

Epi proColon Positive Control

Print date 07.06.2017
Revision date 07.06.2017
Version 4.0

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

1.1 Product identifier

Trade name/designation Epi proColon Positive Control

Article no. (user): Epi proColon Control Kit (M5-02-003)

Other means of identification

SDS 0023

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

Relevant identified uses

remark

Epi proColon Control Kit (M5-02-003)

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) CAS 60-00-4 EC 200-449-4 INDEX 607-429-00-8 Eye Irrit. 2, H319	<0,1 %
Albumin, Blutplasma, Cohn Fraktion V CAS 90604-29-8	5 %
2-Amino-2-hydroxymethyl-propan-1,3-diol CAS 77-86-1 EC 201-064-4 Skin Irrit. 2, H315 / Eye Irrit. 2, H319 / STOT SE 3, H335	0,1 - <1 %

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.

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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 $\geq 0,11$ 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

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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 fulfills 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 duration 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

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Effective dose

EC50

Test duration 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 duration 72 h**species**

Pseudokirchneriella subcapitata

Method

OECD 201

Toxicity to microorganisms >1000 mg/L**Effective dose**

EC50

Test duration 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.

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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.

Epi proColon Negative Control

Print date 07.06.2017
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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name/designation Epi proColon Negative Control

Article no. (user): Epi proColon Control Kit (M5-02-003)

Other means of identification

SDS 0024

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

Relevant identified uses

remark

Epi proColon Control Kit (M5-02-003)

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

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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) CAS 60-00-4 EC 200-449-4 INDEX 607-429-00-8 Eye Irrit. 2, H319	<0,1 %
Albumin, Blutplasma, Cohn Fraktion V CAS 90604-29-8	5 %
2-Amino-2-hydroxymethyl-propan-1,3-diol CAS 77-86-1 EC 201-064-4 Skin Irrit. 2, H315 / Eye Irrit. 2, H319 / STOT SE 3, H335	0,1 - <1 %

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.

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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 $\geq 0,11$ 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 fulfills 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 duration 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 duration 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 duration 72 h

species

Pseudokirchneriella subcapitata

Method

OECD 201

Toxicity to microorganisms >1000 mg/L

Effective dose

EC50

Test duration 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.

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Key literature references and sources for data

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