

# SAFETY DATA SHEET

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

## 9133-ORA BLEND 473 ML

Version 1 Date of compilation: 9/11/2017

Version 7 (replaces version 6)

Revision date: 23/10/2023

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

#### 1.1 Product identifier.

Product Name: ORA BLEND 473 ML  
Product Code: 9133

#### 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.

Company: **GUINAMA**  
Address: C/ Oslo Nº3  
City: 46185 La Pobla de Vallbona  
Province: Valencia  
Telephone: +34961869090 / 902119816  
Fax: +34961850352  
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.

Contains:  
trisodium orthophosphate

#### 2.3 Other hazards.

The mixture does not contain substances classified as PBT.  
The mixture does not contain substances classified as vPvB.  
The mixture does not contain any endocrine disrupting properties substances.

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.

Not applicable.

#### 3.2 Mixtures.

Substances posing a danger to health or the environment in accordance with the Regulation (EC) No. 1272/2008, assigned a Community exposure limit in the workplace, and classified as PBT/vPvB or included in the Candidate List:

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate

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CAS No: 56-81-5 EC No: 200-289-5 Registration No: 01-2119471987-18-XXXX	glycerol	0%	-	-
CAS No: 57-50-1 EC No: 200-334-9	sucrose	0%	-	-
CAS No: 7601-54-9 EC No: 231-509-8 Registration No: 01-2119489800-32-XXXX	trisodium orthophosphate	0%	Eye Irrit. 2, H319 - Skin Irrit. 2, H315 - STOT SE 3, H335	-
CAS No: 9004-34-6 EC No: 232-674-9	Cellulose	0%	-	-

(\*) The complete text of the H phrases is given in section 16 of this Safety Data Sheet.

[2] Substance with a national workplace exposure limit (see section 8.1).

### 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.

#### Inhalation.

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 CO<sub>2</sub>. 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.

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### 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.

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.

The product does not require special storage measures. As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided.

Keep away from oxidising agents and from highly acidic or alkaline materials.

Store the containers between 15 and 25 °C, in a dry and well-ventilated place.

Store according to local legislation. Observe indications on the label. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

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.

Concentration levels DNEL/DMEL:

Name	DNEL/DMEL	Type	Value
glycerol CAS No: 56-81-5	DNEL (Workers)	Inhalation, Chronic, Local effects	56 (mg/m <sup>3</sup> )

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EC No: 200-289-5	DNEL (Consumers)	Inhalation, Chronic, Local effects	33 (mg/m3)
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DNEL: Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.

DMEL: Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.

Concentration levels PNEC:

Name	Details	Value
glycerol CAS No: 56-81-5 EC No: 200-289-5	Fresh water	0,885 (mg/l)
	Agua del mar	0,088 (mg/l)
	Intermitente, agua dulce	8,85 (mg/l)
	Sedimentos agua dulce	3,3 (mg/kg)
	Sedimentos agua de mar	0,33 (mg/kg)
	Tierra	0,141 (mg/kg)
	Estación depuradora	1000 (mg/l)

PNEC: Predicted No Effect Concentration, concentration of the substance below which adverse effects are not expected in the environmental compartment.

### 8.2 Exposure controls.

#### Measures of a technical nature:

<b>Concentration:</b>	<b>100 %</b>
<b>Uses:</b>	<b>Excipient pharmaceutical use</b>
<b>Breathing protection:</b>	
If the recommended technical measures are observed, no individual protection equipment is necessary.	
<b>Hand protection:</b>	
If the product is handled correctly, no individual protection equipment is necessary.	
<b>Eye protection:</b>	
If the product is handled correctly, no individual protection equipment is necessary.	
<b>Skin protection:</b>	
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

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

### 9.1 Information on basic physical and chemical properties.

Physical state: Liquid

Colour: Pink

Odour: Sweet fruity

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

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

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

Boiling point or initial boiling point and boiling range: Not applicable/Not available due to the nature/properties of the product

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

Lower explosion limit: Not applicable/Not available due to the nature/properties of the product

Upper explosion limit: Not applicable/Not available due to the nature/properties of the product

