

Safety data sheet
according to 1907/2006/EC, Article 31

Printing 10.06.2020

version number 1

Revision: 10.06.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking***1.1 Product identifier*****Trade name:** Osmolality Standard 100mOsm/Kg H2O***Article number:** A01242***Registration number**

A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

No further relevant information available.

Application of the substance / the mixture** Laboratory Chemicals1.3 Details of the supplier of the safety data sheet*****Manufacturer/Supplier:**

Reagecon Diagnostics Ltd.

Shannon Free Zone,

Shannon,

Co. Clare,

Ireland.

Tel +353 61 472622

Fax +353 61 472642

Further information obtainable by contacting:** sds@reagecon.ie1.4 Emergency telephone number:**

For Hazardous Materials [or Dangerous Goods] Incident

Spill, Leak, Fire, Exposure, or Accident

Call CHEMTREC

For Ireland call +(353)-19014670

For Outside Ireland call +1 703-741-5970 / 1-800-424-9300 CCN849800

SECTION 2: Hazards identification***2.1 Classification of the substance or mixture*****Classification according to Regulation (EC) No 1272/2008**

The product is not classified, according to the CLP regulation.

2.2 Label elements**Labelling according to Regulation (EC) No 1272/2008** Void***Hazard pictograms** Void***Signal word** Void***Hazard statements** Void***2.3 Other hazards*****Results of PBT and vPvB assessment*****PBT:** Not applicable.***vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients*****3.2 Chemical characterisation: Mixtures*****Description:** Mixture of substances listed below with nonhazardous additions.***Dangerous components:** Void***Additional information:** For the wording of the listed hazard phrases refer to section 16.**SECTION 4: First aid measures*****4.1 Description of first aid measures*****General information:** No special measures required.

(Contd. on page 2)

GB

Safety data sheet
according to 1907/2006/EC, Article 31

Printing 10.06.2020

version number 1

Revision: 10.06.2020

Trade name: Osmolality Standard 100mOsm/Kg H2O

(Contd. of page 1)

***After inhalation:**

Provide fresh air, warmth and rest. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Obtain medical attention if any discomfort continues.

After skin contact:** Generally the product does not irritate the skin.After eye contact:**

Promptly wash eyes with plenty of water for up to 15 minutes. Open eyes wide apart and rinse well to remove any contact lenses. Do not remove contact lenses by hand. Continue to rinse. Get medical attention if symptoms persist.

After swallowing:** If symptoms persist consult doctor.4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.***4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

SECTION 5: Firefighting measures***5.1 Extinguishing media*****Suitable extinguishing agents:**

Indications shall be given whether any extinguishing media are inappropriate for a particular situation involving the substance or mixture

Use fire extinguishing methods suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture** No further relevant information available.5.3 Advice for firefighters*****Protective equipment:**

Fire fighters should wear complete protective clothing including self-contained breathing apparatus. Do not breathe fumes. Keep containers cool by spraying with water if exposed to fire. Avoid run off to waterways and sewers

SECTION 6: Accidental release measures***6.1 Personal precautions, protective equipment and emergency procedures** Not required.***6.2 Environmental precautions:**

Advice shall be provided on any environmental precautions to be taken related to accidental spills and release of the substance or mixture, such as keeping away from drains, surface and ground water

***6.3 Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

***6.4 Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage***7.1 Precautions for safe handling** No special measures required.***Information about fire - and explosion protection:** No special measures required.***7.2 Conditions for safe storage, including any incompatibilities*****Storage:*****Requirements to be met by storerooms and receptacles:** No special requirements.***Information about storage in one common storage facility:** Not required.***Further information about storage conditions:** None.***7.3 Specific end use(s)** No further relevant information available.

GB

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing 10.06.2020

version number 1

Revision: 10.06.2020

Trade name: **Osmolality Standard 100mOsm/Kg H2O**

(Contd. of page 2)

SECTION 8: Exposure controls/personal protection

***Engineering Controls:** No further data; see item 7.

***8.1 Control parameters**

***Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

***Additional information:** The lists valid during the making were used as basis.

***8.2 Exposure controls**

***Personal protective equipment:**

***General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

***Respiratory protection:** Not required.

***Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Always ensure that gloves are inspected before use.

Selection of protective gloves must include consideration of the penetration times along with rates of diffusion and degradation. The selected glove should comply with the specifications of EU Directive 89/686/EEC and the standard EN374 derived from it.

***Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

***Penetration time of glove material**

In the absence of data above, the exact break through time has to be sourced from the manufacturer of the protective gloves and has to be observed.

***Eye protection:**



Goggles recommended during refilling: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU)

GB

(Contd. on page 4)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing 10.06.2020

version number 1

Revision: 10.06.2020

Trade name: Osmolality Standard 100mOsm/Kg H2O

(Contd. of page 3)

SECTION 9: Physical and chemical properties

*9.1 Information on basic physical and chemical properties

*General Information

*Appearance:

Form:	Liquid
Colour:	According to product specification
*Odour:	Characteristic
*Odour threshold:	Not determined.

*pH-value: Not determined.

*Change in condition

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	100 °C

*Flash point: Not applicable.

*Flammability (solid, gas): Not applicable.

*Decomposition temperature: Not determined.

*Auto-ignition temperature: Product is not selfigniting.

*Explosive properties: Product does not present an explosion hazard.

*Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

*Vapour pressure at 20 °C: 23 hPa

*Density at 20 °C: 1.00358 g/cm³

*Relative density: Not determined.

*Vapour density: Not determined.

*Evaporation rate: Not determined.

*Solubility/ miscibility with water:

Not miscible or difficult to mix.

*Partition coefficient: n-octanol/water: Not determined.

*Viscosity:

Dynamic:	Not determined.
Kinematic:	Not determined.

*9.2 Other information: No further relevant information available.

SECTION 10: Stability and reactivity

*10.1 Reactivity: No further relevant information available.

*10.2 Chemical stability

*Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

*10.3 Possibility of hazardous reactions: No dangerous reactions known.

*10.4 Conditions to avoid: No further relevant information available.

*10.5 Incompatible materials: No further relevant information available.

*10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

*11.1 Information on toxicological effects

*Acute toxicity: Based on available data, the classification criteria are not met.

(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing 10.06.2020

version number 1

Revision: 10.06.2020

Trade name: Osmolality Standard 100mOsm/Kg H2O

(Contd. of page 4)

- ***Primary irritant effect:**
- ***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 or skin sensitisation** Based on available data, the classification criteria are not met.
- ***CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- ***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.

SECTION 12: Ecological information

- ***12.1 Toxicity**
- ***Aquatic toxicity:** No further relevant information available.
- ***12.2 Persistence and degradability** No further relevant information available.
- ***12.3 Bioaccumulative potential** No further relevant information available.
- ***12.4 Mobility in soil** No further relevant information available.
- ***Additional ecological information:**
- ***General notes:** Not hazardous for water.
- ***12.5 Results of PBT and vPvB assessment**
- ***PBT:** Not applicable.
- ***vPvB:** Not applicable.
- ***12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- ***13.1 Waste treatment methods**
- ***Recommendation** Smaller quantities can be disposed of with household waste.
- ***Uncleaned packaging:**
- ***Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|-----------------|
| * 14.1 UN-Number
* ADR, IMDG, IATA | Void |
| * 14.2 UN proper shipping name
* ADR, IMDG, IATA | Void |
| * 14.3 Transport hazard class(es)
* ADR, IMDG, IATA
* Class | Void |
| * 14.4 Packing group
* ADR, IMDG, IATA | Void |
| * 14.5 Environmental hazards: | Not applicable. |
| * 14.6 Special precautions for user | Not applicable. |
| * 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |

(Contd. on page 6)

GB

Safety data sheet
according to 1907/2006/EC, Article 31

Printing 10.06.2020

version number 1

Revision: 10.06.2020

Trade name: Osmolality Standard 100mOsm/Kg H2O

(Contd. of page 5)

***UN "Model Regulation":**

Void

SECTION 15: Regulatory information***15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture*****Directive 2012/18/EU*****Named dangerous substances - ANNEX I** None of the ingredients is listed.***National regulations:*****Waterhazard class:** Generally not hazardous for water.***15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Department issuing SDS:** Health and SafetyContact:** sds@reagecon.ie***Abbreviations and acronyms:**

REACH (Registration, Evaluation, Authorisation and restriction of Chemicals)

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative