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

1.1 Product identifier

Trade name/designation Epi proLung Positive Control
Article no. (user): Epi proLung Control Kit (M6-02-003)

Other means of identification
SDS_0028

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

Relevant identified uses

remark
Epi proLung Control Kit (M6-02-003)

Product categories [PC]
PC21 Laboratory chemicals

Process categories [PROC]
PROC15 Use as laboratory reagent

1.3 Details of the supplier of the safety data sheet

Importer/Only Representative
Epigenomics AG
Geneststrasse 5
D-10829 Berlin
P.O. Box: ---
Telephone: +49 (0)30 24345-0 (9:00 - 16:30)
Telefax: +49 (0)30 24345-555
E-mail: contact@epigenomics.com
www.epigenomics.com

1.4 Emergency telephone number

Giftnotruf Berlin: +49 (0)30 30686-700 (24h)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

remark
This mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2 Label elements

2.3 Other hazards

No data available

SECTION 3: Composition / information on ingredients

3.1/3.2 Substances/Mixtures

Hazardous ingredients

edetic acid; (EDTA) <0,1 %
CAS 60-00-4
EC 200-449-4
INDEX 607-429-00-8
Eye Irrit. 2, H319

Albumin, Blutplasma, Cohn Fraktion V 5 %
CAS 90604-29-8

2-Amino-2-hydroxymethyl-propan-1,3-diol 0,1 - <1 %
CAS 77-86-1
EC 201-064-4
Skin Irrit. 2, H315 / Eye Irrit. 2, H319 / STOT SE 3, H335

SECTION 4: First aid measures

4.1 Description of first aid measures

General information
Change contaminated, saturated clothing.

Following inhalation
Provide fresh air. In case of respiratory tract irritation, consult a physician.

Following skin contact
After contact with skin, wash immediately with plenty of water and soap.

After eye contact
In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of eye irritation consult an ophthalmologist.

After ingestion
Rinse mouth immediately and drink plenty of water. Do not induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

No data available

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor
Treat symptomatically.

SECTION 5: Firefighting measures

Additional information
The product itself does not burn. Co-ordinate fire-fighting measures to the fire surroundings.

5.1 Extinguishing media

No data available

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products
Can be released in case of fire:
Nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective equipment for firefighters:
protective clothing. In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Personal precautions
Provide adequate ventilation. Use personal protection equipment.

For emergency responders

Personal protection equipment
Wear breathing apparatus if exposed to vapours/dusts/aerosols.

6.2 Environmental precautions

Do not allow to enter into surface water or drains.

6.3 Methods and material for containment and cleaning up

For containment

Suitable material for taking up:
Absorbing material, organic

For cleaning up

Suitable material for diluting or neutralizing:
Water

6.4 Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advices on general occupational hygiene
Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500. When using do not eat, drink, smoke, sniff. Remove contaminated, saturated clothing. Avoid contact with skin, eyes and clothes.

Protective measures

Advices on safe handling
Avoid:
Inhalation of vapours or spray/mists
Skin contact
Eye contact

Measures to prevent fire
The product is not:
Combustible
Explosive
No special fire protection measures are necessary.

Environmental precautions
See section 8.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels
Keep/Store only in original container. Keep container tightly closed.

Hints on joint storage

Storage class
Non-combustible liquids

Further information on storage conditions

storage temperature -25 - -15 °C

7.3 Specific end use(s)

Recommendation
Observe instructions for use.

SECTION 8: Exposure controls/personal protection

Additional information
Preventive industrial medical examinations are to be offered.

8.1 Control parameters

remark
Does not contain substances above concentration limits fixing an occupational exposure limit.

8.2 Exposure controls

Appropriate engineering controls

Technical measures to prevent exposure
refer to chapter 7. No further action is necessary.

Personal protection equipment

Eye/face protection

Suitable eye protection:
Eye glasses with side protection

Skin protection

Suitable gloves type:
Disposable gloves

Suitable material:
NBR (Nitrile rubber)

Required properties:
liquid-tight

Breakthrough time (maximum wearing time) >=480 min

Thickness of the glove material >=0,11 mm

additional hand protection measures
Check leak tightness/impermeability prior to use. Use gloves only once.

remark
Breakthrough times and swelling properties of the material must be taken into consideration.

Body protection:

Suitable protective clothing:
lab coat

Recommended material:
Natural fibres (e.g. cotton)

Respiratory protection

remark
Usually no personal respirative protection necessary.

Environmental exposure controls

Technical measures to prevent exposure
refer to chapter 7. No further action is necessary.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state
liquid

Colour
colourless

Odour
odourless

Odour threshold:
odourless

		parameter	Method - source - remark
pH	7,4	Temperature 20 °C	
Melting point/freezing point			not determined
Initial boiling point and boiling range			not determined
Flash point (°C)			No flash point according to standard method.
Evaporation rate			not determined
flammability			not determined
Upper explosion limit			not determined
lower explosion limit			not determined
Vapour pressure			not determined
Vapour density			not determined
Density			not determined
Fat solubility (g/L)			not determined
Water solubility (g/L)			completely miscible
Soluble (g/L) in			not determined

		parameter	Method - source - remark
Partition coefficient: n-octanol/water	-2,31	Temperature 20 °C	OECD 107 Merck AG
Auto-ignition temperature			not determined
Decomposition temperature			not determined

9.2 Other safety information

Physical hazards

Flammable solids

Assessment/classification
Non-flammable.

SECTION 10: Stability and reactivity

10.1 Reactivity
No information available.

10.2 Chemical stability
The product is stable under storage at normal ambient temperatures.

10.3 Possibility of hazardous reactions
No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid
No information available.

10.5 Incompatible materials

Materials to avoid
Reacts with :
Oxidising agent
Alkali (lye)

10.6 Hazardous decomposition products
No information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Acute dermal toxicity

ingredient 2-Amino-2-hydroxymethyl-propan-1,3-diol

Acute dermal toxicity >5000 mg/kg

Effective dose
LD50:

Species:
Rat

Method
OECD 402

Acute oral toxicity

ingredient 2-Amino-2-hydroxymethyl-propan-1,3-diol

Acute oral toxicity >5000 mg/kg

Effective dose
LC50:

Species:
Rat

Method
OECD 425

skin corrosion/irritation

Assessment/classification
Not an irritant.

Species:
Rabbit

Method
OECD 404

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Overall Assessment on CMR properties
Due to missing data no statement can be made whether the substance fullfills the criteria of CMR categories 1 or 2.

STOT-single exposure

STOT SE 3

exposure route
inhalative

Assessment/classification
May cause respiratory irritation.

STOT SE 3

Irritation to respiratory tract

Assessment/classification
May cause respiratory irritation.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity

Acute (short-term) fish toxicity 460 mg/L

Effective dose
LC50:

Test durarion 96 h

species
Leuciscus idus (golden orfe)

Method
OECD 203

Acute (short-term) toxicity to crustacea

ingredient 2-Amino-2-hydroxymethyl-propan-1,3-diol

Acute (short-term) toxicity to crustacea >960 mg/L

Effective dose
EC50
Test durarion 48 h
species
Daphnia magna (Big water flea)
Method
OECD 202

Acute (short-term) toxicity to aquatic algae and cyanobacteria
ingredient 2-Amino-2-hydroxymethyl-propan-1,3-diol
Acute (short-term) toxicity to aquatic algae and cyanobacteria 397 mg/L
Effective dose
EC50
Test durarion 72 h
species
Pseudokirchneriella subcapitata
Method
OECD 201

Toxicity to microorganisms >1000 mg/L
Effective dose
EC50
Test durarion 3 h
Method
OECD 209

12.2 Persistence and degradability

Biodegradation
Degradation rate (%): 89 %
Method
OECD 301D/ EEC 92/69/V, C.4-E
remark
The aquatic toxic ingredients are biodegradable.

12.3 Bioaccumulative potential

Assessment/classification
Based on the n-octanol/water partition coefficient accumulation in organisms is not expected.

Partition coefficient: n-octanol/water
Distribution coefficient (n-octanol / water) (log P O/W): -2,31
Method
OECD 107

12.4 Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment
This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

12.6 Other adverse effects
No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Appropriate disposal / Product
Waste disposal according to official state regulations.

Appropriate disposal / Package
Handle contaminated packaging in the same way as the substance itself.

SECTION 14: Transport information

	Land transport (ADR/RID)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1 UN-No.	not applicable	not applicable	not applicable
14.2 Proper Shipping Name			
14.3 Class(es)			
14.4 Packing group			
14.5 ENVIRONMENTALLY HAZARDOUS			
14.6 Special precautions for user			
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code			

Additional information

All transport carriers
Not a hazardous material with respect to transportation regulations.

SECTION 15: Regulatory information

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

National regulations

15.2 Chemical Safety Assessment

For this substance a chemical safety assessment is not required.

SECTION 16: Other information

Abbreviations and acronyms
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Relevant R-, H- and EUH-phrases (Number and full text)
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
R36 Irritating to eyes.
R36/37/38 Irritating to eyes, respiratory system and skin.

Key literature references and sources for data

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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

1.1 Product identifier

Trade name/designation Epi proLung Negative Control
Article no. (user): Epi proLung Control Kit (M6-02-003)

Other means of identification
SDS_0029

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

Relevant identified uses

remark
Epi proLung Control Kit (M6-02-003)

Product categories [PC]
PC21 Laboratory chemicals

Process categories [PROC]
PROC15 Use as laboratory reagent

1.3 Details of the supplier of the safety data sheet

Importer/Only Representative
Epigenomics AG
Geneststrasse 5
D-10829 Berlin
P.O. Box: ---
Telephone: +49 (0)30 24345-0 (9:00 - 16:30)
Telefax: +49 (0)30 24345-555
E-mail: contact@epigenomics.com
www.epigenomics.com

1.4 Emergency telephone number

Giftnotruf Berlin: +49 (0)30 30686-700 (24h)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

remark
This mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2 Label elements

2.3 Other hazards

No data available

SECTION 3: Composition / information on ingredients

3.1/3.2 Substances/Mixtures

Hazardous ingredients

edetic acid; (EDTA) <0,1 %
CAS 60-00-4
EC 200-449-4
INDEX 607-429-00-8
Eye Irrit. 2, H319

Albumin, Blutplasma, Cohn Fraktion V 5 %
CAS 90604-29-8

2-Amino-2-hydroxymethyl-propan-1,3-diol 0,1 - <1 %
CAS 77-86-1
EC 201-064-4
Skin Irrit. 2, H315 / Eye Irrit. 2, H319 / STOT SE 3, H335

SECTION 4: First aid measures

4.1 Description of first aid measures

General information
Change contaminated, saturated clothing.

Following inhalation
Provide fresh air. In case of respiratory tract irritation, consult a physician.

Following skin contact
After contact with skin, wash immediately with plenty of water and soap.

After eye contact
In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of eye irritation consult an ophthalmologist.

After ingestion
Rinse mouth immediately and drink plenty of water. Do not induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

No data available

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor
Treat symptomatically.

SECTION 5: Firefighting measures

Additional information
The product itself does not burn. Co-ordinate fire-fighting measures to the fire surroundings.

5.1 Extinguishing media

No data available

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products
Can be released in case of fire:
Nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective equipment for firefighters:
protective clothing. In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Personal precautions
Provide adequate ventilation. Use personal protection equipment.

For emergency responders

Personal protection equipment
Wear breathing apparatus if exposed to vapours/dusts/aerosols.

6.2 Environmental precautions

Do not allow to enter into surface water or drains.

6.3 Methods and material for containment and cleaning up

For containment

Suitable material for taking up:
Absorbing material, organic

For cleaning up

Suitable material for diluting or neutralizing:
Water

6.4 Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advices on general occupational hygiene
Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500. When using do not eat, drink, smoke, sniff. Remove contaminated, saturated clothing. Avoid contact with skin, eyes and clothes.

Protective measures

Advices on safe handling
Avoid:
Inhalation of vapours or spray/mists
Skin contact
Eye contact

Measures to prevent fire
The product is not:
Combustible
Explosive
No special fire protection measures are necessary.

Environmental precautions
See section 8.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels
Keep/Store only in original container. Keep container tightly closed.

Hints on joint storage

Storage class
Non-combustible liquids

Further information on storage conditions

storage temperature -25 - -15 °C

7.3 Specific end use(s)

Recommendation
Observe instructions for use.

SECTION 8: Exposure controls/personal protection

Additional information
Preventive industrial medical examinations are to be offered.

8.1 Control parameters

remark
Does not contain substances above concentration limits fixing an occupational exposure limit.

8.2 Exposure controls

Appropriate engineering controls

Technical measures to prevent exposure
refer to chapter 7. No further action is necessary.

Personal protection equipment

Eye/face protection

Suitable eye protection:
Eye glasses with side protection

Skin protection

Suitable gloves type:
Disposable gloves

Suitable material:
NBR (Nitrile rubber)

Required properties:
liquid-tight

Breakthrough time (maximum wearing time) >=480 min

Thickness of the glove material >=0,11 mm

additional hand protection measures
Check leak tightness/impermeability prior to use. Use gloves only once.

remark
Breakthrough times and swelling properties of the material must be taken into consideration.

Body protection:

Suitable protective clothing:
lab coat

Recommended material:
Natural fibres (e.g. cotton)

Respiratory protection

remark
Usually no personal respirative protection necessary.

