Response to Comments Concerning the Notice of Intent to List
\(\text{N,N-Dimethylformamide, 2-Mercaptobenzothiazole, and Tetrabromobisphenol A}\)
as Causing Cancer under Proposition 65

Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
October 27, 2017

On June 30, 2017, the Office of Environmental Health Hazard Assessment (OEHHA) issued a Notice of Intent to List\(^1\) N,N-Dimethylformamide (DMF), 2-Mercaptobenzothiazole (MBT), and Tetrabromobisphenol A (TBBPA) under Proposition 65\(^2\) as chemicals known to the state to cause cancer. The June 30 notice initiated a 30-day public comment period that closed on July 31, 2017. This document responds to comments received on the Notice of Intent to List.

Effective October 1, 2015, the process by which OEHHA lists chemicals and substances via the Labor Code listing mechanism was adopted in regulation at Title 27, Cal. Code of Regs., section 25904\(^3\). Section 25904 outlines OEHHA’s existing procedures for Labor Code listings and incorporates court decisions interpreting the Proposition 65 statute as it applies to Labor Code listings\(^4\). In accordance with OEHHA’s longstanding practice and now required by that regulation, OEHHA provided an opportunity for the public to comment on whether the chemicals identified in the Notice of Intent to List meet the requirements for listing as causing cancer pursuant to Health and Safety Code section 25249.8(a) and Labor Code section 6382(b)(1).

OEHHA received three sets of comments addressing one or more of the chemicals in the Notice of Intent to List during the comment period from the Green Science Policy Institute, the American Chemistry Council North American Flame Retardant Alliance

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\(^1\) Notice of Intent to List Chemicals by the Labor Code mechanism: N,N-Dimethylformamide, 2-Mercaptobenzothiazole, and Tetrabromobisphenol A, available online at https://oehha.ca.gov/proposition-65/crnr/notice-intent-list-nn-dimethylformamide-2-mercaptobenzothiazole-and

\(^2\) The Safe Drinking Water and Toxic Enforcement Act of 1986 (codified at Health and Safety Code section 25249.5 \textit{et seq.}) hereinafter referred to as Proposition 65 or the Act.

\(^3\) All further references are to sections of Title 27, Cal. Code of Regs unless otherwise stated.

\(^4\) Specifically, Section 25904 excludes from listing any chemicals or substances classified by the International Agency for Research on Cancer (IARC) as Group 2B based on limited evidence of carcinogenicity in experimental animals as required by \textit{Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment}, (2012) 210 Cal. App. 4th 1082. Additionally, in the Second Interim Order of the \textit{Sierra Club v. Schwarzenegger (Brown)} case (Case No. RG07356881), the court ordered OEHHA to list chemicals when IARC concludes there is sufficient evidence of carcinogenicity in humans or animals, regardless of whether the final IARC Monograph on the substance or chemical has been published. See also, \textit{California Chamber of Commerce v Schwarzenegger et al.}, (2011) 196 Cal. App 4th, 233 clarifying that Labor Code listings are ministerial acts required by statute.
The three chemicals were identified by the International Agency for Research on Cancer (IARC) as having sufficient evidence of carcinogenicity in animals. DMF, MBT, and TBBPA were classified in Group 2A (probably carcinogenic to humans). Pursuant to Health and Safety Code section 25249.8(a), Title 27, Cal. Code ofRegs., section 25904(c) and in compliance with relevant case law, a chemical must be included on the Proposition 65 list if it is identified by IARC in the IARC Monographs series on the Evaluation of Carcinogenic Risks to Humans (most recent edition), based on sufficient animal or human evidence, as probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B). The three chemicals meet this criterion for listing.

After careful consideration of all the public comments received, OEHHA has determined that DMF, MBT, and TBBPA meet the requirements for listing as known to the state to cause cancer.

The public comments are summarized and grouped by commenter and chemical(s), and responses follow.

Green Science Policy Institute – all three chemicals

Comment: Supports listing of all three chemicals

Response: Comment noted, no response required.

ACC–NAFRA (North American Flame Retardant Alliance) – TBBPA

Comment: The IARC monographs are designed to identify a cancer hazard but not the potential risk expected from exposure to the hazard. The distinction between hazard and risk is critically important. For example, in the case of TBBPA, IARC identified it as a cancer hazard even when the risks are very low at current exposure levels.

