Date: January 2013

Material Safety Data Sheet (MSDS):

Reference: This MSDS is prepared to comply with Directive 93/42/EEC amended to 2007/47/EC. CE Conformance Declaration according to annex II (Full Quality Assurance system).

Section 1 - Identification of Product and Company

Product Name: *Activon Tube*
Product Code: CR3830
Product Information: 100% Medical Grade Manuka honey
Classification: IIb Medical Device Directive 93/42/EEC amended by Directive 2007/47/EC, Rule 4 (Secondary Intent)

Manufacturer:

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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 Name	CAS-No.	EC-No.
Polyurethane film/ paper liner	N/A	
Polyurethane Film	N/A	
Polyurethane Foam	N/A	
Cardboard Containers (Retail Box)	N/A	
Paper Pouch (Primary Pack)	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 copius amounts of water. If irritation persists seek medical advice.
In case of skin contact	This product is not a skin irritant. Intended to be in contact with skin when used as directed on the IFU.
If inhaled	This product is not respirable
If ingested/ swallowed	No specific intervention is indicated as the compound is not hazardous by ingestion but if symptoms occur, consult medical 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 and 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. Store at room temperature (23°C +/- 5°C) and use straight away when opened.
Waste Disposal	If unused dispose as non-hazardous waste in accordance with local regulations in the UK. If used, dispose of as clinical waste.

Section 8 - Exposure Controls/ Personal Protection

Engineering Measures	None identified.
Personal Protective Measures	Good clinical practice (gloves to prevent contamination to treating physician)
Exposure Limit Values	None

Section 9 - Physical and Chemical Properties

Appearance	Liquid honey
Odor	Sweet honey smell
Physical State	Liquid
pH	N/A
Vapor Pressure	Not determined
Vapor Density	Not determined
Boiling Point	Not determined
Melting Point/ Freezing Point	Not determined
Solubility	Not determined
Density	Not determined
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	Not determined
Carcinogenicity	Not determined
Mutagenicity	Not determined
Reproductive Effects	No data
Developmental Effects	No data

Section 12 - Ecological/ Environmental Information

Ecotoxilogical 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.

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. If used, dispose of as clinical 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.

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 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

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, Brighwake/ Advancis Medical cannot give any guarantees regarding information from other sources and expressly does not make any warranties, nor assumes any liability, for its use.