

SAFETY DATA SHEET

Water for Injectable (WFI)

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

1.1. Product identifier

Trade name

Water for Injectable (WFI)

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

Relevant identified uses of the substance or mixture

None known.

Restricted to professional users.

Uses advised against

None known.

1.3. Details of the supplier of the safety data sheet

Company and address

Greenfield Global LFS Ireland Ltd.,

IDA Business & Technology Park,

Mountrath Road,

Portlaoise,

Co. Laois,

Ireland

+353 057 867 1400

E-mail

exports@greenfield.com

Revision

02/01/2024

SDS Version

1.0

1.4. Emergency telephone number

The National Poisons Information Centre (NPIC)

Public: +353 (0) 1 809 2166 (7 days a week, 8am- 10pm)

Healthcare professionals: +353 (0) 1 809 2566 (24 h service)

See also section 4 "First aid measures"

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Not classified according to Regulation (EC) No. 1272/2008 (CLP).

2.2. Label elements

Hazard pictogram(s)

Not applicable.

Signal word

Not applicable.

Hazard statement(s)

Not applicable.

Precautionary statement(s)

General

-

Prevention

-

Response

-

Storage

-

According to EC-Regulation 1907/2006 (REACH), annex II, including changes implemented by EC-Regulation 2020/878

Disposal

-

Hazardous substances

None known.

Additional labelling

Not applicable.

2.3. Other hazards

Additional warnings

This mixture/product does not contain any substances known to fulfil the criteria for PBT and vPvB classification. This product does not contain any substances considered to be endocrine disruptors in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable. This product is a mixture.

3.2. Mixtures

Does not contain any substances required to report

See full text of H-phrases in section 16. Occupational exposure limits are listed in section 8, if these are available.

Other information

-

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In the case of accident: Contact a doctor or casualty department – take the label or this safety data sheet. Contact a doctor if in doubt about the injured person's condition or if the symptoms persist. Never give an unconscious person water or other drink.

Inhalation

In case of discomfort: bring the person into fresh air.

Skin contact

Upon irritation: rinse with water. In the event of continued irritation, seek medical assistance.

Eye contact

If in eyes: Flush eyes with plenty of water or salt water (20-30 °C) and continue until irritation stops. Remove contact lenses.

Ingestion

Rinse and flush mouth thoroughly and consume large quantities of water. In case of continued discomfort: seek medical assistance and bring this safety data sheet.

Burns

Not applicable.

4.2. Most important symptoms and effects, both acute and delayed

None known.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

Information to medics

Bring this safety data sheet or the label from this product.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Alcohol-resistant foam, carbon dioxide, powder, water mist.

Unsuitable extinguishing media: Waterjets should not be used, since they can spread the fire.

5.2. Special hazards arising from the substance or mixture

Fire will result in dense smoke. Exposure to combustion products may harm your health. Closed containers, which are exposed to fire, should be cooled with water. Do not allow fire-extinguishing water to enter the sewage system and nearby surface waters.

According to EC-Regulation 1907/2006 (REACH), annex II, including changes implemented by EC-Regulation 2020/878

5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact. Upon direct exposure contact the National Poisons Information Centre (NPIC) on +353 (0) 1 809 256 (24 h service) in order to obtain further advice. Fire fighters should wear appropriate personal protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Contaminated areas may be slippery.

6.2. Environmental precautions

Avoid discharge to lakes, streams, sewers, etc.

Keep unauthorized persons away from the spill

6.3. Methods and material for containment and cleaning up

Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

Wherever possible cleaning should be performed with normal cleaning agents. Avoid use of solvents.

6.4. Reference to other sections

See section 13 "Disposal considerations" on handling of waste.

See section 8 "Exposure controls/personal protection" for protective measures.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Smoking, drinking and consumption of food is not allowed in the work area.

See section 8 "Exposure controls/personal protection" for information on personal protection.

7.2. Conditions for safe storage, including any incompatibilities

Recommended storage material

Always store in containers of the same material as the original container.

Storage temperature

Store in tightly closed original container in a dry, cool and well-ventilated place.

Incompatible materials

Metallic Sodium.

7.3. Specific end use(s)

This product should only be used for applications quoted in section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No substances are listed in the "List of Chemical Agents and Occupational Exposure Limit Values" with an occupational exposure limit.

DNEL

No data available.

PNEC

No data available.

8.2. Exposure controls

Control is unnecessary if the product is used as intended.

General recommendations

Smoking, drinking and consumption of food is not allowed in the work area.

Exposure scenarios

There are no exposure scenarios implemented for this product.

Exposure limits

Occupational exposure limits have not been defined for the substances in this product.

Appropriate technical measures

Apply standard precautions during use of the product. Avoid inhalation of vapours.

Hygiene measures

Wash hands after use.

Measures to avoid environmental exposure

No specific requirements.

Individual protection measures, such as personal protective equipment

According to EC-Regulation 1907/2006 (REACH), annex II, including changes implemented by EC-Regulation 2020/878

Generally

No specific requirements

Respiratory Equipment

No specific requirements

Skin protection

No specific requirements.

Hand protection

No specific requirements.

Eye protection

No specific requirements.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state

Liquid

Colour

Clear

Odour / Odour threshold

None

pH

7

Density (g/cm³)

1

Kinematic viscosity

Testing not relevant or not possible due to the nature of the product.

