

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Prealbumin-Ceruloplasmin Control Set

Version
1.6

Revision Date:
17.02.2015

Date of last issue: 03.08.2014
Date of first issue: 30.08.2012

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

1.1 Product identifier

Commercial Product Name : Prealbumin-Ceruloplasmin Control Set
Mat.-No./ Genisys-No. : 04567021190

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

Recommended restrictions : For professional users only.
on use

1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH
-
Sandhoferstrasse 116
68305 Mannheim
E-mail address : mannheim.umweltschutz@roche.com
Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-2012+49(0)621-759-4848+49(0)8856-60-2629

1.4 Emergency telephone number

In case of emergencies: : Central Works Security +49(0)621-759-2203
Roche Diagnostics GmbH
Centre for detoxification: : Mainz +49(0)6131-19240
Munich +49(0)89-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard statements	: H412	Harmful to aquatic life with long lasting effects.
Precautionary statements	: Prevention: P273 Disposal: P501	Avoid release to the environment. Dispose of contents/ container to an approved waste disposal plant.

2.3 Other hazards

See SECTION 3

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SECTION 3: Composition/information on ingredients

F1

Classification (REGULATION (EC) No 1272/2008)

Chronic aquatic toxicity, Category 3

H412: Harmful to aquatic life with long lasting effects.

Classification (67/548/EEC, 1999/45/EC)

Harmful

R22: Harmful if swallowed.

Dangerous for the environment

R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Chemical nature : Handle as potentially infectious.

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
sodium azide	26628-22-8 247-852-1	T+; R28 R32 N; R50-R53	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 0,25 - < 1

For explanation of abbreviations see section 16.

F2

Classification (REGULATION (EC) No 1272/2008)

Chronic aquatic toxicity, Category 3

H412: Harmful to aquatic life with long lasting effects.

Classification (67/548/EEC, 1999/45/EC)

Harmful

R22: Harmful if swallowed.

Dangerous for the environment

R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Chemical nature : Handle as potentially infectious.

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
sodium azide	26628-22-8 247-852-1	T+; R28 R32	Acute Tox. 2; H300 Aquatic Acute 1;	>= 0,25 - < 1

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		N; R50-R53	H400 Aquatic Chronic 1; H410	
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For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
Keep eye wide open while rinsing.
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.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.

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5.3 Advice for firefighters

- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : Avoid dust formation.
Avoid breathing dust.

6.2 Environmental precautions

- Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

- Methods for cleaning up : Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

- Treat recovered material as described in the section "Disposal considerations".

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Advice on safe handling : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
- Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.
- Hygiene measures : When using do not eat or drink. When using do not smoke.
Wash hands before breaks and at the end of workday.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully re-sealed and kept upright to prevent leakage. Electrical installations / working materials must comply with the technological safety standards.

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Further information on storage conditions : See label, package insert or internal guidelines

Storage class (TRGS 510) : 13, Non Combustible Solids

Other data : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

F1

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
sodium azide	26628-22-8	TWA	0,1 mg/m3	2000/39/EC
Further information	Identifies the possibility of significant uptake through the skin, Indicative			
		STEL	0,3 mg/m3	2000/39/EC
Further information	Identifies the possibility of significant uptake through the skin, Indicative			
		AGW	0,2 mg/m3	DE TRGS 900
Peak-limit: excursion factor (category)	2;(I)			
Further information	Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., European Union (The EU has established a limit value: deviations in value and peak limit are possible)			

F2

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
sodium azide	26628-22-8	TWA	0,1 mg/m3	2000/39/EC
Further information	Identifies the possibility of significant uptake through the skin, Indicative			
		STEL	0,3 mg/m3	2000/39/EC
Further information	Identifies the possibility of significant uptake through the skin, Indicative			
		AGW	0,2 mg/m3	DE TRGS 900
Peak-limit: excursion factor (category)	2;(I)			
Further information	Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., European Union (The EU has established a limit value: deviations in value and peak limit are possible)			

