

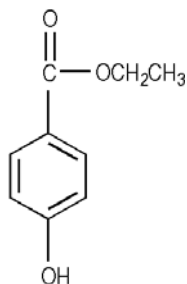
NipaginTM A

Preservative for the cosmetic industry

Chemical name

Ethyl 4-Hydroxybenzoate

Chemical structure



INCI designation

Ethylparaben

Product properties ^{*)}

Appearance (20°C)

White, or almost white crystalline powder.

Chemical and physical data

Melting point 115 - 118 °C

Assayacc. BP/PH.Eur 98.0 - 102.0 %

Uses

Nipagin A is a broad spectrum antimicrobial agent designed for preservation of a wide range of cosmetics, toiletries and topical pharmaceuticals. Nipagin A is suitable to preserve both rinse-off and leave-on formulations.

Applications

Typical use concentrations of Nipagin A is 0.1 – 0.3 %. Combinations of p- Hydroxybenzoic acid esters, e.g. with Nipasol M, Nipagin M or Nipabutyl exhibit increased activity compared with individual esters.

Regulatory Status

Europe: maximum concentration 0.4 % (acid) for 1 ester, and 0.8 % (acid) for mixtures of esters, no restrictions, Annex VI, 76/768/EEC.

Japan: maximum concentration 1 % in cosmetic product, no restrictions.

USA: considered safe as used by Cosmetic Ingredient Review (1984).

Incorporation

Nipagin A is freely soluble in most oils, waxes, fatty alcohols, but have relatively low solubility in water. The low aqueous solubility does not affect the microbiological efficacy of the esters.

Most formulations requiring preservation contain a significant amount of water.

This may mean that Nipagin A cannot readily be added directly to the formulation.

Other methods of incorporation are quite straightforward however, and are listed below.

^{*)} 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.

Dissolving in water

The solubility of Nipagin A increases greatly as the temperature of the water rises. Therefore a concentrate may be made up by heating an appropriate quantity of water to 60- 100 °C prior to addition of Nipagin A. This concentrate may then be added to the formulation, provided that the ester concentration does not exceed its solubility in the formulation at normal ambient temperatures.

Dissolving in organic solvents

Nipagin A is readily soluble in polar organic solvents. Where such a solvent is already part of a formulation an Nipagin A concentrate may be made up prior to addition. If a suitable solvent is not already part of the formulation, a highly concentrated solution may be made up e.g. 32 % in Ethanol, which would give insignificant residual levels of ethanol in the end product.

Solubilisation in oils, emulsifiers etc.

Nipagin A is readily soluble in lipophilic ingredients and may be introduced to a formulation by adding to the oil phase with some warming before any emulsification stage. In multiphase systems, such as emulsions, it is often advisable to use a combination of aqueous dissolution with either of the other methods to ensure adequate preservation. The ester may be incorporated in the water to its maximum solubility and any further quantities may be dissolved in the oil phase, or solvent, as appropriate.

pH stability

Nipagin A remains fully stable over a wide pH range from 4- 8. In general the lower the pH of the formulation, the more active is Nipagin A. That can result in a lower use concentration when the pH of the formulation is more acidic.

Temperature stability

Nipagin A is stable up to 80 °C.

Solubility

The solubility of Nipagin A in different solvents is illustrated in the following table.

Solvent	% (w/w)
Water 10 °C	0.06
Water 25 °C	0.11
Water 80 °C	0.86
Water 100 °C	1.7
Acetone	46
Methanol	45
Ethanol	41
Propylene Glycol	20
Glycerol	0.5
Vegetable oils (arachis)	1.0
Liquid paraffin	0.025

Microbial Activity

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

Microorganisms	MIC level (%)
Gram Negative Bacteria	
<i>Pseudomonas aeruginosa</i>	0.10
<i>Escherichia coli</i>	0.05
<i>Klebsiella aerogenes</i>	0.05
<i>Klebsiella pneumoniae</i>	0.05
<i>Serratia marcescens</i>	0.05
<i>Proteus vulgaris</i>	0.06
<i>Salmonella enteritidis</i>	0.05
<i>Salmonella typhi</i>	0.10

Microorganisms	MIC level (%)
Gram Positive Bacteria	
<i>Staphylococcus aureus</i>	0.07

<i>Streptococcus haemolyticus</i>	0.06
<i>Bacillus cereus</i>	0.025
<i>Bacillus subtilis</i>	0.10
<i>Lactobacillus buchneri</i>	0.06
Yeasts	
<i>Candida albicans</i>	0.07
<i>Saccharomyces cerevisiae</i>	0.05
Molds	
<i>Aspergillus niger</i>	0.04
<i>Penicillium digitatum</i>	0.025
<i>Rhizopus nigricans</i>	0.025

Storage instructions

The product must be stored in tightly closed container in a cool, well-ventilated, dry place.

Further information on handling, storage and dispatch is given in the EC safety data sheet.

This information is based on our present state of knowledge and is intended to provide general notes on our products and their uses. It should not therefore be construed as guaranteeing specific properties of the products described on their suitability for a particular application. Any existing industrial property rights must be observed. The quality of our products is guaranteed under our General Conditions of Sale.