

GAMA Healthcare Ltd.
2 Regal Way
Watford
WD24 4YJ
UK

20th July 2017

Dear Sir/Madam,

The Therapeutic Goods Administration (TGA) recently published a Medical Devices Safety Update (vol. 5, no. 3, May 2017) which contained an article entitled 'Disinfectants and detergents can damage medical equipment plastics'. GAMA Healthcare are aware that this has caused a lot of concern and confusion in the Australian marketplace.

We welcome the publication of the following clarifications to the alert which is now available to view on the TGA website (<https://www.tga.gov.au/publication/medical-devices-safety-update>):

- i. Certain disinfectant wipes and detergents can damage medical devices if the cleaning agent is incompatible with the device's plastic surfaces*.

* The TGA considers cleaning agents that contain levels of benzalkonium chloride below 5-10% are safe to use on medical devices. Disinfectants generally use about 0.5% benzalkonium chloride, which is considered noncorrosive at these levels.

- ii. Detergent wipes used by the hospital to clean the pumps contained the ingredient 'benzalkonium chloride'. This is classed as a quaternary ammonium compound which is a corrosive ingredient and therefore should not be used.**

** Benzalkonium chloride is unsafe at a concentration above 10% and therefore should not be used without being diluted.

- iii. When cleaning medical devices the TGA recommends that health facilities:

- Review all decontamination processes that use a disinfectant wipe or detergent containing quaternary ammonium compounds on a plastic surface ***

*** Particularly if the surface is made of polycarbonate material.

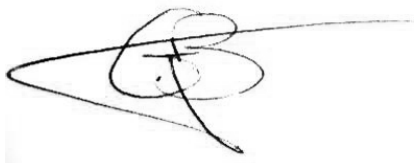
GAMA Healthcare Ltd. would like to confirm to all our customers that Clinell Universal Wipes contain benzalkonium chloride at a concentration of less than 0.5% and therefore per the TGA clarification are considered non-corrosive at this level.

We have also been advised that the wording of the alert specifically referencing detergent wipes has been interpreted to mean neutral detergent wipes. GAMA Healthcare would like to confirm Clinell Detergent wipes do not contain benzalkonium chloride.

We fully support the TGA statement that equipment manufacturers' cleaning recommendations should be followed.

GAMA Healthcare continues to work with equipment manufacturers on material compatibility and welcomes the opportunity to collaborate on any items which require disinfection and are not currently listed on our approved equipment list.

Signed, on behalf of GAMA Healthcare Ltd.,



Dr. Guy Braverman
Managing Director & Co-Founder