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8.2 Exposure controls

Personal protective equipment

Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles

Hand protection

Material : Protective gloves

Remarks : The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

F1

Appearance : solid

Colour : light yellow

Odour : odourless

Odour Threshold : No data available

pH : No data available

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Sustains combustion

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

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Density	: No data available
Solubility(ies)	
Water solubility	: soluble
Partition coefficient: n-octanol/water	: No data available
Ignition temperature	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

F2

Appearance	: solid
Colour	: light yellow
Odour	: odourless
Odour Threshold	: No data available
pH	: No data available
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Evaporation rate	: No data available
Flammability (solid, gas)	: Sustains combustion
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	
Water solubility	: soluble
Partition coefficient: n-octanol/water	: No data available
Ignition temperature	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

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9.2 Other information

F1

No data available

F2

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.
No decomposition if stored and applied as directed.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Direct sources of heat.

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

F1

Acute toxicity

Not classified based on available information.

Components:

sodium azide:

Acute oral toxicity : LD50 Oral (Rat): 27 mg/kg
LD50 Oral (Mouse): 27 mg/kg

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Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Components:

sodium azide:

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Not classified based on available information.

Components:

sodium azide:

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

F2

Acute toxicity

Not classified based on available information.

Components:

sodium azide:

Acute oral toxicity : LD50 Oral (Rat): 27 mg/kg

LD50 Oral (Mouse): 27 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

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Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Components:

sodium azide:

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Not classified based on available information.

Components:

sodium azide:

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

SECTION 12: Ecological information

12.1 Toxicity

F1

Components:

sodium azide:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1 mg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): < 8 mg/l
Exposure time: 96 h

LC50 (Fish): 0,7 mg/l

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia pulex (Water flea)): 4,2 mg/l
Exposure time: 96 h

Toxicity to algae : IC50 (Scenedesmus quadricauda (Green algae)): 272 mg/l

Toxicity to bacteria : EC50 (Photobacterium phosphoreum): > 43 mg/l

EC50 (Photobacterium phosphoreum): < 66 mg/l

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Ecotoxicology Assessment

Acute aquatic toxicity : Very toxic to aquatic life.

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

F2

Components:

sodium azide:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1 mg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): < 8 mg/l
Exposure time: 96 h

LC50 (Fish): 0,7 mg/l

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia pulex (Water flea)): 4,2 mg/l
Exposure time: 96 h

Toxicity to algae : IC50 (Scenedesmus quadricauda (Green algae)): 272 mg/l

Toxicity to bacteria : EC50 (Photobacterium phosphoreum): > 43 mg/l
EC50 (Photobacterium phosphoreum): < 66 mg/l

Ecotoxicology Assessment

Acute aquatic toxicity : Very toxic to aquatic life.

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

12.2 Persistence and degradability

F1

No data available

F2

No data available

12.3 Bioaccumulative potential

F1

No data available

F2

No data available

12.4 Mobility in soil

F1

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No data available

F2

No data available

12.5 Results of PBT and vPvB assessment

F1

Not relevant

F2

Not relevant

12.6 Other adverse effects

F1

No data available

F2

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration).
The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
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

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

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14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADNR, IMDG-Code, ICAO/IATA-DGR

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

Remarks : Not applicable

SECTION 15: Regulatory information

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

Seveso II - Directive 2003/105/EC amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances
Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Water contaminating class : WGK 1 slightly water endangering
(Germany)

F1

Labelling (REGULATION (EC) No 1272/2008)

Hazard statements : H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P273 Avoid release to the environment.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

F2

Labelling (REGULATION (EC) No 1272/2008)

Hazard statements : H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P273 Avoid release to the environment.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

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The Roche logo, consisting of the word "Roche" in a bold, sans-serif font, enclosed within a hexagonal border.

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15.2 Chemical Safety Assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

SECTION 16: Other information

Full text of R-Phrases

R28	: Very toxic if swallowed.
R32	: Contact with acids liberates very toxic gas.
R50	: Very toxic to aquatic organisms.
R53	: May cause long-term adverse effects in the aquatic environment.

Full text of H-Statements

H300	: Fatal if swallowed.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Aquatic Acute	: Acute aquatic toxicity
Aquatic Chronic	: Chronic aquatic toxicity

Further information

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.

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