

INITIAL STATEMENT OF REASONS

SAFER CONSUMER PRODUCTS REGULATIONS – Listing Motor Vehicle Tires Containing N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) as a Priority Product

Department of Toxic Substances Control Reference Number: R-2022-04R

INTRODUCTION AND BACKGROUND

The Department of Toxic Substances Control (DTSC) proposes to amend section 69511 and add section 69511.7 to Article 11, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations [Safer Consumer Products (SCP) regulations] to add motor vehicle tires containing N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) as a Priority Product to the Priority Products List.

Pursuant to section 69503.2(b), DTSC may identify and list as a Priority Product, one or more product-chemical combinations that it determines to be of high priority. DTSC's decision to identify and list a product-chemical combination is based on an evaluation of potential exposures and adverse impacts. DTSC has identified motor vehicle tires containing 6PPD as a Priority Product.

DTSC is required to establish and update the Priority Products List through rulemaking under the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Division 3 of Title 2 of the California Government Code).

Statutory Intent and Requirements

In April 2007, California's Secretary for Environmental Protection launched the California Green Chemistry Initiative, a six-part initiative to develop policy options to implement a green chemistry program and reduce public and environmental exposures to toxic chemicals through improved knowledge about and regulation of chemicals. In 2008, Assembly Bill 1879 (Chapter 559, Statutes of 2008) was signed into law to implement a key recommendation of the California Green Chemistry Initiative Final Report: accelerate the quest for safer consumer products. These statutory mandates are outlined in Health and Safety Code sections 25252 and 25253.

Specifically, Health and Safety Code section 25252 requires DTSC to establish a process to identify and prioritize chemicals or chemical ingredients in consumer products that may be considered Chemicals of Concern. This process must include consideration of the following factors:

- The volume of a chemical in commerce in California;
- The potential for exposure to a chemical in a consumer product; and
- The potential effects of the Chemical of Concern on sensitive subpopulations.

Health and Safety Code section 25252 also requires DTSC to develop criteria by which chemicals and their alternatives may be evaluated. At a minimum, the criteria must include hazard traits, physicochemical characteristics, and toxicological endpoints identified by the California Office of Health Hazard Assessment (OEHHA) in regulations set forth in Chapter 54 of Division 4.5 of Title 22 of the California Code of Regulations (CCR) adopted pursuant to Health and Safety Code section 25256.1. DTSC is also required to reference and use, to the extent feasible, available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes.

Health and Safety Code section 25253 requires the establishment of a process to evaluate the availability of potential alternatives to the use of Chemical(s) of Concern in a Priority Product, and potential hazards posed by those alternatives, through use of lifecycle assessment tools. Health and Safety Code section 25253 also authorizes DTSC to implement a range of Regulatory Responses following completion of an evaluation and comparison of the Priority Product and alternatives by the manufacturer through an Alternatives Analysis (AA).

Safer Consumer Products Regulations Overview

The SCP regulations were adopted in October 2013 to meet the statutory requirements outlined in Health and Safety Code sections 25252 and 25253. The regulations outline a science-based process for evaluating Chemicals of Concern in consumer products and safer alternatives by:

- Establishing a list of Candidate Chemicals and specifying criteria by which these may be designated a Chemical of Concern;
- Establishing a process to identify and prioritize product and Candidate Chemical combinations that may be listed as Priority Products;
- Requiring manufacturers to notify DTSC when their product is listed as a Priority Product;
- Requiring manufacturers of a Priority Product to decide whether to perform an AA to determine how best to reduce exposures to the Chemical(s) of Concern in the product;
- Allowing DTSC to identify and require implementation of Regulatory Responses following the completion on an AA, as needed; and

- Creating a process for persons to petition DTSC to add or remove chemicals from the Candidate Chemicals list, add or remove Candidate Chemicals lists in their entirety, or to add or remove a product-chemical combination from the Priority Products List.

Priority Products List

DTSC previously added the following product-chemical combinations to the Priority Products List:

- Children’s foam-padded sleeping products containing tris(1,3-dichloro-2-propyl) phosphate (TDCPP) or tris(2-chloroethyl) phosphate (TCEP);
- Spray polyurethane foam (SPF) systems containing methylene diphenyl diisocyanates;
- Paint or varnish strippers containing methylene chloride;
- Carpets and rugs with perfluoroalkyl or polyfluoroalkyl substances; and
- Treatments containing perfluoroalkyl or polyfluoroalkyl substances for use on converted textile or leathers.

DTSC is updating the Priority Product List by conducting this rulemaking to adopt motor vehicle tires containing 6PPD as a Priority Product.

Prioritization Criteria for Listing a Priority Product

DTSC is required to use the identification and prioritization criteria and process specified in California Code of Regulations, title 22, sections 69503.2, 69503.3, and 69503.5 to identify and add a Priority Product to the Priority Products List.

Section 69503.2 requires that any product-chemical combination listed as a Priority Product meet the following two key prioritization criteria:

- There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and
- There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

The first key prioritization principle requires DTSC to evaluate the potential for public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product by considering routes of exposure to the product and the Candidate Chemical(s) in the product throughout its full life cycle. This evaluation considers available information regarding one or more exposure scenarios, assesses

the extent and quality of the relevant available information, and includes consideration of one or more of the exposure potential factors listed in section 69503.3(b).

The second key prioritization principle requires DTSC to evaluate whether one or more exposures to a Candidate Chemical in the product have a potential to contribute to or cause significant or widespread adverse public health and/or environmental impacts. Evaluating the potential for significant adverse impacts may include consideration of the Candidate Chemical's toxicity, and impacts on sensitive subpopulations or sensitive environmental receptors. Similarly, the evaluation of the potential for widespread adverse impacts could include consideration of the Candidate Chemical's mobility in different types of environmental media or how widely products containing that chemical are sold or used.

