

201-15615

September 29, 2004

Michael O. Leavitt, Administrator
U.S. Environmental Protection Agency
Ariel Rios Bldg. (1101A)
1200 Pennsylvania Ave. NW
Washington, DC 20460

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Comments on the HPV test plan for carbamodithoic acid, dibutyl-, methylene ester

Dear Administrator Leavitt:

These comments on R.T. Vanderbilt, Inc.'s HPV test plan for carbamodithoic acid, dibutyl-, methylene ester, or Vanlube 7723 (CAS no. 10254-57-6), are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These animal, health, and environmental protection organizations represent a combined membership of more than ten million Americans.

Vanderbilt states that all required data on the ecotoxicity and mammalian toxicity of Vanlube 7723 are available, so no further animal studies are needed. While we appreciate the approach of using existing data, we are concerned that all six of the animal tests referenced were carried out by a contract testing facility, Epona Associates, LLC, in 2003 and 2004 (IUCLID data-set document, pp. 12, 17-23). The appearance is therefore that these tests (one of each of the following toxicity tests: rat acute oral, rabbit acute dermal, rat repeated-dose, rat reproductive, rat developmental, and fish) may have been commissioned to meet the requirements of the HPV program and to circumvent the requirement that test plans be subjected to public review and comment. These tests included two "LD-50" studies conducted in 2003. While the robust summary does not specify which guideline was used for these LD-50 tests, clearly OECD test guideline 401 should not have been performed since it was repealed in 2002. Further, the HPV program guidelines call for the use of *in vitro* cytotoxicity testing to further reduce the number of animals killed in lethal poisoning tests (<http://www.epa.gov/chemrtk/toxprtow.htm>) but it does not appear that this was done. If it is, in fact, the case that these studies were conducted for the purposes of the HPV program, it would represent an egregious violation of the HPV framework agreement to which all participants agreed to adhere.

Lastly, Vanderbilt is planning on conducting an *in vitro* chromosomal aberration test on Vanlube 7723. The cells to be used are not stated in the test plan, and we urge R.T. Vanderbilt to use either human lymphocytes or mammalian cells obtained from established cultures, in order to avoid killing additional animals to supply the cells.

We look forward to receiving a clarification of this matter from the sponsor and I can be reached at 757-622-7382, ext. 8001, or via e-mail at JessicaS@peta.org.

Sincerely,

Jessica Sandler
Federal Agency Liaison