

### 3) Ocular and Dermal Irritation Test™

The ocular and dermal assays are quantitative *in vitro* test methods that mimic acute ocular and dermal irritation test. The ocular irritancy potential of a test sample is expressed as an **Irritation Draize Equivalent (IDE)**, whereas the dermal irritancy potential of a test sample is expressed as a **Human Irritancy Equivalent (HIE)** score.

A sample using 2% and 5% of **NataPres** in water was evaluated with the Irritation Assay System in order to predict its potential for Ocular and Dermal Irritation.

Irritation Draize Equivalent (IDE)	Predicted Ocular Irritancy Classification
0.0 - 12.5	Minimal Irritant
12.5 - 30	Mild
30 - 51	Moderate
51 - 80	Severe

Human Irritancy Equivalent (HIE)	Predicted Dermal Irritancy Classification
0.00 - 0.9	Non-irritant
0.9 - 1.2	Non-irritant/irritant
1.2 - 5.00	Irritant

### Results

Sample Tested	IDE	HIE
NataPres™ 2%	13.2	0.57
NataPres™ 5%	12.2	0.62

### 4) Repeat Insult Patch Testing (RIPT)

Tested on healthy volunteers as an occlusive patch test at 2.5% **NataPres** in a Nonionic cream is well tolerated and no adverse reaction of any kind were reported during the course of the study..

Further testing is being performed on **NataPres™**.



**NP**  
NataPres™

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PATENT PENDING



No animal testing was used in the development or testing of **NataPres™**.

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## Product Benefits

- Globally approved
- Effective at pH levels between 2 & 8
- Chemically stable
- Will not change the color of the formulation
- Odorless
- Made with naturally-derived ingredients
- Non-formaldehyde donor
- Paraben-free
- Compatible with most raw materials
- Water soluble
- Safe-to-use at recommended levels
- Additional protection against fungi and yeast may be necessary

## Applications

### Skin Care

Hand Creams  
Body Creams & Lotions  
Facial Products

### Hair Care

Shampoos  
Conditioners

**NataPres** is a globally approved ingredient based on the synergy exhibited by multiple plant extracts. **NataPres** was developed for paraben and formaldehyde-free preservation with effectiveness in a broad pH range. It is easy to use and will not impart any additional color or odors to your formulation.

**NataPres** provides predominantly a spectrum of activity against Gram-positive and Gram-negative bacteria. In formulations tested **NataPres** demonstrated activity against fungi and yeast when used at typical levels.

## Typical Properties

- Appearance: Yellow Viscous Liquid
- pH: 4.9
- Density (20°C): 1.25 g/ml

## Formulation Guidelines

- Recommended use level for cosmetic formulations: 0.5% - 2.5%
- Potential anti-acne application at concentrations of 3.0% - 10.0% (based on MIC testing of p. acnes)
- Can be added directly to the formulation post-emulsification at or below 50°C
- Effective in a broad pH range from 2 to 8
- Compatible with most ingredients used in the personal care and pharmaceutical industry
- Products which are highly prone to mold or yeast growth might need additional fungal protection

## Safety and Regulatory Profile

- **NataPres** is safe to use at the recommended use levels in a wide range of personal care and pharmaceutical applications.
- **NataPres Ingredient List** - Glycerin, Leuconostoc/Radish Root Ferment Filtrate, Lonicera Japonica (Honeysuckle) Flower Extract, Lonicera Caprifolium (Honeysuckle) Extract, Populus Tremuloides Bark Extract, Gluconolactone

## Challenge Data

**NataPres** was tested in several systems and found to effectively preserve a variety of personal care formulations against the microorganisms listed. More challenge testing is currently being performed.

### 1) Pre-USP Challenge Screening Test

This microbiological test is used as a screen to test for the preservative efficacy of a formula. This eleven-day test is a general test to predict the potential performance a product may have with the USP preservative (efficacy) challenge test. The test organisms are pooled into two groups, a bacterial mixture (*E. coli*, *S. aureus*, *P. aeruginosa*) and a fungal mixture (*C. albicans*, *A. niger*).

Non-ionic Emulsion using 2.0% NataPres™		
Test Organism	Day: 11	Pass/Fail
Bacterial mixture	<10	Pass
Fungal mixture	<10	Pass

**Non-ionic Emulsion Ingredient List** - Water, Emulsifying Wax NF, Ethylhexyl Stearate, Cyclopentasiloxane, Glycerin, Aloe Barbadensis Leaf Juice, Leuconostoc/Radish Root Ferment Filtrate, Lonicera Japonica (Honeysuckle) Flower Extract, Lonicera Caprifolium (Honeysuckle) Extract, Populus Tremuloides Bark Extract, Tocopheryl Acetate, Gluconolactone, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Disodium EDTA

Facial Cream using 2.0% NataPres™*						
Test Organism	Inoc. Level	Day: 7	Day: 14	Day: 21	Day: 28	Log Reduction
Escherichia coli	2.63 x 10 <sup>5</sup>	<10	<10	<10	--	5.42
Staphylococcus aureus	3.25 x 10 <sup>5</sup>	<10	<10	<10	--	5.51
Pseudomonas aeruginosa	3.50 x 10 <sup>5</sup>	<10	<10	<10	--	5.54
Candida albicans	5.06 x 10 <sup>5</sup>	13,000	151,000	2,908	--	2.24
Aspergillus niger	3.25 x 10 <sup>5</sup>	6,240	55,000	53,000	--	.79

\* Preliminary USP Challenge data still in progress

## 2) Synergy Test

A test was performed to check the synergy of **NataPres** together with other anti fungal ingredients. To measure this synergy a **USP Challenge Method** was applied. The challenge test is a 28-day test used to verify the effectiveness of a preservative system in a finished personal care formulation.

