

ULTRASOUND GEL CLEAR

Security data sheet

In accordance with art. 32 of REACH - Regulation (EU) 2020/878

SECTION 1. Identification of the substance/mixture and the company/company

1.1. Product identifier

Code: 19888
Denomination: ULTRASOUND GEL CLEAR 250 ML. CETRO MEDICAL REF.4151

1.2. Relevant identified uses of the substance or mixture and uses not recommended

Description/Usage: **GEL for medical applications**
Not Recommended Uses: **Do not use the product for purposes other than that indicated**

1.3. Information about the provider of the factsheet

Name: CERACARTA S.p.A.
Address: via Secondo Casadei, 14
Location & State: 47122 Forlì (FC)
ITALY
tel. +390543780055

e-mail address of the competent person,
Safety Data Sheet Responsible

info@ceracarta.it

1.4. Emergency telephone number

For urgent information, please contact

If you feel unwell, consult one of the following poison control centers:

Hospital	City	Address	Zip code	Telephone
CAV "Osp. Pediatric Bambino Gesù"	Rome	Piazza Sant'Onofrio, 4	00165	06-68593726
Az. Osp. Univ. Foggia	Foggia	V.le Luigi Pinto, 1	71122	0881-732326
Az. Osp. "A. Cardarelli"	Naples	Via A. Cardarelli, 9	80131	081-7472870
CAV Policlinico "Umberto I"	Rome	V.le del Policlinico, 155	00161	06-49978000
CAV Policlinico "A. Gemelli"	Rome	Largo Agostino Gemelli, 8	00168	06-3054343
Az. Osp. "Careggi" U.O. Medical Toxicology	Florence	Largo Brambilla, 3	50134	055-7947819
CAV National Centre for Toxicological Information	Pavia	Via Salvatore Mauzeri, 10	27100	0382-24444
Osp. Niguarda Ca' Granda	Milan	Piazza Ospedale Maggiore, 3	20162	02-66101029
Pope John XXIII Hospital	Bergamo	Piazza OMS, 1	24127	800883300
Verona Integrated Hospital	Verona	Piazzale Aristide Stefani, 1	37126	800011858

SECTION 2. Hazard Identification

2.1. Classification of the substance or mixture

The product is not classified as hazardous according to the provisions of Regulation (EC) 1272/2008 (CLP).
Classification and hazard statements:

2.2. Label Elements

Hazard labelling in accordance with Regulation (EC) 1272/2008 (CLP) and subsequent amendments and adaptations.

Hazard pictograms: --

Warnings: --

Hazard statements:

- -

ULTRASOUND GEL CLEAR

Precautionary statements:

--

2.3. Other hazardsAccording to the available data, the product does not contain PBT or vPvB substances in a percentage \geq to 0.1%.The product does not contain substances with endocrine-disrupting properties in a concentration \geq 0.1%.**SECTION 3. Composition/Ingredient Information****3.2. Mixtures**

The product does not contain substances classified as hazardous to health or the environment pursuant to the provisions of Regulation (EU) 1272/2008 (CLP) (as subsequently amended and adapted):

SECTION 4. First Aid Measures**4.1. Description of first aid measures**

EYES: Remove any contact lenses. Wash immediately and abundantly with water for at least 15 minutes, opening the eyelids well. Seek medical attention if the problem persists.

SKIN: Take off contaminated clothing. Wash immediately and thoroughly with water. If irritation persists, seek medical attention. Wash contaminated clothing before reuse.

INHALATION: Bring the subject to fresh air. If breathing is difficult, call a doctor immediately.

INGESTION: Seek medical attention immediately. Induce vomiting only on the doctor's direction. Do not administer anything orally if the person is unconscious and unless authorized by the physician.

4.2. Main Symptoms and Effects, Both Acute and Delayed

No specific information is known about the symptoms and effects caused by the product.

4.3. Indication of whether a doctor needs immediate attention and special treatment

No information available

SECTION 5. Fire-fighting measures**5.1. Extinguishing Means**

SUITABLE EXTINGUISHING MEDIA

The means of extinguishing are the traditional ones: carbon dioxide, foam, dust and water spray.

UNSUITABLE EXTINGUISHING MEDIA

No one in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS DUE TO EXPOSURE IN THE EVENT OF FIRE

Avoid breathing in combustion products.

5.3. Recommendations for firefighters

GENERAL INFORMATION

Cool the containers with water jets to avoid the decomposition of the product and the development of substances that are potentially dangerous to health. Always wear full fire protection equipment. Collect extinguishing water that should not be discharged into sewers. Dispose of contaminated water used for extinguishing and fire residue in accordance with current regulations.

EQUIPMENT

Normal clothing for firefighting, such as an open-circuit compressed air breathing apparatus (EN 137), flame retardant suit (EN469), flame retardant gloves (EN 659) and firefighters' boots (HO A29 or A30).

SECTION 6. Measures in case of accidental release**6.1. Personal Precautions, Protective Equipment and Emergency Procedures**

Block the leak if there is no danger.

Wear appropriate protective equipment (including personal protective equipment referred to in section 8 of the safety data sheet) to prevent contamination of skin, eyes and personal clothing. These indications are valid for both processing workers and emergency interventions.

6.2. Environmental precautions

Prevent the product from entering sewers, surface waters, groundwater.

6.3. Methods and Materials for Containment and Remediation

Vacuum the spilled product into a suitable container. Assess the compatibility of the vessel to be used with the product, checking section 10. Absorb the

ULTRASOUND GEL CLEAR

remainder with inert absorbent material.

Ensure sufficient ventilation of the leak site. Disposal of contaminated material shall be carried out in accordance with the provisions of point 13.

6.4. Reference to other sections

Any information regarding personal protection and disposal can be found in sections 8 and 13.

SECTION 7. Handling & Storage**7.1. Precautions for safe handling**

Handle the product after consulting all the other sections of this MSDS. Avoid dispersion of the product into the environment. Do not eat, drink or smoke during use. Remove contaminated clothing and protective equipment before entering eating areas.

7.2. Conditions for safe storage, including possible incompatibilities

Store only in the original container. Store the containers closed, in a well-ventilated place, away from direct sunlight. Store containers away from any incompatible materials, checking section 10.

7.3. Particular end-uses

No information available

SECTION 8. Exposure/Personal Protection Control**8.1. Verifiers**

No information available

8.2. Exposure Controls

Considering that the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation in the workplace by means of effective local extraction.

When choosing personal protective equipment, seek advice from your chemical suppliers.

Personal protective equipment must bear the CE market certifying its compliance with current standards.

HAND PROTECTION

Protect your hands with category III work gloves (ref. EN 374).

For the final choice of the material of work gloves, the following must be considered: compatibility, degradation, breaking time and permeation.

In the case of preparations, the resistance of work gloves to chemical agents must be checked before use as it is not foreseeable. Gloves have a wear time that depends on the duration and mode of use.

SKIN PROTECTION

Wear long-sleeved work clothes and category I safety footwear for professional use (ref. Directive 89/686/EEC and EN ISO 20344). Wash with soap and water after removing protective clothing.

EYE PROTECTION

It is recommended to wear hermetic protective goggles (ref. EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) of the substance or one or more of the substances present in the product is exceeded, it is recommended to wear a type A filter mask whose class (1, 2 or 3) must be chosen in relation to the limit concentration of use. (ref. EN 14387). If gases or vapours of different nature and/or gases or vapours with particles (aerosols, fumes, mists, etc.) are present, combined filters must be provided.

The use of respiratory protective equipment is necessary if the technical measures taken are not sufficient to limit the exposure of the worker to the threshold values taken into account. However, the protection offered by masks is limited.

In the event that the substance in question is odourless or its olfactory threshold is higher than the relevant TLV-TWA and in case of emergency, wear an open-circuit compressed air breathing apparatus (ref. EN 137) or an external air intake respirator (ref. EN 138). For the correct choice of respiratory protective equipment, refer to EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS

Emissions from production processes, including those from ventilation equipment, should be controlled in order to comply with environmental protection legislation.

ULTRASOUND GEL CLEAR

SECTION 9. Physical and Chemical Properties

9.1. Information on Fundamental Physical and Chemical Properties

Property	Value	Information
Physical Status	Liquid Gel	
Color	colourless	
Smell	Weak butyl odor	
Melting or freezing point	-66,15°C	
Initial boiling point	230°C	
Inflammability	Not applicable	Non-flammable
Lower Explosive Limit	Not applicable	Non-flammable
Upper Explosive Limit	Not applicable	Non-flammable
Flash point	Not applicable	Non-flammable
Auto-ignition temperature	210°C	
Decomposition Temperature	unavailable	Not relevant for classification purposes
ph	unavailable	Not relevant for classification purposes
Kinematic viscosity	6 mPa*s	
Solubility	955000 mg/l	
Partition coefficient: n-octanol/water:	1,0	
Vapor Pressure	2.9 Pa	
Density and/or Relative Density	955 kg/m3	
Relative Vapor Density	unavailable	Not relevant for classification purposes
Particle Characteristics	Not applicable	

9.2. Other information

9.2.1. Information on Physical Hazard Classes

No information available

9.2.2. Other Safety Features

No information available

SECTION 10. Stability and responsiveness

10.1. Responsiveness

There is no particular danger of reaction with other substances under normal conditions of use.

10.2. Chemical Stability

The product is stable under normal conditions of use and storage.

10.3. Possibility of Dangerous Reactions

Under normal conditions of use and storage, dangerous reactions are not to be expected.

10.4. Conditions to be avoided

None in particular. However, the usual precautions should be taken with regard to chemicals.

10.5. Incompatible Materials

No one in particular.

10.6. Hazardous Decomposition Products

By thermal decomposition it develops: carbon oxides.

ULTRASOUND GEL CLEAR

SECTION 11. Toxicological information

In the absence of experimental toxicological data on the product itself, the possible health hazards of the product have been assessed on the basis of the properties of the substances contained, according to the criteria provided for by the reference legislation for classification.

Therefore, the concentration of the individual hazardous substances mentioned in Sec. 3 should be taken into account in order to assess the toxicological effects of exposure to the product.

11.1. Information on hazard classes defined in Regulation (EC) No 1272/2008Metabolism, kinetics, mechanism of action, and other information

No information available

Information on Probable Routes of Exposure

No information available

Immediate, delayed, and chronic effects from short- and long-term exposures

No information available

Interactive Effects

No information available

ACUTE TOXICITY

LC50 (Inhalation) of the mixture:

Unclassified (no relevant components)

LD50 (Oral) of the mixture:

Unclassified (no relevant components)

LD50 (Skin) of the mixture:

Unclassified (no relevant components)

SKIN CORROSION / SKIN IRRITATION

Does not meet the classification criteria for this hazard class

SEVERE EYE DAMAGE/EYE IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITIZATION

Does not meet the classification criteria for this hazard class

MUTAGENICITY ON GERM CELLS

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

SPECIFIC TARGET ORGAN TOXICITY (STOT) - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

SPECIFIC TARGET ORGAN TOXICITY (STOT) - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

DANGER IN CASE OF SUCTION

Does not meet the classification criteria for this hazard class

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed on the main European lists of potential or suspected endocrine disruptors with effects on human health under evaluation.

ULTRASOUND GEL CLEAR**SECTION 12. Ecological information**

Use according to good working practices, avoiding dispersing the product into the environment. Notify the relevant authorities if the product has reached waterways or if it has contaminated soil or vegetation.

12.1. Toxicity

No information available

12.2. Persistence and Degradability

No information available

12.3. Bioaccumulation Potential

No information available

12.4. Mobility in the Soil

No information available

12.5. PBT and vPvB Assessment Results

According to the available data, the product does not contain PBT or vPvB substances in a percentage greater than 0.1%.

12.6. Endocrine Disrupting Properties

Based on the available data, the product does not contain substances listed on the main European lists of potential or suspected endocrine disruptors with effects on the environment under evaluation.

12.7. Other Adverse Effects

No information available

SECTION 13. Disposal Considerations**13.1. Waste Treatment Methods**

Reuse, if possible. The residues of the product as they are are to be considered special non-hazardous waste.

Disposal must be entrusted to an authorized waste management company, in compliance with national and, if necessary, local legislation.

CONTAMINATED PACKAGING

Contaminated packaging must be sent for recovery or disposal in compliance with national waste management regulations.

SECTION 14. Transportation Information

The product is not to be considered dangerous under the regulations in force on the transport of dangerous goods by road (A.D.R.), by rail (RID), by sea (IMDG Code) and by air (IATA).

