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

1.1 Product identifier

Commercial Product Name : RealTime ready Cell Lysis Kit
Mat.-No./ Genisys-No. : 05943523001

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

Recommended restrictions on use : For professional users only.

1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH
-
Sandhoferstrasse 116
68305 Mannheim
E-mail address : mannheim.umweltschutz@roche.com
Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-2012+49(0)621-759-4848+49(0)8856-60-2629

1.4 Emergency telephone number

In case of emergencies:	:	Central Works Security Roche Diagnostics GmbH	+49(0)621-759-2203
Centre for detoxification:	:	Mainz Munich	+49(0)6131-19240 +49(0)89-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Additional Labelling:

EUH210 Safety data sheet available on request.

2.3 Other hazards

See SECTION 3

SECTION 3: Composition/information on ingredients

Lysis reagent

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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

Not a hazardous substance or mixture.

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
guanidinium thiocya-nate	593-84-0 209-812-1	Xn; R20/21/22 R32 R52-R53	Acute Tox. 4; H302 Acute Tox. 4; H332 Acute Tox. 4; H312 Aquatic Chronic 3; H412	>= 1 - < 2,5

For explanation of abbreviations see section 16.

RNasin

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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

Not a hazardous substance or mixture.

Hazardous components

Remarks : No hazardous ingredients

Shrimp DNase

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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

Not a hazardous substance or mixture.

Hazardous components

Remarks : No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : Do not leave the victim unattended.

If inhaled : Move to fresh air.
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	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. 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. Rinse mouth with water.

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.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting	:	No information available.

5.3 Advice for firefighters

Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if necessary.
Further information	:	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	:	Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

Environmental precautions	:	Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
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 : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Advice on common storage : No materials to be especially mentioned.

Storage class (TRGS 510) : 12, Non Combustible Liquids

Other data : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Lysis reagent

Contains no substances with occupational exposure limit values.

RNasin

Contains no substances with occupational exposure limit values.

Shrimp DNase

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Personal protective equipment

Eye protection	:	Safety glasses
Hand protection		
Material	:	Protective gloves
Remarks	:	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	:	Protective suit
Respiratory protection	:	No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Lysis reagent

Appearance	:	liquid
Colour	:	colourless
Odour	:	none
Odour Threshold	:	No data available
pH	:	5,5
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Does not sustain combustion.
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available

Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	completely miscible
Partition coefficient: n-octanol/water	:	No data available
Ignition temperature	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

RNasin

Appearance	:	liquid
Colour	:	colourless
Odour	:	none
Odour Threshold	:	No data available
pH	:	7,6
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Does not sustain combustion.
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	completely miscible
Partition coefficient: n-octanol/water	:	No data available
Ignition temperature	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available

Viscosity	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

Shrimp DNase

Appearance	:	liquid
Colour	:	colourless
Odour	:	none
Odour Threshold	:	No data available
pH	:	7,6
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Does not sustain combustion.
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	completely miscible
Partition coefficient: n-octanol/water	:	No data available
Ignition temperature	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Lysis reagent

No data available

RNasin

No data available

Shrimp DNase

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.

10.3 Possibility of hazardous reactions

Hazardous reactions : Reacts with the following substances:
Acids

Stable under recommended storage conditions.
No hazards to be specially mentioned.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : Acids

10.6 Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Lysis reagent

Acute toxicity

Not classified based on available information.

Components:

guanidinium thiocyanate:

Acute oral toxicity : LD50 Oral (Rat): 593 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: 1,5 mg/l
Test atmosphere: dust/mist
Method: Expert judgement

Acute dermal toxicity : Acute toxicity estimate: 1.100 mg/kg
Method: Expert judgement

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.
Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Components:

guanidinium thiocyanate:
Remarks: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

RNasin

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.
Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Shrimp DNase

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.
Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12: Ecological information

12.1 Toxicity

Lysis reagent

Components:

guanidinium thiocyanate:

Toxicity to fish	:	LC50 (Poecilia reticulata (guppy)): 89,1 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia (water flea)): 42,4 mg/l Exposure time: 48 h
Ecotoxicology Assessment Chronic aquatic toxicity	:	Harmful to aquatic life with long lasting effects.

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

Other organisms relevant to the environment : No data available

RNasin

No data available

Shrimp DNase

No data available

12.2 Persistence and degradability

Lysis reagent

No data available

RNasin

No data available

Shrimp DNase

No data available

12.3 Bioaccumulative potential

Lysis reagent

Components:

guanidinium thiocyanate:

Partition coefficient: n-octanol/water : log Pow: -1,38

RNasin

No data available

Shrimp DNase

No data available

12.4 Mobility in soil

Lysis reagent

No data available

RNasin

No data available

Shrimp DNase

No data available

12.5 Results of PBT and vPvB assessment

Lysis reagent

Not relevant

RNasin

Not relevant

Shrimp DNase

Not relevant

12.6 Other adverse effects

Lysis reagent

No data available

RNasin

No data available

Shrimp DNase

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Can be disposed as waste water, when in compliance with local regulations.
Contaminated packaging	:	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

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks	:	Not dangerous goods in the meaning of ADR/RID, ADNR, IMDG-Code, ICAO/IATA-DGR

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

Remarks	:	Not applicable

SECTION 15: Regulatory information

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

Seveso II - Directive 2003/105/EC amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances

Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Water contaminating class (Germany) : WGK 1 slightly water endangering

Lysis reagent

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Additional Labelling:

EUH210 Safety data sheet available on request.

RNasin

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Shrimp DNase

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

SECTION 16: Other information

Full text of R-Phrases

R20/21/22	:	Harmful by inhalation, in contact with skin and if swallowed.
R32	:	Contact with acids liberates very toxic gas.
R52	:	Harmful to aquatic organisms.
R53	:	May cause long-term adverse effects in the aquatic environment.

Full text of H-Statements

H302	:	Harmful if swallowed.

H312	:	Harmful in contact with skin.
H332	:	Harmful if inhaled.
H412	:	Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Chronic	:	Chronic aquatic toxicity

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.

DE / EN