(in accordance with Regulation (EU) 2020/878)

94490-Codliver oil

Version 1 Date of compilation: 23/07/2019





SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name: Codliver oil 94490 Product Code: Chemical Name: Cod-liver oil CAS No: 8001-69-2 EC No: 232-289-6

1.2 Relevant identified uses of the substance or mixture and uses advised against.

Excipient pharmaceutical use

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

GUINAMA S.L Company:

Address: C/ Oslo Nº3

City: 46185 - La Pobla de Vallbona

Province: Valencia

+34961869090 / 902119816 Telephone:

+34961850352 Fax: E-mail: ventas@guinama.com Web: www.guinama.com

1.4 Emergency telephone number: +34961869090 / 902119816 (Only available during office hours; Monday-Friday; 08:00-

18:00)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

The product is not classified as hazardous within the meaning of Regulation (EC) No 1272/2008.

2.2 Label elements.

Este producto no esta clasificado como peligroso según el Reglamento CE 1272/2008.

2.3 Other hazards.

The substance is not PBT

The substance is not vPvB

Substance does not have endocrine disrupting properties.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

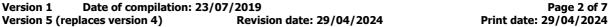
3.1 Substances.

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 8001-69-2 EC No: 232-289-6	Cod-liver oil	100%	-	-

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Not applicable.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

If breathing stops, seek emergency medical attention. Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

Skin contact.

Remove contaminated clothing.

Ingestion.

Keep calm. NEVER induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed.

No known acute or delayed effects from exposure to the product.

4.3 Indication of any immediate medical attention and special treatment needed.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious

SECTION 5: FIREFIGHTING MEASURES.

5.1 Extinguishing media.

Suitable extinguishing media:

Extinguisher powder or CO2. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance or mixture.

Special risks.

Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.

Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up.

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Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

The product does not require special handling measures, the following general measures are recommended:

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

Store according to local legislation. Observe the indications of the tag. Store the containers between 5 and 25 °C, in a dry and well-ventilated place, away from sources of heat and direct sunlight. Keep away from ignition points. Keep away from oxidizing agents and strongly acid or alkaline materials. No Smoking. Send the invite to unauthorized people. Once the containers have been opened, they must be carefully closed again and placed vertically to avoid spillage. Other specifications on storage conditions: Store containers in a dry place

hermetically closed. Protect from light. Store under dry nitrogen.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls.

Measures of a technical nature:

Concentration:	 100 %			
Uses:	Oral use			
	Excipient pharmaceutical use			
Breathing protection:				
If the recommended	l technical measures are observed, no individual protection equipment is necessary.			
Hand protection:				
If the product is handled correctly, no individual protection equipment is necessary.				
Eye protection:				
If the product is handled correctly, no individual protection equipment is necessary.				
Skin protection:				
PPE:	Work footwear.			
Characteristics:	«CE» marking, category II.			
CEN standards:	EN ISO 13287, EN 20347			
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should			
	not be used by other people.			
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any			
	injury resulting from an accident			

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Physical state: Liquid Colour: Yellowish Odour: Like fish.

Odour threshold: Not applicable/Not available due to the nature/properties of the product

Melting point: <20 °C

Freezing point: Not applicable/Not available due to the nature/properties of the product

Boiling point or initial boiling point and boiling range: >260 °C

Flammability: It is not easily flammable

Lower explosion limit: For liquids not relevant for the Upper explosion limit: For liquids not relevant for the

Flash point: 225 °C

Auto-ignition temperature: 240 °C Decomposition temperature: >250 °C

pH: Not applicable/Not available due to the nature/properties of the product

Kinematic viscosity: Not applicable/Not available due to the nature/properties of the product

Solubility: Not applicable/Not available due to the nature/properties of the product

Hydrosolubility: Water insoluble

Liposolubility: Not applicable/Not available due to the nature/properties of the product

Partition coefficient n-octanol/water (log value): Not applicable/Not available due to the nature/properties of the product

Vapour pressure: <10 Pa

Absolute density: Not applicable/Not available due to the nature/properties of the product

Relative density: 0.918-0.927

Relative vapour density: Heavier than air

Particle characteristics: Particle size distribution: The substance or product is placed on the market or used in

9.2 Other information

Not applicable/Not available due to the nature/properties of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008.

There are no tested data available on the product.

a) acute toxicity;

Not conclusive data for classification.

b) skin corrosion/irritation;

Not conclusive data for classification.

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- c) serious eye damage/irritation; Not conclusive data for classification.
- d) respiratory or skin sensitisation; Not conclusive data for classification.
- e) germ cell mutagenicity; Not conclusive data for classification.
- f) carcinogenicity; Not conclusive data for classification.
- g) reproductive toxicity; Not conclusive data for classification.
- h) STOT-single exposure; Not conclusive data for classification.
- i) STOT-repeated exposure; Not conclusive data for classification.
- j) aspiration hazard; Not conclusive data for classification.

11.2 Information on other hazards.

Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

There is no information available on other adverse health effects.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

Aquatic Toxicity Assessment:

There is a high probability that the product is not harmful to aquatic organisms. During a discharge in small concentrations in biological treatment plants, they are not of expect variations in the function of the activated sludge.

12.2 Persistence and degradability.

Assessment biodegradation and elimination (H2O):

Biodegradable.

No information is available on the degradability

No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation.

12.4 Mobility in soil.

No information is available about the mobility in soil. The product must not be allowed to go into sewers or waterways. Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

According to Annex XIII of Regulation (EC) No. 1907/2006 on registration, evaluation, authorization and restriction of chemical substances and preparations (REACH): The product does not contains no substance that meets the PBT criteria (persistent/bioaccumulative/toxic) or with the vPvB criterion (very persistent/very bioaccumulative) Self-classification

12.6 Endocrine disrupting properties.

The substance has not been identified as having endocrine properties according to the Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 and is not included in the Candidate List of Substances of High Concern according to Article 59 of EU REACH for having endocrine disrupting properties

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12.7 Other adverse effects.

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

The product does not contain substances listed in Regulation (EC) 1005/2009 on the ozone depleting substances

SECTION 13: DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.

Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

14.1 UN number or ID number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR/RID: Not classified as hazardous for transport. IMDG: Not classified as hazardous for transport.

ICAO/IATA: Not classified as hazardous for transport.

14.3 Transport hazard class(es).

Transportation is not dangerous.

14.4 Packing group.

Transportation is not dangerous.

14.5 Environmental hazards.

Transportation is not dangerous.

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): Not applicable.

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Maritime transport in bulk according to IMO instruments.

Not classified as hazardous for transport.

SECTION 15: REGULATORY INFORMATION.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

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SECTION 16: OTHER INFORMATION.

Changes regarding to the previous version:

- Changes in the information of the supplier (SECTION 1.3).
- Changes in the composition of the product (SECTION 3.2).

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards On basis of test data Calculation method Health hazards **Environmental hazards** Calculation method

It is recommended that the product only be employed for the purposes advised.

Information on the TSCA Inventory (Toxic Substances Control Act) USA:

CAS No	Name	State
8001-69-2	Cod-liver oil	Registered

Risk classification system NFPA 704:



Health hazard: 0 (Normal Material)

Flammability: 0 (Will not burn)

Reactivity: 0 (Stable)

Abbreviations and acronyms used:

CEN: European Committee for Standardization.

PPF: Personal protection equipment.

Key literature references and sources for data: http://eur-lex.europa.eu/homepage.html http://echa.europa.eu/

Regulation (EU) 2020/878. Regulation (EC) No 1907/2006. Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.