GUIDANCE FOR
MINERAL OIL DIELECTRIC FLUID
EMERGENCY RESPONSE ACTION PROTOCOL

Florida Department of Environmental Protection (FDEP)
Division of Waste Management
Tallahassee, FL

May 2016

Introduction

This guidance document outlines emergency response actions that may be followed to respond to highly/severely refined mineral oil dielectric fluid (MODEF) (e.g., CAS Nos. 64742-53-6, 64742-46-7, 64742-54-7, and 64741-88-4) discharges from transformers and other MODEF filled electrical equipment. The protocol is founded on certain of the requirements of 40 CFR Section 761.125(b), which applies to cleanup of spills from equipment containing concentrations of PCBs ranging from 50 to 499 parts per million (ppm), (however this protocol is only to be used for spills where the concentration of PCBs is less than 50 ppm). The proposed protocol is also based on the toxicological profile of MODEF, provided in Attachments "A" and “B”, which concludes that MODEF used in transformers and other electrical equipment exhibit a negligible degree of toxic potential. This protocol adequately protects human health and the environment while allowing operational flexibility to utilities as necessary. This document provides guidance on complying with the de minimis discharge provisions of Chapter 62-780, F.A.C. In responding to MODEF discharges, including those into or near waters of the state, responders should also comply with all other applicable laws and regulations, including applicable notification requirements.

Emergency response to electric equipment outages consists of mobilization of utility company personnel and/or its contractors to assist with the immediate restoration of electrical service including remediation of any newly released MODEF to the environment that may have occurred during the equipment failure. During emergency response, remediation of newly released MODEF typically occurs during the time period in which the failed electrical equipment is being replaced. This activity is normally initiated no later than 48 hours from the time the failed electrical equipment is discovered or reported and is completed within 30 days.

Non-emergency response to MODEF discharges is a planned process that may require an electrical outage so that the electrical equipment may be removed or safely worked around (i.e., in substations) so that remediation of the MODEF discharge may be completed. Non-emergency response actions may take longer than 48 hours to initiate but are completed within 30 days of discovery. Non-emergency response activities may include newly released MODEF discharges as well as any older MODEF discharges that are identified.

Responses should only be made after a determination regarding whether the MODEF release is believed to have resulted from a PCB transformer or other PCB-contaminated electrical equipment as defined in 40 CFR part 761, based on company knowledge, records search, screening (e.g., Clor-N-Oil), etc. MODEF releases containing PCB concentrations of 50 ppm or greater should be remediated in accordance with all applicable sections of the U.S. Environmental Protection Agency regulations contained in 40 CFR Part 761. MODEF releases containing PCB concentrations greater than 0 and less than 50 ppm may be remediated according to this protocol and disposed of in accordance with applicable solid waste laws and regulations.

The MODEF discharge response process under an "emergency" response scenario should consist of the following:

(1) Removal of all soil contaminated with freshly released MODEF within the spill area (i.e., visible traces of oily soil and a buffer of 1 lateral foot around the visible traces) and the ground restored to its original configuration; and

(2) Physically removing all visible traces of oil/oil sheen observed in the groundwater with oil absorbent pads/material or via vacuum assisted equipment.

(3) Solid surfaces should be washed and rinsed and the rinse water collected, or such surfaces should be cleaned using appropriate chemical, sorbent or absorbent materials;

(4) These emergency response actions are initiated within 48 hours after the Florida electric utility is notified or becomes aware of the electrical outage, unless such actions are delayed in case of circumstances including but not limited to civil emergency, adverse weather conditions, lack of access to the site, or emergency operating conditions.

