The GC3 Collaborative Innovation Project on Preservatives: Outcomes, Learnings, and What's Next

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GC3 Preservatives Project





Goals

1. Raise awareness, interest, activity and funding globally in industry, academia, and government for R&D, commercialization and scale of novel, safe and effective preservative technologies

2. To expand the palette of safe and effective preservatives for personal care and household products



The need for preservatives

Water-based consumer products require preservation

Preservatives prevent:



- Growth of bacteria, yeast, and mold
- Odor issues
- Product performance
- Pathogens



The need for new preservative technologies

- Regulatory restrictions; consumer, NGO, and retailer pressure have reduced the current palette of safe and effective preservatives available to formulators
- Too few effective preservatives used in products can increase sensitization and allergic reactions
- Formulators are seeking new, safe, and effective preservatives systems for use in their products to meet the diverse needs of their customers and other stakeholders



EU Cosmetics Regulation / Annex V List of allowed preservatives

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- Benzoic acid, its salts and esters
- 2 Propionic acid and its salts
- 3 Salicylic acid and its salts
- 4 Sorbic acid (hexa-2,4-dienoic acid) and its salts
- 5 Formaldehyde
- 7 Biphenyl-2-ol (o-phenylphenol) and its salts
- 8 Zinc pyrithione
- 9 Inorganic sulphites and hydrogensuphites
- 11 Chlorobutanol
- 12 Methylparaben, Ethylparaben
- 12 Propylparaben, Butylparaben
- 13 Dehydroacetic acid and its salts
- 14 Formic acid and its sodium salt
- 15 Dibromohexamidine and its salts (including isethionate)
- 16 Thiomersal
- 17 Phenylmercuric salts (incl. borate)
- 18 Undecylenic acid and salts
- 19 Hexetidine
- 20 5-Bromo-5-nitro-1,3-dioxane

- 21 Bronopol
- 22 Dichlorobenzyl Alcohol
- 23 Triclocarban
- 24 4-Chloro-m-cresol
- 25 Triclosan
- 26 Chloroxylenol
- 27 Imidazolidinyl Urea
- 28 Polyaminopropyl Biguanide
- 29 Phenoxyethanol
- 30 Methenamine
- 31 Quaternium-15
- 32 Climbazole
- 33 DMDM-Hydantoin
- 34 Benzyl alcohol
- 35 Piroctone Olamine
- 37 Bromochlorophen
- 38 o-Cymen-5-ol
- 39 Methylchloroisothiazolinone / Methylisothiazolinone (CMI/MI)
- 40 Chlorophene
- 41 Chloroacetamide Chlorhexidine and its
- 42 digluconate, diacetate and dihydrochloride

- 43 Phenoxyisopropanol Behentrimonium chloride, cetrimonium bromide, cetrimonium chloride.
- 44 laurtrimonium bromide, laurtrimonium chloride, steartrimonium bromide, steartrimonium chloride
- 45 Dimethyl Oxazolidine
- 46 Diazolidinyl Urea
- Hexamidine, Hexamidine
- 47 diisethionate, Hexamidine paraben
- 48 Glutaraldehyde
- 49 7-Ethylbicyclooxazolidine
- 50 Chlorphenesin
- 51 Sodium Hydroxymethylglycinate
- 52 Silver chloride
- 53 Benzethonium Chloride
- 54 Benzalkonium Chloride
- 55 Benzylhemiformal
- 56 Iodopropynyl Butylcarbamate
- 57 Methylisothiazolinone
- 58 Ethyl Lauroyl Arginate HCI
- 59 Citric Acid and Silver Citrate

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Market demands

Free-of List (No-No List)

- No formaldehyde donors
- No halogenated materials
- No isothiazolinones
- No long-chain parabens
- No CMR substances
- No allergenic compounds
- No aromatic compounds
- No warnings on the final product
- No substances which cannot be used for children under the age of 3 years

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2	Propionic acid and its salts				Behentrimonium chloride, cetrimonium bromide,
4	Sorbic acid (hexa-2,4-dienoic acid) and its salts			44	cetrimonium chloride, laurtrimonium bromide, laurtrimonium chloride, steartrimonium bromide, steartrimonium chloride
	Inorganic sulphites and hydrogen-				
9	suphites				
13	Dehydroacetic acid and its salts	35	Piroctone Olamine		
				52	Silver chloride
18	Undecylenic acid and salts				
				58	Ethyl Lauroyl Arginate HCI
					Citric Acid and Silver Citrate

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Need Statement & Development Criteria for

New Preservatives for

Personal Care & Household Products

Developed by the Green Chemistry & Commerce Council (GC3) with contributions from:

Aubrey Organics Aveda BabyGanics Beautycounter Colgate-Palmolive Henkel Johnson & Johnson L'Oreal

Method Procter & Gamble Seventh Generation Unilever

Version 1.0





GC3 Need Statement & Development Criteria for New Preservatives for Personal Care & Household Products

