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### **MATERIAL SAFETY DATA SHEET:**

Reference: This MSDS is prepared to comply with: 29 CFR 1910.1200; Directive 91/155/EEC.

SECTION 1. ------IDENTIFICATION OF PRODUCT AND COMPANY ------

PRODUCT NAME SenSura X-Pro click flat

10015, 10016, 10017, 10025, 10026, 10027, 10035, 10036, 10045 PRODUCT CODE

**Product Information:** Ostomy

### Manufacturer:

Coloplast A/S Holtedam 1 DK-3050 Humlebaek Denmark

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#### SECTION 2. ------ HAZARDS IDENTIFICATION -----

This product consists primarily of polymer materials. The product poses no immediate hazard, but can give rise to toxic fumes in a fire.

## SECTION 3. ----- COMPOSITION / INFORMATION ON INGREDIENTS -----

This product does not contain substances classified as hazardous under EC nor US OSHA regulations. Main ingredients and packaging materials are listed below.

Chemical Name CAS -No. EC-No.

Adhesive liner

Siliconized film Adhesive

Coupling plate

EVA (ethylenevinylacetate) 24937-78-8 PE (polyethylene) 9002-88-4

Packaging:

Paper Corrugated cardboard -

### SECTION 4. ------FIRST-AID MEASURES -----

In Case of Eye Contact: Not relevant

In Case of Skin Contact: This product is intended to be in contact with the skin when used as

directed in the instructions for use

**If Inhaled:** Not relevant

If Ingested/Swallowed: Not relevant

**Other:** Show this Safety Data Sheet to a physician or emergency ward.

### SECTION 5. -----FIRE FIGHTING MEASURES -----

**Extinguishing Media:** Use water spray, carbon dioxide, dry chemical powder or appropriate foam. **Special Firefighting Procedures:** Keep personnel removed from and upwind of fire. Wear full fire fighting turnout gear and respiratory protection.

**Exposure Hazard:** Smoke, soot, CO/CO2, and other toxic fumes. Avoid contact with heated or molten product. Do not breathe vapors from heated product.

#### SECTION 6. ------ACCIDENTAL RELEASE MEASURES -----

No specific measures.

## SECTION 7. ----- HANDLING AND STORAGE -----

Handling: See instructions for use.

**Storage:** Store until use as supplied and at normal temperatures.

## SECTION 8. ----- EXPOSURE CONTROLS / PERSONAL PROTECTION -----

Engineering Measures: None required

Personal Protective Measures: None required

Exposure limit values: None

# SECTION 9. ------PHYSICAL AND CHEMICAL PROPERTIES -----

Appearance: Coupling plate

Odor: None

Physical State: Solid pH: Not applicable

Vapor Pressure: Not applicable

**Vapor Density:** Not applicable **Boiling Point:** Not applicable

Melting Point/Freezing Point: Not applicable

Solubility: Not applicable Density: Not applicable Flash Point: Unknown

## SECTION 10. ----- STABILITY AND REACTIVITY -----

Stability: The product is stable under ambient conditions

Conditions to avoid: High temperatures

Materials to avoid: None known

Hazardous Decomposition Products: Heating may produce toxic fumes

Hazardous polymerization: No

### SECTION 11. ----- TOXICOLOGICAL INFORMATION -----

This product is a medical device and has been evaluated according to the requirements of medical devices. According to current knowledge this product is considered non-toxic.

For further information please contact Coloplast A/S at the telephone number found in section 1.

## SECTION 12. ----- ECOLOGICAL INFORMATION -----

Ecotoxicological data have not been determined specifically for this product. Based on toxicity data on the ingredients no ecotoxicological effects are expected. However, the product is not biodegradable and discharge to the environment should be avoided.

For further information please contact Coloplast A/S at the telephone number found in section 1.

### SECTION 13. ----- DISPOSAL CONSIDERATIONS -----

The recommended disposal technology is incineration at any approved facility. The disposal should always be in compliance with National, Federal, State and local regulations. The product should not be discharged to the environment.

US: If this product as supplied becomes a waste, is does not meet the criteria of a hazardous waste as defined under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261. Under normal private use the product may be disposed of together with other household waste per RCRA 40 CFR 261.4.B1.

European Union: Per The European Waste Catalogue (EWC), in accordance with EC Directive 75/442/EEC, the following Waste Code can be used: 18 01 04 00 wastes whose collection and disposal is not subject to special requirements in view of the prevention of infection (e.g. dressings, plaster casts, linen, disposable clothing, diapers). However, if the waste in view of the prevention of infection needs special requirements, other Waste Codes should be used. It is the responsibility of the holder of the waste to determine the actual classification. Waste from private household may be disposed of together with other household waste.

## SECTION 14. ----- TRANSPORT INFORMATION -----

Not dangerous goods (ADR 2003, RID, DOT).\_\_\_