MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

January 15, 2016

TO: Methysilane File (CAS # 992-94-9)

FROM: Mike Depa, Toxics Unit, Air Quality Division

SUBJECT: Initial Threshold Screening Level

The Initial Threshold Screening Level (ITSL) for methysilane is 30 μ g/m³ with annual averaging time.

Previously, the averaging time (AT) assigned to methysilane was 24 hours, as per the default methodology (see attached memo from Gary Butterfield dated August 10, 2010). 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.

As noted in the attached memo, the ITSL for methylsilane is based on the ITSL for silane (CAS # 7803-62-5)(also attached). Silicon tetrahydride is another name for silane.

MICHIGAN DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENT

INTEROFFICE COMMUNICATION

TO: Methysilane File (CAS # 992-94-9)

FROM: Gary Butterfield

SUBJECT: Review/update of screening level for Methysilane

DATE: August 10, 2010

Methysilane had a default ITSL established in the early 1990s due to a lack of available toxicity data. Literature searches conducted June 21, 2010 also did not find any published toxicity studies for this chemical upon which the ITSL could be set.

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 2010), National Library of Medicine (NLM) - Toxline, and National Toxicology Program (NTP) Status Report.

Due to a lack of available toxicity data on methylsilane, other possible means for establishing a screening level were considered. There have been several different substituted silane compounds reviewed in the past for screening level development. Some of those chemicals were looked at again. A trend indicating that with greater substitution the degree of toxicity of the silane compound decreases can be observed. This trend can also be seen when comparing the silane (CAS # 7803-62-5) screening level (30 µg/m³ 24-hour) to the higher substituted trimethyl silane (CAS # 993-07-7) screening level (340 µg/m³ annual) and tetramethylsilane (CAS # 75-76-3) screening level (1300 µg/m³ annual). In other words, methylsilane would probably be less toxic than the unsubstituted silane. Following this logic, because the methylsilane may be assumed to be less toxic than silane, the methylsilane ITSL (if there was toxicity data available) would probably be greater than the silane ITSL. This leads to the conclusion that using the ITSL for silane as a substitute for a methylsilane ITSL would probably be sufficiently protective for toxic effects from methylsilane exposure. Therefore, it is considered to be appropriate to set the methylsilane ITSL at 30 µg/m³ with 24hour averaging (equivalent to the silane ITSL) rather than continue use of the overly protective default ITSL of 0.1 μ g/m³ with annual averaging.

GB:lh

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

- TO: Silicon Tetrahydride File (CAS # 7803-62-5)
- FROM: Keisha Williams, Air Quality Division (AQD)
- SUBJECT: Screening level for silicon tetrahydride
- DATE: July 2, 2015

The initial threshold screening level (ITSL) for silicon tetrahydride is $30 \ \mu g/m^3$ (annual averaging time) based on the study by Omae et al. (1992). This ITSL was established by AQD on August 5, 2010 (MDNR, 2010).

The averaging time was originally set at 24 hours, the default averaging time, per Rule 232 (2). It is being changed at this time to annual, as allowed per Rule 229 (2), because the derivation of the ITSL included an accounting for chronic exposure.

References:

Omae et al. 1992. Acute and subacute inhalation toxicity of silane 1000 ppm in mice. Arch Toxicol 66:750-3.

MDNR. 2010. Memo from Gary Butterfield to File. Subject: Silicon Tetrahydride (CAS# 7803-62-5). August 5, 2010. AQD, MDNR.

MICHIGAN DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENT

INTEROFFICE COMMUNICATION

TO: Silicon Tetrahydride File (CAS # 7803-62-5)

- FROM: Gary Butterfield
- SUBJECT: Review/update of screening level for silicone tetrahydride

DATE: August 5, 2010

Silicon tetrahydride is also known as silane. The 2002 ITSL for silane was re-evaluated, along with the assessment of screening levels, for some similar chemicals - methylsilane (992-94-9) and dimethylsilane (1111-74-6). The 2002 ITSL was based on 1/100 of the ACGIH TLV for silane under R232(1)(c). Unfortunately the TLV documentation for silane is not based on any toxicity information for silane. The TLV committee assumed silane was less toxic than germanium tetrahydride and adjusted the germanium tetrahydride TLV for the less toxic silicon tetrahydride. The TLV documentation adjusting the ratio of toxicities could not be reproduced by our staff. This lead to our conclusion that the TLV reasoning is considered to be less reliable for setting a screening level, rather than basing the silane ITSL upon actual silicon tetrahydride toxicity data.

Most of the silane compounds do not have adequate amounts of toxicity data available or published. The literature review for silane covered the past 15 years but did not find much recent toxicity data available. The EPA is in the process of setting AEGLs for silane, and has published interim acute values and has documentation of the reasoning used to obtain those values. The AEGL documentation briefly discusses a 28-day mouse inhalation study reported by Omae et al (1992). This 4-week study with toxicity information on the chemical of concern, silane, is considered to be a more appropriate basis for setting the screening level, than is the TLV, which assumed comparable toxicity to another questionably related chemical.

In the study by Omae et al (1992), groups of 10 male ICR mice were exposed to a target dose of 1000 ppm (measured dose of 966 ppm) silane for acute (1, 2, 4 and 8 hours) and subacute (6/24x5/7 for 2 and 4 weeks) durations. The 4-week exposure data will be used to establish a new ITSL. Irritation of the nasal cavities following exposure was evident as increased incidence of nasal exudate, and the occurrence of inflammatory and/or necrotic cells in the nasal mucosa.

The ITSL was calculated using the EPA RfC methodology for using a LOAEL, as follows.

LOAEL = 966 ppm or 1265 mg/m³ LOAEL(adj) = 1265 x 6/24 x 5/7 = 226 mg/m³

RGDR for nasal effects in 24 g male mice, from category 1 gas

$$RGDR = \frac{(Ve/SA)a}{(Ve/SA)h} = \frac{(0.0276/3)}{(13.8/200)} = 0.13$$

LOAEL(hec) = $226 \text{ mg/m}^3 \times 0.13 = 29.4 \text{ mg/m}^3$

 $ITSL = 29.4/(1000) = 30 \text{ ug/m}^3 24\text{-hour average}$

The total uncertainty factor for the above ITSL calculation includes: factors of 10 for sensitive humans; subacute to chronic (the 10 fold factor is generally used for 90-day to chronic); factors of 3 for animal-to-human (in conjunction with use of RGDR), and LOAEL-to-NOAEL (as the observed adverse effects were considered to be mild). This resulted in a total uncertainty factor of 1000. UF = $10 \times 10 \times 3 \times 3 = 1000$

References:

ACGIH. 1999. Documentation of threshold limit values (TLV) for silicon tetrahydride.

Omae et al. 1992. Acute and subacute inhalation toxicity of silane 1000 ppm in mice. Arch Toxicol 66:750-3.

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