GREEN CHEMISTRY & COMMERCE COUNCIL
Business Mainstreaming Green Chemistry

Need Statement

&

Development Criteria for New Preservatives for Personal Care & Household Products

Developed collaboratively by

Aubrey Organics	Colgate-Palmolive	Method
Aveda	Henkel	Procter & Gamble
BabyGanics	Johnson & Johnson	Seventh Generation
Beautycounter	L'Oreal	Unilever

and

The Green Chemistry & Commerce Council (GC3)

Version 1.0

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The Green Chemistry & Commerce Council (GC3) is a cross sectoral, business-to-business network of companies and other organizations working collaboratively to advance green chemistry across sectors and supply chains.

The GC3 is a project of the
Lowell Center for Sustainable Production at the University of Massachusetts Lowell

For more information contact:
The Green Chemistry & Commerce Council

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Overview

Regulatory bans and restrictions as well as consumer, NGO, and retailer pressure to eliminate the use of certain preservatives are reducing the current palette of safe and effective preservatives available to formulators in the personal care and household products sector. Therefore, the companies listed above are seeking new, safe, and effective preservatives for use in their personal care and household products to meet the diverse needs of their customers and other stakeholders.

This document contains a set of criteria developed by these companies to inform the development and evaluation of new preservatives by solution providers. The criteria were created through a collaborative process with the goal of broadcasting the need for new, safe preservatives and encouraging and accelerating their development and commercialization.

The Preservative Criteria

The criteria are presented in two parts, starting on page 5. Stage 1 criteria are designed to provide guidance during the early R&D and testing phase. Stage 2 includes additional, important considerations for later stages of development and commercialization – when more costly testing and evaluation are conducted – such as human health and environmental safety criteria. Criteria specific to personal care, household, natural, and organic products are noted.

The GC3 Collaborative Project on Preservatives

The Green Chemistry & Commerce Council (the GC3) convened and is facilitating this group of personal care and household product companies to work collaboratively to accelerate the commercialization of new, safe preservatives for their products. The group is considering other

collaborative activities such as efficacy and/or health and safety screening of promising chemicals and sponsoring research or other efforts to bring new, promising preservative technologies to market.

Additional Background

Preservatives in Personal Care & Household Products. Preservatives are chemical compounds used in products to protect against undesirable microorganisms—bacteria, molds, and yeasts. Most personal care and many household products, particularly those that contain water are susceptible to microbial contamination and growth and require preservatives to maintain product quality and safety. Personal care and household products are not manufactured in a sterile environment, so even when manufacturers follow good manufacturing practices, microorganisms will be present in the product during use and need to be controlled. In addition, microorganisms are commonly introduced into the product during normal use by the consumer.

Preservatives provide the critical function of keeping products safe for consumer use over their shelf life, preventing product degradation, odor, and growth of pathogenic microorganisms. Preservatives are used in many personal care product categories, including hair and skin care, liquid soap, oral hygiene, and cosmetics; they are also used in household products such as dish detergent, laundry detergent, and fabric softener. They are used in other sectors as well, notably food, pharmaceuticals, and paint.

Current Technology & Regulatory Landscape. Recently, a number of preservatives have come under intense scrutiny due to consumer and government concerns. Regulatory bans and restrictions as well as consumer, NGO, and retailer pressure to eliminate the use of specific, effective preservatives are reducing the palette of preservatives available to formulators in personal care and household products. Formulators are concerned that too few effective preservatives are currently being used in products, which can lead to overexposure to a small number of preservatives in multiple products and cause sensitization and allergic reactions. As a result, product manufacturers are under pressure to identify new, safe, and effective preservatives.

