SAFETY DATA SHEET

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Commission Regulation (EU) 2020/878

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

1.1 Product identifier

Product name **Custom lyophilised product - Antibiotics**

Catalogue Number 28990028

Product description Not available.

Product type Solid.

Other means of identification Not available.

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

Identified uses

Use in laboratories
Analytical chemistry.
Scientific research and development

1.3 Details of the supplier of the safety data sheet

Supplier

Cytiva
Amersham Place
Little Chalfont
Buckinghamshire
HP7 9NA United Kingdom
+44 1494 508000

Hours of operation
08.30 - 17.00

Person who prepared the SDS : sds_author@cytiva.com

1.4 Emergency telephone number

Switzerland

Pall (Schweiz) GmbH
Schaeferweg 16
4057 Basel
Switzerland
t: 0848 8028 10

Call INFOTRAC 24 Hour number:
001-352-323-3500 (Calll Collect).

National advisory body/Poison Centre

Switzerland

Vergiftungsnotruf
Tel: 145

Aus dem Ausland oder bei technischen Problemen: +41 44 251 51 51

https://www.toxinfo.ch/notruf-145

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Repr. 1B, H360FD

The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

Ingredients of unknown toxicity
68 percent of the mixture consists of component(s) of unknown acute oral toxicity
72 percent of the mixture consists of component(s) of unknown acute dermal toxicity
71 percent of the mixture consists of component(s) of unknown acute inhalation toxicity

Ingredients of unknown ecotoxicity Contains 69% of components with unknown hazards to the aquatic environment

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms

Signal word	Danger
Hazard statements	May damage fertility. May damage the unborn child.
Precautionary statements	
General	Not applicable.
Prevention	Obtain special instructions before use. Wear protective gloves. Wear protective clothing: Recommended: lab coat. Wear eye or face protection. Wear hearing protection.
Response	IF exposed or concerned: Get medical advice or attention.
Storage	Not applicable.
Disposal	Dispose of contents and container in accordance with all local, regional, national and international regulations.
Supplemental label elements	Not applicable.
Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	Restricted to professional users.
Special packaging requirements	
Containers to be fitted with child-resistant fastenings	Not applicable.
Tactile warning of danger	Not applicable.

2.3 Other hazards

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Other hazards which do not result in classification None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures Mixture

Product/ingredient name	Identifiers	%	Classification Regulation (EC) No. 1272/2008 [CLP]		Type
disodium tetraborate decahydrate	REACH #: 01-2119490790-32 EC: 215-540-4 CAS: 1303-96-4 Index: 005-011-00-4	2	Acute Tox. 3, H331 Repr. 1B, H360FD	ATE [Inhalation (vapours)] = 3 mg/l	[1] [2] [3]
boric acid	REACH #: 01-2119486683-25 EC: 233-139-2 CAS: 10043-35-3 Index: 005-007-00-2	2	Repr. 1B, H360FD	-	[1] [2] [3]
			See Section 16 for the full text of the H statements declared above.		

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

[1] Substance classified with a physical, health or environmental hazard
[2] Substance with a workplace exposure limit
[3] Substance with carcinogenic, mutagenic or reproductive toxicity properties

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

Inhalation Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Skin contact Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Protection of first-aiders No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

Eye contact No specific data.

Inhalation Adverse symptoms may include the following:
reduced foetal weight
increase in foetal deaths
skeletal malformations

Skin contact Adverse symptoms may include the following:
reduced foetal weight
increase in foetal deaths
skeletal malformations

Ingestion Adverse symptoms may include the following:
reduced foetal weight
increase in foetal deaths
skeletal malformations

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture No specific fire or explosion hazard.

Hazardous combustion products Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
halogenated compounds
metal oxide/oxides

5.3 Advice for firefighters

Special precautions for fire-fighters Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
For emergency responders	If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
6.2 Environmental precautions	Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

Small spill	Move containers from spill area. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.
Large spill	Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.
6.4 Reference to other sections	See Section 1 for emergency contact information. See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

Protective measures	Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
Advice on general occupational hygiene	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store between the following temperatures: 18 to 25°C (64.4 to 77°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

7.3 Specific end use(s)

Recommendations	Analytical reagent. Laboratory chemicals Research and Development
Industrial sector specific solutions	Not available.

SECTION 8: Exposure controls/personal protection

The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario (s).

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
disodium tetraborate decahydrate	**SUVA (Switzerland, 1/2025) [Tetraborate]** Repr 1B. STEL 15 minutes: 0.8 mg/m³ (as Boron). Form: Inhalable fraction. TWA 8 hours: 0.8 mg/m³ (as Boron). Form: Inhalable fraction.
boric acid	**SUVA (Switzerland, 1/2025)** Repr 1B. STEL 15 minutes: 1.8 mg/m³ (as Boron). Form: Inhalable fraction. TWA 8 hours: 1.8 mg/m³ (as Boron). Form: Inhalable fraction.
dimethyl sulfoxide	**SUVA (Switzerland, 1/2025)** Absorbed through skin. TWA 8 hours: 50 ppm. TWA 8 hours: 160 mg/m³. STEL 15 minutes: 320 mg/m³. STEL 15 minutes: 100 ppm.
succinic acid	**SUVA (Switzerland, 1/2025)** TWA 8 hours: 2 mg/m³. Form: Inhalable fraction. STEL 15 minutes: 5 mg/m³. Form: Inhalable fraction.

Biological exposure indices

No exposure indices known.

Recommended monitoring procedures

Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

Product/ingredient name	Result
boric acid	**DNEL - General population - Short term - Oral** 0.98 mg/kg bw/day Effects: Systemic **DNEL - General population - Long term - Oral** 0.98 mg/kg bw/day Effects: Systemic **DNEL - General population - Long term - Inhalation** 4.15 mg/m³ Effects: Systemic **DNEL - Workers - Long term - Inhalation** 8.3 mg/m³ Effects: Systemic **DNEL - General population - Long term - Dermal** 196 mg/kg bw/day Effects: Systemic **DNEL - Workers - Long term - Dermal** 392 mg/kg bw/day Effects: Systemic

PNECs

Not available.

8.2 Exposure controls

Appropriate engineering controls

If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Individual protection measures

Hygiene measures

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Recommended: lab coat
Other skin protection	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory protection	Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use. Recommended: A respirator is not needed under normal and intended conditions of product use.
Environmental exposure controls	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

9.1 Information on basic physical and chemical properties

Appearance

Physical state	Solid.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
Melting point/freezing point	Not available.
Boiling point or initial boiling point and boiling range	Not available.
Flammability	Not available.
Lower and upper explosion limit	Not applicable.
Flash point	Not applicable.
Auto-ignition temperature	Not applicable.
Decomposition temperature	Not available.
pH	8
Viscosity	Dynamic (room temperature): Not available. Kinematic (room temperature): Not available. Kinematic (40°C): Not available.
Solubility in water	Not available.
Partition coefficient: n-octanol/ water	Not applicable.
Vapour pressure	Not available.
Relative density	Not available.
Relative vapour density	Not applicable.

Particle characteristics

Median particle size	Not available.

9.2 Other information

9.2.1 Information with regard to physical hazard classes

Burning time	Not available.
Burning rate	Not available.
Explosive properties	Not considered to be a product presenting a risk of explosion.
Oxidising properties	Not available.

9.2.2 Other safety characteristics

Evaporation rate	Not available.

Not applicable.

SECTION 10: Stability and reactivity

10.1 Reactivity No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability The product is stable.

10.3 Possibility of hazardous reactions Under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid No specific data.

10.5 Incompatible materials No specific data.

10.6 Hazardous decomposition products Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Product/ingredient name	Result
disodium tetraborate decahydrate	**Rat - Oral - LD50** 4500 mg/kg **Rabbit - Dermal - LD50** >2000 mg/kg **Rat - Oral - LD50** 2660 mg/kg **Rat - Inhalation - LC50 Vapour** >2 g/m³ [4 hours]
boric acid	**Rat - Oral - LD50** 2660 mg/kg

Conclusion/Summary [Product] Not available.

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
Custom lyophilised product - Antibiotics	N/A	N/A	N/A	43.5	19.4
disodium tetraborate decahydrate	2660	N/A	N/A	3	N/A
boric acid	2660	N/A	N/A	N/A	N/A

Skin corrosion/irritation

Not available.

Conclusion/Summary [Product] Not available.

Serious eye damage/eye irritation

Not available.

Conclusion/Summary [Product] Not available.

Respiratory corrosion/irritation

Not available.

Conclusion/Summary [Product] Not available.

Respiratory or skin sensitization

Not available.

Skin

Conclusion/Summary [Product] Not available.

Respiratory

Conclusion/Summary [Product] Not available.

Germ cell mutagenicity

Not available.

Conclusion/Summary [Product] Not available.

Carcinogenicity

Not available.

Conclusion/Summary [Product] Not available.

Reproductive toxicity

Not available.

Conclusion/Summary [Product] Not available.

Ingredient name	Conclusion/Summary
boric acid	Reproductive toxin

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

Potential acute health effects

Inhalation	No known significant effects or critical hazards.
Ingestion	No known significant effects or critical hazards.
Skin contact	No known significant effects or critical hazards.
Eye contact	No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Inhalation	Adverse symptoms may include the following: reduced foetal weight increase in foetal deaths skeletal malformations
Ingestion	Adverse symptoms may include the following: reduced foetal weight increase in foetal deaths skeletal malformations
Skin contact	Adverse symptoms may include the following: reduced foetal weight increase in foetal deaths skeletal malformations
Eye contact	No specific data.

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

Short term exposure

Potential immediate effects Not available.

