

# Safety Data Sheet

**Product Name:** Hydroset – Injectable HA Bone Substitute

**Product Numbers:** see page 2

	<b>Australian Sponsor</b>	<b>New Zealand Sponsor</b>
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**Product name** HYDROSET - Injectable HA Bone Substitute  
**Revision Date** 28/05/2020  
**Revision** 10  
**Supersedes date** 11/01/2017



**Product name** HYDROSET - Injectable HA Bone Substitute

**Manufactured and Distributed by: (other than the US):** Howmedica International S. de R. L.  
Raheen Business Park,  
Limerick,  
Republic of Ireland  
Telephone: +353 61 498200 (Ireland)  
Emergency: +353 61 498200 (Ireland) (24 Hours)

**Distributed in the US by:** Howmedica Osteonics Corp.,  
300 Commerce Court,  
Mahwah NJ 07430,  
USA.  
US Telephone: 1-877-946-9678  
Emergency: 1-800-424-9300

**Identified uses** HYDROSET - Injectable HA Bone Substitute is a Medical Device for Professional Use in the Health Services only.

HYDROSET - Injectable HA Bone Substitute is a two component product containing HydroSet Injectable HA Bone Substitute Powder and HydroSet Injectable HA Bone Substitute Liquid, which when packed together form the following product codes:

<b>397005X</b>	HRDROSET 5CC – SAMPLE
<b>397005</b>	HYDROSET INJECT CEMENT KIT 5CC
<b>397010</b>	HYDROSET INJECT CEMENTKIT 10CC
<b>397015</b>	HYDROSET INJECT CEMENTKIT 15CC
<b>397003</b>	HYDROSET INJECT CEMENT KIT 3CC
<b>7943903</b>	3CC HYDROSET INJECTABLE CEMENT
<b>7943905</b>	5CC HYDROSET INJECTABLE CEMENT
<b>7943915</b>	15CC HYDROSET INJECT CEMENT
<b>7943910</b>	10CC HYDROSET INJECT CEMENT
<b>897010</b>	HYDROSET XT FINAL KIT 10CC
<b>897005</b>	HYSROSET XT FINAL KIT 5CC
<b>897003</b>	HYDROSET XT FINAL KIT 3CC
<b>897015</b>	HYDROSET XT FINAL KIT 15CC

HYDROSET - Injectable HA Bone Substitute is an injectable, self-setting bone substitute composed of tetra-calcium phosphate that is formulated to convert to hydroxyapatite, the principal mineral component of bone.

This safety data sheet is written to provide health, safety and environmental information for professional health care people handling this product. This safety data sheet is not intended to provide information relevant to the use of this product as a medical device. Professional health care people should consult the prescribing information, information for use leaflets and product labels for further information about this medical device.

Product HydroSet Injectable HA Bone Substitute Powder  
 Revision date 28 May 2020  
 Revision 10



**Safety Data Sheet (SDS)**  
 according to Regulation (EC) No. 1907/2006

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**Section 1: Identification of the substance/preparation and of the company/undertaking**

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**1.1 Product identifier**

<b>Product name</b>	<b>HydroSet Injectable HA Bone Substitute Powder</b>
<b>Synonyms, Trade names</b>	No information available.

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

<b>Identified uses</b>	No specific uses identified. Restricted to Medical and professional users only.
<b>Uses advised against</b>	No uses advised against are identified.

**1.3 Details of the supplier of the safety data sheet**

<b>Supplier</b>	Howmedica Intl S. de R.L. Raheen Business Park Limerick Ireland Tel: 0035361498200 info@ecoonline.com
<b>Contact person</b>	

**1.4 Emergency telephone number**

<b>Emergency telephone</b>	0035361498200 (24hrs)
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**Section 2: Hazards identification**

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**2.1 Classification of the substance or mixture**

<b>Classification (EC 1272/2008)</b>	
Physical and chemical hazards	Not classified
Human health	Not classified
Environment	Not classified

**2.2 Label elements**

<b>Contains</b>	Not applicable
<b>Label in accordance with (EC) no. 1272/2008</b>	No pictogram required
<b>Signal word</b>	No Signal Word
<b>Hazard statements</b>	No hazard statements required
<b>Precautionary statements</b>	No precautionary statements required

**2.3 Other hazards**

The product is regulated as a medical device and is exempt from the requirements of Title IV of REACH Regulation No. 1907/2006.

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**Section 3: Composition/identification of ingredients**

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**3.1 Substance**

Not applicable.

### 3.2 Mixtures

Name	Product identifier	Reg. EU 1272/2008	%
tetracalcium diphosphorus nonaoxide	CAS-No.: 1306-01-0 EC No.: 215-143-6		50-70%
Aksepillen	CAS-No.: 7789-77-7 EC No.:		25-35%
Sodium citrate	CAS-No.: 6132-04-3 EC No.:		5-15%

The full text for all hazard statements are displayed in section 16.

**Composition comments**

The data shown are in accordance with the latest EC Directives.