In the context of the SCP regulations, the ability of a chemical to cause an adverse impact depends on the hazard trait(s) of that chemical. The potential for an exposure to that chemical to result in an adverse impact depends on particular exposure factors, such as the route or pathway of exposure under evaluation. The term "potential" is a critical term because the regulations incorporate not only experienced harm, but also address the possibility that a chemical could contribute to or cause harm. Section 69501.1(a)(51)(A) defines "potential" as "the phenomenon described is reasonably foreseeable based on reliable information." "Reasonably foreseeable" is a term of art in law that means a reasonable person would be able to predict or expect a given outcome. This ensures that assessment of adverse impacts is based on both reasonable grounds and evidence. Another criterion for the determination of "potential" is that consideration must be based on reliable information, which is defined in section 69501.1 of the SCP regulations to mean scientific studies or scientific information that meets certain specified criteria.

Section 69503.3 describes the factors DTSC is required to consider in its evaluation of adverse impacts and exposure to the Candidate Chemical(s) in the product. DTSC's evaluation must include consideration of one or more adverse impact factors listed in section 69503.3(a) and one or more exposure factors listed in section 69503.3(b). Following this evaluation, DTSC uses procedures specified in section 69503.5 to identify and list product-chemical combinations as Priority Products.

Requirement to Conduct Alternatives Analysis

Following the adoption of a Priority Product in regulation, manufacturers are required to submit a Priority Product Notification and determine whether they will conduct an AA. The AA is a systematic process for evaluating the life cycle impacts of a Priority Product and any alternatives considered. In lieu of submitting an AA Report, a manufacturer could remove the Chemical of Concern from the Priority Product, replace it with a safer

chemical, or stop selling the product in California. Section 69505.1(a) and sections 69505.4(b), (c), and (d) identify the options a manufacturer has to comply with SCP requirements in lieu of conducting an AA. The duty to comply with the regulation falls first to the manufacturer. If a manufacturer fails to submit a Priority Product Notification, this responsibility shifts to the importer of the product, if applicable, and then to the retailers or assemblers of the product. Once a manufacturer has failed to comply with the regulation and DTSC provides notice of this noncompliance, the requirements for importers, retailers, or assemblers, as applicable, call for importers to cease placing the product into the stream of commerce in California and for retailers and assemblers to cease ordering the product.

The AA is a two-stage process that considers many facets of product manufacturing, including process engineering, environmental management, financial analysis, and research and development. In the first stage of the AA process, manufacturers are required to identify the legal, functional, and performance requirements of the Priority Product and the Chemical of Concern, and use this information to identify an array of alternatives to consider. When the first stage is completed, the manufacturer documents the findings in a Preliminary AA Report and submits this report to DTSC. During the second stage of the AA, the manufacturer compares the Priority Product with possible alternatives using a more in-depth analysis and considers additional factors, including additional life cycle and economic impacts. This information is then submitted to DTSC in the Final AA Report.

If, after completing the first five steps of the first stage of the AA, a manufacturer determines there are no functionally acceptable or technically feasible alternatives to the use of the Chemical of Concern in the Priority Product, it may submit an Abridged AA Report in lieu of submitting the Preliminary and Final AA Reports required by the two-stage process. The Abridged AA process requires the manufacturer to document the screening of potential alternatives. Because the Abridged AA process allows for the continued sales and use of the Priority Product, the Abridged AA Report must include an implementation plan to carry out the following required Regulatory Responses:

- providing product safety information to consumers, including information on chemical hazards, safe handling and disposal procedures, and other information needed to protect public health and the environment; and
- advancing green chemistry and green engineering principles, including initiating research and development projects or funding challenge grants to design safer alternatives or to improve performance, lower cost, or increase market penetration of existing safer alternatives.

Following submission of an Abridged AA Report or Final AA Report, DTSC will post the report using the Safer Consumer Products Information Management System (CalSAFER) located at <https://calsafes.dtsc.ca.gov/> on the DTSC website and provide the public with an opportunity to submit comments. DTSC is required to review the public comments and may require the manufacturer to address all substantive comments before initiating departmental review. DTSC must evaluate each report on its own merits, taking into consideration unique conclusions and proposals. Because the information provided by manufacturers in the AA reports and proposed Regulatory Responses address specific business situations, DTSC cannot predetermine whether any Regulatory Response will be proposed by DTSC after the AA process is complete.

DETAILED STATEMENT OF SPECIFIC PURPOSE AND RATIONALE

Amend Section 69511. General.

Purpose. Section 69511 describes the scope and purpose of article 11 and establishes a Priority Products List. This section is modified to add subsection (b)(7) to identify motor vehicle tires containing N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) as a Priority Product on the Priority Products List.

Necessity. DTSC proposes to adopt motor vehicle tires containing 6PPD as a Priority Product because this product-chemical combination meets the criteria in section 69503.2(a), which requires that:

- There must be potential public and/or aquatic, avian, or terrestrial animal, or plant organism exposure to the Candidate Chemical(s) in the product; and
- There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

Following an extensive review of the scientific literature and analysis of the known hazard traits of 6PPD and its reaction product 6PPD-quinone, DTSC concluded that there is a potential for humans and the environment to be exposed to 6PPD and its reaction product 6PPD-quinone during the manufacturing, normal use, and end-of-life of motor vehicle tires. These exposures could potentially contribute to or cause significant or widespread adverse impacts. Each prioritization criterion is discussed below.

