

PhiCal Test

Issued 2010.04.26 – Rev. n. 1 of 2013.10.10

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

1.1. Product identification

Trade name : **PhiCal Test (code 9053)**

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

Professional use : In vitro diagnostic medical device.
Uses advised : All those not specifically identified.

1.3. Details of the supplier of the safety data sheet

EUROSPITAL S.p.A. - Via Flavia, 122 – 34147 TRIESTE (TS) - ITALY
phone +39 040 89971 - fax +39 040 280944

e-mail of the competent person: msds@eurospital.it

1.4. Emergency phone number

+39 040 89971 (from Monday to Friday 09.00 – 17.30)

2. Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 1999/45/EC

Classification : Not dangerous.
Nature of special risk attributed : None.

2.2. Label elements

Symbols : None.
Nature of special risk attributes : No R-phrases.
Safety advice : No S-phrases.

2.3. Other hazards

The diagnostic kit consists of 9 components and it is classified as non-hazardous according to Directive 1999/45/EC. Although it is not classified as hazardous, handle the kit carefully and follow the instructions available on label/instruction for use, as required by the Good Laboratory Practice. During the use, do not pipette by mouth and avoid contact with skin and eyes.

Calibrators and controls contain materials of human origin, therefore they are potentially infectious. The source material for calprotectin extraction was negative when tested for hepatitis B virus surface antigens (HbsAg), hepatitis C virus (HCV) and HIV virus type I and II.

3. Composition/information on ingredients

3.1. Substances

The diagnostic kit consists of the following elements, each with its own characteristics.							
1	SOLID PHASE (wells with antibodies) Plastic microplate with 96 wells, filled with anti-calprotectin antibodies.						
2	DILUTION SOLUTION (10x) Buffer solution classified as non-hazardous, coloured with erioflavine. Contains Proclin 300 as a preservative at a concentration of < 0.1 % weight.						
3	EXTRACTION SOLUTION (2.5x) Buffer solution classified as non-hazardous. Contains Proclin 300 as a preservative at a concentration of < 0.1 % weight, a non-ionic tension-active substance and trizma base.						
	Substance	Concentration	Classification	Index	CAS	EINECS	REACH
	Polyoxyethylene (10) octylphenyl ether	1 ÷ 5	Xn; R22 Xi; R41 R52/53 GHS05, GHS07 Acute Tox. 4, Eye Dam. 1, Aquatic Chronic 3 H302, H318, H412	-	9002-93-1	-	-
	Trizma base	< 5	Xi; R36/37/38 GHS07 Skin Irrit. 2, Eye Irrit. 2, STOT SE 3 H315, H319, H335	-	77-86-1	201-064-4	-
	Refer to section 16 for description of risk phrases and description of risk set out.						
4	Anti-IgG CONJUGATE Buffer solution classified as non-hazardous, with anti-human calprotectin IgG antibodies (rabbit), labelled with alkaline phosphatase and coloured with phenol red and erioflavine. Contains Proclin 300 as a preservative at a concentration of < 0.1 % weight.						
5	CALIBRATORS (5 vials) Potentially infectious buffer solution, classified as non-hazardous, containing calprotectin (of human origin) at 5 known concentrations (6.25 – 12.5 – 25 – 50 – 100 ng/ml). The solutions are coloured with phenol red. Contains Proclin 300 as a preservative at a concentration of < 0.1 % weight. The source material for calprotectin extraction was negative when tested for hepatitis B virus surface antigens (HbsAg), hepatitis C virus (HCV) and HIV virus type I and II.						

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6	CONTROL 1 Potentially infectious buffer solution, classified as non-hazardous, coloured with phenol red. Contains Proclin 300 as a preservative at a concentration of < 0.1 % weight. The control contains human calprotectin at a known concentration. The source material for calprotectin extraction was negative when tested for hepatitis B virus surface antigens (HbsAg), hepatitis C virus (HCV) and HIV virus type I and II.
7	CONTROL 2 Potentially infectious buffer solution, classified as non-hazardous, coloured with phenol red. Contains Proclin 300 as a preservative at a concentration of < 0.1 % weight. The control contains human calprotectin at a known concentration. The source material for calprotectin extraction was negative when tested for hepatitis B virus surface antigens (HbsAg), hepatitis C virus (HCV) and HIV virus type I and II.
8	WASH SOLUTION (20x) Concentrated buffer solution, with detergents, classified as non-hazardous.
9	SUBSTRATE Buffer solution, classified as non-hazardous, contains p-nitro phenyl phosphonate (pNPP, [4264-83-9]) and magnesium chloride. Contains sodium azide as a preservative at a concentration of < 0.1 % weight.

