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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

Commercial Product Name : Cytokeratin 10 (SP99) PAB

Mat.-No./ Genisys-No. : 06425135001

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 Limited

Charles Avenue Burgess Hill

RH15 9RY West Sussex

E-mail address :

Telephone : +44 1444 256000 Telefax : +44 1444 256239

Responsible Department

In case of emergencies: : Health, Safety & +44 1444 256500 or +44

(Roche Diagnostics Ltd.) Environment 7802 260498

+44 1444 256561 or +44

Product Safety / Vigilance 7710 391653

Toxicology 24Hr help-line: : NPIS: +44 844 892 0111
Health Advice 24Hr help-line: NHS Direct: +44 845 4647
NHS 24: +44 8454 242424

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Skin sensitization, Category 1 H317: May cause an allergic skin reaction.

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

Sensitising R43: May cause sensitization by skin contact.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



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Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements : **Prevention**:

P261 Avoid breathing dust/ fume/ gas/ mist/

vapours/ spray.

P272 Contaminated work clothing should not be

allowed out of the workplace.

P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical

advice/ attention.

P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an

approved waste disposal plant.

2.3 Other hazards

No information available.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration [%]
mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9	T; R23/24/25 C; R34 R43 N; R50-R53	Acute Tox. 3; H301 Acute Tox. 3; H331 Acute Tox. 3; H311 Skin Corr. 1B; H314 Skin Sens. 1; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 0.0015 - < 0.06

For the full text of the R-phrases mentioned in this Section, see Section 16. For the full text of the H-Statements mentioned in this Section, see Section 16.

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SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice : Move out of dangerous area.

Show this safety data sheet to the doctor in attendance.

Do not leave the victim unattended.

If inhaled : 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 : Flush eyes with water as a precaution.

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.

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

firefighting

: No information available.

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5.3 Advice for firefighters

for firefighters

Special protective equipment : Wear self contained breathing apparatus for fire fighting if

necessary.

Further information : The product itself does not burn.

: Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Refer to protective measures listed in sections 7 and 8.

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 materials for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel,

acid binder, universal binder, sawdust).

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 : Do not breathe vapours/dust.

Avoid exposure - obtain special instructions before use.

Avoid contact with skin and eyes. 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.

Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being

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used.

Advice on protection against

fire and explosion

: Normal measures for preventive fire protection.

7.2 Conditions for safe storage, including any incompatibilities

Further information on

storage conditions

: See label or package insert

7.3 Specific end uses

Specific use(s) : Laboratory chemicals

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Contains no substances with occupational exposure limit values.

Eye protection : Eye wash bottle with pure water

Tightly fitting safety goggles

Hand protection

Latex gloves

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 : impervious clothing

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

Hygiene measures : Wash hands before breaks and at the end of workday.

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance : liquid

Colour : light yellow

Odour : none

pH : 7.7, 22 °C

Melting point/range : no data available
Boiling point/boiling range : no data available
Flash point : not applicable

Lower explosion limit : no data available
Upper explosion limit : no data available
Vapour pressure : no data available

Density : 1.005 g/cm3

Water solubility : completely miscible

Partition coefficient: n-

octanol/water

: no data available

Ignition temperature : no data available

Thermal decomposition : Hazardous decomposition products formed under fire

conditions.

Viscosity, dynamic : no data available

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Conductivity : no data available
Oxidising potential : no data available
Surface tension : 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.

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10.3 Possibility of hazardous reactions

Hazardous reactions : Reacts with the following substances:

Oxidizing agents

: Further information: No decomposition if stored and applied as

directed.

10.4 Conditions to avoid

Conditions to avoid : Exposure to light.

10.5 Incompatible materials

Materials to avoid : no data available

10.6 Hazardous decomposition products

Hazardous decomposition

products

: Hazardous decomposition products formed under fire

conditions.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Product

Acute oral toxicity : no data available

: no data available Acute inhalation toxicity

Acute dermal toxicity : no data available

Acute toxicity (other routes of : no data available

administration)

: Assessment: The substance or mixture is not classified as STOT - single exposure

specific target organ toxicant, single exposure.

STOT - repeated exposure : Assessment: The substance or mixture is not classified as

specific target organ toxicant, repeated exposure.

: no data available Aspiration toxicity

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

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Product:

Toxicity to fish Toxicity to daphnia and other : no data available

aquatic invertebrates

: no data available

Toxicity to algae : no data available

: no data available Toxicity to bacteria

Ecotoxicology Assessment

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

Other organisms relevant to : no data available

the environment

12.2 Persistence and degradability

Product:

Biodegradability : no data available

12.3 Bioaccumulative potential

Product:

Bioaccumulation : no data available

12.4 Mobility in soil

Product:

: no data available Mobility Distribution among : no data available

environmental compartments

Environmental fate and

pathways

: no data available

Physico-chemical : no data available

removability

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance is not considered to be persistent,

> bioaccumulating nor toxic (PBT)., This substance is not considered to be very persistent nor very bioaccumulating

(vPvB).

12.6 Other adverse effects

Product:

Biochemical Oxygen Demand (BOD)

: no data available

Dissolved organic carbon : no data available

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(DOC)

Chemical Oxygen Demand

(COD)

: no data available

Adsorbed organic bound

halogens (AOX)

: no data available

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product : 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

DOT

Not dangerous goods

IATA

Not dangerous goods

IMDG

Not dangerous goods

SECTION 15. REGULATORY INFORMATION

OSHA Hazards : No OSHA Hazards

WHMIS Classification : Not Rated

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This product has been classified according to the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

CERCLA Reportable Quantity

Product : This material does not contain any components with a CERCLA

RQ.

SARA 302 Reportable Quantity

Product : This material does not contain any components with a SARA 302

RQ.

SARA 311/312 Hazards : No SARA Hazards

EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 302: No chemicals in this material are subject to the

reporting requirements of SARA Title III, Section 302.

SARA 304 : This material does not contain any components with a section

304 EHS RQ.

Clean Air Act

Ozone-Depletion : This product neither contains, nor was manufactured with a

Potential Class I or Class II ODS as defined by the U.S. Clean Air Act

Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

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Components : water 60 - 100 %

New Jersey Right To Know

Components : water 60 - 100 %

Albumins, blood serum 1 - 5 %

California Prop 65 : This product does not contain any chemicals known to State of

Components California to cause cancer, birth defects, or any other

reproductive harm.

SECTION 16. OTHER INFORMATION

Full text of R-phrases referred to under sections 2 and 3

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R34 Causes burns.

R43 May cause sensitization by skin contact.

R50 Very toxic to aquatic organisms.

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

Full text of H-Statements referred to under sections 2 and 3.

H301 Toxic if swallowed.
H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H331 Toxic if inhaled.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

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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