

Safety Data Sheet CryoSure–DEX40 in accordance to Regulation (EC) no.: 1907/2006 (REACH) and 1272/2008 (CLP)

Date of issue/last revision: 10/2018

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

1.1. Product identifier:

Name: CryoSure-DEX40
Cat. No..: WAK-DEX40-25
CAS #: 67-68-5; 9004-54-0
MF: C₂H₆OS; (C₆H₁₀O₅)
EU No.: 200-664-3; 232-677-5

Molecular weight: 78.13 AMU

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

Cryoprotectant for the cryopreservation of hematopoietic stem cells for transplantation.

1.3. Details of the supplier of the safety data sheet:

WAK-Chemie Medical GmbH

Siemensstr. 9 61449 Steinbach/Ts Tel: +49 6171 2843 0 Fax: +49 6171 695 646 E-Mail: <u>info@wak-chemie.com</u>

1.4. Emergency phone: +49 6171 2843 0

(on weekdays during office hours, 9 am - 5 pm CET)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture:

2.1.1 Classification of the substance or mixture according to EC No 1272/2008:

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2. Label elements according to EC No 1272/2008:

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3. Other Hazards:

None known.

Section 3: Composition/information on ingredients

3.1. Substance:

This product is a mixture.

3.2. Mixture:

Name	CAS No./ EC No.	concentration value (weigth/volume)	Classification according to Regulation (EC) No. 1272/2008 (CLP)	REACH Registration no.:
Dimethyl Sulfoxide (DMSO)	67-68-5 / 200-664-3	55 %	Not classified	*
Dextran	9004-54-0/ 232-677-5	5 %	Not classified	*

^{*} A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2. and 6. REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.



Section 4: First aid measures

4.1. Description of first aid measures:

Eyes: Flush with running water for >15 minutes. Get medical attention if irritation develops.

Skin: Wash skin thoroughly with soap and water. Get medical attention if irritation develops.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention if symptoms appear.

Inhalation: remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention symptoms appear.

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

No data available

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

No data available

Section 5: Firefighting measures

5.1. Extinguishing media:

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

5.2. Special hazards arising from the substance or mixture:

Carbon oxides, Sulphur oxides, Hydrogen chloride gas, Sodium oxides

5.3. Advice for firefighters:

Wear self-contained breathing apparatus for firefighting if necessary.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation.

For non-emergency personnel: no additional information available For emergency responders: no additional information available

6.2. Environmental precautions:

Do not let product enter drains.

6.3. Methods and materials for containment and cleaning up:

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

6.4. Reference to other sections:

For disposal see section 13.

Section 7: Handling and storage

7.1. Precautions for safe handling:

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.

7.2. Conditions for safe storage, including any incompatibilities:

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Recommended storage temperature: 2 - 8 °C. Protect from light.

7.3. Specific end use(s):

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated



Section 8: Exposure controls/personal protection

8.1. Control parameters:

Ingredient	CAS-No	Value	Parameters to be monitored	Basis
Dimethyl sulfoxide	67-68-5	OELs	160 mg/m3	Germany: TRGS 900 Limit values in the air at the workplace

8.2. Exposure controls:

Engineering Controls:

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment:

Eye/face protection:

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection:

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection:

Impervious clothing, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection:

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multipurpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties:

a) Appearance form:	liquid, clear
b) Odour no:	no data available
c) Odour Threshold:	no data available
d) pH:	no data available
e) Melting point/freezing point:	no data available
f) Initial boiling point and boiling range:	no data available
g) Flash point:	no data available
h) Evaporation rate:	no data available
i) Flammability (solid, gas):	no data available
j) Upper/lower flammability or explosive limits:	no data available
k) Vapour pressure:	no data available
I) Vapour density:	no data available
m) Relative density:	no data available
n) Water solubility:	no data available
o) Partition coefficient: n-octanol/water:	no data available
p) Autoignition temperature:	no data available
q) Decomposition temperature:	no data available
r) Viscosity:	no data available
s) Explosive properties:	no data available

9.2. Other information:

No additional information available.



Section 10: Stability and reactivity

10.1. Reactivity:

No data available.

10.2. Chemical stability:

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions:

No data available.

10.4. Conditions to avoid:

Heat, flames and sparks.

10.5. Incompatible materials:

Acid chlorides, Phosphorus halides, Strong acids, Strong oxidizing agents, Strong reducing agents.

10.6. Hazardous decomposition products:

No data available.

Section 11: Toxicological Information

11.1 Information on toxicological effects:

Acute toxicity:

Skin corrosion/irritation:

Serious eye damage/eye irritation:

Respiratory or skin sensitization:

Germ cell mutagenicity:

No data available

No data available

No data available

Carcinogenicity:

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable,

possible or confirmed human carcinogen by IARC.

Reproductive toxicity:

Specific target organ toxicity - single exposure:

Specific target organ toxicity - repeated exposure:

No data available

No data available

No data available

No data available

Not applicable

Section 12: Ecological information

12.1. Toxicity:

Not data available.

12.2. Persistence and degradability:

Not data available.

12.3. Bioaccumulative potential:

Not data available.

12.4. Mobility in soil:

Not 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

Not data available.



Section 13: Disposal considerations

13.1 Waste treatment methods:

13.1.1. Product/packaging disposal:

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging: dispose of as unused product

13.1.2 Waste treatment-relevant information:

Not data available.

13.1.3 Sewage disposal-relevant information:

Not data available.

13.1.4 Other disposal recommendations:

Not data available.

Section 14: Transport information

14.1. UN class:
14.2. Proper shipping name:
14.3. Transport Hazard Class:
14.4. Packing group:
14.5. Environmental Hazard no.:
Not a hazardous substance or mixture.

14.6. Special precautions for end user: see sections 6. and 8.

14.7. Transport in bulk according

to Annex II of MARPOL 73/78 and the IBC Code: not applicable

Section 15: Regulatory information

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

Labelling according EC No 1272/2008

15.2. Chemical safety assessment:

A chemical safety assessment is not required.

Section 16: Other information

16.1 Indication of changes

See sections: 1, 3 and 16.

Composed by: Florian Pobitschka

Date of issue/last revision: 10.2018

Internal number: L-02-041-02-0-02

16.2 Legend:

CAS: Chemical Abstract Service Number

IBC-Code: The International Building Code (IBC) is a model building code developed by the International

Code Council (ICC).

LC: lethal concentration

LD: lethal dose

log Kow: The ratio of the concentration of a solute between water and octanol MARPOL: International Convention for the Prevention of Pollution from Ships

PBT: Persistent, bioaccumulative and toxic

RID: Convention concerning International Carriage by Rail

UN: United Nations

vPvB: very persistent and very bioaccumulative



16.3. References and data sources:

Regulation:

REACH- Regulation (EC) No. 1907/2006 CLP-Regulation (EC) No. 1272/2008 Regulation (EC) No. 2015/830

Internet:

www.reach-clp-biozid-helpdesk.de https://echa.europa.eu http://www.reach-info.de

16.4 Methods according to Article 9 of the Regulation (EC) No 1272/2008 of the evaluation of data for classification purposes:

Classification in accordance with Regulation (EC) No 1272/2008, Annex VII (Conversion table)

16.5. Hazard statements

Not data available.

16.6 Training advice

For activities with this mixture= no training required.

Legal Disclaimer:

The above mentioned information is believed to be accurate and represents the best information currently available to us. However, we make no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall WAK-Chemie Medical GmbH be liable for any claims, losses or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if WAK-Chemie Medical has been advised of the possibility of such damages.