

Recombinant Bovine Aprotinin Apollo Scientific

Part Number: **BITP1462** Version No: **1.1** Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878) Chemwatch Hazard Alert Code: 2

Issue Date: 06/07/2023 Print Date: 06/07/2023 S.REACH.GB-NIR.EN

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

1.1. Product Identifier

Product name	Recombinant Bovine Aprotinin	
Synonyms	Not Available	
Other means of identification	Not Available	

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

Relevant identified uses	Use according to manufacturer's directions.
Uses advised against	No specific uses advised against are identified.

1.3. Details of the manufacturer or supplier of the safety data sheet

Registered company name	Apollo Scientific
Address	Whitefield Road, Bredbury SK62QR United Kingdom
Telephone	01614060505
Fax	0161 406 0506
Website	http://www.apolloscientific.co.uk/
Email	sales@apolloscientific.co.uk

1.4. Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	Not Available
Other emergency telephone numbers	Not Available

SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

Classification according to
regulation (EC) No 1272/2008
[CLP] and amendments [1]

H315 - Skin Corrosion/Irritation Category 2, H319 - Serious Eye Damage/Eye Irritation Category 2, H335 - Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3

1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

2.2. Label elements

Hazard pictogram(s)



Signal word

Warning

Hazard statement(s)

. ,	
H315	Causes skin irritation.
H319	Causes serious eye irritation.

Part Number: BITP1462 Page 2 of 11

Version No: 1.1

Recombinant Bovine Aprotinin

Issue Date: **06/07/2023**Print Date: **06/07/2023**

H335

May cause respiratory irritation.

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

P271	Use only outdoors or in a well-ventilated area.	
P261	Avoid breathing dust/fumes.	
P280	Wear protective gloves, protective clothing, eye protection and face protection.	
P264	Wash all exposed external body areas thoroughly after handling.	

Precautionary statement(s) Response

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 CENTER/doctor/physician/first aider/if you feel unwell.	
P337+P313	If eye irritation persists: Get medical advice/attention.	
P302+P352	IF ON SKIN: Wash with plenty of water.	
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.	
P332+P313	If skin irritation occurs: Get medical advice/attention.	
P362+P364	Take off contaminated clothing and wash it before reuse.	

Precautionary statement(s) Storage

P405	Store locked up.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

Precautionary statement(s) Disposal

P501 Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

2.3. Other hazards

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3 Composition / information on ingredients

3.1.Substances

See 'Composition on ingredients' in Section 3.2

3.2.Mixtures

1. CAS No 2.EC No 3.Index No 4.REACH No	%[weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
Not Available	100	Recombinant Bovine Aprotinin	Not Applicable	Not Applicable	Not Available
Legend:	1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties				

SECTION 4 First aid measures

4.1. Description of first aid measures

·	
Eye Contact	If this product comes in contact with the eyes: Wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	 If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. Transport to hospital, or doctor, without delay.
Ingestion	 Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Part Number: BITP1462 Version No: 1.1

Page 3 of 11 **Recombinant Bovine Aprotinin**

Issue Date: 06/07/2023 Print Date: 06/07/2023

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures

5.1. Extinguishing media

- ▶ There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

5.2. Special hazards arising from the substrate or mixture

·			
Fire Incompatibility	None known.		
5.3. Advice for firefighters			
Fire Fighting	 Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. Use fire fighting procedures suitable for surrounding area. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use. 		
Fire/Explosion Hazard	 Non combustible. Not considered a significant fire risk, however containers may burn. May emit poisonous fumes. May emit corrosive fumes. 		

SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

See section 8

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

Minor Spills	 Clean up all spills immediately. Avoid breathing dust and contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust. Sweep up, shovel up or Vacuum up (consider explosion-proof machines designed to be grounded during storage and use). Place spilled material in clean, dry, sealable, labelled container.
Major Spills	Moderate hazard. CAUTION: Advise personnel in area. Alert Emergency Services and tell them location and nature of hazard. Control personal contact by wearing protective clothing. Prevent, by any means available, spillage from entering drains or water courses. Recover product wherever possible. If DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal. ALWAYS: Wash area down with large amounts of water and prevent runoff into drains. If contamination of drains or waterways occurs, advise Emergency Services.

6.4. Reference to other sections

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

7.1. Precautions for safe handling

	Wear protective clothing when risk of exposure occurs.
	Use in a well-ventilated area.
	Prevent concentration in hollows and sumps.
Safe handling	DO NOT enter confined spaces until atmosphere has been check
	DO NOT allow material to contact humans, exposed food or food

- cked. od utensils.
- Avoid contact with incompatible materials.
- ▶ When handling, **DO NOT** eat, drink or smoke.

▶ Avoid all personal contact, including inhalation.

Part Number: BITP1462 Page 4 of 11

Version No: 1.1

Recombinant Bovine Aprotinin

Issue Date: **06/07/2023**Print Date: **06/07/2023**

- ▶ Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- ▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use.
- Use good occupational work practice.
- Observe manufacturer's storage and handling recommendations contained within this SDS.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

Fire and explosion protection See section 5

- Store in original containers.Keep containers securely sealed.
- Store in a cool, dry area protected from environmental extremes.
- Store away from incompatible materials and foodstuff containers
- Protect containers against physical damage and check regularly for leaks.
- ▶ Observe manufacturer's storage and handling recommendations contained within this SDS.

Other information

For major quantities:

- Consider storage in bunded areas ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams).
- Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities.

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	 Polyethylene or polypropylene container. Check all containers are clearly labelled and free from leaks.
Storage incompatibility	None known
Hazard categories in accordance with Regulation (EC) No 1272/2008	Not Available
Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of	Not Available

7.3. Specific end use(s)

See section 1.2

SECTION 8 Exposure controls / personal protection

8.1. Control parameters

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
Not Available	Not Available	Not Available

^{*} Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not Available						

Not Applicable

Emergency Limits

Ingredient	TEEL-1	TEEL-2		TEEL-3
Recombinant Bovine Aprotinin	Not Available	Not Available		Not Available
Ingredient	Original IDLH		Revised IDLH	
Recombinant Bovine Aprotinin	Not Available		Not Available	

8.2. Exposure controls

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are:

Process controls which involve changing the way a job activity or process is done to reduce the risk.

Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.

Employers may need to use multiple types of controls to prevent employee overexposure.

8.2.1. Appropriate engineering controls

- Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction.
- If in spite of local exhaust an adverse concentration of the substance in air could occur, respiratory protection should be considered. Such protection might consist of:
- (a): particle dust respirators, if necessary, combined with an absorption cartridge;
- (b): filter respirators with absorption cartridge or canister of the right type;

Part Number: BITP1462 Page 5 of 11 Issue Date: 06/07/2023 Version No: 1.1

Recombinant Bovine Aprotinin

Print Date: 06/07/2023

(c): fresh-air hoods or masks.

Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)
grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted. accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 4-10 m/s (800-2000 f/min) for extraction of crusher dusts generated 2 metres distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

8.2.2. Individual protection measures, such as personal protective equipment











- ► Safety glasses with side shields.
- Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]

Eye and face protection

Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

Skin protection

See Hand protection below

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.

Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- · frequency and duration of contact,
- $\boldsymbol{\cdot}$ chemical resistance of glove material,
- · glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- · When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- · When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- · Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.
- · Contaminated gloves should be replaced.

As defined in ASTM F-739-96 in any application, gloves are rated as:

- · Excellent when breakthrough time > 480 min Hands/feet protection
 - \cdot Good when breakthrough time > 20 min
 - · Fair when breakthrough time < 20 min
 - · Poor when glove material degrades

For general applications, gloves with a thickness typically greater than $0.35\ mm$, are recommended.

It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times

Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task

Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:

- · Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.
- · Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present

- polychloroprene.
- nitrile rubber.
- butvl rubber.
- ▶ fluorocaoutchouc

Version No: 1.1

Recombinant Bovine Aprotinin

Issue Date: **06/07/2023**Print Date: **06/07/2023**

	polyvinyl chloride. Gloves should be examined for wear and/ or degradation constantly.
Body protection	See Other protection below
Other protection	 Overalls. P.V.C apron. Barrier cream. Skin cleansing cream. Eye wash unit.

Respiratory protection

Type -P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	-	PAPR-P1
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- · Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- · Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)
- · Use approved positive flow mask if significant quantities of dust becomes airborne.
- · Try to avoid creating dust conditions.

