

MATERIAL SAFETY DATA SHEET

according to ISO/DIS 11014



PEFAKIT® APC-R FACTOR V LEIDEN CONTROLS

502-22

C1 FV-L NEGATIVE CONTROL

55025R5 / 502-15

1 Identification

Product identifier

Product FV-L Negative Control
Reagent C1 of Pefakit® APC-R Faktor V Leiden Controls

Article number 55025R5 / 502-15 (reagent)
502-22 (kit)

Application of the substance / the mixture Diagnostic reagent
Component of in-vitro diagnostics kit

Details of the supplier of the safety data sheet

Manufacturer/Supplier DSM Nutritional Products Ltd Branch Pentapharm
Dornacherstrasse 112
CH- 4147 Aesch BL / Switzerland
Phone +41 61 706 48 48
Fax +41 61 706 48 00

Information department pentapharm@pentapharm.com

Emergency phone number

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

2 Hazard(s) identification

Classification of the substance or mixture

The product is not classified and labeled according to OSHA Hazard Communication Standard (29 CFR 1910.1200).

The product is not classified and labeled according to the Globally Harmonized System (GHS).

Label elements

GHS label elements	Void
Hazard pictograms	Void
Signal word	Void
Hazard statements	Void

Other hazards

Reagent 5 (55025R5) contains Human plasma (50 - 100%). Each donor unit used in the preparation of APC-R C1 FV-L Negative Control (R5) has been tested for antibodies against HIV Typ 1 and 2, Hepatitis C-virus antibodies, Treponema pallidum antibodies as well as Hepatitis B surfacantigen 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.

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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.

3 Composition/information on ingredients

Chemical characterization: Mixtures

Description

Mixture of substances listed below with nonhazardous additions.

Dangerous components

Void

4 First-aid measures

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 CENTRE/doctor.

Most important symptoms and effects, both acute and delayed

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

Extinguishing media

Suitable extinguishing agents

CO₂, dry chemical powder, or appropriate foam

Specific hazards arising from the substance or mixture

No further relevant information available.

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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

Personal precautions, protective equipment and emergency procedures

Avoid skin and eye contact and particle inhalation.

Environmental precautions

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

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.

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

Handling

Precautions for safe handling

Avoid skin and eye contact and particle inhalation.

Information about fire - and explosion protection

No special measures required.

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 the product in a dry place protected from heat and direct sunlight at a temperature between 2 to 8°C.

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Specific end use(s)

No further relevant information available.

8 Exposure controls/personal protection

Control parameters

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

Exposure controls

Personal protective equipment

General protective and hygienic measures

Keep away from foodstuffs, beverages and feed.

Ensure good ventilation/exhaustion at the workplace.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Breathing equipment

Use suitable respiratory protective device in case of insufficient ventilation.

Protection of hands



Protective gloves

Material of gloves

Nitrile rubber, NBR

Eye protection



Safety glasses

Limitation and supervision of exposure into the environment

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

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9 Physical and chemical properties

Information on basic physical and chemical properties

General Information	
Appearance	
Form	Lyophilised solid
Colour	Beige/brown
Odour	Not determined.
Odour threshold	Not determined.
pH-value	7.45 - 7.55
Change in condition	
Melting point/Melting range	Not determined.
Boiling point/Boiling range	Not determined.
Flash point	Not applicable.
Flammability (solid, gaseous)	Not determined.
Ignition temperature	
Decomposition temperature	Not determined.
Self-igniting	Product is not self-igniting.
Danger of explosion	Product does not present an explosion hazard.
Explosion limits	
Lower	Not determined.
Upper	Not determined.
Oxidising properties	Not determined.
Vapour pressure	Not applicable.
Density	
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
Water	Soluble.
Partition coefficient (n-octanol/water)	Not determined.
Viscosity	
Dynamic	Not applicable.
Kinematic	Not applicable.
Other information	No further relevant information available.

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10 Stability and reactivity

Reactivity

No further relevant information available.

Chemical stability

No information available

Thermal decomposition / conditions to be avoided

No decomposition if used according to specifications.

Possibility of hazardous reactions

No dangerous reactions known.

Conditions to avoid

Heat may cause this product to decompose.

Avoid freezing.

Incompatible materials

No further relevant information available.

Hazardous decomposition products

Nature of decomposition products not known.

11 Toxicological information

Information on toxicological effects

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

on the skin: No irritating effect.

on the eye: No irritating effect.

Sensitization: No sensitizing effects known.

Other information (about experimental toxicology):

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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.

OSHA-Ca (Occupational Safety & Health Administration)
None of the ingredients is listed.

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12 Ecological information

Toxicity

Aquatic toxicity

No further relevant information available.

Persistence and degradability

No further relevant information available.

Behavior in environmental systems

Bioaccumulative potential

No further relevant information available.

Mobility in soil

No further relevant information available.

Other adverse effects

No further relevant information available.

13 Disposal considerations

Waste treatment methods

Recommendation: Dispose product according to federal, state, and local law.

Uncleaned packagings

Recommendation: Dispose unclean packaging according to federal, state, and local law.

14 Transport information

UN-number

DOT, ADR, ADN, ADN, IMDG, IATA Void

UN Proper shipping name

DOT, ADR, ADN, ADN, IMDG, IATA Void

Transport hazard class(es)

DOT, ADR, ADN, ADN, IMDG, IATA
Class Void

Packing group

DOT, ADR, ADN, IMDG, IATA Void

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<u>Environmental hazards</u>	Not applicable.
<u>Special precautions for user</u>	Not applicable.
<u>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</u>	Not applicable.
<u>UN "Model Regulation"</u>	Void

15 Regulatory information

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

SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

SARA Section 313 (specific toxic chemical listings)

None of the ingredients is listed.

TSCA (Toxic Substances Control Act)

Product is not subject to TSCA (devices/ in vitro diagnostics exempted to TSCA Section 3).

California Proposition 65

Chemicals known to cause cancer

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for females

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males

None of the ingredients is listed.

Chemicals known to cause developmental toxicity

None of the ingredients is listed.

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. DSM Nutritional Products Ltd Branch Pentapharm 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.

NFPA-ratings (scale 0 - 4)

Health = 0

Fire = 0

Reactivity = 0

Date of preparation / last revision

09/07/2016 / -

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Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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)

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit