
SAFETY DATA SHEET

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1. Product and Company Identification

Tradename: primaGARD or primaSOFT Procedure or Surgical Face Mask

Manufacturer: priMED Medical Products, Inc.
 Tel: 780.497.7600 | Fax: 780.497.7670 | www.primed.ca

Product ID:

| | | | | |
|-----------|-----------|----------|----------|-----------|
| PG4-1001 | PG4-1421 | PG4-2092 | PG4-3073 | PG4-4441 |
| PG4-1053 | PG4-1553 | PG4-2121 | PG4-3092 | PG4-4442 |
| PG4-1063 | PG4-1563 | PG4-2161 | PG4-3332 | PG4-4991 |
| PG4-1073 | PG4-1573 | PG4-2321 | PG4-3443 | PG4-4993 |
| PG4-1083 | PG4-1573M | PG4-2331 | PG4-3473 | PG4-5033 |
| PG4-1091 | PG4-1583 | PG4-2332 | PG4-3492 | PG4-5063 |
| PG4-1092 | PG4-1592 | PG4-2333 | PG4-3532 | PG4-5073 |
| PG4-1093 | PG4-1593 | PG4-2421 | PG4-3573 | PG4-5073M |
| PG4-1201 | PG4-1640 | PG4-2441 | PG4-3592 | PG4-5083 |
| PG4-1211 | PG4-1680 | PG4-2442 | PG4-4021 | PG4-5443 |
| PG4-1211M | PG4-1703 | PG4-2443 | PG4-4043 | PG4-5553 |
| PG4-1221 | PG4-1921 | PG4-2473 | PG4-4051 | PG4-5993 |
| PG4-1241 | PG4-1993 | PG4-2492 | PG4-4053 | PG4-6001 |
| PG4-1273 | PG4-2001 | PG4-2501 | PG4-4063 | PG4-6003 |
| PG4-1291 | PG4-2072 | PG4-2561 | PG4-4073 | PG4-6401 |
| PG4-1331 | PG4-2001M | PG4-2562 | PG4-4241 | PG4-6403 |
| PG4-1401 | PG4-2073 | PG4-2592 | PG4-4331 | |
| PG4-1411 | PG4-2083 | PG4-3033 | PG4-4332 | |

Intended use of product:

To be worn during non-surgical or surgical procedures to protect both the patient and healthcare personnel from transfer of potentially infectious or otherwise harmful microorganisms, body fluids, and particulate material.

Limitations on use of product:

Not intended to be worn as a respirator.

2. Hazards Identification

Critical hazards: None known

3. Composition/Information on Ingredients

| Ingredient | CAS Number | Content (wt%) |
|----------------------|---------------|---------------|
| Polypropylene | 9003-07-0 | 25 – 95% |
| Cellulose | Not available | 0 - 80% |
| Polyester | Not available | 0 - 50% |
| Polyurethane foam | Not available | <10% |
| Latex free elastomer | Not available | <5% |
| Polyethylene | 9002-88-4 | <5% |
| Latex free adhesive | Not available | <5% |
| Starch | Not available | <5% |
| Aluminum | 7429-90-5 | <5% |
| Ink | Not available | <0.5% |

NOTE: each percentage is expressed as the ratio of the weight of the ingredient to the weight of the product. Any of the products listed in section 1 may or may not contain the above listed ingredients

4. First Aid Measures

| | |
|--------------------------------|--|
| Instructions for Eye Contact: | No need for first aid is expected. |
| Instructions for Skin Contact: | No need for first aid is expected. |
| Instructions for Inhalation: | Not applicable. |
| Instructions for Ingestion: | May present a choking hazard if ingested. No need for first aid is expected. |

5. Fire Fighting Measures

| | |
|--------------------------------|--|
| Suitable Extinguishing Media: | Ordinary combustible solid. Use fire extinguishers with class A or B extinguishing agents (e.g., water, foam, dry chemical, carbon dioxide). |
| Exposure Hazards during Fire: | No unusual fire or explosion hazards are anticipated. |
| Combustion Products from Fire: | Smoke |

Carbon monoxide from combustion
Carbon dioxide from combustion

Under recommended usage conditions, hazardous decomposition products are not expected. Hazardous decomposition products may occur as a result of oxidation, heating or reaction with another material.

Fire Fighting Procedures:

Wear full protective clothing, including helmet, self-contained positive pressure or pressure demand breathing apparatus, bunker coat and pants, band around arms, waist and legs, face mask and protective covering for exposed areas of the head.

