



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 2023-12-26

Revision Number 8

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

1.1. Product identifier

Product Code SL0019
Product Name Hepatocyte Maturation Medium Supplement (3B)
Pure substance/mixture Mixture

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

Identified uses For research use only. Not for use in diagnostic procedures
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
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	CAV "Osp. Pediatrico Bambino Gesù" Dip. Emergenza e Accettazione DEA Roma, Piazza Sant'Onofrio,4 00165 0668593726
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to

Regulation (EC) No. 1272/2008 [CLP]

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

Causes mild skin irritation.

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)
Acetic acid 64-19-7	0.1 - 1	No data available	200-580-7 (607-002-00-6)	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	Eye Irrit. 2 :: 10%≤C<25% Skin Corr. 1A :: C≥90% Skin Corr. 1B :: 25%≤C<90% Skin Irrit. 2 :: 10%≤C<25%	-	-

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
Acetic acid 64-19-7	3310	1060	11.4	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration ≥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	Prolonged contact may cause redness and irritation.
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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.
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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.
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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.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

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
Acetic acid 64-19-7	TWA: 25 mg/m ³ TWA: 10 ppm STEL: 50 mg/m ³ STEL: 20 ppm	TWA: 10 ppm TWA: 25 mg/m ³ STEL 20 ppm STEL 50 mg/m ³	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 15 ppm STEL: 38 mg/m ³	TWA: 25 mg/m ³ TWA: 10 ppm STEL: 50 mg/m ³ STEL: 20 ppm	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Acetic acid 64-19-7	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 50 mg/m ³ STEL: 20 ppm	TWA: 25 mg/m ³ Ceiling: 50 mg/m ³	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 50 mg/m ³ STEL: 20 ppm	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 10 ppm STEL: 25 mg/m ³	TWA: 5 ppm TWA: 13 mg/m ³ STEL: 10 ppm STEL: 25 mg/m ³
Chemical name	France	Germany TRGS	Germany DFG	Greece	Hungary
Acetic acid 64-19-7	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³	TWA: 10 ppm TWA: 25 mg/m ³	TWA: 10 ppm TWA: 25 mg/m ³ Peak: 20 ppm Peak: 50 mg/m ³	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 15 ppm STEL: 37 mg/m ³	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³
Chemical name	Ireland	Italy MDLPS	Italy AIDII	Latvia	Lithuania
Acetic acid 64-19-7	TWA: 20 ppm TWA: 50 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³	TWA: 25 ppm TWA: 10 mg/m ³ STEL: 50 mg/m ³ STEL: 20 ppm	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 15 ppm STEL: 37 mg/m ³	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 50 mg/m ³ STEL: 20 ppm	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 50 mg/m ³ STEL: 20 ppm
Chemical name	Luxembourg	Malta	Netherlands	Norway	Poland

Acetic acid 64-19-7	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 50 mg/m ³ STEL: 20 ppm	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³ A+	TWA: 25 mg/m ³ STEL: 50 mg/m ³
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Acetic acid 64-19-7	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³	TWA: 10 ppm TWA: 25 mg/m ³ Ceiling: 50 mg/m ³	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 50 mg/m ³ STEL: 20 ppm	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³
Chemical name	Sweden		Switzerland		United Kingdom
Acetic acid 64-19-7	NGV: 5 ppm NGV: 13 mg/m ³ Bindande KGV: 10 ppm Bindande KGV: 25 mg/m ³		TWA: 10 ppm TWA: 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³		TWA: 10 ppm TWA: 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³

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 Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

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	No data available	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. Causes mild skin irritation.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Prolonged contact may cause redness and irritation.

Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (dermal) 99,999.00 mg/kg

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Acetic acid	= 3310 mg/kg (Rat)	= 1060 mg/kg (Rabbit)	= 11.4 mg/L (Rat) 4 h

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

Skin corrosion/irritation	Classification based on data available for ingredients. Causes mild skin irritation.
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 0.58026 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Acetic acid	-	LC50: =79mg/L (96h, Pimephales promelas) LC50: =75mg/L (96h, Lepomis macrochirus)	-	EC50: =65mg/L (48h, Daphnia magna)

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
Acetic acid	-0.17

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment
Acetic acid	The substance is not PBT / vPvB

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

Germany

TA Luft (German Air Pollution Control Regulation)

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
Acetic acid - 64-19-7	75.	-

Persistent Organic Pollutants

Not applicable

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

Not applicable

EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Acetic acid - 64-19-7	Plant protection agent

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Acetic acid - 64-19-7	Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals Simplified procedure - Category 1

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)
 U.S. 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 2023-12-26

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