

Safety Notice

Medical Devices

Risk of harmful reactions in laboratories using certain chemicals in combination with bleach

Priority 2 – Warning

HPRA Safety Notice: SN2020(05)

Issue Date: 11 June 2020

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Multiple	V44026

ISSUE

The HPRA seeks to raise awareness of the risk posed by the use of some transport media/sample processing reagents (e.g. lysis buffers) in conjunction with bleach (Sodium Hypochlorite). Solutions containing Guanidine Thiocyanate (**GuSCN**), Guanidine Hydrochloride (**GuHCl**) or similar when used in conjunction with bleach can result in the generation of cyanide or chlorine gas respectively.

The FDA has recently issued a [communication](#) to outline these concerns. Through discussions with laboratory experts, the HPRA understands that these chemicals are also used in laboratories in Ireland. To date, the HPRA has not received any reports of adverse incidents relating to this issue.

The HPRA recommends that users exercise caution when using bleach for decontamination purposes. In general, transport media/sample processing reagents containing guanidine thiocyanate or similar chemicals, should not be used with testing platforms that use bleach or in laboratories/workflows that use bleach as part of the waste disposal/decontamination processes.

ACTION OR RECOMMENDATIONS

The HPRA has the following advice:-

1. Maintain awareness of the potential for harmful reactions to occur when using certain chemicals in combination with bleach
2. For laboratories where bleach is used for waste disposal/decontamination processes, familiarise yourself with the composition of the transport media/sample processing reagents and take the necessary safety precautions
3. Discuss this Safety Notice with your Chief Medical Scientist
4. Forward a copy of this Safety Notice, to all relevant personnel within your organisation, or to any organisation/persons to which/whom these devices have been transferred
5. Report any adverse incidents associated with these devices to the manufacturer and to the HPRA

TARGET GROUPS

Chief Medical Scientists
Hospital Managers / CEOs
Laboratory Managers
Health & Safety Officers
Laboratory Staff
Laboratory Technicians

Medical Scientists
Microbiologists
Private laboratory and testing facilities
Purchasing / Supplies Managers
Risk Managers

BACKGROUND

Certain chemicals such as strong acids and transport media/sample processing reagents containing guanidine thiocyanate or guanidine hydrochloride, can react with bleach resulting in the generation of harmful/toxic gases such as chlorine or cyanide gas.

The HPRA understands that these chemicals are commonly used for molecular testing in Ireland.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to the contact details found on the device labelling / instructions for use.

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie