MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

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INTEROFFICE COMMUNICATION

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April 8, 2014

TO: File for Hydrogen Chloride (CAS No. 7647-01-0)

FROM: Michael Depa, Toxics Unit, Air Quality Division

SUBJECT: Development of the Screening Level

There are two initial threshold screening levels (ITSL) for hydrogen chloride: 20 µg/m³ with an annual averaging time and 2,100 µg/m³ with a 1-hr averaging time.

The following references or databases were searched to identify data to determine the screening level: U.S. Environmental Protection Agency's (EPA's) Integrated Risk Information System (IRIS), the EPA Acute Exposure Guideline Level (AEGL) Program, the State of California's Office of Environmental Health Hazard and Assessment (OEHHA) Acute, 8-hour and Chronic Reference Exposure Levels (RELs), The U.S. Agency for Toxic Substances and Disease Registry (ATSDR), the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLV), National Institute of Occupational Safety and Health (NIOSH) Pocket Guide to Hazardous Chemicals. EPA established a reference concentration (RfC) of 20 µg/m³. Both the ACGIH and NIOSH have established Occupational Exposure Limits (OELs). The ACGIH Ceiling TLV for hydrogen chloride is 2 ppm (3 mg/m³) and the NIOSH Ceiling REL is 5 ppm (7 mg/m³).

Basis for the Screening Levels

The chronic ITSL was based on the US EPA RfC of 20 µg/m³ and assigned an annual averaging time. The short-term ITSL of 2100 µg/m³ with a 1-hr averaging time was based on a human study in asthmatics where a No-Observable-Adverse-Effect-Level (NOAEL) was identified. Typically, an RfC derived ITSL will have a 24-hr averaging time pursuant to Rule 232(2)(b). However, the RfC is designed to be protective of life-long (i.e., 70 years) exposure scenarios. Coupled with a short-term ITSL, the annual averaging time was deemed sufficient to protect the nasal mucosa and lungs from extended exposure durations. The regulatory authority to use an alternative averaging time for an RfC derived ITSL is provided by Rule 229(2)(b).

Summary of EPA's RfC Derivation

In a chronic inhalation study, Sellakumar et al. (1985) exposed 99 male Sprague-Dawley rats, 9 weeks of age, for 6 hours/day, 5 days/week for life to 0 or 10 ppm (14.9 mg/m³) HCl. The critical effects observed were hyperplasia of nasal mucosa larynx and trachea. Specifically, laryngeal hyperplasia was observed in 22% of the test animals, compared with 2% of control animals, and tracheal hyperplasia in 26% of the test animals, compared with 6% of controls. A No-Observable-Adverse-Effect-Level (NOAEL) was not identified in this study. The Lowest Observable-Adverse-Effect-Level (LOAEL) of 15 mg/m³ was adjusted (ADJ):

LOAEL(ADJ) = LOAEL x 6 hours/24 hours x 5 days/7 days

LOAEL(ADJ) = 15 mg/m³ x 6 hours/24 hours x 5 days/7 days

LOAEL(ADJ) = 2.7 mg/m³

According to EPA methodology (EPA, 1994), the LOAEL(HEC) was calculated using the regional deposited dose ratio (RGDR) for a gas as a respiratory effect in the extrathoracic (ET) and tracheobronchial (TB) regions combined.

RGDR(ET+TB) = (MVa/Sa)/(MVh/Sh)

Where, MVa (minute volume of animal) = 0.5 m^3/day, MVh (minute volume of human) = 20 m^3/day, Sa (surface area animal) = (15.0 ET + 22.5 TB) = 37.5 cm^2, and Sh (surface area human) = (200 ET + 3200 TB) = 3400 cm^2.

RGDR(ET+TB) = [(0.5 m^3/day)/(37.5 cm^2)]/[(20 m^3/day)/(3400 cm^2)]

RGDR(ET+TB) = 2.27

The LOAEL human equivalent concentration (HEC) then becomes:

LOAEL(HEC) = LOAEL(ADJ) x RGDR

LOAEL(HEC) = 2.7 mg/m^3 x 2.27

LOAEL(HEC) = 6.1 mg/m^3

The RfC is then calculated by using uncertainty factors (UF):

3	Intraspecies differences
10	Intraspecies differences
10	Extrapolate from a LOAEL to a NOAEL

The total UF is 300.