4. First aid measures

4.1. Description of first aid measures

Inhalation

Although unlikely under normal conditions of use, you may experience a situation that requires first aid in case of unforeseeable event leading to inhale the solution. Remove the victim from the environment and take in a fresh and ventilated area. If the person feels unwell, seek for medical attention immediately.

Direct contact (pure product) with Skin

Remove any contaminated clothing: they will have to be washed before re-use. Rinse immediately and thoroughly (at least for 15 minutes) with water and antiseptic soap all body parts coming in contact with the product, even if only suspected.

In the presence of damaged skin, facilitate bleeding and disinfect with a suitable product. In case of involvement of the mucosal membranes, wash immediately with plenty of water and seek for medical advice. Any possible liquid leftover must be given to the physician.

Direct contact (pure product) with Eyes

Rinse immediately and thoroughly with water (at least for 15 minutes), keeping eyelids open and CONTACT THE SPECIALIST FOR AN INSPECTION. Do not rub your eyes and keep them closed. Any possible liquid leftover must be given to the physician.

Ingestion

SEEK FOR MEDICAL ATTENTION. Drink plenty of water and keep the victim relaxed until the physician arrives. Preserve possible residuals of the ingested liquid and deliver them to the physician.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication about possible requirement for immediate medical attention and special treatment

See paragraph 4.1 Description of first aid measures.

5. Fire fighting measures

5.1. Extinguishing media

Suitable extinguishing media:

The product has no risk of fire, however, if the product is involved in a fire, use dry chemical, foam, and carbon dioxide for the extinction.

Unsuitable extinguishing media:

None known.

5.2. Special hazards arising from the substance or mixture

During combustion, fumes may form with potentially harmful health effects.

5.3. Advice for fire-fighters

Wear protection for the respiratory tract, eyes and skin. Water spray may be used to disperse vapours and protect the people involved in the fire extinction. Self-contained breathing apparatus might be used, especially if working in an enclosed or poorly ventilated areas and always when using halogenated fire-extinction products.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Due to the limited risk that large quantities can be accidentally released, general indications for the most of accidental releases of products are reported.

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For non-emergency personnel:

Move away from the area close to the escape or release. Do not smoke.

For emergency responders:

Do not smoke. Limit leakages with earth or sand. If the product has entered into a water course, the drainage system or has contaminated ground or vegetation, notify the competent authorities. Prevent it from entering the drainage system. Evacuate the danger area and, if necessary, consult an expert.

6.2. Environmental precautions

Collect spilled product with inert absorbent material covering it. Prevent spills into drains and surface waters.

6.3. Methods and material for containment and cleaning up

Deliver exclusively to specialized companies. Contain and absorb spilled liquid with inert absorbent material (sand, earth, sepiolite and other specific products) and place into containers fitted with closing.

6.4. Reference to other sections

Refer to paragraphs 8 and 13 for more information.

7. Handling and storage

7.1. Precautions for safe handling

Normal precautions for handling diagnostic products protecting against accidental contacts and ensuring accurate ventilation in the workplace. Do not smoke, eat or drink when handling. The control solutions and the calibrators must be handled as potentially infectious materials, avoiding handling them in the presence of damaged skin.

7.2. Conditions for safe storage, including any non-compatible situations

Store in original containers in a cool and dry place. Do not expose to direct sunlight. Keep at temperature between 2°C and 8°C.

7.3. Specific enduser(s)

No data available for other uses than those specified on the label.

8. Exposure controls/personal protection

8.1. Exposure parameters

No data available.

8.2. Exposure controls

Individual protection measures

- a) **Eye/face protection**
Use safety glasses with side protection to EN 166 standard. Provide a designated area for safety shower.
- b) **Skin protection**
 - i) Hand protection
Rubber gloves according to EN 374-1, EN 374-2 and EN 374-3 standards. Wash and disinfect after handling.
 - ii) Other
Wear normal work clothing as described in the risk evaluation analysis.
- c) **Respiratory protection**
Working below the hood and/or use suitable masks. Ask to the responsible of the security what the most suitable mask is.
- d) **Thermal hazards**
No data available.

