

Issue Date: 08/08/2003
Last Revision Date: 15/11/2021
Superseded Date: 27/07/2018
Version Number: 05

SAFETY DATA SHEET

Product Code: CR18P
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SECTION 1 PRODUCT IDENTIFICATION

Product Name: Rectal Catheters
Product Uses: For a traumatic rectal drainage and irrigation procedures

SECTION 2 HAZARD IDENTIFICATION

Not classified as hazardous according to NOHSC/ASCC Criteria
Not classified as dangerous goods by the criteria of the ADG Code

Emergency Overview

This material when properly handled according to good working and hygienic practices is not dangerous to human health and the environment at ambient temperature. However, mechanical operations associated with the use of PVC material can produce elevated concentrations of airborne PVC particulates. Contact with PVC particulates can be irritating to the eyes and respiratory tract. Operations that produce airborne dusts should be conducted in well ventilated areas. Appropriate personal protective equipment (PPE) should be worn to protect workers from exposures to airborne PVC particulates.

General Precautionary Measures

Code	General Precautionary Statements	Hazard Class	Hazard Category	Conditions for use
P101	If medical advice is needed, have product container or label at hand.	As appropriate	N/A	Consumer products
P102	Keep out of reach of children.	As appropriate	N/A	Consumer products
P103	Read label before use.	As appropriate	N/A	Consumer products

Inhalation: This product in the natural state does not present an inhalation, ingestion or contact hazard. However, vapor from the heated product and dust from mechanical operations may cause mild discomfort and respiratory irritation.
Eye Contact: Eye contact with PVC dusts may cause irritation or corneal injury due to mechanical action. Vapor from heated product may also cause redness of the eyes.
Skin Contact: Prolonged skin contact is essentially non-irritating. Contact with the heated product may cause burns.
Ingestion: Ingestion of harmful amount of this product as distributed may cause nausea or vomiting and can cause damage to digestive system.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	Chemical Formula	CAS No.
Polyvinyl Chloride (PVC)	(C ₂ H ₃ Cl) _n	9002-86-2

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SECTION 4 FIRST AID MEASURES

- Inhalation:** For over-exposure to airborne fumes and particulate, remove exposed person to fresh air. If breathing is difficult or has stopped, administer artificial respiration or oxygen as indicated. Seek medical attention promptly.
- Eye Contact:** Treat for foreign body in the eye. Flush with large amount of clean water to remove particles. Seek immediate medical attention.
- Skin Contact:** Remove contaminated clothing; wash affected area thoroughly with mild soap and water. If irritation, inflammation or other symptoms develop, seek medical attention.
- Ingestion:** Do not induce vomiting and seek immediate medical advice.

SECTION 5 FIRE FIGHTING MEASURES

- Suitable Extinguishing Equip:** Use water spray, foam, dry chemical or carbon dioxide fire extinguisher. Must also use extinguishing media most appropriate for the surrounding fire.
- Fire & Explosion Hazard:** This product does not present fire or explosion hazards under normal conditions. Avoid accumulation and dispersion of dust to reduce explosion potential. Product may produce toxic fumes like carbon monoxide, carbon dioxide, hydrogen chloride and etc. when burning.
- Special Protective Equip.:** Fire fighters should wear a self contained breathing apparatus (SCBA) which meets appropriate standards operated in positive pressure mode, and full protective equipment, including full bunker gear.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Recycling is highly supported and encouraged before disposal. Disposed in an appropriately permitted waste landfill, or disposed by other methods in accordance with local, state, and federal regulations.

- Spill/Leak Procedures:** Not applicable to product in solid state. For spills involving finely divided particles, clean-up personnel should be protected against contact with eyes and skin. If material is in a dry state, avoid inhalation of dust. Fine, dry material should be removed by vacuuming or wet sweeping methods to prevent spreading of dust. Avoid using compressed air. Do not release into sewers or waterways. Collect material in appropriate, labelled containers for recovery or disposal in accordance with federal, state, and local regulations.
- Regulatory Requirements:** Follow applicable OSHA regulations (29 CFR 1910.120) and all other pertinent state and federal requirements.
- Disposal:** Follow applicable federal, state, and local regulations.

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SECTION 7 HANDLING AND STORAGE

Safe Handling: Handle the product in accordance with directions for use. Do not eat, drink and smoke in working area. Wash hand before and after handling. Remove contaminated clothing and protective equipment before entering eating areas.

Storage Conditions: Store in a cool and dry place with ambient temperature not below 3°C and not exceeding 30°C. Keep out of reach of children. Keep protected from sunlight, strong oxidizers, fire/heat sources, electrical wirings/sources and other incompatible materials.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards

Chemical Name	OSHA PEL ¹	ACGIH TLV ²
PVC Dust	15 mg/m ³ – Total dust (PNOR ³) 5 mg/m ³ – Respirable fraction (PNOR ³)	5 mg/m ³ – Respirable fraction

¹ **OSHA Permissible Exposure Limits (PELs)** are 8-hour TWA (time-weighted average) concentrations unless otherwise noted. A (C) designation denotes a ceiling limit, which should not be exceeded during any part of the working exposure unless otherwise noted. A Short Term Exposure Limit (STEL) is defined as a 15-minute exposure, which should not be exceeded at any time during a workday.

