

SAFETY DATA SHEET

according to US Regulation 29 CFR 1910.1200 and the Canadian HPA

X-Vivo™ 15 w/o Gentamicin and Phenol Red

Version 3.1

Revision Date 2025.03.20

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SECTION 1. IDENTIFICATION

Product name : X-Vivo™ 15 w/o Gentamicin and Phenol Red

Manufacturer or supplier's details

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel
Switzerland
Business Telephone +41 61 316 81 11

Lonza Rockland Inc.
191 Thomaston Street
Rockland, ME 04841-2994
USA
Business Telephone: 1-207-594-3400

Lonza Walkersville Inc.
8830 Biggs Ford Road
Walkersville, MD 21793-0127
USA
Business Telephone 1-301-898-7025

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

Recommended use of the chemical and restrictions on use

Recommended use : Suitable for GMP manufacturing.

Restrictions on use : Not for human or animal in vivo or diagnostic use.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture according to US Regulation 29 CFR 1910.1200 and the Canadian HPA.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

X-Vivo™ 15 w/o Gentamicin and Phenol Red

Hazardous components

Chemical name / Synonyms	CAS-No.	Concentration (% w/w)
Ethanol	64-17-5	0.1

SECTION 4. FIRST AID MEASURES

If inhaled	: Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	: Wash with water and soap as a precaution. If on clothes, remove clothes. In the case of skin irritation or allergic reactions see a physician.
In case of eye contact	: Flush eyes with water as a precaution. Remove contact lenses. Keep eye wide open while rinsing. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	: Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician.
Most important symptoms and effects, both acute and delayed	: No information available.
Notes to physician	: Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray
Unsuitable extinguishing media	: High volume water jet
Specific hazards during firefighting	: Heating or fire can release toxic gas.
Hazardous combustion products	: No hazardous combustion products are known
Further information	: Use a water spray to cool fully closed containers.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment.
Environmental precautions	: Try to prevent the material from entering drains or water courses.

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Methods and materials for containment and cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Advice on safe handling : No special precautions required.
For personal protection see section 8.

Conditions for safe storage : Keep container tightly closed.
Keep in a well-ventilated place.
To maintain product quality, do not store in heat or direct sunlight.

Materials to avoid : No special restrictions on storage with other products.

Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	STEL	1,000 ppm	ACGIH
	Only with the data for the liquid form	TWA	1,000 ppm 1,900 mg/m ³	NIOSH REL
		TWA	1,000 ppm 1,900 mg/m ³	OSHA Z-1

Engineering measures : Avoid splashes.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.
In the case of vapour formation use a respirator with an approved filter.

Hand protection

Remarks : Wear protective gloves. Break through time : > 480 min

Eye protection : Safety glasses

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Skin and body protection	:	Choose body protection according to the amount and concentration of the dangerous substance at the work place. Lightweight protective clothing
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aqueous solution
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	6.8 - 7.4
Melting point/freezing point	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Flammability (liquids)	:	No data available
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available

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SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No decomposition if stored and applied as directed.
Chemical stability	: Stable under recommended storage conditions.
Possibility of hazardous reactions	: Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	: Heat
Incompatible materials	: Oxidizing agents Strong acids and strong bases
Hazardous decomposition products	: No decomposition if used as directed. No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Acute oral toxicity	: Remarks: No data available
Acute inhalation toxicity	: Remarks: No data available
Acute dermal toxicity	: Remarks: No data available

Skin corrosion/irritation

Remarks	: No data available
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Serious eye damage/eye irritation

Remarks	: No data available
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Respiratory or skin sensitisation

Remarks	: No data available
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Germ cell mutagenicity

Genotoxicity in vitro	: Remarks: No data available
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Carcinogenicity

Remarks	: No data available
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IARC

Group 1: Carcinogenic to humans
Ethanol

64-17-5

OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Effects on fertility	: Remarks: No data available
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STOT - single exposure

Remarks : No data available

STOT - repeated exposure

Remarks : No data available

Aspiration toxicity

No aspiration toxicity classification

Further information

Remarks : No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Toxicity to fish : Remarks: No data available

Persistence and degradability

Biodegradability : Remarks: No data available

Bioaccumulative potential

Bioaccumulation : Remarks: No data available

Components:

Ethanol:

Partition coefficient: n-octanol/water : log Pow: -0.3

Mobility in soil

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Ozone-Depletion Potential : Regulation: US. EPA Clean Air Act (CAA) Section 602 Ozone-Depleting Substances (40 CFR 82, Subpt. A, App A & B)
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of contents/container in accordance with local regulation.
Contact waste disposal services.

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Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

DOT : Not dangerous goods

UN number : Not applicable
Proper shipping name : Not applicable
Transport hazard class : Not applicable
Packing group : Not applicable

TDG : Not dangerous goods

UN number : Not applicable
Proper shipping name : Not applicable
Transport hazard class : Not applicable
Packing group : Not applicable

IATA : Not dangerous goods

UN number : Not applicable
Proper shipping name : Not applicable
Transport hazard class : Not applicable
Packing group : Not applicable

IMDG : Not dangerous goods

UN number : Not applicable
Proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Packing group : Not applicable

ADR : Not dangerous goods

UN number : Not applicable
Proper shipping name : Not applicable
Transport hazard class : Not applicable
Packing group : Not applicable

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RID	:	Not dangerous goods
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Transport hazard class	:	Not applicable
Packing group	:	Not applicable
Special precautions for user	:	none
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	:	Not applicable

SECTION 15. REGULATORY INFORMATION

TSCA SNUR/Export notifications

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium selenite	10102-18-8	100	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 311/312 Hazards

See above: SECTION 2. Hazard Identification-GHS Classification

SARA 313

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

The following chemical(s) are listed as HAP under the U.S. Clean Air Act, Section 112 (40 CFR 61):

Components	CAS-No.	Concentration
Sodium selenite	10102-18-8	0.01 PPM

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

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The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489):

Components	CAS-No.	Concentration
Ethanol	64-17-5	0.1 %
Glycine	56-40-6	0.003 %
2-Aminoethanol	141-43-5	1 PPM

This product does not contain any VOC exemptions listed under the U.S. Clean Air Act Section 450.

Clean Water Act

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Components	CAS-No.	Component RQ (lbs)
Sodium selenite	10102-18-8	100

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Components	CAS-No.	Concentration
Sodium selenite	10102-18-8	0.01 PPM

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Components	CAS-No.
Water	7732-18-5

California Prop. 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Canadian lists

No substances are subject to a Significant New Activity Notification.

NPRI

Components	CAS-No.
Ethanol	64-17-5

The product components have the following inventory status:

TSCA : This product is regulated under the United States Food and Drug Act (FDA).

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits

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OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 2025.03.20

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.

Date format : yyyy/mm/dd

US / EN