



HUNT MANAGEMENT SERVICES, LLC

941 Rhonda Place SE ▲ Leesburg, VA 20175
Phone: 703-669-5688 ▼ Fax: 703-669-5689
E-Fax: 413-294-6349 ▲ ehunt@adelphia.net

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Kristie Stoick, MPH
Chad Sandusky, PhD
PCRM
5100 Wisconsin Avenue, Suite 400
Washington, DC 20016

Dear Ms. Stoick and Dr. Sandusky:

Thank you for your letter of 25 June 2004 regarding the 2,6-dimethyl-4-heptanol (DIBC CAS 108-82-7) HPV test plan.

Contrary to what is stated in the test plan, testing on this molecule is not "in progress". Rather the test plan should have reflected the current status of "scheduled or planned". The test plan will be updated to reflect the correct terminology.

Dow conducted a thoughtful review of the GRAS status of this material as part of our overall robust summary preparation process. Unfortunately, there is no adequate reliable data in the public domain that supports DIBC's GRAS status. It is presumed that GRAS status is based upon historical use and acceptability of the molecule. It's also worthy to note that the U.S. EPA did not exempt this chemical from the HPV Chemical Challenge Program based upon its GRAS status.

You also stated that "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." Dow made a significant effort to consider structural and toxicological analogs to this molecule. In the end, however, our chemists and toxicologist could not make a scientifically justifiable and defensible case for the use of surrogate data. There are no structurally similar molecules with robust datasets that would be satisfactory to meet the needs of our OEM customers or the HPV Chemical Challenge Program. In addition, there are no metabolism data to definitively show that DIBC is metabolized to another molecule for which toxicology data could be used as a surrogate.

In closing, we do not believe that Dow violated the voluntary framework of the HPV Chemical Challenge Program. Utilizing the term "in-progress" was inadvertent, and will be corrected when the dossier and test plan are updated.

Sincerely,

Elizabeth K. Hunt
Technical Contact for
The Dow Chemical Company