MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

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INTEROFFICE COMMUNICATION

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TO: File for Bisphenol A/Epichlorohydrin resin (CAS # 25068-38-6)

FROM: Keisha Williams, Air Quality Division (AQD)

DATE: February 2, 2017

SUBJECT: Screening level update for Bisphenol A/Epichlorohydrin resin

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 bisphenol A/epichlorohydrin resin.

The AQD Toxics Unit conducted a thorough review of the toxicological literature for bisphenol A/epichlorohydrin resin in 1998 (see attached memo dated February 11, 1998). That assessment determined that if an Initial Threshold Screening Level (ITSL) were to be derived using the available research, the 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 ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

February 11, 1998

TO: File for Bisphenol A/Epichlorohydrin resin (CAS #25068-38-6)
FROM: Gary Butterfield, Toxics Unit, Air Quality Division
SUBJECT: Initial Threshold Screening Level (ITSL) for Bisphenol A/Epichlorohydrin resin

Bisphenol A/Epichlorohydrin resin is also commonly known as diglycidyl ether of bisphenol A, or DGEBPA. This material is also known by many different manufacturer names, including: EPON 828, Araldite GY250, Epikote 828, and Epidian 5 to mention some of the more common ones.

There are no OELs and EPA has no RfD or RfC for DGEBPA. An on-line literature search of CAS and NLM articles (on April 24, 1997) was conducted to look for relevant toxicity studies that could be used to develop the screening level. Patty's Industrial Hygiene and Toxicology has a good summary of the health effects. Gardiner et al (1992) also does a good summary of available toxicity data. However, both of these summaries contain many references to unpublished toxicity studies that were performed by the manufacturers of this compound. There are a few published animal studies, and fewer human occupational studies available that evaluated the toxicity of DGEBPA. Many of the animal studies were dermal application type toxicity studies which are of little use for calculation of the screening level.

The screening level request from the Permit Section described this material as being a thick liquid with very low vapor pressure. This is the general description for the uncured resin. Toxicity studies conducted with the uncured resin were reported by Hine et al (1958). In this study, groups of 10 male Long-Evans rats were fed diets containing the resin for 26 weeks, at dose levels of 0.2, 1 or 5% of diet. The uncured resin, Epon 828, killed 10 of 10 rats when fed in the diet at 5%. This study found that at the 1% diet dose level, there was a significant decrease in body weight gain. There were no significant lesions either grossly or microscopically observed at any dose level. However, the kidney/body weight ratio was significantly increased at both the 1 and 0.2% dose levels. In the absence of microscopic lesions it will be assumed that the 0.2% dose level, which converts to 150 mg/kg (from 0.002x0.076 kg/kg the default food consumption for Long-Evans rats) is the NOAEL. This no effect level is also supported by unpublished studies reported by Gardiner et al (1992) - see Appendix A. Subchronic toxicity tests, reproductive and teratogenicity rats studies found no effects at doses lower than this NOAEL, but these unpublished studies also found reduced body weights at doses higher than this NOAEL. The unpublished reproductive and teratology studies also found no observed increases in embryo/fetal toxicity or teratogenicity at doses that weren't maternally toxic.

Calculation of the screening level based on the equation from R232(e), and the no effects observed in rats at dietary levels of 0.2% or 150 mg/kg, from Hine et al (1958), is as follows.

$$ITSL = \left[\frac{\frac{150\ mg}{kg}}{10x100}\right] x \frac{1\ kg}{0.94\ m^3} = 160\ \frac{\mu g}{m^3}\ with\ annual\ averaging\ time$$

Where the 35 fold uncertainty factor in the equation from R232(e) was modified to 10 because the study length was 26 weeks instead of 7 days. This factor was maintained at 10, which is the factor usually applied to 13 week studies, because the study length is not significantly close to lifetime length to reduce it below the 10 fold factor.

It should be noted that the use of a dietary dose study for calculation of the screening level may not take in to consideration direct effects of the material on the pulmonary system. In the case of oils, there may be some concern for

development of lipid pneumonia, or other effects from the oil depositing on the surface of the lungs. Because the calculated screening level number is less than the occupational exposure level for oil mist of 5 mg/m^3, and the lack of any inhalation data for this particular chemical makes it impossible to recommend altering the above calculated screening level.

The DGEBPA material is a liquid with a very low vapor pressure. Its existence in the atmosphere would likely be as an aerosol, and would therefore be a contributor to atmospheric particulate matter. When considering limits for airborne emissions of this material, the NAAQS for particulate matter should be considered. The above calculated screening level is more than the NAAQS for PM, however, the presence of other PM (background) should also be considered when determining that NAAQS would not be violated.

References:

Clayton and Clayton. 1993. Patty's Industrial Hygiene and Toxicology, 4th Ed. pgs 39 1-402.

Gardiner et al. 1992. Glycidyloxy compounds used in epoxy resin systems: a toxicology review. Reg Toxicol Pharm 15:sl-s77.

Hine et al. 1958. The toxicology of epoxy resins. AMA Arch Ind Health 17: 129-144.

GB:SLB

cc: Mary Lee Hultin, AQD

APPENDIX A

The toxicity summary of Gardiner et al (1992) gave brief descriptions of some unpublished toxicity studies which gives supporting evidence to the 150 mg/kg oral NOAEL from Nine et al (1958) by identifying some type of adverse effects that occurred at doses higher than 150 mg/kg, or in some cases identified no effect levels that were higher than 150 mg/kg.

1.) Smith et al. 1989. A study of the effect of TK10490 on the reproductive function of one generation in the rat. Report to Ciba-Geigy Limited, Huntingdon Research Center Ltd.

Gavage doses of 0, 20, 60, 180 or 540 mg/kg were administered to male rats for 10 weeks prior to mating, and to female rats for 2 weeks prior to mating in a one generation study. There was a decrease in mean male body weight at 540 mg/kg. There were no effects on mating performance, gestation period, or ability of the females to successfully raise off spring to weaning. There were no changes in organ weights, or histological changes in the reproductive or alimentary tracts.

Note that this brief summary indicates that the NOAEL would be 180 mg/kg which is slightly higher than 150 mg/kg.

2.) Smith et al. 1988. A study of the effect of TK10490 on pregnancy of the rat. Report to Ciba-Geigy Limited, Huntingdon Research Center Ltd.

Pregnant rats received gavage doses of 0, 60, 180 or 540 mg/kg. Signs of maternal toxicity occurred at 540 mg/kg. There were no effects on: mean litter size, pre- or post-implantation losses, evidence of teratogenic or embryotoxic effects at any dose level. Note that this brief summary indicates that the NOAEL would be 180 mg/kg which is slightly higher than 150 mg/kg.

3.) Smith et al. 1988. A study of the effect of TK10490 on pregnancy of the rabbit. Report to Ciba-Geigy Limited, Huntingdon Research Center Ltd. CBG 440/871639.

Pregnant rabbits were given gavage doses of 0, 20, 60 or 180 mg/kg. Signs of maternal toxicity occurred at 180 mg/kg. The were no effects on mean litter size, pre- or post- implantation losses, evidence of teratogenic or embryotoxic effects at any dose level. Note that this brief summary indicates that the LOAEL would be 180 mg/kg which is only slightly higher than the rat oral NOAEL of 150 mg/kg.

4.) Wolf. 1958. Results of dietary feeding of 2,2'-bis(p-2,3-epoxypropoxy)phenyl propane to male rats. Dow Chemical Company.

Rats were fed diets containing up to 3% DGE3PA for 3 months. At the highest dose level rats rejected consumption of the diet and exhibited signs of malnutrition. There was no evidence of systemic toxicity at any dose level tested.

5.) Basler et al. 1984. TK 10490: 28 Day subacute oral toxicity study in rats. GU project 830199. Ciba-Geigy Ltd, Basel.

Rats were given gavage doses of 0, 50, 200 or 1000 mg/kg of Araldite GY250 for 28 days. There were no effects on body weight, food consumption, water consumption, food conversion, mortality, clinical signs, hematology, blood chemistry, organ weights, histopathology of spleen, heart, liver, kidney, adrenal glands.

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