MINERAL OIL
Livestock

Executive Summary

In 1995, mineral oil was approved for use in livestock production for topical use and as a lubricant by the National Organic Standards Board. Farmers are once again petitioning the use of mineral oil for the use of livestock medical treatment used as an oral drench as treatment for impaction and diarrhea. Additionally, it is being used as a feed supplement, being added to livestock vitamin/mineral supplement blends as a dust suppressant.

The farmers are requesting the use of mineral oil in the case of 'omasal impaction', in which the ruminant's third stomach (omasmum) essentially becomes bound up, compressed, resulting in excruciating pain for the animal. The mineral oil is applied as a 'drench', at the rate of 1-2 gallons every 12 hours until the viscous nature of the mineral oil lubricates the impaction. Failure to treat often leads to the need for surgery. For this particular herd health problem, there is no substitute to mineral oil. Another (seemingly counter-intuitive) use for Mineral Oil is in diarrhea where it acts to line the gut so toxins are not re-absorbed as well as quelling the excessive fermentation and putrefaction occurring in the duodenum, jejunum, and ileum. Another ailment which inflicts baby calves is called 'retained mecomium', whereby the calf's first manure is blocked and the animal is unable to excrete normally. Again, the mineral oil serves as an internal lubricant in conjunction with administering an enema to unblock the digestive obstruction.

Used as a dust control, mineral oil is used in the formulation of vitamin/mineral supplements for livestock production. Also, it is considered a flowability material to enhance the uniform distribution of nutrients of extremely small inclusion (vitamins, trace minerals). Mineral oil is considered to be irreplaceable in its function. Vegetable oil sources are known to oxidize vitamins and lead to rancidity. The inclusion of mineral oil also serves the function of the respiratory aggravation facing the livestock and the human participants in the manufacturing and/or feeding and reduced intake of essential nutrients. According to the farmers' petition, the literal inclusion of mineral oil in the above mentioned function is typically less than 2% of the total batch of mineral. Therefore, it is less than 40# per ton. However, 1% is the standard. The finished product, the vitamin/mineral supplement for a lactating dairy animal, is often fed at the rate of 0.5 lb. per day, contributing less than 0.2% ounce to the cow's daily diet.

Summary of TAP Reviewer's Analyses[1]

Synthetic/ Nonsynthetic	*Allow without restrictions?*	*Allow only with restrictions? (See Reviewers' comments for restrictions)*
Synthetic (2) Nonsynthetic (1)	Yes (1) No (2)	Yes (2)

Identification

[1] *This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the investigator's ability, and has been reviewed by experts on the TAP. The substance is evaluated against the criteria found in section 2119(M) of the OFPA [7 USC 6517(m)]. The information and advice presented to the NOSB is based on the technical evaluation against that criteria, and does not incorporate commercial availability, socio-economic impact, or other factors that the NOSB and the USDA may want to consider in making decisions.*

Chemical names: White Mineral Oil
Molecular Formula: UVCB

Other Names: ADEPSINE OIL, ALBOLINE, Balneol, BAYOL F, Bayol 55, Blandlube, (component of) Agoral, (component of) Alpha Keri, (component of) Keri Lotion, Crystosol, Drakeol, FLEXON 845, Fonoline, GLYMOL, HEAVY LIQUID PETROLATUM, HEAVY MINERAL OIL, IRGAWAX 361, KAYDOL, Kondremul, LIQUID PARAFFIN, LIQUID PETROLATUM, LIQUID VASELINE, MagieSol 44, Mineral oils, Molol, Neo-Cultol, NUJOL, PARAFFIN OIL, PARAFFIN OILS, Paraffins, Parol, PAROLEINE, Peneteck, Penreco, Perfecta, Petrogalar, Petrolatum, liq, PETROLATUM, LIQUID, PRIMOL D, Primol 355, Protopet, SAXOL, SHELLFLEX 371N, SUNPAR 150, Tech Pet F, ULTROL 7, UVASOL, WHITE MINERAL OIL, WHITE OILS

CAS Number: 8012-95-1
RTECS Number: NIOSH/PY8030000[2]

Characterization

Composition:

MINERAL OIL, USP (LIQUID PETROLATUM), IS AVAILABLE IN NUMEROUS PREPN, OFTEN UNDER VARIOUS TRADE NAMES.
[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 1009]**PEER REVIEWED**

AGORAL, PLAIN (PARKE, DAVIS), FLEET **MINERAL OIL** ENEMA (FLEET), **KONDREMUL** PLAIN (FISONS), **PETROGALAR**, PLAIN (WYETH) (ALL NONPRESCRIPTION).
[American Medical Association, AMA Department of Drugs. AMA Drug Evaluations. 5th ed. Chicago: American Medical Association, 1983. 1308]**PEER REVIEWED**

DOMOL (DOME), LUBATH (WARNER/LAMBERT), SURFOL (STIEFEL).
[American Medical Association, AMA Department of Drugs. AMA Drug Evaluations. 4th ed. Chicago: American Medical Association, 1980. 1015]**PEER REVIEWED**

JELLY, ORAL, 55% WEIGHT/WEIGHT (NEO-CULTOL); OIL (**NUJOL**); OIL, RECTAL (FLEET **MINERAL OIL** ENEMA); SUSPENSION, ORAL 1.6 ML/5 ML (AGORAL PLAIN); 2.75 ML/5 ML (**KONDREMUL** PLAIN EMULSION) & 3.25 ML/5 ML (**PETROGALAR** PLAIN). /**MINERAL OIL**, HEAVY/
[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 56:12]**PEER REVIEWED**

OIL, RECTAL (SAF-TIP OIL RETENTION ENEMA); OIL (AVAILABLE BY NONPROPRIETARY NAME). /**MINERAL OIL**, LIGHT/
[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 56:12]**PEER REVIEWED**

Medical /and technical/ white oils may contain alpha-tocopherol (Vitamin E) at levels up to 10 mg/kg as an antioxidant

[2] *Mineral Oil Full Record on Toxnet* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAa8a4Ss:1

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer,1972-PRESENT. (Multivolume work).,p. V33 94 (1984)]**PEER REVIEWED**[3]

Mineral oils, refined from petroleum crude oils, are complex mixtures of straight- and branched-chain paraffinic, naphthenic, and aromatic hydrocarbons with 15 or more carbons.[4]

Properties:

Appearance: Colorless, oily liquid, practically odorless[5]
Odor: Practically odorless even when warmed
Odor like burned lubricating oil.
Taste: Practically tasteless even when warmed
Boiling Point: 360 DEG C
Solubilities: Insoluble in water, alcohol
Soluble in benzene, chloroform, ether, carbon disulfide, petroleum ether
Miscible with most fixed oils
Not miscible with castor oil
Soluble in volatile oils
Surface Tension: 25 deg C slightly below 35 dynes/cm
Viscosity: Kinematic viscosity not less than 38.1 centistokes @ 37.8 deg C
Other Chemical/Physical Properties: Develops not more than a faint odor of petroleum when heated; free or nearly free from fluorescence.
Density: 0.83-0.860 /light/
Boiling Point: 300-600°C
Molecular Weight: NA[6]
Specific Gravity: 0.84
Stability: Stable under ordinary conditions of use and storage. May solidify at room temperature.[7]
Viscosity: 97-107@ 100°F

How Made:

...BY REFINING CRUDER LUBRICATING OILS TO REMOVE UNSATURATED OR VOLATILE COMPOUNDS, AS WELL AS RESINS & COMPOUNDS OF NITROGEN & SULFUR. LIQUID PETROLATUM CONSISTS LARGELY OF SATURATED ALIPHATIC (C14 TO C18) & CYCLIC HYDROCARBONS.
[Gosselin, R.E., R.P. Smith, H.C. Hodge. Clinical Toxicology of Commercial Products. 5th ed. Baltimore: Williams and Wilkins, 1984.,p. II-156]**PEER REVIEWED**

AN OIL EITHER PRESSED OR DRY-DISTILLED FROM PARAFFIN DISTILLATE.
[Sax, N.I. and R.J. Lewis, Sr. (eds.). Hawley's Condensed Chemical Dictionary. 11th ed. New York: Van Nostrand Reinhold Co., 1987. 873]**PEER REVIEWED**

AFTER REMOVING THE LIGHTER HYDROCARBONS FROM PETROLEUM...THE RESIDUE IS AGAIN.../DISTILLED/ BETWEEN 330-390 DEG C & THE DISTILLATE TREATED FIRST WITH

[3] *Mineral Oil Full Record on Toxnet* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAa8a4Ss:1
[4] Tars and Mineral Oils http://ehp.niehs.nih.gov/roc/ninth/known/tars.pdf
[5] Amco Chemical – Mineral Oil (Kaydol) - Petrolatum, Liquid, Technical http://www.healthy-communications.com/msdsmineraloilpetrolatum.html

[6] *Mineral Oil Full Record on Toxnet* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAa8a4Ss:1
[7] Mineral Oil, Material Data Safety Sheet http://www.jtbaker.com/msds/m7700.htm

SULFURIC ACID, THEN SODIUM HYDROXIDE &...DECOLORIZED BY FILTERING... THE PURIFIED PRODUCT IS AGAIN CHILLED, TO REMOVE PARAFFIN, & REDISTILLED @ TEMP ABOVE 330 DEG C.
[Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980. 746]**PEER REVIEWED**

General Manufacturing Information:

A MIXTURE OF LIQUID HYDROCARBONS FROM PETROLEUM.
[Budavari, S. (ed.). The Merck Index - Encyclopedia of Chemicals, Drugs and Biologicals. Rahway, NJ: Merck and Co., Inc., 1989. 1139]**PEER REVIEWED**

LIGHT **MINERAL OIL** IS SIMILAR TO **MINERAL OIL** BUT LOWER MOLECULAR WEIGHT HYDROCARBONS PREDOMINATE, RESULTING IN LOWER VISCOSITY & SPECIFIC GRAVITY. /LIGHT **MINERAL OIL**/
[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 56:12]**PEER REVIEWED**

GRADES: BY VISCOSITY & COLOR.
[Sax, N.I. and R.J. Lewis, Sr. (eds.). Hawley's Condensed Chemical Dictionary. 11th ed. New York: Van Nostrand Reinhold Co., 1987. 873]**PEER REVIEWED**

OILS MAY CONTAIN TOCOPHEROL OR BUTYLATED HYDROXYTOLUENES TO INHIBIT OXIDATION. /HEAVY & LIGHT/
[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 56:12]**PEER REVIEWED**

/LIQUID PETROLATUM IS/ THE OFFICIAL USP NAME FOR A MIXTURE OF REFINED LIQ HYDROCARBONS OF HIGH VISCOSITY.
[Gosselin, R.E., R.P. Smith, H.C. Hodge. Clinical Toxicology of Commercial Products. 5th ed. Baltimore: Williams and Wilkins, 1984.,p. II-156]**PEER REVIEWED**

...IT HAS BEEN DIFFICULT FOR MANY TO ACCEPT WHEN THE UNITED STATES PERMITS ITS USE IN ANIMAL FEEDS TO REDUCE DUSTINESS OF FEEDS OR MINERAL SUPPLEMENTS; AS A LUBRICANT IN PRODUCING PELLETS, CUBES, BLOCKS; & TO PREVENT SEGREGATION OF TRACE MINERALS IN MINERALIZED SALT... US REGULATIONS SET A MAXIMUM OF 3.0% FOR...USE IN MINERAL SUPPLEMENTS & 0.06% OF THE TOTAL RATION WHEN USED IN FEED OR FEED CONCENTRATES.
[Rossoff, I.S. Handbook of Veterinary Drugs. New York: Springer Publishing Company, 1974. 367]**PEER REVIEWED**

IN REFINEMENT FOR HUMAN USE, AROMATIC AMINES & UNSATURATED HYDROCARBONS ARE REMOVED FROM PETROLEUM, LEAVING A VARIETY OF SATURATED HYDROCARBONS. PALATABILITY...IS IMPROVED WHEN IT IS EMULSIFIED WITH ACACIA.
[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 56:12]**PEER REVIEWED**

PESTICIDE TOLERANCES & EXEMPTIONS FOR POSTHARVEST USE ON GRAIN CROPS: PESTICIDE TOLERANCES IN PPM: **MINERAL OIL:** 200 PPM ON CORN & GRAIN SORGHUM. /FROM TABLE/
[White-Stevens, R. (ed.). Pesticides in the Environment: Volume 3. New York: Marcel Dekker, Inc., 1977. 304]**PEER REVIEWED**

Formulations/Preparations:

MINERAL OIL, USP (LIQUID PETROLATUM), IS AVAILABLE IN NUMEROUS PREPN, OFTEN UNDER VARIOUS TRADE NAMES.
[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 1009]**PEER REVIEWED**

AGORAL, PLAIN (PARKE, DAVIS), FLEET **MINERAL OIL** ENEMA (FLEET), **KONDREMUL** PLAIN (FISONS), **PETROGALAR,** PLAIN (WYETH) (ALL NONPRESCRIPTION).
[American Medical Association, AMA Department of Drugs. AMA Drug Evaluations. 5th ed. Chicago: American Medical Association, 1983. 1308]**PEER REVIEWED**

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[American Medical Association, AMA Department of Drugs. AMA Drug Evaluations. 4th ed. Chicago: American Medical Association, 1980. 1015]**PEER REVIEWED**

JELLY, ORAL, 55% WEIGHT/WEIGHT (NEO-CULTOL); OIL (**NUJOL**); OIL, RECTAL (FLEET **MINERAL OIL** ENEMA); SUSPENSION, ORAL 1.6 ML/5 ML (AGORAL PLAIN); 2.75 ML/5 ML (**KONDREMUL** PLAIN EMULSION) & 3.25 ML/5 ML (**PETROGALAR** PLAIN). /**MINERAL OIL,** HEAVY/
[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 56:12]**PEER REVIEWED**

OIL, RECTAL (SAF-TIP OIL RETENTION ENEMA); OIL (AVAILABLE BY NONPROPRIETARY NAME). /**MINERAL OIL,** LIGHT/
[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 56:12]**PEER REVIEWED**

Medical /and technical/ white oils may contain alpha-tocopherol (Vitamin E) at levels up to 10 mg/kg as an antioxidant
[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer,1972-PRESENT. (Multivolume work).,p. V33 94 (1984)]**PEER REVIEWED**

Impurities:

Polynuclear aromatic compounds have been detected in samples of **mineral oil** for medicinal and cosmetic uses
[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International

Agency for Research on Cancer,1972-PRESENT. (Multivolume work).,p. V33 94 (1984)]**PEER REVIEWED**[8]

Mineral oil or "petroleum" occurs naturally in the form of pitch, tar, or bitumen and has been used as a sealing and building material or for medicinal purposes for thousands of years. Mineral oil and natural gas are formed by the accumulation of the decomposing remains of large quantities of marine micro-organisms.[9] To obtain mineral oil, gasoline and kerosene are removed from the crude petroleum by heating, in a method called functional distillation. By using sulphuric acid, applying absorbents, and washing with solvents and alkalis, hydrocarbons and chemicals are removed.[10]

Mineral oil is currently separated into intermediate and finished products by fractional distillation.

Due to its very complex composition, mineral oil has a continuous boiling behavior. Its initial boiling point is below room temperature, but the constituents with the highest carbon contents cannot be distilled because of thermal decomposition. Fractional distillation up to 360° C under atmospheric pressure produces distillates like gasoline, diesel fuel and light heating fuel. Further distillation under vacuum yields lubricants, medium-heavy fuel, or an intermediate product which can be transformed into motor fuel by cracking. However, the thermal decomposition limit (in this case 390° C) is again reached before complete separation is achieved. The residues from vacuum and atmospheric distillations and from cracking can be combined to produce heavy fuel or tar, but this approach doesn't make good use of their higher value components.[11]

Specific Uses:

Mineral oils are primarily used as lubricant base oils to produce further refined oil products. These products include: engine oils, automotive and industrial gear oils, transmission fluids, hydraulic fluids, circulating and hydraulic oils, bearing oils, machine oils, machine-tool oils, compressor and refrigerator oils, steam-engine oils, textile machine oils, air-tool oils, metalworking oils (cutting oils, roll oils, can-forming oils, drawing oils), rust preventative oils, heat-treating oils, transformer oils, greases, medicinal and technical-grade white oils, and processing oils (product extenders, processing aids, carriers and diluents, water repellents, surface-active agents, batching oils, mold-release oils, wash oils).

These oils are used in manufacturing (78.5% of the oils produced), mining (5.0%), construction (1.8%), and miscellaneous industries (14.7%). Approximately 57% of the lubricating oils produced are used by the automotive industry and the remaining 43% by other industries. In the automotive industry, lubricating oils are used as multigrade engine oils (23% of the lubricating oils produced), monograde engine oils (22%), transmission and hydraulic fluids (8%), gear oils (2%), and aviation oils (1%). Other industrial uses for lubricating oils include general industrial diesel engine oils (19%), process oils (13%), metalworking oils (4%), railroad diesel engine oils (3%), and marine diesel engine oils (2%). Technical-grade white oils are used in cosmetics (hair oils, creams), textile-machine lubricants, horticultural sprays, wrapping paper, for corrosion protection in the meat-packing industry, and as lubricants for watches, bicycles, and spindles. Medicinal white oils are used in pharmaceutical preparations (processing aids, intestinal lubricants), food additives (release agents, binders, flotation sealants, defoamants, protective coatings), food packaging and processing, and animal feed products. Medicinal white oils are also used in the chemical and plastics industry as processing media, extenders, and plasticizers.[12]

Mineral oils can be found in facial creams and cleansers as well as in certain hair products such as conditioners. Its lipid solvent qualities make it a prime product for make-up removal.[13]

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[8] *Mineral Oil Full Record on Toxnet* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAa8a4Ss:1
[9] Mineral Oil and Natural Gas http://www.deutsches-museum.de/ausstell/dauer/erd/e_erdoel.htm
[10] April 1997 Newsletter. http://www.essentiallyoils.com/Newsletters/April_1997_Newsletter/april_1997_newsletter.html
[11] *UIC* http://www.uic-gmbh.de/PDF/fisch2.pdf
[12] *Tars and Mineral Oil* http://ehp.niehs.nih.gov/roc/ninth/known/tars.pdf
[13] ***eMedicine Journal, January 7 2002, Volume 3, Number 1*** http://www.emedicine.com/derm/topic508.htm

Action:

MINERAL OIL IS ABSORBED TO A LIMITED EXTENT FROM THE INTESTINAL TRACT... STABLE EMULSIONS OF OIL PENETRATE & SOFTEN STOOL MORE EFFECTIVELY THAN DOES NON-EMULSIFIED OIL... EMULSIFICATION ENHANCES ABSORPTION OF THE OIL.
[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 1009]**PEER REVIEWED**

VET: ...PARENTERALLY, IN...VACCINES TO PROLONG ANTIGEN EFFECT. HISTOLOGICAL STUDIES INDICATE THAT GREAT DEAL OF...OIL REMAINS AT INJECTION SITE FOR LONG TIME, WITH MACROPHAGES PICKING UP SMALL AMT & TRANSPORTING IT THROUGH LYMPHATIC SYSTEM. ITS ULTIMATE FATE IS STILL UNKNOWN.
[Rossoff, I.S. Handbook of Veterinary Drugs. New York: Springer Publishing Company, 1974. 367]**PEER REVIEWED**

ABSORPTION OF **MINERAL OIL** IS REPORTEDLY MINIMAL FOLLOWING ORAL OR RECTAL ADMIN.
[McEvoy, G.K. (ed.). American Hospital Formulary Service--Drug Information 94. Bethesda, MD: American Society of Hospital Pharmacists, Inc. 1994 (Plus Supplements). 1894]**PEER REVIEWED**

ALTHOUGH 30-60% OF ORALLY ADMIN **MINERAL OIL** EMULSION REPORTEDLY IS ABSORBED FROM INTESTINE, SOME CLINICIANS BELIEVE THAT THERE IS NO EVIDENCE THAT EMULSION IS ABSORBED TO A GREATER EXTENT THAN IS NONEMULSIFIED **MINERAL OIL.**
[McEvoy, G.K. (ed.). American Hospital Formulary Service--Drug Information 94. Bethesda, MD: American Society of Hospital Pharmacists, Inc. 1994 (Plus Supplements). 1894]**PEER REVIEWED**

ON THE BASIS OF (14)C MEASUREMENTS IN RATS & SQUIRREL MONKEYS GIVEN **MINERAL OIL** EMULSIONS INCORPORATING N-((14)C)HEXADECANE, SC OR IM, IT WAS CONCLUDED THAT **MINERAL OIL** WAS RETAINED FOR A LONG TIME @ THE INJECTION SITE. AFTER 1 MONTH, GREATER THAN 60% WAS STILL PRESENT THERE, & AFTER 10 MONTHS, GREATER THAN 25%.
[The Chemical Society. Foreign Compound Metabolism in Mammals. Volume 2: A Review of the Literature Published Between 1970 and 1971. London: The Chemical Society, 1972. 112]**PEER REVIEWED**

When large amounts of liquid petrolatum were fed to rabbits, rats and guinea pigs, small quantities were deposited in the mesenteric lymph nodes and, in several cases, in the intestinal mucosa, live and spleen.
[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer,1972-PRESENT. (Multivolume work).,p. V33 132 (1984)]**PEER REVIEWED**

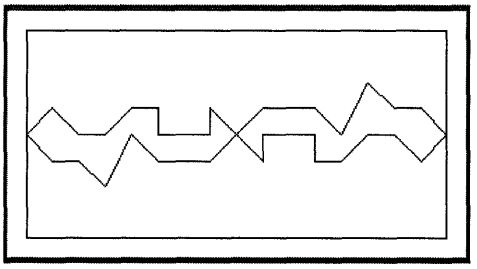
Tritiated **mineral oil** was administered orally or by ip injection to Sprague-Dawley and Holtzman rats. Five hours after oral administration of 0.66 ml/kg body weight, 1.5% of the dose had been absorbed unchanged, and an additional 1.5% was found in the carcasses as non-**mineral oil** substances. Liver, fate, kidney, brain and spleen contained **mineral oil.** Within two days, only 0.3% remained in the animals. After ip administration, the **mineral oil** was retained to a greater extent, and only 11% had been excreted in the feces eight days after treatment.
[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International

Agency for Research on Cancer,1972-PRESENT. (Multivolume work).,p. V33 133 (1984)]**PEER REVIEWED**

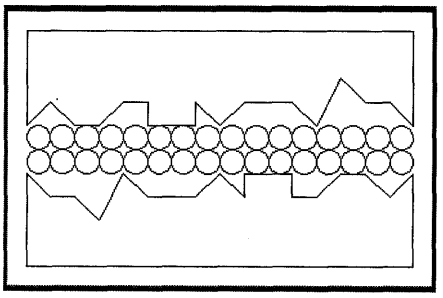
In general, **mineral oil** is absorbed to only a limited extent from the gastrointestinal tract. However, it as found in the liver, spleen, mesenteric and portal-hepatic lymph nodes and lungs of a man known to have ingested large amounts of **liquid paraffin** over many years. **Mineral oil** has been observed by differential staining and GC procedures in the lung tissue of many individuals who routinely use **mineral oil** by oral or nasal administration
[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer,1972-PRESENT. (Multivolume work).,p. V33 136 (1984)]**PEER REVIEWED**[14]

Mineral Oil works as a lubricant:

> An understanding of how lubricating systems work is crucial to the selection of a lubricant for a particular application. This essay could be summarized in one sentence: lubricants provide a protective film that separates the two rubbing surfaces and reduces the level of friction in the two rubbing surfaces.
>
> Any surface contains irregularities, even when polished to a mirror finish. These irregularities may not be visible, except under a microscope. When two highly-polished surfaces are brought gently together, only some points on the surfaces will make contact. These contacts will be brought closer together when a force is applied at right angles to the surfaces (this force is referred to as a 'normal load'), and the number of contact points will increase:



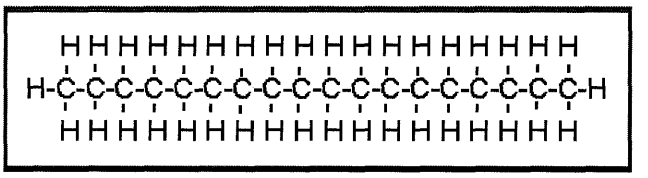
If a protective film were present on each of the surfaces, the surfaces could be separated:



[14] *Mineral Oil Full Record on Toxnet* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAa8a4Ss:1

The protective film must adhere to each surface in order not to be sheared off or pushed aside by the movement of the surfaces, particularly under a load.

The most commonly available lubricants today are manufactured from petroleum. A typical lubricant molecule consists of a long chain of carbon and hydrogen atoms, called an alkane:



An oil usually has between 15 and 20 carbon atoms. A grease has between 20 and 25 carbon atoms. The hydrogen atoms form very weak bonds with the surfaces. In the cases of brass and steel, metals consist of atomic nuclei surrounded by a sea of electrons. The hydrogen atoms are bonded to the carbon atoms by a pair of shared electrons, which face the carbon atoms: since there are no electrons on the other side of each hydrogen atom, the other side has a slightly positive charge because of the hydrogen nucleus. This positive charge attracts the hydrogen atoms to the sea of electrons of the metals. While the bonding is very weak, the total bonding caused by a large number of hydrogen atoms in a long carbon chain is considerably greater than in a short carbon chain. A shorter carbon chain could therefore be removed more easily by the force acting upon the surfaces. The forces that attract the molecule to the surface must be greater than the forces that attract the molecule to other molecules: this makes it possible to have the lubricant adhere to the surface yet easily slip over other lubricant molecules, and the level of friction is reduced by having lubricant molecules rubbing against one another rather than brass and steel surfaces rubbing together. This is as simple a description of lubrication theory as you would find anywhere!

Longer carbon chains get tangled together like spaghetti, thereby making the ability of the lubricant to flow more difficult. This is why lubricants with longer carbon chains are thicker than lubricants with shorter carbon chains.

A lubricant with a longer carbon chain is less volatile. As the temperature increases, the molecules vibrate more vigorously until the vibration causes the weak intermolecular bonds to break. As they break, molecules become free to float away or evaporate. Molecules with longer carbon chains vibrate less at a given temperature because they have more mass, so they are less likely to evaporate. Situations in which a lot of heat is generated, such as a car engine, require oils that will not evaporate easily. Bearings with slow-moving parts do not experience such levels of heat, so a different lubricant is required. A lubricant with larger molecules should be used to minimize evaporation, particularly on bearing surfaces that are subjected to high torque and low speeds (revolutions per minute). However, thicker lubricants can interfere with the action of the mechanism when applied to bearing surfaces that are subjected to very low torque and high speeds, so a thinner lubricant must be used, even though thinner lubricants are more likely to evaporate! The purpose of application is particularly important in selecting a lubricant because of the need to consider heat, torque and speed. If a shaft rotates very quickly in a bearing, the fast motion has the effect of bringing more lubricant into the bearing, called a hydrodynamic effect, which increases the separation of the rubbing surfaces. Slower-moving applications do not benefit from the hydrodynamic effect.[15]

[15] *How Lubricants Work.* http://home.talkcity.com/Terminus/mvhw/aoiltwo.html

Mineral oil acts as a lipid solvent; administered with meals, it may interfere with absorption of essential fat-soluble substances.[16]

Fatty acids fill two major roles in the body:

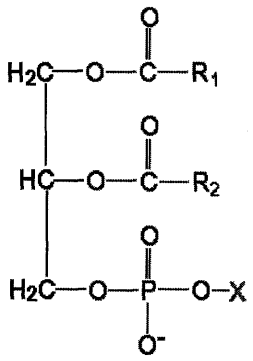
- 1. as the components of more complex membrane lipids.
- 2. as the major components of stored fat in the form of triacylglycerols.

Fatty acids are long-chain hydrocarbon molecules containing a carboxylic acid moiety at one end. The numbering of carbons in fatty acids begins with the carbon of the carboxylate group. At physiological pH, the carboxyl group is readily ionized, rendering a negative charge onto fatty acids in bodily fluids.

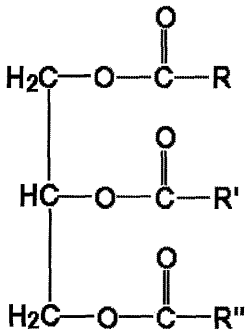
Fatty acids that contain no carbon-carbon double bonds are termed saturated fatty acids; those that contain double bonds are unsaturated fatty acids. The numeric designations used for fatty acids come from the number of carbon atoms, followed by the number of sites of unsaturation (eg, palmitic acid is a 16-carbon fatty acid with no unsaturation and is designated by 16:0).

The site of unsaturation in a fatty acid is indicated by the symbol D and the number of the first carbon of the double bond (e.g. palmitoleic acid is a 16-carbon fatty acid with one site of unsaturation between carbons 9 and 10, and is designated by $16{:}1^{D9}$).

Saturated fatty acids of less than eight carbon atoms are liquid at physiological temperature, whereas those containing more than ten are solid. The presence of double bonds in fatty acids significantly lowers the melting point relative to a saturated fatty acid.[17]



Basic phospholipids



Basic triglyceride

Lipids do not dissolve well in water because of their non-polar character. Lipids contain high proportions of energy-rich, carbon-hydrogen bonds. Because fats can be stored without water, lipids yield more energy than water stored carbohydrates. Thus, it can be predicted that substances containing primarily fats and oils would have less water content but more calories.[18]

Mineral oil is naturally very nonpolar unlike coconut oil. Because of this difference, mineral oil acts as a good lipid solvent.[19] When it comes to solubility, it is always important to remember the "like dissolves like" rule. Polar solutes will dissolve in polar solvents. Non-polar solutes will dissolve in non-polar

[16] *Mineral Oil.* http://216.239.51.100/search?q=cache:gXuXW63vVA8C:www.nature.nps.gov/toxic/minoil.pdf+%22mineral+oil+acts%22&hl=en&ie=UTF-8

[17] *Major Roles of Biological Lipids* http://www.indstate.edu/theme/mwking/lipids.html#fatty%20acids

[18] *The Occurrence of Water in Biological Substances* http://matrix.mvhs.fuhsd.org/~i-heng/Biowebsite/journals/vol2/2/a4.html

[19] *Journal of Cosmetic Science* http://www.scconline.org/education/publications/journal_52_3.htm

solvents.[20] The term 'dissolve' is in reference to the fact that the ions dissociate and their bonds broken—making them soluble.

Combinations:
There are many different types of oils that are considered mineral oils. They are not generally applied along with other substances because they are not soluble in water and this hinders the amount of substances they are actually compatible with.

MINERAL OIL IS COMBINED WITH PHENOLPHTHALEIN IN SOME MULTIPLE INGREDIENT [Miller, R. R., and D. J. Greenblatt. Handbook of Drug Therapy. New York: Elsevier North Holland, 1979. 1057]**PEER REVIEWED**

IT IS USED AS "FOOD-SAFE" LUBRICANT ON PANS, ROLLERS, BELTS, & MACHINERY IN CLOSE PROXIMITY TO MANY FOODS, & AS A DEFOAMING AGENT IN FOODS. IT IS A COMMON OR MAIN INGREDIENT IN "BABY OILS" OR AGENTS USED TO IMPROVE SHEEN OF LIVESTOCK HAIR FOR SHOWS. APPARENTLY SUCCESSFUL AS THE MAIN INGREDIENT IN VIGOROUSLY APPLIED TOPICAL OILS FOR NON-SPECIFIC DERMATITIS OR SEBORRHEAS IN DOGS. TOPICALLY, AS A MITICIDE FOR SNAKES (BY IMMERSION), & AS AN INSECTICIDE ADJUVANT ON MANY CLASSES OF LIVESTOCK. IT HAS BEEN USED AGAINST EAR MITES. APPLIED TOPICALLY WITHIN THE CLOACA IT HAS BEEN OF VALUE IN EGG BOUND CAGED BIRDS. MORTALITY AND HYPERKERATOSIS ASSOCIATED WITH TOPICAL APPLICATION IN YOUNG CHICKS APPEARS TO BE SECONDARY TO MICROBIAL INFECTION. HAS BEEN USED AS A CAPILLARY SEAL FOR EGGS IN COLD STORAGE.
[Rossoff, I.S. Handbook of Veterinary Drugs. New York: Springer Publishing Company, 1974. 367]**PEER REVIEWED**[21]

Status

Historic Use by Organic Farmers

Mineral oil has been used as a pesticide in agriculture since the 1920s -- mostly on citrus to control scale insects and greasy spot disease. The general consensus amongst researchers has been that the mode of action of mineral oil as an insecticide is by suffocation of the pest.

It would seem plausible that many plant feeding insect species would be vulnerable to the behavior modifying effects from mineral oil. The exact mechanism by which this occurs is not known but is most likely physical (hence, resistance should never develop) and probably quite simple.

We do know that plant feeding insects have evolved host detection mechanisms. In order to feed or lay eggs on a host plant, insects must first detect a host plant at the chemical level. This is accomplished by use of tiny, hollow hairs (called *sensillae,* see photo opposite) located on their mouthparts, feet and abdomen. Each hair has a small canal which opens to the outside through a microscopic pore (as small as *one-millionth* of an inch).

Inside the canal are nerve endings which are stimulated by specific chemicals (called *secondary* chemicals) produced within the host plant and are detected in the process of probing. Contact with these secondary chemicals can trigger or stimulate an insect to feed or lay eggs at specific locations within the plant. Plugging these pores would effectively 'blind' the insect from communicating with its primary food source or egg laying site.

[20] *The Xe Files: Case 6* http://library.thinkquest.org/C0110275/case6.htm?tqskip1=1&tqtime=0724
[21] *Mineral Oil Full Record on Toxnet* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAa8a4Ss:1

Over the past 20 years we have seen abundant evidence that beneficial insect behaviors are **not** affected by Stylet-Oil applications. As a prime example, on cucurbit crops treated twice per week with Stylet-Oil in Central America and south Florida we have consistently observed high rates of parasitism of leafminer larvae as well as development of all 4 stages of lady beetle and lacewing predators.

We believe the reason beneficial insect feeding and egg laying behaviors are not affected by Stylet-Oil is because these insects have evolved a totally different set of host detection mechanisms (see photo of predatory mite mouthpart, opposite). In lieu of plant sensing sensillae, beneficial insects have evolved mandibles, ovipositors, claws and large eyes to detect and catch their prey. Disruption of an insect behavior can be a powerful tool in the hands of a competent grower. By managing behavior (preventing eggs) early in the first population cycle there is a high likelihood that future generations will be significantly suppressed making it possible for beneficial insects to forage and develop at the same time oil is being applied. Though contact with sufficient oil can suffocate beneficial insects, we have not seen evidence that oil significantly impacts beneficial populations.[22]

Cattle: Mineral oil is used to dilute insecticide applied to back rubbers given to cows. These are used by farmers to keep their horn fly numbers below the 50 fly per side treatment threshold.[23]

Backrubbers allow cattle to treat themselves while loafing and scratching. The insecticide should be diluted with a good grade of mineral oil (diesel oil evaporates more quickly and is harder on the cattle's skin) according to label instructions. Do not use motor oil.[24]

Type III vagus indigestion causes hypokalemia, hypochloremia and metabolic alkalosis. Intravenous fluid administration can be used to correct these abnormalities. A left paralumbarfossaceliotomy and rumenotomy allows the clinician to administer mineral oil directly into the abomasum via the omasal-abomasal orifice, or removal of impacted abomasalingesta. Severe cases of abomasalimpaction may require an abomasotomy via a right paracostalapproach, but affected animals have a poor prognosis.[25]

Dust Control: Mineral oil, vegetable oils, and fats can all be used in selected premixes. Intended purpose of the premix, type of carrier, amount of carrier, and cost of oil or fat all influence one's choice. Mineral oil is the most widely used dust control agent for concentrated premixes while other oils and fats are used in the more diluted products. Many times the type and amount of dust control/binding agent used is compromised because of cost competitiveness, which can result in poorer quality premixes. Some fats, if not stabilized, can cause destruction of vitamins. Application of oils to mixes under pressure to create an atomized oil droplet is the preferred method of application. This will ensure uniform application and a better quality mix.[26]

The Weak Cria: Measure body temperature, if low still force feed (bottle first, otherwise stomach tube) warmed colostrum/milk, <u>but only</u> when body temperature reaches 98.5F. (heat lamps, hot water bottles, heating pads). Consider to store (frozen) colostrum (to start at <24h/old) and/or plasma (>24h/old); intervene if the cria has not nursed during the first 4-5 hours after birth. Colostrum might also originate from i.e. goat, vaccinated and kept on the farm (but have it checked for Johne's disease). A bottle fed cria could get constipated; give mineral oil and fluids.

Animals of different age-sex-physiological status should be kept separate (i.e. weaning females from males to avoid premature mating; males of different age for risk of fighting and pecking order. pregnant from non-pregnant for different nutritional needs). [27]

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[22] *Using Stylet-Oil As An Insecticide* http://www.stylet-oil.com/Using_Stylet-oil_As_An_Insecticide_Body_Frame.htm
[23] *Horse Flies and Cattle* http://www.uky.edu/Agriculture/Entomology/entfacts/livestc/ef509.htm
[24] *Horn Flies and Cattle* http://www.uky.edu/Agriculture/Entomology/entfacts/livestc/ef509.htm
[25] ***Vagus Indigestion in Dairy and Beef Cattle*** http://www.addl.purdue.edu/newsletters/1996/fall/vagus.shtml
[26] *Premixing* http://www.oznet.ksu.edu/library/grsci2/MF2056.pdf
[27] *Alpaca Care and Husbandry* http://www.alpacasearch.com/SWAG/meeting181100.htm

Oxen: Since shaving does weaken the horn, shave only the part you wish to bend. If you weaken the entire shell, the horn will droop. Always leave the shaved horn perfectly smooth, then apply mineral oil to replace the natural protection you have removed.[28]

OFPA, USDA Final Rule:

USDA:
From Section 205.603 Synthetic substances allowed for use in organic livestock production:
In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:
Vaccines
(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(1) Iodine
(2) Lidocaine - as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals
(3) Lime, hydrated - (bordeaux mixes), not permitted to cauterize physical alterations or deodorize animal wastes.
(4) Mineral oil - for topical use and as a lubricant[29]

Policies from the FDA:

Note: The following excerpted law pertains to Polysorbate 60. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 172--FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION--Table of Contents

Subpart I--Multipurpose Additives

Sec. 172.836 Polysorbate 60.

The food additive polysorbate 60 (polyoxyethylene (20) sorbitan monostearate) which is a mixture of polyoxyethylene ethers of mixed partial stearic and palmitic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield a product with a maximum acid number of 10 and a maximum water content of 0.2 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

[28] *Reshaping Crooked Horns in Oxen.* http://www.ruralheritage.com/ox_paddock/ox_horn.htm
[29] The National List of Allowed and Prohibited Substances http://www.ams.usda.gov/nop/nop2000/Final%20Rule/regtext/reg-natlist.htm based on the recommendations provided by the National Organic Standards Board in 1995

Saponification number 45-55.
Acid number 0-2.
Hydroxyl number 81-96.
Oxyethylene content 65 percent-69.5 percent.

(c) It is used or intended for use as follows:

(12) As an emulsifier, alone or in combination with sorbitan monostearate, in the minimum quantity required to accomplish the intended effect, in formulations of white mineral oil conforming with Sec. 172.878 and/or petroleum wax conforming with Sec. 172.886 for use as protective coatings on raw fruits and vegetables.

Note: The following excerpted law pertains to Sorbitan monostearate. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 172--FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION--Table of Contents

Subpart I--Multipurpose Additives

Sec. 172.842 Sorbitan monostearate.

The food additive sorbitan monostearate, which is a mixture of partial stearic and palmitic acid esters of sorbitol anhydrides, may be safely used in or on food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield essentially a mixture of esters.

(b) The food additive meets the following specifications:

Saponification number, 147-157
Acid number, 5-10
Hydroxyl number, 235-260

(c) It is used or intended for use, alone or in combination with polysorbate 60 as follows:

(7) As an emulsifier, alone or in combination with polysorbate 60, in the minimum quantity required to accomplish the intended effect, in formulations of white mineral oil conforming with Sec. 172.878 and/or petroleum wax conforming with Sec. 172.886 for use as protective coatings on raw fruits and vegetables.

Note: The following law pertains to White Mineral Oil in relation to food additives.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 172--FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION--Table of Contents

Subpart I--Multipurpose Additives

Sec. 172.878 White mineral oil.

White mineral oil may be safely used in food in accordance with the following conditions:

(a) White mineral oil is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum. It is refined to meet the following specifications:

(1) It meets the test requirements of the United States Pharmacopeia XX (1980) for readily carbonizable substances (page 532).

(2) It meets the test requirements of U.S.P. XVII for sulfur compounds (page 400).

(3) It meets the specifications prescribed in the ``Journal of the Association of Official Analytical Chemists,'' Volume 45, page 66 (1962), which is incorporated by reference, after correction of the ultraviolet absorbance for any absorbance due to added antioxidants. Copies of the material incorporated by reference are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(b) White mineral oil may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

(c) White mineral oil is used or intended for use as follows:

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)
1. As a release agent, binder, and lubricant in or on capsules and tablets containing concentrates of flavoring, spices, condiments, and nutrients intended for addition to food, excluding confectionery.	Not to exceed 0.6% of the capsule or tablet.
2. As a release agent, binder, and lubricant in or on capsules and tablets containing food for special dietary use.	Not to exceed 0.6% of the capsule or tablet.
3. As a float on fermentation fluids in the manufacture of vinegar and wine to prevent or retard access of air, evaporation, and wild yeast contamination during fermentation.	In an amount not to exceed good manufacturing practice.
4. As a defoamer in food.....	In accordance with Sec. 173.340 of this chapter.
5. In bakery products, as a release agent	Not to exceed 0.15% of

and lubricant.	bakery products.
6. In dehydrated fruits and vegetables, as a release agent.	Not to exceed 0.02% of dehydrated fruits and vegetables.
7. In egg white solids, as a release agent..	Not to exceed 0.1% of egg white solids.
8. On raw fruits and vegetables, as a protective coating.	In an amount not to exceed good manufacturing practice.
9. In frozen meat, as a component of hot-melt coating.	Not to exceed 0.095% of meat.
10. As a protective float on brine used in the curing of pickles.	In an amount not to exceed good manufacturing practice.
11. In molding starch used in the manufacture of confectionery.	Not to exceed 0.3 percent in the molding starch.
12. As a release agent, binder, and lubricant in the manufacture of yeast.	Not to exceed 0.15 percent of yeast.
13. As an antidusting agent in sorbic acid for food use.	Not to exceed 0.25 percent in the sorbic acid.
14. As release agent and as sealing and polishing agent in the manufacture of confectionery.	Not to exceed 0.2 percent of confectionery.
15. As a dust control agent for wheat, corn, soybean, barley, rice, rye, oats, and sorghum.	Applied at a level of no more than 0.02 percent by weight of grain.
16. As a dust control agent for rice.....	ISO 100 oil viscosity (100 centistokes (cSt) at 100F) applied at a level of no more than 0.08 percent by weight of the rice grain.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 8764, Mar. 2, 1982; 47 FR 11838, Mar. 19, 1982; 48 FR 55728, Dec. 15, 1983; 49 FR 10105, Mar. 19, 1984; 54 FR 24897, June 12, 1989; 63 FR 66014, Dec. 1, 1998]

Note: The following excerpted law pertains to Petrolatum. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 172--FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION--Table of Contents

Subpart I--Multipurpose Additives

Sec. 172.880 Petrolatum.

Petrolatum may be safely used in food, subject to the provisions of this section.

(a) Petrolatum complies with the specifications set forth in the United States Pharmacopeia XX (1980) for white petrolatum or in the National Formulary XV (1980) for petrolatum.

(b) Petrolatum meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in Sec. 172.886(b):

Ultraviolet absorbance per centimeter path length:

Millimicrons	Maximum
280-289	0.25
290-299	.20
300-359	.14
360-400	.04

(c) Petrolatum is used or intended for use as follows:

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with petrolatum)
In bakery products; as release agent and lubricant.	***With white mineral oil, not to exceed 0.15 percent of bakery product.***
In confectionery; as release agent and as sealing and polishing agent.	Not to exceed 0.2 percent of confectionery.
In dehydrated fruits and vegetables; as release agent.	Not to exceed 0.02 percent of dehydrated fruits and vegetables.
In egg white solids; as release agent..	Not to exceed 0.1 percent of egg white solids.
On raw fruits and vegetables; as protective coating.	In an amount not to exceed good manufacturing practice.
In beet sugar and yeast; as defoaming agent.	As prescribed in Sec. 173.340 of this chapter.

Note: The following excerpted law pertains to Secondary Food Additives. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 173--SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION--Table of Contents

Subpart D--Specific Usage Additives

Sec. 173.340 Defoaming agents.

Defoaming agents may be safely used in processing foods, in accordance with the following conditions:

(a) They consist of one or more of the following:

(1) Substances generally recognized by qualified experts as safe in food or covered by prior sanctions for the use prescribed by this section.

(2) Substances listed in this paragraph (a)(2) of this section, subject to any limitations imposed:

White mineral oil: Conforming with Sec. 172.878 of this chapter.	***As a component of defoaming agents for use in wash water for sliced potatoes at a level not to exceed 0.008 percent of the wash water.***

Note: The following excerpted law pertains to Indirect Food Additives. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 175--INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS--Table of Contents

Subpart C--Substances for Use as Components of Coatings

Sec. 175.210 Acrylate ester copolymer coating.

Acrylate ester copolymer coating may safely be used as a food-contact surface of articles intended for packaging and holding food, including heating of prepared food, subject to the provisions of this section:

(a) The acrylate ester copolymer is a fully polymerized copolymer of ethyl acrylate, methyl methacrylate, and methacrylic acid applied in emulsion form to molded virgin fiber and heat-cured to an insoluble resin.

(b) Optional substances used in the preparation of the polymer and in the preparation and application of the emulsion may include substances named in this paragraph, in an amount not to exceed that required to accomplish the desired technical effect and subject to any limitation prescribed: Provided, however, That any substance named in this paragraph and covered by a specific regulation in subchapter B of this chapter must meet any specifications in such regulation.

List of substances	Limitations
Aluminum stearate.....	
Ammonium lauryl sulfate.....	
Borax.....	Not to exceed the amount

	required as a preservative in emulsion defoamer.
Disodium hydrogen phosphate.....	Do.
Formaldehyde.....	
Glyceryl monostearate.....	
Methyl cellulose.....	
***Mineral oil*.....**	
Paraffin wax.....	
Potassium hydroxide.....	
Potassium persulfate.....	
Tallow.....	
Tetrasodium pyrophosphate.....	
Titanium dioxide.....	

Note: The following excerpted law pertains to Indirect Food Additives. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 175--INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS--Table of Contents

Subpart C--Substances for Use as Components of Coatings

Sec. 175.230 Hot-melt strippable food coatings.

Hot-melt strippable food coatings may be safely applied to food, subject to the provisions of this section.

(a) The coatings are applied to and used as removable coatings for food.

(b) The coatings may be prepared, as mixtures, from the following substances:

(1) Substances generally recognized as safe in food.

(2) Substances identified in this subparagraph.

List of substances	Limitations
Acetylated monoglycerides.....	Complying with 172.828 of this chapter.
Cellulose acetate butyrate.....	
Cellulose acetate propionate.....	
***Mineral oil, white*.....**	***For use only as a component of hot-melt strippable food coatings applied to frozen meats and complying with Sec. 172.878 of this chapter.***

Note: The following excerpted law pertains to Indirect Food Additives. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 176--INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS--Table of Contents

Subpart B--Substances for Use Only as Components of Paper and Paperboard

Sec. 176.200 Defoaming agents used in coatings.

The defoaming agents described in this section may be safely used as components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The defoaming agents are prepared as mixtures of substances described in paragraph (d) of this section.

(b) The quantity of any substance employed in the formulation of defoaming agents does not exceed the amount reasonably required to accomplish the intended physical or technical effect in the defoaming agents or any limitation further provided.

(c) Any substance employed in the production of defoaming agents and which is the subject of a regulation in parts 174, 175, 176, 177, 178 and Sec. 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the formulation of defoaming agents include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in defoaming agents and used in accordance with such sanction or approval.

(3) Substances identified in this paragraph (d)(3) and subject to such limitations as are provided:

List of substances	Limitations
Mineral oil.....	

Note: The following excerpted law pertains to Indirect Food Additives. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 176--INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS--Table of Contents

Subpart B--Substances for Use Only as Components of Paper and Paperboard

Sec. 176.210 Defoaming agents used in the manufacture of paper and paperboard.

Defoaming agents may be safely used in the manufacture of paper and paperboard intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) The defoaming agents are prepared from one or more of the substances named in paragraph (d) of this section, subject to any prescribed limitations.

(b) The defoaming agents are used to prevent or control the formation of foam during the manufacture of paper and paperboard prior to and during the sheet-forming process.

(c) The quantity of defoaming agent or agents added during the manufacturing process shall not exceed the amount necessary to accomplish the intended technical effect.

(d) Substances permitted to be used in the formulation of defoaming agents include substances subject to prior sanctions or approval for such use and employed subject to the conditions of such sanctions or approvals, substances generally recognized as safe for use in food, substances generally recognized as safe for use in paper and paperboard, and substances listed in this paragraph, subject to the limitations, if any, prescribed.

(3) Miscellaneous:

Mineral oil.

Note: The following excerpted law pertains to Indirect Food Additives. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 177--INDIRECT FOOD ADDITIVES: POLYMERS--Table of Contents

Subpart C--Substances for Use Only as Components of Articles Intended for Repeated Use

Sec. 177.2260 Filters, resin-bonded.

Resin-bonded filters may be safely used in producing, manufacturing, processing, and preparing food, subject to the provisions of this section.

(a) Resin-bonded filters are prepared from natural or synthetic fibers to which have been added substances required in their preparation and finishing, and which are bonded with resins prepared by condensation or polymerization of resin-forming materials, together with adjuvant

substances required in their preparation, application, and curing.

(b) The quantity of any substance employed in the production of the resin-bonded filter does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of resin-bonded filters that is the subject of a regulation in parts 174, 175, 176, 177, 178 and Sec. 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the production of resin-bonded filters include the following, subject to any limitations provided:

List of Substances and Limitations:

(2) Substances employed in fiber finishing:

BHT.

Butyl (or isobutyl) palmitate or stearate.

2,5-Di-tert-butyl hydroquinone for use only in lubricant formulations for rayon fiber finishing and at a usage level not to exceed 0.1 percent by weight of the lubricant formulations.

Dimethylpolysiloxane.

4-Ethyl-4-hexadecyl morpholinium ethyl sulfate for use only as a lubricant in the manufacture of polyethylene terephthalate fibers specified in paragraph (d)(1) of this section at a level not to exceed 0.03 percent by weight of the finished fibers.

Fatty acid (C10-C18) diethanolamide condensates.

Fatty acids derived from animal or vegetable fats and oils, and salts of such acids, single or mixed, as follows:

Aluminum.

Ammonium.

Calcium.

Magnesium.

Potassium.

Sodium.

Triethanolamine.

Fatty acid (C10-C18) mono- and diesters of polyoxyethylene glycol (molecular weight 400-3,000).

Methyl esters of fatty acids (C10-C18).

Mineral oil.

Polybutene, hydrogenated; complying with the identity prescribed under Sec. 178.3740 (b) of this chapter.

Polyoxyethylene (4 mols) ethylenediamine monolauramide for use only in lubricant formulations for rayon fiber finishing and at a usage level not to exceed 10 percent by weight of the lubricant formulations.

Ricebran oil.

Titanium dioxide.

Note: The following excerpted law pertains to Indirect Food Additives. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 177--INDIRECT FOOD ADDITIVES: POLYMERS--Table of Contents

Subpart C--Substances for Use Only as Components of Articles Intended for Repeated Use

Sec. 177.2800 Textiles and textile fibers.

Textiles and textile fibers may safely be used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The textiles and textile fibers are prepared from one or more of the fibers identified in paragraph (d) of this section and from certain other adjuvant substances required in the production of the textiles or textile fibers or added to impart desired properties.

(b) The quantity of any adjuvant substance employed in the production of textiles or textile fibers does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of textiles or textile fibers that is the subject of a regulation in parts 174, 175, 176, 177, 178 and Sec. 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the production of or added to textiles and textile fibers may include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in textiles and textile fibers and used in accordance with such sanction or approval.

(3) Substances generally recognized as safe for use in cotton and cotton fabrics used in dry-food packaging.

(4) Substances that by regulation in this part may safely be used in the production of or as a component of textiles or textile fibers and subject to provisions of such regulation.

(5) Substances identified in this paragraph (d)(5), subject to such limitations as are provided:

List of substances	Limitations
(i) Fibers:	
Mineral oil	***For use only at a level not to exceed 0.15 percent by weight of finished fibers.***

Note: The following excerpted law pertains to Mineral Oil.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 178--INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS--Table of Contents

Subpart D--Certain Adjuvants and Production Aids

Sec. 178.3620 Mineral oil.

Mineral oil may be safely used as a component of nonfood articles intended for use in contact with food, subject to the provisions of this section:

(a) White mineral oil meeting the specifications prescribed in Sec. 172.878 of this chapter may be used as a component of nonfood articles provided such use complies with any applicable limitations in parts 170 through 189 of this chapter. The use of white mineral oil in or on food itself, including the use of white mineral oil as a protective coating or release agent for food, is subject to the provisions of Sec. 172.878 of this chapter.

(b) Technical white mineral oil identified in paragraph (b)(1) of this section may be used as provided in paragraph (b)(2) of this section.

(1) Technical white mineral oil consists of specially refined distillates of virgin petroleum or of specially refined distillates that are produced synthetically from petroleum gases. Technical white mineral oil meets the following specifications:

(i) Saybolt color 20 minimum as determined by ASTM method D156-82, ``Standard Test Method for Saybolt Color of Petroleum Products (Saybolt Chromometer Method),'' which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(ii) Ultraviolet absorbance limits as follows:

Wavelength (m)	Maximum absorbance per centimeter optical pathlength
280 to 289	4.0
290 to 299	3.3
300 to 329	2.3
330 to 350	0.8

Technical white mineral oil containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application to mineral oil under ``Specification'' on page 66 of the ``Journal of the Association of Official Agricultural Chemists,'' Volume 45 (February 1962) (which is incorporated by reference; copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408), disregarding the last two sentences of that procedure and substituting therefor the following: Determine the absorbance of the mineral oil extract in a 10-millimeter cell in the range from 260-350 m, inclusive, compared to the solvent control. If the absorbance so measured exceeds 2.0 at any point in range 280-350 m, inclusive, dilute the extract and the solvent control, respectively, to twice their volume with dimethyl sulfoxide and remeasure the absorbance. Multiply the remeasured absorbance values by 2 to determine the absorbance of the mineral oil extract per centimeter optical pathlength.

(2) Technical white mineral oil may be used wherever mineral oil is permitted for use as a component of nonfood articles complying with Secs. 175.105, 176.200, 176.210, 177.2260, 177.2600, and 177.2800 of this chapter and Secs. 178.3570 and 178.3910.

(3) Technical white mineral oil may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

(c) Mineral oil identified in paragraph (c)(1) of this section may be used as provided in paragraph (c)(2) of this section.

(1) The mineral oil consists of virgin petroleum distillates refined to meet the following specifications:

(i) Initial boiling point of 450 deg.F minimum.

(ii) Color 5.5 maximum as determined by ASTM method D1500-82, ``Standard Test Method for ASTM Color of Petroleum Products (ASTM Color Scale),'' which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section.

(iii) Ultraviolet absorbance limits as follows as determined by the analytical method described in paragraph (c)(3) of this section:

Wavelength (m)	Maximum absorbance per centimeter optical pathlength
280 to 289	0.7
290 to 299	0.6
300 to 359	0.4
360 to 400	.09

(2) The mineral oil may be used wherever mineral oil is permitted for use as a component of nonfood articles complying with Secs. 175.105 and 176.210 of this chapter and Sec. 178.3910 (for use only in rolling of metallic foil and sheet stock), Secs. 176.200, 177.2260, 177.2600, and 177.2800 of this chapter.

(3) The analytical method for determining ultraviolet absorbance limit is as follows:

general instructions

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of oil samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

apparatus

Separatory funnels. 250-milliliter, 500-milliliter, 1,000-milliliter, and preferably 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Reservoir. 500-milliliter capacity, equipped with a 24/40 standard taper male fitting at the bottom and a suitable ball-joint at the top for connecting to the nitrogen supply. The male fitting should be equipped with glass hooks.

Chromatographic tube. 180 millimeters in length, inside diameter to be 15.7 millimeters 0.1 millimeter, equipped with a coarse, fritted-glass disc, a tetrafluoroethylene polymer stopcock, and a female 24/40 standard tapered fitting at the opposite end. (Overall length of the column with the female

joint is 235 millimeters.) The female fitting should be equipped with glass hooks.

Disc. Tetrafluoroethylene polymer 2-inch diameter disk approximately \3/16\-inch thick with a hole bored in the center to closely fit the stem of the chromatographic tube.

Suction flask. 250-milliliter or 500-milliliter filter flask.

Condenser. 24/40 joints, fitted with a drying tube, length optional.

Evaporation flask (optional). 250-milliliter or 500-milliliter capacity all-glass flask equipped with standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5,000 centimeter 0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1,000 centimeter 0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Spectral range 250 millimicrons--400 millimicrons with spectral slit width of 2 millimicrons or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, 0.01 at 0.4 absorbance.

Absorbance accuracy \1\ 0.05 at 0.4 absorbance.

\1\ As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

Wavelength accuracy, 1.0 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

reagents and materials

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane, benzene, acetone, and methyl alcohol designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified n-hexadecane and evaporate on the steam bath under a stream of nitrogen (a loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 10-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.)

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and n-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 25 milliliters volume. Determine the absorbance in the 5-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per

centimeter path length between 280 and 400 m. For methyl alcohol this absorbance value shall be 0.00.

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters for the test described in the preceding paragraph. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Company, Baltimore, Maryland, or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

Benzene, A.C.S. reagent grade. Use 150 milliliters for the test. Purify, if necessary, by distillation or otherwise.

Acetone, A.C.S. reagent grade. Use 200 milliliters for the test. Purify, if necessary, by distillation.

Eluting mixtures:

1. 10 percent benzene in isooctane. Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask and adjust to volume with isooctane, with mixing.

2. 20 percent benzene in isooctane. Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask and adjust to volume with isooctane, with mixing.

3. Acetone-benzene-water mixture. Add 20 milliliters of water to 380 milliliters of acetone and 200 milliliters of benzene, and mix.

n-Hexadecane, 99-percent olefin-free. Dilute 1.0 milliliter of n-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference point between 280 m-400 m. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

Methyl alcohol, A.C.S. reagent grade. Use 10.0 milliliters of methyl alcohol. Purify, if necessary, by distillation.

Dimethyl sulfoxide. Spectrophotometric grade (Crown Zellerbach Corporation, Camas, Washington, or equivalent). Absorbance (1-centimeter cell, distilled water reference, sample completely saturated with nitrogen).

Wavelength	Absorbance (maximum)
261.5	1.00
270	.20
275	.09
280	.06
300	.015

There shall be no irregularities in the absorbance curve within these wavelengths.

Phosphoric acid. 85 percent A.C.S. reagent grade.

Sodium borohydride. 98 percent.

Magnesium oxide (Sea Sorb 43, Food Machinery Company, Westvaco Division, distributed by chemical supply firms, or equivalent). Place 100 grams of the magnesium oxide in a large beaker, add 700 milliliters of distilled water to make a thin slurry, and heat on a steam bath for 30 minutes with intermittent stirring. Stir well initially to insure that all the adsorbent is completely wetted. Using a Buchner funnel and a filter paper (Schleicher & Schuell No. 597, or equivalent) of suitable diameter, filter with suction. Continue suction until water no longer drips from the funnel. Transfer the adsorbent to a glass trough lined with aluminum foil (free from rolling oil). Break up the magnesia with a clean spatula and spread out the adsorbent on the aluminum foil in a layer about 1 centimeter to 2 centimeters thick. Dry for 24 hours at 160 deg.C 1 deg.C. Pulverize the magnesia with mortar and pestle. Sieve the pulverized adsorbent between 60-180 mesh. Use the magnesia retained on the 180-mesh sieve.

Celite 545. Johns Mansville Company, diatomaceous earth, or equivalent.

Magnesium oxide-Celite 545 mixture (2+1) by weight. Place the magnesium oxide (60-180 mesh) and the Celite 545 in 2 to 1 proportions, respectively, by weight in a glass-stoppered flask large enough for adequate mixing. Shake

vigorously for 10 minutes. Transfer the mixture to a glass trough lined with aluminum foil (free from rolling oil) and spread it out on a layer about 1 centimeter to 2 centimeters thick. Reheat the mixture at 160 deg.C 1 deg.C for 2 hours, and store in a tightly closed flask.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter course, fritted-glass funnel or in a 65-millimeter filter funnel with glass wool plug; wash with successive 15-milliliter portions of the indicated solvent until a 15-milliliter portion of the wash shows 0.00 absorbance per centimeter path length between 280 m and 400 m when tested as prescribed under ``Organic solvents.'' Usually three portions of wash solvent are sufficient.

Before proceeding with analysis of a sample, determine the absorbance in a 5-centimeter path cell between 250 millimicrons and 400 millimicrons for the reagent blank by carrying out the procedure, without an oil sample, recording the spectra after the extraction stage and after the complete procedure as prescribed. The absorbance per centimeter pathlength following the extraction stage should not exceed 0.02 in the wavelength range from 280 m to 400 m; the absorbance per centimeter pathlength following the complete procedure should not exceed 0.02 in the wavelength range from 280 m to 400 m. If in either spectrum the characteristic benzene peaks in the 250 m-260 m region are present, remove the benzene by the procedure under ``Organic solvents'' and record absorbance again.

Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stoppered.) Add 150 milliliters of isooctane and shake to pre-equilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

Weigh a 20-gram sample of the oil and transfer to a 500-milliliter separatory funnel containing 100 milliliters of pre-equilibrated sulfoxide-phosphoric acid mixture. Complete the transfer of the sample with small portions of preequilibrated isooctane to give a total volume of the oil and solvent of 75 milliliters. Shake the funnel vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of pre-equilibrated isooctane. After separation of liquid phases, carefully draw off lower layer into the first 250-milliliter separatory funnel and wash in tandem with the 30-milliliter portions of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture and wash each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter) containing 480 milliliters of distilled water; mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes.

Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 80-milliliter extractives three times with 100-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see Sodium sulfate under ``Reagents and Materials'' for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of n-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter

of residue remains. To the residue, add a 10-milliliter portion of isooctane, reevaporate to 1 milliliter of hexadecane, and repeat this operation once.

Quantitatively transfer the residue with isooctane to a 200-milliliter volumetric flask, make to volume, and mix. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to isooctane as reference between 280 m-400 m (take care to lose none of the solution in filling the sample cell). Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without an oil sample. If the corrected absorbance does not exceed the limits prescribed in this paragraph, the oil meets the ultraviolet absorbance specifications. If the corrected absorbance per centimeter pathlength exceeds the limits prescribed in this paragraph, proceed as follows: Quantitatively transfer the isooctane solution to a 125-milliliter flask equipped with 24/40 joint, and evaporate the isooctane on the steam bath under a stream of nitrogen to a volume of 1 milliliter of hexadecane. Add 10 milliliters of methyl alcohol and approximately 0.3 gram of sodium borohydride. (Minimize exposure of the borohydride to the atmosphere. A measuring dipper may be used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with a drying tube into the flask, mix until the borohydride is dissolved, and allow to stand for 30 minutes at room temperature, with intermittent swirling. At the end of this period, disconnect the flask and evaporate the methyl alcohol on the steam bath under nitrogen until the sodium borohydride begins to come out of the solution. Then add 10 milliliters of isooctane and evaporate to a volume of about 2-3 milliliters. Again, add 10 milliliters of isooctane and concentrate to a volume of approximately 5 milliliters. Swirl the flask repeatedly to assure adequate washing of the sodium borohydride residues.

Fit the tetrafluoroethylene polymer disc on the upper part of the stem of the chromatographic tube, then place the tube with the disc on the suction flask and apply the vacuum (approximately 135 millimeters Hg pressure). Weigh out 14 grams of the 2:1 magnesium oxide-Celite 545 mixture and pour the adsorbent mixture into the chromatographic tube in approximately 3-centimeter layers. After the addition of each layer, level off the top of the adsorbent with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed.

Loosen the topmost few millimeters of each adsorbent layer with the end of a metal rod before the addition of the next layer. Continue packing in this manner until all the 14 grams of the adsorbent is added to the tube. Level off the top of the adsorbent by pressing down firmly with a flat glass rod or metal plunger to make the depth of the adsorbent bed approximately 12.5 centimeters in depth. Turn off the vacuum and remove the suction flask. Fit the 500-milliliter reservoir onto the top of the chromatographic column and prewet the column by passing 100 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off the column is between 2-3 milliliters per minute. Discontinue pressure just before the last of the isooctane reaches the level of the adsorbent. (Caution: Do not allow the liquid level to recede below the adsorbent level at any time.) Remove the reservoir and decant the 5-milliliter isooctane concentrate solution onto the column and with slight pressure again allow the liquid level to recede to barely above the adsorbent level. Rapidly complete the transfer similarly with two 5-milliliter portions of isooctane, swirling the flask repeatedly each time to assure adequate washing of the residue. Just before the final 5-milliliter wash reaches the top of the adsorbent, add 100 milliliters of isooctane to the reservoir and continue the percolation at the 2-3 milliliters per minute rate. Just before the last of the isooctane reaches the adsorbent level, add 100 milliliters of 10 percent benzene in isooctane to the reservoir and continue the percolation at the aforementioned rate. Just before the solvent mixture reaches adsorbent level, add 25 milliliters of 20 percent benzene in isooctane to the reservoir and continue the percolation at 2-3 milliliters per minute until all this solvent mixture has been removed from the column. Discard all the elution solvents collected up to this point. Add 300 milliliters of the acetone-benzene-water mixture to the reservoir and percolate through the column to eluate the polynuclear compounds. Collect the eluate in a clean 1-liter separatory funnel. Allow the column to drain until most of the

solvent mixture is removed. Wash the eluate three times with 300-milliliter portions of distilled water, shaking well for each wash. (The addition of small amounts of sodium chloride facilitates separation.) Discard the aqueous layer after each wash. After the final separation, filter the residual benzene through anhydrous sodium sulfate pre-washed with benzene (see Sodium sulfate under ``Reagents and Materials'' for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the separatory funnel with two additional 20-milliliter portions of benzene which are also filtered through the sodium sulfate. Add 1 milliliter of n-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under ``Organic solvents.'' Quantitatively transfer the residue with isooctane to a 200-milliliter volumetric flask and adjust to volume. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to isooctane as reference between 250 m-400 m. Correct for any absorbance derived from the reagents as determined by carrying out the procedure without an oil sample. If either spectrum shows the characteristic benzene peaks in the 250 m-260 m region, evaporate the solution to remove benzene by the procedure under ``Organic solvents.'' Dissolve the residue, transfer quantitatively, and adjust to volume in isooctane in a 200-milliliter volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits proposed in this paragraph, the oil meets the proposed ultraviolet absorbance specifications.

(d) Mineral oil identified in paragraph (d)(1) of this section may be used as provided in paragraph (d)(2) of this section.

(1) The mineral oil consists of virgin petroleum distillates refined to meet the following specifications:

(i) Distillation endpoint at 760 millimeters pressure not to exceed 371 deg.C, with a maximum residue not to exceed 2 percent, as determined by ASTM method D86-82, ``Standard Method for Distillation of Petroleum Products,'' which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section.

(ii) Ultraviolet absorbance limits as follows as determined by the method described in paragraph (d)(3) of this section.

Wavelength (m)	Maximum absorbance per centimeter optical pathlength
280 to 299	2.3
300 to 319	1.2
320 to 359	.8
360 to 400	.3

(iii) Pyrene content not to exceed a maximum of 25 parts per million as determined by the method described in paragraph (d)(3) of this section.

(2) The mineral oil may be used only in the processing of jute fiber employed in the production of textile bags intended for use in contact with the following types of food: Dry grains and dry seeds (for example, beans, peas, rice, and lentils); whole root crop vegetables of the types identified in 40 CFR 180.34(f); unshelled and shelled nuts (including peanuts); and dry animal feed. The finished processed jute fiber shall contain no more than 6 percent by weight of residual mineral oil.

(3) The analytical method for determining ultraviolet absorbance limits and pyrene content is as follows:

I. Apparatus. A. Assorted beakers, separatory funnels fitted with

tetrafluoroethylene polymer stopcocks, and graduated cylinders.

B. Volumetric flasks, 200-milliliter.

C. A chromatographic column made from nominal 1.3 centimeters outside diameter x 75 centimeters glass tubing tapered at one end and joined to a 2-millimeter-bore tetrafluoroethylene polymer stopcock. The opposite end is flanged and joined to a female 24/40 standard taper fitting. This provides for accommodating the 500-milliliter reservoir described in item I.E below.

D. A chromatographic column made from nominal 1.7 centimeters outside diameter x 115 centimeters glass tubing tapered at one end and joined to a 2-millimeter-bore tetrafluoroethylene polymer stopcock. The opposite end is flanged and joined to a 2.5 centimeters outside diameter x 9.0 centimeters glass tube having a female 24/40 standard taper fitting. This provides for accommodating the 500-milliliter reservoir described in item I. E below.

E. A 500-milliliter reservoir having a 24/40 standard taper male fitting at bottom and a suitable ball joint at the top for connecting to the nitrogen supply. The female fitting of the chromatographic columns described in items I. C and D above and the male fitting of the reservoir described in this item E should both be equipped with glass hooks.

(Note: Rubber stoppers are not to be used. Stopcock grease is not to be used on ground-glass joints in this method.)

F. A spectrophotometer equipped to automatically record absorbance of liquid samples in 1-centimeter pathlength cells in the spectral region of 280-400 m with a spectral slit width of 2 m or less. At an absorbance level of about 0.4, absorbance measurements shall be repeatable within 0.01 and accurate within 0.05. Wavelength measurements shall be repeatable with 0.2 m and accurate within 1.0 m. Instrument operating conditions are selected to realize this performance under dynamic (automatic) recording operations. Accuracy of absorbance measurements are determined at 290, 345, and 400 m, using potassium chromate as the reference standard. (National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, 1949.)

G. Two fused quartz cells having pathlengths of 1.000.005 centimeter or better.

II. Purity of reagents and materials. Reagent-grade chemicals shall be used in all tests. It is further specified that each chemical shall be tested for purity in accordance with the instruction given under ``Reagents and Materials'' in III below. In addition, a blank run by the procedure shall be made on each purified lot of reagents and materials. Unless otherwise indicated, references to water shall be understood to mean distilled water.

III. Reagents and materials-- A. Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this section III. The isooctane, benzene, cyclohexane, nitromethane, and n-hexadecane designated shall pass the following test:

To the specified quantity ofsolvent in a 150-milliliter beaker, add 1 milliliter of purified n-hexadecane and evaporate on the steam bath under a stream of nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains (to the residue from benzene and nitromethane add a 10-milliliter portion of purified isooctane, re-evaporate, and repeat once to insure complete removal of solvent). Dissolve the 1 milliliter of n-hexadecane residue in isooctane and make to 10-milliliter volume. Determine the absorbance in 1.0-centimeter pathlength cells compared to water as reference. The absorbance of the solution of solvent residue shall not exceed 0.05 between 280 and 400 m.

1. Isooctane (2,2,4-trimethylpentane). Use 240 milliliters for the above test. Purify, if necessary, by passage through a column of activated silica gel.

2. Benzene. Use 200 milliliters for the above test. Purify, if necessary, by distillation or otherwise.

3. Cyclohexane. Use 70 milliliters for the above test. Purify, if necessary, by distillation, silica gel percolation, or otherwise.

4. Nitromethane. Use 125 milliliters for the above test. Purify, if necessary, by distillation or otherwise.

5. n-Hexadecane. Determine the absorbance on this solvent directly. Purify, if necessary, by silica gel percolation or otherwise.

B. Other materials--1. Pyrene standard reference. Pyrene, reagent grade, melting point range 150-152 deg.C. (Organic Chemical 3627, Eastman Kodak Co., Rochester, N.Y., or equivalent). The standard reference absorbance is the absorbance at 334 millimicrons of a standard reference solution of pyrene containing a concentration of 1.0 milligram per liter in purified isooctane measured against isooctane of the same spectral purity in 1.0-centimeter cells. (This absorbance will be approximately 0.28.)

2. Chrysene solution. Prepare a solution at a concentration of 5.0 milligrams per liter by dissolving 5.0 milligrams of chrysene in purified isooctane in a 1-liter volumetric flask. Adjust to volume with isooctane.

3. Nitrogen gas. Water pumped or equivalent purity, cylinder with regulator, and valve control flow at 5 p.s.i.

4. Silica gel. 100-200 mesh (Davison Chemical, Baltimore, Md., Grade 923, or equivalent), purified and activated by the following procedure: Place about 1 kilogram of silica gel in a large column and wash with contaminant-free benzene until a 200-milliliter sample of the benzene coming off the column will pass the ultraviolet absorption test for benzene. This test is performed as stipulated under ``Organic solvents'' in A under III above. When the silica gel has been sufficiently cleaned, activate the gel before use by placing the 1-kilogram batch in a shallow container in a layer no greater than 1 inch in depth and heating in an oven (Caution! Explosion Hazard) at 130 deg.C. for 16 hours, and store in a vacuum desiccator. Reheating about once a week is necessary if the silica gel is repeatedly removed from the desiccator.

5. Aluminum oxide (Aluminum Co. of America, Grade F-20, or equivalent grade). 80-200 mesh, purified and activated by the following procedure: Place about 1 kilogram of aluminum oxide in a large column and wash with contaminant-free benzene until a 200-milliliter sample of the benzene coming off the column will pass the ultraviolet absorption test for benzene. This test is performed as stipulated under ``Organic solvents'' in A under III above. (Caution! Remove Benzene From Adsorbent Under Vacuum To Minimize Explosion Hazard in Subsequent Heating!) When the aluminum oxide has been sufficiently cleaned and freed of solvent, activate it before use by placing the 1-kilogram batch in a shallow container in a layer no greater than 1 inch in depth. Heat in an oven at 130 deg.C for 16 hours. Upon removal from heat, store at atmospheric pressure over 80 percent (by weight) sulfuric acid in a desiccator for at least 36 hours before use. This gives aluminum oxide with between 6 to 9.5 percent volatiles. This is determined by heating a weighed sample of the prepared aluminum oxide at 2,000 deg.F for 2 hours and then quickly reweighing. To insure the proper adsorptive properties of the aluminum oxide, perform the following test:

a. Weigh 50 grams 1 gram of the activated aluminum oxide and pack into the chromatographic column (1.3 centimeters x 75 centimeters) described under ``Apparatus'' in C under I above. Use glass wool at the column exit to prevent the aluminum oxide from passing through the column.

b. Place a 250-milliliter graduated cylinder under the column to measure the amount of eluate coming from the column.

c. Prewet the aluminum oxide by passing 40 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off the column is between 1.5 to 2.5 milliliters per minute.

d. Just prior to the last of the isooctane reaching the top of the aluminum oxide bed, add 10 milliliters of the isooctane solution containing 5.0 milligrams of chrysene per liter.

e. Continue percolation until the isooctane is just above the aluminum oxide. Then add 200 milliliters of a mixture of benzene and isooctane (33\1/3\ percent benzene and 66\2/3\ percent isooctane by volume) to the reservoir and continue percolation.

f. Continue percolation, collecting the eluates (40 milliliters of the prewet solution, 10 milliliters of the sample solution, and 200 milliliters of the gradient solution) in the 250-milliliter graduated cylinder until the level of the gradient solution is just above the aluminum oxide. Add 200 milliliters of the eluting solution of benzene and isooctane (90 percent benzene and 10 percent isooctane by volume) to the column and continue collecting until a

total of 250 milliliters of solution has been obtained. This may be discarded. Now begin to collect the final eluate.

g. Place a 100-milliliter graduated cylinder under the column and continue the percolation until a 100-milliliter eluate has been obtained.

h. Measure the amount of chrysene in this 100-milliliter fraction by ultraviolet analysis. If the aluminum oxide is satisfactory, more than 80 percent of the original amount of chrysene should be found in this fraction. (Note: If the amount of chrysene recovered is less than 80 percent, the original batch of aluminum oxide should be sieved between 100-160 mesh. Activation and testing of this sieved batch should indicate a satisfactory aluminum oxide for use.)

IV. Sampling. Precautions must be taken to insure that an uncontaminated sample of the mineral oil is obtained since ultraviolet absorption is very sensitive to small amounts of extraneous material contaminating the sample through careless handling.

V. Procedure. A. Blank. Before proceeding with the analysis of a sample, determine the absorbance of the solvent residues by carrying out the procedure without a sample.

B. Sample. 1. Weigh out 20.0 grams 0.1 gram of the mineral oil into a beaker and transfer to a 250-milliliter separatory funnel fitted with a tetrafluoroethylene polymer stopcock, using enough cyclohexane (25 milliliters) to give a final total volume of 50 milliliters (mineral oil plus cyclohexane).

2. Add 25 milliliters of nitromethane saturated with cyclohexane and shake by hand vigorously for 3 minutes. Recover the lower nitromethane layer in a 150-milliliter beaker containing 1 milliliter of n-hexadecane and evaporate on the steam bath under nitrogen. Repeat the extraction four more times, recovering each extract in the 150-milliliter beaker. Exercise care not to fill the beaker to such a capacity that solvent losses may occur. Evaporate the combined nitromethane extracts to 1 milliliter of n-hexadecane residue containing the nitromethane-soluble mineral oil extractives. (Note: Complete removal of the nitromethane is essential. This can be assured by two successive additions of 5 milliliters of isooctane and reevaporation.)

3. Remove the beaker from the steam bath and allow to cool.

4. Weigh 50 grams 1 gram of activated aluminum oxide and pack into the chromatographic column (1.3 centimeters x 75 centimeters) described under ``Apparatus'' in C under I above. (Note: A small plug of glass wool is placed at the column exit to prevent the aluminum oxide from passing through the column. After adding aluminum oxide, tap the column lightly to remove air voids. All percolations using aluminum oxide are performed under nitrogen pressure. The 500-milliliter reservoir described under ``Apparatus'' in E under I above is to be used to hold the elution solvents.)

5. Prewet the column by adding 40 milliliters of isooctane to the column. Adjust nitrogen pressure so that rate of descent of the isooctane coming off the column is 2.0 to 3.0 milliliters per minute. Be careful to maintain the level of solvent in the reservoir to prevent air from entering the aluminum oxide bed. New or additional solvent is added just before the last portion of the previous solvent enters the bed. To minimize possible photo-oxidation effects, the following procedures (steps 6 through 18) shall be carried out in subdued light.

6. Before the last of the isooctane reaches the top of the aluminum oxide bed, release the nitrogen pressure and turn off the stopcock on the column. Transfer the n-hexadecane residue from the 150-milliliter beaker from procedure step 3 above onto the column, using several washes of isooctane (total volume of washes should be no greater than 10-15 milliliters).

7. Open the stopcock and continue percolation until the isooctane is about 1 centimeter above the top of the aluminum oxide bed. Add 200 milliliters of isooctane to the reservoir, and continue the percolation at the specified rate.

8. Just before the isooctane surface reaches the top of the aluminum oxide bed, add 200 milliliters of a mixture of benzene and isooctane (33\1/3\ percent benzene and 66\2/3\ percent isooctane by volume) to the reservoir, and continue the percolation.

9. Just before the surface of this mixture reaches the top of the aluminum oxide bed, release the nitrogen pressure, turn off the stopcock, and discard all the elution solvents collected up to this point.

10. Add to the reservoir 300 milliliters of a mixture of benzene and isooctane (90 percent benzene and 10 percent isooctane by volume), place a 25-milliliter graduated cylinder under the column, continue the percolation until 20 milliliters of eluate has been collected, and then discard the eluate.

11. At this point, place a clean 250-milliliter Erlenmeyer flask under the column. Continue the percolation and collect all the remaining eluate.

(Note: Allow the column to drain completely. An increase in the nitrogen pressure may be necessary as the last of the solvent comes off the column.)

12. Place 1 milliliter of n-hexadecane into a 150-milliliter beaker. Place this onto a steam bath under a nitrogen stream and transfer in small portions the eluate from step 11 above. Wash out the Erlenmeyer flask with small amounts of benzene and transfer to the evaporation beaker. Evaporate until only 1 milliliter of hexadecane residue remains.

(Note: Complete removal of the benzene is essential. This can be assured by two successive additions of 5 milliliters of isooctane and reevaporation.)

13. Remove the beaker from the steam bath and cool.

14. Place a sample of 113.5 grams activated 100- 200-mesh silica gel in a 500-milliliter glass-stoppered Erlenmeyer flask. Add to the silica gel 46.2 grams (41 milliliters) of nitromethane. Stopper and shake the flask vigorously until no lumps of silica gel are observed and then shake occasionally during a period of 1 hour. The resultant nitromethane-treated silica gel is 29 weight-percent nitro-methane and 71 weight-percent silica gel.

15. Place a small plug of glass wool in the tapered end of the 1.7 centimeters outside diameter x 115 centimeters column, described under ``Apparatus'' in D of I above, adjacent to the stopcock to prevent silica gel from passing through the stopcock. Pack the nitromethane-treated silica gel into the column, tapping lightly. The resultant silica gel bed should be about 95 centimeters in depth. Place into a flask 170 milliliters of isooctane saturated with nitromethane.

16. Place a 100-milliliter graduated cylinder under the column and transfer the residue from the beaker in procedure step 13 above with several washes of the 170 milliliters of isooctane, saturated with nitromethane, onto the top of the column. (Total volume of washes should be no greater than 10 to 15 milliliters.) Permit isooctane solution to enter the silica gel bed until the liquid level is at the top bed level. Place the remaining amount of the 170 milliliters of isooctane, saturated with nitromethane, in the reservoir above the bed for percolation through the silica gel. Apply nitrogen pressure to the top of the column, adjusting the pressure so that the isooctane is collected at the rate of 2.5 to 3.5 milliliters per minute, and percolate isooctane through the bed until a quantity of 75.0 milliliters of eluate is collected. Discard the 75 milliliters of eluate. Turn off the stopcock and add 250 milliliters of benzene to the reservoir above the bed. Use a 400-milliliter beaker to collect the remaining eluate.

17. Open the stopcock, renew the pressure, and percolate the remaining isooctane and benzene through the column eluting the remaining aromatics. Transfer the eluate in small portions from the 400 milliliter beaker to a 150-milliliter beaker containing 1 milliliter of n-hexadecane and evaporate on the steam bath under nitrogen. Rinse the 400-milliliter beaker well with small portions of isooctane to obtain a complete transfer.

(Note: Complete removal of the nitromethane and benzene is essential. This can be assured by successive additions of 5 milliliters of isooctane and reevaporation.)

18. Transfer the residue with several washes of isooctane into a 200-milliliter volumetric flask. Add isooctane to mark.

19. Record the spectrum of the sample solution in a 1-centimeter cell compared to isooctane from 270 to 400 m. After making necessary corrections in the spectrum for cell differences and for the blank absorbance, record the maximum absorbance in each of the wavelength intervals (m), 280-299, 300-319, 320-359, 360-400.

a. If the spectrum then shows no discernible peak corresponding to the absorbance maximum of the pyrene reference standard solution at 334 m, the maximum absorbances in the respective wavelength intervals recorded shall not exceed those prescribed in paragraph (d)(1)(ii) of this section.

b. If such a peak is evident in the spectrum of the sample solution, and the spectrum as a whole is not incompatible with that of a pyrene contaminant yielding such a peak of the observed absorbance, calculate the concentration of pyrene that would yield this peak (334 m) by the base-line technique described in ASTM method E169-63 (Reapproved 1981), ``Standard Recommended Practices for General Techniques of Ultraviolet Quantitative Analysis,'' which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section. Correct each of the maximum absorbances in the respective specified wavelength intervals by subtracting the absorbance due to pyrene, determined as follows:

$$\text{Absorbance due to pyrene} = \frac{Cp \times Sa}{Sp}$$

where:
Cp=Calculated concentration of pyrene in sample solution;
Sp=Concentration of pyrene reference standard solution in same units of concentration;
Sa=Absorbance of pyrene reference standard solution at wavelength of maximum absorbance of sample solution in the respective specified wavelength intervals.

Also calculate the pyrene content of the oil sample in parts per million as follows:

$$\underset{\text{(p.p.m.)}}{\text{Pyrene content}} = \frac{(200/1000) \times C}{20/1000} = 10C$$

where:
C=Calculated concentration of pyrene in milligrams per liter of sample solution.

c. The pyrene content so determined shall not exceed 25 p.p.m. The maximum absorbances corrected for pyrene content as described in this step 19 for each of the specified wavelength intervals shall not exceed the limits prescribed in paragraph (d)(1)(ii) of this section.

d. If the spectrum as a whole of the sample solution is in any respect clearly incompatible with the presence of pyrene as the source of the peak at 334 m, then the maximum absorbances in the respective wavelength intervals without correction for any assumed pyrene content shall not exceed the limits prescribed in paragraph (d)(1)(ii) of this section.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 49 FR 10112, Mar. 19, 1984; 54 FR 24898, June 12, 1989]

Note: The following excerpted law pertains to Indirect Food Additives. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 178--INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS--Table of Contents

Subpart D--Certain Adjuvants and Production Aids

Sec. 178.3910 Surface lubricants used in the manufacture of metallic articles.

The substances listed in this section may be safely used in surface lubricants employed in the manufacture of metallic articles that contact food, subject to the provisions of this section.

(a) The following substances may be used in surface lubricants used in the rolling of metallic foil or sheet stock provided that total residual lubricant remaining on the metallic article in the form in which it contacts food does not exceed 0.015 milligram per square inch of metallic food-contact surface:

(3) Mineral oil conforming to the identity prescribed in Sec. 178.3620(c).

Note: The following excerpted law pertains to Packaging Materials for Irradiated Foods. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 179--IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD--Table of Contents

Subpart C--Packaging Materials for Irradiated Foods

Sec. 179.45 Packaging materials for use during the irradiation of prepackaged foods.

The packaging materials identified in this section may be safely subjected to irradiation incidental to the radiation treatment and processing of prepackaged foods, subject to the provisions of this section and to the requirement that no induced radioactivity is detectable in the packaging material itself:

(a) The radiation of the food itself shall comply with regulations in this part.

(b) The following packaging materials may be subjected to a dose of radiation, not to exceed 10 kilograys, unless otherwise indicated, incidental to the use of , electron beam, or X-radiation in the radiation treatment of prepackaged foods:

(1) Nitrocellulose-coated or vinylidene chloride copolymer-coated cellophane complying with Sec. 177.1200 of this chapter.

(2) Glassine paper complying with Sec. 176.170 of this chapter.

(3) Wax-coated paperboard complying with Sec. 176.170 of this chapter.

(4) Polyolefin film prepared from one or more of the basic olefin polymers complying with Sec. 177.1520 of this chapter. The finished film may contain:

(i) Adjuvant substances used in compliance with Secs. 178.3740 and 181.22 through 181.30 of this chapter, sodium citrate, sodium lauryl sulfate, polyvinyl chloride, and materials as listed in paragraph (d)(2)(i) of this section.

(ii) Coatings comprising a vinylidene chloride copolymer containing a minimum of 85 percent vinylidene chloride with one or more of the following

comonomers: Acrylic acid, acrylonitrile, itaconic acid, methyl acrylate, and methyl methacrylate.

(5) Kraft paper prepared from unbleached sulfate pulp to which rosin, complying with Sec. 178.3870 of this chapter, and alum may be added. The kraft paper is used only as a container for flour and is irradiated with a dose not exceeding 500 grays.

(6) Polyethylene terephthalate film prepared from the basic polymer as described in Sec. 177.1630(e)(4)(i) and (ii) of this chapter. The finished film may contain:

(i) Adjuvant substances used in compliance with Secs. 178.3740 and 181.22 through 181.30 of this chapter, sodium citrate, sodium lauryl sulfate, polyvinyl chloride, and materials as listed in paragraph (d)(2)(i) of this section.

(ii) Coatings comprising a vinylidene chloride copolymer containing a minimum of 85 percent vinylidene chloride with one or more of the following comonomers: Acrylic acid, acrylonitrile, itaconic acid, methyl acrylate, and methyl methacrylate.

(iii) Coatings consisting of polyethylene conforming to Sec. 177.1520 of this chapter.

(7) Polystyrene film prepared from styrene basic polymer. The finished film may contain adjuvant substances used in compliance with Secs. 178.3740 and 181.22 through 181.30 of this chapter.

(8) Rubber hydrochloride film prepared from rubber hydrochloride basic polymer having a chlorine content of 30-32 weight percent and having a maximum extractable fraction of 2 weight percent when extracted with n-hexane at reflux temperature for 2 hours. The finished film may contain adjuvant substances used in compliance with Sec. Sec. 178.3740 and 181.22 through 181.30 of this chapter.

(9) Vinylidene chloride-vinyl chloride copolymer film prepared from vinylidene chloride-vinyl chloride basic copolymers containing not less than 70 weight percent of vinylidene chloride and having a viscosity of 0.50-1.50 centipoises as determined by ASTM method D729-81, ``Standard Specification for Vinylidene Chloride Molding Compounds,'' which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408. The finished film may contain adjuvant substances used in compliance with Secs. 178.3740 and 181.22 through 181.30 of this chapter.

(10) Nylon 11 conforming to Sec. 177.1500 of this chapter.

(c) Ethylene-vinyl acetate copolymers complying with Sec. 177.1350 of this chapter. The ethylene-vinyl acetate packaging materials may be subjected to a dose of radiation, not to exceed 30 kilogray (3 megarads), incidental to the use of, electron beam, or X-radiation in the radiation treatment of packaged foods.

(d) The following packaging materials may be subjected to a dose of radiation, not to exceed 60 kilograys incidental to the use of electron beam, or X-radiation in the radiation processing of prepackaged foods:

(1) Vegetable parchments, consisting of a cellulose material made from waterleaf paper (unsized) treated with concentrated sulfuric acid, neutralized, and thoroughly washed with distilled water.

(2) Films prepared from basic polymers and with or without adjuvants, as follows:

(i) Polyethylene film prepared from the basic polymer as described in Sec. 177.1520(a) of this chapter. The finished film may contain one or more of the following added substances:

Substances	Limitations
Amides of erucic, linoleic, oleic, palmitic, and stearic acid.	Not to exceed 1 pct by weight of the polymer.
BHA as described in Sec. 172.110 of this chapter.	Do.

BHT as described in Sec. 172.115 of this chapter.	Do.
Calcium and sodium propionates.....	Do.
Petroleum wax as described in Sec. 178.3710 of this chapter.	Do.
Polypropylene, noncrystalline, as described in Sec. 177.1520(c) of this chapter.	Not to exceed 2 pct by weight of the polymer.
Stearates of aluminum, calcium, magnesium, potassium, and sodium as described in Sec. 172.863(a) of this chapter.	Not to exceed 1 pct by weight of the polymer.
Triethylene glycol as described in Sec. 178.3740(b) of this chapter.	Do.
Mineral oil as described in Sec. 178.3620 (a) or (b) of this chapter.	***Do.***

Note: The following law pertains to Specific labeling requirements for specific drug products.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 201--LABELING--Table of Contents

Subpart G--Specific Labeling Requirements for Specific Drug Products

Sec. 201.302 Notice to manufacturers, packers, and distributors of drugs for internal use which contain mineral oil.

(a) In the past few years research studies have altered medical opinion as to the usefulness and harmfulness of mineral oil in the human body. These studies have indicated that when mineral oil is used orally near mealtime it interferes with absorption from the digestive tract of provitamin A and the fat-soluble vitamins A, D, and K, and consequently interferes with the utilization of calcium and phosphorus, with the result that the user is left liable to deficiency diseases. When so used in pregnancy it predisposes to hemorrhagic disease of the newborn.

(b) There is accumulated evidence that the indiscriminate administration of mineral oil to infants may be followed by aspiration of the mineral oil and subsequent ``lipoid pneumonia.''

(c) In view of these facts, the Department of Health and Human Services will regard as misbranded under the provisions of the Federal Food, Drug, and Cosmetic Act a drug for oral administration consisting in whole or in part of mineral oil, the labeling of which encourages its use in pregnancy or indicates or implies that such drug is for administration to infants.

(d) It is also this Department's view that the act requires the labelings of such drugs to bear a warning against consumption other than at bedtime and against administration to infants. The following form of warning is suggested: ``Caution: To be taken only at bedtime. Do not use at any other time or administer to infants, except upon the advice of a physician.''

(e) This statement of interpretation does not in any way exempt

mineral oil or preparations containing mineral oil from complying in all other respects with the requirements of the Federal Food, Drug, and Cosmetic Act.

Note: The following law pertains to Opthalmic drug products for over-the-counter use in humans. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 349--OPHTHALMIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE--Table of Contents

Subpart B--Active Ingredients

Sec. 349.14 Ophthalmic emollients.

The active ingredients of the product consist of any of the following:

(a) Lanolin preparations:

(1) Anhydrous lanolin, 1 to 10 percent in combination with one or more oleaginous emollient agents included in the monograph.

(2) Lanolin, 1 to 10 percent in combination with one or more oleaginous emollient agents included in the monograph.

(b) Oleaginous ingredients:

(1) Light mineral oil, up to 50 percent in combination with one or more other emollient agents included in the monograph.

(2) Mineral oil, up to 50 percent in combination with one or more other emollient agents included in the monograph.

(3) Paraffin, up to 5 percent in combination with one or more other emollient agents included in the monograph.

(4) Petrolatum, up to 100 percent.

(5) White ointment, up to 100 percent.

(6) White petrolatum, up to 100 percent.

(7) White wax, up to 5 percent in combination with one or more other emollient agents included in the monograph.

(8) Yellow wax, up to 5 percent in combination with one or more other emollient agents included in the monograph.

Note: The following law pertains to food additives permitted in feed and drinking water of animals. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 573--FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS--Table of Contents

Subpart B--Food Additive Listing

Sec. 573.220 Feed-grade biuret.

The food additive feed grade biuret may be safely used in ruminant feed in accordance with the following prescribed conditions:

(a) The food additive is the product resulting from the controlled pyrolysis of urea conforming to the following specifications:

	Percent
Biuret	55 minimum.
Urea	15 maximum.
Cyanuric acid and triuret	30 maximum.
Mineral oil	***0.5 maximum.***
Total nitrogen (equivalent to 218.75 pct crude protein).	35 minimum.

(b) It is used in ruminant feeds as a source of nonprotein nitrogen.

(c) To assure safe use of the additive:

(1) The label and labeling of the additive and that of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall contain, in addition to other information required by the act, the following:

(i) The name of the additive.

(ii) The maximum percentage of equivalent crude protein from nonprotein nitrogen.

(iii) The statement ``Do not feed to animals producing milk for human consumption.''

(2) The label shall recommend that the diet be balanced to provide adequate nutrients when equivalent crude protein from all forms of nonprotein nitrogen exceed one-third of the total crude protein in the total daily ration.

Note: The following law pertains directly to mineral oil as a feed additive for animals.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 573--FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS--Table of Contents

Subpart B--Food Additive Listing

Sec. 573.680 Mineral oil.

Mineral oil may be safely used in animal feed, subject to the provisions of this section.

(a) Mineral oil, for the purpose of this section, is that complying with the definition and specifications contained in Sec. 172.878 (a) and

(b) or in Sec. 178.3620(b)(1) (i) and (ii) of this chapter.

(b) It is used in animal feeds for the following purposes:

(1) To reduce dustiness of feeds or mineral supplements.

(2) To serve as a lubricant in the preparation of pellets, cubes, or blocks and to improve resistance to moisture of such pellets, cubes, or blocks.

(3) To prevent the segregation of trace minerals in mineralized salt.

(4) To serve as a diluent carrier in the manufacture of feed grade biuret in accordance with good manufacturing practice.

(5) For the removal of water from substances intended as ingredients of animal feed.

(c) The quantity of mineral oil used in animal feed shall not exceed 3.0 percent in mineral supplements, nor shall it exceed 0.06 percent of the total ration when present in feed or feed concentrates.

Note: The following law pertains to Petrolatum used in animal feed. Relevant information regarding mineral oil has been highlighted and italicized.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 573--FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS--Table of Contents

Subpart B--Food Additive Listing

Sec. 573.720 Petrolatum.

Petrolatum may be safely used in or on animal feed, subject to the following prescribed conditions:

(a) Petrolatum complies with the specifications set forth in the U.S. Pharmacopeia XVI for white petrolatum or in The National Formulary XII for yellow petrolatum.

(b) Petrolatum meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in Sec. 172.886(b) of this chapter.

Ultraviolet absorbance per centimeter path length:

Millimicrons	Maximum
280 to 289	0.25
290 to 299	.20
300 to 359	.14
360 to 400	.04

(c) It is used in animal feed for the following purposes:

(1) To reduce dustiness of feeds or mineral supplements.

(2) To serve as a lubricant in the preparation of pellets, cubes, or blocks, and to improve resistance to moisture of such pellets, cubes, or blocks.

(d) The quantity of petrolatum present in animal feeds from the uses specified in paragraph (c) of this section shall not exceed 3 percent in mineral supplements nor shall it exceed 0.06 percent of the total ration when present in feed or feed concentrates.

(e) When used in combination with technical white mineral oil for the uses described in paragraph (c) of this section, the total quantity of combined petrolatum and technical white mineral oil shall not exceed the limits prescribed in paragraph (d) of this section.

(f) Petrolatum may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the act, in an amount not greater than that required to produce its intended effect.

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Regulatory: EPA/NIEHS/Other Sources

NOSB:

The following materials have been determined to be synthetic and allowed for the use in organic livestock production:

Mineral Oil - For topical use and as a lubricant.[31]

OSHA:

Permissible Exposure Limit: Table Z-1 8-hr Time Weighted Avg: 5 mg/cu m. /Mist/
[29 CFR 1910.1000 (7/1/98)]**QC REVIEWED**

Threshold Limit Values:

8 hr Time Weighted Avg (TWA) 5 mg/cu m, as sampled by method that does not collect vapor; 15 min Short Term Exposure Limit (STEL) 10 mg/cu m /Oil mist, mineral/
[American Conference of Governmental Industrial Hygienists. Threshold Limit Values (TLVs) for Chemical Substances and Physical Agents Biological Exposure Indices for 1998. Cincinnati, OH: ACGIH, 1998. 53]**QC REVIEWED**

Notice of Intended Change (first notice appeared in 1998 edition): The ACGIH has listed chemicals for which either a limit has been proposed for the first time, for which a change in the "Adopted" listing has been proposed, or for which retention on the Notice of Intended Changes has been proposed. The proposed limits should be considered trial limits that will remain in the listing for a period of at least one year. If, after one year no evidence comes to light that questions the appropriateness of the values herein, the values will be reconsidered for the "Adopted" list. Short Term Exposure Limit value is removed. /Oil mist, mineral/
[American Conference of Governmental Industrial Hygienists. Threshold Limit Values (TLVs) for Chemical Substances and Physical Agents Biological Exposure Indices for 1998. Cincinnati, OH: ACGIH, 1998. 76]**QC REVIEWED**

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[30] All above laws regarding mineral oil and its legal use were directly copied and pasted from the government archives found on the web under relevant sections that pertained to this research. No alterations were made except certain significant information within the original text was highlighted for convenience purposes as previously noted. http://www.accessdata.fda.gov/scripts

[31] *SUMMARY OF NOSB RECOMMENDATIONS FOR MATERIALS CONSIDERED AT AUSTIN, TEXAS in NOVEMBER 1995* http://web.iquest.net/ofma/nosb16.htm

Notice of Intended Change (first notice appeared in 1998 edition): The ACGIH has listed chemicals for which either a limit has been proposed for the first time, for which a change in the "Adopted" listing has been proposed, or for which retention on the Notice of Intended Changes has been proposed. The proposed limits should be considered trial limits that will remain in the listing for a period of at least one year. If, after one year no evidence comes to light that questions the appropriateness of the values herein, the values will be reconsidered for the "Adopted" list. Time Weighted Avg (TWA): 0.005 mg/cu m, as sampled by method that does not collect vapor. /Oil mist, mineral, sum total of 15 polynuclear aromatic hydrocarbons (PAHs) listed as carcinogens by the U.S. National Toxicology Program (NTP)/
[American Conference of Governmental Industrial Hygienists. Threshold Limit Values (TLVs) for Chemical Substances and Physical Agents Biological Exposure Indices for 1998. Cincinnati, OH: ACGIH, 1998. 76]**QC REVIEWED**

Notice of Intended Changes (first appeared in 1998 edition): A1. A1= Confirmed human carcinogen. /Oil mist, mineral, sum total of 15 polynuclear aromatic hydrocarbons (PAHs) listed as carcinogens by the U.S. National Toxicology Program (NTP)/
[American Conference of Governmental Industrial Hygienists. Threshold Limit Values (TLVs) for Chemical Substances and Physical Agents Biological Exposure Indices for 1998. Cincinnati, OH: ACGIH, 1998. 76]**QC REVIEWED**[32]

Acute and chronic exposure to mineral oil mists is regulated in the United States by an OSHA permissible exposure limit (PEL) of 5 mg/m^3 as an 8-hour time-weighted average (TWA) concentration.[33]

In proposing to classify all mineral oils as suspect carcinogens, the TLV (Threshold Limit Value) ignores the significance of using highly refined, noncarcinogenic mineral oils to eliminate risks. [34]

NIOSH, ACGIH:

NIOSH Recommendations:

Recommended Exposure Limit: 10 Hr Time-Weighted Avg: 5 mg/cu m.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 236]**QC REVIEWED**

Recommended Exposure Limit: 15 Min Short-Term Exposure Limit: 10 mg/cu m.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 236]**QC REVIEWED**

Immediately Dangerous to Life or Health:

2500 mg/cu m
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 236]**QC REVIEWED**

Other Occupational Permissible Levels:

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[32] *Mineral Oil Full Record on Toxnet* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAa8a4Ss:1
[33] *Worker Health and Safety* http://www.plasticsindustry.org/public/worksafe/mineraloil.htm
[34] *Mineral Oil Exposure – What's The Limit?* https://mows.aiag.org/source/3/actionline/2002/04_April/April02_p20.pdf

Australia: 5 mg/cu m, STEL 10 mg/cu m (substance under review) (1990); Sweden: 1mg/cu m, short-term value 3 mg/cu m, 15 minutes (1990); United Kingdom: 5 mg/cu m, 10-minute STEL 10 mg/cu m (1991) [American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1147]**PEER REVIEWED**

Exposure to mineral oil mist can occur through inhalation, ingestion, and eye or skin contact. Both the National Institute for Occupational Safety and Health (NIOSH) and the American Conference of Governmental Industrial Hygienists (ACGIH) have established 5 mg/m^3 recommended exposure limits to mineral oil mists based on the risk of respiratory effects. By definitions in the documentations for these regulatory/authoritative bodies, mineral oils and their mists include: white mineral oil (considered food-grade), paraffin oil, cutting oil, hydraulic oil, transformer oil, lubricating oil, and others. Mineral oils are a component of metalworking and machining fluids.[35]

Status Among U.S. Certifiers

NOFA: includes agreements for the states of Connecticut, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont.

State Organic Certifiers:
Oregon does not have specific limitations on materials used for crops and livestock. If the materials comply with USDA regulations, they are deemed acceptable for use in the state of Oregon. (Contact- Ron McKay) [36]

Pennsylvania is in accordance with guidelines proposed by OMRI.
(Contact- Martha Melton- state certifier) [37]

Minnesota does not have specific limitations on materials used for crops and livestock. If the materials comply with USDA regulations, they are deemed acceptable for use in the state of Minnesota. (Contact- Mary Hanks- state certifier) [38]

International

European Union:
Most spinning oils that are used today are based on mineral oils, fatty acid esters or polyalkylene glycolether products. Mineral oil based spinning oils are restricted in Europe because they may contain components that are bio-accumulators and not readily biodegradable. Because low concentrations of oils and greases are difficult to remove from waste water the requirement that oils be readily biodegradable is well justified.[39]

According to the Plant Protection Products allowed under Soil Association and UKROFS Standards for Organic Farming in the UK, Mineral Oils used for insecticides and fungicides are allowed for use only in fruit and olive trees, vines, and other tropical crops.

Section 2119 OFPA U.S.C. 6518(m)(1-7) Criteria

[35] *Worker Health and Safety* http://www.plasticsindustry.org/public/worksafe/mineraloil.htm
[36] Information was referenced from a phone interview with Ron McKay, State Certifier, June 5, 2002.
[37] Information was referenced from a phone interview with Martha Melton, State Certifier, June 5, 2002
[38] Information was referenced from a phone interview with Mary Hanks, State Certifier, June 12, 2002
[39] *Environmental Criteria for Textiles*
http://216.239.51.100/search?q=cache:QFzM7ZYqYSMC:www.snf.se/bmv/english/textile.doc+%22mine

1. *The potential of the substance for detrimental interactions with other materials used in organic farming systems.*

Interactions:

Concurrent use of /anticoagulants, coumarin- or indandione-derivative, oral, or contraceptive, oral, or digitalis glycosides or vitamins, fat-soluble, such as A, D, E, and K/ with **mineral oil** may interfere with the proper absorption of these or other medications and reduce their effectiveness.
[USP Convention. USPDI-Drug Information for the Health Care Professional. 14th ed. Volume I. Rockville, MD: United States Pharmacopeial Convention, Inc., 1994. (Plus Updates). 1706]**PEER REVIEWED**

In addition to interfering with absorption of oral anticoagulants, **mineral oil** also decreases absorption of vitamin K, which may lead to increased anticoagulant effects.
[USP Convention. USPDI-Drug Information for the Health Care Professional. 14th ed. Volume I. Rockville, MD: United States Pharmacopeial Convention, Inc., 1994. (Plus Updates). 1706]**PEER REVIEWED**

Concurrent use /with stool softener laxatives/ may cause increased absorption of **mineral oil** and result in the formation of tumor-like deposits in tissues.
[USP Convention. USPDI-Drug Information for the Health Care Professional. 14th ed. Volume I. Rockville, MD: United States Pharmacopeial Convention, Inc., 1994. (Plus Updates). 1706]**PEER REVIEWED**

Fire Potential:

Fire hazard: Low
[Sax, N.I. Dangerous Properties of Industrial Materials. 6th ed. New York, NY: Van Nostrand Reinhold, 1984. 1949]**PEER REVIEWED**

NFPA Hazard Classification:

Health: 0. 0= Materials that on exposure under fire conditions, offer no hazard beyond that of ordinary combustible material.
[Fire Protection Guide to Hazardous Materials. 12 ed. Quincy, MA: National Fire Protection Association, 1997.,p. 325-73]**QC REVIEWED**

Flammability: 1. 1= Materials that must be preheated before ignition will occur, such as class IIIB combustible liquids and solids and semi-solids whose flash point exceeds 200 deg F (93.4 deg C), as well as most ordinary combustible materials. Water may cause frothing if it sinks below the surface of the burning liquid and turns to steam. However, a water fog that is gently applied to the surface of the liquid will cause a frothing which will extinguish the fire.
[Fire Protection Guide to Hazardous Materials. 12 ed. Quincy, MA: National Fire Protection Association, 1997.,p. 325-73]**QC REVIEWED**

Reactivity: 0. 0= Includes materials that are normally stable, even under fire exposure conditions, and that do not react with water. Normal fire fighting procedures may be used.
[Fire Protection Guide to Hazardous Materials. 12 ed. Quincy, MA: National Fire Protection Association, 1997.,p. 325-73]**QC REVIEWED**

Flash Point:

380 deg F (193 deg C) (Open cup)
[Fire Protection Guide to Hazardous Materials. 12 ed. Quincy, MA: National Fire Protection Association, 1997.,p. 325-73]**QC REVIEWED**

135 deg C (275 deg F) (closed cup) /**Mineral oil** mist/
[Mackison, F. W., R. S. Stricoff, and L. J. Partridge, Jr. (eds.). NIOSH/OSHA - Occupational Health Guidelines for Chemical Hazards. DHHS(NIOSH) PublicationNo. 81-123 (3 VOLS). Washington, DC: U.S. Government Printing Office, Jan. 1981.]**PEER REVIEWED**

Autoignition Temperature:

Ignition Temperature: 500-700 deg F
[U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.]**PEER REVIEWED**

Fire Fighting Procedures:

Dry chemical, foam, or carbon dioxide. Water or foam may cause frothing.
[U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.]**PEER REVIEWED**[40]

2. *The toxicity and mode of action of the substance and of its break down products or any contaminants, and their persistence and areas of concentration in the environment.*

Tolerances for residues of **mineral oil** as specified in paragraph (a) of this section are established in or on the following grains from postharvest application: shelled corn and grain sorghum.
[40 CFR 180.149(b) (7/1/92)]**PEER REVIEWED**

Residues of **mineral oil** are exempted from the requirement of a tolerance when used as a diluent, carrier, and solvent in accordance with good agricultural practices as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.
[40 CFR 180.1001(c) (7/1/92)]**PEER REVIEWED**

Mineral oil is exempted from the requirement of a tolerance when used as a solvent, diluent in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals.
[40 CFR 180.1001(e) (7/1/92)]**PEER REVIEWED**[41]

Note: The following is a study conducted on the effects of mineral oil and its remnants left in soil.

Objective

This project was conducted with the objective to measure the degradation rate of mineral oil in the soil under in situ landfarming conditions, as well as the ecological recovery of the soil, dependent on a number of practical circumstances, under low energy input landfarming conditions. The relation between the biological degradation rate and the ecological recovery is being considered.

[40] *Mineral Oil Full Record on Toxnet* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAa8a4Ss:1
[41] *Mineral Oil Full Record on Toxnet* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAa8a4Ss:1

Bottlenecks
- The field measurement of the degradation rates of oil in relation to environmental conditions;
- The influence of the non-homogeneous composition of the soil on the (measurement of) degradation rates;
- The role of vegetation in the degradation of a mineral oil contamination;
- The development of an availability test in relation to leaching and micro-biological degradation;
- Social acceptance and risk perception in case of aerial redevelopment.

Approach
The project is conducted in three phases. Phases 2 and 3 are primarily repetitions of the measurement strategy in phase 1, adapted on the basis of the results obtained so far. Various practical conditions are applied, which vary with respect to the extent of homogenisation (coarse, well and very well homogenised), additives (none, fertiliser and organic material) and oil concentrations. During phase 2, phyto-remediation was expressly included in the project. In phase 3 the risk aspects of functional embedding in the environment were also taken into account.

Results
The results indicate that there is substantial degradation of mineral oil in the zone between 0 and 50 cm below ground level. The degradation of mineral oil appears to be practically independent of the extent of homogenisation and the addition of fertiliser or compost. Significant differences in oil concentrations in the various measurement fields could not be observed. Deeper than 50 cm below ground level the degradation of mineral oil appears to stagnate as a result of a lack of oxygen.[42]

3. *The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*

A study was conducted on the evaporation of **mineral oil** from polyvinyl-chloride and glass fiber filters, the materials recommended by NIOSH for the collection and analysis of **mineral oil** mists. The volatilization of **mineral oil** was assessed by comparing the weights of filters 4 hours following collection of fresh and used **mineral oil** mists on glass fiber and polyvinyl-chloride filters with the weights determined immediately after oil deposition. A similar analysis was conducted using an electrostatic precipitator. About 35% of the original mass of fresh **mineral oil** on glass fiber and polyvinyl-chloride filters was lost, while used **mineral oil** lost about 12% of its original mass after 4 hours. Significantly fewer evaporative losses were seen using the electrostatic precipitator. The authors conclude that use of the current NIOSH recommended analytical method for evaluation of worker exposure to **mineral oil** mist may underestimate the true mist concentration if the **mineral oil** contains volatile fractions.[43]

Chemical Safety & Handling:

Immediately Dangerous to Life or Health:

2500 mg/cu m
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 236]**QC REVIEWED**

Stability/Shelf Life:

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[42] *Project summary 95-1-44: Test remediation Measuring Station 1, NAM Schoonebeek* http://www.bodembreed.nl/nobisuk/pages/projectsamenvattingen/project95-1-44.htm
[43] *Volatilization of Mineral Oil Mist Collected on Sampling Filters* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAOuaWLV:5

OXIDATION & PEROXIDATION WHEN IT OCCURS IN MINERAL OILS CONTINUES ALMOST @ LOGARITHMIC RATE
[Rossoff, I.S. Handbook of Veterinary Drugs. New York: Springer Publishing Company, 1974. 366]**PEER REVIEWED**

Cleanup Methods:

1. Ventilate area of spill or leak. 2. For small quantities, absorb on paper towels. Evaporate in a safe place (such as a fume hood). Allow sufficient time for evaporating vapors to completely clear the hood ductwork. Burn the paper in a suitable location away from combustible materials. Large quantities can be collected and atomized in a suitable combustion chamber. /**Mineral oil** mist/
[Mackison, F. W., R. S. Stricoff, and L. J. Partridge, Jr. (eds.). NIOSH/OSHA - Occupational Health Guidelines for Chemical Hazards. DHHS(NIOSH) PublicationNo. 81-123 (3 VOLS). Washington, DC: U.S. Government Printing Office, Jan. 1981.]**PEER REVIEWED**

Disposal Methods:

SRP: At the time of review, criteria for land treatment or burial (sanitary landfill) disposal practices are subject to significant revision. Prior to implementing land disposal of waste residue (including waste sludge), consult with environmental regulatory agencies for guidance on acceptable disposal practices. **PEER REVIEWED**

Incineration & landfill: Contaminated **mineral oil** can be disposed of by controlled incineration. An alternative can be the use of oily sand and debris for landfill at sites carefully chosen to avoid any risk of the oil causing contamination of water supplies.
[United Nations. Treatment and Disposal Methods for Waste Chemicals (IRPTC File). Data Profile Series No. 5. Geneva, Switzerland: United Nations Environmental Programme, Dec. 1985. 211]**PEER REVIEWED**

Recycling & incineration: There are several stages of treatment. The final wastewater will probably require treatment, usually biological degradation, or perhaps carbon adsorption. The separated oil may be recycled, burnt for its heat content, incinerated if it is a difficult waste, or dumped. There are several ways of handling special wastes where the oil is relatively valuable and/or easily recoverable, and these include solvent extraction into an immiscible solvent, steam distillation, and air stripping of more volatile cmpd. It is always worth considering whether the recovery or reuse is technically and economically viable.
[United Nations. Treatment and Disposal Methods for Waste Chemicals (IRPTC File). Data Profile Series No. 5. Geneva, Switzerland: United Nations Environmental Programme, Dec. 1985. 211]**PEER REVIEWED**

... By atomizing in a suitable combustion chamber. /**Mineral oil** mist/
[Mackison, F. W., R. S. Stricoff, and L. J. Partridge, Jr. (eds.). NIOSH/OSHA - Occupational Health Guidelines for Chemical Hazards. DHHS(NIOSH) PublicationNo. 81-123 (3 VOLS). Washington, DC: U.S. Government Printing Office, Jan. 1981.]**PEER REVIEWED**[44]

4. *The effects of the substance on human health.*

Emergency Medical Treatment:

EMT Copyright Disclaimer:

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[44] *Mineral Oil Full Record on Toxnet* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAa8a4Ss:1

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The following Overview, *** LAXATIVES-EMOLLIENT ***, is relevant for this HSDB record chemical.

Life Support:

- This overview assumes that basic life support measures have been instituted.

Clinical Effects:

SUMMARY OF EXPOSURE

0.2.1.1 ACUTE EXPOSURE

- Toxicity following acute ingestion of excessive amounts of these laxatives is generally minimal and limited to the gastrointestinal tract.

1. Onset of symptoms may be delayed for up to 1 to 3 days. Nausea, vomiting, and diarrhea may be noted. Aspiration of **mineral oil** may result in lipoid pneumonia, which may cause permanent lung injury.
2. SPECIFIC REPRESENTATIVES of the class of emollient laxatives include; **mineral oil,** dioctyl calcium sulfosuccinate, dioctyl sodium sulfosuccinate, dioctyl potassium sulfosuccinate.

RESPIRATORY

0.2.6.1 ACUTE EXPOSURE

- **Mineral oil,** if aspirated, may result in lipoid pneumonia.

GASTROINTESTINAL

0.2.8.1 ACUTE EXPOSURE

- Nausea, vomiting, diarrhea, foreign body reaction, intestinal obstruction, melanosis coli, cathartic colon, and fecal leakage may be noted.

Laboratory:

- Plasma levels of these agents are not clinically useful.
- Obtain serum electrolytes in patients with significant diarrhea.
- Monitor for respiratory distress after ingestion of **mineral oil.** Monitor ABGs/pulse oximetry and chest radiographs in patients with respiratory distress.

Treatment Overview:

ORAL EXPOSURE

- Due to aspiration hazard and generally low toxicity of these compounds, emesis is not recommended.
- Due to potential for inducing vomiting and aspiration, use activated charcoal only if there is a coingestant with potentially serious toxicity.
- DO NOT ADMINISTER A CATHARTIC.
- EXCESSIVE DIARRHEA should be treated with high fluid intake (Pedialyte or Gatorade) and monitoring of fluid and electrolyte status. Restrict solid food intake until diarrhea resolves.

Range of Toxicity:

- Toxic dose is unknown.
- Dehydration and electrolyte imbalance are the most common manifestations of toxicity. Lipoid pneumonia may develop after aspiration of small amounts of **mineral oil.**

[Rumack BH: POISINDEX(R) Information System. Micromedex, Inc., Englewood, CO, 2002; CCIS Volume 113, edition exp August, 2002. Hall AH & Rumack BH (Eds):TOMES(R) Information System. Micromedex, Inc., Englewood, CO, 2002; CCIS Volume 113, edition exp August, 2002.] **PEER REVIEWED**

Antidote and Emergency Treatment:

... **MINERAL OIL** /IS/ ... CONSIDERED TO BE RELATIVELY NONTOXIC & /DOES NOT/ ... REQUIRE /VOMITING/.
[Amdur, M.O., J. Doull, C.D. Klaasen (eds). Casarett and Doull's Toxicology. 4th ed. New York, NY: Pergamon Press, 1991. 935]**PEER REVIEWED**

IN A CASE OF CHRONIC **MINERAL OIL** PNEUMONIA (CAUSED BY LAXATIVE ADMIN), EXPTL TREATMENT WITH SCHEDULED COUGHING SPELLS & EXPECTORATION CAN IMPROVE PATIENT PROGNOSIS.
[HECKERS H ET AL; LUNG 155 (2): 101-10 (1978)]**PEER REVIEWED**

Human Health Effects:

IF IT GAINS ACCESS TO LUNGS **MINERAL OIL** PRODUCES LIPID PNEUMONITIS. ALTHOUGH MORE FREQUENTLY OBSERVED WHEN OIL WAS USED AS VEHICLE FOR APPLICATION OF DRUGS TO NASAL MUCOUS MEMBRANES, LIPID PNEUMONITIS CAN ALSO OCCUR FOLLOWING ORAL INGESTION OF OIL, PARTICULARLY IF...TAKEN @ BEDTIME. ... LEAKAGE OF OIL PAST ANAL SPHINCTER IS AN ANNOYING SIDE EFFECT AND AN OCCASIONAL CAUSE OF PRURITUS ANI. IT IS ALSO CLAIMED THAT OIL INTERFERES WITH HEALING OF POSTOPERATIVE WOUNDS IN ANORECTAL REGION AND THAT CONTINUOUS PRESENCE OF OIL IN RECTUM DISTURBS NORMAL DEFECATORY REFLEXES.
[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 1009]**PEER REVIEWED**

MINERAL OIL ACTS AS A LIPID SOLVENT; ADMIN WITH MEALS, IT MAY INTERFERE WITH ABSORPTION OF ESSENTIAL FAT-SOLUBLE SUBSTANCES. REGULAR INGESTION OF **MINERAL OIL** DURING PREGNANCY MAY REDUCE ABSORPTION OF VITAMIN K & PRODUCE HYPOPROTHROMBINEMIA. /IN INTESTINAL TRACT/...ELICITS TYPICAL FOREIGN-BODY REACTION IN INTESTINAL MUCOSA, MESENTERIC LYMPH NODES, LIVER, AND SPLEEN. ALTHOUGH NO PHYSIOLOGICAL DISTURBANCES HAVE BEEN RELATED TO PRESENCE OF OIL AT THESE SITES, IT MUST BE QUESTIONED WHETHER /OIL/...CAN BE USED SAFELY OVER LONG PERIODS OF TIME.
[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 1009]**PEER REVIEWED**

...IF TAKEN CONTINUOUSLY IN LARGE AMT IT MAY IMPAIR APPETITE...
[Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980. 746]**PEER REVIEWED**

/IN NASAL DROPS & SPRAYS/...OIL GRAVITATES TO LOWER LOBES OF LUNGS, WHERE IT SETS UP A GRANULOMATOUS REACTION, FOLLOWED BY MARKED FIBROSIS & ENCYSTMENT. DAILY ORAL DOSES OF 30-90 ML FOR MANY MONTHS HAS PRODUCED THE SAME EFFECT. THE FATALITY OF THIS COMPLICATION IS HIGH.
[Thienes, C., and T.J. Haley. Clinical Toxicology. 5th ed. Philadelphia: Lea and Febiger, 1972. 192]**PEER REVIEWED**

IN AN INSTANCE OF POSSIBLE EMBOLISM FROM AN OIL INJECTION, ONE PATIENT HAD RAPID LOSS OF VISION, SEVERE HEADACHE, CONVULSIONS, & COMA IMMEDIATELY AFTER INJECTION OF...**MINERAL OIL** PREPN, GRANUGENOL, INTO PLEURAL CAVITY IN TREATMENT OF EMPYEMA. RECOVERING GRADUALLY...WITHIN 3 WK VISION HAD RETURNED ESSENTIALLY TO NORMAL.
[Grant, W. M. Toxicology of the Eye. 2nd ed. Springfield, Illinois: Charles C. Thomas, 1974. 803]**PEER REVIEWED**

LIQ PETROLATUM...CAN BE APPLIED TO HUMAN EYES WITHOUT CAUSING DISCOMFORT OR SIGNS OF IRRITATION.
[Grant, W. M. Toxicology of the Eye. 2nd ed. Springfield, Illinois: Charles C. Thomas, 1974. 801]**PEER REVIEWED**

MASSIVE VISCERAL LIPID DEPOSITION FOLLOWING THE PROLONGED ORAL USE OF **MINERAL OIL** IS REPORTED.
[NOCHOMOVITZ LE, UYS CJ; S AFR J LAB CLIN MED 20 (2): 1226 (1974)]**PEER REVIEWED**

/**Mineral oil**/ occasionally may cause miliaria and folliculitis.
[American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994. 1221]**PEER REVIEWED**

Foreign-body granulomas or paraffinomas in the liver, spleen, or mesenteric lymph nodes have been reported following systemic absorption of **mineral oil.**
[American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994. 952]**PEER REVIEWED**

Hypoprothrombinemia and hemorrhagic disease of the newborn has occurred when **mineral oil** was chronically administered orally to pregnant women.
[McEvoy, G.K. (ed.). American Hospital Formulary Service--Drug Information 94. Bethesda, MD: American Society of Hospital Pharmacists, Inc. 1994 (Plus Supplements). 1885]**PEER REVIEWED**

The major findings in a laxative abuse patient include chronic diarrhea, vomiting, abdominal pain, lassitude, thirst, weakness (15%), edema, bone pain resulting from osteomalacia, and weight loss. Findings may disclose a protein-losing enteropathy, steatorrhea, pathologic colon changes associated with featureless radiologic findings (10%-30%), acid-base abnormalities (20%-25%), and hypokalemia (20%-25%).
/Laxative abuse/
[Ellenhorn, M.J. and D.G. Barceloux. Medical Toxicology - Diagnosis and Treatment of Human Poisoning. New York, NY: Elsevier Science Publishing Co., Inc. 1988. 542]**PEER REVIEWED**

The NIOSH investigated complaints from workers in plants where oil mist was known to occur. None of the studies identified evidence of skin or respiratory tract irritation from exposures to oil mists tht were at levels below the 5 mg/cu m TLV-TWA. /Oil mist, mineral/
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1146]**PEER REVIEWED**

In a Norwegian cross-sectional matched pair study, 5 cable plant workers exposed to mists and vapors of **mineral oil** and kerosene for 5 to 35 years were investigated. An increased prevalence of slight basal lung fibrosis was found in the chest films of the exposed workers. Although oil mist levels were reported in the range of 0.15 to 0.30 mg/cu m, ... /it was/ suggested that the sampling methodology underestimated the actual exposure. Furthermore, the contribution of substantial short-term vapor exposures (reported up to 4000 mg/cu m) to lung fibrosis is uncertain. /Oil mist, mineral/
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1146]**PEER REVIEWED**

Lipoid pneumopnia has been reported following heavy exposure to oil mist in the absence of adequate ventilation. /Oil mist, mineral/
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1146]**PEER REVIEWED**

In a survey of cause-specific mortality rates of 5189 workers exposed to oil mist and employed for at least 1 year on metal machinery in a heavy industrial plant, no excess of digestive tract or respiratory tract cancers was reported or dose-response relationship shown. /Oil mist, mineral/
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1146]**PEER REVIEWED**

Injection of liquid petrolatum into the lacrimal system of patients with chronic epiphora produced a mass in the lower lid with inflammation in one, and infiltration of the orbit with interference in motion of the eye in another, both requiring surgery for relief.
[Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986. 715]**PEER REVIEWED**

Up to 1978, more than 400 cases of lipid pneumonia were reported in the literature to be related to oral administration of **mineral oil,** to oil-based nose drops or to intralaryngeal injection of medicinal oil.
[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer,1972-PRESENT. (Multivolume work).,p. V33 135 (1984)]**PEER REVIEWED**

Peritoneal lipid granuloma was observed in an individual who received **mineral oil** in the chest for a permanent collapse of the lung (oleothorax); it was noted that the substance had been introduced inadvertently into the abdominal cavity.
[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer,1972-PRESENT. (Multivolume work).,p. V33 135 (1984)]**PEER REVIEWED**

Lipid granulomas of the lung are localized lipid pneumonia, usually found in adults as a result of habitual use of large amounts of **mineral oil** (liquid petrolatum) by nasal, oral or pharyngeal administration for prolonged periods of time.
[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer,1972-PRESENT. (Multivolume work).,p. V33 135 (1984)]**PEER REVIEWED**

Drug Warnings:

...CAN CAUSE VARIETY OF UNTOWARD EFFECTS, & ITS USE AS A LAXATIVE REQUIRES APPRECIATION OF ITS POTENTIAL HAZARDS... HABITUAL USE OF **MINERAL OIL** MUST BE AVOIDED. ... INDISCRIMINATE USE...BY ELDERLY, DEBILITATED, OR DYSPHAGIC INDIVIDUALS SHOULD BE DISCOURAGED.
[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 1009]**PEER REVIEWED**

ORAL USE FOR MORE THAN TWO WEEKS COATS THE MUCOSA OF THE SMALL INTESTINE AND REDUCES THE ADSORPTION OF VITAMINS, ESPECIALLY THE FAT-SOLUBLE VITAMINS (A, D, E, AND K). THE PATIENT SHOULD BE WARNED THAT LIPID PNEUMONIA MAY OCCUR IF **MINERAL OIL** IS ASPIRATED AND THAT UNTOWARD EFFECTS, SUCH AS HEPATIC INFILTRATION, CAN RESULT FROM ITS ABSORPTION. BECAUSE OF THE THEORETICAL POSSIBILITY THAT CONCURRENT USE OF THE VARIOUS DETERGENT DOCUSATE SALTS MAY FURTHER ENHANCE THE ABSORPTION OF **MINERAL OIL**, THEIR CONCOMITANT ADMINISTRATION IS NOT RECOMMENDED.
[Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980. 1307]**PEER REVIEWED**

MINERAL OIL STILL PRESCRIBED BY SOME SURGEONS AFTER ANORECTAL SURGERY DESPITE THE FACT THAT IT SOMETIMES CAUSES PRURITUS ANI, & LACERATION OF THE AREA FROM SCRATCHING OR RUBBING INTERFERES WITH HEALING.
[Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980. 1308]**PEER REVIEWED**

In recent years, the oral use of **mineral oil** has not been advocated because of the possibility of interference with the absorption of fat-soluble vitamins and the danger of pulmonary aspiration. The dose required for the former effect exceeds that normally used in clinical practice. ... Oral **mineral oil** should not be given to patients with swallowing abnormalities.
[American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994. 951]**PEER REVIEWED**

Oral **mineral oil** is not recommended for bedridden elderly patients since they are more prone to aspiration of oil droplets, which amy produce lipid pneumonia.
[USP Convention. USPDI-Drug Information for the Health Care Professional. 14th ed. Volume I. Rockville, MD: United States Pharmacopeial Convention, Inc., 1994. (Plus Updates). 1705]**PEER REVIEWED**

Oral **mineral oil** is not recommended for children up to 6 years of age since patients in this age group are more prone to aspiration of oil droplets, which may produce lipid pneumonia.
[USP Convention. USPDI-Drug Information for the Health Care Professional. 14th ed. Volume I. Rockville, MD: United States

Pharmacopeial Convention, Inc., 1994. (Plus Updates). 1705]**PEER REVIEWED**

... The use of olive or **mineral oil** /for treating petroleum distillate poisoning is controversial. The oil is used to/ increase the viscosity, thereby decreasing the chance of aspiration if vomiting occurs after the initial ingestion. Such oil also acts as a cathartic to hasten the petroleum distillate from the gastrointestinal tract. however, if aspirated, the oil can cause lipoid pneumonia. A 6 year retrospective study showed as increased incidence of pneumonia in children who were given oil, therefore the use of oils should be avoided.
[Haddad, L.M., Clinical Management of Poisoning and Drug Overdose. 2nd ed. Philadelphia, PA: W.B. Saunders Co., 1990. 1184]**PEER REVIEWED**

Populations at Special Risk:

Oral **mineral oil** should not be given to patients with swallowing abnormalities.
[American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994. 951]**PEER REVIEWED**

Oral administration of **mineral oil** is contraindicated in children younger than 6 years of age; in bedridden, geriatric, debilitated, or pregnant patients; and in patients with esophageal or gastric retention, dysphagia, or hiatal hernia.
[McEvoy, G.K. (ed.). American Hospital Formulary Service--Drug Information 94. Bethesda, MD: American Society of Hospital Pharmacists, Inc. 1994 (Plus Supplements). 1885]**PEER REVIEWED**

Minimum Fatal Dose Level:

1= PRACTICALLY NON-TOXIC: PROBABLE ORAL LETHAL DOSE (HUMAN) ABOVE 15 G/KG, MORE THAN 1 QUART (2.2 LB) FOR 70 KG PERSON (150 LB).
[Gosselin, R.E., R.P. Smith, H.C. Hodge. Clinical Toxicology of Commercial Products. 5th ed. Baltimore: Williams and Wilkins, 1984.,p. II-156]**PEER REVIEWED**

Protective Equipment & Clothing:

Wear appropriate personal protective clothing to prevent skin contact.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 237]**QC REVIEWED**

Recommendations for respirator selection. Max concn for use: 50 mg/cu m. Respirator Class(es): Any air-purifying respirator with a high-efficiency particulate filter. Any supplied-air respirator.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 237]**QC REVIEWED**

Recommendations for respirator selection. Max concn for use: 125 mg/cu m. Respirator Class(es): Any supplied-air respirator operated in a continuous flow mode. Any powered, air-purifying respirator with a high-efficiency particulate filter.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 237]**QC REVIEWED**

Recommendations for respirator selection. Max concern for use: 250 mg/cu m. Respirator Class(es): Any air-purifying, full-facepiece respirator with a high-efficiency particulate filter. Any supplied-air respirator that has a tight-fitting facepiece and is operated in a continuous-flow mode. Any powered, air-purifying

respirator with a tight-fitting facepiece and a high-efficiency particulate filter. Any self-contained breathing apparatus with a full facepiece. Any supplied-air respirator with a full facepiece.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 237]**QC REVIEWED**

Recommendations for respirator selection. Max concern for use: 2500 mg/cu m. Respirator Class(es): Any supplied-air respirator operated in a pressure-demand or other positive-pressure mode.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 237]**QC REVIEWED**

Recommendations for respirator selection. Condition: Emergency or planned entry into unknown concern or IDLH conditions: Respirator Class(es): Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive pressure mode. Any supplied-air respirator with a full facepiece and operated in pressure-demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in pressure-demand or other positive pressure mode.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 237]**QC REVIEWED**

Recommendations for respirator selection. Condition: Escape from suddenly occurring respiratory hazards: Respirator Class(es): Any air-purifying, full-facepiece respirator with a high-efficiency particulate filter. Any appropriate escape-type, self-contained breathing apparatus.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 237]**QC REVIEWED**

Goggles or faces shield.
[U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.]**PEER REVIEWED**

SRP: Contaminated protective clothing should be segregated in such a manner so that there is no direct personal contact by personnel who handle, dispose, or clean the clothing. Quality assurance to ascertain the completeness of the cleaning procedures should be implemented before the decontaminated protective clothing is returned for reuse by the workers. Contaminated clothing should not be taken home at end of shift, but should remain at employee's place of work for cleaning.
PEER REVIEWED

Preventive Measures:

The worker should immediately wash the skin when it becomes contaminated.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 237]**QC REVIEWED**

Work clothing that becomes wet or significantly contaminated should be removed and replaced.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 237]**QC REVIEWED**

Workers whose clothing may have become contaminated should change into uncontaminated clothing before leaving the work premises.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 237]**QC REVIEWED**[45]

[45] *Mineral Oil Full Record on Toxnet* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAa8a4Ss:1

Mineral oil is a common ingredient in many household products. It is found in lotions, soaps, cosmetics and motor oil. Once the oil is absorbed, it is broken down by the liver. But because it is an unnatural product, the liver must work extra hard to remove it from the body. And once the oil is present in the intestinal tract, it will absorb all of the fat-soluble vitamins found there. It is essentially stealing important vitamins from the body, which the body will not be able to replace. This can eventually lead to nutritional deficiencies. Studies have also shown forms of pneumonia caused by mineral oil decreasing lung function, known as lipoid pneumonia. Because of these dangers, the medical community has condemned the use of mineral oil taken orally or as in ingredient in medications.[46]

As white **mineral oils** are present in many topically applied drug and non-drug products, it is of interest to review the toxicological effects of **mineral oil** produced by this route of exposure. Specifically, the concern regarding the safety of white **mineral oils** has arisen, in part, from results of subchronic (e.g. 90 day) feeding studies that reported the presence of granulomas in liver and histiocytosis in mesenteric lymph nodes of Fischer 344 rats after oral ingestion of select white **mineral oils.** In contrast to these subchronic oral studies, repeated topical exposure to white **mineral oils** has not been found to produce.[47]

CASE A. Evidence for carcinogenicity to humans (sufficient for untreated and mildly-treated oils; inadequate for highly-refined oils) Exposure to **mineral oils** that have been used in a variety of occupations, including mulespinning, metal machining and jute processing, has been associated strongly and consistently with the occurrence of squamous-cell cancers of the skin, and especially of the scrotum. Production processes for these oils have changed over time, and with more recent manufacturing methods highly-refined products are produced that contain smaller amounts of contaminants, such as polycyclic aromatic hydrocarbons. Excess mortality or morbidity from gastrointestinal malignancies was seen in two out of three cohort studies of metal workers (stomach cancer in two studies, large-bowel cancer in one); however, the only significant excess was for the sum of stomach cancer plus largebowel cancer in one study. Four cases of scrotal cancer were detected in one relatively small cohort study of metal industry workers. Among 682 turners with five or more years of exposure to **mineral oils,** five cases of squamous-cell carcinoma of the skin (four of the scrotum) occurred, with 0.3 expected. In a case-control study, a relative risk of 4.9 was reported for the association of scrotal cancer with potential exposure of metal workers to **mineral oils.** Neither the actual levels of exposure nor the classification of the **mineral oil** to which the machine workers were potentially exposed was available in the reports of the epidemiological studies. In a case-control study, an excess of sinonasal cancers was seen in toolsetters, set-up men and toolmakers. In a series of 344 cases of scrotal cancer from 1936 to 1976, 62% had held occupations in which exposure to **mineral oils** was likely to have occurred. The median latent period was 34 years. An examination of the incidence of second primary cancers among men with scrotal cancer demonstrated excesses of respiratory, upper alimentary tract and skin cancers; when the occupations were grouped, the excess was largely confined to those with exposure to oil. Excesses of bladder cancer have been reported in case-control studies in several countries among machinists and engineers, who were possibly exposed to cutting oils containing aromatic amines as additives. With regard to printing pressmen, one of two cohort studies addressing lung cancer showed an excess and one of two proportionate mortality studies showed a small, statistically nonsignificant excess of lung cancer among newspaper pressmen but no excess among non-newspaper pressmen; the other study did not address lung cancer. One of three proportionate mortality studies on manual workers in the printing industry, not specifically addressing printing pressmen, did not show an increased lung cancer risk, whereas the other two studies found a statistically significant excess. One of two proportionate mortality studies of printing pressmen indicated a statistically significant increase of deaths from rectal cancer, and the other showed a statistically nonsignificant increase of deaths from colon cancer; the cohort study considering colorectal cancers did not show an increased occurrence. One proportionate mortality study among newspaper and other commercial printing pressmen showed a statistically significant excess of mortality from cancers of the buccal cavity and pharynx, whereas no such excess was observed in a cohort study. One case-control study indicated a statistically significant excess of cancers of the buccal cavity and pharynx. The findings regarding other malignancies were inconsistent; scrotal cancers were not mentioned. The type and amount of exposure were usually not described; exposure

[46] *Mineral Oil Facts* http://www.babysweetcheeks.com/Pages/Mineral%20Oil.htm
[47] *A toxicological review of topical exposure to white mineral oils.* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAOuaWLV:11

to both **mineral oils** and carbon blacks would probably have been involved. In mortality statistics from the UK and from Washington State, USA, excesses of lung and skin cancer have been registered for jobs entailing exposure to **mineral oils.**

CASE C. Other relevant data An increase in the frequency of chromosomal aberrations was observed in the peripheral blood lymphocytes of glass workers exposed to **mineral oil** mists. Urine from workers in a cold-rolling steel plant exposed to oil mists of solvent-refined oils was mutagenic to Salmonella typhimurium in the presence of an exogenous metabolic system. Special test protocols may be necessary to evaluate **mineral oils** adequately in short-term tests. Vacuum distillates from oil refining were reported to be mutagenic to S. typhimurium in the presence of an exogenous metabolic system. Positive findings were also obtained when the concentration of the exogenous metabolic system was five to ten fold that used generally. Acid-treated oils were not mutagenic to S. typhimurium in the presence of an exogenous metabolic system; solvent-refined oils were reported to be mutagenic in the presence of an exogenous metabolic system. Hydrotreated oil was reported to be mutagenic to 5. typhimurium in the presence of an exogenous metabolic system, while white oils, highly-refined steel-hardening oil and solvent-refined steel-rolling oils were not. Unused crankcase oil was mutagenic to S. typhimurium in the presence of an exogenous metabolic system, while in other studies no mutagenic activity was found. Used crankcase oil from both gasoline and diesel engines was mutagenic to S. typhimurium both in the presence and absence of a metabolic system. Two insulation oils from highly-refined mineral-base oils induced transformation of Syrian hamster embryo cells and enhanced transformation of mouse C3H 10TI/2 cells. Unused new, re-refined and used crankcase oils induced transformation in Syrian hamster embryo cells.[48]

5. *The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.*

Note: The following is a study conducted on the effects of mineral oil and its remnants left in soil.