The RfC then becomes:

RfC = LOAEL(HEC)/UF

RfC = (6.1 mg/m^3) / 300

RfC = 0.02 mg/m^3 or 20 µg/m^3

Excerpt from EPA IRIS:

> The Albert et al. (1982) study, discussed in detail by Sellakumar et al. (1985), reported data from a chronic inhalation exposure study in rats. One hundred male Sprague-Dawley rats were exposed to 10 ppm hydrogen chloride (HCl) for 6 hours/day, 5 days/week (duration-adjusted concentration = 2.5 mg/m^3) for their lifetimes. All animals were observed daily, weighed monthly, and allowed to die naturally or killed when moribund. Complete necropsy was performed on all animals, with particular attention given to the respiratory tract. Histologic sections were prepared from the nasal cavity (one lateral section from each side of the head), lung (one section from each lobe), trachea, larynx, liver, kidneys, testes, and other organs where gross pathological signs were present. However, Sellakumar et al. (1985) did not discuss histopathological events in organs other than the respiratory tract. HCl-exposed animals showed no differences in body weights or survival when compared with air controls. The data indicated 62/99 exposed animals with epithelial or squamous hyperplasia in the nasal mucosa (location not specified) vs. 51/99 in the concurrent control group. Incidence of squamous metaplasia was 9 and 5 in the exposed and control rats, respectively. There was

a 24% incidence of hyperplasia of laryngeal-tracheal segments in HCl- exposed rats (larynx 2/22, trachea 6/26) vs. 6% in the controls. The authors did not make any comments concerning the severity of these changes. Based on these results, the 10-ppm (15-mg/m^3) concentration can be considered a LOAEL [LOAEL(HEC) = 6.1 mg/m^3].

Summary of Acute Screening Level Derivation

The acute ITSL for HCl was based on the acute Reference Exposure Limit (REL) derived by California (California OEHHA, 2008). A summary of data used to calculate the REL is shown below:

Reference Exposure Level (protective against mild adverse effects): 1.4 ppm (2,100 µg/m^3)

Study	Stevens et al., 1992
Study population	10 asthmatics, aged 18-25
Exposure method	inhalation via half face mask to 0.8 or 1.8 ppm HCl
Critical effects	upper respiratory system symptoms of sore throat; nasaldischarge
LOAEL	not observed
NOAEL	1.8 ppm
Exposure duration	45 minutes
Extrapolated 1 hour concentration	1.4 ppm (1.81 ppm* 0.75 h = C1 * 1 h)
LOAEL uncertainty factor	1
Interspecies uncertainty factor	1
Intraspecies uncertainty factor	1
Cumulative uncertainty factor	1
Reference Exposure Level	1.4 ppm (2.1 mg/m^3; 2,100 µg/m^3)

References

Albert, R.E., A.R. Sellakumar, S. Laskin, M. Kuschner, N. Nelson and C.A. Snyder. 1982. Gaseous formaldehyde and hydrogen chloride induction of nasal cancer in rats. J. Natl. Cancer Inst. 68(4): 597-603.

EPA. 2012. Reference Concentration for Hydrochloric Acid. U.S. Environmental Protection Agency, Integrated Risk Information System (IRIS) on-line database. http://www.epa.gov/iris/subst/0396.htm

California OEHHA. 2008. Acute Toxicity Summary for Hydrogen Chloride. TSD for Noncancer RELs June 2008. Air Toxicology and Epidemiology Branch, Office of Environmental Health Hazard Assessment (OEHHA). Appendix D2. Pages 112-118. http://oehha.ca.gov/air/hot_spots/2008/NoncancerTSD_final.pdf

Sellakumar, A.R., C.A. Snyder, J.J. Solomon and R.E. Albert. 1985. Carcinogenicity for formaldehyde and hydrogen chloride in rats. Toxicol. Appl. Pharmacol. 81: 401-406.