

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

June 22, 2016

TO: 2-Chloro-1,1,1,2-Tetrafluoroethane (CAS No. 2837-89-0)
FROM: Mike Depa, Toxics Unit, Air Quality Division
SUBJECT: Initial Threshold Screening Level

The Initial Threshold Screening Level (ITSL) for 2-chloro-1,1,1,2-tetrafluoroethane is 5000 µg/m³, with annual averaging time. The ITSL was derived pursuant to Rule 232(1)(a).

Previously, the averaging time (AT) assigned to 2-chloro-1,1,1,2-tetrafluoroethane was 24 hours, as per the default methodology (see attached memo from Gary Butterfield dated May 24, 1994). The current file review concludes that the AT may appropriately be set at annual, based on the nature and duration of the key study and the ITSL value derivation, as allowed under Rule 229(2)(b). Therefore, the AT is set to annual.

*Attachment***MICHIGAN DEPARTMENT OF NATURAL RESOURCES**

INTEROFFICE COMMUNICATION

May 24, 1994

TO: 2-Chloro-1,1,1,2-tetrafluoroethane file (CAS No. 2837-89-0)

FROM: Gary Butterfield

SUBJECT: ITSL for 2-Chloro-1,1,1,2-tetrafluoroethane

2-Chlore-1,1,1,2-tetrafluoroethane is also commonly known as HCFC-124, an alternative to stratospheric ozone depleting chlorofluorocarbons. EPA currently has this material listed in IRIS as having an RfC under review. No occupational exposure limits have been established by ACGIH, NIOSH or OSHA. Although not many published toxicity studies were located during the May 3, 1994 NLM and CAS-online literature search. Several unpublished studies, including some 90 day inhalation studies, have been submitted to EPA and have been summarized by EPA in the 1990 Hydrofluorocarbon and hydrochlorofluorocarbon interim report and WHO in the 1992 Environmental health criteria document, or the original study can be obtained for review through inter-library loans.

Among these toxicity studies are teratology studies in rats and rabbits, and repeated dose studies of 2 and 4 week durations. In general these studies seem to indicate that exposure to high levels of HCFC-124 cause animals to become lethargic and uncoordinated. These conditions have been observed at short term doses of 50000 to 100000 ppm in rats and rabbits. Two 90 day studies conducted by Haskell Laboratory identify NOEL levels. In a mouse study, Haskell Laboratory (1992), a NOAEL for male and female Crl:CD-1(ICR)BR mice of 15000 ppm was identified. Females exposed to the next higher dose, 50000 ppm, had a reduced response to auditory stimulus during exposure periods. A NOEL for male mice was not identified in this study. Even though some non-toxicologically significant changes were observed in the males, decreased body weights and serum triglycerides and increased hepatic beta-oxidation activity.

In a 90 day rat study, Haskell Laboratory (1991), a NOAEL of 5000 ppm was identified based on effects in male rats at 15000 ppm, reduced serum triglyceride levels and decreased arousal - a change in behavioral activity. The decreased arousal is also consistent with observations made at higher doses with shorter term exposures.

Although there have been some non-toxicologically significant changes found sporadically with low level exposure to HCFC-124 in some of these studies, the NOAEL of 5000 ppm (or 28 g/m³) from Haskell Laboratory (1991) appears to be the best basis for establishing an ITSL. Following the methods for calculation of an RfC from EPA (1990), an ITSL can be established as follows based on that NOAEL, for a gas with extra-respiratory effects.

$$\text{NOAEL(adj)} = 28 \text{ g/m}^3 \times 6/24 \times 5/7 = 5 \text{ g/m}^3$$

$$\text{NOAEL(hec)} = \text{NOAEL(adj)} \times 1a/1b = 5 \text{ g/m}^3 \times 1 = 5 \text{ g/m}^3$$

Attachment

where the default value for la/lb of 1 was used (see EPA 1990).
 $RfC = NOAEL(hec)/[uf \times mf] = (5 \text{ g/m}^3)/(1000) \times 1000 \text{ mg/g} = 5 \text{ mg/m}^3$
where an uncertainty factor (uf) of 1000 is based on 10 for each of the following: animal to human, sensitive individuals, and sub-chronic to chronic.

According to Rule 232(1)(a) the ITSL is equivalent to the RfC.

ITSL = RfC = 5 mg/m³ with 24 hour average

References:

EPA. 1990. Interim methods for development of inhalation reference concentrations. EPA/600/8-90/066A.

Haskell Laboratory. 1991. Subchronic inhalation toxicity: 90 day study with HCFC-124 in rats. HLR # 79-91. EPA OTS0529977 86910001000s.

Haskell Laboratory. 1992. Subchronic inhalation toxicity: 90 day study with HCFC-124 in mice. HLR I 695-91. EPA OTS0543411 86930000045.