SAFETY DATA SHEET

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=== Section 1 –Identification ==========

Product: Ostomy Stoma paste
Product Use: Absorbent adhesive paste used as skin filler
Product ID Other: Fortis 6300
CAS Number: Mixture
SDS Date: 07/28/2014 SDS Revision Date: 10/01/2015
Manufacturer: Fortis Medical Products
Address: 10216 Werch Drive
City: Woodridge
State: IL
ZIP: 60517
Country: US
Phone Number: (855)550-2600

=== Section 2 - Hazards Identification ==========
Routes of Entry: Inhalation: NO Skin: NO (may cause slight irritation on sensitized skin) Ingestion: NO
Reports of Carcinogenicity: NTP: NO IARC: NO OSHA: NO
Health Hazards Acute and Chronic: NO ADVERSE REACTIONS ARE KNOWN TO EXIST FROM THE USE OF THIS PRODUCT FOR ITS INTENDED PURPOSE.
Explanation of Carcinogenicity: NONE
Effects of Overexposure: NO ADVERSE REACTIONS ARE KNOWN TO EXIST FROM THE USE OF THIS PRODUCT FOR ITS INTENDED PURPOSE.

This substance is not classified as dangerous according to Directive 67/548/EEC as amended and adapted.

=== Section 3 - Composition/Information on Ingredients ==========
Ingred Name: Isobutylene/butene copolymer
CAS: 9003-29-6
Ingred Name: Ethanol, 10-20%
CAS: 64-14-5
Ingred Name: Heterogeneous mixture of water-soluble proteins
CAS:9000-70-8
RTECS #:LX8580000
Ingred Name: Poly-D-galacturonic acid methyl ester
CAS:9000-69-5
RTECS #:RX4280000
Ingred Name: CARBOXYMETHYLCELLULOSE (CELLULOSE, CARBOXYMETHYL ETHER, SODIUM SALT)
CAS:9004-32-4
RTECS #:FJ5950000
Ingred Name: BRANCHED POLYSACCHARIDE GUM
CAS:9000-01-5

****Proprietary formula and contains no hazardous ingredients. All ingredients are medical or food grade. Latex free and phthalate free****

=== Section 4 - First Aid Measures ==========
First Aid: EYES: FLUSH W/COPIUS AMOUNTS OF WATER. SKIN: IN THE CASES OF SKIN IRRATION, DISCONTINUE USE AND WASH AREA WITH SOAP AND WATER. IN OTHER UNFORSEEN MEDICAL ISSUES: OBTAIN MEDICAL ATTENTION IN ALL CASES.

=== Section 5 - Fire Fighting Measures ==========
Extinguishing Media: WATER FOG, DRY CHEMICAL/CO2
Fire Fighting Procedures: USE A SELF CONTAINED BREATHING APPARATUS.

=== Section 6 – Accidental Release Measures ==========
Personnel Precautions: For large spills: Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid breathing vapor, aerosol or mist. Avoid contact with skin, eyes and clothing.
Environmental Precautions: For large spills: Avoid runoff into storm sewers, ditches and waterways.
Methods for containment: For large spills: Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup: For large spills: Remove all sources of ignition. Collect the wipes with a non sparking tool and wipe any residual liquids. Place in a suitable container for proper disposal. Use appropriate protective apparel as described in Section 8. Avoid contact with skin and eyes.

=== Section 7 - Handling and Storage ==========
Handling and Storage Precautions: STORE AT ROOM TEMPERATURE, AVOID REFRIGERATION & EXPOSURE TO HIGH HUMIDITY. USE FOR INTENDED PURPOSE ONLY, NOT INTENDED FOR USE ON OPEN WOUNDS.

Hygiene Practices: Wash thoroughly after handling. Avoid inhaling vapors, mists or fumes.

=== Section 8 - Exposure Controls/Personal Protection ==========
Supplemental Safety and Health: PASTE IS FOR FILLING SKIN FOLD WHILE APPLYING OSTOMY APPLIANCES TO THE BODY OR ACTING AS A FOUNDATION. USE FOR INTENDED PURPOSE ONLY, NOT INTENED FOR USE ON OPEN WOUNDS.

ethanol:
Guide line AC GIH: TLV-STEL: 1000 ppm
Guide line O SHA: PEL-TW A: 1000 ppm

=== Section 9 - Physical/Chemical Properties ==========
Appearance, Stability and Odor: (TAN COLORED VISOUS PASTE/STABLE NORMAL CONDITIONS/SLIGHT ALCOHOL ODOR/SWELLS IN WATER)

=== Section 10 - Stability and Reactivity Data ==========
Stability Indicator/Materials to Avoid: YES
Stability Condition to Avoid: REFRIGERATION & EXPOSURE TO HIGH HUMIDITY.
Hazardous Decomposition Products: BY THERMAL DECOMPOSITION/BURNING: CO, CO2, NITROGEN OXIDES, HYDROGEN CYANIDE & OTHER TOXIC GASES.

=== Section 11 - Toxicological Information ==========
sodium carboxymethylcellulose :
Skin: Administration onto the skin - Rabbit LD50 - Lethal dose, 50 percent kill: >2 gm/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
Inhalation: Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: >5800 m g/m 3/4H [Details of toxic effects not reported other than lethal dose value] (RTECS)
Ingestion: Oral - Rat LD50 - Lethal dose, 50 percent kill: 27000 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

ethanol :
Eye: Administration into the eye - Rabbit Standard Draize test: 500 mg [Severe]
Administration into the eye - Rabbit Standard Draize test: 500 mg/24H [Mild]
Administration into the eye - Rabbit Rinsed with water: 100 mg/4S [Moderate]
Administration into the eye - Rabbit Standard Draize test: 100 uL [Moderate] (R TEC S)
Inhalation: Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 20000 ppm /10H [Details of toxic effects not reported other than lethal dose value]
Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 5900 mg/m3/6H [Details of toxic effects not reported other than lethal dose value]
Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 124700 mg/m3/4H [Details of toxic effects not reported other than lethal dose value](RTECS)
Ingestion: Oral- Rat LD50 - Lethal dose, 50 percent kill: 7060 mg/kg [Lungs, Thorax or Respiration-Other changes]
Oral - Rat LD50 - Letha l dose, 50 percent kill: 7gm/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Rat LD50 - Lethal dose, 50 percent kill: 15010 mg/kg [Behavioral-Somnolence (general Depressed activity) Lungs, Thorax or Respiration-Respiratory depression Gastrointestinal-Gastritis](RTECS)

=== Section 12 – Ecological Information ===========================
Ecotoxicity: No environmental information found for this product.
Environmental Fate: No environmental information found for this product.

=== Section 13 - Disposal Considerations ===========================
Waste Disposal Methods: DISPOSE OF IN ACCORDANCE W/LOCAL, STATE & FEDERAL REGULATIONS

=== Section 14 – Transport Information ===========================
DOT Shipping Name: Not Restricted in accordance with CFR 49 Section 173.125(1)
DOT UN Number: Not Restricted in accordance with CFR 49 Section 173.125(1)

Notes: The data provided in this section is for information only. Please apply the appropriate regulations to properly classify your shipment.

=== Section 15 – Regulatory Information ==========+================
pectin:
TSCA Inventory Status: Listed
Canada DSL: Listed
sodium carboxymethylcellulose:
TSCA Inventory Status: Listed
Canada DSL: Listed
ethanol:
TSC A Inventory Status: Listed
Canada DSL: Listed

=== Section 16 – Other Information ================================
Disclaimer: This product is exempt from Safety Data Sheet regulations as the product is for consumer use. (provided with this information by the compiling agencies): This information contained in this SDS is offered as a guide to the handling of this specific material. The information contained in this Safety Data Sheet (SDS) is offered as a guide to the use and handling of this

material. It has been prepared in good faith by technically knowledgeable personnel and is believed to be correct as of the effective date listed. All safety aspects of all Fortis Medical Product's products are thoroughly evaluated prior to commercialization. Fortis Medical Products shall not be held liable for any damages, losses or injuries of any nature which may result from the use of or reliance upon any information contained in this SDS. Each individual should make a determination as to the suitability of the information for his or her particular purposes. Fortis Medical Products and the United States of America in no manner whatsoever, expressly or implied, warrants this information to be accurate and disclaims all liability for its use. Any person utilizing this document should seek competent professional advice to verify and assume responsibility for the suitability of this information to their particular situation.