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PCRM	P H Y S I C I A N S	
	C O M M I T T E E	5100 WISCONSIN AVENUE, N.W., SUITE 400
	F O R	WASHINGTON, DC 20016
	R E S P O N S I B L E	T: (202) 686-2210 F: (202) 686-2216
M E D I C I N E		PCRM@PCRM.ORG WWW.PCRM.ORG

June 25, 2004

Michael O. Leavitt, Administrator
 US Environmental Protection Agency
 Ariel Rios Building
 Room 3000, #1101-A
 1200 Pennsylvania Avenue, NW
 Washington, DC 20460

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Subject: Comments on the HPV test plan for the chemical 4-Heptanol, 2,6-dimethyl-

Dear Administrator Leavitt:

The following are comments on the test plan for the chemical 4-Heptanol, 2,6-dimethyl- (DIBC, CAS# 108-82-7) for the HPV program, submitted by The Dow Chemical Company (Dow). These comments are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These animal, health and environmental protection organizations have a combined membership of more than ten million Americans.

Dow proposes to do an OECD 422 screening protocol on this chemical, which will kill approximately 675 animals. Dow is also proposing to do a chromosomal aberration test, using OECD protocol 473. Yet again, any comments that any interested party would provide are apparently moot, since **Dow has already begun the proposed studies.** This is another violation of both the 1999 animal welfare agreement and the original HPV framework agreement to which all HPV participants agreed to adhere (Wayland 1999; Federal Register 2000). Both the EPA and the public are to be given the opportunity to comment on all test plans, and their comments are to be considered by the sponsor, BEFORE any experimental work is undertaken. This test plan sets a disturbing precedent, as in a number of instances public commenters have been able to suggest ways in which proposed tests could be eliminated or modified, resulting in the saving of a demonstrable number of animal lives.

In this particular case, it is especially distressing that Dow is already conducting the 422, since DIBC is found on the FDA GRAS list as a food additive. As the EPA has clearly stated,

“In analyzing the adequacy of screening data for chemicals that are substances Generally Recognized as Safe (GRAS) for a particular use by the Food and Drug Administration (FDA), participants should consider all relevant and available information supporting the FDA’s conclusions. Participants reviewing the adequacy of existing data for these chemicals should specifically consider whether the information available makes it unnecessary to proceed with further testing involving animals. As with all chemicals, before generating new information, participants should further

consider whether any additional information obtained would be useful or relevant.”

(Please see: <http://www.epa.gov/chemrtk/ceoltr2.htm>.) Dow has made no obvious attempt to follow this guidance nor has it made any attempt to conduct a thoughtful analysis of the toxicity of DIBC. It is unclear whether Dow has considered the use of toxicity information from other chemicals that may share similar physicochemical or toxicological properties with DIBC, which is indefensible considering the common structure and chemical group of DIBC, i.e., a linear seven-chain carbon group, with a hydroxyl group at C4 and methyl groups at C2 and C6.

Thank you for your attention to this issue. We ask that the EPA contact Dow and resolve the issue of its continuing and deliberate violations of the HPV program framework agreement, and look forward to a prompt and favorable response to our concerns from both Dow and the EPA. We can be reached at 202-686-2210 ext. 335 or via email at kstoick@pcrm.org.

Sincerely,

Kristie Stoick, MPH
Research Analyst

Chad B. Sandusky, PhD
Director of Research

References:

Federal Register Vol. 65, No. 248, December 28, 2000.

Wayland, S.H., “Letters to manufacturers/importers”, October 14, 1999, <http://www.epa.gov/chemrtk/ceoltr2.htm>.