Material Safety Data Sheet 1907/2006

according to Regulation (EC)

Product name: Adjustable ostomy belt Revision: 25-July-2013 Version: 1.0

Print date 25-July-2013



Material Safety Data Sheet (MSDS):

<u>Section 1 – Identification of Product and Company</u>

Product Name: Pelican Adjustable Ostomy Belt

Product Code: 839520, 839521

Product Information: Adjustable Ostomy Belt

Supplier:

TG Eakin Ltd
15 Ballystockart Road
Comber
County Down
Northern Ireland
BT23 5OY

Telephone / Telefax

T+44 2891 871000 F +44 2891 871111

Contact

Aaron Hewitt (E-mail: aaron.hewitt@eakin.co.uk)

Emergency information

+44 2891 871000 (only at office hours 9:00 - 17:30)

This product does not contain any medicinal substances and any tissues of animal origin and meets the provisions of the European Medical Devices Directive 93/42/EEC.

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

Section 2 - Composition/Information on Ingredients		
Chemical/Material Name	CAS- No.	EC-No.
Dyed Nylon	N/A	N/A
Dyed Polyester	N/A	N/A
Elastane	N/A	N/A

Section 3 — Hazards Identification	
None Identified	
This product is intended to be used in contact with skin and used in accordance with	
the Instructions For Use (IFU).	

Section 4 — First Aid Measures	
In case of eye contact	Should irritation occur, flush the entire eyeball with copious amounts of water. If irritation persists seek medical advice.
In case of skin contact	This product is not a skin irritant. It is intended to be in contact with skin. However, only in accordance with the IFU

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If inhaled	This product is not a respiratory irritant.
If ingested/swallowed	No specific intervention is indicated as
_	the compound is not hazardous by
	ingestion but if symptoms occur, consult
	medial advice.
Other	Show this MSDS to a treating physician or
	treating doctor at an Emergency ward

Section 5 — Fire Fighting Measures	
Extinguishing Media	CO2
Special Fire fighting Procedures	Wear respiratory apparatus. Use water spray, dry chemical, carbon dioxide & foam
Exposure Hazard	Avoid inhalation of fumes

Section 6 – Accidental Release Measures	
None	

Section 7 — Handling and Storage	
Handling	See Instructions for Use
Storage	Store away from direct heat and damp conditions.
Waste Disposal	If unused dispose of as non-hazardous waste in accordance with local regulations in the UK.

Section 8 – Exposure Controls/Personal Protection	
Engineering Measures	None Identified
Personal Protective Measures	Good Clinical Practice
Exposure Limit Values	None

Section 9 - Physical and Chemical Properties	
Appearance Caramel coloured elasticated belt	
Odour	N/A
Physical State	Dry and elasticated
pH	N/A
Vapour Pressure	N/A
Vapour Density	N/A

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Boiling Point	N/A
Melting Point/Freezing Point	N/A
Solubility	N/A
Density	N/A
Flash Point	N/A

Section 10 - Stability and Reactivity	
Stability Stable under normal user conditions	
Conditions to avoid	See IFU
Materials to avoid	N/A
Hazardous Decomposition	N/A
Hazardous Polymerization	N/A

Section 11 - Toxicological Information			
Acute Effects	Not Determined		
Chronic Effects			
Carcinogenicity	Not Determined		
Mutagenicity	Not Determined		
Reproductive Effects	No data		
Developmental Effects	No data		

Section 12- Ecological/Environmental Information

Eco-toxilogical data has not been determined specifically for this product. Based on toxicity data on the materials no affects are expected to the environment. However, the product is not biodegradable and discharge to the environment should be avoided.

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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. This product should not be discharged to the environment.

USA: if this product as supplied becomes waste, it does not meet the criteria of a hazardous waste as defined under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261

EU: as per the European Waste Catalogue (EWC), in accordance with EC Directive 75/44EEC, 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 prevention (e.g dressings). However, if the waste in view of prevention of infection needs special requirements, other waste codes shall be used. It is the responsibility of the holder of the waste to determine the actual classification. Waste from private households may be disposed of together with other household waste

If unused dispose of as non hazardous waste in accordance with local regulations in the UK.

Section 14 – Transport Information

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

Section 15 – Regulatory Information

<u>United States:</u> 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.

<u>European Union:</u> 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 date 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

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Section 16 – Other Information

The above information has been complied from sources believed to be reliable and is accurate to the best of our knowledge. However, TG Eakin Ltd cannot give any guarantees regarding information from other sources and expressly does not make any warranties, nor assumes any liability, for its use.