The MODEF discharge response process under a "non-emergency" response scenario consists of the following:

(A) If the MODEF spill is 25 gallons or less and not resulted in contact with groundwater, follow items (1), (2) and (3) above.
(B) If the MODEF spill is greater than 25 gallons, or (regardless of quantity discharged) if MODEF is found to be in groundwater or a sheen is removed from groundwater, follow (1), (2) and (3) above. Confirmatory field screening should be conducted via approved field test kits to ensure/verify that impacted soil has been removed. Verification (e.g., Petroflag) may be confirmed by ensuring the TRPH levels remaining in the soil are below the lower of the direct exposure or leachability soil cleanup target level for TRPH. For MODEF found to be in groundwater or where a sheen is removed from groundwater, confirmatory laboratory analysis should be conducted to ensure that TRPH levels are below the groundwater cleanup target level stated in Chapter 62-777, F.A.C., or an alternative number agreed to with the Department. Removal should continue until TRPH levels are below the aforementioned concentrations, unless prevented by a physical obstacle such as a tree, building, etc. To the extent such removal cannot take place within 30 days, then the responder should contact the relevant Department district office to develop an appropriate discharge response in accordance with Chapter 62-780, F.A.C.
(C) Non-emergency response actions may be initiated more than 48 hours after the utility is notified or becomes aware of the MODEF discharge.

(5) Upon completion of response action activities, the following records should be maintained for a period of at least 5 years constituting adherence to the Interim Source Removal Report requirement found in Rule 62-780.525(7), F.A.C.:
   (a) Date of discharge or date of discovery of discharge;

(b) Location of discharge (e.g., street address of discharge, if known).
(c) A statement regarding whether the MODEF release is believed to have resulted from a PCB transformer or other PCB-contaminated electrical equipment as defined in 40 CFR Part 761, based on company knowledge, records search, screening, etc.
(d) Estimate of quantity of MODEF released;
(e) Estimate of free MODEF collected, if any;
(f) Estimate of volume of impacted soil excavated or groundwater recovered; and
(g) Name and address of facility where free MODEF, impacted soil or groundwater was disposed or treated, including disposal and/or treatment manifests or certifications.
(h) For non-emergency cleanups greater than 25 gallons,
    (1) Narrative description or illustration indicating where discharge occurred;
    (2) Narrative description or illustration indicating where samples were taken;
    (3) Screening method used;
    (4) TRPH information and a description of any physical obstacles, if applicable, preventing removal to levels below the lower of the direct exposure or leachability soil cleanup target level for TRPH (or the groundwater cleanup target level for TRPH stated in Chapter 62-777, F.A.C.), or an alternative number agreed to with the Department;
    (5) Narrative description or illustration of the limits of the excavation.

Toxicological Synopsis for Mineral-based Transformer Oils (CAS#64742-53-6)

(*November, 2004*)

Technical Evaluation

Mineral oils, specifically those defined as "hydrotreated light naphthenic petroleum distillates" and assigned Chemical Abstract Service Number (CAS#) 64742-53-6 (also known as transformer oil or mineral oil dielectric fluid (MODEF)) commonly are used as lubricants and heat transfer agents in transformer applications. A mineral oil of this CAS # complies with ASTM specifications for mineral insulating oil used in electrical apparatus (ASTM, 2001). As a result of widespread transformer applications, there are potential environmental issues related to the release of these transformer oils to soils following damage to, or a malfunction of, in-service equipment. This synopsis reviews relevant toxicological information for this class of mineral oils, as distinguished by CAS # 64742-53-6 including a Texaco Material Safety Data Sheet (MSDS; Texaco, 1999) on transformer oils, prepared by Equilon Enterprises and dated 01/04/99, as well as additional references from the toxicological literature. The Texaco MSDS, which was essentially unchanged from the 1993 version (Texaco, 1993), concluded that the transformer oil was "practically non-toxic" for oral and dermal exposures, was "slightly irritating" following dermal application, and exhibited "no appreciable effect" following application to the eyes. Similar MSDS documents from other petroleum manufacturers draw essentially equivalent conclusions regarding this product (e.g., Chevron MSDS for Texaco Transformer Oils, no date).

When evaluating the toxicological profile of mineral transformer oils, it is useful to consider why this product should be viewed differently from other petroleum distillates, and why it should be considered in a separate category. As a practical matter, the literature is clouded by use of the term "mineral oil" in a way that includes products ranging from used vehicle lubricating oils to industrial cutting oils (NTP, 2002). In contrast, the transformer oil used by most electric utility companies is required to conform to carefully articulated ASTM specifications that are in place to ensure the oil's stability to oxidation, good electrical insulating properties, and ability to maintain low-temperature fluidity (ASTM, 2001).

