MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

TO: File for Vinyl Chloride-Vinyl Acetate Copolymer (CAS # 9003-22-9)

FROM: Keisha Williams, Air Quality Division (AQD)

DATE: February 2, 2017

SUBJECT: Screening Level Update for Vinyl Chloride-Vinyl Acetate Copolymer

The AQD Toxics Unit has determined that it is appropriate to use the approach described in footnote #26 of the air toxics screening level list, where a toxic air contaminant (TAC) is regulated under the national ambient air quality standards (NAAQS) for particulate matter (PM). This will be done rather than use health-based screening levels for vinyl chloride-vinyl acetate.

The AQD Toxics Unit conducted a thorough review of the toxicological literature for vinyl chloride-vinyl acetate in 1994 (see attached memo dated August 24, 1994). That assessment determined that if an Initial Threshold Screening Level (ITSL) were to be established using the methodologies for ITSL development, the resulting ITSL would be higher than the PM NAAQS. This TAC is reasonably anticipated to appear in regulated air emissions as PM. So, to ensure health protection, this TAC will be regulated through the current, applicable PM NAAQS along with the combined ambient impact of all particulate emissions from a process.

MICHIGAN DEPARTMENT OF NATURAL RESOURCES

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INTEROFFICE COMMUNICATION

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AUGUST 24, 1994

TO: File for Vinyl Chloride-Vinyl Acetate Copolymer (CAS # 9003-22-9)

FROM: Michael Depa, Toxics Unit

SUBJECT: Screening Level Determination

The initial threshold screening level (ITSL) for vinyl chloride-vinyl acetate copolymer is 50 µg/m^3 based on annual averaging time.

The following references or databases were searched to identify data to determine the ITSL: IRIS, RTECS, ACGIH Threshold Limit Values, NIOSH Pocket Guide to Hazardous Chemicals, Environmental Protection Bureau Library, IARC Monographs, CAS Online (1967-April 16, 1994), National Library of Medicine, Health Effects Assessment Summary Tables, and NTP Status Report. Review of these sources found that EPA has not established a RfC or RfD for vinyl chloride-vinyl acetate copolymer. Occupational exposure limits were not available for vinyl chloride-vinyl acetate copolymer. There was no inhalation data meeting the minimum criteria for establishing an RfC. However, vinyl chloride-vinyl acetate copolymer is a particulate at standard temperature a pressure. Therefore it was deemed appropriate to use the National Ambient Air Quality Standard for particulates (50 µg/m^3 based on annual averaging time) for the screening level. The safety of this value was supported by using data obtained from an oral bioassay. This oral bioassay is described below.

Groups of 12-15 Wistar rats of each sex received 0, 0.61 or 5.75 g/kg/day vinyl chloride-vinyl acetate copolymer for up to 2 years (Smyth, 1966). Each dose group was allowed to reproduce and their offspring receive the same diet as their parents. The number and size of the litters were not statistically different from control. At death or sacrifice gross pathology was recorded, and neoplasms were sought. Body length was measured, and liver and kidneys were weighed. Adrenal, small intestine, kidney, liver, lung, pancreas, spleen, testis and neoplasms were examined histopathologically. At one year, the livers of rats fed the dose of 5.75 g/kg/day were significantly heavier ($p < 0.05$) than those of the controls. The livers were histologically normal. After two years, the mean relative kidney weight (relative to body weight) of the rats fed the dose of 5.75 g/kg/day was significantly lower ($p < 0.05$) than control rats.

The confidence of this study is low. This study was completed in 1947, but was not presented until 1966. The published results of this study do not provide the number of rats examined at the one year or two year point. However, the authors state, “The tissues of the 38 rats sacrificed for examination after one or two years were histopathologically normal.” Seventy-five rats died of lung infection. Seventeen were killed for middle ear infection, and four for other reasons. A careful search of all rats dying or sacrificed revealed 6 neoplasms. The authors said that this is “possibly because half the rats did not survive the

lung infection into the second year of feeding. At the 5.75 g/kg/day dose level there were two neoplasms in the mesentery, at the 0.61 g/kg/day dose level there was one uterine neoplasm, and the controls had one neoplasm in the mesentery and two in the lung.

A NOAEL of 0.61 g/kg/day was identified from this study. However, because of the low confidence of this study a modifying factor of 10 was used to account for the uncertainty associated with the results. Safety factors used in this study included a factor of 10 for subchronic to chronic, a factor of 10 for extrapolating from rats to humans, and a factor of 10 to account for sensitive sub-populations. The surrogate screening level was calculated as follows:

$$ITSL = \frac{NOAEL}{10\ x\ 10\ x\ 10\ x10} x \frac{weight\ of\ animal^{a}}{inhalation\ rate\ of\ animal^{a}}$$

$$ITSL = \frac{0.61 \frac{g}{kg}/day}{10{,}000} x \frac{0.41\ kg}{0.38\ m^3}$$

$$ITSL = 6.58\ x\ 10^{-5} g/m^3$$

$$ITSL = 66\ \mu g/m^3$$

The surrogate screening level for vinyl chloride-vinyl acetate copolymer was determined to be 66 µg/m^3 based on an annual averaging time. However, as mentioned above the National Ambient Air Quality Standard for particulates is 50 µg/m^3 based on a annual averaging time. This value was used for the ITSL because of the inert property of vinyl chloride-vinyl acetate copolymer.

Smyth, H., Well, C. 1966. Chronic oral toxicity of a vinyl chloride-vinyl acetate copolymer. Toxicology and Applied Pharmacology. 9: 501-504.

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a. EPA, 1988. Recommendation for and documentation of biological values for use in risk assessment. PB 88-179874.