



**USE AND DECONTAMINATION OF TRANSOESOPHAGEAL
AND EPICARDIAL ECHO PROBES IN THE
OPERATING THEATRE DEPARTMENT GUIDELINE**

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Date of Issue	March 2017
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1.0 Introduction

Our Lady's Children's Hospital, Crumlin - Operating Theatre Department is committed to best practice in the prevention of infection in relation to the use and decontamination of Transoesophageal (TOE) and Epicardial echo probes.

2.0 Purpose

The purpose of this document is to direct staff on the use and decontamination of transoesophageal and epicardial echo probes and their role in infection prevention and control relative to their use.


3.0 Applicable to

This procedure applies to all hospital departments where the TOE and Epicardial echo probes are used.

This procedure applies to all users of TOE and Epicardial echo probes, i.e., Doctors, Nurses, Health Care Assistants and Echo technicians.

4.0 Roles and Responsibilities

- It is the responsibility of the clinical area manager to update this document as required in line with best practice.
- It is the responsibility of the Infection Prevention and Control team to give advice regarding the update of this document in line with best practice.
- It is the responsibility of users (medical and nursing staff) to implement this procedure when using transoesophageal and epicardial echo probes.
- It is the responsibility of the user to ensure that the TOE and the epicardial echo probes and its associated equipment has been appropriately cleaned and disinfected before use, after use, between patient use and on a scheduled basis. This should be documented on the TOE and Epicardial echo probe decontamination and traceability log book and this information should also be recorded on the patient's perioperative notes.
- It is the responsibility of the person doing the scan to record on the patient's clinical notes that the TOE and/or epicardial echo probe has been appropriately decontaminated prior to use.
- It is the responsibility of the clinical area manager to ensure that Echo ultrasound machines used in their clinical area of responsibility are managed according to manufacturer's instructions and in accordance with hospital policies, procedures and guidelines.

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5.0 Definition of Terms

Transoesophageal probe (TOE)

Is a special intra-cavity probe that is placed in a sterile sheath along with sterile ultrasound gel and is inserted into the oesophagus for the purposes of cardiac imaging.

Epicardial echo probe

Is an echo probe that is placed in a sterile sheath along with sterile ultrasound gel and then taken onto the surgical field where it is placed on the epicardial surface of the heart for the purposes of cardiac imaging.

Transoesophageal echo

Is a diagnostic procedure that uses echocardiography to assess the heart's function. These images are unobstructed by lungs and ribs due to the position of the probe.

Epicardial echo

This is a diagnostic procedure that uses echocardiograph to assess the heart's function. The position of the probe on the epicardial surface of the heart provides a 2-dimensional colour flow and spectral Doppler image in multiple planes.

Docking station

Is the protective housing on the scan machine where the probes are stored between uses.

Storage box trolley

Is a separate trolley which holds the boxes where the TOE probes are stored between uses.

Storage box

Is the rigid box which holds individual TOE probes between uses.

Cleaning

A process of using friction, detergent or water to remove soil, including organic debris.

Detergent


A substance that suspends organic material making subsequent removal easier.

Decontamination

This is a term used to describe the destruction or removal of microbial contamination to render an item safe for use.

Tristel

A chlorine dioxide compound/disinfectant used to achieve high level disinfection on the TOE and the epicardial echo probes.

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Tristel Pre Clean Wipe

A wipe impregnated with a low foaming surfactant system combined with triple enzymes producing low surface tension for rapid cleaning.

Tristel Sporicidal Wipe

A high level disinfectant wipe that incorporates Tristel's patent chlorine dioxide (ClO²). It can kill organisms on a pre- cleaned surface, from which oil and organic matter have been removed, with a contact time of only 30 seconds. This wipe is sporicidal, mycobacterial, virucidal and fungicidal.

Tristel Activator Foam

A foam that will generate chlorine dioxide (ClO²) once applied to the surface of sporicidal wipe.

Tristel Rinse Wipe

This wipe is impregnated with de-ionised water and a low level of antioxidant which will remove and neutralise chemical residues from a surface that have been decontaminated with a Tristel sporicidal wipe.

