



SDS Service Summary

No.: CANHL24000244201

Date: 08 Jan 2024

Page 1 of 1

SGS Job No. : GZHL2401000528IP
Product Name : ICE PACK;HOT COLD PACK
Manufacturer / Supplier : JIANGSU YISHUN MEDICAL EQUIPMENT CO.,LTD
Country of Origin : CHINA
Country of Destination : Europea
Composition/Ingredient of product (as per applicant submission) : See *section 3 Composition/information on ingredients* on the SDS
Job Receiving Date : 04 Jan 2024
SDS Preparation Period : 04 Jan 2024-08 Jan 2024

Service Requested : Preparation of Safety Data Sheet (SDS) for the product with submitted information, with calculation of the classification and labeling requirement according to the submitted composition and European Commission Regulation (EC) No 1272/2008.

Summary : As per request, the contents and formats of the SDS are prepared in accordance with European Commission Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) No 2020/878, and is provided per attached.

Disclaimer

This Safety Data Sheet (SDS) is provided to applicant to fulfill European Commission Regulation (EC) No 1907/2006 and communicate the hazard information of chemicals through the supply chain to ensure safe use. It is not a test report or a certificate ensuring the safety of a product.

SGS has consolidated product information based on documents provided by Applicant (i.e. product name, the supplier details, product composition, available physical data, etc.) without independent verification from SGS. The information is provided without any warranty, express or implied, regarding its correctness.

Zm guan
Project Engineer

Safety data sheet

Regulation (EC) 1907/2006 and 1272/2008

Printing date: 09.01.2024



Version number: 1

Revision date: 05.01.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** ICE PACK;HOT COLD PACK
- **UFI:** DWH0-10NQ-7001-DJH2
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture:** COLD USE
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer / Supplier:** JIANGSU YISHUN MEDICAL EQUIPMENT CO.,LTD
- **Full address:**
NO.25 HAIYAN ROAD, BINHAI INDUSTRIAL ZONE, QIDONG, NANTONG CITY, JIANGSU PROVINCE,CHINA
- **Phone number:** 0513-83905760
- **Email:** yishun02@yishun.cn
- **Only Representative / other EU contact point:** Not available
- **1.4 Emergency telephone number:**
IRELAND
National Poisons Information Centre
Tel: +353 (01) 809 2566 (For healthcare professionals)
+353 (01) 809 2166 (For public; 8am - 10pm)
- Darren Tao
18918308751
- **1.5 Reference Number:** CANHL24000244201,GZHL2401000528IP

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
- 
GHS07
- Skin Sens. 1 H317 May cause an allergic skin reaction.
- Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
- **Information concerning particular hazards for human and environment:**
The product has to be labelled due to the calculation procedure of Regulation (EC) No.1272/2008.
- **Classification system:**
The classification is according to the latest edition of EU Regulation (EC) No. 1272/2008, and extended by company and literature data.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No. 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**
- 
GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
5-chloro-2-methyl-2H-isothiazol-3-one
- **Hazard statements**
H317 May cause an allergic skin reaction.

(Contd. on page 2)

EII

Safety data sheet

Regulation (EC) 1907/2006 and 1272/2008

Printing date: 09.01.2024

Version number: 1

Revision date: 05.01.2024

Trade name: ICE PACK;HOT COLD PACK

(Contd. from page 2)

- **4.2 Most important symptoms and effects, both acute and delayed:**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed:**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture:** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures:** Not required.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water source.
Inform respective authorities in case of seepage into water course or sewage system.
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
- **6.4 Reference to other sections:**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
For the general occupational hygienic measures refer to Section 8.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:**
Store away from foodstuffs.
Store away from water.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s):** No further relevant information available.

EU

(Contd. on page 4)

Safety data sheet

Regulation (EC) 1907/2006 and 1272/2008

Printing date: 09.01.2024

Version number: 1

Revision date: 05.01.2024

Trade name: ICE PACK;HOT COLD PACK

(Contd. from page 3)

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· **Ingredients with limit values that require monitoring at the workplace:**

CAS: 56-81-5 Glycerol (25%)

AGW (Germany) Long-term value: 200 E mg/m³
2 (I);DFG, Y

VLEP (France) Long-term value: 10 mg/m³

OEL (Ireland) Long-term value: 10 mg/m³

CAS: 26172-55-4 5-chloro-2-methyl-2H-isothiazol-3-one (0.02%)

MAK (Germany) Long-term value: 0.2E mg/m³
vgl.Abschn.Xc

· **Regulatory information**

AGW (Germany): TRGS 900

VLEP (France): ED 1487 05.2021

OEL (Ireland): 2021 CoP for the Safety, Health and Welfare at Work

MAK (Germany): MAK- und BAT-Liste

· **DNELs:** Not available

· **PNECs:** Not available

· **Additional information:** The lists valid during the making were used as basis.

· 8.2 Exposure controls

Based on the composition shown in Section 3, the following measures are suggested for occupational safety measure.

· **Appropriate engineering controls:**

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

See Section 7 for information about design of technical facilities.

· **Individual protection measures, such as personal protective equipment**

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **Hand protection:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

· **Material of gloves:**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material:**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye/face protection:** Goggles recommended during refilling

· **Body protection:** Protective work clothing

· **Thermal hazards:** Not required for normal conditions of use.

(Contd. on page 5)

Safety data sheet

Regulation (EC) 1907/2006 and 1272/2008

Printing date: 09.01.2024

Version number: 1

Revision date: 05.01.2024

Trade name: ICE PACK;HOT COLD PACK

(Contd. from page 4)

- **Environmental exposure controls:**
Control measures must be made in accordance with Community environmental protection legislation.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

- **Physical state:** Gel
- **Colour:** According to product specification
- **Odour:** Odourless
- **Odour threshold:** Not available
- **Melting point/Freezing point:** Not available
- **Boiling point or initial boiling point and boiling range:** Not available
- **Flammability:** Not available
- **Lower and upper explosion limit**
- **Lower:** Not available
- **Upper:** Not available
- **Flash point:** Not available
- **Auto-ignition temperature:** Not available
- **Decomposition temperature:** Not available
- **pH:** Not available
- **Viscosity**
- **Kinematic viscosity:** Not available
- **Dynamic viscosity:** Not available
- **Solubility**
- **Water:** Not available
- **Partition coefficient n-octanol/water (log value):** Not available
- **Vapour pressure:** Not available
- **Density and/or relative density**
- **Density:** Not available
- **Relative density:** Not available
- **Relative vapour density:** Not available
- **Particle characteristics:** Not available

· 9.2 Other information

- **Appearance**
- **Form:** Gel

· Information with regard to physical hazard classes

- **Explosives:** Not applicable
- **Flammable gases:** Not applicable
- **Aerosols:** Not applicable
- **Oxidising gases:** Not applicable
- **Gases under pressure:** Not applicable
- **Flammable liquids:** Not applicable
- **Flammable solids:** Not applicable
- **Self-reactive substances and mixtures:** Not applicable
- **Pyrophoric liquids:** Not applicable
- **Pyrophoric solids:** Not applicable
- **Self-heating substances and mixtures:** Not applicable
- **Substances and mixtures, which emit flammable gases in contact with water:** Not applicable
- **Oxidising liquids:** Not applicable
- **Oxidising solids:** Not applicable
- **Organic peroxides:** Not applicable
- **Corrosive to metals:** Not applicable
- **Desensitised explosives:** Not applicable

(Contd. on page 6)

Safety data sheet

Regulation (EC) 1907/2006 and 1272/2008

Printing date: 09.01.2024

Version number: 1

Revision date: 05.01.2024

Trade name: ICE PACK;HOT COLD PACK

(Contd. from page 5)

· **Other safety characteristics:** Not available

SECTION 10: Stability and reactivity

- **10.1 Reactivity:** No further relevant information available.
- **10.2 Chemical stability:** No further relevant information available.
- **10.3 Possibility of hazardous reactions:** No dangerous reactions known.
- **10.4 Conditions to avoid:** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

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

- **Acute toxicity**

- **LD/LC50 values relevant for classification:**

CAS: 56-81-5 Glycerol

Oral	LD50	12,600 mg/kg (rat)
------	------	--------------------

CAS: 9004-32-4 Cellulose, carboxymethyl ether, sodium salt

Oral	LD50	>27,000 mg/kg (rat)
------	------	---------------------

Dermal	LD50	>2,000 mg/kg (rabbit)
--------	------	-----------------------

- **Skin corrosion/irritation:** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation:** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitization:** May cause an allergic skin reaction.
- **Germ cell mutagenicity:** Based on available data, the classification criteria are not met.
- **Carcinogenicity:** Based on available data, the classification criteria are not met.
- **Reproductive toxicity:** Based on available data, the classification criteria are not met.
- **STOT-single exposure:** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure:** Based on available data, the classification criteria are not met.
- **Aspiration hazard:** Based on available data, the classification criteria are not met.

