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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

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

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

Not classified

14.6 Special precautions for user

No special precautions are required for this product

14.7 Maritime transport in bulk according to IMO instrument

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)

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

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

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

Revision No. 2.0.0. Revised June 2017.

Changes made: Revised to conform to latest version of REACH. Minor changes to layout.

Revision No. 3.0.0. 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

EC₅₀: Effective Concentration, 50%

GHS: Globally Harmonised System

SECTION 16: Other information (....)

LC₅₀: Lethal Concentration, 50%
LD₅₀: 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