The refining process for transformer oils typically includes hydrogenation of the distillate under pressure and in the presence of a catalyst, followed by steam stripping, and may include final treatment with Fuller's earth. Recent alternative treatment methods use a combination process with an initial solvent extraction to remove aromatics, resins and sulfur compounds, that is then followed by hydrogenation. This specifically removes undesirable constituents including nitrogen and oxygen compounds, most sulfur compounds, tars and unsaturated hydrocarbons, as well as solid hydrocarbons, particularly amorphous and crystalline waxes. The product resulting from these specifications is a highly refined mineral oil with properties and toxicity potential that distinguish it from other petroleum distillates. The high level of refining may account for the U.S. Food and Drug Administration (FDA) approval of mineral oil for certain common medicinal purposes, such as laxatives and as a delivery vehicle for application of drugs to nasal mucous membranes (HSDB, 2004), and for "contact uses" as food additives (Klaassen, 2001). As a point of interest, it has been estimated that an average person in a developed country ingests approximately 50 grams per year of mineral oil from food products (Heimbach et al., 2002).

Three studies published prior to 1993 that were not referenced in the Texaco MSDS contain important relevant information. Evans et al. (1989) tested mineral oil used in a large manufacturing facility. Samples taken at yearly intervals over five years were independently tested for skin irritation in New Zealand rabbits, sensitizing potential in guinea pigs, and carcinogenic potential in the mouse. No evidence of skin irritancy, sensitizing potential or carcinogenicity was observed in any of the samples.

Leighton (1990) tested the effects of ingestion of up to 16 ml/kg per day of several types of petroleum oils, including mineral oil, on laboratory mice. Liver enlargement was pronounced in the test animals, along with atrophy of thymus and spleen, following ingestion of all petroleum oils <u>except</u> mineral oil. No adverse effects were reported for mineral oil except for a small reduction in thymus weight. The authors concluded that the thymus reduction was a non-specific response to stress imposed by the forced ingestion of the treatment oils. Neither of these references would result in a conclusion different from that presented in the Texaco MSDS documents.

A topical 90-day study conducted by the National Toxicology Program (NTP, 1992), exposed male and female F344/N rats and C3H mice to "Mineral Oil, USP." The NTP concluded that the only treatment-related dermal effect was cutaneous irritation in the mouse. An increase in liver and kidney weights was observed in the male and female F344/N rats and liver weights were increased in both sexes of C3H mice treated topically with mineral oil. These effects were not reported consistently in other published studies.

Several relevant studies have been published subsequent to the development of the original toxicological information section of the 1993 MSDS on Texaco transformer oils. Using C3H mice in a 2-year study, Freeman et al. (1993) investigated the influence of chronic skin irritation on the tumorigenic potential of several middle distillate petroleum products with and without use of a highly refined mineral oil as a diluent and control. A few of the animals (e.g., 2 to 22%) that were treated with mineral oil evidenced some skin irritation (e.g., rated "minimal to moderate"); however, none of the mineral oil treated mice developed tumors or any other reported effects in what was essentially a lifetime duration study.

Nash et al. (1996), published a toxicological review regarding topical exposure to white mineral oils, that were described by those authors as "highly refined", being produced by processes similar to those defined earlier as hydrotreatment and hydrogenation in the formation of transformer oils. Those processes are designed to remove the PAH components that have been implicated in toxic effects of other types of mineral oils. Those authors concluded that "there is no evidence of any hazard identified for topical exposure to white mineral oils at any dose in multiple species." They pointed out that oral studies of white mineral oils in rats have suggested toxicity (Firriolo et al., 1995), including microgranulomata in the liver and histiocytosis in the mesenteric lymph nodes. No tumors were noted in the latter study. It should be noted that the material tested in that latter study was a paraffinic, hydrotreated mineral oil, <u>not</u> a naphthenic, hydrotreated mineral oil. Two other oral studies in F344 rats cited by Nash et al. (1996), that implicate mineral oils in toxic responses, have shown a much less significant effect for the white mineral oil (transformer-oil-like) product as opposed to a different mineral oil product (Baldwin et al., 1992; BIBRA, 1992). Of equal importance is the fact that, in contrast to the F344 rats, adverse effects were <u>not</u> observed in dogs or in two other strains of rats (Nash et al., 1996). The strain-specific nature of the effect lessens its importance.

Smith et al. (1995) studied the effects of four different highly refined mineral oils on Long-Evans rats and beagle dogs. The oils were administered at levels ranging from 300 to 1500 parts per million (ppm) in the diet for 90 days. No adverse treatment-related effects were reported from any of the mineral oils tested on mortality rate, physical appearance, behavior, organ weights or histopathology of tissues in the rats. In dogs, other than a slight laxative effect, no adverse effects were observed in the analyses of body weights, hematology, clinical chemistry, red/white blood cell counts and histopathology of the tissues. The authors concluded that "repeated exposure to relatively high levels of white mineral oil in the diets does not produce significant subchronic toxicity" in dogs or rats.

Chronic dermal studies in mice, performed by Broddle et al. (1996) with various petroleum streams, included hydrotreated light naphthenic petroleum distillate (CAS No. 64742-53-6). These authors reported that this hydrotreated light naphthenic distillate caused low levels of alopecia (hair loss), erythema (inflammatory reddening of the skin) and scabbing after approximately one year of repetitive exposure, and was a "dermal carcinogen of low potency." The number of mice with tumors (e.g., incidence was 15% with a mean latency of 94 weeks) was relatively low, but statistically significant when compared to the sham-treated controls. The authors attributed the carcinogenic potential to the presence of polynuclear aromatic hydrocarbons (PNAs) in the product. Hydrotreatment is intended to reduce or eliminate unsaturation and aromaticity of PNAs and to cleave heterocyclic compounds with consequent reduction or elimination of carcinogenicity. However, the authors state that the degree of hydrotreatment of the stream used in this study was undetermined. Therefore, it is possible that the carcinogenicity was a result of inadequate hydrotreatment of the stream which would otherwise have eliminated the PNAs.

More recently, NTP listed mineral oils (untreated and mildly treated) in the category of "known human carcinogens" in the 10th Report on Carcinogens (NTP, 2002). The determination was based on the occurrence of squamous cell carcinoma of the skin and scrotum, sinonasal cancers, and possibly lung cancer among workers in a variety of occupations. Experimental studies with these mineral oils in animals have shown variable results (NTP, 2002). While this NTP classification shouldn't be ignored, there are two reasons why it doesn't apply strictly to the case of transformer oils in soil. First, the NTP classification [and the IARC (1984) and IARC (1987) which it cites in support] addresses primarily occupational circumstances where inhalation, ingestion and dermal exposure to mineral oil mists and concentrated liquids were the medium of direct exposure. That circumstance is quite different from the conditions encountered with soils that may be impacted by what typically are small volume releases from transformer equipment. Second, the term "mineral oils" in that document is used to describe a much broader category of oils, many of which are much less refined than the highly refined naphthenic transformer oils.

Although most mineral oils are generally considered nontoxic, it should be noted that some authors have demonstrated immune system effects from mineral oil components (e.g., pristane; Shaheen et al., 1999). Such demonstrations of immunotoxicity from hydrotreated, light naphthenic mineral transformer oils are lacking. The specific mineral oil identified as Bayol F (also known as Incomplete Freund's Adjuvant), and certain mineral oil components (e.g., squalene and η-hexadecane), have been reported to induce lupus-related autoantibodies in nonautoimmune mice (Kuroda et al., 2004). All hydrocarbons tested in that study, including medicinal mineral oils, induced hypergammaglobulinemia, as well as autoantibodies. The data of these authors suggest that the induction of autoantibodies correlated with the amount of C15 - C25 hydrocarbons present in an oil. The significance of these findings for pathogenesis of human disease is unclear, and the authors correctly note that hydrocarbon exposure via the intraperitoneal route may be different from other routes of exposure, and thus may pose less risk (Kuroda et al., 2004).

Another condition that reportedly was associated with mineral oil exposure is exogenous lipoid pneumonia. This pneumonia is an uncommon condition resulting from aspirating or inhaling fatlike material, such as mineral oil found in laxatives and various aerosolized industrial materials. Acute toxicity of this type can occur, but the disease is usually slow to develop (Spickard and Hirschmann, 1994). While there may be some occupational application for that information, the significance to environmental exposures (e.g., soil) is negligible.

