January 30, 2025

California Department of Toxic Substances Control
California Environmental Protection Agency
1001 I Street
Sacramento, CA 95814-2828

Re: Background Document on DTSC's Microplastics in Consumer Products Research

Dear DTSC:

The American Cleaning Institute (ACI) appreciates the opportunity to provide comments on the Department of Toxic Substances Control (DTSC) Background Document on Microplastics in Consumer Products Research. In these comments, we highlight that: (1) detergent-grade polyvinyl alcohol (PVA) is a safe, water-soluble, and biodegradable solution, (2) methods for measuring water solubility and biodegradability have been thoroughly developed and refined, (3) water-insoluble polymers are essential for proper cleaning, but reformulation is occurring where it is needed, and (4) alternative materials for polymeric fragrance encapsulations will be deployed in North America, but adequate time is required.

ACI is the home of the U.S. Cleaning Products Industry® and represents the $60 billion U.S. cleaning product supply chain. ACI members include the manufacturers and formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and chemical distributors. ACI promotes industry growth, stewardship, and innovation; to this end, ACI's members conduct extensive research to ensure that the products they market are safe and effective.

Best Regards,

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Introduction
DTSC has an ongoing proposed rulemaking to add "microplastics" to its Candidate Chemicals List with a broad definition ("plastics that are less than 5 millimeters in their longest dimension, inclusive of those materials that are intentionally manufactured at those dimensions or are generated by the fragmentation of larger plastics"). In contrast to other regulatory definitions that narrow in on chemical properties that characterize microplastics, the Department's current definition currently captures all polymer types, including those that are chemically distinct from microplastics.

During this rulemaking period, the Department has published a Background Document outlining its research on the occurrence in consumer products of substances that fall within its definition. The document outlines several product categories evaluated during preliminary screening that have been determined by DTSC to "contain microplastics or to have the potential to release microplastics." This includes: (a) laundry and dishwashing detergents pods containing water-soluble polymers, (b) laundry and dishwashing detergents containing intentionally added water-insoluble polymers, and (c) laundry detergents and fabric softeners containing polymeric fragrance microcapsules.

ACI aligns with DTSC's goals, fundamentally among them reducing the release of microplastics to the environment during all stages of the consumer product life cycle. Laundry and dish detergents are critical in keeping clothing and food handling equipment clean and safe, and can do so without releasing microplastics. Our comments provide information on the cleaning product industry's use of ingredients that offer environmentally favorable solutions despite potentially meeting the Department's microplastics definition.

1. **Detergent-grade polyvinyl alcohol (PVA) is a safe, water-soluble, and biodegradable solution.**

Based on its chemical properties, toxicological profile, and environmental behavior, polyvinyl alcohol (PVA or PVOH) used in detergents is not and does not form microplastics.

Despite being represented by one primary CAS Number (9002-89-5), PVA appears in different 'grades' that vary in their degree of polymerization (viscosity/molecular weight) and degree of hydrolysis during production. Both of these properties have an inverse relationship with the molecule's level of water solubility. This allows PVA to serve a variety of uses, including in textiles, adhesives, films, and construction. Grades are often named with numbers that represent their viscosity (in millipascal-second or mPa·s) and their hydrolysis (%); for example, 'PVA 4-88' refers to PVA with 4 mPa·s viscosity that is 88% hydrolyzed. For detergent pods, a highly water-soluble molecule is required, so 'detergent-grade' PVA (including PVA 4-88) is produced with less polymerization and less hydrolysis than other grades of PVA are. While detergent-grade PVA can range from approximately 79-89% hydrolysis, textile-grade and adhesive-grade PVA feature approximately 98-100% hydrolysis.

DTSC is not the first regulatory body to evaluate the performance and safety of detergent-grade PVA; importantly, other regulators have affirmed its safety for use by consumers in the market. For example, the EPA's Safer Choice is a certification program through which the agency evaluates ingredients used in cleaning products based on all available hazard information (i.e.

environmental fate, toxicological data). Substances that EPA has evaluated have been compiled into the Safer Chemical Ingredients List (SCIL). SCIL-listed substances must pass stringent criteria, including: (1) no carcinogens, mutagens, or reprotoxicants (CMR), (2) no persistent, bioaccumulative, or toxic chemicals (PBT), (3) no asthmagens, (4) no sensitizers, and (5) no substances on authoritative lists of chemicals of concern. Additionally, all entries on SCIL receive a designation of a green circle (lowest concern), half green circle (low concern, but more data would strengthen confidence), yellow triangle (some hazard association, but safest available option for a particular function), or grey square (data required to justify continued listing).

Detergent-grade PVA has a green circle rating on the SCIL based on regulatory opinions and scientific studies. It does not carry an EU Hazard or Risk Phrase for any human health endpoints and is not on authoritative lists as a known or suspected CMR. It is poorly absorbed, shows a lack of carcinogenic effects, and has been cleared as a food additive. Due to its rapid biodegradation, it does not meet the EPA criteria for PBT. EPA reviewed several studies following guidelines from the Organization for Economic Cooperation and Development (OECD) that examined the aquatic toxicity of PVA (Table 1).

Table 1. OECD guideline-following aquatic toxicity studies on detergent-grade PVA.

OECD Guideline	Test	Species	Duration	Result
201	Acute algal inhibition	*Selenastrum capricornutum*	96 hours	EC50 = 1–10 mg/L
201	Acute algal inhibition	*Raphidocelis subcapitata*	96 hours	No effects on growth or biomass at concentrations >100 mg/L
202	Acute invertebrate	*Daphnia magna*	48 hours	IC50 = 1–10 mg/L
202	Acute invertebrate	*Daphnia magna*	48 hours	No effects on mortality, EC50 >100 mg/L
203	Acute fish	7+ fish species	96 hours	Low aquatic toxicity
236	Acute fish embryo	*Danio rerio*	96 hours	LC50 >100 mg/L

In 2023, the US Environmental Protection Agency (EPA) was petitioned to change the safety status of detergent-grade PVA in its Safer Choice program and to require increased testing. The EPA denied this petition after a thorough review, stating that the petition did "not demonstrate that existing information and experience on PVA used in laundry and dishwasher detergent pods and sheets is insufficient to determine or predict human health and environmental risks from such use of PVA." Furthermore, to address claims that the OECD standards governing biodegradability (as discussed above) are insufficient, EPA stated that "the OECD biodegradation test conditions are more conservative than real world conditions [in wastewater treatment plants] and are appropriate tools for predicting biodegradation of PVA." EPA also added that "the Agency identified peer-reviewed literature using OECD guideline studies showing PVA chemical structures used in laundry detergent packets are readily biodegradable." Further, EPA dismissed the argument that PVA bioaccumulates because "the source materials in the references cited by the petitioners are specific to microplastics and not relevant to the types of PVA used in Safer Choice-certified products."

In addition to its safety, the water solubility of PVA of all grades has been well-characterized (Finch, 1983). PVA grades with a degree of hydrolysis up to 90% are highly water-soluble at 20°C. Additionally, manufacturers individually test detergent-grade PVA products through the OECD 120 method; although specific results are proprietary, we have attached an example of a Certificate of Solubility from a manufacturer following OECD 120 testing at accredited external laboratories on detergent-grade PVA. Most recently, a study using three different techniques on detergent-grade PVA concluded that it maintains a stable single molecular chain conformation in water with a nonsolid interface, distinguishing it from known microplastics or nanoplastics (Gummel et al., 2025).

Detergent-grade PVA has also been extensively studied for ready, inherent, and ultimate biodegradability through OECD 301, 302, and 303 testing, respectively (Table 2). Through biodegradation, detergent-grade PVA is effectively removed from wastewater treatment plants (WWTPs), consistently across geographies in the US and EU (Menzies et al., 2023, McDonough et al., 2023).

Table 2. OECD guideline-following biodegradation studies on detergent-grade PVA. OECD 301 tests screen using stringent, unfavorable conditions, while OECD 303 tests closely simulate the conditions of wastewater treatment plants. In addition to theoretical carbon dioxide ($ThCO_2$) generation, the Menzies et al., 2023 studies measured dissolved organic compound (DOC) decrease to confirm mineralization.

