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Steven John son, Administrator
US En vironmental Protection Agency
Ariel Rios Bu ilding
Room 3000, #1101-A
1200 Pennsylvan ia Avenue, NW
Washington, DC 2046 0

Subject: Comments on the HPV test plan for HPHP

Dear Administrator Johnso n:

The fo llowing comment s on the BASF Corporation (BASF) test p lan for propanoic acid,3 - hyd oroxy-2,2-dimethyl-, 3-hydroxy-2,2-dimethylpropyl ester (HPHP) (CAS RN 1 115-20-4) are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethica l Treatment of Animals, the Humane Society of the Un ited States, the Dor is Day Animal League, and Earth Is land Institute. These hea lth, anima l protection, and environmental organizat ions have a combined mem bership of more tha n ten mil lion America ns.

BASF submitted its test plan for HPHP in November 2 006. According to the test plan, HPHP is a chemical intermediate , used in the production of binding agents, coatings, and polymers. The chemical is apparently not present in consumer products, and likely huma n exp osure occurs in a n occupational setting through mostly dermal but also possibly inhalation and/or oral routes of exposure. BASF uses analogs and knowledge of metabolic processes to complete the test plan endp oints, and d oes not pro pose any fur ther testing.

Ava ilable data on HPHP include physico -chemical properti es, ecotoxicity and env ironmental fate data, and mammalian acute and genetic toxic ity data. The remainder of the HPV endpoints is fulfilled by data from an HPHP metab olite, neopentyl glycol (NPG) (repeated dose/repro ductive/developmental and in v itro cytogenic ity) and a re lated chemica l and its metabolite, isobutyl isobutyrate (IBI B) and isobutanol (in vivo mic ronucleus testing). Addit ional data is g iven for these two chemica ls for the a cute, repeated dose, reproductive and developmental toxicity endpoints, to su pport the data in the test plan.

We sup port this tho ughtful toxicology approach. At the same time, we would also like to suggest some strategies that could help fort ify the infor mat ion contained in this test plan, whi le still avoid ing addit ional an imal test ing.

First, we appreciat e the comparative toxic ity tab les prepared for the acute and repeated dose toxicity endpoints. These are a very good way to evaluate the adequacy of the analog for

informing the toxic ity knowledge base for endpoints in which data is not ava ilable from the original test plan chemica l; if the data are available, it may be that the preparation of data tables for other mammalian toxicity endpoints, and also f or other data categories such as phy sicochemical properti es or env ironmental fate, could be v ery helpful in incre asing confidence in the analog approach use d by BASF here.

Additional ly, whi le it is clear to us from reading the enti re test plan what BASF intends in its justific ation of the use of IB IB and isopropan ol, the discussion could be further enha nced by expan ding the chemical structure pictures and discussion provided into metabolism pathway diagrams. This would c larify the re lationships of the chem icals discussed in the test plan for the reader.

This test plan is an example of the thoughtful toxicology that is needed to be con sistent with the EPA's stated goal of maximiz ing the use of exist ing data in order to l imit addit ional an imal testing and to avoid a mere box-checking approach to the HPV program. Thank you for your attention to these co mments. I may be reached at 510.834.8320, or via e-mail at kstoick@pcrm.org.

Sincere ly,

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Research Analyst

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