

PIF SUMMARY

Dermatitis Treatment Cream

Part Number: WB070

1. Product Registration Information

Is the product intended to be used on children under 3 years old?	No
Does the product contain nanomaterials?	No
Is the product a multi-item kit	No
Is the product available in different shades?	No
Physical Form	Cream/Paste/Gel
What is the product contained in	A typical non-pressurised bottle, jar, sachet or other package
Does the product contain category 1A or 1B CMR substances?	N/a
Category	Skin Products
	Skin Care products
	Body care products

2. Shelf Life

30 months stored and sealed in original packaging in cool and dry environment.

Retail labels - PAO symbol can be applied as stability has been validated for 12 weeks

6 months - Open containers (product can be directly interacted with)

12 months - Sealed containers (product cannot be directly interacted with i.e Pump)

2. Toxicology Assessment

Local toxicity: Phototoxic materials are not included in this formulation at levels of concern.

Nano materials are not included in this formulation.

The toxicological profile and concentration of ingredients in this product do not present a risk to human health when the product is used under normal or reasonably foreseeable conditions of use.

Margins of safety were calculated; the ingredients are considered safe.

The fragrances used (if applicable) are compliant with current IFRA standards at the level of inclusion in this product category.

3. Method of manufacture

Oil and Water phases are heated then mixed under high shear. Additional ingredients are then added.

4. Evidence of compliance with Good Manufacturing Practices (GMP)

All ingredients sourced from reputable UK suppliers.

Best practice followed in terms of hygiene and working standards.

Appropriate packaging used.

Regular inspections and stability testing carried out.

5. Proof of the effect claimed

No claims made.

6. Data on Animal Testing

No testing on animals

7. Responsibility/Traceability

Responsible person

Andrew Kennedy

C/o Hera Beauty Ltd

Manufacturer

Hera Beauty Ltd

Person responsible for packaging

Andrew Kennedy

C/o Hera Beauty Ltd

8. Labeling

Compliant with EU and UK guidelines.

Warnings: For external use only. Avoid contact with eyes. Keep out of the reach of children. Do not store in direct sunlight.

9. Data on serious undesirable effects

None to declare.

APPENDIX

A. Handling and Storage

No special handling techniques required.

Keep out of reach of children. Store in a cool dry place. Keep from extreme heat, cold & sunlight.

B. Exposure controls and personal protection

No special personal protective equipment required.

C: Stability & Reactivity

The product is stable non-reactive. Avoid strong oxidising agents.

D: Toxicological Information

No acute or chronic toxic effects when used as directed.

E: Ecological information

No ecological hazards are associated with this product. It is biodegradable.

F: Disposal considerations

Dispose of product according to local and national regulations.

G: Transport information

Non Hazardous / Non-flammable. No shipping restrictions

H: Declaration of Allergens

The customer should satisfy themselves that the product is suitable for the intended purpose, and that a suitable and sufficient assessment of any risks created by any activity using this product is undertaken before use. This information is based upon our knowledge of the product at the time of publication. The data is given in good faith and should be viewed as guidance only. This product sheet cannot cover all possible situations which the user may experience. We do not assume any responsibility and expressly disclaim any liability for any use of this product.

Should the customer subsequently alter the product, it is the customer's responsibility to ensure any allergens are declared on the end user packaging.

I. Other Information

This PIF Summary does not constitute a legal document. Customers who retail Hera Beauty products under their own label are responsible for ensuring that their packaging and labels are compliant with the relevant legislation in the jurisdiction of sale.

Any customers who modify or add to our standard products are responsible for ensuring their product complies with legislation requirements in their jurisdiction of sale and Hera Beauty accept no liability.

Any product marketed under customer brand must be registered with the CPNP/OPSS and have a responsible person and registered address assigned to the brand that the product is being traded under.

To the best of our knowledge, the information contained in this document is correct.