## Section 4: First aid measures

### 4.1 Description of first aid measures

<b>General information</b>	General first aid, rest, warmth and fresh air.
<b>Inhalation</b>	Dry Powder. Nuisance dust. If inhaled, remove to fresh air. Get medical attention.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Rinse mouth thoroughly. Get medical attention if symptoms occur.
<b>Skin contact</b>	Remove contaminated clothing immediately and wash skin with soap and water. Seek medical attention if irritation persists.
<b>Eye contact</b>	Remove contact lenses if worn. Promptly wash eyes with plenty of water while lifting the eye lids. If irritation persists, seek medical attention immediately.

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

<b>General information</b>	The severity of the symptoms described will vary dependant of the concentration and the length of exposure.
<b>Inhalation</b>	May cause respiratory tract irritation.
<b>Ingestion</b>	No specific symptoms noted.
<b>Skin contact</b>	No specific symptoms noted.
<b>Eye contact</b>	May cause temporary eye irritation.

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

<b>Notes to the physician</b>	Treat symptomatically.
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## Section 5: Fire-fighting measures

### 5.1 Extinguishing media

<b>Extinguishing media</b>	Use fire-extinguishing media appropriate for surrounding materials. The product is non-combustible
<b>Unsuitable extinguishing media</b>	No unsuitable extinguishing media identified.

### 5.2 Special hazards arising from the substance or mixture

<b>Hazardous combustion products</b>	When heated, toxic and corrosive vapours/gases may be formed
<b>Unusual fire &amp; explosion hazards</b>	No unusual fire or explosion hazards noted.
<b>Specific hazards</b>	No specific hazards are identified for the product.

### 5.3 Advice for firefighters

<b>Special fire fighting procedures</b>	If possible, fight fire from protected position. Ventilate closed spaces before entering them. Keep up-wind to avoid fumes. Avoid breathing fire vapours. Containers close to fire should be removed immediately or cooled with water if safe to do so.
<b>Protective equipment for firefighters</b>	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

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**Section 6: Accidental release measures**

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**6.1 Personal precautions, protective equipment and emergency procedures**

<b>Personal precautions</b>	For personal protection, see section 8. Eliminate all sources of ignition. Ensure adequate ventilation.
<b>For emergency responders</b>	Follow safe handling advice and personal protective equipment recommendations for normal use of product.

**6.2 Environmental precautions**

<b>Environmental precautions</b>	Do not discharge into drains, water courses or onto the ground.
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**6.3 Methods and material for containment and cleaning up**

<b>Spill clean up methods</b>	Keep in suitable, closed containers for disposal.
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**6.4 Reference to other sections**

<b>Reference to other sections</b>	See section 1 for emergency contact. For personal protection, see section 8. For waste disposal, see section 13.
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**Section 7: Handling and storage**

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**7.1 Precautions for safe handling**

<b>Handling</b>	Provide good ventilation. Use under well-ventilated conditions. Avoid generation of dust clouds. Ensure good dust ventilation during handling.
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**7.2 Conditions for safe storage, including any incompatibilities**

<b>Storage precautions</b>	Store in tightly closed original container in a dry, cool and well-ventilated place.
<b>Storage class</b>	No information available.

**7.3 Specific end use(s)**

<b>Specific end use(s)</b>	The identified uses for this product are detailed in Section 1.
<b>Usage description</b>	Use only according to directions.

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**Section 8: Exposure controls/Personal protection**

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**8.1 Control parameters**

<b>Ingredient comments</b>	Ireland, Occupational Exposure Limits 2020. Occupational Safety and Health Standards (OSHA) 29 CFR 1910. Australia, Safe Work Australia Italian Legislative Decree no. 81/2008, Annex XXXVIII. Occupational Exposure Limits to Occupational Exposure to Chemical Agents in France, ED 984, INRS, Paris, 2012. Quebec, Canada: Chapitre S-2.1, r. 11, Règlement sur la qualité du milieu de travail Loi sur la santé et la sécurité du travail (chapitre S-2.1, a. 223 )Loi sur la qualité de l'environnement (chapitre Q-2) / Chapter S-2.1, r. 11, Quality of Workplace Health and Safety Regulations (chapter S-2.1, section 223) Environment Quality Act (chapter Q-2). Germany: Committee for Hazardous Substances (AGS). Germany:Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe der DFG (MAK-Kommission). Portuguese Quality Institute - NP 1796: Safety and health at work, occupational exposure limits to chemicals in the workplace. Spain: Occupational exposure limits for chemical agents 2018. HTP VALUES 2016, known as harmful concentrations, Ministry of Social Affairs and Health, Finland. Sweden: Hygiene Limits (AFS 2018:1). Executive Order No. 292 of 26 April 2001 as subsequently amended, issued by the the Danish Working Environment Authority. Norway, Regulations concerning Action and Limit values No exposure limits noted for ingredient(s).
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## 8.2 Exposure Controls

### Protective equipment



### Engineering measures Respiratory equipment

Provide adequate general and local exhaust ventilation.

