

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

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

Version 1.0

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product name : X-Vivo™ 15 w/o Gentamicin and Phenol Red
Material number : BE08-879P1

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

Use of the Substance/Mixture : For Further Manufacturing or Laboratory Use. Performance characteristics have not been established.

1.3 Details of the supplier of the safety data sheet

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

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com

Responsible/issuing person

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Remarks : No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.

In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.

If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

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

Treatment : No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for 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).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : Take precautionary measures against static discharges.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Countries not listed may have their own country specific values.

Occupational Exposure Limits

Switzerland

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	TWA	500 ppm 960 mg/m ³	SMAK
		STEL	1 000 ppm 1 920 mg/m ³	SMAK

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Germany

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5		500 ppm 960 mg/m ³	TRGS 900
Peak-limit: excursion factor (category)		Peak-limit: excursion factor (category) 2		
		MAK	200 ppm 380 mg/m ³	DFG MAK
Peak-limit: excursion factor (category)		Peak-limit: excursion factor (category) 4		

Belgium

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	TWA	1 000 ppm 1 907 mg/m ³	BE/OEL

Denmark

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	GV	1 000 ppm 1 900 mg/m ³	GV (DK)

France

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	VLE	5 000 ppm 9 500 mg/m ³	FVL
		VME	1 000 ppm 1 900 mg/m ³	FVL

Italy

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	STEL	1 000 ppm	OEL (IT)

Netherlands

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	TGG	260 mg/m ³	NL OEL
		TGG 15	1 900 mg/m ³	NL OEL

Spain

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	STEL	1 000 ppm 1 910 mg/m ³	VLA

Sweden

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	TWA	500 ppm 1 000 mg/m ³	SWO
		STEL	1 000 ppm 1 900 mg/m ³	SWO

United Kingdom

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Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	TWA	1 000 ppm 1 920 mg/m ³	EH40 WEL

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Ethanol	Consumers	Oral	Long-term systemic effects	87 mg/kg
	Consumers	Dermal	Long-term systemic effects	206 mg/kg
	Consumers	Inhalation	Long-term systemic effects	114 mg/m ³
	Workers	Inhalation	Long-term systemic effects	950 mg/m ³
	Workers	Dermal	Long-term systemic effects	343 mg/kg

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Ethanol	Fresh water	0,96 mg/l
	Soil	0,63 mg/kg
	Fresh water sediment	3,6 mg/kg
	Marine water	0,79 mg/l
	Sewage treatment plant	580 mg/l
	Marine sediment	2,9 mg/kg
	Oral	380 mg/kg

8.2 Exposure controls

Engineering measures

Avoid splashes.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection

: Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

Respiratory protection

: No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : Aqueous solution

Colour : no data available

Odour : no data available

Odour Threshold : no data available

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pH	:	6,8 - 7,4
Freezing point	:	no data available
Boiling point/boiling range	:	no data available
Flash point	:	does not flash
Evaporation rate	:	no data available
Flammability (solid, gas)	:	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
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	no data available
Auto-ignition temperature	:	no data available
Decomposition temperature	:	no data available
Viscosity	:	no data available
Explosive properties	:	no data available
Oxidizing properties	:	no data available

9.2 Other information

no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

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Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on toxicological effects****Further information**

Remarks: No data is available on the product itself.

SECTION 12: Ecological information**12.1 Toxicity**

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Additional ecological information : no data available

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

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

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SECTION 14: Transport information

IATA Not dangerous goods

- 14.1 UN number : Not applicable
- 14.2 Proper shipping name : Not applicable
- 14.3 Transport hazard class : Not applicable
- 14.4 Packing group : Not applicable
- 14.5 Environmental hazards : no

IMDG Not dangerous goods

- 14.1 UN number : Not applicable
- 14.2 Proper shipping name : Not applicable
- 14.3 Transport hazard class : Not applicable
- 14.4 Packing group : Not applicable
- 14.5 Environmental hazards : Marine pollutant: no

ADR Not dangerous goods

- 14.1 UN number : Not applicable
- 14.2 Proper shipping name : Not applicable
- 14.3 Transport hazard class : Not applicable
- 14.4 Packing group : Not applicable
- 14.5 Environmental hazards : no

RID Not dangerous goods

- 14.1 UN number : Not applicable
- 14.2 Proper shipping name : Not applicable
- 14.3 Transport hazard class : Not applicable
- 14.4 Packing group : Not applicable
- 14.5 Environmental hazards : no

DOT Not dangerous goods

- 14.1 UN number : Not applicable
- 14.2 Proper shipping name : Not applicable
- 14.3 Transport hazard class : Not applicable
- 14.4 Packing group : Not applicable
- 14.5 Environmental hazards : no

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TDG	:	Not dangerous goods
14.1 UN number	:	Not applicable
14.2 Proper shipping name	:	Not applicable
14.3 Transport hazard class	:	Not applicable
14.4 Packing group	:	Not applicable
14.5 Environmental hazards	:	no
14.6 Special precautions for user	:	none
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	:	Not applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Ethanol

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water contaminating class (Germany) : WGK 1 slightly hazardous to water
Classification according to AwSV, Annex 1 (5.2)

15.2 Chemical safety assessment

not required

SECTION 16: Other information

Further information

Full text of other abbreviations

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden

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Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; 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; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Date format : dd.mm.yyyy

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