

SAFETY DATA SHEET

1. Product and Company Identification

- 1.1 Product Identifier**
Product code: ATP02-
Product name: Proteinase 3 (cANCA) antigen
CAS number Not relevant
Product of human origin: Yes
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Relevant identified uses: For research use or further manufacturing use only.
- 1.3 Details of the supplier of the safety data sheet**
Company name: AROTEC Diagnostics Limited
Address: 207 Gracefield Road, Lower Hutt 5010, New Zealand
Telephone/Fax: Telephone: +64-4-5690361, Fax: +64-4-5690366
e-mail (competent person): info@arodia.com
- 1.4 Emergency telephone**
 0800-764-766 (NZ); for international world directory of poison centres with local phone numbers refer:
http://www.who.int/gho/phe/chemical_safety/poisons_centres/en/#.VERM5zTweO4.email

2. Hazards Identification

- 2.1 Classification of the substance or mixture**
 Not a hazardous substance or mixture
- 2.2 Label Elements**
 Not a hazardous substance or mixture
 Signal Word Not required
 Pictograms Not required
 Hazard Statements Not required
 Precautionary Statements Not required
- 2.3 Other hazards**
 PBT and vPvB assessment Not required
 Endocrine disrupting properties Does not contain an endocrine disruptor

3. Composition/Information on Ingredients

- 3.1 Substances**
 Not relevant (mixture).

- 3.2 Mixtures**
 Description hazardous ingredients of the mixture.

Name	GHS classification	CAS Registry Number	Concentration	Pictograms
2-Methyl-4-Isothiazolin-3-one hydrochloride	Acute toxicity, Oral (category C), H301 Acute toxicity, Inhalation (Category B), H330 Acute toxicity, Dermal (Category C), H311 Skin corrosion (Category A), H318 Serious eye damage (Category A), H318 Skin sensitisation (Category B), H317 Aquatic toxicity (Acute or chronic) (Category A), H410	26172-54-3	<0.008%	

Products of human origin may contain agents which pose a potential biological hazard to humans. The source materials (blood from consenting donors) were tested and found to be negative for Hep B surface antigen, anti-Hep C virus antibodies, anti-HIV type I antibodies, anti-HIV type II antibodies, HIV RNA, HCV RNA and syphilis. No test method can provide complete assurance that infectious agents are absent, therefore all products of human origin should be handled as if they are potentially infectious.

4. First Aid Measures

4.1 Description of first aid measures

General advice:	Consult a physician, show this Safety Data Sheet to the doctor in attendance
Eye contact:	Flush immediately with plenty of water then consult a physician
Skin contact:	Remove contaminated clothing and shoes immediately, wash with soap and plenty of water
Inhalation:	Move into a fresh air environment
Ingestion:	Do <u>not</u> induce vomiting, rinse mouth with water, consult a physician

4.2 Most important symptoms and effects, both acute and delayed

This information is not available

4.3 Indication of any immediate medical attention and special treatment needed

This information is not available

5. Fire-Fighting Measures

5.1 Extinguishing Media

Suitable extinguishing media: Water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO₂), use extinguishing measures that are appropriate to the surrounding environment

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: None known

5.3 Advice for firefighters

Precautions for fire-fighters: Non-combustible.
Wear self-contained breathing apparatus for firefighting if necessary.
Coordinate firefighting measure the fire surrounds.
Do not allow firefighting water to enter drains or water courses.
Collect contaminated firefighting water separately.

6. Accidental Release Measures

6.1 Personal precautions, protective equipment, and emergency procedures

Non-emergency personnel:	Remove persons to safety, ensure adequate ventilation, wear suitable personal protective equipment to prevent skin, eyes or clothing contamination.
Emergency Responders:	Wear breathing apparatus if exposed to vapours/dust/spray/gases.

6.2 Environmental precautions

Do not let product enter drains and ground water.
Retain contaminated washing water and dispose of it.
If substance has entered a water course or sewer, inform the responsible authority

6.3 Methods & material for containment and cleaning up

Spill clean-up:	Collect spill (absorbent materials) and transfer to a suitable container. Ventilate the area
Containment:	Use of absorbent materials.

7. Handling and Storage

7.1 Precautions for safe handling

Measures to prevent fire, aerosol and dust generation:
Use local and general ventilation.
No specific notes / details available

Notes on general hygiene:
Do not eat, drink, smoke in work areas, wash hands after use, use of a skin barrier is recommended.

