last 7 years. Research results from DBSFRC and cooperating scientists indicate that the best way to inoculate logs with Shiitake is to drill holes into the log, pack the holes with Shiitake spawn and cover the spawn with cheese wax. Under such a protocol, the cheese wax is not input. The cheese wax covers the inoculation site to maintain the moisture in the spawn to keep it alive until colonization of the log has started. Essentially the cheese wax is acting like a Band-Aid over a wound. The cheese wax used by most growers, and here at DBSFRC, is approved by the FDA for use 'in and around food', thereby making it safe for human use and consumption.

Depriving the use of cheese wax for the production of the log-grown Shiitake would make it nearly impossible for family farmers to grow this very fine product. The inability to use cheese wax would greatly increase the cost of Shiitake production because the high cost of alternatives and decreases in productivity by use of inferior product. I hope that you consider the use of food-grade cheese wax for inclusion on your approved list.

If you have any questions, please contact me using the information in the letterhead.

Sincerely,

David Brauer

David Brauer, Ph.D.
Research Leader

ars

Southern Plains Area • Dale Bumpers Small Farms Research Center
6883 South State Highway 23, Booneville, AR 72927
Voice: 479-675-3834 • Fax: 479-675-2940 • E-mail: lalbright@spa.ars.usda.gov

Tom Kimmons

From: "Tom Kimmons" <shirlcdc@artelco.com>
To: "Tom Kimmons" <shirlcdc@artelco.com>
Sent: Thursday, April 13, 2006 12:42 PM
Subject: cheese wax

the NOSB:

ave worked with shiitake mushroom production on natural hardwood logs for nearly 20 years now, both keeping a monstration project going and hosting cooperative extension workshops for the public on how to produce these mushrooms. In that time, I have always encouraged prospective growers to use food grade cheese wax because a) it nears a boil at a very gh temperature and therefore provides excellent sterilization at the inoculation sites, and b) it will stay on the logs for the ration of their productive lives, which, even if they are in a forced production mode, is likely to be multiple years. When the fruit ushrooms) of the shiitake organism emerge from the logs, they may or may not emerge at the inoculation sites and therefore e quite likely to have no direct contact with the wax. I see no reason why, especially if producers have gone to the trouble and pense of inoculating their logs with certified organic shiitake spawn, that they cannot continue to use this most appropriate aterial (food grade cheese wax) to seal the inoculation sites on their logs. I hope the NOSB will agree.

ank you for your attention to this important matter. Please feel free to contact me by phone or email if you would like further formation.

incerely,

r. Deborah B. Hill

rofessor and Forestry Extension Specialist

epartment of Forestry

niversity of Kentucky

exington, KY 40546-0073

hone: 859-257-7610

mail: dbhill@uky.edu

4112 West Pine Boulevard – St. Louis Missouri 63108
tel: 314-531-9935
www.ozarkforest.com

To Whom It May Concern, April 12th 2006

Ozark Forest Mushrooms is a 15,000 Natural Shiitake Oak Log family owned farm located in the Missouri Ozarks, an area designated by the Nature Conservancy as one of the "Last Great Places". Ozark Forest Mushrooms takes pride in our sustainable forestry program which is administered by the Missouri Department of Conservation that provides a sustainable supply of oak logs and does not contribute to clear felling. All our mushrooms and dried mushroom products are processed and packaged on the farm using local labor. Most of our products are marketed to the St Louis region restaurants and stores.

We have been growing shiitakes for over 17 years and have been certified organic continuously for 15 years.

1991 – 1993 Ozark Organic Growers Association Viability Project (OOGA), Arkansas

1994 – 2003 Organic Crop Improvement Association (OCIA) Nebraska

2004- 2005 Missouri Organic Program, Missouri Department of Agriculture. Missouri

Due to the closure of our local state organic program last year Ozark Forest Mushrooms has recently applied to OneCert Missouri as my certification was due for renewal at the end of January 2006. At this point I was made aware that the FDA cheese wax that we have been using for 17 years from our organic supplier (Field and Forest Products) is no longer acceptable by OneCert and as a result we have been issued with a 90 day deadline to complete all inoculation using this wax.

There appears to be no available research material concerning alternative waxes and discussions with other organic log grown shiitake farmers at the recent University of Missouri, Columbia Specialty Mushroom Workshop

4112 West Pine Boulevard – St. Louis Missouri 63108
tel: 314-531-9935
www.ozarkforest.com

Meeting on Feb 18th 2006 are not aware of a commercially viable wax that is cost effective and can provide the same sealing ability as cheese wax. The summers in the Ozarks can often be hot (100 F) and a wax with a high melting point is required. Beeswax has a melting point of 62 – 65 F.

Ozark Forest Mushrooms promotes sustainable products and it is of paramount importance to clearly point out that the cheese wax sealant is used only as a barrier for the spawn, just as a farmer would use a plastic plant pot to hold a growing medium. The wax is not used as a growing input or as a growing additive or fertilizer for shiitake production. The inoculated shiitake spawn only grows mycelium into the sap wood of the log and does not grow into the wax.

Ozark Forest Mushrooms history and organic track record would highly recommend that the cheese wax be allowed for natural log use to maintain the quality and health of our shiitake logs.

Nicola Macpherson B.Sc
Ozark Forest Mushrooms LLC

Tom Kimmons

From: "Gene" <mountainbrook@hotsprings.net>
To: <shirlcdc@artelco.com>
Sent: Tuesday, March 28, 2006 3:40 PM
Subject: cheese wax

sed cheese wax in the production of shiitake mushrooms for several years, as a physical barrier to prevent moisture loss rough holes in the bark of oak logs. The shiitake mycelium did not grow on the wax or the bark of the log. The bark and the wax nply protect the wood media from moisture loss. To suggest that the use of this wax on the outside of logs nullifies the organic ture of organically grown shiitake would be incorrect.
ene Sparling

DEPARTMENT *of* AGRICULTURE
STATE OF MISSOURI
JEFFERSON CITY

MATT BLUNT
GOVERNOR

FRED FERRELL
DIRECTOR

Serving, promoting and protecting the agricultural producers, processors and consumers of Missouri's food, fuel and fiber products.

April 18, 2006

National Organic Standards Board
c/o Katherine Benham
Room 4008 - South Building
1400 and Independence Avenue, SW
Washington, D.C. 20250-0001.
Fax (202) 205-7808

National Organic Standards Board,

I am writing on behalf of two organic shiitake mushroom growers in Missouri. Recently these growers were informed by their USDA NOP accredited certifier that the FDA cheese wax that they are using is no longer an acceptable material for organic production of shiitake mushrooms.

These growers, Nicola Macpherson of Ozark Forest Mushrooms and Earnie Bohner of Persimmon Hill have tremendous integrity in their operations and take great pride in producing the highest quality of organic shiitake mushrooms. I would like to reassure the NOSB board that these growers would not knowingly use a prohibited material that would threaten the organic integrity of the shiitake mushrooms.

As far as the FDA cheese wax issue, a similar situation was before the NOSB involving oils (horticultural). The issue was that the natural product replacement was not known to be appropriate or effective. While not an exact corollary, by not being able to use the cheese wax it will leave the shiitake growers without an adequate natural alternative just as the crops committee saw in the oils situation.

Crops Committee Final Recommendation March 17, 2006
I. List: 205.601 Synthetic substances allowed for use in organic crop production
II. Category Use
(e) As insecticides (including acaricides or mite control).
(i) As plant disease control.
III. Committee Summary: Pertaining to oils (horticultural), comments were received saying that natural alternatives were available as replacements. Vegetable oils were mentioned as the natural product replacement, but were questioned to see if these are appropriate and effective. According to a representative of one California organic certifier, all the vegetable oil formulations for crop protection use have synthetic emulsifiers in them. Without the emulsifier, the oils would not work as a spray material for crops. It could be argued that these products would not be wholly natural substitutes. Further comments were received stating that multi-year grower comparative tests between vegetable oil products and the petroleum derived oils showed that the vegetable oils did not control certain target pests adequately. Research data that could verify the claim that the vegetable oil alternatives are truly adequate as a replacement is needed.
IV. Committee Recommendation:
Recommendations based upon comments received- 205.601(e) and (i)
The Crops Committee recommends the renewal of the following material in these categories of uses:
(e) As insecticides (including acaricides or mite control).
(6) Oils, horticultural- narrow range oils as dormant, suffocating, and summer oils.
(i) As plant disease control.
(6) Oils, horticultural- narrow range oils as dormant, suffocating, and summer oils.
Moved: Rigoberto Delgado Second: Jeff Moyer Committee vote: 3-1 Absent: Ostiguy ***Board vote:***

My question for the NOSB Crops Committee is by using the cheese wax in this manner does it threaten the organic integrity of the shiitake mushrooms. I am sure the NOSB will resolve this issue in a way that protects the organic consumers while not harming the organic growers of Missouri.

Sincerely,

Allan Benjamin
Allan Benjamin

Division of Agriculture Business Development
Phone (573) 751-4762 • 1616 Missouri Boulevard • P.O. Box 630 • Jefferson City, MO 65102-0630 • FAX (573) 751-2868
www.mda.mo.gov

Alabama A&M University

P. O. Box 69
Normal, AL 35762

To Whom It May Concern:

I have been conducting research on shiitake mushrooms At Alabama A&M University for 16 years. During that time we have almost exclusively used cheese wax as a sealant for log inoculation sites. Cheese wax is derived, through a natural process, from the ground, from oil, a natural product. There is no other more natural product that works as well and is as safe. Even bees wax is a hazard as it attracts bees while you are heating it and subjects workers to potential bee stings.

My research into this product has revealed that it is certified organic by the Organic Crop Improvement Association International, Inc., for International Certification Standards for Organic Foods and Food Products as well as the Mississippi Organic Farming Regulations and numerous other organic certification organizations.

Cheese wax, when used for shiitake production, is not an input into the production of the mushrooms. It is no different than covering a stack of logs with plastic. The mushrooms I have harvested have never had a wax residue on them and quite often the wax peels off before the first harvest. The contact that the mushrooms have with the wax is LESS than the contact they might have in a plastic wrapped container used for shipping or display in a supermarket.

The shiitake mushroom industry is growing and provides a valuable product to consumers. Our research has shown that mushrooms grown on logs have as much as THREE times the medicinal value of mushrooms grown on artificial or sawdust substrate blocks. We are,

in fact conducting a conference on April 20, 2006, to demonstrate and promote the use of log grown shiitake mushrooms over substrate grown mushrooms. The results of our research imply great potential for the medicinal use of log grown mushrooms. If cheese wax is removed from the approved organic certification use list, it will not only be a hardship on producers, but it will significantly increase the cost of production and even encourage producers to grow mushrooms of inferior medicinal quality.

If I can provide further assistance, please feel free to contact me at 256.372.4257.

Catherine Sabota

Cathy Sabota, Professor/Horticulturist
Department of Plant and Soil Science
Alabama Cooperative Extension System
Alabama A&M University

Tom Kimmons

From: "Tom Kimmons" <shirlcdc@artelco.com>
To: "Deborah Hill" <dbhill@uky.edu>
Cc: "Cathy Sabota" <catherine.sabota@email.aamu.edu>; <Allan.Benjamin@mda.mo.gov>
Sent: Tuesday, April 25, 2006 4:13 PM
Attach: NOP.rtf

Friends,colleagues and proxies. This is an update on my trip to Penn State to address the NOSB on cheese wax use in log-grown shiitake. Joe Krawczyk and myself spoke to the NOSB National Organic Standards Board) board last Wednesday. We both thought it was stupid to even have to speak about using food grade cheese wax but this is not the first time the government has acted stupidly. Mark Bradley, director of the NOP, sat alongside the NOSB with his staff of bureaucrats and Organicrats. I wont get into the entire history or nuances of how and why this issue came about but basically an inexperienced organic inspector questioned a grower in MO about cheese wax use then the uninformed state director of the organic certification agency agreed with the inspector but kicked it up to D.C. for an opinion from NOP who agreed with the inexperienced inspector and declared food grade cheese wax to be an "input" that was "synthetic", petrol based and prohibited. I got with my ICO certifier and Joe and we asked growers to send proxies to us with which to build our case. I will attach the text of my presentation to NOSB FYI. After Joe(first) I presented our positions and many of the NOSB board members wondered out loud what we were doing there. Two stated that from hearing us, observing the mini log we showed, examining the organically certified cheese we displayed (dipped in cheese wax) + the organically certified substrate(wrapped in a plastic(petrol based) bag we demonstrated.....they saw no problem with our certification and suggested that we file a petition with NOP to get cheese wax on the approved list. I replied that just in case the overwhelming power of my logic failed or the overpowering persuasion of my presentation wavered, that I had also brought along a petition to have cheese wax put on the approved list. I then turned to the NOP staff and Mark Bradley and presented the petition to them. NOSB seemed impressed and NOP seemed pissed off. Anyway the scuttlebutt after we left and came back home was that Bradley announced to the Friday closing group that he was amazed that their was that much concern and comment about cheese wax(let them eat cake). He also stood by his original decision(his unilateral, monolithic decision offered Ex Cathedra-as if setting in the chair of St. Peter) that cheese wax was a synthetic, input and must be prohibited. Further, he stated that the inspectors who inspect us this year must write us up as using a prohibited substance. We will then need to appeal the prohibition and it will all be sent back to the NOSB and they will decide who is correct. If this seems like a huge, silly, wastefull, organicrat circle....it is! This whole process could take 3 to 5 or more years before cheese wax is approved or prohibited. In the meantime, as I understand it, we will still be certified and can still use cheese wax. It's easy to grow tired and weary of these things...first because their dumb and second because there demanding and expensive. We at the Shiitake Mushroom Center have done and will continue to do our best to give a damm about such issues. All of the proxies you sent were included in our presentation except the one's from Alabama and Missouri that came after I had already left. We feel good about the effort put forth to defend the methods of shiitake log growers. It was expensive and tiring and came at the busiest time of our year. But, all in all, I'm

lad our industry showed up and I think we made a difference. Thanks for proxies from Mark hillips, Dave Brauer,Nicola Macpherson, Gene Sparling, Tim Bennet, Doug Williams, Deborah lill, Earnie Bohner, Allan Benjamin and Cathy Sabota. Most of all for Joe and Mary Ellen and issy Bowman. tom k

Company: IGI
Parafflex 4669A

INDEX

for IGI Information

Attachment I - "The Blend"

Attachment II - Microcrystalline Wax Substance #64742-42-3 (57 pages)

Attachment III - Paraffin Substance #8002-74-2(53 pages)

Attachment IV - Petrolatum (22 pages) Substance #8009-03-8

Attachment I
"The Blend"

(4 pages)

1. Wax Overview
2. Properties of Paraffin Wax
3. Wax Refining/flow Diagram

(Blue)

Tom Kimmons

From: "Garber, Greg" <ggarber@igiwax.com>
To: <shirlcdc@artelco.com>
Sent: Friday, September 22, 2006 8:34 AM
Attach: USDA 4669A.doc; CAS 64742423 EU IUCLID.pdf; CAS 8002742 EU IUCLID.pdf; CAS 8009038 EU IUCLID.pdf
Subject: PARAFFLEX 4669A - mfg info

'om,
Please find attached some manufacturing process information from IGI's website that summarizes our manufacturing process for he wax. I have also included some other regulatory info – re: CAS #'s of ingredients and summary info on these ingredients. Please let me know if this satisfies your requirements. I apologize for the delay, however I have been out of the office on business or a few days.
Regards,
Greg Garber
Q.A. Manager
The International Group Inc.
ggarber@igiwax.com

THE INTERNATIONAL GROUP, INC.

50 Salome Drive · Agincourt, Ontario, Canada M1S 2A8 · (416) 293-4151 · Fax (416) 293-5749

September 22, 2006

PARAFFLEX® 4669A wax.

Please find below extracts of the wax process from descriptions on our website.

PARAFFLEX® 4669A wax is made up of all three categories of wax, primarily

Microcrystalline wax	> 50 %	CAS # 64742-42-3
Petroleum waxes		CAS # 8002-74-2
Petrolatum.		CAS # 8009-03-8
antioxidant, BHT		CAS # 128-37-0 is also added at 50 ppm.

I have also included information from the European Chemical Bureau that has a summary reports on Toxicology, Environmental impacts etc. for each of the 3 main ingredients.

PARAFFLEX® 4669A wax meets FDA requirements in 21 CFR 178.3710 for use in non-food articles in contact with food and in 21 CFR 172.886 for use in food.

Petroleum Wax Overview

Petroleum wax is ultimately derived from crude oil. Obtained from the ground, crude oil is a compositionally varied product, consisting of a mixture of hydrocarbons. It is the resultant product of the decomposition of tiny aquatic plants and animals that lived in the ancient seas millions of years ago. Another name for crude oil is fossil fuel. Crude oil is transported to refineries where it is refined into finished products by complex processes. One of the many products derived from refining is lubricating oil. It is from the lube oil refining process that petroleum waxes are derived.

There are three general categories of petroleum wax that are obtained from lube oil refining. They include paraffin, microcrystalline and petrolatum. Paraffin waxes are derived from the light lubricating oil distillates. Paraffin waxes contain predominantly straight-chain hydrocarbons with an average chain length of 20 to 30 carbon atoms. The general properties of paraffin waxes are described in more detail below.

Microcrystalline waxes are produced from a combination of heavy lube distillates and residual oils. They differ from paraffin waxes in that they have poorly defined crystalline structure, darker color, and generally higher viscosity and melting points. Microcrystalline waxes (sometimes also called micro wax) tend to vary much more widely than paraffin waxes with regard to physical characteristics. Microcrystalline waxes can range from being soft and tacky to being hard and brittle, depending on the compositional balance.

The last category of petroleum wax is referred to as petrolatums. Petrolatums are derived from heavy residual oils and are separated by a dilution and filtering (or centrifuging) process. Petrolatums are microcrystalline in nature and semi-solid at room temperature.

Other terms are also used to refer to petroleum wax. In general these terms refer to the amount of oil contained in the product. Slack wax refers to petroleum wax containing anywhere from 3 to 50% oil content. Scale wax refers to wax containing 1 to 3%

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oil. Fully refined paraffin (FRP) wax is wax that has had nearly all of the oil refined out of it. Fully refined paraffins typically have less than 0.5% oil content.

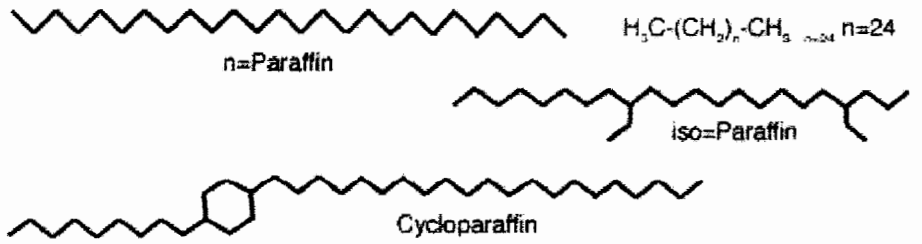
General Properties of Paraffin Wax

Paraffin Wax is a natural product derived from the molecular components of decayed vegetable and animal material. Paraffin wax consists of a complex mixture of hydrocarbons with the following general properties.

- Non-reactive
- Non-toxic
- Good water barrier
- Clean-burning fuel
- Colorless

Paraffin waxes are characterized by a clearly defined crystal structure and have the tendency to be hard and brittle. The melt point of paraffin waxes generally falls between 120° and 160°F.

Individual wax properties are determined by molecular size & structure, chemical composition and oil content. Paraffin wax consists mostly of straight chain hydrocarbons with 80 to 90% normal paraffin content and the balance consists of branched paraffins (iso-paraffins) and cycloparaffins.



Typical wax properties that can be measured and controlled include melt point, congealing point, hardness, oil content, viscosity and color. However, these physical properties alone do not completely define the suitability of a wax for a particular application. The functional properties of wax should be considered as well. These include the translucency & opaqueness of the wax, solid appearance (e.g. dry, waxy, mottled, shiny), flexibility, etc. It is the combination of physical and functional properties that ultimately determine if a particular wax is right for a given application.

Multi-step processing of wax provides clean, high quality organic products that meet U.S. Food and Drug Administration (FDA) requirements for use in food applications and in food packaging.

WAX REFINING

One of the many products derived from refining is lubricating oil, from which a byproduct called slack wax is obtained. Slack

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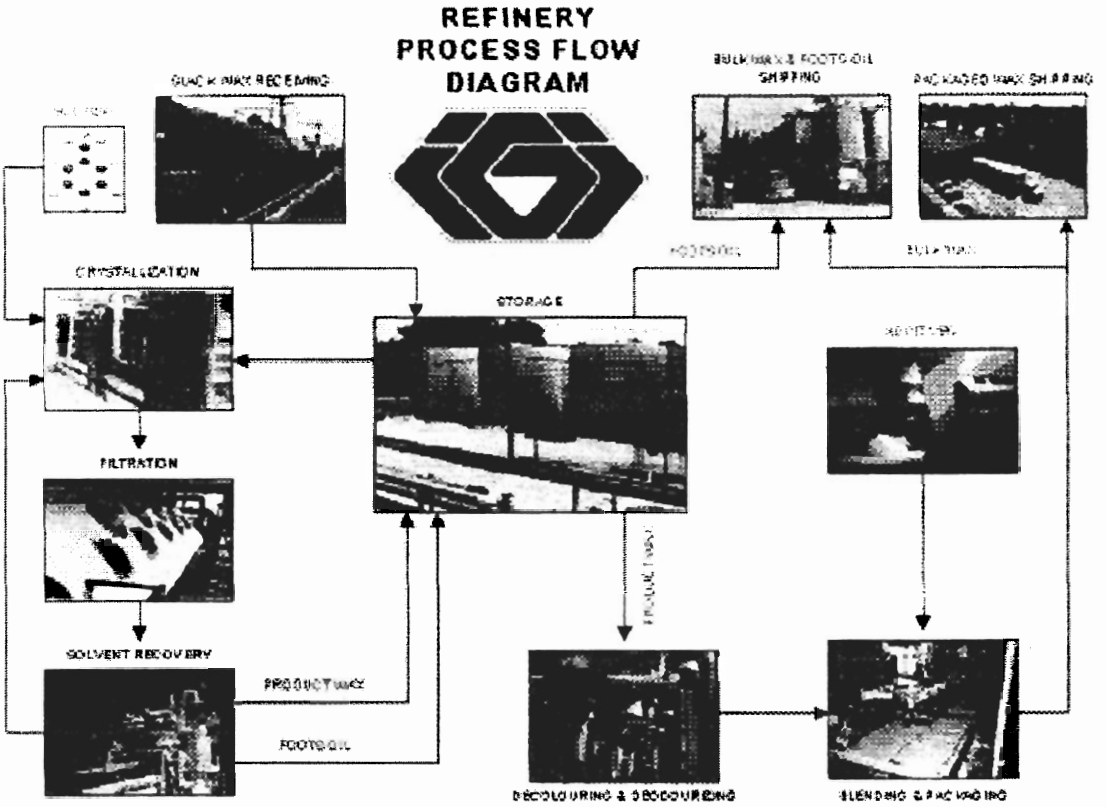
wax is a mixture of oil and wax. It is the product, which serves as IGI's feedstock and that is further refined and blended to create value-added petroleum wax products.



The principal steps in IGI's refinery operation include:

Crystallization - Slack wax is heated, mixed with solvent and then cooled. As it is cooled, wax crystallizes out leaving oil in solution. Wax specifications such as melt point, penetration, and oil content are controlled primarily by the amount of solvent added, the rate of cooling and the temperature from the crystallization process.

Filtration - The crystallized wax is filtered from the solvent in totally enclosed, inert gas blanketed, rotary drum filters. In order to obtain the low oil content required in final wax products, two and sometimes three stages of filtration are required.

Solvent Recovery - Two streams come from each drum filter, one containing the wax and some solvent and the other containing extracted oil and solvent. These streams go to the solvent recovery plant where solvent is removed by continuous distillation in steam-heated kettle heat exchangers and stripping towers. The recovered solvent is recycled to the crystallization process and to the drum filters as a wash. The solvent-free wax and oil streams go to separate storage. At this point the wax is known as a "product wax" and the oil is called "foots oil". The product wax is usually processed further and most of the foots

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oil is sold as catalytic cracker feedstock.

The solvents used in the process are a blend of Toluene and MEK (methyl ethyl ketone).

Decoloring & Deodorizing - To produce a "fully refined" wax from a product wax requires that the wax be passed through a bed of clay to remove color and through a vacuum stripping tower for odor removal. The decoloring operation is known as "percolation" and is a batch process. The clay is regenerated before reuse by passing it through a multiple hearth furnace to remove the absorbed color bodies.

Blending and Manufacturing - Fully refined paraffin waxes are blended together to give certain desired properties such as melt point and penetration. These blended waxes are then either sold in a liquid state or converted into slabs, chicklets, pastilles or granules in one of our manufacturing plants. Blended waxes are also used for base stock for further blending with other petroleum based products such as resins and polymers to incorporate special properties such as flexibility, toughness and/or gloss.

Greg Garber
Q.A. Manager
The International Group Inc.
ggarber@igiwax.com

Attachment II
Microcrystalline Wax Substance
CAS#64742-42-3

(57 Pages)

1. General Info
2. Physico-Chemical Data
3. Environmental Fate and Pathways
4. Ecotoxicity
5. Toxicity
6. References

(Blue)

I U C L I D

D a t a s e t

Existing Chemical	Substance ID: 64742-42-3
CAS No.	64742-42-3
EINECS Name	Hydrocarbon waxes (petroleum), clay-treated microcryst.
EINECS No.	265-144-0
Molecular Formula	<no data>
Substance Group	11A

Dataset created by: EUROPEAN COMMISSION - European Chemicals Bureau

This dossier is a compilation based on data reported by the European Chemicals Industry following 'Council Regulation (EEC) No. 793/93 on the Evaluation and Control of the Risks of Existing Substances'. All (non-confidential) information from the single datasets, submitted in the IUCLID/HEDSET format by individual companies, was integrated to create this document.

The data have not undergone any evaluation by the European Commission.

