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To Whom It May Concern:

Since the incorporation of the "Consolidated List of C/M/R Substances," the European Union has adopted Regulation 1272/2008/EC, which changed the regulation on the "classification, labeling, and packaging of substances and mixtures." In regard to cosmetic products, a CMR substance is classified as being carcinogenic, mutagenic or toxic for reproduction.

The new rules in the European Union regarding the use of CMR substances in cosmetic products can be found in Article 15 of the Cosmetics Regulation 1223/2009. Article 15 laid down the rule that any CMR substance categorized as 1A, 1B or 2 were banned for use in cosmetic products. As of December 1, 2010, any substances categories as 1A, 1B or 2 are automatically prohibited for use in cosmetic products.

Calumet Penreco, LLC produces USP grade petrolatums that fall under the CAS number of 8009-03-8 which are categorized as a CMR 2 substance or probable human carcinogen. The CAS number of 8009-03-8 does not describe a purity specification; therefore, this CAS number is used for both refined and unrefined petrolatum.

Calumet Penreco's USP grade petrolatums are not carcinogenic, mutagenic or toxic to reproduction. They meet the purity requirements in the FDA regulation 21 CFR 172.880 that includes an analytical procedure that is specifically intended to indicate the level of total polycyclic aromatic hydrocarbons. Our experience tells us that petrolatum meeting this test will also pass the European Pharmacopoeia (EP) test for polycyclic aromatic hydrocarbons. Petrolatums meeting the FDA test can be used in certain contact food applications.

The technical literature for petrolatum was first reviewed with mineral oils in IARC (International Agency for Research on Cancer) Volume 33, 1984. The report produced by IARC and a supplement published in 1987, concluded that there was inadequate evidence of carcinogenicity in humans and animals for highly refined oils (petrolatum was included in class 5 of petroleum products). Calumet Penreco's USP petrolatums are severely hydrotreated during manufacture. They do not fall into a "mildly" hydrotreated definition that OSHA (Occupational Safety and Health Administration) used in 1985 (FR50, No.245) to describe petroleum oils that had the potential to cause cancer.

The European Inventory of Existing Commercial Chemical Substances (EINECS) along with the European Union's Dangerous Substances Directive lists a note "N" in the entry for petrolatum. Note "N" states: "The classification of carcinogen need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen." The CosIng database which lists information on cosmetic substances and ingredients has three entries for petrolatum; however, one of the entries is listed as "Petrolatum, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen." Colipa (The European Cosmetic, Toiletry,



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and Perfumery Association) and EWF (The European Wax Federation) recommended that refined petrolatum include the following statement on their certificates of analysis:

**It is hereby guaranteed that the product is produced from substances that are not carcinogens according to the (EU's) \* Dangerous Substances Directive and of which the full refining history is known.**

As we stated above Calumet Penreco USP grade petrolatums are not carcinogenic, mutagenic or toxic for reproduction. We include a statement above on all of our certificates of analysis for our USP grade petrolatums. This letter applies to the following Calumet Penreco products:

Ultima White Pet USP  
Super White Pet USP  
Snow White Pet USP  
Regent White Pet USP  
Lily White Pet USP  
Cream White Pet USP  
Special White Pet USP  
Royal Pet USP  
Blond Pet USP  
Amber Pet USP  
Ointment Base No. 4  
Ointment Base No. 6  
Ointment Base No. 8  
Snow Pet CG

Please feel free to contact our Technical Services Department with any additional questions. \*(EU's) added by Penreco.

Sincerely,

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