	Dossier technique et réglementaire / <i>Technical and regulatory document</i> PARAOXYBENZOATE D'ETHYLE	Octobre 2020 / <i>October 2020</i>
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INCI: **Ethylparaben**
N°CAS: 120-47-8
N°EINECS/ELINCS: 204-399-4

DESCRIPTION / DESCRIPTION:

Parahydroxybenzoate d'éthyle C₉H₁₀O₃. Poudre cristalline, blanche ou sensiblement blanche / *Ethyl parahydroxybenzoate C₉H₁₀O₃. White or almost white, crystalline powder*
Produit conforme à la Pharmacopée Européenne en vigueur (monographie : parahydroxybenzoate d'éthyle) / *Product in accordance with the current European Pharmacopoeia (monograph : Ethyl Parahydroxybenzoate)*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Aspect / <i>Aspect</i>	Conforme / <i>Compliant</i>	Pharmacopée Européenne en vigueur / <i>European Pharmacopoeia in force</i>
Point de fusion / <i>Melting point</i>	115 – 118°C	
Pureté / <i>Assay</i>	98 – 102 %	
Substances apparentées / <i>Related substances</i>	Conforme / <i>Compliant</i>	
Cendre sulfurique / <i>Sulfuric ash</i>	Conforme / <i>Compliant</i>	
Acidité / <i>Acidity</i>	≤ 0.1 mL NaOH 0.1M	
Perte au séchage / <i>Loss on drying</i>	≤ 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:


Identification: O.K
Impuretés A : pas plus de 0.5 % / *Impurity A: not more than 0.5 %*
Impuretés non spécifiées : pas plus de 0.5 % / *Unspecified impurities : not more than 0.5 %*
Impuretés totales : pas plus de 0.5 % / *Total impurities : not more than 0.5 %*
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*

APPLICATIONS:


Conservateur pour industrie cosmétique / *Preservative for cosmetic industry*

CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

Carton de 25 kg / *25 kg cardboards boxes*
A conserver au frais et au sec dans un emballage hermétiquement fermé / *Store in a cool, dry place in a tightly closed container*
Matière première non classifiée comme substance dangereuse (voir fiche de données de sécurité) / *Raw material not classified as dangerous substance (see safety data sheet)*
Ce produit est végétalien / *This product is vegan*

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Additives	This product doesn't contain antioxidants, stabilizers, formaldehyde donors, buffers / pH correctors, nitro musk and polycyclic musk cpd's, cashmeran, halogen organic cpd's, nitrosamines, aflatoxins .This product contain ethanol ($\leq 0.1\%$), PHBA ($\leq 0.5\%$)
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 and doesn't contain allergen according to the Cosmetics regulation (EC) No 1223/2009, annex III
Animal Testing	This product has not been tested on animals
BSE - Bovine Spongiform Encephalopathy	This product is not of animal origin – no risk of BSE
California Prop 65	This product contain ingredients known to the state of California to cause cancer or reproductive toxicity as listed under Proposition 65 certificate
Carcinogenic, Mutagenic and Reprotoxic (CMR)	This product doesn't contain CMR according to Cosmetics regulation (EC) No 1223/2009 (part 3 of annex VI (EC) No 1272/2008)
Composition	Ethylparaben (98 – 102 %) + 4-hydroxybenzoic acid ($\leq 0.5\%$) + unspecified impurities ($\leq 0.5\%$) + ethanol (less than 5000 ppm)
Cosmetic	This product is in compliance with Cosmetics regulation (EC) No 1223/2009
Cosmos / Ecocert	This product is not compliant with Cosmos and Ecocert standards
Danger	This product is not classified as dangerous in accordance to CLP and ADR
Dioxane	This product doesn't contain 1,4 dioxan
Ecolabel	<i>No data available</i>
European Pharmacopeia	This product is compliant with American Pharmacopoeia USP31 – NF26, British Pharmacopoeia 2009, and European Pharmacopoeia 6th edition
Food	<i>No data available</i>
Genetically Modified Organisms (GMO)	This product doesn't contain GMO
Inventories	This product is compliant with Switzerland / Europe (Reach / EINCS), USA TCSA, Canada DSL/NDSL, Australia AICS, Japan ENCS and ISHL, China IECSC, Korea KECI, New Zealand NZIoC, Philippines PICCS, Mexico INSQ, Taiwan NECI, Thailand TECI
Geographic origin (for plant)	Not concerned
Glycol ether	This product doesn't contain glycol ether
Halal	This product is not Halal certified
Heavy Metals	This product contain heavy metals: arsenic ≤ 1 ppm, lead ≤ 1 ppm, antimony ≤ 2 ppm, copper ≤ 1 ppm, zinc ≤ 1 ppm. This product can contain cadmium, mercury, selenium, tellurium, thallium, uranium, chromate (not traceable)
HS code	29182900
Irradiation / ionization	This product is neither subject to irradiation nor to ionizing treatment
Kosher	This product is Kosher certified
Latex	<i>No data available</i>
Manufacturing location	Japan
Microbiological data	This product is a cosmetic preservative of strong anti-microbial activity. Due to the nature of this substance and his properties, a microbiological analysis is irrelevant and therefore not performed as part of the QC of the product. It is most unlikely to find any living microorganisms in this product. Several microbiological analysis are performed randomly, the results obtained are < 10 CFU/gr
Nanomaterials	This product doesn't contain nanomaterials according to regulation (EC) No 1223/2009 article 2 (1k) and the EU recommendation (18 October 2001)
Nutritional data	This product doesn't have any nutritional value
Origin	Synthetic
Pesticide	This product doesn't contain pesticide
Phthalate	This product doesn't contain phthalate
Preservative	This product is a cosmetic preservative

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Process	P-hydroxybenzoic acid (+ ethanol) → esterification process → ethyl paraben → purification → drying & milling → packing
REACH	This product is registered 01-2119967787-13
Residual Solvents	This product contain ethanol (≤ 0.1 %) and PHBA (≤ 0.5 %)
RSPO	This product doesn't contain palm – not concerned
Shelf Life before re-check	3 years
Substances of Very High Concern (SVHC)	Doesn't contain any SVHC
Volatiles organic compounds (VOC)	This product contain ethanol ≤ 0.1 % according to SR 814.018 (Swiss directive concerning steering tax on volatile organic carbon)

----- **END**

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