Smart Innovation:

THE OPPORTUNITY FOR SAFER PRESERVATIVES

Executive Summary

EDF ENVIRONMENTAL DEFENSE FUND™
Finding the ways that work

FULL REPORT AVAILABLE AT:
www.edf.org/preservatives

ABOUT ENVIRONMENTAL DEFENSE FUND

The goal of the health program at Environmental Defense Fund (EDF) is to improve human and ecological health through reductions in exposure to harmful chemicals and pollution. EDF's health program uses the dual levers of public policy and corporate leadership to phase harmful substances and practices out of the market and introduce safer products and practices into mainstream use. We encourage and support innovations that work toward this end.

ABOUT THIS REPORT

The Preservative Innovation Project (PIP) offers a framework to direct innovation for specific functional classes of chemicals (e.g., preservatives) in order to drive safer chemicals and products into the marketplace. The primary output of the framework is a uniformly-developed, baseline set of toxicological information for a representative set of chemicals in a functional class. Such baseline toxicological information can be used to inform design criteria for new chemical research and development (R&D); provide a basis of toxicological comparison for new chemicals entering the market; and direct additional chemical testing and research where data are lacking or insufficient. The PIP was led by Environmental Defense Fund, with input from several companies including Active Micro Technologies, Beautycounter, Clariant, and Seventh Generation as well as the Green Chemistry and Commerce Council. However, EDF is the sole author of this report. Organizations that provided input into its development should not be interpreted as endorsers of the content.

This report describes the PIP framework, and the findings and conclusions drawn from the toxicological evaluation of a subset of commercially available preservatives.

ACKNOWLEDGEMENTS

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Executive Summary

More and more consumers, commercial purchasers, and retailers are seeking products that are responsibly and sustainably produced (Headwaters, 2016), and as part of this movement, are increasingly attentive to the potential health and environmental hazards of product ingredients. Recent reports show that the health impacts of products are a number one priority for consumers (Headwaters, 2016; UL, 2013). Finding ways to innovate safer ingredients and products is proving to be good for consumers and the environment, and for business growth. By using safer chemicals in products, retailers and manufacturers stay ahead of regulatory developments, better manage brand and financial risk, and demonstrate that they are responsive to consumer demand.

Some of the most important chemicals in consumer products today are preservatives. Preservatives play an important role in preventing microbial growth in products such as personal care products. However, certain preservatives have come under regulatory and market pressure for human health and environmental concerns (see Appendix A in full report). Given these realities and the ubiquity of preservatives in products, the development of safer, effective preservatives is crucial and offers a prime opportunity for innovation.

Did you know?

66%

of consumers worldwide are **willing to pay more** for sustainable products.

87%

of consumers globally say **"uses no harsh chemicals or toxins"** is a major driver when buying beauty and personal care products.

Many major retailers, including **Walmart** and **Target**, are creating or expanding upon chemical policies that ban or limit the use of toxic chemicals in the products they sell.

The lack of comprehensive, structured, transparent, and comparable toxicological information across different functional classes (e.g., preservatives) is a major obstacle to safer chemical innovation. Such baseline information is invaluable for setting safer chemical design criteria that chemical and product developers can use in their efforts to design or select safer chemicals.

EDF launched the Preservative Innovation Project (PIP) in 2015 to show the utility of generating baseline sets of toxicological information to guide chemical innovation efforts.

Focusing on preservatives used in personal care products, EDF assembled a small group of leading preservative suppliers and product manufacturers (PIP working group) to identify a set of 16 commercially available preservatives (PIP preservatives) on which to conduct a toxicological evaluation. Specifically, PIP preservatives were evaluated using the GreenScreen® for Safer Chemicals Method (GreenScreen®) — a comprehensive chemical hazard assessment method that has been used by government, public interest groups, researchers, and businesses alike to evaluate and characterize the potential hazards of chemicals.

Meaningful baseline toxicological information should be the following:

COMPREHENSIVE

An extensive set of human and ecological toxicity endpoints are evaluated.

STRUCTURED

Data collection, assessment, and integration is accomplished in a consistent manner for all chemicals evaluated. Hazard characterizations are assigned according to pre-specified criteria.

TRANSPARENT

The approach used to research hazard characterizations including how data are identified, collected, and integrated is clear, documented, and made available. Similarly, full chemical hazard assessments are made available.

COMPARABLE

Hazard characterizations across all endpoints are presented in a consistent, accessible manner that allows for easy comparison.

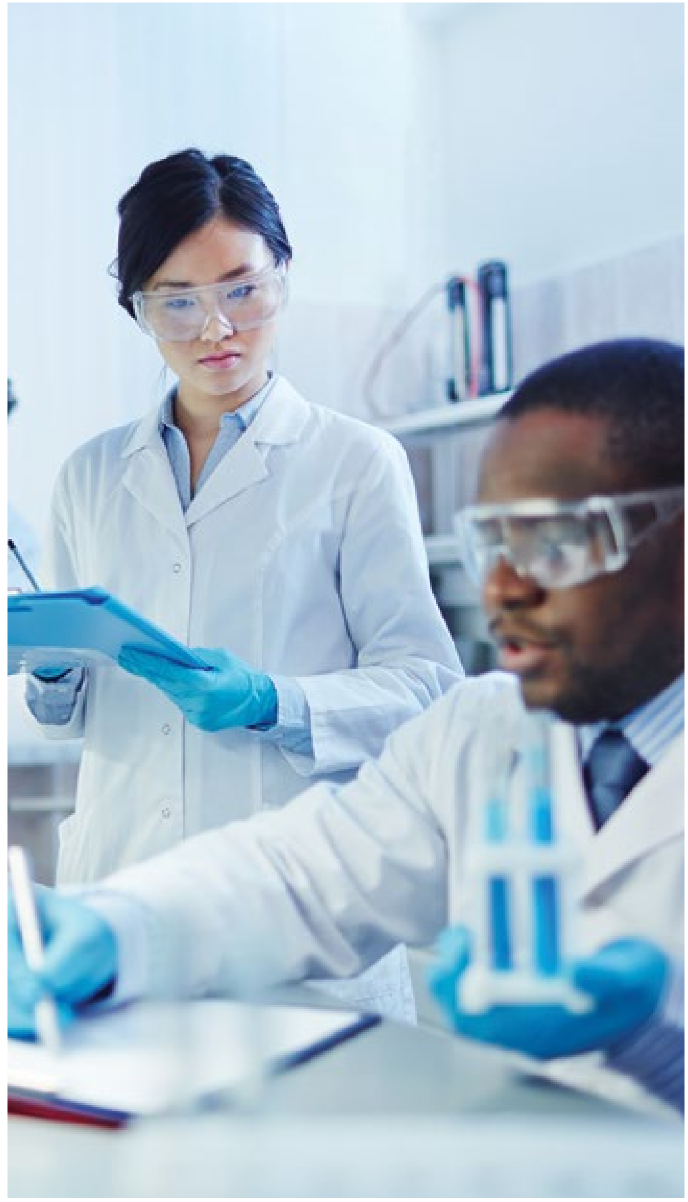
GreenScreen® for Safer Chemicals Method

In the GreenScreen® method, a licensed GreenScreen® assessor evaluates chemicals across 18 human health, environmental, and physical hazard endpoints and assigns a hazard score for each endpoint using prescribed criteria.

An indication of the degree of confidence in the assignment of a hazards score, based on the quality of the available data, is also provided. Where data are insufficient to assign a hazard score, the assessor will assign the endpoint as a Data Gap.

Finally, an overall toxicity 'Benchmark' score that integrates hazard scores and data gaps across all 18 endpoints is determined using a specified algorithm (CPA, 2011).

CPA, 2011, 2012a, 2013
See Appendix C in full report for a fuller description of GreenScreen®



GreenScreen® is strictly a hazard assessment method, developed to rigorously evaluate the intrinsic hazard of chemicals. GreenScreen® does not assess how much exposure there may be to a given chemical, an important aspect in the evaluation of the overall risk a chemical may present to an individual or ecosystem. Often product manufacturers will manage chemical risk by limiting the amount of a chemical in a product, in other words, by managing the extent of exposure to the chemical. However, identification and use of ingredients with lower intrinsic hazard is an important and effective way to reduce overall potential health concerns. Individuals are often exposed to mixtures of chemicals presenting similar hazards, and certain subpopulations can be more susceptible than others to these exposures. Innovation efforts focused on creating inherently safer chemicals complement important restrictions on the amount of chemicals presenting hazard permitted in products—together reducing overall impacts to human health and the environment.

Key Findings

GreenScreen® evaluations of the 16 PIP preservatives yielded the following key findings:

- Several PIP preservatives scored Moderate to Very High for skin sensitization, skin irritation, eye irritation, and acute and chronic aquatic toxicity.
- Only one PIP preservative, DMDM hydantoin, received a High hazard score for a GreenScreen® Group I human health endpoint. Specifically, DMDM hydantoin scored High for carcinogenicity, as a result of its release of formaldehyde, a known human carcinogen. GreenScreen® Group I human health endpoints represent hazards that lead to chronic or life-threatening health effects that may result from low dose exposures and include carcinogenicity, mutagenicity, reproductive toxicity, developmental toxicity, and endocrine activity (see Appendix C).
- Confidence in the assignment of hazard scores varied widely across the PIP preservatives. For any given preservative, endpoints assigned scores with high confidence ranged from two (caprylohydroxamic acid, Lactobacillus ferment, sorbitan caprylate) to 14 (methylisothiazolinone and piroctone olamine), with an average of ten endpoints assigned scores with high confidence.
- All PIP preservatives had data gaps for at least two hazard endpoints. The number of data gaps ranged from two (IPBC, methylisothiazolinone, propylparaben, and sorbic acid) to 13 (Lactobacillus ferment), and the average number of data gaps across the preservatives was four.
- Data gaps were consistently encountered in the assessment of endocrine activity, neurotoxicity, and respiratory sensitization.

Endpoints often scored as Moderate to Very High

PIP PRESERVATIVE	HAZARD ENDPOINT			
	Skin sensitization	Skin irritation	Eye irritation	Acute and/or chronic aquatic toxicity
Benzyl alcohol	●		●	
Caprylohydroxamic acid			●	●
Caprylyl glycol			●	●
DMDM Hydantoin	●	●		●
EDTA		●	●	●
Ethylhexylglycerin	●		●	●
Gluconolactone				
IPBC	●		●	●
Lactobacillus ferment				
Methylisothiazolinone	●	●	●	●
Phenoxyethanol			●	
Piroctone olamine		●	●	●
Propylparaben	●	●		●
Sorbic acid	●	●	●	●
Sorbitan caprylate				●
Undecylenic acid	●	●	●	●
TOTAL	**8**	**7**	**11**	**12**

Overall GreenScreen® Benchmark (BM) scores for the PIP preservatives were as follows:

BENCHMARK	4	Safer chemical	• None
BENCHMARK	3	Use but still opportunity for improvement	• Caprylyl glycol • Sorbitan caprylate
BENCHMARK	3DG	[Data gaps exist] Use but still opportunity for improvement[1]	• Gluconolactone
BENCHMARK	2	Use but search for safer alternatives	• Benzyl alcohol • EDTA • Ethylhexylglycerin • IPBC • Methylisothiazolinone • Phenoxyethanol • Piroctone olamine • Propylparaben • Sorbic acid • Undecylenic acid
BENCHMARK	1	Avoid - Chemical of high concern	• DMDM Hydantoin
BENCHMARK	U	Unspecified due to insufficient data	• Caprylohydroxamic acid • Lactobacillus ferment

1 A Benchmark score of 3DG means that the chemical meets the hazard classification requirements of a Benchmark 4 but does not meet the data gap requirements; however, it does meet the data gap requirements for a Benchmark 3

The EDF Preservative Innovation Project was successful in identifying human and ecological hazard hotspots among the preservatives evaluated, such as skin sensitization and aquatic toxicity as well as identifying endpoints for which data were frequently lacking or insufficient, such as endocrine activity and neurotoxicity. The baseline information generated through the PIP can be used to set design criteria and define data needs for safer preservative R&D, as well as provide a basis of toxicological comparison for new preservatives entering the market.

One element not pursued in the PIP was a measure of performance—that is how well a particular chemistry provides the function of interest, in this case product preservation. Performance is key to evaluate when comparing safer alternative options. For example, a product manufacturer typically needs to prevent the growth of a broad spectrum of pathogenic microorganisms including certain bacteria, yeast, and molds.

Because preservatives can be effective against some microorganisms and not others, a product manufacturer needs to consider preservative performance or efficacy alongside potential toxicity. Indeed, product manufacturers often use blends of preservative chemicals in their products to achieve broad spectrum preservation. Similarly, alternative preservative chemicals may be effective against the same microorganism but under different formulation conditions or at different concentrations, which in turn can impact product cost and toxicological risk. EDF was ultimately unable to pursue performance testing of the PIP preservatives due to funding and time constraints.

Full GreenScreen® reports are available online at: **www.edf.org/preservatives**

Skin sensitization is of particular relevance for ingredients in personal care products like lotion where normal use of the product results in prolonged and repeated contact with skin.

SKIN ALLERGIES

Recommendations

MAKE HAZARD A PRIORITY INNOVATION CRITERION.

Certain preservatives are under increased scrutiny by regulators, consumers, and the marketplace due to concerns around impacts to human health or the environment. Though safety is considered in the development of new chemicals, it is not often touted as the major benefit or driving force of innovation. EDF maintains that the development of inherently safer chemicals should be recognized as just as significant and innovative as the development of chemicals with improved performance. Innovation efforts focused on creating inherently safer chemicals complement important restrictions on the amount of potentially hazardous chemicals permitted in products—together reducing overall impacts to human health and the environment.

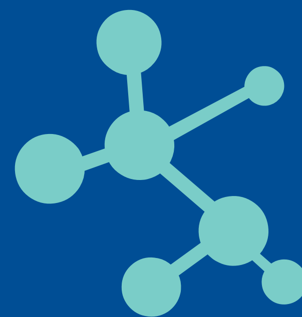
TACKLE HAZARD HOTSPOTS.

Preservative innovation efforts should focus on tackling identified hazard hotspots (i.e., endpoints that received the highest hazard scores in this assessment): skin sensitization, skin irritation, eye irritation, acute aquatic toxicity, and chronic aquatic toxicity.

AVOID TRADING OFF HAZARDS.

While certain hazard endpoints were not identified as hazard hotspots for the preservatives evaluated in the PIP, as a general practice, chemical innovators should continue to consider all potential hazards in the development of new preservatives. This is to avoid the introduction of a new hazard while tackling another.

Did you know?



The inherent hazard of a chemical is a critical component in evaluating its relative safety. The reduction of hazard is a defining element in the **Twelve Principles of Green Chemistry** and leading alternatives assessment methodologies.

FOR MORE INFORMATION SEE:

- National Academy of Sciences - A Framework to Guide Selection of Chemical Alternatives
- BizNGO - The Commons Principles for Alternatives Assessment
- Interstate Chemicals Clearinghouse - Alternatives Assessment Guide, Version 1.1
- U.S. Environmental Protection Agency - Design for the Environment (DfE) Alternatives Assessments

CREATE A CHEMICALS ASSESSMENT CLEARINGHOUSE.

EDF calls for the creation of an independent chemicals assessment clearinghouse that would provide comprehensive, structured, transparent, and comparable health and safety assessments of chemicals in a centralized, web-accessible repository. Operational standards would be established for qualifying assessors to develop and contribute assessments to the clearinghouse, ensuring quality assurance, and updating assessments to reflect the most current science—all with an eye toward producing assessments that are meaningful, actionable, and credible to actors along the supply chain. Such a clearinghouse would serve as a significant resource to various stakeholders looking to move the dial on safer chemistry, whether as a chemical innovator looking for information to inform design criteria or to show how a new chemistry represents an improvement over the status quo; as a product manufacturer searching for safer product formulation and fabrication options; or as a retailer interested in understanding what alternatives may be available for chemicals they are looking to move away from. Assessments from the clearinghouse would also indicate where toxicity data are lacking or insufficient, and thus where more chemical testing is needed.

Finally, an independent chemical assessment clearinghouse holds the potential for participating parties to share the cost burden of producing objective, mutually desired and beneficial toxicological assessments of chemicals.

In sum, the framework employed in the EDF PIP provides valuable baseline toxicological information for preservative innovation, and can be similarly applied to other chemical functional classes.

Additional evaluation lenses, for example performance, could be included in future similar efforts so long as these evaluations are also conducted in a consistent and transparent manner. Ultimately an independent chemical assessment clearinghouse is needed to replicate the work of the PIP at scale across multiple chemical functional classes.

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Of the 16 preservatives evaluated, 12 received scores of Moderate or above for acute aquatic toxicity, with nine receiving scores of High or Very High.

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