 5-DIAGNOSTICS	Material Safety Data Sheet (In Accordance with REACH regulation (EC) N° 1907/2006)	
Date: 07.02.2019		Version: 1

Aprotinin (Trypsin inhibitor, pancreatic Alkaline) from bovine lung

SECTION 1: IDENTIFICATION OF THE SUBSTANCE /MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier

Product name: Aprotinin (Trypsin inhibitor, pancreatic alkaline) from bovine lung

CAS N° : 9087-70-1

EC N° : 232-994-9

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

Laboratory chemicals use only (For Research Use Only. For in Vitro Use Only). Any non-intended usage is prohibited.

1.3 Details of the Supplier of the Material Safety Data Sheet

Company name: Manufactured for 5-Diagnostics

Address: Heuberg 7, 4051 Basel, Switzerland

Contact information for 5-Diagnostics

Email: info@5-diagnostics.com

Internet: www.5-diagnostics.com

Tel: +41 61 588 07 84

1.4 Emergency telephone number: 112 (European emergency number)

SECTION 2 : HAZARDS IDENTIFICATION

2.1 Substance or Mixture Classification


In compliance with EC regulation NO. 1272/2008 and its amendments. This mixture is not classified as hazardous.

2.2 Label Elements

Regulation (EC) No. 1272/2008

Precautions Statements:

P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P103	Read label before use.
P233	Keep container tightly closed.

 5-DIAGNOSTICS	Material Safety Data Sheet (In Accordance with REACH regulation (EC) N° 1907/2006)	
		Version: 1

P234	Keep only in original container.
P262	Do not get in eyes, on skin, or on clothing.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P411+P235+410	Store at temperatures not exceeding 8 °C/46 °F. Keep cool. Protect from sunlight.

2.3 Other Hazards

The substances in the mixture do not comply with the criteria of PBT/vPvB based on REACH, annex XIII. No risks worthy of mention. Please keep in mind the information stated in the safety data sheet.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCE

Not applicable.


3.2 MIXTURES

Chemical Characterization:

Protein obtained from natural sources.

Composition:

Chemical Name	Trypsin inhibitor, pancreatic (basic)
Formula	C284H432N84O79S7
Molecular Weight	6511, 61g/mol
CAS Number :	9087-70-1
EC N°	232-994-9
REACH N°	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Quantity	>90%

 5-DIAGNOSTICS	Material Safety Data Sheet (In Accordance with REACH regulation (EC) N° 1907/2006)	
Date: 07.02.2019		Version: 1

Additional Information:

Origin and Source of Raw material:

Bovine lung is the raw material to produce Aprotinin. These cattle lungs are collected in the country of China where no single case of BSE/TSE infection is known to date.

Methods and Results for TSE/BSE and other infectious agents:

For the production of Aprotinin, the following suitable TSE/BSE inactivation/removal methods are used. The clearance factor for TSE/BSE agents during manufacturing process has been assessed and an assumable reduction factor of > 5 log 10 is estimated (refer to Charles River Validation Report). In conclusion, this Aprotinin product is considered to be safe because of the risk minimization of transmitting Animal Spongiform Encephalopathy agents and CJD/VCJD via medicinal products. The product does not contain listed SVHC substances > 0.1% according to regulation (EC) N° 1907/2006 article 59 of REACH.

SECTION 4 : FIRST AID MEASURES

4.1 Description of First-aid Measures

First-aid Measures General:

Never give anything by mouth to an unconscious person. Seek medical advice immediately in case of accident or unwellness (show the label where possible).

First-aid Measures After Inhalation:

Go into open air and ventilated suspected area. Keep at rest. In case of respiratory tract irritation, consult a physician.

First-aid Measures After Skin Contact:

Remove contaminated clothing. Wash with plenty of soap and water. In case of skin irritation, obtain medical treatment.

First-aid Measures After Eye Contact:

Rinse cautiously with flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do so. Afterwards, get medical advice.

First-aid Measures After Ingestion:


Rinse mouth thoroughly with water. Do not induce vomiting. Obtain medical attention.

4.2 Most Important Symptoms and Effects Both Acute and Delayed

No Information Available.

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

Treat symptomatically.

 5-DIAGNOSTICS	Material Safety Data Sheet (In Accordance with REACH regulation (EC) N° 1907/2006)	
Date: 07.02.2019		Version: 1

SECTION 5 : FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media

Carbon dioxide (CO₂). Dry extinguishing powder. Alcohol resistant foam. Atomized water.

Unsuitable extinguishing media

High power water jet.

5.2 Special hazards arising from the substance or mixture

In the event of fire, the following can be released: Carbon monoxide Carbon dioxide (CO₂). Nitrogen oxides (NO_x).

5.3 Advice for firefighters

In case of fire: Do not enter fire area without proper protective equipment, including respiratory protection. Do not allow extinguishing water to enter sewer or any water course. Do not breathe fire/explosive fumes.

Further Information

Collect contaminated fire extinguishing water separately. Do not allow run-off from firefighting to enter drains or water courses. Coordinate firefighting measures to the fire surroundings.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Do not get in eyes, on skin, or on clothing. Dust formation to be avoided. No smoking. Do not breathe the dust. Use appropriate personal protective equipment (PPE).

6.2 Environmental precautions

Discharge into the environment must be avoided.


6.3 Methods and material for containment and cleaning up

For Containment: Contain any spills with dikes or absorbent to prevent migration. As an immediate precautionary measure, isolate spill or leak area in all directions.

Methods of Cleaning Up: Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal. Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4 Reference to other sections

Safe handling: see section 7

 5-DIAGNOSTICS	Material Safety Data Sheet (In Accordance with REACH regulation (EC) N° 1907/2006)	
Date: 07.02.2019		Version: 1

Personal protection equipment: see section 8

Disposal : see section 13

SECTION 7 : HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on Safe Handling

Do not handle until all safety precautions have been read and understood. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not get in eyes, on skin, or on clothing. Do not breathe mist, spray, vapors. Handle empty containers with care because they may still present a hazard. Use appropriate personal protective equipment (PPE) (refer to section 8).

Advice on protection against fire and explosion

Usual measures for fire prevention. Dust clouds may present an explosion hazard.

Additional Information on handling

Generation of dust must be avoided. General protection and hygiene measures: refer to chapter 8.

7.2 Conditions for Safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep the container tightly closed. Put in a cool, dry, and well-ventilated place.

Advice on storage compatibility

Do not store together with explosives, oxidizing solids, oxidizing liquids, radioactive substances and infectious substances.

Recommended storage temperature

Value: 2-8° C


Requirements for storage rooms and vessels

Containers which are opened must be carefully closed and kept upright to prevent leakage.

Keep the packing dry and well-sealed to prevent contamination and absorption of humidity.

7.3 Specific end use(s)

Aside from the uses mentioned in section 1.2., no other specific uses are stipulated.

 5-DIAGNOSTICS	Material Safety Data Sheet (In Accordance with REACH regulation (EC) N° 1907/2006)	
Date: 07.02.2019		Version: 1

SECTION 8 : EXPOSURE CONTROLS/ PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limit values

No data available.

Biological limit values

No data available.

8.2 Exposure controls

Appropriate engineering controls

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. Dust should be exhausted directly at the point of origin. Always close containers tightly after the removal of precuts. Any measure taken shall comply with good hygiene practice.

Personal Protective Equipment

During handling the product, use appropriate protective clothing in compliance with the applicable rules. When using the product do not eat, drink, smoke, and sniff. Wash hands before breaks and after work.

Respiratory protection

The proper usage of product and under normal conditions does not required breathing protection.


Environmental exposure controls

No special precautionary measures are needed. Avoid release to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

PROPERTIES	
Appearance	Lyophilised Powder
Color	White
Odour	Odourless
pH value	5-7
Melting point	Slow decomposition
Boiling point	NA
Flash point	NA
Sustaining combustion	Non sustaining combustion

 5-DIAGNOSTICS	Material Safety Data Sheet (In Accordance with REACH regulation (EC) N° 1907/2006)	
Date: 07.02.2019		Version: 1

Explosive properties	NONE
Oxidizing properties	NONE
Water solubility	VERY SOLUBLE
Flow time	NA
Vapour density	NA
Evaporation rate	NA
Solvent separation test	NA

Legend: NA (not applicable), ND (not determined/no data available)

9.2 Further information

Solid content: ND (not determined)

SECTION 10 : STABILITY AND REACTIVITY

10.1 Reactivity

No information available.

No dangerous reactions known if handled in compliance with applicable provisions/under normal conditions of use.

10.2 Chemical stability

Decomposition takes place from temperature above 40°C.

10.3 Possibility of hazardous reactions

No information available

10.4 Conditions to avoid.


Protect against exposure to heat, sunlight, and UV radiation.

10.5 Incompatible materials

Avoid strong oxidizing agents and strong reducing agents' materials.

10.6 Hazardous decomposition products

In case of fire incident, can release carbon monoxide carbon dioxide (CO₂). Nitrogen oxides (NO_x).

 5-DIAGNOSTICS	Material Safety Data Sheet (In Accordance with REACH regulation (EC) N° 1907/2006)	
Date: 07.02.2019		Version: 1

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxological effects

EFFECTS	
Acute oral toxicity	ND
Acute dermal toxicity	ND
Acute inhalational toxicity	ND
Skin corrosion/irritation	ND
Serious eye damage/eye irritation	ND
Respiratory or skin sensitisation	ND
Germ cell mutagenicity	ND
Reproductive toxicity	ND
Carcinogenicity	ND
Specific target organ toxicity : - Single exposure - Repeated exposure	ND
Aspiration hazard	ND
Specific effects in experiment on an animal	ND

Legend: NA (not applicable), ND (not determined/no data available)

SECTION 12 : ECOLOGICAL INFORMATION

12.1 Toxicity


Toxicity	
Fish toxicity - Acute - Chronic	ND
Daphnia toxicity - Acute - Chronic	ND
Algae toxicity - Acute - Chronic	ND
Bacteria toxicity - Acute - Chronic	ND

Legend: NA (not applicable), ND (not determined/no data available)

12.2 Persistence and degradability

Easily biodegradable (concerning to the criteria of the OECD)

12.3 Bioaccumulative potential

 5-DIAGNOSTICS	Material Safety Data Sheet (In Accordance with REACH regulation (EC) N° 1907/2006)	
Date: 07.02.2019		Version: 1

No indication of bioaccumulation potential.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

The substances in the mixture do not comply the PBT/vPvB criteria based on REACH, annex XIII.

12.6 Other adverse effects

No data available.

Additional information

Do not allow to enter into surface water or drains.

SECTION 13 : DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods

Product

Waste must be disposed in compliance with national rules and regulations and it can be consulted with your available environmental services. Waste disposal code is established with your designated regional waste disposer.

Packaging

Completely emptied packaging or empty packaging containing residues must be disposed properly. Seek consultation from your designated regional waste disposer.

SECTION 14 : TRANSPORT INFORMATION

The product is not covered by international regulations on transport of dangerous goods (IMDG, IATA, ADR/RID).

SECTION 15 : REGULATORY INFORMATION

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


EU regulations

2010/75/EU (VOC):

No information available.

2004/42/EC (VOC):

No information available.

 5-DIAGNOSTICS	Material Safety Data Sheet (In Accordance with REACH regulation (EC) N° 1907/2006)	
Date: 07.02.2019		Version: 1

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

Further information

This MSDS file is comply to the requirements described on the Regulation (EC) No 1907/2006 (REACH) and 1272/2008 (CLP).

15.2 Chemical safety assessment

No data available.

SECTION 16 : OTHER INFORMATION

16.1 Key literature references and data sources

This data safety sheet is according to the current version of Regulation EC 1907/2006(REACH), Regulation (EC) 1272/2008 (CLP). The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding section of this SDS.

The above information describes exclusively the safety requirements of the product and based on our present-day knowledge and experience. The information mention above is intended to provide advices of safety handling of the product for storage, processing, transport and disposal, etc. This information is only intended for this product and can not be transfer to other products. Mixing this product with other products or in case of processing, the information on this safety data sheet is no longer valid for a new processed material.

5-Diagnostics and its appointed agents/distributors will not be held liable for any damage(s) resulting from or from contact with the products included in the kit.

16.2 Abbreviations and acronyms

ADR: European Agreement Concerning the International Carriage of Dangerous Goods by Road

CAS: Chemical Abstracts Service

CLP: European Regulation on Classification, Labelling and Packaging of Substances and Mixtures

CMR: Carcinogenic, Mutagenic or Toxic to Reproduction

DNEL: Derived NO Effect Level

IARC: International Agency for Research on Cancer

IATA-DGR: International Air Transport Association- Dangerous Goods Regulations


IMDG: International Maritime Code for Dangerous Goods

ICAO: International Civil Aviation Organization

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

NIOSH: National Institute for Occupational Safety and Health in the U.S.

NTP: National Toxicology Program

 5-DIAGNOSTICS	Material Safety Data Sheet (In Accordance with REACH regulation (EC) N° 1907/2006)	
Date: 07.02.2019		Version: 1

PBT: Persistent Bioaccumulative Toxic

REACH: Union European Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals

RID: International Rule for Transport of Dangerous Substances by Rail

TSCA: Toxic Substances Control Act

VOC: Volatile Organic Compounds

vPvB: Very Persistent, Very Bioaccumulative