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator and suitable respirator cartridges as a backup to engineering controls. Consult manufacturer for specific advice. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as CEN (EU). Use respiratory equipment with particle filter - Type P3. ABEK (EN 14387).

### Hand protection

Use suitable protective gloves if there is a risk of skin contact. Consult glove manufacturer for specific advice. Selection of the glove material depends on consideration of the penetration times, rates of diffusion and degradation, and concentration specific to the workplace. Use of gloves approved to relevant standards (e.g. Europe: EN374) is recommended. 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. Suggested material: Butyl rubber. Minimum layer thickness: 0.7 mm. Minimum breakthrough time / gloves: 480 min.

### Eye protection

Wear safety goggles or face shield to prevent any possibility of eye contact. Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU).

### Other protection

Wear appropriate clothing to prevent any possibility of skin contact: Chemical resistant, flame retardant protective clothing recommended. Select appropriate protective clothing based on chemical resistance data and an assessment of local exposure potential. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist. The selected clothing must satisfy the European norm standard EN 943.

### Hygiene measures

DO NOT SMOKE IN WORK AREA! Wash hands at the end of each work shift and before eating, smoking and using the toilet. Handle in accordance with good industrial hygiene and safety practice.

### Process conditions

Ensure that eye flushing systems and safety showers are located close by in the work place.

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## Section 9: Physical and chemical properties

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### 9.1 Information on basic physical and chemical properties

<b>Appearance</b>	Powder.
<b>Colour</b>	White.
<b>Odour</b>	Odourless.
<b>Odour threshold - lower</b>	No information available.
<b>Odour threshold - upper</b>	No information available.
<b>pH-Value, Conc. Solution</b>	7 to 7.5 (25% in water)
<b>pH-Value, Diluted solution</b>	No information available.
<b>Melting point</b>	No information available.
<b>Initial boiling point and boiling range</b>	No information available.
<b>Flash point</b>	No information available.
<b>Evaporation rate</b>	No information available.
<b>Flammability state</b>	No information available.
<b>Flammability limit - lower(%)</b>	No information available.

<b>Flammability limit - upper(%)</b>	No information available.
<b>Vapour pressure</b>	No information available.
<b>Vapour density (air=1)</b>	No information available.
<b>Relative density</b>	No information available.
<b>Bulk density</b>	No information available.
<b>Solubility</b>	Insoluble.
<b>Decomposition temperature</b>	No information available.
<b>Partition coefficient; n-Octanol/Water</b>	No information available.
<b>Auto ignition temperature (°C)</b>	No information available.
<b>Viscosity</b>	No information available.
<b>Explosive properties</b>	Not classified as explosive.
<b>Oxidising properties</b>	The product does not meet the criteria to be classified as oxidising.

## **9.2 Other information**

<b>Molecular weight</b>	No information available.
<b>Volatile organic compound</b>	No information available.
<b>Other information</b>	None noted.

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## **Section 10: Stability and reactivity**

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### **10.1 Reactivity**

<b>Reactivity</b>	Stable under normal conditions.
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### **10.2 Chemical stability**

<b>Stability</b>	Stable under normal temperature conditions and recommended use.
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### **10.3 Possibility of hazardous reactions**

<b>Hazardous reactions</b>	Unknown.
<b>Hazardous polymerisation</b>	None under normal processing.
<b>Polymerisation description</b>	Unknown.

### **10.4 Conditions to Avoid**

<b>Conditions to avoid</b>	None known.
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### **10.5 Incompatible materials**

<b>Materials to avoid</b>	None noted.
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### **10.6 Hazardous decomposition products**

<b>Hazardous decomposition products</b>	None under normal conditions.
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## **Section 11: Toxicological information**

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### **11.1 Information on toxicological effects**

<b>Toxicological information</b>	No toxicological information for the overall finished product.
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<b>Acute toxicity (Oral LD50)</b>	No information available.
<b>Acute toxicity (Dermal LD50)</b>	No information available.
<b>Acute toxicity (Inhalation LD50)</b>	No information available.
<b>Serious eye damage/irritation</b>	Product is not classified as an eye irritant, however high dust levels in air may cause eye irritation.
<b>Skin corrosion/irritation</b>	The product is not classified as a skin corrosion/irritation hazard.
<b>Respiratory sensitisation</b>	The product is not classified as a respiratory hazard.
<b>Skin sensitisation</b>	The product is not classified as a skin sensitisation hazard.
<b>Germ cell mutagenicity</b>	The product is not classified as a mutagen.
<b>Carcinogenicity</b>	The product is not classified as a carcinogen hazard.
<b>Specific target organ toxicity - Single exposure:</b>	
<b>STOT - Single exposure</b>	The product is not classified as a single exposure specific target organ toxin.
<b>Specific target organ toxicity - Repeated exposure:</b>	
<b>STOT - Repeated exposure</b>	The product is not classified as a repeat exposure specific target organ toxin.
<b>Inhalation</b>	May cause respiratory tract irritation.
<b>Ingestion</b>	No specific symptoms noted.
<b>Skin contact</b>	No specific symptoms noted.
<b>Eye contact</b>	May cause temporary eye irritation.
<b>Waste management</b>	When handling waste, consideration should be made to the safety precautions applying to handling of the product.
<b>Routes of entry</b>	Eyes, skin ingestion or inhalation.
<b>Target organs</b>	Respiratory system, lungs.
<b>Aspiration hazards:</b>	The product is not classified as an aspiration hazard.
<b>Reproductive toxicity:</b>	The product is not classified as a reproductive hazard.

