

# Guidance on the use of upcycled Ingredients – Key Considerations

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**CTPA Role:**

The Cosmetic Toiletry and Perfumery Association (CTPA) is the trade association for the UK cosmetic and personal care industry.

The Association's role is to advise manufacturers, distributors and suppliers about the strict legal framework for cosmetics, to represent industry views to UK government, and external stakeholders and help promote information to the media on issues relating to the safety of cosmetic products. The CTPA acts as the voice of the UK industry and provides the most up-to-date interpretation of, and guidance on, regulatory matters affecting cosmetic products in the United Kingdom and internationally.

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If appropriate, then 'Why Join' can be added – either to the front inside page or on the inside back page

## Why Join the CTPA?

CTPA membership gives companies access to experienced regulatory, scientific and technical staff to help them market safe, effective products that provide a wide range of consumer choice both in the UK and overseas.

Membership provides companies with peace of mind with easy access to:

- up-to-date legislative references;
- guidance on compliance;
- confidential one-to-one advice;
- advice on best practice;
- advance knowledge of upcoming changes;
- global updates on key issues;
- media and consumer information; and
- 24/7 online resources accessible worldwide.

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CTPA supports the transition towards a circular economy and the use of otherwise waste materials is recognised as a key element in the drive towards the overall reduction of waste and resources.

The advice below takes into consideration the safety, manufacturing, labelling and general requirements under the **UK<sup>1</sup> and EU<sup>2</sup> Cosmetics Regulations** and may not be appropriate for all cosmetic product types or markets outside Great Britain.

Whilst a multi-disciplinary approach is recommended, if necessary, members are advised to seek expert assistance in each key area.

## Defining an Upcycled Ingredient

Whilst there is no legal definition for what defines an ‘upcycled’ ingredient, for the purpose of this document, it is considered as unwanted waste, that would otherwise be diverted to a fate that diminishes its value, such as landfill, animal feed, biofuel or compost. By repurposing it, the value of that material might be increased, and the use of a virgin resource becomes unnecessary.

The EU Waste Framework Directive<sup>3</sup> provides definitions and criteria for by-products and end-of-waste criteria for when a material ceases to be waste and becomes a product or raw material. In the UK, the Waste (Circular Economy) (Amendment) Regulations 2020<sup>4</sup> amends article 6 of the Directive relating to ‘end of waste’.

## Sourcing, Product Development and Safety Assessment

Cosmetic ingredients sourced from upcycled materials must comply with the requirements of the UK Cosmetics Regulation, as with all other cosmetic ingredients. It is therefore important to consider any inclusion within the ingredients Annexes, safety requirements in relation to traces and impurities, and the microbiological and production implications, according to Good Manufacturing Practice<sup>5</sup> (GMP).

It is vital that formulation chemists, microbiologists and safety assessors are made aware of the nature of the intended ingredient, including how the ingredient is created and how the product is manufactured and packaged. For example, a product containing upcycled ingredients may require a different preservative mix owing to the increase potential for contamination.

### Traces and Impurities

Depending on the source, upcycled ingredients may be at higher risk of containing traces and impurities of ingredients that are prohibited in cosmetic products or that require additional labelling information such as allergens. Relevant analyses will identify any possible traces and impurities and ensure that the ingredients comply with the requirements of Article 17 of the Cosmetics Regulation. The Responsible Person (RP) shall ensure that any traces are technically unavoidable from the manufacturing process; and the safety assessor must take this matter into account as part of the safety assessment of the finished product.

### Positive Annexes to the Cosmetics Regulation

Any upcycled ingredients that are used in cosmetic products exclusively or mainly for the purpose of colourants, preservatives or UV filters must be listed in Annexes IV, V, VI respectively.

### Consistency of Supply

Upcycled ingredients may be susceptible to challenges around the availability of quantities sufficient to enable scaling up, and not producing standardised batches owing to variations of composition. This last point can impact on the presence of traces and impurities, safety consideration for the safety assessment, reproducibility of production batches, and the ability to make claims made about the presence of actives.

## Ingredients of Human Origin

Cells and tissues of human origin are banned from use in cosmetic products via the Annex II (list of banned substances) entry number 416 of both the UK and EU Cosmetics Regulations: “Cells, tissues or products of human origin”. In 2018, the European Commission confirmed that its interpretation is the following. This is likely to also be applicable in the UK, although this has not been confirmed:

- Materials, e.g. peptides/proteins, directly extracted from the human body fall under the provisions of entry 416 of Annex II and therefore must not form part of the composition of cosmetic products.
- Materials, e.g. peptides/proteins, obtained via a manufacturing process involving a human gene and/or any other material of human origin, fall also under the provisions laid down in entry 416 of Annex II and therefore must not form part of the composition of cosmetic products. It must be noted that the objective of entry 416 was to limit the risk of transmission of viral infections to humans through the use of cosmetic products, and therefore to ensure a high level of protection of human health. Such objective justifies an extensive interpretation of the above-mentioned provision.
- Materials, e.g. peptides/proteins, synthesised to be identical or similar to a human peptides/proteins, but not originating with human genes are not covered by the provisions laid down in entry 416 of Annex II, provided that no human material has been involved at any stage of their manufacturing process. This is without prejudice of other provisions that may apply to them.