Peristianis (1989) reported on an unconventional assay for possible carcinogenic activity of mineral oils, termed the short-term "sebaceous gland suppression" (SGS) test. The cutaneous carcinogenic activity of mineral oils reportedly could be estimated effectively by the SGS test. However, the test has not been routinely reported in the literature as a validated methodology in the 15 years since this paper was published. Thus, its applicability and predictive relevance are not clear.

Summary and Conclusions

As judged from the body of available toxicological data from standard tests, the hydrotreated, light naphthenic mineral oils, such as those typically used in utility transformer applications, exhibit a negligible degree of toxic potential. The only reproducible effect appears to be slight irritation following repetitive dermal application. The existing classification of "mineral oils" as carcinogens by NTP and IARC appears to be based upon inhalation, ingestion and dermal exposure under occupational scenarios to mists and liquids of a wide variety of refined and unrefined oil products, and is not directly applicable to the subset of mineral oils represented by the electric utility transformer oils. U.S. EPA does not presently classify "mineral oils" as carcinogens.

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Hopping Green & Sams

Attorneys and Counselors

December 14, 2006

By Electronic Mail

Doug Jones
Chief, Bureau of Waste Cleanup
Florida Department of Environmental Protection
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Re: Mineral Oil Dielectric Fluid (MODEF)
Emergency Response Action Protocol

Dear Doug:

As we previously discussed by telephone, I am enclosing the response of Dr. Christopher Teaf of Hazardous Substance and Waste Management Research (HSWMR) to the August 7, 2006, letter from the University of Florida's Drs. Stephen Roberts and Leah Stuchal. The letter from Drs. Roberts and Stuchal addressed HSWMR's July 19, 2006 toxicological evaluation of additional mineral oil products that may be used in transformers and other oil-filled electrical equipment. I am also enclosing those letters for your ease of reference.

As you know, the FCG tasked HSWMR's evaluation to determine whether the use of the existing Department-approved MODEF protocol might be appropriate for the additional mineral oil products that were evaluated. As was the case in HSWMR's original 2004 toxicological evaluation of mineral oil products similar to those products having Chemical Abstract Service (CAS) number 6474253-6, the most recent HSWMR investigation concludes that the additional mineral oil products evaluated do not pose a significant degree of toxic potential. That conclusion was concurred in by Drs. Roberts and Stuchal.

As a result of the foregoing and consistent with its original request of July 27, 2006, the FCG respectfully requests that the Department provide its written concurrence that FCG member use of the existing MODEF protocol is appropriate for the general category of "highly/severely refined mineral oils" (e.g., CAS # 64742-46-7, CAS #

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64742-54-7, and CAS # 64741-88-4). Thank you in advance for your prompt consideration of this request.

Sincerely,

Hopping Green & Sams, P.A.

Mike

Michael P. Petrovich

MPP/rlh

cc: Dr. Christopher Teaf, HSWMR
Tanya Portillo, FCG

HSWMR

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December 7, 2006

Dr. Stephen M. Roberts, Director
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Re: *Comment Letter to Florida Department of Environmental Protection (FDEP) on Mineral Oil Dielectric Fluid (MODEF) Emergency Response Action Protocol*

Dear Steve:

I have reviewed your letter to Ligia Mora-Applegate dated August 7, 2006, regarding the "Mineral Oil Dielectric Fluid (MODEF) Emergency Response Action Protocol". I appreciate the comments that you and Dr. Stuchal presented, and your concurrence with our human-health-based conclusion that "highly/severely refined" mineral oils are non-carcinogenic and essentially "non-toxic".

In response to your comment regarding potential effects that might be relevant if a MODEF spill occurred in or near surface water, I would acknowledge that those considerations may apply in some cases; however the protocol is focused exclusively on MODEF releases to soil or groundwater "on residential, commercial, and industrial properties". While the letter does not specifically address MODEF releases in or near surface water, if a MODEF release occurred in such a situation, the MODEF protocol already provides that "FCG members will also comply with all other applicable laws and regulations, including applicable notification requirements." On balance, that latter provision may adequately address the concern such that if a release occurred in or near surface water, then "all other applicable laws and regulations", including relevant technical elements, would apply.