The European Union's (EU) Cosmetics Directive's List of Preservatives Allowed in Cosmetic Products is widely used by personal care products companies as a guide for selecting preservatives for their formulations. In the U.S., the Personal Care Products Council's Cosmetic Ingredients Review (CIR) conducts safety assessments of cosmetic ingredients, including preservatives, and determines whether the ingredients are safe under existing conditions of use. In the U.S., the EPA regulates the use of preservatives in household products under FIFRA. In the EU, preservatives for household products are regulated under the Biocidal Products Regulation 528/2012.

There are a number of safe alternatives to the preservatives listed in the EU Cosmetics Directive in the market today, but few offer the desired broad spectrum protection across a useful range of conditions (such as neutral pH), require relatively high concentrations, have undesirable odors or colors, or are inactivated by manufacturing processes.

For household products, some companies choose to formulate at either higher pH (alkaline) or lower pH (acidic) to prevent bacteria growth but this can limit the flexibility of the formulation and make it less mild. Some formulators may seek to avoid preservatives altogether; however, this option can reduce shelf life, require special care by the user to maintain safety, and limit the scope of products that can be safely formulated.

The Innovation Need. Many formulators – large and small, in the conventional and natural and organic market segments – want to increase preservative diversity in their products and therefore need new, safe and effective preservative options. The criteria presented in this document describe the attributes that a broad range of companies in the personal care and household products sectors are seeking in new preservatives.

Stage 1 Criteria

	GENERAL CRITERIA (For Personal Care, Household, and Natural/Organic Products)	ADDITIONAL WANTS
1. Performance		
Activity	Broad spectrum activity: gram-positive & gram-negative bacteria, yeast & mold	Not likely to build microbial resistance
	In formulation, at use levels, meets preservative challenge test acceptance criteria (e.g., USP 51, CTFA M-3, or similar)	
	Low number of ingredients needed to get broad spectrum activity (ideally 1 - 3 ingredients)	
pH Activity	pH 5 – 8	pH 5 – 10, best is pH 2 – 11
Shelf Life in Formulated Product	Shelf life of 2 years	Shelf life of 3 years
	Can withstand freeze/thaw	Stable from 25 to 50°C
		UV stable for 3 months in package
Concentration	Effective in use at less than 2% actives	Lower effective use level (ideally <0.5%)
Solubility/Compatibility	Depending on application, may need to be water and/or oil soluble	Depending on application, may need to be compatible with one or more of the following: - Anionic surfactants - Nonionic surfactants - Cationic surfactants - Amphoteric surfactants - Strong and weak chelants - Enzymes - Polymers
Odor & Color	Does not significantly affect product color or odor	If preservative affects color or odor, there are ways to manage
Compositional information	Composition is known. Preservative is characterized.	
Additional performance benefits in product		Provides benefits to product beyond preservative, e.g., fragrance, cleaning, emollient, antioxidant
Track record		Demonstrated safety and efficacy track record in another sector, e.g., industrial, household, food, or pharma
Safe for….		Hard and/or soft surfaces at required use level (e.g., counters, fabrics)
Mfg/Processing/Use		Can withstand heating to 50°C
		Can be formulated using a cold process

	GENERAL CRITERIA (For Personal Care, Household, and Natural/Organic Products)	ADDITIONAL WANTS
2. Regulatory		
Restricted substances	Not on restricted substances lists for cosmetics, personal care, household, and biocidal products in any jurisdiction worldwide (for example: not on the Canadian Hotlist, not on lists of known or suspected carcinogens, or reproductive toxins)	
Regulatory approval	Should be able to gain approval as a preservative under US EPA FIFRA and EU Biocidal Products Regulation (528/2012). For personal care products: Should be able to gain approval as a preservative under EU Cosmetic Dir., Annex VI (76/768/EEC)	
Animal Testing	No animal testing specific for cosmetic applications (EU Dir. 2010/63/EU and regulation (EC) No 1223/2009)	Some companies will not accept animal testing for any personal care or household product application

Stage 2 Criteria

	Minimum	Optimum	Applies to:
3. Health & Safety **a. Human Health**			
Genotoxicity	Not genotoxic	Not genotoxic	Preservative
Eye & skin irritation	For household products: Slight irritant under usage conditions (diluted) may be acceptable. For personal care products: Non-irritant under usage conditions (diluted) Undiluted preservative could be irritant.	Non-irritant under usage conditions (diluted)	Formulated Product
Skin Sensitization/ Allergenicity	Weak to moderate sensitizer	Non-sensitizer. Favorable risk assessment.	Preservative
Respiratory Sensitization/ Allergenicity	Not sensitizing	Not sensitizing	Preservative
Acute Mammalian Toxicity	Not acutely toxic in diluted concentration. Undiluted biocide could be toxic or harmful.	Not acutely toxic in diluted concentration.	Preservative
Carcinogenicity*	Not carcinogenic	Not carcinogenic	Preservative
Neurotoxicity	Not neurotoxic	Not neurotoxic	Formulated Product (Minimum) Preservative (Optimum)
Reproductive & Developmental Toxicity*	Not a reproductive or developmental toxicant	Not a reproductive or developmental toxicant	Formulated Product (Minimum) Preservative (Optimum)
Systemic toxicity (LD50)	>10mg/kg/d (oral), favorable risk assessment	>100 mg/kg/d (oral), favorable risk assessment	Preservative

*** Includes endocrine activity as a mode of action**

Stage 2 Criteria (cont.)

Health & Safety

	Minimum	Optimum	Applies to
b. Environmental			
Aquatic acute toxicity (LC50)	>0.01 mg/L	>1 mg/L	Preservative
Biodegradation	Inherently degradable	Readily degradable	Preservative
Endocrine effects	No structural similarity to confirmed endocrine disrupting compounds (see EU Annex 15 List of Category 1 Substances)	No structural similarity to suspected endocrine disrupting compounds (see EU Annex 1 Candidate List of Substances or TEDX list)	Preservative

Additional Health & Safety requirements:

Some personal care product companies seek:

- Exposure assessment (not referring to risk assessment)
- Minimum human health & safety data set, following endpoints used by the Personal Care Product Council's (PCPC) Cosmetic Ingredient Review (CIR)
- Clinical data on skin (e.g., sensitization, irritation, photoallergy)

Regulatory:

- Registered with US EPA (Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) pesticide) and the EU Biocidal Products Regulation.
- REACH registered

For personal care products:

- Listed on EU Cosmetic Directive - Annex VI

Performance:

- Have validated analytical method to be able to assay preservative to ensure concentration in finished product and over shelf life
- Have INCI name
- Prefer to know mechanism of action

Commercial Availability:

- Can be commercially produced & broadly available to all US product manufacturers
- Have supply assurance

Origin:
Some companies require or desire one or more of the following:

- Natural (plant or mineral-based)
- Biobased
- Organic
- Non-GMO
- Vegan/vegetarian

Certifications:
For natural products: Natural Products Association Certification
For organic products: NSF & Ecocert COSMOS Certifications

Sustainability:
Some companies require one or more of the following:

- Sustainably sourced
- Sustainably produced – e.g., non-toxic byproducts, water and energy efficient manufacturing, cold processed
- Minimum impact on carbon footprint

Manufacturing/Processing/Use:

- Producers should follow good manufacturing practices (GMP)
- Minimum capital investment in factory to use
- Safe to handle in factory
- Simplicity, easy to use (e.g., processing and solubility) for global factory implementation

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Green chemistry is the design of chemical products and processes that reduce or eliminate the use and generation of hazardous substances. Green chemistry applies across the life cycle of a chemical product, including its design, manufacture and use and includes 12 fundamental principles. Green chemistry is a critical element of sustainable chemistry, which seeks to reduce the environmental impact of processes and products, optimize the use of finite resources, minimize waste, and meet social needs. Sustainable chemistry is a key element of a broader business strategy for sustainability.

For more information on the project or the Green Chemistry & Commerce Council please contact Monica Becker.