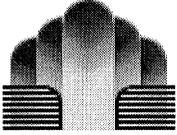


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Peter Wendol kowski
04/30/2003 10:44 AM

To: Peter Wendolkowski/DC/USEPA/US@EPA
cc:
cc:
Subject: Environmental Defense comments on 1,3-Butanediol (CAS # 107-88-o)



Richard_Denison@environmentaldefense.org on 04/24/2003 02:26:29 PM

To: oppt.ncic@epamail.epa.gov, hpv.chemrtk@epamail.epa.gov, Rtk Chem/DC/USEPA/US@EPA, Karen Boswell/DC/USEPA/US@EPA, pmsurana@celanese.com
cc: MTC@mchsi.com, LUCIERG@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on 1,3-Butanediol (CAS # 107-88-o)

(Submitted via Internet 4/24/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and pmsurana@celanese.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 1,3-Butanediol (CAS # 107-88-o).

Celanese Limited has submitted a Robust Summary/Test Plan for 1,3-butanediol under the High Production Volume Challenge Program. Our review of the Test Plan indicates it is very well-written and concisely describes the uses, sources of environmental and human exposure and considerable amount of experimental data amassed on this chemical over the past 40 to 50 years. Because 1,3-butanediol has been used in industry and commerce, including as a food and cosmetic additive regulated by the FDA, for over 50 years, some of the available data are somewhat dated and were conducted prior to the development of GLP. Nevertheless, these studies appear to have been carefully conducted and are thus adequate to address the requested SIDS elements. All available data indicate that 1,3-butanediol is rapidly degraded in the environment and that it has low aquatic and animal toxicity. It is approved as a food cosmetic additive by the FDA and has actually been investigated as a component of a "synthetic" diet for animals and humans. Repeat dose and lifetime exposure studies of 1,3-butanediol in laboratory animals indicate that it induced no toxicity even when administered at doses of up to 10% of the diet for the lifetime of the animals. Data for genotoxicity are somewhat limited, but studies of a very closely related chemical, 1,4-butanediol, as well as other closely related chemicals, indicate this and similar chemicals are not likely to be genotoxic.

The Robust Summary is well-organized in presenting data to address each of the SIDS elements. We compliment Celanese on the quality of this Robust Summary/Test Plan and for providing an excellent list of references for the data cited in each. In our opinion, the data described in this Robust Summary/Test Plan are quite adequate to address the requested SIDS elements, and no further work under the Challenge Program is required for 1,3-butanediol.

Thank you for this opportunity to comment.

Hazel B. Matthews, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.

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