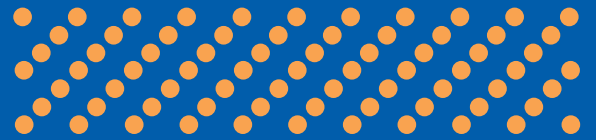




OPTIPHEN™ PLUS



Paraben-Free and Formaldehyde-Free Preservation
for Effective Broad Spectrum Protection



Sun Care



Body and Face Care



Color Cosmetics



Hair Care



INTERNATIONAL SPECIALTY PRODUCTS



OPTIPHEN™ PLUS

→ INTRODUCTION

Optiphen™ Plus is the second globally approved preservative in the family of Optiphen™ products developed for paraben- and formaldehyde-free preservation, particularly within lower pH systems.

Optiphen™ Plus is an ISP patent-pending liquid preservative formulation featuring an innovative blend of phenoxyethanol, sorbic acid and an emollient base that is ideal for slightly acidic personal care products requiring broad spectrum protection. The combination of all three ingredients offers effective protection against bacteria, yeast and mold growth while imparting emolliency. Optiphen™ Plus performs best in formulations below 6.0 pH. Depending on the formulation, Optiphen™ Plus has also been proven effective at pH levels above 6.0.

This preservative is effective as a stand-alone system and functions well with other preservatives. Optiphen™ Plus has an extensive range of applications in aqueous and emulsion-type personal care formulations and is compatible with most raw materials in the personal care industry.

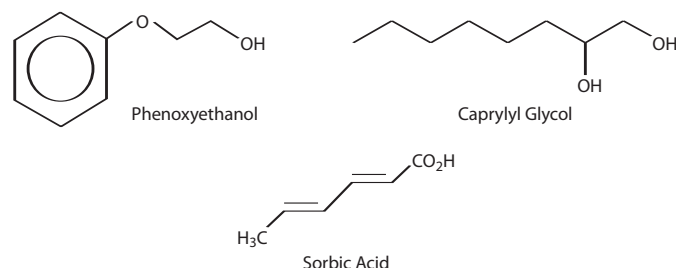
→ PRODUCT BENEFITS

- + Globally approved
- + Highly effective broad spectrum antimicrobial
- + Effective at pH levels below 6.0
- + Non-formaldehyde donor
- + Paraben-free
- + Non-isothiazolinone
- + Imparts emolliency
- + Compatible with most raw materials
- + Excellent safety and toxicological profile

→ CHEMISTRY

The ingredient phenoxyethanol, is an aromatic ether alcohol commonly used for preservation of personal care products. Sorbic acid is often used in lower pH personal care formulations and functions as a complementary preservative. Lastly, 1,2 octanediol – INCI name: caprylyl glycol – is the emollient base, giving the product exceptional feel.

Structurally, Optiphen™ Plus is represented as:



Proposed INCI Name:

Phenoxyethanol (and) Caprylyl Glycol (and) Sorbic Acid

→ TYPICAL PROPERTIES

Odor.....	Characteristic
Appearance.....	Liquid
Color.....	Clear to pale straw (100 max.)
Specific Gravity.....	1.0140 – 1.0240

→ SOLUBILITY (g/100g solvent at 25°C)

Water.....	1.0
Ethanol.....	>100 miscible
Isopropanol.....	>100 miscible
Ethylene Glycol.....	>100 miscible
Propylene Glycol.....	>100 miscible
Butylene Glycol.....	>100 miscible
Glycerin.....	>100 miscible
Mineral Oil.....	0.6

→ RECOMMENDED APPLICATIONS

Sun Care

Sunscreen Creams and Lotions
Daily Wear Sun Protection Products

Body and Face Care

Moisturizers
Hand and Body Creams and Lotions
Night Creams
Wipes

Color Cosmetics

Foundations
Concealers
Blush

Hair Care

Styling Gels
Shampoos

→ FORMULATION GUIDELINES

Optiphen™ Plus can be easily added to the formulation during pre- or post-emulsification at or below 80°C. Optiphen™ Plus works best when used in formulations with a pH below 6.0 and is compatible with most ingredients used in the personal care industry.

Recommended Use Levels: 0.75 – 1.5%

→ SAFETY PROFILE

Optiphen™ Plus has an excellent safety and toxicological profile and is safe to use in a wide range of personal care applications.

CAS Numbers:

- + Phenoxyethanol: 122-99-6
- + Caprylyl Glycol: 1117-86-8
- + Sorbic Acid: 110-44-1

→ PRESERVATIVE SYSTEM EFFICACY IN FORMULATION

The challenge test is a 28-day test used to verify the effectiveness of a preservative system in a finished personal care formulation. Selected formulations were inoculated with microorganisms at the onset of testing (0 hours), then sampled at 48 hours, 7 days, 14 days, 21 days, and 28 days. At 21 days the formulations were re-inoculated with the same microorganisms. Pass/fail criteria were based on modified CTFA* protocol.