Environmental exposure controls

Technical measures to prevent exposure
refer to chapter 7. No further action is necessary.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state
liquid

Colour
colourless

Odour
odourless

Odour threshold:
odourless

		parameter	Method - source - remark
pH	7,4	Temperature 20 °C	
Melting point/freezing point			not determined
Initial boiling point and boiling range			not determined
Flash point (°C)			No flash point according to standard method.
Evaporation rate			not determined
flammability			not determined
Upper explosion limit			not determined
lower explosion limit			not determined
Vapour pressure			not determined
Vapour density			not determined
Density			not determined
Fat solubility (g/L)			not determined
Water solubility (g/L)			completely miscible
Soluble (g/L) in			not determined

		parameter	Method - source - remark
Partition coefficient: n-octanol/water	-2,31	Temperature 20 °C	OECD 107 Merck AG
Auto-ignition temperature			not determined
Decomposition temperature			not determined

9.2 Other safety information

Physical hazards

Flammable solids

Assessment/classification
Non-flammable.

SECTION 10: Stability and reactivity

10.1 Reactivity
No information available.

10.2 Chemical stability
The product is stable under storage at normal ambient temperatures.

10.3 Possibility of hazardous reactions
No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid
No information available.

10.5 Incompatible materials

Materials to avoid
Reacts with :
Oxidising agent
Alkali (lye)

10.6 Hazardous decomposition products
No information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Acute dermal toxicity

ingredient 2-Amino-2-hydroxymethyl-propan-1,3-diol

Acute dermal toxicity >5000 mg/kg

Effective dose
LD50:

Species:
Rat

Method
OECD 402

Acute oral toxicity

ingredient 2-Amino-2-hydroxymethyl-propan-1,3-diol

Acute oral toxicity >5000 mg/kg

Effective dose
LC50:

Species:
Rat

Method
OECD 425

skin corrosion/irritation

Assessment/classification
Not an irritant.

Species:
Rabbit

Method
OECD 404

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Overall Assessment on CMR properties
Due to missing data no statement can be made whether the substance fullfills the criteria of CMR categories 1 or 2.

STOT-single exposure

STOT SE 3

exposure route
inhalative

Assessment/classification
May cause respiratory irritation.

STOT SE 3

Irritation to respiratory tract

Assessment/classification
May cause respiratory irritation.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity

Acute (short-term) fish toxicity 460 mg/L

Effective dose
LC50:

Test durarion 96 h

species
Leuciscus idus (golden orfe)

Method
OECD 203

Acute (short-term) toxicity to crustacea

ingredient 2-Amino-2-hydroxymethyl-propan-1,3-diol

Acute (short-term) toxicity to crustacea >960 mg/L

Effective dose
EC50
Test durarion 48 h
species
Daphnia magna (Big water flea)
Method
OECD 202

Acute (short-term) toxicity to aquatic algae and cyanobacteria
ingredient 2-Amino-2-hydroxymethyl-propan-1,3-diol
Acute (short-term) toxicity to aquatic algae and cyanobacteria 397 mg/L
Effective dose
EC50
Test durarion 72 h
species
Pseudokirchneriella subcapitata
Method
OECD 201

Toxicity to microorganisms >1000 mg/L
Effective dose
EC50
Test durarion 3 h
Method
OECD 209

12.2 Persistence and degradability

Biodegradation
Degradation rate (%): 89 %
Method
OECD 301D/ EEC 92/69/V, C.4-E
remark
The aquatic toxic ingredients are biodegradable.

12.3 Bioaccumulative potential

Assessment/classification
Based on the n-octanol/water partition coefficient accumulation in organisms is not expected.

Partition coefficient: n-octanol/water
Distribution coefficient (n-octanol / water) (log P O/W): -2,31
Method
OECD 107

12.4 Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment
This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

12.6 Other adverse effects
No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Appropriate disposal / Product
Waste disposal according to official state regulations.

Appropriate disposal / Package
Handle contaminated packaging in the same way as the substance itself.

SECTION 14: Transport information

	Land transport (ADR/RID)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1 UN-No.	not applicable	not applicable	not applicable
14.2 Proper Shipping Name			
14.3 Class(es)			
14.4 Packing group			
14.5 ENVIRONMENTALLY HAZARDOUS			
14.6 Special precautions for user			
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code			

Additional information

All transport carriers
Not a hazardous material with respect to transportation regulations.

SECTION 15: Regulatory information

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

National regulations

15.2 Chemical Safety Assessment

For this substance a chemical safety assessment is not required.

SECTION 16: Other information

Abbreviations and acronyms
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Relevant R-, H- and EUH-phrases (Number and full text)
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
R36 Irritating to eyes.
R36/37/38 Irritating to eyes, respiratory system and skin.

Key literature references and sources for data

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.