



FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY  
PRESS RELEASE

30 December 2010

**HSA ALERTS PUBLIC OF THE VOLUNTARY RECALL OF “CARE WIPES”,  
“TRIHEXID CHLORHEXIDINE 0.2% MOUTH RINSE” AND “PEARLIE  
WHITE FLUORINZE FLUORIDE MOUTH RINSE”**

The Health Sciences Authority (HSA) is alerting the public on the voluntary consumer level recall by the companies distributing the following products:

- “Care Wipes” by Tai Sun Paper Products Pte Ltd (Singapore)
- “Trihexid Chlorhexidine 0.2% Mouth Rinse” by Trident Pharm Pte Ltd
- “Pearlie White Fluorinze Fluoride Mouth Rinse” by Corlison Pte Ltd

2 Certain batches of these products were found to be contaminated with the bacteria, *Burkholderia cepacia* (*B. cepacia*).

3 “Care Wipes” is a disposable skin cleansing wipe. “Trihexid Chlorhexidine 0.2% Mouth Rinse” is labelled for use in the prevention of bad breath, tooth and gum diseases, reduction of plaque build-up, mouth ulcers and oral care following surgery. “Pearlie White Fluorinze Fluoride Mouth Rinse” is labelled to help kill bacteria that cause bad breath, plaque and gum problems, relieve tooth sensitivity, prevent tooth decay, strengthen tooth enamel and freshen breath.

4 Says Ms Chan Cheng Leng, Division Director of Vigilance “Following the detection of contamination of Oral Guard Mouthwash last month, HSA stepped up our routine surveillance and testing of health products as a precautionary measure to ensure that these products meet the required standards of quality. A risk-based approach towards product sampling was taken, which took into consideration the products most likely to be contaminated by *B. cepacia*. The products tested include those used in hospitals and the more commonly used mass-market brands of consumer health products. HSA will also continue to keep members of the public informed of any significant safety findings arising from its surveillance and product testing.”

5 *B. cepacia* is a bacterium that can be found in water, soil and other moist environmental sources. *B. cepacia* poses little medical risk to healthy people. However, people who have certain health problems like weakened immune systems or chronic lung diseases may be more susceptible to infections with *B. cepacia*. There have been reported cases of *B. cepacia* detected in products such as mouth rinses and cleansing wipes in other parts of the world.

6 Due to the potential risk of infections associated with *B. cepacia* in susceptible individuals, a voluntary consumer level recall of all batches of “Care Wipes”, “Trihexid Chlorhexidine 0.2% Mouth Rinse” and “Pearlie White Fluorinze Fluoride Mouth Rinse” has been initiated as a precautionary measure.

### HSA’s actions

7 HSA is currently overseeing the voluntary recall of the affected products and working with the companies to identify the root cause of *B. cepacia* contamination in the products. Meanwhile, HSA will continue to monitor the situation closely and continue with its tests. Members of the public will be informed of any significant safety findings arising from its surveillance and product testing.

### Consumer advisory

8 Consumers should stop the use of “Care Wipes”, “Trihexid Chlorhexidine 0.2% Mouth Rinse” and “Pearlie White Fluorinze Fluoride Mouth Rinse”. Those who have already used the products should not be unduly concerned as *B. cepacia* poses little medical risk to healthy people. Those who have health concerns should contact their doctors.

9 Consumers who have queries relating to the recall of the affected products may wish to contact the respective companies as follows:

Affected product	Distributor	Contact
“Care Wipes”	Tai Sun Paper Products Pte Ltd (Singapore)	6442 0212
“Trihexid Chlorhexidine 0.2% Mouth Rinse”	Trident Pharm Pte Ltd	6288 7723
“Pearlie White Fluorinze Fluoride Mouth Rinse”	Corlison Pte Ltd	6288 2277 <a href="mailto:service@corlison.com">service@corlison.com</a>

## HEALTH SCIENCES AUTHORITY 30 DECEMBER 2010

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### ▪ About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) is a multidisciplinary agency that applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services, Applied Sciences, to protect and advance national health and safety. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. It operates the national blood bank, Bloodbank@HSA, securing the nation’s blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit [www.hsa.gov.sg](http://www.hsa.gov.sg).

