



SECTION 1: IDENTIFICATION	
<b>1.1 Product identifier</b>	
<b>Product name:</b>	Sterilised Water® (for Injections BP)
<b>Synonyms:</b>	None
<b>Proper Shipping name:</b>	Not Available
<b>Other means of identification:</b>	None
<b>1.2 Relevant identified uses of the substances or mixture and uses advised against</b>	
<b>Recommended uses:</b>	As a sterile solvent for dissolving or diluting medicaments for parenteral administration.
<b>Uses advised against:</b>	None known.
<b>1.3 Details of the supplier of the substance or mixture</b>	
<b>Registered company name:</b>	Dechra Ltd
<b>Address:</b>	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK
<b>Telephone:</b>	+44 (0) 1756 791311
<b>Fax:</b>	+44 (0) 1756 798604
<b>Email:</b>	Not available
<b>1.4 Emergency Telephone Numbers</b>	
	+44 (0) 1756 791311

SECTION 2: HAZARDS IDENTIFICATION	
<b>2.1 Classification of the substance or mixture</b>	
<b>DSD Classification (EU):</b>	Not Available
<b>DPD Classification (EU):</b>	Not Available
<b>Classification according to regulation (EC) No 1272/2008 [CLP] (EU):</b>	Not Available
<b>2.2 Label Elements</b>	
<b>Signal Word:</b>	Not Available

<b>Hazard Statement(s)</b>
Not Available
<b>Additional Statement(s)</b>
Not Available
<b>Precautionary Statement(s) Prevention:</b>
Not Available
<b>Precautionary Statement(s) Response:</b>
Not Available
<b>Precautionary Statement(s) Storage:</b>
Not Available
<b>Precautionary Statement(s) Disposal:</b>
Not Available
<b>2.3 Other Hazard Information</b>
Not Available

### SECTION 3: INFORMATION ON THE INGREDIENTS

#### 3.1 Substances

See section below for composition of mixtures

#### 3.2 Mixtures

1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% w/v	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 7732-18-5 2. 231-791-2 3. Not Available 4. Not Available	100	Water for injections	None

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

<b>Eye contact:</b>	Not Applicable
<b>Skin contact:</b>	Not Applicable
<b>Inhalation:</b>	Not Applicable

<b>Ingestion:</b>	Not Applicable
<b>Self-injection:</b>	Not Applicable
<b>4.2 Most important symptoms and effects, both acute and delayed</b>	
See Section 11	
<b>4.3 Indication of immediate medical attention and special treatment needed</b>	
N/a	

<b>SECTION 5: FIRE FIGHTING MEASURES</b>	
<b>5.1 Extinguishing media</b>	
<b>Suitable:</b>	Not applicable
<b>Unsuitable:</b>	Not applicable
<b>5.2 Special hazards arising from the substance or mixture</b>	
<b>Fire incompatibility:</b>	None known.
<b>5.3 Special protective actions for fire-fighters:</b>	
<b>Firefighting:</b>	Alert Fire Brigade and tell them location and nature of hazard. Wear full breathing apparatus and self-contained breathing apparatus.
<b>Fire / explosion hazard:</b>	None

<b>SECTION 6: ACCIDENTAL RELEASE MEASURES</b>	
<b>6.1 Personal precautions, protective equipment and emergency procedures</b>	
For information on protective equipment, see section 8.	
<b>6.2 Environmental Precautions</b>	
Do not allow product to reach sewage system or any water course.	
<b>6.3 Methods and material for containment and cleaning up</b>	
<b>Minor Spills:</b>	Absorb solution and place into a suitable disposal container.
<b>Major Spills:</b>	Absorb solution and place into a suitable disposal container.



**SECTION 7: HANDLING AND STORAGE**

**7.1 Precautions for safe handling**

<b>Safe Handling:</b>	Observe manufacturer's storage and handling recommendations.
<b>Other Information:</b>	This product does not contain an antimicrobial preservative. Any product remaining in the vial following withdrawal of the required volume should be discarded. Keep out of the reach and sight of children.

