



**Medical Devices Bureau, Ministry of Health Malaysia**  
**Level 4&5, Block E6, Parcel E, Precinct 1,**  
**Federal Government Administration Centre,**  
**62590 Putrajaya**  
**Tel: 03-8883 2248/2249/2264**  
**Fax: 03-8888 6184**

**Medical Device / Equipment RECALL**

**Date Issued : 24<sup>th</sup> Oktober 2008**

**Ref:MDB/R/2008/014**

<b>IMMEDIATE ACTION</b>	√
<b>ACTION</b>	√
<b>UPDATE</b>	
<b>INFORMATION REQUEST</b>	

*Note: This dissemination of information is based on the Australia's Therapeutic Goods Administration website and Singapore's Health Sciences Authority electronic communication.*

<b>PRODUCT</b>	<b>HOT/COLD PACKS VARIOUS BRANDS</b>
<b>CLASS</b>	n/a
<b>USE</b>	<p>Hot/cold packs are <b><u>low-risk medical devices</u></b> used as an external compress to relieve headache, toothache, aching muscles and strains. The products can be frozen for cold therapy or heated for heat therapy and applied to the area where the pain is.</p> <p>They can also be used as masks for the eyes and face, as well as cold therapy for relief of fever discomfort in children and adults.</p> <p>It should contain a non-toxic substance, propylene glycol, as the anti-freeze ingredient instead of ethylene glycol, which is toxic.</p>
<b>SOURCE OF MEDICAL DEVICE RECALL / ALERT</b>	<ol style="list-style-type: none"> <li><b>Therapeutic Goods Administration (TGA) Australia's Website,</b></li> <li><b>Singapore's Health Sciences authority (HSA) Website and</b></li> <li><b>Letter of communication from OSIM (M) Sdn. Bhd. dated 24<sup>th</sup> October 2008.</b></li> </ol>
<b>ALERTING / RECALLING FIRM</b>	<p><b>Currently, in Malaysia market:-</b></p> <ol style="list-style-type: none"> <li><b>For OSIM brands (OSIM):</b></li> </ol> <p><b>OSIM (M) Sdn. Bhd.</b></p>

	<p><b>2. For TYCO products (brand name:Surgipack)</b></p> <p><b>Tyco Healthcare Medical Supplies Sdn. Bhd.</b></p> <p><b>*for other affected brands, currently no information is available locally.</b></p>
<p><b>REASON</b></p>	<p>According to the information gathered from the source, ten hot/cold packs marketed under three brands sold in Singapore market have been voluntarily recalled by their companies <u><i>after laboratory tests revealed that they contained a toxic anti-freeze ingredient, ethylene glycol.</i></u></p> <p>*Ethylene glycol is harmful or fatal if swallowed, and can cause serious effects if inhaled or absorbed through skin. Ethylene glycol may also cause allergic skin reactions.</p> <p><i>*Users are advised to refer to Attachment for details.</i></p>
<p><b>SCENARIO IN MALAYSIA</b></p>	<p>There is no incident involving injury and illness reported locally from the usage of the hot/cold packs.</p> <p>Based on the laboratory test conducted by the HSA Singapore, some brands as mentioned in the Attachment contain ethylene glycol-which is toxic.</p> <p>OSIM (M) Sdn. Bhd., the owner of the OSIM brand has initiated its voluntary recall for Malaysian market <u><i>while Tyco Healthcare Singapore confirmed – via electronic mail</i></u> that their affected products are not available in our market. <i>*Attached is the letter from OSIM (M) Sdn. Bhd. confirming they have initiated a voluntary recall.</i></p> <p>However, users feedback are always welcome to alert the authority about the existence of any affected products as in the Attachment.</p>
<p><b>ACTION</b></p>	<p><b>There are probabilities that the affected products (for certain brands) might be available in our market.</b></p> <p><b>Users are advised to alert us at <u>www.mdb.gov.my</u> if the affected products are available on our market.</b></p>
<p><b>RECOMMENDATION</b></p>	<p>1. Users of the abovementioned products are advised to contact the distributors/supplier of this device (if available) and <b>inform the Medical Device Bureau,</b></p>

	<p><b>Ministry of Health</b> providing the following information:-</p> <ol style="list-style-type: none"> <li>a. Name of healthcare centre/hospital/clinic</li> <li>b. Contact person and contact number</li> <li>c. Numbers of units available/purchased</li> </ol> <ol style="list-style-type: none"> <li>2. Manufacturers/Distributors/Suppliers of the affected products are advised to initiate a voluntary recall.</li> <li>3. Manufacturers/Distributors/Suppliers of other brands of Hot/Cold Pack to contact Medical Device Bureau.</li> </ol>
<p><b>CONTACT/ENQUIRIES IN MALAYSIA</b></p>	<p><b>1. For OSIM brands,</b></p> <p><b>OSIM (M) Sdn. Bhd.</b>  <b>No. 4, Jalan 13/6, Section 13,</b>  <b>46200 Petaling Jaya,</b>  <b>Selangor Darul Ehsan</b>  <b>Tel:-03-79659812</b>  <b>Fax:-03-79659999</b></p> <p><b>2. For TYCO products, can ask information from:</b></p> <p><b>Tyco Healthcare Medical Supplies Sdn. Bhd.</b>  <b>Suite A-17-1, Menara Atlas, Plaza Pantai</b>  <b>No.5, Jalan 4/83A, Off Jalan Pantai Baru</b>  <b>59200</b>  <b>Kuala Lumpur</b>  <b>Tel:-03-22976000</b>  <b>Fax:-03-22976100</b></p>
<p><b>REFERENCE</b></p>	<p><a href="http://www.atsdr.cdc.gov/MHMI/mmg96.html">http://www.atsdr.cdc.gov/MHMI/mmg96.html</a></p>

## Attachment

### THREE BRANDS OF HOT/COLD PACKS FOUND TO CONTAIN TOXIC SUBSTANCE ; as from Heath Sciences Authority Singapore

#### **LIST OF HOT/COLD PACKS RECALLED**

1. SURGIPACK® Soft Hot/Cold Pack Large and Small



2. Soft R&R Cold/Hot Pack – size M and Size L

# SOFT

R&R

## Cold/Hot Pack

● Microwaveable ● Reusable ● Freezable



With a durable nylon cover, R&R soft Cold/Hot Pack contains gel which remains soft even when frozen, ensuring comfort whether applied hot or cold. Ideal for Headache, Fever, Sport Injuries, Tooth extraction, Aching Muscles, Back Pain, Sinusitis, Menstrual Cramps, Minor Burns.



3. OSIM uBaby Fever Band



4. OSIM Shoulder Pad



5. OSIM uKids Fever Band



6. OSIM Face Mask



7. OSIM Eye Mask



8. OSIM Hot/Cold Compress

