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SECTION 1. IDENTIFICATION

Product name : ISE Deproteinizer

Mat.-No./ Genisys-No. : 04838181001

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

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Address : 9115 Hague Road

46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone number:

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or

Canada)

1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

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.

GHS Label element

Hazard pictograms



Signal word : Warning

Hazard statements : H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy

to do. Continue rinsing.

P332 + P313 If skin irritation occurs: Get medical advice/

attention.

P337 + P313 If eye irritation persists: Get medical advice/

attention.

P362 Take off contaminated clothing and wash before reuse.



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Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

R1 (B,C)

GHS Classification

Skin irritation, Category 2 H315: Causes skin irritation.

Eye irritation, Category 2A H319: Causes serious eye irritation.

Hazardous components

| Chemical Name | CAS-No. | Concentration (%) |
|---------------------|-----------|-------------------|
| sodium hypochlorite | 7681-52-9 | >= 1 - < 5 |

SECTION 4. 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 : 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 skin irritation persists, call a physician.

> If on skin, rinse well with water, If on clothes, remove clothes,

In case of eye contact : Immediately flush eye(s) with plenty of water.

> Remove contact lenses. Protect unharmed eye.

Keep eye wide open while rinsing.

If eye irritation persists, consult a specialist.

If swallowed : Clean mouth with water and drink afterwards plenty of water.

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.

Most important symptoms and effects, both acute and

delayed

: No information available.

: The first aid procedure should be established in consultation Notes to physician

with the doctor responsible for industrial medicine.

SECTION 5. FIREFIGHTING MEASURES



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Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

: High volume water jet

Specific hazards during

firefighting

: No information available.

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Special protective equipment

for firefighters

Wear self-contained breathing apparatus for firefighting if

necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.

Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Prevent further leakage or spillage if safe to do so.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for

containment and 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.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Do not breathe vapours/dust.

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.

Conditions for safe storage : Keep container

Keep container tightly closed in a dry and well-ventilated

place.

Electrical installations / working materials must comply with

the technological safety standards.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

R1 (B,C)

Components with workplace control parameters

| Components | CAS-No. | Value type | Control | Basis |
|------------|---------|------------|---------------|-------|
| | | (Form of | parameters / | |
| | | exposure) | Permissible | |
| | | | concentration | |



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sodium hypochlorite 7681-52-9 STEL 2 mg/m3 US WEEL

Personal protective equipment

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.

Eye protection : Eye wash bottle with pure water

Tightly fitting safety goggles

Wear face-shield and protective suit for abnormal processing

problems.

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 : When using do not eat or drink.

When using do not smoke.

Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

R1 (B,C)

Appearance : liquid

Colour : yellow

Odour : characteristic

pH : 11.0, (20 °C)

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Flammability (solid, gas) : The product is not flammable.

Upper explosion limit : No data available

Lower explosion limit : No data available

Density : 1.02 g/cm3 (20 °C)



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Solubility(ies)

Water solubility : completely miscible

Auto-ignition temperature : No data available

Thermal decomposition : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous

reactions

: No decomposition if stored and applied as directed.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition

products

: No data available

SECTION 11. TOXICOLOGICAL INFORMATION

R1 (B,C)

Information on likely routes of exposure

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Causes skin irritation.

Product:

Remarks: May cause skin irritation in susceptible persons.

Components:

sodium hypochlorite:

Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Remarks: May cause irreversible eye damage.

Components:

sodium hypochlorite:

Remarks: May cause irreversible eye damage.



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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.

IARC 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.

ACGIH No component of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential

carcinogen by ACGIH.

OSHA No component of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential

carcinogen by OSHA.

NTP No component of this product present at levels greater than or

equal to 0.1% is identified as a known or anticipated carcinogen

by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Components:

sodium hypochlorite:

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Components:

sodium hypochlorite:

No data available

SECTION 12. ECOLOGICAL INFORMATION

R1 (B,C)

Ecotoxicity

Product:

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.



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Chronic aquatic toxicity : This product has no known ecotoxicological effects.

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

Other organisms relevant to

the environment

: No data available

Components:

sodium hypochlorite:

Ecotoxicology Assessment

Acute aquatic toxicity : Very toxic to aquatic life.

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

Other organisms relevant to

the environment

: No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation 40 CFR Protection of Environment; Part 82 Protection of

Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks This product neither contains, nor was manufactured with a

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).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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.



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SECTION 14. TRANSPORT INFORMATION

International Regulation

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

R1 (B,C)

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

CERCLA Reportable Quantity

| Components | CAS-No. | Component RQ (lbs) | Calculated product RQ (lbs) |
|--------------------------------------|-----------|--------------------|-----------------------------|
| Sodium hypochlorite% active chlorine | 7681-52-9 | 100 | * |

^{*:} Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

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

requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

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).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

sodium hypochlorite 7681-52-9 1.9 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

sodium hypochlorite 7681-52-9 1.9 %



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This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section

Massachusetts Right To Know

| sodium hypochlorite | 7681-52-9 | 1 - 5 % |
|---------------------|-----------|---------|
| | | |

Pennsylvania Right To Know

| water | 7732-18-5 | 90 - 100 % |
|---------------------|-----------|------------|
| sodium hypochlorite | 7681-52-9 | 1 - 5 % |

New Jersey Right To Know

| water | 7732-18-5 | 90 - 100 % |
|---------------------|-----------|------------|
| sodium hypochlorite | 7681-52-9 | 1 - 5 % |

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

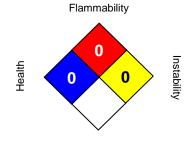
of California to cause cancer, birth defects, or any other

reproductive harm.

SECTION 16. OTHER INFORMATION

Further information

R1 (B,C) NFPA:



Special hazard.

HMIS III:

| HEALTH | 0 |
|-----------------|---|
| FLAMMABILITY | 0 |
| PHYSICAL HAZARD | 0 |

0 = not significant, 1 = Slight,

2 = Moderate, 3 = High 4 = Extreme, * = Chronic

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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.