

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

Revision date: 14/7/2022
Version: 14.0
Language: en-GB,IE
Date of print: 6/9/2022

NEFA FS Reagent R1

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

1.1 Product identifier

Trade name: NEFA FS Reagent R1

As part of the kits: 1 5781 XX XX XXX (The positions X code different packages.)

UFI: GX20-D07K-S00E-AQW7

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

General use: 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: DiaSys Diagnostic Systems GmbH

 Street/POB-No.:
 Alte Strasse 9

 Postal Code, city:
 65558 Holzheim

 WWW:
 http://www.diasys.de

 E-mail:
 mail@diasys.de

 Telephone:
 +49 (0) 6432-9146-0

 Telefax:
 +49 (0) 6432-9146-32

Department responsible for information:

Corporate headquarters, Telephone: +49 (0) 6432-9146-0, Email: mail@diasys.de

1.4 Emergency telephone number

Infraserv, Telephone: +49 (0) 69-305-6418

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008 (CLP)

Eye Dam. 1; H318 Causes serious eye damage.

2.2 Label elements

Labelling (CLP)



Signal word: Danger

Hazard statements: H318 Causes serious eye damage.

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.



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Special labelling

Text for labelling: Contains Alcohol, secondary, C12-C14, ethoxylated

2.3 Other hazards

No risks worthy of mention.

Results of PBT and vPvB assessment:

No data available

SECTION 3: Composition/information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterisation: Aqueous solution of inorganic salts and organic compounds.

Hazardous ingredients:

Ingredient	Designation	Content	Classification
	Alcohol, secondary, C12-C14, ethoxylated	3 %	Acute Tox. 4; H302. Acute Tox. 4; H312. Skin Irrit. 2; H315. Eye Dam. 1; H318.
EC No. 233-465-5 CAS 10191-18-1	2-[bis(2-Hydroxyethyl)amino] ethanesulphonic acid	< 2 %	Skin Irrit. 2; H315. Eye Irrit. 2; H319. STOT SE 3; H335.

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

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

First aider: Pay attention to self-protection!

If medical advice is needed, have product container or label at hand.

Provide fresh air. Seek medical aid in case of troubles.

Following skin contact:

Take off contaminated clothing and wash it before reuse. Remove residues with water. Seek medical aid in case of troubles.

After eye contact:

Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently seek the immediate attention of an ophthalmologist.

After swallowing: Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an

unconscious person. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye damage.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.



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SECTION 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

Special protective equipment for firefighters:

Wear self-contained breathing apparatus.

Additional information: Hazchem-Code: -

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes. Wear appropriate protective equipment. Provide adequate ventilation. Keep unprotected people away. Avoid breathing vapours/spray. Take off contaminated clothing and wash it before reuse.

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.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advices on safe handling:

Avoid contact with skin and eyes. Wear appropriate protective equipment. Keep all containers, equipment and working place clean. Provide adequate ventilation, and local exhaust as needed. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Have eye wash bottle or eye rinse ready at work place. Avoid breathing vapours/spray. Take off contaminated clothing and wash it before reuse.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep containers tightly closed and at a temperature between 2 $^{\circ}\text{C}$ and 8 $^{\circ}\text{C}.$ Do not

freeze. Protect from light. Keep sterile.

Hints on joint storage: Keep away from food, drink and animal feedingstuffs.



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7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

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: Use a breathing protection against vapours/aerosol.

Use combination filter type A/P according to EN 14387.

Hand protection: Protective gloves according to EN 374.

Glove material: Butyl caoutchouc (butyl 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: Wear suitable protective clothing.

General protection and hygiene measures:

Avoid contact with skin and eyes. Avoid breathing vapours/spray. Take off contaminated clothing and wash it before reuse. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product. Have eye wash bottle or eye rinse ready at work

place.

Environmental exposure controls

Refer to "6.2 Environmental precautions".

SECTION 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

at 20 °C: 1.0165 g/mL

Colour: colourless up to weak brown, clear

Odour: no characteristic odour
Odour threshold: No data available

at 25 °C: 7.0 No data available Melting point/freezing point: Initial boiling point and boiling range: No data available Flash point/flash point range: not combustible Evaporation rate: No data available Flammability: No data available Explosion limits: No data available Vapour pressure: No data available Vapour density: No data available

Density:



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Water solubility:

Partition coefficient: n-octanol/water:

Auto-ignition temperature:

Decomposition temperature:

Viscosity, kinematic:

Explosive properties:

Oxidizing characteristics:

No data available

No data available

No data available

No data available

9.2 Other information

Additional information: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Refer to subsection "Possilbility of hazardous reactions".

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

No data available

10.6 Hazardous decomposition products

No hazardous decomposition products when regulations for storage and handling are

observed.

Thermal decomposition: No data available



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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Toxicological effects: The statements are derived from the properties of the single components. No toxicological

data is available for the product as such.

Acute toxicity (oral): Lack of data.

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Lack of data.

Serious eye damage/irritation: Eye Dam. 1; H318 = Causes serious eye damage.

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

After eye contact: Upon direct contact with eyes may cause burning, tearing, redness.

SECTION 12: Ecological information

12.1 Toxicity

Further details: No data available

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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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

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

including mixtures of laboratory chemicals.

* = Evidence for disposal must be provided.

Recommendation: Special waste. Dispose of waste according to applicable legislation.

Package

Waste key number: 15 01 02 = Plastic packaging

Recommendation: Dispose of waste according to applicable legislation.

Non-contaminated packages may be recycled.

SECTION 14: 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

Marine pollutant: no

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

SECTION 15: Regulatory information

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

National regulations - Great Britain

Hazchem-Code:

No data available



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National regulations - EC member states

Further regulations, limitations and legal requirements:

Use restriction according to REACH annex XVII, no.: 3

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

SECTION 16: Other information

Further information

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

H302 = Harmful if swallowed.

H312 = Harmful in contact with skin.

H315 = Causes skin irritation.

H318 = Causes serious eye damage.

H319 = Causes serious eye irritation.

H335 = May cause respiratory irritation.

Abbreviations and acronyms:

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR: European Agreement concerning the International Carriage of Dangerous Goods by

Road

AS/NZS: Australian Standards/New Zealand Standards

CAS: Chemical Abstracts Service

CFR: Code of Federal Regulations

CLP: Classification, Labelling and Packaging

DMEL: Derived minimal effect level DNEL: Derived no-effect level

EC: European Community

EN: European Standard

EQ: Excepted quantities

EU: European Union

IATA: International Air Transport Association

IATA-DGR: International Air Transport Association – Dangerous Goods Regulations IBC Code: International Code for the Construction and Equipment of Ships carrying

Dangerous Chemicals in Bulk

IMDG Code: International Maritime Dangerous Goods Code

MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution

from Ships

OSHA: Occupational Safety and Health Administration

PBT: Persistent, bioaccumulative and toxic PNEC: Predicted no-effect concentration

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals

RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail

STOT SE: Specific target organ toxicity - single exposure

TRGS: Technical Rules for Hazardous Substances

vPvB: Very persistent and very bioaccumulative

Reason of change: Changes in section 1: Product Identification

Date of first version: 13/3/2008

Department issuing data sheet

Contact person: see section 1: Department responsible for information



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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.