8.2.3. Environmental exposure controls

See section 12

SECTION 9 Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Not Available		
Physical state	Solid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Available
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Not Available	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available

Page **7** of **11**

Recombinant Bovine Aprotinin

Issue Date: **06/07/2023**Print Date: **06/07/2023**

Particle Size

Not Available

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

10.1.Reactivity	See section 7.2
10.2. Chemical stability	 Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
10.3. Possibility of hazardous reactions	See section 7.2
10.4. Conditions to avoid	See section 7.2
10.5. Incompatible materials	See section 7.2
10.6. Hazardous decomposition products	See section 5.3

SECTION 11 Toxicological information

11.1. Information on toxicological effects

Inhaled	The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.		
Ingestion	The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.		
Skin Contact	This material can cause inflammation of the skin on contact in some persons. The material may accentuate any pre-existing dermatitis condition Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. This material can cause eye irritation and damage in some persons.		
Eye			
Chronic		ult in airways disease, involving difficulty breathing and related whole-bo occur and may cause some concern following repeated or long-term occ	
Recombinant Bovine	TOXICITY	IRRITATION	
Aprotinin	Not Available	Not Available	
Legend:	Nalue obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances		

Recombinant Bovine Aprotinin

Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.

Acute Toxicity	×	Carcinogenicity	×
Skin Irritation/Corrosion	✓	Reproductivity	×
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✓
Respiratory or Skin sensitisation	×	STOT - Repeated Exposure	×
Mutagenicity	×	Aspiration Hazard	×

Legend

🗶 - Data either not available or does not fill the criteria for classification

Data available to make classification

11.2 Information on other hazards

Version No: 1.1

Recombinant Bovine Aprotinin

Issue Date: **06/07/2023**Print Date: **06/07/2023**

No evidence of endocrine disrupting properties were found in the current literature.

11.2.2. Other information

See Section 11.1

SECTION 12 Ecological information

12.1. Toxicity

D. I. I. I. I. I.	Endpoint	Test Duration (hr)	Species	Value	Source
Recombinant Bovine Aprotinin	Not Available	Not Available	Not Available	Not Available	Not Available
Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Su Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard A - Bioconcentration Data 8. Vendor Data					

DO NOT discharge into sewer or waterways.

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
	No Data available for all ingredients

12.4. Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

12.5. Results of PBT and vPvB assessment

	P	В	Т
Relevant available data	Not Available	Not Available	Not Available
PBT	×	×	×
vPvB	X	×	X
PBT Criteria fulfilled?			No
vPvB			No

12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.

SECTION 13 Disposal considerations

13.1. Waste treatment methods

Product / Packaging disposal	 Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill. Recycle containers if possible, or dispose of in an authorised landfill.
Waste treatment options	Not Available
Sewage disposal options	Not Available

SECTION 14 Transport information

Labels Required

Marine Pollutant	NO	
HAZCHEM	Not Applicable	

Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number or ID number	Not Applicable
14.2. UN proper shipping name	Not Applicable

Part Number: BITP1462 Page 9 of 11 Issue Date: 06/07/2023 Print Date: 06/07/2023 Version No: 1.1

