



Plastic Pipe and Fittings Association

800 Roosevelt Rd., Bldg. C, Suite 20 ▪ Glen Ellyn, IL 60137-5833
Phone: 630/858-6540 ▪ Fax: 630/790-3095 ▪ www.ppfa.org

July 22, 2021

VIA ELECTRONIC SUBMISSION (<https://oehha.ca.gov/comments>)

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

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:

The Plastic Pipe and Fittings Association (PPFA) hereby submits comments in response to the California Environmental Protection Agency Office of Environmental Health Hazard Assessment's (OEHHA) Notice of Intent to List Chemicals by the Labor Code Mechanism, dated June 11, 2021 (Notice), and request for comments on its intent to list Tetrahydrofuran (THF), Chemical Abstracts Service Registry Number (CAS RN) 109-99-9, among other chemicals, as a chemical known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). PPFA submits these comments to formally document its strong opposition to the listing of THF under Proposition 65 as a carcinogen. In addition, PPFA voices its support of the comments submitted on behalf of the Tetrahydrofuran Task Force.

PPFA is the trade association that represents the companies that manufacture plastic piping, fittings and solvent cements for plumbing and related applications, or supply raw materials, ingredients or machinery for the manufacturing process. PPFA and its members are strongly committed to the sustainable manufacture and use of plastic piping systems and works to (i) promote a regulatory environment in which the superior value of plastic piping products is recognized; (ii) provide users with relevant information needed to properly design, specify and install plastic piping systems; and (iii) promote an understanding of the environmental impact and benefits of thermoplastic piping products. PPFA works collaboratively with federal, state and local regulatory bodies to help develop and implement effective standards and regulations to meet those goals and stands ready to continue that work with OEHHA.

Further to OEHHA's Notice, it intends to list THF as a chemical known to the state to cause cancer under Proposition 65 pursuant to California Health and Safety Code, Section 25249.8(a); California Labor Code, Section 6382(b)(1); and Title 27, California Code of Regulations,

Section 25904(b) (the Labor Code mechanism). The Labor Code mechanism requires OEHHA, under the California Labor Code, Section 6382(b)(1), to add a chemical to the list of substances as known to the state to cause cancer under Proposition 65 when such substance has been identified by the International Agency for Research on Cancer (IARC) as a possible human or animal carcinogen.

While PPFA recognizes that OEHHA's proposed listing of THF is "ministerial", that "OEHHA cannot consider scientific arguments concerning the weight or quality of the evidence considered by IARC when it identified these chemicals," and that OEHHA "will not respond to such comments if they are submitted (Title 27, Cal. Code of Regs., section 25904(c))"¹, PPFA is nevertheless compelled to put OEHHA on formal notice that the IARC's evaluation of THF is inadequate and does not reflect the best available science.

Specifically, IARC's 2019 monograph classifying THF as a class 2B carcinogen, citing "*inadequate evidence* in humans" and "*sufficient evidence* in experimental animals for the carcinogenicity of tetrahydrofuran,"² fails to consider data regarding the human relevance of the animal tumors. Two reviews available in the published, open literature conclude, respectively, that (i) THF-induced liver carcinogenicity in mice is likely mediated in female mice via constitutive androstane receptor (CAR) activation, a non- genotoxic mode of action that has limited, if any, relevance to humans; and (ii) a quantitative weight of evidence analysis of mode of action information does not support classification of THF as a possible human carcinogen. PPFA asserts that if such data had informed IARC's evaluation of THF, the 2B classification would not be supported. Set forth below for OEHHA's reference are links to these reviews:

- [Choi, C. J.; Rushton, E. K.; Vardy, A.; Higgins, L.; Augello, A.; and Parod, R. J. \(2017\). Mode of action and human relevance of THF-induced mouse liver tumors. *Toxicology Letters* 276: 138-143, July; and](#)
- [Dekant, W. \(2019\). Tetrahydrofuran-induced tumors in rodents are not relevant to humans: Quantitative weight of evidence analysis of mode of action information does not support classification of tetrahydrofuran as a possible human carcinogen, *Regulatory Toxicology and Pharmacology* 109, 104499, December.](#)

Additionally, PPFA notes that, while the European Chemicals Agency (ECHA) is obligated to apply the harmonized classification of THF as a Category 2 carcinogen under the European Union's Classification, Labelling and Packaging legislation (EU CLP) (EC No. 1272/2008), the registrants of this substance state, "...THF should not be rated for carcinogenicity."³

The science surrounding the carcinogenicity of THF is unresolved and does not support IARC's determination or OEHHA's decision to list THF as a chemical known to the state to

¹ OEHHA, [Notice of Intent to List Chemicals by the Labor Code Mechanism: Tetrahydrofuran; 2-ethylhexyl Acrylate; Methyl Acrylate; and Trimethylolpropane Triacrylate, Technical Grade.](#)

² IARC, Some Chemicals That Cause Tumours of the Urinary Tract in Rodents. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 119. Lyon, France: IARC; 2019 at 220, available at <http://publications.iarc.fr/575>.

³ See ECHA, Tetrahydrofuran, Carcinogenicity, available at <https://echa.europa.eu/registration-dossier/-/registered-dossier/15474/7/8>. Accessed July 6, 2021.

cause cancer under Proposition 65. Moreover, listing THF as a carcinogen does not further the purposes of California's Labor Code, which was "enacted for the purpose of assuring safe and healthful working conditions for all California working men and women by authorizing the enforcement of effective standards, assisting and encouraging employers to maintain safe and healthful working conditions..." (California Labor Code, Section 6300). Simply put, THF is not known to pose a threat to the health of Californians and listing it as such diverts resources and energy that should be focused on identifying known carcinogens. PPFA urges OEHHA to avail itself of any mechanism possible to avoid listing THF as a chemical known to the state to cause cancer under Proposition 65. Should the listing nevertheless occur, PPFA respectfully requests that it be accompanied immediately by a No Significant Risk Level (NSRL) to assist responsible parties in ensuring compliance with the duty to warn.

We appreciate the opportunity to provide these comments. Please do not hesitate to contact Kimberly A. Pendo, PPFA General Counsel, at (312) 929-1964 (or at kpendo@clpchicago.com) if you have any questions.

Respectfully submitted,

PLASTIC PIPE AND FITTINGS
ASSOCIATION