Creation date: 18-FEB-2000

Number of Pages: 57

Chapters: all

Edition: Year 2000 CD-ROM edition

Flags: non-confidential

1.0.1 OECD and Company Information

Name: Bareco Products
Street: 148 East Main Street
Town: Rock Hill, SC 29730
Country: United States
Phone: 803/327-3663

Name: BASF AG
Street: Karl-Bosch-Str
Town: 67056 Ludwigshafen
Country: Germany

Name: CLARIANT (ITALIA) S.p.A
Street: VIA CALDERA 21
Town: 20153 MILANO
Country: Italy
Phone: 0039 2 93524238
Telefax: 0039 2 99045944

Name: PETROLEOS DE PORTUGAL - PETROGAL,S.A.
Street: RUA DAS FLORES 7
Town: 1200 LISBOA
Country: Portugal
Phone: 3474330
Telefax: 3102910
Telex: NO
Cedex: 2539

Name: REPSOL PETROLEO,S.A.
Street: PASEO DE LA CASTELLANA, 278-280
Town: 28046 MADRID
Country: Spain
Phone: 91-3488000
Telefax: 3489494/3142821
Telex: 49840

Name: Shell Italia S.p.A.
Street: Via Chiese, 74
Town: I-20126 MILANO
Country: Italy

Name: WITCO BV
Street: Wezelstraat 12, P.O. Box 5
Town: 1540AA Koog aan de Zaan
Country: Netherlands
Phone: (31)75283854
Telefax: (31)75210811
Telex: 19270

1.0.2 Location of Production Site

-

1.0.3 Identity of Recipients

-

1.1 General Substance Information

Substance type: organic
Physical status: solid

Substance type: petroleum product
Physical status: liquid

Substance type: petroleum product
Physical status: solid

1.1.1 Spectra

-

1.2 Synonyms

495D (Clay-treated paraffin wax from bright stock oil)
Source: REPSOL PETROLEO,S.A. MADRID

Clay treated microcrystalline wax (petroleum)
Source: BASF AG Ludwigshafen

Hydrocarbon waxes (petroleum), clay-treated microcryst.
Source: BASF AG Ludwigshafen

HYDROTREATED HEAVY NAPHTHA
Source: CLARIANT (ITALIA) S.p.A MILANO

Micro Wax, Microcrystalline Wax, Petroleum Wax
Source: WITCO BV Koog aan de Zaan

1.3 Impurities

-

1.4 Additives

-

1.5 Quantity

Quantity 50 000 - 100 000 tonnes

1.6.1 Labelling

-

1.6.2 Classification

-

1.7 Use Pattern

Type: type
Category: Non dispersive use

Type: type
Category: Use resulting in inclusion into or onto matrix

Type: type
Category: Wide dispersive use

Type: industrial
Category: Polymers industry

Type: industrial
Category: Public domain

Type: industrial
Category:

Type: industrial
Category: other

Type: use
Category: Softeners

Type: use
Category: other: insulating, impregnating materials and candle industry.

Type: use
Category: other

1.7.1 Technology Production/Use

-

1.8 Occupational Exposure Limit Values

Type of limit: TLV (US)
Limit value: 2 mg/m3
Remark: ATMOSPHERE CONTROL MEASURES: The product is solid at room temperature and it does not present potential exposure risk.
HANDLING AND STORAGE: Stored in form of pearls in containers properly labelled and sealed. Avoid contact with melted product.
The value is for paraffin fumes CAS n° 8002-74-2
USE OF PERSONAL PROTECTIVE EQUIPMENT:
Respiratory protection: protective mask in presence of hot vapours.
Skin protection: gloves when handling melted product.
Eye protection: Safety gogles when handling the liquid product.

Source: REPSOL PETROLEO,S.A. MADRID

Type of limit:
Limit value:
Remark: keine Festlegung
Source: BASF AG Ludwigshafen

(1)

1.9 Source of Exposure

-

1.10.1 Recommendations/Precautionary Measures

-

1.10.2 Emergency Measures

-

1.11 Packaging

-

1.12 Possib. of Rendering Subst. Harmless

-

1.13 Statements Concerning Waste

-

1.14.1 Water Pollution

Classified by: other: Selbsteinstufung BASF AG
Labelled by:
Class of danger: 0 (generally not water polluting)
Source: BASF AG Ludwigshafen

1.14.2 Major Accident Hazards

Legislation:
Substance listed:
Remark: kein Stoff der StoerfallVO
Source: BASF AG Ludwigshafen

(2)

1.14.3 Air Pollution

Classified by: TA-Luft (DE)
Labelled by:
Number: 3.1.7 (organic substances)
Class of danger:
Source: BASF AG Ludwigshafen

1.15 Additional Remarks

Remark: DISPOSAL OPTIONS: Specific prepared and controlled areas and incineration.
The full HEDSET for substances in this petroleum product group has been included for "Paraffin waxes and hydrocarbon waxes", CAS n°8002-74-2.
TRANSPORT INFORMATION: no data
Source: REPSOL PETROLEO,S.A. MADRID

1.16 Last Literature Search

-

1.17 Reviews

-

1.18 Listings e.g. Chemical Inventories

-

2.1 Melting Point

Value: 45 - 95 degree C
Decomposition: no
Sublimation: no
Method: other: ASTM D87, D938 and D127
GLP: no data
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
(3) (4) (5)

Value: 45 - 95 degree C
Decomposition: no
Sublimation: no
Method: other: ASTM D87, D938 and D127
GLP: no data
Source: REPSOL PETROLEO,S.A. MADRID
(6) (7) (8)

2.2 Boiling Point

-

2.3 Density

Type: density
Value: .73 - .84 g/cm3 at 100 degree C
Method: other: ASTM D1298
GLP: no data
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
(3) (4) (9) (5)

Type: density
Value: .73 - .84 g/cm3 at 100 degree C
Method: other: ASTM D1298
GLP: no data
Source: REPSOL PETROLEO,S.A. MADRID
(6) (7) (10) (8)

2.3.1 Granulometry

-

2.4 Vapour Pressure

-

2.5 Partition Coefficient

log Pow: > 6
Method: other (calculated)
Year:
Remark: The calculation was done by the CLOGP Version 3.5 program (Calculation of LOG Partition coefficient octanol/water).

As an example, the calculated value for eicosane (n-C20H42) is 11.3. However, such values are notional, since no correlation has been established between calculated and experimental values for Log Pow values greater than 6.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA

(11)

log Pow: > 6
Method: other (calculated)
Year:
Remark: The calculation was done by the CLOGP Version 3.5 program (Calculation of LOG Partition coefficient octanol/water).

As an example, the calculated value for eicosane (n-C20H42) is 11.3. However, such values are notional, since no correlation has been established between calculated and experimental values for Log Pow values greater than 6.
Source: REPSOL PETROLEO,S.A. MADRID

(11)

2.6.1 Water Solubility

-

2.6.2 Surface Tension

-

2.7 Flash Point

Value: > 215 degree C
Type: open cup
Method: other: ASTM D92
Year:
GLP: no data
Remark: Values range from 215 to 296 degree C.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA

(3) (12) (5)

Value: > 215 degree C
Type: open cup
Method: other: ASTM D92
Year:
GLP: no data
Remark: Values range from 215 to 296 degree C.
Source: REPSOL PETROLEO,S.A. MADRID

(6) (13) (8)

2.8 Auto Flammability

-

2.9 Flammability

-

2.10 Explosive Properties

-

2.11 Oxidizing Properties

-

2.12 Additional Remarks

Remark: Viscosity ranges from 3 to 30 mm2/sec at 100 Deg C by test method ASTM D445.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA

(3) (12) (5)

Remark: Refractive index ranges from 1.149 to 1.448 at 100 Deg C by test method ASTM D1747.
Source: Bareco Products Rock Hill, SC 29730

(3) (12) (5)

Remark: Petroleum waxes are rarely characterised in terms of boiling range and autoflammability. They are very involatile materials, almost totally insoluble in water and do not contain any oxidizing constituents.

Petroleum waxes consist of high molecular weight alkanes and cycloalkanes. There are three classifications viz, paraffin, intermediate and microcrystalline waxes. All are obtained from petroleum fractions by either solvent crystallization, solvent de-oiling or by a sweating process. Paraffin waxes typically contain C20 - C50 n-alkanes with smaller quantities of iso-alkanes. They form visible crystalline structures, and are also known as macrocrystalline waxes.

Intermediate waxes typically contain C20 - C60 alkanes and are intermediate between paraffin and microcrystalline

waxes.

Microcrystalline waxes typically contain C25 - C85 alkanes and although they contain very small crystals, much of the material is amorphous.

Compositional information on food-grade petroleum waxes is contained in a CONCAWE report (see Reference).

Source: Bareco Products Rock Hill, SC 29730

(14)

Remark: The technical information contained in Chapters 2 to 5 of this Data Set has been compiled by the Oil Companies' European Organization for Environmental and Health Protection, CONCAWE, based at Madouplein-1, B-1030 Brussel, Belgium, and this organization holds copies of the reference articles cited in this Data Set.

Source: Bareco Products Rock Hill, SC 29730

Remark: Refractive index ranges from 1.149 to 1.448 at 100 Deg C by test method ASTM D1747.

Source: WITCO BV Koog aan de Zaan

(3) (12) (5)

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Source: WITCO BV Koog aan de Zaan

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Source: WITCO BV Koog aan de Zaan

Remark: Viscosity ranges from 3 to 30 mm2/sec at 100 Deg C by test method ASTM D445.
Source: REPSOL PETROLEO,S.A. MADRID
(6) (13) (8)

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Source: REPSOL PETROLEO,S.A. MADRID
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Compositional information on food-grade petroleum waxes is contained in a CONCAWE report (see Reference).
Source: REPSOL PETROLEO,S.A. MADRID
(15)

Remark: The technical information contained in Chapters 2 to 5 of this Data Set has been compiled by the Oil Companies' European Organization for Environmental and Health Protection, CONCAWE, based at Madouplein-1, B-1030 Brussel, Belgium, and this organization holds copies of the reference articles cited in this Data Set.
Source: REPSOL PETROLEO,S.A. MADRID

Remark: Refractive index ranges from 1.149 to 1.448 at 100 Deg C by test method ASTM D1747.

Source: PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA (3) (12) (5)

Remark: Petroleum waxes are rarely characterised in terms of boiling range and autoflammability. They are very involatile materials, almost totally insoluble in water and do not contain any oxidizing constituents.

Petroleum waxes consist of high molecular weight alkanes and cycloalkanes. There are three classifications viz, paraffin, intermediate and microcrystalline waxes. All are obtained from petroleum fractions by either solvent crystallization, solvent de-oiling or by a sweating process. Paraffin waxes typically contain C20 - C50 n-alkanes with smaller quantities of iso-alkanes. They form visible crystalline structures, and are also known as macrocrystalline waxes.

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Compositional information on food-grade petroleum waxes is contained in a CONCAWE report (see Reference).

Source: PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA (14)

Remark: The technical information contained in Chapters 2 to 5 of this Data Set has been compiled by the Oil Companies' European Organization for Environmental and Health Protection, CONCAWE, based at Madouplein-1, B-1030 Brussel, Belgium, and this organization holds copies of the reference articles cited in this Data Set.

Source: PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA

3.1.1 Photodegradation

Type: air
Light source: Sun light
Conc. of subst.: at 25 degree C
INDIRECT PHOTOLYSIS
Sensitizer: OH
Conc. of sens.: 1000000 molecule/cm3
Method: other (calculated): according to Atkinson, 1990.
Year: **GLP:**
Test substance: other TS
Remark: Most hydrocarbon components of substances in this Group will have little or no tendency to partition to air (see Sub-chapter 3.3.2). The half lives for degradation of these hydrocarbons by reaction with hydroxyl radicals, in the troposphere, under the influence of sunlight, will all be less than one day, by extrapolation from the data quoted by Atkinson. Accordingly, any hydrocarbon material which does partition to air will be rapidly photodegraded.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: Alkanes (>C12) found in paraffin waxes.

(16)

Type: air
Light source: Sun light
Conc. of subst.: at 25 degree C
INDIRECT PHOTOLYSIS
Sensitizer: OH
Conc. of sens.: 1000000 molecule/cm3
Method: other (calculated): according to Atkinson, 1990.
Year: **GLP:**
Test substance: other TS
Remark: Most hydrocarbon components of substances in this Group will have little or no tendency to partition to air (see Sub-chapter 3.3.2). The half lives for degradation of these hydrocarbons by reaction with hydroxyl radicals, in the troposphere, under the influence of sunlight, will all be less than one day, by extrapolation from the data quoted by Atkinson. Accordingly, any hydrocarbon material which does partition to air will be rapidly photodegraded.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Alkanes (>C12) found in paraffin waxes.

(17)

3.1.2 Stability in Water

Type:
Method:
Year: **GLP:**
Test substance:
Remark: Hydrocarbons present in paraffin waxes are not susceptible to hydrolysis under environmental conditions.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA

(18)

Type:
Method:
Year: **GLP:**
Test substance:
Remark: Hydrocarbons present in paraffin waxes are not susceptible to hydrolysis under environmental conditions.
Source: REPSOL PETROLEO,S.A. MADRID

(19)

3.1.3 Stability in Soil

Type: field trial **Radiolabel:** no
Concentration:
Soil classif.: other: Woodland park origin **Year:**
Content of clay: = 23 %
silt: = 32 %
sand: = 58 %
Organ. carbon: = 6.9 %
pH: = 7.3
Cation exch. capac.
Microbial biomass:
Method: other: litter bag test, protocol described in paper by de Kreuk
Year: 1988 **GLP:** yes
Test substance: other TS
Remark: Samples were all applied to paper, enclosed in nylon mesh bags, placed in woodland soil and covered in leaf litter. Tests were done using mesh sizes of 5 mm and 45 um for two six-month periods, viz. spring/summer and autumn/winter. Degradation was judged visually, by weighing and by gas chromatographic analysis.
Result: Microcrystalline waxes were degraded by about 20% in all tests. Paraffin and intermediate waxes in 5 mm bags were 100% degraded in six months in spring/summer and 100% degraded in three months in autumn/winter. Paraffin and intermediate waxes in 45 um bags were approximately 75% degraded in each six-month period.

The study concluded that waxes are initially attacked by soil microfauna and are mainly degraded by soil microflora.
Source: Bareco Products Rock Hill, SC 29730

WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA

Test substance: Two paraffin waxes, CAS no. 8002-74-2; an intermediate wax, CAS no. 97489-05-9; and a microcrystalline wax, CAS no. 63231-60-7 (note: CAS nos. were not assigned in the original study).

(20) (21)

Type: field trial **Radiolabel:** no
Concentration:
Soil classif.: other: Woodland park origin **Year:**
Content of clay: = 23 %
silt: = 32 %
sand: = 58 %
Organ. carbon: = 6.9 %
pH: = 7.3
Cation exch. capac.
Microbial biomass:
Method: other: litter bag test, protocol described in paper by de Kreuk
Year: 1988 **GLP:** yes
Test substance: other TS
Remark: Samples were all applied to paper, enclosed in nylon mesh bags, placed in woodland soil and covered in leaf litter. Tests were done using mesh sizes of 5 mm and 45 um for two six-month periods, viz. spring/summer and autumn/winter. Degradation was judged visually, by weighing and by gas chromatographic analysis.
Result: Microcrystalline waxes were degraded by about 20% in all tests. Paraffin and intermediate waxes in 5 mm bags were 100% degraded in six months in spring/summer and 100% degraded in three months in autumn/winter. Paraffin and intermediate waxes in 45 um bags were approximately 75% degraded in each six-month period.

The study concluded that waxes are initially attacked by soil microfauna and are mainly degraded by soil microflora.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Two paraffin waxes, CAS no. 8002-74-2; an intermediate wax, CAS no. 97489-05-9; and a microcrystalline wax, CAS no. 63231-60-7 (note: CAS nos. were not assigned in the original study).

(22) (23)

3.2 Monitoring Data (Environment)

-

3.3.1 Transport between Environmental Compartments

-

3.3.2 Distribution

Media: air - biota - sediment(s) - soil - water
Method: Calculation according Mackay, Level I
Year: 1981
Remark: Distribution has been calculated according to Mackay Level I using the parameters defined in a paper by van der Zandt and van Leeuwen.

Any lower molecular weight alkanes will mainly partition to air, but the majority of the hydrocarbon constituents of paraffin waxes will distribute to soil and sediment.
Result: Results for typical hydrocarbons found in paraffin waxes are shown in tabular form as follows:

	air %	water %	soil %	sediment %	susp. matter %	biota %
n-tetradecane	76.7	0.0	22.8	0.5	0.0	0.0
n-eicosane	0.0	0.0	97.7	2.2	0.1	0.0

Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA

(24) (25)

Media: air - biota - sediment(s) - soil - water
Method: Calculation according Mackay, Level I
Year: 1981
Remark: Distribution has been calculated according to Mackay Level I using the parameters defined in a paper by van der Zandt and van Leeuwen.

Any lower molecular weight alkanes will mainly partition to air, but the majority of the hydrocarbon constituents of paraffin waxes will distribute to soil and sediment.
Result: Results for typical hydrocarbons found in paraffin waxes are shown in tabular form as follows:

	air %	water %	soil %	sediment %	susp. matter %	biota %
n-tetradecane	76.7	0.0	22.8	0.5	0.0	0.0
n-eicosane	0.0	0.0	97.7	2.2	0.1	0.0

Source: REPSOL PETROLEO,S.A. MADRID

(26) (27)

3.4 Mode of Degradation in Actual Use

-

3.5 Biodegradation

Type: aerobic
Inoculum: other: oil-polluted soil (adapted)
Concentration: 20 mg/l related to Test substance
Degradation: = 21 % after 28 day
Result: other: only partially degraded
Method: OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO2 evolution)"
Year: 1981 **GLP:** no data
Test substance: other TS
Remark: In these tests samples were exposed on glass fibre filters. Adapted micro-organisms were used. An 84-day study gave a biodegradability of 25%.
Partially degraded hydrocarbons were identified from microcrystalline waxes by gas chromatographic analysis.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note CAS no. was not assigned in original study).

(28)

Type: aerobic
Inoculum: other: oil-polluted soil (adapted)
Concentration: 20 mg/l related to Test substance
Degradation: = 21 % after 28 day
Result: other: only partially degraded
Method: OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO2 evolution)"
Year: 1981 **GLP:** no data
Test substance: other TS
Remark: In these tests samples were exposed on glass fibre filters. Adapted micro-organisms were used. An 84-day study gave a biodegradability of 25%.
Partially degraded hydrocarbons were identified from microcrystalline waxes by gas chromatographic analysis.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note CAS no. was not assigned in original study).

(29)

Type: aerobic
Inoculum: other: oil-polluted soil (adapted)
Concentration: 20 mg/l related to Test substance
Degradation: = 66 % after 28 day
Result: inherently biodegradable
Method: OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO2 evolution)"
Year: 1981 **GLP:** no data
Test substance: other TS
Remark: In these tests samples were exposed on glass fibre filters. Adapted micro-organisms were used. An 84-day study gave a biodegradability of 77%.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: Intermediate wax, CAS no. 97489-05-9 (note: CAS no. was not assigned in original study).

(28)

Type: aerobic
Inoculum: other: oil-polluted soil (adapted)
Concentration: 20 mg/l related to Test substance
Degradation: = 66 % after 28 day
Result: inherently biodegradable
Method: OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO2 evolution)"
Year: 1981 **GLP:** no data
Test substance: other TS
Remark: In these tests samples were exposed on glass fibre filters. Adapted micro-organisms were used. An 84-day study gave a biodegradability of 77%.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Intermediate wax, CAS no. 97489-05-9 (note: CAS no. was not assigned in original study).

(29)

Type: aerobic
Inoculum: other: oil-polluted soil (adapted)
Concentration: 20 mg/l related to Test substance
Degradation: 78 - 84 % after 28 day
Result: inherently biodegradable
Method: OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO2 evolution)"
Year: 1981 **GLP:** no data
Test substance: other TS
Remark: In these tests samples were exposed on glass fibre filters. Adapted micro-organisms were used. Two 84-day studies gave biodegradabilities of 85% and 89%.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(28)

Type: aerobic
Inoculum: other: oil-polluted soil (adapted)
Concentration: 20 mg/l related to Test substance
Degradation: 78 - 84 % after 28 day
Result: inherently biodegradable
Method: OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO_2 evolution)"
Year: 1981 **GLP:** no data
Test substance: other TS
Remark: In these tests samples were exposed on glass fibre filters. Adapted micro-organisms were used. Two 84-day studies gave biodegradabilities of 85% and 89%.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(29)

3.6 BOD5, COD or BOD5/COD Ratio

-

3.7 Bioaccumulation

-

3.8 Additional Remarks

-

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

-

4.2 Acute Toxicity to Aquatic Invertebrates

-

4.3 Toxicity to Aquatic Plants e.g. Algae

-

4.4 Toxicity to Microorganisms e.g. Bacteria

-

4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish

-

4.5.2 Chronic Toxicity to Aquatic Invertebrates

-

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Soil Dwelling Organisms

-

4.6.2 Toxicity to Terrestrial Plants

-

4.6.3 Toxicity to other Non–Mamm. Terrestrial Species

-

4.7 Biological Effects Monitoring

-

4.8 Biotransformation and Kinetics

-

4.9 Additional Remarks

Remark: No ecotoxicity studies have been done on substances in this Group. However, work by Adema and van den Bos Bakker on the ecotoxicity of alkanes to Daphnia magna, Chaetogammarus marinus and Mysidopsis bahia has shown that alkanes of carbon number greater than C10 are not acutely toxic to these species at their limit of solubility in water. Since paraffin waxes are largely composed of straight-chain alkanes of carbon number greater than C12, they will not be acutely toxic to aquatic invertebrates.

Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA

(30)

Remark: No ecotoxicity studies have been done on substances in this Group. However, work by Adema and van den Bos Bakker on the ecotoxicity of alkanes to Daphnia magna, Chaetogammarus marinus and Mysidopsis bahia has shown that alkanes of carbon number greater than C10 are not acutely toxic to these species at their limit of solubility in water. Since paraffin waxes are largely composed of straight-chain alkanes of carbon number greater than C12, they will not be acutely toxic to aquatic invertebrates.

Source: REPSOL PETROLEO,S.A. MADRID

(31)

5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: > 5000 mg/kg bw
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Remark: A limit test at one dose level was conducted on 5 animals. Administration was by gavage. No deaths resulted.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(32) (33)

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: > 3750 mg/kg bw
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Remark: A limit test was done in which the test substance was administered by gavage to rats as a 75% dispersion in corn oil. No deaths resulted.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(34) (33)

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: = 10000 mg/kg bw
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Remark: Five groups, each of 5 rats, were given single doses of 0.464, 1.0, 2.15, 4.64 and 10.0 g/kg of the test substance as a 20% suspension in corn oil. Administration was by gavage. Animals were observed over 14 days. Effects were

only found at the highest dose, where three of the animals died. These exhibited bloody discharges from the mouth and nose, excessive salivation, loss of righting reflex and diarrhoea. At necropsy, findings included congestion of lungs and kidneys, hyperemia of large and small intestines and solid wax in the stomach.

It was concluded that the LD50 was about 10 g/kg.

Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA

Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. was not assigned in original study).

(35) (33)

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: > 5000 mg/kg bw
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Remark: A limit test at one dose level was conducted on 5 animals. Administration was by gavage. No deaths resulted.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(36) (37)

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: > 3750 mg/kg bw
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Remark: A limit test was done in which the test substance was administered by gavage to rats as a 75% dispersion in corn oil. No deaths resulted.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(38) (37)

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: = 10000 mg/kg bw
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Remark: Five groups, each of 5 rats, were given single doses of 0.464, 1.0, 2.15, 4.64 and 10.0 g/kg of the test substance as a 20% suspension in corn oil. Administration was by gavage. Animals were observed over 14 days. Effects were only found at the highest dose, where three of the animals died. These exhibited bloody discharges from the mouth and nose, excessive salivation, loss of righting reflex and diarrhoea. At necropsy, findings included congestion of lungs and kidneys, hyperemia of large and small intestines and solid wax in the stomach.

It was concluded that the LD50 was about 10 g/kg.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. was not assigned in original study).

(39) (37)

5.1.2 Acute Inhalation Toxicity

-

5.1.3 Acute Dermal Toxicity

Type: LD50
Species: rabbit
Sex:
Number of Animals:
Vehicle:
Value: > 3600 mg/kg bw
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Remark: A limit test was done at a single dose level of 4 ml/kg on an unknown number of animals. A closed patch was applied for 24 hours. At necropsy, no abnormalities or systemic effects were noted.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: A 50/50 blend of paraffin wax, CAS no. 8002-74-2 and petrolatum (note: CAS no. was not assigned in original study).

(40) (33)

Type:	LD50
Species:	rabbit
Sex:	
Number of Animals:	
Vehicle:	
Value:	> 3600 mg/kg bw
Method:	other: protocol not available
Year:	**GLP:** no data
Test substance:	other TS
Remark:	A limit test was done at a single dose level of 4 ml/kg on an unknown number of animals. A closed patch was applied for 24 hours. At necropsy, no abnormalities or systemic effects were noted.
Source:	REPSOL PETROLEO,S.A. MADRID
Test substance:	A 50/50 blend of paraffin wax, CAS no. 8002-74-2 and petrolatum (note: CAS no. was not assigned in original study).

(41) (37)

5.1.4 Acute Toxicity, other Routes

-

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

Species:	rabbit
Concentration:	
Exposure:	
Exposure Time:	
Number of Animals:	
PDII:	
Result:	not irritating
EC classificat.:	not irritating
Method:	other: modification of Draize-Test
Year:	**GLP:** no data
Test substance:	other TS
Remark:	Nine animals were treated for 24 hours, applying 3 x 0.5 ml of test substance to the clipped intact skin and covering with a closed patch. Scoring was done according to the Draize scale. There was no irritation.
Source:	Bareco Products Rock Hill, SC 29730 WITCO BV Koog aan de Zaan PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance:	Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(42) (33)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: slightly irritating
EC classificat.: not irritating
Method: other: modification of Draize-Test
Year: **GLP:** no data
Test substance: other TS
Remark: Six animals were treated for 24 hours, applying 3 x 0.5 ml of test substance to the clipped intact skin and covering with an open patch. After patch removal the treatment area was observed and scored according to the Draize scale. Three samples of the test substance were evaluated in this way. Scores are not available, but 2 samples produced erythema in 4 animals, the effect persisting for 3 days. The third sample produced erythema in a single animal, and this persisted for 2 days.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: A 50/50 blend of paraffin wax, CAS no. 8002-74-2 and petrolatum (note: CAS no. was not assigned in original study).