	GENERAL CRITERIA (For Personal Care, Household, and Natural/Organic Products)	ADDITIONAL WANTS	
1. Performance			
	Broad spectrum activity: gram- positive & gram-negative bacteria, yeast & mold	Not likely to build microbial resist	Articulates the need for new
Activity	In formulation, at use levels, meets preservative challenge test acceptance criteria (e.g., USP 51, CTFA M-3, or similar)		preservatives Provides a set of detailed
	Low number of ingredients needed to get broad spectrum activity (ideally 1 - 3 ingredients)		development criteria for new preservatives, including:
pH Activity	pH 5 – 8	pH 5 – 10, best is pH 2 – 11	
Shelf Life in Formulated	Shelf life of 2 years	Shelf life of 3 years	Performance
Product	Can withstand freeze/thaw	Stable from 25 to 50°C	Regulatory
		UV stable for 3 months in packag	• •
			Human health

- Environment
- Business factors



http://greenchemistryandcommerce.org/projects/preservatives-project

Approach

- Sought to identify a large and diverse pool of novel:
 - Ideas white papers
 - Early stage technologies proof-of-concept
 - More mature technologies, perhaps used in other domains
 - From small companies, startups, universities, and individuals with promising ideas or technologies
- Facilitate partnerships with strategics for evaluation, development, investment, commercialization & scale

Approach

Partnered with INNOCENTIVE®

- Administrative, legal and fiscal agent
- Spearheaded design & execution of the Challenge



The Seekers are looking for submissions on

- 1. Broad spectrum or single action chemical agents on gram-positive tracteria, gram-negative tracteria, yeset, and mold
- Preservative boosters (optimizers or potentiators)/multi-functional ingredients that have a primary non-preserving function, yet enhance antimicrobial efficacy

The Seekers expect to award 3 - 5 cash propertion a price pool of \$175,000, with a minimum single price award of \$25,500. No awards are guaranteed unless the submissions meet or located the criteria.



<u>Approach</u>

2 Categories of Sponsorship & Participation:

Category 1 Sponsors: CPG companies, 1 retailer and other stakeholders, N=14

- Designed the challenge, e.g., technical and safety criteria
- Judged the submissions, based on their needs and experience using and evaluating preservatives for their products
- Potential development partners

Category 2 Sponsors: Preservative Suppliers: N=5

- Potential development, commercialization and scaling partners
- Given all 48 submissions after judging
- Given safety assessments and performance test results
- Given detailed results of judging by Category 1 Sponsors



GC3 Preservative Challenge Sponsors

CPG Companies Babyganics Beautycounter Beiersdorf **Colgate-Palmolive L&I** Kao USA Method P&G RB **SC** Johnson Unilever

Retailers

Target

Walmart

Preservative Suppliers

Dow

Lonza

Schuelke

Symrise

Thor

Other Organizations

Environmental Defense Fund

State of Minnesota

GC3 Preservative Challenge Sponsors



GC3 Preservative Challenge Sponsors

CPG Companies

Babyganics

Beautycounter

Beiersdorf

Colgate-Palmolive

J&J

Kao USA

Method

P&G

RB

SC Johnson

Unilever

Retailers

Target

Walmart

Preservative Suppliers

Dow	
	Category 2 Sponsors -
Lonza	Potential
Schuelke	Development,
Symrise	Commercialization
Thor	and Scaling Partners
Other Orga	nizations
Environmer	ntal Defense

Environmental Defense Fund

State of Minnesota

Approach (cont.)

- Awards for "Solvers"
 - \$175,000 prize pool
 - Received feedback from judging
 - Received results from safety assessment and performance evaluation
 - Received visibility and opportunities to partner with formulators and suppliers for evaluation, joint development, investment, licensing, etc. to bring to market & scale
 - Retain their IP

Approach

- Yesterday: Final Event 7 Semi-Finalists + Sponsors (48 total submissions received)
- Winners will be selected in June
- Going Forward: One-on-one discussions with solvers, suppliers and CPG companies





48 Submissions

First Round of Judging



First Round of Judging

Submission		ХҮХ			ł	ABC	LMNOP			
		28				29 30				
Judges	HS2	M2	F3	M5	HS3	F3	M4	HS2	M2	F6
Main Requirements:										
Activity on at least one of the following: a. Gram-negative bacteria b. Gram-positive bacteria c. Mold d. Yeast	N/A activity is just asserted, no empircal	+	N/A	+ all 4 groups	+ data to support	+ all 4 groups	+ Hand soap formulatio n	+ Did not test for antifungal or antiviral	+	+
Active within the pH range of 5 to 8	N/A suggested , no empircal data is provided	+	N/A	+	+ data to support	+	N/A	- no info/data provided	N/A	NA
Maintain shelf life of a formulated product for 2 years	- no	N/A	N/A	+	+	+	N/A	- no	N/A	NA
Can withstand multiple freeze/thaw cycles	- no	N/A	N/A	N/A statement	+	N/A	N/A	- no	N/A	NA
Effective in use at a concentration of less than 2%	- no info/data provided	+	N/A	+	+	+	N/A	- no info/data provided	N/A MIC only	+ Indicates Iow MIC