Flash point: > 60 °C

Auto-ignition temperature: Not applicable/Not available due to the nature/properties of the product

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

pH: 3.5-5.0

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: Soluble

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

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Partition coefficient n-octanol/water (log value): Not applicable/Not available due to the nature/properties of the product  
Vapour pressure: Not applicable/Not available due to the nature/properties of the product  
Absolute density: Not applicable/Not available due to the nature/properties of the product  
Relative density: Not applicable/Not available due to the nature/properties of the product  
Relative vapour density: Not applicable/Not available due to the nature/properties of the product  
Particle characteristics: Not applicable/Not available due to the nature/properties of the product

### 9.2 Other information

#### Other safety characteristics

Viscosity: 700

## 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) N° 1272/2008.

#### Toxicological information about the substances present in the composition.

Name	Acute toxicity			
	Type	Test	Kind	Value
glycerol	Oral	LD50	Rat	27200 mg/kg bw [1]
		LD50	Rat	15750 mg/kg bw [2]
		LD50	Rat	12600 mg/kg bw [3]
CAS No: 56-81-5      EC No: 200-289-5	Dermal	LD50	Rabbit	> 10000 mg/kg bw [1]
		[1] BIOFAX Industrial Bio-Test Laboratories, Inc., Data Sheets. Vol. 9-4/1970		
		LC50	Rat	>2.75 mg/l (4h) [1]
Cellulose	Oral	[1] Valor experimental		
		LD50	Rat	> 5000 mg/kg bw [1]
		[1] Toxicology Letters. Vol. (Suppl), Pg. 243, 1992		

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CAS No: 9004-34-6 EC No: 232-674-9	Dermal	LD50 Rabbit > 2000 mg/kg bw [1] [1] Toxicology Letters. Vol. (Suppl), Pg. 243, 1992
	Inhalation	LC50 Rat > 5,8 mg/l/4 h [1] [1] Toxicology Letters. Vol. (Suppl), Pg. 243, 1992

a) acute toxicity;

Not conclusive data for classification.

b) skin corrosion/irritation;

Based on available data, the classification criteria are not met.

c) serious eye damage/irritation;

Based on available data, the classification criteria are not met.

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;

Based on available data, the classification criteria are not met.

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.

Name	Ecotoxicity			
	Type	Test	Kind	Value
glycerol	Fish	LC0	Leuciscus idus	
		LC100	Leuciscus idus	250 mg/L (48 h) [1]
		LC50	melanotus	10000 mg/L [2]
		LC50	Carassius auratus	>5000 mg/L (24 h) [3]
		LC100		184000 mg/L (96 h) [4]
		LC50	Oncorhynchus mykiss	51000 mg/L (96 h) [5]
		-	Pesacado	>1000 mg/l (96h)
	Salmo gairdneri	54000 mg/l (-) [6]		