Response: The commenter is correct in acknowledging that hazard is different and distinct from risk. The listing of chemicals under Proposition 65 is based on hazard, not risk. Health and Safety Code section 25249.8(a) incorporates California Labor Code section 6382(b)(1) into Proposition 65. The law requires that certain substances identified by IARC be listed as known to cause cancer under Proposition 65. Labor Code section 6382(b)(1) refers to substances identified as human or animal carcinogens by IARC. OEHHA’s implementing regulation in Title 27, Cal. Code of Regs., section 25904 provides in relevant part as follows:
b) A chemical or substance shall be included on the list if it is classified by the International Agency for Research on Cancer (IARC) in its IARC Monographs series on the Evaluation of Carcinogenic Risks to Humans (most recent edition), or in its list of Agents Classified by the IARC Monographs, as:

…(2) Probably carcinogenic to humans (Group 2A) with sufficient evidence of carcinogenicity in experimental animals, …

(Emphasis added)

IARC published on its website a list entitled “Agents Classified by the IARC Monographs, Volumes 1 - 115” (IARC, 2016). IARC concluded that TBBPA is classified in Group 2A (“probably carcinogenic to humans”), and that there is sufficient evidence of carcinogenicity in animals for TBBPA (Grosse et al., 2016). Thus, the chemical meets the criteria for listing in both the statute and regulation. Nothing in the law or regulation allows OEHHA to consider the potential levels of human exposure to the chemical at the listing stage of the process. Such information will be taken into account in the event OEHHA proposes a No Significant Risk Level (NSRL) for the chemical pursuant to Section 25701, et seq. of the regulations.

Comment: Assessments of TBBPA conducted in both Canada and the European Union that have considered real-world exposure scenarios have found that consumer exposures to TBBPA are not likely to cause adverse human health effects.

TBBPA that is used in a reactive application where it is transformed into a polymer resin, predominantly no longer exists and is therefore not available to migrate out of the product. Additionally, this polymer resin is typically in parts that are not readily accessible or handled by consumers.

ACC requests that OEHHA propose a NSRL for TBBPA if it proceeds with the listing.

Response: As noted above, the chemical TBBPA has been identified as posing a cancer hazard by IARC (Group 2A; probably carcinogenic to humans) and meets the criteria for listing in the statute and regulations. OEHHA makes an effort to propose NSRLs for carcinogens within the year following their listing if sufficient resources and scientific information is available. We will take ACC’s request for an NSRL for TBBPA under advisement.

Information provided in the comment about the manner in which TBBPA is incorporated into products (additive vs. reactive application) has implications for exposure, and can be taken into account when assessing exposure from use of a given product. Where a chemical is merely present in a product but there is no exposure to the chemical from use of the product, no warning is required.

Comment: When considering TBBPA for listing, OEHHA should evaluate current possible exposure pathways for reactive and additive TBBPA and the limited likelihood
of human exposure to reacted TBBPA. As such, we would recommend that any future listing of TBBPA be limited only to additive TBBPA uses.

**Response:** IARC did not limit its evaluation or identification of TBBPA to additive uses only. Limiting the listing in that manner would therefore be inappropriate. As noted above, the manner in which TBBPA is incorporated into products (additive vs. reactive applications) has implications for exposure, and can be taken into account by businesses when assessing exposure from use of a given product.

**Truscott MedSciAssociates – DMF**

**Comment:** In the context of the use of DMF in the manufacture of specialized gloves, the commenter requests that OEHHA work with state laboratories and industry accessible contract test laboratories to establish standardized sample preparation and test methods to reliably quantify available DMF, and require assessments to be made using the approved method(s).

**Response:** Proposition 65 does not expressly require the testing of products to determine exposure. Nonetheless, a business may determine the likelihood of exposure based on testing, knowledge of the product’s intended uses, and other factors. Businesses are free, if they choose, to conduct laboratory testing of their products to determine likely exposure to listed chemicals. The business could then determine the likely level of exposure from the product and use that information when deciding whether or not to provide a warning. OEHHA has not established test methodologies for calculating exposures to listed chemicals from specific products. OEHHA has adopted regulations that provide guidance concerning evaluating exposures to chemicals listed as known to cause cancer in Title 27, Cal. Code of Regs., section 25701 *et seq.*

**Comment:** Given that the development of successful alternative coatings or post-coating DMF reduction methods to reach acceptable inhalation and dermal exposure limits will take time, the commenter requests a 2.5-year grace period.

**Response:** Proposition 65 provides a 12-month “grace” period following the listing of a chemical before warnings are required. OEHHA does not have the authority to extend the period of time between the listing of a chemical and the date when warnings are required. Nothing in the law requires a business to stop using a chemical once it is listed. The law simply requires that warnings be provided where there are significant exposures to the chemical. Further, in the context of occupational exposures, if a warning is already provided under the federal or state Hazard Communication program, no additional warning is required. In the alternative, the business can provide warnings to consumers by using the warning methods and content in Title 27, Cal. Code of Regs., section 25600 *et seq.* of the regulations.
**Truscott MedSci Associates – MBT**

**Comment:** Requests that OEHHA continue to permit zinc mercaptobenzothiazole (ZMBT) to be used in gloves where chemical splash protection is needed (e.g., protection from hazardous chemicals including those that are carcinogenic – as are a majority of the 200 therapeutic chemicals listed by the FDA).

**Response:** Nothing in the law requires a business to stop using a chemical once a listing occurs. In this case, ZMBT is not being listed, only MBT. Further, the law simply requires that, 12 months after the listing, warnings be provided where there are significant exposures to the listed chemical. Further, in the context of occupational exposures, if a warning is already provided under the federal or state Hazard Communication program, no additional warning is required. In the alternative, the business can provide warnings to consumers by using the warning methods and content in Article 6 of the regulations.

**Comment:** In order to address residual ZMBT or MBT levels or concerns, glove extraction methods should appropriately represent the mode of potential exposure to the wearer. In this case, sweat from the hand would be the most common extracting fluid. Water or phosphate buffered saline (PBS) would be the most realistic extracting fluid to leach any unbound chemicals from the glove.

**Response:** Proposition 65 does not expressly require the testing of products to determine exposure. Nonetheless, a business may determine the likelihood of exposure based on testing, the product’s intended uses, and other factors. The business could also determine the likely level of exposure from the product. Businesses are free if they choose to conduct laboratory testing of their products to determine likely exposure to listed chemicals. OEHHA generally does not establish test methodologies for calculating exposures to listed chemicals from products. OEHHA has adopted regulations that provide guidance concerning evaluating exposures to chemicals listed as known to cause cancer in Title 27, Cal. Code of Regs., section 25701 et seq.

OEHHA notes that in cases where sweat is determined to be the most common ‘real world’ extracting fluid, then consideration should be given to the use of artificial sweat.

**Comment:** Requests a test method that appropriately distinguishes between MBT (CAS 149-30-4) and ZMBT (CAS 155-04-4). Recommends a GC-MS analysis, or any other method that provides the said differentiation.

**Response:** Proposition 65 does not expressly require the testing of products to determine exposure and OEHHA does not specify the use of any particular test method. A business may test for the concentration of the chemical in the product in order to estimate exposure to a listed chemical. The business could use this information in determining the likely level of exposure from the product. Businesses are free if they choose to conduct laboratory testing of their products to determine likely exposure to listed chemicals. OEHHA generally does not establish test methodologies for...
calculating exposures to listed chemicals from products. OEHHA has adopted regulations that provide guidance concerning evaluating exposures to chemicals listed as known to cause cancer in Title 27, Cal. Code of Regs., section 25701 et seq.

**Comment:** Requests that alternatively, OEHHA exempt gloves from the proposed Proposition 65 listing to avoid the differentiating test methods and apply a logical assessment of weighing the risk vs. benefit; or minimal, if any, risk vs. far greater proven risk of Chemo-drug carcinogen exposure.

**Response:** OEHHA cannot exempt a particular product from the application of the law. Proposition 65 does not allow OEHHA to take into account the risk versus the benefit of using a chemical when making a listing decision. However, Proposition 65 does not ban or limit the use of a given chemical in a product. It simply requires that a warning be provided when a business exposes a person to a significant amount of a listed chemical.

**Comment:** If reformulation of all gloves containing any trace of MBT is required or mandated, a 3-year grace period is requested to enable manufacturers to ensure the safety and quality performance of the new glove formulations, and obtain the required pre-market authorization from the FDA.

**Response:** Nothing in the Proposition 65 law requires a business to stop using a chemical once it is listed. The law simply requires that warnings be provided where there are significant exposures to the chemical. Further, in the context of occupational exposures, if a warning is provided under the federal or state Hazard Communication program, no additional warning is required. In the alternative, the business can provide warnings to consumers by using the warning methods and content in Article 6 of the regulations. Proposition 65 provides a 12-month "grace" period following the listing of a chemical before warnings are required. OEHHA does not have the authority to extend the period of time between the listing of a chemical and the date when warnings are required.