Potential for public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the Priority Product

DTSC has identified motor vehicle tires as a major source of human and ecological exposure to 6PPD and 6PPD-quinone. 6PPD is a high-production volume chemical, one of its main uses being motor vehicle tires, where it is added at concentrations of 1 to 2%

to protect the rubber from degradation by oxygen and ozone. 6PPD is used in nearly all motor vehicle tires in California. 6PPD slowly migrates from the interior of the tire towards its surface over the lifetime of the tire, such that there is a constant supply of 6PPD and its oxidation products at the surface of the tire. By design, 6PPD is highly reactive and forms a number of reaction products when in contact with oxygen and ozone, including 6PPD-quinone.

Tires release 6PPD and its reaction products into the environment through mechanical tire abrasion on the roads, which produces microplastics known as tire wear particles. It is estimated that, in the United States, between 2.5 and 4.7 kilograms of tire wear particles are generated per person each year. This translates to between 98,750 and 185,650 metric tons of tire wear particles generated each year in California, a sizeable fraction of which ends up in the aquatic environment. Once in the environment, tire wear particles can release chemicals including 6PPD and its reaction product 6PPD-quinone.

In 2020 alone, over 171 million tires were driven on California's roads. The large number of tires used in California each year poses major challenges to their end-of-life disposition. After their useful life, tires can be landfilled, recycled, or reused. Many of the end-of-life uses of tires (such as for erosion control, flood control, stormwater treatment, or playground surfaces) provide a pathway for chemicals like 6PPD and its reaction products to migrate into the aquatic environment.

Stormwater runoff, particularly from urban areas, can serve as a substantial source of tire-derived contaminants to local aquatic environments.

6PPD-quinone has been detected in California waterways at concentrations above those shown to kill at least half of coho salmon exposed to the chemical in laboratory experiments. Coho salmon are already extirpated in California waters near highly populated, high traffic density areas. The remaining coho populations, which are in the less heavily populated areas of the state, are either threatened or endangered.

The highest concentration of 6PPD-quinone measured to date in the San Francisco Bay Area came from a sample collected near a heavily trafficked road passing through a watershed that is approximately 90% open space, indicating that proximity to roads and associated tire wear particles may be more important than the extent of development of surrounding land. This indicates the potential for exposure of coho salmon and other aquatic organisms to lethal concentrations of 6PPD-quinone outside dense urban regions of the state if traffic patterns result in release of tire wear particles to streams. The presence of 6PPD-quinone in California waterways at concentrations proven to be lethal to coho salmon indicates that current stormwater handling practices are often insufficient for the removal of 6PPD-quinone.

Potential for one or more exposures to the Candidate Chemical to contribute to or cause significant or widespread adverse impacts

Both 6PPD and 6PPD-quinone display hazard traits referenced by the Green Chemistry Hazard Traits regulations (California Code of Regulations, Title 22, Division 4.5, Chapter 54). 6PPD displays dermatotoxicity; hepatotoxicity; hematotoxicity; ocular toxicity; phytotoxicity; reproductive toxicity; and wildlife survival impairment; 6PPD-quinone displays loss of genetic diversity and biodiversity, reactivity in biological systems, respiratory toxicity, and wildlife survival impairment (including to coho salmon, a threatened and endangered species in California). The proposed regulation is based on evidence of the potential for tire-derived 6PPD and its transformation product, 6PPD-quinone, to contribute to significant or widespread adverse impacts to aquatic organisms. While some of the hazard traits listed indicate potential concern for human exposure to 6PPD, that is not the primary basis for this regulation at this time.

Researchers in Washington state recently demonstrated that 6PPD-quinone is the causal agent in urban runoff mortality syndrome, which has been observed in Puget Sound. Exposure to very small concentrations of 6PPD-quinone can kill coho salmon as they migrate upstream, before they are able to spawn.

The ubiquity of 6PPD-quinone in tires and its presence in California runoff and waterways at concentrations above levels that kill at least half of coho salmon exposed to the chemical in lab studies suggests that exposure to 6PPD-quinone may have contributed to the decline in the coho population over the past 60-70 years. This decline has adversely impacted important marine food webs in California. Coho salmon represent a food source for many marine organisms such as seals and sharks and are a source of ocean-derived nutrients to inland ecosystems.

In addition to impacts to aquatic organisms, loss of coho salmon in California has contributed to adverse impacts on California's Native American tribes. The loss of core traditional food sources for tribal communities can be tied to loss of culture, increased physical and mental health issues, and increased poverty. The human toll of the decline of salmon has been well-documented by the Karuk Tribe in the Klamath Basin: diabetes, heart disease, hypertension, and stroke, diseases that are strongly influenced by diet, have become more common in the Karuk since the decline of the salmon fishery, costing the tribe an estimated \$1.9 million per year. Native American advocates assert that access to traditional food sources, such as salmon, helps to promote self-reliance among Indigenous peoples and is fundamentally important to protecting Native communities' health, well-being, economic resilience, and cultural heritage.

6PPD-quinone is also potentially toxic to other economically important species that are closely related to coho such as chinook salmon, steelhead, and the California golden trout. Additionally, 6PPD itself is known to be toxic to several aquatic invertebrates,

although because 6PPD is highly reactive, the toxicity assessments are complicated by probable co-exposure to transformation products during experiments.

Given the number of tires used in California each year – over 171 million tires were driven on California’s roads in 2020 alone—their end-of-life disposition is a major challenge. At the end of their useful life, tires are landfilled, recycled, or reused—either as is or after processing (e.g., by cutting or shredding). Many of the end-of-life uses of tires provide direct pathways for chemicals to migrate into the aquatic environment and may represent a source of contaminants like 6PPD and 6PPD-quinone. California’s extensive efforts to reuse and recycle used tires may contribute to ongoing environmental releases and exposures to these contaminants.

Given this potential for significant and widespread adverse impacts, the presence of 6PPD in tires and associated release of 6PPD-quinone to the aquatic environment represent a threat to California’s aquatic resources and the tribal communities that rely on them, may interfere with California’s ability to reuse and recycle tires, and may require expensive special handling of stormwater runoff to mitigate adverse impacts.

Add Section 69511.7. Motor Vehicle Tires Containing N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD).

Purpose. In its entirety, this section identifies motor vehicle tires containing 6PPD as a Priority Product.

Necessity. This section is necessary because it describes the product-chemical combination being listed as a Priority Product, therefore informing responsible entities and the public which products are subject to regulation.

Benefits. The primary goal of SCP regulations is to protect public health by reducing exposures to potentially harmful chemicals. By listing motor vehicle tires containing 6PPD as a Priority Product, DTSC sets in motion a strategy to reduce aquatic exposure to 6PPD and 6PPD-quinone from the manufacturing, use, and end-of-life this product. A reduction in exposure to 6PPD and 6PPD-quinone could benefit the health of California’s wildlife. The development of safer alternatives benefits California’s environment.

DTSC cannot predetermine the alternatives that each manufacturer will propose; therefore, it is impossible to accurately predict or quantify the full range of potential benefits associated with their development. DTSC’s process encourages the use of alternatives of least concern and prefers those that provide the greatest level of inherent protection. In general, economic benefits to California workers and business owners may include expanded employment opportunities in the fields of consulting, worker and consumer education, and marketing. Additional benefits may accrue because of

increased research and product development collaboration between manufacturers and California-based research entities. Institutional and corporate financial support of chemical and material science programs focused on developing safer alternatives to 6PPD could advance the field. These research initiatives could provide manufacturers with employees that are highly skilled in the research and design of products for newly emerging global markets.

Add Section 69511.7(a).

Purpose. This section provides a description of the product-chemical combination.

“Motor vehicle tires containing N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD)” means a motor vehicle tire, as defined below, that contains the chemical N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD). “Tire” means any product that can be described or observed as a covering for a wheel, usually made of rubber reinforced with cords of nylon, fiberglass, or other material, whether filled with compressed gas (such as air or nitrogen), solid, or non-pneumatic (airless).

“Motor vehicle tire” includes any tire, as defined above, that is intended for use on light duty vehicles (passenger cars, light trucks, vans, and sport utility vehicles); motorcycles; motor homes; medium- and heavy-duty trucks; buses; and trailers (including trailer coaches, park trailers, and semitrailers). “Motor vehicle tire” also includes tire tread material: circular or linear precured tread and raw rubber solely for use in mold cure retreading of a tire.

“Motor vehicle tire” does not include a tire imported into or sold in California as a component of a motor vehicle. It also does not include a tire intended for exclusive use on off-road vehicles including aircraft; vehicles intended exclusively for off-road (e.g., dirt track) use; construction and agricultural equipment such as excavators, paving equipment, tractors, combines, bulldozers, and skidders (but not farm labor vehicles); industrial equipment such as forklifts, airport service equipment, and ice-grooming machines; and military vehicles (except those that are equivalent to civilian vehicles covered by this product definition, such as light-duty vehicles used as staff cars, buses, and delivery vehicles). Additionally, “motor vehicle tire” does not include the used component(s) of a retreaded tire; however, the new tire tread material that is used in a retreaded tire is included in the definition.

Necessity. This description is necessary for a responsible entity to determine whether one or more of its products is a Priority Product, as required by section 69503.5(b)(1)(A). DTSC selected these products because of their widespread use in California and high potential to lead to ecological exposures to 6PPD and its transformation products.

6PPD is found in tire tread, and tread is the tire component most likely to be worn off and deposited in the environment during typical use. Nevertheless, 6PPD is found throughout tire rubber, and 6PPD-quinone has been found on both the tire tread and the tire sidewall. Therefore, defining the Priority Product to include only tire tread would ignore the potential for exposure to 6PPD and 6PPD-quinone that originated in the sidewall or other parts of tires. To meaningfully protect California's aquatic environment, DTSC decided to include the entire motor vehicle tire in its Priority Product designation. This definition of "tire" is a modification of the definition used by the Global Product Classification system.

Furthermore, all tires contain 6PPD and release tire wear particles to the environment, resulting in exposure of aquatic organisms to 6PPD and 6PPD-quinone. Industry stakeholders recommended that DTSC focus on a narrower definition of motor vehicle tire – specifically replacement, all-season tires. However, while there is great variety in the types of tires available, industry stakeholders have also indicated that any alternatives to 6PPD found for replacement, all-season tires intended for use on passenger cars would work for all tires. Choosing a broader definition allows DTSC to ensure that any available alternatives are adopted across the tire market, not just in replacement, all-season tires intended for use on passenger cars, and thus increases protection of California's aquatic environment.

DTSC chose to exclude motor vehicles containing tires from the product definition to make clear that these regulations are intended to cover tires and manufacturers of tires, not vehicles that use tires. Similarly, DTSC chose to exclude the used component(s) of a retreaded tire from the product definition but has included the new tire tread used on a retreaded tire in the definition of "motor vehicle tire" in section 695011.7(a)(2)(B). The intent of this inclusion in the regulation is to capture manufacturers of new tread material as responsible entities and not manufacturers or assemblers of retreaded tires.

