MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

TO: File for C11-14 branched alkyl acetates (CAS # 108419-35-8)

FROM: Robert Sills, AQD Toxics Unit Supervisor

SUBJECT: C11-14 branched alkyl acetates ITSL change in the averaging time from 24 hrs to annual

DATE: January 17, 2017

The current ITSL for C11-14 branched alkyl acetates is 300 ug/m^3, with annual averaging time (AT).

Previously, the ITSL was established on April 22, 2009 at 300 ug/m^3 with 24 hr averaging time (see attached justification memo). The averaging time (AT) assigned to the ITSL previously was 24 hours, as per the default methodology at that time (Rule 232(2)(b)). The ITSL derivation applied a total uncertainty factor (UF) = 1000, which consisted of a UF = 10 for each interspecies extrapolation, intraspecies variability, and subchronic-to-chronic conversion. 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).

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

TO: C11-14 branched alkyl acetates file (CAS # 108419-35-8)

FROM: Gary Butterfield

SUBJECT: Screening level for C11-14 branched alkyl acetates

DATE: April 22, 2009

C11-14 Branched alkyl acetates is also known as C11-14 branched alkyl esters of acetic acid, and oxo-tridecyl acetate. The molecular formula is $C_{15}H_{30}O_2$. It is liquid at ambient temperatures with a density of 0.87. The water solubility is reported to be 0.2 mg/L. The melting point is -2C. The boiling point is 240 - 285C. The vapor pressure is 0.01 mmHg at 25C.

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 - April 2009), National Library of Medicine (NLM) - Toxline, and National Toxicology Program (NTP) Status Report.

The CAS and NLM on-line literature searches were conducted on April 20, 2009. There were no published toxicity studies located in the literature search.

The search of EPA's web page located HPV documents for C11-14 branched alkyl acetates. In those HPV summary documents were descriptions of three unpublished toxicity studies in rats that were conducted by Biodynamics. Those studies included an acute oral rat, an oral developmental toxicity in rats, and a 90-day oral rat toxicity study.

In the acute study (Biodynamics 1983), groups of 5 male and 5 female Sprague-Dawley rats were given 5 g/kg and observed for 14 days. There were no deaths observed during this study. Therefore, the LD50 was reported to be greater than 5 g/kg.

In the developmental study (Biodynamics 1985a), groups of 22 pregnant female Sprague-Dawley rats were gavaged dosed with 0, 500, 1300 or 2500 mg/kg on gestation days 6 to 15. Maternal toxicity was observed at the two highest doses – decreased body weight. There was no effect on fetuses at any dose level. The maternal NOAEL is 500 mg/kg. The fetal NOAEL is 2500 mg/kg.

In the 90-day rat gavage study (Biodynamics 1985b), groups of 20 male and 20 female Sprague-Dawley rats were administered 0, 100, 500 or 1000 mg/kg 5 days per week for 90 days. An interim sacrifice of 5 male and 5 female rats per dose level were sacrificed after 45 days. The 100 mg/kg level was identified as the NOAEL. The high two doses resulted in altered blood glucose values, the highest dose females had altered blood protein values, the high two doses also had male rat kidney tubular nephropathy consistent with alpha-2u-globulin effects.

The 90-day rat gavage study provides the best scientific basis for setting the screening level. There is no evidence available of any special route specific concerns for this chemical – it is assumed that oral exposure can be used to establish an inhalation screening level with no problems. The subchronic study provides longer term exposure with added confidence of finding possible longer term adverse effects from exposure to this chemical. The screening level will be calculated using EPA RfD methodology to calculate the oral RfD, which can then be converted to an ITSL following methods of R232(**1**)(b).

NOAEL = 100 mg/kg
RfD = 100 mg/kg / (10x10x10) = 0.1 mg/kg
Uncertainty factors of 10 for (a) sensitive individuals, (b) animal-to-human, (c) subchronic-to-chronic were used in the above RfD calculation.

ITSL = 0.1 mg/kg x (70 kg/20m^3) = 350 rounded to 300 ug/m^3 with 24-hour averaging

References:

Bio/dynamics. 1983. Acute Oral Toxicity Study in the Rat; Bio/dynamics, East Millstone, NJ, Project # 330601.

Bio/dynamics. 1985a. Oral Teratology Study in Rats; Bio/dynamics Inc., East Millstone, NJ, Project # 352134.

Biodynamics. 1985b. Subchronic Oral Gavage Study in Rats; Bio/dynamics Inc., East Millstone, NJ, Project # 252170.

GB:lh