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## Section 12: Ecological information

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### 12.1 Toxicity

<b>Acute toxicity - Fish</b>	No information available.
<b>Acute toxicity - Aquatic invertebrates</b>	No information available.
<b>Acute toxicity - Aquatic plants</b>	No information available.
<b>Acute toxicity - Microorganisms</b>	No information available.
<b>Chronic toxicity - Fish</b>	No information available.
<b>Chronic toxicity - Aquatic invertebrates</b>	No information available.
<b>Chronic toxicity - Aquatic plants</b>	No information available.
<b>Chronic toxicity - Microorganisms</b>	No information available.
<b>Ecotoxicity</b>	Not classified as dangerous for the environment according to the criteria of Regulation (EC) No 1272/2008. No Ecological information on the finished product.
<b>Eco toxicological information</b>	Not classified as dangerous for the environment according to the criteria of Regulation (EC) No 1272/2008.

### 12.2 Persistence and degradability

<b>Degradability</b>	The product is not readily biodegradable.
<b>Biological oxygen demand</b>	No information available.
<b>Chemical oxygen demand</b>	No information available.

### 12.3 Bioaccumulative potential

<b>Bioaccumulative potential</b>	No data available on bioaccumulation.
<b>Bioaccumulation factor</b>	No information available.
<b>Partition coefficient; n-Octanol/Water</b>	No information available.

### 12.4 Mobility in soil

<b>Mobility</b>	Insoluble in water.
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### **12.5 Results of PBT and vPvB assessment**

**Results of PBT and vPvB assessment** The product does not contain any PBT or vPvB Substances.

### **12.6 Other adverse effects**

<b>Other adverse effects</b>	None known.
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## **Section 13: Disposal considerations**

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<b>Waste management</b>	When handling waste, consideration should be made to the safety precautions applying to handling of the product.
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### **13.1 Waste treatment methods**

<b>Disposal methods</b>	Dispose of waste and residues in accordance with local authority requirements, and in accordance with all local, national and international regulations.
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## **Section 14: Transport information**

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### **14.1 UN number**

<b>UN no. (ADR)</b>	Not applicable.
<b>UN no. (IMDG)</b>	Not applicable.
<b>UN no. (IATA)</b>	Not applicable.

### **14.2 UN proper shipping name**

<b>ADR proper shipping name</b>	Not applicable.
<b>IMDG proper shipping name</b>	Not applicable.
<b>IATA proper shipping name</b>	Not applicable.

### **14.3 Transport hazard class(es)**

<b>ADR class</b>	Not applicable.
<b>IMDG class</b>	Not applicable.
<b>IATA class</b>	Not applicable.

<b>Transport labels</b>	Not applicable
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### **14.4 Packing group**

<b>ADR/RID/ADN packing group</b>	Not applicable.
<b>IMDG packing group</b>	Not applicable.
<b>IATA packing group</b>	Not applicable.

### **14.5 Environmental hazards**

<b>ADR</b>	No
<b>IMDG</b>	No
<b>IATA</b>	No

### **14.6 Special precautions for user**

<b>EMS</b>	Not applicable.
<b>Emergency action code</b>	Not applicable.
<b>Hazard no. (ADR)</b>	Not applicable.
<b>Tunnel restriction code</b>	Not applicable.

### **14.7 Transport in bulk according to annex II of MARPOL73/78 and the IBC code**

Not applicable.

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## **Section 15: Regulatory information**

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

<b>EU legislation</b>	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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 with amendments. The UN Globally Harmonized System (GHS) Safety Data Sheet format (Annex IV) is implemented as Annex II of REACH EU No 453/2010 of 20th May 2010 amending regulation (EC) No 1907/2006.
<b>Approved code of practice</b>	<p>2020 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations (2001-2015) and the Safety, Health and Welfare at Work (Carcinogens) Regulations (2001-2019)</p> <p>Italian Legislative Decree no. 81/2008, Annex XXXVIII.</p> <p>Executive Order No. 292 of 26 April 2001 as subsequently amended, (decree on limit values for substances and materials No. 655/2018), issued by the the Danish Working Environment Authority.</p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS).</p> <p>Quebec, Canada: Chapitre S-2.1, r. 11, Règlement sur la qualité du milieu de travail Loi sur la santé et la sécurité du travail (chapitre S-2.1, a. 223 )Loi sur la qualité de l'environnement (chapitre Q-2) / Chapter S-2.1, r. 11, Quality of Workplace Health and Safety Regulations (chapter S-2.1, section 223) Environment Quality Act (chapter Q-2).</p> <p>HTP VALUES 2016, known as harmful concentrations, Ministry of Social Affairs and Health, Finland.</p> <p>Limites d'exposition professionnelle à l'exposition professionnelle aux agents chimiques en France, ED 984, INRS, Paris, 2012.</p> <p>Spain: Occupational exposure limits for chemical agents 2018.</p> <p>Germany: Committee for Hazardous Substances (AGS). Germany: Senate Commission for the Testing of Hazardous Substances of the DFG (MAK Commission).</p> <p>Sweden: Hygiene Limits (AFS 2018:1).</p> <p>Portuguese Quality Institute - NP 1796: Safety and health at work, occupational exposure limits to chemicals in the workplace.</p> <p>Australia, Model Work Health and Safety Regulaions(WHS) 2019.</p> <p>Norway, Regulations concerning Action and Limit values</p>
<b>Chemical safety assessment</b>	No chemical safety assessment has been carried out.

**Section 16: Other information**

<b>General information</b>	This Safety Data Sheet is in accordance with Reach Regulation (EC) No 453/2010.
<b>Revision comments</b>	This is a tenth issue. [2]Information updated. [5]Information updated. [8]Information updated. [9]Information updated. [11]Information updated. [12]Information updated. [15]Information updated.
<b>Revision date</b>	28 May 2020
<b>Revision</b>	10
<b>Safety data sheet status</b>	Approved.

**Hazard statements in full****Disclaimer**

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.

Product HydroSet Injectable HA Bone Substitute Liquid  
 Revision date 28 May 2020  
 Revision 10



**Safety Data Sheet (SDS)**  
 according to Regulation (EC) No. 1907/2006

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**Section 1: Identification of the substance/preparation and of the company/undertaking**

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**1.1 Product identifier**

<b>Product name</b>	<b>HydroSet Injectable HA Bone Substitute Liquid</b>
<b>Synonyms, Trade names</b>	No information available.

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

<b>Identified uses</b>	No specific uses identified. Restricted to Medical and professional users only.
<b>Uses advised against</b>	No uses advised against are identified.

**1.3 Details of the supplier of the safety data sheet**

<b>Supplier</b>	Howmedica Intl S. de R.L. Raheen Business Park Limerick Ireland Tel: 0035361498200 info@ecoonline.com
<b>Contact person</b>	

**1.4 Emergency telephone number**

<b>Emergency telephone</b>	0035361498200 (24hrs)
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**Section 2: Hazards identification**

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**2.1 Classification of the substance or mixture**

<b>Classification (EC 1272/2008)</b>	
Physical and chemical hazards	Not classified
Human health	Not classified
Environment	Not classified

**2.2 Label elements**

<b>Contains</b>	Not applicable
<b>Label in accordance with (EC) no. 1272/2008</b>	No pictogram required
<b>Signal word</b>	No Signal Word
<b>Hazard statements</b>	No hazard statements required
<b>Precautionary statements</b>	No precautionary statements required

**2.3 Other hazards**

The product is regulated as a medical device and is exempt from the requirements of Title IV of REACH Regulation No. 1907/2006.

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**Section 3: Composition/identification of ingredients**

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**3.1 Substance**

Not applicable.

### 3.2 Mixtures

Name	Product identifier	Reg. EU 1272/2008	%
Sodium phosphate, dihydrate	CAS-No.: 10028-24-7 EC No.:	Eye Irrit.2A - H319	1-10%

The full text for all hazard statements are displayed in section 16.

**Composition comments** The data shown are in accordance with the latest EC Directives.

## Section 4: First aid measures

### 4.1 Description of first aid measures

<b>General information</b>	General first aid, rest, warmth and fresh air.
<b>Inhalation</b>	If this product is Inhaled, move the exposed person to fresh air promptly. Seek medical attention if symptoms persist.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Rinse mouth thoroughly. Get medical attention if symptoms occur.
<b>Skin contact</b>	Remove contaminated clothing immediately and wash skin with soap and water. Seek medical attention if irritation persists.
<b>Eye contact</b>	Remove contact lenses if worn. Promptly wash eyes with plenty of water while lifting the eye lids. If irritation persists, seek medical attention immediately.

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

<b>General information</b>	The severity of the symptoms described will vary dependant of the concentration and the length of exposure.
<b>Inhalation</b>	No specific symptoms noted.
<b>Ingestion</b>	No specific symptoms noted.
<b>Skin contact</b>	No specific symptoms noted.
<b>Eye contact</b>	No specific symptoms noted.

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

**Notes to the physician** Treat symptomatically.

## Section 5: Fire-fighting measures

### 5.1 Extinguishing media

<b>Extinguishing media</b>	Use fire-extinguishing media appropriate for surrounding materials. The product is non-combustible
<b>Unsuitable extinguishing media</b>	No unsuitable extinguishing media identified.

