BASIC ACRYLIC MONOMER MANUFACTURERS, INC.
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July 20, 2021

Tyler Saechao
Office of Environmental Health Hazard Assessment 1001 I Street
P.O. Box 4010, MS-12B
Sacramento, California 95812-4010

Submitted via OEHHA Online Comment Submissions

RE: Comments on Notice of Intent to List Chemicals by the Labor Code Mechanism: Tetrahydrofuran; 2-ethylhexyl Acrylate; Methyl Acrylate; and Trimethylolpropane Triacrylate, Technical Grade

Dear Mr. Saechao:

Basic Acrylic Monomer Manufacturers, Inc. (BAMM)[1] appreciates the opportunity for comment in response to the Office of Environmental Health Hazard Assessment (OEHHA)'s proposal to list, among others, 2-ethylhexyl acrylate (2-EHA) and methyl acrylate (MA) under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). BAMM's members manufacture these acrylates, which have long been used safely as part of polymers in many products.

MA and 2-EHA are proposed for listing pursuant to the "Labor Code mechanism," following the International Agency for Research on Cancer (IARC) classification of these chemicals as Group 2B carcinogens with sufficient animal evidence. BAMM is aware that OEHHA will not respond to comments relating to scientific arguments, because OEHHA considers such listings "ministerial." Nonetheless, BAMM wishes to state its position on the scientific evidence for the public record.

[1] BAMM members are Arkema Inc., BASF Corporation, and Dow. Chemicals represented by BAMM are acrylic acid, n-butyl acrylate, ethyl acrylate, i-butyl acrylate, methyl acrylate, t-butyl acrylate, 2-ethylhexyl acrylate, hydroxyethyl acrylate and hydroxypropyl acrylate. *See* www.bamm.net.

As explained in more detail in BAMM's position statement on the IARC classifications, which is attached to this comment letter, BAMM strongly believes that these Group 2B classifications are erroneous and misleading, and are based on poor science and a flawed process. For example, IARC did not take into account the high dosage and associated corrosion effects in certain studies or the genetic deficiencies in the animals used for other studies. In short, the observed tumors in animal studies are not relevant to humans. Therefore, BAMM believes an IARC Group 2B listing (and Proposition 65 listing) is inappropriate, unwarranted and misleading.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Elizabeth Hunt
Executive Director

Encl.

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STATEMENT OF THE BASIC ACRYLIC MONOMER MANUFACTURERS, INC. (BAMM) REGARDING THE RECENT IARC CANCER CLASSIFICATIONS FOR THREE ACRYLATES

JULY 9, 2018

The International Agency for Research on Cancer (IARC) has announced the cancer classifications made at its June 5-12, 2018 meeting.[1] This includes classifications for three acrylates represented by BAMM.[2] Ethyl acrylate (EA) remains in Group 2B ("possibly carcinogenic to humans"). Methyl acrylate (MA) and 2-ethylhexyl acrylate (2EHA) also have been classified as Group 2B.

BAMM strongly believes that the Group 2B classifications for MA, EA, and 2EHA are erroneous and misleading, based on poor science and a flawed, non-transparent process. All these substances are well studied and the evidence strongly shows they are highly unlikely to cause cancer in humans. BAMM member companies stand behind the safety of their acrylates for their intended uses. Acrylates are building blocks for polymers used to produce goods that for decades have provided added benefits and convenience to consumers and manufacturers worldwide, such as acrylic paints and textiles, water purification substances, and self-adhesive bandages.

IARC first classified EA in Group 2B in 1986 based on forestomach tumors in treated rats and mice. However, the evidence strongly indicates the tumors do not result from built-in ability of EA to cause cancer, but from tissue corrosion due to the huge amount of EA delivered directly to the rodent forestomach. For this reason, the U.S. National Toxicology Program removed EA from its Report on Carcinogens in 2000, finding the rodent forestomach tumors are not relevant for humans.

IARC now refers to thyroid tumors in rodent studies of EA, but the tumor incidence was within the background range of other studies or the incidence did not increase with the amount of treatment. Neither the study authors nor any other reviewer has considered these studies to show cancer-causing potential for EA. IARC also points to some positive genotoxicity assays, but admits that "overall the findings were equivocal due to inconsistencies and lack of reproducibility." In fact, the overwhelming majority of genotoxicity studies on EA show no genotoxicity.

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[1] Carcinogenicity of isobutyl nitrite, β-picoline, and some acrylates. www.thelancet.com/oncology, published online June 28, 2018, http://dx.doi.org/10.1016/S1470-2045(18)30491-1.

[2] BAMM members are Arkema Inc., BASF Corporation, and The Dow Chemical Company. Chemicals represented by BAMM are acrylic acid, n-butyl acrylate, ethyl acrylate, i-butyl acrylate, methyl acrylate, t-butyl acrylate and 2-ethylhexyl acrylate. See www.bamm.net.

For MA, IARC cites to tumors in two studies where MA was inhaled by the animals. Th authors of one study concluded that observed tumors, which appeared in non-treated animals as well as treated animals, were age-related and not due to MA. No other expert body has disagree with this conclusion. The other cited study was conducted recently in Japan and has not been published in the open literature nor publicly translated into English. The available Japanese summary does not include detailed data tables, bringing into question whether IARC adhered to its Preamble requirement to consider only publicly available government reports. The limited information BAMM has been able to obtain on this study indicates that the MA doses given to the animals were much higher than guidelines would advise. The MA was delivered in the air and the tumors were in the nasal passages, raising the strong possibility the tumors resulted fron tissue corrosion rather than intrinsic ability of MA to cause cancer.

As noted by IARC, 2EHA is not genotoxic. In a type of mouse with a genetic deficiency in wound healing, amounts of 2EHA applied directly to the skin in excess of the regulatory testing guidance caused skin tumors. The evidence indicates that the tumors were related to the tissue damage rather than to intrinsic ability of 2EHA to cause cancer. In another type of mouse without the genetic deficiency, 2EHA did not cause skin tumors.

Thus, for all of MA, EA and 2EHA, in some studies, treatment of rodents with very high corrosive doses produced tumors at the site of contact. These artificial laboratory conditions hav no relation to real-world use of the acrylates – humans simply would not have such exposures, and the evidence strongly indicates the observed tumors are not relevant for evaluating human cancer potential. The IARC Group 2B classifications are therefore inappropriate, unwarranted and misleading.

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For further information, please contact Elizabeth Hunt at e.hunt@comcast.net.