1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Identification of the substance or preparation

Product name: PYCEZE 500 mg/mL

1.2 Use of the substance/preparation

The preparation is indicated for the following uses:

- Prevention of the development of fungal infections (Saprolegnia spp) in common salmon eggs and farmed rainbow trout in case of suspected or confirmed presence of this kind of infection
- Prevention or reduction of fungal infections (Saprolegnia spp) in common salmon and rainbow trout kept in fresh water.

1.3 Company/undertaking identification

Supplier: CZ Vaccines S.A.U.
A Relva s/n - Torneiros
36410 O Porriño
Pontevedra
Spain

1.4 Emergency telephone

Supplier: +34 986 33 04 00
Monday to Thursday 8:00 - 17:30. Friday: 8:00 – 14:30

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture.

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification
applies.

Classification according to Regulation (EC) No 1272/2008 as amended

Physical hazards

Corrosive to metals	Category 1	H290 - May be corrosive to metals.

Health hazards

Acute toxicity, oral	Category 4	H302 - Harmful if swallowed
Skin corrosion/irritation	Category 2	H315 - Causes skin irritation.
Serious eye damage/eye irritation	Category 1	H318 - Causes serious eye damage.
Specific target organ toxicity – single exposure	Category 3 respiratory tract irritation	H335 - May cause respiratory irritation.

Environmental hazards

Hazardous to the aquatic environment, acute aquatic hazard	Category 1	H400 - Very toxic to aquatic life.
Hazardous to the aquatic environment, long-term aquatic hazard	Category 2	H411 - Toxic to aquatic life with long lasting effects.

2.2 Label element

Contains: BRONOPOL

Hazard pictograms

Signal word Danger

Hazard statements

H290	May be corrosive to metals.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention

P234	Keep only in original container.
P261	Avoid breathing mist or vapour.
P264	Wash thoroughly after handling.
P273	Avoid release to the environment.

Respuesta

P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P312	Call a POISON CENTRE/doctor if you feel unwell.
P390	Absorb spillage to prevent material damage.
P390	Absorb spillage to prevent material-damage.

Storage

P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P406	Store in corrosive resistant container with a resistant inner liner.

Disposal

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental label information

None.

2.3 Other hazards

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

API (mg/mL):

Bronopol……..500 mg

4. FIRST AID MEASURES

General information

If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show
this safety data sheet to the doctor in attendance.

Inhalation Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or doctor/physician if you feel unwell.

Skin contact Take off immediately all contaminated clothing. Rinse skin with water/shower. Call a physician or poison control centre immediately. Chemical burns must be treated by a physician. Wash contaminated clothing before reuse.

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician or poison control centre immediately.

Ingestion Call a physician or poison control centre immediately. Rinse mouth. Do not induce vomiting. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

Most important symptoms and effects, both acute and delayed

Harmful if swallowed. Skin irritation. Causes serious eye damage. May cause respiratory irritation.

Indication of any immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media Suitable extinguishing media
Alcohol resistant foam. Powder. Carbon dioxide (CO2). No water stream, it would spread the fire.

5.2 Special hazards arising from the substance or mixture
During fire, gases hazardous to health may be formed.

5.3 Advice for firefighters

Special protective equipment for firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures
Move containers from fire area if you can do so without risk.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions:
Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapour. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

6.2 Environmental precautions:
Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

6.3 Methods for cleaning up:
Use water spray to reduce vapours or divert vapour cloud drift. Should not be released into the environment. Prevent entry into waterways, sewer, basements or confined areas.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth
and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

7. HANDLING AND STORAGE

7.1 Handling
Provide adequate ventilation. Do not breathe mist or vapour. Do not get in eyes, on skin, or on clothing. When using, do not eat, drink or smoke. Wear appropriate personal protective

equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.

7.2 Storage
Store locked up. Store in original tightly closed container.

7.3 Specific use
Not available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limit values

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Occupational Exposure Limit: 8 hour TWA 0.5 mg/m3
Derived no effect levels (DNELs)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

8.2 Exposure controls

Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Eye wash facilities and emergency shower must be available when handling this product.

Individual protection measures, such as personal protective equipment

Eye/face protection	Safety glasses with side-shields conforming to EN 166.
Skin protection	
- Hand protection	Protective gloves complying with EN 374.
- Other	Wear appropriate chemical resistant clothing.
Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator. Use respirators and components tested

	and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Thermal hazards	Not available.
Hygiene measures	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants
Environmental exposure controls	Inform appropriate managerial or supervisory personnel of all environmental releases.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information

Appearance

- **Physical state**	Liquid.
- **Form**	Liquid.
- **Colour**	Clear, colorless to Pale yellow
Odour	Characteristic.
Odour threshold	Not available.
pH	< 4,5
Melting point/freezing point	0 °C (32 °F)
Initial boiling point and boiling range	104,3 °C (219,74 °F)
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

9.2 Important health, safety and environmental information

Density	1,23 g/cm^3

10. STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable and non reactive under normal conditions of use, storage and transport.

10.2 Chemical stability

Material is stable under normal conditions.

10.3 Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid
Contact with incompatible materials. Do not mix with other chemicals.

10.5 Incompatible materials
Strong oxidising agents. Bases. Aluminium. Metals.

10.6 Hazardous decomposition products
No hazardous decomposition products are known

11. TOXICOLOGICAL INFORMATION

General information Not available.

11.1. Information on toxicological effects

Acute toxicity Harmful if swallowed. May cause respiratory irritation.

Components	Species	Test Results
BRONOPOL (CAS 52-51-7)		
Acute		
Dermal		
LD50	Rat	> 1600 mg/kg (mortality)
Inhalation		
LC50	Rat	> 5000 mg/m³, 6 hours
Oral		
LD50	Rat	254 mg/kg

Skin corrosion/irritation Rabbit: Severe skin irritation. (Bronopol)

Serious eye damage/eye irritation Rabbit: Corrosive. (Bronopol)

Respiratory sensitisation Due to lack of data the classification is not possible

Skin sensitisation Guinea pig: Not a skin sensitiser. (Bronopol) Based on available data, the classification criteria are not met.

Germ cell mutagenicity Result in genetic toxicity assays (in vitro and in vivo): Negative (Bronopol). Based on available data, the classification criteria are not met.

Carcinogenicity No effects identified in animal studies. (Bronopol) Based on available data, the classification criteria are not met.

Reproductive toxicity	Developmental effects have been reported at doses toxic to the mother. Animal testing did not show any effects on reproductive performance. (Bronopol) Based on available data, the classification criteria are not met.
Specific target organ toxicity – single exposure	May cause respiratory irritation. (Bronopol)
Specific target organ toxicity – Repeated exposure	No significant target organ toxicity reported. (Bronopol). Based on available data, the classification criteria are not met.
Aspiration hazard	Not an aspiration hazard.
Mixture versus substance information	No information available.
Other information	Not available.

12. ECOLOGICAL INFORMATION

12.1. Toxicity Very toxic to aquatic life.

Components		Species	Test Results
BRONOPOL (CAS 52-51-7)			
Other	EC50	Pseudokirchneriella subcapitata	0,37 mg/l, 72 hours
	NOEC	Pseudokirchneriella subcapitata	0,1 mg/l, 72 hours
Aquatic			
Crustácea	EC50	Water flea (Daphnia magna)	1,4 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna)	0,27 mg/l, 21 days (flow-through)
Pez	LC50	Bluegill (Lepomis macrochirus)	36 mg/l, 96 hours
		Rainbow trout,donaldson trout (Oncorhynchus mykiss)	41 mg/l, 96 hours (flow-through) 39 mg/l, 49 days (flow-through) 20 mg/l, 96 hours (static)
	NOEC	Rainbow trout,donaldson trout (Oncorhynchus mykiss)	21 mg/l, 49 days (flow-through)

12.2. Persistence and degradability No data is available on the degradability of this product.

12.3. Bioaccumulative potential

Partition coefficient n-octanol/agua (log Kow)

BRONOPOL	-0,64
Bioconcentration factor (BCF)	Not available.

12.4. Mobility in soil No data available.

12.5. Results of PBT and vPvB assessment No Chemical Safety Assessment has been carried out.

12.6. Other adverse effects Not available.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Disposal methods/information Dispose of contents/container in accordance with local/regional/national/international regulations.

14. TRANSPORT INFORMATION

ADR

14.1. NU number
UN3265

14.2. UN proper shipping name
Corrosive liquid, acidic, organic, n.o.s. (Bronopol)

14.3. Transport hazard class(es)

Class	8
Subsidiary risk	-
Label(s)	8
Hazard No. (ADR)	80
Tunnel restriction code	E

14.4. Packing group
III

14.5. Environmental hazards
No.

14.6. Special precautions for user
Not available

RID

14.1. UN number
UN3265

14.2. UN proper shipping name
Corrosive liquid, acidic, organic, n.o.s. (Bronopol)

14.3. Transport hazard class(es)

Class	8
Subsidiary risk	-
Label(s)	8

14.4. Packing group
III

14.5. Environmental hazards
No

14.6. Special precautions for user
Not available

ADN

14.1. UN number
UN3265

14.2. UN proper shipping name
Corrosive liquid, acidic, organic, n.o.s. (Bronopol)

14.3. Transport hazard class(es)

Class	8
Subsidiary risk	-
Label(s)	8

14.4. Packing group
III

14.5. Environmental hazards
No

14.6. Special precautions for user
Not available

IATA

14.1. UN number
UN3265

14.2. UN proper shipping name
Corrosive liquid, acidic, organic, n.o.s. (Bronopol)

14.3. Transport hazard class(es)

Class	8

Subsidiary risk -

14.4. Packing group
III

14.5. Environmental hazards
ERG Code 8

14.6. Special precautions for user
Not available

Other information
Passenger and cargo aircraft Allowed with restrictions
Cargo aircraft only Allowed with restrictions

IMDG

14.1. UN number
UN3265

14.2. UN proper shipping name
CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (BRONOPOL)

14.3. Transport hazard class(es)
Class 8
Subsidiary risk -

14.4. Packing group III

14.5. Environmental hazards
Marine pollutant Yes
EmS F-A, S-B

14.6. Special precautions for user Not available.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established

ADN; ADR; IATA; IMDG; RID

Marine pollutant

15. REGULATORY INFORMATION

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended
Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended
Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended
Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended
Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended
Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended
Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA
Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended
Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended
Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Bronopol (CAS 52-51-7)

Other regulations
The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended and respective national laws implementing EC directives.

National regulations
Not available.

15.2. Chemical safety assessment
No Chemical Safety Assessment has been carried out.

16. OTHER INFORMATION

List of abbreviations	Not available.
References	Not available.
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any H-statements not written out in full under Sections 2 to 15	H301 Toxic if swallowed. H312 Harmful in contact with skin. H315 Causes skin irritation. H318 Causes serious eye damage. H335 May cause respiratory irritation. H400 Very toxic to aquatic life. H411 Toxic to aquatic life with long lasting effects.
Revision information	Product and Company Identification: Product Codes SECTION 8: Exposure controls/personal protection: Recommended monitoring procedures SECTION 12: Ecological information: 12,5. Results of PBT and vPvB assessment SECTION 16: Other information: Disclaimer

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