

Aprotinin, 10mg

Version Revision Date: Date of last issue: 11-04-2021 2.0 04-26-2022 Date of first issue: 11-30-2015

SECTION 1. IDENTIFICATION

Product name Aprotinin, 10mg

Product code 10236624001

Manufacturer or supplier's details

Company name of supplier Roche Diagnostics Deutschland GmbH

Address 116 Sandhoferstrasse

Mannheim, 68305

Germany

Telephone +496217590 Telefax +496217592890

E-mail address info.dia-sds@roche.com

Emergency telephone

In case of emergencies: : CHEMTREC +1 703-741-5970 /

1-800-424-9300

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

GHS label elements

Signal Word : Warning

Hazard Statements : May form combustible dust concentrations in air.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Substance

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine Substance name

CAS-No. 9087-70-1

Components

Chemical name	CAS-No.	Concentration (% w/w)
AprotininTrypsin inhibitor, pancreas	9087-70-1	<= 100
type (BPTI) from bovine lung		



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Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : Move to fresh air.

If unconscious, place in recovery position and seek medical

advice.

If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Immediately flush eye(s) with plenty of water.

Remove contact lenses. Protect unharmed eye.

If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.

Do not give milk or alcoholic beverages.

Never give anything by mouth to an unconscious person.

If symptoms persist, call a physician.

Rinse mouth with water.

Most important symptoms and effects, both acute and

delayed

None known.

Notes to physician : The first aid procedure should be established in consultation

with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Carbon dioxide (CO2)

Foam Dry powder Water

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Specific hazards during fire

fighting

No information available.

Hazardous combustion prod: :

ucts

Sulfur oxides
Carbon oxides

Nitrogen oxides (NOx)

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Special protective equipment:

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.



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SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : Avoid dust formation.

tive equipment and emer-

gency procedures

Environmental precautions

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for

containment and cleaning up

Pick up and arrange disposal without creating dust.

Sweep up and shovel.

Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against :

fire and explosion

Provide appropriate exhaust ventilation at places where dust

is formed.

Advice on safe handling For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the ap-

plication area.

Electrical installations / working materials must comply with Conditions for safe storage

the technological safety standards.

Further information on stor-

age conditions

See label, package insert or internal guidelines

Materials to avoid No materials to be especially mentioned.

Further information on stor-

age stability

Keep in a dry place.

No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection No personal respiratory protective equipment normally requi-

red.

Hand protection

In case of contact through splashing:

Material Nitrile rubber Break through time > 30 min Glove thickness > 0.11 mm

In case of full contact:

Material butyl-rubber Break through time > 480 min Glove thickness $> 0.4 \, \text{mm}$



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Remarks : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : Handle in accordance with good industrial hygiene and safety

practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : crystalline

Color : white

Odor : none

Odor Threshold : Not applicable

pH : 5.0 - 7.0

(as aqueous solution)

Melting point/range : not determined

Boiling point/boiling range : No data available

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : Sustains combustion

Flammability (liquids) : Sustains combustion

Self-ignition : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : Not applicable

Relative density : No data available

Solubility(ies)



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Water solubility : soluble

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : Not applicable

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : 6,511.52 g/mol

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

No dangerous reaction known under conditions of normal use.

Stable under recommended storage conditions.

No hazards to be specially mentioned. Dust may form explosive mixture in air.

Conditions to avoid : Exposure to moisture.

Direct sources of heat.

Incompatible materials : Strong oxidizing agents

Hazardous decomposition

products

In case of fire hazardous decomposition products may be

produced such as:

Sulfur oxides Carbon oxides

Nitrogen oxides (NOx)

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.



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Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Remarks : slight irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Remarks : Mild eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Remarks : May cause sensitization of susceptible persons.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT-single exposure

Not classified based on available information.

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

STOT-repeated exposure

Not classified based on available information.



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Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Assessment The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Ecotoxicology Assessment

Toxicity Data on Soil Not expected to adsorb on soil.

Other organisms relevant to : No data available

the environment

Persistence and degradability

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Biodegradability : Remarks: Expected to be biodegradable

Bioaccumulative potential

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Partition coefficient: n-: Remarks: No data available

octanol/water

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential Regulation: 40 CFR Protection of Environment; Part 82 Pro-

tection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S.



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Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Additional ecological infor-

mation

: No information on ecology is available.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Can be disposed as waste water, when in compliance with

local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Domestic regulation

49 CFR

Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,

IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.



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SARA 311/312 Hazards : Combustible dust

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine 9087-70-1 lung

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

The ingredients of this product are reported in the following inventories:

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine

lung

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory



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ISHL : Not in compliance with the inventory

KECI: On the inventory, or in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : On the inventory, or in compliance with the inventory

TCSI : On the inventory, or in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

TECI: Not in compliance with the inventory

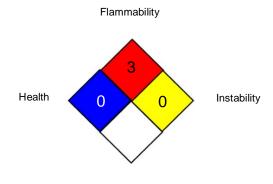
TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

NFPA 704:



Special hazard

HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Distributor

MilliporeSigma 3050 Spruce Street SAINT LOUIS MO 63103 USA

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Sub-



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stances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC -International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods: vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 04-26-2022

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2104



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SECTION 1. IDENTIFICATION

Product name Aprotinin, 50mg

Product code 10981532001

Manufacturer or supplier's details

Company name of supplier Roche Diagnostics Deutschland GmbH

Address 116 Sandhoferstrasse

Mannheim, 68305

Germany

Telephone +496217590 Telefax +496217592890

E-mail address info.dia-sds@roche.com

Emergency telephone

In case of emergencies: : CHEMTREC +1 703-741-5970 /

1-800-424-9300

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

GHS label elements

Signal Word : Warning

Hazard Statements : May form combustible dust concentrations in air.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Substance

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine Substance name

CAS-No. 9087-70-1

Components

Chemical name	CAS-No.	Concentration (% w/w)
AprotininTrypsin inhibitor, pancreas	9087-70-1	<= 100
type (BPTI) from bovine lung		



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Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : Move to fresh air.

If unconscious, place in recovery position and seek medical

advice.

If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Immediately flush eye(s) with plenty of water.

Remove contact lenses. Protect unharmed eye.

If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.

Do not give milk or alcoholic beverages.

Never give anything by mouth to an unconscious person.

If symptoms persist, call a physician.

Rinse mouth with water.

Most important symptoms

and effects, both acute and

delayed

None known.

Notes to physician : The first aid procedure should be established in consultation

with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Carbon dioxide (CO2)

Foam Dry powder Water

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Specific hazards during fire

fighting

No information available.

Hazardous combustion prod: :

ucts

Sulfur oxides
Carbon oxides

Nitrogen oxides (NOx)

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Special protective equipment:

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.



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SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : Avoid dust formation.

tive equipment and emer-

gency procedures

Environmental precautions Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for

containment and cleaning up

Pick up and arrange disposal without creating dust.

Sweep up and shovel.

Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against :

fire and explosion

Provide appropriate exhaust ventilation at places where dust

is formed.

Advice on safe handling For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the ap-

plication area.

Electrical installations / working materials must comply with Conditions for safe storage

the technological safety standards.

Further information on stor-

age conditions

See label, package insert or internal guidelines

Materials to avoid No materials to be especially mentioned.

Further information on stor-

age stability

Keep in a dry place.

No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection No personal respiratory protective equipment normally requi-

red.

Hand protection

In case of contact through splashing:

Material Nitrile rubber Break through time > 30 min Glove thickness > 0.11 mm

In case of full contact:

Material butyl-rubber Break through time > 480 min Glove thickness $> 0.4 \, \text{mm}$



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Remarks : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : Handle in accordance with good industrial hygiene and safety

practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : crystalline

Color : white

Odor : none

Odor Threshold : Not applicable

pH : 5.0 - 7.0

(as aqueous solution)

Melting point/range : not determined

Boiling point/boiling range : No data available

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : Sustains combustion

Flammability (liquids) : Sustains combustion

Self-ignition : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : Not applicable

Relative density : No data available

Solubility(ies)



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Water solubility : soluble

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : Not applicable

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : 6,511.52 g/mol

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

No dangerous reaction known under conditions of normal use.

Stable under recommended storage conditions.

No hazards to be specially mentioned. Dust may form explosive mixture in air.

Conditions to avoid : Exposure to moisture.

Direct sources of heat.

Incompatible materials : Strong oxidizing agents

Hazardous decomposition

products

In case of fire hazardous decomposition products may be

produced such as:

Sulfur oxides Carbon oxides

Nitrogen oxides (NOx)

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.



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Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Remarks : slight irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Remarks : Mild eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Remarks : May cause sensitization of susceptible persons.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT-single exposure

Not classified based on available information.

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

STOT-repeated exposure

Not classified based on available information.



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Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Assessment The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Ecotoxicology Assessment

Toxicity Data on Soil Not expected to adsorb on soil.

Other organisms relevant to : No data available

the environment

Persistence and degradability

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Biodegradability : Remarks: Expected to be biodegradable

Bioaccumulative potential

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Partition coefficient: n-: Remarks: No data available

octanol/water

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential Regulation: 40 CFR Protection of Environment; Part 82 Pro-

tection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S.



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Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Additional ecological infor-

mation

: No information on ecology is available.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Can be disposed as waste water, when in compliance with

local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Domestic regulation

49 CFR

Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,

IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.



Aprotinin, 50mg

Version Revision Date: Date of last issue: 11-04-2021 2.0 04-26-2022 Date of first issue: 11-30-2015

SARA 311/312 Hazards : Combustible dust

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine 9087-70-1 lung

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

The ingredients of this product are reported in the following inventories:

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine

lung

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory



Aprotinin, 50mg

Version Revision Date: Date of last issue: 11-04-2021 2.0 04-26-2022 Date of first issue: 11-30-2015

ISHL : Not in compliance with the inventory

KECI : On the inventory, or in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : On the inventory, or in compliance with the inventory

TCSI : On the inventory, or in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

TECI: Not in compliance with the inventory

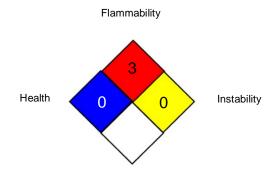
TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

NFPA 704:



Special hazard

HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Distributor

MilliporeSigma 3050 Spruce Street SAINT LOUIS MO 63103 USA

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Sub-



Aprotinin, 50mg

Version Revision Date: Date of last issue: 11-04-2021 2.0 04-26-2022 Date of first issue: 11-30-2015

stances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC -International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods: vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 04-26-2022

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2104



Aprotinin, 100mg

Version Revision Date: Date of last issue: 11-04-2021 2.0 04-26-2022 Date of first issue: 11-30-2015

SECTION 1. IDENTIFICATION

Product name : Aprotinin, 100mg

Product code : 11583794001

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics Deutschland GmbH

Address : 116 Sandhoferstrasse

Mannheim, 68305

Germany

Telephone : +496217590 Telefax : +496217592890

E-mail address : info.dia-sds@roche.com

Emergency telephone

In case of emergencies: : CHEMTREC +1 703-741-5970 /

1-800-424-9300

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

GHS label elements

Signal Word : Warning

Hazard Statements : May form combustible dust concentrations in air.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance

Substance name : AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine

lung

CAS-No. : 9087-70-1

Components

Chemical name	CAS-No.	Concentration (% w/w)
AprotininTrypsin inhibitor, pancreas	9087-70-1	<= 100
type (BPTI) from bovine lung		



Aprotinin, 100mg

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Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : Move to fresh air.

If unconscious, place in recovery position and seek medical

advice.

If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Immediately flush eye(s) with plenty of water.

Remove contact lenses. Protect unharmed eye.

If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.

Do not give milk or alcoholic beverages.

Never give anything by mouth to an unconscious person.

If symptoms persist, call a physician.

Rinse mouth with water.

Most important symptoms and effects, both acute and

delayed

None known.

