

Ing No. 386/15 IC



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16 June 2016

Dr. C J L Swann
H.M. Coroner
The Town Hall
Town Hall Square
Leicester
LE1 9BG



Dear Dr. Swann,

Firstly, we want to express our deep sorrow towards the family of Mr Holyoake, who we understand perished tragically.

We have confirmed in our records that no previous adverse events have been reported to RB relating to the flammability of E45. The labelling and usage instructions of our cosmetic products is in full compliance with the Cosmetic Product Regulation, or in case of our medicinal products approved by the Medicines and Healthcare products Regulatory Agency (MHRA).

Despite regularly assessing our products we have taken this tragedy as a reason to conduct an additional safety assessment and reassess the labelling across our entire E45 product portfolio in respect to its potential risk of flammability. As a result of our safety review, we will be submitting an application to the MHRA to update the labelling to include guidance on potential flammability, of the following medicinal product:

- E45 Cream 50g, 125g, 350g, 500g (PL 00063/0404)

and the following cosmetic products:

- E45 Body Lotion Hydrate & Protect 250ml, 400ml
- E45 Body Lotion Intense Recovery 250ml, 400ml
- E45 Body Lotion Nourish & Restore 250ml, 400ml
- E45 Moisturising Lotion 200ml, 500ml
- E45 Intense Recovery Fast Action 24H Spray Moisturiser 200ml
- E45 Junior Moisturising Lotion 200ml

The above products have been identified due to their use, being leave on products (i.e. not being removed after application) with potentially high single dose or high frequency of low dosing containing >5% w/v levels of combined paraffins.



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The below warning will be added to the product labelling:

"If using large quantities, regularly change clothing, bedding or dressings impregnated with the product and keep away from fire as it may pose a fire hazard."

We aim to make these changes according to the following timeline:

- Submission of our variation package to the MHRA in July 2016
- Subject to a favourable approval by the MHRA release products with revised labels in summer 2017
- Cosmetic range of products will follow a similar timing of release

Thank you for raising this issue with us. We will implement this additional safety information to ensure the safe use of E45 for all consumers.

Yours sincerely,

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