MICHIGAN DEPARTMENT OF NATURAL RESOURCES

INTEROFFICE COMMUNICATION

September 10, 1993

TO: Files for cetylpyridinium chloride (CAS No. 123-03-5) and
            cetylpyridinium chloride monohydrate (CAS No. 6004-24-6)

FROM: Bob Sills, Surface Water Quality Division

SUBJECT: Screening Level Development

There is a lack of occupational exposure levels, and EPA RfC's and RfD's, for cetylpyridinium chloride and the monohydrate form of this chemical. Although these two forms of the quaternary ammonium salt are distinguished by separate CAS numbers, they may reasonably be expected to have identical chemical and toxicological behavior. The expected similarity of toxicities of the two forms is supported by comparison of LD50's and LDLO's reported in RTECS in several species by several routes (oral, intraperitoneal, intravenous, and subcutaneous) (NIOSH, 1993).

The literature review determined that there is a complete lack of useful toxicological data from human studies or repeated-dose animal studies. The best available study is an acute inhalation toxicity study in rats, with cetylpyridinium chloride (CPC) in aerosolized powder form (Lin et al., 1991).

Groups of five Sprague-Dawley rats per sex were exposed to aerosols containing 0 (control), 0.05, 0.07, 0.13 and 0.29 mg CPC/litre for 4 hr. and observed for toxicity and ocular effects for 14 days thereafter. There was no apparent difference in toxicity to the two sexes. The LC50 (sexes combined) of CPC was 0.09 mg/l, with 95% confidence bounds of 0.07 and 0.13 mg/l, as calculated using probit analysis. The authors estimated the dose to be 4-8 mg/kg body weight, based on the animals measured weight and assumed values for tidal volume and respiration rate. They therefore reasoned that CPC is more toxic by inhalation than by oral exposure, noting that the oral rat LD50's are reported as 108 mg/kg and 200 mg/kg (Lin et al., 1991).

The ITSL are derived from the 4-hour LC50 of 0.09 mg/l (or 90 mg/m^3, 90,000 μg/m^3) as follows:

$$ITSL = \frac{LC50}{500 \times 100} = \frac{90,000 \ \mu g/m^3}{500 \times 100} = 1.8 \ \mu g/m^3 \text{ based on annual averaging.}$$

As discussed above, this ITSL is applicable to CPC and the monohydrate form.

REFERENCES

Lin, G.H.Y., K.A. Voss and T.J. Davidson. 1991. Acute inhalation toxicity of cetylpyridinium chloride. Fd. Chem. Toxicol. 29(12):851-854.

NIOSH. 1993. RTECS database. January, 1993.