Environmental exposure controls: Avoid disposing of the product in the environment.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

	Solid phase	Dilution solution	Extraction solution	Conjugate	Calibrators	Controls	Wash solution	Substrate
Appearance	Plastic material	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid
Colour	-	Blue	Colourless	Purple	Red	Red	Colourless	Light yellow
pH at 20°C	Not Applicable	8.0	7.9 ÷ 8.1	8.0	7.4	7.4	7.4	-
Relative density at 20°C	Not Applicable	1.170	1.336	1.030	1.020	1.020	1.070	-

9.2. Other information

The properties listed are not product specific standards for which reference are made to the specific analysis reports.

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10. Stability and reactivity

10.1. Reactivity

Under normal conditions of use, no risk of reactivity.

10.2. Chemical stability

Stable under normal conditions of use and storage, until the expiry date.

10.3. Possibility of hazardous reactions

There are no dangerous reactions.

10.4. Conditions to avoid

Temperature outside the range of 2°C ÷ 8°C. The elements of the kit are sensitive to the light.

10.5. Incompatible materials

In general, chemical products; in particular: halogenated compounds, strong oxidants (permanganate, dichromate, nitrate, chloride), nitrous acid and nitrites, strong acid and strong bases.

10.6. Hazardous decomposition products

Heat decomposition causes the production of toxic fumes.

11. Toxicological information

11.1. Information on toxicological effects

In reference to the calibrators and controls:

They must be considered preparations with a potential biological risk. They may be infectious if ingested, inhaled or absorbed by skin. The toxicological properties have not further been investigated.

In reference to the substrate solution:

It may be harmful if inhaled, ingested or absorbed by skin. It may cause skin irritation and eye irritation. Further toxicological data on the preparation is not available.

In reference to the extraction solution:

Acute toxicity: may be harmful if ingested and may cause respiratory and cutaneous irritation. May cause serious ocular irritation.

Chronic toxicity: targeted organs: cardiovascular system, liver, eyes and skin. May cause headache. May alter hepatic function.

Further toxicological data on the preparation is not available.

12. Ecological information

Use the product according to the Good Laboratory Practice, avoiding releasing the product into the environment.

12.1. Toxicity

The elements of the kit are not classified hazardous to the aquatic environment.

12.2. Persistence and degradability

Data not available.

12.3. Bio-accumulative potential

Data not available.

12.4. Mobility in soil

Data not available.

12.5. Results of PBT and vPvB assessment

Data not available.

12.6. Other adverse effects

Avoid releasing in water and drains.

13. Disposal considerations

13.1. Waste treatment methods

Do not re-use empty containers. Dispose wastes in compliance with the regulations in force. Any product residues may be burnt in an incinerator, equipped with post-combustion and demolition.

E.W.C. 180103.

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14. Transport information

14.1. UN number

Not established.

14.2. UN proper shipping name

Not established.

14.3. Transport hazard class(es)

Not established.

14.4. Packaging group

Not established.

14.5. Environmental hazards

Data not available.

14.6. Special precautions for user

Data not available.

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

Bulk cargo transportation is not expected.

15. Regulatory information

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

Legislative Decree no. 81 of 09/04/2008 – Title IX Item II

It does not contain carcinogenic substances, as per art. 234.

15.2. Chemical safety assessment

Chemical safety assessment not provided.

16. Other information

16.1. Other information

Description of risk phrases set out in paragraph 3:

R22 = Harmful if swallowed.

R36 = Irritating to eyes.

R37 = Irritating to respiratory system.

R38 = Irritating to skin.

R41 = Risk of serious damage to eyes.

R52 = Harmful to aquatic organisms.

R53 = May cause long-term adverse effects in the aquatic environment.

Description of risk set out in paragraph 3:

H302 = Harmful if swallowed.

H315 = Causes skin irritation.

H318 = Causes serious eye damage.

H319 = Causes serious eye irritation.

H335 = May cause respiratory irritation.

H412 = Harmful to aquatic life with long lasting effects.

Classification made on the basis of data of all the components of the mixture.

REFERENCES

ACGIH - American Conference of Governmental Industrial Hygienists

ECB - European Chemicals Bureau

IARC - International Agency for Research on Cancer

IPCS - International Programme on Chemical Safety (Cards)

NIOSH - Registry of toxic effects of chemical substances (1983)

OSHA - European Agency for Safety and Health at Work

PHATOX - Pharmacological and Toxicological Data and Information Network

This Material Safety Data Sheet completely replaces all previous versions.

The information in this MSDS was obtained from either the best knowledge available or the market at the date of the present release. Neither the registered Company holding this form or any subsidiaries will be able to accept any complaint arising from improper use of the information contained herein or improper application of the product. Particular attention should be paid to the use of preparations, because improper use can increase the danger.