









Revision: 14 March 2023

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**SECTION 10: Stability and reactivity (....)**

Decomposition products may include carbon oxides

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**SECTION 11: Toxicological information**

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

Reviewed in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices

## Acute Toxicity

Based on available data, the classification criteria are not met

## Skin corrosion/irritation

Based on available data, the classification criteria are not met

## Serious eye damage/irritation

Based on available data, the classification criteria are not met

## Respiratory or skin sensitisation

Based on available data, the classification criteria are not met

## Germ cell mutagenicity

No evidence of mutagenic effects

## Carcinogenicity

No evidence of carcinogenic effects

## Reproductive toxicity

No evidence of reproductive effects

## Specific target organ toxicity (STOT) - single exposure

Based on available data, the classification criteria are not met

## Specific target organ toxicity (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

## Contact with eyes

No hazard expected under normal conditions of use

## Contact with skin

No hazard expected under normal conditions of use

## Ingestion

The ingestion of significant quantities may cause nausea/vomiting

## Inhalation

Inhalation is unlikely to occur

## 11.2 Information on other hazards

Does not contain any substances with endocrine disrupting properties

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**SECTION 12: Ecological information**

## 12.1 Toxicity

No information available

## 12.2 Persistence and degradability

No information available

## 12.3 Bioaccumulative potential

No information available

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**SECTION 12: Ecological information (....)**

## 12.4 Mobility in soil

Insoluble in water

## 12.5 Results of PBT and vPvB assessment

No information available

## 12.6 Endocrine disrupting properties

Does not contain any substances with endocrine disrupting properties

## 12.7 Other adverse effects

No information available

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**SECTION 13: Disposal considerations**

## 13.1 Waste treatment methods

Avoid release to the environment.

Disposal should be in accordance with local, state or national legislation

## 13.2 Classification

The waste must be identified according to the List of Wastes (2000/532/EC)

Hazardous Property Code(s): None assigned

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**SECTION 14: Transport information**

Not classified as hazardous for transport

## 14.1 UN number or ID number

UN No.: Not applicable

## 14.2 UN proper shipping name

Proper Shipping Name: Not applicable

## 14.3 Transport hazard class(es)

Hazard Class: Not applicable

## 14.4 Packing group

Packing Group: Not applicable

## 14.5 Environmental hazards

Presents little or no hazard to the environment

## 14.6 Special precautions for user

No special precautions are required for this product

## 14.7 Maritime transport in bulk according to IMO instruments

Not applicable

## 14.8 Road/Rail (ADR/RID)

Proper Shipping Name: Not applicable

ADR UN No.: Not applicable

ADR Hazard Class: Not applicable

ADR Packing Group: Not applicable

Tunnel Code: Not applicable

## 14.9 Sea (IMDG)

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**SECTION 14: Transport information (....)**

Proper Shipping Name: Not applicable  
IMDG UN No.: Not applicable  
IMDG Hazard Class: Not applicable  
IMDG Packing Group.: Not applicable

**14.10 Air (ICAO/IATA)**

Proper Shipping Name: Not applicable  
ICAO UN No.: Not applicable  
ICAO Hazard Class: Not applicable  
ICAO Packing Group: Not applicable

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

A safety data sheet is not required for this product under Article 31 of REACH. This safety data sheet has been created on a voluntary basis to communicate relevant information.

This safety data sheet is provided in compliance with REACH Regulation (EC) No 1907/2006 (as amended by Regulation (EU) 2020/878) and UK REACH

The GB Classification, Labelling and Packaging Regulation (GB CLP) applies in Great Britain Regulation (EC) No. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) applies in Europe

This product is covered by the Medical Devices Regulation (EU) 2017/745 (MDR)

Reviewed in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices

**15.2 Chemical safety assessment**

A REACH chemical safety assessment has not been carried out

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**SECTION 16: Other information**

This information is intended to cover potential hazards at the place of work and does not detail medical uses, indications, contra-indications and precautions for the treatment of patients.

Sources of data: Information from company data, published literature and supplier safety data sheets

Created by ChemRegs (UK) Ltd June 2017

Revision No. 2.0.0. Revised March 2023.

Changes made: Updated to conform to the latest version of REACH Annex II and the Medical Devices Regulation (EU) 2017/745 (MDR)

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Not classified as hazardous for supply

Text not given with phrase codes where they are used elsewhere in this safety data sheet:

None assigned

**Acronyms**

ATE: Acute Toxicity Estimate  
CAS: Chemical Abstracts Service  
DNEL: Derived No-Effect Level  
EC: European Community  
EC<sub>50</sub>: Effective Concentration, 50%  
GHS: Globally Harmonised System

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**SECTION 16: Other information (....)**

LC<sub>50</sub>: Lethal Concentration, 50%  
LD<sub>50</sub>: Lethal Dose, 50%  
NOAEC: No Observed Adverse Effect Concentration  
NOAEL: No Observed Adverse Effect Level  
OEL: Occupational Exposure Limit  
PBT: Persistent, Bioaccumulative and Toxic  
PNEC: Predicted No-Effect Concentration  
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals  
SCL: Specific Concentration Limit  
STOT RE: Specific Target Organ Toxicity Repeated Exposure  
STOT SE: Specific Target Organ Toxicity Single Exposure  
SVHC: Substances of Very High Concern  
vPvB: very Persistent and very Bioaccumulative  
WEL: Workplace Exposure Limit