Version 3.0, Date: April 8, 2021

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

1.1. Product identification

 Synonyms: 1,4-Dioxan-2-one homopolymer, p-Dioxanone homopolymer, Poly(1,4-dioxanone), Poly(oxy(1-oxo-1,2-ethanediyl)oxy-1,2-ethanediyl), Poly(1,4-dioxane-2-one), Poly(oxycarbonylmethyleneoxyethylene),PDS

1.4. Chemical name:

Poly(p-dioxanone)

- 1.5. Chemical formula: (C₄H₆O₃)_n
- 1.6. CAS number: -
- 1.7. Product use: Medical Device

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]:

Not a hazardous substance or mixture

Classification according to EU Directives 67/548/EEC or 1999/45/EC:

Not a hazardous substance or mixture

Version 3.0, Date: April 8, 2021

2.2. Label element

Labelling according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]: No labeling applicable

2.3. Other hazards- none

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

MATERIAL

CAS #

CONCENTRATION

Poly(p-dioxanone)

31621-87-1

≥99.93%

Dye(D&C violet No.2)

81-48-1

≤0.07%

SECTION 4: FIRST AID MEASURES

4.1. Eyes:

Flush eyes with plenty of water for at least 15mines occasionally lifting the upper and lower lids. Get medical aid. Check and remove a contact lenses if easily possible

4.2. Skin:

Immdiately remove containinated clothing and shoes. Wash off with soap and plenty of water. Get medical attention if symptoms develops

4.3. Ingestion:

Never give anything by mouth to an unconscious person. Rinse mouth with water Get medical attention immediately. Induce vomiting as directed by medical personnel

4.4 Inhalation:

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Special hazards arising from the substance or mixture:

This material does not ignite easily, but will burn if involved in a fire. Products of combustion include irritating and poisonous gases. Decomposition product is carbon dioxide.

Version 3.0, Date: April 8, 2021

5.2. Extinguishing media:

Suitable extinguishing media

- Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide

5.3. Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

Keep unnecessary and unprotected personnel away. Remove containers to safe place if possible.

Keep containers and surroundings cool by spraying with water

5.4. Fire fighting equipment

Respiratory and eye protection required for fire-fighting personnel Full protective equipment and self-contained breathing appraturs(SCBA) should be used for all indoor fires and any significant outdoor fires

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precutions, protective equipment and emergency procedures

Keep unnecessary and unprotected personnel away. Remove all sources of ignition.

Wear appropriate personal protective equipment.

Avoid dust formation. Avoid breathing vapors, mist or gas.

6.2. Environmental precautions

Do not let product enter drains

6.3. Methods and materials for containment and cleaning up

Sweep up and shovel. Keep in suitable, closed containers for disposal.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Provide appropriate exhaust ventilation at places where dust is formed. Keep away from heat, sparks and flame. Use explosion-proof electrical equipment and take precautions against build-up of electrostatic charges, if necessary. Avoid contact with eyes, skin, and clothing. Wear appropriate personal protective equipment. Wash thoroughly after handling

Version 3.0, Date: April 8, 2021

7.2. Conditions for safe storage, including any incompatibilities

Store in cool place. Keep away from light.

Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature : ≤0 °C (Temperatue at zero or below)

Packaging material: Polyethylene laminated with aluminium

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure controls

8.1.1.Appropriate engineering controls

Provide general ventialation. Use closed system or local exhaust ventilation. Provide safety shower and eye wash station near work area.

8.1.2.Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. 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. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection is not required. Where protection from nuisance le (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Version 3.0, Date: April 8, 2021

8.2. Control of environmental exposure

Do not let product enter drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

-Appearance :

solid

-Colour:

white or pale-yellow

-Odour:

odorless

-pH:

No data available

-Melting point/freezing point :

105 ~ 110°C

-Initial boiling point and

boiling range:

No data available

-Flash point:

No data available

-Evaporation rate:

No data available

-Flammability (solid, gas):

No data available

-Upper/lower

flammability or explosive limits:

No data available

-Vapour pressure:

No data available

-Vapour density:

No data available

-Relative density:

No data available

-Water solubility:

insoluble

-Partition coefficient: noctanol/

Water:

No data available

-Auto-ignition temperature:

No data available

-Decomposition temperature:

No data available

-Viscosity:

No data available

-Explosive properties:

No data available

-Oxidizing properties:

No data available

Version 3.0, Date: April 8, 2021

9.2. Other safety information

No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Chemical stability:

This product is relatively unstable under normal temperature.

10.2. Incompatibilities with other materials:

Strong oxidizing agents

10.3. Hazardous combustion or decomposition products:

Carbon monoxide, and carbon dioxide

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Acute Toxicity: No data available

11.2. Skin corrosion/irritation:

No data available

11.3. Serious eye damage/eye irritation:

No data available

11.4. Respiratory or skin sensitization:

No data available

11.5.Germ cell mutagenicity:

No data available

11.6. Carcinogenicity:

No data available

11.7. Reproductive toxicity:

No data available

11.8. Specific target organ toxicity:

No data available

11.9. Aspiration hazard:

No data available

Version 3.0, Date: April 8, 2021

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available(Poly(dioxanone))

Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

13.2. Contaminated packaging

Dispose of as unused product. Empty the container completely before disposal

SECTION 14: TRANSPORT INFORMATION

Not available

SECTION 15: REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

No available

Version 3.0, Date: April 8, 2021

15.2. Chemical Safety Assessment:

Not available

SECTION 16: OTHER INFORMATION

16.1. MSDS status:

Date This Revision: Apirl 08, 2021

Version: 3.0

16.3. BSE:

No portions of the polymers or raw materials are derived from any animal sources.

16.4. Disclaimer:

The information contained herein is based on data believed to be accurate. However, no Representation, warranty, or guarantee is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability and completeness of such information for its own particular use.