AHLSTROM

Subject: Declarations related to Sterile Barrier System for packaging medical devices:

Dear Sir/ Madam

Herewith declares that the Ahlstrom Specialties sheets non-sterile sterilisation wrap to be used as “packaging materials for terminally sterilized medical devices”, namely **Reliance 310 and Reliance 310s** comply with:

EN 868-2:
Packaging material for terminally sterilized medical devices Part. 2: Sterilization wrap - requirements and tests methods (EN ISO 868-2:2009).
EN ISO 11607-1:
Packaging for terminally sterilized medical devices - Part. 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006);
MDD 93/42/EEC 1993 / 47EC5 2007:
Packaging materials are considered as accessories to medical devices, therefore belonging to Class I non sterile (self certification) and complies with the 93/42/EEC Directive and CE marking. All products are registered at « Ministère de l’Emploi et de la solidarité, direction des hôpitaux ».
Latex free:
The above products are Latex free. This includes synthetic latex materials or natural rubber materials containing any of the proteins linked to Types I & IV latex allergies
Intended use:
Sterile Barrier System for packaging medical devices which can be terminally sterilized by the following methods: Steam (134°C), Ethylene Oxide, Gamma Irradiation according to EN 868-2:2009. It is recommended that the end user validates the final packaging system as suitable with the intended sterilisation process to maintain compliance to local regulations.

Yours sincerely,

Sylviane Lardeur
Quality Manager

Pont-Audemer,
12/03/2012

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OHSAS 18001 Certificat N°FR10/0241SE

SAS Capital 11.875.317 Euros - UE/TVA FR 53 352 703 201 – 352 703 201 RCS Roubaix-Tourcoing

Ahlstrom Specialties

Material Safety Data Sheet
CREPE PAPER

0. Introduction

The information and recommendations contained herein are based upon data believed to be correct. However, since much of the information has been received from sources outside our company, we cannot guarantee its accuracy or completeness. Health and safety precautions contained within this data sheet may not be adequate for all individuals and/or situations. It is the user's obligation to evaluate and use this data in order to comply with all applicable laws and regulations. Additionally, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein.

1. Product Identification

1.1. Identification of the product

RELIANCE 310 SENSITIVE WHITE

1.2 Company Identification

Company/Plant where information on the product safety is available

Location:	Pont-Audemer
Name:	Ahlstrom, Specialties, Plant
Address:	rue des Papetiers
City:	Pont-Audemer
State/Province:	France – Haute-Normandie
Zip Code:	F-27 501
Country:	FRANCE
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Name and address of the informant in emergency cases

Department:	Quality
Contact Person:	Sylviane Lardeur
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Issue Date/Date Last Reviewed: 02/23/2007

2. Composition

Identification of the type of paper product.

2.1. colour: white

2.2. Nature of the fiber(s): Cellulose that contains 100 % ECF pulp

2.3. Web surface treatment

- Concentration above 1%?: None

2.4. Binder: YES

2.5. Additives:

2.6. Other major components: None

2.7. Chemicals (in relevant concentrations) that are in the list of hazardous constituents: None

3. Hazards Identification

No hazardous product under normal conditions. Accidental thermal decomposition or melting state can present hazards.

4. First-aid Measures

Under normal conditions

4.1. Inhalation: No specific measure to be taken.

4.2. Skin contact: No specific measure to be taken.

4.3. Eye contact: No specific measure to be taken.

4.4. Ingestion: No specific measure to be taken.

5. Fire Fighting Measures

5.1. Suitable extinguishing media:

Water, foam, carbon dioxide, dry chemical or other suitable media.

5.2. Extinguishing media not to be used:

None

5.3. Special exposure hazard:

For flammable and toxic fumes, see Section 10.

5.4. Special protective clothing for fire-fighter:

None

6. Accidental Release Measures

Not applicable

7. Handling and Storage

7.1. Handling Be careful when handling heavy paper rolls and especially if the rolls are wetted.

7.2. Storage Store at a dry place.

8. Exposure Controls/Personal Protection

8.1. Special instructions for protection and hygiene	No requirements.
8.2. Respiratory protection	Not required.
8.3. Hand protection	Not required.
8.4. Eye protection	Not required.
8.5. Skin protection	Not required.

9. Physical and Chemical Properties

Appearance

(color of product as supplied and odour):	White fabric , odourless
pH:	Not applicable
Boiling Point (boiling range):	Not applicable
Melting Point (melting range):	Not applicable
Flash Point:	Not applicable
Flammability:	Easily flammable (See section 10)
Autoflammability (temperaure),	
Autoignition Temperature:	232 degrees C cellulose
Explosive Properties:	Not applicable
Oxidizing Properties:	Not applicable
Vapor Pressure:	Not applicable
Relative Density:	Not applicable
Solubility - in water:	Insoluble
- in fat:	Insoluble
Partition Coefficient (octanol/water):	Not applicable

10. Stability and Reactivity

Conditions to avoid:

Under thermal decomposition, flammable and toxic fumes can be generated. Above 300 °C may be released: toxic and flammable gases, carbon monoxide. The generation of cleavage and oxidation products is subject to fire conditions. After fire fighting, the unburned residues and contaminated water should be disposed of in compliance with official regulations.

11. Toxicological Information

No toxic reaction under normal conditions. Note: Under decomposition conditions, toxic fumes and contaminated water, see Section 10.