## New-to-the-market Cosmetic Ingredients

Article 19 of the Cosmetics Regulation requires that cosmetic ingredients are labelled using their International Nomenclature of Cosmetic Ingredients (INCI) names. It may be the case that some upcycled ingredients are difficult to identify chemically and may have not previously been used in cosmetics and therefore have no INCI name. Those using such recovered substances should understand the sources and gain knowledge about the substances. Assuming that the ingredient is not banned or restricted according to Annex II and III respectively, the ingredient without an INCI name may be labelled on-pack using “a term as contained in a generally accepted nomenclature shall be used” (a name that accurately describes the raw material). However, CTPA advises that an application for an INCI name be made. INCI names are issued by the International Nomenclature Committee<sup>6</sup> sponsored by the Personal Care Products Council (PCPC), the US Trade Association. Therefore, to create an INCI name, applications should be made to the PCPC<sup>7</sup>.

## Animal Testing Ban

Animal testing of cosmetic products and ingredients has been banned in the UK since 2013. It is important to ensure that the safety data associated with the chemical complies with the strict animal testing bans for cosmetic products and ingredients.

## Irradiation of Ingredients

Upcycled ingredients often have a limited shelf life as limits for food ingredients are generally less stringent than for cosmetic ingredients. Therefore, such ingredients may require additional processing. Irradiation is a technique that can be used to improve the microbiological integrity of an ingredient. There are no restrictions or regulations banning this treatment, however, it must be used appropriately to ensure that the final product is safe. Use of this technique to attempt to sanitise badly contaminated ingredients is not recommended because irradiation of badly contaminated ingredients may leave behind contaminants. Careful consideration is required for ingredients which might be used in products for use around the eyes or other vulnerable populations or areas. Irradiation of aqueous ingredients can form free radicals which then react to form new compounds. The supplier should verify that any new impurities generated are safe. It may be necessary to increase the amount of preservative in the formulation, but this will need to be balanced with the regulatory restrictions in place around maximum concentrations and consumer expectation to use minimum preservation.

## Classification, Labelling and Packaging (CLP) Regulations<sup>8</sup>

Cosmetic ingredients as raw materials fall under the scope of the EU and GB CLP Regulations. Therefore, upcycled ingredients that are used in cosmetic products must also comply with the requirements of this chemical legislation. It is important to consider the classification of the chemicals, as this may influence its safety and its use as a cosmetic ingredient. In addition, its supply may require information to be shared through the supply chain via a Safety Data Sheet (SDS). Further requirements under CLP may also apply.

## Registration, Evaluation and Authorisation of Chemicals (REACH) Regulations

Cosmetic ingredients, as raw materials or as part of a finished cosmetic product, manufactured or imported above one tonne per year per legal entity, fall under the scope of the UK REACH<sup>8</sup> Regulations. Some upcycled ingredients may be natural and possibly exempted from REACH; however, this depends on the chemical or physical process that such ingredients have been through. Upcycled ingredients that are used as cosmetic ingredients must therefore be assessed for their scope under REACH and, if applicable, ensure compliance. Data from the above, in addition to the relevant stability, compatibility and challenge testing will be required to ensure the product's integrity and safety throughout the full lifecycle of the product and should be supplied to the duly qualified safety assessor for consideration for the Cosmetic Product Safety Report, and form part of the Product Information File.

## Good Manufacturing Practice

To maintain compliance with Good Manufacturing Practice (GMP) throughout the supply, testing and storing of upcycled ingredients and their use in the manufacture of a finished product, it is recommended that the procedures of the supplier and manufacturer will be revisited. This may lead to changes in company operations, facilities, production lines and equipment, and therefore additional consideration should be given to microbiological controls, procedure validation and mapping the differing risk areas within a site.

Any additional strategies necessary to minimise risk, must be fully defined by the Responsible Person (RP) with this being documented in the Product Information File (PIF).

## Sustainability

It cannot be assumed that because an ingredient has been upcycled from waste, it is sustainable. As with all ingredients, it is essential to understand the entire supply chain to ensure that there are no question marks over the environmental impact of the whole supply chain or production, or the wellbeing of workers.

When sourcing upcycled ingredients, it is essential to understand the impact of the raw materials on natural resources, land use and biodiversity, to ensure that the materials were grown and harvested using sustainable agricultural practices. It is also essential that due diligence is undertaken to ensure that those ingredients have not contributed to human exploitation at any stage in the supply chain.

To determine whether the use of a specific ingredient is the best option for the environment, a full life-cycle assessment should demonstrate that the option is:

- more sustainable than a relevant equivalent ingredient, and/or
- the material being disposed of in a potentially productive way, such as biofuel.

It should also include realistic expectations on the practicality of using such an ingredient, such as how consistent and plentiful the source of the material is, and whether it is available all year round.

