

Safety Data Sheet

Product Name: Direct Inject Aqueous Paste

Product Numbers: 7945903, 7945905 & 7945910

	Australian Sponsor	New Zealand Sponsor
Name:	Stryker Australia	Stryker New Zealand
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Emergency:	Poisons Information Centre: Ph: 131 126	Poisons and hazardous chemicals emergency: Ph: 0800 764 766

Product name Direct Inject Aqueous Paste
Revision Date 28/05/2020
Revision 10
Supersedes date 11/01/2017



Product name Direct Inject Aqueous Paste

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 Direct Inject Aqueous Paste is a Medical Device for Professional Use in the healthcare sector.

Direct Inject Aqueous Paste has the following product codes:

7945905 DIRECTINJECT 5CC
7945903 DIRECTINJECT 3CC
7945910 DIRECTINJECT 10CC

Direct Inject consists of a sterile dual paste system which is calcium phosphate based. Upon injection through the Mixer-Cannula, the two pastes form a cement paste which is moldable. The injected cement paste will harden under normal body conditions to form hydroxyapatite. The Delivery Syringe, prefilled with two pastes, is presented within a double blister tray along with two Mixer-Cannulae and a Spatula. The contents of the sealed outer blister are supplied sterile for single patient use'.

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 Direct Inject Aqueous Paste
 Revision date 28 May 2020
 Revision 10



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

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

1.1 Product identifier

Product name	Direct Inject Aqueous Paste
Synonyms, Trade names	No information available.

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

Identified uses	This product is a medical device. For professional use only in the healthcare sector.
Uses advised against	No uses advised against are identified.

1.3 Details of the supplier of the safety data sheet

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

1.4 Emergency telephone number

Emergency telephone	0035361498200 (24hrs)
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Section 2: Hazards identification

2.1 Classification of the substance or mixture

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

2.2 Label elements

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

Section 3: Composition/identification of ingredients

3.1 Substance

Not applicable.

3.2 Mixtures

Name	Product identifier	Reg. EU 1272/2008	%
calcium bis(dihydrogenorthophosphate)	CAS-No.: 7758-23-8 EC No.: 231-837-1	Eye Dam. 1 - H318	50-60%
CITRIC ACID MONOHYDRATE	CAS-No.: 5949-29-1 EC No.:	Eye Irrit.2A - H319	5-10%
glycerol	CAS-No.: 56-81-5 EC No.: 200-289-5		1-5%
Poly(oxy-1,2-ethanediyl),?-hydro-?-hydroxy-Ethane-1,2-diol, ethoxylated	CAS-No.: 25322-68-3 EC No.: 500-038-2		1-5%

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

General information	Provide general first aid, rest, warmth and fresh air. As a general rule, in case of doubt or if symptoms persist, always call a doctor. Seek medical attention for all burns and eye injuries, regardless how minor they may seem. First aid personnel must be aware of own risk during rescue.
Inhalation	Remove patient to fresh air, allow to rest and keep warm. If the exposed person is not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion	Provide fresh air, warmth and rest, preferably in comfortable upright sitting position. Do not induce vomiting. Rinse mouth thoroughly. Never give anything by mouth to an unconscious person. Get medical attention.
Skin contact	Remove affected person from source of contamination. Remove contaminated clothing. Wash the skin immediately with soap and water. Get medical attention if irritation persists after washing.
Eye contact	Avoid contaminating unaffected eye. Remove victim immediately from source of exposure. Immediately flush with plenty of water for up to 15 minutes. Remove any contact lenses and open eyes wide apart. Get medical attention immediately. Continue to rinse.

4.2 Most important symptoms and effects, both acute and delayed

General information	The severity of the symptoms described will vary dependant of the concentration and the length of exposure.
Inhalation	Inhalation of vapors or fumes may cause slight to moderate irritation to mucous membranes and respiratory tract.
Ingestion	May cause irritation of digestive tract. May be harmful if swallowed.
Skin contact	Prolonged skin contact may cause redness and irritation.
Eye contact	Corrosive! Vapours are irritating and may cause damage to the eyes. Contact may cause severe burns and permanent eye damage.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to the physician	Treat symptomatically.
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Section 5: Fire-fighting measures

5.1 Extinguishing media

Extinguishing media	This product is not flammable. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	No unsuitable extinguishing media identified.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products	When heated, vapours/gases hazardous to health may be formed.
Unusual fire & explosion hazards	Fire causes formation of toxic gases.
Specific hazards	In case of fire, toxic and corrosive gases may be formed. Water used for fire extinguishing, which has been in contact with the product, may be corrosive.

5.3 Advice for firefighters

- Special fire fighting procedures** If possible, fight fire from protected position. Keep up-wind to avoid fumes. Ventilate closed spaces before entering them. Containers close to fire should be removed immediately or cooled with water.
- Protective equipment for firefighters** 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**

- Personal precautions** Mark out the contaminated area with signs and limit access to authorised personnel. Do not attempt to take action without suitable protective clothing - see Section 8. Turn leaking containers leak-side up to prevent the escape of liquid. Do not touch or walk through spilled material. Eliminate all sources of ignition. Evacuate and ventilate area.
- For emergency responders** Follow safe handling advice and personal protective equipment recommendations for normal use of product.

6.2 Environmental precautions

- Environmental precautions** Do not allow product to reach sewage system or any water course. Prevent from spreading (by using oil barriers, for example).

6.3 Methods and material for containment and cleaning up

- Spill clean up methods** Wear appropriate personal protective equipment as specified in Section 8. Ventilate and evacuate the area. Eliminate all ignition sources. Stop leak if possible without risk. Absorb spillage with non-combustible, absorbent material - sand. Ensure that waste and contaminated materials are collected and removed from the work area as soon as possible in a suitably labelled container.

6.4 Reference to other sections

- Reference to other sections** See section 1 for emergency contact. For waste disposal, see section 13. For personal protection, see section 8.

Section 7: Handling and storage**7.1 Precautions for safe handling**

- Handling** Keep away from acids. Do not mix with any other chemicals unless advised by the supplier. Wear suitable personal protective equipment, as detailed in Section 8. Adequate ventilation is required. Avoid contact with skin and eyes. Do not inhale mist. Do not use contact lenses. Handle in accordance with good industrial hygiene and safety procedures.

7.2 Conditions for safe storage, including any incompatibilities

- Storage precautions** Product quality requires storage between +10 °C and +40 °C. Store in tightly closed original container in a dry, cool and well-ventilated place. Keep away from incompatible materials (see section 10).
- Storage class** Corrosive storage.

7.3 Specific end use(s)

- Specific end use(s)** The identified uses for this product are detailed in Section 1.2.
- Usage description** Use only according to directions. Replace and tighten cap after use.

Section 8: Exposure controls/Personal protection**8.1 Control parameters**

Component	STD	TWA (8 Hrs)	STEL (15mins)	Notes
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glycerol	OSHA		15 inhalable dust mg/m ³			USA - OSHA
glycerol	OSHA		5 respirable dust mg/m ³			USA - OSHA
glycerol	OEL		10 (1) mg/m ³			Australia
glycerol	OEL		10 mg/m ³			Canada - Québec
glycerol	OEL		10 mg/m ³			Spain
glycerol	OEL		10 mg/m ³			
glycerol	OEL		20 mg/m ³			Finland
glycerol	OEL		200 E mg/m ³			Germany (AGS)
glycerol	OEL		200 I mg/m ³			Germany (DFG)
Poly(oxy-1,2-ethanediyl),?-hydro-?-hydroxy-Ethane-1,2-diol, ethoxylated	OEL		1000 mg/m ³		2000 mg/m ³	Denmark
Poly(oxy-1,2-ethanediyl),?-hydro-?-hydroxy-Ethane-1,2-diol, ethoxylated	OEL		250 mg/m ³			Germany (DFG)
Poly(oxy-1,2-ethanediyl),?-hydro-?-hydroxy-Ethane-1,2-diol, ethoxylated	OEL		200 mg/m ³			Germany (AGS)

Ingredient comments

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

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.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	Paste.
Colour	Colourless.
Odour	Slight odour.
Odour threshold - lower	No information available.
Odour threshold - upper	No information available.
pH-Value, Conc. Solution	13.00
pH-Value, Diluted solution	No information available.
Melting point	No information available.
Initial boiling point and boiling range	100.00 °C
Flash point	No information available.
Evaporation rate	No information available.
Flammability state	No information available.
Flammability limit - lower(%)	No information available.
Flammability limit - upper(%)	No information available.
Vapour pressure	No information available.
Vapour density (air=1)	No information available.
Relative density	No information available.
Bulk density	No information available.
Solubility	Soluble in water.
Decomposition temperature	No information available.
Partition coefficient; n-Octanol/Water	No information available.
Auto ignition temperature (°C)	No information available.
Viscosity	No information available.
Explosive properties	Not classified as explosive.
Oxidising properties	The product does not meet the criteria to be classified as oxidising.

9.2 Other information

Molecular weight	No information available.
Volatile organic compound	No information available.

Other information None.

Section 10: Stability and reactivity

10.1 Reactivity

Reactivity Reactions may occur with strong oxidising agents.

10.2 Chemical stability

Stability Stable under normal temperature conditions and recommended use.

10.3 Possibility of hazardous reactions

Hazardous reactions For information on hazardous reaction see section 10.1.
Hazardous polymerisation Unknown.
Polymerisation description Unknown.

10.4 Conditions to Avoid

Conditions to avoid Heat, sparks, open flames, temperature extremes and direct sunlight.

10.5 Incompatible materials

Materials to avoid Do not mix with other chemicals unless listed on directions. Strong oxidising substances.

10.6 Hazardous decomposition products

Hazardous decomposition products When heated, vapours/gases hazardous to health may be formed.

Section 11: Toxicological information

11.1 Information on toxicological effects

Toxicological information No toxicological information for the overall finished product.

Acute toxicity (Oral LD50) No information available.
Acute toxicity (Dermal LD50) No information available.
Acute toxicity (Inhalation LD50) No information available.

Serious eye damage/irritation Causes serious eye damage.

Skin corrosion/irritation The product is not classified as a skin corrosion/irritation hazard.

Respiratory sensitisation The product is not classified as a respiratory hazard.
Skin sensitisation The product is not classified as a skin sensitisation hazard.

Germ cell mutagenicity The product is not classified as a mutagen.

Carcinogenicity The product is not classified as a carcinogen hazard.

Specific target organ toxicity - Single exposure:
STOT - Single exposure The product is not classified as a single exposure specific target organ toxin.
Specific target organ toxicity - Repeated exposure:
STOT - Repeated exposure The product is not classified as a repeat exposure specific target organ toxin.

Inhalation Inhalation of vapors or fumes may cause slight to moderate irritation to mucous membranes and respiratory tract.

Ingestion May cause irritation of digestive tract. May be harmful if swallowed.
Skin contact Prolonged skin contact may cause redness and irritation.
Eye contact Corrosive! Vapours are irritating and may cause damage to the eyes. Contact may cause severe burns and permanent eye damage.

Waste management When handling waste, consideration should be made to the safety precautions applying to handling of the product.

Routes of entry Eyes, skin, ingestion or inhalation.
Target organs Eyes, skin, digestive system, respiratory system.

Aspiration hazards: The product is not classified as an aspiration hazard.
Reproductive toxicity: The product is not classified as a reproductive hazard.