- **11.2 Information on other hazards**

- **Endocrine disrupting properties:**

None of the ingredients is listed.

- **Other information:** No further relevant information available.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability:** No further relevant information available.
- **12.3 Bioaccumulative potential:** No further relevant information available.
- **12.4 Mobility in soil:** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable
- **vPvB:** Not applicable

(Contd. on page 7)

Safety data sheet

Regulation (EC) 1907/2006 and 1272/2008

Printing date: 09.01.2024

Version number: 1

Revision date: 05.01.2024

Trade name: ICE PACK;HOT COLD PACK

(Contd. from page 6)

- **12.6 Endocrine disrupting properties:**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects:** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|---------------------|
| <ul style="list-style-type: none"> · 14.1 UN number or ID number · ADR/RID/ADN, IMDG, IATA | Not applicable |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR/RID/ADN, IMDG, IATA | Not applicable |
| <ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR/RID/ADN, IMDG, IATA · Class · Label | Not applicable
- |
| <ul style="list-style-type: none"> · 14.4 Packing group · ADR/RID/ADN, IMDG, IATA | Not applicable |
| <ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: | No |
| <ul style="list-style-type: none"> · 14.6 Special precautions for user: · Hazard identification number (Kemler code): | Not applicable
- |
| <ul style="list-style-type: none"> · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable |
| <ul style="list-style-type: none"> · 14.8 Transport/Additional information: | Not applicable |
| <ul style="list-style-type: none"> · UN "Model Regulation": | Not applicable |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category** Not applicable
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** Not applicable
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** Not applicable

· REGULATION (EU) 2019/1021 on persistent organic pollutants (POP)

None of the ingredients is listed.

· Regulation (EU) No 649/2012

None of the ingredients is listed.

(Contd. on page 8)

Safety data sheet

Regulation (EC) 1907/2006 and 1272/2008

Printing date: 09.01.2024

Version number: 1

Revision date: 05.01.2024

Trade name: ICE PACK;HOT COLD PACK

(Contd. from page 7)

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **REGULATION (EC) No 1005/2009 on substances that deplete the ozone layer – ANNEX I (Ozone-depleting potential)**

None of the ingredients is listed.

· **Other regulations, limitations and prohibitive regulations**

· **SVHC Candidate List of REACH Regulation Annex XIV Authorisation (14/6/2023)**

None of the ingredients is listed

· **REACH Regulation Annex XVII Restriction (25/9/2023)**
See Section 16 for information about restriction of use.

None of the ingredients is listed

· **REACH Regulation Annex XIV Authorisation List (8/4/2022)**

None of the ingredients is listed

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

SECTION 16: Other information

· **Recommended restriction of use** Not applicable

· **Relevant hazard statements**

H301 Toxic if swallowed.
H310 Fatal in contact with skin.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H330 Fatal if inhaled.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
EUH071 Corrosive to the respiratory tract.

· **Classification according to Regulation (EC) No. 1272/2008**

Skin sensitisation Hazardous to the aquatic environment - long-term (chronic) aquatic hazard	The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No. 1272/2008.
---	---

The contents and format of this SDS are in accordance with Regulation (EC) No 1907/2006, 1272/2008 and Regulation (EU) No 2020/878.

DISCLAIMER OF LIABILITY

The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reason, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or

(Contd. on page 9)

Safety data sheet

Regulation (EC) 1907/2006 and 1272/2008

Printing date: 09.01.2024

Version number: 1

Revision date: 05.01.2024

Trade name: ICE PACK;HOT COLD PACK

(Contd. from page 8)

disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable.

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 2: Acute toxicity – Category 2

Skin Corr. 1C: Skin corrosion/irritation – Category 1C

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1A: Skin sensitisation – Category 1A

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

End of document