

SAFETY DATA SHEET

according to ChemO 2015 - SR 813.11

C1 CONTROL UFH 1

55055R9

* 1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name	C1 Control UFH 1
Article number	55055R9

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

Application of the substance / the mixture	Diagnostic reagent
	Kit component

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier	Pentapharm AG Dornacherstrasse 112 CH- 4147 Aesch BL / Switzerland Phone +41 61 706 48 48 Fax +41 61 706 48 00
Further information obtainable from	pentapharm@pentapharm.com

1.4 Emergency telephone number

Tox Info Suisse : +41 44 251 51 51 (24h; 7 days a week)
Information desk: +41 44 251 66 66

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
The product is not classified, according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Void

Hazard pictograms

Void

Signal word

Void

Hazard statement

Void

2.3 Other hazards

The control reagent contains human derived blood plasma. As complete absence of infectious agents can never be assured, all materials derived from human or bovine tissue or body fluids should always be handled with care, observing the precautions recommended for bio-hazardous material. The human plasma used is tested on antibodies against HIV Type 1 and 2, Hepatitis C-

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virus, Treponema pallidum and Hepatitis B surface antigen.
Hepatitis C was tested by PCR screen. The plasma was found to be negative.

Results of PBT and vPvB assessment

PBT: According to current knowledge, the product contains no PBT substance.

vPvB: According to current knowledge, the product contains no vPvB substance.

Determination of endocrine-disrupting properties

Taking into account the current state of scientific knowledge, no data on endocrine disrupting properties of the product are available.

3 Composition/information on ingredients

3.1 Mixtures

Description

Mixture of substances listed below with nonhazardous additions.

Dangerous components

Void

SVHC

According to current knowledge no SVHC contained.

Additional information

For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

4.1 Description of first aid measures

General information

No special measures required.

After inhalation

Remove person to fresh air and keep comfortable for breathing.

If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

After skin contact

Wash with plenty of soap and water.

If skin irritation or rash occurs: Get medical advice/attention.

After eye contact

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

After swallowing

Immediately call a POISON CENTER/doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

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5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents

CO₂, dry chemical powder, or appropriate foam.

5.2 Specific hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment

Wear self-contained respiratory protective device.

Wear protective clothing to prevent contact with skin and eyes.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid skin and eye contact and particle inhalation.

6.2 Environmental precautions

Do not allow product to reach sewage system or any water course.

6.3 Methods and material for containment and cleaning up

Pick up mechanically.

Collect in suitable containers.

Clean the affected area carefully and ensure adequate ventilation.

Avoid dust formation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

7.1 Precautions for safe handling

Avoid skin and eye contact and particle inhalation.

Information about fire – and explosion protection

No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles

No special requirements.

Information about storage in one common storage facility

Not required.

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Further information about storage conditions

Store the product in a dry place protected from light at a temperature between 2°C to 8°C.

7.3 Specific end use(s)

No further relevant information available.

8 Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit value that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information

The lists valid during the making were used as basis.

8.2 Exposure controls

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Ensure good ventilation/exhaustion at the workplace.

Keep away from foodstuffs, beverages and feed.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work

Respiratory protection

Use suitable respiratory protective device in case of insufficient ventilation.

Respiratory protection must be compliant with the specifications of Directive 2016/425 and be in accordance with the EN standards resulting thereof.

Protection of hands



Protective gloves

Material of gloves

Protective gloves must be compliant with the specifications to Directive 2016/425 and be in accordance with the standards EN374. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. Nitrile rubber, NBR

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Eyeface protection



Safety glasses

Protective goggles must be compliant with the specifications of Directive 2016/425 and be in accordance with the standard EN166 (EU) or NIOSH (US).

Environmental exposure controls Do not allow product to reach ground water, water course or sewage system.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information	
Physical state:	Solid
Colour:	beige / brown
Odour:	Not determined.
Odour threshold:	Not determined.
Melting point/freezing point:	Not determined.
Boiling point or initial boiling point and boiling range:	Not determined.
Flammability:	Not determined.
Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Ignition temperature:	Not determined.
Decomposition temperature:	Not determined.
pH:	7.5 (Content in 1 mL H ₂ O)
Viscosity	
Kinematic:	Not applicable
Dynamic:	Not applicable
Solubility	
Water:	Soluble.
Partition coefficient n-octanol/water (log value):	Not determined.
Vapour pressure:	Not applicable
Density and/or relative density	

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Relative density:	Not determined.
Vapour density:	Not determined.
Particle characteristics:	Not determined.

9.2 Other information

Appearance Form:	Lyophilised solid
Important Information on protection of health, environment and on safety Auto-ignition temperature: Explosive properties:	The product is not self-igniting. The product does not present an explosion hazard.
Change in condition Softening point/range: Oxidising properties: Evaporation rate:	Not determined. Not applicable.

