

MICHIGAN DEPARTMENT OF NATURAL RESOURCES

INTEROFFICE COMMUNICATION

October 12, 1993

TO: File for n-Butylglucamine (CAS # Not Available)

FROM: Dennis Bush, Surface Water Quality Division

SUBJECT: ITSL Derivation

n-Butylglucamine is a pharmaceutical intermediate which is currently being studied by Zeeland Chemical Company for use in the treatment of viral infections. The predicted ambient impact (PAI) for this chemical is 0.42 $\mu\text{g}/\text{m}^3$ with an annual averaging time. No CAS number is available for this compound and a CAS search conducted on July 1, 1993 using the key work "n-Butylglucamine" revealed no studies.

The only information on the toxicity of this compound was found in a Material Safety Data Sheet (MSDS) provided by the company. According to the MSDS, this chemical "is to be used only for research purposes in small amounts under controlled laboratory conditions. The toxicological and other potential hazards associated with this chemical have not been fully characterized." The only specific toxicity information provided on the MSDS is an oral rat LD_{50} of greater than 2000 mg/kg. n-Butylglucamine is also considered to be a respiratory irritant.

An abstract of the LD_{50} study conducted by Kiplinger and Guzzia (1991) was provided by the Zeeland Chemical Company. According to the abstract, n-Butylglucamine (SC-48501A) was administered once via gastric intubation to a single group of 5 male and 5 female fasted albino rats at a dose level of 2000 mg/kg. No deaths occurred and no significant findings were observed during the necropsy. Two males had a slight decrease in body weight from day 0 to day 7, but later regained their prestudy weights. The LD_0 dose of 2000 mg/kg was used as an LD_{50} to derive an ITSL. This is a conservative calculation since the "true" LD_{50} would be expected to be higher than 2000 mg/kg. This calculation is a final ITSL and not an interim value because it is a conservative estimate and it is very unlikely that a better study is presently available.

ITSL Derivation:

$$ITSL = \frac{1}{500} \times \frac{1}{40} \times \frac{1}{100} \times \frac{LD_{50} \times WA}{0.167 \times IA}$$
$$Interim ITSL = 0.002 \times 0.025 \times 0.01 \times \frac{2000 \text{ mg/kg}^*}{0.167} \times \frac{\text{kg}^{**}}{0.931 \text{ m}^3}$$
$$Interim ITSL = 6.4 \text{ } \mu\text{g/m}^3, \text{ annual averaging time}$$

*The dose of 2000 mg/kg is an LD₀ not an LD₅₀.

**Derived from data provided in EPA (1988).

REFERENCES

Kiplinger, G.R. and P.J. Guzzia. 1991. Acute Oral Toxicity Study in Albino Rats with SC-48501A. Report # PSA-91-C-3674.

U.S. EPA. 1988. Recommendations for an Documentation of Biological Values for Use in Risk Assessment. PB 88-179874.

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