MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

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INTEROFFICE COMMUNICATION

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TO: File for p-Chlorobenzotrifluoride [CAS# 98-56-6]

FROM: Doreen Lehner, Toxics Unit, Air Quality Division

DATE: January 19, 2017

SUBJECT: p-Chlorobenzotrifluoride [CAS# 98-56-6] ITSL change in the averaging time from 24 hours to annual

The current initial threshold screening level (ITSL) for p-chlorobenzotrifluoride is 70 µg/m^3 based on an annual averaging time. The ITSL established on 12/10/1998 based on a Newton et al. (1998) 13-week inhalation study on rats. When the screening level was derived in 1998 the averaging time was set at 24 hours. As the basis for the screening level used a 13-week inhalation study, the averaging time may appropriately be set at annual. Therefore, the averaging time is being changed from 24 hours to annual at this time.

References:

APCR. 2016. Air Pollution Control Rules, Promulgated pursuant to Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, Michigan Department of Environmental Quality. 1994. Act 451, as amended (NREPA).

Newton PE, Bolte HF, Richter WR, et al. 1998. Inhalation toxicity, neurotoxicity, and toxicokinetic studies of p-Chlorobenzotrifluoride. Inhal Toxicol 10:33-48.

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

December 10, 1998

TO: File for p-Chlorobenzotrifluoride (CAS #98-56-6)

FROM: Gary Butterfield, Toxics Unit, Air Quality Division

SUBJECT: Screening level for p-Chlorobenzotrifluoride

p-Chlorobenzotrifluoride also known as PCBTF is a volatile liquid (vapor pressure of 8 mm Hg at 25C) used as a chemical intermediate in manufacture of herbicides, dyes, and used as a solvent and a dielectric fluid.

An October 27, 1998 CAS and NLM on-line literature search was conducted to identify available toxicity information. A few inhalation toxicity studies have been conducted with this material, as well as, several oral toxicity studies. The majority of toxicity studies have been conducted in rats, with a couple studies using both rats and mice. Although comments from EPA have indicated that the oral route of exposure studies may not be an appropriate basis for determining an inhalation screening level for PCBTF, the reasoning was related to the livers weight changes observed in the oral studies being due to first pass liver effects following oral administration. Although several of the inhalation studies also reported finding these liver effects too, causing some doubt as to whether this reasoning is correct. In any case, a recent 13 week inhalation toxicity, neurotoxicity, and toxicokinetic study with p-chlorobenzotrifluoride was just published (Newton et al 1998) and can provide the basis for calculating a screening level.

In consideration of the completeness of toxicity testing database for PCBTF, oral studies must be considered to evaluate reproductive effects. One study, oral exposure to PCBTF was evaluated in a multigenerational study conducted by Elars Bioresearch Labs 1981. Sprague-Dawley rats were administered 0, 5, 15, or 45 mg/kg to adults and their offspring generation. In this study, the authors concluded that there were no toxic effects observed at any of the dose levels. However, a non-statistically significant increase in liver weights was observed in this study too. Many of the other oral studies report NOAEL's in the same 10 to 50 mg/kg dose range.

The 13 week inhalation study (Newton et al 1998) looked at potential neurotoxic effects of PCBTF. There were no adverse effects on motor activity, a functional observational battery of assessments, or neuropathology, which lead to the authors concluding that there was no neurotoxicity related to a 13 week PCBTF exposure. In this 13 week inhalation toxicity study, groups of Sprague-Dawley rats were exposed for 6 hours a day for 13 weeks to concentrations of 0, 10, 51, or 252 ppm (which converts to

concentrations of 0, 73, 375, or 1850 mg/m3). The 51 ppm exposure was identified as the NOEL in this study. Exposure to 252 ppm caused increased liver weights, changes in clinical chemistry of increased total protein and albumin in females, and males with increased kidney weights.

The NOEL of a 13 week study is the minimum data set needed to calculate an RfC. Thus the NOEL of 51 ppm can be used to calculate the ITSL using the RfC methods described by EPA. The ITSL can be calculated as follows.

NOEL(adj) = 51 ppm x (7.36mg/m3/ppm) x 6/24 x 5/7 = 67 mg/m3
NOEL(hec) = 67 mg/m3
RfC = NOEL(hec) x 1/(10x10x10) = 67 mg/m3 x 1/(1000) = 70 ug/m3

Where uncertainty factors of 10 were used for rat to human, sensitive individuals, and subchronic to chronic adjustments, it was assumed that there was no difference between rats and humans. Therefore, no dosimetric adjustments to the NOEL(adj) to obtain the NOEL(hec) was made, ie. NOEL(adj) = NOEL(hec).

The ITSL is being established at 70 ug/m3 with 24 hour averaging, based on the estimated RfC calculated above.

References:

Elars Bioresearch Lab. 1981. Gas chromatographic assay PCBTF modified 90 day gavage and reproduction study in rats – Part II. EPA OTS # 508148.

Newton et al. 1998. Inhalation toxicity, neurotoxicity, and toxicokinetic studies of p-Chlorobenzotrifluoride. Inhal Toxicol 10:33-48.

GB:SLB
Cc: Mary Lee Hultin, AQD