



Safety Notice 008/16

20th September 2016

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Associate Director, Private Health Care Unit, MOH
- Chief Health Officer, MOH
- HealthShare NSW Product Manager
- HAI Expert Advisory Committee, CEC

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- ICU, Renal units, Haematology units, transplant units, Aged Care units
- Infection Prevention and Control Unit staff
- Directors of Nursing and Midwifery
- Clinical Product Managers

Expert Reference Group

- Content reviewed by:
- CEC Infection Control Clinical Adviser
 - HealthShare
 - Office of the Chief Health Officer

Clinical Excellence Commission

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<http://internal.health.nsw.gov.au/quality/sabs/>

Review date

September 2017

COMFORT IMPREGNATED CLOTH TOPICAL SKIN PRODUCTS: POTENTIAL FOR BACTERIAL CONTAMINATION

Background

On 5th September, 2016 the Therapeutic Goods Administration (TGA) issued an urgent recall of Sage Comfort impregnated cloth topical skin products (impregnated with barrier creams and/or antiseptic agents and used to protect and/or clean areas of skin) due to potential for bacterial contamination with *Burkholderia cepacia*.

The recall was initiated due to product contamination of a few lots of Comfort Shield Barrier Cream Cloths with the bacteria, *Burkholderia cepacia*, that were manufactured on two production lines. Although the contamination has not been identified in any other products, all products manufactured on the same production lines in the relevant period have also been recalled.

Applying a product contaminated with *Burkholderia cepacia* to the skin may cause serious infections in immunocompromised patients.

Sage Comfort impregnated cloth topical skin products are used in both acute and community clinical settings as a chlorhexidine based skin wash. Alternative chlorhexidine products may be used as a suitable alternative.

Products involved

- Comfort Shield Barrier Cream Cloths
- Comfort Shield Perineal Washcloths
- Comfort Personal Cleansing Antiseptic Body Cleansing Washcloths
- Comfort Personal Cleansing Essential Bath Cleansing Washcloths
- Comfort Personal Cleansing Impreva Bath Cleansing Washcloths

Further information, including **product batch numbers**, can be obtained from <https://www.tga.gov.au/alert/comfort-impregnated-cloth-topical-skin-products>

Suggested actions by Local Health Districts/Networks

1. Identify clinical units using this product.
2. Forward this Safety Notice to appropriate areas for action.
3. Develop a local plan to quarantine these products, and manage supply shortage including identifying alternate products for use.
4. Consult your infectious diseases unit and infection prevention and control unit for further advice.
5. Notify any adverse events related to use of these products in the NSW Incident Management system.