Safety data sheet

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific

legislation

# bio<mark>sera</mark>

## XC-A4110 \_ Antibiotic-Antimycotic 100X



# SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING 1.1 Product identifier: XC-A4110 \_ Antibiotic-Antimycotic 100X

## Other means of identification: UFI:

PA00-H0DD-G003-TT55

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

Relevant uses: Used in biotechnology. For professional users/industrial user only.

Uses advised against: All uses not specified in this section or in section 7.3

## 1.3 Details of the supplier of the safety data sheet:

MSE SAS FRANCE 15 Rue du Mans 49300 Cholet - France Phone: +33 02 41 64 73 41 biosera@mse-sas.fr www.biosera.com

## **1.4 Emergency telephone number:**

## SECTION 2: HAZARDS IDENTIFICATION \*\*

## 2.1 Classification of the substance or mixture:

## CLP Regulation (EC) No 1272/2008:

Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.

Skin Sens. 1: Sensitisation, skin, Category 1, H317

#### 2.2 Label elements:

## CLP Regulation (EC) No 1272/2008:





#### Hazard statements:

Skin Sens. 1: H317 - May cause an allergic skin reaction.

#### **Precautionary statements:**

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

- P272: Contaminated work clothing should not be allowed out of the workplace.
- P280: Wear protective gloves/protective clothing/respiratory protection/eye protection/protective footwear.
- P302+P352: IF ON SKIN: Wash with plenty of water.

P321: Specific treatment is urgently needed (go to see a doctor with the Safety data sheet for this product).

P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

P362+P364: Take off contaminated clothing and wash it before reuse.

P501: Dispose of contents/container in accordance with regulations on hazardous waste or packaging and packaging waste respectively.

#### Supplementary information:

 $Contains \ so dium \ [2S-(2a,5a,6\beta)]-3,3-dimethyl-7-oxo-6-(phenylacetamido)-4-thia-1-azabicyclo \ [3.2.0] heptane-2-carboxylate.$ 

#### Substances that contribute to the classification

Streptomycin sulphate

**UFI:** PA00-H0DD-G003-TT55

#### 2.3 Other hazards:

Product does not meet PBT/vPvB criteria

Endocrine-disrupting properties: The product does not meet the criteria.

\*\* Changes with regards to the previous version

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS



#### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

#### 3.1 Substance:

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Non-applicable

#### 3.2 Mixture:

Chemical description: Mixture composed of additives and biocides

#### Components:

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

	Identification	Chemical name/Classification		Concentration
CAS:		Streptomycin sulphate <sup>(1)</sup> Sel	f-classified	
EC: Index: REACH:	223-286-0 Non-applicable Non-applicable	Regulation 1272/2008 Skin Sens. 1: H317; STOT SE 3: H335 - Warning	<b>()</b>	1 - <2,5 %
CAS: EC:	200-710-2	sodium         [2S-(2α,5α,6β)]-3,3-dimethyl-7-oxo-6-(phenylacetamido)-4-thia-1-         Sel           azabicyclo         [3.2.0]heptane-2-carboxylate <sup>(1)</sup> Sel	f-classified	
Index: REACH:	Non-applicable Non-applicable	Regulation 1272/2008 Resp. Sens. 1: H334; Skin Sens. 1: H317 - Danger	٠	<1 %

<sup>(1)</sup> Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2020/878

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

#### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

#### By inhalation:

This product is not classified as hazardous through inhalation. However, in case of intoxication symptoms it is recommended to remove the person affected from the area of exposure, provide clean air and keep at rest. Request medical attention if symptoms persist.

#### By skin contact:

May cause an allergic skin reaction. In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes on the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety Data Sheet

#### By eye contact:

Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

#### By ingestion/aspiration:

In case of consumption, seek immediate medical assistance showing the SDS for the product.

#### 4.2 Most important symptoms and effects, both acute and delayed:

Acute and delayed effects are indicated in sections 2 and 11.

#### 4.3 Indication of any immediate medical attention and special treatment needed:

Non-applicable

#### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media:

#### Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

#### Unsuitable extinguishing media:

Non-applicable





#### SECTION 5: FIREFIGHTING MEASURES (continued)

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

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

#### 5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

#### Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

#### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures:

#### For non-emergency personnel:

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

#### For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

#### 6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

#### 6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

#### 6.4 Reference to other sections:

See sections 8 and 13.

#### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling:

#### A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

B.- Technical recommendations for the prevention of fires and explosions

Revised: 01/12/2023

Product is non-flammable under normal conditions of storage, handling and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

#### 7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

## 7.3 Specific end use(s):





#### SECTION 7: HANDLING AND STORAGE (continued)

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

#### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):

There are no applicable occupational exposure limits for the substances contained in the product

#### **DNEL (Workers):**

Non-applicable

#### DNEL (General population):

Non-applicable

PNEC:

Non-applicable

#### 8.2 Exposure controls:

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
Mandatory respiratory tract protection	Filter mask for gases and vapours		EN 405:2002+A1:2010	Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment.

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
Mandatory hand protection	Protective gloves against minor risks	CATI		Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN ISO 21420:2020 and EN ISO 374-1:2016+A1:2018

As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance with total reliability and has therefore to be checked prior to the application.

#### D.- Eye and face protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
Mandatory face protection	Panoramic glasses against splash/projections.	CAT II	EN 166:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing	CATI		Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 6529:2013, EN ISO 6530:2005, EN ISO 13688:2013, EN 464:1994.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Pictogran	n	PPE	Labelling	CEN Standard	Remarks
		ip work shoes	CAT II	EN ISO 20347:2012	Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulation in EN ISO 20345:2012 y EN 13832-1:2007
F Additional emergency measures					
Emergen	cy measure	Si	itandards	Emergency measu	ire Standards
Emerger	+ ncy shower		ISI Z358-1 011, ISO 3864-4:20	11 Eyewash station	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011 s
Environmenta	l exposure co	ontrols:		•	·
spillage of both Volatile organ	the product an ic compounds	d its container. s:	For additional in	nformation see subsection	s recommended to avoid environmental n 7.1.D
-				owing characteristics:	
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,		/m³ (0 g/L)			
-	lecular weight:	Non-	applicable applicable PERTIES		
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- CONTINUED ON NEXT PAGE -

1,01 mm²/s

Non-applicable \*

pH:

Kinematic viscosity at 20 °C:

Kinematic viscosity at 40 °C:



SEC	TION 9: PHYSICAL AND CHEMICAL PROPERTIES	S (continued)
	Solubility in water at 20 °C:	Non-applicable *
	Solubility properties:	Non-applicable *
	Decomposition temperature:	Non-applicable *
	Melting point/freezing point:	Non-applicable *
	Flammability:	
	Flash Point:	Non Flammable (>60 °C)
	Flammability (solid, gas):	Non-applicable *
	Autoignition temperature:	Non-applicable *
	Lower flammability limit:	Non-applicable *
	Upper flammability limit:	Non-applicable *
	Particle characteristics:	
	Median equivalent diameter:	Non-applicable
9.2	Other information:	
	Information with regard to physical hazard clas	ses:
	Explosive properties:	Non-applicable *
	Oxidising properties:	Non-applicable *
	Corrosive to metals:	Non-applicable *
	Heat of combustion:	Non-applicable *
	Aerosols-total percentage (by mass) of flammable components:	Non-applicable *
	Other safety characteristics:	
	Surface tension at 20 °C:	Non-applicable *
	Refraction index:	Non-applicable *
	*Not relevant due to the nature of the product, not providing infor	mation property of its hazards.

## SECTION 10: STABILITY AND REACTIVITY

#### 10.1 Reactivity:

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No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.

#### 10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

#### 10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

#### 10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

#### **10.5** Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

#### 10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide ( $CO_2$ ), carbon monoxide and other organic compounds.

#### SECTION 11: TOXICOLOGICAL INFORMATION

legislation



## XC-A4110 \_ Antibiotic-Antimycotic 100X



#### SECTION 11: TOXICOLOGICAL INFORMATION (continued)

#### **11.1** Information on hazard classes as defined in Regulation (EC) No 1272/2008:

The experimental information related to the toxicological properties of the product itself is not available

#### Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

- A- Ingestion (acute effect):
  - Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for consumption. For more information see section 3

- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

- B- Inhalation (acute effect):
  - Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for inhalation. For more information see section 3.
  - Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it contains substances classified as hazardous for inhalation. For more information see section 3.
- C- Contact with the skin and the eyes (acute effect):
  - Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for skin contact. For more information see section 3.
  - Contact with the eyes: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):
  - Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.
  - IARC: Non-applicable
  - Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
  - Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- E- Sensitizing effects:
  - Respiratory: Based on available data, the classification criteria are not met. However, it contains substances classified as dangerous with sensitising effects. For more information see section 3.
  - Skin: Prolonged contact with the skin can result in episodes of allergic contact dermatitis.
- F- Specific target organ toxicity (STOT) single exposure:

Based on available data, the classification criteria are not met. However, it contains substances classified as hazardous for inhalation. For more information see section 3.

- G- Specific target organ toxicity (STOT)-repeated exposure:
  - Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as
  - it does not contain substances classified as hazardous for this effect. For more information see section 3.
  - Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

#### Other information:

Non-applicable

#### Specific toxicology information on the substances:

Identification	A	Acute toxicity		
Streptomycin sulphate	LD50 oral	430 mg/kg	Rat	
CAS: 3810-74-0	LD50 dermal	Non-applicable		
EC: 223-286-0	LC50 inhalation	Non-applicable		

11.2 Information on other hazards:

Endocrine disrupting properties

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#### SECTION 11: TOXICOLOGICAL INFORMATION (continued)

Endocrine-disrupting properties: The product does not meet the criteria.