Notes to physician : The first aid procedure should be established in consultation

with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Carbon dioxide (CO2)

Foam Dry powder Water

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Specific hazards during fire

fighting

No information available.

Hazardous combustion prod: :

ucts

Sulfur oxides
Carbon oxides

Nitrogen oxides (NOx)

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Special protective equipment:

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.



Aprotinin, 100mg

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SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : Avoid dust formation.

tive equipment and emer-

gency procedures

Environmental precautions Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for

containment and cleaning up

Pick up and arrange disposal without creating dust.

Sweep up and shovel.

Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against :

fire and explosion

Provide appropriate exhaust ventilation at places where dust

is formed.

Advice on safe handling For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the ap-

plication area.

Electrical installations / working materials must comply with Conditions for safe storage

the technological safety standards.

Further information on stor-

age conditions

See label, package insert or internal guidelines

Materials to avoid No materials to be especially mentioned.

Further information on stor-

age stability

Keep in a dry place.

No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection No personal respiratory protective equipment normally requi-

red.

Hand protection

In case of contact through splashing:

Material Nitrile rubber Break through time > 30 min Glove thickness > 0.11 mm

In case of full contact:

Material butyl-rubber Break through time > 480 min Glove thickness $> 0.4 \, \text{mm}$



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Remarks : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : Handle in accordance with good industrial hygiene and safety

practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : crystalline

Color : white

Odor : none

Odor Threshold : Not applicable

pH : 5.0 - 7.0

(as aqueous solution)

Melting point/range : not determined

Boiling point/boiling range : No data available

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : Sustains combustion

Flammability (liquids) : Sustains combustion

Self-ignition : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : Not applicable

Relative density : No data available

Solubility(ies)



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Water solubility : soluble

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : Not applicable

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : 6,511.52 g/mol

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

No dangerous reaction known under conditions of normal use.

Stable under recommended storage conditions.

No hazards to be specially mentioned. Dust may form explosive mixture in air.

Conditions to avoid : Exposure to moisture.

Direct sources of heat.

Incompatible materials : Strong oxidizing agents

Hazardous decomposition

products

In case of fire hazardous decomposition products may be

produced such as:

Sulfur oxides Carbon oxides

Nitrogen oxides (NOx)

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.



Aprotinin, 100mg

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Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Remarks : slight irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Remarks : Mild eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Remarks : May cause sensitization of susceptible persons.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT-single exposure

Not classified based on available information.

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

STOT-repeated exposure

Not classified based on available information.



Aprotinin, 100mg

Version Revision Date: Date of last issue: 11-04-2021 2.0 04-26-2022 Date of first issue: 11-30-2015

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Assessment The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Ecotoxicology Assessment

Toxicity Data on Soil Not expected to adsorb on soil.

Other organisms relevant to : No data available

the environment

Persistence and degradability

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Biodegradability : Remarks: Expected to be biodegradable

Bioaccumulative potential

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Partition coefficient: n-: Remarks: No data available

octanol/water

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential Regulation: 40 CFR Protection of Environment; Part 82 Pro-

tection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S.



Aprotinin, 100mg

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Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung:

Additional ecological infor-

mation

: No information on ecology is available.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Can be disposed as waste water, when in compliance with

local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Domestic regulation

49 CFR

Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,

IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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Aprotinin, 100mg

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Clean Air Act

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No components are subject to the Massachusetts Right to Know Act.

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Product does not contain any listed chemicals

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Product does not contain any listed chemicals

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PICCS : Not in compliance with the inventory

IECSC : On the inventory, or in compliance with the inventory

TCSI : On the inventory, or in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

TECI: Not in compliance with the inventory

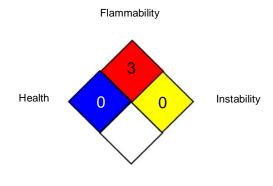
TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

NFPA 704:



Special hazard

HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Distributor

MilliporeSigma 3050 Spruce Street SAINT LOUIS MO 63103 USA

Full text of other abbreviations

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Revision Date : 04-26-2022

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US / Z8 / 2104