



SDS NO.: A001R2009150601
Creation Date: September 19, 2020

Applicant: REED Instruments
Address: 312 Raleigh Street, Suite 9 Wilmington, North Carolina 28412

Sample information:

Sample name: Ultrasound gel
Model: R7950, R7950/12, R7950/5L
Sample composition/raw material (supplied by client): Refer to section 3 of the SDS“Composition/Information on Ingredient”
Edit period: From September 15, 2020 to September 19, 2020

Required service : As specified by the client, to edit Safety Data Sheet (SDS) by the submitted sample information.

Summary : As specified by the client, This safety data sheet was prepared in accordance with Regulation(EC) No.1907/2006 (REACH), 1272/2008(CLP), as amended by Regulation(EU) No. 2015/830 and UN GHS (the 8th revised edition). Please refer to the attached report for details.

Shanghai Fajin Testing Technology Co.,Ltd

Approved by



Safety Data Sheet (SDS)

Conforms to Regulation(EC) No.1907/2006(REACH), 1272/2008(CLP),as amended by Regulation(EU) No. 2015/830

Section 1 - Chemical Product and Company Identification

1.1 Product Identification:

Product Name: Ultrasound gel
Product Model: R7950, R7950/12, R7950/5L

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

Identified uses: Medical Examination
Use advised against: No data available.

1.3 Details of the Manufacture or supplier

Manufacture: REED Instruments
Address: 312 Raleigh Street, Suite 9312 Raleigh Street, Suite 9 Wilmington, North Carolina
Telephone: 1-877-849-2127
Fax: 1-800-361-1152
Email: info@reedinstruments.com

1.4 Emergency telephone number

Emergency Telephone: 1-877-849-2127

Section 2 - Hazards Identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] and its amendments:

This product is not classified as hazardous according to Regulation (EC) No. 1272/2008 [CLP] and its amendments.

2.2 Label elements, including precautionary statements

Pictogram(s): No pictogram is used.
Signal Word: No signal word is used.
Hazard Statement: No hazard statement.
Precautionary statements: No precautionary statement.

2.3 Description of any hazards not otherwise classified

No additional information available.

Section 3 - Composition/Information on Ingredient

Substance () Preparation (√) Article ()

Composition:

| Chemical name | CAS No. | EC No. | Content (% w/w) | Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP] |
|---------------------|-----------|-----------|-----------------|-----------------------------------------------------------------------|
| Water | 7732-18-5 | 231-791-2 | 98.895% | Not Classified. |
| Carbomer | 9007-20-9 | 618-435-5 | 0.5% | Not Classified. |
| Triethanolamine | 102-71-6 | 203-049-8 | 0.5% | Not Classified. |
| Preservative | - | - | 0.1% | Not Classified. |
| Approved food color | - | - | 0.005% | Not Classified. |

Abbreviation: CAS No. is Chemical Abstract Service Registry Number.

Section 4 - First Aid Measures

4.1 Description of first aid measures:

Eye Contact: Flush eyes with plenty of water, occasionally lifting the upper and lower eyelids.

Skin Contact: No need for first aid is anticipated. Wash with water if necessary.

Inhalation: No need for first aid is anticipated.

Ingestion: Rinse mouth with water. Obtain medical attention if symptoms appear or if large quantities have been ingested.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

No special medical treatment measure under normal condition.

Section 5 -Extinguishing media

5.1 Extinguishing media

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products formed under fire conditions. - Carbon oxides, etc..

5.3 Advice for firefighters

As in any fire, Wear self-contained breathing apparatus and full protective gear for firefighting if necessary.

5.4 Further information

No data available.

Section 6 - Accidental Release Measures

For guidance on selection of personal protective equipment see Chapter 8 of this Material Safety Data Sheet. See Chapter 13 for information on disposal. Observe the relevant local and international regulations.

6.1 Personal precautions, protective equipment and emergency procedures:

No special requirements under normal condition.

6.2 Environmental precautions:

No special environmental precautions required. Do not release large amount of undiluted product to environment.

6.3 Methods and materials for containment and cleaning up:

Use suitable tools to collect for recycle or disposal. Clean up contaminated area with towel and water. No special measures required.

Section 7 - Handling and Storage**7.1 Precautions for safe handling:**

Use according to the product instructions and identified uses, no special precaution measures required.

7.2 Conditions for safe storage, including any incompatibilities:

Keep package tightly closed. Store in cool area. Avoid direct sunlight. Do not store together with strong oxides. Keep out of reach of children.

Section 8 - Exposure Controls, Personal Protection

8.1 Exposure Limits: Not established.

8.2 Exposure controls

Engineering Control: No special measures required.

Personal protective equipment:

Respiratory Protection: Not required for consumer under normal usage.

Eyes Protection: Not required for consumer under normal usage.

| | |
|---------------------------|-----------------------------------------------|
| Body Protection: | Not required for consumer under normal usage. |
| Hands Protection: | Not required for consumer under normal usage. |
| Other Protections: | Not required for consumer under normal usage. |

Section 9 - Physical and Chemical Properties

Information on basic physical and chemical properties

| | |
|-----------------------------------------------------|---------------------------------|
| Appearance | Gel |
| Color | Light blue or colorless |
| Odor | Odorless |
| Odour Threshold | Not available. |
| pH | Not available. |
| Melting point/freezing point | Not available. |
| Initial boiling point and boiling range | Not available. |
| Flash point | Not applicable. Will not flash. |
| Evaporation rate | Not available. |
| Flammability(solid, gas) | Not flammable. |
| Upper/lower flammability or explosive limits | Not applicable. Will not occur. |
| Vapor pressure | Not available. |
| Vapor density | Not available. |
| Density/Relative density | Not available. |
| Water solubility | Soluble in water. |
| Partition coefficient: n-octanol/water | Not available. |
| Auto-ignition temperature | Not applicable. Will not occur. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |

Section 10 - Stability and Reactivity

10.1 Stability: Stable under normal storage temperature and pressure.

10.2 Conditions to Avoid: Overheat.

10.3 Incompatible materials: Strong oxidizing agents.

10.4 Hazardous Decomposition Products: Other decomposition products- no data available. In the event of fire:see section 5.

10.5 Possibility of hazardous reactions: None hazardous reactions known under normal condition.

Section 11 - Toxicological Information

| | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| Acute Toxicity: | No data available. |
| Skin Corrosion/Irritation: | No known irritating effect. |
| Serious Eye Damage/Eye Irritation: | Based on available data, the classification criteria are not met. |
| Skin Sensitization | Based on available data, the classification criteria are not met. |
| Respiratory Sensitization | No sensitizing effects known. |
| Germ Cell Mutagenicity | Based on available data, the classification criteria are not met. |
| Carcinogenicity: | None of the components of this product is listed as a carcinogen by IARC, NTP, US OSHA. |
| Reproductive Toxicity: | Based on available data, the classification criteria are not met. |
| Specific Target Organ Toxicity - Single Exposure (Globally Harmonized System): | No known human health effects upon single exposure. |
| Specific Target Organ Toxicity - Repeated Exposure (Globally Harmonized System): | No known human health effects upon repeated exposure. |
| Aspiration Hazard: | Based on available data, the classification criteria are not met. |
| Potential Health Effects: | |
| Inhalation: | No significant effects under normal condition. |
| Skin Contact: | No significant effects under normal condition. |
| Eye Contact: | No significant effects under normal condition. |
| Ingestion: | Ingestion is unlikely under normal conditions. May be harmful if largely ingested. |

Section 12 - Ecological Information

12.1 Toxicity

Expected to be nonhazardous to environment under normal usage.

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No bioaccumulative potential

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

No negative ecological effects are expected according to the present state of knowledge.

Section 13 - Disposal Considerations**Waste treatment methods****Product**

Non hazardous waste. Small quantity can be disposed as household waste. As for big quantity, Observe according to the national and local related regulations.