Optiphen™ Plus was tested in several systems and found to be an effective preservative system in a variety of personal care formulations against the microorganisms listed:

Abbreviation	Microorganism
SA	Staphylococcus aureus
ECOLI	Escherichia coli
PSA	Pseudomonas aeruginosa
BC	Burkholderia cepacia
CAN	Candida albicans
AN	Aspergillus niger

Based on challenge test data, Optiphen™ Plus is recommended for use in personal care products at levels between 0.75 - 1.5%. Please note that every personal care formulation requires a preservative system that meets its specific needs. Therefore, every newly developed or modified product must be challenge tested to ensure adequate preservation.



*Cosmetic, Toiletry, and Fragrance Association



FORMULATIONS

+ Velvet Effect Sunscreen (#11089-37-1)

Ingredients	%W/W	Supplier
Phase A		
Deionized Water	67.25	
Disodium EDTA (Versene NA)	0.10	Dow Chemical
Xanthan Gum (Keltrol T)	0.50	CP Kelco
Glycerin	1.00	
Phase B		
Glyceryl Stearate (and) Cetyl Alcohol (and) Stearyl Alcohol (and) Behenyl Alcohol (and) Palmitic Acid (and) Stearic Acid (and) Hydroxyethyl Cetearamidopropylidmonium Chloride (PROLIPID® 151)	4.00	ISP
Octinoxate (ESCALOL® 557)	7.50	ISP
Oxybenzone (ESCALOL® 567)	3.00	ISP
Diocetyl Malate (CERAPHYL® 45)	5.00	ISP
Isodecyl Neopentanoate (CERAPHYL® SLK)	10.00	ISP
Phase C		
Phenoxyethanol (and) Caprylyl Glycol (and) Sorbic Acid (OPTIPHEN™ PLUS)	1.50	ISP
Fragrance (Apple RA-45)	0.15	Robertet
	100.00%	

Procedure:

1. Combine water and Disodium EDTA in a proper vessel. Pre-mix Xanthan Gum and Glycerin and slowly add it to Phase A. Begin to heat to 75°C; continue mixing.
2. Combine Phase B with stirring and heat to 75°C.
3. Add Phase B to Phase A with homogenization.
4. Switch to stirring and begin to cool.
5. Add Phase C at 35°C.
6. QS for water loss and mix to RT.

pH: 3.90

Viscosity: 4,800 cps (Brookfield Model RVT, TB @ 5 RPM)



→ MICROBIOLOGICAL STUDIES

Preservative Efficacy (CFU/g)

Organism	48 Hrs	7 Days	14 Days	21 Days	28 Days
SA	<10	<10	<10	<10	<10
ECOLI	<10	<10	<10	<10	<10
PSA	<10	<10	<10	<10	<10
BC	<10	<10	<10	<10	<10
CAN	<10	<10	<10	<10	<10
AN	5.0E3	<10	<10	<10	1.5E2

(replate on AN after 28 days: <10)

Inoculum Concentration (CFU/g)

Organism	0 Hours	21 Days
SA ATCC 6538	6.0 x 10 ⁶	2.0 x 10 ⁶
ECOLI ATCC 8739	2.2 x 10 ⁶	3.0 x 10 ⁶
PSA ATCC 9027	1.8 x 10 ⁶	2.0 x 10 ⁶
BC ATCC 25416	1.1 x 10 ⁶	1.0 x 10 ⁶
CAN ATCC 10231	1.0 x 10 ⁶	1.0 x 10 ⁶
AN ATCC 16404	3.0 x 10 ³	2.0 x 10 ⁶

This formula has passed a 28-day double challenge efficacy test. However, the preservative system has not been optimized to its lowest effective level.

+ After Shave Balm (#11089-41-1)