PVA Grade	Reference	OECD Guideline	Biodegradation Rate	Conclusion
PVA 79	Menzies et al., 2023	301B	>75% by 28 d, >87% by 60 d	Readily Biodegradable
PVA 4-88	Menzies et al., 2023	301B	>75% by 28 d, >87% by 60 d	Readily Biodegradable
PVA 8-88	Menzies et al., 2023	301B	>75% by 28 d, >87% by 60 d	Readily Biodegradable
PVA 18-88	Menzies et al., 2023	301B	>75% by 28 d, >87% by 60 d	Readily Biodegradable
PVA 18-88	McDonough et al., 2023	301B	81% by 28 d	Readily Biodegradable
PVA 18-88	McDonough et al., 2023	301B	55% by 28 d, 84% by 52 d	Readily Biodegradable
PVA 18-88	McDonough et al., 2023	301F	65% by 28 d, 86% by 60 d	Readily Biodegradable
PVA 18-88	McDonough et al., 2023	301F	81% by 28 d, 88% by 56 d	Readily Biodegradable
PVA 18-88	McDonough et al., 2023	301F	62% by 28 d, 86% by 65 d	Readily Biodegradable

PVA 18-88	McDonough et al., 2023	301F	57% by 28 d, 67% by 60 d	Readily Biodegradable
PVA 18-88	McDonough et al., 2023	301F	65% by 28 d, 86% by 76 d	Readily Biodegradable
PVA 18-88	McDonough et al., 2023	301F	73% by 28 d, 79% by 60 d	Readily Biodegradable
PVA 18-88	McDonough et al., 2023	301F	84% by 28 d, 95% by 56 d	Readily Biodegradable
PVA 18-88	McDonough et al., 2023	301F	70% by 28 d, 87% by 65 d	Readily Biodegradable
PVA 79	Menzies et al., 2023	302B	> 88% by 28 d	Inherently Biodegradable
PVA 4-88	Menzies et al., 2023	302B	> 88% by 28 d	Inherently Biodegradable
PVA 8-88	Menzies et al., 2023	302B	> 88% by 28 d	Inherently Biodegradable
PVA 18-88	Menzies et al., 2023	302B	> 88% by 28 d	Inherently Biodegradable
PVA 18-88	McDonough et al., 2024	303A	97.4% by 60 d	Ultimate Biodegradation

Primary wastewater treatment involves the removal of solids and insoluble materials through physical processes like sedimentation. However, detergent-grade PVA is highly water-soluble (Finch, 1983; Bao et al., 2022); therefore, it is not removed through primary treatment. Secondary treatment involves removal through biological processes like biodegradation; this is overwhelmingly how detergent-grade PVA is removed. Secondary treatment is widespread in California WWTPs (Wong et al., 2024). The microbes that break down detergent-grade PVA are diverse, including common genera such as *Pseudomonas, Bacillus, Sphingopyxis, Alcaligenes, Flavobacterium, Acinetobacter,* and *Xanthomonas* (Kawai & Hu, 2009; Halima, 2016), and do not require pre-adaptation (McDonough et al., 2023; Menzies et al., 2023). Due to high removal efficiency of detergent-grade PVA from secondary treatment through biodegradation, tertiary treatment is not required but may be applied for final effluent polishing for other purposes. This provides support for the effectiveness of California's existing wastewater treatment infrastructure to manage detergent-grade PVA.

The OECD 301B studies in Menzies et al., 2023 took approximately 15-20 days to reach the threshold of 60% $ThCO_2$ generation, while the OECD 302B studies took approximately 14-16 days. The OECD 301B and 301F studies in McDonough et al., 2023 took approximately 15-28 days to reach the threshold. Following wastewater treatment, any residual PVA present in treated effluent is discharged to receiving surface waters in the dissolved phase. Available biodegradation data indicates that PVA continues to undergo progressive biodegradation in the freshwater compartment (i.e., rivers) (McDonough et al., 2023; Menzies et al., 2023), ultimately leading to further mineralization rather than persistence or accumulation as a stable polymer.

OECD 301 studies are conservative screening studies which are predictive of complete biodegradation in environmentally relevant compartments. Although the hydraulic retention time in WWTPs is usually only a few days, biodegradation does not stop there. According to EPA guidance on environmental fate, substances classified as *readily biodegradable* are assumed to have a half-life of about 1 hour in wastewater treatment systems and approximately 5 days in surface waters. These assumptions reflect that readily biodegradable materials degrade quickly and are effectively removed in treatment and natural aerobic environments, including in river water, which has been shown for PVA (e.g., McDonough et al., 2023). Furthermore, during the short time it spends in wastewater before breaking down, unmodified PVA is unlikely to adsorb with pollutants (Muller et al., 2021).

Laundry and dish detergents are available in liquid and powder forms without pre-measurement into pods with PVA film. However, product variety helps meet diverse consumer preferences, lifestyles, and levels of accessibility. Pods' ease of use makes them ideal for people with mobility challenges or who have difficulty measuring liquids/powders. Further, pre-measurement prevents overuse, which reduces chemical discharge and water needed for rinsing. Many pods are also optimized for cold-water washing, cutting energy use and emissions. Alternative materials for the film would still be considered as generating "microplastics" under DTSC's current definition. Unless the definition is refined, there is no viable alternative.

2. **Methods for measuring water solubility and biodegradability of polymers and other chemistries have been thoroughly developed and refined.**

To provide support for the studies outlined in the section above, we elaborate below on the best available methodologies for measuring water solubility and biodegradability.

The OECD is a global forum that promotes policies to improve economic and social well-being, in part through coordinated international efforts to harmonize chemical safety testing. OECD has created evidence-based universal standards for evaluating physical/chemical properties, toxicological endpoints, and environmental fate. These standards are developed collaboratively by government regulators, industry representatives, academic researchers, environmental scientists, and non-governmental organizations (NGOs) to ensure scientific rigor. They are widely accepted in regulatory frameworks and are considered to be the best available science (Strotmann et al., 2023). OECD has developed test methods for solubility and biodegradability.

Solubility can be a beneficial trait for cleaning ingredients because dissolution in water prevents persistence of solid particles, reduces the likelihood of adsorption to pollutants, and increases the opportunity for biodegradation. There are several OECD test methods to assess water solubility (such as OECD 105), often using the "flask method." This involves adding a known amount of test substance to a fixed volume of water in a closed flask, shaking or stirring the flask at a controlled temperature for a set time (to reach equilibrium), and separating the aqueous phase to analyze the dissolved concentration. Typically, regulatory frameworks require a result of ≥1 mg/L or ≥10 mg/L dissolved test material for a substance to be considered water-soluble.

The OECD 120 guideline was designed specifically to evaluate solution and extraction behavior of polymers, and involves a modified flask method: larger amount of test sample, longer stirring duration, filtering or centrifugation to separate undissolved material, and possible extraction steps to quantify partially dissolved polymer. These modifications allow the OECD 120 test to evaluate the extent of dissolution or extraction rather than absolute solubility.

There is also a diverse set of OECD test guidelines to measure biodegradability. Biodegradability is a beneficial trait for cleaning ingredients because it rapidly reduces their persistence in the environment, thereby maintaining low exposure levels. Polymers that undergo true biodegradation (under wastewater treatment or environmentally relevant conditions) are converted to non-polymeric substances and do not persist as microplastic particles, even if a transient particulate phase occurs. Experimental evidence demonstrates that certain biodegradable microparticles disposed down the drain undergo substantial mineralization and do not persist as microplastics (McDonough et al., 2017).

OECD biodegradability guidelines provide a tiered framework for evaluating the environmental fate and persistence of chemical substances under progressively more realistic conditions. The central principle of this framework is that meeting any one of the specified test methods and associated pass criteria, either individually or in combination, provides strong evidence that a substance is unlikely to persist in the environment. The framework spans conservative screening-level tests, inherent biodegradability assays, and higher-tier simulation studies, allowing biodegradation potential to be assessed across a range of environmental and exposure scenarios. Below, please find general information about the various OECD methods (Table 3) used by the cleaning industry to test many of their ingredients.