(34) (43) (33)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: slightly irritating
EC classificat.: not irritating
Method: other: modification of Draize-Test
Year: **GLP:** no data
Test substance: other TS
Remark: Six rabbits were treated with 0.5 ml of test substance, which was applied on both intact and abraded skin for 24 hours. The treatment sites were observed over the following 72 hours and scored according to the Draize scale. Slight erythema and slight oedema were observed, with a primary irritation index of 0.42 out of a maximum score of 8.0.
Source: Bareco Products Rock Hill, SC 29730
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. was not assigned in original study).

(44) (33)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: slightly irritating
EC classificat.: not irritating
Method: other: modification of Draize-Test
Year: **GLP:** no data
Test substance: other TS
Remark: Six rabbits were treated with 0.5 ml of test substance, which was applied on both intact and abraded skin for 24 hours. The treatment sites were observed over the following 72 hours and scored according to the Draize scale. Slight erythema and slight oedema were observed, with a primary irritation index of 0.42 out of a maximum score of 8.0.
Source: WITCO BV Koog aan de Zaan
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. was not assigned in original study).

(44) (33)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.: not irritating
Method: other: modification of Draize-Test
Year: **GLP:** no data
Test substance: other TS
Remark: Nine animals were treated for 24 hours, applying 3 x 0.5 ml of test substance to the clipped intact skin and covering with a closed patch. Scoring was done according to the Draize scale. There was no irritation.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(45) (37)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: slightly irritating
EC classificat.: not irritating
Method: other: modification of Draize-Test
Year: **GLP:** no data
Test substance: other TS
Remark: Six animals were treated for 24 hours, applying 3 x 0.5 ml of test substance to the clipped intact skin and covering with an open patch. After patch removal the treatment area was observed and scored according to the Draize scale. Three samples of the test substance were evaluated in this way. Scores are not available, but 2 samples produced erythema in 4 animals, the effect persisting for 3 days. The third sample produced erythema in a single animal, and this persisted for 2 days.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: A 50/50 blend of paraffin wax, CAS no. 8002-74-2 and petrolatum (note: CAS no. was not assigned in original study).

(38) (46) (37)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: slightly irritating
EC classificat.: not irritating
Method: other: modification of Draize-Test
Year: **GLP:** no data
Test substance: other TS
Remark: Six rabbits were treated with 0.5 ml of test substance, which was applied on both intact and abraded skin for 24 hours. The treatment sites were observed over the following 72 hours and scored according to the Draize scale. Slight erythema and slight oedema were observed, with a primary irritation index of 0.42 out of a maximum score of 8.0.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. was not assigned in original study).

(47) (37)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: slightly irritating
EC classificat.: not irritating
Method: other: modification of Draize-Test
Year: **GLP:** no data
Test substance: other TS
Remark: Six rabbits were treated with 0.5 ml of test substance, which was applied on both intact and abraded skin for 24 hours. The treatment sites were observed over the following 72 hours and scored according to the Draize scale. Slight erythema and slight oedema were observed, with a primary irritation index of 0.42 out of a maximum score of 8.0.
Source: PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. was not assigned in original study).

(44) (33)

Species: human
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.: not irritating
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Remark: The test substance was applied under occlusion to the forearm or upper back for 24 hours to a panel of 20 subjects. After removal, scores were taken immediately and at intervals over the following 96 hours. Two samples were tested in this way. The first caused barely perceptible erythema in one person, all the others being negative. The second produced uniform erythema in one of the 20 subjects, all the others being negative.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(48) (49) (33)

Species: human
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.: not irritating
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Remark: The test substance was applied for 21 days under occlusive conditions to a panel of 8 subjects. None of the subjects exhibited any signs of skin irritancy.
Source: Bareco Products Rock Hill, SC 29730
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. was not assigned in original study).

(50) (33)

Species: human
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.: not irritating
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Remark: The test substance was applied for 21 days under occlusive conditions to a panel of 8 subjects. None of the subjects exhibited any signs of skin irritancy.
Source: WITCO BV Koog aan de Zaan
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. was not assigned in original study).

(50) (33)

Species: human
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.: not irritating
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Remark: The test substance was applied under occlusion to the forearm or upper back for 24 hours to a panel of 20

subjects. After removal, scores were taken immediately and at intervals over the following 96 hours. Two samples were tested in this way. The first caused barely perceptible erythema in one person, all the others being negative. The second produced uniform erythema in one of the 20 subjects, all the others being negative.

Source: REPSOL PETROLEO,S.A. MADRID

Test substance: Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(51) (52) (37)

Species: human
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.: not irritating
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Remark: The test substance was applied for 21 days under occlusive conditions to a panel of 8 subjects. None of the subjects exhibited any signs of skin irritancy.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. was not assigned in original study).

(53) (37)

Species: human
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.: not irritating
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Remark: The test substance was applied for 21 days under occlusive conditions to a panel of 8 subjects. None of the subjects exhibited any signs of skin irritancy.
Source: PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. was not assigned in original study).

(50) (33)

5.2.2 Eye Irritation

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: slightly irritating
EC classificat.: not irritating
Method: other: protocol not available, but procedure resembles Draize-Test
Year: **GLP:** no data
Test substance: other TS
Remark: Six animals were treated with 0.1 ml of test substance without water rinsing. Eye irritation was scored according to the Draize scale for 3 days.

Four samples of the test substance were evaluated in this way. Two of the samples caused mild irritation in one rabbit at the 24 hour point; the remaining scores were zero. The other two samples did not cause any eye irritation.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: A 50/50 blend of paraffin wax, CAS no. 8002-74-2 and petrolatum (note: CAS no. was not assigned in original study).

(40) (54) (42) (33)

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: slightly irritating
EC classificat.: not irritating
Method: Draize Test
Year: 1959 **GLP:** no data
Test substance: other TS
Remark: Six animals were each treated with 0.1 ml of test substance. Eyes were observed for 3 days, and scored according to the Draize scale.

Five of the animals showed no eye irritation. One animal showed slight conjunctival erythema and oedema after 24 hours.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. was not assigned in original study).

(55) (33)

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: slightly irritating
EC classificat.: not irritating
Method: other: protocol not available, but procedure resembles Draize-Test
Year: **GLP:** no data
Test substance: other TS
Remark: Six animals were treated with 0.1 ml of test substance without water rinsing. Eye irritation was scored according to the Draize scale for 3 days.

Four samples of the test substance were evaluated in this way. Two of the samples caused mild irritation in one rabbit at the 24 hour point; the remaining scores were zero. The other two samples did not cause any eye irritation.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: A 50/50 blend of paraffin wax, CAS no. 8002-74-2 and petrolatum (note: CAS no. was not assigned in original study).

(41) (56) (45) (37)

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: slightly irritating
EC classificat.: not irritating
Method: Draize Test
Year: 1959 **GLP:** no data
Test substance: other TS
Remark: Six animals were each treated with 0.1 ml of test substance. Eyes were observed for 3 days, and scored according to the Draize scale.

Five of the animals showed no eye irritation. One animal showed slight conjunctival erythema and oedema after 24 hours.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. was not assigned in original study).

(57) (37)

5.3 Sensitization

-

5.4 Repeated Dose Toxicity

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: oral feed
Exposure period: 90 days
Frequency of treatment: daily
Post. obs. period: 28 days for reversibility studies in Groups B and D. See Remark: Doses.
Doses: See Remark: Doses for full details
Control Group: yes, concurrent no treatment
LOAEL: 1.8 mg/kg bw
Method: other: see Remark: Method for full details
Year: **GLP:** yes
Test substance: other TS
Remark: Remark: Doses

Test group doses were as follows:

(A) four groups at 1.8, 18.5, 185 and 1850 mg/kg/day (each group consisting 20 male/20 female animals)
(B) one group at 1850 mg/kg/day (10 male/10 female)
(C) one group at 1850 mg/kg/day (5 male/5 female)
(D) one group at 1850 mg/kg/day (5 male/5 female)

There were four control groups, all concurrent, no treatment, corresponding to the treatment groups. The sizes of these control groups were:

(A) 60 male/60 female
(B) 30 male/30 female
(C) 5 male/5 female
(D) 5 male/5 female
Remark: Method

The protocol was a compilation of the procedures outlined by the OECD, EEC and US FDA Guidelines for 90-day sub-chronic oral studies. The procedure is detailed in the Reference.

The test substance was mixed with rat diet to give the required concentrations for the various groups.

In addition to (A), the test and control groups, there were three other pairs of groups. (B) was a high dose group which, after treatment for 90 days, was left for 28 days, after which the animals were examined to look for possible reversibility of effects. (C) was a high dose group treated for 90 days, after which tissues were analysed for their hydrocarbon content. (D) was a high dose group, treated for 90 days and left for 28 days, following which tissues were analysed for their hydrocarbon content.

Result: Significant effects were found in the lymph node, the liver and the mitral valves of the heart. The MESENTERIC LYMPH NODE, the LIVER and the SPLEEN showed SIGNIFICANTLY INCREASED WEIGHTS in animals treated at the highest dose.

HYSTIOCYTOSIS was present in the LYMPH NODE at all doses, with females showing the greater effect. In the LIVER, there were GRANULOMATOUS LESIONS at the two highest doses. In the HEART, an INFLAMMATORY REACTION was seen around the MITRAL VALVE in the highest dose animals, and in female animals it was also present at the second highest dose.

Other effects were a DECREASE IN RED BLOOD CELL COUNT for the females at the highest dose, and an INCREASE IN WHITE BLOOD CELL COUNT for females at the two highest doses. RAISED SERUM ENZYME LEVELS were found for male and female animals at the highest dose, and a DECREASE IN ALKALINE PHOSPHATASE at the highest dose.

Hydrocarbons were found by analysis in the liver, mesenteric lymph nodes and in the perirenal fat of group (C) animals treated at the highest dose, the material being particularly evident in the females.

There was no discernible difference in the toxicological effects, or in the hydrocarbon levels in tissues, in animals after a 28-day period without treatment.

Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA

Test substance: Low melting point hydrotreated paraffin wax, CAS no. 64742-51-4 (note: CAS no. was not assigned in original study).

(58)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: oral feed
Exposure period: 90 days
Frequency of treatment: daily
Post. obs. period: 28 days for reversibility studies in Groups B and D. See Remark: Doses.
Doses: See Remark: Doses for full details
Control Group: yes, concurrent no treatment
NOAEL: 1850 mg/kg bw
Method: other: see Remark: Method for full details
Year: **GLP:** yes
Test substance: other TS
Remark: Remark: Doses

Test group doses were as follows:

(A) four groups at 1.8, 18.5, 185 and 1850 mg/kg/day (each group consisting 20 male/20 female animals)
(B) one group at 1850 mg/kg/day (10 male/10 female)
(C) one group at 1850 mg/kg/day (5 male/5 female)
(D) one group at 1850 mg/kg/day (5 male/5 female)

There were four control groups, all concurrent, no treatment, corresponding to the treatment groups. The sizes

of these control groups were:

(A) 60 male/60 female
(B) 30 male/30 female
(C) 5 male/5 female
(D) 5 male/5 female
Remark: Method

The protocol was a compilation of the procedures outlined by the OECD, EEC and US FDA Guidelines for 90-day sub-chronic oral studies. The procedure is detailed in the Reference.

The test substance was mixed with rat diet to give the required concentrations for the various groups.

In addition to (A), the test and control groups, there were three other pairs of groups. (B) was a high dose group which, after treatment for 90 days, was left for 28 days, after which the animals were examined to look for possible reversibility of effects. (C) was a high dose group treated for 90 days, after which tissues were analysed for their hydrocarbon content. (D) was a high dose group, treated for 90 days and left for 28 days, following which tissues were analysed for their hydrocarbon content.

Result: NO SIGNIFICANT TREATMENT-RELATED EFFECTS were found with this test substance.

Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA

Test substance: High melting point hydrotreated microcrystalline wax, CAS no. 64742-60-5 (note: CAS no. was not assigned in original study).

(58)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: oral feed
Exposure period: 90 days
Frequency of treatment: daily
Post. obs. period: 28 days for reversibility studies in Groups B and D. See Remark: Doses.
Doses: See Remark: Doses for full details
Control Group: yes, concurrent no treatment
NOAEL: 1850 mg/kg bw
Method: other: see Remark: Method for full details
Year: **GLP:** yes
Test substance: other TS
Remark: Remark: Doses

Test group doses were as follows:

(A) four groups at 1.8, 18.5, 185 and 1850 mg/kg/day (each group consisting 20 male/20 female animals)
(B) one group at 1850 mg/kg/day (10 male/10 female)
(C) one group at 1850 mg/kg/day (5 male/5 female)

(D) one group at 1850 mg/kg/day (5 male/5 female)

There were four control groups, all concurrent, no treatment, corresponding to the treatment groups. The sizes of these control groups were:

(A) 60 male/60 female
(B) 30 male/30 female
(C) 5 male/5 female
(D) 5 male/5 female
Remark: Method

The protocol was a compilation of the procedures outlined by the OECD, EEC and US FDA Guidelines for 90-day sub-chronic oral studies. The procedure is detailed in the Reference.

The test substance was mixed with rat diet to give the required concentrations for the various groups.

In addition to (A), the test and control groups, there were three other pairs of groups. (B) was a high dose group which, after treatment for 90 days, was left for 28 days, after which the animals were examined to look for possible reversibility of effects. (C) was a high dose group treated for 90 days, after which tissues were analysed for their hydrocarbon content. (D) was a high dose group, treated for 90 days and left for 28 days, following which tissues were analysed for their hydrocarbon content.

Result: NO SIGNIFICANT TREATMENT-RELATED EFFECTS were found with this test substance.
Source: Bareco Products Rock Hill, SC 29730
Test substance: High sulphur clay-treated microcrystalline wax, CAS no. 64742-42-3 (note: CAS no. was not assigned in original study).

(58)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: oral feed
Exposure period: 90 days
Frequency of treatment: daily
Post. obs. period: 28 days for reversibility studies in Groups B and D. See Remark: Doses.
Doses: See Remark: Doses for full details
Control Group: yes, concurrent no treatment
NOAEL: 1850 mg/kg bw
Method: other: see Remark: Method for full details
Year: **GLP:** yes
Test substance: other TS
Remark: Remark: Doses

Test group doses were as follows:

(A) four groups at 1.8, 18.5, 185 and 1850 mg/kg/day (each group consisting 20 male/20 female animals)

(B) one group at 1850 mg/kg/day (10 male/10 female)
(C) one group at 1850 mg/kg/day (5 male/5 female)
(D) one group at 1850 mg/kg/day (5 male/5 female)

There were four control groups, all concurrent, no treatment, corresponding to the treatment groups. The sizes of these control groups were:

(A) 60 male/60 female
(B) 30 male/30 female
(C) 5 male/5 female
(D) 5 male/5 female
Remark: Method

The protocol was a compilation of the procedures outlined by the OECD, EEC and US FDA Guidelines for 90-day sub-chronic oral studies. The procedure is detailed in the Reference.

The test substance was mixed with rat diet to give the required concentrations for the various groups.

In addition to (A), the test and control groups, there were three other pairs of groups. (B) was a high dose group which, after treatment for 90 days, was left for 28 days, after which the animals were examined to look for possible reversibility of effects. (C) was a high dose group treated for 90 days, after which tissues were analysed for their hydrocarbon content. (D) was a high dose group, treated for 90 days and left for 28 days, following which tissues were analysed for their hydrocarbon content.

Result: NO SIGNIFICANT TREATMENT-RELATED EFFECTS were found with this test substance.

Source: WITCO BV Koog aan de Zaan

Test substance: High sulphur clay-treated microcrystalline wax, CAS no. 64742-42-3 (note: CAS no. was not assigned in original study).

(58)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: oral feed
Exposure period: 90 days
Frequency of treatment: daily
Post. obs. period: 28 days for reversibility studies in Groups B and D. See Remark: Doses.
Doses: See Remark: Doses for full details
Control Group: yes, concurrent no treatment
LOAEL: 1.8 mg/kg bw
Method: other: see Remark: Method for full details
Year: **GLP:** yes
Test substance: other TS
Remark: Remark: Doses

Test group doses were as follows:

(A) four groups at 1.8, 18.5, 185 and 1850 mg/kg/day (each group consisting 20 male/20 female animals)
(B) one group at 1850 mg/kg/day (10 male/10 female)
(C) one group at 1850 mg/kg/day (5 male/5 female)
(D) one group at 1850 mg/kg/day (5 male/5 female)

There were four control groups, all concurrent, no treatment, corresponding to the treatment groups. The sizes of these control groups were:

(A) 60 male/60 female
(B) 30 male/30 female
(C) 5 male/5 female
(D) 5 male/5 female
Remark: Method

The protocol was a compilation of the procedures outlined by the OECD, EEC and US FDA Guidelines for 90-day sub-chronic oral studies. The procedure is detailed in the Reference.

The test substance was mixed with rat diet to give the required concentrations for the various groups.

In addition to (A), the test and control groups, there were three other pairs of groups. (B) was a high dose group which, after treatment for 90 days, was left for 28 days, after which the animals were examined to look for possible reversibility of effects. (C) was a high dose group treated for 90 days, after which tissues were analysed for their hydrocarbon content. (D) was a high dose group, treated for 90 days and left for 28 days, following which tissues were analysed for their hydrocarbon content.

Result: Significant effects were found in the lymph node, the liver and the mitral valves of the heart. The MESENTERIC LYMPH NODE, the LIVER and the SPLEEN showed SIGNIFICANTLY INCREASED WEIGHTS in animals treated at the highest dose.

HYSTIOCYTOSIS was present in the LYMPH NODE at all doses, with females showing the greater effect. In the LIVER, there were GRANULOMATOUS LESIONS at the two highest doses. In the HEART, an INFLAMMATORY REACTION was seen around the MITRAL VALVE in the highest dose animals, and in female animals it was also present at the second highest dose.

Other effects were a DECREASE IN RED BLOOD CELL COUNT for the females at the highest dose, and an INCREASE IN WHITE BLOOD CELL COUNT for females at the two highest doses. RAISED SERUM ENZYME LEVELS were found for male and female animals at the highest dose, and a DECREASE IN ALKALINE PHOSPHATASE at the highest dose.

Hydrocarbons were found by analysis in the liver, mesenteric lymph nodes and in the perirenal fat of group (C) animals treated at the highest dose, the material being particularly evident in the females.

There was no discernible difference in the toxicological effects, or in the hydrocarbon levels in tissues, in animals after a 28-day period without treatment.

Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Low melting point hydrotreated paraffin wax, CAS no. 64742-51-4 (note: CAS no. was not assigned in original study).

(59)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: oral feed
Exposure period: 90 days
Frequency of treatment: daily
Post. obs. period: 28 days for reversibility studies in Groups B and D. See Remark: Doses.
Doses: See Remark: Doses for full details
Control Group: yes, concurrent no treatment
NOAEL: 1850 mg/kg bw
Method: other: see Remark: Method for full details
Year: **GLP:** yes
Test substance: other TS
Remark: Remark: Doses

Test group doses were as follows:

(A) four groups at 1.8, 18.5, 185 and 1850 mg/kg/day (each group consisting 20 male/20 female animals)
(B) one group at 1850 mg/kg/day (10 male/10 female)
(C) one group at 1850 mg/kg/day (5 male/5 female)
(D) one group at 1850 mg/kg/day (5 male/5 female)

There were four control groups, all concurrent, no treatment, corresponding to the treatment groups. The sizes of these control groups were:

(A) 60 male/60 female
(B) 30 male/30 female
(C) 5 male/5 female
(D) 5 male/5 female
Remark: Method

The protocol was a compilation of the procedures outlined by the OECD, EEC and US FDA Guidelines for 90-day sub-chronic oral studies. The procedure is detailed in the Reference.

The test substance was mixed with rat diet to give the required concentrations for the various groups.

In addition to (A), the test and control groups, there were three other pairs of groups. (B) was a high dose group which, after treatment for 90 days, was left for 28 days, after which the animals were examined to look for possible reversibility of effects. (C) was a high dose group treated for 90 days, after which tissues were analysed for their hydrocarbon content. (D) was a high dose group, treated for 90 days and left for 28 days, following which tissues were analysed for their hydrocarbon content.

Result: NO SIGNIFICANT TREATMENT-RELATED EFFECTS were found with this test substance.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: High melting point hydrotreated microcrystalline wax, CAS no. 64742-60-5 (note: CAS no. was not assigned in original study).

(59)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: oral feed
Exposure period: 90 days
Frequency of treatment: daily
Post. obs. period: 28 days for reversibility studies in Groups B and D. See Remark: Doses.
Doses: See Remark: Doses for full details
Control Group: yes, concurrent no treatment
NOAEL: 1850 mg/kg bw
Method: other: see Remark: Method for full details
Year: **GLP:** yes
Test substance: other TS
Remark: Remark: Doses

Test group doses were as follows:

(A) four groups at 1.8, 18.5, 185 and 1850 mg/kg/day (each group consisting 20 male/20 female animals)
(B) one group at 1850 mg/kg/day (10 male/10 female)
(C) one group at 1850 mg/kg/day (5 male/5 female)
(D) one group at 1850 mg/kg/day (5 male/5 female)

There were four control groups, all concurrent, no treatment, corresponding to the treatment groups. The sizes of these control groups were:

(A) 60 male/60 female
(B) 30 male/30 female
(C) 5 male/5 female
(D) 5 male/5 female
Remark: Method

The protocol was a compilation of the procedures outlined by the OECD, EEC and US FDA Guidelines for 90-day sub-chronic oral studies. The procedure is detailed in the Reference.

The test substance was mixed with rat diet to give the required concentrations for the various groups.

In addition to (A), the test and control groups, there were three other pairs of groups. (B) was a high dose group which, after treatment for 90 days, was left for 28 days, after which the animals were examined to look for possible reversibility of effects. (C) was a high dose group treated for 90 days, after which tissues were analysed for their hydrocarbon content. (D) was a high dose group, treated for 90 days and left for 28 days, following which tissues were analysed for their hydrocarbon content.

Result: NO SIGNIFICANT TREATMENT-RELATED EFFECTS were found with this test substance.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: High sulphur clay-treated microcrystalline wax, CAS no. 64742-42-3 (note: CAS no. was not assigned in original study).

(59)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: oral feed
Exposure period: 90 days
Frequency of treatment: daily
Post. obs. period: 28 days for reversibility studies in Groups B and D. See Remark: Doses.
Doses: See Remark: Doses for full details
Control Group: yes, concurrent no treatment
NOAEL: 1850 mg/kg bw
Method: other: see Remark: Method for full details
Year: **GLP:** yes
Test substance: other TS
Remark: Remark: Doses

Test group doses were as follows:

(A) four groups at 1.8, 18.5, 185 and 1850 mg/kg/day (each group consisting 20 male/20 female animals)

(B) one group at 1850 mg/kg/day (10 male/10 female)
(C) one group at 1850 mg/kg/day (5 male/5 female)
(D) one group at 1850 mg/kg/day (5 male/5 female)

There were four control groups, all concurrent, no treatment, corresponding to the treatment groups. The sizes of these control groups were:

(A) 60 male/60 female
(B) 30 male/30 female
(C) 5 male/5 female
(D) 5 male/5 female
Remark: Method

The protocol was a compilation of the procedures outlined by the OECD, EEC and US FDA Guidelines for 90-day sub-chronic oral studies. The procedure is detailed in the Reference.

The test substance was mixed with rat diet to give the required concentrations for the various groups.

In addition to (A), the test and control groups, there were three other pairs of groups. (B) was a high dose group which, after treatment for 90 days, was left for 28 days, after which the animals were examined to look for possible reversibility of effects. (C) was a high dose group treated for 90 days, after which tissues were analysed for their hydrocarbon content. (D) was a high dose group, treated for 90 days and left for 28 days, following which tissues were analysed for their hydrocarbon content.

Result: NO SIGNIFICANT TREATMENT-RELATED EFFECTS were found with this test substance.

Source: PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA

Test substance: High sulphur clay-treated microcrystalline wax, CAS no. 64742-42-3 (note: CAS no. was not assigned in original study).

(58)

5.5 Genetic Toxicity 'in Vitro'

-

5.6 Genetic Toxicity 'in Vivo'

-

5.7 Carcinogenicity

Species: mouse **Sex:** male/female
Strain: Swiss
Route of admin.: dermal
Exposure period: 2 years
Frequency of treatment: 3 times/week
Post. obs. period: no data
Doses: Test group: 0.05 ml of 15% test substance in benzene (60 male/30 female animals). Vehicle control group (60 male/30 female animals). Negative control group (140 male/140 female animals).
Result:
Control Group: yes, concurrent no treatment
Method: other: protocol is detailed in Reference
Year: **GLP:** no data
Test substance: other TS
Remark: This work was undertaken to determine the toxicological status of petroleum waxes as direct and indirect food additives.
Result: Dermal studies produced NO EVIDENCE OF CARCINOGENIC EFFECTS.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: Five petroleum waxes of varying aromatic hydrocarbon content were studied. The nature of the waxes is not stated, but from the properties it appears that two paraffinic and three microcrystalline waxes were evaluated.
(60)

Species: mouse **Sex:** male/female
Strain: Swiss
Route of admin.: dermal
Exposure period: 2 years
Frequency of treatment: 3 times/week
Post. obs. period: no data
Doses: Test group: 0.05 ml of 15% test substance in benzene (60 male/30 female animals). Vehicle control group (60 male/30 female animals). Negative control group (140 male/140 female animals).
Result:
Control Group: yes, concurrent no treatment
Method: other: protocol is detailed in Reference
Year: **GLP:** no data
Test substance: other TS
Remark: This work was undertaken to determine the toxicological status of petroleum waxes as direct and indirect food additives.
Result: Dermal studies produced NO EVIDENCE OF CARCINOGENIC EFFECTS.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Five petroleum waxes of varying aromatic hydrocarbon content were studied. The nature of the waxes is not stated, but from the properties it appears that two

paraffinic and three microcrystalline waxes were evaluated.
(61)

Species: rabbit **Sex:** male/female
Strain: other: New Zealand albino
Route of admin.: dermal
Exposure period: 4 years
Frequency of treatment: 3 times/week
Post. obs. period: no data
Doses: Test group: 0.08 ml of 15% test substance in benzene (4 male/4 female animals). Vehicle control group (4 male/4 female animals).
Result:
Control Group: yes, concurrent vehicle
Method: other: protocol is detailed in Reference
Year: **GLP:** no data
Test substance: other TS
Remark: This work was undertaken to determine the toxicological status of petroleum waxes as direct and indirect food additives.
Result: Dermal studies produced NO EVIDENCE OF CARCINOGENIC EFFECTS.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: Five petroleum waxes of varying aromatic hydrocarbon content were studied. The nature of the waxes is not stated, but from the properties it appears that two paraffinic and three microcrystalline waxes were evaluated.
(60)

Species: rabbit **Sex:** male/female
Strain: other: New Zealand albino
Route of admin.: dermal
Exposure period: 4 years
Frequency of treatment: 3 times/week
Post. obs. period: no data
Doses: Test group: 0.08 ml of 15% test substance in benzene (4 male/4 female animals). Vehicle control group (4 male/4 female animals).
Result:
Control Group: yes, concurrent vehicle
Method: other: protocol is detailed in Reference
Year: **GLP:** no data
Test substance: other TS
Remark: This work was undertaken to determine the toxicological status of petroleum waxes as direct and indirect food additives.
Result: Dermal studies produced NO EVIDENCE OF CARCINOGENIC EFFECTS.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Five petroleum waxes of varying aromatic hydrocarbon content were studied. The nature of the waxes is not stated, but from the properties it appears that two paraffinic and three microcrystalline waxes were evaluated.

