Coloplast

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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 Assura® Convex Light 1 PC Ileo Pouch
PRODUCT CODE 14424
Product Information: Ostomy

Manufacturer:
Coloplast A/S
Holtedam 1
DK-3050 Humlebæk
Denmark
Telephone: +45 49 11 11 11
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SECTION 2. --------- COMPOSITION / INFORMATION ON INGREDIENTS ----------

This product contains Titanium Dioxide A-HR, CAS 13463-67-7, which is classified as hazardous under OHSA regulations. Due to its containment in a polymer matrix, the substance poses no immediate hazard. Main ingredients and packaging materials are listed below.

Chemical Name	CAS -No.	EC-No.
Ostomy Pouch:		
CPE (chlorinated polyethylene)	64754-90-1	
PA (polyamide)	25038-54-4	
PVdC (polyvinylidene chloride)	9011-06-7	
PP (polypropylene)	9003-07-0	
PET (polyester)	25038-59-9	
PE (polyethylene)	9002-88-4	
Activated carbon	-	
PO (polyolefin) foam	-	
Adhesive Liner:		
Adhesive	-	
Siliconized film	-	

Packaging:		
Corrugated cardboard	-	
Paper	-	

SECTION 3. ---------- HAZARDS IDENTIFICATION ----------

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

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: Light brown/transparent ostomy pouch
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 Ressource Conservation and Recovery Act (RCRA) 40 CFR 261.

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).

SECTION 15. - - - - - - - - - - REGULATORY INFORMATION - - - - - - - - - -

United States: This product is regulated under the Federal Food Drug and Cosmetic Act and do not require an MSDS for hazard communication as stated in 29 CFR 1910.1200.

This MSDS is supplied as an additional service.

Comment:

European Union: This product is a medical device and is regulated under the Council Directive 93/42/EEC (commonly known as the Medical Device Directive). Medical devices do not require a safety data sheet for hazard communication.

This safety data sheet is supplied as an additional service.

Hazardous chemicals according to Directive 67/548/EEC and later amendments	Risk Phrase	Safety Phrase
None	None	None

Comment:

SECTION 16. - - - - - - - - - - OTHER INFORMATION - - - - - - - - - -

THE ABOVE INFORMATION HAS BEEN COMPILED FROM SOURCES BELIEVED TO BE RELIABLE AND IS ACCURATE TO THE BEST OF OUR KNOWLEDGE. HOWEVER, COLOPLAST CORP. CANNOT GIVE ANY GUARANTEES REGARDING INFORMATION FROM OTHER SOURCES AND EXPRESSLY DOES NOT MAKE ANY WARRANTIES, NOR ASSUMES ANY LIABILITY, FOR ITS USE.