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Department of Toxic Substances Control

### NOTICE OF DEFICIENCY

This Attachment describes deficiencies identified by the DTSC in the Abridged Alternatives Analysis (AA) Report on Two-component Low- and High-pressure Spray Polyurethane Foam Systems Containing Unreacted Methylene Diphenyl Diisocyanate dated May 1, 2020, submitted by the responsible entities (REs) participating in the American Chemistry Council's Spray Foam Coalition.

All code section references are to the Safer Consumer Products (SCP) regulations, found in chapter 55 of division 4.5 of title 22 of the California Code of Regulations.

During the DTSC's review, additional information provided in the Abridged AA Report (dated May 1, 2020) and the REs' response to the public comments received by the DTSC on the Abridged Alternative Analysis Report for two-component low- and high-pressure spray foam insulation systems containing unreacted MDI (dated August 23, 2019) are considered. Several overarching issues and the areas of deficiencies were identified. In general, the Abridged AA Report mischaracterizes which products can be considered alternative must fit the definition of a Priority Product. Further, it is stated a reduction in exposure to the Chemical of Concern will not be considered an alternative due to it still being a Priority Product. These statements are inconsistent with the definition of alternative in the SCP regulations, as alternatives are not required to meet the definition of the Priority Product and a reduction in exposure is considered an alternative.

Further, there is a lack of supporting information and rationale for decisions made. Section 69505.7(a)(2)(A) states "the responsible entity shall include in the AA reports sufficient information for the Department to determine compliance with the substantive and administrative requirements ...." Several statements are made such as "what is readily known or readily available information," "currently available information," "there appears to be," "there is no expectation," and "there is no evidence." Neither references nor sufficient details are provided to support these statements. Additionally, "lack of commercialization" was used as rationale to eliminate many alternatives. However, these statements do not provide clear





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Gavin Newsom Governor rationale and are not sufficient to support decision-making. Lack of commercialization alone is not a reason to eliminate an alternative.

The Abridged AA Report is lacking some required information. The SCP regulations section 69505.7(a)(1) states that "Abridged AA Reports must include all of the applicable information specified ...." All required sections must be complete and submitted to DTSC to comply with the SCP regulations. This NOD identifies specific missing information below.

In addition to a general lack of supporting information and rationale, there are internal inconsistencies between the narrative provided, the tables summarizing the information, and the decisions made using the provided supporting information. Decisions, along with the narrative and information provided to support them, must provide a clear, consistent rationale. To ensure consistency and clarity, several sections of this Abridged AA Report will need to be revised, as further discussed below.

## **1.0 GENERAL COMMENTS**

#### 1.1 Supply Chain

The supply chain information for each responsible entity (RE) must be included in the Abridged AA Report, per section 69505.7(d)(1) of the SCP regulations and must include all defined contact information. This includes both mailing and electronic addresses, headquarters locations, phone number(s), title(s) if applicable, and website address, per section 69501.1(25). Supply chain information is missing for Icynene-lapolla, SES Foam, Barnhardt, and Rhino Linings Corporation. Additional contact information is missing for the following REs:

- Accella The full set of contact information is missing. Email, phone number, and website are required.
- SWD The full set of contact information is missing. Email, phone number, and website are required. These only need to be provided for the headquarters.
- BASF The full set of contact information is missing. Email, phone number, and website are required.
- DAP Email and website information is missing.
- DuPont Address, email, phone number, and website information is missing.
- Firestone Address, email, phone number, and website information is missing.
- A & B Filling Email and some addresses information is missing.
- ICP Website information is missing.

#### **1.2 Priority Product Information**

Please update the Abridged AA Report or advise on missing products from the RE's Priority Product Notifications (PPNs) to ensure product consistency between the PPN and the submitted Abridged AA Report. The following discrepancies currently exist for the listed responsible entities:

- [Barnhardt] The RE should clarify in their PPNs and in the Abridged AA Report that the A-side is included for all of their products.
- [Demilec] The submitted SDSs include the products Demilec APX 1.2 and Demilec APX 2.0. The Abridged AA Report and the submitted PPN include one Product, Demilec APX. Corrections are necessary to ensure consistency between the PPN, Abridged AA Report and submitted safety data sheets.
- [A & B Filling] Reconcile Product 1 Brand A in the PPN and the Abridged AA Report to be consistent with the SDSs submitted. Four different SDSs were submitted for Product 1 Brand A.
- [Accella] The RE needs to clarify the names of several products so that they can be properly tracked through the Abridged AA Report review process.
  - a. Foamsulate 220 Series is not included on the PPN but is listed in the Abridged AA Report and in the SDSs (Appendix A).
  - b. Foamsulate 200 is on the PPN, but it is not listed in the Abridged AA Report nor in the SDSs (Appendix A). Clarification is needed as to if this is a unique product or is meant to be Foamsulate 220.
  - c. The Abridged AA Report states that Premiseal 305 and 350 have been replaced.
    Please clarify when these two products were replaced to determine whether a
    Product Removal Notification must be filed or the PPN needs to be updated.
  - d. Please clarify in the Abridged AA Report whether a product name represents a series, e.g., Arctic, Winter, Regular, for example SealTite Pro Closed Cell, SealTite Pro One Zero, Foamsulate Closed Cell, and Foamsulate HFO.
  - e. Please clarify if SealTite Pro No Trim, as identified by the PPN, is the same as SealTite Pro No Trim 21, as identified by the SDS.
- [Firestone]
  - a. Please add F2780 Polyol Component B to the Abridged AA Report, as submitted in the PPN.
  - b. In some cases, multiple SDSs were submitted (e.g., 4500 and 4500R, 2733 and 2733R). Please clarify in the Abridged AA Report and in PPNs if these are unique products.
  - c. Please clarify the name of uploaded document #5887. The SDS name is listed as GacoFlashFoam without a corresponding product number. If needed, please submit the proper documentation.
- [Rhino Linings Corporation] All products currently in the market should be included on the PPN. Currently there are several products included in the Addendum to the Abridged AA Report and the submitted SDSs not included on the PPN (including Duratite CC2.5, B Component; Duratite CC2.8, B Component; Duratite CC3.0, B Component;

ThermalGuard CC2, B Component; ThermalGuard OC1.0, B Component; and ThermalGuard OC0.5, B Component).

- [BASF] Please clarify in the Abridged AA Report which products represent a series (e.g., 81255 F, R, S, SAZ, XF) and which are individual products.
- [Henry Company] Three B-side SDSs were submitted. Please clarify in the Abridged AA Report and update the PPN if these are unique products.
- [General Coatings] Please clarify:
  - a. a. Is the A- and B-side SDSs for Ultra-Thane 230 the same for Ultra-Thane 230 2.0 wall insultation closed cell, and Ultra-Thane 2.5, 2.7, and 3.0 roofing?
  - b. b. Is Ultra-Thane 050 the same as Ultra-Thane 050 OCX?
  - c. c. Is UPC Polymeric MDI the A-side SDS for 2.0, 500 MAX, and 500OCX?
  - d. d. What product on the PPN corresponds to Ultra-Thane 200?

All products entering the stream of commerce in California must be included on a PPN, per Section 69503.7(a) of the SCP regulations. In Section 3.1 (p. 8) "Priority Products Made by Responsible Entities Participating in this Alternatives Analysis Report," it states "...some REs wish to include certain products in the AA that were not sold in California at the time the Priority Product listing became effective, but may be sold in California in the future as part of expected product development (see Table 3.2)." In section 3.3 (p. 14) the Abridged AA Report states that "many of the products in Table 3.2 are likely available in California." For these products that are available in California, regardless of if the A-side was included with the original PPN, a PPN should be submitted. For REs whose products are currently not in the California market (e.g., Foam Supplies, Inc. and Creative Polymer Group), a PPN must be submitted when the product is introduced for sale in California. For REs that have already submitted a PPN (e.g., DAP Products, Inc., Johns Manville, General Coatings, Rhino Linings Corporation, and SWD Urethane), a new PPN needs to be submitted for all products introduced for sale in California if they are not listed on the current PPN.

#### **1.3 Scope of Relevant Comparison Factors**

The Abridged AA Report must be revised to include performance and cost in the scope of relevant factors, per SCP regulations sections 69505.4(b)(1) and 69505.4(b)(2). The statement in Section 4.2 (p. 21) *Optional Relevant Factors Included in Stage 1 of the AA*, is not accurate for the purpose of an Abridged AA Report.

Regarding the information in the "Basis" column of Table 4.3 (pp. 51-61), a statement on whether a material contribution or material difference is negligible should be clarified before the justification for each SPF grouping. This will help the author communicate clearly to the reader the decision made for relevancy of a given factor (e.g., economic impacts, technical feasibility, etc.). Presently, some of the wording in the "Basis" column leads the reader to think the factor is relevant when it is listed as not and vice versa.

#### **1.4 Relevant Exposure Pathways**

Please revise the exposure conceptual model as necessary according to specific comments listed in Section 2.11 of this notice. The exposure conceptual model is incomplete, as it does not incorporate information about exposure routes and potential adverse impacts. The exposure conceptual model should reflect both human and environmental exposure for the Priority Product and its alternatives throughout the life cycle of a product.

The evaluation of potential exposure should be expanded to other chemicals and not limited to the inadequately defined "MDI alternative." The concept of "MDI alternative" is vague and could be misleading. If the product is based on polyurethane chemistry (e.g., Section 4.4.1.4), the chemical replacement is relatively easy to identify. However, if the product is based on other types of chemical reactions (e.g., Michael addition, Section 4.4.1.5), it is not straightforward or appropriate to define a chemical as the MDI replacement. Even if a product is based on polyurethane chemistry, the definition of A-side and B-side could be misleading (e.g., Section 4.4.1.4). In addition, other components might also be important to consider while comparing exposure potential of MDI and "its replacement."

Additional analysis is needed to identify chemicals formed through environmental or biological transformations, and exposure potentials of these transformed chemicals need to be compared across the Priority Products and their alternatives. The discussion on exposure assessment focuses on the parent chemicals, with environmental fate and transformation chemicals missing from the discussion.

#### **1.5 Scope and Comparison of Alternatives**

Per section 69505.7(g)(1) of the SCP regulations, the Abridged AA Report must include a matrix, or other summary format, that provides a clear visual comparison that summarizes the information collected regarding the relevant adverse impacts, and their associated relevant exposure pathways and life cycle segments, for the Chemical of Concern and each alternative replacement chemical being considered, and the comparative results of evaluating this information.

Additional discussion is required regarding the information in Tables 5.2-5.4 of the Abridged AA Report. The tables contain a lot of data, but an analysis is lacking for how the data is used to support the conclusion.

#### **1.6 Supporting Information**

Please provide supporting information requested in the <u>Section II Specific Comments</u>, per section 69505.7(i)(1) of the SCP regulations.

#### **1.7 Implementation Plan**

Please revise the implementation plan as necessary according to specific comments listed in Section 2.14 of this notice. The Abridged AA Report Section 7 (p. 77-78) excludes manufacturers of high-pressure SPF systems from the Regulatory Response "Product Information for Consumers" due to the misinterpretation of section 69506.3 of the SCP regulations. Highpressure SPF systems are considered a "consumer product" under the SCP regulations and the users (or applicators) of high-pressure SPF systems are the consumers. Therefore, manufacturers of high-pressure SPF systems should provide the required information to the users (or applicators) of high-pressure SPF systems. In addition, the RE needs to evaluate their future products individually to determine whether it is appropriate to submit new PPNs under section 69503.7 of the SCP regulations. The conclusion made by Section 7.3 (p. 78) is not applicable to all the future products based on similar chemistry.

### **2.0 SPECIFIC COMMENTS**

#### 2.1 Functional, Performance, and Legal Requirements

Performance factors must be evaluated for the Priority Products, and if possible, the selected alternatives. Section 4.2 (p. 21) of the Abridged AA report states "[...] we encountered limitations in the available performance and cost data for some alternatives that are not commercialized." This statement is not logical on "performance." A prediction may be made, either quantitatively or qualitatively, for product performance based on chemical ingredients, which are known for some alternatives. Further, of the evaluated alternatives, Firestone/Gaco Canary (Patent # US 9359471 B2) and two Dupont Formulations (Patent # WO 2013/101682 A1 and Patent # WO 2018/005142 A1) have patents held by REs included in this Abridged AA report; therefore, additional information should be available from these entities. In the Response to Public Comments, it is stated in regard to performance information that "if additional information is available, it is likely proprietary to each company and thus not available for consideration." However, proprietary information is available to the REs who control that information and should be included in an appendix submitted along with a claim of trade secret protection for those REs. Please provide all available referenced performance parameters for both the Priority Products and evaluated alternatives using a visual matrix for comparison. In the Abridged AA report, Section 3.4 (pp. 14-15), various performance parameters are mentioned as relevant to the Priority Product. For the evaluated alternatives in the referenced patents these parameters have not been provided. Further, thermal resistance (R-value) is mentioned several times in the Abridged AA Report, but an acceptable baseline value is never quantified, making comparison between the Priority Products and alternatives difficult.

Please clarify if "reaction time," described in Section 3.7 (p. 20) of the Abridged AA Report is the same as "curing or polymerization rate" listed in Section 3.4 (p. 14).

Please provide a more detailed discussion on the useful life of the product and component shelf-life to support your relevance decision in Table 4.3 (p. 61), *Product Function and Performance, Are there material differences in the terms of the useful life of the product?* It is not clear if the decision is based on the useful life of the foam, the shelf-life of the components, or both.

Additionally, all applicable legal requirements for the Priority Product must be addressed in the Abridged AA Report, as per Section 69505.5(a)(1) of the SCP regulations. The REs must look at the legal requirements for labeling and packaging for the Chemical of Concern and the Priority Product that need to be met under California (CA) and federal law, as outlined by Section 69501.1(a)(41) of the SCP regulations, including the Federal Hazardous Substances Act (FHSA), California Hazardous Substances Act (CHSA), and California Air Resources Board (CARB) AB 1807 (Category IIb toxic air contaminant). Because MDI is a toxic air contaminant, the REs should address if any maximum achievable control technologies (MACTs) have been identified for SPF or if any National Emissions Standard for HAPs (NESHAPs) apply to the SPF warehouses, packaging facilities, or other related stationary sources.

#### **2.2 Identification of Alternatives**

Additional discussion is required regarding alternatives that are not spray polyurethane foam. Alternatives are not required to meet the definition of the Priority Product and not meeting that definition is thus not a reason to eliminate an alternative from consideration. For example, in section 4.4.2 (p. 34), lower MDI exposure approaches are eliminated from consideration because they themselves are Priority Products. However, under the definition of an alternative as defined below, an alternative includes any redesign of a Priority Product to reduce the concentration of the Chemical(s) of Concern in the Priority Product or to reduce exposures to the Chemical(s) of Concern in the Priority Product.

A more robust discussion of alternatives that reduce exposure should also be included, per Section 69501.1(a)(10)(D) of the SCP regulations. Further review of alternatives considered in the Abridged AA Report is required. Section 4.3 states "Alternatives' have a narrow definition in the context of the SCP program and are defined under [...]." The SCP definition of an alternative, per section 69501.1(a)(10), includes:

(A) Removal of Chemical(s) of Concern from a Priority Product, with or without the use of one or more replacement chemicals;

(B) Reformulation or redesign of a Priority Product and/or manufacturing process to eliminate or reduce the concentration of Chemical(s) of Concern in the Priority Product;

(C) Redesign of a Priority Product and/or manufacturing process to reduce or restrict potential exposures to Chemical(s) of Concern in the Priority Product; or

(D) Any other change to a Priority Product or a manufacturing process that reduces the potential adverse impacts and/or potential exposures associated with the Chemical(s) of Concern in the Priority Product, and/or the potential adverse waste and end-of-life effects associated with the Priority Product.

[Firestone] Further, additional information is required regarding alternatives included in the Abridged AA Report, including performance details and the current stage of product development. For the Gaco Canary alternative, the Abridged AA Report (p. 23) states that "the patent lists R values that the formulation "may" attain (but that is not supported by a publicly available report)" as part of the justification for exclusion; however, this information should be available to Firestone/Gaco as they are a RE and the holder of the patent. The Abridged AA Report also mentions that the Firestone/Gaco Canary product is not commercialized; however, lack of commercialization is not a valid reason to exclude an alternative. For the Firestone/Gaco Profill System<sup>™</sup>, please clarify whether a specific SPF formulation must be used with the ProFill System<sup>™</sup> or whether the system can be used more broadly with a variety of SPF products.

[Dupont] The Abridged AA Report also mentions that both Dupont products are not commercialized; however, lack of commercialization is not a valid reason to exclude an alternative

Please provide a group designation, like the Priority Products in Section 3.5 and Table 3.3, for each of the alternatives presented. Since each group has a unique application, performance requirements might differ across the groups, and some alternatives may be viable for certain groups or applications.

#### 2.3 Scope and Comparison of Relevant Factors – Adverse Environmental Impacts

#### 2.3.1 Adverse Air Quality Impacts

The Abridged AA Report must be corrected to reflect that MDI is a Hazardous Air Pollutant (HAP), as identified by the Clean Air Act and a <u>Toxic Air Contaminant (TAC</u>), as regulated by California Air Resources Board (CARB).

Please move the sentence " $CO_2$  emissions are likely dominated by the transport phase which, as noted is similar among all the products," from Table 4.3 (p. 53) "*Other global warming gas emissions*" to the cell " $CO_2$  emissions" (p. 53), if this is supported by SPFA's Lifecycle Assessment.

Particulate matter emissions in Table 4.3 (p. 53) should be evaluated during the "Use" phase (e.g., spraying the SPF). Currently, particulate matter emissions are only evaluated during the production phase.

Please provide CARB's determination on whether MDI contributes to tropospheric ozone production in Table 4.3 (p. 54). The opinion of the RE's is less impactful than the determinations of authoritative bodies and the data provided in the listed reference.

#### 2.3.2 Adverse Ecological Impacts

Table 4.3 (p. 54) *Adverse Ecological Impacts* must include all hazard traits associated with "adverse ecological impacts" and these factors should be considered for relevance. Adverse ecological impacts are defined in Section 69501.1(a)(3) of the SCP regulations and includes "biological or chemical contamination of soils" and "any other adverse effect as defined in section 69401.2(a), for environmental hazard traits and endpoints specified in article 4 of <u>chapter 54</u>." Environmental hazard traits include domesticated animal toxicity, eutrophication, impairment of waste management organisms, loss of genetic diversity, including biodiversity, phytotoxicity, and wildlife impairments to development, growth, reproduction, and survival.

Please revise the basis of relevance for the last four factors listed in Table 4.3 (p. 54) *Adverse Ecological Impacts* to consider the potential releases from the Priority Product and alternatives to the environment through accidental spills, leaks, or other reasonably foreseeable scenarios during the useful life and at the end-of-life of the product.

#### 2.3.3 Adverse Water Quality Impacts

In Table 4.3 (p. 55) *Adverse Water Quality Impacts,* under the *Municipal storm water systems section*, please consider the potential releases due to accidental spills, leaks, or other reasonably foreseeable scenarios during the useful life and at the end of life of the product. For clarity, please characterize the products of MDI's reaction with water. It seems that sedimentation and/or clogging of pipes could be issues, if waste is improperly dumped into storm drains or spills occur. If this is believed to be irrelevant, please provide additional clarification to exclude improper disposal.

#### 2.4 Scope and Comparison of Relevant Factors – Adverse Public Health Impacts

Additional information is required to support the claim in Section 5.1 (p. 65) of the Abridged AA Report that potential hazards from B-side ingredients in the alternative formulations would be expected to be similar to each other and to the B-side ingredients of the Priority Product. Table 5.1 *Comparison of A- and B-Side Components for Priority Products (Generic Formulae) and Identified Alternatives* lists chemicals and their functions associated with either the A- or B-side for the Priority Product and potential alternative; however, ingredients and their functions across the Priority Product and alternatives would be helpful in understanding the statement (Section 5.1, p. 65) "Thus any potential hazards from these B-side components would be expected to be similar across the identified alternatives."

DTSC recommends clearly defining how the A-side differs from the B-side, especially in the case of the potential alternative formulations. If a clear distinction cannot be made, DTSC may recommend evaluating all ingredients in alternative formulations that are functionally similar to pMDI and are identified to replace unreacted MDI, even if the ingredient is considered a B-side chemical. Section 6.1 *Potential Alternatives to Priority Products* states that BPA resins, silicon-based technologies, acetoacetate and tin catalyst, acrylates, or polycarbamates have been identified to replace the unreacted MDI in the Priority Product. Table 5.1 *Comparison of A- and B-Side Components for Priority Products (Generic Formulae) and Identified Alternatives* lists the function of ingredients for the Priority Product and potential alternative formulations. Even though pMDI's function is as a "Main Reactant" according to Table 5.1, the current assessment compares pMDI to A-side alternative ingredients that aren't listed as a "main reactant" but rather function as flame retardants (e.g., tetrabromo phthalate diol and triethyl phosphate), silicone based surfactants (e.g., DC-1107, DC-197, Tegostab B8469, and silicone polyether copolymer surfactant), or blowing agents (e.g., HFC-245fa and HFC-134a). Refining the scope of comparisons to MDI/pMDI would focus the assessment.

In Table 5.2 *Data for Relevant Factors – Ingredient-specific Hazards (Primarily from Pharos and ECHA)*, DTSC recommends separating human health from environmental hazard endpoints (e.g., acute and chronic toxicity, persistence, bioaccumulation). Group A and B human health endpoints could be summarized together. DTSC also recommends separating physical hazards (e.g., flammability) from human health and environmental hazard endpoints as well.

DTSC recommends using all available data sources to classify hazards. The methods in Section 5.1 (p. 71) state that Pharos outputs are used first to classify hazard traits and then additional sources (e.g., the European Chemicals Agency (ECHA), Australia Inventory Multi-tiered Assessment and Prioritasation (IMAP) assessments, and US EPA Robust Hazard Summaries) would be used to address remaining relevant factors such as the "Group B" endpoints. If data gaps are identified using Pharos, then there should be an attempt to fill those data gaps using the additional sources. It also appears that some data gaps for human health and environmental hazards have already been filled using the ECHA dossier findings reported in Table 5.3. These findings should be combined and reported in Table 5.2. Another example is with the classification of neurotoxicity hazards for difunctional acrylate A (CAS No. 55818-57-0). This hazard trait is listed as a Group A and Group B endpoint in Table 5.2, where research of ECHA finds that there is 'potential concern' due to a "Reduction in locomotive activity at a high dose, but dossier did not classify" but Pharos had neurotoxicity as a data gap. In this case, Table 5.2 should be revised to remove the data gap designation for neurotoxicity of difunctional acrylate A and replace it with potential concern.

With consideration to the scoring rationale in Section 5.1 of the Abridged AA Report, overall hazard score for each chemical ingredient based on human health, environmental, and physical hazard traits should be considered before determining a qualitative hazard score for the A-side

systems. The current method of counting hazard endpoints with a 'high' or 'very high' classification does not allow for a direct comparison between the Priority Product and potential alternatives, as conceded in Section 5.1 (p. 71).

In Section 5.1 of the Abridged AA Report, DTSC recommends providing additional analysis and discussion of the hazard screen. Even though the count approach does not allow for direct comparison between the Priority Product and potential alternatives, several hazard traits were identified. Dermatotoxicity, respiratory sensitization, and eye irritation are the hazard traits with high or very high hazard scores identified for the Priority Product. While the comparison of the Priority Product with alternative formulations tends to focus on the respiratory sensitization endpoint, hazard traits such as skin sensitization or aquatic toxicity were identified for some alternative formulation ingredients and should be considered in the decision making for retaining an alternative formulation. Additionally, please address the uncertainties and data gaps on the hazard identification for potential alternatives. Due to the lack of CAS numbers identified, four ingredients (sucrose acetoacetate, glycerin acetoacetate, polycarbamate, and polycarbamate 2) have data gaps for "all endpoints."

DTSC recommends adding the hazards listed in Pharos for pMDI to Table 5.2 *Data for Relevant Factors – Ingredient-specific Hazards (Primarily from Pharos and ECHA).* Table 5.2 states that hazards for pMDI (CAS No 9016-67-9) are not available in Pharos, however, DTSC has checked Pharos and information is currently available for pMDI.

DTSC recommends considering the mutagenicity hazard endpoint in Table 4.3 (p. 57) to be potentially relevant based on some chemical ingredients having "Potential Concern" (i.e., a hazard reported in sources that are not GreenScreen<sup>©</sup> authoritative or screening sources) reported for this endpoint.

# 2.5 Scope and Comparison of Relevant Factors – Adverse Waste and End-of-life Effects

Please include additional consideration in the Abridged AA Report concerning the potential accidental release and improper disposal. Accidental release of MDI and other chemicals due to a disaster, such as fire, is documented multiple times in the *Summary of Technical Information and Scientific Conclusions for Designating Spray Polyurethane Foam Systems with unreacted MDI as Priority Product*. Table 4.3 (p.57) *Effects on Storm Drains and Sewers* does not consider some reasonably foreseeable scenarios at the end of life such as improper disposal, accidental spills, or leaks. Further, Table 4.3 (p. 56) *Special Handling* does not consider the scenario where a high-pressure system may be reused as outlined in Section 4.7.11 (p. 50) of the Abridged AA Report.

#### 2.6 Scope and Comparison of Relevant Factors – Environmental Fate

In Table 4.3 (p. 58), the relevancy of "*Environmental fate, aerobic and anaerobic half-lives of the product, its constituents, or its likely breakdown products*" should be revisited and more supporting information should be provided. Considering the Conceptual Model in Figure 4.1 (p. 46) illustrates the life cycle of the Priority Product, degradation of the Priority Product in each environmental medium should also be considered for the whole life cycle of the product. For example, some alternatives contain metal oxides (*i.e.*, DuPont Formulations Patent No. WO 2018/005142 A1) with environmental residence times that will vary for different formulations. In addition, the "*Basis*" should consider the potential releases of component A and B to the environment due to accidental spills, leaks, or other reasonably foreseeable scenarios during the useful life and at the end of life of the products.

Further, in Table 4.3 (p. 58) *Environmental fate, bioaccumulation of the product, its constituents, or its likely breakdown products,* please thoroughly examine data availability, reevaluate bioaccumulation for the chemicals present in the Priority Products and alternatives, and re-evaluate its relevance accordingly. Although Pharos does not have bioaccumulation data, bioaccumulation factors and bioconcentration factors could be estimated using publicly available models such as US EPA's EpiSuite. For example, bioaccumulation factors could be estimated for a few chemicals (e.g., CASRN: 68928-76-7).

The relevance of soil in Table 4.3 (p. 58) *Environmental Fate, Mobility in Environmental Media* should be re-evaluated. Although DTSC concurs with the "Yes" assigned to *Mobility in Environmental Media* in Table 4.3 (p. 58), we disagree with the statement "However, not all environmental media are likely to be relevant (e.g., not soil)" listed under "Basis." Some chemicals (e.g., 1,4-dioxane as a component in SPF products) with low K<sub>oc</sub> and K<sub>ow</sub> can move very quickly through soil, but some will retain in soil for a long time (e.g., MgO).

# 2.7 Scope and Comparison of Relevant Factors – Materials and Resources Consumption Impacts

Clear rationale and the identification of the supporting information for the determination of irrelevant factors must be provided, per Section 69505.7(f) of the SCP regulations. In the Abridged AA Report, Table 4.3 (p. 59) *Impacts on consumption of non-renewable resources, including petroleum, coal, metals, minerals, and other finite resources, throughout the product life cycle*, states that, "the Priority Product and alternative formulations are likely produced from petroleum-based chemicals" as the basis for the justification that non-renewable resources, *including energy and raw materials, throughout the product life cycle*, states that, "Some spray foam insulation products (including some variants of the Priority Product) and one of the alternative formulations use renewable materials in the B-side. This should not result in a material difference between the Priority Product and alternative formulations." These

statements do not provide clear rationale and are not sufficient to support the assertion of irrelevance for non-renewable and renewable resources. More information regarding the percentage of Priority Products that always use bio-based polyols would provide valuable information.

#### 2.8 Scope and Comparison of Relevant Factors – Physical Chemical Hazards

Specific available information to support the statements, "Based on available chemical composition information, none of the products exhibit the oxidizing properties that facilitate combustion, explosivity, and flammability" in Table 4.3 (p. 59) must be provided. For example, provide flash points for the chemical ingredients of the products.

#### 2.9 Scope and Comparison of Relevant Factors – Physicochemical Properties

Clarification should be provided about the physical state of MDI and pMDI as it is found in the Priority Product. Table 5.4 states that MDI is a solid. However, Table 4.3 (p. 59) says that MDI is a liquid when applied. Please ensure consistency and update supporting information on the determination of relevance as needed.

Justification is required to support the determination of no relevance for diffusivity in air and water in Table 4.3 (p. 60), particularly for air.

In Table 4.3 (p. 60) *Redox potential* the statement "Organic chemicals do not possess this property" should be corrected. This is not accurate. Redox potential of organic molecules drives respiration.

Consider changing Table 4.3 (p. 60), *Water Solubility* to relevant. While, MDI has low solubility, the alternatives do not in all cases (Table 5.4). This could change exposure pathways along the entire lifecycle. Similarly, *Organic carbon partition coefficient* ( $K_{OC}$ ) values vary by as much as four orders of magnitude, which reflects a material difference.

Please consider better supporting the basis for the relevance determination in Table 4.3 (pp. 59-61). For example, the text clearly and succinctly states that vapor pressure is a better predictor of exposure than molecular weight. At a quick glance, that better justifies your determination that molecular weight is not relevant.

#### 2.10 Scope and Comparison of Relevant Factors – Life Cycle Segments

The Abridged AA Report needs to clearly explain the rationale and identify the supporting information for determining a life cycle segment as irrelevant.

Please clarify the statement in the conceptual exposure model in Figure 4.1 (p. 46) under Raw Material Extraction "Likely similar [among alternatives and Priority Products] unless bio-based or recycled ingredients are used (no evidence of this)." This is inconsistent with the narrative in

Section 4.7.1 (p. 47) and the rationale is not clear to sufficiently support the conclusion. In Section 4.7.1 (p. 47) on raw materials extraction, the Abridged AA Report states that "Based on the available information, they appear to be based on synthetic chemicals, primarily derived from petroleum-based feedstocks. On the B-side, some Priority Products have polyols obtained from renewable materials and it is not clear if this would be the case for the alternative formulations." These statements are not consistent because some renewable materials are used in the B-side feedstock. These are not plausible justifications because petroleum-based chemicals are diverse and have different toxicological properties. The conclusion does not consider any different quantities likely involved in any manufacturing and production processes of these products. Please consider and reevaluate the potential difference of adverse environmental and human health impacts associated with different quantities and different classes/groups of petroleum-based chemicals. In the case that the detailed quantitative analysis cannot be conducted due to the data availability, the qualitative estimate still needs be considered to determine whether a materials difference exists between the Priority Products and the alternatives.

In addition, the discussion of petrochemical-derived feedstocks for MDI and alternatives would more appropriately fall under the discussion for Chemical Ingredient Production (in the Conceptual Model) or Intermediate Materials Processes section (text) as opposed to raw material extraction. For example, as noted in Section 4.7.1 (p. 47), the synthesis of MDI directly involves three concerning Toxic Air Contaminants (TACs) (formaldehyde, aniline, and phosgene). Feedstocks for the alternatives may have different or similar concerns of toxicity. This may be more thoroughly noted in the discussion of Section 4.7.3 (p. 48) of intermediate materials processes.

Furthermore, please clarify the relevancy determination of transportation/distribution, operation and maintenance, and reuse/recycling segment. There is a discrepancy between the narrative provided in Section 4.7.6 (p. 49) and the summaries of determination of relevance of life cycle segments presented in Table 4.3 (p. 51). The statement "Based on their understanding of the industry, the REs would expect that these would be similar between the Priority Products and the possible alternative formulations..." leads the reader to deduce there is no material difference and therefore, this life cycle segment is not relevant. It is not clear that the decision to list transportation/distribution as "potentially" relevant is due to the data availability or uncertainty. Similarly, the narrative provided in Section 4.7.8 (p. 49) and Section 4.7.10 (p. 50) is inconsistent with the basis and conclusion for "operation and maintenance" and "reuse/recycling" segment in Table 4.3 (p. 52). Cleaning the spray rigs and the potential for exposure to workers during cleaning could also be considered under the "operation and maintenance" segment.

In addition, please consider revisiting the relevancy of life cycle segments after addressing the comments in Sections 2.3, 2.4, and 2.11 for consistency because the life cycle analysis

is intertwined with adverse environmental and public health impacts and their associated exposure pathways.

#### 2.11 Scope and Comparison of Relevant Factors – Exposure Pathways

Please revise conflicting statements in Section 4.4.1.1 (p. 27) *Firestone/Gaco Canary*, included in the Abridged AA Report. This section states "The hazards and relative exposure potential of these example chemicals can be qualitatively assessed and compared ....." However, it also states (on p. 28) "Over-all, Canary is not a viable alternative formulation for the Priority Products that can be further considered ... due to a lack of ... exposure potential ...." Exposure potential could be estimated based on physicochemical properties of known ingredients.

Exposure potential for the Hybrid Coatings Technology/Nanotech Industries Green Polyurethane<sup>™</sup> alternative should be estimated based on physicochemical properties since all major chemical ingredients have been listed. Section 4.4.1.3 (p. 29) states, "Green Polyurethane is not a viable alternative formulation for the Priority Products that can be further considered in the Abridged AA due to a lack of commercialization, exposure potential, and performance information." DTSC disagrees with the conclusion that there is a lack of exposure potential information as stated in the Abridged AA report.

In Section 4.5 (p. 44) *Relevant Factors*, please clarify the functional use of MDI in the Priority Product and re-evaluate the scope of relevant factor comparison to other ingredients. This section states "we had to tabulate data for the MDI functional replacement chemicals in the Aside of the alternative formulations ...." If the product is based on polyurethane chemistry, then the chemical replacement is relatively obvious to identify. However, if the product is based on other types of chemical reactions (*e.g.*, carbon-Michael chemistry, Section 4.4.1.5), it is neither straightforward nor appropriate to define a chemical as the MDI replacement, unless the function of MDI and its "replacement" in the chemical reaction can be clearly defined. In addition, as stated in Section 4, other components might affect the function of an active component, and therefore, exposure. Other components might also be important to consider while comparing exposure potential of MDI and "its replacement."

Please search product use data thoroughly and revise the product use statement. Section 4.6 (p. 44) *Relevant Exposure Pathways* states "We determined that these data ["product use (duration, frequency) as well as the volume of sales in California"] are not readily available for the Priority Products." Please refer to product use pattern as summarized by the USEPA in the <u>1,4-Dioxane Draft Risk Evaluation</u> (p. 68). Please evaluate the references listed in Table 3-17 on the page referenced above for details. The REs should have their own readily available data for the production volume and sales and use these data as a proxy to evaluate exposure factors per section 69503.3.(b)(1) of the SCP regulations. When identifying the relevant exposure pathways, the REs should also consider the chemical quantity information including estimated volume or mass of the Chemical of Concern or alternative replacement chemicals that is or would be placed into the stream of commerce in California (§ 69505.5.(c)(3)(A)).

Exposure to other chemicals in the vapor/particulate phase should also be considered in the Abridged AA Report. Section 4.6.1 (p. 44) *Conceptual Model for Product Life Cycle* states "due to MDI being heated to approximately 120°F during application of the product." In addition to MDI, other ingredients may also be vaporized in the process. In contrast, products not based on an exothermic reaction may reduce the chance of evaporating chemicals. Also, in addition to MDI vapors, please include MDI aerosols and dusts with unreacted chemicals as an exposure concern to workers via the inhalation pathway. For additional information please refer to DTSC's <u>Summary of Technical Information and Scientific Conclusions for Designating Spray</u> Polyurethane Foam Systems with unreacted MDI as Priority Product (DTSC 2017).