Ingredients	%W/W	Supplier
Phase A		
Deionized Water	80.12	
Disodium EDTA (Versene NA)	0.10	Dow Chemical
Acrylates Copolymer (Aculyn® 33)	2.00	Rohm & Haas
Acrylates/Steareth-20 Methacrylate Copolymer (Aculyn® 22)	1.00	Rohm & Haas
Propylene Glycol	3.00	
Phase B		
Sodium Hydroxide (10% Aq. Soln.)	1.28	Fisher Scient.
Phase C		
Glyceryl Stearate (and) Cetyl Alcohol (and) Stearyl Alcohol (and) Behenyl Alcohol (and) Palmitic Acid (and) Stearic Acid (and) Hydroxyethyl Cetearamidopropyldimonium Chloride (PROLIPID® 151)	3.50	ISP
Isocetyl Stearate (CERAPHYL® 494)	1.00	ISP
C ₁₂₋₁₅ Alkyl Lactate (CERAPHYL® 41)	1.50	ISP
Octyldodecyl Stearate (CERAPHYL® ODS)	3.00	ISP
Phase D		
Glyceryl Polymethacrylate (and) Propylene Glycol (and) PVM/MA Copolymer (LUBRAJEL® OIL)	1.00	ISP
Polyquaternium-11 (GAFQUAT® 755N)	0.50	ISP
Phase E		
Phenoxyethanol (and) Caprylyl Glycol (and) Sorbic Acid (OPTIPHEN™ PLUS)	1.00	ISP
Fragrance CK-1 Type EE54017	1.00	Ungerer
	100.00%	

Procedure:

1. Combine Phase A with stirring, heat to 75-80°C.
2. Add Phase B to Phase A and mix until uniform.
3. Combine Phase C and heat to 75°C while mixing.
4. Add Phase C to Phases A&B with homogenization.
5. Add Phase D in order listed with stirring. Mix between additions; begin cool down.
6. Add Phase E in order listed at 40°C; mix between additions.
7. Mix to RT and QS for water loss.

pH: 6.40

Viscosity: 14,800 cps (Brookfield Model RVT, TB @ 5 RPM)



→ MICROBIOLOGICAL STUDIES

Preservative Efficacy (CFU/g)

Organism	48 Hrs	7 Days	14 Days	21 Days	28 Days
SA	<10	<10	<10	<10	<10
ECOLI	<10	<10	<10	<10	<10
PSA	<10	<10	<10	<10	<10
BC	<10	<10	<10	<10	<10
CAN	<10	<10	<10	<10	<10
AN	<10	<10	<10	<10	<10

Inoculum Concentration (CFU/g)

Organism	0 Hours	21 Days
SA ATCC 6538	1.3 x 10 ⁶	6.4 x 10 ⁶
ECOLI ATCC 8739	3.0 x 10 ⁶	6.1 x 10 ⁶
PSA ATCC 9027	3.3 x 10 ⁶	4.3 x 10 ⁶
BC ATCC 25416	1.5 x 10 ⁶	4.4 x 10 ⁶
CAN ATCC 10231	1.7 x 10 ⁶	2.9 x 10 ⁶
AN ATCC 16404	3.3 x 10 ⁶	6.0 x 10 ⁵

This formula has passed a 28-day double challenge efficacy test. However, the preservative system has not been optimized to its lowest effective level.

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FORMULATIONS

+ Light Moisturizer (#11094-53-5)

Ingredients	%W/W	Supplier
Phase A		
Deionized Water	58.90	
Disodium EDTA (Versene NA)	0.10	Dow Chemical
PVM/MA Decadiene Crosspolymer (STABILEZE® QM)	0.50	ISP
Glycerin	3.00	
Phase B		
Oxybenzone (ESCALOL® 567)	2.00	ISP
Octinoxate (ESCALOL® 557)	7.50	ISP
Avobenzone (ESCALOL® 517)	1.00	ISP
Ethylhexyl Palmitate (CERAPHYL® 368)	2.00	ISP
Phenethyl Benzoate (X-TEND™ 226)	10.00	ISP
Isodecyl Oleate (CERAPHYL® 140A)	1.540	ISP
Isodecyl Neopentanoate (CERAPHYL® SLK)	3.00	ISP
PEG-20 Stearate (CERASYNT® 840)	1.50	ISP
Glyceryl Stearate (and) Laureth-23 (CERASYNT® 945)	2.00	ISP
Phase C		
Triethanolamine, 99%	0.50	
Deionized Water	5.00	
Phase D		
Phenoxyethanol (and) Caprylyl Glycol (and) Sorbic Acid (OPTIPHEN™ PLUS)	1.50	ISP
	100.00%	

Procedure:

1. Slowly sprinkle in Stabileze QM to water of Phase A with mixing.
2. Once Stabileze is completely dispersed; heat and maintain at 80°C for approximately 45 minutes with mixing.
3. Add Disodium EDTA and Glycerin to Phase A with mixing.
4. Combine ingredients in Phase B and heat to 75-80°C with mixing.
5. Add Phase C to Phase A; mix for 5 minutes.
6. Add Phase B to Phases A&C; mix until homogeneous.
7. Cool to 45°C then add Phase D with mixing.
8. QS for water loss.

pH: 5.50

Viscosity: 17,600 cps (Brookfield Model RVT, TB @ 5 RPM)