As always, thanks for taking the time to review the protocol letter, and I look forward to talking with you soon.

Regards,

Chris

Christopher M. Teaf, Ph.D.
President & Director of Toxicology

cc: *Doug Jones, FDEP*
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August 7, 2006

Ligia Mora-Applegate
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Re: Mineral Oil Dielectric Fluid (MODEF) Emergency Response Action Protocol

Dear Ms. Mora-Applegate:

We have reviewed at your request the letter from Hazardous Substance & Waste Management Research, Inc. (HSWMR) dated July 19, 2006 for the Florida Electric Power Coordinating Group, Inc. (FCG). The letter is a supplement to the HSWMR November 2004 report entitled *Toxicological Synopsis for Mineral-based Transformer Oils (CAS# 64742-53-6)*. In that report, HSWMR concluded that hydrotreated, light naphthenic mineral oils exhibit a negligible degree of toxic potential. We concurred with this conclusion in a review letter dated January 11, 2005, and provided some additional literature citations. In our review letter, we cautioned that the toxicological review was directed to human health, and that it is conceivable that mineral oil dielectric fluids might have effects in aquatic ecosystems that would be relevant if a spill were to occur in or near surface water.

The current letter requests that other "highly/severely refined" mineral oils (CAS# 64742-46-7, CAS# 64742-54-7, and CAS# 64741-88-4) be added to the substances that can be safely addressed by the provisions contained in the existing MODEF Protocol dated February 25, 2005. As the letter points out, current literature has concluded that "severely" refined minerals oils are non-carcinogenic and are essentially nontoxic pertaining to human health. The only reproducible effect of "severely" refined mineral oils appears to be skin irritation following repeated dermal application, and the toxic potential appears to be negligible. We agree with this assessment of the human toxicology of severely refined mineral oils.

The issue of potential effects on aquatic ecosystems from a spill near surface water remains. We recommend revision of the MODEF Emergency Response Action Protocol to address explicitly this possible scenario. If sufficient data on aquatic toxicity of these mineral oils are available, risk-based criteria to evaluate surface water impacts could be developed and included in the emergency response action protocol. We suspect, however, that the ecotoxicology literature on this class of compounds may be too limited to develop sound risk-based criteria. In this situation, part of the emergency response when a spill occurs in or near a surface water body should include empirical testing using standard aquatic toxicity bioassays. The results of these bioassays could be used to show compliance with Chapter 62-302.500(4) and 62-302.530(62), F.A.C.

Sincerely,

Stephen M. Roberts, Ph.D.

Leah D. Stuchal, Ph.D.

HSWMR

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July 19, 2006

Mr. Michael Petrovich, Esq.
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Dear Mike:

As we discussed recently with Florida Electric Power Coordinating Group (FCG) representatives, this letter report is presented as a supplement to our November 2004 report (HSWMR, 2004) entitled *Toxicological Synopsis for Mineral-based Transformer Oils (CAS#64742-53-6).* In that report, we concluded that:

> *"As judged from the body of available toxicological data from standard tests, the hydrotreated, light naphthenic mineral oils, such as those typically used in utility transformer applications, exhibit a negligible degree of toxic potential."*

In that original evaluation, we narrowly addressed the Chemical Abstract Service Number (CAS#) 64742-53-6 ("hydrotreated light naphthenic petroleum distillates") as an appropriate representative for the mineral-based transformer oils. The Florida Department of Environmental Protection (FDEP) concurred with the conclusion of the November, 2004 report, as indicated by agency approval in February, 2005 of the Mineral Oil Dielectric Fluid Emergency Response Action Protocol ("MODEF Protocol") that was proposed by FCG. More recently, the FCG has expressed an interest in including additional similar mineral oils in the MODEF Protocol. The FCG wishes to ensure that these other materials that are used in some transformers and other electrical equipment also "... exhibit a negligible degree of toxic potential." Toward that end, we have reviewed many material safety data sheets (MSDS) that were submitted by FCG members and have conducted literature reviews on mineral oil components of those products.

The MSDSs identify by CAS# several individual or, in other cases, multiple chemical compounds grouped generally as either "lubricant base oils" or "petroleum distillates." Of the many CAS #s presented for these groups, three of them (CAS# 64742-46-7, CAS#64742-54-7, and CAS# 64741-88-4) appear repeatedly and also have sufficient toxicological information on which to base an opinion that may be applicable to the mineral oil group as a whole.

Although the compounds present in commercial products identified in the MSDSs vary in such characteristics as carbon chain length, viscosity, and refinement method, they are all classified as "highly/severely refined mineral oils", a definition with distinct toxicological significance. As demonstrated by the following literature synopses, mineral oil products of the "highly/severely refined" type are essentially nontoxic.

Kane et al. (1984) demonstrated that, although unprocessed petroleum refinery distillates have the capacity to cause tumors, conventional solvent refining is a sufficient process to remove the tumorigenic components as verified by their mouse skin painting bioassay. In another study using the standard mouse skin painting bioassay on C3H/HeJ mice, the authors concluded that the refining processes commonly used to produce lubricating oils with viscosity indexes (VIs) of 85-100 (which are levels normally used in commercial operations), were sufficient to effectively eliminate dermal carcinogenic activity in mice (Halder et al, 1984). It also was reported that severe hydroprocessing alone can be used to reduce or eliminate many of the troublesome aromatic compounds and the associated carcinogenic potential.

In a review by Mackerer et al. (2003) the authors concluded that it is appropriate to consider a non-carcinogenic base oil to be one that is "severely" refined. Beck et al. (1984) tested the acute toxicity of nineteen untreated petroleum hydrocarbons and found that the paraffinic and naphthenic oils were the least toxicologically reactive of all materials tested. The middle distillates did not produce a sensitization reaction in guinea pigs, did not exhibit acute dermal toxicity, nor did they produce serious ocular lesions even upon direct instillation to the eye.

Dalbey et al. (1991) studied the effects of three lubricant base oils on Sprague-Dawley rats. The rats were exposed to varying concentrations of either a solvent refined oil, a white oil or a hydrotreated base oil (CAS # 64742-54-7) for 6 hours/day, 5 days/week, for a total of 4 weeks. Based on laboratory findings, the authors concluded that, aside from ambiguous accumulation of "free cells" in the lung, exposure to high concentrations of aerosols of severely treated oils resulted in a low degree of toxicity.

The solvent extraction process for petroleum distillates selectively removes undesirable compounds, solubilizing first the aromatics, then olefins, naphthenes, and (least soluble) the paraffins. In the 1980's, approximately 74% of lubricant base oils produced in the US and Canada were "highly refined" (IARC, 1984). Kane et al. (1984) performed skin tumorigenicity studies on male C3H mice and found CAS # 64741-88-4 followed by dewaxing to be noncarcinogenic. Gerhart et al. (1988) demonstrated that, comparing lifetime skin-painting assays lasting 2-2.5 years and initiation/promotion assays in male CD-1 mice, the solvent-extracted lubricant base oil having the CAS# 64741-88-4 exhibited no carcinogenic activity, tumor initiator activity or tumor promoter activity.

Long-term topical application studies using female CF1 mice concluded that hydrotreatment or solvent extraction methods can yield oils with no carcinogenic potential (Doak et al., 1983).

With respect to the classification of "highly/severely refined" mineral oils (e.g., CAS# 64742-46-7, CAS# 64742-54-7, and CAS# 64741-88-4) that are the focus of this letter and the subject of the cited literature, one can conclude that they are of limited toxicological significance. The same conclusion was reached for the original "severely refined" substance of interest (CAS# 64742-53-6). In that light, it would be reasonable to include "highly/severely refined" mineral oils as substances which can be safely addressed by the provisions contained in the existing MODEF Protocol dated February 25, 2005.

A list of cited technical references is included as an Attachment to this letter.

Please call Doug Covert or me at (850) 681-6894 when you have had an opportunity to review these materials, so that we can decide how best to proceed.

Regards,

Christopher M. Teaf

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Attachment

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