In Section 4.6.1 (p. 44) *Conceptual Model for Product Life Cycle,* please include chemical reaction time and yield information. Further, the addition of specific recommended re-entry and re-occupancy times per the manufacturer would be beneficial. This section states "For alternatives that may not cure as quickly, exposures for both workers and residents could be a concern." Although true, chemical reaction time and yield information are required to substantiate this statement. Additionally, in this section (p. 45), define workers as the applicator, the applicator helper, or other workers (defined as those on site, not involved in spray operations).

Please include exposures to toxic chemicals from thermal degradation of SPF, as well as information on how long post spray a worker should wait before trimming formed foam in Section 4.6.1 (p. 45) *Conceptual Model for Product Life Cycle*. The DTSC *Summary of Technical Information and Scientific Conclusions for Designating Spray Polyurethane Foam Systems with unreacted MDI as Priority Product* (DTSC 2017) states "Thermal degradation may be caused by fires and other heat-generating processes such as welding, soldering, grinding, sawing on or near SPF isolation, which may generate a range of airborne degradation chemicals including isocyanates, hydrogen cyanide, and others.

Worker exposures to MDI through accidental spills or leaks, cleaning and maintenance of the equipment, and as cited in the DTSC *Summary of Technical Information and Scientific Conclusions for Designating Spray Polyurethane Foam Systems with unreacted MDI as Priority Product* (2017) should be considered in Section 4.6.1 (p. 45).

In Section 4.6.1 (pp. 44-45) *Conceptual Model for Product Life Cycle,* please expand the discussion of personal protective equipment (PPE) to include the improper use of and imperfect fit or malfunction of PPE in addition to the failure to use PPE as stated in the DTSC *Summary of Technical Information and Scientific Conclusions for Designating Spray Polyurethane Foam Systems with unreacted MDI as Priority Product* (2017).

Figure 4.1 (p. 46) *Conceptual Exposure Model* should be modified, incorporating exposure media, exposure route, human and ecological receptors, and potential adverse impacts. If the exposure pathways for the Priority Product and alternatives are expected to be dramatically

different, multiple diagrams can be used to illustrate detailed exposure pathways. The conceptual exposure model in the "Preliminary (Stage 1) Alternatives Analysis Report, Methylene Chloride-Containing Paint or Varnish Removers" is one option to use as a starting point to re-develop the conceptual exposure model.

In Table 4.3 (p. 63) *Potential Exposure – Is there a difference in the frequency, extent, level, and duration of exposure potential for the product and its alternatives at the end-of-life, "Relevant?"* should reflect "Yes." Considering the chemical diversity in the Priority Product and alternatives, the environmental fate and transport, and therefore, the exposure potential, would be different between the Priority Product and its alternatives. This applies to both the cured products and chemical residues in cans, bottles, and drums.

Please fill in data gaps in Table 5.4 *Data for Relevant Factors* by using model-predicted values. A lot of property values are missing from Table 5.4. If measured data are not available, EpiSuite estimation results would be acceptable for use, and, with a spot check, DTSC could find EpiSuite modeling results for Tin Catalyst (CASRN: 68928-76-7) and Tetrafunctional Acrylate (CASRN: 94108-97-1). Please conduct a thorough check and fill in all data gaps. Also, an expansion of chemicals listed in the table is required. Column 4 in this table is entitled "MDI and Potential Replacement ingredients for MDI." If the product is based on polyurethane chemistry, the chemical replacement is relatively obvious to identify. However, if the product is based on other types of chemical reactions (*e.g.,* DuPont Patent No WO 2013/101682 A1), it is neither straightforward nor appropriate to define a chemical as the MDI replacement. In that situation, chemicals from both A- side and B-side should be listed and examined. In addition, as stated in Section 4, other components might affect the function of an active component (and therefore, exposure). Other components might also be important to consider while comparing exposure potential of MDI and "its replacement."

#### 2.12 Scope and Comparison of Relevant Factors – Economic Impacts

Claims that economic factors are not available must be substantiated. This can be accomplished by providing a rough estimate on the internal and external costs associated with changes to the Priority Product (e.g., manufacturing costs, marketing costs, materials and equipment acquisition costs, resource consumption costs). In Section 4.2 (p. 21), the Abridged AA Report states "That said, we encountered limitations in the available performance and cost data for some alternatives."

In Section 5.4 (p. 75), the RE should discuss the sources reviewed and available information, if any, to address the public health costs, cost to government, and costs to NGOs that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife. The RE should present information on internal costs based on a rough estimate of the internal and external costs associated with changes to the Priority Product (e.g., manufacturing costs, marketing costs, materials and equipment acquisition costs, resource consumption costs). Please describe your efforts in quantifying the costs by including resources and searches conducted, etc. Also, provided details to help the reader understand the general costs involved in commercializing a product (e.g., manufacturing costs, marketing costs, materials and equipment acquisition costs, resource consumption costs) and how these may impact an existing product line. A discussion on how these impacts eventually affect consumers based on the cost of existing versus new products would also be useful. An example is found in Section 4.4.3 where you state "Having an alternative for only certain types of the Priority Products could adversely complicate product production, requiring additional production facilities (I.e., more land use) and greater raw material transportation. It could also complicate worker training, as all spray foam workers currently need to receive training regarding the proper use of a single type of material."

In Section 5.4 (p. 75), a price range or typical industry price of a high-pressure SPF system will help the reader to understand the potential cost of the Firestone/Gaco Profill System<sup>TM</sup>.

In Section 5.4 (p. 75), a price range or typical industry price for traditional low-pressure kits and high-pressure SPF systems would be helpful for the reader to understand the potential HPLV system cost.

To satisfy the requirements of section 69505.6(a)(3) of the SCP regulations, the REs must demonstrate an attempt to "...evaluate, monetize, and compare the impacts for the relevant exposure pathways and life cycle segments the following impacts of the Priority Product and the alternatives:" (§69505.6(a)(3)(A))

- Public health costs (§69505.6(a)(3)(A)1.)
- Cost to government (§69505.6(a)(3)(A)2.)
- Costs to NGOs that manage waste, oversee environmental cleanup and restoration efforts, and/or charged with protecting natural resources, water quality, and wildlife (§69505.6(a)(3)(A)2.)
- Internal costs (§69505.6(a)(3)(B))

The cost discussions presented in Sections 4.2 and 5.4 of the Abridged AA Report lacked the information demonstrating the RE considered these costs.