Add Section 69511.7(b).

Purpose. This section identifies N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) as the Candidate Chemical and the basis for proposing to list motor vehicle tires containing 6PPD as a Priority Product. For the purposes of this chapter, 6PPD has a chemical formula of $C_{18}H_{24}N_2$ and is identified by the CAS Registry Number 793-24-8, European Community number 212-344-0, InChI 1S/C18H24N2/c1-14(2)13-15(3)19-17-9-11-18(12-10-17)20-16-7-5-4-6-8-16/h4-12,14-15,19-20H,13H2,1-3H3, InChIKey ZZMVLMMVFYMGSMY-UHFFFAOYSA-N and Distributed Structure-Searchable Toxicity Substances ID DTXSID9025114. Common synonyms or trade names include 4-N-(4-methylpentan-2-yl)-1-N-phenylbenzene-1,4-diamine, 1,4-benzenediamine, N-(1,3-dimethylbutyl)-N'-phenyl, 4-(dimethylbutylamino)diphenylamine, N-(1,3-dimethylbutyl)-

N'-phenyl-p-phenylenediamine, N-(4-Methyl-2-pentyl)-N-phenyl-1,4-benzenediamine, N-(4-Methyl-2-pentyl)-N-phenyl-1,4-diaminobenzene, N-dimethylbutyl-N'-phenyl-p-phenylenediamine, 6-PPD, and HPPD. 6PPD is an antidegradant added to tire rubber to protect the rubber from reaction with oxygen and ozone.

Necessity. This section is needed to clearly identify to responsible entities and the public that 6PPD is the Candidate Chemical that is the basis for listing motor vehicle tires containing 6PPD as a Priority Product.

Consistent with section 69503.6(a) of the SCP regulations, 6PPD is a Candidate Chemical because it is included on the OSPAR Priority Action Part A list, one of the authoritative lists specified in section 69502.2(a), and because 6PPD exhibits one or more exposure potential, toxicological, or environmental hazard traits as specified in sections 69402 through 69405 of Chapter 54 of Division 4.5 of Title 22 of the California Code of Regulations (Green Chemistry Hazard Traits for California's Toxics Information Clearinghouse), including:

- Dermatotoxicity;
- Hematotoxicity;
- Hepatotoxicity;
- Ocular toxicity;
- Phytotoxicity;
- Reproductive toxicity; and
- Wildlife survival impairment.

Add Section 69511.7(c).

Purpose. This section identifies 6PPD as the Candidate Chemical that is the basis for listing motor vehicle tires as a Priority Product and identifies the hazard traits and endpoints associated with 6PPD. Section 69503.5(b)(2)(A) requires that DTSC, in listing a Priority Product, specify the Candidate Chemicals that are the basis for the listing and the hazard traits and environmental or toxicological endpoints known to be associated with these chemicals.

Necessity. The hazard traits identified in this section support DTSC's conclusion that exposure to 6PPD from motor vehicle tires has the potential to harm California's, aquatic wildlife. Specifying them is required by section 69503.5(b)(2)(A). The hazard traits associated with 6PPD include dermatotoxicity; hepatotoxicity; hematotoxicity; ocular toxicity; phytotoxicity; reproductive toxicity; and wildlife survival impairment.

Add Section 69511.7(d)

Purpose. This section identifies the hazard traits associated with 6PPD-quinone, a reaction product of 6PPD. Section 69503.3(a)(1)(G) requires DTSC to evaluate the potential for a Candidate Chemical to form a reaction product that exhibits one or more hazard traits or environmental or toxicological endpoints when identifying and prioritizing Priority Products. 6PPD-quinone is a reaction product formed when 6PPD reacts with oxygen or ozone.

Necessity. The identified hazard traits support DTSC's conclusion that the use of 6PPD in motor vehicle tires has the potential to harm California's aquatic wildlife as a result of exposure to the 6PPD reaction product 6PPD-quinone. Hazard traits associated with 6PPD-quinone include loss of genetic diversity and biodiversity, reactivity in biological systems, respiratory toxicity, and wildlife survival impairment,

Add Section 69511.7(e).

Purpose. This section specifies the toxicological endpoints associated with 6PPD, pursuant to section 69503.5(b)(2)(A). DTSC has identified the following toxicological endpoints for 6PPD :

- Acute lethality in fish;
- Anemia in rats;
- Decreased cell count in algae;
- Dystocia in rats;
- Edema and erythema of the eye, discharge from the eye, and dullness of cornea in rabbits;
- Immobilization or mortality in aquatic invertebrates;
- Increased liver weight, fatty degeneration of the liver, and vacuolar degeneration of the liver in rats; and
- Skin sensitization in guinea pigs and humans, and skin erythema in rabbits.

Necessity. This section is necessary to identify toxicological endpoints associated with 6PPD as required by section 69503.5(b)(2)(A). Clearly describing the toxicological endpoints of 6PPD associated with exposure to 6PPD from motor vehicle tires is necessary to ensure that responsible entities performing Alternatives Analyses can identify relevant factors for comparison of alternatives associated with 6PPD, pursuant to section 69505.5 (c).

Add Section 69511.7(f)

Purpose. This section identifies the toxicological endpoints associated with the 6PPD reaction product 6PPD-quinone. Section 69503.3(a)(1)(G) requires DTSC to evaluate the potential for a Candidate Chemical to form a reaction product that exhibits one or more hazard traits or environmental or toxicological endpoints when identifying and prioritizing Priority Products. DTSC has identified the following toxicological endpoints for 6PPD-quinone:

- Acute lethality and pre-spawn mortality in fish;
- Erratic surface swimming, gaping, fin splaying, and loss of orientation and equilibrium in fish; and
- Increased hematocrit, dysregulation of blood plasma ions, and disruption of the blood brain barrier in fish.