### 5.2 Special hazards arising from the substance or mixture

<b>Hazardous combustion products</b>	When heated, toxic and corrosive vapours/gases may be formed
<b>Unusual fire &amp; explosion hazards</b>	No unusual fire or explosion hazards noted.
<b>Specific hazards</b>	No specific hazards are identified for the product.

### 5.3 Advice for firefighters

<b>Special fire fighting procedures</b>	If possible, fight fire from protected position. Ventilate closed spaces before entering them. Keep up-wind to avoid fumes. Avoid breathing fire vapours. Containers close to fire should be removed immediately or cooled with water if safe to do so.
<b>Protective equipment for firefighters</b>	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

## Section 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

<b>Personal precautions</b>	For personal protection, see section 8. Eliminate all sources of ignition. Ensure adequate ventilation.
<b>For emergency responders</b>	Follow safe handling advice and personal protective equipment recommendations for normal use of product.

## **6.2 Environmental precautions**

<b>Environmental precautions</b>	Do not discharge into drains, water courses or onto the ground.
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## **6.3 Methods and material for containment and cleaning up**

<b>Spill clean up methods</b>	Keep in suitable, closed containers for disposal.
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## **6.4 Reference to other sections**

<b>Reference to other sections</b>	See section 1 for emergency contact. For personal protection, see section 8. For waste disposal, see section 13.
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## **Section 7: Handling and storage**

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### **7.1 Precautions for safe handling**

<b>Handling</b>	Provide good ventilation. Use under well-ventilated conditions.
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### **7.2 Conditions for safe storage, including any incompatibilities**

<b>Storage precautions</b>	Store in tightly closed original container in a dry, cool and well-ventilated place.
<b>Storage class</b>	No information available.

### **7.3 Specific end use(s)**

<b>Specific end use(s)</b>	The identified uses for this product are detailed in Section 1.
<b>Usage description</b>	Use only according to directions.

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## **Section 8: Exposure controls/Personal protection**

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### **8.1 Control parameters**

<b>Ingredient comments</b>	<p>Ireland, Occupational Exposure Limits 2020.</p> <p>Occupational Safety and Health Standards (OSHA) 29 CFR 1910.</p> <p>Australia, Safe Work Australia</p> <p>Italian Legislative Decree no. 81/2008, Annex XXXVIII.</p> <p>Occupational Exposure Limits to Occupational Exposure to Chemical Agents in France, ED 984, INRS, Paris, 2012.</p> <p>Quebec, Canada: Chapitre S-2.1, r. 11, Règlement sur la qualité du milieu de travail Loi sur la santé et la sécurité du travail (chapitre S-2.1, a. 223 )Loi sur la qualité de l'environnement (chapitre Q-2) / Chapter S-2.1, r. 11, Quality of Workplace Health and Safety Regulations (chapter S-2.1, section 223) Environment Quality Act (chapter Q-2).</p> <p>Germany: Committee for Hazardous Substances (AGS). Germany:Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe der DFG (MAK-Kommission).</p> <p>Portuguese Quality Institute - NP 1796: Safety and health at work, occupational exposure limits to chemicals in the workplace.</p> <p>Spain: Occupational exposure limits for chemical agents 2018.</p> <p>HTP VALUES 2016, known as harmful concentrations, Ministry of Social Affairs and Health, Finland.</p> <p>Sweden: Hygiene Limits (AFS 2018:1).</p> <p>Executive Order No. 292 of 26 April 2001 as subsequently amended, issued by the the Danish Working Environment Authority.</p> <p>Norway, Regulations concerning Action and Limit values</p> <p>No exposure limits noted for ingredient(s).</p>
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### **8.2 Exposure Controls**

<b>Protective equipment</b>	
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**Engineering measures**  
**Respiratory equipment**

Provide adequate general and local exhaust ventilation.

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator and suitable respirator cartridges as a backup to engineering controls. Consult manufacturer for specific advice. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as CEN (EU). Use respiratory equipment with particle filter - Type P3. ABEK (EN 14387).

**Hand protection**

Use suitable protective gloves if there is a risk of skin contact. Consult glove manufacturer for specific advice. Selection of the glove material depends on consideration of the penetration times, rates of diffusion and degradation, and concentration specific to the workplace. Use of gloves approved to relevant standards (e.g. Europe: EN374) is recommended. 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. Suggested material: Butyl rubber. Minimum layer thickness: 0.7 mm. Minimum breakthrough time / gloves: 480 min.

**Eye protection**

Wear safety goggles or face shield to prevent any possibility of eye contact. Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU).

**Other protection**

Wear appropriate clothing to prevent any possibility of skin contact: Chemical resistant, flame retardant protective clothing recommended. Select appropriate protective clothing based on chemical resistance data and an assessment of local exposure potential. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist. The selected clothing must satisfy the European norm standard EN 943.

**Hygiene measures**

DO NOT SMOKE IN WORK AREA! Wash hands at the end of each work shift and before eating, smoking and using the toilet. Handle in accordance with good industrial hygiene and safety practice.

**Process conditions**

Ensure that eye flushing systems and safety showers are located close by in the work place.