Particle characteristics

Testing not relevant or not possible due to nature of the product.

Phase changes

Melting point/Freezing point (°C)

0

Softening point/range (waxes and pastes) (°C)

Does not apply to liquids.

Boiling point (°C)

100

Vapour pressure

17 mmHg (20 °C)

Relative vapour density

0.013kg/m³

Decomposition temperature (°C)

Testing not relevant or not possible due to nature of the product.

Data on fire and explosion hazards

Flash point (°C)

Not applicable - the product is not classified as flammable.

Flammability (°C)

The material is not combustible.

Auto-ignition temperature (°C)

Testing not relevant or not possible due to the nature of the product.

Lower and upper explosion limit (% v/v)

Testing not relevant or not possible due to the nature of the product.

Solubility

Solubility in water

Soluble

n-octanol/water coefficient (LogKow)

Testing not relevant or not possible due to the nature of the product.

Solubility in fat (g/L)

Testing not relevant or not possible due to the nature of the product.

9.2. Other information

Evaporation rate (n-butylacetate = 100)

According to EC-Regulation 1907/2006 (REACH), annex II, including changes implemented by EC-Regulation 2020/878

Testing not relevant or not possible due to nature of the product.

Other physical and chemical parameters

No data available.

Oxidizing properties

Testing not relevant or not possible due to nature of the product.

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

The product is stable under the conditions, noted in section 7 "Handling and storage".

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

Avoid extremes of temperature.

10.5. Incompatible materials

Metallic Sodium.

10.6. Hazardous decomposition products

The product is not degraded when used as specified in section 1.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Based on available data, the classification criteria are not met.

Respiratory sensitisation

Based on available data, the classification criteria are not met.

Skin sensitisation

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2. Information on other hazards

Long term effects

None known.

Endocrine disrupting properties

This mixture/product does not contain any substances known to have hormone-disrupting properties in relation to health.

Other information

None known.

SECTION 12: Ecological information

12.1. Toxicity

No data available.

According to EC-Regulation 1907/2006 (REACH), annex II, including changes implemented by EC-Regulation 2020/878

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This mixture/product does not contain any substances known to fulfil the criteria for PBT and vPvB classification.

12.6. Endocrine disrupting properties

This mixture/product does not contain any substances considered to have endocrine-disrupting properties in relation to the environment.

12.7. Other adverse effects

None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product is not covered by regulations on dangerous waste.

Commission Regulation (EU) No 1357/2014 of 18 December 2014 on waste.

EWC code

Not applicable.

Contaminated packing

Packaging containing residues of the product must be disposed of similarly to the product.

SECTION 14: Transport information

	14.1 UN / ID	14.2 UN proper shipping name	14.3 Hazard class(es)	14.4 PG*	14.5 Env**	Other information:
ADR	-	-	-	-	-	-
IMDG	-	-	-	-	-	-
IATA	-	-	-	-	-	-

* Packing group

** Environmental hazards

Additional information

Not dangerous goods according to ADR, IATA and IMDG.

14.6. Special precautions for user

Not applicable.

14.7. Maritime transport in bulk according to IMO instruments

No data available.

SECTION 15: Regulatory information

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

Restrictions for application

Restricted to professional users.

Demands for specific education

No specific requirements.

SEVESO - Categories / dangerous substances

Not applicable.

Additional information

Not applicable.

Sources

Commission Regulation (EU) No 1357/2014 of 18 December 2014 on waste.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP).

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

According to EC-Regulation 1907/2006 (REACH), annex II, including changes implemented by EC-Regulation 2020/878

15.2. Chemical safety assessment

No

SECTION 16: Other information

Abbreviations and acronyms

ADN = European Provisions concerning the International Carriage of Dangerous Goods by Inland Waterway
ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
CAS = Chemical Abstracts Service
CE = Conformité Européenne (European conformity)
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
CSA = Chemical Safety Assessment
CSR = Chemical Safety Report
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EINECS = European Inventory of Existing Commercial chemical Substances
ES = Exposure Scenario
EUH statement = CLP-specific Hazard statement
EuPCS = European Product Categorisation System
EWC = European Waste Catalogue
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IARC = International Agency for Research on Cancer (IARC)
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
OECD = Organisation for Economic Co-operation and Development
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail
RRN = REACH Registration Number
SCL = A specific concentration limit
SVHC = Substances of Very High Concern
STOT-RE = Specific Target Organ Toxicity - Repeated Exposure
STOT-SE = Specific Target Organ Toxicity - Single Exposure
TWA = Time weighted average
UN = United Nations
UVBC = Unknown or variable composition, complex reaction products or of biological materials
VOC = Volatile Organic Compound
vPvB = Very Persistent and Very Bioaccumulative

Additional information

In accordance with Article 31 of REACH, a safety data sheet is not required for this product. This safety data sheet has been created on a voluntary basis to distribute relevant information as required under Article 32 of REACH.

The safety data sheet is validated by

EcoOnline

Other

A change (in proportion to the last essential change (first cipher in SDS version, see section 1)) is marked with a blue triangle.

The information in this safety data sheet applies only to this specific product (mentioned in section 1) and is not necessarily correct for use with other chemicals/products.

It is recommended to hand over this safety data sheet to the actual user of the product. Information in this safety data sheet cannot be used as a product specification.

Country-language: IE-en