9.2.1 Information with regard to physical hazard classes

Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Void
Flammable solids	Void
Self-reactive substances and mixtures	Void
Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable gases in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
Desensitised explosives	Void

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10 Stability and reactivity

10.1 Reactivity

No further relevant information available.

10.2 Chemical stability

Thermal decomposition / conditions to be avoided

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

Heat may cause this product to decompose.

Avoid freezing.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

Nature of decomposition products not known.

11 Toxicological information

11.1 Information on hazards classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification

No further relevant information available.

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

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Aspiration hazard

Based on available data, the classification criteria are not met.

Other information

The control reagent contains human derived blood plasma. As complete absence of infectious agents can never be assured, all materials derived from human or bovine tissue or body fluids should always be handled with care, observing the precautions recommended for bio-hazardous material. The human plasma used is tested on antibodies against HIV Type 1 and 2, Hepatitis C-virus, Treponema pallidum and Hepatitis B surface antigen. Hepatitis C was tested by PCR screen. The plasma was found to be negative.

11.2 Information on other hazards

Endocrine disrupting properties

Taking into account the current state of scientific knowledge, no data on endocrine disrupting properties of the product are available.

None of the ingredients listed.

12 Ecological information

12.1 Toxicity

Aquatic toxicity

No further relevant information available.

12.2 Persistence and degradability

No further relevant information available.

12.3 Bioaccumulative potential

No further relevant information available.

12.4 Mobility in soil

No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT

According to current knowledge, the product contains no PBT substance.

vPvB

According to current knowledge, the product contains no vPvB substance.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

No further relevant information available.

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13 Disposal considerations

13.1 Waste treatment methods

Recommendation

Disposal must be made according to official regulations.

Ordinance of the Federal Department of the Environment, Transport, Energy and Communications (DETEC) on Lists for Waste Traffic (SR 814.610.1)

In Switzerland od for hazardous waste are marked with an "S" ("Sonderabfall") instead of an asterisk.

18 00 00	Wastes from human or animal healthcare and/or related research (except kitchen and restaurant wastes not arising from immediate health care)
18 01 00	Wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 03	Wastes whose collection and disposal is subject to special requirements in order to prevent infection Classification S = hazardous waste (Sonderabfall)

Uncleaned packaging

Recommendation

Disposal must be made according to official regulations.

14 Transport information

14.1 UN-number or ID number

ADR/ADN, ADN, IMDG, IATA Void

14.2 UN Proper shipping name

ADR/ADN, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)

ADR/ADN, ADN, IMDG, IATA
Class Void

14.4 Packing group

ADR/ADN, IMDG, IATA Void

14.5 Environmental hazards

Not applicable.

14.6 Special precautions for user

Not applicable.

14.7 Maritime transport in bulk according

to IMO instruments Not applicable.

UN "Model Regulation" Void

15 Regulatory information

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

National regulations:

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Special handling regulations (follow-up obligations) of the chemical legislation:

No additional regulations.

Ordinance on Air Pollution Control (OAPC; SR 814.318.142.1) Annex 1:

The provisions of the Air Pollution Control (OAPC; SR 814.318.142.1) Annex 1 are to be complied with.

Ordinance on Protection against Major Accidents (Major Accidents Ordinance, MAO; SR 814.012) Annex 1:

Volume threshold according to MAO in kg: without limitation

(Source: FOEN - List 2015 - Volume thresholds in accordance with the Major Accidents Ordinance / Volume Threshold Calculator)

Chemical Risk Reduction Ordinance (ORRChem; SR 814.81):

The product contains no substances subject to authorization according to Annex 1.17 in concentrations $\geq 0.1\%$ w/w or above specific concentration limits (if $< 0.1\%$ w/w).

Chemical Risk Reduction Ordinance (ORRChem; SR 814.81):

The preparation or substances contained therein are not subject to any prohibition or restriction in accordance with Annexes 1 and 2.

Chemicals Ordinance (ChemO; SR 813.11):

The product contains no substances of very high concern according to Annex 3 in concentrations $\geq 0.1\%$ w/w.

Waterhazard class

Swiss Waterhazard class B (self classification)

OVOC (CH)

0.0%

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

16 Other information

All information and instructions provided in this Safety Data Sheet are based on the current state of scientific and technical knowledge at the date indicated on this Safety Data Sheet. Pentapharm AG shall not be held responsible for any defect in the product covered by this Safety Data Sheet, should the existence of such a defect not be detectable considering the current state of scientific and technical knowledge.

An asterisk (*) in the left hand margin indicates an amendment from the previous version.

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Abbreviations and acronyms

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

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.