

Product Fact Sheet

PHENONIP[®]



Preservative for the cosmetic industry

Chemical name	Preservative blend consisting of Methyl <i>p</i> -hydroxybenzoate, Ethyl <i>p</i> -hydroxybenzoate, Propyl <i>p</i> -hydroxybenzoate, Butyl <i>p</i> -hydroxybenzoate, Isobutyl <i>p</i> -hydroxybenzoate and Phenoxyethanol.
INCI designation	Phenoxyethanol and Methylparaben and Ethylparaben and Propylparaben and Butylparaben and Isobutylparaben

CLARIANT INTERNATIONAL LTD

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PRODUCT PROPERTIES¹

Appearance (20°C) Colourless to light straw viscous liquid

Chemical and physical data

Methyl Paraben	14.5 – 16.5 % w/w
Ethyl Paraben	3.5 – 4.3 % w/w
Propyl Paraben	1.7 – 2.3 % w/w
<i>n</i>-Butyl Paraben	3.7 – 4.3 % w/w
Isobutyl Paraben	1.7 – 2.3 % w/w
Phenoxyethanol	70.0 – 75.0 % w/w
Specific gravity	1.124 g/cm ³

Solubility

Water	approx. 0.5 %
Ethanol	Miscible
Ethanol/ Water (50/50)	> 95 %
Isopropanol	miscible
Acetone	miscible
Propylene Glycol	miscible
Isopropyl Myristate	Miscible
Peanut Oil	25 %
Liquid Paraffin	< 0.1 %
Glycerol	10 %
Triethanolamine	Miscible
Polysorbate- 80	Miscible
Triethanolamine Lauryl Sulphate (40 %)	35 %

¹ These characteristics are for guidance only and not to be taken as product specifications. The tolerances are given in the product specification sheet. For further product properties, specifications, safety and ecological data, please refer to the MSDS.

Uses

Phenonip® is a broad spectrum antimicrobial agent comprising a synergistic blend of esters of para-hydroxybenzoic acid (parabens) in phenoxyethanol designed for preservation of a wide range of cosmetics and toiletries.

pH stability

Phenonip® remains fully stable over a wide pH range from 3- 8.

Temperature stability

Phenonip® is highly stable, aqueous solutions of Phenonip® can withstand autoclave sterilization with no loss of activity.

Applications

Phenonip® provides activity against gram positive and gram negative bacteria, yeasts and molds.

It retains activity in the presence of most cosmetic ingredients.

Phenonip® has been successfully used to protect most types of personal care products from microbial contamination. As with other preservatives, the correct use concentration depends upon several factors, including the chemical and physical nature of the product, its ability to support microbial growth and the likelihood of recontamination during use.

Experience has shown that Phenonip® will preserve cosmetics and toiletries when incorporated at concentrations from 0.25 % to 1 %. The higher concentrations are generally required only for formulations which, by nature, are particularly difficult to preserve.

Shampoos and foam baths may be preserved with Phenonip® at concentrations between 0.25 % to 0.65 %. Products with high protein content may require levels from 0.5 % - 1 %. Other surfactant- based products, for example liquid dishwashing detergents, are generally preserved with Phenonip® over the range 0.2 %- 0.6 %. Emulsified systems, both O/W and W/O types, may be effectively preserved by the addition of Phenonip® at 0.4 %- 0.7 %. Phenonip® can also be used to preserve emulsions based on nonionic surfactants, but slightly increased concentrations may be required, e.g. 0.5 -1 %.

The table below illustrates the retention of microbiocidal activity of Phenonip® in the presence of 5 % Polysorbate- 80.

Test species	Colony forming units per mL after time:			
	0 day	1 day	2 days	7 days
<i>Staphylococcus aureus</i>	3.5 x 10 ⁶	1.4 x 10 ³	< 10	< 10
<i>Pseudomonas fluorescens</i>	5.0 x 10 ⁶	3.9 x 10 ⁴	< 10	< 10
<i>Pseudomonas aeruginosa</i>	3.8 x 10 ⁶	2.8 x 10 ⁵	< 10	< 10
<i>Candida albicans</i>	2.4 x 10 ⁶	< 10	< 10	< 10
<i>Penicillium expansum</i>	2.0 x 10 ⁶	1.0 x 10 ⁵	300	< 10

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The effectiveness of Phenonip® in controlling gram negative bacteria has led to its use in some skin antiseptic products where traditional antiseptic agents have a weakness in their spectrum of activity against these organisms.