² **Threshold Limit Values (TLV)** established by the American Conference of Governmental Industrial Hygienists (ACGIH) are 8-hour TWA concentrations unless otherwise noted.

³ **PNOR (Particulates Not Otherwise Regulated).** All inert or nuisance dusts, whether mineral, inorganic, or organic not listed specifically by substance name are covered by the PNOR limit which is the same as the inert or nuisance dust limit of 15mg/m³ for total dust and 5mg/m³ for the respirable fraction.

Engineering Controls

Use controls as appropriate to minimize exposure to fumes and dusts during handling operations. Use lifting and work devices, e.g., crane, hoist, etc., within rated capacities and in accordance with manufacturer's instructions when handling these products.

- (1) Avoid breathing dust and fume.
- (2) Evaluate potential employee exposure.
- (3) Minimize generation of airborne emissions.
- (4) Maintain surfaces free as practical of accumulated material.
- (5) Use protective clothing as specified by an industrial hygienist or safety professional where exposure levels may be excessive.
- (6) Do not smoke in work area.
- (7) Wash hands before eating, drinking or smoking and after handling.
- (8) Change contaminated clothing before leaving work premises.

Ventilation

Provide general or local exhaust ventilation systems to minimize airborne concentrations. Local exhaust ventilation is preferred because it prevents contaminant dispersion into the work area by controlling it at its source.

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Administrative Controls: Do not use compressed air to clean-up spills.

Respiratory Protection

Seek professional advice prior to respirator selection and use. Follow OSHA respirator regulations (29 CFR 1910.134) and, if necessary, wear a NIOSH-approved respirator. Select respirator based on its suitability to provide adequate worker protection for given working conditions, level of airborne contamination, and presence of sufficient oxygen.

Skin and eye protection

For operations which result in elevating the temperature of the product to or above its melting point or result in the generation of airborne particulates, use protective clothing, gloves and safety glasses to prevent skin and eye contact. Use safety glasses or goggles and protective gloves as required for handling operations.

SECTION 9

PHYSICAL/CHEMICAL PROPERTIES

Appearance and Odor:	Solid, tubular, translucent to clear and odorless
pH:	Not applicable
Melting Point/Freezing Point:	100 – 260 °C
Density:	1100 – 1350 kg/m ³
Boiling Point:	Not applicable
Flash Point:	> 370 °C
Auto- ignition Temperature:	505 °C
Thermal Decomposition:	No data available.
Evaporation Rate:	Not applicable
Flammability:	Non-flammable, non-combustible
Vapor Pressure:	Not Applicable
Vapor Density:	Not Applicable
Solubility in Water:	Insoluble

SECTION 10

STABILITY AND REACTIVITY

Stability:	This product is stable under normal storage and handling conditions.
Polymerization:	Hazardous polymerization cannot occur.
Chemical Incompatibilities:	Acetal or acetal copolymers and amines (derivatives of ammonia).
Conditions to Avoid:	Direct sunlight, temperature below 3 °C and exceeding 30°C, fire/heat sources, electrical wirings/sources and other incompatible materials.
Hazardous Decomposition Products:	Thermal oxidative decomposition of products can produce fumes containing carbon monoxide, carbon dioxide, hydrogen chloride and other toxic fumes.

SECTION 11

TOXICOLOGICAL INFORMATION

The product is non-toxic by composition. However, it should be treated as nuisance particulates, avoiding breathing dust and fumes that may generate during its process.

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SECTION 12 ECOLOGICAL INFORMATION

The environmental aspects of any packaging material do not imply waste issues but have to be considered in relation with the use of natural resources, the preservations of foodstuff, etc. This product is believed and considered to be an environmentally efficient material.

Environmental Degradation: This product is non-biodegradable in nature.

Ecotoxicity: No known data available for the product.

Environmental Fate: No data available.

Soil Absorption/Mobility: No data available.

SECTION 13 DISPOSAL CONSIDERATIONS

Recycling of this materials is supported whenever ecological and social benefits are achieved and where a social infrastructure for selective collecting and sorting of packaging is fostered. Whenever "thermal" recycling of this product is carried out, polyvinyl chloride – with its fairly simple molecular structure and low amount of additives – is considered to be trouble-free fuel. However, if recycling is not possible, the product and its packaging must be disposed of in accordance with the local and national regulations.

SECTION 14 TRANSPORT INFORMATION

This product is not classified as dangerous good under transport regulations.

UN No: N/A

DG Class: N/A

Packaging Group: N/A

Hazchem Code: N/A

SECTION 15 REGULATORY INFORMATION

No regulatory information available.

SECTION 16 OTHER INFORMATION

This product is latex-free and for single-use only. Sterilization method used is ETO.
Duration of use may be intermittent but less than 60 minutes duration.

Reason for revision: To bring to date.

END OF SDS