

Cosmetic Product Safety Report Guide



This brochure has been designed to guide you through our CPSR services.

The Soap Kitchen (2011) Ltd
Unit 8, Caddsdwn Industrial Park,
Clovelly Road, Bideford, Devon. EX39 3DX
01237 420872
enquiries@thesoapkitchen.co.uk

Because current EU legislation and the requirement for safety assessments (CPSR's) on cosmetic products has now been in existence for several years we have taken the opportunity to provide the following advice. We offer these guidelines based upon our own experiences and understanding of the law as it currently stands in the UK.

EC Regulation 1223/2009 on cosmetics sets binding requirements for cosmetic products that have been made available on the market within the European Union.

If you would like to read Regulation (EC) no 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetic products it can be viewed here <http://eur-lex.europa.eu/eli/reg/2009/1223/2016-08-12>

Do I need a cosmetic product safety report (CPSR)?

Ok, so put simply, any cosmetic that is produced to sell must have a CPSR before it is made available for sale. The same rules apply whether you are a small business of one person selling at craft fairs or a huge company employing hundreds of staff selling in supermarkets.

The legal bit:

According to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products;

“any cosmetic product made available on the market falls under the legislation and will need a CPSR. For the purposes of this Regulation, the following definitions shall apply:

(a) ‘cosmetic product’ means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours”.

There are different rules/legislation for medical products and aromatherapy products like candles and room sprays. Sometimes the definition of what is cosmetic and what is medical is difficult to determine, so we cover this further on.

How do I apply for a cosmetic safety report?

When you are happy with what you have made, have the perfect formula and decide to take the next step towards selling legally, the process is quite simple.

We offer several different packages (which can be viewed here www.thesoapkitchen.co.uk/safety-assessments)

[CP and HP Soap.](#)

[Melt and Pour Soap](#)

[Bath Products. \(Bath bombs, bath salts and creamers \(melts\)](#)

[Body Oils and Butters](#)

[Lip Balms](#)

[Eyeshadows](#)

[Soap Kitchen Base Products \(products made using Soap Kitchen supplied bases to include Creams, Lotions, Shampoos, Body washes and other Base Products\)](#)

Choose the package that meets your requirements and once we have received your order, we'll email a formulation form for you to enter your recipes and then return to us - we will double check these for you and get back to you if we have suggestions for any changes that need to be made. Don't worry we'll send a guide to completing the forms too. All forms and supporting documents must be submitted within 28 days.

If you are using a fragrance oil you will need to submit the IFRA Statement also (you can find more information regarding this below).

If you are using any pre-made bases or products as part of your recipe you will need to submit the INCI bandings for the product. This allows the chemists to see the full ingredients and amounts included in your formula.

Without these the chemists can not start the assessment and may delay the time taken to complete the assessment.

What Happens Next?

At the soap kitchen we have lots of experience with ingredients and recipes and can help with your initial queries, but we're makers and creators but we are not chemists. Once we have received all your completed formulation forms we will check for any obvious mistakes or issues and then forward it onto our consultant chemists.

The chemists then perform all the technical bits...

The Cosmetic Product Safety Report takes the form of two distinct sections, Parts A & B

PART A – Cosmetic product safety information

1. Quantitative and qualitative composition of the product
2. Physical/chemical characteristics and stability of the cosmetic product
3. Microbiological quality
4. Impurities, traces, information about the packaging material
5. Normal and reasonably foreseeable use
6. Exposure to the cosmetic product
7. Exposure to the substances
8. Toxicological profile of the substances
9. Undesirable effects and serious undesirable effects
10. Information on the cosmetic product

PART B – Cosmetic product safety assessment

1. Assessment conclusion
2. Labelled warnings and instructions of use
3. Reasoning
4. Assessor's credentials and approval of part B

How much does it cost?

Our packages certify up to 6 different variations of your basic recipe, the total fee for this package is £150 (+ VAT)

Each variation can have up to 5 different ingredients such as essential oils, colours, flavouring oils etc.

