

# Safety Notice

## Medical Devices

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### Paraffin-based skin products

#### Priority 2 – Warning

HPRA Safety Notice: SN2017(29)

Issue Date: 22 August 2017

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Various manufacturers	V32845

#### ISSUE

The HPRA is aware of the potential flammability risk of paraffin-based topical products that may come into contact with dressings, clothing and bedding.

Barrier creams, skin creams and emollients can be absorbed into dressings, clothing and bedding, after which these fabrics can be easily ignited by smoking or with a naked flame.

#### ACTION OR RECOMMENDATIONS

The HPRA advises that users:

- 1 Keep away from sources of fire, including naked flames and lit cigarettes.
- 2 Adequately clean any clothing or bedding which has come into contact with the product.
- 3 Change any clothing, bedding or dressings that become soaked with emollient, in particular, where they cover a large area of the body.
- 4 Please pass this notice on to all those who need to be aware within your organisation or to any organisation / persons, where the potentially affected devices are used.
- 5 Report any adverse events / incidents associated with these devices to the relevant manufacturer and the HPRA.

## TARGET GROUPS

All Hospital Staff	Hospital CEOs
All Nursing Home Staff	Hospital Managers
A&E Departments	Members of the public
Carers	Nursing Managers
Community Pharmacists	Nursing Staff
Day Surgery units	Public and Private Hospitals
Dermatology units	Purchasing Managers
Hospital Pharmacists	Risk Managers

## BACKGROUND

The HPRA is aware of fatalities in the UK related to the use of paraffin-based topical products. Many of these products are placed on the market as medical devices and may be used for the topical treatment of conditions such as eczema and psoriasis.

When patients are being treated with a paraffin-based product that is covered by a dressing or clothing, there is a danger that smoking or using a naked flame could cause dressings or clothing to catch fire. The risk is greater when these preparations are applied to large areas of the body, or when dressings or clothing become soaked with emollient.

Examples of paraffin-based topical products include, but are not limited to:

- Emollients
- Emulsifying ointment
- White soft paraffin
- Liquid paraffin

The HPRA is not aware of any occurrences of fire related to the use of these products in Ireland. Users and healthcare professionals are encouraged to report any adverse incidents to the HPRA.

## MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR 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  
Fax: +353-1-6344033  
E-mail: [devicesafety@hpra.ie](mailto:devicesafety@hpra.ie)  
Website: [www.hpra.ie](http://www.hpra.ie)