6. Accidental Release Measures

Personal Precautions: Not applicable
Spill Response: Not applicable
Methods for Disposal: Reclaim undamaged product, dispose of damaged materials in a sanitary landfill.

7. Handling and Storage

Storage Requirements: Normal room temperature and humidity
Ventilation: Not applicable
Use Instructions: This product does not release or otherwise result in exposure to a hazardous chemical under normal use and storage conditions.

8. Exposure Controls/Personal Protection

Eye Protection: Not applicable
Hand Protection: Not applicable
Skin Protection: Not applicable
Respiratory Protection: Not applicable
Ingestion Prevention: Not applicable
Recommended ventilation: Not applicable

Ingredient Exposure Data: No data available
Exposure limits: Not applicable / No data available

9. Physical and Chemical Properties

Physical form: Solid face mask
Color: Varies: blue, green, white, indigo, yellow
Odor: Not applicable
Odor Threshold: Not applicable
pH: Not applicable
Boiling point/boiling range: Not applicable
Melting point/melting range: Not applicable

| | |
|--------------------------------------|----------------|
| Flash point: | Not applicable |
| Evaporation rate: | Not applicable |
| Flammability | Not applicable |
| Lower Explosive Limit: | Not applicable |
| Upper Explosive Limit: | Not applicable |
| Vapour pressure: | Not applicable |
| Vapor density: | Not applicable |
| Specific gravity: | Not applicable |
| Water solubility: | Not soluble |
| Octanol/Water partition Coefficient: | Not applicable |
| Autoignition temperature: | Not applicable |
| Decomposition temperature: | Not available |
| Viscosity: | Not applicable |
| Volatile organic compounds: | Not applicable |
| Percent volatile: | Not applicable |

10. Stability and Reactivity

| | |
|---------------------------|---|
| Stability and Reactivity: | Stable. Hazardous polymerization will not occur. |
| Conditions to Avoid: | None known |
| Incompatible Materials: | Strong oxidizers |
| Hazardous Decomposition: | Carbon monoxide from combustion Carbon dioxide from combustion |

Under recommended usage, hazardous decomposition products are not expected. Hazardous decomposition products may occur as a result of oxidation, heating or reaction with another material.

11. Toxicological Information

All skin contact surfaces of these products have been tested for cytotoxicity, irritation and sensitization as per ISO 10993.

| | |
|------------------------------|--|
| Effects from Eye Contact: | No health effects are expected |
| Effects from Skin Contact: | No health effects are expected |
| Effects from Inhalation: | No health effects are expected |
| Effects from Ingestion: | No health effects are expected |
| Sensitization Information: | No health effects are expected |
| Carcinogenicity: | No health effects are expected |
| Mutagenicity: | No health effects are expected |
| Reproductive Effect: | No health effects are expected |
| Component Based Information: | For further details contact priMED at the above |
| Product Based Information: | All listed products have met, or exceed, regulatory requirements of Health Canada. |

This product, when used as instructed and under reasonable conditions, should not present a health hazard. However, when used in a manner outside the norm of use, product performance may be affected and potential health and safety issues could result.

12. Ecological Information

| | |
|---------------------|-----------------|
| Environmental Data: | Not applicable. |
| Ecotoxicity Data: | Not applicable |
| Ecofate Data: | Not applicable |

13. Disposal Considerations

| | |
|-----------------------|---|
| Product as sold: | Dispose of waste in a sanitary landfill. |
| Product as used: | Sterilize as required based on use and dispose of in a sanitary landfill. |
| Product packaging: | Coated and uncoated cardboard, Dispose of waste in sanitary landfill. Recycle where possible. |
| Special Instructions: | Consult regulatory authorities before disposal. |

14. Transportation Information

| | |
|---|------------------------|
| Transportation of Dangerous Goods Classification: | Non-Regulated Material |
| International Dangerous Goods Classification: | Non-Regulated Material |

For further information, contact priMED Medical Products Inc.

15. Regulatory Information

| | |
|----------------------------|-------------------------|
| WHMIS Classification: | Exempt |
| Product Certification: | Defined article exempt |
| Health Canada Information: | Medical device, class 1 |

This product has been classified in accordance with the Canadian Medical Device Regulations (MDR SOR/98-282).

Note: this document has been provided out of consideration for our customers. As per the Canadian Hazardous Products Act, medical devices are exempt from SDS requirements. (For further details, refer to Part II – Application, paragraph 12 (j) and Schedule 1, line 3 with reference to devices regulated under the Food and Drugs act.)

16. Other Information

The information in this Safety Data Sheet (SDS) is believed to be correct as of July 25, 2019.