Potential delayed effects Not available.

Long term exposure

Potential immediate effects Not available.

Potential delayed effects Not available.

Potential chronic health effects

Not available.

Conclusion/Summary [Product] Not available.

General	No known significant effects or critical hazards.
Carcinogenicity	No known significant effects or critical hazards.
Mutagenicity	No known significant effects or critical hazards.
Reproductive toxicity	May damage fertility. May damage the unborn child.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

Not available.

Conclusion/Summary [Product] The product does not meet the criteria to be considered as having endocrine disrupting properties according to the criteria set out in either Regulation (EC) No. 1907/2006 or Regulation (EC) No 1272/2008.

11.2.2 Other information

Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result
disodium tetraborate decahydrate	**Acute - LC50** Fish - *Salmo trutta* 27 mg/l [27 hours] **Acute - EC50** Daphnia 141 mg/l [48 hours]
boric acid	**Chronic - NOEC - Fresh water** Fish - Rainbow trout,donaldson trout - *Oncorhynchus mykiss* 2100 µg/l [87 days] Effect: Mortality **Chronic - NOEC - Fresh water** Daphnia - Water flea - *Daphnia magna* Age: <24 hours 6000 µg/l [21 days] Effect: Reproduction **Acute - LC50 - Fresh water** US EPA Crustaceans - Water flea - *Ceriodaphnia dubia* Age: <24 hours 45.5 mg/l [48 hours] Effect: Mortality **Acute - LC50 - Marine water** OECD Fish - Red sea bream - *Pagrus major* Weight: 0.6 g 75 mg/l [96 hours] Effect: Mortality

Conclusion/Summary [Product] Not available.

12.2 Persistence and degradability

Not available.

Conclusion/Summary [Product] Not available.

12.3 Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
boric acid	-1.09	-	Low

12.4 Mobility in soil

Soil/water partition coefficient

Not available.

Results of PMT and vPvM assessment

Product/ingredient name	PMT	P	M	T	vPvM	vP	vM
disodium tetraborate decahydrate	No	No	No	No	No	No	No
boric acid	No	No	No	No	No	No	No

Mobility Not available.

Conclusion/Summary The product does not meet the criteria to be considered as a PMT or vPvM.

12.5 Results of PBT and vPvB assessment

Regulation (EC) No. 1907/2006 [REACH]

Product/ingredient name	PBT	P	B	T	vPvB	vP	vB

disodium tetraborate decahydrate	No	No	No	No	No	No	No
boric acid	No	No	No	No	No	No	No

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

Product/ingredient name	PBT	P	B	T	vPvB	vP	vB
disodium tetraborate decahydrate	No	No	No	No	No	No	No
boric acid	No	No	No	No	No	No	No

Conclusion/Summary Regulation (EC) No. 1272/2008 [CLP] The product does not meet the criteria to be considered as a PBT or vPvB.

12.6 Endocrine disrupting properties

Not applicable.

Conclusion/Summary [Product] The product does not meet the criteria to be considered as having endocrine disrupting properties according to the criteria set out in either Regulation (EC) No. 1907/2006 or Regulation (EC) No 1272/2008.

12.7 Other adverse effects

No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.
Additional information	-	-	-	-

14.6 Special precautions for user **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Transport in bulk according to IMO instruments Not available.

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

Intrinsic property	Ingredient name	Status	Reference number	Date of revision
Toxic to reproduction	disodium tetraborate, anhydrous	Recommended	6th recommendation	7/1/2015
	boric acid	Recommended	6th recommendation	7/1/2015

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Product/ingredient name	%	Designation [Usage]
Custom lyophilised product - Antibiotics	≥90	30
disodium tetraborate decahydrate	≤3	30
boric acid	≤3	30

Labelling Restricted to professional users.

Other EU regulations

Industrial emissions (integrated pollution prevention and control) - Air Not listed

Industrial emissions (integrated pollution prevention and control) - Water Not listed

Explosive precursors Not applicable.

Ozone depleting substances (EU 2024/590)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Persistent Organic Pollutants

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

VOC content Exempt.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

United States Not determined.

Canada inventory Not determined.

China Not determined.

Japan **Japan inventory (CSCL)**: Not determined.
Japan inventory (ISHL): Not determined.

15.2 Chemical safety assessment This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Indicates information that has changed from previously issued version.

Abbreviations and acronyms

ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
N/A = Not available
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Repr. 1B, H360FD	Calculation method

Full text of abbreviated H statements

H331 Toxic if inhaled.
H360FD May damage fertility. May damage the unborn child.

Full text of classifications [CLP/GHS]

Acute Tox. 3 ACUTE TOXICITY - Category 3
Repr. 1B REPRODUCTIVE TOXICITY - Category 1B

Date of printing 16 February 2026

Date of issue/ Date of revision 16 February 2026

Date of previous issue 29 April 2024

Version 2.02

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.
Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.