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## Section 9: Physical and chemical properties

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### 9.1 Information on basic physical and chemical properties

<b>Appearance</b>	Viscous Paste.
<b>Colour</b>	Pale, straw yellow.
<b>Odour</b>	Odourless.
<b>Odour threshold - lower</b>	No information available.
<b>Odour threshold - upper</b>	No information available.
<b>pH-Value, Conc. Solution</b>	3 to 7 (5% in water)
<b>pH-Value, Diluted solution</b>	No information available.
<b>Melting point</b>	No information available.
<b>Initial boiling point and boiling range</b>	No information available.
<b>Flash point</b>	No information available.
<b>Evaporation rate</b>	No information available.
<b>Flammability state</b>	No information available.
<b>Flammability limit - lower(%)</b>	No information available.
<b>Flammability limit - upper(%)</b>	No information available.
<b>Vapour pressure</b>	No information available.

<b>Vapour density (air=1)</b>	No information available.
<b>Relative density</b>	No information available.
<b>Bulk density</b>	No information available.
<b>Solubility</b>	Partial.
<b>Decomposition temperature</b>	No information available.
<b>Partition coefficient; n-Octanol/Water</b>	No information available.
<b>Auto ignition temperature (°C)</b>	No information available.
<b>Viscosity</b>	No information available.
<b>Explosive properties</b>	Not classified as explosive.
<b>Oxidising properties</b>	The product does not meet the criteria to be classified as oxidising.

## **9.2 Other information**

<b>Molecular weight</b>	No information available.
<b>Volatile organic compound</b>	No information available.
<b>Other information</b>	None noted.

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## **Section 10: Stability and reactivity**

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### **10.1 Reactivity**

<b>Reactivity</b>	Stable under normal conditions.
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### **10.2 Chemical stability**

<b>Stability</b>	Stable under normal temperature conditions and recommended use.
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### **10.3 Possibility of hazardous reactions**

<b>Hazardous reactions</b>	Unknown.
<b>Hazardous polymerisation</b>	None under normal processing.
<b>Polymerisation description</b>	Unknown.

### **10.4 Conditions to Avoid**

<b>Conditions to avoid</b>	None known.
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### **10.5 Incompatible materials**

<b>Materials to avoid</b>	None noted.
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### **10.6 Hazardous decomposition products**

<b>Hazardous decomposition products</b>	None under normal conditions.
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## **Section 11: Toxicological information**

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### **11.1 Information on toxicological effects**

<b>Toxicological information</b>	No toxicological information for the overall finished product.
<b>Acute toxicity (Oral LD50)</b>	No information available.
<b>Acute toxicity (Dermal LD50)</b>	No information available.
<b>Acute toxicity (Inhalation LD50)</b>	No information available.

<b>Serious eye damage/irritation</b>	Product is not classified as an eye irritant.
<b>Skin corrosion/irritation</b>	The product is not classified as a skin corrosion/irritation hazard.
<b>Respiratory sensitisation</b>	The product is not classified as a respiratory hazard.
<b>Skin sensitisation</b>	The product is not classified as a skin sensitisation hazard.
<b>Germ cell mutagenicity</b>	The product is not classified as a mutagen.
<b>Carcinogenicity</b>	The product is not classified as a carcinogen hazard.
<b>Specific target organ toxicity - Single exposure:</b>	
<b>STOT - Single exposure</b>	The product is not classified as a single exposure specific target organ toxin.
<b>Specific target organ toxicity - Repeated exposure:</b>	
<b>STOT - Repeated exposure</b>	The product is not classified as a repeat exposure specific target organ toxin.
<b>Inhalation</b>	No specific symptoms noted.
<b>Ingestion</b>	No specific symptoms noted.
<b>Skin contact</b>	No specific symptoms noted.
<b>Eye contact</b>	No specific symptoms noted.
<b>Waste management</b>	When handling waste, consideration should be made to the safety precautions applying to handling of the product.
<b>Routes of entry</b>	Eyes, skin, ingestion or inhalation.
<b>Target organs</b>	No target organs specified.
<b>Aspiration hazards:</b>	The product is not classified as an aspiration hazard.
<b>Reproductive toxicity:</b>	The product is not classified as a reproductive hazard.

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## Section 12: Ecological information

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### 12.1 Toxicity

<b>Acute toxicity - Fish</b>	No information available.
<b>Acute toxicity - Aquatic invertebrates</b>	No information available.
<b>Acute toxicity - Aquatic plants</b>	No information available.
<b>Acute toxicity - Microorganisms</b>	No information available.
<b>Chronic toxicity - Fish</b>	No information available.
<b>Chronic toxicity - Aquatic invertebrates</b>	No information available.
<b>Chronic toxicity - Aquatic plants</b>	No information available.
<b>Chronic toxicity - Microorganisms</b>	No information available.
<b>Ecotoxicity</b>	Not classified as dangerous for the environment according to the criteria of Regulation (EC) No 1272/2008. No Ecological information on the finished product.
<b>Eco toxicological information</b>	Not classified as dangerous for the environment according to the criteria of Regulation (EC) No 1272/2008.

### 12.2 Persistence and degradability

<b>Degradability</b>	The product is not readily biodegradable.
<b>Biological oxygen demand</b>	No information available.
<b>Chemical oxygen demand</b>	No information available.

### 12.3 Bioaccumulative potential

<b>Bioaccumulative potential</b>	Does not bioaccumulate.
<b>Bioaccumulation factor</b>	No information available.
<b>Partition coefficient; n-Octanol/Water</b>	No information available.

### 12.4 Mobility in soil

<b>Mobility</b>	Insoluble in water.
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### 12.5 Results of PBT and vPvB assessment

<b>Results of PBT and vPvB assessment</b>	No information available.
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**12.6 Other adverse effects**

<b>Other adverse effects</b>	No information available.
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**Section 13: Disposal considerations**

<b>Waste management</b>	When handling waste, consideration should be made to the safety precautions applying to handling of the product.
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**13.1 Waste treatment methods**

<b>Disposal methods</b>	Dispose of waste and residues in accordance with local authority requirements, and in accordance with all local, national and international regulations.
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**Section 14: Transport information****14.1 UN number**

<b>UN no. (ADR)</b>	Not applicable.
<b>UN no. (IMDG)</b>	Not applicable.
<b>UN no. (IATA)</b>	Not applicable.

**14.2 UN proper shipping name**

<b>ADR proper shipping name</b>	Not applicable.
<b>IMDG proper shipping name</b>	Not applicable.
<b>IATA proper shipping name</b>	Not applicable.

**14.3 Transport hazard class(es)**

<b>ADR class</b>	Not applicable.
<b>IMDG class</b>	Not applicable.
<b>IATA class</b>	Not applicable.

<b>Transport labels</b>	Not applicable
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**14.4 Packing group**

<b>ADR/RID/ADN packing group</b>	Not applicable.
<b>IMDG packing group</b>	Not applicable.
<b>IATA packing group</b>	Not applicable.

**14.5 Environmental hazards**

<b>ADR</b>	No
<b>IMDG</b>	No
<b>IATA</b>	No

**14.6 Special precautions for user**

<b>EMS</b>	Not applicable.
<b>Emergency action code</b>	Not applicable.
<b>Hazard no. (ADR)</b>	Not applicable.
<b>Tunnel restriction code</b>	Not applicable.

**14.7 Transport in bulk according to annex II of MARPOL73/78 and the IBC code****Section 15: Regulatory information****15.1 Safety, health and environmental regulations/Legislation specific for the substance or mixture**

<b>EU legislation</b>	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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 with amendments. The UN Globally Harmonized System (GHS) Safety Data Sheet format (Annex IV) is implemented as Annex II of REACH EU No 453/2010 of 20th May 2010 amending regulation (EC) No 1907/2006.
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<b>Approved code of practice</b>	2020 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents)
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Regulations (2001-2015) and the Safety, Health and Welfare at Work (Carcinogens) Regulations (2001-2019)

Italian Legislative Decree no. 81/2008, Annex XXXVIII.

Executive Order No. 292 of 26 April 2001 as subsequently amended, (decree on limit values for substances and materials No. 655/2018), issued by the the Danish Working Environment Authority.

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS).

Quebec, Canada: Chapitre S-2.1, r. 11, Règlement sur la qualité du milieu de travail Loi sur la santé et la sécurité du travail (chapitre S-2.1, a. 223 )Loi sur la qualité de l'environnement (chapitre Q-2) / Chapter S-2.1, r. 11, Quality of Workplace Health and Safety Regulations (chapter S-2.1, section 223) Environment Quality Act (chapter Q-2).

HTP VALUES 2016, known as harmful concentrations, Ministry of Social Affairs and Health, Finland.

Limites d'exposition professionnelle à l'exposition professionnelle aux agents chimiques en France, ED 984, INRS, Paris, 2012.

Spain: Occupational exposure limits for chemical agents 2018.

Germany: Committee for Hazardous Substances (AGS). Germany: Senate Commission for the Testing of Hazardous Substances of the DFG (MAK Commission).

Sweden: Hygiene Limits (AFS 2018:1).

Portuguese Quality Institute - NP 1796: Safety and health at work, occupational exposure limits to chemicals in the workplace.

Australia, Model Work Health and Safety Regulaions(WHS) 2019.

Norway, Regulations concerning Action and Limit values

#### Chemical safety assessment

No chemical safety assessment has been carried out.

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#### Section 16: Other information

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<b>General information</b>	This Safety Data Sheet is in accordance with Reach Regulation (EC) No 453/2010.
<b>Revision comments</b>	This is a tenth issue. [1]Information updated. [5]Information updated. [8]Information updated. [9]Information updated. [11]Information updated. [15]Information updated.
<b>Revision date</b>	28 May 2020
<b>Revision</b>	10
<b>Safety data sheet status</b>	Approved.

#### Hazard statements in full

**H319** Causes serious eye irritation.

#### Disclaimer

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.