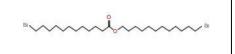


## Dossier technique et réglementaire / Technical and regulatory document

Mai 2021 / May 2021

### **PALMITATE DE CETYLE 95**



INCI: **Cetyl palmitate** N°CAS: 540-10-3

N°EINECS/ELINCS: 208-736-6

#### **DESCRIPTION / DESCRIPTION:**

Le palmitate de cétyle est un ester de l'acide palmitique et de l'alcool cétonique / Cetyl palmitate is an ester of palmitic acid and ketone alcohol

Matière première d'origine végétale et conforme à la Pharmacopée Européenne en vigueur (monographie : Palmitate de cétyle) / Raw material of vegetable origin and in conformity with the European Pharmacopoeia in force (monograph: Cetyl palmitate)

### **CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:**

CARACTERISTIQUES	SPECIFICATIONS
Aspect / Aspect	Pastilles blanches ou crèmes, cassantes, de faible odeur / White or creamy, brittle, low odor lozenges
Couleur (HAZEN) / Color (HAZEN)	≤ 100
Point de fusion / Melting point	50 – 53°C
Teneur en eau / Water content	≤ 0.3 %
Impureté à réaction alcaline / Alkaline impurities	≤ 0.4 ml HCl (0.01M)
Teneur en cendres totales / Total ashes content	≤ 0.2 %
Teneur en nickel / Nickel content	≤ 1 ppm
Indice d'acide / Acid content	≤ 1 mg KOH/g
Indice de saponification / Saponification value	105 – 120 mg KOH/g
Indice d'iode / Iodine value	≤ 2 g l₂/ 100g
Indice d'hydroxyle / Hydroxyl value	≤ 20 mg KOH/g
Indice de peroxyde / Peroxide value	≤ 2.5 Meq /kg
Teneur en palmitate de cétyle / Palmitate cetyl content	≥ 90 %

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

Ces caractéristiques sont conformes aux précédentes spécifications datées de Novembre 2002 / These features are in accordance with previous specifications dated on November 2002

#### CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Point d'ébullition / Boiling point : > 360°C Densité à 80°C / Density at 80°C: ca. 0.82g/cm<sup>3</sup>

Ce produit est végétalien / This product is suitable for vegan

#### **APPLICATIONS:**

Préparations cosmétiques / Cosmetic preparations (emollient, masking, skin conditionning)



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### PALMITATE DE CETYLE 95

### CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

Sac de 20 kg / 20 kg bag

Matière première non classifiée comme substance dangereuse / Raw material not classified as dangerous substance

A conserver à une température comprise entre 15 et 25°C. A conserver dans l'emballage d'origine à l'abri de la lumière du soleil, de l'humidité et des températures extrêmes / Store at a temperature between 15 and 25°C. Keep closed in original packaging away from sunlight, moisture and extreme temperatures.

Additives	Additives as antioxidants, PAH, formol or fragrances are not added to this product
	during the manufacturing process, therefore these substances are not monitored
	analytically.
	A contamination with nitrosamines is not expected to be present.
	This product doesn't contain nitrosable or nitrosating substances as ingredients
	which allow a formation of nitrosamines, therefore these additives are not
	monitored analytically.
	This product is not classified as PBT or vPvB and doesn't contain any ingredients
	classified as PBT/vPvB according to regulation (EC) No.1907/2006
Allergen	For the production of this product, none ingredients are used that are listed as
	allergens according to annex III (no. 67 – 92) of regulation (EC) No.1223/2009.
	Allergens are not monitored analytically.
	This product is not derived from gluten containing cereals. The raw material is not
	representing a natural source of gluten source for gluten. Therefore, gluten is not
	monitored analytically. This product is not derived from nuts (allergen associated);
	analyses, to determine nut allergens in traces are not performed
Animal Testing	This product has not been tested on animals in terms of regulation (EC)
J	No.1223/2009, Article 18
BSE - Bovine Spongiform	This product is from vegetable raw materials and does therefore not represent a
Encephalopathy	source for BSE/TSE pathogens
California Prop 65	Substances listed in California Proposition 65 are not used as ingredients
Carcinogenic, Mutagenic	This product is not rated as a CMR (category 1A, 1B, and 2) and doesn't contain any
and Reprotoxic (CMR)	ingredients rated as CMR (category 1A, 1B, and 2) according to regulation (EC)
	No.1223/2009 in association with regulation (EC) No.1272/2008
Composition	Cetyl palmitate
Cosmetic	This product is not cited in annex II or III of regulation (EC) No.1223/2009, therefore
	the application in cosmetic preparations is not prohibited or restricted according to
	this regulation
Cosmos / Ecocert	With available information, this product is expected to be accepted by cosmos
Danger	This product is not classified as dangerous in accordance to CLP and ADR
Dioxane	A contamination with 1, 4-dioxane is not expected to be present as the
	manufacturing process doesn't include an ethoxylation step. Therefore 1,4-dioxane is
	not monitored analytically
Ecolabel	No data available
European Pharmacopeia	This product is compliant with the European Pharmacopoeia
Food	Is not a food grade product
Genetically Modified	This product doesn't contain GMO and is not derived from GMO.
Organisms (GMO)	PCR analyses, to determine GMO traces are therefore not performed
Inventories	Compliant with China IECSC, USA TSCA, New Zealand NZIoC, Taiwan TCSI, Korea KECI,
	Philippines PICCS, Australia AICS, Canada DSL
Geographic origin (for	No data available
plant)	
Glycol ether	Glycol ether is not added to this product during the manufacturing process. The
	process itself doesn't expect the formation of glycol ether, therefore this product is
	not monitored analytically



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Halal	No data available
Heavy Metals	This product is monitored periodically for the sum of heavy metals with a threshold
	value of 10 ppm (as Pb)
HS code	29157000
Irradiation / ionization	This product has not been treated with ionizing radiation during or after the
	manufacturing process
Kosher	No data available
Latex	No data available
Manufacturing location	No data available
Microbiological data	This product is not monitored on microbiological parameters, High processing
	temperatures and very low water content of the final product decrease the risk of
	microbial growth
Nanomaterials	This product doesn't contain any ingredients classified as nanomaterials according to
	Commission Recommendation 2011/696 and regulation (EC) No 1223/2009
Nutritional data	No data available
Origin	100% vegetable (palme)
Pesticide	This product is not monitored on pesticides. A presence of pesticides in the finished
	product is not expected to be present, with respect to the feedstock and the
	production process
Phthalate	Phthalates are not added to this product during the manufacturing process. The
	process itself doesn't expect the formation of phthalates, therefore this substance
	class is not monitored analytically
Preservative	Preservatives are not added to this product during the manufacturing process,
	therefore not monitored analytically
Process	Fatty acid (palmitic acid) + fatty alcohol (cetyl alcohol) → mixing → esterification →
	post treatment → packaging
REACH	This product is registered 01-2120760446-51
Residual Solvents	For the production of this product, class 1, 2 or 3 solvents, referring to EP chapter
	5.4, are not added or used. These solvents are not monitored analytically
RSPO	This product is derived from palm oil or palm kernel oil. This product is not certified
	RSPO. This same product is also available with RSPO-MB grade on request only. See
	our product "PALMITATE DE CETYL 95-RSPO-MB"
Shelf Life before re-check	2 years
Substances of Very High	Substances cited in the SVHC candidate list or already included in annex XIV of (EC)
Concern (SVHC)	No 1907/2006, are not used as ingredients
Volatiles organic	This product doesn't show a vapor pressure above or equal to 0.01 kPa at 20°C and
compounds (VOC)	needs therefore not to be classified as a VOC according to directive (EC) No 1999/13
	and Swiss VOCV

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