Table 3. The OECD 301 and 310 series comprise screening-level tests for ready biodegradability conducted under deliberately stringent conditions using small, non-acclimated microbial populations, no acclimation period, and short test durations. The OECD 302 series assess inherent biodegradability under conditions that are less stringent and more representative, making them particularly relevant for substances with more complex structures. Higher-tier simulation methods, including the OECD 303 and OECD 314 series for sewer and wastewater treatment systems, and the OECD 309 and OECD 314D test for surface waters and mixing zones, evaluate biodegradation under environmentally relevant conditions using realistic microbial communities, exposure concentrations, and extended test durations. These simulation studies generate robust, quantitative evidence of biodegradation and are particularly important for substances that may underperform in conservative screening tests yet biodegrade rapidly under realistic environmental conditions, including polymers (Wilcox et al., 2025). These OECD guideline methods are recognized and accepted within EU regulatory frameworks (such as REACH) and by the US EPA as scientifically valid tools for environmental fate and persistence assessment when applied within a weight-of-evidence framework.

Test Method	**Pass Criteria**
Ready biodegradation screening test: OECD 301, 310	≥60% ultimate biodegradation or 70% DOC removal in 28 d pass criteria (no 10-d window)
Enhanced ready biodegradation test (ERBT): OECD 301, 310, 306	≥60% ultimate biodegradation or 70% DOC removal in 60 d
Inherent biodegradation tests: OECD 302B, 302C	≥60% ultimate biodegradation or 70% DOC removal in 28 d
Ultimate aerobic biodegradability in aqueous media test: ISO 14851/14852	≥60% ultimate biodegradation in 6 months

Sewer and wastewater treatment plant simulation studies: OECD 303A, 314A, 314B	≥80% primary biodegradation or DOC removal
Freshwater simulation studies: OECD 309, 314D	Primary biodegradation half-life < 60 d
Weight of evidence non-standard assays, modelling and read across	High levels of biodegradation predicted in weight of evidence assessment

3. **Water-insoluble polymers are essential for proper cleaning, but reformulation is occurring where it is needed.**

Insoluble polymers should not automatically be considered contributors to long-term microplastic pollution. Many insoluble polymers have a toxicological profile of low concern and have been extensively studied and vetted through multiple regulatory programs. Polymers that are truly biodegradable (under wastewater treatment or environmentally relevant conditions) are broken down into non-polymeric substances and therefore do not persist as microplastic particles, even if a temporary particulate phase occurs during degradation. Experimental evidence shows that certain biodegradable microparticles disposed of down the drain undergo substantial mineralization and do not remain in the environment as microplastics (McDonough et al., 2017) warranting their exclusion from microplastic pollution consideration.

Insoluble polymers critically enable cleaning products to function correctly and help guide consumers to use products as directed. For example, excessive foaming in cleaning products can interfere with rinsing and compromise the friction needed for effective cleaning; therefore, anti-foaming agents help maintain product performance and efficiency in both manual and machine applications. Opacifiers add visibility to a product formulation, enabling users to gauge and portion the correct amount, thereby preventing overuse or underuse. Rheology modifiers control viscosity and flow behavior, ensuring stability of a formulation and easy pourability without phase separation or stringy residues. This maintains a product's performance and shelf-life, and eases the user experience.

The European Union's Synthetic Polymer Microparticle Restriction (EU 2023/2055) defines "synthetic polymer microparticles (SPMs)" as "solid, organic, insoluble, resistant to degradation, and less than 5mm in size (or <15mm for fibers with a >3 length-to-diameter ratio) and intentionally added to products." This was developed through an extensive scientific process involving government, academics, industry, non-profit organizations, and the public to accurately identify the chemical properties that define these particles. The focus of the EU definition is to characterize a specific set of substances whose properties are believed or evidenced to have negative environmental effects, namely bioaccumulation, lack of biodegradability, low solubility (leading to persistence and accumulation), or the presence of a hard surface capable of adsorbing and transporting toxic pollutants.