### ▪ About HSA’s Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework. It ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards.

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FLUORINZE FLUORIDE MOUTH RINSE”**

**Care Wipes**



**Trihexid Chlorhexidine 0.2%  
Mouth Rinse**



**Pearlie White Fluorinze  
Fluoride Mouth Rinse**



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**FREQUENTLY ASKED QUESTIONS**

**About *Burkholderia cepacia* (*B. cepacia*) Contamination in Health Products**

**1. Is this the first time a health product was found contaminated in Singapore?**

The first incident of a health product found to be contaminated by *Burkholderia cepacia* (*B. cepacia*) was in November 2010. The affected product was 'Oral Guard Antiseptic-Antiplaque Mouthwash'. Please refer to the following weblink on the Press Release on 'Oral Guard Antiseptic-Antiplaque Mouthwash':

[http://www.hsa.gov.sg/publish/hsaportal/en/news\\_events/press\\_releases/Latest/hsa\\_alert\\_s\\_public1.html](http://www.hsa.gov.sg/publish/hsaportal/en/news_events/press_releases/Latest/hsa_alert_s_public1.html)

**2. Where are 'Trihexid Chlorhexidine Mouth Rinse', 'Pearlie White Fluorinze Fluoride Mouth Rinse' and 'Care Wipes' sold/distributed?**

'Trihexid Chlorhexidine Mouth Rinse' are distributed to dental clinics and a limited number of healthcare institutions; 'Care Wipes' are distributed to a limited number of hospitals, nursing homes and selected retail pharmacies in Singapore. 'Pearlie White Fluorinze Fluoride Mouth Rinse' is available through retail outlets such as Guardian and Watson.

**3. Does the bacterial contamination affect all products or only specific batches?**

The bacterial contamination was tested to be present only in specific batches of 'Trihexid Chlorhexidine Mouth Rinse', 'Pearlie White Fluorinze Fluoride Mouth Rinse' and 'Care Wipes'. However, a consumer level recall of all batches was initiated as a precautionary measure even though the health risk to the healthy individual is remote as the contaminated product may pose a potential health risk to susceptible individuals such as those with certain health problems like weakened immune systems, cystic fibrosis or chronic lung diseases.

**4. Did HSA test other brands of mouth washes or wipes available in the market?**

There have been reports from overseas of *B. cepacia* contamination of certain types of products such as mouthwashes.

HSA has taken a risk-based approach towards product testing, taking into consideration the health products most likely to be contaminated by *B. cepacia*. The range of products tested includes those used in hospitals and the more commonly used mass-market brands of consumer health products. HSA will continue to monitor the situation closely and continue with its testing. Members of the public will be informed of any significant safety findings arising from our surveillance and product testing.

To date, apart from these four products tested to be contaminated with *B. cepacia* (namely 'Oral Guard Antiseptic-Antiplaque Mouthwash', 'Trihexid Chlorhexidine 0.2%

Mouth Rinse', 'Pearlie White Fluorize Fluoride Mouth Rinse' and 'Care Wipes'), other tested products have passed HSA's product quality requirements.

### **About *Burkholderia cepacia* (*B. cepacia*)**

#### **5. What is *Burkholderia cepacia*?**

*B. cepacia* is the name for a group of gram-negative bacteria that can be found in water, soil and other moist environmental sources.

#### **6. How is the bacteria transmitted? Who is at risk of acquiring the bacteria? Is it life threatening?**

As *B. cepacia* is present in our environment, it can be passed through contact with contaminated surfaces or products, person-to-person contact. However, *B. cepacia* poses little medical risk to healthy people. There are usually no symptoms as the bacteria do not usually cause clinical infection. People who have certain health problems like weakened immune systems, cystic fibrosis or chronic lung diseases may be more susceptible to infections with *B. cepacia*.

#### **7. What happens to people who have acquired the bacterial infection?**

In the majority of people, there will be no symptoms as the bacteria do not usually cause clinical infections. In certain susceptible people such as those with cystic fibrosis, it may cause respiratory infections.

#### **8. Should a person with weakened immune systems who may have used these contaminated products be concerned?**

Those with weakened immune systems who had used the affected products should stop using them and see a doctor if they are not feeling well.