Wound drape

A sterile drape used to provide protection for the plug socket and the probe handle of the TOE probe inside the rigid storage box.

Cleanascope tray liner

This is a plastic liner and cover that are used to line the rigid storage box where the TOE probe is stored. A green cover denotes CLEAN while a red cover means CONTAMINATED.

Transoesophageal probe sheath / protector cover

This is used to facilitate the sterile gel of lubricant that is required when using a TOE probe. Sheaths are additional physical barriers to infection and probe damage. (British Society of Echocardiography, 2011).

General purpose probe cover

This is a sterile probe cover with sterile ultrasound gel that is used to cover the epicardial echo probe.


6.0 Health and Safety

When carrying out the decontamination process on the TOE and the epicardial echo probes, staff must don proper personal protective equipment. This includes face mask, goggles, plastic apron and double gloves. Studies to date have shown no reactions when Tristel has been tested for eye or skin irritation.

7.0 Procedures

7.1 Decontamination of Transoesophageal and Epicardial Echo Probes


- Standard precautions apply for all patients at all times in all clinical settings. Transmission based precautions apply when there is a known or suspected risk of infection.
- All equipment must be appropriately decontaminated for the purpose of which it is being used and staff must satisfy themselves that standards are maintained at all times in all clinical locations.

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- Intracavity probes are considered semi critical medical devices because of their potential for contact with mucous membranes, e.g., esophagus. Intracavity probes are an identified infection risk. A case of HBV infection has been linked to use of an intracavity probe (*MDA 2012*). Intracavity probes must be cleaned and disinfected to high level disinfection standards prior to use, after use, between patient use, when visibly soiled or contaminated and on a scheduled basis. A disposable TOE and epicardial echo probe cover must be used for each examination (CDC 2008). Sterile gel must be used to lubricate the TOE and Epicardial echo probe prior to insertion.

7.2 Procedure for Cleaning and Disinfection of TOE and Epicardial Echo Probes

- TOE and epicardial echo probes should be cleaned and disinfected before patient use, after patient use, and before storage. The first step in the decontamination process is the thorough cleaning of the surface to remove soil and organic matter prior to high level disinfection.
- Donning in PPE (personal protective equipment), i.e., plastic apron, goggles, face mask and two pairs of disposable gloves.
- Contaminated sheaths should be visibly inspected for damage after use and where damage is identified it should be recorded in the decontamination records and in the patient notes. Sheaths and gels should be disposed of into clinical waste.
- Remove visible dirt or gel from the probe with a paper towel, moving from handle to tip.
- Using a detergent wipe, i.e., a damp J cloth with Brial solution, clean and dry before using a disinfectant product. This should be performed ideally in a separate area i.e. a dirty room, the sluice room.
- Once cleaning with detergent is complete decontamination of the TOE and Epicardial probe should take place in a separate room in the clinical setting if possible.
- Using the Tristel pre clean wipe, thoroughly wipe the entire length of the TOE and the epicardial echo probe (end of control to handle and to tip of probe). Make sure the wipe is covering the entire diameter of the probe.
- In cases of heavy soiling, more than one wipe may have to be used.
- Discard wipes and first gloves into clinical waste.
- The second step in the decontamination process is the high level disinfection. Wearing the second disposable gloves take the Tristel sporicidal wipes, unfold and lay out in the palm of your hand.
- Take the lid off the activator foam bottle. If the bottle is being used for the first time, depress the pump two to four times to prime the foamer. The first output from the foam bottle can be left on the wipe, to be followed by two complete pumps. Ensure the wipe is completely covered in foam. The foam bottle is


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then primed for subsequent pumps. Once the pump bottle is primed, two pump measures of the Tristel activator foam onto the sporicidal wipe is used to decontaminate the TOE probe.

