| INTERCHIMIE | Dossier technique et réglementaire / Technical and regulatory<br>document<br>PALMITATE D'ISOPROPYLE |                                                                                   | Mai 2022 / May<br>2022 |
|-------------|-----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|------------------------|
| Ви          | o<br>Jo<br>iPr                                                                                      | INCI: <b>Isopropyl palmitate</b><br>N°CAS: 142-91-6<br>N°EINECS/ELINCS: 205-571-1 |                        |

# **DESCRIPTION / DESCRIPTION :**

Ester de l'alcool isopropylique et de l'acide palmitique / *Ester of isopropyl alcohol and palmitic acid* Matière première conforme à la Pharmacopée Européenne en vigueur / *Raw material according to the European Pharmacopoeia in force* 

# CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS :

| CARACTERISTIQUES                                              | SPECIFICATIONS      |
|---------------------------------------------------------------|---------------------|
| Indice de réfraction à 20°C / <i>Refractive index at 20°C</i> | 1.436 - 1.440       |
| Indice d'acide / Acid value                                   | ≤ 1 mg KOH /g       |
| Indice de saponification / Saponification value               | 183 – 193 mg KOH /g |
| Indice d'iode / Iodine value                                  | ≤ 1 g l₂/ 100g      |
| Teneur en eau / Water content                                 | ≤ 0.10 %            |
| Viscosité à 20°C / Viscosity at 20°C                          | 5 – 10 mPa.s        |

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

Ces caractéristiques sont conformes aux précédentes spécifications datées de Mars 2010 / These features are in accordance with previous specifications dated on March 2010

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

Couleur APHA / Color APHA:  $\leq$  70 (HAZEN) Densité à 20°C / Density at 20°C: 0.850 – 0.855 g/ml C 14 :  $\leq$  2 % C 16 : 98 – 100 % C 18 :  $\leq$  2 % Ce produit est végétalien / This product is suitable for vegan

## **APPLICATIONS :**

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

## CONDITIONNEMENT STANDARD / STANDARD PACKAGING :

Tonnelet de 50 kg – Fût de 175 kg – IBC de 850kg/ 50kg keg – 175kg drum – 850kg IBC 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<br>during the manufacturing process, therefore these substances are not monitored<br>analytically.<br>A contamination with nitrosamines is not expected to be present.                          |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|           | This product doesn't contain nitrosable or nitrosating substances as ingredients<br>which allow a formation of nitrosamines, therefore these additives are not<br>monitored analytically.<br>This product is not monitored on aflatoxins. A presence of aflatoxins in the finished |



Dossier technique et réglementaire / Technical and regulatory document PALMITATE D'ISOPROPYLE

|                          | product is not expected to be present, with 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                 | Ingredients which are listed as allergens according to annex III (no. 67 – 92)           |
|                          | regulation (EC) No.1223/2009 are not used for production of this product. Therefore,     |
|                          | these ingredients are not monitored analytically.                                        |
|                          | This product is not derived from any gluten containing cereals; the used raw             |
|                          | materials do not represent a source for gluten; therefore, gluten is not monitored       |
|                          | analytically.                                                                            |
|                          | This product is not derived from nuts (allergen associated); traces of nut allergens are |
|                          | not monitored analytically                                                               |
| Animal Testing           | This product has not been tested on animals in terms of regulation (EC)                  |
|                          | No.1223/2009, Article 18                                                                 |
| BSE - Bovine Spongiform  | This product is derived from vegetable and petrochemical/synthetical raw materials       |
| Encephalopathy           | and does 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  | 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              |                                                                                          |
| Cosmetic                 | >99 % isopropyl 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    |
| <u> </u>                 | this regulation                                                                          |
| Cosmos / Ecocert         | Due to isopropanol, this product is not accepted by Ecocert or 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 to the European Pharmacopeia                                   |
| Food                     | Is not food grade product                                                                |
| Genetically Modified     | This product doesn't contain GMO and is not derived from a GMO. PCR analyses, to         |
| Organisms (GMO)          | determine GMO traces are therefore not performed                                         |
| Inventories              | Compliant with China IECSC, USA TSCA, New Zealand NZIoC, Taiwan TCSI and NCSI,           |
|                          | Philippines PICCS, Japan ENCS, Korea KECI, Australia AICS, Canada DSL                    |
| Geographic origin (for   | No data available                                                                        |
| plant)                   |                                                                                          |
| Glycol ether             | Glycol ether are 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                    | No data available                                                                        |
| Heavy Metals             | Elemental impurities as listed in the "ICH guideline Q3D on elemental impurities"        |
|                          | (EMA/CHMP/ICH/353369/2013) and in the Ph. Eur. General Text "5.20. Metal                 |
|                          | catalyst or metal reagent residues are not intentionally added or used during the        |
|                          | manufacturing process of this product. Therefore, it is unlikely that elemental          |
|                          | impurities are present in this product in appreciable amounts.                           |
|                          | However, this product is analyzed on heavy metals including Cd, As, Pb, Hg, Ni, and      |
|                          | Sb on a periodical basis. The sum of heavy metals, expressed as Pb, doesn't exceed       |
|                          | 10 ppm                                                                                   |
| HS code                  | 29157040                                                                                 |
| Irradiation / ionization | This product has not been treated with ionizing radiation during or after the            |
|                          | manufacturing process                                                                    |
|                          |                                                                                          |



Dossier technique et réglementaire / Technical and regulatory document PALMITATE D'ISOPROPYLE

| 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 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           | Not concerned                                                                                                                                                                                              |
| Origin                     | Palmitic acid is derived from vegetable (palm oil)<br>Isopropanol is from petrochemical/synthetic origin                                                                                                   |
| 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 or antioxidants are not added to this product during the manufacturing process, therefore not monitored analytically                                                                         |
| Process                    | Fatty acid (palmitic acid) + alcohol (isopropanol) $\rightarrow$ mixing $\rightarrow$ esterification $\rightarrow$ post treatment $\rightarrow$ packaging                                                  |
| REACH                      | This product is registered 01-2119541808-31                                                                                                                                                                |
| Residual Solvents          | The class 3 solvent isopropanol is used as a starting material for the production of this product. The residue of this solvent is monitored with a threshold value of 50 ppm                               |
| RSPO                       | This product is derived from palm 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 "PALMITATE D'ISOPROPYL-RSPO-MB" |
| Shelf Life before re-check | 2 years                                                                                                                                                                                                    |
| Substances of Very High    | Substances cited in the current SVHC candidate list or already included in annex XIV                                                                                                                       |
| Concern (SVHC)             | of regulation (EC) 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 EU directive 1999/13 and Swiss VOCV                                                                                                             |

----- END

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