

PUBLIC CALENDAR NOTICE

CPSC 6 (M) Cleared
11/8/96
Products Identified
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Firms Notified

May 15, 1996

Val Schaeffer and Laureen Burton, Health Sciences, attending a meeting to discuss an industry toxicity testing proposal for dibasic esters solicited by the EPA; 3 p.m., EPA Headquarters, Washington D.C. The meeting was requested by the Dibasic Esters Group of the Synthetic Organic Chemical Manufacturers Association. For additional information contact Val Schaeffer, (301) 504-0994 x1390. (S)

MEETING LOG

DATE: May 15, 1996 at 3 to 5 PM

PLACE: Room 542, East Tower, EPA Headquarters, Washington DC

ATTENDEES: Charles Auer, EPA/OPPT; George Semenuik, EPA/OPPT; other EPA/OPPT staff; Val Schaeffer, CPSC/EHHE; Laureen Burton, CPSC/EHHE; Jorge Olguin, SOCMA/Dibasic Esters Group; Gerald Kennedy, DuPont/Haskell Labs; other members of the Dibasic Esters Group

Background

Dibasic esters (DBEs) are paint stripping solvents of interest to the CPSC as methylene chloride substitutes. In 1993, the Commission formally directed its staff to acquire toxicity data necessary to assess the comparative hazard of the widely-used and well-studied paint stripping solvent, methylene chloride, with that of the major substitute formulations. Because of the limited toxicity information available for DBEs, CPSC nominated dimethyl adipate to the National Toxicology Program (NTP) to conduct a full toxicological evaluation as its priority chemical for 1994. Dimethyl adipate is a principal DBE used in paint stripping formulations. At the urging of EPA, the Executive Committee of the NTP referred the nomination to EPA for testing under Section 4 of the Toxic Substances Control Act (TSCA). In 1995, the Dibasic Esters Group, representing the manufacturers of these chemicals, submitted a proposal for a TSCA Enforceable Consent Agreement (ECA) to conduct toxicity testing of dimethyl adipate and two other dibasic esters used in paint strippers. The Dibasic Esters Group requested this meeting to discuss aspects of their proposal.

Discussion

Mr. Auer opened the meeting by extending a welcome to the DBE Group. He stated the EPA/CPSC position that the manufacturers' initial proposals satisfied Tier 1 testing of the DBEs, but not all the Tier 2 data needs as expressed in the 1995 EPA solicitation for testing proposals (60 FR 15143, March 22, 1995). The additional testing sought by EPA/CPSC were for developmental toxicity, two generation reproductive toxicity, and oncogenicity.

Dr. Olguin thanked EPA for the opportunity to meet with the agency staff. He indicated that the DBE Group had amended its testing proposal to address the EPA/CPSC concerns. He would present some information on DBE product stewardship and exposure. Dr. Kennedy would present the toxicological aspects of their proposal. He highlighted the recycling benefits of DBEs, namely that the dicarboxylic acid waste stream from the production of Nylon 6,6 was being converted to DBEs for further industrial use. DBEs have advantages as a paint stripping solvent because of their low vapor pressure. Exposure monitoring during the manufacturing process indicate air concentrations ranging from <0.01 ppm to 0.3 ppm. DBE blends used for paint stripping are primarily dimethyl adipate and dimethyl glutarate with only minor amounts of dimethyl succinate. DBE air concentration between 0.05-1.5 ppm were measured during consumer use simulations. These levels are still generally lower than those found in a more comprehensive chamber study which showed 1.0-2.0 ppm in the breathing zone under conditions of actual consumer use of a commercially available DBE-based paint stripper. These air concentrations are much lower

than those from use of paint strippers containing methylene chloride and volatile solvents. The Dibasic Ester Group offered to work with EPA/CPSC to develop a comprehensive exposure profile of consumer paint stripping use under actual conditions. Under questioning, they agreed to consider experiments designed to estimate dermal as well as inhalation exposure.

Dr. Kennedy reviewed the existing toxicity data on the DBEs. This consists of acute animal toxicity studies on the DBE homologues and repeated dose inhalation studies in rats with a DBE mixture. Toxicity and related endpoints that were studied with the DBE homologues are genotoxicity, lethality, sensory /eye/skin irritation, and biotransformation. Histopathology, clinical chemistry and developmental/reproductive toxicity were evaluated following daily exposure to a DBE mixture over a three to four month period. Dr. Kennedy concluded from these studies that DBEs were not genotoxic, had a low order of acute toxicity, and did not produce significant systemic toxicity upon repeated exposure. DBEs did cause some reversible damage to the nasal epithelium upon inhalation. The mechanism of action involves substantial uptake of DBEs in the nose and metabolism to toxic metabolites. The DBE Group proposes to do; (1) additional genotoxicity experiments, (2) 90 day repeated dose inhalation studies on the three DBE homologues evaluating additional special toxicity endpoints such as neurotoxicity, an in-depth evaluation of the male reproductive organs, and cell proliferation, and (3) a developmental toxicity study in the rabbit. These would constitute phase 1 toxicity testing. They would discuss the need for the two generation reproductive toxicity and oncogenicity studies as well as other data (exposure, mechanism, pharmacokinetics, etc.) following the outcome of the phase 1 testing.

Questions were raised regarding what phase 1 outcomes would motivate the manufacturers to conduct the phase 2 testing. EPA/CPSC representatives reiterated that they were committed to addressing comparative hazard and risk with other paint stripping solvents; thus the phase 2 studies were needed regardless of phase 1 outcomes. EPA/CPSC are seeking a toxicity testing program similar in scope to the one negotiated for another paint stripping solvent, N-methylpyrrolidone (58 FR 61814, November 23, 1993). Questions were also raised regarding the absence of the two week dermal toxicity studies that were previously proposed by the DBE Group. These were considered a data need by EPA/CPSC because of the importance of skin contact as an exposure route during paint stripping and use of DBE-containing hand cleaners. The DBE Group argued that the low acute toxicity by the dermal route and the lack of systemic toxicity from inhalation exposures convinced them that toxicity from repeated dermal exposure is low and additional testing is not needed.