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Subject: Environmental Defense comments on Carbamodithioic Acid, Dibutyl-, Methylene Ester (CAS# 10254-57-6)

(Submitted via Internet 9/28/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and mmayes@rtvanderbilt.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for **Carbamodithioic Acid, Dibutyl-, Methylene Ester (CAS# 10254-57-6)**.

R. T. Vanderbilt Company, Inc., in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing available data to address SIDS elements required for the lubricant additive, carbamodithioic acid, dibutyl-, methylene ester. According to the test plan this chemical is used exclusively as an additive in lubricants at a maximum concentration of 5%. Occupational exposure is said to be limited by the use of automated production and handling equipment and consumer exposure is said to be limited to those handling lubricants containing this chemical and by its relatively low concentration in the lubricants. Environmental release and exposure potential is not mentioned, but as a result of transport, use and disposal of lubricants containing this chemical, such potential would appear to be significant. Some indication that the risk posed by this chemical may be low risk is provided, however, by data indicating that this chemical has low oral, dermal and repeated dose toxicity to mammals as well as low environmental toxicity.

The test plan submitted for carbamodithioic acid, dibutyl-, methylene ester is somewhat cursory and fails to discuss the rather limited data for this chemical in any appreciable detail. Deficiencies we note in the test plan are the absence of the molecular weight and a list of synonyms, even though the chemical is referred to by another synonym in the robust summaries. Also, the structural formula provided for this chemical is poorly drawn. A matrix of calculated and experimental data addressing the SIDS elements required under the HPV Challenge is provided.

On review of the robust summaries we note that water solubility was determined in several different studies and that the lowest result was selected for inclusion in the matrix of data presented in the test plan. No rationale for selection of this lowest value was provided, however; either the selection of this value needs to be justified by the sponsor or a more representative value used. In addition, there is some conflict between the numbers provided for water solubility and aquatic toxicity. That is, each of the values indicated for aquatic toxicity is greater than the lowest value used for water solubility of the chemical. Additional work is proposed to determine in vitro chromosomal aberration for

carbamodithioic acid, dibutyl-, methylene ester.

The robust summaries submitted for carbamodithioic acid, dibutyl-, methylene ester contain numerous blank or uninformative pages, but overall provide an adequate description of studies necessary to address the required SIDS elements. We note and support the conduct of a recent study (2004) designed and conducted according to GLP guidelines to address the SIDS elements for repeated dose and reproductive/developmental toxicity. However, the use of a single study to address several SIDS elements should be made clear in the robust summaries, rather than repeating the experimental design verbatim for each of the elements.

In summary, data appear to be adequate to address most SIDS elements for carbamodithioic acid, dibutyl-, methylene ester, and the proposed additional work is appropriate. However, this submission could be significantly improved if it was revised to better describe these data.

Thank you for this opportunity to comment.

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