



2780 Waterfront Pkwy. E. Dr. Suite 200, Indianapolis, IN 46214

Phone: 317-328-5660 Fax: 317-328-5668 Sales: 1-800-437-3188 www.calumetspecialty.com

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To Our Valued **Calumet Refining, LLC**, Customers:

This letter is in regard to MOSH and MOAH content for our **Penreco** branded products.

Our Penreco-branded white mineral oil and petrolatum products are compliant with the toolbox process developed by the BLL (German Federation of Food Law and Food Science), based on feedback on pages 25/26 of which calls for the use of H1 lubricants. Our **Drakeol**<sup>®</sup> mineral oil and USP petrolatum/white petrolatum products are compliant to 21 CFR 172.878 and 21 CFR 172.880, respectively, which supersede H1 compliance (for INCIDENTAL food contact). Their FDA compliances are consistent with their DIRECT use approvals in foods, per the regulation.

Calumet has submitted a range of materials for 3<sup>rd</sup> party MOSH and MOAH analysis according to the method published by the German National Reference Laboratory for Materials in Contact with Food (hexane extraction, analysis by online coupled HPLC-GC-FID).

In all materials tested, typical MOSH content for hydrocarbons less than C16 in length are not detectable at 20 g/kg (the detection limit for the method at this chain length).

In all materials tested, typical MOSH content for hydrocarbons of C16-C25 range from 50 to 920 g/kg, C16-C35 range from 350 to >980 g/kg, C20-C35 range from not detectable at 10 g/kg (the detection limit for the method at this chain length) to 960 g/kg.

In all materials tested, typical MOAH content was not detectable at 20 g/kg (<C16) or 10 g/kg (C16-C25, C16-C35).

Calumet also confirms that the same representative **Drakeol**<sup>®</sup> and USP petrolatum/white petrolatum products have been submitted for BS EN 16143 PAH content testing, all materials maintaining typical results of **NOT DETECTED at 10 parts per billion** for the following PAH analytes:

ANALYTE	CASRN
Naphthalene	91-20-3
Acenaphthylene	208-96-8
Acenaphthene	83-32-9
Fluorene	86-73-7
Phenanthrene	85-01-8
Anthracene	120-12-7
Fluoranthene	206-44-0
Pyrene	129-00-0
Benzo [b] naphtho [2,1-d] thiophene	239-35-0
Cyclopenta [c,d] Pyrene, 3,4 dihydro	25732-74-5
Benzo [a] anthracene	56-55-3
Cyclopenta [c,d] Pyrene	27208-37-3
Triphenylene	217-59-4
Chrysene	218-01-9
5 Methylchrysene	3697-24-3
1 Nitro pyrene	5522-43-0
Benzo [b] fluoranthene	205-99-2
7,12-Dimethylbenzo [a] anthracene	57-97-6
Benzo [k] fluoranthene	207-08-9
Benzo [j] fluoranthene	205-82-3
Benzo [e] pyrene	192-97-2
Benzo [a] pyrene	50-32-8
3-Methylcholanthrene	56-49-5
Dibenzo [a, j] acridine	224-42-0
Dibenzo [a, h] acridine	226-36-8
Indeno [1,2,3-cd] pyrene	193-39-5
Dibenzo [a, h] anthracene	53-70-3
Benzo [g, h, i] perylene	191-24-2
7H Dibenzo [c, g] carbazole	194-59-2
Dibenzo [a, e] fluoanthene	2997-45-7
Dibenzo [a, e] pyrene	192-65-4
Benzo [rst] pentaphene *	189-55-9
Dibenzo [a, i] pyrene	191-30-0
Dibenzo [a, h] pyrene	189-64-0
Benzo [b] thiophene	95-15-8
Dibenzo thiophene	132-65-0
Carbazole	86-74-8
Benzo [a] acridine	225-11-6
Benzo [b] naphtho [2,3-d] thiophene	243-46-9
Benzo [c] acridine	225-51-4
Dibenzo [c, h] acridine	224-53-3
7H-Benzo [c] fluorine	205-12-9
Dibenzo [a, i] pyrene *	189-55-9

\* Dibenzo [a, i] pyrene (syn: Benzo [rst] pentaphene (CAS 189-55-9))



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Most recently, the Concawe Mineral Hydrocarbons Task Force Special MOCRINIS (STF-33) issued an extensive report regarding the uses of highly refined base oil feedstocks. Excerpting from the 23 October 2017 Concawe publication, "Mineral Oils are Safe for Human Health?"

[https://www.concawe.eu/wp-content/uploads/2017/10/DEF\\_C\\_MM\\_digital.pdf](https://www.concawe.eu/wp-content/uploads/2017/10/DEF_C_MM_digital.pdf)

**MOSH is a chromatographic measure of the alkane content of an oil.** Some MOSH substances have been found to accumulate and cause inflammation of human livers and therefore its presence is undesirable.

*The concern around long term toxicity of mineral oil is derived from observations in animal experiments which are extrapolated to the human situation. From all the experiments, it appears that with the exception of the Fischer 344 rat (F- 344) model, none of the tested animals (rat strains other than F-344 and dogs) developed adverse effects. The F-344 rat shows unique adverse effects, including liver accumulation of n-alkanes commonly found in natural products such as apples. These adverse effects have been extrapolated to humans and serve as the basis for the health concern to MOSH. From the weight of the available evidence, including decades of safe use, humans do not develop adverse effects to alkanes whether from natural origin or from mineral oils.*

**MOAH is a chromatographic measure of the aromatic content of an oil,** and is considered as an indicator of the presence of unrefined petroleum based products that are not intended to be used in food related, pharmaceutical or cosmetics applications. The concern is based on the possibility that MOAH containing 3-7 membered rings may be potentially carcinogenic. Although aromatics are present in refined petroleum products, the refining processes used to produce mineral oils remove the potentially carcinogenic 3-7 Polycyclic Aromatic Compounds (PAC). The remaining highly alkylated aromatics (mostly 1-2 rings) are harmless making them safe for their intended use.

We confirm that the concern over MOSH and MOAH content in USP/FDA-credentialed hydrocarbon materials is unwarranted for Penreco **Drakeol**<sup>®</sup> and USP petrolatum/white petrolatum products.

These materials meet all FDA and USP/NF requirements for safe, intentional use in foods, pharmaceuticals, and personal care products.

Please do not hesitate to contact us if we may be of any additional assistance.

Best regards,

Lynn Massad  
Technical Market Development Manager  
[Lynn.Massad@calumetspecialty.com](mailto:Lynn.Massad@calumetspecialty.com)

Mark A. Voelker  
Technical Director  
Specialty Oils and Waxes  
[mark.voelker@calumetspecialty.com](mailto:mark.voelker@calumetspecialty.com)