



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 4

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

1.1. Product identifier

Product Code ST2216
Product Name Amplification Enzyme
Pure substance/mixture Mixture
Contains Glycerol

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 Roma, Piazza Sant'Onofrio,4 00165 0668593726
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Inhalation (Dusts/Mists)	Category 4 - (H332)
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2.2. Label elements

Contains Glycerol



Signal word

Warning

Hazard statements

H332 - Harmful if inhaled

Precautionary Statements - EU (§28, 1272/2008)

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P271 - Use only outdoors or in a well-ventilated area

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing

P312 - Call a POISON CENTER or doctor if you feel unwell

Additional information

This product requires tactile warnings if supplied to the general public.

2.3. Other hazards

This mixture contains substances considered to be persistent, bioaccumulating and toxic (PBT). This mixture contains substances considered to be very persistent and very bioaccumulating (vPvB).

Endocrine Disruptor Information

Chemical name	EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation	EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances
Poly(oxyethylene) nonylphenyl ether (NP-40)	Endocrine disrupting properties	-

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)
Glycerol	60 - 70	No data available	200-289-5	No data available	-	-	-

56-81-5							
Sodium chloride 7647-14-5	0.1 - 1	No data available	231-598-3	No data available	-	-	-
Poly(oxyethylene) nonylphenyl ether (NP-40) 9016-45-9	0.1 - 1	No data available	-	No data available	-	-	-

Full text of H- and EUH-phrases: see section 16Acute 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
Glycerol 56-81-5	12600	10000	2.75	No data available	No data available
Sodium chloride 7647-14-5	3000	10000	No data available	No data available	No data available
Poly(oxyethylene) nonylphenyl ether (NP-40) 9016-45-9	2590	1774.66	No data available	No data available	No data available

This product contains one or more candidate substance(s) of very high concern (Regulation (EC) No. 1907/2006 (REACH), Article 59)

Chemical name	CAS No	SVHC candidates
Poly(oxyethylene) nonylphenyl ether (NP-40)	9016-45-9	X

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air. If symptoms persist, call a physician. If breathing has stopped, give artificial respiration. Get medical attention immediately.
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	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Get medical attention.
Self-protection of the first aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid breathing vapors or mists. Use personal protective equipment as required. See section 8 for more information.

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

Symptoms	Coughing and/ or wheezing. Difficulty in breathing.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

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.

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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation. Avoid breathing vapors or mists. Use personal protective equipment as required.

Other information Refer to protective measures listed in Sections 7 and 8.

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 Handle in accordance with good industrial hygiene and safety practice. Avoid breathing vapors or mists. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product.

General hygiene considerations Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

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
Glycerol 56-81-5	-	-	TWA: 10 mg/m ³	-	TWA: 10 mg/m ³
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Glycerol 56-81-5	-	TWA: 10 mg/m ³ Ceiling: 15 mg/m ³	-	TWA: 10 mg/m ³	TWA: 20 mg/m ³
Chemical name	France	Germany	Germany MAK	Greece	Hungary
Glycerol 56-81-5	TWA: 10 mg/m ³	TWA: 200 mg/m ³	TWA: 200 mg/m ³ Peak: 400 mg/m ³	TWA: 10 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
Chemical name	Luxembourg	Malta	Netherlands	Norway	Poland
Glycerol 56-81-5	-	-	-	-	TWA: 10 mg/m ³
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Glycerol 56-81-5	TWA: 10 mg/m ³	-	TWA: 11 mg/m ³	TWA: 200 mg/m ³ STEL: 400 mg/m ³	TWA: 10 mg/m ³
Chemical name	Sweden		Switzerland	United Kingdom	
Glycerol 56-81-5	-		TWA: 50 mg/m ³ STEL: 100 mg/m ³	TWA: 10 mg/m ³ STEL: 30 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 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 Do not eat, drink or smoke when using this product.

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	Clear, colorless
Color	No information available
Odor	Unpleasant.
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	392.8 °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 Excessive heat.

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. Harmful by inhalation. (based on components).
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 Coughing and/ or wheezing.

Numerical measures of toxicity

Acute toxicity

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

ATEmix (dermal)	15,860.40 mg/kg
ATEmix (inhalation-dust/mist)	4.36 mg/l

Unknown acute toxicity

2.51046 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Glycerol	= 12600 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 2.75 mg/L (Rat) 4 h
Sodium chloride	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h
Poly(oxyethylene) nonylphenyl ether (NP-40)	= 2590 mg/kg (Rat)	= 1780 µL/kg (Rabbit)	-

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

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

Unknown aquatic toxicity Contains 1.51046 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Glycerol	-	LC50: 51 - 57mL/L (96h, <i>Oncorhynchus mykiss</i>)	-	-
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>)

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
Glycerol	-1.75
Poly(oxyethylene) nonylphenyl ether (NP-40)	3.7

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
Glycerol	The substance is not PBT / vPvB
Sodium chloride	The substance is not PBT / vPvB PBT assessment does not apply
Poly(oxyethylene) nonylphenyl ether (NP-40)	PBT / vPvB substance

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	-

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
Poly(oxyethylene) nonylphenyl ether (NP-40) - 9016-45-9	46[b]. 46a.	-

Persistent Organic Pollutants

Not applicable

Export Notification requirements

This product contains substances which are regulated pursuant to Regulation (EC) No. 649/2012 of the European parliament and of the council concerning the export and import of dangerous chemicals

Chemical name	European Export/Import Restrictions per (EC) 689/2008 - Annex Number
Poly(oxyethylene) nonylphenyl ether (NP-40) - 9016-45-9	I.1 I.2

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

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:

PBT: Persistent, Bioaccumulative, and Toxic (PBT) Chemicals

vPvB: Very Persistent and very Bioaccumulative (vPvB) Chemicals

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