

Submitted to **Proposed warning statement regarding a fire hazard on the labels of paraffin-based skin products**

Consultation

1 Should a warning statement about a fire hazard be included on the package labels of paraffin-based skin products

No

Please add your comments:

With correct adherence to directions for use, this warning should not be necessary for safe use of paraffin-based skin products.

2 Would you prefer Option 1 or Option 2 as a warning statement?

Option 2

Please add your comments:

This would depend of what pack sizes the warning statement would be required on. It may be difficult to find enough space for the text in Option 1 on smaller pack sizes.

3 Does Option 1 adequately address the fire hazard risk (ie, Caution: If this product comes into contact with dressings and clothing the fabric can be more easily ignited with a naked flame. You should keep away from fire when using this product)?

Yes

Please add your comments:

'Words to the effect' of this warning would be appropriate.

4 Does Option 2 adequately address the fire hazard risk (ie, Caution: This product may make dressings and clothing more easily ignited with a naked flame)?

Yes

Please provide your comments:

'Words to the effect' of this warning would be appropriate.

5 Should the warning statement only apply to products containing 50% or more of paraffin

Yes

Please provide your comments:

If such warning statement is deemed necessary, it should only apply to products containing 50% or more of paraffin for final use.

In light of incidents in the UK involving the use of paraffin-containing topical products, in particular the cases of Mrs. Pauline Taylor and Mr. Brian Bicat, both patients were in contact with naked flames whilst lighting cigarettes.

MHRA published a reminder for Healthcare professionals to:

- Advise patients not to: smoke; use naked flames (or be near people who are smoking or using naked flames); or go near anything that may cause a fire while emollients are in contact with their medical dressings or clothing;
- Change patient clothing and bedding regularly—preferably daily—because emollients soak into fabric and can become a fire hazard.

It is understood that the use of paraffin-based emollients, although generally safe to use, can become flammable when exposed to an ignition source, such as a naked flame. Emollient products are used to treat dry skin conditions and with regular use can lead to impregnation into clothing, dressings and bed sheets. This buildup of residue can become highly flammable and can act as an accelerant if there is an ignition source used in close proximity.

QV Flare Up Bath Oil (TT50-6525a) contains 65.1% w/w light liquid paraffin. However, this is diluted in water during use, as such does not cause a buildup of residue that is a fire risk.

6 Should the warning statement only apply to packs intended for use in large quantities (eg. pack size of 50g or more)?

Yes

Please add your comments:

If such warning statement is deemed necessary, it should only apply to a larger pack size.

The Proprietary Association of Great Britain (PAGB) issued a statement in 2017 (<https://www.pagb.co.uk/latest-news/pagb-response-bbc-radio-5-investigation-regarding-use-paraffin-based-emollients/>) describing the cautions healthcare professionals should take regarding the use of significant volumes of emollients:

"The current guidance on the use of emollients issued by the MHRA, the British National Formulary and the former National Patient Safety Agency is based on specific fire risk tests conducted by the Health & Safety Executive. The guidance seeks to ensure healthcare workers exercise caution in the specific situation where they are applying significant volumes of emollients to patients that are permitted to smoke or who may be near to a naked flame. Other risks are seen to be far higher, such as ensuring bedding and clothing is washed regularly to remove any build-up of residue."

The PAGB detailed that 'significant volumes' are amounts of 100g or more for a professional care setting and not in the home by people treating common levels of eczema and other dry skin conditions. The reassurance was made to people that the normal use of emollients in the home is considered appropriate and safe provided the products are used in accordance with directions and cautions made on packs.

This would support the inclusion of the proposed warning on larger pack sizes only.

7 Do you have any other comments about a proposed warning statement regarding a fire hazard on the labels of paraffin-based skin products?

Please add your comments:

Many of the paraffin-based topical products that Douglas Pharmaceuticals Ltd. distribute in New Zealand are manufactured by Ego Pharmaceuticals (Ego).

Ego have evaluated the potential risks that can occur with their products, including that of fire. This was in the form of flammability testing to determine the flash point of the product. Flash point testing involves measuring the temperature at which a volatile material vaporises, forming an ignitable mixture. All Ego products containing > 50% w/w paraffin currently tested were found to be non-flammable by the test method used.

It is important to note that QV Flare Up Bath Oil is intended as a 'wash-off' product. The directions for use for QV Flare Up Bath Oil instruct the product to be diluted with water (in the bath) and the skin is patted dry. This is unlikely to result in an accumulation of paraffin onto clothing, dressings or bed sheets.

The preferred target date for implementation would be 18 months from the date of the consultation outcome.

Your details

8 Your details

Name and designation:

[REDACTED]

Company/organisation name (if applicable):

Douglas Pharmaceuticals Limited

Address:

[REDACTED]
[REDACTED]
[REDACTED]

Phone number:

Email address:

[REDACTED]

9 This submission is:

made on behalf of a group or organisation(s)

10 I am, or I represent an organisation, based in:

New Zealand

If you selected other, please specify:

11 I am, or I represent, a:

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