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CAS No: 56-81-5      EC No: 200-289-5		[1] Wierich, Glycerin (Henkel KGaA Reg. no. 1518), 1968 (rewrite) of September 1996) (110). [2] Juhnke I. & Luedemann D., Ergebnisse der Untersuchung von 200 chemischen Verbindungen auf akute Fischtoxizität mit dem Goldorfenfisch, Z.f. Wasser- und Abwasser-Forschung 11(5) 161-164, 1978 (71) [3] Bridie A., Wolff C. & Winter M., The acute toxicity of some petrochemicals to goldfish, Water Res. 13: 623-626, 1979(90) [4] EPIWIN v3.04, 1994-1999. [5] Johnson, W.W. et al. (1980). Handbook of acute toxicity of chemicals to fish and aquatic invertebrates. Resour. Publ. 137, Fish. Wildl. Serv., U.S.D.I., Washington, D.C. [6] -
	Aquatic invertebrates	EC100 Daphnia magna 10000 mg/L (24 h) [1] EC50 Daphnia magna >10000 mg/L (24 h) [2] EC0 Daphnia magna 500 mg/L (24 h) [3] LC50 Daphnia 153000 mg/L (48 h) [4]  [1] Bringmann G. & Kuehn R., Ergebnisse der Schadwirkung wassergefährdender Stoffe gegen Daphnia magna in einem weiterentwickelten standardisierten Testverfahren, Z. Wasser/Abwasser Forsch. 15 (1): 1-6, 1982 (73) [2] Bringmann, G. & Kuehn, R., Z. Wasser Abwasser Forsch. 10(1977), 161-166 (72). [3] Henkel KGaA, unpublished data (Reg. no. 1518) [4] EPIWIN v3.04, 1994-1999.
	Aquatic plants	Microcystis aeruginosa 2900 mg/L (8 d) [1] EC3 Scenedesmus 10000 mg/L (8 d) [2] EC50 quadricauda 77712 mg/L (96 h) [3] EC50 Green Algae 77712 mg/L (96 h) [4] Green algae  [1] Bringmann and Kuehn, Vergleichende Befunde der Schadwirkung wassergefährdender Stoffe gegen Bakterien (Pseudomonas putida) und Blaualgen (Microcystis aeruginosa), Gwf-wasser/abwasser 117 (9): 410-413, 1976 (98) [2] Bringmann G. & Kuehn R., Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Blaualgen (Microcystis aeruginosa) und Gruenalgen (Scenedesmus quadricauda) im Zellvermehrungshemmtest. Vom Wasser 50: 45-60, 1978 (75) [3] EPIWIN v3.04, 1994-1999. [4] EPIWIN v3.04, 1994-1999.
Cellulose  CAS No: 9004-34-6      EC No: 232-674-9	Fish	
	Aquatic invertebrates	EC50 Daphnia > 1000 mg/l
	Aquatic plants	

### 12.2 Persistence and degradability.

No information is available regarding the biodegradability of the substances present.  
No information is available on the degradability of the substances present.  
No information is available about persistence and degradability of the product.

### 12.3 Bioaccumulative potential.

Information about the bioaccumulation of the substances present.

Name	Bioaccumulation
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	Log Pow	BCF	NOECs	Level
glycerol CAS No: 56-81-5                      EC No: 200-289-5	-1,76	-	-	Very low
sucrose CAS No: 57-50-1                      EC No: 200-334-9	-2,7	-	-	Very low

### 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.

No information is available about the results of PBT and vPvB assessment of the product.

### 12.6 Endocrine disrupting properties.

This product doesn't contain components with environmental endocrine disrupting properties.

### 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.  
No information is available about other adverse effects for the environment.

## 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.

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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.

### SECTION 16: OTHER INFORMATION.

Complete text of the H phrases that appear in section 3:

H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.

Classification codes:

Eye Irrit. 2 : Eye irritation, Category 2  
Skin Irrit. 2 : Skin irritant, Category 2  
STOT SE 3 : Specific target organ toxicity following a single exposure, Category 3

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).
- Change in the hazard classification (SECTION 11.1).

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

Physical hazards On basis of test data  
Health hazards Calculation method  
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
56-81-5	glycerol	Registered
57-50-1	sucrose	Registered
7601-54-9	trisodium orthophosphate	Registered
9004-34-6	Cellulose	Registered

Risk classification system NFPA 704:

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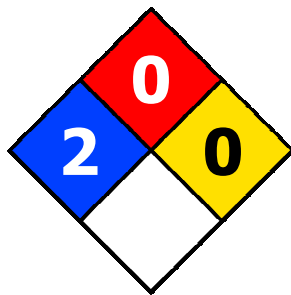
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Health hazard: 2 (Hazardous)

Flammability: 0 (Will not burn)

Reactivity: 0 (Stable)

#### Abbreviations and acronyms used:

BCF: Bioconcentration factor.

CEN: European Committee for Standardization.

DMEL: Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.

DNEL: Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.

EC50: Half maximal effective concentration.

PPE: Personal protection equipment.

LC50: Lethal concentration, 50%.

LD50: Lethal dose, 50%.

NOEC: No observed effect concentration.

PNEC: Predicted No Effect Concentration, concentration of the substance below which adverse effects are not expected in the environmental compartment.

#### 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.