MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

_____

INTEROFFICE COMMUNICATION

_____

May 31, 2016

TO: 1,1-Dichloro-1-fluoroethane (CAS #1717-00-6)

FROM: Mike Depa, Air Quality Division, Toxics Unit

SUBJECT: Initial Threshold Screening Level Update

The Initial Threshold Screening Level (ITSL) for 1,1-dichloro-1-fluoroethane is 12,800 µg/m^3 with annual averaging time.

Previously, the averaging time (AT) assigned to 1,1-dichloro-1-fluoroethane was 24 hours, as per the default methodology. See the attached memo from Marco Bianchi dated April 16, 1997. 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 ENVIRONMENTAL QUALITY

_____

INTEROFFICE COMMUNICATION

_____

April 16, 1997

TO: 1,1-Dichloro-1-fluoroethane (CAS #1717-00-6)

FROM: Marco Bianchi, Toxics Unit, Air Quality Division

SUBJECT: Initial Threshold Screening Level

The initial threshold screening level (ITSL) for 1,1-dichloro-1-fluoroethane is 12,800 µg/m^3 based on a 24-hr averaging time.

The following references or databases were searched to identify data to determine the ITSL: IRIS, HEAST, NTP Management Status Report, RTECS, EPB-CCD, EPB library, CAS-online, NLM-online, IARC, NIOSH Pocket Guide, and ACGIH Guide.

A full range of toxicological studies were found for 1,1-Dichloro-l-fluoroethane (HCFC-141b) due to the fact that it is a candidate replacement chemical for other more ozone damaging chlorofluorocarbons. Acute and subacute studies have shown very low toxicity for this compound. A 4-hr LC50 of 62,000 ppm was listed for rats. HCFC-141b was not a skin irritant in rabbits and not a skin sensitizer in guinea pigs. Skin application of HCFC-141b to rabbits at 2,000 mg/kg body weight produced no adverse effects. However, this compound was a mild eye irritant in rabbits. Oral administration at 5000 mg/kg body weight did not cause any deaths or clinical signs of toxicity in rats.

Minor, but close-dependent, reductions in body weight were observed in male and female rats during a 90-day inhalation study. Decreased responsiveness was also observed in rats but only at 20,000 ppm. An increase in serum cholesterol or triglycerides was observed in male and female rats at 20,000 ppm, and in males at 8000 ppm. No organ pathology was noted in these subchronic inhalation studies. The no-observable-adverse-e fleet (NOA ll) level from these studies was 8,000 ppm. Results from other studies demonstrate that HCFC-l4lb was not neurotoxic in rats. As with trichlorofluoroethane (CFC-11), a cardiac sensitization response to an intravenous epinephrine challenge occurred in dogs with HCFC-141b at 5,000 ppm and higher concentrations in experimental screening studies.

Teratology and reproductive studies also showed minimal toxicity of HCFC-141b in rats. Pregnant rats in the teratology study were exposed to levels of 0, 3200, 8000, and 20,000 ppm from days 6-15 of gestation (6 hr/day). In the 20,000 ppm exposure group, there was an increase in implantation losses; furthermore, in this group, fetal weights tended to be lower than controls. However, there was no evidence of a teratogenic effect. The reproduction study was conducted at exposure levels of 0, 2000, 8000, and 20,000 ppm, 7 days/wk starting approximately 10 weeks before the first pairing. Adult rats exposed at 20,000 ppm (and, to a lesser extent, those exposed to 8000 ppm) showed increases in water intake, slight increases in food consumption, and decreases in body weight. Following the mating of the F0 parents, there were fewer litters in the 20,000 ppm exposure level group than in controls.

attachment

When the F1 animals were mated to produce the second generation, the number of litters was comparable for all groups. In the second F0 mating and the F1 mating, the number of pups per litter was lower at 20,000 ppm; although birth weights were comparable, body weight gain tended to be slower in the high-level exposure group. Survival was good in all groups. At 8000 ppm no significant effects were observed in the pups and only minimal signs in the adults. The 2000 ppm exposure level represented a clear NOAEL for all indices.

A battery of in vitro and in vivo tests were conducted on HCFC-141b as a vapor. Bacterial gene mutation assays with E. coli and S. typhimurium were negative in all tested strains. In vitro chromosomal aberration assays were positive on CHO cells hut negative on human lymphocytes. Moreover, HCFC-141b was negative in vivo in a mouse micronucleus inhalation assay. On the basis of these data and previously reported genotoxicity testing, HCFC-141 b is considered non genotoxic.

In a two year bioassay, groups of 80 male and 80 female Sprague-Dawley rats were exposed, by inhalation (6 h/day, 5 days/wk) to vapors of HCFC-141b at target concentrations of 0, 1500, 5000, and 20,000 ppm (increased from 15,000 ppm after 17 weeks of exposure). No exposure- related effects of toxicological significance were noted with respect to survival clinical sign, ophthalmoscopy, hematology clinical chemistry, urinalysis, or organ weighing analysis. Reduced food intake and body weight gain were noted in both sexes of the 15,000 ppm group during the first 16 weeks; thereafter, body weight gains in all groups were similar although the intergroup differences in body weight remained evident. Reduced food intake persisted in both sexes through week 52 and in females during the second year of exposure. Treatment-related effects on macroscopic pathology were confined to increased incidences of testicular masses and altered appearance. Microscopic pathologic examinations confirmed the testes as the target organ with findings of increased incidences of benign interstitial cell tumors and hypoplasia at 5000 and 20,000 ppm. The NOAEL was 1500 ppm. The testicular changes at high exposure levels were considered to be due to a change of the senile hormonal imbalance in geriatric rats and of little significance for the assessment of human health effects.

Due to a full range of toxicological studies for 1,1-dichloro-1-flouroethane, there is enough supportive evidence to establish an inhalation reference concentration (RfC) for this chemical. These studies have included: acute oral toxicity, acute ocular irritation, acute dermal irritation, dermal sensitization, acute inhalation toxicity, repeated 2 and 4-week inhalation studies, cardiac sensitization, neurobehavioral toxicity, subacute (90 day inhalation) toxicity, inhalation teratology, two-generation reproduction toxicity, a suite of in vitro and in vivo genotoxicity assays and a 104 week rat inhalation bioassay. The NOAEL established from the chronic study was 1500 ppm or 7,175 mg/m^3. This value will he used to establish an RfC for 1,1-dichloro-1-fluoroethane.

The RfC (and ITSL) was determined as follows:

NOAEL = 1500 ppm
MW of HCFC-141b = 116.95g

conversion of ppm to mg/m^3:

MW x ppm/24.45 = mg/m^3
116.95x1500ppm/24.45 = 7175 mg/m^3

The NOAEL (HEC) is calculated for a gas:extrarespiratory effect assuming periodicity was attained. Since the b:a lambda values are unknown for the experimental animals species (a) and humans (h), a default value of 1.0 is used for this ratio.

attachment

Duration adjustment:

7175 mg/m^3 x 6 hrs/24 hrs = 1794 mg/m^3

1794 mg/m^3 x 5 days/7 days = 1281 mg/m^3

Uncertainly factors

10 = interspecies

10 = sensitive populations

RfC = 1281 mg/m^3/(10 x 10) = 12.81 mg/m^3

Conversion of mg/m^3 to µg/m^3

12.81 mg/m^3 x 1000µg/mg = 12810 µg/m^3

The ITSL for 1,1-dichloro-1-fluoroethane = 12,800 µg/ m^3 based on a 24-hr averaging.

MB:slb