# **Yearly Progress Report**

Motor Vehicle Tires Containing N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD)

Prepared for U.S. Tire Manufacturers Association (USTMA) 1400 K St NW #900 Washington, DC 20005

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## **TABLE OF CONTENTS**

ABLE OF CONTENTS	i
Acronyms and Abbreviations	ii
Summary of Achievements	1
ssues and Their Resolutions	3
Pending Work	6
Assessment of Work Plan	7

## **ACRONYMS AND ABBREVIATIONS**

6PPD N-(1,3-Dimethylbutyl)-N''-phenyl-p- phenylenediamine

6PPDQ N-(1,3-Dimethylbutyl)-N''-phenyl-p- phenylenediamine Quinone

AA Alternatives Analysis

ARDL Akron Rubber Development Laboratory
CEPA Canadian Environmental Protection Act, 1999
DTSC Department of Toxic Substances Control

EIA Economic Impacts Analysis

EU European Union

NDA Non-Disclosure Agreement
PPDs Paraphenylene Diamines

QSAR Quantitative Structure-Activity Relationship

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals

SCP Safer Consumer Products
TSCA Toxic Substances Control Act
USGS United States Geological Survey
USTMA U.S. Tire Manufacturers Association

## **SUMMARY OF ACHIEVEMENTS**

- 1. A U.S. Tire Manufacturers Association (USTMA) 6PPD Alternatives Analysis Consortium (Consortium) working group has met approximately every two weeks since the approval of the Preliminary Alternatives Analysis (Preliminary AA) to review new toxicity and performance data on possible alternatives, work on testing plans, and review data provided by chemical suppliers at the working group's request.
- 2. USTMA developed and sent a survey to Consortium member companies asking if they had obtained additional data on toxicity and/or performance for possible alternatives (including any not identified in the Preliminary AA). This is in addition to the original member survey conducted as part of the Preliminary AA process. Our outside counsel collected and anonymized the survey responses. We then analyzed the data to determine if there were additional alternatives to be included in Stage 2. As a result, additional alternatives were added to the Stage 2 evaluation.
- 3. USTMA met with a number of individual chemical suppliers who are also researching 6PPD alternatives, signed non-disclosure agreements (NDAs) where necessary, and engaged in discussions to obtain performance and toxicity test data and to follow up where critical information was lacking.
- 4. We engaged with the Akron Rubber Development Laboratory (ARDL), a highly regarded rubber testing group, to conduct screening performance tests of different alternatives in rubber tire sidewall compound. Tire sidewall compound is being used for initial testing because compounding tire tread has many more variables (in part due to the inclusion of silica). USTMA worked with ARDL to identify several screening-level performance tests and sponsored two series of testing (we are currently waiting for the full results of the second series). Results from the initial series of testing suggested some inconsistencies and the USTMA working group members are engaging with ARDL scientists to address these.
- 5. USTMA is working to develop a novel mixing procedure that would avoid residual amounts of 6PPD in rubber compounds containing possible alternatives. We found that trace amounts of 6PPD may remain on equipment used to mix tire rubber compound. While it would not impact performance, we observed that residual 6PPD (converted to 6PPDQ during ozonation prior to testing) could affect the results of the laboratory toxicity tests that were run independently by United States Geological Survey (USGS). This is further discussed in Section 2.

- 6. We reviewed and summarized newly available (2021 to early 2025) *in vitro* and *in vivo* coho salmon toxicity data on possible alternatives to evaluate in Stage 2. This information will be used to help screen possible alternatives in Stage 2.
- 7. We consolidated performance data from members, chemical suppliers, and publicly-available scientific literature and patents in order to conduct an initial screen of possible alternatives to evaluate in Stage 2. Alternatives that had data clearly indicating ineffective performance as an antiozonant would be eliminated for consideration in Stage 2.
- 8. We compiled an initial list of 30-plus possible alternatives for consideration in Stage 2. These alternatives were compiled from the results of our Preliminary AA, the member survey mentioned above, a new patent search focusing on the years 2021 to present, discussions with suppliers, and a review of other AAs submitted to the Department of Toxic Substances Control (DTSC). We incorporated the collected toxicity data (mentioned in bullet 6) and performance data (bullet 7 above) into our list of possible alternatives, and are using that information to narrow down our list of possible alternatives. Currently, 24 of the total potential alternatives, including the seven Stage 2 possible alternatives from our Stage 1 AA, are still being considered, and this process is ongoing. The remaining list of possible alternatives includes both PPDs and non-PPDs.
- USTMA evaluated the scope of the Economic Impacts Analysis (EIA) required in Stage 2 in consultation with a retained economic analysis firm. The EIA will be conducted on the final set of Stage 2 alternatives that are expected to be available in early 2026.
- 10. Members of the Consortium attended/presented at various conferences that were relevant to the search for 6PPD alternatives in tires.

## **ISSUES AND THEIR RESOLUTIONS**

Residual 6PPD found in samples used in initial laboratory toxicity testing. Initial studies at USGS identified residual levels of 6PPD and 6PPDQ in non-6PPD samples due to the mixing process.
 Typical procedures used for equipment cleaning during tire compound mixing do not remove trace levels of 6PPD. In order to eliminate the risk of cross-contamination leading to erroneous testing results, the Consortium is developing an alternative mixing protocol. Further in vitro testing of rubber compound was paused while an alternative mixing protocol is developed and tested.

To address this issue, we are developing an alternative mixing protocol at the rubber testing laboratory and we will evaluate the protocol with the rubber testing laboratory and USGS.

2. The Stage 2 Consortium member survey was a major effort. The results of the Stage 2 member survey were randomized and anonymized by outside counsel to protect confidential business information. In some instances, follow-up inquiries were needed to substantiate the conclusions from the responses. For example, if a response indicated that a possible alternative had "poor performance" or "was unsatisfactory" as a replacement for 6PPD, details regarding the test methods and specific results were requested. If detailed information regarding test methods or results were unavailable, comparison across different Consortium member companies was more challenging.

To address this issue, where appropriate, USTMA, its consultants, and outside counsel developed a list of follow-up questions to get more details regarding test methods and results from Consortium members. Outside counsel directed the questions to the appropriate company and then anonymized the results for reporting back to USTMA. The additional information should make it possible to compare data across member companies.

3. Performance information was difficult to compare due to different metrics. Ozone resistance and other performance characteristics (e.g., scorch time) were evaluated using different methodologies (e.g., different ways of assessing tire cracks, different test conditions) which made aggregating data and comparing the various possible alternatives more challenging.

To address this issue, Gradient is developing a heat map approach that utilizes a color scheme for the relative performance of alternatives to 6PPD to help illustrate differences in performance amongst possible alternatives.

4. Potential loss of federal funding for the USGS laboratory engaged in the toxicity screening program have led to a pause in discussions regarding further testing. A loss of federal funding for the USGS laboratory could jeopardize the toxicity screening program.

To address this issue, USTMA contacted members of Congress and the Executive Branch urging continued funding for the USGS laboratory due to its important work for the tire AA effort. The USGS laboratory remains operational, although future funding remains uncertain. USTMA is exploring other laboratory capacity to expand our third-party capabilities.

5. The purpose of the performance screening tests at ARDL is to evaluate possible alternatives using the same laboratory and testing methods for better comparison. Alternatives with poor performance results from these screening tests would be expected with high certainty to fail more advanced testing. This performance screening is therefore critical to the Stage 2 AA. After the initial series of testing was completed, USTMA members observed some inconsistencies in the results. For example, alternatives with similar chemical structures showed very dissimilar performance results in the same test.

To address this issue, USTMA commissioned a second series of testing at ARDL that included some repeated measures and tests designed to confirm the results of the first series of testing. USTMA Consortium members will also be chemically analyzing the rubber compounds tested in both series one and two as a quality control confirmation measure. The need to finetune performance tests with an outside lab is expected. We are currently awaiting the results of the current ozone testing at ARDL.

