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Subject: Environmental Defense comments on the Lubricating Grease Thickeners Category

(Submitted via Internet 6/30/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and twerdokl@api.org)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the Lubricating Grease Thickeners Category .

The test plan and robust summaries for the lubricating grease thickeners category were submitted by the American Petroleum Institute. This proposed category is comprised of 11 different CAS numbers. All proposed members are comprised of lithium or calcium salts of various fatty acids, and are all used by the lubricants industry to thicken greases. They are prepared by dissolving one or more fatty acids in mineral oil, followed by the addition of calcium hydroxide or lithium hydroxide. According to the test plan other additives may be incorporated, such as extreme pressure agents and antioxidants. However, the test plan does not indicate concentrations of the other additives or the applications for which they are used. According to the test plan, the thickener salt does not readily dissociate from the grease matrix in the environment, although pH, temperature and other factors appear to influence the dissociation rate.

The sponsor makes a convincing justification that the fatty acid moieties included in this test plan belong in the same category. However, the justification for including calcium and lithium salts together does not rest on a reasonable toxicological foundation. Lithium has been shown to possess toxic properties and biological interactions much different from those of calcium. Therefore, category formation is not consistent with the guidelines established for the HPV program. However, we would support a proposal for two categories; one for the lithium salts and the other for the calcium salts.

The test plan relies heavily on technical discussions, modeling data and the use of surrogate data for magnesium salts of fatty acids (not in a grease matrix) to address SIDS endpoints, with the exceptions that several repeat dose and acute studies are available for the lithium salts and the sponsor proposes to conduct a combined reproductive/developmental toxicity study on one of the lithium salts. While we agree that a reproductive/developmental study is needed, we do not agree that all other SIDS endpoints have adequate existing data. We are concerned about the following endpoints:

1. The physicochemical endpoint data are all derived from models. It seems that experimental data should be provided for at least two of the proposed members, but we defer to EPA on this point.

2. The environmental fate data are all derived from models. Since the lubricating grease thickeners are a complex mixture and there is

opportunity for environmental releases, experimental data should be generated on at least two of the proposed members. These studies should employ test substances that include the other additives of the lubricating grease thickeners.

3. The test plan states that no aquatic toxicology studies have been conducted on any of the proposed members, but that these endpoints are addressed in a technical discussion found in the robust summaries. However, the robust summaries do not contain any discussion on these endpoints. In any event, we recommend that the three aquatic toxicology endpoints be addressed by the generation of experimental data on at least two of the proposed members, using the same test substances used for our recommended studies on the environmental fate endpoints.

There are considerable acute and repeat dose toxicity data available that, in general, do not indicate adverse effects, including an NTP study and a carcinogenicity study. While these studies appear to satisfy HPV requirements, it is not clear if the other additives were part of the test substances. This information should be provided in the robust summaries and noted in the test plan. Also, are there bioavailability/tissue distribution data for lithium from the repeat dose studies? This is an important issue for evaluating toxicity studies on the lubricating grease thickeners.

Thank you for this opportunity to comment.

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