Contaminated packaging

Dispose of as unused product.

Section 14 - Transport Information**14.1 UN-Number**

ADR/RID/ADN, IMDG, IATA Not applicable.

14.2 UN proper shipping name

ADR/RID/ADN, IMDG, IATA Not applicable.

14.3 Transport hazard class(es)

ADR/RID/ADN, IMDG, IATA

Class Not applicable.

Label Not applicable.

14.4 Packing group

ADR/RID/ADN, IMDG, IATA Not applicable.

14.5 Environmental hazards Not applicable.

14.6 Special precautions for user Not applicable.

14.7 Transport in bulk according to Annex 1 of

Marpol and the IBC Code Not applicable.

14.8 Transport/Additional information: Not dangerous according to the above specifications.

UN 'Model Regulation' : Not applicable.

Section 15 - Regulatory Information

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

EU Regulations

Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2019/521(ATP 14).

Other regulations, limitations and prohibitive regulations

SVHC Candidate List of REACH Regulation Annex XIV Authorisation (15/1/2018)None of the ingredients is listed

REACH Regulation Annex XVII Restriction (101/2018)

See Section 1 for information about restriction of use.

None of the ingredients is listed.

REACH Regulation Annex XIV Authorisation List (13/6/2017)

None of the ingredients is listed

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

Section 16 - Additional Information

16.1 Reference

- | | | |
|-----|----------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| [1] | IPCS:The International Chemical Safety Cards (ICSC) | website: http://www.ilo.org/dyn/icsc/showcard.home |
| [2] | IARC | website: http://www.iarc.fr/ |
| [3] | OECD: The Global Portal to Information on Chemical Substances, | website: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en |
| [4] | CAMEO Chemicals, | website: http://cameochemicals.noaa.gov/search/simple |
| [5] | NLM:ChemIDplus, | website: http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp |
| [6] | EPA: Integrated Risk Information System, | website: http://cfpub.epa.gov/iris/ |
| [7] | U.S. Department of Transportation:ERG, | website: http://www.phmsa.dot.gov/hazmat/library/erg |
| [8] | Germany GESTIS-database on hazard substance | website: http://gestis-en.itrust.de/ |

16.2 Abbreviations and acronyms

| | |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------|
| pH | Relates to hydrogen ion concentration - this value will relate to a scale of 0 - 14, where 0 is highly acidic and 14 is highly alkaline |
| OSHA | Occupational Safety and Health Administration |
| NTP | National Toxicology Program |
| IARC | International Agency for Research on Cancer |
| ACGIH | The American Conference of Governmental Industrial Hygienists |

| | |
|---------|-----------------------------------------|
| UN | The United Nations |
| ADR | Agreement on Dangerous Goods by Road |
| IATA | International Air Transport Association |
| IMDG | International Maritime Dangerous Goods |
| PC-STEL | Short term exposure limit |
| PC-TWA | Time Weighted Average |
| LC50 | Lethal Concentration 50% |
| LD50 | Lethal Dose 50% |
| NOEC | No Observed Effect Concentration |
| EC50 | Effective Concentration 50% |
| PBT | Persistent, Bioaccumulative, Toxic |
| vPvB | very Persistent, very Bioaccumulative |

16.3 Disclaimer

-This Safety Data Sheet (SDS) was prepared according to Regulation(EC) No.1907/2006 (REACH), 1272/2008(EU-GHS/CLP),as amended by Regulation(EU) No. 2015/830.

-The data included was derived from international authoritative database and provided by the enterprise. Other information was based on the present state of our knowledge. We try to ensure the correctness of all information. However, due to the diversity of information sources and the limitations of our knowledge, this document is only for user's reference. Users should make their independent judgment of suitability of this information for their particular purposes. We do not assume responsibility for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product

16.4 Information on revision

| | |
|----------------------|--------------------|
| SDS Creation Date: | September 19, 2020 |
| SDS Revision Date: | - |
| Reason For Revision: | - |
| SDS Edition: | 1.0 |

End of SDS