# Claims and Labelling for the Consumer

Environmental claims for cosmetic products, including those regarding the origin of the ingredients, must follow the same requirements as all other cosmetic claims, including Article 20 of both the UK and EU Cosmetic Regulations, the Common Criteria for Cosmetic Claims Regulation (which is still applicable in the UK) and the EU Unfair Commercial Practices Directive<sup>9</sup> as implemented in the UK with the Consumer Protection from Unfair Trading Regulations<sup>10</sup> 2008. All cosmetic claims must be true and fully substantiated by robust evidence.

According to available guidance documents and recommendations from the EU Commission, the Advertising Standards Authority (ASA) and the UK Department for the Environment, Food and Rural Affairs (Defra), environmental claims should meet the below requirements.

- Reflect a verifiable environmental benefit over the full product lifecycle; or companies should be transparent about which area of the supply chain the environmental benefit is related to.
- Consumers must not be misled and should instead be educated on the topic, to be allowed to make an informed decision. Relevant information to the consumer should not be omitted.
- Environmental claims should be accurate and based on sound science.

When using these types of claims it is important to consider the understanding of the averagely well-informed consumer. It is possible that consumers could interpret claims regarding upcycled ingredients, or similar wording, to mean that the ingredient is waste from another industry or product manufacture and would otherwise be discarded.

Stating that a product contains a specific ingredient is ultimately a claim. By attributing a performance benefit to one or more ingredients or active components, the ingredients should be at a level whereby they can deliver said benefit within the cosmetic product. Claim substantiation data should also be held to show that the ingredients or actives are delivering the stated benefits in the final cosmetic product.

There is no minimum percentage that an ingredient must be present at in cosmetic products, because ingredient potency varies. Therefore, as part of the compliance with all the Common Criteria, the Honesty criterion is key in this context and the following points should be considered when featuring an ingredient on pack or in advertisement/marketing material including websites:

- the ingredient must have been deliberately added to the cosmetic product and should be listed in the ingredients list;
- the inclusion level should be sufficient that it is analytically detectable but also that the ingredient is at a level whereby it can deliver the benefit (explicitly claimed or implied) within the cosmetic product;
- there should be claim substantiation data to show that the ingredient is delivering the stated benefit/s (if any) in the cosmetic product.

The Responsible Person placing cosmetic products on the market is responsible for any claims made, including the wording and has the burden of proof for the appropriate claim substantiation. It is important to consider that the competent authorities and/or Self-Regulatory Organisations (SROs) can inspect and will potentially challenge the substantiation held by the Responsible Person.



# Variable Ingredients and the Presence of Allergens

During manufacture it is often the case that adjustments have to be made on a batch-by-batch basis, for viscosity and pH, for example. This may be done with the addition of an extra ingredient. Whilst the UK Cosmetics Regulation makes no such allowance for this type of situation, the common industry practice is to include the variable ingredient(s) in the body of the ingredient listing. These ingredients should not be listed in the 'may contain' provision - this is reserved for colours.

Article 19 of the UK Cosmetics Regulations requires products containing fragrances to label the word 'parfum' within the ingredients list. Furthermore, all fragrance allergens present in a cosmetic product (**independent of whether these are coming from the fragrance, or an essential oil, or a natural extract, as examples**) must also be labelled if they are present within the product above 0.01% (for rinse-off products) or 0.001% (for leave-on products). Fragrance allergens are regulated under Annex III of the Cosmetics Regulations. If the constituents of an upcycled material are subject to change, there is the potential for a particular allergen to occasionally be present in levels exceeding the thresholds above.

This situation should be monitored closely, and the appropriate labelling provided.

For transparency, a brand may wish to share additional information on the use of an upcycled material, either through labelling or by directing consumers at the point-of-sale or on-line. Examples of such information are:

- the source of the upcycled component,
- from what waste the ingredient has been diverted,
- whether it has been processed and whether it is chemically changed since it was considered a 'waste' material, and
- whether to expect any natural variations in the final product colour or odour.

## References

1. [Regulation \(EC\) No 1223/2009 on Cosmetic Products, as amended by the Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#)
2. [EU \(EC\) No. 1223/2009](#)
3. [EU Waste Framework Directive Directive 2008/98/EC](#)
4. [Waste \(Circular Economy\) \(Amendment\) Regulations 2020.](#)
5. [GMP - A Practical Guide for the Cosmetic Industry](#)
6. [International Nomenclature Committee](#)
7. [INCI Application Information](#)
8. [Regulation \(EC\) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures \(CLP\) as amended by GB law.UK REACH Legislation](#)
9. [Guidance on the interpretation and application of Directive 2005/29/EC on Unfair Commercial Practices](#)
10. [The Consumer Protection from Unfair Trading Regulations 2008](#)

## Further Reading

[Microbiological Criteria for Foodstuffs of Animal and Plant Origin](#)

[Guidelines for Assessing the Microbiological Safety of Ready-to-Eat Foods Placed on the Market](#)

[Modern Slavery Act 2015.](#)

[Transparency in Supply Chains](#)

[CTPA Guide to Advertising Claims](#)

[Upcycled Food Association \(USA\)](#) – information on criteria for upcycled certification standards.

[ECHA 'Guidance on waste and recovered substances'](#)

[CMA 'The Green Claims Code'](#)

[The use of recycled materials in consumer products and potential chemical safety concerns](#)