As a result, many insoluble polymers used in cleaning products that are *not* SPMs are derogated in this regulation (and thus remain compliant) because they undergo biodegradation, are not in solid form, are inorganic, or fall outside of the size range in the definition. Modification of a solid insoluble polymer to non-solid form also enables compliance. Where needed to comply with EU regulations or to further enhance product safety, alternatives are being developed and will be deployed around the world.

However, without a clear and specific definition of “microplastics” from DTSC, it is uncertain whether EU-compliant insoluble polymers would be compliant with DTSC regulations. Therefore, we urge the Department to refine its definition by adding the appropriate exclusions.

4. **Alternative materials for polymeric fragrance encapsulations will be deployed in North America, but adequate time is required.**

Global and multinational companies want to use materials that are consistent and universally compliant with regulations based on safety and sustainability attributes. Therefore, the cleaning industry intends to deploy EU-compliant alternative materials in North America as well. However, the reformulation process is lengthy and complex; therefore, adequate time is needed.

EU 2023/2055 began applying on October 17, 2023. Notably, the previously mentioned EU definition of “SPMs” contains exclusions based on water solubility, biodegradability, and other properties to encourage innovation of safe and non-persistent polymers. Detergents with fragrance encapsulations were granted a 6-year transition period, meaning that non-compliant materials will be prohibited beginning October 17, 2029. However, this timeline may be further extended to ensure that the best possible alternatives can be employed in the reformulation process.

Research and development time (which can be variable) is needed to optimize alternative materials. Once alternatives are developed, there are regulatory barriers – particularly the US EPA’s Toxic Substances Control Act (TSCA) New Chemicals program, which has exhibited significant delays since 2016. Due to the TSCA New Chemicals backlog, many alternatives are stifled from coming to market in the United States – even those that are already available overseas. Aside from TSCA, uncertainties about how DTSC may define “microplastics” also complicate regulatory compliance. As mentioned, the EU has added exclusions based on water solubility and biodegradability, but it is unclear whether DTSC’s definition will be consistent.

The EU’s current transition period is a good starting place, but flexibility is needed to account for TSCA uncertainties, other possible regulatory inconsistencies, and the possibility for EU extensions.

Alternatives are focused on biodegradability. However, it is important to note that the function of fragrance encapsulation technology would not be achievable if it were water-soluble. Fragrance encapsulation polymers serve as shells that surround liquid fragrance oils. These shells gradually rupture or slowly diffuse fragrance during use, lengthening the duration that the fragrance lasts on fabrics or surfaces. If the shells were water-soluble, they would dissolve rapidly when exposed to water (i.e., during washing), causing the fragrance to release all at once rather than gradually. Thus, these shells must remain intact in water-based environments and only break or diffuse under specific conditions (such as friction, heat, or pH changes) so that the scent lasts longer and is delivered in a controlled manner. This is in contrast to scent booster beads, which *are* designed to fully degrade during the laundry cycle.

Although alternatives will include innovations that may be considered natural, a DTSC definition for "natural" is needed to understand if these innovations would meet the Department's criteria. Nonetheless, it is worth noting that natural materials are not inherently more biodegradable (i.e., wood).

Conclusion

We underscore that ACI members support efforts to prevent or minimize microplastic pollution. To accomplish this, a focused and accurate definition of "microplastics" is required. Many polymers used in cleaning products are chemically distinct from microplastics, and a clear definition will help to guide replacement/reformulation where necessary. We hope DTSC will consider ACI's input and are happy to serve as a resource for DTSC throughout this process.

Certificate of Solubility

Cert. no. ST2022005

MonoSol has conducted Solubility testing, using Charles River Laboratories Den Bosch BV., a 1e GLP endorsed, AAALAC-accredited environmental laboratory, in accordance with OECD 120: Solution/Extraction Behaviour of Polymers in Water on the product identified as:

M8630

The above product meets requirements for

SOLUBILITY

(as per COMMISSION REGULATION (EU) 2023/2055 of 25 September 2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles: Criteria for demonstrating solubility > 2 g/L according APPENDIX 16)

CRL Report No. 20303094

Yash Parulekar, Ph.D.
Global Product Strategy and Stewardship

11-28-2023