

201-15785



Richard Denison
<rdenison@environmentaldefense.org>

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To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, NCIC HPV@EPA, Karen Boswell/DC/USEPA/US@EPA, rauckman@toxicsolutions.com
cc: lucierg@msn.com, Karen Florini <KFlorini@environmentaldefense.org>, Richard Denison <rdenison@environmentaldefense.org>
bcc:
Subject: FW: Environmental Defense comments on Alcohols, C4, Distillation Residues (CAS# 68551-11-1)

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From: Richard Denison

Sent: Friday, January 07, 2005 4:09 PM

To: oppt.ncic@epa.gov; hpv.chemrtk@epa.gov; chem.rtk@epa.gov; NCIC_HP@EPA.GOV; boswell.karen@epa.gov; rauckman@toxicsolutions.com

Cc: lucierg@msn.com; Karen Florini; Richard Denison

Subject: Environmental Defense comments on Alcohols, C4, Distillation Residues (CAS# 68551-11-1)

(Submitted via Internet 1/7/05 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and rauckman@toxicsolutions.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for **Alcohols, C4, Distillation Residues (CAS# 68551-11-1)**.

The test plan and robust summaries for alcohols, C4, distillation residues (EP-202MP) were submitted by BASF Corporation. Overall, the test plan is informative and well-written, but the category justification is not convincing, so we do not agree that existing data meet the requirements of the HPV program.

EP-202MP, also termed butanol bottoms, is a byproduct from the production of butanol and butyraldehyde. This substance, according to the test plan, is used as a fuel and also as a solvent. It is apparently produced at a single facility. EP-202MP is a complex mixture comprised of well over 20 constituents, ten of which are often found in concentrations in excess of 10%. Carbon chain length appears to range between 4 and at least 14, as indicated in Table 1 and Figure 1 of the test plan. The mixture consists of a wide array of esters, alcohols and aldehydes. Fifty percent of the constituents are not identified in Table 1.

The sponsor proposes to use 2-ethylhexanol as a surrogate for most of the mammalian and ecotoxicity endpoints. However, 2-ethylhexanol comprises only 1-2% of the mixture. Since the vast majority of EP-202MP constituents differ significantly in structure, physicochemical properties and toxic properties from 2-ethylhexanol, we must reject the notion that 2-ethylhexanol can be used as a surrogate for the mixture itself and/or the other constituents of the mixture. Therefore, we recommend that the sponsor conduct studies on all mammalian endpoints (except acute toxicity) and all ecotoxicity endpoints using the EP-202MP mixture as the test substance. We also recommend that the sponsor conduct a combined repeat dose/reproductive/developmental toxicity study to minimize the use of animals. However, the individual ecotoxicity studies (fish, aquatic invertebrate, and algae) need to be conducted, since the model estimates predict a wide range of values for individual constituents of EP-202MP.

Additional specific comments are as follows:

1. There are adequate data on physicochemical and environmental fate endpoints for the major constituents of EP-202MP to satisfy requirements of the HPV program.
2. The sponsor uses metabolism data to justify the category formation. However, the data are incomplete, as many of the constituents are not included and it is well known that a wide variety of metabolic pathways operate on the varied constituents of EP202MP.
3. The environmental fate models predict that some of the EP202MP chemicals are biodegraded slowly. It is said to be produced at only one site, so we ask if any of the constituents of EP202MP have been detected in environmental samples taken in proximity to this site.
4. The estimates of acute fish toxicity for EP202MP on Table 9 do not make mathematical sense. 2-Ethylhexene and 2-ethylhexanol comprise 20% of the mixture and they have a combined LC50 of 7 mg/ml. The estimate of 35 mg/ml for the whole mixture must then assume that the fish toxicity of all the other constituents is zero, an assumption that is clearly wrong.

Thank you for this opportunity to comment.

George Lucier, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense