

**94481 - CASTOR OIL****1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1 Identification of the substance or preparation.**

Name: Castor oil

Bulk code: 94481

Internal code: 404825

**1.2 Synonyms.**

Castor oil.

**2. DESCRIPTION**

Appearance: Clear, viscous liquid at 40°C.

Colour: Clear, almost colourless or slightly yellowish.

Part of the plant used: Seeds.

Botanical origin: *Ricinus communis* L.

Origin: India.

**3. COMPOSITION/INFORMATION ON COMPONENTS.**

CAS: 8001-79-4

EINECS: 232-293-8

INCI: Ricinus Communis Seed Oil

Composition: 100% castor oil

**Method of production:** Fatty oil that is obtained via cold pressing from the seeds of the *Ricinus communis* L. During pressing, the temperature does not exceed 50°C.

Since the product is filtered during the manufacturing process and there is no moisture in the oil, the presence of microorganisms is not only reduced, but their proliferation is not expected either.

**4. PHYSICO-CHEMICAL DATA.**

For further information, see the analysis report.

**Solubility:** Slightly soluble in petroleum ether, miscible with glacial acetic acid and ethanol.

Hygroscopic.

**5. PROPERTIES/USES.**

Excipient for pharmaceutical use.

**94481 - CASTOR OIL**

*This product CANNOT be used as an API in compounded formulations; it can only be used as an excipient in compounded formulations.*

*Examples of excipients:*

*Salicylic acid 5%*

*Castor oil 50%*

*Olive oil q.s.*

*In this case, the castor oil acts as a solvent for the salicylic acid.*

Cosmetic use.

NOT SUITABLE for use as a food product.

**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 place in a tightly closed container away from sunlight, heat sources and moisture. Do not freeze.

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

**BSE/TSE:**

The product is of plant origin, thus there is no risk of BSE/TSE. The supply chain for vegetable oils is completely separate to the supply chain for animal fats.

**GMOs:**

The product is free of GMOs and is produced from plants that have not been genetically modified according to Regulations (EC) 1829/2003 and 1830/2003.

**CMR:**

The product does not contain substances at levels that are toxic.



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### **SVHC:**

The product does not contain any SVHC included in the ECHA Candidate List reported in January 2021.

### **NANOTECHNOLOGY:**

These products are not used or added.

### **VOCs:**

The product is free of VOCs.

### **IRRADIATION:**

The product has not been treated with ionising radiation.

### **PRESERVATIVES/ANTIOXIDANTS:**

The product is free of additives. An appropriate antioxidant may only be added on express request and it would be clearly indicated in the analysis report.

### **RESIDUAL SOLVENTS:**

Compliant with guidelines CPMP/ICH/283/95 and CPMP/ICH/1940/00 corr. (residual solvents). The product is free of residual solvents.

### **CONTAMINANTS/IMPURITIES:**

The product is free of:

- Latex
- Micronised plastics
- Phthalates
- Glycol ether
- Formaldehyde or any type of formaldehyde releaser
- Melamine
- Alcohol

Aflatoxins: The product is compliant with Regulation 2006/1881/EC and its amendments.

The product complies with the maximum residual limit (MRL) for fats and oils set in the European Pharmacopoeia for pesticides and other contaminants (PAHs and dioxins). Given the origin and manufacturing process for this oil, no contaminants are expected to be found.

The product does not contain silicone or latex as an ingredient, for which reason they are not expected to be present. These products are not analysed.

**94481 - CASTOR OIL****HEAVY METALS:**

Due to the product's origins and manufacturing process none are expected to be present. The product is not made via metal catalysis. The product is free of aluminium.

**CALIFORNIA PROPOSITION 65:**

California Proposition 65 currently lists several hundred chemical products. None of the substances listed are used as an ingredient in the product, for which reason they are not expected to be present, but they are not analysed or guaranteed.

**NAGOYA PROTOCOL:**

Exempt.

**ALLERGENS:**

- **Food allergens:** The product is free of lactose, maltodextrin and gluten.
- **Cosmetic allergens:** Due to the product's origins and manufacturing process none are expected to be present. The product is free of substances listed in Annex III of this regulation. The traces of substances listed in Appendix II as contaminants are below the maximum residual limit according to Regulations (EC) 1881/2006 and 396/2005.

**VEGAN/VEGETARIAN:**

The product is fit for vegan/vegetarian use, given the absence of ingredients or process contributions of animal origin.

**KOSHER:**

The product is 100% of vegetable origin but it is not certified.

**HALAL:**

The product is 100% of vegetable origin but it is not certified.

**TESTED ON ANIMALS:**

The product has not been tested on animals.

**RSPO:**

Not applicable.

**CITES:**

The product is not obtained from any species catalogued in the CITES treaty and is exempt from compliance with the Nagoya Protocol.

**ECOCERT:**

Not applicable.



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### **COSMOS:**

Not applicable.

### **ISO 16128:**

Natural index: 1

Natural origin index: 1

Organic index: 0

Organic origin index: 0

### **REACH:**

Exempt according to Appendix V.

### **TARIFF CODE:**

1515 30 90

### **INVENTORIES:**

Australia (AICS), Canada (DSL), China (IECSC), Europe (EINECS), Japan (CHRIP), Korea (NCIS), New Zealand (NZioC), Philippines (PICCS), Taiwan (CSNN), USA (TSCA).

### **CSAR:**

001334-04464-4903