Necessity. This section is necessary to identify toxicological endpoints associated with the 6PPD reaction product 6PPD-quinone. Clearly describing the toxicological endpoints of 6PPD-quinone is necessary to ensure that responsible entities performing Alternatives Analyses can identify relevant factors for comparison of alternatives associated with 6PPD, pursuant to section 69505.5 (c).

Add Section 69511.7(g).

Purpose. This section designates the Candidate Chemical 6PPD as the Chemical of Concern for the Priority Product. Section 69503.5(b)(2)(B) states that any Candidate Chemical that has been identified as the basis for a product being listed as a Priority Product is then designated as the Chemical of Concern for that product.

Necessity. This section is necessary to clearly identify to responsible entities and the public that 6PPD is the Chemical of Concern in motor vehicle tires affected by this proposed regulation. Clearly identifying the Chemical of Concern in a Priority Product ensures that responsible entities understand that their Alternatives Analyses must identify and evaluate alternatives to the use of this chemical and take the appropriate steps to comply with the applicable notification and reporting requirements in the SCP regulations.

Add Section 69511.7(h).

Purpose. This section provides responsible entities a due date for submission of the Preliminary AA Report.

Necessity. This section is necessary to comply with section 69503.5(b)(3) and to provide responsible entities with a time frame for complying with the notification and reporting requirements included in the SCP regulations.

ECONOMIC IMPACT ASSESSMENT

Summary of Non-Major Regulation

As required by Government Code section 11346.3, DTSC has assessed the potential for this proposed regulation to cause adverse economic impacts to California businesses and individuals. Following a review of available market data for motor vehicle tires containing 6PPD and communications with affected manufacturers and industry organizations, DTSC has determined the proposed regulation is not a major regulation and is unlikely to have a significant adverse impact on business (see the definition of a major regulation at the end of this subsection). This Economic Impact Assessment is also based on the assumption that manufacturers of motor vehicle tires containing 6PPD will comply fully with the SCP regulations by submitting Priority Product Notifications and AA Reports to DTSC by the dates specified in regulation, as this is the most fiscally conservative assumption.

Manufacturers of motor vehicle tires containing 6PPD that do not submit AA Reports may choose to comply with the regulations in a number of other ways. They may 1) remove the 6PPD from their motor vehicle tires; 2) replace the 6PPD with a different chemical that meets certain regulatory requirements for those products; or 3) stop selling motor vehicle tires containing 6PPD in California. If a manufacturer fails to comply with the regulation and DTSC provides notice of this noncompliance, the requirements for importers, retailers, or assemblers, as applicable, call for importers to cease placing the product into the stream of commerce in California, and for retailers and assemblers to cease ordering the product.

DTSC estimates the implementation of the proposed regulation will result in a total economic impact on the state's businesses of less than \$10 million. This proposal is not a major regulation as defined by Health and Safety Code section 57005.

All manufacturers of motor vehicle tires containing 6PPD that sell their products in California or, in some instances, their distributors must submit notifications and may produce AA reports. Costs incurred by out-of-state businesses to comply with these requirements fall outside the scope of the Economic Impact Analysis. The DTSC SCP program considers a business "California-based" if it is incorporated or headquartered in California or employs over 50 percent of its employees in California. DTSC estimates the cumulative cost for all affected California manufacturers of motor vehicle tires containing 6PPD to submit Priority Product Notifications, AA Reports, and to respond to

DTSC's reviews of these submittals to be between \$451,840 and \$1,219,840. DTSC estimates there are a maximum of four manufacturers of motor vehicle tires containing 6PPD that make and sell their products in California that would be required to comply with this regulation.

Each manufacturer is required to submit an online Priority Product Notification to DTSC, using its CalSAFER portal, that includes business contact information and the types, brand names, and product names of the 6PPD-containing motor vehicle tires it manufactures. This is a one-time requirement. DTSC estimates that manufacturers would require a maximum of 16 hours to prepare a Priority Product Notification at a cost of approximately \$60/hour. DTSC estimates that each manufacturer could spend up to \$960 to complete the required notification.

DTSC derived the estimated costs of an AA utilizing authoritative sources of information. These included the Interstate Chemicals Clearinghouse (IC2) Alternative Assessment guide, the State of Washington's Alternative Assessment Guide for Small and Medium Businesses, University of California Santa Barbara's Life Cycle Analysis and Pilot AA studies, as well as guidance from the European Chemicals Agency. DTSC's estimated costs to individual manufacturers based on these sources range from \$48,000 to \$78,000 for an Abridged AA and \$86,000 to \$161,000 for a two-stage AA.

DTSC has surveyed manufacturers of prior Priority Products and was informed that the expected cost for the first stage of an AA ranges from \$100,000 to \$135,000. Manufacturers further estimated that the cost to prepare Abridged AA Reports ranges from \$50,000 to \$150,000 or \$120,000 to \$250,000 to prepare a two-stage AA Report.

Given the high degree of uncertainty in the estimated cost of an AA, DTSC opted to use the higher range of estimates provided by manufacturers of proposed Priority Products (\$100,000 to \$150,000 for an Abridged AA and \$120,000 to \$250,000 for a two-stage AA). For an individual manufacturer, the estimated total cost to comply with the Priority Product Notification and the AA report requirements, including responding to DTSC's review, ranges from \$112,960 to \$182,960 for an Abridged AA and \$139,960 to \$304,960 for a two-stage AA. Feedback from the author of one AA submitted to DTSC confirms that this estimate remains reasonable.