**7.2 Conditions for safe storage, including any incompatibilities**

<b>Suitable Container:</b>	Do not store above 25°C Shelf life of the veterinary medicinal product as packaged for sale: 4 years.
<b>Storage incompatibility:</b>	Water is considered a non-regulated product, but may react vigorously with some specific materials. Avoid contact with all materials until investigation shows substance is compatible.

**7.3 Specific end uses**

Not available

**SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**

**8.1 Control parameters**

**DERIVED NO EFFECT LEVEL - DNEL**

Not Available

**PREDICTED NO EFFECT LEVEL - PNEC**

Not Available

**OCCUPATIONAL EXPOSURE LIMITS (OEL)**

**INGREDIENT DATA:**

Not Available


**EMERGENCY LIMITS:**

Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
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Not Available

Ingredient	Original IDLH	Revised IDLH
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Not Available

<b>8.2 Exposure controls</b>	
<b>Appropriate engineering controls:</b>	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.
<b>Personal protection:</b>	
<b>Eye and face protection:</b>	Safety glasses with side shields / chemical goggles
<b>Skin protection:</b>	See hand protection below
<b>Hands/ feet protection:</b>	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves
<b>Body protection:</b>	Wear appropriate clothing
<b>Other protection:</b>	No special equipment needed when handling small quantities
<b>Thermal hazards:</b>	Not applicable
<b>Respiratory protection:</b>	Not applicable
<b>8.3 Environmental exposure controls</b>	
See Section 12	

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties**

**Appearance:** Sterilised Water®: Solvent for parenteral use.  
**Container:** 100ml Type I clear glass vial with a chlorobutyl rubber closure and aluminium seal.  
**Physical state:** Liquid  
**Odour:** Not available  
**Odour Threshold:** Not available  
**pH (as supplied):** Not available  
**Melting point / freezing point (degrees C):** 0°C  
**Initial boiling point and boiling range:** 100°C  
**Flash Point:** Not available  
**Evaporation rate:** Not available  
**Flammability:** Not available  
**Upper/lower flammability or explosive limits:** Not available  
**Vapour pressure:** Not available  
**Relative Density (at degrees C):** Not available  
**Solubility in water and solvents (mg/l):** Soluble  
**Vapour density:** Not available  
**Auto ignition temperature (degrees C):** Not available  
**Decomposition temperature (degrees C):** Not available  
**Viscosity: (degrees C):** Not available  
**Explosive properties:** Not available  
**Oxidising properties:** Not available  
**Partition Coefficient:** Not available  
**Molecular weight:** 18  
**Taste:** Not available  
**Surface tension:** Not available  
**Volative component:** Not available  
**Gas group:** Not available  
**pH as a solution:** 7  
**VOC g/L:** Not available

**9.2 Other information**  
 Not Available

**10: REACTIVITY AND STABILITY**

<b>10.1 Reactivity:</b>	See Section 7
<b>10.2 Chemical stability:</b>	Product is considered stable.
<b>10.3 Possibility of hazardous reactions:</b>	Stable under normal temperatures and conditions.
<b>10.4 Conditions to avoid:</b>	None known.
<b>10.5 Incompatible materials:</b>	See section 7.

<b>10.6 Hazardous decomposition:</b>	See Section 5.
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SECTION 11: TOXICOLOGICAL INFORMATION		
<b>Inhalation:</b>	Not expected to cause respiratory tract irritation.	
<b>Ingestion:</b>	Accidental oral intake or self-injection may cause sedation and changes in blood pressure.	
<b>Skin contact:</b>	Irritation, sensitisation, contact dermatitis and systemic effects cannot be excluded after skin contact.	
<b>Eye contact:</b>	Not expected to cause eye irritation.	
<b>Chronic:</b>	Prolonged exposure to the product is not expected to cause chronic effects that are harmful to health (in the classification according to EC standards based on animal models); However, exposure through all routes should be minimised.	
<b>Sterilised Water®:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Not Available	Not Available
<b>Water for Injection:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Not Available	Not Available
<b>Skin corrosion / irritation:</b>		
Not expected to cause serious skin corrosion or irritation.		
<b>Serious eye damage / irritation:</b>		
Not expected to cause serious eye damage or irritation.		
<b>Respiratory or skin sensitization:</b>		
Not expected to be a skin sensitizer.		
<b>Germ cell mutagenicity:</b>		
Not expected to be a mutagen.		
<b>Carcinogenicity:</b>		
Not expected to be carcinogenic.		
<b>Reproductive toxicity:</b>		
Not contraindicated.		
<b>STOT – single exposure:</b>		
Not available		



**SECTION 11: TOXICOLOGICAL INFORMATION**

<b>STOT–repeated exposure:</b>
Not available
<b>Aspiration hazard:</b>
Not available

**SECTION 12: ECOLOGICAL INFORMATION**

<b>Not expected to be an environmental hazard.</b>
<b>12.1 Toxicity</b>
N/a
<b>12.2 Persistence and degradability</b>
N/a
<b>12.3 Bioaccumulative potential</b>
N/a
<b>12.4 Mobility in Soil</b>
N/a
<b>12.5 Results of PBT and vPvB assessment</b>
N/a
<b>12.6 Other adverse effects</b>
N/a

**SECTION 13: DISPOSAL CONSIDERATIONS**

<b>13.1 Waste treatment methods</b>	
<b>Product / packaging disposal:</b>	<p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.</p> <p>Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.</p>



<b>Waste Treatment Options:</b>	Not Available
<b>Sewage Disposal Options:</b>	No environmental effects are anticipated.

**SECTION 14: TRANSPORT INFORMATION**

<b>Labels required:</b>	None	
<b>Marine pollutant:</b>	NO	
<b>Hazchem:</b>	Not Applicable	
<b>Land transport (ADR):</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	Class	N/a
	Sub risk	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	
<b>14.6 Special precautions for user</b>	Special provisions	N/a
	Classification code	N/a
	Hazard Label	N/a
	Special provisions	N/a
	Limited quantity	N/a

<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a
<b>Air transport (ICAO-IATA / DGR):</b>	
<b>14.1 UN Number</b>	N/a

<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	
<b>14.6 Special precautions for user</b>	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	
<b>Sea transport (IMDG-Code / GGVSee):</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	IMDG Class	N/a
	IMDG Sub risk	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	
<b>14.6 Special</b>	EMS Number	N/a

<b>precautions for user</b>	Special provisions	N/a	
	Limited quantities	N/a	
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a		
<b>Inland waterways transport (ADN):</b>			
<b>14.1 UN Number</b>	N/a		
<b>14.2 UN Proper Shipping Name</b>	N/a		
<b>14.3 Transport hazard class(es)</b>	N/a		N/a
<b>14.4 Packing group</b>	N/a		
<b>14.5 Environmental hazard</b>	N/a		
<b>14.6 Special precautions for user</b>	Classification Code	N/a	
	Special provisions	N/a	
	Limited quantity	N/a	
	Equipment required	N/a	
	Fire cones number	N/a	
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a		

## SECTION 15: REGULATORY INFORMATION

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

#### WATER (7732-18-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

- European Union-the European inventory of existing chemical substances (EINECS) (English)
- EU REACH Regulation (EC) No 1907/2006-Annex IV-Exemptions from the obligation to tender met in accordance with article 2 (7) (a) (English)
- European Customs Inventory of Chemical substances ECICS (English)

**15.2 Chemical Safety Assessment**

**ECHA SUMMARY**

Ingredient	CAS number	Index Number	ECHA Dossier
Water	7732-18-5	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified		
2	Flam. Liq. 3, Acute Tox. 3, Skin Corr. 1A, Acute Tox. 2	GHS05, Dgr, GHS02, GHS06	H318, H226, H314, H301, H411

Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification

Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (Water)
China - IECSC	Y
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (Water)
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y
<b>Legend:</b>	<i>Y = All ingredients are on the inventory        N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)</i>

## SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS and ECHA.

### **Ingredients with multiple CAS numbers:**

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 166 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms
- EN 13832 Footwear protecting against chemicals
- EN 133 Respiratory protective devices

### **Definitions and abbreviations**

- PC—TWA: Permissible Concentration-Time Weighted Average
- PC—STEL: Permissible Concentration-Short Term Exposure Limit
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit

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- PC—TWA: Permissible Concentration-Time Weighted Average
- PC—STEL: Permissible Concentration-Short Term Exposure Limit
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit
- IDLH: Immediately Dangerous to Life or Health Concentrations

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