Recombinant Bovine Aprotinin

	4.3 Transport hazard Class Not Applicable			
14.3	. Transport hazard class(es)	Subsidiary risk Not Applicable		
		• 1		
	. Packing group	Not Applicable		
14.5	. Environmental hazard	Not Applicable		
		Hazard identification (Kemler) Not Applicable		
		Classification code	Not Applicable	
14.6	. Special precautions for	Hazard Label	Not Applicable	
	user	Special provisions Not Applicable		
		Limited quantity	Not Applicable	
		Tunnel Restriction Cod	de Not Applicable	
		- -	FOR TRANSPORT OF DANGEROU	JS GOODS
	. UN number	Not Applicable		
14.2	. UN proper shipping name	Not Applicable		
		ICAO/IATA Class	Not Applicable	
14.3	. Transport hazard class(es)	ICAO / IATA Subrisk	Not Applicable	
	01400(00)	ERG Code	Not Applicable	
14.4	. Packing group	Not Applicable		
	. Environmental hazard	Not Applicable		
		0		Nist Applicable
		Special provisions	note: until and	Not Applicable
		Cargo Only Packing Ir		Not Applicable
14.6	. Special precautions for	Cargo Only Maximum Qty / Pack		Not Applicable
	user	Passenger and Cargo Packing Instructions		Not Applicable
		Passenger and Cargo Maximum Qty / Pack Passenger and Cargo Limited Quantity Packing Instructions		Not Applicable Not Applicable
			Limited Maximum Qty / Pack	Not Applicable Not Applicable
		rassenger and Gargo	LIIIIILEU WAXIIIIUIII QIY / FACK	
		0 0		Teet / ppilodule
Sea to	ransport (IMDG-Code / GG		TED FOR TRANSPORT OF DANG	
	ransport (IMDG-Code / GO		<u> </u>	
14.1		GVSee): NOT REGULA	<u> </u>	
14.1	. UN number . UN proper shipping name	SVSee): NOT REGULA' Not Applicable Not Applicable	TED FOR TRANSPORT OF DANG	
14.1	UN number UN proper shipping	Not Applicable IMDG Class Not Applicable	<u> </u>	
14.1	UN number UN proper shipping name Transport hazard	Not Applicable IMDG Class Not Applicable	TED FOR TRANSPORT OF DANG	
14.1	UN number UN proper shipping name Transport hazard class(es)	Not Applicable Not Applicable IMDG Class IMDG Subrisk Not	TED FOR TRANSPORT OF DANG	
14.1	UN number UN proper shipping name Transport hazard class(es) Packing group	Not Applicable IMDG Class Not IMDG Subrisk Not Not Applicable	TED FOR TRANSPORT OF DANG	
14.1 14.2 14.3 14.4 14.5	UN number UN proper shipping name Transport hazard class(es) Packing group Environmental hazard Special precautions for	Not Applicable IMDG Class Not IMDG Subrisk Not Not Applicable Not Applicable	TED FOR TRANSPORT OF DANG Applicable Applicable	
14.1 14.2 14.3 14.4 14.5	. UN number . UN proper shipping name . Transport hazard class(es) . Packing group . Environmental hazard	Not Applicable IMDG Class Not IMDG Subrisk Not Not Applicable Not Applicable Not Applicable EMS Number	TED FOR TRANSPORT OF DANG Applicable Applicable Not Applicable	
14.1 14.2 14.3 14.4 14.5	UN number UN proper shipping name Transport hazard class(es) Packing group Environmental hazard Special precautions for	Not Applicable IMDG Class Not IMDG Subrisk Not Not Applicable Not Applicable Not Applicable EMS Number Special provisions	TED FOR TRANSPORT OF DANG Applicable Applicable Not Applicable Not Applicable	
14.1 14.2 14.3 14.4 14.5	. UN number . UN proper shipping name . Transport hazard class(es) . Packing group . Environmental hazard . Special precautions for user	Not Applicable IMDG Class Not IMDG Subrisk Not Not Applicable Not Applicable Not Applicable EMS Number Special provisions Limited Quantities	TED FOR TRANSPORT OF DANG Applicable Applicable Not Applicable Not Applicable	EROUS GOODS
14.1 14.2 14.3 14.4 14.5	. UN number . UN proper shipping name . Transport hazard class(es) . Packing group . Environmental hazard . Special precautions for user	Not Applicable IMDG Class Not IMDG Subrisk Not Not Applicable Not Applicable Not Applicable EMS Number Special provisions Limited Quantities	TED FOR TRANSPORT OF DANG Applicable Applicable Not Applicable Not Applicable Not Applicable	EROUS GOODS
14.1 14.2 14.3 14.4 14.5 14.6	. UN number . UN proper shipping name . Transport hazard class(es) . Packing group . Environmental hazard . Special precautions for user	Not Applicable IMDG Class Not IMDG Subrisk Not Not Applicable Not Applicable Not Applicable EMS Number Special provisions Limited Quantities DN): NOT REGULATED	TED FOR TRANSPORT OF DANG Applicable Applicable Not Applicable Not Applicable Not Applicable	EROUS GOODS
14.1 14.2 14.3 14.4 14.5 14.6 Inlance 14.1 14.2	. UN number . UN proper shipping name . Transport hazard class(es) . Packing group . Environmental hazard . Special precautions for user d waterways transport (Al. UN number . UN proper shipping	Not Applicable IMDG Class Not IMDG Subrisk Not Not Applicable Not Applicable Not Applicable EMS Number Special provisions Limited Quantities DN): NOT REGULATED Not Applicable Not Applicable	TED FOR TRANSPORT OF DANG Applicable Applicable Not Applicable Not Applicable Not Applicable	EROUS GOODS