(61)

Species: rat **Sex:** male/female
Strain: Sprague-Dawley
Route of admin.: oral feed
Exposure period: 2 years
Frequency of treatment: daily
Post. obs. period: no data
Doses: Test group: 5000 mg/kg/day (50 male/50 female animals). Negative control group (140 male/157 female animals).
Result:
Control Group: yes, concurrent no treatment
Method: other: protocol is detailed in the Reference
Year: **GLP:** no data
Test substance: other TS
Remark: This work was undertaken to determine the toxicological status of petroleum waxes as direct and indirect food additives. The test substance was "powdered" and added to the diet to give 10% concentration.
Result: Oral studies produced NO EVIDENCE OF CARCINOGENIC EFFECTS.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: Five petroleum waxes of varying aromatic hydrocarbon content were studied. The nature of the waxes is not stated, but from the properties it appears that two paraffinic and three microcrystalline waxes were evaluated.

(60)

Species: rat **Sex:** male/female
Strain: Sprague-Dawley
Route of admin.: oral feed
Exposure period: 2 years
Frequency of treatment: daily
Post. obs. period: no data
Doses: Test group: 5000 mg/kg/day (50 male/50 female animals). Negative control group (140 male/157 female animals).
Result:
Control Group: yes, concurrent no treatment
Method: other: protocol is detailed in the Reference
Year: **GLP:** no data
Test substance: other TS
Remark: This work was undertaken to determine the toxicological status of petroleum waxes as direct and indirect food additives. The test substance was "powdered" and added to the diet to give 10% concentration.
Result: Oral studies produced NO EVIDENCE OF CARCINOGENIC EFFECTS.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Five petroleum waxes of varying aromatic hydrocarbon content were studied. The nature of the waxes is not stated, but from the properties it appears that two paraffinic and three microcrystalline waxes were evaluated.

(61)

Species: mouse **Sex:** male/female
Strain: Sprague-Dawley
Route of admin.: s.c.
Exposure period: 2 years
Frequency of treatment: single subcutaneous implantation
Post. obs. period: 2 years
Doses: Test group: 0.5 g (50 male/45 female animals). Negative control group (140 male/140 female animals).
Result:
Control Group: yes, concurrent no treatment
Method: other: protocol is detailed in the Reference
Year: **GLP:** no data
Test substance: other TS
Remark: This work was undertaken to determine the toxicological status of petroleum waxes as direct and indirect food additives.
Result: IMPLANTATION STUDIES RESULTED IN SARCOMAS, but these are considered to be due to the physical rather than the chemical properties of the waxes.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
Test substance: Five petroleum waxes of varying aromatic hydrocarbon content were studied. The nature of the waxes is not stated, but from the properties it appears that two paraffinic and three microcrystalline waxes were evaluated.

(60)

Species: mouse **Sex:** male/female
Strain: Sprague-Dawley
Route of admin.: s.c.
Exposure period: 2 years
Frequency of treatment: single subcutaneous implantation
Post. obs. period: 2 years
Doses: Test group: 0.5 g (50 male/45 female animals). Negative control group (140 male/140 female animals).
Result:
Control Group: yes, concurrent no treatment
Method: other: protocol is detailed in the Reference
Year: **GLP:** no data
Test substance: other TS
Remark: This work was undertaken to determine the toxicological status of petroleum waxes as direct and indirect food additives.
Result: IMPLANTATION STUDIES RESULTED IN SARCOMAS, but these are considered to be due to the physical rather than the chemical properties of the waxes.
Source: REPSOL PETROLEO,S.A. MADRID
Test substance: Five petroleum waxes of varying aromatic hydrocarbon content were studied. The nature of the waxes is not stated, but from the properties it appears that two paraffinic and three microcrystalline waxes were evaluated.

(61)

Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Frequency of treatment:
Post. obs. period:
Doses:
Result:
Control Group:
Method:
Year: **GLP:**
Test substance:
Remark: Paraffin waxes, CAS No. 8002-74-2, are derived from slack waxes, CAS No. 64742-61-5, and the carcinogenicity of the latter has been studied by Kane et al. with completely negative results. This topic is addressed more fully in the Data Set for Group 11C.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA

(62)

Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Frequency of treatment:
Post. obs. period:
Doses:
Result:
Control Group:
Method:
Year: **GLP:**
Test substance:
Remark: Paraffin waxes, CAS No. 8002-74-2, are derived from slack waxes, CAS No. 64742-61-5, and the carcinogenicity of the latter has been studied by Kane et al. with completely negative results. This topic is addressed more fully in the Data Set for Group 11C.
Source: REPSOL PETROLEO,S.A. MADRID

(63)

5.8 Toxicity to Reproduction

-

5.9 Developmental Toxicity/Teratogenicity

-

5.10 Other Relevant Information

Type: other: bladder effects from paraffin wax implants
Remark: In a study reported by Chapman et al., pellets of paraffin wax were surgically implanted into the rat bladder. It was found that the presence of urine was necessary for tumour induction, and that the calculi growing around the pellets were the reason for the tumour-enhancing effect. It was suggested that the pellets may have a possible co-carcinogenic effect.

Similar studies by Ball et al., Bonser et al., Allen et al. and Podilchak have demonstrated that foreign bodies like paraffin wax and glass beads may lead by local irritation to tumours in the urinary bladders of rats and mice. Jull also studied the effects of paraffin wax implants as carriers of carcinogenic chemicals in the mouse bladder. It was concluded that although tumours may be produced by foreign bodies alone, the effect was not unique to paraffin wax.
Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA
(64) (65) (66) (67) (68) (69) (70)

Type: other: bladder effects from paraffin wax implants
Remark: In a study reported by Chapman et al., pellets of paraffin wax were surgically implanted into the rat bladder. It was found that the presence of urine was necessary for tumour induction, and that the calculi growing around the pellets were the reason for the tumour-enhancing effect. It was suggested that the pellets may have a possible co-carcinogenic effect.

Similar studies by Ball et al., Bonser et al., Allen et al. and Podilchak have demonstrated that foreign bodies like paraffin wax and glass beads may lead by local irritation to tumours in the urinary bladders of rats and mice. Jull also studied the effects of paraffin wax implants as carriers of carcinogenic chemicals in the mouse bladder. It was concluded that although tumours may be produced by foreign bodies alone, the effect was not unique to paraffin wax.
Source: REPSOL PETROLEO,S.A. MADRID
(64) (71) (72) (73) (74) (75) (70)

5.11 Experience with Human Exposure

Remark: A case is reported of a woman who developed breast cancer, about 40 years after receiving paraffin wax injections. The cancer was obscured by the overwhelming granulomatous resection produced by the paraffin wax. The author speculates that the paraffin wax may have been a causative agent in the development of the cancer. Current paraffin waxes that may be used for such treatments will be much more highly refined.

Source: Bareco Products Rock Hill, SC 29730
WITCO BV Koog aan de Zaan
PETROLEOS DE PORTUGAL - PETROGAL,S.A. LISBOA

(76)

Remark: A case is reported of a woman who developed breast cancer, about 40 years after receiving paraffin wax injections. The cancer was obscured by the overwhelming granulomatous resection produced by the paraffin wax. The author speculates that the paraffin wax may have been a causative agent in the development of the cancer. Current paraffin waxes that may be used for such treatments will be much more highly refined.

Source: REPSOL PETROLEO,S.A. MADRID

(77)

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Attachment III
Paraffin Substance
CAS#8002-74-2

(53 Pages)

1. General Info
2. Physico-Chemical Data
3. Fate and Pathways
4. Ecotoxicity
5. Toxicity
6. References

(Blue)

I U C L I D

D a t a s e t

Existing Chemical	Substance ID: 8002-74-2
CAS No.	8002-74-2
EINECS Name	Paraffin waxes and Hydrocarbon waxes
EINECS No.	232-315-6
Molecular Formula	<no data>
Substance Group	11A

Dataset created by: EUROPEAN COMMISSION - European Chemicals Bureau

This dossier is a compilation based on data reported by the European Chemicals Industry following 'Council Regulation (EEC) No. 793/93 on the Evaluation and Control of the Risks of Existing Substances'. All (non-confidential) information from the single datasets, submitted in the IUCLID/HEDSET format by individual companies, was integrated to create this document.

The data have not undergone any evaluation by the European Commission.

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7.1 Risk Assessment

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1.0.1 OECD and Company Information

Name: ADDINOL Mineralöl GmbH
Street: Hauptstraße 1
Town: 06242 Krumpa
Country: Germany
Phone: 034632/72259
Telefax: 034632/72115

Name: Agip Petroli SpA
Street: Laurentina 449
Town: 00142 ROMA
Country: Italy
Phone: +39-6-59881
Telefax: +39-6-59885700
Telex: 614031 I

Name: Astor Stag Ltd
Street: Huette 60
Town: B-4700 Eupen
Country: Belgium
Phone: 87 74 00 06
Telefax: 87 74 36 70
Telex: 49099

Name: Astor Stag Ltd
Street: Tavistock Road
Town: UB7 7RA West Drayton, Middlesex
Country: United Kingdom
Phone: 01895 445511
Telefax: 01895 449199
Telex: 28559

Name: Bang & Bonsomer Oy
Street: Itälahdenkatu 18 A
Town: 00210 HELSINKI
Country: Finland
Phone: +358-0-681081
Telefax: +358-0-6924174
Telex: 121439 BABO FI

Name: Bareco Products
Street: 148 East Main Street
Town: Rock Hill, SC 29730
Country: United States
Phone: 803/327-3663

Name: Clariant (Deutschland) GmbH
Street: Wiesentalstrasse 27
Town: 79540 Loerrach
Country: Germany

Name: Clariant GmbH
Town: 65926 Frankfurt am Main
Country: Germany

Name: CLARIANT PORTUGAL
Street: RUA DELFIM FERREIRA,760
Town: 4100 PORTO
Country: Portugal
Phone: 02-6176143
Telefax: 02-6178524

Name: Clariant UK Ltd.
Street: Calverley lane
Town: 25184RP Horsforth, Leeds
Country: United Kingdom

Name: CONCAWE
Street: Madouplein 1
Town: B-1210 Bruxelles
Country: Belgium

Name: DEA Mineraloel AG
Street: Überseering 40
Town: 22297 Hamburg
Country: Germany
Phone: 040/6375-0
Telefax: 040/6375-3496
Telex: 21151320 tx d

Name: Deutsche Sinochem GmbH
Street: Freidrich-Ebert-Damm 160 a
Town: 22047 Hamburg
Country: Germany
Phone: +49(40)694203-0
Telefax: +49(40)694203-90
Telex: 2161129

Name: Helm AG
Street: Nordkanalstrasse 28
Town: 20097 Hamburg
Country: Germany
Phone: +49402375-0
Telefax: +49402375-90
Telex: 2170150

Name: Henkel KGaA
Street: Henkelstr. 67
Town: 40589 Duesseldorf
Country: Germany

Name: Henkel KGaA
Street: Henkelstrasse 67
Town: 1100 Dusseldorf
Country: Germany
Cedex: D-40191

Name: Huels AG
Street: Postfach
Town: D-45764 Marl
Country: Germany

Name: Hydro Chemicals Norge
Street: Fyrstikkalleen 3B, P.O. Box 23 Haugenstua
Town: N-0604 OSLO
Country: Norway
Phone: 47 2243 2400
Telefax: 47 2243 2402
Telex: 71771 nchem n

Name: Krems Chemie Aktiengesellschaft
Street: Hafenstrasse 77
Town: A-3500 KREMS
Country: Austria
Phone: +43-2732-899/254
Telefax: +43-2732-899/302
Telex: 71121

Name: MB SVEDA AB
Street: Box 4072
Town: 203 11 Malmö
Country: Sweden
Phone: 0094640352800
Telefax: 0094640125172
Telex: 33188

Name: MOBIL OIL AUSTRIA AG
Street: Schwarzengergplatz 3
Town: A-1010 Vienna
Country: Austria
Phone: +43 (1) 71106-0
Telefax: +43 (1) 71106-12
Telex: 131822

Name: Mobil Oil Company Limited
Street: 54-60 Victoria Street
Town: SW1E 6QB London
Country: United Kingdom
Phone: 071 830 3000
Telefax: 071 830 3549

Name: Mobil Oil Francaise
Street: BP No. 2
Town: F-76330 Notre-Dame-de-Gravencon
Country: France
Phone: 33-235-394284
Telefax: 33-235-394065

Name: Morton International Limited
Street: 155-157 Staines Road
Town: MIDDX TW3 3 JB Hounslow
Country: United Kingdom

Name: PETROLEOS DE PORTUGAL - PETROGAL,S.A.
Street: RUA DAS FLORES 7
Town: 1200 LISBOA
Country: Portugal
Phone: 3474330
Telefax: 3102910
Telex: NO
Cedex: 2539

Name: REPSOL DERIVADOS S.A.
Street: ORENSE,34
Town: 28020 MADRID
Country: Spain
Phone: 34-1-348 78 00
Telefax: 34-1-555 77 79
Telex: 49775

Name: REPSOL DERIVADOS, S.A.
Street: ORENSE, 34
Town: 28020 MADRID
Country: Spain
Phone: 91- 3487800
Telefax: 91- 5557779
Telex: 49775

Name: REPSOL PETROLEO,S.A.
Street: PASEO DE LA CASTELLANA, 278-280
Town: 28046 MADRID
Country: Spain
Phone: 91-3488000
Telefax: 3489494/3142821
Telex: 49840

Name:	RÜTGERS VFT Handel GmbH
Street:	Varziner Straße 49
Town:	D-47138 Duisburg
Country:	Germany
Phone:	0049(0)203/4296-01
Telefax:	0049(0)203/4296-328

Name:	TOTAL RAFFINAGE DISTRIBUTION S.A.
Street:	51 Esplanade Charles de Gaulle
Town:	92907 Paris La Défense
Country:	France
Phone:	41 35 00 00
Telefax:	41 35 86 12
Telex:	615700
Cedex:	97

Name:	UniroyalChemical Company
Street:	Benson Road
Town:	06749 Middlebury, CT
Country:	United States
Phone:	203-573-3390
Telefax:	203-573-4531
Telex:	3106710383

Name:	Wintershall AG
Street:	Friedrich-Ebert -Str. 160
Town:	34119 Kassel
Country:	Germany
Phone:	(0561) 3011-059
Telefax:	(0561) 3011-702

1.0.2 Location of Production Site

Name of Plant:	Morton International S.A. - Plastics Additives, Europe
Street:	Le Pressoir Vert
Town:	45400 Semoy
Country:	France
Phone:	+33 (0) 2 38 61 81 00
Telefax:	+33 (0) 2 38 61 81 68

Source: Morton International Limited Hounslow

1.0.3 Identity of Recipients

-

1.1 General Substance Information

Substance type:	organic
Physical status:	solid
Source:	Henkel KGaA Duesseldorf

Substance type: organic
Physical status: solid

Substance type: petroleum product
Physical status: solid
Source: Henkel KGaA Duesseldorf

Substance type: petroleum product
Physical status: solid

1.1.1 Spectra

-

1.2 Synonyms

125F
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

140F
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

150F
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

155F
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

45A
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

45A (wax)
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

AC-P 629
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Advawax 165
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Arcowax 2143G
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Arcowax 4154G
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Arcowax 4158G
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Aristowax
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Aristowax 125
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Aristowax 143
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Aristowax 165
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Bareco 170/175
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Boler 1328
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Boler 1397
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Boler 1421
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Altafin 125
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

AmpliWax
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Anti-Chek
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Antilux 111
Source: Henkel KGaA Duesseldorf

Antilux 660
Source: Henkel KGaA Duesseldorf

Apiezon M
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Apiezon N
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Apiezon W
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Apiezonwachs
Source: Henkel KGaA Duesseldorf

Aqua Bead 325E
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Aquamol 1200
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Arcowax 1150G
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Boler 941
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Bondwax WE 70
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Ceratak
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Ceretal 165
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Chevron 143
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Chevron 159
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Chevron 4042
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Cosmoloid 80H
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Crolene LC
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Diaproof
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

DMW 6064
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

DMW 7074
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

DP 652
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Durowax FT 300
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

DW 5456
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

DW 5658
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Dyedit C 30
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Dyedit EK
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Dyedit S 8
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Ecco Wax 244
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

EM 046H
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

EM 048H
Source: Henkel KGaA Duesseldorf
Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

EM 061H
Source: Henkel KGaA Duesseldorf

Eskar R 25
Source: Henkel KGaA Duesseldorf

Eskar R 45
Source: Henkel KGaA Duesseldorf

Fischer-Tropsch Wax
Source: Henkel KGaA Duesseldorf

Fischer-Tropsch waxes
Source: Huels AG Marl

Glycolube TS
Source: Henkel KGaA Duesseldorf

Glycolube VL
Source: Henkel KGaA Duesseldorf

Hartparaffin, Paraffinwachs
Source: DEA Mineraloel AG Hamburg

Hoechstwachs R21
Source: Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Hydrocarbon waxes
Source: Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Hydrocarbons >C20
Source: Mobil Oil Company Limited London

Isoparaffin (C10-13)
Source: Henkel KGaA Duesseldorf

Microfine 2
Source: Henkel KGaA Duesseldorf

Micropoly 2001
Source: Henkel KGaA Duesseldorf

Paraffin
Source: Henkel KGaA Duesseldorf

Paraffin (INCI)
Source: Henkel KGaA Duesseldorf

paraffin , synthetic
Source: Henkel KGaA Duesseldorf

paraffin , synthetic (INN)
Source: Henkel KGaA Duesseldorf

Paraffin wax
Source: Morton International Limited Hounslow

Paraffin wax, fume
Source: Henkel KGaA Duesseldorf

Paraffin waxes
Source: Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

Paraffin waxes and Hydrocarbon waxes
Source: Henkel KGaA Duesseldorf

Paraffine
Source: Henkel KGaA Duesseldorf

paraffine brute
Source: TOTAL RAFFINAGE DISTRIBUTION S.A. Paris La Défense

Paraffinwachs
Source: RÜTGERS VFT Handel GmbH Duisburg

Paraffinwachs und Kohlenwasserstoffwachs
Source: Henkel KGaA Duesseldorf

Parrafin Wax
Source: Henkel KGaA Duesseldorf

Petroleum wax
Source: MOBIL OIL AUSTRIA AG Vienna

Petroleum Wax
Source: Henkel KGaA Duesseldorf

PFH/PWH (Refined paraffin waxes from heavy vacuum distillate)
Source: REPSOL DERIVADOS, S.A. MADRID
REPSOL PETROLEO,S.A. MADRID
REPSOL DERIVADOS S.A. MADRID

PFL (Refined paraffin wax from light vacuum distillate)
Source: REPSOL DERIVADOS, S.A. MADRID
REPSOL PETROLEO,S.A. MADRID
REPSOL DERIVADOS S.A. MADRID

PFM/PWM (Refined paraffin waxes from medium vacuum distillate)
Source: REPSOL DERIVADOS, S.A. MADRID
REPSOL PETROLEO,S.A. MADRID
REPSOL DERIVADOS S.A. MADRID

PFS (Refined paraffin wax from spindle vacuum distillate)
Source: REPSOL DERIVADOS, S.A. MADRID
REPSOL PETROLEO,S.A. MADRID
REPSOL DERIVADOS S.A. MADRID

PRCE (Refinery paraffin wax from vacuum distillate CE)
Source: REPSOL DERIVADOS, S.A. MADRID
REPSOL PETROLEO,S.A. MADRID
REPSOL DERIVADOS S.A. MADRID

Press-Aid
Source: Henkel KGaA Duesseldorf

Press-Aid SP
Source: Henkel KGaA Duesseldorf

Press-Aid XF
Source: Henkel KGaA Duesseldorf

PRH (Refinery paraffin wax from heavy vacuum distillate)
Source: REPSOL DERIVADOS, S.A. MADRID
REPSOL DERIVADOS S.A. MADRID

PRH/395D (Refinery paraffin wax from heavy vacuum distillate)
Source: REPSOL PETROLEO,S.A. MADRID

PRL (Refinery paraffin wax from light vacuum distillate)
Source: REPSOL DERIVADOS, S.A. MADRID
REPSOL PETROLEO,S.A. MADRID
REPSOL DERIVADOS S.A. MADRID

PRM (Refinery paraffin wax from medium vacuum distillate)
Source: REPSOL DERIVADOS, S.A. MADRID
REPSOL DERIVADOS S.A. MADRID

PRM/295D (Refinery paraffin wax from medium vacuum distillate)
Source: REPSOL PETROLEO,S.A. MADRID

PRS (Refinery paraffin wax from spindle vacuum distillate)
Source: REPSOL DERIVADOS, S.A. MADRID
REPSOL DERIVADOS S.A. MADRID

PRS/1st (Refinery paraffin wax from spindle vacuum distillate)
Source: REPSOL PETROLEO,S.A. MADRID

PT-0602
Source: Henkel KGaA Duesseldorf

Ross Wax #100
Source: Henkel KGaA Duesseldorf

Sunproof 202
Source: UniroyalChemical Company Middlebury, CT

Sunproof Extra
Source: UniroyalChemical Company Middlebury, CT

Sunproof Improved
Source: UniroyalChemical Company Middlebury, CT

Sunproof Junior
Source: UniroyalChemical Company Middlebury, CT

Sunproof Regular
Source: UniroyalChemical Company Middlebury, CT

Sunproof Super
Source: UniroyalChemical Company Middlebury, CT

Synthetic Wax
Source: Henkel KGaA Duesseldorf

Synthetic wax (INCI)
Source: Henkel KGaA Duesseldorf

Synwax
Source: Henkel KGaA Duesseldorf

Uniwax AW-1060
Source: Henkel KGaA Duesseldorf

Vesto-Wax A-217
Source: Henkel KGaA Duesseldorf

Vesto-Wax A-227
Source: Henkel KGaA Duesseldorf

Vesto-Wax A-235
Source: Henkel KGaA Duesseldorf

Vesto-Wax A-415
Source: Henkel KGaA Duesseldorf

Vesto-Wax A-616
Source: Henkel KGaA Duesseldorf

Vesto-Wax AO-1539
Source: Henkel KGaA Duesseldorf

Vesto-Wax AO-1699
Source: Henkel KGaA Duesseldorf

Vesto-Wax FT-150
Source: Henkel KGaA Duesseldorf

Vesto-Wax FT-150P
Source: Henkel KGaA Duesseldorf

Vesto-Wax FT-200
Source: Henkel KGaA Duesseldorf

Vesto-Wax FT-300
Source: Henkel KGaA Duesseldorf

Vestofine A-616 SF
Source: Henkel KGaA Duesseldorf

Vybar 103
Source: Henkel KGaA Duesseldorf

Vybar 260
Source: Henkel KGaA Duesseldorf

Vybar 825
Source: Henkel KGaA Duesseldorf

Wachse
Source: Henkel KGaA Duesseldorf

1.3 Impurities

-

1.4 Additives

-

1.5 Quantity

Quantity 500 000 - 1 000 000 tonnes

1.6.1 Labelling

-

1.6.2 Classification

-

1.7 Use Pattern

Type: type
Category: Non dispersive use
Source: Henkel KGaA Duesseldorf

Type: type
Category: Non dispersive use

Type: type
Category: Use in closed system
Source: Henkel KGaA Duesseldorf

Type: type
Category: Use in closed system

Type: type
Category: Use resulting in inclusion into or onto matrix
Source: Henkel KGaA Duesseldorf

Type: type
Category: Use resulting in inclusion into or onto matrix

Type: type
Category: Wide dispersive use
Source: Henkel KGaA Duesseldorf

Type: type
Category: Wide dispersive use

Type: industrial
Category: Chemical industry: used in synthesis
Source: Henkel KGaA Duesseldorf

Type: industrial
Category: Chemical industry: used in synthesis

Type: industrial
Category: Fuel industry
Source: Henkel KGaA Duesseldorf

Type: industrial
Category: Fuel industry

Type: industrial
Category: Paints, lacquers and varnishes industry
Source: Henkel KGaA Duesseldorf

Type: industrial
Category: Paints, lacquers and varnishes industry

Type: industrial
Category: Paper, pulp and board industry
Source: Henkel KGaA Duesseldorf

Type: industrial
Category: Paper, pulp and board industry

Type: industrial
Category: Personal and domestic use
Source: Henkel KGaA Duesseldorf

Type: industrial
Category: Personal and domestic use

Type: industrial
Category: Polymers industry
Source: Henkel KGaA Duesseldorf

Type: industrial
Category: Polymers industry

Type: industrial
Category: Public domain
Source: Henkel KGaA Duesseldorf

Type: industrial
Category: Public domain

Type: industrial
Category: Textile processing industry
Source: Henkel KGaA Duesseldorf

Type: industrial
Category: Textile processing industry

Type: industrial
Category: other: Automobilindustrie

Type: industrial
Category: other: Candle production

Type: industrial
Category: other: Woodworking
Source: Henkel KGaA Duesseldorf

Type: industrial
Category: other: Woodworking

Type: industrial
Category:

Type: industrial
Category: other

Type: use
Category: Adhesive, binding agents
Source: Henkel KGaA Duesseldorf

Type: use
Category: Adhesive, binding agents

Type: use
Category: Construction materials additives
Source: Henkel KGaA Duesseldorf

Type: use
Category: Construction materials additives

Type: use
Category: Cosmetics
Source: Henkel KGaA Duesseldorf

Type: use
Category: Cosmetics

Type: use
Category: Fillers

Type: use
Category: Food/foodstuff additives
Source: Henkel KGaA Duesseldorf

Type: use
Category: Food/foodstuff additives

Type: use
Category: Impregnation agents
Source: Henkel KGaA Duesseldorf

Type: use
Category: Impregnation agents

Type: use
Category: Intermediates
Source: Henkel KGaA Duesseldorf

Type: use
Category: Intermediates

Type: use
Category: Lubricants and additives
Source: Henkel KGaA Duesseldorf

Type: use
Category: Lubricants and additives

Type: use
Category: Softeners

Type: use
Category: other: Einsatzstoff für Weiterverarbeitung (Raffination)
Source: Henkel KGaA Duesseldorf

Type: use
Category: other: Einsatzstoff für Weiterverarbeitung (Raffination)

Type: use
Category: other: Gleitmittel

Type: use
Category: other: Lackkonservierung für Neuwagen

Type: use
Category: other: Woodworking
Source: Henkel KGaA Duesseldorf

Type: use
Category: other: Woodworking

Type: use
Category: other: insulating, impregnating materials and candle industry.
Source: Henkel KGaA Duesseldorf

Type: use
Category: other: insulating, impregnating materials and candle industry.

Type: use
Category: other

1.7.1 Technology Production/Use

Type: Production

Source: Morton International Limited Hounslow

1.8 Occupational Exposure Limit Values

Type of limit: MAK (DE)
Limit value:
Remark: nicht genannt
Source: MOBIL OIL AUSTRIA AG Vienna

Type of limit: MAK (DE)
Limit value:
Country: Germany
Remark: MAK value not established
Source: Huels AG Marl

(1)

Type of limit: OES (UK)
Limit value: 2 mg/m3
Short term expos.
Limit value: 6 mg/m3
Schedule: 10 minute(s)
Remark: OES is for wax fume
Source: Mobil Oil Company Limited London

Type of limit: TLV (US)
Limit value: 2 mg/m3
Remark: ATMOSPHERE CONTROL MEASURES: The product is solid at room temperature and it does not present potential exposure risk.
HANDLING AND STORAGE: Stored in form of pearls in containers properly labelled and sealed. Avoid contact with melted product.
The value is for paraffin fumes CAS n° 8002-74-2
USE OF PERSONAL PROTECTIVE EQUIPMENT:
Respiratory protection: protective mask in presence of hot vapours.
Skin protection: gloves when handling melted product.
Eye protection: Safety gogles when handling the liquid product.
Source: REPSOL DERIVADOS, S.A. MADRID
REPSOL PETROLEO,S.A. MADRID

Type of limit: TLV (US)
Limit value: 2 mg/m3
Remark: ATMOSPHERE CONTROL MEASURES: The product is solid at room temperature and it does not present potential exposure risk. HANDLING AND STORAGE: Stored in form of pearls in containersproperly labelled and sealed. Avoid contact with melted product.
The value is for paraffin fumes CAS n° 8002-74-2
USE OF PERSONAL PROTECTIVE EQUIPMENT:
Respiratory protection: protective mask in presence of hot vapours.
Skin protection: gloves when handling melted product.
Eye protection: Safety gogles when handling the liquid product.
Source: REPSOL DERIVADOS S.A. MADRID

Type of limit: other
Limit value: 2 mg/m3
Short term expos.
Limit value: 6 mg/m3
Remark: NIOSH recommended exposure limits (RELs): TWA 2mg/m3 (fume). OSHA permissible exposure limits (PELs): none.
REF: NIOSH Pocket Guide.
Type of limit: OEL (CEE)-TWA;(given for the paraffin fume).
Source: RTECS (Registry of Toxic Effects of Chemical Substances). Clariant UK Ltd. Horsforth, Leeds
RTECS (Registry of Toxic Effects of Chemical Substances). Clariant (Deutschland) GmbH Loerrach

Type of limit: other
Limit value:
Remark: no limit value
Source: RÜTGERS VFT Handel GmbH Duisburg

1.9 Source of Exposure

Memo: Emissionserklaerung Huels 1992
Remark: Release into the atmosphere on production site in 1992: less than 25 kg/a
Source: Huels AG Marl

(2)

Source: UniroyalChemical Company Middlebury, CT

Remark: Utilizzato in sistemi chiusi: esposizione possibile durante il campionamento.
Source: Agip Petroli SpA ROMA

Remark: nicht genannt
Source: MOBIL OIL AUSTRIA AG Vienna

Remark: a) The streams are obtained as the insoluble phase from the solvent treatment of atmospheric and vacuum distillates or vacuum residues.

b) One manufacturing site for Mobil Oil Company Limited in the United Kingdom.

c) Production process is a closed system and is only open during sampling and maintenance.
Source: Mobil Oil Company Limited London

Remark: Sehr geringe Expositionsgefahr
Source: DEA Mineraloel AG Hamburg

Remark: no data available due to imported and trading product
Source: RÜTGERS VFT Handel GmbH Duisburg

1.10.1 Recommendations/Precautionary Measures

-

1.10.2 Emergency Measures

-

1.11 Packaging

-

1.12 Possib. of Rendering Subst. Harmless

-

1.13 Statements Concerning Waste

-

1.14.1 Water Pollution

Classified by: KBwS (DE)
Labelled by: KBwS (DE)
Class of danger: 0 (generally not water polluting)
Country: Germany
Remark: No. 766 in catalogue
Source: Huels AG Marl

(1)

Classified by: other: Wassergefährdungsklasse (WGK)
Labelled by:
Class of danger: 0 (generally not water polluting)
Remark: Selbsteinstufung
Source: Hoechst AG Frankfurt/Main
Clariant GmbH Frankfurt am Main

(3)

Classified by:
Labelled by:
Class of danger: 0 (generally not water polluting)
Source: UniroyalChemical Company Middlebury, CT

1.14.2 Major Accident Hazards

Legislation: Stoerfallverordnung (DE)
Substance listed: no
Country: Germany
Remark: Stoerfallverordnung 1991
Source: Huels AG Marl

(1)

1.14.3 Air Pollution

-

1.15 Additional Remarks

Remark: ELIMINATION DECHETS: craquage catalytique
recyclage distillation sous vide
TRANSPORT: pipe
Source: TOTAL RAFFINAGE DISTRIBUTION S.A. Paris La Défense

Remark: DISPOSAL OPTIONS: Specific prepared and controlled areas and incineration.
TRANSPORT INFORMATION: Stable during transport.
Source: REPSOL DERIVADOS, S.A. MADRID

Remark: DISPOSAL OPTIONS: Specific prepared and controlled areas and incineration.
TRANSPORT INFORMATION: no data
Source: REPSOL PETROLEO,S.A. MADRID

Remark: DISPOSAL OPTIONS: Specific prepared and controlled areas andincineration.
TRANSPORT INFORMATION: Stable during transport.
Source: REPSOL DERIVADOS S.A. MADRID

Remark: TRANSPORT INFORMATION

IMO: Not regulated

IATA: Not regulated
WASTE DISPOSAL
Product is suitable for burning in an enclosed, controlled burner for fuel value or disposal by supervised incineration.
Source: Mobil Oil Company Limited London

Remark: Entsorgung: z.B. Verwertung als Brennstoff
Source: DEA Mineraloel AG Hamburg

Remark: no data available due to imported and trading product
Source: RÜTGERS VFT Handel GmbH Duisburg

1.16 Last Literature Search

-

1.17 Reviews

-

1.18 Listings e.g. Chemical Inventories

-

2.1 Melting Point

Value: 45 - 95 degree C
Decomposition: no
Sublimation: no
Method: other: ASTM D87, D938 and D127
GLP: no data
Source: CONCAWE Bruxelles

(4) (5)

2.2 Boiling Point

-

2.3 Density

Type: density
Value: .73 - .84 g/cm3 at 100 degree C
Method: other: ASTM D1298
GLP: no data
Source: CONCAWE Bruxelles

(4) (6) (5)

2.3.1 Granulometry

-

2.4 Vapour Pressure

-

2.5 Partition Coefficient

log Pow: > 6
Method: other (calculated)
Year:
Remark: The calculation was done by the CLOGP Version 3.5 program (Calculation of LOG Partition coefficient octanol/water).

As an example, the calculated value for eicosane (n-C20H42) is 11.3. However, such values are notional, since no correlation has been established between calculated and experimental values for Log Pow values greater than 6.

Source: CONCAWE Bruxelles

(7)

2.6.1 Water Solubility

-

2.6.2 Surface Tension

-

2.7 Flash Point

Value: > 215 degree C
Type: open cup
Method: other: ASTM D92
Year:
GLP: no data
Remark: Values range from 215 to 296 degree C.
Source: CONCAWE Bruxelles

(4) (5)

2.8 Auto Flammability

-

2.9 Flammability

-

2.10 Explosive Properties

-

2.11 Oxidizing Properties

-

2.12 Additional Remarks

Remark: Viscosity ranges from 3 to 30 mm2/sec at 100 Deg C by test method ASTM D445.
Source: CONCAWE Bruxelles

(4) (5)

Remark: Refractive index ranges from 1.149 to 1.448 at 100 Deg C by test method ASTM D1747.
Source: CONCAWE Bruxelles

(4) (5)

Remark: Petroleum waxes are rarely characterised in terms of boiling range and autoflammability. They are very involatile
materials, almost totally insoluble in water and do not contain any oxidizing constituents.

Petroleum waxes consist of high molecular weight alkanes and cycloalkanes. There are three classifications viz, paraffin, intermediate and microcrystalline waxes. All are obtained from petroleum fractions by either solvent crystallization, solvent de-oiling or by a sweating process. Paraffin waxes typically contain C20 - C50 n-alkanes
with smaller quantities of iso-alkanes. They form visible crystalline structures, and are also known as macrocrystalline waxes.

Intermediate waxes typically contain C20 - C60 alkanes and are intermediate between paraffin and microcrystalline waxes.

Microcrystalline waxes typically contain C25 - C85 alkanes and although they contain very small crystals, much of the material is amorphous.

Compositional information on food-grade petroleum waxes is contained in a CONCAWE report (see Reference).

Source: CONCAWE Bruxelles

(8)

Remark: The technical information contained in Chapters 2 to 5 of this Data Set has been compiled by the Oil Companies' European Organization for Environmental and Health Protection, CONCAWE, based at Madouplein-1, B-1210 Brussel, Belgium, and this organization holds copies of the reference articles cited in this Data Set.

Source: CONCAWE Bruxelles

3.1.1 Photodegradation

Type: air
Light source: Sun light
Conc. of subst.: at 25 degree C
INDIRECT PHOTOLYSIS
Sensitizer: OH
Conc. of sens.: 1000000 molecule/cm3
Method: other (calculated): according to Atkinson, 1990.
Year: **GLP:**
Test substance: other TS
Remark: Most hydrocarbon components of the substances in this Group will have little or no tendency to partition to air (see Sub-chapter 3.3.2). The half lives for degradation of these hydrocarbons by reaction with hydroxyl radicals, in the troposphere, under the influence of sunlight, will all be less than one day, by extrapolation from the data quoted by Atkinson. Accordingly, any hydrocarbon material which does partition to air will be rapidly photodegraded.
Source: CONCAWE Bruxelles
Test substance: Alkanes (>C12) found in paraffin waxes.

(9)

3.1.2 Stability in Water

Type:
Method:
Year: **GLP:**
Test substance:
Remark: Hydrocarbons present in paraffin waxes are not susceptible to hydrolysis under environmental conditions.
Source: CONCAWE Bruxelles

(10)

3.1.3 Stability in Soil

Type: field trial **Radiolabel:** no
Concentration:
Soil classif.: other: Woodland park origin **Year:**
Content of clay: = 23 %
silt: = 32 %
sand: = 58 %
Organ. carbon: = 6.9 %
pH: = 7.3
Cation exch. capac.
Microbial biomass:
Method: other: litter bag test, protocol described in paper by de Kreuk
Year: 1988 **GLP:** yes
Test substance: other TS
Method: Samples were all applied to paper, enclosed in nylon mesh bags, placed in woodland soil and covered in leaf litter. Tests were done using mesh sizes of 5 mm and 45 um for two six-month periods, viz. spring/summer and autumn/winter. Degradation was judged visually, by weighing and by gas chromatographic analysis.
Result: Microcrystalline waxes were degraded by about 20% in all tests. Paraffin and intermediate waxes in 5 mm bags were 100% degraded in six months in spring/summer and 100% degraded in three months in autumn/winter. Paraffin and intermediate waxes in 45 um bags were approximately 75% degraded in each six-month period.

The study concluded that waxes are initially attacked by soil microfauna and are mainly degraded by soil microflora.
Source: CONCAWE Bruxelles
Test substance: Two paraffin waxes, CAS no. 8002-74-2; an intermediate wax,CAS no. 97489-05-9; and a microcrystalline wax, CAS no. 63231-60-7 (note: CAS nos. were not assigned in the original study).

(11) (12)

3.2 Monitoring Data (Environment)

-

3.3.1 Transport between Environmental Compartments

-

3.3.2 Distribution

Media: air - biota - sediment(s) - soil - water
Method: Calculation according Mackay, Level I
Year: 1981
Remark: Distribution has been calculated according to Mackay Level Iusing the parameters defined in a paper by van der Zandt andvan Leeuwen.

Any lower molecular weight alkanes will mainly partition to air, but the majority of the hydrocarbon constituents of paraffin waxes will distribute to soil and sediment.
Result: Results for typical hydrocarbons found in paraffin waxes are shown in tabular form as follows:

	air %	water %	soil %	sediment %	susp. matter %	biota %
n-tetradecane	76.7	0.0	22.8	0.5	0.0	0.0
n-eicosane	0.0	0.0	97.7	2.2	0.1	0.0

Source: CONCAWE Bruxelles

(13) (14)

3.4 Mode of Degradation in Actual Use

-

3.5 Biodegradation

Type: aerobic
Inoculum: other: oil-polluted soil (adapted)
Concentration: 20 mg/l related to Test substance
Degradation: = 21 % after 28 day
Result: other: only partially degraded
Method: OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO2 evolution)"
Year: 1981 **GLP:** no data
Test substance: other TS
Remark: In these tests samples were exposed on glass fibre filters. Adapted micro-organisms were used.
Result: An 84-day study gave a biodegradability of 25%. Partially degraded hydrocarbons were identified from microcrystalline waxes by gas chromatographic analysis.
Source: CONCAWE Bruxelles
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note CAS no. was not assigned in original study).

(15)

Type: aerobic
Inoculum: other: oil-polluted soil (adapted)
Concentration: 20 mg/l related to Test substance
Degradation: = 66 % after 28 day
Result: inherently biodegradable
Method: OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO2 evolution)"
Year: 1981 **GLP:** no data
Test substance: other TS
Remark: In these tests samples were exposed on glass fibre filters. Adapted micro-organisms were used.
Result: An 84-day study gave a biodegradability of 77%.
Source: CONCAWE Bruxelles
Test substance: Intermediate wax, CAS no. 97489-05-9 (note: CAS no. was notassigned in original study).

(15)

Type: aerobic
Inoculum: other: oil-polluted soil (adapted)
Concentration: 20 mg/l related to Test substance
Degradation: 78 - 84 % after 28 day
Result: inherently biodegradable
Method: OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO2 evolution)"
Year: 1981 **GLP:** no data
Test substance: other TS
Remark: In these tests samples were exposed on glass fibre filters. Adapted micro-organisms were used.
Result: Two 84-day studies gave biodegradabilities of 85% and 89%.
Source: CONCAWE Bruxelles
Test substance: Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(15)

3.6 BOD5, COD or BOD5/COD Ratio

-

3.7 Bioaccumulation

-

3.8 Additional Remarks

-

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

-

4.2 Acute Toxicity to Aquatic Invertebrates

-

4.3 Toxicity to Aquatic Plants e.g. Algae

-

4.4 Toxicity to Microorganisms e.g. Bacteria

-

4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish

-

4.5.2 Chronic Toxicity to Aquatic Invertebrates

-

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Soil Dwelling Organisms

-

4.6.2 Toxicity to Terrestrial Plants

-

4.6.3 Toxicity to other Non–Mamm. Terrestrial Species

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4.7 Biological Effects Monitoring

-

4.8 Biotransformation and Kinetics

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4.9 Additional Remarks

Remark: No ecotoxicity studies have been done on substances in this Group. However, work by Adema and van den Bos Bakker on theecotoxicity of alkanes to Daphnia magna, Chaetogammarus marinus and Mysidopsis bahia has shown that alkanes of carbon number greater than C10 are not acutely toxic to these species at their limit of solubility in water. Since paraffin waxes are largely composed of straight-chain alkanes of carbon number greater than C12, they will not be acutely toxic to aquatic invertebrates.

Source: CONCAWE Bruxelles

(16)

5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

Type: LD50
Species: rat
Sex: no data
Number of Animals: 5
Vehicle: no data
Value: > 5000 mg/kg bw
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Method: A limit test at one dose level was conducted on 5 animals. Administration was by gavage.
Source: CONCAWE Bruxelles
Test substance: Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(17) (18)

Type: LD50
Species: rat
Sex: no data
Number of Animals:
Vehicle: other: corn oil
Value: > 3750 mg/kg bw
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Method: A limit test was done in which the test substance was administered by gavage to rats as a 75% dispersion in corn oil.
Source: CONCAWE Bruxelles
Test substance: Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(19) (18)

Type: LD50
Species: rat
Sex: no data
Number of Animals: 25
Vehicle: T52-003:corn oil
Value: = 10000 mg/kg bw
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Method: Five groups, each of 5 rats, were given single doses of 0.464, 1.0, 2.15, 4.64 and 10.0 g/kg of the test substance as a 20% suspension in corn oil. Administration was by gavage. Animals were observed over 14 days.
Result: Effects were only found at the highest dose, where three of the animals died. These exhibited bloody discharges from the mouth and nose, excessive salivation, loss of righting reflex and diarrhoea. At necropsy, findings included

congestion of
lungs and kidneys, hyperemia of large and small intestines and solid wax in the stomach.

It was concluded that the LD50 was about 10 g/kg.

Source: CONCAWE Bruxelles

Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. wasnot assigned in original study).

(20) (18)

5.1.2 Acute Inhalation Toxicity

-

5.1.3 Acute Dermal Toxicity

Type: LD50
Species: rabbit
Sex:
Number of Animals:
Vehicle:
Value: > 3600 mg/kg bw
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Method: A limit test was done at a single dose level of 4 ml/kg on an unknown number of animals. A closed patch was applied for 24 hours. At necropsy, no abnormalities or systemic effects were noted.
Source: CONCAWE Bruxelles
Test substance: A 50/50 blend of paraffin wax, CAS no. 8002-74-2 and petrolatum (note: CAS no. was not assigned in original study).

(21) (18)

5.1.4 Acute Toxicity, other Routes

-

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

Species: rabbit
Concentration: undiluted

Exposure: Occlusive
Exposure Time: 24 hour(s)
Number of Animals: 9
PDII:
Result: not irritating
EC classificat.: not irritating
Method: other: modification of Draize-Test
Year: **GLP:** no data
Test substance: other TS
Method: Nine animals were treated for 24 hours, applying 3 x 0.5 ml of test substance to the clipped intact skin and covering with a closed patch. Scoring was done according to the Draize scale. There was no irritation.
Source: CONCAWE Bruxelles
Test substance: Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(22) (18)

Species: rabbit
Concentration: 50 %

Exposure: Open
Exposure Time: 24 hour(s)
Number of Animals: 6
PDII:
Result: slightly irritating
EC classificat.: not irritating
Method: other: modification of Draize-Test
Year: **GLP:** no data
Test substance: other TS
Method: Six animals were treated for 24 hours, applying 3 x 0.5 ml of test substance to the clipped intact skin and covering with an open patch. After patch removal the treatment area was observed and scored according to the Draize scale. Three samples of the test substance were evaluated in this way.
Result: Scores are not available, but 2 samples produced erythema in 4 animals, the effect persisting for 3 days. The third sample produced erythema in a single animal, and this persisted for 2 days.
Source: CONCAWE Bruxelles
Test substance: A 50/50 blend of paraffin wax, CAS no. 8002-74-2 and petrolatum (note: CAS no. was not assigned in original study).

(19) (23) (18)

Species: rabbit
Concentration: no data

Exposure: no data
Exposure Time: 24 hour(s)
Number of Animals: 6
PDII: .42
Result: slightly irritating
EC classificat.: not irritating
Method: other: modification of Draize-Test
Year: **GLP:** no data
Test substance: other TS
Method: Six rabbits were treated with 0.5 ml of test substance, which was applied on both intact and abraded skin for 24 hours. The treatment sites were observed over the following 72 hours and scored according to the Draize scale.
Result: Slight erythema and slight oedema were observed, with a primary irritation index of 0.42 out of a maximum score of 8.0.
Source: CONCAWE Bruxelles
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. wasnot assigned in original study).

(24) (18)

Species: human
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.: not irritating
Method: other: protocol not available
Year: **GLP:** no data
Test substance: other TS
Method: The test substance was applied under occlusion to the forearm or upper back for 24 hours to a panel of 20 subjects. After removal, scores were taken immediately and at intervals over the following 96 hours. Two samples were tested in this way.
Result: The first caused barely perceptible erythema in one person, all the others being negative. The second produced uniform erythema in one of the 20 subjects, all the others being negative.
Source: CONCAWE Bruxelles
Test substance: Paraffin wax, CAS no. 8002-74-2 (note: CAS no. was not assigned in original study).

(25) (26) (18)

Species:	human
Concentration:	
Exposure:	
Exposure Time:	
Number of Animals:	
PDII:	
Result:	not irritating
EC classificat.:	not irritating
Method:	other: protocol not available
Year:	**GLP:** no data
Test substance:	other TS
Remark:	The test substance was applied for 21 days under occlusive conditions to a panel of 8 subjects. None of the subjects exhibited any signs of skin irritancy.
Source:	CONCAWE Bruxelles
Test substance:	Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. wasnot assigned in original study).

(27) (18)

5.2.2 Eye Irritation

Species:	rabbit	
Concentration:	50	%
Dose:	.1	ml
Exposure Time:		
Comment:	not rinsed	
Number of Animals:	6	
Result:	slightly irritating	
EC classificat.:	not irritating	
Method:	other: protocol not available, but procedure resembles Draize-Test	
Year:	**GLP:** no data	
Test substance:	other TS	
Method:	Six animals were treated with 0.1 ml of test substance without water rinsing. Eye irritation was scored according to the Draize scale for 3 days. Four samples of the test substance were evaluated in this way.	
Result:	Two of the samples caused mild irritation in one rabbit at the 24 hour point; the remaining scores were zero. The other two samples did not cause any eye irritation.	
Source:	CONCAWE Bruxelles	
Test substance:	A 50/50 blend of paraffin wax, CAS no. 8002-74-2 and petrolatum (note: CAS no. was not assigned in original study).	

(21) (28) (22) (18)

Species: rabbit
Concentration: no data
Dose: .1 ml
Exposure Time:
Comment: no data
Number of Animals: 6
Result: slightly irritating
EC classificat.: not irritating
Method: Draize Test
Year: 1959 **GLP:** no data
Test substance: other TS
Method: Six animals were each treated with 0.1 ml of test substance. Eyes were observed for 3 days, and scored according to the Draize scale.
Result: Five of the animals showed no eye irritation. One animal showed slight conjunctival erythema and oedema after 24 hours.
Source: CONCAWE Bruxelles
Test substance: Microcrystalline wax, CAS no. 63231-60-7 (note: CAS no. wasnot assigned in original study).

(29) (18)

5.3 Sensitization

-

5.4 Repeated Dose Toxicity

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: oral feed
Exposure period: 90 days
Frequency of treatment: daily
Post. obs. period: 28 days for reversibility studies in Groups B and D. See Remark: Doses.
Doses: See Remark: Doses for full details
Control Group: yes, concurrent no treatment
LOAEL: 1.8 mg/kg bw
Method: other: see Remark: Method for full details
Year: **GLP:** yes
Test substance: other TS
Method: The protocol was a compilation of the procedures outlined by the OECD, EEC and US FDA Guidelines for 90-day sub-chronic
oral studies. The procedure is detailed in the Reference.

The test substance was mixed with rat diet to give the required concentrations for the various groups.

In addition to (A), the test and control groups, there were three other pairs of groups. (B) was a high dose group which, after treatment for 90 days, was left for 28 days, after which the animals were examined to look for possible

carbon number distribution (>C20) and generic composition, it can be predicted that the hydrocarbon constituents will

reversibility of effects. (C) was a high dose group treated for 90 days, after which tissues were analysed for their hydrocarbon content. (D) was a high dose group, treated for 90 days and left for 28 days, following which tissues were analysed for their hydrocarbon content.

Test group doses were as follows:

(A) four groups at 1.8, 18.5, 185 and 1850 mg/kg/day (each group consisting 20 male/20 female animals)
(B) one group at 1850 mg/kg/day (10 male/10 female)
(C) one group at 1850 mg/kg/day (5 male/5 female)
(D) one group at 1850 mg/kg/day (5 male/5 female)

There were four control groups, all concurrent, no treatment, corresponding to the treatment groups. The sizes of these control groups were:

(A) 60 male/60 female
(B) 30 male/30 female
(C) 5 male/5 female
(D) 5 male/5 female

Result: Significant effects were found in the lymph node, the liver and the mitral valves of the heart. The MESENTERIC LYMPH NODE, the LIVER and the SPLEEN showed SIGNIFICANTLY INCREASED WEIGHTS in animals treated at the highest dose. HYSTIOCYTOSIS was present in the LYMPH NODE at all doses, with females showing the greater effect. In the LIVER, there were GRANULOMATOUS LESIONS at the two highest doses. In the HEART, an INFLAMMATORY REACTION was seen around the MITRAL VALVE in the highest dose animals, and in female animals it was also present at the second highest dose.