*Note the anti fungal synergy with sodium dehydroacetate and o-cymen-5-ol*

Facial Cream using 2.0% NataPres™ + 0.5% Sodium Dehydroacetate						
Test Organism	Inoc. Level	Day: 7	Day: 14	Day: 21	Day: 28	Log Reduction
Escherichia coli	2.63 x 10 <sup>5</sup>	<10	<10	<10	<10	5.42
Staphylococcus aureus	2.00 x 10 <sup>5</sup>	<10	<10	<10	<10	5.30
Pseudomonas aeruginosa	2.50 x 10 <sup>5</sup>	<10	<10	<10	<10	5.40
Candida albicans	9.89 x 10 <sup>5</sup>	<10	<10	<10	<10	6.00
Aspergillus niger	3.95 x 10 <sup>5</sup>	<10	<10	<10	<10	5.60

**Facial Cream Ingredient List** - Water, Heptyl Undecylenate, Prasterone, Trimethylpropane Tricaprylate/Tricaprate, Leuconostoc/Radish Root Ferment Filtrate, Cyclopentasiloxane, Dimethicone, Polyacrylate-13, Glycerin, Plukenetia Volubilis Seed Oil, Populus Tremuloides Bark Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Lonicera Caprifolium (Honeysuckle) Extract, Tocopherol, Tocopheryl Acetate, Ubiquinone, Phospholipids, Cetearyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Ethylhexyl Stearate, Steareth-2, Laureth-7, Ceteth-24, Choleth-24, Cetareth-20, Polysorbate 80, Polysorbate 20, Propylene Glycol, Polysilicone-11, Polyisobutene, Polyacrylamide, C13-14 Isoparaffin, PEG/PPG-18/18 Dimethicone, Dimethicone Crosspolymer, Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Gluconolactone, Lactic Acid, Disodium EDTA, Sodium Dehydroacetate

Facial Cleanser using 1.0% NataPres™ + 0.5% Sodium Dehydroacetate						
Test Organism	Inoc. Level	Day: 7	Day: 14	Day: 21	Day: 28	Log Reduction
Escherichia coli	2.00 x 10 <sup>5</sup>	<10	<10	<10	<10	5.30
Staphylococcus aureus	4.75 x 10 <sup>5</sup>	<10	<10	<10	<10	5.68
Pseudomonas aeruginosa	3.25 x 10 <sup>5</sup>	<10	<10	<10	<10	5.51
Candida albicans	8.40 x 10 <sup>5</sup>	<10	<10	<10	<10	5.92
Aspergillus niger	3.05 x 10 <sup>5</sup>	<10	<10	<10	<10	5.48

**Facial Cleanser Ingredient List** - Water, TEA-Cocoyl Glutamate (Amisoft CT 12S), Disodium Cocoyl, Potassium Cocoyl Glycinate, Glycerin, Aloe Barbadensis Leaf Juice, Leuconostoc/Radish Root Ferment Filtrate, Lonicera Japonica (Honeysuckle) Flower Extract, Lonicera Caprifolium (Honeysuckle) Extract, Populus Tremuloides Bark Extract, Gluconolactone, Sodium Dehydroacetate

Vanishing Cream using 1.0% NataPres™ + 0.1% o-Cymen-5-ol						
Test Organism	Inoc. Level	Day: 7	Day: 14	Day: 21	Day: 28	Log Reduction
Escherichia coli	2.00 x 10 <sup>5</sup>	<10	<10	<10	<10	6.08
Staphylococcus aureus	4.75 x 10 <sup>5</sup>	<10	<10	<10	<10	5.46
Pseudomonas aeruginosa	3.25 x 10 <sup>5</sup>	<10	<10	<10	<10	5.67
Candida albicans	8.40 x 10 <sup>5</sup>	<10	<10	<10	<10	5.88
Aspergillus niger	3.05 x 10 <sup>5</sup>	<10	<10	<10	<10	5.51

**Vanishing Cream Ingredient List** - Water, Stearic Acid, Isopropyl Myristate, Dimethicone, Stearyl Alcohol, Cetyl Alcohol, Polyoxyl 40 Stearate, Xanthan Gum, Glycerin, Leuconostoc/Radish Root Ferment Filtrate, Lonicera Japonica (Honeysuckle) Flower Extract, Lonicera Caprifolium (Honeysuckle) Extract, Populus Tremuloides Bark Extract, Butylene Glycol, Gluconolactone, o-Cymen-5-ol