	Dossier technique et réglementaire / <i>Technical and regulatory document</i> TRI-CAPRYLATE / CAPRATE DE GLYCEROL	Juillet 2023 / <i>July 2023</i>
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INCI: **Caprylic/ capric triglyceride**
N°CAS: 73398-61-5 / 65381-09-1
N°EINECS/ELINCS: 277-452-2 / 265-724-3


DESCRIPTION / DESCRIPTION:

Liquide huileux, incolore à légèrement jaunâtre / *Oily liquid, colorless to slightly yellow*
Matière première d'origine végétale et conforme à la Pharmacopée Européenne en vigueur (monographie : Triglycérides à chaîne moyenne) / *Raw material conforming to the European Pharmacopoeia in force (monography : Medium chain triglycerides)*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Aspect de la substance / <i>Aspect of the substance</i>	Limpide et pas fortement colorée que la solution témoin J3 / <i>Clear and not strongly colored than the control solution J3</i>	Ph. Eur. 2.2.1 et 2.2.2 / <i>Ph. Eur. 2.2.1 and 2.2.2</i>
Impuretés à réaction alcaline / <i>Alkaline impurities</i>	≤ 0.15 ml d'HCl 0.01M	Ph. Eur (cf monographie) / <i>Ph. Eur (cf monography)</i>
Densité / <i>Density</i>	0.93 – 0.96 g.cm ³	Ph. Eur. 2.2.5
Indice de réfraction / <i>Refractive index</i>	1.44 – 1.452	Ph. Eur. 2.2.6
Viscosité / <i>Viscosity</i>	25 – 33 mPa.s	Ph. Eur. 2.2.9
Indice d'acide / <i>Acid value</i>	≤ 0.2 mg KOH / g	Ph. Eur. 2.5.1
Indice d'hydroxyle / <i>Hydroxyl value</i>	≤ 10 mg KOH / g	Ph. Eur. 2.5.3
Indice d'iode / <i>Iodine value</i>	≤ 1 g I ₂ / 100g	Ph. Eur. 2.5.4
Indice de peroxyde / <i>Peroxide value</i>	≤ 1 meq O ₂ / kg	Ph. Eur. 2.5.5
Indice de saponification / <i>Saponification value</i>	310 – 360 mg KOH / g	Ph. Eur. 2.5.6
Insaponifiable / <i>Unsaponifiable</i>	≤ 0.5 % (m/m)	Ph. Eur. 2.5.7
Composition en acides gras / <i>Fatty acid composition</i>		
C 6 : 0 Acide caproïque / <i>Caproic acid</i>	≤ 2 %	Ph. Eur. 2.4.22
C 8 : 0 Acide caprylique / <i>Caprylic acid</i>	50 – 80 %	
C 10 : 0 Acide caprique / <i>Capric acid</i>	20 – 50 %	
C 12 : 0 Acide laurique / <i>Lauric acid</i>	≤ 3 %	
C 14 : 0 Acide myristique / <i>Myristic acid</i>	≤ 1 %	
C 8 + C 10 : 0	≥ 95 %	
> C16	≤ 1%	
Métaux lourds / <i>Heavy metals</i>	≤ 10 ppm	Ph. Eur. 2.4.8
Teneur en eau / <i>Water content</i>	≤ 0.2 %	Ph. Eur. 2.5.12
Cendres totales / <i>Total ashes</i>	≤ 0.1 %	Ph. Eur. 2.5.16

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

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CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Pratiquement insoluble dans l'eau, miscible à l'alcool, au chlorure de méthylène, à l'éther de pétrole et aux huiles grasses / *Practically insoluble in water, miscible with alcohol, methylene chloride, petroleum ether and fatty oils*

Couleur / *Color* : ≤ 100 (HAZEN)

Ce produit est végétalien / *This product is suitable for vegan*


APPLICATIONS:

Préparations cosmétiques / *Cosmetic preparations (emollient, skin conditioning, solvent, masking, perfuming)*

CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

Tonnelet de 25, 40 ou 50kg – fût de 190 kg – containers 950 kg / *25, 40 or 50 kg keg –190 kg drum – 950 kg containers*. A conserver en emballage bien rempli et soigneusement fermé, à l'abri de la lumière / *Store in a well-filled and carefully closed container, protected from light*

Additives	Additives as antioxidants, formol, PAH 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 neither contains nitrosable nor nitrosating substances as ingredients which allow a formation of nitrosamines, therefore these additives are not monitored analytically. This product is not monitored on aflatoxins. A presence of aflatoxins in the finished product is not expected to be present, with the respect to the used raw materials and the production process. 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) regulation (EC) No.1223/2009. Therefore, these ingredients are not monitored analytically. This product is not derived from gluten containing cereals. The used raw material do not represent a source of 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) No.1223/2009, Article 18
BSE - Bovine Spongiform Encephalopathy	This product is derived from vegetable raw materials and doesn't therefore not represent a source for BSE/TSE pathogens
California Prop 65	Substances listed in California Proposition 65 are not used as ingredients
Carcinogenic, Mutagenic and Reprotoxic (CMR)	This product is not rated as a CMR (category 1A, 1B, and 2) and doesn't contain any 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	> 99% Caprylic / capric triglyceride
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	This product contains either palm oil or palm kernel oil which are not certified by RSPO. Indeed, not approved by cosmos from beginning January 2020. For a Cosmos approved grade, see our product "TRICAPRYLATE/CAPRATE DE GLYCEROL-RSPO-MB"
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	<i>No data available</i>
European Pharmacopoeia	This product is compliant to the European Pharmacopoeia
Food	Can be used in food industry

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Genetically Modified Organisms (GMO)	This product doesn't contain GMO and is not derived from a GMO. PCR analyses, to determine GMO traces are therefore not performed
Inventories	Compliant with China IECSC, USA TSCA, New Zealand NZIoC, Taiwan NCSI, Philippines PICCS, Japan ENCS, Korea KECI, Australia AICS, Canada DSL
Geographic origin (for plant)	<i>No data available</i>
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
Halal	<i>No data available</i>
Heavy Metals	Elemental impurities as listed in ICH guideline Q3D and in the Ph Eur general text 5.20 are not intentionally added or used during manufacturing process. Therefore, it is unlikely that elemental impurities are present in the product. However, this product is analyzed on a periodical basis. The sum of heavy metals, expressed as Pb, doesn't exceed 10 ppm.
HS code	15162098
Irradiation / ionization	This product has not been treated with ionizing radiation during the manufacturing process
Kosher	<i>No data available</i>
Latex	<i>No data available</i>
Manufacturing location	<i>No data available</i>
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 contamination
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	<i>No data available</i>
Origin	100% vegetable (palm)
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 used raw materials 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 product is not monitored analytically
Preservative	Preservatives are not added to this product during the manufacturing process, therefore not monitored analytically
Process	C8/10 fatty acids + glycerol -> mixing -> esterification -> post treatment: neutralization - bleaching – deodorization -> packaging
REACH	This product is registered 01-2119492306-35
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 and palm kernel oil. This product is not certified RSPO. This same product is also available with RSPO-MB grade on <u>request only</u> . See our product "TRICAPRYLATE/CAPRATE DE GLYCEROL-RSPO-MB"
Shelf Life before re-check	2 years
Substances of Very High Concern (SVHC)	This product doesn't contain substances cited in the current SVHC candidate list
Volatiles organic compounds (VOC)	This product doesn't show a vapor pressure above or equal to 0.01 kPa at 20°C and needs therefore not to be classified as a VOC according to EU directive 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.*