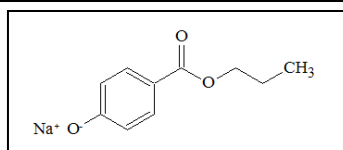


	Dossier technique et réglementaire / <i>technical and regulatory document</i> PARAOXYBENZOATE DE PROPYLE SODÉ	Octobre 2018 / October 2018
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INCI: Sodium propylparaben
N°CAS: 35285-69-9
N°EINECS/ELINCS: 252-488-1

DESCRIPTION / DESCRIPTION:

Nom chimique: 4-hydroxybenzoate de propyle sodique / *Chemical name: Sodium propyl 4-hydroxybenzoate*
 Parahydroxybenzoate de propyle sodique C₁₀H₁₁O₃Na. Poudre cristalline blanche / *Sodium propyl parahydroxybenzoate C₁₀H₁₁O₃Na. White crystalline powder*

Produit conforme à la Pharmacopée Européenne en vigueur (monographie : Parahydroxybenzoate de propyl sodique) / *Product in accordance with the current European Pharmacopoeia (monograph: Sodium Propyl Paraben Hydroxybenzoate)*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Aspect de la solution S / <i>Aspect of the solution S</i>	Conforme / <i>Compliant</i>	Pharmacopée Européenne en vigueur / <i>European Pharmacopoeia in force</i>
Pureté / <i>Assay</i>	94 – 102 %	
Substances apparentées / <i>Related substances</i>	Conforme / <i>Compliant</i>	
Chlorures / <i>Chloride</i>	≤ 350 ppm	
Métaux lourds (comme Pb) / <i>Heavy metals (as Pb)</i>	≤ 10 ppm	
Sulfates / <i>Sulphate</i>	≤ 300 ppm	
pH	9.5 – 10.5	
Teneur en eau / <i>loss on drying</i>	0 – 5 %	

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

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Identification: O.K

Impuretés organiques volatiles / *Organic volatile impurities*: test passé / *passed test*

Impureté A / *Impurity A*: pas plus de 4 % / *Not more than 4 %*

Impuretés non spécifiées / *Unspecified impurities*: pas plus de 0.5 % / *Not more than 0.5 %*

Somme des impuretés autre que A / *Sum of impurities other than A*: pas plus de 1 % / *Not more than 1 %*

Solubilité / *Solubility*: test passé / *Passed test*

Facilement soluble dans l'eau, assez soluble dans l'alcool et pratiquement insoluble dans le chlorure de méthylène / *Easily soluble in water, quite soluble in alcohol and practically insoluble in methylene chloride*

Densité en vrac à 20°C / *Density in bulk at 20°C*: ~ 1000g/l

Coefficient de partage (n-octanol/eau) / *Partition coefficient (n-octanol/water)*: 2.8 log POW

Conforme à: BP, PhEur, et aux spécifications SL981 / *Compliant to: BP, PhEur and SL981 specifications*

Conforme à la Pharmacopée Américaine USP39 – NF34 / *Compliant to America Pharmacopoeia USP39 – NF34*

APPLICATIONS :

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

	Dossier technique et réglementaire / <i>technical and regularoty document</i> PARAOXYBENZOATE DE PROPYLE SODÉ	Octobre 2018 / October 2018
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CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

Carton de 25 kg / 25 kg cardboard

Matière première classifiée comme substance dangereuse (Voir fiche de données de sécurité) / *Raw material classified as dangerous substance (see safety data sheet)*

Additives	<i>No data available</i>
Allergen	This product is free from all allergen ingredients as defined in the 7 th Amendment of the European Cosmetics Directive and in food Guideline 2003/89/EC
Animal Testing	Animal tests has never been performed nor sponsored for the purpose of implementation of the EU Cosmetics Regulation or for the implementation of the European Cosmetics directive (Directive 76/68 EEC)
BSE - Bovine Spongiform Encephalopathy	This product doesn't contain any product of animal origin and has not been in contact with any material of animal origin during manufacture and storage, therefore, there is no risk of BSE
California Prop 65	This product (CAS: 35285-69-9) is not listed
Carcinogenic, Mutagenic and Reprotoxic (CMR)	This product doesn't contain CMR (annex I, directive 67/548/CE)
Composition	Sodium propylparaben (94 – 102 %), 4-hydroxybenzoic acid (max 4 %), sum of impurities other than 4-hydroxybenzoic (max 1%), water (max 5 %)
Cosmetic	This product is in compliance with Regulation (EC) No 1223/2009 on Cosmetics products and with other relevant legislations as Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals REACH
Cosmos / Ecocert	This product contains synthetic derivates – Not accepted by Cosmos
Danger	This product is classified as dangerous and labeled in accordance with CLP and not classified with ADR
Dioxane	This product doesn't contain dioxins
Ecolabel	<i>No data available</i>
European Pharmacopeia	This product is in accordance with the current European Pharmacopoeia 9 th edition
Food	This product is free from all allergen ingredients as defined in the 7 th amendment of the European Cosmetics Directive and in food Guideline 2003/89/EC
Genetically Modified Organisms (GMO)	Doesn't contain GMO and complies with regulation (EC) No 1829/2003 and regulation (EC) No 1830/2003
Inventories	Compliant with China IECSC, New Zealand NZIoC, Japan ENCS, Philippines PICCS, Australia AICS, Canada DSL
Geographic origin (for plant)	Not concerned
Glycol ether	<i>No data available</i>
Halal	<i>No data available</i>
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 < 0.5 ppm, V=0.650 ppm, Ag < 0.5 ppm, Se < 2 ppm, Tl < 1 ppm, Ba < 0.5 ppm, Cr < 0.5ppm, Cu < 0.5 ppm, Li < 0.5 ppm, Mo < 0.5 ppm, Sb < 2ppm, Sn < 2 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

	Dossier technique et réglementaire / <i>technical and regulatory document</i> PARAOXYBENZOATE DE PROPYLE SODÉ	Octobre 2018 / <i>October 2018</i>
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Kosher	This product is Kosher certified
Latex	<i>No data available</i>
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	Doesn't contain phthalates and has not being used during the manufacture, handling and storage of the product
Preservative	This product is preservative of strong anti-microbial activity
Process	<i>No data available</i>
REACH	<i>No data available</i>
Residual Solvents	This product is conforming to acceptable amounts for residual solvents described in the note guidance CPMP/ICH/285/95 and in the USP-NF. The solvent that is used in the manufacturing process is 1-propanol (Class 3) which is limited to less than 5000ppm. There are no other solvents from class 1,2 and 4 that are being used in the process
RSPO	This product doesn't contain palm – not concerned
Shelf Life	12 months
Substances of Very High Concern (SVHC)	This product is free from SVHC
Volatiles organic compounds (VOC)	<i>No data available</i>

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