Other effects were a DECREASE IN RED BLOOD CELL COUNT for the females at the highest dose, and an INCREASE IN WHITE BLOOD CELL COUNT for females at the two highest doses. RAISED SERUM ENZYME LEVELS were found for male and female animals at the highest dose, and a DECREASE IN ALKALINE PHOSPHATASE at the highest dose.

Hydrocarbons were found by analysis in the liver, mesenteric lymph nodes and in the perirenal fat of group (C) animals treated at the highest dose, the material being particularly evident in the females.

There was no discernible difference in the toxicological effects, or in the hydrocarbon levels in tissues, in animals after a 28-day period without treatment.

Source: CONCAWE Bruxelles

Test substance: Low melting point hydrotreated paraffin wax, CAS no. 64742-51-4 (note: CAS no. was not assigned in original study).

(30)

partition almost entirely to soil and sediment.

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: oral feed
Exposure period: 90 days
Frequency of treatment: daily
Post. obs. period: 28 days for reversibility studies in Groups B and D. See Remark: Doses.
Doses: See Remark: Doses for full details
Control Group: yes, concurrent no treatment
NOAEL: 1850 mg/kg bw
Method: other: see Remark: Method for full details
Year: **GLP:** yes
Test substance: other TS
Method: The protocol was a compilation of the procedures outlined by the OECD, EEC and US FDA Guidelines for 90-day sub-chronic
oral studies. The procedure is detailed in the Reference.

The test substance was mixed with rat diet to give the required concentrations for the various groups.

In addition to (A), the test and control groups, there were three other pairs of groups. (B) was a high dose group which, after treatment for 90 days, was left for 28 days, after which the animals were examined to look for possible reversibility of effects. (C) was a high dose group treated for 90 days, after which tissues were analysed for their hydrocarbon content. (D) was a high dose group, treated for 90 days and left for 28 days, following which tissues were analysed for their hydrocarbon content.

Test group doses were as follows:

(A) four groups at 1.8, 18.5, 185 and 1850 mg/kg/day (each group consisting 20 male/20 female animals)
(B) one group at 1850 mg/kg/day (10 male/10 female)
(C) one group at 1850 mg/kg/day (5 male/5 female)
(D) one group at 1850 mg/kg/day (5 male/5 female)

There were four control groups, all concurrent, no treatment, corresponding to the treatment groups. The sizes of these control groups were:

(A) 60 male/60 female
(B) 30 male/30 female
(C) 5 male/5 female
(D) 5 male/5 female

Result: NO SIGNIFICANT TREATMENT-RELATED EFFECTS were found with this test substance.
Source: CONCAWE Bruxelles
Test substance: High melting point hydrotreated microcrystalline wax, CAS no. 64742-60-5 (note: CAS no. was not assigned in original study).

(30)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: oral feed
Exposure period: 90 days
Frequency of treatment: daily
Post. obs. period: 28 days for reversibility studies in Groups B and D. See Remark: Doses.
Doses: See Remark: Doses for full details
Control Group: yes, concurrent no treatment
NOAEL: 1850 mg/kg bw
Method: other: see Remark: Method for full details
Year: **GLP:** yes
Test substance: other TS
Method: The protocol was a compilation of the procedures outlined by the OECD, EEC and US FDA Guidelines for 90-day sub-chronic
oral studies. The procedure is detailed in the Reference.

The test substance was mixed with rat diet to give the required concentrations for the various groups.

In addition to (A), the test and control groups, there were three other pairs of groups. (B) was a high dose group which, after treatment for 90 days, was left for 28 days, after which the animals were examined to look for possible reversibility of effects. (C) was a high dose group treated for 90 days, after which tissues were analysed for their hydrocarbon content. (D) was a high dose group, treated for 90 days and left for 28 days, following which tissues were analysed for their hydrocarbon content.

Test group doses were as follows:

(A) four groups at 1.8, 18.5, 185 and 1850 mg/kg/day (each group consisting 20 male/20 female animals)
(B) one group at 1850 mg/kg/day (10 male/10 female)
(C) one group at 1850 mg/kg/day (5 male/5 female)
(D) one group at 1850 mg/kg/day (5 male/5 female)

There were four control groups, all concurrent, no treatment, corresponding to the treatment groups. The sizes of these control groups were:

(A) 60 male/60 female
(B) 30 male/30 female
(C) 5 male/5 female
(D) 5 male/5 female

Result: NO SIGNIFICANT TREATMENT-RELATED EFFECTS were found with this test substance.
Source: CONCAWE Bruxelles
Test substance: High sulphur clay-treated microcrystalline wax, CAS no. 64742-42-3 (note: CAS no. was not assigned in original study).

(30)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: oral feed
Exposure period: 90 days
Frequency of treatment: daily
Post. obs. period: 90 days for reversibility studies in Groups B and D. See Remark: Doses.
Doses: See Remark: Doses for full details
Control Group: yes, concurrent no treatment
LOAEL: 15.4 mg/kg bw
Method: other: see Remark: Method for full details
Year: **GLP:** yes
Test substance: other TS
Method: The protocol was a compilation of the procedures outlined by the OECD, EEC and US FDA Guidelines for 90-day sub-chronic
oral studies. The procedure is detailed in the Reference.

The test substance was mixed with rat diet to give the required concentrations for the various groups.

In addition to (A), the test and control groups, there were three other pairs of groups. (B) was a high dose group which, after treatment for 90 days, was left for 90 days, after which the animals were examined to look for possible reversibility of effects. (C) was a high dose group treated for 90 days, after which tissues were analysed for their hydrocarbon content. (D) was a high dose group, treated for 90 days and left for 90 days, following which tissues were analysed for their hydrocarbon content.

Test group doses were as follows:

(A) three groups at:
19.5, 193.4 and 1949.2 mg/kg/day (females), and
15.4, 154.8 and 1577.3 mg/kg/day (males)
(each group consisting 20 male/20 female animals)
(B) one group at 1949.2 (female) and 1577.3 (male)
(group consisting of 10 male/10 female)
(C) one group at 1949.2 (female) and 1577.3 (male)
(group consisting of 5 male/5 female)
(D) one group at 1949.2 (female) and 1577.3 (male)
(group consisting of 5 male/5 female)

There were four control groups, all concurrent, no treatment, corresponding to the treatment groups. The sizes of these control groups were:

(A) 20 male/20 female
(B) 10 male/10 female
(C) 5 male/5 female
(D) 5 male/5 female

Result: No deaths or other overt clinical effects were noted in any of the IMPW treatment groups. Minor histopathological effects were noted, generally more severe in female than in

male animals.

Liver effects consisted of increased organ weights, small increases in serum liver enzyme levels, the presence of mineral hydrocarbons, and the development of granulomatous changes. With IMPW, these were observed at the 0.2% level.

Effects found in the mesenteric lymph nodes were characterised by an increase in tissue weight, the presence of mineral hydrocarbons, and an increased incidence of histiocytosis. This was observed at the 0.02% dose level for IMPW.

Where histopathological changes were observed in the liver and mesenteric lymph nodes, haematological and clinical chemistry changes were generally also observed. Many of these findings appeared to be consistent with a relatively mild inflammatory reaction.

An unusual inflammatory lesion of the heart mitral valve was observed in groups given IMPW.

Two groups were subsequently allowed a 90-day recovery period, which resulted in a marked decrease in the severity of the histopathological effects, with associated reductions in haematological and clinical chemistry findings.
The level of hydrocarbon present in the tissue was also reduced.

Source: CONCAWE Bruxelles
Test substance: Intermediate melting point hydrotreated paraffin wax (IMPW),CAS No. 64742-51-4 (note: CAS No. was assigned in original study).

(31)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: oral feed
Exposure period: 90 days
Frequency of treatment: daily
Post. obs. period: 90 days for reversibility studies in Groups B and D. See Remark: Doses.
Doses: See Remark: Doses for full details
Control Group: yes, concurrent no treatment
LOAEL: .02 %
Method: other: see Remark: Method for full details
Year: **GLP:** yes
Test substance: other TS
Method: The protocol was a compilation of the procedures outlined by the OECD, EEC and US FDA Guidelines for 90-day sub-chronic
oral studies. The procedure is detailed in the Reference.

The test substance was mixed with rat diet to give the required concentrations for the various groups.

In addition to (A), the test and control groups, there were three other pairs of groups. (B) was a high dose group which, after treatment for 90 days, was left for 90 days, after which the animals were examined to look for possible reversibility of effects. (C) was a high dose group treated for 90 days, after which tissues were analysed for their hydrocarbon content. (D) was a high dose group, treated for 90 days and left for 90 days, following which tissues were analysed for their hydrocarbon content.

Test group doses were as follows:

(A) three groups at:
19.5, 193.4 and 1949.2 mg/kg/day (females), and
15.4, 154.8 and 1577.3 mg/kg/day (males)
(each group consisting 20 male/20 female animals)
(B) one group at 1949.2 (female) and 1577.3 (male)
(group consisting of 10 male/10 female)
(C) one group at 1949.2 (female) and 1577.3 (male)
(group consisting of 5 male/5 female)
(D) one group at 1949.2 (female) and 1577.3 (male)
(group consisting of 5 male/5 female)

There were four control groups, all concurrent, no treatment, corresponding to the treatment groups. The sizes of these control groups were:

(A) 20 male/20 female
(B) 10 male/10 female
(C) 5 male/5 female
(D) 5 male/5 female

Result: No deaths or other overt clinical effects were noted in any of the BLEND treatment groups. Minor histopathological effects were noted, generally more severe in female than in male animals.

Liver effects consisted of increased organ weights, small increases in serum liver enzyme levels, the presence of mineral hydrocarbons, and the development of granulomatous changes. With BLEND, these were observed at the 0.2% level.

Effects found in the mesenteric lymph nodes were characterised by an increase in tissue weight, the presence of mineral hydrocarbons, and an increased incidence of histiocytosis. This was observed at the 0.02% dose level for BLEND.

Where histopathological changes were observed in the liver and mesenteric lymph nodes, haematological and clinical chemistry changes were generally also observed. Many of these findings appeared to be consistent with a relatively mild inflammatory reaction.

An unusual inflammatory lesion of the heart mitral valve was observed in groups given BLEND.

Two groups were subsequently allowed a 90-day recovery

period, which resulted in a marked decrease in the severity of the histopathological effects, with associated reductions in haematological and clinical chemistry findings.
The level of hydrocarbon present in the tissue was also reduced.

Source: CONCAWE Bruxelles

Test substance: A 1:1 by weight mixture of low melting point hydrotreated paraffin wax (LMPW), CAS No. 64742-51-4, and high melting point hydrotreated microcrystalline paraffin wax (HMPW), CASNo. 64742-60-5. This mixture is referred to in the report as BLEND (note: CAS Nos. were not assigned in original study).

(31)

5.5 Genetic Toxicity 'in Vitro'

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5.6 Genetic Toxicity 'in Vivo'

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5.7 Carcinogenicity

Species: mouse **Sex:** male/female
Strain: Swiss
Route of admin.: dermal
Exposure period: 2 years
Frequency of treatment: 3 times/week
Post. obs. period: no data
Doses: Test group: 0.05 ml of 15% test substance in benzene (60 male/30 female animals). Vehicle control group (60 male/30 female animals). Negative control group (140 male/140 female animals).
Result:
Control Group: yes, concurrent no treatment
Method: other: protocol is detailed in Reference
Year: **GLP:** no data
Test substance: other TS
Remark: This work was undertaken to determine the toxicological status of petroleum waxes as direct and indirect food additives.
Result: Dermal studies produced NO EVIDENCE OF CARCINOGENIC EFFECTS.
Source: CONCAWE Bruxelles
Test substance: Five petroleum waxes of varying aromatic hydrocarbon content were studied. The nature of the waxes is not stated, but from the properties it appears that two paraffinic and three microcrystalline waxes were evaluated.

(32)

Species: rabbit **Sex:** male/female
Strain: other: New Zealand albino
Route of admin.: dermal
Exposure period: 4 years
Frequency of treatment: 3 times/week
Post. obs. period: no data
Doses: Test group: 0.08 ml of 15% test substance in benzene (4 male/4 female animals). Vehicle control group (4 male/4 female animals).
Result:
Control Group: yes, concurrent vehicle
Method: other: protocol is detailed in Reference
Year: **GLP:** no data
Test substance: other TS
Remark: This work was undertaken to determine the toxicological status of petroleum waxes as direct and indirect food additives.
Result: Dermal studies produced NO EVIDENCE OF CARCINOGENIC EFFECTS.
Source: CONCAWE Bruxelles
Test substance: Five petroleum waxes of varying aromatic hydrocarbon content were studied. The nature of the waxes is not stated, but from the properties it appears that two paraffinic and three microcrystalline waxes were evaluated.

(32)

Species: rat **Sex:** male/female
Strain: Sprague-Dawley
Route of admin.: oral feed
Exposure period: 2 years
Frequency of treatment: daily
Post. obs. period: no data
Doses: Test group: 5000 mg/kg/day (50 male/50 female animals). Negative control group (140 male/157 female animals).
Result:
Control Group: yes, concurrent no treatment
Method: other: protocol is detailed in the Reference
Year: **GLP:** no data
Test substance: other TS
Remark: This work was undertaken to determine the toxicological status of petroleum waxes as direct and indirect food additives. The test substance was "powdered" and added to the diet to give 10% concentration.
Result: Oral studies produced NO EVIDENCE OF CARCINOGENIC EFFECTS.
Source: CONCAWE Bruxelles
Test substance: Five petroleum waxes of varying aromatic hydrocarbon content were studied. The nature of the waxes is not stated, but from the properties it appears that two paraffinic and three microcrystalline waxes were evaluated.

(32)

Species: mouse **Sex:** male/female
Strain: Sprague-Dawley
Route of admin.: s.c.
Exposure period: 2 years
Frequency of treatment: single subcutaneous implantation
Post. obs. period: 2 years
Doses: Test group: 0.5 g (50 male/45 female animals). Negative control group (140 male/140 female animals).
Result:
Control Group: yes, concurrent no treatment
Method: other: protocol is detailed in the Reference
Year: **GLP:** no data
Test substance: other TS
Remark: This work was undertaken to determine the toxicological status of petroleum waxes as direct and indirect food additives.
Result: IMPLANTATION STUDIES RESULTED IN SARCOMAS, but these are considered to be due to the physical rather than the chemical properties of the waxes.
Source: CONCAWE Bruxelles
Test substance: Five petroleum waxes of varying aromatic hydrocarbon content were studied. The nature of the waxes is not stated, but from the properties it appears that two paraffinic and three microcrystalline waxes were evaluated.

(32)

Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Frequency of treatment:
Post. obs. period:
Doses:
Result:
Control Group:
Method:
Year: **GLP:**
Test substance:
Remark: Paraffin waxes, CAS No. 8002-74-2, are derived from slack waxes, CAS No. 64742-61-5, and the carcinogenicity of the latter has been studied by Kane et al. with completely negative results. This topic is addressed more fully in the Data Set for Group 11C.
Source: CONCAWE Bruxelles

(33)

5.8 Toxicity to Reproduction

-

5.9 Developmental Toxicity/Teratogenicity

-

5.10 Other Relevant Information

Type: other: bladder effects from paraffin wax implants

Remark: In a study reported by Chapman et al., pellets of paraffin wax were surgically implanted into the rat bladder. It was found that the presence of urine was necessary for tumour induction, and that the calculi growing around the pellets were the reason for the tumour-enhancing effect. It was suggested that the pellets may have a possible co-carcinogenic effect.

Similar studies by Ball et al., Bonser et al., Allen et al. and Podilchak have demonstrated that foreign bodies like paraffin wax and glass beads may lead by local irritation to tumours in the urinary bladders of rats and mice. Jull also studied the effects of paraffin wax implants as carriers
of carcinogenic chemicals in the mouse bladder. It was concluded that although tumours may be produced by foreign bodies alone, the effect was not unique to paraffin wax.

Source: CONCAWE Bruxelles

(34) (35) (36) (37) (38) (39) (40)

5.11 Experience with Human Exposure

Remark: A case is reported of a woman who developed breast cancer, about 40 years after receiving paraffin wax injections. The cancer was obscured by the overwhelming granulomatous reaction produced by the paraffin wax. The author speculates that the paraffin wax may have been a causative agent in the development of the cancer. Current paraffin waxes that may be used for such treatments will be much more highly refined.

Source: CONCAWE Bruxelles

(41)

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ghs

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7.1 Risk Assessment

-

Attachment IV
Petrolatum
CAS#8009-03-8

(22 Pages)

1. General Info
2. Physico-Chemical Data
3. Fate and Pathways
4. Ecotoxicity
5. Toxicity
6. References

(Blue)

I U C L I D

D a t a s e t

Existing Chemical	Substance ID: 8009-03-8
CAS No.	8009-03-8
EINECS Name	Petrolatum
EINECS No.	232-373-2
Molecular Formula	<no data>
Substance Group	11D

Dataset created by: EUROPEAN COMMISSION - European Chemicals Bureau

This dossier is a compilation based on data reported by the European Chemicals Industry following 'Council Regulation (EEC) No. 793/93 on the Evaluation and Control of the Risks of Existing Substances'. All (non-confidential) information from the single datasets, submitted in the IUCLID/HEDSET format by individual companies, was integrated to create this document.

The data have not undergone any evaluation by the European Commission.

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1.0.1 OECD and Company Information

Name: AB Svenska Shell
Town: S-171 79 SOLNA
Country: Sweden
Phone: +46 8 730 80 00
Telefax: +46 8 735 74 33
Telex: 193 60 SHELL S

Name: ADDINOL Mineralöl GmbH
Street: Hauptstraße 1
Town: 06242 Krumpa
Country: Germany
Phone: 034632/72259
Telefax: 034632/72115

Name: Agip Petroli SpA
Street: Laurentina 449
Town: 00142 ROMA
Country: Italy
Phone: +39-6-59881
Telefax: +39-6-59885700
Telex: 614031 I

Name: Astor Stag Ltd
Street: Huette 60
Town: B-4700 Eupen
Country: Belgium
Phone: 87 74 00 06
Telefax: 87 74 36 70
Telex: 49099

Name: Astor Stag Ltd
Street: Tavistock Road
Town: UB7 7RA West Drayton, Middlesex
Country: United Kingdom
Phone: 01895 445511
Telefax: 01895 449199
Telex: 28559

Name: CONCAWE
Street: Madouplein 1
Town: B-1210 Bruxelles
Country: Belgium

Name: H.O. Schümann GmbH & Co KG
Street: Worthdamm 13-27
Town: 20457 Hamburg
Country: Germany
Phone: 00494078115-0

Name: MB SVEDA AB
Street: Box 4072
Town: 203 11 Malmö
Country: Sweden
Phone: 0094640352800
Telefax: 0094640125172
Telex: 33188

Name: Mobil Oil Francaise
Street: BP No. 2
Town: F-76330 Notre-Dame-de-Gravencon
Country: France
Phone: 33-235-394284
Telefax: 33-235-394065

Name: NEUBER GES.M.B.H.
Street: BRÜCKENGASSE 1
Town: 1060 WIEN
Country: Austria
Phone: 0222/599950
Telefax: 0222/5970200

Name: SunChemical
Street: Gl. Lyngvej 2
Town: 4600 Køge
Country: Denmark
Phone: +45 53657585
Telefax: +45 53663019
Telex: 43589 KVK DK
Cedex: 2142007

Name: TOTAL RAFFINAGE DISTRIBUTION S.A.
Street: 51 Esplanade Charles de Gaulle
Town: 92907 Paris La Défense
Country: France
Phone: 41 35 00 00
Telefax: 41 35 86 12
Telex: 615700
Cedex: 97

Name: Union Carbide Benelux
Street: Norderlaan 147
Town: 2030 Antwerpen
Country: Belgium

Name: WITCO BV
Street: Wezelstraat 12, P.O. Box 5
Town: 1540AA Koog aan de Zaan
Country: Netherlands
Phone: (31)75283854
Telefax: (31)75210811

Telex: 19270

1.0.2 Location of Production Site

-

1.0.3 Identity of Recipients

-

1.1 General Substance Information

Substance type: organic
Physical status: solid

Substance type: petroleum product
Physical status: liquid

Substance type: petroleum product
Physical status: solid

1.1.1 Spectra

-

1.2 Synonyms

none
Source: Union Carbide Benelux Antwerpen

Vaselin
Source: NEUBER GES.M.B.H. WIEN

Vaseline
Source: SunChemical Køge

1.3 Impurities

-

1.4 Additives

-

1.5 Quantity

Quantity 50 000 - 100 000 tonnes

1.6.1 Labelling

Labelling: as in Directive 67/548/EEC
Symbols: T
Nota: other RM: H,N
other RM: S
Specific limits: no data
R-Phrases: (45) May cause cancer
S-Phrases: (53) Avoid exposure - obtain special instructions before use
(45) In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

1.6.2 Classification

Classification: as in Directive 67/548/EEC
Class of danger: carcinogenic, category 2
R-Phrases: (45) May cause cancer

1.7 Use Pattern

Type: type
Category: Non dispersive use

Type: type
Category: Use in closed system

Type: type
Category: Use resulting in inclusion into or onto matrix

Type: type
Category: Wide dispersive use

Type: industrial
Category: Fuel industry

Type: industrial
Category: Leather processing industry

Type: industrial
Category: Metal extraction, refining and processing of metals

Type: industrial
Category: Paints, lacquers and varnishes industry

Type: industrial
Category: Paper, pulp and board industry

Type: industrial
Category: Personal and domestic use

Type: industrial
Category: Public domain

Type: industrial
Category: other: cosmetic industry

Type: use
Category: Cosmetics

Type: use
Category: Impregnation agents

Type: use
Category: Intermediates

Type: use
Category: Pharmaceuticals

1.7.1 Technology Production/Use

-

1.8 Occupational Exposure Limit Values

-

1.9 Source of Exposure

Remark: Utilizzato in sistemi chiusi: esposizione possibile durante il campionamento.
Source: Agip Petroli SpA ROMA

1.10.1 Recommendations/Precautionary Measures

-

1.10.2 Emergency Measures

-

1.11 Packaging

-

1.12 Possib. of Rendering Subst. Harmless

-

1.13 Statements Concerning Waste

-

1.14.1 Water Pollution

-

1.14.2 Major Accident Hazards

-

1.14.3 Air Pollution

-

1.15 Additional Remarks

Remark:	ELIMINATION DECHETS : craquage catalytique recyclage distillation sous vide TRANSPORT : pipe
Source:	TOTAL RAFFINAGE DISTRIBUTION S.A. Paris La Défense

1.16 Last Literature Search

-

1.17 Reviews

-

1.18 Listings e.g. Chemical Inventories

-

2.1 Melting Point

Value: 36 - 60 degree C
Decomposition: no
Sublimation: no
Method: other: ASTM D127
GLP: no data
Source: CONCAWE Bruxelles

(1) (2)

2.2 Boiling Point

-

2.3 Density

Type: density
Value: .815 - .865 g/cm3 at 60 degree C
Method: other: ASTM D1480
GLP: no data
Source: CONCAWE Bruxelles

(1) (2)

2.3.1 Granulometry

-

2.4 Vapour Pressure

-

2.5 Partition Coefficient

log Pow: > 6
Method: other (calculated)
Year:
Remark: The calculation was done by the CLOGP Version 3.5 program (Calculation of LOG Partition coefficient octanol/water).

As an example, the calculated value for eicosane (n-C20H42) is 11.3. However, such values are notional, since no correlation has been established between calculated and experimental values for Log Pow values greater than 6.

Source: CONCAWE Bruxelles

(3)

2.6.1 Water Solubility

-

2.6.2 Surface Tension

-

2.7 Flash Point

-

2.8 Auto Flammability

-

2.9 Flammability

-

2.10 Explosive Properties

-

2.11 Oxidizing Properties

-

2.12 Additional Remarks

Remark: Petrolatums are involatile, water-insoluble materials composed of hydrocarbons. They are obtained by solvent dewaxing of residual lube oil feedstocks, and consist essentially of microcrystalline waxes and paraffinic mineral oil. An exception is oxidised petrolatum, CAS No. 64743-01-7, which consists mainly of high molecular weight carboxylic acids.

Petrolatum consists mainly of branched and straight-chain alkanes of carbon number C20 to C85. They may be purified by various techniques to give products ranging in colour from amber to white.

Petrolatums are usually characterised in terms of colour, melting point and penetration index. Oxidised petrolatum is also characterised in terms of its acidity or acid number, i.e. the number of mg of potassium hydroxide required to neutralise the acidity in one gramme of test material.

Results of the chemical analysis of polycyclic aromatic hydrocarbons in ten samples of petrolatum have been reported.

Source: CONCAWE Bruxelles

(4)

Remark: The technical information contained in Chapters 2 to 5 of this Data Set has been compiled by the Oil Companies' European Organization for Environmental and Health Protection, CONCAWE, based at Madouplein-1, B-1210 Brussel, Belgium, and this organization holds copies of the reference articles cited in this Data Set.

Source: CONCAWE Bruxelles

3.1.1 Photodegradation

Type: air
Light source: Sun light
Conc. of subst.: at 25 degree C
INDIRECT PHOTOLYSIS
Sensitizer: OH
Conc. of sens.: 1000000 molecule/cm3
Method: other (calculated): according to Atkinson, 1990.
Year: **GLP:**
Test substance: other TS
Remark: Most hydrocarbon components of substances in this Group will have little or no tendency to partition to air (see Sub-chapter 3.3.2). The half lives for degradation of these hydrocarbons by reaction with hydroxyl radicals, in the troposphere, under the influence of sunlight, will all be less than one day, by extrapolation from the data quoted by Atkinson. Accordingly, any hydrocarbon material which does partition to air will be rapidly photodegraded.
Source: CONCAWE Bruxelles
Test substance: Alkanes (>C20) found in petrolatums.