14.1. UN number or ID number

Not applicable

14.2. Official UN Transport Designation

Not applicable

14.3. Transport-related hazard classes

Not applicable

14.4. Packaging Group

Not applicable

14.5. Hazards to the Environment

Not applicable

14.6. Special Precautions for Users

Not applicable

14.7. Maritime Bulk Transport in accordance with IMO Acts

Not Applicable Information

ULTRASOUND GEL CLEAR

SECTION 15. Regulatory Information**15.1. Health, safety and environmental laws and regulations specific to the substance or mixture**

Category Seveso - Directive 2012/18/EC: None

Restrictions on the product or substances contained in accordance with Annex XVII Regulation (EC) 1907/2006
None

Substances on the Candidate List (Art. 59 REACH)

According to the available data, the product does not contain more than 0.1% SVHC substances.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to export notification Reg. (EC) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Health Checks

No information available

Legislative Decree 152/2006 and subsequent amendments

Emissions according to Part V Annex I: WATER 96.99 %

15.2. Chemical Safety Assessment

A chemical safety assessment has not been prepared for the mixture and the substances contained therein.

SECTION 16. Other information**LEGEND:**

- ADR: European Agreement for the Carriage of Dangerous Goods by Road
- CAS NUMBER: Number of the Chemical Abstract Service
- EC50: Concentration that gives effect to 50% of the test population
- CE NUMBER: Identification number in ESIS (European Repository of Existing Substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived layer with no effect
- EmS: Emergency Schedule
- GHS: Global Harmonized System for the Classification and Labeling of Chemicals
- IATA DGR: International Air Transport Association's Regulations for the Carriage of Dangerous Goods
- IC50: Immobilization concentration of 50% of the test population
- IMDG: International Maritime Code for the Carriage of Dangerous Goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identification number in Annex VI of the CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent, bioaccumulative and toxic according to REACH
- PEC: Predictable Environmental Concentration
- PEL: Predictable level of exposure
- PNEC: Predictable concentration with no effect
- REACH: EC Regulation 1907/2006
- RID: Regulations for the International Carriage of Dangerous Goods by Rail
- TLV: Threshold limit value
- TLV CEILING: Concentration that must not be exceeded during any time of occupational exposure.
- TWA STEL: Short-Term Exposure Limit
- TWA: Weighted Average Exposure Limit
- VOC: Volatile Organic Compound
- vPvB: Very persistent and very bioaccumulative according to REACH
- WGK: Aquatic hazard class (Germany).

ULTRASOUND GEL CLEAR**GENERAL BIBLIOGRAPHY:**

1. Regulation (EC) 1907/2006 of the European Parliament (REACH)
 2. Regulation (EC) 1272/2008 of the European Parliament (CLP)
 3. Regulation (EU) 790/2009 of the European Parliament (I Atp. CLP)
 4. Regulation (EU) 2015/830 of the European Parliament
 5. Regulation (EU) 286/2011 of the European Parliament (II Atp. CLP)
 6. Regulation (EU) 618/2012 of the European Parliament (III Atp. CLP)
 7. Regulation (EU) 487/2013 of the European Parliament (IV Atp. CLP)
 8. Regulation (EU) 944/2013 of the European Parliament (See Atp. CLP)
 9. Regulation (EU) 605/2014 of the European Parliament (VI Atp. CLP)
 10. Regulation (EU) 2015/1221 of the European Parliament (VII Atp. CLP)
 11. Regulation (EU) 2016/918 of the European Parliament (VIII Atp. CLP)
 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
 13. Regulation (EU) 2017/776 (X Atp. CLP)
- The Merck Index. - 10th Edition
 - Handling Chemical Safety
 - INRS - Fiche Toxicologique (toxicological sheet)
 - Patty - Industrial Hygiene and Toxicology
 - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
 - IFA GESTIS website
 - ECHA Agency website
 - Database of SDS models of chemical substances - Ministry of Health and Istituto Superiore di Sanità

Note to the user:

The information contained in this sheet is based on the knowledge available from us as of the date of the latest version. The user must ensure that the information is suitable and complete in relation to the specific use of the product.

This document should not be construed as a guarantee of any specific property of the product.

Since the use of the product is not under our direct control, it is the user's obligation to comply with the laws and regulations in force regarding hygiene and safety under their own responsibility. They do not accept responsibility for improper use.

Provide adequate training to personnel in charge of the use of chemicals.

Changes from the previous revision

Changes have been made to the following sections:

01 / 02 / 03 / 05 / 08 / 09 / 11 / 12 / 16.

Other information:

This article has been created in collaboration with Ecol Studio Bioikòs S.r.l. based in via Rivani 99, BOLOGNA (Tel. 051 5878211).