

Dossier technique et réglementaire / Technical and regulatory document

Mai 2022 / *Mai* 2022

MYRISTATE D'ISOPROPYLE-RSPO-MB

INCI: Isopropyl myristate

N°CAS: 110-27-0

N°EINECS/ELINCS: 203-751-4

DESCRIPTION / DESCRIPTION:

Ester de l'alcool isopropylique et de l'acide myristique / Ester of isopropyl alcohol and myristic 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 |
|--|-----------------------------|
| Pureté / assay | ≥ 98% |
| Indice d'acide / Acid value | ≤ 1 mg KOH /g |
| Indice de saponification / Saponification value | 202-212 mg KOH /g |
| Indice d'iode / lodine value | ≤ 1 g l ₂ / 100g |
| Teneur en eau / Water content | ≤ 0.10 % |
| Indice de réfraction à 20°C / Refractive index at 20°C | 1.432 – 1.437 |
| Viscosité à 20°C / Viscosity at 20°C | 5 – 6 mPa.s |
| Couleur Apha | ≤ 50 |
| Cendre sulfurique / sulfate ash | ≤ 0.1 |

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

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION :

Densité à 20°C / Density at 20°C: 0.846 – 0.855 g/ml

C 14 : ≤ 2 % C 18 : ≤ 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 25/50 kg – Fût de 175 kg / 25/50kg keg – 175kg drum

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.



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| Additives | Additives are not added to this product during the manufacturing process, therefore |
|--------------------------|--|
| Additives | these substances are not monitored analytically. |
| Allergen | Ingredients which are listed as allergens according to annex III (no. 67 – 92) |
| 7.me. Ben | 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) |
| and noprotomo (ching | No.1223/2009 in association with regulation (EC) No.1272/2008 |
| Composition | > 99 % isopropyl myristate |
| 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 | 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 | South east Asia |
| 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 | This product complies to halal requirements |
| 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 | 2915907090 |
| Irradiation / ionization | This product has not been treated with ionizing radiation during or after the |
| | manufacturing process |
| Kosher | This product is kosher certified |
| Latex | No data available |



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| Manufacturing location | South east Asia |
|--|--|
| 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 | For 100g: Energy 900Kcal, fat 0g, fat 100g which saturates 99g |
| Origin | ~ 75-80% Myristic acid is derived from vegetable (palm oil) ~ 20-25% 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 are not added to this product during the manufacturing process, therefore not monitored analytically |
| Process | Fatty acid (myristic acid) + alcohol (isopropanol) → mixing → esterification → post treatment → packaging |
| REACH | This product is registered 01-2119541806-35 |
| 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 RSPO-MB certified, see our certificate on our website www.interchimie.fr |
| Shelf Life before re-check | 2 years |
| Substances of Very High Concern (SVHC) | Substances cited in the current SVHC candidate list or already included in annex XIV of regulation (EC) No 1907/2006, are not used as ingredients |
| 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.