(5)

3.1.2 Stability in Water

Type:
Method:
Year: **GLP:**
Test substance:
Remark: Hydrocarbons present in petrolatums are not susceptible to hydrolysis under environmental conditions.
Source: CONCAWE Bruxelles

(6)

3.1.3 Stability in Soil

-

3.2 Monitoring Data (Environment)

-

3.3.1 Transport between Environmental Compartments

-

3.3.2 Distribution

Media: air - biota - sediment(s) - soil - water
Method: Calculation according Mackay, Level I
Year: 1981
Remark: There is insufficient physico-chemical data on the individual hydrocarbon components typically found in substances in this Group for their Mackay Level I distributions to be determined. However, from their known carbon number distribution (>C20) and generic composition, it can be predicted that the hydrocarbon constituents will partition almost entirely to soil and sediment.
Source: CONCAWE Bruxelles

3.4 Mode of Degradation in Actual Use

-

3.5 Biodegradation

-

3.6 BOD5, COD or BOD5/COD Ratio

-

3.7 Bioaccumulation

-

3.8 Additional Remarks

-

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

-

4.2 Acute Toxicity to Aquatic Invertebrates

-

4.3 Toxicity to Aquatic Plants e.g. Algae

-

4.4 Toxicity to Microorganisms e.g. Bacteria

-

4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish

-

4.5.2 Chronic Toxicity to Aquatic Invertebrates

-

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Soil Dwelling Organisms

-

4.6.2 Toxicity to Terrestrial Plants

-

4.6.3 Toxicity to other Non–Mamm. Terrestrial Species

-

4.7 Biological Effects Monitoring

-

4.8 Biotransformation and Kinetics

-

4.9 Additional Remarks

Remark: No ecotoxicity studies have been done on substances in this Group. However, work by Adema and van den Bos Bakker on the ecotoxicity of alkanes to Daphnia magna, Chaetogammarus marinus and Mysidopsis bahia has shown that alkanes of carbon number greater than C10 are not acutely toxic to these species at their limit of solubility in water. Since petrolatums are largely composed of alkanes of carbon number greater than C20, they will not be acutely toxic to aquatic invertebrates.

Source: CONCAWE Bruxelles

(7)

5.1.1 Acute Oral Toxicity

-

5.1.2 Acute Inhalation Toxicity

-

5.1.3 Acute Dermal Toxicity

Type:	LD50
Species:	rabbit
Sex:	
Number of Animals:	
Vehicle:	
Value:	3600 mg/kg bw
Method:	other: protocol not available.
Year:	**GLP:** no data
Test substance:	other TS
Method:	A limit test was done at a single dose of 4 ml/kg on an unknown number of New Zealand White rabbits. A closed patch was applied for 24 hours.
Result:	At necropsy no abnormalities or systemic effects were revealed.
Source:	CONCAWE Bruxelles
Test substance:	50/50 blend of paraffin wax and petrolatum.

(8) (9)

5.1.4 Acute Toxicity, other Routes

-

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

Species:	rabbit	
Concentration:		other: 50% in paraffin wax
Exposure:		
Exposure Time:	24	hour(s)
Number of Animals:	6	
PDII:		
Result:	slightly irritating	
EC classificat.:	not irritating	
Method:	other: modification of Draize-Test	
Year:		**GLP:** no data
Test substance:	other TS	
Method:	Six New Zealand White rabbits were treated for 24 hours, applying 3 x 0.5ml of test substance to the clipped intact skin, and covering with an open patch. After patch removal, the treated area was observed and scored according to the	

Draize scale. Three samples of test substance were tested.

Result: Scores are not available, but two samples produced erythema in four rabbits that persisted for 3 days, and the remaining samples produced erythema in one rabbit that persisted two days.

Source: CONCAWE Bruxelles

Test substance: 50/50 blend of paraffin wax and petrolatum.

(8) (10) (9)

5.2.2 Eye Irritation

Species: rabbit

Concentration:

Dose: .1 ml

Exposure Time:

Comment:

Number of Animals: 6

Result: slightly irritating

EC classificat.: not irritating

Method: other

Year: **GLP:** no data

Test substance: other TS

Method: Six New Zealand White rabbits were treated with 0.1 ml of test substance without water rinsing. Eye irritation was scored for three days according to the Draize scale.

Remark: Full test protocol is not available, but outline procedure resembles Draize Test.

Result: Four samples were tested. Two of the samples caused mild irritation in one rabbit at the 24 hour time point; the remaining scores were zero. The two further samples did not cause any eye irritation.

Source: CONCAWE Bruxelles

Test substance: 50/50 blend of paraffin wax and petrolatum.

(8) (11) (12) (9)

5.3 Sensitization

Type: Patch-Test

Species: human

Number of Animals:

Vehicle:

Result: not sensitizing

Classification: not sensitizing

Method: other

Year: **GLP:** no data

Test substance: other TS

Remark: Petrolatum is the preferred vehicle for other test substances in human patch studies designed to find allergic reactions. Standard texts by Hjorth and Dooms-Goossens point to its advantages of non-volatility, ability to protect the test substance against air oxidation, and its non-allergenicity to almost all humans. Inevitably, some humans have become sensitized to petrolatum, and this

subject is addressed in Sub-chapter 5.11.
Source: CONCAWE Bruxelles
Test substance: White and yellow petrolatum.

(13) (14)

5.4 Repeated Dose Toxicity

-

5.5 Genetic Toxicity 'in Vitro'

-

5.6 Genetic Toxicity 'in Vivo'

-

5.7 Carcinogenicity

Species: mouse **Sex:** male/female
Strain: Swiss
Route of admin.: dermal
Exposure period: 2 years
Frequency of treatment: twice weekly
Post. obs. period: no data
Doses: See REMARK for doses and group size data.
Result:
Control Group: yes, concurrent vehicle
Method: other: protocol was very similar to that used by Shubik et al. (see Reference)
Year: 1962 **GLP:** no data
Test substance: other TS
Method: For this study the test substance was separated into its aromatic and aliphatic fractions. The aromatic content was 1.2%, and this fraction was sub-divided into two further fractions for testing. It was estimated that the aromatic concentrations of these sub-fractions were 50 times greater than in the original petrolatum.

There were five test groups and a vehicle control group. The doses and group sizes, together with details of the materials studied, were as follows:

(A) petrolatum (15% in iso-octane): 60 ul (30 male and 30 female animals),
(B) aromatic-free fraction of petrolatum (15% in iso-octane): 60 ul (30 male and 30 female animals),
(C) nitromethane-soluble aromatic fraction of petrolatum (9.5% in iso-octane): 20 ul (30 male and 30 female animals),
(D) cyclohexane-soluble aromatic fraction of petrolatum (43.4% in iso-octane): 20 ul (30 male and 30 female animals),
(E) total aromatic extract from petrolatum (26.5% in

iso-octane): 20 ul (30 male and 30 female animals).

The concurrent vehicle control group contained 50 male and 50 female animals.

Result: Amber petrolatum (A) was NOT a DERMAL CARCINOGEN.

Petrolatum (A) induced three dermal tumours, but this compares with two tumours from the iso-octane-treated vehicle control group. The aromatic-free fraction of petrolatum (B) did not produce any dermal tumours.

Both aromatic fractions, (C) and (D), and the combined fraction (E) produced significant numbers of dermal tumours. Thus (C) produced 41 tumours, 11 of which were carcinomas, in 28% of the test group animals; (D) produced 12 tumours, including 6 carcinomas, in 28% of the animals; (E) produced 29 tumours, including 9 carcinomas, in 29% of the animals.

Severe skin irritation was caused by (C), (D) and (E), but not by (A) or (B).

Source: CONCAWE Bruxelles
Test substance: Amber petrolatum.

(15) (16)

Species: mouse **Sex:** male
Strain: C3H
Route of admin.: dermal
Exposure period: 80 weeks
Frequency of treatment: twice weekly
Post. obs. period: no data
Doses: 2 Test groups: 25 mg and 50 mg (50 animals per group). 3 Positive control groups: 0.05% BaP in toluene (30, 50 and 50 animals). 1 Negative control group: no treatment (contained 50 animals).
Result:
Control Group: yes, concurrent no treatment
Method: other: protocol is described in paper by Horton and Denman (see Reference).
Year: 1955 **GLP:** no data
Test substance: other TS
Result: The test substance was NOT a DERMAL CARCINOGEN.

No tumours were found in the mice from the test groups.

In the positive control groups 86% to 100% of the animals developed tumours, most of which were malignant. None of the negative control group animals developed dermal tumours.

Source: CONCAWE Bruxelles
Test substance: Petrolatum derived from a solvent-refined residual oil, CAS No. 8009-03-8.

(17) (18)

Species: rat **Sex:** male/female
Strain: other: BD I, BD III and W
Route of admin.: i.p.
Exposure period: about 2 years
Frequency of treatment: Single injection
Post. obs. period: until spontaneous death
Doses: 3 ml (8 animals).
Result:
Control Group: other: control group was not run simultaneously, but tumour incidence for rat strains was known.
Method: other: the procedure followed is detailed in the Reference.
Year: **GLP:** no data
Test substance: other TS
Method: 100 day old rats were injected with the test substance and observed until their natural death. At post-mortem there was gross and microscopic examination of organs and tissues.
Result: NO CARCINOGENIC EFFECTS were observed.
Source: CONCAWE Bruxelles
Test substance: Yellow petrolatum.

(19)

Species: rat **Sex:** male/female
Strain: other: FDRL
Route of admin.: oral feed
Exposure period: 2 years
Frequency of treatment: daily
Post. obs. period:
Doses: Six test groups: about 3000 mg/kg/day (3 groups of 50 male animals and 3 groups of 50 female animals). Two negative control groups: no treatment (2 groups each of 100 male and 100 female animals). Dose was 5% in rat diet.
Result:
Control Group: yes, concurrent no treatment
Method: other
Year: **GLP:** no data
Test substance: other TS
Method: Studies included observations of behaviour, physical appearance, growth, efficiency of food utilization, mortality, haematological parameters, blood glucose, urea, nitrogen and urine, together with gross and microscopic appearance of organs and tissues examined post mortem.

The work was done to establish the status of petrolatums as indirect food additives.
Result: NO TOXIC or CARCINOGENIC RESPONSE was observed.

No deviations were seen in the test groups which would indicate any difference from the untreated controls.
Source: CONCAWE Bruxelles
Test substance: Three petrolatum samples, two white and one yellow, representing different degrees of refining.

(20)

Species: rat **Sex:** male/female
Strain: other: BD I, BD III and W
Route of admin.: s.c.
Exposure period: about 2 years
Frequency of treatment: single injection
Post. obs. period: until spontaneous death
Doses: 1 ml (26 animals)
Result:
Control Group: yes, historical
Method: other: the procedure followed is detailed in the Reference.
Year: **GLP:** no data
Test substance: other TS
Method: 100 day old rats were injected with the test substance and observed until their natural death. At post-mortem there was gross and microscopic examination of organs and tissues.
Result: There were NO SIGNIFICANT CARCINOGENIC EFFECTS.

One animal developed an osteosarcoma around the injection site after 658 days.
Source: CONCAWE Bruxelles
Test substance: Yellow petrolatum.

(19)

Species: mouse **Sex:** male/female
Strain: Swiss Webster
Route of admin.: s.c.
Exposure period: 1.5 years
Frequency of treatment: one injection
Post. obs. period:
Doses: Six test groups: 100 mg (3 groups of 50 male and 3 groups of 50 female animals).
Result:
Control Group: other: two control groups (50 male and 50 female) were given a single implantation of 100 mg of stripped lard.
Method: other
Year: **GLP:** no data
Test substance: other TS
Method: In these studies the injection site was the interscapular region. The studies included observation of this site, physical appearance, growth, behaviour, and gross and microscopic appearance of organs and tissues examined post mortem.

The work was done to establish the status of petrolatums as indirect food additives.
Result: NO TOXIC or CARCINOGENIC RESPONSE was observed.

There was a sporadic incidence of tumours, principally mammary adenocarcinomas, but no significant difference either in incidence or type between the test and control groups. Sarcomas were observed at various sites, but these were not found in more than one rat per group. The male control group exhibited a greater proportion of reticulum

cell sarcomas than did any of the treatment groups.

Source: CONCAWE Bruxelles

Test substance: Three petrolatum samples, two white and one yellow, representing different degrees of refining.

(20)

5.8 Toxicity to Reproduction

-

5.9 Developmental Toxicity/Teratogenicity

-

5.10 Other Relevant Information

-

5.11 Experience with Human Exposure

Remark: Maibach has reported the case of a patient for whom repeated exposure to petrolatum produced dermatitis but not a sensitization reaction.

Source: CONCAWE Bruxelles

(21)

Remark: Case reports by Malten, Grimalt and Romaguera, and Ayadi and Martin, indicate that sensitization by petrolatum may have occurred. Fisher makes the same observation, and recommends the use of white, rather than yellow, petrolatum for human skin patch testing.

Source: CONCAWE Bruxelles

(22) (23) (24) (25)

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(11) CTFA. Submission of data. Unpublished safety data on raw ingredient paraffin wax. US Cosmetics, Toiletry and Fragrances Association Inc., Washington DC, 24 May 1972 (two reports).

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7.1 Risk Assessment

-

Company:
Blended Wax, Inc.

INDEX

for Blended Wax, Inc.

Generic Process for Blending Cheesewaxes

Tom Kimmons

From: "Paul Gereau" <paulg@blendedwaxes.com>
To: <shirlcdc@artelco.com>
Sent: Thursday, December 14, 2006 12:01 PM
Subject: generic process for blending cheese waxes

Add liquid paraffin to blend tank
Add liquid microcrystalline to blend tank
Mix for 15-40 minutes
Add slabbed paraffin to blend tank
Add slabbed microcrystalline to blend tank
Allow 2-4 hrs for the slabs to completely melt
Start Mixer
Add viscosity modifier under agitation and hold at 220F for 2 hrs.
Add low melt paraffin at 180F
Add FDA pigments for coloring the wax.
Mix and filter for 2 hrs.
Lab approval on Blend
Pour into slabber or desired packaging

Paul Gereau
President
Blended Waxes, Inc.
Phone (800)-294-4692 ext. 108
Fax (920)-236-8085

Product Information - FDA Status:

This product is in compliance with Federal regulations 21CFR-172.886 (for use in food) and 21CFR-178.3710 (for use in non-food articles that are in contact with food).

Product Information

Blended Waxes, Inc. Cheese Waxes

Description
A flexible wax with excellent coating properties available in a variety of colors.

BW-100F01: Clear Cheese Wax
BW-102F01: Brown Cheese Wax BW-107F01: Black Cheese Wax BW-109F01: Cheddar Cheese Wax BW-123F01: Green Cheese Wax BW-130F01: Red Cheese Wax BW-141F01: White Cheese Wax

Applications
This wax is used as an outer protective coating for cheese of all types.
Recommended processing temperature range of 160 °F to 170 °F.

Characteristics
Flexible, non cracking, wax coating available in range of colors. Custom colors available.

Test Description	Typically	Range
Congealing Point (D-938)	143° F	140-147° F
Needle Penetration (D-1321)		
0.1mm @ 77°F	35	30-45
0.1mm @ 100°F	85	75-95
Odor (A.S.T.M.)	1.0	1.0
Brookfield Viscosity @ 210°F (cPs)	12	10-15

FDA Status: This product is in compliance with Federal Regulations 21CFR- 172.886 and 21CFR-178.3710.

Information is subject to changes without notification.

Section V - Reactivity Date

Stability	Unstable		Conditions to Avoid: NA
	Stable	X	

Incompatibility (*Materials to Avoid*): Strong oxidizing agents.

Hazardous Decomposition or Byproducts: CO, CO_2 and unidentified byproducts of combustion.

Hazardous Polymerization	May Occur		Conditions to Avoid: NA
	Will Not Occur	X	

Section VI - Health Hazard Data

Route(s) of Entry:	Inhalation?	Skin?	Ingestion?
	Yes	Yes	No

Health Hazards (*Acute and Chronic*): Fumes from molten material may cause mild respiratory irritation, also contact with molten material may cause burns.

Carcinogenicity:	NTP?	IARC Monographs?	OSHA Regulated?
	No	No	No

Signs and Symptoms of Exposure: Mild respiratory irritation or discomfort.

Medical Conditions Generally Aggravated by Exposure: none known

Emergency and First Aid Procedures: Respiratory - remove affected person to fresh air.
Physical Contact - Molten Material - Flush with cold water, seek medical attention.

Section VII - Precautions for Safe Handling and Use

Steps to Be Taken in Case Material is Released or Spilled: Dike or contain molten material. Allow material to solidify, then scrape up solid material. Handle as solid waste clean up. Clean up solid spills to prevent slipper surface conditions.

Waste Disposal Method: Incineration or burial in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing: Store in cool, dry area away from heat or direct sunlight.

Other Precautions: To prevent build-up of fumes - avoid heating above 300°F and provide adequate ventilation.

Section VIII - Control Measures

Respiratory Protection (*Specify Type*): None generally required.

Ventilation	Local Exhaust: Generally sufficient	Special: None
	Mechanical (*General*): For high temperature applications	Other: None
Protective Gloves: Wax impervious - heat resistant		Eye Protection: Safety glasses or splash goggles

Other Protective Clothing or Equipment: As required to prevent contact with molten wax.

Work/Hygienic Practices: NA

Material Safety Data Sheet
May be used to comply with OSHA's Hazard Communication Standard, 29 CFR 1910, 1200, Standard must be consulted for specific requirements.

U.S. Department of Labor
Occupational Safety and Health Administration
(Non-Mandatory Form)
Form-Approved
OMB No.1218-0072

IDENTITY (*As Used on Label and List*): BW-100F Cheese Wax Series

Note: Blank spaces are not permitted. If any item is not applicable, or no information is available, the space must be marked to indicate that.

Section I

Manufacturer's Name: Blended Waxes, Inc.	Emergency Telephone Number: (920)236-8080
Address (*Number, Street, City, State, and ZIP Code*): 1512 S Main Street, Oshkosh, WI 54901	Telephone Number for Information: (920)236-8080
	Date Prepared: 12/30/2003
	Signature of Preparer (*optional*)

Section II - Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity: Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (*optional*)
Paraffin Wax (fumes only)		2 mg/M^3	STEL 6 mg/M^3	<20

Section III - Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H2O = 1)		<1
Vapor Pressure (mm Hg.)	NA	Congealing Point	(D-938) 140-147F	
Vapor Density(AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)		NA

Solubility in Water: Nil.

Appearance and Odor: Clear or Colored Waxy Solid, Low Odor

Section IV - Fire and Explosion Hazard Data

Flash Point (Method Used): 415° F C.O.C.	Flammable Limits: NA	LEL: NA	UEL: NA

Extinguishing Media: Dry chemical, CO_2, foam or water fog.

Special Fire Fighting Procedures: Treat as an oil fire, do not use direct stream of water.

Unusual Fire and Explosion Hazards: NONE

Material Safety Data - Petrolatum #8009-03-08

Witco
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MATERIAL SAFETY DATA SHEET

Product name: WHITE FONOLINE® Petrolatum

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: **WHITE FONOLINE® Petrolatum**

Chemical name: Petrolatum

Supplier:
Crompton Corporation
One American Lane
Greenwich, CT 06831-2559, USA

Emergency telephone number:
(24 hours) 732-826-6600
(24 hours) 800-424-9300
724-756-2210
Canada (24 hour emergency #): 416-284-1661

For MSDS, Product Safety, or regulatory inquiries, call:
Kenneth Blair 732-826-6600 X295
To request an MSDS, Call: 866-430-2775

Customer Service:
Customer Service 877-948-2688

2. COMPOSITION / INFORMATION ON INGREDIENTS

COMPONENT	CAS#	CONCENTRATION
Petrolatum	8009-03-8	100.0 %
Vitamin E	59-02-9	< 10.0 PPM
2,6-Di-tert-butyl-p-cresol	128-37-0	< 10.0 PPM

Note(s): This is not a dangerous substance

3. HAZARDS IDENTIFICATION

APPEARANCE

Physical state Semi-solid A liquid above the melting point.

Color	White to light yellow
Odor	None

EMERGENCY OVERVIEW

THIS PRODUCT IS A USP GRADE PETROLATUM. IT IS NOT EXPECTED TO PRESENT ANY UNUSUAL HAZARDS, IN PROPER USE.

THIS PRODUCT IS OFTEN TRANSPORTED AND HANDLED HOT. CARE SHOULD BE TAKEN TO PREVENT THERMAL BURNS.

POTENTIAL HEALTH EFFECTS

Swallowing
Acute effects
Ingestion is unlikely to have any toxic effects but the product may act as an intestinal lubricant and result in diarrhea and frequent loose stools.

Skin absorption
Acute effects
Harmful effects are not expected from short periods of contact.

Inhalation
Acute effects
Harmful effects are not expected from static vapor at ambient temperature.
Inhalation of mist or spray may be harmful.

Chronic effects
Aspiration may cause pulmonary edema or aspiration pneumonia.
Oil deposits in the lung may lead to fibrosis and reduced pulmonary function.
Prolonged or repeated inhalation of excessive amounts of oil mist or vapors may cause irritation of the respiratory tract.

Skin contact
Acute effects
No evidence of harmful effects from available information.

Eye contact
Acute effects
No evidence of harmful effects from available information.

POTENTIAL ENVIRONMENTAL EFFECTS

This product is stable in water, and can be mechanically separated from water. The water may be suitable for disposal in a biological waste water treatment plant.

4. FIRST AID MEASURES

Swallowing
Treat symptomatically. Not expected to be toxic by ingestion. WHEN MOLTEN ONLY (molten product can cause thermal burns)

Skin
No emergency care anticipated. Wash skin with soap and water. Remove contaminated clothing. Wash clothing before re-use. Obtain medical attention if irritation persists. WHEN MOLTEN ONLY (molten product can cause thermal burns) If burned by contact with hot molten material, cool burned skin as quickly as possible by immersing in cold water, or applying cold water. Call a physician.

Inhalation
Obtain medical attention. Oxygen may be given by qualified personnel if breathing is difficult or cyanosis (blue discoloration of skin) is noted. Give artificial respiration if not breathing. Remove to fresh air if aerosol spray is inhaled. Aspiration may cause pulmonary edema or aspiration pneumonia. Exposed persons should be kept under medical observation for at least 48 hours because delayed effects may occur. WHEN MOLTEN ONLY (molten product can cause thermal burns)

Eye contact
No emergency care anticipated. Flush eyes thoroughly with water for several minutes. Obtain medical attention if discomfort persists. WHEN MOLTEN ONLY (molten product can cause thermal burns)

5. FIRE-FIGHTING MEASURES

Flash point: > 204 °C (400 °F)
NFPA CLASSIFICATION

Health: 0	Flammability: 1	Reactivity: 0	Special provisions: -

Special fire fighting procedures
Use water spray to cool fire-exposed containers and structures. Do not direct a solid stream of water or foam into burning molten material; this may cause spattering and spread the fire.

Special protective equipment for firefighters
Body covering protective clothing, full "turn-out" gear. Self-contained breathing apparatus with full face-piece operated in positive pressure mode.

Extinguishing media
Suitable: Treat as an oil fire.
Small fires:
- CO_2
- dry powder
- foam
Large fires:
- alcohol-type foam or universal-type foams
- water fog

Unsuitable: Oil will float on water and can spread any fire.

Unusual fire and explosion hazards
This product will burn if involved in a fire. This product will float upon water, so water spray is not a suitable extinguishing agent as it may cause any fire to spread.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions
Eliminate sources of ignition. Use heat protective equipment (such as gloves, long sleeves, and aprons) when handling molten material.

Environmental precautions
This product is insoluble in water and will float on the surface. Prevent from entering sewers or drains. Should this product enter sewers or drains, it should be pumped out into an open vessel. Emergency services may need to be called to assist in this operation.

Methods for cleaning up
Floor may be slippery; use care to avoid falling.

Small spills: Cover remaining spilled product with dry powder, dry sand, or Vermiculite.

Large spills: After cooling solidification, scrape and/or shovel upmaterial.
Large spill: Pump or vacuum transfer spilled product to clean containers for recovery. Absorb unrecoverable product. Transfer contaminated absorbent, soil and other materials to containers for disposal.
Stop leak, if without risk.

7. HANDLING AND STORAGE

HANDLING

Handling precautions
Never use pressure to empty drums. Keep drums tightly closed to prevent contamination. Residual vapors may explode on ignition; do not puncture, drill, grind, or weld near this container. Electrically bond and ground all containers and equipment before transfer or use of material.

STORAGE

Storage requirements
Normal precautions common to safe manufacturing practice should be followed in handling and storage. Store in a dry place. Keep container tightly closed. Keep out of strong sunlight. Do not store at temperatures: >+90 °C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

PERSONAL PROTECTION

Respiratory protection
If vapor and/or mist is generated by heating, spraying, etc., wear an organic vapor respirator with a mist filter. No special; respiratory protection is normally required.

Hand protection / protective gloves
Wear oil resistant gloves.
Heat protective impervious gloves when handling molten product.

Eye protection
Face shield or chemical splash goggles in case of splashing.

Skin protection
Wear protective clothing, such as long sleeves to minimize skin contact.
Coveralls when handling molten product.

Industrial hygiene measures
Remove contaminated clothing and clean it.
Do not eat or drink at work.

ENGINEERING CONTROLS

Ventilation
Local ventilation is needed in the presence of airborne mists.

EXPOSURE LIMITS

Component	Type	Value	Remark
Mineral Oil Mist	TWA (mist), ACGIH	5.0 mg/m3	If used in way that generates a "mist" observe the limits for Mineral Oil Mist.
	STEL (mist), ACGIH	10.0 mg/m3	

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Physical state	Semi-solid A liquid above the melting point.
Color	White to light yellow
Odor	None

OTHER PROPERTIES

Boiling point	No data available.
Melting point	38 - 60 °C at STP unless specified below.
Specific gravity (H2O=1)	< 1
Vapor pressure	< 0.005 hPa (0.00 mmHg) at 20 °C
Solubility in water	Insoluble
Solubility in organic solvents	Soluble
Partitioning coefficient	log POW: > 6 This product is soluble in oil.
Flash point	> 204 °C (400 °F) Method: Cleveland open cup ASTM D 92
Percent volatiles	Nil

10. STABILITY AND REACTIVITY

Stability: Stable.

