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NCIC HPV
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04/16/2003 09:20 AM

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cc:
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Subject: Environmental Defense comments on Polybutylene Succinic Anhydride
Category



Richard_Denison@environmentaldefense.org on 04/15/2003 01:21:16 PM

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Subject: Environmental Defense comments on Polybutylene Succinic Anhydride Category

(Submitted via Internet 4/15/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov,
boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and
sarah_loftus@americanchemistry.com)

Environmental Defense appreciates this opportunity to submit comments on
the robust summary/test plan for the Polybutylene Succinic Anhydride
Category.

The American Chemistry Council Petroleum Additives Panel, through its
Health Environmental, and Regulatory Task Group (HERTG), has submitted a
Robust Summary/Test Plan to describe available data and testing needs for
two polybutylene succinic anhydrides, with the proposal that they be
considered together as a category. On review of this Robust Summary/Test
Plan and related information, we agree that these chemicals have similar
uses, structures and chemical/physical and toxicological properties.
Therefore, we support their consideration as a category.

This Test Plan is well-written and clearly describes the synthesis, uses,
possible sources of human and environmental exposure and toxicities of
these chemicals. According to the Test Plan, chemicals described by these
CAS#s are actually mixtures of large molecules with molecular weight ranges
from 500 to 2500 daltons. Based on information provided by the sponsor they
are synthesized at facilities owned by HERTG members and are used
exclusively as additives in crankcase oils for internal combustion engines.
The sponsor maintains that methods of manufacture and transport are
controlled to limit occupational exposure in the manufacturing plants and
in transport, but because they are produced and transported in large
quantities, considerable potential exists for consumer and environmental
exposure as a result of their use in motor oils as well as through spills
or inappropriate disposal. Fortunately, these compounds appear to have low
environmental and mammalian toxicity.

The Test Plan clearly describes the objectives of each SIDS element
required and concisely describes available data that address the respective
elements. Our review of the Robust Summary indicates data describing the
toxicity of these chemicals is limited, but most available studies are
relatively recent and conducted under GLP. The Robust Summary is
well-organized and describes available studies and their results. These
studies indicate polybutylene succinic anhydrides are not genotoxic in the
Ames Test and that they have very low toxicity to both mammals and aquatic
organisms. Their lack of toxicity is most probably due to the fact that
these are very large molecules and would not be expected to be absorbed
through cell membranes.

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The Test Plan provides data, results of computer modeling, approaches to bridging data or technical discussion to address most of the requested SIDS elements. The only additional testing proposed is that for chromosomal aberrations for CAS# 67762-77-0. Bridging from data obtained from that test is proposed to predict the potential for induction of chromosomal aberration by CAS# 67762-79-0. The Test Plan proposes to "read-across" data from a chemical not in this category, tetrapropenyl butanoic acid, to address the requirements for subchronic and reproductive/developmental toxicity. Our examination of the molecular structure of tetrapropenyl butanoic acid indicates that, whereas it shares some chemical/physical characteristics with the chemicals in this category, there are also significant differences. Tetrapropenyl butanoic acid is a single chemical rather than a mixture, it is a smaller molecule than most of the molecules in the respective mixtures reviewed here, and it is a much more compact molecule than chemicals in this category. We ask that EPA look very closely at these chemicals to determine if the proposal to "read-across" from data for tetrapropenyl butanoic acid to predict these toxicities for chemicals in this class is appropriate.

That being said, we do not propose additional animal testing because we are aware that chemicals in this category have very low toxicity and are unlikely to induce toxicity or reproductive/developmental toxicity at doses anywhere near the range to which humans are likely to be exposed.

One other comment: Numerous references are mentioned in the Test Plan, but are not listed in the bibliography. Many are references that readers may find of use. It would be helpful if they were included in the bibliography.

Thank you for this opportunity to comment.

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