48 Submissions

10 assessed for safety

Plant Extract	Chitosan	Bark Extract	Plant Extract	Bark Extract	Monoterpenoid Phenol	Bio-derived Chemistry	2 Part Reversible Complex	Chitosan	Amino Acid Chemistries	
9	18A	19	22	24	29	35	38	46	65	



Safety Assessment



Endpoint	Preservative XYZ	Analog A
Persistence	Readily biodegradable ^a	-
Bioaccumulation	Not estimated to be bioaccumulative	-
Aquatic toxicity	GHS Category Acute 3 (daphnia and <u>algae)</u> ^a	GHS Category Acute 2 (fish); GHS Category Acute 2-3 (daphnia and algae)
Acute mammalian toxicity	GHS Category 4 (oral <u>toxicity)^b</u>	GHS Category 4 (oral and dermal)
Systemic toxicity	Low concern for systemic toxicity ^b	Low concern for systemi toxicity
Reproductive and Developmental	Low concern for reproductive and developmental toxicity ^b	Low concern for developmental toxicity
Genotoxicity	Low concern for genotoxicity ^b	Low concern for genotoxicity
Carcinogenicity	No data	No data
Dermal irritation	Not irritating or corrosive to skin ^b	GHS Category 2 (Irritant)
Eye irritation	Not irritating to eyes ^b	GHS Category 2 (Reversible effects on the eye)
Skin sensitization	Not a skin <u>sensitizer^b</u>	Not a skin sensitizer

"<u>Not</u> evaluated; ^a Full study report provided by the solver; ^b Based on summary results provided by the solver; ^c Based on estimates performed by SRC.



10 assessed for safety

Plant Extract	Chitosan	Bark Extract	Plant Extract	Bark Extract	Monoterpenoid Phenol	Bio-derived Chemistry	2 Part Reversible Complex	Chitosan	Amino Acid Chemistries
9	18A	19	22	24	29	35	38	46	65
				_					

7 assessed for performance: Stability and antimicrobial effectiveness



Performance Testing

Develop simple base formulations:

- 1. Simple lotion
- 2. Simple Shampoo
- 3. Simple Dish Soap



Stability Testing

PDA Laboratories, Inc.

A Contract Testing Laboratory

Anti-microbial effectiveness testing

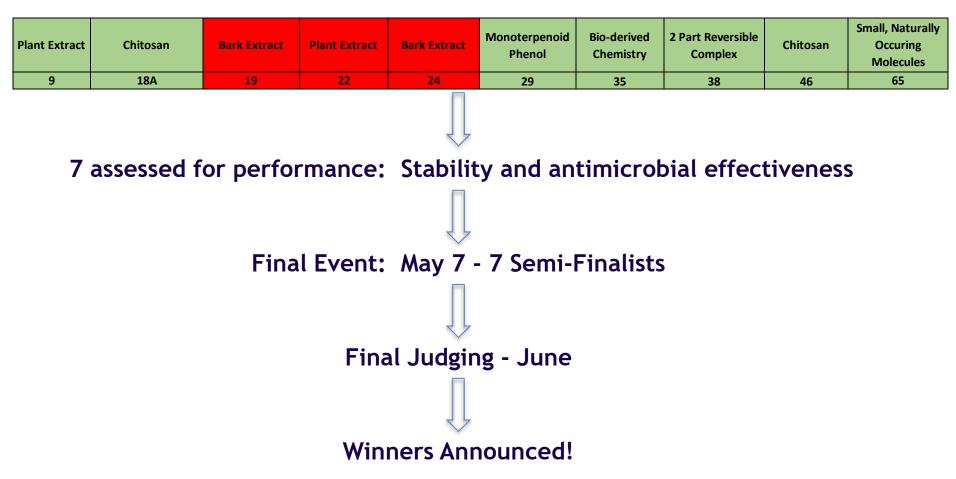


48 Submissions

Judging

First Round of Judging

10 assessed for safety



Results so Far

- 48 Submissions
- 7 Semi-Finalists with promising technology (some early stage) that passed first round of judging, safety screening and still undergoing performance testing
- CPG companies, suppliers, and "solvers" have started one-on-one discussions



Going Forward

- Continue to support the 7 Semi-Finalists in their pursuit of customers and development & commercialization partners
- Continue to support new innovators with promising preservative technology
- Continue to connect "solvers" with "seekers"
- Leverage "infrastructure" developed in the project



Why did the GC3 take on these projects on preservatives?

The GC3 saw the opportunity to:

- Address an important, common area of green chemistry need
- Bring together GC3 member companies to collaborate to seek solutions

Panelists

Homer Swei Johnson & Johnson

Vanita Srinivasan RB

Phil Hindley Lonza

Irena Jevtov Irena Jevtov Research & Innovation