Incompatible materials
Normally unreactive; however avoid contact with:
Strong oxidizing agents.
Sunlight or ultraviolet light.
Heat or high temperature.

Hazardous combustion products
Burning can produce the following combustion products:
Oxides of carbon.
Soot

Hazardous polymerization: Will not occur.

11. TOXICOLOGICAL INFORMATION

GENERAL

No evidence of harmful effects from available information.

SWALLOWING

Test results

Acute toxicity: Remark: No data available.

SKIN ABSORPTION

Test results
Acute toxicity: Remark: No data available.

INHALATION

Test results
Acute toxicity: Remark: No data available.

12. ECOLOGICAL INFORMATION

This product is stable in water, and can be mechanically separated from water. The water may be suitable for disposal in a biological waste water treatment plant.

13. DISPOSAL CONSIDERATIONS

General: Incineration is probably the best means of disposal. Dispose of in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

DOT Classification

Not regulated by ground or rail if shipped or transported at temperatures under 212 °F (100 °C) or in containers less than 450 liters (119 US gal).
If shipped or transported at temperatures over 212 °F (100 °C) and in containers greater than 450 liters (119 US gal), this product is regulated as ELEVATED TEMPERATURE LIQUID, NOS at or above 100 °C and below its flash, Class 9, UN 3257, PGIII, ERG 128.

IMDG Classification

This product is not regulated by IMDG.

ICAO Classification

This product is not regulated by ICAO.

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MATERIAL SAFETY DATA SHEET

Product name: WHITE FONOLINE® Petrolatum

15. REGULATORY INFORMATION

New Jersey Worker and Community Right-To-Know Act (Labeling Requirements)

Chemical name	CAS#	New Jersey TS Number
Petrolatum	8009-03-8	

EPA Hazard Categories (SARA 311, 312): None

CHEMICAL INVENTORY

Canada: The ingredients of this product are on the DSL.

Europe: The ingredients of this product are on the EINECS inventory.

United States: The ingredients of this product are on the TSCA inventory.

Australia: The ingredients of this product are on the AICS inventory.

Japan: The ingredients of this product are on the ENCS inventory.

FDA

Food additive
This product is a USP grade Petrolatum which is used for a variety of applications such as food grade lubricants and in the production of cosmetics and pharmaceuticals. It meets the requirements of the US FDA as per 21 CFR 172.880 and 21 CFR 178.3700.

16. OTHER INFORMATION

HMIS RATING

Health: 0	Flammability: 1	Reactivity: 0	PPI: -

LEGEND

STP	Standard temperature and pressure
W/W	Weight/Weight
0 (HMIS)	Minimal hazard
1 (HMIS)	Slight hazard
2 (HMIS)	Moderate hazard
3 (HMIS)	Serious hazard

Witco
a Crompton business

MATERIAL SAFETY DATA SHEET

Product name: WHITE FONOLINE® Petrolatum

4 (HMIS)	Severe hazard
X (HMIS)	Personal protection rating to be supplied by user depending on use conditions

The opinions expressed herein are those of qualified experts within Crompton Corporation. We believe that the information contained herein is current as of the date of this Safety Data Sheet. Since the use of this information and of these opinions and the conditions of use of this product are not within the control of Crompton Corporation, it is the user's obligation to determine the conditions of safe use of the products.

Parvan 1300
Safety Data Stop
#8196.0

ExxonMobil

792044-00 PARVAN 1300
MATERIAL SAFETY DATA BULLETIN

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1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: PARVAN 1300 (STOCK: 8196.0)
SUPPLIER: EXXONMOBIL CORPORATION
3225 GALLOWS RD.
FAIRFAX, VA 22037

24 - Hour Health and Safety Emergency (call collect): 609-737-4411

24 - Hour Transportation Emergency:
CHEMTREC: 800-424-9300 202-483-7616
LUBES AND FUELS: 281-834-3296

Product and Technical Information:
Lubricants and Specialties: 800-662-4525 800-443-9966
Fuels Products: 800-947-9147
MSDS Fax on Demand: 613-228-1467
MSDS Internet Website: http://emmsds.ihssolutions.com/

2. COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAMES AND SYNONYMS: PETROLEUM HYDROCARBONS

GLOBALLY REPORTABLE MSDS INGREDIENTS:

None.

See Section 8 for exposure limits (if applicable).

3. HAZARDS IDENTIFICATION

This product may be considered hazardous according to regulatory guidelines (See Section 15).

EMERGENCY OVERVIEW: White Wax. May generate irritating vapors/fumes when burning. DOT ERG No. : 128

POTENTIAL HEALTH EFFECTS: Contact with hot material may cause skin burns. When heated, the vapors/fumes given off may cause

7. HANDLING AND STORAGE

HANDLING: If heated, avoid personal contact. Avoid breathing vapors/fumes from heated material. See Section 8 for additional personal protection advice when handling this product.
STORAGE: Do not store in open or unlabelled containers. Store away from strong oxidizing agents or combustible material.
EMPTY CONTAINER WARNING: Empty containers retain residue (liquid and/or vapor) and can be dangerous. DO NOT PRESSURIZE, CUT, WELD, BRAZE, SOLDER, DRILL, GRIND OR EXPOSE SUCH CONTAINERS TO HEAT, FLAME, SPARKS, STATIC ELECTRICITY, OR OTHER SOURCES OF IGNITION; THEY MAY EXPLODE AND CAUSE INJURY OR DEATH. Do not attempt to refill or clean container since residue is difficult to remove. Empty drums should be completely drained, properly bunged and promptly returned to a drum reconditioner. All containers should be disposed of in an environmentally safe manner and in accordance with governmental regulations.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE LIMITS:

OSHA and ACGIH have adopted an 8-hour time-weighted average (TWA) exposure of 2 mg/m3 (paraffin wax fume).

VENTILATION: Use local exhaust over heating operations.
RESPIRATORY PROTECTION: No special requirements under ordinary conditions of use and with adequate ventilation.
EYE PROTECTION: Chemical type goggles and face shield should be worn if contact with hot liquid may occur.
SKIN PROTECTION: Gloves as required to handle hot materials. Good personal hygiene practices should always be followed.

9. PHYSICAL AND CHEMICAL PROPERTIES

Typical physical properties are given below. Consult Product Data Sheet for specific details.

APPEARANCE: Wax
COLOR: White
ODOR: Mild
ODOR THRESHOLD-ppm: NE
pH: NA
BOILING POINT C(F): NE
MELTING POINT C(F): 54(129)
FLASH POINT C(F): 204(400) (ASTM D-92)
FLAMMABILITY (solids): NE
AUTO FLAMMABILITY C(F): NE
EXPLOSIVE PROPERTIES: NA
OXIDIZING PROPERTIES: NA
VAPOR PRESSURE-mmHg 20 C: < 0.1
VAPOR DENSITY: NE
EVAPORATION RATE: NE
RELATIVE DENSITY, 15/4 C: 0.827
SOLUBILITY IN WATER: Negligible
PARTITION COEFFICIENT: > 3.5
VISCOSITY AT 40 C, cSt: NA
VISCOSITY AT 100 C, cSt: 3.5

toxicity at 1000 mg/L loading, therefore long-term adverse effects in the aquatic environment are not expected.

MOBILITY: Not established.

PERSISTENCE AND DEGRADABILITY: This product is expected to be inherently biodegradable, as the principal components have been shown to degrade at slow to moderate rates.

BIOACCUMULATIVE POTENTIAL: Not established.

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13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL: Product is suitable for burning in an enclosed, controlled burner for fuel value. Such burning may be limited pursuant to the Resource Conservation and Recovery Act. In addition, the product is suitable for processing by an approved recycling facility or can be disposed of at an appropriate government waste disposal facility. Use of these methods is subject to user compliance with applicable laws and regulations and consideration of product characteristics at time of disposal.

RCRA INFORMATION: The unused product, in our opinion, is not specifically listed by the EPA as a hazardous waste (40 CFR, Part 261D), nor is it formulated to contain materials which are listed hazardous wastes. It does not exhibit the hazardous characteristics of ignitability, corrosivity, or reactivity. The unused product is not formulated with substances covered by the Toxicity Characteristic Leaching Procedure (TCLP). However, used product may be regulated.

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14. TRANSPORT INFORMATION

USA DOT:

SHIPPING NAME:	Elevated temperature liquid, n.o.s. (contains PETROLEUM WAX)
HAZARD CLASS & DIV:	9
ID NUMBER:	UN3257
ERG NUMBER:	128
PACKING GROUP:	PG III
STCC:	NE
DANGEROUS WHEN WET:	No
POISON:	No
LABEL(s):	Class 9
PLACARD(s):	Class 9
PRODUCT RQ:	NA
MARPOL III STATUS:	NA

RID/ADR:

HAZARD CLASS:	9
PACKING GROUP:	III
LABEL:	9
DANGER NUMBER:	99
UN NUMBER:	3257
SHIPPING NAME:	Elevated temperature liquid, n.o.s. (contains PETROLEUM WAX)
REMARKS:	NA

4=NTP CARC 9=OSHA CARC 14=TSCA 6 19=FL RTK 24=NJ RTK
5=NTP SUS 10=OSHA Z 15=TSCA 12b 20=IL RTK 25=PA RTK
26=RI RTK

Code key: CARC=Carcinogen; SUS=Suspected Carcinogen; REPRO=Reproductive

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16. OTHER INFORMATION

USE: WAX

NOTE: PRODUCTS OF EXXON MOBIL CORPORATION AND ITS AFFILIATED COMPANIES ARE NOT FORMULATED TO CONTAIN PCBS.

Health studies have shown that many hydrocarbons pose potential human health risks which may vary from person to person. Information provided on this MSDS reflects intended use. This product should not be used for other applications. In any case, the following advice should be considered:

INJECTION INJURY WARNING: If product is injected into or under the skin, or into any part of the body, regardless of the appearance of the wound or its size, the individual should be evaluated immediately by a physician as a surgical emergency. Even though initial symptoms from high pressure injection may be minimal or absent, early surgical treatment within the first few hours may significantly reduce the ultimate extent of injury.

Precautionary Label Text:

CONTAINS PETROLEUM WAX

CAUTION!

HOT PRODUCT MAY CAUSE THERMAL BURNS. EXPOSURE TO GREATER THAN 2MG/M3 WAX FUME MAY CAUSE NOSE, THROAT OR LUNG IRRITATION.

Use adequate ventilation during heating operations to keep airborne levels below recommended exposure limits.

FIRST AID: If irritation occurs, remove to fresh air and get medical attention.

For industrial use only. Not intended or suitable for use in or around a household or dwelling.

Refer to product Material Safety Data Sheet for further safety and health information.

****

For Internal Use Only: MHC: 0* 0* NE 0* 0*, MPPEC: A, TRN: 792044-00, CMCS97: 97V339, REQ: PETROLEUM SPECIALTIES, SAFE USE: G
EHS Approval Date: 09JAN2003

Bareco Material Safety Data Sheet

Parafin or Petroleum Hydrocarbon Waxes. CAS# 8002-74-2.

Revised: 3/12/02

MATERIAL SAFETY DATA SHEET

Product Name: **BARECO PETROLEUM HYDROCARBON WAXES**

Manufacturer: Bareco Products
140 E. Main Street, Rock Hill, SC 29730
(814) 677-1333
(800) 424-9300 *emergency

SECTION 1 CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

TRADE NAME **Be Square 175 Amber, Lite, White**

Synonyms BARECO PETROLEUM HYDROCARBON WAXES

NFPA 704M© Rating Health: 1 Fire: 1 Reactivity: 0 Special:
{ 0= Insignificant 1= Slight 2= Moderate 3= High 4= Extreme}

SECTION 02 COMPOSITION AND INFORMATION ON INGREDIENTS

Chemical Ingredients A COMBINATION OF NON-HAZARDOUS **PARAFFIN WAX** (8002-74-2) AND/OR NON-HAZARDOUS **MICROCRYSTALLINE WAX** (63231-60-7) FOR A TOTAL OF UP TO 100%. MAY OR MAY NOT BE BLENDED WITH A NON-HAZARDOUS **SYNTHESIZED PETROLEUM WAX** (9010-79-1). SEE SECTION 15 FOR FURTHER INFORMATION.

SECTION 03 HAZARD IDENTIFICATION

Eye Contact THIS PRODUCT IS MINIMALLY IRRITATING TO THE EYES UPON DIRECT CONTACT. BASED ON TESTING OF SIMILAR PRODUCTS AND/OR COMPONENTS.

Skin Contact THIS PRODUCT IS MINIMALLY IRRITATING TO THE SKIN UPON DIRECT CONTACT. BASED ON TESTING OF SIMILAR PRODUCTS AND/OR COMPONENTS.

Inhalation AVOID INHALATION OF FUMES. CAUTION SHOULD BE TAKEN TO PREVENT GENERATION OF FUMES. PARAFFIN WAX FUMES, IF GENERATED ARE CONSIDERED HAZARDOUS ACCORDING TO THE OSHA HAZARD COMMUNICATION STANDARD. THIS PRODUCT HAS A LOW VAPOR PRESSURE AND IS NOT EXPECTED TO PRESENT AN INHALATION HAZARD AT AMBIENT CONDITIONS. CAUTION SHOULD BE TAKEN TO PREVENT AEROSOLIZATION OR MISTING OF THIS PRODUCT. THE THRESHOLD LIMIT VALUE (TLV) FOR THIS PRODUCT AS PARAFFIN WAX FUMES IS 2 MG/M3. EXPOSURE TO VAPORS GENERATED UNDER UNUSUAL CONDITIONS MAY BE MILDLY IRRITATING TO THE NOSE AND THROAT. *SEE HEALTH DATA SECTION BELOW.*

Ingestion DO NOT INGEST. THIS PRODUCT HAS LAXATIVE PROPERTIES AND MAY RESULT IN ABDOMINAL CRAMPS AND DIARRHEA.

Health Data PETROLEUM WAXES ARE MIXTURES OF HIGH MOLECULAR WEIGHT (C20-C70), SOLID HYDROCARBONS. THEY ARE COMPRISED MOSTLY OF N-ALKANES, BUT SOME ISO AND CYCLOALKANES ARE ALSO PRESENT. PHYSIOLOGICALLY PETROLEUM WAXES ARE INERT AND ARE CONSIDERED NONTOXIC. WORKING WITH MOLTEN WAX IS REPORTED TO BE UNCOMFORTABLE AND NAUSEATING. USE OF WAX SPRAY HAS BEEN REPORTED TO BE OBJECTIONABLE BECAUSE OF ITS PHYSICAL PROPERTIES AND NOT DUE TO ITS TOXICITY. BASED ON THIS DATA THE ACGIH THRESHOLD LIMIT VALUE (TLV) FOR PETROLEUM WAX FUMES IS RECOMMENDED TO PREVENT IRRITATION OF THE RESPIRATORY TRACT AND OTHER UNPLEASANT EFFECTS.PETROLEUM WAXES STUDIED WERE NOT FOUND TO BE CARCINOGENIC IN MOUSE SKIN PAINTING OR IN RAT LIFETIME FEEDING STUDIES. THIS PRODUCT IS NOT CARCINOGENIC ACCORDING TO THE OSHA HAZARD COMMUNICATION STANDARD.

SECTION 04 FIRST AID INFORMATION

Eye Contact	IMMEDIATELY FLUSH EYES WITH LARGE AMOUNTS OF WATER AND CONTINUE FLUSHING UNTIL IRRITATION SUBSIDES. IF MATERIAL IS HOT, TREAT FOR THERMAL BURNS AND TAKE VICTIM TO HOSPITAL IMMEDIATELY.
Skin Contact	REMOVE CONTAMINATED CLOTHING. IF MATERIAL IS HOT, SUBMERGE INJURED AREA IN COLD WATER. IF VICTIM IS SEVERELY BURNED, REMOVE TO A HOSPITAL IMMEDIATELY.
Inhalation	THIS MATERIAL HAS A LOW VAPOR PRESSURE AND IS NOT EXPECTED TO PRESENT AN INHALATION EXPOSURE AT AMBIENT CONDITIONS. IF FUMES ARE GENERATED WHEN THE MATERIAL IS HEATED OR HANDLED, REMOVE VICTIM FROM EXPOSURE.
Ingestion	DO NOT INDUCE VOMITING.

SECTION 05 FIREFIGHTING MEASURES

Flash Point	>350F	**Test Method**	ASTM D92 (C.O.C.)
Autoignition Temperature	NO DATA	**Test Method**	NO DATA
	FLAMMABLE LIMITS IN AIR % BY VOLUME		
Lower	NO DATA	**Upper**	NO DATA

Extinguishing Media	USE DRY CHEMICAL, FOAM, OR CARBON DIOXIDE.
Special Firefighting Procedures	WATER MAY BE INEFFECTIVE BUT CAN BE USED TO COOL CONTAINERS EXPOSED TO HEAT OR FLAME. CAUTION SHOULD BE EXERCISED WHEN USING WATER OR FOAM AS FROTHING MAY OCCUR, ESPECIALLY IF SPRAYED INTO CONTAINERS OF HOT, BURNING LIQUID.
Unusual Fire and Explosive Conditions	DENSE SMOKE MAY BE GENERATED WHILE BURNING. CARBON MONOXIDE, CARBON DIOXIDE, AND OTHER OXIDES MAY BE GENERATED AS PRODUCTS OF COMBUSTION.

SECTION 06 ACCIDENTAL RELEASE MEASURES

Steps to be taken if material is released or spilled	CONSULT HEALTH EFFECT INFORMATION IN SECTION 3, PERSONAL HEALTH PROTECTION INFORMATION IN SECTION 8, FIRE PROTECTION INFORMATION IN SECTION 5, AND REACTIVITY DATA IN SECTION 10. NOTIFY APPROPRIATE AUTHORITIES OF SPILL. CONTAIN SPILL IMMEDIATELY. DO NOT ALLOW SPILL TO ENTER SEWERS OR WATERCOURSES. REMOVE ALL SOURCES OF IGNITION. ABSORB WITH APPROPRIATE INERT MATERIAL SUCH AS SAND, CLAY, ETC. LARGE SPILLS MAY BE PICKED UP USING VACUUM PUMPS, SHOVELS, BUCKETS, OR OTHER MEANS AND PLACED IN DRUMS OR OTHER SUITABLE CONTAINERS.

SECTION 07 HANDLING AND STORAGE

Handling & Storage Requirements	DO NOT TRANSFER TO UNMARKED CONTAINERS. STORE IN CLOSED CONTAINERS AWAY FROM HEAT, SPARKS, OPEN FLAME, OR OXIDIZING MATERIALS. THIS PRODUCT IS NOT CLASSIFIED AS HAZARDOUS UNDER DOT REGULATIONS. FIRE EXTINGUISHERS SHOULD BE KEPT READILY AVAILABLE. SEE NFPA 30 AND OSHA 1910.106--FLAMMABLE AND COMBUSTIBLE LIQUIDS.

SECTION 08 EXPOSURE CONTROLS AND PERSONAL PROTECTION

Eye Protection EYE PROTECTION IS NOT REQUIRED UNDER CONDITIONS OF NORMAL USE. IF MATERIAL IS HANDLED SUCH THAT IT COULD BE SPLASHED INTO EYES, WEAR PLASTIC FACE SHIELD OR SPLASH-PROOF SAFETY GOGGLES.

Skin Protection SKIN PROTECTION IS NOT REQUIRED UNDER CONDITIONS OF NORMAL USE. IF HANDLING HOT MATERIAL, USE INSULATED PROTECTIVE CLOTHING (BOOTS, GLOVES, APRONS, ETC.).

Respiratory Protection RESPIRATORY PROTECTION IS NOT REQUIRED UNDER CONDITIONS OF NORMAL USE. IF FUMES ARE GENERATED WHEN THE MATERIAL IS HEATED OR HANDLED, USE AN ORGANIC VAPOR RESPIRATOR WITH A DUST AND MIST FILTER. ALL RESPIRATORS MUST BE NIOSH CERTIFIED. DO NOT USE COMPRESSED OXYGEN IN HYDROCARBON ATMOSPHERES.

Ventilation IF VAPOR OR MIST IS GENERATED WHEN THE MATERIAL IS HEATED OR HANDLED, ADEQUATE VENTILATION IN ACCORDANCE WITH GOOD ENGINEERING PRACTICE MUST BE PROVIDED TO MAINTAIN CONCENTRATIONS BELOW THE SPECIFIED EXPOSURE OR FLAMMABLE LIMITS.

Other CONSUMPTION OF FOOD AND BEVERAGE SHOULD BE AVOIDED IN WORK AREAS WHERE HYDROCARBONS ARE PRESENT. ALWAYS WASH HANDS AND FACE WITH SOAP AND WATER
BEFORE EATING, DRINKING, OR SMOKING.

CAS Number	Hazardous in Blend	Percentage Min	Percentage Max	Exposure Limit	Unit
8002-74-2	No	0	100		
63231-60-7	No	0	100	OSHA PEL	NO LIMIT
9010-79-1	No	0	100	ACGIH TLV	NO LIMIT

SECTION 09 PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point	No data	**Percentage Volatile**	No data
Melting Point	* See Product Bulletin	**Vapor Density (Air=1)**	> 1
Appearance	White to Brown Solid	**Evaporation Rate (EE=1)**	No data
Odor	None	**Specific Gravity**	Approx 0.78 8/cc @ 100°C
Vapor Pressure	Nil	**Molecular Weight**	Approx 450-700
Solubility	Negligible		

SECTION 10 STABILITY AND REACTIVITY

Stability (thermal, light, etc)	Stable	**Conditions to Avoid**	None
Hazardous Polymerization	Will not occur	**Incompatibility Materials to Avoid**	May react with strong oxidizing agents
Hazardous Decomposition Products	None		

SECTION 11 TOXICOLOGICAL INFORMATION

NO DATA AVAILABLE

SECTION 12 ECOLOGICAL INFORMATION

NO DATA AVAILABLE

SECTION 13 DISPOSAL CONSIDERATIONS

Waste Disposal Method

ALL DISPOSALS MUST COMPLY WITH FEDERAL, STATE, AND LOCAL REGULATIONS. THE MATERIAL, IF SPILLED OR DISCARDED, MAY BE A REGULATED WASTE. REFER TO STATE AND LOCAL REGULATIONS. CAUTION! IF REGULATED SOLVENTS ARE USED TO CLEAN UP SPILLED MATERIAL, THE RESULTING WASTE MIXTURE MAY BE REGULATED. DEPARTMENT OF TRANSPORTATION (DOT) REGULATIONS MAY APPLY FOR TRANSPORTING THIS MATERIAL WHEN SPILLED. WASTE MATERIAL MAY BE LANDFILLED OR INCINERATED AT AN APPROVED FACILITY. MATERIALS SHOULD BE RECYCLED IF POSSIBLE.

SECTION 14 TRANSPORATION INFORMATION

DOT: not regulated

SECTION 15 REGULATORY INFORMATION

Additional Information

THIS PRODUCT IS NOT KNOWN TO CONTAIN ANY SARA TITLE III, SECTION 313 REPORTABLE CHEMICALS AT OR GREATER THAN 1.0% (01.% FOR CARCINOGENS). THIS SUBSTANCE IS LISTED ON THE U.S. TOXIC SUBSTANCES CONTROL ACT (TSCA) INVENTORY. THESE PRODUCTS HAVE BEEN TREATED FOR REMOVAL OF POLYNUCLEAR AROMATIC COMPOUNDS (PNA'S), AND AS SUCH, POTENTIALLY PASS FDA REGULATIONS FOR FOOD USE. PLEASE CONSULT THE PRODUCT BULLETIN OR YOUR SALES REP FOR DETAILS. PLEASE REFER TO CAS NUMBERS FOR LISTING ON OTHER CHEMICAL INVENTORIES. PRODUCTS SUCH AS THIS HAVE BEEN TESTED TO SHOW < 5PPM HEAVY METALS. THESE PRODUCTS ARE NOT SHOWN TO BE CARCINOGENIC OR MUTAGENIC.

SECTION 16 OTHER INFORMATION

Supersedes Date

Original Version

Disclaimer of Warranty

THE INFORMATION CONTAINED HEREIN IS BASED UPON DATA AVAILABLE TO US, AND REFLECTS OUR BEST PROFESSIONAL JUDGEMENT. HOWEVER, NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY USE, OR ANY OTHER WARRANTY IS EXPRESSED OR IMPLIED REGARDING THE ACCURACY OF SUCH DATA, THE RESULTS TO BE OBTAINED FROM THE USE THEREOF, OR THAT ANY SUCH USE DOES NOT INFRINGE ANY PATENT. SINCE THE INFORMATION CONTAINED HEREIN MAY BE APPLIED UNDER CONDITIONS OF USE BEYOND OUR CONTROL AND WITH WHICH WE MAY BE UNFAMILIAR, WE DO NOT ASSUME ANY RESPONSIBILITY FOR THE RESULTS OF SUCH APPLICATION. THIS INFORMATION IS FURNISHED UPON THE CONDITION THAT THE PERSON RECEIVING IT SHALL MAKE HIS OWN DETERMINATION OF THE SUITABILITY OF THE MATERIAL FOR HIS PARTICULAR PURPOSE.

Conclusion

From the foregoing body of research and data, we think that it is clear that we have answered the questions you asked of us in your letter dated August 24, 2006. The microcrystalline cheesewax that we use in our production of organically certified Shiitake mushrooms (since 1987) has undergone massive amounts of testing and analysis and has proven to be the best and safest of all alternative methods of sealing moisture in Shiitake logs. It is the only moisture sealant approved by USDA/FDA for use around food and in food. It has been the primary sealant used in the U.S. log-grown mushroom industry for over twenty-five years. There is no logical reason for NOP to not approve our supplemental information for review by the NOSB and for NOSB to then approve our food-grade cheesewax for inclusion on the approved substance list for organic certification.

Therefore, please make copies of this supplemental information for the full membership of the NOSB and we will await their decision in, hopefully, the near future.

Sincerely,

Tom E. Kimmons

4008

Tom E. Kimmons, Director
Shiitake Mushroom Center/Shirley CDC
366 Brown Rd.
Shirley, AR 72153
Phone: 501-723-4443

SHIP TO:

Mr. Robert Pooler, Agri. Marketing Spec.
USDA/NOP
1400 independence Ave. S.W.
STOP 0268 - Room 4008-S
Washington, D.C. 20250-0200