#### Other information

Non-applicable

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#### SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

12.1 Toxicity:

Not available

12.2 Persistence and degradability:

Not available

**12.3 Bioaccumulative potential:** 

Not available

- **12.4 Mobility in soil:** Not available
- 12.5 Results of PBT and vPvB assessment:

Product does not meet PBT/vPvB criteria

**12.6 Endocrine disrupting properties:** 

Endocrine-disrupting properties: The product does not meet the criteria.

12.7 Other adverse effects:

Not described

## SECTION 13: DISPOSAL CONSIDERATIONS

#### **13.1** Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 05 09	discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08	Non-hazardous

#### Type of waste (Regulation (EU) No 1357/2014):

Non-applicable

#### Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-hazardous residue. Waste should not be disposed of to drains. See paragraph 6.2.

#### **Regulations related to waste management:**

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

#### SECTION 14: TRANSPORT INFORMATION

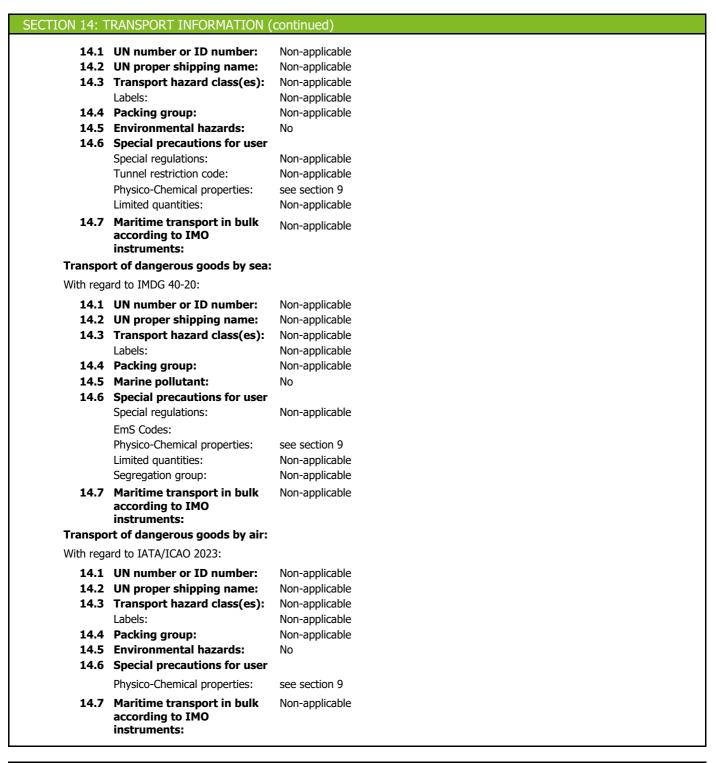
## Transport of dangerous goods by land:

With regard to ADR 2023 and RID 2023:



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#### SECTION 15: REGULATORY INFORMATION

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15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture: Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Non-applicable Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable Article 95, REGULATION (EU) No 528/2012: Non-applicable





#### SECTION 15: REGULATORY INFORMATION (continued)

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

#### Seveso III:

Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc ....):

Shall not be used in:

—ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,

-tricks and jokes,

-games for one or more participants, or any article intended to be used as such, even with ornamental aspects.

#### Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

#### Other legislation:

The product could be affected by sectorial legislation

#### 15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

#### SECTION 16: OTHER INFORMATION

#### Legislation related to safety data sheets:

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

#### Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

CLP Regulation (EC) No 1272/2008 (SECTION 2, SECTION 16):

Precautionary statements

#### Texts of the legislative phrases mentioned in section 2:

H317: May cause an allergic skin reaction.

#### Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

#### CLP Regulation (EC) No 1272/2008:

Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin Sens. 1: H317 - May cause an allergic skin reaction.

STOT SE 3: H335 - May cause respiratory irritation.

## **Classification procedure:**

Skin Sens. 1: Calculation method

#### Advice related to training:

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

#### Principal bibliographical sources:

http://echa.europa.eu

http://eur-lex.europa.eu

Abbreviations and acronyms:

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific

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# biosera

## XC-A4110 \_ Antibiotic-Antimycotic 100X



## SECTION 16: OTHER INFORMATION (continued)

ADR: European agreement concerning the international carriage of dangerous goods by road IMDG: International maritime dangerous goods code IATA: International Air Transport Association ICAO: International Civil Aviation Organisation COD: Chemical Oxygen Demand BOD5: 5day biochemical oxygen demand BCF: Bioconcentration factor LD50: Lethal Dose 50 LC50: Lethal Dose 50 LC50: Effective concentration 50 EC50: Effective concentration 50 LogPOW: Octanolwater partition coefficient Koc: Partition coefficient of organic carbon UFI: unique formula identifier IARC: International Agency for Research on Cancer

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