

August 9, 2005

Dr. Lorraine E. Twerdok
Manager, Health Sciences
Regulatory and Scientific Affairs
American Petroleum Institute
1220 L Street, N.W.
Washington, DC 20005

Dear Dr. Twerdok,

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Lubricating Grease Thickeners posted on the ChemRTK HPV Challenge Program Web site on March 3, 2004. I commend the Petroleum HPV Testing Group of the American Petroleum Institute for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data in reporting test plans used to prioritize a chemical for further work.

EPA has reviewed this submission and has reached the following conclusions:

1. Category Justification. The Lubricating Grease Thickeners category comprises products that may contain one or more of 11 lithium and calcium salts of long-chain fatty acids (C14-C22) that are formed *in situ* during the manufacture of certain lubricating greases. They are made within an oil matrix by adding a metal hydroxide to form insoluble metal salts; these salts gel the mineral oil into a grease that is meant to be highly resistant to water wash-out ("bleed-out"). Although the starting fatty acids used *in situ* to make the corresponding grease thickeners are structurally different acids or derivatives, some with unspecified hydrocarbon chain lengths, they have similar physicochemical properties that include high log Kow and low water solubility. The category is reasonable on the basis of structural similarity, physicochemical properties, and anticipated resistance of the category members to migration from the grease matrix. It would be helpful to include a description of how this latter property is measured.

2. Physicochemical Properties. The submitter's proposal to provide robust summary technical discussions and modeled data for these endpoints will address the data requirements for the purposes of the HPV Challenge Program. Comment: In the robust summary the submitter provided an estimated melting point value of 288 °C for stearic acid, calcium salt; however, in table 2 of the test plan, a value of 179 °C is reported.

3. Environmental Fate. EPA agrees with the submitter's proposal to provide in the robust summaries technical discussions for the stability in water and biodegradation endpoints, and modeled data for the photodegradation and transport and distribution endpoints to address these endpoints.

Transport and distribution. The submitter plans to use the EQC Level I steady state model to develop distribution data for these chemicals. Although EPA had previously recommended the use of EQC Level I, EPA now recommends the use of EQC level III which provides a more rigorous level of analysis.

4. Health Effects. Adequate data were submitted for the acute and repeated-dose toxicity endpoints for lithium salts. No data were provided on the lithium salts for the gene mutation and chromosomal aberration endpoints, and the submitter proposes conducting a combined reproductive/developmental toxicity test (OECD TG 421) using a grease with a lithium fatty acid salt. A proposed dermal protocol for the latter test is based on the principal route of human exposure for the grease products. The proposed testing via the dermal route raises the question of bioavailability of the subject salts from an oil matrix. Because this is an important consideration in determining additional work, EPA requests that the submitter expand the discussion in the test plan on the bioavailability of lithium salts from the grease matrix. EPA suggests that additional work, perhaps an *in vitro* approach, to help characterize the dermal absorption potential of the category members would be beneficial. Finally, a calcium salt substance (CAS No. 68603-11-2) related to one of the category members was addressed as a member of another category in a 2002 submission by the Lubrizol Corporation (<http://www.epa.gov/chemrtk/petroxid/c14068tc.htm>); incorporating those data could strengthen this submission.

5. Ecological Effects. EPA agrees with the submitter's proposal for no further testing and addition of a robust summary technical discussion to explain why further testing for this category is not warranted.

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that API advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail address: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Acting Chief of HPVCB, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: M. E. Weber
N. Patel
J. Willis