7.2 Conditions for safe storage including safe storage

Flammability hazard	None
Incompatibility	See section 10
Other advice	Keep away from food, drink and animal feed.
Ventilation	Provide sufficient ventilation
Storage vessels	Keep containers tightly closed in a cool, contained place
Packaging	Keep only in original container

7.3 Specific end uses

No information available

8. Exposure Controls/Personal Protection

8.1 Control Parameters

Exposure standards: Products do not contain any hazardous materials with workplace exposure limits

8.2 Exposure Controls

Engineering controls: Emergency showers, eyewash stations, ventilation systems
Environmental exposure: Use an appropriate container to avoid environmental contamination

Personal protection

Eye/face: Safety glasses recommended
Skin/body: Handle with gloves, wear suitable clothing such as a lab coat
Respiratory: Respiratory protection is not normally needed when using these products; use a particle respirator for nuisance exposure or when in an area with inadequate ventilation

9. Physical and Chemical Properties

9.1 Basic physical and chemical properties

Appearance: Clear, colourless liquid/frozen liquid
Odour: No information available
pH: 8.0
Vapour pressure: No information available
Vapour density: No information available
Boiling point: No information available
Freezing point: No information available
Solubility: No information available
Specific gravity: No information available
Flammability: Not combustible

9.2 Other Information

Physical hazard class: Not relevant
Other characteristics: No additional information

10. Stability and Reactivity

10.1 Reactivity

Stable under ambient conditions

10.2 Chemical stability

Stable under anticipated storage and handling conditions

10.3 Possibility of hazardous reactions

None known

10.4 Conditions to avoid

There are no specific conditions known which have to be avoided

10.5 Incompatible materials

There is no additional information

10.6 Hazardous decomposition

Reasonably anticipated hazardous decomposition products are not known.

11. Toxicological Information

11.1 Information on toxicological effects

Classification based on the ingredients of the mixture, and according to GHS.

Acute toxicity: No information available on the complete mixture.

Name	CAS	Route	End Point	Value	Species	Source
2-Methyl-4- Isothiazolin-3- one hydrochloride	26172-54-3	Oral	LD50	175mg/kg bw	Mouse	ECHA

Skin corrosion/irritation: Classification could not be established.

Serious eye damage/irritation: Classification could not be established.

Respiratory or skin sensitisation: Classification could not be established.

Germ cell mutagenicity: Classification could not be established.

Carcinogenicity: Classification could not be established.

Reproductive toxicity: Classification could not be established.

Specific target organ toxicity: Classification could not be established.

(single and repeated exposure)

Aspiration hazard: No aspiration hazard

11.2 Information on other hazards

Endocrine disrupting properties: Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0.1\%$.

12. Ecological Information

12.1 Toxicity

Aquatic toxicity

Classification based on the ingredients of the mixture, and according to GHS.

No information available on the complete mixture.

Name	CAS	Endpoint	Exposure Time	Value	Species	Method	Source
2-Methyl-4- Isothiazolin-3- one hydrochloride	26172-54-3	EC50	48hr	2.33mg/L	Daphnia magna (Straus)	OECD Guideline 202	ECHA

12.2 Persistence and degradability

Classification based on the ingredients of the mixture, and according to GHS.

No information available on the complete mixture.

Name	CAS	Conclusion	Exposure Time	Value	Species	Method	Source
2-Methyl-4- Isothiazolin-3- one hydrochloride	26172-54-3	No readily biodegradable	28 days	2.33mg/L	Activated sludge	OECD Guideline 301B	ECHA

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Does not contain a PBT or vPvB substance in a concentration $\geq 0.1\%$.

12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0.1\%$.

13. Disposal Considerations

13.1 Waste treatment methods

Disposal methods: Dispose of material as hazardous waste.
Sewage Disposal: Do not empty into drains
Contaminated packaging: Completely emptied packages can be recycled.

14. Transport Information

14.1 UN number: Not assigned
14.2 Proper shipping name: Not regulated by DOT, IATA, ADR, TDG , IMDG
14.3 Transport hazard class: Not assigned
14.4 Packing group: Not assigned
14.5 Environmental hazards: Not assigned
14.6 Special precautions for user: Not assigned
14.7 Maritime transport in bulk according to IMO instruments: Not assigned

15. Regulatory Information

15.1 Safety health / environment regulations / legislation specific for the substance or the mixture Relevant

This Safety Data Sheet complies with the Commission Regulation (EU) 2020/878.

15.2 Chemical Safety Assessment

No chemical safety assessment has been completed

16. Other Information

Issue Date: April 2023

Disclaimer: The information provided here is correct to the best of our knowledge however neither the above-named company nor any of its subsidiaries or distributors assumes any liability whatsoever for the accuracy or completeness of this information. The information given is designed only as a guide to safe handling, use, storage, processing, transportation and disposal and is not to be considered as a warranty for specification or performance in any particular application. Determination of suitability of any material is ultimately the sole responsibility of the user. Although certain hazards are described here, we do not guarantee that other hazards do not exist. All materials may present unknown hazards and should be handled accordingly.