Given a lack of data and many uncertainties surrounding the effort required to complete the AA process defined in the SCP regulations, these costs may be underestimated. Likewise, if multiple affected manufacturers 1) form a consortium, or 2) work with their industry association (e.g., United States Tire Manufacturers Association) to submit a combined AA Report, overall costs could be lower.

More information regarding potential costs and benefits of this proposed regulation is provided in an attachment to the Economic and Fiscal Impact Statement (STD 399).

Major regulation: Government Code section 11342.548 defines a "major regulation" as any proposed adoption of a regulation that will have an economic impact on California businesses in an amount exceeding \$50 million dollars as estimated by the adopting agency. Section 57005 of the Health and Safety Code further requires DTSC (as part of the California Environmental Protection Agency, "CalEPA") to evaluate alternatives to a "major regulation." Section 57005(b) defines a "major regulation" as any rulemaking that will have an economic impact on business enterprises exceeding \$10 million.

Creation or Elimination of Jobs

The requirement to submit Priority Product Notifications and Abridged AA Reports or two-stage AA Reports is not likely to result in the creation or elimination of jobs in California. DTSC anticipates zero ongoing costs associated with this proposed regulation. DTSC expects that the one-time costs associated with the Priority Product Notifications and AA Reports are low enough for all potentially impacted manufacturers to comply without impacting the number of jobs at their businesses. Manufacturers can significantly reduce their individual costs of compliance by submitting a combined AA Report through a consortium.

The AA process requires manufacturers to provide DTSC with data and analysis to determine whether reasonable alternatives exist. DTSC reviews each AA Report on its own merits, taking into consideration each manufacturer's unique conclusions and proposals. Because each manufacturer's proposal will address its specific business situation, DTSC cannot predetermine the actions that manufacturers of motor vehicle tires containing 6PPD would need to take, either individually or collectively, to meet the goals of protecting the environment and advance green chemistry or green engineering principles. While it is impossible to accurately predict or quantify the full range of potential benefits associated with the implementation of this proposed regulation, DTSC anticipates that it could lead to additional jobs in consulting services, chemical and material science research and support, product research and design, marketing, and the development of consumer product safety information and training materials.

Creation of New Businesses or Elimination of Existing Businesses

DTSC determined that this proposal is unlikely to result in the elimination of any motor vehicle tire manufacturers. DTSC anticipates zero ongoing costs associated with this proposed regulation. DTSC expects that the one-time costs associated with the Priority Product Notifications and AA Reports are low enough for all potentially impacted manufacturers to comply without eliminating their businesses. Manufacturers can

significantly reduce their individual costs of compliance by submitting a combined AA Report through a consortium.

The AA process requires manufacturers to provide DTSC with data and analysis to determine whether reasonable alternatives to the use of the Chemical of Concern in the Priority Product exist. DTSC reviews each AA Report on its own merits, taking into consideration each manufacturer's unique conclusions and proposals. Because each manufacturer's proposal will address its specific business situation, DTSC cannot predetermine the actions that manufacturers of motor vehicle tires containing 6PPD would need to take, either individually or collectively, to meet the goals of protecting the environment and advance green chemistry or green engineering principles. While it is impossible to accurately predict or quantify the full range of potential benefits associated with the implementation of this proposed regulation, DTSC anticipates that it could lead to creation of new businesses in consulting services, chemical and material science research and support, product research and design, marketing, and the development of consumer product safety information and training materials.

Expansion of Businesses Currently doing Business

The AA process requires manufacturers to provide DTSC with data and analysis to determine whether reasonable alternatives exist. DTSC reviews each AA Report on its own merits, taking into consideration each manufacturer's unique conclusions and proposals. Because each manufacturer's proposal will address its specific business situation, DTSC cannot predetermine the actions that manufacturers of motor vehicle tires containing 6PPD would need to take, either individually or collectively, to meet the goals of protecting the environment and advance green chemistry or green engineering principles. While it is impossible to accurately predict or quantify the full range of potential benefits associated with the implementation of this proposed regulation, DTSC anticipates that it could lead to expanded business opportunities in consulting services, chemical and material science research and support, product research and design, marketing, and the development of consumer product safety information and training materials.

Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The primary goal of the SCP regulations is to protect public health and the environment by reducing exposures to potentially harmful chemicals. By listing motor vehicle tires containing 6PPD as a Priority Product, DTSC sets in motion a strategy to reduce exposure to 6PPD from the manufacturing, use, and end-of-life this product. A reduction in exposure to 6PPD could benefit the health of California's wildlife. These improvements will in turn benefit tribal economies by potentially reducing the amount of

resources spent on efforts to preserve impacted wildlife species. Reducing the threat from 6PPD and 6PPD-quinone may help the coho population rebound. Native communities' health, well-being, economic resilience, and preservation of their cultural heritage may benefit from larger salmon populations.

DTSC cannot predetermine the alternatives that each manufacturer of motor vehicle tires containing 6PPD will propose; therefore, it is impossible to accurately predict or quantify the full range of potential benefits associated with their development. DTSC's process encourages the use of alternatives of least concern and prefers those that provide the greatest level of inherent protection. In general, economic benefits to California workers and business owners may include expanded employment opportunities in the fields of consulting, worker and consumer education, and marketing. Additional benefits may accrue because of increased research and product development collaboration between manufacturers and California-based research entities. Institutional and corporate financial support of chemical and material science programs focused on developing safer alternatives to 6PPD could advance the field. These research initiatives could provide manufacturers with employees that are highly skilled in the research and design of products for newly emerging global markets.