11.1. Acute toxicity:	Non-toxic.
11.2. Irritancy and corrosiveness:	None
11.3. Sensitization:	None
11.4. Subacute, subchronic and prolonged toxicity:	None
11.5. Empirical data on effects on humans:	None
11.6. Other information on health effects:	None

12. Ecological Information

Persistence in the environment

Biodegradation

Chemical degradation Cellulose and hemicellulose are hydrolyzed under acidic conditions.

Bioaccumulation

Mobility

Toxic effects on organisms

Aquatic toxicity: Non-toxic

Other toxicity: None

Other information: None

For transportation, storage, and normal use, no toxicological effect known.

13. Disposal Considerations

As non-hazardous solid waste, depending on local regulation, crepe paper can be disposed of through:

Recycling: Yes

Composting: Yes

Incineration: Yes

Landfill: Yes

14. Transport Information

Not regulated by Department of Transportation

UN number: Not subject to transport regulations.

Packaging category: None

14.1 Land transport:

Transport class: Not subject to transport regulations.

Risk code: None

Name according to bill of freight: None

Other information: None

14.2 Sea transport

IMDG class: Not subject to transport regulations.

Correct technical name: None

Other information: None

14.3 Air transport

ICAO/IATA class: Not subject to transport regulations.

Correct technical name: None

Other information: None

15. Regulatory Information

16. Other Information

This product does not contain natural rubber latex or synthetic latex. This product has an odour typical of sheeted or roll goods crepe paper fabrics.

Author: Houte H ASP/Pont-Audemer/QM **Composed:** 02/23/2007 17:45 PM **Document Last Edited**:

Edit History:

Technical Datasheet

Sterile Barrier System

RELIANCE 310s

Characteristics:

Reliance 310 Sensitive (S) is manufactured from cellulosic fibers. It does not contain any natural rubber latex.

Compliance to main standards and directives:
MDD 93/42/EEC 1993 / 47EC5 2007
EN / ISO 11607-1:2009 & EN 868-2:2009

Applications:

Reliance 310s is intended for single use and can be considered as a Medical Device Class 1 accessory, wrapping fabric. Could be used as inner or outer layer. Compatible with all main sterilization methods (except Plasma).

Benefits:

Its good bacterial barrier properties combined with fluid repellency & mechanical characteristics makes R310s the best economical compromise for wrapping purpose. Available in wide set of colours could be combined to provide a full choice of colour coding and technological differentiation.

Its specific softening treatment confers R310s a specific soft touch and increased drapeability for a highly comfortable use.

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Technical Datasheet

RELIANCE 310s

In accordance with EN868 – Part 2: 2009

Chapter	Characteristics	Test Method	Unit	Requirements	Typical Values
4.2	Materials				
4.2.1	General	Visual observation	-	No tears, creases or localised thickening sufficient to impair its functioning	Conform
4.2.1.1	Colour	ISO6588-2	Visual observation	No colour shall leach	Conform
4.2.1.2	Average mass of 1m²	EN ISO 536:1995	g/m²	The average mass shall be within ± 5 % of the nominal value stated by the manufacturer	60
4.2.1.3	pH-value	ISO 6588-2		5 ≤ pH ≤ 8 (hot extraction method)	6.7
4.2.1.4	Chloride	ISO 9197	%	≤ 0,05% (NaCl, hot extraction method)	0.03
4.2.1.5	Sulphate	ISO 9198	%	≤ 0,25% (Na_2SO_4 hot extraction method)	0.055
4.2.1.6	Fluorescence	Annex B	%	No increase in brightness due to the optical brightener of more than 1% and number of spots ≤ 5 ; spots axis > 1mm / 0,01 m²	Conform
4.2.2.2	Specific requirements for creped paper				
4.2.2.2.2	Elongation	EN ISO 1924-2	%	≥ 10 in machine direction ≥ 2 in cross direction	13 5
4.2.2.2.3	Water repellency	Annex D	S	≥ 20 for penetration time	25
4.2.2.2.4	Pore size diameter	Annex E	µm	≤ 50 (maximum equivalent pore size diameter)	20 (average)
4.2.2.2.5	Tensile strength	EN ISO 1924-2	kN/m	≥ 1,33 in machine direction ≥ 0,67 in cross direction	2.4 1.33
4.2.2.2.6	Wet tensile	ISO 3781	KN/m	≥ 0.,33 in machine direction ≥ 0.,277 in cross direction	0.8 0.45

In accordance with ISO 11607 – Part 1: 2009

Chapter	Characteristics	Test Method	Unit	Requirements	Typical Values
5.1.6 a)	Germ proofness in moisture	DIN 58 953-6:2010	Nil	Germ- proof	Conform
	Germ proofness with passage of air	DIN 58 953-6:2010	Nil	Germ- proof	Conform
5.1.6 b).	Biocompatibility and toxicological attributes	ISO 10993-1	n/a	Conform to requirements	Conform
5.1.6 c).	Physical and chemical properties	EN 868-2	n/a	Conform to requirements	Conform
5.1.6 e).	Compatibility with respect to intended sterilisation process(es)	EN 868-2	n/a	Conform to requirements	Conform
5.1.6 f).	Shelf life limitations Pre sterilisation	EN 868-2	years	Conform to requirements	5 years

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