



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

**TECHNICAL DATA SHEET**

Review date:

**10.04.2024**

Version:

**10.0**

## 93893-ISOPROPYL MYRISTATE

### 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

#### 1.1. Identification of the substance or preparation

Name: Isopropyl myristate

Bulk code: 93893

Internal code: 51663

Valid from batch: 0119232

#### 1.2. Synonyms

No information available.

### 2. DESCRIPTION

Appearance: Oily liquid.

Colour: Colourless to slightly yellowish.

Odour: Characteristic.

Origin:

- Myristic acid: Plant product derived from palm kernel oil from Malaysia/India.

- Isopropyl alcohol: Synthetic origin.

Geographical origin: Malaysia.

### 3. COMPOSITION/INFORMATION ON COMPONENTS

CAS: 110-27-0

EINECS: 203-751-4

INCI: Isopropyl myristate

**Method of production:** The product is manufactured through a reaction between fatty acids and alcohol. The resulting product is distilled, filtered and deodorised before final packaging.

### 4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

**Solubility:** It is immiscible with water, miscible with ethanol, methylene chloride, fatty acids and paraffin.

### 5. PROPERTIES/USES

Excipient for pharmaceutical use.

Cosmetic use.

Food use.

This product is suitable for use in food products (food grade) as the principles of general food laws, including HACCP, apply. This includes the sourcing, manufacturing and distribution stages.



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JECFA Flavouring name: Isopropyl myristate

JECFA Number (Flavouring): 311

The Union list of flavouring substances is published in the Annex I of the EU Regulation 1334/2008 as amended, identified by their respective Flavis number (FL No.).

Flavis FL n°: 09.105

Flavis name: Isopropyl tetradecanoate

CoE n°: 386

This product has no E-number. Commission Regulation (EU) N° 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 does not apply.

The safe use as cosmetic ingredient has been assessed by the CIR Expert Panel under ingredient reference(s) Isopropyl Myristate.

This product can be used in cosmetics as a binder, to manufacture fragrances or perfumes or as a skin conditioner. It is not considered an allergenic substance.

### 6. DOSAGE

No information available.

### 7. REMARKS

The product has been handled in a NON-sterile room; so the product is NOT STERILE.

#### **STORAGE:**

Store at room temperature in a cool, dry, well-ventilated place away from sunlight and moisture, in a tightly closed container and away from heat sources.

The documentation available related to the product's regulatory compliance is included below.

#### **BSE/TSE:**

The product does not derive from or contain products of animal origin or derivatives and thus this legislation is not applicable.

#### **GMOs:**

This product is free of genetically modified organisms, in the following sense:

- it does not contain or consist of GMOs
- it does not have to be labelled in accordance with Regulation (EC) 2003/1830
- it does not produce or contain ingredients produced from GMOs



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### CMR substances:

Substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) in this context are listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008, as amended. This product is compliant with the provisions of Article 15 of Regulation (EC) 1223/2009 on CMR substances, as amended.

### SVHC:

The product does not contain any substances identified as an "SVHC" (substances of very high concern) referred to in the "Candidate List" published by the ECHA in the context of REACH Regulation (EC) No 1907/2006 at the threshold of 0.1% w/w. This statement includes all substances listed by the ECHA, including the 10 June 2022 update.

### NANOMATERIALS:

This product is compliant with the provisions of Article 16 of EU Regulation 1223/2009 on nanomaterials, as applicable; 'nano' labelling is not required. This product is free of any substance declarable in a nanoparticulate state according to the provisions of French Decree 2012-232.

### MICROPLASTICS:

Microplastics are not intentionally added in this product. Microplastics are defined in RAC Opinion of ECHA on the Annex XV report proposing restrictions on intentionally added microplastics adopted in June 2020.

### VOCs:

The content is < 3% (1999/13/EC; 2004/42/EC; 2010/75/EU; SR 814.018).

### IONISING RADIATION:

This product has not been subjected to irradiation or ionising treatment. Consequently, it should not be labelled as such in accordance with EU Regulation 1169/2011 (Annex VI; Part A; pt. 3.) and 21 CFR §179.26.

### PESTICIDES:

This product is compliant with Regulation 396/2005/EC (as amended) on maximum residue levels of pesticides in or on food and feed, to the extent applicable and with the pesticide limits defined in the Pharmacopoeia monograph 2.8.13. and USP monograph 561.

### COLOURANTS/PRESERVATIVES:

The product does not contain colourants or preservatives.

### RESIDUAL SOLVENTS:

This product is compliant with the current version of the ICH Q3C guideline on residual solvents.

This product is manufactured without the use or intentional addition of any listed Class 1 solvents. This product is compliant with the concentration limit of any listed Class 2 solvent.

This product satisfies the GMP requirements for any listed Class 3 solvent.

This product is free of any listed Class 4 solvents.



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This product is compliant with the limits for "residual solvents" as defined by the US Pharmacopeia under "Organic volatile impurities" (chemical test <467> of the General Chapters). Class 1 solvents are not used nor added during manufacture; Class 2 solvents are below the stated concentration limits; Class 3 solvents are used below GMP / quality-based requirements and solvents listed under "Other Residual Solvents" are not used.

### IMPURITIES:

- Dioxins: The product is free of dioxins.
- Aflatoxins: The product is free of aflatoxins.
- This product is compliant with the applicable limits defined in EU Directive 2011/65 (RoHS Directive), as amended. Restricted substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBBs), polybrominated diphenylethers (PBDEs) and the four mentioned phthalates), if present, are below the defined maximum values. This product is compliant with EU Directive 2012/19 (WEEE Directive), to the extent applicable.
- Nitrosamines: The manufacturer has carried out a risk assessment applying the principles described in the note "Information on nitrosamines for marketing authorization holders (September 19, 2019)" and no risk of the presence of nitrosamines was identified based on the starting materials and to the manufacturing process. The product is not analyzed for nitrites, nitrates or nitrosamines.
- Contaminants: This product complies with the specified limits according to EU Regulation 2023/915, as far as applicable:
  - o Nitrate
  - o Mycotoxins
  - o Metals and other elements
  - o Polycyclic aromatic hydrocarbons (PAHs)
  - o Melamine
  - o Plant toxins
  - o This compliance does not apply to foodstuffs for babies, infants and young children.

### HEAVY METALS:

This product is compliant with the legislation on Toxics in Packaging Clearinghouse (TPCH), as applicable. The four heavy metals listed (mercury, lead, cadmium and hexavalent chromium) are not intentionally introduced as an element during manufacture or during distribution and, if present, are below the limit of 100 ppm.

None of the below mentioned elemental impurities are intentionally added during the manufacturing of the product. However, considering the manufacturing process and the raw materials involved, we declare that the following elements are technically unavoidable in good manufacturing practices with following limits:

ELEMENT	LIMIT (ppm)
Antimony (Sb)	< 0.5
Arsenic (As)	< 0.5
Cadmium (Cd)	< 0.1
Chromium (Cr)	< 5



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Cobalt (Co)	< 1
Nickel (Ni)	< 1
Lead (Pb)	< 2
Mercury (Hg)	< 0.1

Based on risk analysis on the raw materials the heavy metal content is not analyzed on every batch.

### CALIFORNIA PROPOSITION 65:

The product has been manufactured without intentionally adding any substances known to the State of California to cause cancer or developmental or reproductive harm.

### ALLERGENS:

- **Food allergens:** The product does not contain any of the substances listed in Annex II to Regulation (EC) 1169/2011 that can cause allergies or intolerances. This product is free from food allergens or proteins derived from food allergens as defined by the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA, Public Law 108-282) and the FASTER Act of 2021 (Public Law 117-11). The 9 major food allergens identified by FALCPA are: milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans and sesame.
- **Cosmetic allergens:** This product is free of any allergen as defined in Regulation (EC) 1223/2009 as amended (Annex III reference numbers 45, 46, 67, 69-92, 109, 114, 122, 124, 131, 133, 154, 157, 175, 196, 324 and 327-371); This statement includes fragrances allergens listed in Regulation (EU) 2023/1545. This product complies with Article 17 of EU Regulation 1223/2009, as amended, relating to technically unavoidable prohibited substances.

### VEGAN/VEGETARIAN:

The product does not contain and is not a derivative of animal products or derivatives.

The product is made from plant and synthetic raw materials. This does not and has not involved the use of any animal products. The product does not involve and has not involved tests of any kind in animals (this includes tests for efficacy, toxicity, safety, cosmetic purposes, etc.). Therefore, it is also suitable for vegans.

### WADA:

Doping substances as defined by the World Anti-doping Agency are not produced nor added intentionally during the manufacturing process

### TESTED ON ANIMALS:

This product is compliant with the provisions of Article 18 of EU Regulation 1223/2009 on animal testing, as amended.

“Animal” refers to the definition given in the article 1 of Directive 2010/63/EU.

No animal testing has been conducted nor commissioned on this substance on behalf of the manufacturer. However competent authorities may request or have requested animal studies to assess the safety of the chemical substance.



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### ISO 16128:

Values were calculated according to ISO 16128-2:2017, which applies to ingredient categories defined in ISO 16128-1:2016. The molecular weight method was used to quantify the degree of natural origin of the ingredient.

Natural index	Natural content	Natural origin index	Natural origin content
0	0%	0.78	78%

### CHEMICAL INVENTORIES:

Chemical inventories	Complies with AICS, DSL, EAEU, ECST, ENCS, EU REACH, IECSC, INSQ, KECL, NZIoC, PICCS, TECI, TSCA, VNCI.
Chemical inventories legend	AICS = Australian Inventory of Chemical Substances DSL = Canadian Domestic Substances List EAEU = Eurasian Economic Union Unified list of chemicals ECST = Existing Chemical Substances Inventory of Taiwan ENCS = Japanese Existing and New Chemicals Substances List EU REACH = European Union REACH Regulation 1907/2006 IECSC = Inventory of Existing Chemicals Substances in China INSQ = Mexico National Inventory of Chemical Substance KECL = Korean Existing Chemical List NZIoC = New Zealand Inventory of Chemicals PICCS = Philippine Inventory of Chemicals and Chemical Substances TECI = Thailand FDA Existing Chemicals Inventory TSCA = USA Toxic Substances Control Act VNCI = Vietnam National Chemicals Inventory

### CSAR:

005608-02700-7495

### REACH:

01-2119541806-35

### TARIFF ITEM NUMBER:

HTS code (goods code): 2915.90.5050

CN Code (EU goods code): 2915907098