

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 2025-01-17 **Revision Number** 7

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

1.1. Product identifier

Product Code 631277

Product Name Lenti-X Packaging Single Shots (Integrase Deficient)

Pure substance/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

No information available Uses advised against

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).

Marco Marano Italy

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to

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

Hazardous to the aquatic environment - chronic Category 3 - (H412)

2.2. Label elements

Hazard statements

H412 - Harmful to aquatic life with long lasting effects

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

P273 - Avoid release to the environment

P501 - Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable

2.3. Other hazards

Harmful to aquatic life.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

The product contains no substances which at their given concentration, are considered to be hazardous to health

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 >=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 contactWash 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.

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing mediaDo 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.

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 upTake 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 This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

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

regulatory bodies.

Derived No Effect Level (DNEL)
Predicted No Effect Concentration

(PNEC)

No information available. No information available.

8.2. Exposure controls

Personal Protective Equipment

Eye/face protectionNo special protective equipment required.

Skin and body protectionNo 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 Solid

Appearance Lyophilized cake

Color White

Odor Odorless

Odor Threshold No information available

Property Values Remarks • Method

Melting point / freezing point

No data available

No data available

None known

No data available

None known

No data available

None known

None known

None known

None known

None known

None known

Upper flammability limit: No data available Lower flammability limit: No data available

Flash pointNo data availableOpen cupAutoignition temperatureNo data availableNone knownDecomposition temperatureNone known

pH No data available None known

No data available None known

No data available No information available

No data available Kinematic viscosity None known **Dynamic Viscosity** No data available None known None known No data available Water solubility Solubility in other solvents No data available None known Partition coefficient No data available None known Vapor pressure No data available None known None known

Vapor pressure
Relative density
No data available
Vapor density
No data available
No data available

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

None known

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

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

ATEmix (oral) 4,732.40 mg/kg **ATEmix (dermal)** 10,052.80 mg/kg

ATEmix (inhalation-dust/mist) 7.54 mg/l

Unknown acute toxicity

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

Skin corrosion/irritationNo 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 exposureNo 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 Harmful to aquatic life with long lasting effects.

Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessmentNo 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

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)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated 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)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special precautions for user

Special Provisions

14.7 Maritime transport in bulk No information available according to IMO instruments

None

<u>RID</u>

14.1 UN number or ID number Not regulated

14.2 UN proper shipping name No information available

14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special precautions for user

Special Provisions None

<u>ADR</u>

14.1 UN number or ID number Not regulated

14.2 UN proper shipping name No information available

14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated 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 (EU) 2024/590

Not applicable

International Inventories

TSCA DSL/NDSL EINECS/ELINCS ENCS IECSC KECI 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 Chemicals Inventory

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 * 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	

631277 - Lenti-X Packaging Single Shots (Integrase Deficient)

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)

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)

National Institute of Technology and Evaluation (NITE)

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 2025-01-17

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