according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No 2015/830

Iron R2 - Material number: 01 00028

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

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1.1 Product identifier

Name of product: Iron Reagent R2

as part of the kits: 01 00028 XX XX XXXX (The positions X code different packages.)

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

Reagent for in-vitro diagnostics in human samples

For professional use only

1.3 Details of the supplier of the safety data sheet

Company name: DiaSystem Scandinavia AB

Street/POB-No.: Datorgatan 3
State/city/postal code: 561 33 Jönköping

Sweden

World Wide Web: http://www.diasystem.se
Email: info@diasystem.se

Telephone: +46 (0) 36 12 62 20
Telefax: +46 (0) 36 18 77 30

Dept. responsible for information:

DiaSystem, Telephone: +46 (0)36 126220

1.4 Emergency telephone number

Giftinformationscentralen, Telephone +46 112

2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008 (CLP)

Skin Irrit. 2; H315 Causes skin irritation. Eye Dam. 1;

H318 Causes serious eye damage.

2.2 Label elements

Labelling (CLP)

Hazard statements: not applicable Precautionary statements: not applicable

Special labelling

Text for labelling: EUH210: Safety data sheet available on request.

2.3 Other hazards

National regulations - EC member states Further regulations, limitations and legal requirements: Use

restriction according to REACH annex XVII, no.: 3

Results of PBT and vPvB assessment:

No data available

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3. Composition/information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterization: Aqueous solution

Hazardous ingredients:

Ingredient	Designation	Content	Classification
EC No. 200-543-5 CAS 62-56-6	Thiourea	< 1 %	Acute Tox. 4; H302. Carc. 2; H351. Repr. 2; H361d. Aquatic Chronic 2; H411.

Full text of H- and EUH-statements: see section 16.

4. First aid measures

4.1 Description of first aid measures

In case of inhalation: Provide fresh air. Seek medical treatment in case of troubles.

Following skin contact: Change contaminated clothing. After contact with skin, wash immediately with plenty of water. In case of

skin irritation, consult a physician

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of

Rinse mouth immediately and drink plenty of water. Do not induce vomiting. Seek medical attention

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4.2Most important symptoms and effects, both acute and delayed

In case of ingestion: May cause irritations. After contact with skin: May cause irritations. After eye

contact: Irritation and redness may occur

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Product is non-combustible. Extinguishing materials should therefore be selected according to

surroundings.

5.2 Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours. In case of fire may be

liberated: Nitrogen oxides (NOx), sulphur oxides, carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

 $\label{thm:continuous} \mbox{Special protective equipment for firefighters:}$

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information:

Hazchem-Code: -

Do not allow fire water to penetrate into surface or ground water.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes, and clothing. Wear suitable protective clothing. In enclosed areas: Provide fresh air. Do not breathe vapours.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of water. Final cleaning.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

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Iron R2 - Material number: 01 00028

7. Handling and storage

7.1 Precautions for safe handling

Advices on safe handling: Provide adequate ventilation. Do not breathe vapours. Avoid contact with skin and eyes. Keep all

containers, equipment and working place clean. Change contaminated clothing. Work place should be

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equipped with a shower and an eye rinsing apparatus

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep containers tightly closed and at a temperature between + 2 $^{\circ}$ C and + 8 $^{\circ}$ C. Protect against heat /sun

rays. Keep sterile. Do not freeze. Unsuitable materials: Aluminium, copper, copper alloys, zinc.

7.3 Specific end use(s)

No information available.

8. Exposure controls / Personal protection equipment

8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area

Personal protection equipment

Occupational exposure controls

Respiratory protection: If vapours form, use respiratory protection. Use combination filter type A/P according to EN 14387.

Hand protection: Protective gloves according to EN 374. Glove material: Nitrile rubber Breakthrough time: >480 min.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to EN 166.

Body protection: Lab coat General protection and hygiene measures:

Avoid contact with skin, eyes, and clothing. Change contaminated clothing. Do not breathe vapours. Wash

hands before breaks and after work

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: Physical state at 20 °C and 101.3 kPa: liquid

yellow Colour: Like sulfur Odour: No data available Odour threshold: at 25 °C: 2.5 No data available Melting point/freezing point: No data available Initial boiling point and boiling range: Flash point/flash point range: not combustible No data available Evaporation rate: No data available Flammability: No data available **Explosion limits:** No data available Vapour pressure: Vapour density: No data available at 20 °C: 1.022 g/mL Density:

Water solubility: at 20 °C: completely miscible

Partition coefficient: n-octanol/water:

Auto-ignition temperature:

Decomposition temperature:

No data available

No data available

Viscosity, kinematic:

No data available

Explosive properties:

No data available

Oxidizing characteristics:

No data available

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9.2 Other information

Additional information: No data available

10. Stability and reactivity

10.1 Reactivity

Refer to 10.3

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

Protect from frost, heat and sunlight.

10.5 Incompatible materials

strong acids, alkalis, aluminium, copper, copper alloys, zinc.

10.6 Hazardous decomposition products

In case of fire may be liberated: Sulphur oxides, nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

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Thermal decomposition:

No data available

11. Toxicological information

11.1 Information on toxicological effects

Toxicological effects: Acute toxicity (oral): Based on available data, the classification criteria are not met

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Lack of data.

Serious eye damage/irritation: Lack of data.

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Lack of data.

Germ cell mutagenicity/Genotoxicity: Lack of data.

Carcinogenicity: Lack of data.
Reproductive toxicity: Lack of data.
Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Lack of data. Specific target organ toxicity (repeated exposure): Lack of data.

Aspiration hazard: Lack of data.

Symptoms

Can cause skin, eye and respiratory tract irritation

12. Ecological information

12.1 Toxicity

Aquatic toxicity: In case of spills of large quantities: Harmful effects on water organisms by modification of pH-value.

12.2. Persistence and degradability

Further details: No data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

General information: Do not allow to enter into ground-water, surface water or drains

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13. Disposal considerations

13.1 Waste treatment methods

Product

Waste key number 16 05 06* = Laboratory chemicals, consisting of or containing hazardous substances, including

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mixtures of laboratory chemicals.

* = Evidence for disposal must be provided.

Recommendation: Special waste. Waste disposal according to official state regulations.

Contaminated packaging

Waste key number 150102 = Plastic packaging.

Recommendation: Dispose of waste according to applicable legislation.

Non-contaminated packages may be recycled.

14.1 Transport information

14.1 UN number

ADR/RID, IMDG, IATA-DGR: not applicable **14.2 UN proper shipping name**ADR/RID, IMDG, IATA-DGR: Not restricted

14.3 Transport hazard class(es)ADR/RID, IMDG, IATA-DGR: not applicable

14.4 Packing group

ADR/RID, IMDG, IATA-DGR: not applicable

14.5 Environmental hazards

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

No data available

15. Other information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture National regulations - Great Britain

Hazchem-Code: -

No data available

15.2 Chemical Safety Assessment

For this substance a chemical safety assessment is not required.

16. Other information

Further information

Wording of the H-phrases under paragraph 2 and 3:

H302 = Harmful if swallowed. H351 = Suspected of causing cancer.

H361d = Suspected of damaging the unborn child. H411 = Toxic to aquatic life with long lasting effects EUH210 = Safety data sheet available on request.

Reason of change: General revision (Regulation (EU) No 2015/830)

Date of first version: 2011-07-01 **Department issuing data sheet**

Contact person: see section 1: Dept. responsible for information

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations). The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.

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