- Crunch the wipe for 15 seconds. Ensure that it is evenly covered with the foam. The presence of “chlorine” like odour confirms that the wipe is ready for use.
- Wipe the surface of the probe until it has been covered with Tristel.
- Once the entire surface of the probe has been covered with Tristel wipe with activator foam wait for 30 seconds.
- Discard the wipe into clinical waste.
- Still wearing the gloves take the Tristel rinse wipe and thoroughly wipe the entire length of the probe ensuring all traces of foam is removed.
- Discard the rinse wipe into clinical waste.
- The TOE and the Epicardial echo probe is now decontaminated and ready for use.
- The TOE probe is then stored in a clean rigid storage box which has been lined with a cleanascope tray liner. The rigid storage box is kept on a storage box trolley.
- The epicardial echo probes are stored on the echo trolley. These probes hang on the side of the echo trolley.
- Two sterile wound drapes are used wrapping one around the probe handle and one around the plug socket to provide protection inside the rigid storage box.
- The rigid storage box for the TOE probe is cleaned after each patient use. This cleaning process, involves manually washing the rigid storage box with warm water and Brial detergent. Then left to air dry. Once the storage box is dry, wipe with an alcohol wipe.
- Post decontamination, the TOE probe can be stored ready for use in a rigid storage box using a green cleanascope tray liner for 24hours. (The British Society of Echocardiography, October 2011). Best Practice is to decontaminate the TOE probe before use.

8.0 Traceability and Audit

- All three Tristel wipes is incorporated into Tristel traceability system. Recording the Lot number and expiry date on all wipes used.
- The Tristel traceability book is to be completed on each decontamination process performed on the TOE and the epicardial echo probes.

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- Each TOE probe, i.e., the adult and the paediatric TOE probe has a separate traceability book. This provides better quality and accuracy for documentation of the decontamination process.
- The epicardial echo probes have a separate traceability book.
- The Information recorded in the traceability books for the TOE and Epicardial probes is also reflected in the patient notes and this links the decontamination process to the patient on whom the devices have been used.
- The traceability system acts as an audit tool for the decontamination process and the accompanying documentation, which is a valuable reference for the future.

9.0 Training and Implementation Plan

All relevant staff working in the Operating Theatre Department will be provided with regular education, training and demonstration into the cleaning and decontamination process of the TOE and Epicardial echo probes. The content of the programme is reviewed as required by local policy. Details of all training sessions and training requirements are recorded for staff future developments.

10.0 References

Tristel Solutions Limited, Lynx Business Park, Fordham Road, Snailwell, Cambridgeshire
 CB8 7NY. Tele +44(0)168 721500 Fax +44(0)1638 721911.
 Email: mail@tristel.com www.tristel.com

MHRA Medical Device Alert MDA/2012/037 (June 2012)

Tristel Wipe System user guide

CDC Disinfection Guidelines 2008 www.cdc.gov/hicpac/disinfection Sterilization/3
 The British Society of Echocardiography (October 2011)

Guidelines for Performing a Comprehensive Epicardial Echocardiography Examination: Recommendations of the American Society of the American Society of Cardiovascular Anesthesiologists. Scott et al (April 2007)

Epicardial Echocardiography: diagnostic utility for evaluating aortic valve disease during coronary surgery. J Clin Anesth, Frenk VE, Sherman SK, Eltzchig HK. (June 2003).

Health Service Executive Guidance for Decontamination of Semi-critical Ultrasound Probes; invasive and non-invasive November 2016

APPENDIX 1 - Safety Data Sheet - Tristel Rinse Wipe



SAFETY DATA SHEET
TRISTEL RINSE WIPE

Page: 1
Compilation date: 28/06/2012
Revision date: 10/01/2013
Revision No: 2

Section 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product Identifier

Product name: TRISTEL RINSE WIPE

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of substance / mixture: Rinse wipe for use in Tristel Wipe System. For professional use only.

1.3. Details of the supplier of the safety data sheet

Company name: Tristel Solutions Limited
Lynx Business Park
Fordham Road
Newmarket
Cambridgeshire
CB8 7NY
United Kingdom
Tel: +44 (0) 1638 721 500
Fax: +44 (0) 1638 721 911
Email: healthandsafety@tristel.com

1.4. Emergency telephone number

Emergency tel: +44 (0) 1638 721 500
(office hours only)

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CHIP: This product has no classification under CHIP.

2.2. Label elements

Label elements: This product has no label elements.

2.3. Other hazards

PBT: This product is not identified as a PBT substance.

Section 3: Composition/information on ingredients

3.2. Mixtures

Section 4: First aid measures

[cont...]

SAFETY DATA SHEET
TRISTEL RINSE WIPE

4.1. Description of first aid measures

Skin contact: Wash immediately with plenty of soap and water.
Eye contact: Bathe the eye with running water for 15 minutes.
Ingestion: Wash out mouth with water.

First aid

4.2. Most important symptoms and effects, both acute and delayed

Skin contact: There may be irritation and redness at the site of contact.
Eye contact: There may be irritation and redness.
Ingestion: There may be soreness and redness of the mouth and throat.

Symptoms

4.3. Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: Not applicable.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

5.2. Special hazards arising from the substance or mixture

5.3. Advice for fire-fighters

Advice for fire-fighters: Wear protective clothing to prevent contact with skin and eyes.

PPE

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Do not attempt to take action without suitable protective clothing - see section 8 of SDS.

6.2. Environmental precautions

6.3. Methods and material for containment and cleaning up

6.4. Reference to other sections

Reference to other sections: Refer to section 8 of SDS.

Section 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements: Avoid direct contact with the substance.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in cool, well ventilated area.

Storage

7.3. Specific end use(s)

Specific end use(s): Rinse wipe for use in Tristel Wipe System. For professional use only.

[cont...]

SAFETY DATA SHEET
TRISTEL RINSE WIPE

Section 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limits: No data available.

8.1. DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls

Hand protection: Protective gloves.

Eye protection: Safety glasses. Ensure eye bath is to hand.

Skin protection: Protective clothing.

PPE

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

State: Impregnated Wipe

9.2. Other information

Other information: No data available.

Section 10: Stability and reactivity

10.1. Reactivity

Reactivity: Stable under recommended transport or storage conditions.

10.2. Chemical stability

Chemical stability: Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.
Decomposition may occur on exposure to conditions or materials listed below.

10.4. Conditions to avoid

Conditions to avoid: Heat.

10.5. Incompatible materials

Materials to avoid: Strong oxidising agents. Strong acids.

10.6. Hazardous decomposition products

Section 11: Toxicological information

11.1. Information on toxicological effects

Toxicity values: No data available.

Symptoms / routes of exposure

Skin contact: There may be irritation and redness at the site of contact.

[cont...]

SAFETY DATA SHEET
TRISTEL RINSE WIPE

Eye contact: There may be irritation and redness.

Ingestion: There may be soreness and redness of the mouth and throat.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available.

12.2. Persistence and degradability

Persistence and degradability: No data available.

12.3. Bioaccumulative potential

Bioaccumulative potential: No data available.

12.4. Mobility in soil

Mobility: No data available.

12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT substance.

12.6. Other adverse effects

Other adverse effects: No data available.

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal operations: Transfer to a suitable container and arrange for collection by specialised disposal company.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Handwritten note: 7m
o Disposal

Section 14: Transport information

Transport class: This product does not require a classification for transport.

Section 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.2. Chemical Safety Assessment

Section 16: Other information

Other information

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

* indicates text in the SDS which has changed since the last revision.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.

APPENDIX 2 – Safety Data Sheet – Tristel Sporicidal Wipe



SAFETY DATA SHEET
TRISTEL SPORICIDAL WIPE

Page: 1
Compilation date: 28/06/2012
Revision date: 10/01/2013
Revision No: 2

Section 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: TRISTEL SPORICIDAL WIPE

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of substance / mixture: Sporicidal wipe for use in Tristel Wipe System. For professional use only.

1.3. Details of the supplier of the safety data sheet

Company name: Tristel Solutions Limited
Lynx Business Park
Fordham Road
Newmarket
Cambridgeshire
CB8 7NY
United Kingdom

Tel: +44 (0) 1638 721 500

Fax: +44 (0) 1638 721 911

Email: healthandsafety@tristel.com

1.4. Emergency telephone number

Emergency tel: +44 (0) 1638 721 500
(office hours only)

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CHIP: This product has no classification under CHIP.