6. PPDs as a chemical class are increasingly a regulatory focus for various jurisdictions. There is currently discussion of a regulatory proposal in the European Union (EU) which may prohibit or restrict the use of PPDs as a chemical class. The EU is expected to release a regulatory proposal in early 2027. The timing of any implementation, the scope of potential restrictions, and the possibility of exemptions for industries where no viable non-PPD alternatives exist are all unknown. Additionally, we are aware that on July 11, 2025, DTSC initiated rulemaking to add PDD derivatives to the Candidate Chemicals list. The details of any final rule are not known at this time. These regulatory developments are major sources of uncertainty for the AA.

USTMA will continue to monitor these regulatory developments in the EU and California. As a global industry with a global supply chain, it is impracticable to have a 6PPD replacement that is customized for each jurisdiction. Given the long timeline to verify that an alternative can be safely used in commercially produced tires (discussed further in point 7), it is also not practical to transition to an interim solution in one jurisdiction while waiting for regulations to develop in another. Therefore, potential EU restrictions or California regulations for PPDs may affect the scope, type, and testing of alternatives considered as part of the tire AA process. Consequently, these regulatory developments will be considerations (not necessarily deciding factors) in identifying possible alternatives.

7. The time frame allowed by the Safer Consumer Products (SCP) AA process is shorter than the time frame required to fully determine whether an alternative to 6PPD can be safely used in

commercially produced tires. As mentioned in the Consortium's Preliminary AA report, an extensive set of tests are required for a new tire formulation or design before new tires can be safely placed in the market. Two example issues related to the limited time frame are provided below:

- a. If chemicals have passed the initial performance and toxicity testing screens, they will then need to be evaluated more comprehensively in a complete battery of rubber compound tests and then eventually tested in actual tires (refer to Section 3.4 of the Consortium members' Preliminary AA for a discussion of the tests required). While efforts will be undertaken to expedite the process where appropriate, in general, tire research and development, design, and performance testing processes using an identified chemistry that is commercially available and known to perform as necessary in tires, can take a minimum of 4 to 6.5 years. For potential 6PPD alternatives, an additional 4 years (minimum) of limited-scale field testing would be required to ensure ozone performance as the tire ages.
- b. If any of the identified alternatives need additional physical-chemical or toxicological data to allow market access for a 6PPD alternative (*i.e.*, under TSCA, REACH, CEPA) then that testing and/or risk assessment work will also need to be conducted before the alternative can be used at the scale needed to replace the priority product. Although this type of testing will be the responsibility of the chemical manufacturer, a chemical must be available for commercial use before it can be adopted by Consortium members to replace 6PPD. If required, we anticipate that completing such additional regulatory steps could take numerous years. Consequently, the need to conduct such testing will be a consideration (not necessarily a deciding factor) in identifying possible alternatives.

Consortium members will discuss these issues as part of the detailed implementation plan that will be in the Stage 2 AA report.

## PENDING WORK

- Performance testing at ARDL. The Consortium is currently waiting for the second series of
  ozone resistance test results in tire sidewall compounds at ARDL (expected November 2025).
  These results will inform future testing of tire tread compounds. USTMA is exploring other
  laboratory capacity to expand third-party support for the AA. The Consortium's objective is to
  complete testing in tread compounds by December 2025.
- 2. Toxicity testing. Once we have determined the most promising possible alternatives from the performance testing (expected December 2025), we will initiate toxicity testing at USGS. This will likely involve in vitro screening followed by testing using live coho salmon for those possible alternatives that indicate less potential for toxicity from in vitro results. While the performance testing is being completed, in vitro and in vivo toxicity test design details will be finalized with the laboratory such that testing can start in early 2026. Hopefully, the results of the in vitro screening (at least) will be available within several months. Additionally, we are exploring other laboratory options to expand our testing capabilities.
- 3. Economic Impacts Analysis. As noted earlier, this EIA will be conducted once the possible alternatives for evaluation in Stage 2 have been well-defined by the screening level performance testing at ARDL. The Consortium's objective is to complete performance testing in tread compounds by December 2025, followed by the EIA.
- 4. Data gap filling. We will conduct final hazard and exposure evaluations, including any data gap filling, for the most promising alternatives that remain in consideration by December 2025. We will prepare the same color-coded tables used in the Preliminary AA to illustrate this information.
- 5. Toxicity data from chemical suppliers. The Consortium is still waiting for toxicity testing data from some chemical suppliers of the newer possible alternatives. We hope to obtain those test reports in the next few months.

