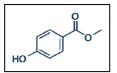


Dossier technique et réglementaire / technical and regularoty document

Octobre 2018 / October 2018

PARAOXYBENZOATE DE METHYLE



INCI: **Methylparaben** N° CAS: 99-76-3

N°EINECS/ELINCS: 202-785-7

DESCRIPTION / DESCRIPTION:

Nom chimique: 4-hydroxybenzoate de méthyle / Chemical name: methyl 4-hydroxybenzoate
Parahydroxybenzoate de méthyle C₈H₈O₃. Poudre crystalline, blanche ou cristaux incolores / Methyl
parahydroxybenzoate C₈H₈O₃. Crystalline powder, white or colorless crystals
Produit conforme à la Pharmacopée Européenne en vigueur (monographie: Parahydroxybenzoate de methyle)
/ Product in accordance with the current European Pharmacopoeia (monograph: Methyl Paraben
Hydroxybenzoate)

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS.		
CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Aspect de la solution S / Aspect of the solution S	Conforme / Compliant	
Point de fusion / Melting point	125 – 128°C	Pharmacopée
Pureté / Assay	98 – 102 %	Européenne en vigueur / European
Substances apparentées / Related substanses	Conforme / Compliant	Pharmacopoeia in
Acidité / Acidity	≤ 0.1 mL NaOH 0.1M	force
Cendre sulfurique / Sulfuric ash	Conforme / Compliant	
Métaux lourds (Pb) / Heavy metals (Pb)	≤ 10 ppm	
Perte au séchage / Loss on drying	0 – 0.5 %	

Ces éléments seront repris sur nos BA / these elements will be on our CoA

Ces caractéristiques sont conformes aux précédentes spécifications datées de Mai 2007 / These features are in accordance with previous specifications dated on May 2007

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Residue à l'allumage / Residue on ignition: test passé / passed test

Identification: O.K

Impureté A / Impurity A: ≤ 0.5 %

Impuretés non spécifiées / Unspecified impurities: ≤ 0.5 %

Impuretés totales / Total impurities: ≤ 1 %

Conforme à: NF, BP, PhEur, et aux spécifications SL98I / Compliant to: BP, PhEur and SL98I specifications
Très peu soluble dans l'eau, facilement soluble dans l'alcool et dans le méthanol / Very slightly soluble in water,

easily soluble in alcohol and methanol

Point d'ébullition / Boiling point: 190 – 280°C

Temperature d'inflammation / Ignition temperature: > 403°C

Densité à 20°C / Density at 20°C: 1.377,5 g/cm³

Conforme à la Pharmacopée Americaine USP39 - NF34 / Compliant to America Pharmacopoeia USP39 - NF34

Ce produit convient aux végétaliens / This product is suitable for Vegan



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APPLICATIONS:

Conservateur pour industrie cosmétique et pharmaceutique / *Preservative for cosmetic and pharmaceutical industry*

CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

Carton de 25 kg / Cardboard boxes of 25 kg

Additives	No data available
Allergen	This product is free from all allergen ingredients as defined in the 7th amendment of the European Cosmetics Directive and in food Guideline 2003/89/EC
Animal Tasting	Animal tests has never been performed nor sponsored for the purpose of
Animal Testing	implementation of the EU Cosmetics Regulation or for the implementation of the
	European Cosmetics Directive (Directive 76/768/EEC)
BSE - Bovine	This product doesn't contain any product of animal origin and has not been in contact
Spongiform	with any material of animal origin during manufacture and storage, therefore, there is
Encephalopathy	no risk of BSE
California Prop 65	This product (CAS:99-76-3) is not listed
Carcinogenic,	This product doesn't contain CMR (annex I, directive 67/548/CE)
Mutagenic and	This product doesn't contain civin (diffex i, directive 07/340/CE)
Reprotoxic (CMR)	
Composition	Methylparaben (98 – 102 %), 4-hydroxybenzoic acid (max 0.5 %), unspecified
	impurities (max 0.5 %), methanol (≤ 3000 ppm)
Cosmetic	This product is in compliance with regulation (EC) No 1223/2009 on Cosmetics
	products and with other relevant legislations as Regulations (EC) No 1907/2006
	concerning the Registration, Evaluation, Authorization and Restriction of Chemicals
	REACH
Cosmos / Ecocert	This product contain synthetic derivates – Not accepted by Cosmos
Danger	This product is not classified as dangerous and labeled in accordance with CLP and not
g	classified with ADR
Dioxane	This product doesn't contain dioxins
Ecolabel	No data available
European	This product is compliant with the European Pharmacopoeia 9th edition
Pharmacopeia	
Food	This product is free from all allergen ingredients as defined in the 7th amendment of
	the European Cosmetics Directive and in food Guideline 2003/89/EC
Genetically Modified	Doesn't contain GMO and complies with Regulation (EC) No 1829/2003 and regulation
Organisms (GMO)	(EC) No 1830/2003
Inventories	Compliant with China IECSC, USA TSCA, New Zealand NZIoC, Japan ENCS, Korea KECI,
	Philippines PICCS, Australia AICS, Canada DSL
Geographic origin (for	Not concerned
plant)	
Glycol ether	No data available
Halal	This product is not Halal certified, but meet the criteria normally associated with Halal
	status as defined below:
	-This product doesn't contain alcohol (ethanol or grain alcohol), natural L-cysteine
	extracted hair or feathers, animals fats, animal extracts, bloods of any origin, blood
	plasma, pork and / or other meat by-products
	-Alcohol (ethanol or grain alcohol) is not used in the manufacturing process, or as a
	process aid
	-The equipment used in the manufacture is not used for manufacturing any product of
	animal origin or products containing ingredients of animal origin



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Heavy Metals	Contain heavy metals ≤ 10 ppm, and likely to be present As < 1 ppm, Cd < 0.1 ppm,
	Hg < 0.5 ppm, Pb < 1 ppm, Co < 0.5 ppm, Ni =2.761 ppm, V < 0.5 ppm, Ag < 0.5 ppm,
	Se < 2 ppm, Tl <1 ppm, Ba < 0.5 ppm, Cr = 0.767 ppm, Cu = 31.708 ppm, Li < 0.5 ppm,
	Mo < 0.5 ppm, Sb < 2ppm, Sn = 6.803 ppm in reference to ICH Q3D Guideline for
	Elemental Impurities, Step 4 version, December 2014
HS code	29182900
Irradiation / ionization	This product has never been subject to irradiation nor to ionizing treatment
Kosher	This product is Kosher certified
Latex	No data available
Manufacturing location	Israel
Microbiological data	Due to the nature of the substance and his properties, a microbiological analysis is
	irrelevant and therefore not performed. It is most unlikely to find any living
	microorganisms in the product. Several microbiological analysis are randomly
	performed, the results obtained are < 10 CFU/gr
Nanomaterials	This product doesn't contain engineered nanomaterials as defined in the Regulation
	(EU) No 2015/2283
Nutritional data	This product doesn't have any nutritional value
Origin	100% synthetic
Pesticide	Doesn't contain pesticides
Phthalate	This product doesn't contain Phthalates and has not being used during the
	manufacture, handling and storage
Preservative	This product is preservative of strong anti-microbial activity
Process	p-Hydroxybenzoic acid + methanol -> esterification process -> methyl paraben
	->purification -> drying & milling -> packing
REACH	Registrated 01-2119463264-40
Residual Solvents	This product is conforming to acceptable amounts for residual solvents described in
	the note for guidance CPMP/ICH/283/95 and in the USP-NF.
	The solvent that is being used in the process of the above product is methanol (Class
	2), and it is limited to less than 3000ppm. There are no other solvents from class 1, 3
	and 4 that are being used in the process of the above products
RSPO	This product doesn't contain palm – not concerned
Shelf Life	36 months
Substances of Very High	The product is free of SVHC
Concern (SVHC)	
Volatiles organic	No data available
compounds (VOC)	

---- END

Ce document annule et remplace tous documents techniques et réglementaires précédents / This document cancel and replace all technical and regulatory previous documents.