PLEASE NOTE:

1. If you are blending fragrance oils or a blend of essential and fragrance oils together in a variation, a further fee of £15.00+VAT per fragrance oil will be incurred, this is to ensure the levels of inclusion can be checked that they are appropriate to the type of product. There would be no fee for using a blend of essential oils together.

2. If you are using fragrances from suppliers other than the Soap Kitchen, you will need to source and submit the IFRA information and for this, your supplier should be able to send the IFRA certificate to you.

If you don't currently have 6 different variations, you can use this package to certify what you already make, and then add to your reports at a later date as your business grows. Please note that there will be a small administration fee payable each time further variations are added (up to the maximum of 6) and so it is advisable to add several at a time. The base recipe must not change across each variation.

It is your formula which is assessed, not the product itself, so typically we will not require any actual sample of your product.

If the chemists have preservation concerns the product itself will need challenge testing, in which case we will need a sample of the product to send to the laboratory for microbiological preservative efficacy test (PET). It may be because it has a large water content, or there are concerns regarding the packaging or preservatives used. Challenge testing takes approx. 6 weeks and will incur extra fees.

If you are making melt and pour soaps clear and white bases of the same variety from the same manufacturer can count as 1 base, but extra fees will apply if you are using 2 different bases with different ingredient lists (inci).

If you have not submitted your forms within 28 days you have the right to cancel your order and receive a full refund.

If you cancel your order after 28 days and/or we have already received your information and started work on preparing your CPSR we reserve the right to charge an administration fee of minimum 20%.

What does 6 different variations of your basic recipe mean?

Ok this bit can confuse people so we'll try to explain it;

Each assessment offers 1 base recipe and 6 variations.

Base Recipe

So this is the basic recipe for your product with no colour and no fragrance added. The base recipe can have up to 10 different ingredients (check the information for each product as the permitted ingredients may vary). This forms the base for all your variants of the same product. The base recipe must not change across each variation

Variations

You can have 6 variations to your base recipe. Each variation can have a further 5 ingredients such as essential oils, colours, fragrance oils, but as a total must not exceed 10% of the recipe.

For Example;

Your base recipe for soap is;

- 340g Water
- 125g Caustic Soda
- 454g Olive Oil
- 284g Coconut Oil
- 170g Palm oil

Variations

1. Gardeners

- 10g Sweet Orange Essential Oil
- 6g Cedarwood Atlas Essential Oil
- 50g Ground Walnut Shells

2. Lemon & Lime

- 10g Lime Fragrance Oil
- 10g Lemon Essential Oil
- 2.5g Water Dispersible Yellow (liquid) Pigment (ci11680)
- 2.5g Water Dispersible Blue (liquid) Pigment (ci74160)

How long will it take?

Obviously we try to get the assessment completed as quickly as possible and it does depend greatly on the chemist's workload and can take longer in busy periods like Christmas.

We will only submit your assessment to the chemists once we have received fully completed formulation forms and any supporting documents such as IFRA statements.

The Chemists will only produce your report once they have checked your formulation. If there are any problems, they will advise us of the changes that should be made.

We'll contact you with the info and then relay any feedback to the chemist, or ask you to fill out a new formulation form. Depending on how this affects the formula and testing that needs to be completed it may delay the time taken to issue the certificate.

Once the Chemists have all the relevant information and documents and given the ok, the assessments usually take approximately 4 weeks for completion.

The more accurate and complete your initial information is, the quicker your CPSR will be to complete. Missing information will result in delays.

If you are not resident in the UK, please contact us first as local regulations may vary and there may be extra charges for supplementary paperwork.

Please note that once your recipes have been submitted, if you don't receive any feedback from the chemist, that usually means they're writing your assessments and your recipes are fine!

Bespoke Reports

Our safety assessment packages are designed for adults and children over 36 months old only. If your product is designed for babies and/or infants please make us aware before purchasing an assessment package, as it will require a bespoke report.

Limited Assessment Package

Alternatively we offer limited assessment package's designed as a low cost entry-level CPSR.

These packages have been developed in conjunction with Cosmetic Safety Consultants, and for reasons of cost and simplicity they are tied in to products exclusively supplied by The Soap Kitchen. Because these assessments are for specific base products and have only specific additions, there can be NO VARIATIONS.

You can find out more about our Limited Assessment packages here www.thesoapkitchen.co.uk/base-product-safety-reports

What is an IFRA statement?

Fragrances are often very complicated chemical mixtures and the exact formulation is usually strictly confidential. To enable fragrance manufacturers to keep their formulations secret, but still provide information about the safety of the ingredients, IFRA certificates are used. IFRA (International Fragrance Association) certificates provide information on the safety of a fragrance and the limits at which it can be used in different cosmetic products. There are 11 IFRA product categories relating to how and where the product is used - if it is leave-on, or rinse-off etc.

Medical or cosmetic?

We are often asked to certify natural products formulated using essential oils and other natural actives with a view to providing;

- Pain relief - for example joint rubs and salves, headache temple balms
- Healing - balms and salves for example that are described as being suitable to help the healing process for chapped or broken skin, after injury or due to diseases or post tattoo
- Specific products marketed to treat or cure specific medical conditions such as eczema and psoriasis

You may be surprised to know that these are actually NOT cosmetic products, and as such will not conform to the same regulations (REGULATION (EC) No 1223/2009 These types of products may be classed as medicines - any therapeutic claim may result in the product being classed as a medicine and become subject to regulation and intervention from the appropriate agencies.

If you wish to make this type of product we advise that you contact the MHRA for further advice www.gov.uk/guidance/contact-mhra

What are CI numbers and INCI?

When labelling cosmetics there is a standard system for ingredient names across the UK and EU. This is known as INCI - International Nomenclature of Cosmetic Ingredients. You will see when you look at the labelling of cosmetic products that some of the names seem to be in Latin, such as the botanical name for lavender - *lavandula angustifolia* - in fact, these are INCI names and it is these that you need to use on your product labels. There is nothing to stop you using the common name in brackets alongside, so that your customers know exactly what you are using. For example "Lavandula angustifolia (Lavender) flower oil" is perfectly acceptable.

When you include a colour in your formulation, we need to see what is known as the CI (Colour Index) number. This tells us exactly which colour you are using and avoids delays in producing your reports.

For example - we see formulations where a customer says "1g red colour" - as you can imagine, there are so many different variations available it is almost impossible for us to know exactly what is being used .

All we need you to do is include this reference in your formulation please. So instead of "1g red colour" we would like to see "1g red Colour (CI 12085)"

If you are using ingredients from a supplier other than the Soap Kitchen you will need to ask them for the INCI names of your ingredients or the CI Number for a colour.

Why can't we make cupcake soaps?

Soaps and bath bombs which resemble food are becoming increasingly popular and as such we are being asked more frequently to provide Cosmetic Product Safety Reports for this type of product.

Cosmetic Regulation EC 1223/2009 states that "The presentation of a cosmetic product and in particular its form, odour, colour, appearance, packaging, labelling, volume, or size should not endanger health and safety of consumers due to confusion with food stuffs".

This means that it is illegal to sell any product which resembles food that is not made entirely from food ingredients. In the case of cosmetics "endangering health and safety" would include choking, poisoning or even causing a child to vomit.

You can read advice from the chemists at www.cosmeticsafetyassessment.com

Products which imitate food

If you require any further information please contact us enquiries@thesoapkitchen.co.uk

You may also find these guides helpful

[Permitted essential oils for leave on cosmetic products.](#)

[Permitted essential oils for rinse off cosmetic products.](#)

[The Next Step - Selling Your Products](#) including information on correct product labelling, good manufacturing practice, product information file (PIF) and product notification portal

This brochure is designed to guide you through our CPSR service, we reserve the right to change any of the information without notice