Michigan Department of Natural Resources

Interoffice Communication

To : Isobutyl isobutyrate file Sept. 5, 1991

From : G. Butterfield

Subject : Review of AAC

The available toxicity data on isobutyl isobutyrate (CAS # 97-85-8) is not very plentiful. The only reference to an inhalation study was in Patty's (also cited in RTECs). This was an acute inhalation exposure at 5000 ppm which reportedly killed two of three rats in six hours, and at 600 ppm (or 3500 mg/m3) no rats died. These are virtually all the details given, therefore this study is considered to be of inadequate quality for quantitative assessment.

An eighteen week gavage study conducted by Drake et al (1978) appears to be of adequate quality upon which to base an AAC. In this study, Wistar rats, 15 male and 15 female per dose level, were gavaged daily with isobutyl isobutyrate in corn oil. There were no significant changes in body weight, food consumption, water consumption, hematology values, organ weights, histopathology, serum or urine analysis in any of the groups. The authors concluded the highest dose level, 1000 mg/kg, was the no untoward effect level (no observed adverse effect level).

Using the NOAEL of 1000 mg/kg from the gavage study,

$$AAC = \frac{(1000\ mg/kg)}{35 \times 100 \times 0.93} = 0.31\ mg/m3 \quad or \quad 310\ ug/m3$$

where (1 kg)/(.93 m3) is the inhalation rate for Wistar rats as cited in EPA 1988.

Therefore an AAC of 300 ug/m3, with annual averaging, should be acceptable.

References :

Clayton G.D. and F.E. Clayton (Eds). 1981. Patty's Industrial Hygiene. 3rd Ed. John Wiley and Sons, NY. Vol II, pg 2286.

Drake et al. 1978. Short term toxicity study of isobutyl isobutyrate in rats. Fd Cosmet Toxicol 16:337-342.

EPA. 1988. Recommendation for and documentation of biological values for use in risk assessment. EPA ORD. PB88-179874.

Patty, F.A. (Eds). 1963. Patty's Industrial Hygiene. 2nd Ed. John Wiley and Sons, NY. Vol II, pg 1867-8.