Name	LD50 oral	LD50 dermal	LD50 inhalation
Poly(oxy-1,2-ethanediyl),?-hydro-?-hydroxy- Ethane-1,2-diol, ethoxylated	28.00mg/kg Rat	>20.00mg/kg Rabbit	
CITRIC ACID MONOHYDRATE	3000.00mg/kg Rat		
glycerol	12.60mg/kg Rat	18.70mg/kg Rabbit	

Section 12: Ecological information

12.1 Toxicity

Acute toxicity - Fish No information available.
Acute toxicity - Aquatic invertebrates No information available.
Acute toxicity - Aquatic plants No information available.
Acute toxicity - Microorganisms No information available.
Chronic toxicity - Fish No information available.
Chronic toxicity - Aquatic invertebrates No information available.
Chronic toxicity - Aquatic plants No information available.
Chronic toxicity - Microorganisms No information available.
Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Eco toxicological information The product may affect the acidity (pH-factor) in water with risk of harmful effects to aquatic organisms.

12.2 Persistence and degradability

Degradability The product is easily biodegradable.
Biological oxygen demand No information available.
Chemical oxygen demand No information available.

12.3 Bioaccumulative potential

Bioaccumulative potential The product does not contain any substances expected to be bioaccumulating.
Bioaccumulation factor No information available.
Partition coefficient; n-Octanol/Water No information available.

12.4 Mobility in soil

Mobility Readily absorbed into soil.

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

Other adverse effects None known.

Name	Acute toxicity (Fish)	Acute toxicity (Aquatic invertebrates)	Acute toxicity (Aquatic plants)
Poly(oxy-1,2-ethanediyl),?-hydro-?-hydroxy- Ethane-1,-diol, ethoxylated	LC50 96 Hours >100.00mg/l Cyprinus carpio (Common Carp)	EC50 48 Hours >100.00mg/l Daphnia magna	
CITRIC ACID MONOHYDRATE	LC50 96 Hours 760.00mg/l Leuciscus idus (Golden Orfe)	EC50 72 Hours 120.00mg/l Daphnia magna	
glycerol	LC50 >5.00mg/l Carassius auratus (Goldfish)	EC50 >10.00mg/l Daphnia magna	

Section 13: Disposal considerations

Waste management	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

Disposal methods	Dispose of waste and residues in accordance with local authority requirements, and in accordance with all local, national and international regulations. For waste disposal, use a licensed industrial waste disposal agent.
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Section 14: Transport information**14.1 UN number**

UN no. (ADR)	Not applicable.
UN no. (IMDG)	Not applicable.
UN no. (IATA)	Not applicable.

14.2 UN proper shipping name

ADR proper shipping name	Not applicable.
IMDG proper shipping name	Not applicable.
IATA proper shipping name	Not applicable.

14.3 Transport hazard class(es)

ADR class	Not applicable.
IMDG class	Not applicable.
IATA class	Not applicable.

Transport labels	Not applicable
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14.4 Packing group

ADR/RID/ADN packing group	Not applicable.
IMDG packing group	Not applicable.
IATA packing group	Not applicable.

14.5 Environmental hazards

ADR	No
IMDG	No
IATA	No

14.6 Special precautions for user

EMS	Not applicable.
Emergency action code	Not applicable.
Hazard no. (ADR)	Not applicable.
Tunnel restriction code	Not applicable.

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

Not applicable.

Section 15: Regulatory information**15.1 Safety, health and environmental regulations/Legislation specific for the substance or mixture**

EU legislation	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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Approved code of practice	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)
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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.

Section 16: Other information

General information	This Safety Data Sheet is in accordance with Reach Regulation (EC) No 453/2010.
Revision comments	This is a tenth issue. [1]Information updated. [2]Information updated. [3]Information updated. [4]Information updated. [5]Information updated. [6]Information updated. [7]Information updated. [8]Information updated. [9]Information updated. [10]Information updated. [11]Information updated. [12]Information updated. [13]Information updated. [15]Information updated.
Revision date	28 May 2020
Revision	10
Safety data sheet status	Approved.

Hazard statements in full

H318	Causes serious eye damage.
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.