Incorporation

Phenonip® can be added to the aqueous phase readily up to its limit of solubility. The relatively low aqueous solubility of Phenonip® means that if the water content of the formulation is low, it may not be convenient to add the preservative directly to water during manufacture. Heating the water to 60 – 70 °C prior to Phenonip® addition will, in most instances, allow the appropriate quantity to be dissolved. For aqueous systems which cannot be heated, Phenonip® can be incorporated by preparing a concentrate in a suitable solvent, e.g. Propylene Glycol, and stirring this concentrate into the water to give a final Phenonip® concentration below its maximum water solubility.

In emulsified systems, Phenonip® is readily dissolved in the lipid phase prior to emulsification although it is often good practice to divide the Phenonip® content between the aqueous and the lipid phases during their preparation. To add Phenonip® into the final emulsion during the cooling stage is also possible for a lot of emulsions.

In surfactant and detergent based products Phenonip® can be dissolved in the surfactant prior to the addition of water and other ingredients.

Examples of the use of Phenonip® are given below:

Time taken to achieve a complete microbiocidal effect in days						
Product type	% Phenonip	PA	EC	SA	CA	AN
<i>Shampoo</i>	0.3	< 1	< 1	< 1	< 1	< 1
<i>Foam Bath</i>	0.3	< 1	< 1	< 1	< 1	< 2
<i>Skin Toner</i>	0.4	1	1	1	1	2

The following are examples of formulations subjected to the British Pharmacopoeia (1988) microbial challenge test:

Test species	Colony forming units per g after				
	1 day	2 days	7 days	14 days	28 days
0.3 % Phenonip in a hair conditioner					
<i>PA</i>	< 10	< 10	< 10	< 10	< 10
<i>SA</i>	< 10	< 10	< 10	< 10	< 10
<i>CA</i>	< 10	< 10	< 10	< 10	< 10
<i>AB</i>	2.3 x 10 ²	< 10	< 10	< 10	< 10
0.5 % Phenonip in an O/W suntan cream					
<i>PA</i>	< 10	< 10	< 10	< 10	< 10
<i>SA</i>	< 10	< 10	< 10	< 10	< 10
<i>CA</i>	1 x 10 ³	< 10	< 10	< 10	< 10
<i>AB</i>	1.6 x 10 ⁴	1.2 x 10 ⁴	2.4 x 10 ³	< 10	< 10
1 % Phenonip in an O/W moisturizing cream					
<i>PA</i>	1.8 x 10 ³	< 10	< 10	< 10	< 10
<i>SA</i>	6.6 x 10 ⁶	2.6 x 10 ⁴	< 10	< 10	< 10
<i>CA</i>	2.5 x 10 ⁶	90	< 10	< 10	< 10
<i>AB</i>	2.5 x 10 ⁵	3.3 x 10 ³	< 10	< 10	< 10

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PA: *Pseudomonas aeruginosa*
 EC: *Escherichia coli*
 SA: *Staphylococcus aureus*
 CA: *Candida albicans*
 AB: *Aspergillus brasiliensis*

Microbial Activity

Phenonip® exhibits microbiostatic activity against a wide range of bacteria, yeast and molds. This is illustrated by the following table which shows the minimum inhibitory concentration (MIC) of Phenonip® against examples of different groups of microorganisms.

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Microorganisms	Stock Culture and Number	MIC level (%)
Gram Negative Bacteria		
<i>Pseudomonas aeruginosa</i>	NCIB 8626	0.225
<i>Escherichia coli</i>	NCIB 8545	0.20
<i>Proteus vulgaris</i>	NCTC 4175	0.225
<i>Salmonella enteritidis</i>	NCTC 5188	0.225
Gram Positive Bacteria		
<i>Staphylococcus aureus</i>	ATCC 6538	0.20
<i>Enterococcus faecium</i>	DVG 8582	0.20
<i>Bacillus cereus</i>	NCTC 7464	0.15
Yeasts		
<i>Candida albicans</i>	NCPF 3179	0.15
<i>Saccharomyces cerevisiae</i>	NCYC 200	0.15
Molds		
<i>Aspergillus brasiliensis</i>	IMI 149007	0.125
<i>Penicillium puprogenum</i>	Nipa Stock 0344	0.10

Regulatory Status

Phenonip® can be used up to a maximum concentration of 1.33 % in cosmetic product, no further restrictions, according to Annex VI, 76/768/EEC (Europe).

Phenonip® is permitted for Japan up to 1.33 %, no further restrictions.

Phenonip® is considered safe as used (CIR 2006).

Storage instructions

The product must be protected from excessively high and low temperatures during storage. Further information on handling, storage and dispatch is given in the EC safety data sheet.

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