→ MICROBIOLOGICAL STUDIES

Preservative Efficacy (CFU/g)

Organism	48 Hrs	7 Days	14 Days	21 Days	28 Days
SA	<10	<10	<10	<10	<10
ECOLI	<10	<10	<10	<10	<10
PSA	<10	<10	<10	<10	<10
BC	<10	<10	<10	<10	<10
CAN	3.7E4	<10	<10	<10	<10
AN	2.6E4	<10	<10	<10	5E1

(replate on AN after 28 days: <10)

Inoculum Concentration (CFU/g)

Organism	0 Hours	21 Days
SA ATCC 6538	6.4 x 10 ⁶	2.8 x 10 ⁶
ECOLI ATCC 8739	6.1 x 10 ⁶	3.1 x 10 ⁶
PSA ATCC 9027	4.3 x 10 ⁶	3.3 x 10 ⁶
BC ATCC 25416	4.4 x 10 ⁶	2.1 x 10 ⁶
CAN ATCC 10231	2.9 x 10 ⁶	1.9 x 10 ⁶
AN ATCC 16404	6.0 x 10 ⁵	4.0 x 10 ⁵

This formula has passed a 28-day double challenge efficacy test. However, the preservative system has not been optimized to its lowest effective level.

+ Nourishing Sunscreen SPF 18 (#11089-38-1)

Ingredients	%W/W	Supplier
Phase A		
Deionized Water	55.45	
Disodium EDTA (Versene NA)	0.10	Dow Chemical
Magnesium Aluminum Silicate (Veegum Ultra)	0.50	RT Vanderbilt
Xanthan Gum (Kelco T)	0.50	Kelco
Butylene Glycol	3.00	
Phase B		
Octinoxate (ESCALOL® 557)	7.50	ISP
Oxybenzone (ESCALOL® 567)	3.00	ISP
Octisalate (ESCALOL® 587)	3.00	ISP
Stearic Acid	3.00	
Glyceryl Stearate (CERASYNT® SD)	1.50	ISP
Cetyl Alcohol (Lanette 16 NF)	0.75	Cognis
Ethylhexyl Palmitate (CERAPHYL® 368)	4.00	ISP
Myristyl Myristate (and) Myristyl Laurate (CERAPHYL® 424)	0.50	ISP
Isostearyl Neopentanoate (CERAPHYL® 375)	2.00	ISP
Phase C		
Deionized Water	5.00	
Triethanolamine, 99%	1.20	
Phase D		
Disodium Lauriminodipropionate Tocopheryl Phosphates (VITAL ET™)	7.50	ISP
Phenoxyethanol (and) Caprylyl Glycol (and) Sorbic Acid (OPTIPHEN™ PLUS)	1.50	ISP
	100.00%	

Procedure:

1. Combine water, Disodium EDTA; sprinkle in Magnesium Aluminum Silicate. Pre-mix Xanthan Gum and Butylene Glycol; slowly add to Phase A. Begin heating to 70-75°C; continue mixing.
2. Combine ingredients in Phase B with mixing and heat to 75-80°C.
3. When Phase B is at 70-75°C add to Phase A with good mixing.
4. Combine ingredients in Phase C; add to batch with mixing.
5. After batch is uniform, begin to cool.
6. Add Phase D at 30-35°C in order listed.
7. QS for water loss and mix to RT.

pH: 7.25

Viscosity: 6,400 cps (Brookfield Model RVT, TB @ 5 RPM)



→ MICROBIOLOGICAL STUDIES

Preservative Efficacy (CFU/g)

Organism	48 Hrs	7 Days	14 Days	21 Days	28 Days
SA	<10	<10	<10	<10	<10
ECOLI	<10	<10	<10	<10	<10
PSA	<10	<10	<10	<10	<10
BC	<10	<10	<10	<10	<10
CAN	5.2 x 10 ²	<10	<10	<10	<10
AN	<10	<10	<10	<10	<10

Inoculum Concentration (CFU/g)

Organism	0 Hours	21 Days
SA ATCC 6538	6.0 x 10 ⁶	3.0 x 10 ⁶
ECOLI ATCC 8739	2.2 x 10 ⁶	3.0 x 10 ⁶
PSA ATCC 9027	1.8 x 10 ⁶	2.0 x 10 ⁶
BC ATCC 25416	1.1 x 10 ⁶	1.0 x 10 ⁶
CAN ATCC 10231	1.0 x 10 ⁶	1.0 x 10 ⁶
AN ATCC 16404	3.0 x 10 ⁵	2.0 x 10 ⁶

This formula has passed a 28-day double challenge efficacy test. However, the preservative system has not been optimized to its lowest effective level.



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