Safety data sheet

according to ChemO 2015 – SR 813.11

Version number 4 (replaces version 3) *Revision: 19.02.2026*

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

1.1 Product identifier

Trade name: **C2 FV-L Heterozygous Control**

Article number: 55025R6

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 / 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
24-h-emergency number: 145 (from abroad: +41 44 251 51 51)
information desk: +41 44 251 66 66

SECTION 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 statements Void

2.3 Other hazards

Reagent 6 (55025R6) contains Human plasma (50 – 100%). Each donor unit used in the preparation of APC-R C2 FV-L Heterozygous Control (R6) has been tested for antibodies against HIV Typ 1 and 2, Hepatitis C-virus antibodies, Treponema pallidum antibodies as well as Hepatitis B surface antigen and Hepatitis C genome by PCR. The tests used are all CE certified tests according to list A of the European Directive for IVD (98/79/EC) and are under supervision by the responsible European governmental authority. The plasmas were found to be negative on the test parameters.
However, since no test can completely rule out the presence of blood borne diseases these control plasmas have to be handled as potentially infectious material.
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.

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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.

SECTION 3: Composition/information on ingredients

3.2 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.

SECTION 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 water and soap.
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.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing agents: CO_2, dry chemical powder or appropriate foam.

5.2 Special 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.

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Wear protective clothing to prevent contact with skin and eyes.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Avoid eye and skin 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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling Avoid eye and skin 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
Further information about storage conditions:
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Ingredients with limit values 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.

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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 the Regulation (EU) 2016/425 and be in accordance with the EN standards resulting thereof.

Hand protection:

Protective gloves

Material of gloves
Protective gloves must be compliant with the specifications of the Regulation (EU) 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.

Eye/face protection

Safety glasses

Protective goggles must be compliant with the specifications of the Regulation (EU) 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.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
General Information

Physical state:	Solid
Colour:	White

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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
Auto-ignition temperature:	Not determined
Decomposition temperature:	Not determined
pH at 20 °C:	7.45 – 7.55
Viscosity	
Kinematic:	Not applicable
Dynamic:	Not applicable
Solubility	
water:	Not determined
Partition coefficient n-octanol/water (log value):	Not determined
Vapour pressure:	Not applicable
Density and/or relative density	
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 and environment, and on safety	
Ignition temperature:	The product is not self-igniting.
Explosive properties:	The product does not present an explosion hazard.
Solvent content:	
VOCV (CH)	0.00 %
Change in condition	
Softening point/range:	
Oxidising properties:	Not determined
Evaporation rate:	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

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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

SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical stability No information available.
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.

SECTION 11: Toxicological information

11.1 Information on hazard 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.
Primary irritant effect:
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.
Aspiration hazard Based on available data, the classification criteria are not met.

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Other information:
Reagent 6 (55025R6) contains Human plasma (50 – 100%). Each donor unit used in the preparation of APC-R C2 FV-L Heterozygous Control (R6) has been tested for antibodies against HIV Typ 1 and 2, Hepatitis C-virus antibodies, Treponema pallidum antibodies as well as Hepatitis B surface antigen and Hepatitis C genome by PCR. The tests used are all CE certified tests according to list A of the European Directive for IVD (98/79/EC) and are under supervision by the responsible European governmental authority. The plasmas were found to be negative on the test parameters.
However, since no test can completely rule out the presence of blood borne diseases these control plasmas have to be handled as potentially infectious material.

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 is listed.

SECTION 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.

SECTION 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 codes for hazardous waste are marked with an „S“ (“Sonderabfall”) instead of an asterisk
18 00 00: Wastes from human or animal health care 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 03S: wastes whose collection and disposal is subject to special requirements in order to prevent infection
Classification S = hazardous waste

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Uncleaned packaging
Recommendation: Disposal must be made according to official regulations.

SECTION 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

SECTION 15: Regulatory information

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

National regulations:
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 ≥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.

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Chemicals Ordinance (ChemO; SR 813.11):
The product contains no substances of very high concern according to Annex 3 in concentrations ≥0.1% w/w.
OVOC (CH) 0.00 %

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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.
This safety data sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.
An asterisk (*) in the left hand margin indicates an amendment from the previous version.

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)
VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
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

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