



# 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 2021-02-08

Revision Number 8

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

### 1.1. Product identifier

**Product Code** ST0344  
**Product Name** 5X In-Fusion® HD Enzyme Premix

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.  
1290 Terra Bella Avenue  
Mountain View, CA 94043  
Phone: 800.662.2566/888.251.6618  
Web: [www.takarabio.com](http://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](http://www.takarabio.com)

##### Europe:

Takara Bio Europe AB  
Arvid Wallgrens Backe 20,  
SE-413 46 Goteborg, Sweden  
Phone: +46 31 758 09 00  
Web: [www.takarabio.com](http://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 11 30886717

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).

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

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

Contains Glycerol

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



#### Signal word

None

#### Hazard statements

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

H332 - Harmful if inhaled

EUH210 - Safety data sheet available on request

#### 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

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	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Glycerol 56-81-5	60 - 100	No data available	200-289-5	No data available	-	-	-

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

Acute Toxicity Estimate

No information 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

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air. If symptoms persist, call a physician. If breathing has stopped, give artificial respiration. Get medical attention immediately.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
<b>Ingestion</b>	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get medical attention.
<b>Self-protection of the first aider</b>	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

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

<b>Note to physicians</b>	Treat symptomatically.
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## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

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

### 5.2. Special hazards arising from the substance or mixture

<b>Specific hazards arising from the chemical</b>	No information available.
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### 5.3. Advice for firefighters

<b>Special protective equipment for fire-fighters</b>	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

<b>Personal precautions</b>	Ensure adequate ventilation. Avoid breathing vapors or mists. Use personal protective
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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)

**Identified uses**

## 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 <sup>3</sup>	-	TWA 10 mg/m <sup>3</sup>
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Glycerol 56-81-5	-	-	-	TWA 10 mg/m <sup>3</sup>	TWA 20 mg/m <sup>3</sup>
Chemical name	France	Germany	Germany MAK	Greece	Hungary
Glycerol 56-81-5	TWA 10 mg/m <sup>3</sup>	-	AGW 200 mg/m <sup>3</sup>	TWA 10 mg/m <sup>3</sup>	-
Chemical name	Ireland	Italy	Italy REL	Latvia	Lithuania
Glycerol 56-81-5	-	200 mg/m <sup>3</sup> TWA AGW (the risk of damage to the	-	-	-

		embryo or fetus can be excluded when AGW and BGW values are observed, inhalable fraction, exposure factor 2)			
Chemical name	Luxembourg	Malta	Netherlands	Norway	Poland
Glycerol 56-81-5	-	-	-	-	TWA 10 mg/m <sup>3</sup>
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Glycerol 56-81-5	TWA 10 mg/m <sup>3</sup>	-	TWA 11 mg/m <sup>3</sup>	STEL 400 mg/m <sup>3</sup> TWA 200 mg/m <sup>3</sup>	TWA 10 mg/m <sup>3</sup>
Chemical name	Sweden		Switzerland		United Kingdom
Glycerol 56-81-5	-		SS-C** TWA 50 mg/m <sup>3</sup> STEL 100 mg/m <sup>3</sup>		STEL 30 mg/m <sup>3</sup> TWA 10 mg/m <sup>3</sup>

**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** Clear  
**Odor** Unpleasant.  
**Odor Threshold** No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>Melting point / freezing point</b>	No data available	None known
<b>Boiling point/boiling range (°C)</b>	No data available	None known
<b>Flammability (solid, gas)</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability limit:</b>	No data available	
<b>Lower flammability limit:</b>	No data available	

Flash point	No data available	Open cup
Autoignition temperature	392.8 °C	None known
Decomposition temperature		None known
pH		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		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**

<b>Inhalation</b>	Specific test data for the substance or mixture is not available. Harmful by inhalation. (based on components).
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available.
<b>Ingestion</b>	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

<b>ATEmix (oral)</b>	21,477.00 mg/kg
<b>ATEmix (dermal)</b>	20,020.00 mg/kg
<b>ATEmix (inhalation-dust/mist)</b>	4.3624 mg/l

**Unknown acute toxicity**

- 1 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
- 5.05819 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
- 55.05819 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
- 55.05819 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).
- 55.05819 % 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

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

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	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 5.0801 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Glycerol	-	51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static	-	-

### 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	-1.76

### 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.

### 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 Dispose of in accordance with local regulations. Dispose of waste in accordance with



products	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

#### 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 does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

#### Persistent Organic Pollutants

Not applicable

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

Not applicable

**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** 2021-02-08

**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.

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**End of Safety Data Sheet**