# Preparing to sell a cosmetic product in the UK (Bath bombs)

- Appoint a Responsible Person. If you sell in the UK and the UK you will need a Responsible Person based in both areas.
- o Get a Cosmetic Product Safety Report (CPSR).
- Put together a Product Information File (PIF)
- Notify your product on the UK portal.
  <a href="https://submit.cosmetic-product-notifications.service.gov.uk/">https://submit.cosmetic-product-notifications.service.gov.uk/</a>
- Make sure that your label is compliant.
- Make your product to GMP
- o Report any Severe Undesirable Effects that you receive.

# Other elements that you may need to consider:

- Weights and Measures Act 1985.
- Your product cannot imitate food.
- o If your product is marketed towards children you may need to consider the impact of The General Product Safety Regulations 2005.
- o You cannot make medical claims for your products.
- o It is strongly recommended that you have product/public liability insurance.
- Health and Safety Guidelines whilst making the cosmetic product.
- The safe disposal of chemicals (The Pollution Prevention & Control Regulations 2000 (SI 2000 No 1973).
- o You should consider the impact of Trademarks in the naming of your brand and products.

#### **CPSR**

Please place your CPSR from Stansfield's in your Product Information File. You must adhere to the recipe provided, any changes are likely to invalidate the CPSR.

# **Product Information File (PIF)**

The legal requirements of a PIF is:

- 1. Description of the cosmetic Product
- 2. CPSR
- 3. Method of manufacture, statement of GMP compliance
- 4. Proof of effect
- 5. Animal testing compliance statement.

However, we would also recommend adding the following:

- 6. Ingredient information (Certificates of Analysis, MSDSs, IFRA documentation, technical sheets).
- 7. Batch records.
- 8. Records of complaints, adverse reactions and severe undesirable effects.

A PIF can be paper based, cloud based or electronically stored. The key thing is that you can collect all the information required for the PIF within 48 hours.

# Notify your product on the UK portal

Every product that you sell needs to have a notification on the UK cosmetic portal (and the EU portal if you sell in the EU).

Please use our guide for the UK portal.

### Labelling:

| UK Cosmetics<br>Regulation | Labelling Requirement                                   | Container<br>(a bottle, jar) | Packaging<br>(a carton, box) |
|----------------------------|---|------------------------------|------------------------------|
| 19.1(a)                    | UK Address of the Responsible Person                    | Yes                          | Yes                          |
| 19.1(a)                    | Country of origin (for imported products)               | Yes                          | Yes                          |
| 19.1(b)                    | Declared quantity of contents*                          | Yes                          | Yes                          |
| 19.1(c)                    | Date of minimum durability*                             | Yes                          | Yes                          |
| 19.1 (c)                   | Period After Opening (PAO)*                             | Yes                          | Yes                          |
| 19.1(d)                    | Warning statements and precautionary information*       | Yes                          | Yes                          |
| 19.1(e)                    | Batch code  | Yes                          | Yes                          |
| 19.1(f)                    | Function of the product* Declaration of the ingredients | Yes                          | Yes                          |
| 19.1(g)                    | Declaration of the ingredients                          | No**                         | Yes                          |

### Notes:

- \* Where required
- \*\* Ingredient labelling is required on the primary packaging where there is no secondary packaging

Image: Supplying Cosmetic Products on the UK Market? <a href="https://www.ctpa.org.uk/legislation">https://www.ctpa.org.uk/legislation</a>

The ingredient list should start with the word 'INGREDIENTS' in upper or lower case and then follow with each ingredient in descending order of weight. However, ingredients of less than 1% may be listed in any order after those of 1% or more. Colouring agents may be listed in any order after the other ingredients using their Colour Index (CI) number.

There are also 26 fragrance allergens that require placing on the label. The threshold levels for declaration are 0.001% for leave-on products and 0.01% for rinse-off products.

### **Good Manufacturing Practice (GMP)**

All cosmetic products must be made in accordance with GMP. In general, GMP means having adequate procedures and in place to ensure that the products are made in a clean environment which minimises the risk of contamination. GMP can cover aspects such as the maintenance and use of machinery, storage of raw materials, batch recording and the training of staff (not an exhaustive list).

In general, companies are considered to be compliant is the abide by ISO 22716 guidelines, which is the International Standard Organisation GMP guidelines for the manufacture of cosmetic products.

Following ISO 22716 is not a legal requirement, but is a internationally accepted guideline.

The UK has not provided GMP guidance for small scale cosmetic manufacturers, however this guide from the HPRA (Ireland) may be useful when you are documenting your own GMP process.

 $\frac{https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/guide-to-good-manufacturing-practice-of-cosmetic-products.pdf?sfvrsn=11$ 

### **Reporting of Severe Undesirable Effects (SUEs)**

The UK regulations defines Undesirable Effects and Severe Undesirable Effects as:

Undesirable Effect: an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product

Serious Undesirable Effect: an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death.

For Undesirable Effects, please record any reports of Severe Undesirable Effects and pass on to your Safety Assessor.

Severe Undesirable Effects are exceptionally rare, but it is still essential that you prepare for them. We have provided an example form for you to look at, however this may be subject to change, click on the link below for the most up-to date version.

If an SUE occurs download the most recent form from the link below, fill in as much information as you can and submit to <a href="mailto:seriousundesirableeffects@beis.gov.uk">seriousundesirableeffects@beis.gov.uk</a>.

https://www.gov.uk/government/publications/cosmetic-products-reporting-sues