



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

Type of document:

TECHNICAL DATA SHEET

Review date:

20.07.2023

Version:

8.0

1085-MEDICINAL LIQUID PARAFFIN

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1. Identification of the substance or preparation

Name: Medicinal liquid paraffin

Bulk code: 1085

Internal code: 405886

1.2. Synonyms

Paraffinum liquidum. White Mineral Oil (Paraffinum Liquidum).

2. DESCRIPTION

Appearance: Oil.

Colour: White.

Odour: Odourless.

Origin: Synthetic.

Geographical origin: India.

Tariff item number: 2710 19 85

3. COMPOSITION/INFORMATION ON COMPONENTS

CAS No.: 8042-47-5

EC: 232-455-8

Medicinal-grade highly pure white oil, of paraffinic mineral origin.

Method of production: Hydrogenation.

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: Practically insoluble in water and alcohol, soluble in chloroform and ether. Miscible with petroleum ether, fixed oils (except castor oil) and volatile oils.

5. PROPERTIES/USES

Excipient for pharmaceutical use.

Cosmetic use.

- The product complies with the standards and quality requirements of international pharmacopeias: European Pharmacopeia, British Pharmacopeia, US Pharmacopeia (USP/NF), CODEX Alimentarius.
- Fit for use in food industry: The product complies with FDA. 21 CFR 172.878 (USA), regulating its direct use in foodstuffs, and FDA. 21 CFR 178.3620(a) (USA), regulating its indirect use in foodstuffs.
- NOT FIT for direct oral ingestion.
- NOT FIT for use as a foodstuff or as a food ingredient.



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This is a highly pure and highly refined oil that is especially suitable for formulas and processes in which it comes into direct and indirect contact with foodstuffs, drugs, personal hygiene products, etc.

Its applications are generally within the pharmaceutical, cosmetic, chemical, food, rubber and plastics, agro-chemical, etc. industries, such as:

Lubricant for machines, moulds, tracks or other demoulding equipment for bread, pastries, etc.

Food paste extrusion.

Food-processing machines.

Cosmetics, such as in bronzers, creams, lotions, body oils.

Demoulding of tablets, capsules, ointments, laxatives.

Plasticiser in food packaging and packing materials, rubbers and thermoplastics.

Base for insecticides that are less harmful to plants.

Industrial uses:

Manufacture of the substance.

Use of the substance as an intermediate.

Distribution of the substance.

Formulation and repackaging of substances and mixtures.

Use in coatings.

Use in cleaning agents.

Use in metalworking fluids/laminating oils.

Use as a release agent or binder.

Rubber production and processing.

Use in polymer treatment.

Lubricants.

Use in laboratories.

Use in water treatment chemicals.

Use as functional liquids.

Professional uses:

Use in coatings.

Use in cleaning agents.

Use in metalworking fluids/laminating oils.

Use as a release agent or binder.

Use in agrochemicals.

Lubricant (high and low emission).

Use in laboratories.

Use in water treatment chemicals.

Manufacture of explosives.

Use as functional liquids.

Consumer uses:

Use in coatings.

Use in cleaning agents.

Use in metalworking fluids/laminating oils.

Use in agrochemicals.

Use as fuel.

Lubricant (high and low emission).



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Other uses: SU21, PROC 28, PROC 29.

6. DOSAGE

No information available.

7. REMARKS

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

STORAGE:

Store in a cool, dry, well-ventilated place, away from sunlight, at room temperature ($25\pm 2^{\circ}\text{C}$), in a tightly closed container.

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

BSE/TSE:

The product does not transmit this disease.

GMOs:

The product does not contain genetically modified organisms.

CMR substances:

Does not contain carcinogenic (cancer-causing), mutagenic (genotype change) and reprotoxic (influencing normal reproduction, also known as teratogenic) substances. The product does not contain any of the category 1A, 1B or 2 substances listed in Part 3 of Annex VI 1272/2008.

SVHC:

The product does not contain any of the substances listed in the latest update (19/01/2021, or earlier) of the REACH "Candidate List of Substances of Very High Concern for Authorisation" regulation.

VOCs:

The product does not contain volatile organic compounds.

NANOMATERIALS:

The product is not manufactured with nanomaterials.

IONISING RADIATION:

The product does not generate ionising radiation.



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IMPURITIES:

The product is free of impurities.

ICHQ3D:

Does not contain elemental impurities.

COLOURANTS/PRESERVATIVES:

The product does not contain colourants or preservatives.

RESIDUAL SOLVENTS:

The product does not contain residual solvents.

CONTAMINANTS:

The product does not contain contaminants.

HEAVY METALS:

The product does not contain metals or traces thereof.

PCBS/MELAMINE:

The product is free of PCBs and melamine.

DIOXINS:

The product is free of dioxins.

AFLATOXINS:

The product is free of aflatoxins.

LATEX:

The product does not contain latex.

SILICONES:

The product does not contain silicones.

PESTICIDES:

The product does not contain pesticides.

PROHIBITED SUBSTANCES:

The product does not contain prohibited substances for the uses described.

CALIFORNIA PROPOSITION 65:

The product does not contain any of the substances listed in this proposition.

ALLERGENS:

The product does not contain allergen traces.



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LACTOSE, FRUCTOSE:

The product does not contain lactose or fructose.

HALAL:

The product is Halal certified.

KOSHER:

The product is Kosher certified.

VEGAN/VEGETARIAN:

The product is suitable for vegan/vegetarian use.

TESTED ON ANIMALS:

It has not been tested on animals.

CITES:

Not applicable.

RSPO:

The product does not contain palm oil.

ISO 16128:

Not applicable.

REACH:

01-2119487078-27

ECOCERT/COSMOS:

The product is not Ecocert/Cosmos certified.

GRAS:

The product is not a food ingredient.