## ASSESSMENT OF WORK PLAN

Table 1 below is an update of the schedule provided in the Preliminary AA (Table 7.1 from the Preliminary AA report). As demonstrated in Table 1, there were some changes from the submitted work plan. The initial review of new alternatives took longer than expected, largely due to the need for meetings with suppliers and to develop and implement a new member survey. These steps were especially critical because the search for a 6PPD alternative is an active area of research both within and outside the tire industry. While we believe it was valuable to take the time to complete a comprehensive review, the search delayed some of the other steps in the AA.

Testing at ARDL has been slower than anticipated. We also decided to use the results of this testing to screen alternatives for full evaluation in Stage 2. Full hazard and exposure evaluations and/or toxicity screening on alternatives will proceed after performance screening.

Table 1. Proposed Updated Stage 2 AA Completion Schedule

As Written in the Preliminary AA (2024)		Updates to the Schedule (2025)
Action Item	Potential Completion Date*	
Update possible alternatives search  Revisit conceptual model	Weeks 1 to 8	This work has been initiated and is largely complete, although the time frame was
Initiate more in-depth hazard and exposure factor review		longer than anticipated.
Develop preliminary performance testing plan (NOT REQUIRED UNDER SCP)		Completed.
Develop additional toxicological testing plan (USGS, also NOT REQUIRED UNDER SCP)		Having discussions with USGS, toxicity screening follows completion of initial performance screening.

As Written in the Preliminary AA (2024)		Updates to the Schedule (2025)
Action Item	Potential Completion Date*	
Engage with economist, begin assessment of economic impacts	Weeks 3 to 12	Discussions started, assessment requires refined set of Stage 2 alternatives. Expected start in assessment of economic impacts in January 2026.
Meeting with DTSC to discuss issues expected in Stage 2	Week 4 to 6	USTMA is in routine dialogue with DTSC on the Stage 2 AA.
Preliminary performance testing begins	Week 8	Testing design with ARDL started in August, 2024. Testing at ARDL is on-going.
Additional tox testing begins	Week 8	Tox testing will follow performance testing to maximize USGS resources.
Update performance database, determine if newer data are available	Weeks 8 to 48	Completed with the exception of current testing.
Determine if newer hazard data on identified possible alternatives are available	Weeks 8 to 48	In progress.
Revisit relevant factors for Stage 2 in light of reduced possible alternative set	Week 8	Pending results of performance screen and final Stage 2 alternatives list.
Initial data review/tabulation for hazard, exposure, performance, life cycle, and economics impact phase	Weeks 20 to 30	In progress.
Discuss progress/outstanding questions with DTSC	Week 30	USTMA is in routine dialogue with DTSC on the Stage 2 AA.
Explore decision frameworks	Weeks 30 to 32	In progress.
Preliminary performance testing results available	Week 80	Testing is in progress.
Evaluate preliminary performance testing results, follow up questions	Week 80	Testing is in progress.
Incorporate preliminary performance testing results into decision framework	Week 81	No update at this time.

As Written in the Preliminary AA (2024)		Updates to the Schedule (2025)
Action Item	Potential Completion Date*	
Initial decision using appropriate decision framework	Week 82	No update at this time.
Internal review of initial decision, QC by larger group	Week 85	No update at this time.
Prepare final AA report	Weeks 86 to 92	No update at this time.
Report review by working group	Weeks 92 to 94	No update at this time.
Report review by full Consortium	Weeks 95 to 98	No update at this time.
Revise final AA report, final edits	Weeks 99 to 103	No update at this time.
Submit final AA report to DTSC	Week 104	No update at this time.

Notes: Gray shading is to indicate information contained in the 2024 Preliminary AA.

AA = Alternatives Analysis; ARDL = Akron Rubber Development Laboratory; DTSC = Department of Toxic Substances Control; QC = Quality Control; SCP = Safer Consumer Products; USGS = United States Geological Survey; USTMA = U.S. Tire Manufacturers Association.

<sup>\*</sup> All times indicated are after DTSC acceptance of the Preliminary AA report.