#### 2.13 Evaluation and Screening of Alternatives

The Abridged AA Report needs to include the required matrix, or other summary format, that provides a clear visual comparison that summarizes the information collected regarding the relevant adverse impacts, and their associated relevant exposure pathways and life cycle segments, for the Chemical of Concern and each alternative replacement chemical being considered, and the comparative results of evaluating this information per Section 69505.7(g)(1) of the SCP regulations.

Please check and clarify the decision logic in the following statements. For example, Section 5.1 (p. 65) states "An evaluation of these potential alternative products revealed a similar B-side composition compared to that of the Priority Products (see Table 5.1),""a review of the information shown in Table 5.1 indicates that all of the alternatives have essentially similar chemistries (i.e., involving highly reactive chemicals and catalysts)," and "thus any potential hazards from these B-side components would be expected to be similar across the identified alternatives." An evaluation of the SDSs of the Priority Products and some of the alternative products provided by the Abridged AA Report revealed a varied composition of A-side and Bside chemicals. Even with similar chemistries for these products, the quantity of the different Aside and B-side chemicals could potentially change the hazards for the alternative formulations compared to the Priority Product formulations. Section 5.2 (p. 73) states "We could not evaluate performance parameters between the Priority Products and the potential alternatives because a complete set of necessary performance was lacking from each formulation or they are existing Priority Products." It is not clear which performance parameters and their minimum performance requirements are critical for what kind of specific applications in terms of different groups of SPF product systems or alternatives.

Similarly, in Section 5.3 (p. 74) and Section 5.4 (p. 75), it states the product-level exposure parameters and cost between the Priority Products and the alternative formulations cannot be evaluated due to data gaps. However, in these sections and previous discussions in the Abridged AA Report, there is some qualitative information and estimated quantitative data available, especially when for some commercially available, functionally acceptable, and lower exposure products, such as Firestone/Gaco Profill and Nitrosys HVLP. It is not clear why this available information is excluded to substantiate the RE's conclusion that there are no potentially viable alternatives.

In addition, it is recommended to provide a clear visual comparison that summarizes the information collected regarding the performance, exposure potentials, and cost for the Priority Products and the alternatives. Comparing this information will help to clarify the rationale for the REs' decision. Although the lack of information is a concern, the Abridged AA Report should show deliberate work and adequate supporting information for making a conclusion that "there are no potential alternatives to the Priority Products that can be appropriately explored in an AA" as stated in Section 6.1 (p. 76).

#### 2.14 Implementation Plan

The Abridged AA Report, Section 7 *Potential Regulatory Responses* (pp. 77-78), should include an implementation plan that specifies the milestones and dates for implementation of proposed regulatory responses, which shall, at a minimum, include *Product Information for Consumers* and *Advancement of Green Chemistry and Green Engineering*, per Section 69505.4(b)(4) of the SCP regulations. In addition to the two required regulatory responses, the Abridged AA Report may also include any regulatory responses that the RE wishes to propose to best limit exposure to or reduce the adverse impacts of the chemical of concern in the Priority Product, per Section 69505.7(k)(2)(B) of the SCP regulations.

Further, please provide product information for all the SPF applicators, including high-pressure SPF applicators, as part of the Regulatory Response "Product Information for Consumers." The Abridged AA Report, Section 7.1 (p. 77) asserts that high-pressure SPF systems are not a traditional consumer product and the required Regulatory Response "Product Information for Consumers" (Cal. Code of Regs., tit. 22, § 69506.3) is not applicable to manufacturers of high-pressure SPF systems. Please remove this incorrect information. The SCP regulations define a "consumer product" or "product" to mean either of the following: (1) A consumer product as defined in Health and Safety Code section 25251<sup>1</sup> or (2) when applicable, a component of an assembled "consumer product" (Refer to Cal. Code of Regs., tit. 22, section 69501.1(a)(24)(A)). By this definition, high-pressure SPF systems are considered a "consumer product" under the SCP regulations and the users (or applicators) of high-pressure SPF systems are the consumers. Please list the specific labeling requirements and product information you are providing to meet the OSHA Hazard Communication Standards.

As the SCP regulations define the applicators of high-pressure SPF systems as the "consumers," information provided to these consumers could broadly include training programs for applicators that provide "Any safe handling and storage procedures and/or other information needed to protect public health or the environment during the useful life of the product, including precautions that consumers may take to prevent or limit exposure to the Chemical(s) of Concern or replacement Candidate Chemicals..." (§69506.3(b)(5)).

DTSC encourages the REs to propose other Regulatory Response(s) that would help to best limit exposure to or reduce the adverse impacts of the Chemical of Concern in the Priority Product. Such examples might include administrative controls that mandate the currently voluntary training program for the SPF installers.

#### 2.15 Other Comments

Please change "relevant factors such as nephrotoxicity and cardiovascular toxicity" in Section 5.1 (p. 71) *Hazard* to "hazard traits such as nephrotoxicity and cardiovascular toxicity." Also, in the last paragraph of this section, please change "3 relevant factors with "High" or "Very High" scores to "3 hazard traits with "High" or "Very High" scores.

Please update Neurotoxicity in Table 5.1 to reflect either a Group A or Group B endpoint, as it is currently listed as both.

<sup>&</sup>lt;sup>1</sup> Health and Safety Code section 25251 defines a consumer product as "a product or part of the product that is used, brought, or leased for use *by a person for any purposes*." (Emphasis added)

In addition, DTSC notes that in Section 5.1 (p. 71) of the Abridged AA Report, the second paragraph states "The California SCP regulations (and AA in general) do not allow for the consideration of risk [...] in making decisions about selecting alternative products." This statement is not consistent with the SCP regulations. The AA process in the SCP regulations specifically requires considering both hazard and exposure information when evaluating a broad spectrum of adverse impacts amongst the alternatives. It is different from traditional risk assessment that quantifies the probability of adverse human health and ecosystem effects from exposure to a hazardous chemical. Although the SCP AA process does not require using the traditional model of risk assessment, both hazard and exposure information are used to inform a decision regarding safer alternatives.