Mineral oil has a negative effect on the organisms present in the soil (nematodes and worms). Along with the decrease of the oil concentrations over time, life in the soil appears to recover.

In the scope of this project a study into the risks for man and cattle was also conducted. This study renders insight in the possible risks that might occur when taking into use locations with a (residual) contamination of mineral oil. This risks study included a series of interviews with experts in the field of agriculture and cattle breeding, a literature study via the internet and a risk assessment on the basis of the TPH-CWG method.

For the MS 1 location it is expected that the set-up of low energy input, in situ, landfarming will probably lead to such a reduction of the concentrations of mineral oil that no risks for man or cattle are to be expected, and that the ecology will recover to a sufficient extent.

On the basis of all findings of the investigation, it is concluded that the degradation of mineral oil (in the soil) under in situ landfarming conditions, can be a reliable method in practice. The technical elaboration of the method has been described and optimised. In this the relation between biological degradation, ecological recovery and risks takes up a central position and it has been quantified and made measurable. The result is a methodology consisting of processes that can be controlled and steered.[49]

CASE B. Evidence for carcinogenicity to animals (sufficient for untreated and mildly-treated oils; inadequate for highly-refined oils) Vacuum-distillate fractions, acid-treated oils, mildly-treated solvent-

[48] *Mineral Oils: Untreated and Mildly Treated Oils (group 1); Highly Refined Oils (group 3)* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAOuaWLV:4

[49] *Project summary 95-1-44: Test remediation Measuring Station 1, NAM Schoonebeek* http://www.bodembreed.nl/nobisuk/pages/projectsamenvattingen/project95-1-44.htm

refined oils, mildly treated hydrotreated oils, solvent extracts (aromatic oils) and some cutting oils produced skin tumours after repeated skin applications to mice. Similar treatment with high-boiling, catalytically-cracked oils produced skin tumours in rabbits and rhesus monkeys. Some severely solvent-refined oils did not produce skin tumours in mice. Highly-refined foodgrade **mineral oils** did not produce skin tumours when applied to the skin of mice, although after intraperitoneal injection they produced plasma-cell neoplasms and reticulum-cell sarcomas in certain strains of mice. It was agreed that, in accordance with the previous evaluation, the significant latter finding is difficult to interpret.[50]

Non-Human Toxicity Excerpts:

/PARENTERALLY IN VACCINES/...GRANULOMATOUS REACTIONS AT INJECTION SITES ARE NOT UNCOMMON. SIMILAR REACTIONS CAN OCCUR FROM ITS USE AS A LUBRICANT ON EXPLORATORY INSTRUMENTS...
[Rossoff, I.S. Handbook of Veterinary Drugs. New York: Springer Publishing Company, 1974. 367]**PEER REVIEWED**

REGULAR ORAL USE MAY INTERFERE WITH ABSORPTION OF FAT SOLUBLE VITAMINS...150 ML DAILY TO COWS CAUSED MARKED DECR IN CAROTENE & TOCOPHEROL BLOOD LEVELS AS WELL AS ACCELERATING POSTPARTURIENT DECR IN CAROTENE, VITAMIN A ESTER, TOCOPHEROL, & XANTHOPHYLL IN MILK...IT MAY ALSO PREVENT GROWTH OF INTESTINAL MICROORGANISMS AS FEEDING IT TO RATS PRODUCES VITAMIN K DEFICIENCY.
[Rossoff, I.S. Handbook of Veterinary Drugs. New York: Springer Publishing Company, 1974. 366]**PEER REVIEWED**

INJECTION OF **MINERAL OIL**...INTO ANTERIOR CHAMBER OF RABBITS, REPLACING THE AQUEOUS HUMOR, HAS BEEN USED TO OBSTRUCT AQUEOUS OUTFLOW & TO INDUCE GLAUCOMA EXPTL. THIS PRESUMABLY IS A MECHANICAL EFFECT RATHER THAN TOXIC REACTION.
[Grant, W. M. Toxicology of the Eye. 2nd ed. Springfield, Illinois: Charles C. Thomas, 1974. 803]**PEER REVIEWED**

RABBITS INJECTED IP WITH 30 CC PARAFFIN OIL SCORED AN UNUSUALLY HIGH FREQUENCY (2.8%) OF WELL-SPREAD METAPHASES IN THE PERITONEAL CAVITY.
[PLASSARA M ET AL; RES J RETICULOENDOTHEL SOC 12: 340-2 (1972)]**PEER REVIEWED**

PLASMACYTOMAS WERE FOUND IN 58% OF 373 BALB/CANN (C) MICE GIVEN 3 0.5-ML DOSES OF **MINERAL OIL.**
[POTTER M ET AL; J NATL CANCER INST 54 (6): 1413-8 (1975)]**PEER REVIEWED**

DOGS, RATS, MICE, & GERBILS WERE EXPOSED FOR 6 HR, 5 DAYS/WK UP TO 2 YR TO AN ATMOSPHERE CONTAINING A **MINERAL OIL**-BASE MIST @ CONCN OF 5 & 100 MG/CU M. ONLY @ 100 MG/CU M IN DOGS & RATS, BUT NOT IN MICE & GERBILS, DID MICROGRANULOMAS DEVELOP.
[STULA EF, KWON BK; AM IND HYG ASSOC J 39 (5): 393-9 (1978)]**PEER REVIEWED**

Groups of 25 9 day old chicken embryos were exposed to 10 or 20 ul pharmaceutical **mineral oil** on the eggshell. There were no mortalities or embryos with edema, ascites or liver lesions in either treated group.

[50] *Mineral Oils: Untreated and Mildly Treated Oils (group 1); Highly Refined Oils (group 3)* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAOuaWLV:4

No histological changes were observed in the livers or kidneys, however embryos exposed to 20 ul **mineral oil** had slight dilation of the heart. Body wt, liver wt, crown-rump length, and body wt/crown-rump length ratio of the embryos exposed to **mineral oil** did not differ from those of controls.
[Couillard CM, Leighton FA; Fundam Appl Toxicol 13 (1): 165-73 (1989)]**PEER REVIEWED**

Mineral oil mists derived from highly refined oils and several formulated products appear to have a low acute and low sub-acute toxicity in animals. Single and short term repeated exposures (up to six months) to relative high conc (well in excess of 100 mg/cu m) have resulted in lung inflammatory reaction, lipoid granuloma formation, and lipoid pneumonia. /Oil mist, mineral/
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1145]**PEER REVIEWED**

Long term inhalation studies indicate that those oils within a limited range which have actually been tested have a low chronic toxicity. ... Repeated prolonged exposures up to yr to very high conc (100 mg/cu m and above) have resulted in lung inflammatory reactions and lipoid granuloma formation. No carcinogenic effects have been reported in any species, including susceptible strains of mice. Adverse effects have not been found in long-term inhalation studies at lower oil mist conc more similar to actual workplace levels. /Oil mist, mineral/
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1145]**PEER REVIEWED**

In groups of 30 rats of strains BDI, BD111, and W (sex unspecified) that received 2% **liquid paraffin** in the diet (total dose, 136 mg/animal in 500 days), no significant tumor induction was reported.
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1145]**PEER REVIEWED**

... Three samples of petrolatum (snow-white U.S. Pharmacopeia (USP) XVI grade, white USP XVI grade, and yellow National Formulary XI grade) were fed at a conc of 5% in the diet to groups of 50 male and 50 female weanling rats (FDRL strain) for 2 years. None of the tests yielded a treatment-related tumor increase. /Oil mist, mineral/
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1145]**PEER REVIEWED**

A group of 30 rats of strains BDI. BDII and W (sex unspecified) received 2% **liquid paraffin** in the diet (total dose, 136 ml/animal in 500 days); no significant tumor induction was reported.
[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer,1972-PRESENT. (Multivolume work).,p. V33 119 (1984)]**PEER REVIEWED**

Treatment of male Sherman rats thrice weekly by gavage with **mineral oil** at a dose of 2 ml/kg body weight for three months did not produce toxic effects.
[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International

Agency for Research on Cancer,1972-PRESENT. (Multivolume work).,p. V33 131 (1984)]**PEER REVIEWED**[51]

6. *The alternatives to using the substance in terms of practices or other available materials.*

Oil has always had its own very unique properties that make it useful in many day-to-day practices. As such, there are very few replacements found that could demonstrate its very same properties. Being that it is used as a lubricant, there are not any real alternative practices or substances that could interact to provide the same lubrication as mineral oil itself. The problems that mineral oil can mitigate are not easily avoidable and as a result, it is difficult to find its replacement in the farming world.

7. *Its compatibility with a system of sustainable agriculture.*

There are many different types of mineral oils – some hazardous and some not. To view full text of listed toxic mineral oils, please visit this cite: http://www.nature.nps.gov/toxic/minoil.pdf and obtain a list of the various mineral oils that have been labeled as toxic.

Being that there are many different types of mineral oils, there are some that are compatible with a system of sustainable agriculture and some that are not. In general, when discussing a system of sustainable agriculture, there are many things that should be considered: the animal's welfare, the environmental effects of the substance, as well as the overall effects in relation to human health.

There are obviously some mineral oils that are detrimental to both humans and animals and should thus be avoided, but this does not necessarily mean that ALL mineral oils are hazardous to the health of its consumers. Additionally, the referenced mineral oils that could perhaps lead to serious damage are only dangerous when taken over the limit. For the case of the farmers, they are only requesting a small dosage to add to the feed which they use for their animals. If this small dosage is adhered to, there should be no real problem with the use of approved mineral oil.

In regards to the animal's welfare, cattle sometimes suffer from various disorders in their digestive tract that cause regular excretion to be endangered. Mineral oil has been found to help regulate excretion for the animal, in particular, newborn calves who suffer from retained mecomium. Mineral oil can also be used for dust control.

Agreed, there are many hazards that accompany the use of mineral oil in general, but if precautionary efforts are made to ensure the safety of mineral oil, then there should really be no problem with its use on the organic farm. After all, mineral oil has been used in human consumed products for years now and has continued its impact in the consumer's world to this day.

TAP Reviewers' Discussion

Reviewer 1 *[PhD, M.S, Poultry Nutrition. Assistant Professor, Poultry Science. Central U.S.]*

Observations

- The use of mineral oil in animal feeds would appear to be contra to the principles of organic production.
    - Mineral oil is obtained by distillation crude petroleum to remove the gasoline and kerosene present in the raw material. The mineral oil is then further refined using sulphuric acid, absorbents, solvents and alkalis to remove the hydrocarbons and

[51] *Mineral Oil Full Record on Toxnet* http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAa8a4Ss:1

chemicals. Oil seed meals produced with solvent extraction (e.g., soybean meal) are prohibited from inclusion in organic livestock feeds. Approval of mineral oil would appear to conflict with this rule. The discrepancy can be justified, however, by the difference in the levels of inclusion in the diets. Soybean meals are major diet constituents while mineral oil inclusion would be very minor.
  - Because mineral oil is obtained from crude petroleum, it is a non-renewable resource.
  - Mineral oil can have a negative effect on the environment in that it has been shown to be detrimental to nematodes and worms in the soil. Over time, however, life in the soil appears to recover.

- Chronic mineral oil use may reduce intestinal absorption of the fat-soluble vitamins A, D, E and K. As a result, calcium and phosphorus utilization is also reduced, possibly leading to deficiencies. If approved, levels of inclusion should be at a minimum.

- There is some risk to the farmer in the handling of the mineral oil.
  - Inhalation of mineral oil can lead to lipoid pneumonia.
  - Mineral oil can contain phenolphthalein, which is a suspected cancer hazard. However, with the low levels of inclusion in the mineral oil, together with the low levels of mineral oil inclusion in the feeds (for dust control), the hazard is minimal. The risk is a little higher when used in the quantities needed for treatment of constipation and diarrhea.

The executive summary states that mineral oil is the only alternative for the treatment of omasal impaction. This is not the case. Dioctyl sodium sulfosuccinate (DSS) is also an option, although it too is not yet approved by NOSB for this purpose and is not without its own problems. DSS can have detrimental effects on the rumen protozoa population.

Mineral oil has also been used in livestock production for many years. As already stated, mineral oil is commonly used for the treatment of omasal impaction. Mineral oil is also commonly used in lubricant laxatives for horses and to promote passage of hairballs in cats. Mineral oils are also often used as immune adjuvants for vaccines.

Reviewer 1 Conclusions

I would support limited approval of mineral oil for use in organic livestock production. While there are hazards associated with mineral oil use, the options available have hazards of their own.

Reviewer 1 Recommendations Advised to the NOSB

The substance is Synthetic.

For Livestock, the substance should be Added to the National List with restrictions.

Reviewer 2 *[PhD, M.S. Animal Nutrition. Professor, Animal Nutrition. Central U.S.]*

Observations

Major Items Considered

I. Human Safety

From the vast amount of data collected over several decades, it is obvious that white mineral oil when inhaled as finely dispersed droplets can cause serious health problems in people. As it should be used in animal production systems, there is no chance of people being in contact with this type of product. Taken orally, unless in very large doses, mineral oil is not likely to cause any serious problems in man. Even though oral doses could cause diarrhea (it has been used to

prevent constipation) and even decrease absorption of fat soluble vitamins, the use as directed for animals does not pose a threat to humans.

II. Animal Safety

As stated above, man or animals exposed to a "mist" of mineral oil may experience health problems but that would not occur in any animal production system. Any health problems incurred by animals from consuming white mineral oil would exist only if the animal consumed large quantities over a long period of time. The levels suggested in this petition would have virtually no effect on the animal. Very little of the "oil" is absorbed from the intestinal track and would, therefore, have little metabolic effect on the animal.

III. Environmental Impact

It is my opinion that the environmental impact of the quantities of white mineral oil fed to "organically" produced animals would be virtually zero. White mineral oil is biodegradable in the presence of oxygen and the waste from these animals would be applied to the soil surface or in the top layers of the soil. Even if the waste were incorporated, it would be catabolized by the soil microbiota.

Reviewer 2 Conclusions

White mineral oil has been used in the quantities indicated in this petition for at least 100 years without known adverse reactions to man, animals or the environment. It was cleared for use seven years ago, and in my opinion, there is no scientific evidence presented to suggest the ruling be changed. Therefore, I recommend that white mineral oil receive approval without restrictions for use in "organic" animal production. It should be considered as a "synthetic".

Reviewer 2 Recommendations Advised to the NOSB

The substance is Synthetic.

For Livestock, the substance should be Added to the National List with restrictions.

Reviewer 3 *[PhD, Microbiology. Research Assistant Professor of Microbiology and Adjunct Professor, Department of Food Science and Technology. Southeast U.S.]*

Observations

Upon examination of the TAP Report, I have determined that mineral oil should be allowed both as an impaction treatment lubricant and as a dust suppressant. Each application will be discussed individually below.

I found the information in the TAP Report to be comprehensive and in principle, I agree with the information described in the report.

Mineral Oil is refined from petroleum crude oils and is complex mixtures of straight- and branched-chain aliphatic and cyclic hydrocarbons with 15 or more carbons. It occurs naturally in the form of pitch or tar and has been used in medicine for thousands of years. To obtain mineral oil, gasoline and kerosene are removed from crude petroleum by fractional distillation.

Mineral oil is currently approved for use in livestock production for topical use and as a lubricant by the NOSB. This report describes broadening its use in livestock medical treatment and as a feed supplement to function as a dust suppressant.

As stated in the report, there is no substitute to mineral oil to alleviate omasal impaction. By providing a mineral oil drench at the rate of 1-2 gallons every 12 hours, the need for surgery is significantly reduced. Studies have shown there is little adsorption of mineral oil into the intestine of treated animals and should pose no threat. The USDA has approved mineral oil as a lubricant and should be allowed in the grouping of organic standards for this application.

There is also a question of the use of mineral oil as a dust suppressant. Here its intended purpose is for concentrated premixes for vitamin and mineral supplements. The FDA recommendation for mineral oil as an antidusting agent for food use is concentrations not to exceed 0.25 percent by weight.

The inclusion of mineral oil as an antidusting agent is considered to be irreplaceable. Other candidates such as vegetable oils oxidized fat-soluble vitamins leading to rancidity and non-delivery of the necessary supplement. The inclusion of mineral oil into concentrated premixes should be allowed at the 2% level of the total batch of mineral.

Reviewer 3 Conclusions

Mineral oil should be allowed both as an impaction treatment lubricant and as a dust suppressant. Based upon my understanding, mineral oil should be allowed at acceptable levels for the described applications with little or no restrictions.

Reviewer 3 Recommendations Advised to the NOSB

The substance is Nonsynthetic.

For Livestock, the substance should be Added to the National List.

TAP Conclusion

Of the three reviewers, one reviewer supported the use of mineral oil without restriction and considered it a nonsynthetic material, while the other two supported restricted use as a synthetic material. Possible concerns included the derivation of mineral oil from petroleum. All three reviewers noted the long history of mineral oil use in livestock production.