2.2. Label elements

Label elements: This product has no label elements.

2.3. Other hazards

PBT: This product is not identified as a PBT substance.

Section 3: Composition/information on ingredients

3.2. Mixtures

Section 4: First aid measures

[cont...]

SAFETY DATA SHEET
TRISTEL SPORICIDAL WIPE

Page: 2

4.1. Description of first aid measures

- * **Skin contact:** Wash immediately with plenty of soap and water.
- Eye contact:** Bathe the eye with running water for 15 minutes.
- Ingestion:** Wash out mouth with water.

*
FIRST AID
Measures

4.2. Most important symptoms and effects, both acute and delayed

- ✓ **Skin contact:** There may be irritation and redness at the site of contact.
- Eye contact:** There may be irritation and redness. The eyes may water profusely.
- Ingestion:** There may be soreness and redness of the mouth and throat.

*

4.3. Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: Not applicable.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

5.2. Special hazards arising from the substance or mixture

5.3. Advice for fire-fighters

Advice for fire-fighters: Wear protective clothing to prevent contact with skin and eyes.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Do not attempt to take action without suitable protective clothing - see section 8 of SDS.

6.2. Environmental precautions

6.3. Methods and material for containment and cleaning up

6.4. Reference to other sections

Reference to other sections: Refer to section 8 of SDS.

Section 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements: Avoid direct contact with the substance.

PPE

7.2. Conditions for safe storage, including any incompatibilities

✓ **Storage conditions:** Store in cool, well ventilated area.

✓

Storage

7.3. Specific end use(s)

Specific end use(s): Sporidical wipe for use in Tristel Wipe System. For professional use only.

[cont...]

SAFETY DATA SHEET
TRISTEL SPORICIDAL WIPE

Section 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limits: No data available.

8.1. DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls

Engineering measures: Ensure there is sufficient ventilation of the area.

Hand protection: Protective gloves.

Eye protection: Safety glasses.

Skin protection: Protective clothing.

PPE

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

State: Impregnated Wipe

9.2. Other information

Other information: No data available.

Section 10: Stability and reactivity

10.1. Reactivity

Reactivity: Stable under recommended transport or storage conditions.

10.2. Chemical stability

Chemical stability: Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.
Decomposition may occur on exposure to conditions or materials listed below.

10.4. Conditions to avoid

Conditions to avoid: Heat.

10.5. Incompatible materials

Materials to avoid: Strong oxidising agents. Strong acids.

10.6. Hazardous decomposition products

Section 11: Toxicological information

11.1. Information on toxicological effects

Toxicity values: No data available.

[cont...]

SAFETY DATA SHEET
TRISTEL SPORICIDAL WIPE

Page: 4

Symptoms / routes of exposure

Skin contact: There may be irritation and redness at the site of contact.
Eye contact: There may be irritation and redness. The eyes may water profusely.
Ingestion: There may be soreness and redness of the mouth and throat.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available.

12.2. Persistence and degradability

Persistence and degradability: No data available.

12.3. Bioaccumulative potential

Bioaccumulative potential: No data available.

12.4. Mobility in soil

Mobility: No data available.

12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT substance.

12.6. Other adverse effects

Other adverse effects: No data available.

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal operations: Transfer to a suitable container and arrange for collection by specialised disposal company.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Disposal

Section 14: Transport information

Transport class: This product does not require a classification for transport.

Section 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.2. Chemical Safety Assessment


Section 16: Other information

Other information

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

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[cont...]


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[final page]

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APPENDIX 3 – Safety Data Sheet – Tristel Sporicidal Wipes Activator Foam Pump Solution



SAFETY DATA SHEET

TRISTEL SPORICIDAL WIPES ACTIVATOR FOAM PUMP SOLUTION

Page: 1

Compilation date: 23/03/2012

Revision date: 12/09/2013

Revision No: 4

Section 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product Identifier

Product name: TRISTEL SPORICIDAL WIPES ACTIVATOR FOAM PUMP SOLUTION

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of substance / mixture: To be used in conjunction with Tristel Sporicidal Wipe. For professional use only.

