MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

TO: File for 1,1-Difluoroethane (CAS # 75-37-6)

FROM: Robert Sills, AQD Toxics Unit Supervisor

SUBJECT: 1,1-Difluoroethane change in the ITSL and change in the averaging time from 24 hrs to annual

DATE: December 8, 2016

The ITSL for 1,1-difluoroethane is 400,000 ug/m³, with annual averaging time.

The previous ITSL for 1,1-difluoroethane (40,000 ug/m³) was established on June 15. 2005 (see attached). The averaging time (AT) assigned to the ITSL at that time was 24 hours, as per the default methodology at that time (Rule 232(2)(b)). The ITSL was based on and consistent with an EPA (1994) Reference Concentration (RfC) of 40,000 ug/m³, which EPA derived from a chronic (2 year) animal bioassay. EPA (1994) applied a total uncertainty factor (UF) = 300, which consisted of a UF = 3 for interspecies extrapolation, UF = 10 for intraspecies variability, and UF = 10 for database deficiencies. "...that include the lack of chronic inhalation and developmental studies in a second species and two-generation reproductive toxicity studies." EPA (1994) noted that: the key study provided a point-of-departure that was a free-standing NOAEL: the chemical is "practically nontoxic following acute inhalation exposure"; reversible CNS depression has been demonstrated at 100,000 ppm; and, the database includes a NOAEL for maternal and developmental effects at 50,000 ppm in rats. Therefore, the current file review concludes that the AT for the ITSL 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). Also, the application of a database gaps uncertainty factor of 10 by EPA (1994) in this particular case does not appear to be justified based on chemical-specific data or considerations, and it is therefore not adopted in the ITSL derivation. Therefore, the ITSL is now being recalculated as 400,000 ug/m³, which is 10-fold higher than the EPA (1994) RfC of 40,000 ug/m³ because of the removal of UF_{db} = 10, and, the averaging time is being changed from 24 hrs to annual.

References:

EPA. 1994. Integrated Risk Information System (IRIS database). Chemical file for 1,1difluoroethane. Inhalation RfC assessment last revised 9/1/94. Still current as of 12/8/16.

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

June 15, 2005

To: 1,1-Difluoroethane file (CAS # 75-37-6)

From: Gary Butterfield

Subject: Screening level for 1,1-difluoroethane

1,1-Difluoroethane is also known as ethylidene fluoride, and HFC-152a. The material is a gas with a vapor pressure of 4550 mm Hg at 25C. The boiling point is -24.7 degrees Celsius. The molecular weight is 66 g/mol. 1,1-Difluoroethane is used as a blend component of several refrigerant blends, a foam blowing agent, and as an aerosol propellant. It has greater global warming potential than carbon dioxide. However, it is not an ozone depleting substance.

The following references or databases were searched to identify data to determine the screening level: U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS), National Institute for Occupational Safety and Health (NIOSH) Registry for Toxic Effects of Chemical Substances (RTECS), American Conference of Governmental and Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), Michigan Department of Environmental Quality (DEQ) library, International Agency for Research on Cancer (IARC) Monographs, Chemical Abstract Service (CAS) Online (1968 - June 2005), National Library of Medicine (NLM) - Toxline, and National Toxicology Program (NTP) Status Report.

The 1994 IRIS RfC for 1,1-difluoroethane is 40 mg/m3 based on an unpublished DuPont (1982) two year rat inhalation study where no adverse effects were observed at any dose level, even at the highest dose of 25000 ppm, the NOAEL.

The CAS and NLM on-line literature searches were conducted on June 13, 2005 to look for more recent, since 1994, toxicity information. There are no recently published toxicity studies that surpass the quality of the DuPont (1982) study upon which to base the ITSL calculation. Therefore, it is considered that the most appropriated information available upon which to base the ITSL is the 1994 RfC. The ITSL can be calculated from that RfC under R232(1)(a) as follows.

ITSL = RfC = 40 mg/m3 = 40,000 ug/m3 with 24 hour averaging

References:

EPA. 2005. Integrated Risk Information System (IRIS).

DuPont. 1982. Two-year inhalation study with 1,1-difluoroethane (FC-152a) in rats. DuPont Haskell Laboratory report # 8-82. EPA OTS # 0520846.