MICHIGAN DEPARTMENT OF NATURAL RESOURCES

INTEROFFICE COMMUNICATION

January 6, 1994

TO: File for Diphenhydramine HCl (Benadryl HCl)

FROM: George Eurich, AQD - Toxics Unit

SUBJECT: Correction to Diphenhydramine HCl screening level

The CORRECTED Screening Level for DIPHENHYDRAMINE HCl (CAS # 147-24-0) has been set at 50 ug/m^3 (annual average) based on the particulate standard.

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MICHIGAN DEPARTMENT OF NATURAL RESOURCES

INTEROFFICE COMMUNICATION

November 29, 1993

TO: File for Benadryl HCl (Diphenhydramine HCI)
(CAS # 147-24-0)

FROM: George Eurich

SUBJECT: Screening Level for Benadryl Hcl

Until an ITSL can be determined from inhalation data, the screening level for BENADRYL HCl will be set at the particulate standard of 150 ug/m^3 based on annual averaging time.

There is no RfC or RfD established for BENADRYL HCl (CAS # 147-24-0). A search of the following databases turned up no inhalation data on this compound:

RTECS
IRIS
EPB LIBRARY
ACGIH TLV
HEAST
NLM SEARCH (1981-1993)
NIOSH REL
NTP MANAGEMENT STATUS REPORT
IARC MONOGRAPHS
EPB CHEMICAL CRITERIA DATABASE
CAS ONLINE SEARCH (1967-1993)

Therefore, the estimated screening level was based on the maximum daily therapeutic dose of 400 mg/24 hrs (5.7 mg/kg/d for a 70 kg person), considered an oral NOAEL. This is the maximum recommended daily dose according to the Physicians Desk Reference (1991). There is not a limit on the duration of therapy at the maximum daily dose.

The maximum therapeutic dose of 5.7 mg/kg/d BENADRYL HCl was used to estimate an ITSL that would provide adequate protection of public health based on systemic effects. The estimated ITSL was derived according to Rule 232 (1) (b) as follows:

ITSL = Oral RfD x 70kg/20m^3

$$ITSL = \frac{NOAEL\ (mg/kg/d)}{UF} \times \frac{70\ kg}{20\ m^3}$$: UF = 10 normal to sensitive
10 subchronic to chronic

$$ITSL = \frac{5.7\ mg/kg/d}{100} \times \frac{70kg}{20m^3} = 200\ ug/m^3$$ based on 24 hour averaging time.

No known inhalation data exists on benadryl, consequently the estimated ITSL determined above does not reflect the pulmonary effects of benadryl. Furthermore, the estimated ITSL for benadryl would not be protective of pulmonary effects based on the particulate standard of 150 ug/m^3 (annual average). Therefore, the ITSL will not be set until inhalation data is available. Predicted ambient impacts will be evaluated on a case by case basis.

References:

Physicians Desk Reference. 1991.

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