



TECHNICAL DATA SHEET

002692-TDS-ENG-2019

NIPAGIN M (METILE P-HIDROXIBENZOATO)PH.EUR		
DESCRIPTION DCI: METHYL PARAHYDROXYBENZOATE		DESCRIPTION DOE: PARAHIDROXOBENZOATO DE METILO
CAS Nº: 99-76-3	EC Nº: 202-785-7	AEMPS CODE: ---
MOL. WEIGHT: 152.15	MOL. FORMULA: C8H8O3	ARTICLE CODE: 002692

ATTRIBUTES	SHOULD BE
Appearance	white or almost white, crystalline powder or colourless crystals
Solubility	very slightly soluble in water, freely soluble in ethanol (96 %) and in methanol
Melting point	125 - 128 °C
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY6
Acidity	=< 0.1 mL NaOH 0.1 M
Related substances	
Impurity A	=< 0.5 %
Unspecified impurities	=< 0.5 %
Total impurities	=< 1.0 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 9.0

STORAGE

Keep the containers tightly closed. Store in a dry and cool place.

REMARKS

Gluten - Not applicable.**BSE/TSE** - Not applicable**GMO** - The product does not contain or derive from GMOs (Reg. 1829/1830 / CE).**Irradiation** - The product has not been irradiated.**Residual solvents** (ICH / 283/95) - Methanol <10 ppm in a limit of 0.3%**Latex** - The product is "LATTEX FREE"**Cosmetic allergens** - The product does not contain any of the 26 substances considered potential allergens and mentioned in the VII amendment of the Cosmetics Directive.**Grain** - Retention percentage size

10% 14.27 µm

50% 75.67 µm

90% 255.23 µm

The product is of synthetic origin and is produced only from raw materials of synthetic origin. The product does not contain any material of animal origin and does not come into contact with materials of animal origin during production and storage.

Properties and uses

It is an ester of p-hydroxybenzoic acid, with preservative properties. It acts by direct action on the membrane of the germ, and by competition with the coenzymes of these.

It is more active against Gram + bacteria than against fungi and yeasts

Dosage

The most common dose is 0.02-0.3% for all of them



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Side effects

Occasionally it may cause hypersensitivity reactions (contact dermatitis). In ocular applications, possible painful irritations.

Incompatibilities

Non-ionic surfactants (Tween, Span), bentonite and magnesium aluminum silicates, talcum, iron salts, weak alkalis, strong acids, atropine, sorbitol, sodium alginate, and tragacanth gum.

Before use, it is necessary to check possible incompatibilities with the container to be used, especially if it is made of plastic, as they can be absorbed (polyethylene, polypropylene, PVC ...). It seems that polyethylene, both high and low density, do not interfere.

Other observations

All are hygroscopic and photosensitive.

Compounding examples

Concentrated solution of hydroxybenzoates (FN)

For O/W emulsions

NIPAGIN - **8 g**

Nipasol - **2 g**

Propielnglicol c.s.p. - **100 mL**

For W/O emulsions

NIPAGIN - **2 g**

Nipasol - **8 g**

Propielnglicol c.s.p. - **100 mL**