14.1 14.2 14.3 14.4 14.5 14.6 Inlane 14.1 14.2	. UN number . UN proper shipping name . Transport hazard class(es) . Packing group . Environmental hazard . Special precautions for user d waterways transport (Al. UN number . UN proper shipping name . Transport hazard	Not Applicable IMDG Class Not IMDG Subrisk Not Not Applicable Not Applicable Not Applicable EMS Number Special provisions Limited Quantities DN): NOT REGULATED Not Applicable Not Applicable	TED FOR TRANSPORT OF DANG Applicable Applicable Not Applicable Not Applicable Not Applicable Not Applicable The Applicable Not Applicable The Applicable Th	EROUS GOODS
14.1 14.2 14.3 14.4 14.5 14.6 Inland 14.1 14.2 14.3	UN number UN proper shipping name Transport hazard class(es) Packing group Environmental hazard Special precautions for user UN number UN proper shipping name Transport hazard class(es)	Not Applicable IMDG Class Not IMDG Subrisk Not Applicable Not Applicable Not Applicable EMS Number Special provisions Limited Quantities DN): NOT REGULATED Not Applicable Not Applicable Not Applicable	TED FOR TRANSPORT OF DANG Applicable Applicable Not Applicable Not Applicable Not Applicable Not Applicable The Applicable Not Applicable The Applicable Th	EROUS GOODS
14.1 14.2 14.3 14.4 14.5 14.6 Inland 14.1 14.2 14.3	UN number UN proper shipping name Transport hazard class(es) Packing group Environmental hazard Special precautions for user UN number UN proper shipping name Transport hazard class(es) Packing group	Not Applicable IMDG Class Not IMDG Subrisk Not Applicable Not Applicable Not Applicable EMS Number Special provisions Limited Quantities DN): NOT REGULATED Not Applicable Not Applicable	TED FOR TRANSPORT OF DANGE Applicable Applicable Not Applicable Not Applicable Not Applicable To FOR TRANSPORT OF DANGER Applicable Applicable	EROUS GOODS
14.1 14.2 14.3 14.4 14.5 14.6 Inland 14.1 14.2 14.3	UN number UN proper shipping name Transport hazard class(es) Packing group Environmental hazard Special precautions for user UN number UN proper shipping name Transport hazard class(es) Packing group	Not Applicable IMDG Class Not IMDG Subrisk Not Not Applicable Not Applicable EMS Number Special provisions Limited Quantities DN): NOT REGULATED Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable Classification code	TED FOR TRANSPORT OF DANG Applicable Applicable Not Applicable Not Applicable Not Applicable To FOR TRANSPORT OF DANGER Applicable Applicable Not Applicable Not Applicable	EROUS GOODS
14.1 14.2 14.3 14.4 14.5 14.6 Inland 14.1 14.2 14.3 14.4 14.5	UN number UN proper shipping name Transport hazard class(es) Packing group Environmental hazard Special precautions for user UN number UN proper shipping name Transport hazard class(es) Packing group Environmental hazard	Not Applicable IMDG Class Not IMDG Subrisk Not Applicable Not Applicable Not Applicable Not Applicable EMS Number Special provisions Limited Quantities ON): NOT REGULATED Not Applicable Not Applicable Not Applicable Classification code Special provisions	TED FOR TRANSPORT OF DANG Applicable Applicable Not Applicable Not Applicable Not Applicable To FOR TRANSPORT OF DANGER Applicable To Applicable To Applicable Not Applicable Not Applicable	EROUS GOODS
14.1 14.2 14.3 14.4 14.5 14.6 Inland 14.1 14.2 14.3 14.4 14.5	UN number UN proper shipping name Transport hazard class(es) Packing group Environmental hazard Special precautions for user UN number UN proper shipping name Transport hazard class(es) Packing group Environmental hazard	Not Applicable IMDG Class Not IMDG Subrisk Not Applicable Not Applicable EMS Number Special provisions Limited Quantities DN): NOT REGULATED Not Applicable Not Applicable Not Applicable Not Applicable Classification code Special provisions Limited quantity	TED FOR TRANSPORT OF DANGE Applicable Applicable Not Applicable Not Applicable Not Applicable To FOR TRANSPORT OF DANGER Applicable To Applicable Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable	EROUS GOODS
14.1 14.2 14.3 14.4 14.5 14.6 Inland 14.1 14.2 14.3 14.4 14.5	UN number UN proper shipping name Transport hazard class(es) Packing group Environmental hazard Special precautions for user UN number UN proper shipping name Transport hazard class(es) Packing group Environmental hazard	Not Applicable IMDG Class Not IMDG Subrisk Not Applicable Not Applicable Not Applicable Not Applicable EMS Number Special provisions Limited Quantities ON): NOT REGULATED Not Applicable Not Applicable Not Applicable Classification code Special provisions	TED FOR TRANSPORT OF DANG Applicable Applicable Not Applicable Not Applicable Not Applicable To FOR TRANSPORT OF DANGER Applicable To Applicable To Applicable Not Applicable Not Applicable	EROUS GOODS

