



Safety Data Sheet

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 2022-12-25

Revision Number 7

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

1.1. Product identifier

Product Code SL0020
Product Name Hepatocyte Maintenance Medium (4)
Pure substance/mixture Mixture
1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses No information available
Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Supplier

USA:

Takara Bio USA, Inc.
2560 Orchard Parkway
San Jose, CA 95131, USA
Phone: 800.662.2566/888.251.6618
Web: www.takarabio.com

Europe:

Takara Bio Europe S.A.S.
34, Rue de la Croix de Fer
78100 Saint-Germain-en-Laye, France
Phone: +33.1.39.04.68.80
Web: www.takarabio.com

Europe:

Takara Bio Europe AB
Arvid Wallgrens Backe 20,
SE-413 46 Göteborg, Sweden
Phone: +46.31.758.09.00
Web: www.takarabio.com

India:

DSS Takara Bio India Pvt. Ltd.
A-5 Mohan Co-operative Industrial Estate, Mathura Road,
New Delhi 110044, India
Phone: +91.1800.212.4922 (Toll free)
Web: www.takarabio.com

For further information, please contact:

1.4. Emergency telephone number

Emergency telephone In case of emergency, call PERS (Professional Emergency Resource Services)
1-800-633-8253 (US) or 801-629-0667 (international).

Italy	Marco Marano CAV "Osp. Pediatrico Bambino Gesù" Dip. Emergenza e Accettazione DEA
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Roma, Piazza Sant'Onofrio,4 00165 0668593726

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

Hazard statements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sodium chloride 7647-14-5	0.1 - 1	No data available	231-598-3	No data available	-	-	-
Dimethyl sulfoxide 67-68-5	0.1 - 1	No data available	200-664-3	No data available	-	-	-
Sodium bicarbonate 144-55-8	0.1 - 1	No data available	205-633-8	No data available	-	-	-

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Sodium chloride 7647-14-5	3000	10000	No data available	No data available	No data available
Dimethyl sulfoxide 67-68-5	28300	40000	No data available	No data available	No data available
Sodium bicarbonate 144-55-8	4220	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Rinse mouth.

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

Symptoms	No information available.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	No information available.
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5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions	See Section 12 for additional Ecological Information.
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6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
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Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Advice on safe handling Ensure adequate ventilation.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place.

7.3. Specific end use(s)**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****Exposure Limits**

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
Dimethyl sulfoxide 67-68-5	-	TWA: 50 ppm TWA: 160 mg/m ³ H*	-	-	-
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Dimethyl sulfoxide 67-68-5	-	-	TWA: 50 ppm TWA: 160 mg/m ³	TWA: 50 ppm TWA: 150 mg/m ³ STEL: 150 ppm STEL: 500 mg/m ³ A*	TWA: 50 ppm iho*
Sodium bicarbonate 144-55-8	-	TWA: 5 mg/m ³ Ceiling: 10 mg/m ³	-	-	-
Chemical name	France	Germany	Germany MAK	Greece	Hungary
Dimethyl sulfoxide 67-68-5	-	TWA: 50 ppm TWA: 160 mg/m ³ H*	TWA: 50 ppm TWA: 160 mg/m ³ Peak: 100 ppm Peak: 320 mg/m ³ *	-	-
Chemical name	Ireland	Italy	Italy REL	Latvia	Lithuania
Sodium chloride 7647-14-5	-	-	-	TWA: 5 mg/m ³	TWA: 5 mg/m ³
Dimethyl sulfoxide 67-68-5	-	-	-	-	O* TWA: 50 ppm TWA: 150 mg/m ³ STEL: 150 ppm STEL: 500 mg/m ³
Sodium bicarbonate 144-55-8	-	-	-	TWA: 5 mg/m ³	-
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Dimethyl sulfoxide	-	-	-	TWA: 160 mg/m ³	-

67-68-5				TWA: 50 ppm STEL: 100 ppm STEL: 320 mg/m ³ K*	
Chemical name	Sweden	Switzerland	United Kingdom		
Dimethyl sulfoxide 67-68-5	NGV: 50 ppm NGV: 150 mg/m ³ Vägledande KGV: 150 ppm Vägledande KGV: 500 mg/m ³ H*	TWA: 50 ppm TWA: 160 mg/m ³ STEL: 100 ppm STEL: 320 mg/m ³ H*	-		

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls**Personal Protective Equipment**

Eye/face protection No special protective equipment required.

Skin and body protection No special protective equipment required.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	Liquid
Appearance	Frozen liquid
Color	No information available
Odor	No information available.
Odor Threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	No data available	None known
Boiling point/boiling range (°C)	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability limit:	No data available	
Lower flammability limit:	No data available	
Flash point	No data available	Open cup
Autoignition temperature	215 °C	None known
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic Viscosity	No data available	None known

Water solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient	No data available	None known
Vapor pressure	No data available	None known
Relative density	No data available	None known
Bulk Density	No data available	
Liquid Density	No data available	
Vapor density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

9.2.1. Information with regard to physical hazard classes
Not applicable

9.2.2. Other safety characteristics
No information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion Data

Sensitivity to mechanical impact None.
 Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous Decomposition Products None known based on information supplied.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Information on likely routes of exposure****Product Information**

Inhalation Specific test data for the substance or mixture is not available.
 Eye contact Specific test data for the substance or mixture is not available.
 Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity

Acute toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium chloride	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h
Dimethyl sulfoxide	= 28300 mg/kg (Rat)	= 40000 mg/kg (Rat)	> 5.33 mg/L (Rat) 4 h
Sodium bicarbonate	= 4220 mg/kg (Rat)	-	-

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

Unknown aquatic toxicity Contains 0.96841 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium chloride	-	LC50: 5560 - 6080mg/L (96h, <i>Lepomis macrochirus</i>) LC50: =12946mg/L (96h, <i>Lepomis macrochirus</i>) LC50: 6020 - 7070mg/L (96h, <i>Pimephales promelas</i>) LC50: =7050mg/L (96h, <i>Pimephales promelas</i>) LC50: 6420 - 6700mg/L (96h, <i>Pimephales promelas</i>) LC50: 4747 - 7824mg/L (96h, <i>Oncorhynchus mykiss</i>)	-	EC50: =1000mg/L (48h, <i>Daphnia magna</i>) EC50: 340.7 - 469.2mg/L (48h, <i>Daphnia magna</i>)
Dimethyl sulfoxide	-	LC50: =34000mg/L (96h, <i>Pimephales promelas</i>) LC50: 33 - 37g/L (96h, <i>Oncorhynchus mykiss</i>) LC50: >40g/L (96h, <i>Lepomis macrochirus</i>) LC50: =41.7g/L (96h, <i>Cyprinus carpio</i>)	-	-
Sodium bicarbonate	-	LC50: 8250 - 9000mg/L (96h, <i>Lepomis macrochirus</i>)	-	EC50: =2350mg/L (48h, <i>Daphnia magna</i>)

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

Component Information

Chemical name	Partition coefficient
Dimethyl sulfoxide	-1.35

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Sodium chloride	The substance is not PBT / vPvB PBT assessment does not apply
Dimethyl sulfoxide	The substance is not PBT / vPvB PBT assessment does

	not apply
Sodium bicarbonate	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

- 14.1 UN number or ID number Not regulated
- 14.2 UN proper shipping name No information available
- 14.3 Transport hazard class(es) Not regulated
- 14.4 Packing group Not regulated
- 14.5 Environmental hazards Not applicable
- 14.6 Special precautions for user
Special Provisions None

IMDG

- 14.1 UN number or ID number Not regulated
- 14.2 UN proper shipping name No information available
- 14.3 Transport hazard class(es) Not regulated
- 14.4 Packing group Not regulated
- 14.5 Environmental hazards Not applicable
- 14.6 Special precautions for user
Special Provisions None
- 14.7 Maritime transport in bulk according to IMO instruments No information available

RID

- 14.1 UN number or ID number Not regulated
- 14.2 UN proper shipping name No information available
- 14.3 Transport hazard class(es) Not regulated
- 14.4 Packing group Not regulated
- 14.5 Environmental hazards Not applicable
- 14.6 Special precautions for user
Special Provisions None

ADR

- 14.1 UN number or ID number Not regulated
- 14.2 UN proper shipping name No information available
- 14.3 Transport hazard class(es) Not regulated
- 14.4 Packing group Not regulated
- 14.5 Environmental hazards Not applicable
- 14.6 Special precautions for user
Special Provisions None

SECTION 15: Regulatory information

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

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
Sodium chloride 7647-14-5	RG 78	-
Dimethyl sulfoxide 67-68-5	RG 84	-

Netherlands

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Dimethyl sulfoxide - 67-68-5	75.	-

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Plant protection products directive (91/414/EEC)

Chemical name	Plant protection products directive (91/414/EEC)
Sodium chloride - 7647-14-5	Plant protection agent
Sodium bicarbonate - 144-55-8	Plant protection agent

EU - Biocides

International Inventories

TSCA	-
DSL/NDSL	-
EINECS/ELINCS	-
ENCS	-
IECSC	-
KECL	-
PICCS	-
AICS	-

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Assessment No information available

SECTION 16: Other information**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend**

SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	Time weighted average	STEL	Short term exposure limit
Ceiling	Maximum limit value	*	Skin designation
**	Hazard Designation	+	Sensitizers

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
 U.S. Environmental Protection Agency ChemView Database
 European Food Safety Authority (EFSA)
 EPA (Environmental Protection Agency)
 Acute Exposure Guideline Level(s) (AEGl(s))
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
 U.S. Environmental Protection Agency High Production Volume Chemicals
 Food Research Journal
 Hazardous Substance Database
 International Uniform Chemical Information Database (IUCLID)
 Japan GHS Classification
 Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
 NIOSH (National Institute for Occupational Safety and Health)
 National Library of Medicine's ChemID Plus (NLM CIP)
 National Library of Medicine's PubMed database (NLM PUBMED)
 National Toxicology Program (NTP)
 New Zealand's Chemical Classification and Information Database (CCID)
 Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision Date 2022-12-25

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet