MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY
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INTEROFFICE COMMUNICATION

To: File for Aniline (CAS# 62-53-3)
From: George Eurich
Date: 4-17-2012
Subject: Screening levels for Aniline (CAS# 62-53-3)

The Initial Threshold Screening Level (ITSL) for aniline is 1 µg/m^3 (annual averaging time). The Second ITSL is 76 µg/m^3 (8 hour averaging time). The Initial Risk Screening Level (IRSL) for aniline is 0.6 µg/m³ (annual averaging time).

The Air Quality Division (AQD) previously established a screening level for aniline based on the 1993 US Environmental Protection Agency (EPA) reference concentration (RfC) of 1 µg/m³ (24 hour avg.). EPA's Integrated Risk Information System (IRIS) database denotes the bases for the RfC were the co-principal inhalation studies of Oberst et al. (1956) which demonstrated a NOAEL, complimented by a duPont deNemours (1982) study which established a LOAEL.

A Second ITSL has been derived based on the American Conference of Governmental and Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) of 1 ppm (7.6 mg/m^3). The TLV was developed to protect against methemoglobinemia. The Second ITSL was determined according to R336.1232(c) where the ITSL = 1% of TLV. The TLV has 1 significant figure, therefore the ITSL shall have 1 significant figure: 7.6 mg/m³ rounds up to 8 mg/m³. In calculating the shorter average time (i.e., 8-hr) for the second ITSL, the average time for the chronic ITSL has been revised to annual averaging time from previously used 24 hour averaging time.

The chronic ITSL is based on an RfC (or RfD) which typically is assigned an averaging time of 24-hrs pursuant to Rule 232(2)(b). However, if the RfC-based (or RfD-based) ITSL is established in conjunction with an acute ITSL, the chronic RfC-based ITSL can more appropriately have an annual averaging time. ITSLs based on a chronic inhalation study and/or derived using uncertainty factors to adjust for lifetime exposure, are typically associated with long averaging times such as an annual average. Coupling a chronic ITSL with an acute ITSL ensures that exposure levels below both ITSLs will provide effective health protection.

EPA also classifies Aniline as B2 – Probable Human Carcinogen, and has calculated an oral cancer slope factor, but not an inhalation cancer slope factor. The oral slope factor is based on the CIIT (1982) chronic study in which CD-F rats were dosed with dietary aniline for two years. The results showed increased combined spleen fibrosarcoma, stromal sarcoma, capsular sarcoma and hemangiosarcoma in male rats during the study.

The EPA oral slope factor of 5.7E-3 (mg/kg)$^{-1}$ can be converted to an equivalent inhalation slope using 70 kg person inhaling 20 m^3 per day, resulting in the inhalation unit risk estimate (URE) of 1.5E-6 (µg/m^3)$^{-1}$. Based on this inhalation factor, the resulting IRSL = 0.6 µg/m^3 annual average. CAL-OEHHA (California Office of Environmental

Health Hazard Assessment) and EPA (National Air Toxics Assessment; NATA) also used the oral slope factor in establishing this inhalation URE.

Conversion of oral slope factor to inhalation:
Unit Risk Estimate = q_1^* $(\mu g/m^3)^{-1}$ = q_1^* $(mg/kg/day)^{-1}$ x $20m^3/70$ kg x $1mg/1000\mu g$

URE = 5.7E-3 $(mg/kg/day)^{-1}$ x $20m^3/70$ kg x 1mg/1000ug = 1.54 E-6 $(\mu g/m^3)^{-1}$

Inhalation URE conversion to IRSL:
IRSL = 1E-6/1.54E-6 $(\mu g/m^3)^{-1}$ = 0.648 $\mu g/m^3$
        Rounding to 1 significant figure yields 0.6 $\mu g/m^3$ (annual average)

This review is in concert with an AQD Toxics Unit initiative to re-evaluate screening levels for Hazardous Air Pollutants (HAPs) for consistency with EPA's health protective benchmarks. The AQD has concluded that the ITSL of 1 ug/m^3 (annual avg), the Second ITSL of 76 $\mu g/m^3$ (8 hr avg.) and IRSL of 0.6 $\mu g/m^3$ (annual avg.) are appropriate screening levels for aniline. Previous Toxic Unit reviews (1991, 2006) had considered the ITSL of 1 $\mu g/m^3$ (24 hr avg.) to be close enough to the IRSL of 0.6 ug/m^3 (annual avg.) to be protective of cancer effects. However, per Rule 336.1225 (2) and (3), if a source qualifies for the secondary risk screening level (SRSL) and therefore qualifies for 10-fold higher impacts on industrial property or public roadways, the allowable impact would be considerably higher than those allowed by the ITSL. Therefore the derivation of the IRSL is justified.

References:
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