14.7. Maritime transport in bulk according to IMO instruments

Recombinant Bovine Aprotinin

Issue Date: 06/07/2023 Print Date: 06/07/2023

Not Applicable

Version No: 1.1

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

14.7.3. Transport in bulk in accordance with the IGC Code

Product name Ship Type

SECTION 15 Regulatory information

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

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable -: Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, -2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

Information according to 2012/18/EU (Seveso III):

Seveso Category Not Available

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

ECHA SUMMARY

Not Applicable

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Not Available
Canada - DSL	Not Available
Canada - NDSL	Not Available
China - IECSC	Not Available
Europe - EINEC / ELINCS / NLP	Not Available
Japan - ENCS	Not Available
Korea - KECI	Not Available
New Zealand - NZIoC	Not Available
Philippines - PICCS	Not Available
USA - TSCA	Not Available
Taiwan - TCSI	Not Available
Mexico - INSQ	Not Available
Vietnam - NCI	Not Available
Russia - FBEPH	Not Available
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

SECTION 16 Other information

Revision Date	06/07/2023
Initial Date	06/07/2023

Full text Risk and Hazard codes

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered. For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices

Definitions and abbreviations

PC - TWA: Permissible Concentration-Time Weighted Average

PC - STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit₀

IDLH: Immediately Dangerous to Life or Health Concentrations

ES: Exposure Standard

OSF: Odour Safety Factor

NOAEL :No Observed Adverse Effect Level

Part Number: BITP1462 Page 11 of 11 Issue Date: 06/07/2023 Version No: 1.1 Print Date: 06/07/2023

Recombinant Bovine Aprotinin

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value LOD: Limit Of Detection OTV: Odour Threshold Value BCF: BioConcentration Factors BEI: Biological Exposure Index

AIIC: Australian Inventory of Industrial Chemicals

DSL: Domestic Substances List

NDSL: Non-Domestic Substances List

IECSC: Inventory of Existing Chemical Substance in China

EINECS: European INventory of Existing Commercial chemical Substances

ELINCS: European List of Notified Chemical Substances

NLP: No-Longer Polymers

ENCS: Existing and New Chemical Substances Inventory

KECI: Korea Existing Chemicals Inventory NZIoC: New Zealand Inventory of Chemicals

PICCS: Philippine Inventory of Chemicals and Chemical Substances

TSCA: Toxic Substances Control Act TCSI: Taiwan Chemical Substance Inventory INSQ: Inventario Nacional de Sustancias Químicas

NCI: National Chemical Inventory

FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	Classification Procedure
Skin Corrosion/Irritation Category 2, H315	Expert judgement
Serious Eye Damage/Eye Irritation Category 2, H319	Expert judgement
Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, H335	Expert judgement

Powered by AuthorITe, from Chemwatch.