

94392-ISOPROPYL ALCOHOL**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1. Identification of the substance or preparation**

Name: Isopropyl alcohol

Bulk code: 94392

Internal code: 50834

1.2. Synonyms

2-propanol, isopropanol, IPA

2. DESCRIPTION

Appearance: Clear liquid free from suspended matter.

Colour: Transparent.

Origin: Petroleum (acetone) and mineral (hydrogen).

Geographical origin: European Union.

3. COMPOSITION/INFORMATION ON COMPONENTSFormula: OH, CH₃CHCH₃

CAS: 67-63-0

EINECS: 200-661-7

Molecular weight: 60.10 g/mol

Method of production: The product is manufactured by a mixture obtained from a hydrogenation reaction between acetone and demineralised water, which is decanted before adding diisopropylether. Throughout the process, several distillations take place until the final product is obtained.

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: It is miscible with water, ethanol, chloroform, ether and glycerine.

5. PROPERTIES/USES

Excipient for pharmaceutical use.

6. DOSAGE

No information available.

94392-ISOPROPYL ALCOHOL**7. REMARKS****STORAGE:**

Store in a cool, dry, well-ventilated place away from sunlight, in a tightly closed container and away from ignition sources. Its storage is subject to the requirements of ITC-MIE-APQ 1 concerning the storage of flammable and combustible liquids.

Keep away from direct solar irradiation and other heat and ignition sources, aiming to keep it between 5 and 25°C.

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

BSE/TSE:

No material (including raw material, reagents, solvents and additives) of animal, human, plant or biological origin is used to manufacture the aforementioned product at any time in the course of production, nor does it come into contact with them. Therefore, the product is BSE/TSE free.

GMOs:

The product is free of substances arising from genetically modified organisms (GMOs).

SVHC:

According to the documentation available from the manufacturers, there are no materials included in Annex XIV to Regulation (EC) No 1907/2006 and/or in the "Candidate List of Substances of Very High Concern for Authorisation" (SVHC) published and updated by the ECHA as of January 2022.

PRESERVATIVES:

No additives (neither stabilisers nor preservatives) are introduced during the manufacturing process.

ICH Q3C IMPURITIES:

Substances from pyrolysis operations are not used.

The product may contain the following residual solvents. The total combined amount of them is less than 1,000 mg/kg.

CLASS	TYPE	CONTENT
CLASS 1 SOLVENTS		
Benzene	Impurity	<2 mg/kg
CLASS 2 SOLVENTS		
Cyclohexane	Impurity	<1000 mg/kg
Methanol	Impurity	<1000 mg/kg
CLASS 3 SOLVENTS		
Acetone	Raw material	<1000 mg/kg
2-Butanol	Impurity	<1000 mg/kg
Ethanol	Impurity	<1000 mg/kg
Methylethylcetone	Impurity	<1000 mg/kg
Methylisobutylcetone	Impurity	<1000 mg/kg

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2-Methyl-Propanol-1	Impurity	<1000 mg/kg
Propanol-1	Impurity	<1000 mg/kg
Cumene	Impurity	<1000 mg/kg
Propanol-2	Manufactured product	N/A
Acetic acid	Impurity	<0.0010%
CLASS 4 SOLVENTS		
Isopropylether	Purification solvent	<1000 mg/kg

CONTAMINANTS:

The following substances are not intentionally added during the manufacturing process:

Acrylamide	Melamine, Cyanuric acid
Alkylphenols or Alkylphenolthoxylates, TNPP	Natural rubbers, Latex
Antimony, Arsenic, Beryllium, Bismuth, Gold, Indium,	Organotin compounds
Nickel, Palladium, Selenium, Silver, Tellurium, Thorium	Parabene
Artificial Musk	Pentachlorophenol (PCP)
Benzophenones (e.g. 4-MBP, 4-HBP, 2,2 Dimethoxy-2-phenylacetophenone)	Perfluorinated tensides – PFT (e.g. PFOA, PFOS)
BHA or BHT	Plasticisers (e.g. Adipates, ESBO, Phtalates)
Bisphenol A and its compounds (e.g. NOGE, BFDGE, BADGE)	Polychlorinated Bi-, Terphenyls and Naphtalenes
Brominated Flame retardants (e.g. PBB, PBDE)	UV-hardeners (e.g. ITX, Titanyl-acetylacetone)
Cadmium, Chromium (VI), Lead, Mercury,	Vinylchloride, Vinylidenechloride, PVC or PVDC
CFC, HCFC	Nanomaterials
Di-2-ethyl-hexyl maleate (DEHM)	Mesylate esters
Dimethylfumarate (DMF), Dibutylfumarate	Stabilizing, preservatives, antioxidants
Dioxines and furanes	Ionizing radiation or irradiation treatment
2-Ethylhexanoic acid, Ethoxyquin, ITX, Thiurams,	Glycerin
Formaldehyde	Diethyleneglycol
Glycol ethers (EGME, EGMEA, EGEE, EGEEA)	Iodine
	Crystalline silica
	Antibiotic

AFLATOXINS: Isopropanol is produced from raw materials derived from petroleum and of mineral origin. These materials are not known to present a risk with regard to the presence of aflatoxins. Isopropanol is not a food product.

ALLERGENS:

- **Food allergens:** Isopropanol is free from: gluten, silicone, latex, egg, casein, fructose, benzopyrene, fish and fish-based products, peanuts and peanut-based products, soy and soy-based products, milk and milk-based products (including lactose), nuts, i.e., almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Western Anacardium*), pecans (*Carya illinoiesis* [Wangenh.] K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachios (*Pistacia vera*), Queensland macadamia nuts (*Macadamia ternifolia*), and products made from these fruits, celery and celery products, mustard and mustard products, sesame seeds and sesame seeds produced from sulphur dioxide and sulphites in concentrations exceeding 10 mg/kg or 10 mg/litre expressed as SO₂.

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- **Cosmetic allergens:** The product is not contaminated for:

INCI Name	CAS #	INCI Name	CAS #
Alpha-Isomethyl Ionone	127-51-5	Evernia Furfuacea (Treemoss) Extract	90028-67-4
Amyl Cinnamal	122-40-7	Evernia Prunastri (Oakmoss) Extract	90028-68-5
Amylcinnamyl Alcohol	101-85-9	Farnesol	4602-84-0
Anise Alcohol	105-13-5	Geraniol	106-24-1
Benzyl Alcohol	100-51-6	Hexyl Cinnamal	101-86-0
Benzyl Benzoate	120-51-4	Hydroxycitronellal	107-75-5
Benzyl Cinnamate	103-41-3	Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde	31906-04-4
Benzyl Salicylate	118-58-1	Isoeugenol	97-54-1
Butylphenyl Methylpropional	80-54-6	Limonene	5989-27-5
Cinnamal	104-55-2	Linalool	78-70-6
Cinnamyl Alcohol	104-54-1	Methyl Octine Carbonate	111-80-8
Citral	5392-40-5	Phenyl Acetaldehyde	122-78-1
Citronellol	106-22-9	Methyl 2-Octynoate	111-12-6
Coumarin	91-64-5		
Eugenol	97-53-0		

REACH:

01-2119457558-25