MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

February 6, 2017

TO: File for Butyraldehyde (CAS No. 123-78-8)

FROM: Mike Depa, Air Quality Division, Toxics Unit

SUBJECT: Derivation of Initial Threshold Screening Level

The initial threshold screening level (ITSL) for butyraldehyde is 7 µg/m^3, with annual averaging time.

Previously, the averaging time (AT) assigned to the butyraldehyde ITSL was 24 hours, pursuant to Rule 232(2)(b) of the Air Pollution Control Rules promulgated at that time (April 13, 1994; see attached memo). The recently promulgated (December 22, 2016) Air Pollution Control Rule 232(2)(b) states that ITSLs based on Rule 232(1)(a) are assigned an annual averaging time. An updated literature review was not performed at this time.

MICHIGAN DEPARTMENT OF NATURAL RESOURCES

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INTEROFFICE COMMUNICATION

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April 13, 1994

TO: File for BUTYRALDEHYDE (CAS #123-72-8)

FROM: George Eurich

SUBJECT: Screening Level for Butyraldehyde

The following sources were searched for information on this compound:

RTECS	NIOSH REL
IRIS	NTP MANAGEMENT STATUS REPORT
EPB LIBRARY	IARC MONOGRAPHS
ACGIH	EPS CHEMICAL CRITERIA DATABASE
HEAST	CAS ONLINE (1967—1994)
NLM SEARCH (1981—1993)	

The ITSL is based on a 14 week inhalation LOAEL in beagle dogs of 125 ppm. Beagle dogs (4 male/dose, 9.5-12 mos. old, 11.5 kg avg. wt.) were exposed to a butyraldehyde vapor of 0, 125, 500, or 2000 ppm for 6 hrs/day, 5 days/week, for 14 weeks. Treatment parameters measured included body and organ weights, urinalysis, hematology and blood chemistry, ophthalmology, and gross and histopathology. No dogs died during the treatment period. All were sacrificed at the end of the experiment. Tissues for histopathology were collected from all highest exposure dogs and lower exposure dogs if a lesion was detected at the 2000 ppm dose group. There were no significant differences in body weight or organ weight, with respect to controls, at any dose level. Significant differences in hematology and clinical chemistry were random and not considered exposure related. All dogs at the 2000 ppm dose exhibited conjunctivitis as well as one dog at the 500 ppm dose. Histopathology revealed significant microscopic lesions of the upper respiratory tract in the 2000 ppm dose, including chronic rhinitis, nasal mucosal ulceration, and alteration to squamous type cells in the nose and possible larynx and trachea. Dose at the 125 and 500 ppm dose exhibited goblet cell hyperplasia but no mucosal damage. There were no other significant differences from controls due to butyraldehyde inhalation. All treatment levels exhibited lacrimation, salivation, and nasal discharge. The 125 ppm dose level will be used as a LOAEL to calculate a RfD. This dose level produced squamous cell metaplasia in Sprague-Dawley rats in a 13 week inhalation study. There was no evidence that there was progression to carcinogenic endpoints. If a chronic bioassay provides data to the contrary, this screening level will be adjusted to take such information into account.

The ITSL = RfC, calculated as follows:

RfC Determination for Butyraldehyde:

LOAEL = 125 ppm
NOAEL = LOAEL/10 = 12.5 ppm

Uncertainty factors: 10 animal to human, 10 normal to sensitive, 10 subchronic to chronic

Conversion to mg/m^3 (12.5 ppm x 72.12)/24.45 = 37 mg/m^3

NOAEL(adj) = 37 mg/m^3 x 6 hrs/day x 5 days/week = 7 mg/m^3 (Eq. 4-3)

$NOAEL(hec) = NOAEL(adj) \times RDDR_{ER}$ (Eq. 4-7)

$RDDR_{ER} = (RDD_{ER})_A / (RDD_{ER})_H$, the ratio of the dose available for uptake from the entire respiratory system of the experimental animal species to that of humans, = 1 when each is unknown.

NOAEL(hec) = 7 mg/m^3 x 1 = 7 mg/m^3 (Eq. 4-1)

RfC = NOAEL(hec))/(UFxUFxUF)

RfC = 7 mg/m^3/1000 = 0.007 mg/m^3 = 7 $\mu g/m^3$

ITSL = RfC = $\mu g/m^3$ based on 24 hr average time.

Reference:

EPA-OTS (1988). Butyraldehyde vapor inhalation by dogs and rats for 14 and 13 weeks respectively and a 12 week vapor inhalation study in rats with attached cover letter 2/22/88. Carnegie—Mellon Institute for Union Carbide Corporation, provided to Environmental Protection Agency, Office of Toxic Substances. Washington, D.C., EPA-OTS Document FYI-OTS-1088-0647D.

EPA. 1990. Interim methods for development of inhalation reference concentrations - review draft. EPA/600/8-90/066A.

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