While some of these economic benefits will arise from individual DTSC regulatory responses crafted for specific responsible entities, many of the benefits will also arise from the Alternatives Analysis (AA) process. For example, responsible entities that explore safer alternatives, as opposed to simply removing the product from the market, will need to perform rigorous scientific research into alternative chemical-product combinations during the AA development process. This research may stimulate economic activity.

REASONABLE ALTERNATIVES CONSIDERED

Government Code section 11346.2, subdivision (b)(4) requires DTSC to consider and evaluate reasonable alternatives to the proposed regulatory action and provide reasons for rejecting those alternatives. This section discusses alternatives evaluated and provides reasons why these alternatives were not included in the proposal. As explained below, no alternative proposed was found to be less burdensome and equally effective in achieving the purposes of the regulation in a manner than ensures full compliance with the authorizing law. DTSC has not identified reasonable alternatives that would lessen any adverse impact on small business.

Alternative 1: List "motor vehicle tires containing 6PPD" as a Priority Product.

This is the chosen alternative, because it is the only alternative effective in achieving the purposes of the regulation.

Alternative 2: List “motor vehicle tire tread containing 6PPD” as a Priority Product.

While 6PPD is found in tire tread, and tire tread is what is most likely to be worn off and deposited in the environment, 6PPD is found throughout the tire. Similarly, 6PPD-quinone has been found on both the tire tread and the tire sidewall. As such, restricting the definition of the Priority Product to only include the tire tread would ignore the potential for exposure to 6PPD and 6PPD-quinone that originated in the sidewall or other parts of the tire. To meaningfully protect California’s aquatic environment, DTSC decided to include the entire motor vehicle tire in its Priority Product designation.

Alternative 3: Narrow the scope of the definition of “motor vehicle tires” to replacement, all-season tires intended for use on passenger cars.

Tire industry stakeholders suggested to DTSC that the definition of “motor vehicle tires” for the purposes of this regulation should be limited to replacement, all-season tires intended for use on passenger cars. However, all tires contain 6PPD and release tire wear particles to the environment, resulting in exposure of aquatic organisms to 6PPD and 6PPD-quinone. While there is great variety in the types of tires available, industry stakeholders have indicated that any alternatives to 6PPD found for replacement, all-season tires intended for use on passenger cars would work for all tires. As a result, DTSC anticipates that only one Alternatives Analysis will be needed to encompass a broader definition of tires in this regulation. Choosing a broader definition allows DTSC to ensure that any available alternatives are adopted across the tire market, not just in replacement, all-season tires intended for use on passenger cars, and thus increases protection of California’s aquatic environment.

DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS

The SCP regulations established a unique approach to regulating Chemicals of Concern in consumer products that grants DTSC authority to take actions to protect people and the environment when such actions are outside the scope of other regulatory programs. There are no equivalent federal regulations that require product manufacturers to determine if the chemical in their product is necessary, if there is a safer alternative, and to take steps to protect human health and the environment. DTSC has determined that no federal regulations overlap or conflict with this proposal to list motor vehicle tires containing 6PPD, nor with any subsequent regulation that may result from such listing.

The federal Clean Water Act prohibits the discharge of stormwater containing specific pollutants without a National Pollutant Discharge Elimination System (NPDES) permit. U.S. EPA delegates this federal permitting program to the State of California. California’s Municipal Storm Water Program manages NPDES permits for municipalities

and the statewide permit for Caltrans. Neither 6PPD nor 6PPD-quinone is currently regulated by the California State Water Resources Control Board.

The National Highway Traffic Safety Administration (NHTSA) regulates the safety of tires. NHTSA has established several Federal Motor Vehicle Safety Standards setting safety and performance requirements for tires (Code of Federal Regulations, title 49, subtitle B, chapter V, part 571, subpart B). DTSC has determined that these regulations do not overlap or conflict with the proposal to list motor vehicle tires containing 6PPD, as they do not address the potential exposures or adverse impacts under consideration.

Motor vehicle tires would be required to meet current federal standards for safety and performance whether or not DTSC lists motor vehicle tires containing 6PPD as a Priority Product. The SCP Regulations do not allow DTSC to require the use of alternatives to a Chemical of Concern that would compromise a Priority Product's compliance with health and safety requirements.

Current laws and regulations require people who store, stockpile, accumulate, or discard waste tires to comply with tire storage and disposal standards and to obtain a waste tire facility permit. CalRecycle is responsible for administering waste tire programs in California and has established technical standards and a permitting program for waste tire facilities. DTSC has determined that these regulations do not overlap or conflict with the proposal to list motor vehicle tires containing 6PPD, as they do not address the potential exposures or adverse impacts under consideration. If motor vehicle tires containing 6PPD were listed as a Priority Product, they would still be subject to CalRecycle's storage and disposal requirements.

To date, no federal regulation has been developed to address 6PPD used in motor vehicle tires, and therefore there is no conflict or duplication between any federal regulation and this proposed rule.

REFERENCES

Assembly Bill 1879 (Feuer, Chapter 559, Stats. 2008) was signed into law on September 29, 2008, laying the critical foundation for the Green Chemistry Program. This bill provides the authority and mandate to adopt proposed SCP regulations.

Division 4.5, Title 22, California Code of Regulations, Chapter 55. Safer Consumer Products.

DOCUMENT RELIED ON

DTSC (2021) Product-Chemical Profile for Motor Vehicle Tires Containing N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD).

APPENDIX

A. Proposed Regulatory Text