1.3. Details of the supplier of the safety data sheet

Company name: Tristel Solutions Limited
Lynx Business Park
Fordham Road
Newmarket
Cambridgeshire
CB8 7NY
United Kingdom
Tel: +44 (0) 1638 721 500
Fax: +44 (0) 1638 721 911
Email: healthandsafety@tristel.com

1.4. Emergency telephone number

Emergency tel: +44 (0) 1638 721 500
(office hours only)

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CHIP: -: R32

Most important adverse effects: Contact with acids liberates very toxic gas.

2.2. Label elements

Label elements under CHIP:

Risk phrases: R32: Contact with acids liberates very toxic gas.

2.3. Other hazards

PBT: This product is not identified as a PBT substance.

Section 3: Composition/information on ingredients

3.2. Mixtures

[cont...]

SAFETY DATA SHEET

TRISTEL SPORICIDAL WIPES ACTIVATOR FOAM PUMP SOLUTION

Hazardous ingredients:

SODIUM CHLORITE 100%

EINECS	CAS	CHIP Classification	CLP Classification	Percent
231-836-6	7758-19-2	O: R8; Xn: R22; T: R24; -: R32; C: R34; Xi: R41; Xn: R48/22; N: R50	Eye Dam. 1: H318; Ox. Sol. 2: H272; Acute Tox. 4: H302; Acute Tox. 3: H311; Skin Corr. 1B: H314; Aquatic Acute 1: H400; STOT SE 2: H371; -: EUH032; STOT RE 2: H373	<1%

Section 4: First aid measures

4.1. Description of first aid measures

- Skin contact:** Wash immediately with plenty of soap and water.
- Eye contact:** Bathe the eye with running water for 15 minutes.
- Ingestion:** Wash out mouth with water.
- Inhalation:** Move to fresh air in case of accidental inhalation of vapours.

4.2. Most important symptoms and effects, both acute and delayed

- Skin contact:** There may be mild irritation at the site of contact.
- Eye contact:** There may be irritation and redness.
- Ingestion:** There may be irritation of the throat.
- Inhalation:** There may be irritation of the throat with a feeling of tightness in the chest.

4.3. Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: Not applicable.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

5.2. Special hazards arising from the substance or mixture

Exposure hazards: In combustion emits toxic fumes.

5.3. Advice for fire-fighters

Advice for fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Refer to section 8 of SDS for personal protection details. Turn leaking containers leak-side up to prevent the escape of liquid.

[cont...]

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6.2. Environmental precautions

Environmental precautions: Do not discharge into drains or rivers. Contain the spillage using bunding.

6.3. Methods and material for containment and cleaning up

?? Spillage
Clean-up procedures: Absorb into dry earth or sand. Transfer to a closable, labelled salvage container for disposal by an appropriate method.

6.4. Reference to other sections

Reference to other sections: Refer to section 8 of SDS.

Section 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements: Ensure there is sufficient ventilation of the area.

7.2. Conditions for safe storage, including any incompatibilities

X **Storage conditions:** Store in cool, well ventilated area. Keep container tightly closed. *X Storage*

7.3. Specific end use(s)

Specific end use(s): No data available.

Section 8: Exposure controls/personal protection

8.1. Control parameters

Hazardous ingredients:

SODIUM CHLORITE 100%

Workplace exposure limits:

Respirable dust

State	8 hour TWA		15 min. STEL	
	8 hour TWA	15 min. STEL	8 hour TWA	15 min. STEL
EU	-	0.41mg/m3	-	-

8.1. DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls

Engineering measures: Ensure there is sufficient ventilation of the area.

Respiratory protection: Respiratory protection not required.

Hand protection: Protective gloves.

Eye protection: Safety glasses. Ensure eye bath is to hand.

Skin protection: Protective clothing.

wearing PPE

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

? **State:** Liquid

Colour: Colourless

[cont...]

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Relative density: 1.000 - 1.010

pH: 10 - 11.5

9.2. Other information

Other information: No data available.

Section 10: Stability and reactivity

10.1. Reactivity

Reactivity: Stable under recommended transport or storage conditions.

10.2. Chemical stability

Chemical stability: Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.
Decomposition may occur on exposure to conditions or materials listed below.

10.4. Conditions to avoid

Conditions to avoid: Heat.

10.5. Incompatible materials

Materials to avoid: Strong oxidising agents. Strong acids.

10.6. Hazardous decomposition products

Haz. decomp. products: In combustion emits toxic fumes.

Section 11: Toxicological information

11.1. Information on toxicological effects

Toxicity values: No data available.

Symptoms / routes of exposure

Skin contact: There may be mild irritation at the site of contact.

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat.

Inhalation: There may be irritation of the throat with a feeling of tightness in the chest.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available.

12.2. Persistence and degradability

Persistence and degradability: Biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential: No bioaccumulation potential.

[cont...]

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12.4. Mobility in soil

Mobility: Readily absorbed into soil.

12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT substance.

12.6. Other adverse effects

Other adverse effects: Negligible ecotoxicity.

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal operations: Transfer to a suitable container and arrange for collection by specialised disposal company.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Section 14: Transport information

Transport class: This product does not require a classification for transport.

Section 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.2. Chemical Safety Assessment

Chemical safety assessment: A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

Section 16: Other information


Other information

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

* indicates text in the SDS which has changed since the last revision.

- Phrases used in s.2 and 3:**
- EUH032: Contact with acids liberates very toxic gas.
 - H272: May intensify fire; oxidiser.
 - H302: Harmful if swallowed.
 - H311: Toxic in contact with skin.
 - H314: Causes severe skin burns and eye damage.
 - H318: Causes serious eye damage.
 - H373: May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
 - H400: Very toxic to aquatic life.
 - R8: Contact with combustible material may cause fire.

[cont...]

Our Lady's Children's Hospital, Crumlin /Operating Theatre Department		
Document Name: Use and Decontamination of Transoesophageal and Epicardial Echo Probes in the Operating Theatre Department		
Reference Number: UDTEEPOTD-03-2017-MCG-V2	Version Number: V2	
Date of Issue: March 2017	Page 23 of 24	

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R22: Harmful if swallowed.

R24: Toxic in contact with skin.

R32: Contact with acids liberates very toxic gas.

R34: Causes burns.

R41: Risk of serious damage to eyes.

R48/22: Harmful; danger of serious damage to health by prolonged exposure if swallowed.

R50: Very toxic to aquatic organisms.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.

APPENDIX 4 – Philips Approval for Use Statement: Tristel Sporicidal Wipes and Tristel Fuse for Instruments



August 20, 2012

Ref: Approval for Use Statement: Tristel Sporicidal Wipes and Tristel Fuse for Instruments.

Based on component level and finished device testing it has been determined that Tristel Solutions Limited products: Tristel Sporicidal Wipes and Tristel Fuse For Instruments is a method of decontamination that is compatible with the Philips TEE/TOE probes indicated in the table below.

(Note: Tristel Fuse for Instruments is used with the Stella semi-automated decontamination device)

Transducer Name	Type	Comments	Approved
S7-3t	Mini		Yes
S8-3t	Mini		Yes
T6207	Mini		Yes
T6210	Adult	Omni II	Yes
S6-2mpt	Adult	21478A	Yes
S7-2 Omni	Adult	21778A	Yes
S7-2t	Adult	S7-2 Omni	Yes
X7-2t	Adult		Yes
T6H	Adult	21378A OMNI III	Yes

This approval is based on both component level and finished device testing. Since it is impossible to predict with absolute certainty that these laboratory conditions mimic all field use conditions, approval for use can be withdrawn should field reliability of these devices become compromised.

Reference Philips Test Report

- PDM Memo 221759 Tristel Qualification - TEE Probes.

NOTE: This approval for use is limited to those customers that specifically request permission to use this product. Updates to the IFU manuals and the web site will occur after sufficient historical field data exist to confirm compatibility in actual use settings.

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