Medicines & Healthcare products Regulatory Agency

NFCC National Fire Chiefs Council

Emollients – risk of severe and fatal burns

Medicines & Healthcare products Regulatory Agency

Executive Agency of the Department of Health and Social Care

- UK regulator for medicines, medical devices and blood products
- Ensures these meet acceptable standards of quality, effectiveness and safety

Key learning objectives

1. What are emollients?
2. What is the risk?
3. Mechanism of the risk
4. Scope of the risk
5. Size and nature of the risk
6. Population at risk and risk factors
7. Options for minimising the risk
8. Advice for healthcare professionals
9. Know where to find resources to support the safe use of emollients

Emollients

- Important and effective moisturising treatments
- Widely used to maintain the skin barrier, restore skin suppleness, prevent dry skin and itching and reduce the number of flare-ups in dry skin conditions (eg, eczema, psoriasis and ichthyosis)
- Available as ointments, creams, lotions, gels, sprays
- Leave on, wash-off, bath and shower products
- Contain paraffin, lanolin, colloidal oatmeal, mineral oils, fruit/nut/seed oils or butters
- Once applied to the skin, may be covered by a bandage
- Some dressings and bandages may come with paraffin already on them (eg, used to promote wound healing, including burns)

Risk of severe and fatal burns

- Emollients can transfer from skin onto clothing, bedding and bandages
- When fabric with dried-on emollient comes into contact with an ignition source, the resulting fire burns more quickly and intensely (hotter), and is harder to extinguish than a clean fabric fire
- The speed of development and intensity of the fire means there are just seconds to react before serious and life-threatening burns are sustained
- The risk increases with:
  - use of greater amounts of emollient
  - more frequent application
  - greater surface area of application

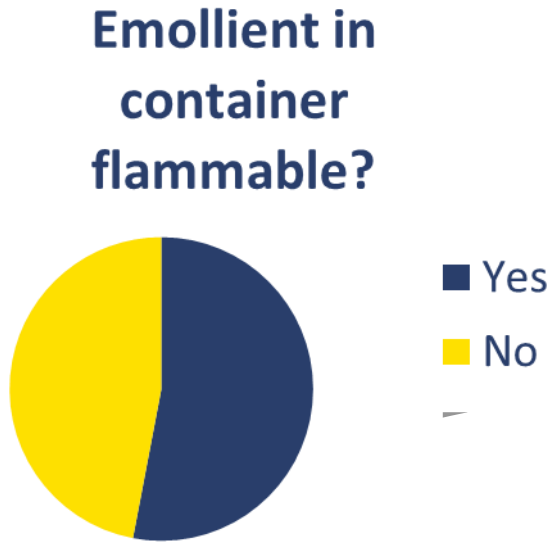
Understanding the mechanism of the risk

- Emollients are not flammable in their raw state or in their container*
- Emollients are not flammable on the skin
- Emollients act as an accelerant, increasing the speed of ignition and intensity of the fire, when fabric with emollient residue dried on it is ignited
- There must be fabric or other wicking material and an ignition source present for the accelerant effect of emollients to occur

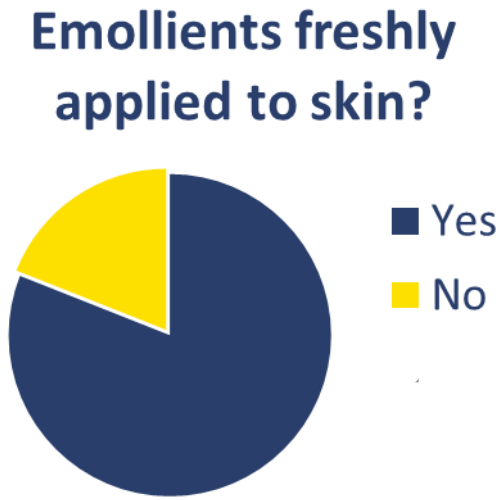
* Some spray emollients come in pressurised containers with flammable aerosol propellants (eg butane, isobutane, propane). These spray products are highly flammable, but it is the aerosol propellant not the emollient which makes them flammable.

Misunderstanding the risk – survey of pharmacists

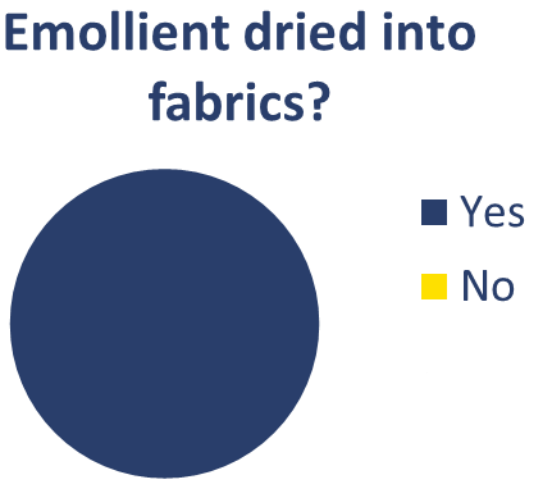
150 pharmacists were asked whether emollients are flammable in 3 different states: in the container; when they are freshly applied to the skin; and when dried into fabrics?



Correct answer: No



Correct answer: No



Correct answer: Yes

Correcting misunderstanding is important as it can lead to difficulties in delivering risk prevention messages and confusion about what the effective risk minimising actions are. eg, Putting the cream away in a cupboard will not mitigate the risk, because the products themselves are not flammable.

Survey conducted by West Yorkshire Fire & Rescue Service

Scope of the risk – which emollients have this risk?

Initially it was thought that there was a risk only with emollients containing >50% paraffins (NPSA Alert, 2007)

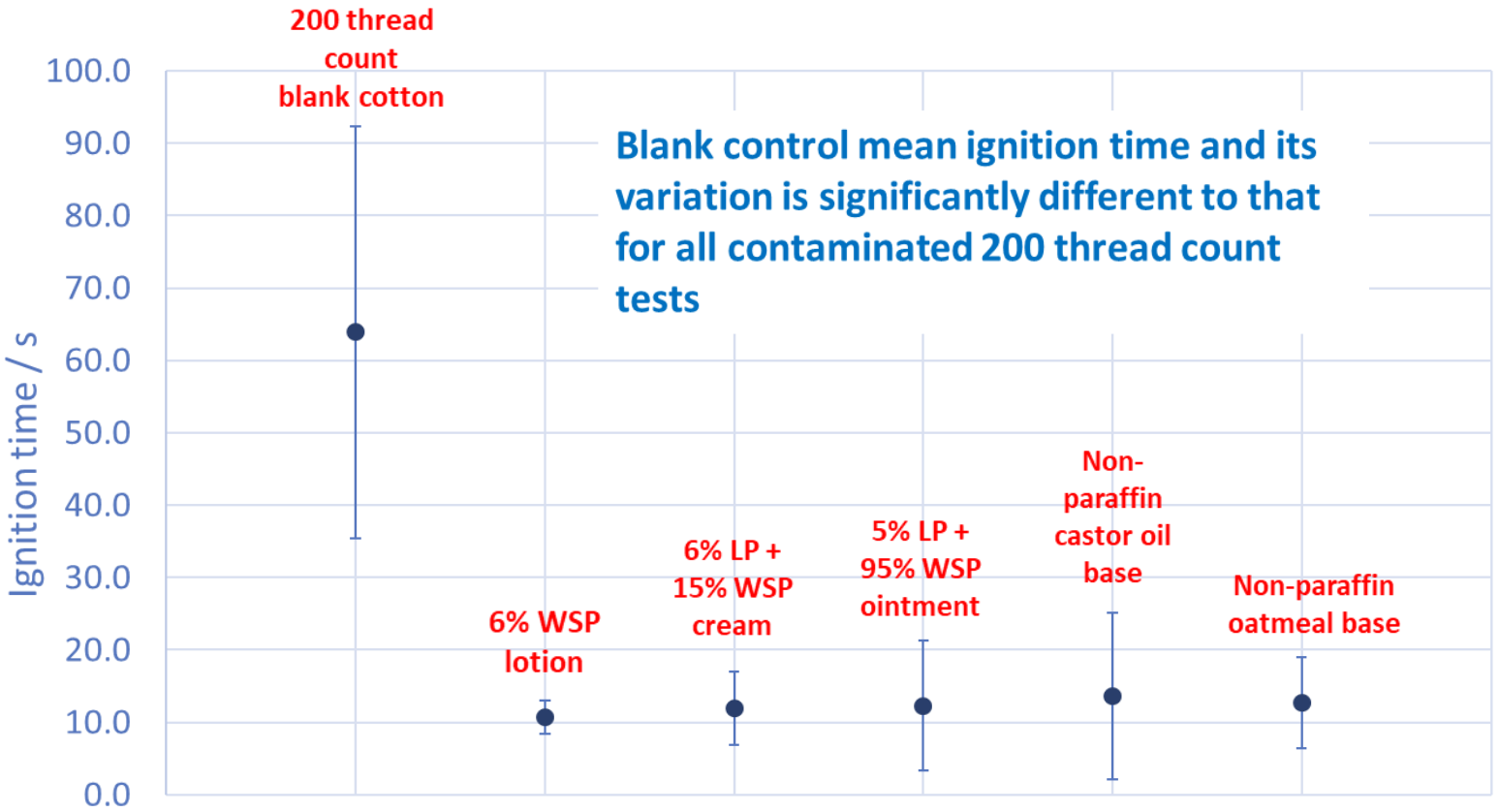
Since 2007

- MHRA received reports of fatal fire incidents suspected to be related to emollients containing <50% paraffins
- Laboratory fire testing conducted by Anglia Ruskin University demonstrated that, when dried on to fabric and an ignition source is introduced:
  - emollients containing as little as 6% paraffin act as an accelerant
  - paraffin-free products act as an accelerant

There is a risk with <u>all</u> emollients, including paraffin-free emollients

Research conducted by Anglia Ruskin University[1]

Time to ignition results on cotton (200 thread count) with skin product (contaminant) left for 24 hours



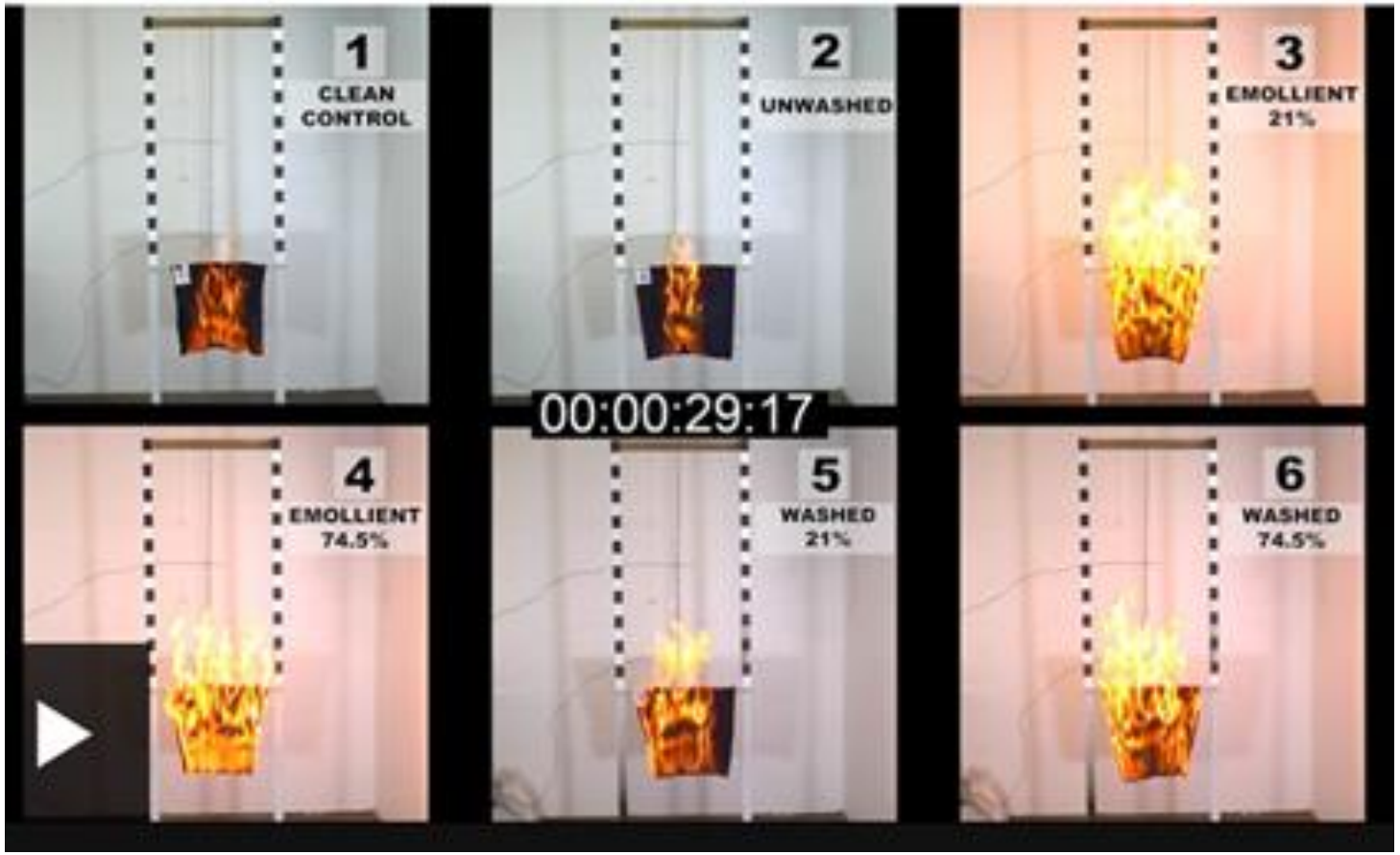
All paraffin base emollients (containing from 6% to 100% paraffins) AND the paraffin-free products (castor oil or oatmeal base) significantly reduced the time to ignition from ~65 seconds to 10-15 seconds

WSP – White soft paraffin; LP – Liquid paraffin

Fire Tests conducted by West Yorkshire Fire & Rescue Service

West Yorkshire Fire & Rescue Service

Making West Yorkshire Safer
www.westyorksfire.gov.uk



The videos are paused 29 seconds after ignition with a naked flame

- Time to ignition and spread of fire are significantly quicker with the emollient contaminated fabric (vs control)
- Washing the fabric had little effect in reducing the accelerant effect of the 21% paraffin emollient (picture 5) or the 74.5% paraffin emollient (picture 6)

Credit: WYFRS. Still images taken from video recordings of WYFRS fire tests conducted as part of investigations into fatalities

Size and nature of the risk (UK data)

- 15 fatalities reported to MHRA by Coroners or via the Yellow Card Scheme (as of July 2020)
- > 50 fatal fire incidents reported by fire and rescue services in England since 2010 in which emollients were known to have been used by the victim or were present at fire premises

  - risk is very rare given extensive use of emollients over many years, but
  - has devastating and fatal consequences
  - likely to be under-recognised and under-reported

Yellow Card Scheme – the UK system for collecting reports of suspected side effects to medicines and adverse incidents (AIs) with medical devices. The scheme is run by MHRA (www.yellowcard.mhra.gov.uk)

Population at risk and risk factors

Amongst the 15 cases reported to MHRA, the following factors were present in most cases:

- Age >60 years
- Smoking = source of naked flame for ignition (eg, lighter, lit match etc)
- Impaired mobility, bedbound

Additional factors (3 cases):

- Use of an airflow mattress or cushion

Real life case study: Pauline Taylor

- 74-years old
- Lived alone in a 2 bedroom ground floor flat, daily visits from carers
- Visited frequently by her daughters
- Fire alarm system linked to a CarePhone facility (monitored 24hr)
- Regular smoker – she didn't want to give up
- Had psoriasis for many years
- Emollient (Zerobase, 11% paraffin) applied daily
- Had recently become increasingly immobile and was bedbound
- Used a dynamic airflow mattress

Photo courtesy of Pauline's family

Real life case study: Brian Bicat

- 82 years old, retired academic
- Well known on the local jazz scene
- Living at home with his wife
- Fully mobile
- Regular smoker

- Skin condition – had used emollients (Hydromol, Diprobase) for 30 years or more
- New treatment for ulcer on lower leg
- Preferred Hydromol ointment and applied 3-4 times a day
- Also washed with Hydromol in the shower
- Used his dressing gown to pat himself dry after shower

Photo courtesy of Brian's family

Brian Bicat – Coroner's Report

Coroner's Regulation 28 Report to Prevent Future Deaths (PFD)

The **MATTER OF CONCERN** is as follows. –

- Paraffin based ointments and emollient creams which contain a low level of paraffin pose a potential fire hazard risk
- Warnings of such risks are not displayed on all product packaging
- Consider more prominent labels and alerts re fire hazard on product containers
- Health care professionals in both hospital and community setting may not be aware of the potential fire hazard poised by emollient creams which contain a low level of paraffin
- To consider fire warning labelling on all emollients including those below 50% content, making clear the mechanisms of the risk
- Health care professionals including pharmacists to verbalize product warnings at the point of prescription, dispensing or point of sale.
- Members of the public are able to purchase such products in retail outlets and online where verbal warnings from healthcare professionals are not given

"..products… which contain a low level of paraffin…pose potential fire risk"

"Healthcare professionals….may not be aware of the potential fire hazard…"

"more prominent labels and alerts…making clear the mechanism of the risk"

https://www.judiciary.uk/wp-content/uploads/2018/10/Brian-Bicat-2018-0277_Redacted.pdf

Options for minimising risk

- Washing may remove some emollient build up on fabric, but even at high temperatures does not completely remove it

- Mitigation primarily about behaviour change
  - Not to smoke, cook or get too close to open fires or other heat sources (eg gas, halogen, or electric bar heater) if there is any chance that clothing, dressings or bedding have emollient residue on them
- Interventions (secondary to behaviour change) eg
  - Smoking cessation advice
  - Supervised smoking, safety lighters and safety ashtrays, e-cigarettes
  - Flame retardant bedding or aprons (may themselves get contaminated with emollients)
- For complex cases, approach the local fire & rescue service for further advice and support

Advice for healthcare professionals (1)

- ✓ Emollients are vital in helping manage dry skin conditions and it is important that people do not stop using them – advise people to continue to use these products as directed
- ✓ Ensure patients and their carers understand the fire risk associated with the build-up of dried emollient residue on clothing and bedding and can take action to minimise the risk

Advice for healthcare professionals (2)

- ✓ When prescribing, recommending, dispensing, selling, or applying an emollient, instruct patients not to smoke, cook or go near any naked flames or heat source (gas, halogen, electric bar or open fire) whilst wearing clothing or dressings that have been in contact with emollients. If the patient cannot do this advise on measures to do so safely (eg, use safety lighters or e-cigarettes; remove long sleeved or loose clothing before cooking; put on a thick uncontaminated shirt, overalls or apron, move chairs further away from the open fire or other heat source)
- ✓ Be aware that washing clothing or bedding at a high temperature may reduce emollient build up but does not totally remove it – it is important to minimise risk in additional other ways (as above)
- ✓ For complex cases contact the local fire and rescue service for advice and support

Expert Advice – UK Commission on Human Medicines*

MHRA reviewed the new data and sought expert advice from the Commission on Human Medicines on the impact of the new information on the benefit-risk balance of emollients and on the need for regulatory action to minimise the risk and protect public health

In December 2018, the CHM advised that:

Overall benefit-risk balance of emollients

- The balance of benefits and risks is positive taking into account the very rare risk, the important therapeutic role and wide use over many years

But, measures to minimise risk and protect public health required

- Product labelling and packaging for all emollients to include a warning
- Stakeholder group to be convened to propose measures to promote education and awareness of the risk, and embed safe emollient use across healthcare practice

* The Commission on Human Medicines (CHM) is MHRA's independent expert advisory committee

Expert Advice – Commission on Human Medicines

Label warning should be applied to

- all emollients (paraffin and paraffin-free)
- some non-emollient topical medicines depending on intended use incl. quantity, frequency, duration and location of application

Active communication also warranted because

- Product information updates alone unlikely to be enough to raise awareness
- Evidence of lack of awareness of risk despite previous alerts for >50% paraffin products
- Evidence of misunderstanding of mechanism of risk (products believed to be flammable in themselves, but are not) – need to be corrected to ensure effective risk minimizing actions are taken

Awareness campaign and resources

- Awareness campaign launched 29 July 2020
- Joint campaign - MHRA, National Fire Chief's Council, fire and rescue services and health charities
- Toolkit of resources available for healthcare professionals and the public to use to support safe use of emollients
- These resources are available to download for free from https://www.gov.uk/guidance/safe-use-of-emollient-skin-creams-to-treat-dry-skin-conditions
  - [60 second film]
  - Poster
  - Information leaflet for patients
  - Sticker
  - Social Media

What else can you do?

1. Share this information with colleagues
2. Use the emollients toolkit and encourage others to do so
3. Report any fire incidents associated with the use of emollients to the Yellow Card Scheme (www.mhra.gov.uk/yellowcard)

References and further reading

1. Hall, S. and Morrissey, J (2019) “The fire hazard associated with fabrics contaminated with skin care products” UK Association of Fire Investigators, 16th annual training conference: A fatal fire investigation master class, Leeds, U.K.
2. Hall, S., Franklin, L., Bull, J., Beard, A., Phillips, G and Morrissey, J. (2019) 'The flammability of textiles when contaminated with paraffin base products' *Fire Safety Journal*, 104, pp. 109-116
3. Hall, S., Morrissey, J. and Blackburn K. (2020) 'The awareness of emollient flammability and current research' *International Fire Professional-The Journal of the Institution of Fire Engineers,* 32, pp. 21-24.
4. Hall, S., Morrissey, J. and Blackburn K. (2019) 'Medical skin creams could be a lethal fire risk when soaked into fabric – here’s what you need to know' *The Conversation*
5. Drug Safety Update volume 12 issue 5: December 2018: 3

Acknowledgements

- With thanks to the families of Pauline Taylor and Brian Bicat for allowing us to share their stories in this presentation
- Thanks also to:
  - ADC Chris Bell, West Yorkshire Fire & Rescue Service
  - Claire Tabert, West Yorkshire Fire & Rescue Service
  - WM Jamie Lister, West Yorkshire Fire & Rescue Service
  - Dr Sarah Hall, De Montfort University (formerly of Anglia Ruskin University)
  - Jo Morrissey, Anglia Ruskin University

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