CTPA TRAINING 'THE COSMETIC BORDERLINES: ASSESSING PRODUCT CLASSIFICATION'
31 AUGUST 2023 - Q&A

Article 2 of the UK and EU Cosmetics Regulations provide the definition of cosmetic products, which allows companies to assess whether a product can be classified as a cosmetic or not. Product classification is essential to understand the regulatory requirements applicable to each specific product. It allows companies to understand their legal compliance requirements and protects consumers from being misled into believing products may have functions which they do not.

To classify products, each regulation may contain definitions of the products included within their scope. Classifying products under these definitions usually relies on a series of fundamental factors which need to be assessed on a case-by-case basis. 'Borderline' is a term used when classification of products is not straightforward, and requires careful examination of their composition, overall presentation, claims and other factors which determine the final classification decision. Cosmetic products share a borderline with other product categories, such as medicines, biocides, or general products.

There are two main public resources on the cosmetics borderlines in the EU and UK available to industry:

- the EU Borderline Products Manual
- the MHRA Guidance Note 8

To guide companies through the classification process and the assessment of a product with specific relevance to claims, CTPA has created the CTPA Decision Tree for Borderline Assessment. This includes examples of products in different contexts and how to assess them to minimise the risk of making unsuitable claims.

CTPA members can also access the CTPA Borderline Reference Zone.

Disclaimer: it is impracticable to provide defined advice on borderline scenarios. Classification is done on a case-by-case approach, depending on the product overall presentation.

On 31 August 2023, CTPA presented an online training session titled 'The Cosmetic Borderlines: Assessing Product Classification'. This webinar was aimed at examining borderlines and providing an understanding on how to ensure products are correctly classified.

CTPA members can access the webinar recording here.

Below are the answers to questions asked by the attendees during the webinar:

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Question. Can the position of where an item is located within a retail store also be a consideration to the final product classification?

Answer. The overall presentation of a product determines the classification. When making a classification decision, competent authorities will take several factors into consideration including the primary function or purpose of the product, its composition, the packaging and presentation, any claims and advertising materials, etc. Authorities take into account what the perception of the 'averagely well-informed consumer' will be with regards to the product and the factors that may influence their purchase decision, among these factors can be where the product is sold.

For example, some consumer products that are generally regarded as food products, such as oils, may on occasion be placed on the market with a cosmetic function or benefit (for example, a hair oil). If these products remain available in store alongside other food products, it is likely that this would be an influencing factor in the final classification decision.

Article 2 of the UK Cosmetics Regulation (UKCR) and EU Cosmetic Products Regulation (CPR) includes the legal definition of a cosmetic product and outlines the application zones applicable to cosmetics. In the above example, ingestion is not a legally recognised area or form of cosmetic application and therefore it cannot be presented as a cosmetic, even if it does have a cosmetic function.

Q. Can products with sport claims, such as after workout spray, be classified as cosmetics?

A. The definition of a 'cosmetic' contained in Article 2 of the UKCR and CPR includes three considerations: the composition of the product, the intended function, and the area of application. For a product to be classified as a cosmetic, all three branches of the definition must be met.

Therefore, it is imperative that a product has a cosmetic function as defined, which includes cleaning, perfuming, changing the appearance, correcting body odours, protecting or keeping in good condition.

A product with functions outside of this definition, such as a spray to help or relieve tired aching muscles, would not be compatible with the given cosmetic functions. Therefore, a product such as this could not be classified as a cosmetic product.

However, sports sprays intended to clean, refresh, or modify body odours, such as a sports fragrance or a spray to aid the removal of sweat or dirt could be classed as cosmetic products.

Q. Can a probiotic claim be made on a cosmetic product?

A. Currently, there is no legal definition of 'probiotic' for cosmetics, however the International Cooperation on Cosmetics Regulation (ICCR) defines 'probiotics' as:

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Viable (active or dormant) microorganisms added to a cosmetic product with an intended cosmetic benefit to the host at the application site, either directly or via an effect on the host microbiome, when utilized in adequate amounts.

There are no restrictions placed on 'probiotic' claims specifically, and there is no immediate impact on product classification, but a case-by-case assessment will still be required to ensure the product can be classed as a cosmetic.

It will be important for classification that the benefit associated to the claim remains under the remit of the functions provided under the cosmetic definition, whether explicit called out alongside the word 'probiotic' or implicitly considering the average consumer understanding. If these claims communicate or imply to the consumer that the product is intended to treat or prevent an adverse condition, the product may be considered as a medicine by the MHRA. Claims substantiation should additionally be able to demonstrate a cosmetic benefit, and substantiation related to medicinal benefits may not constitute adequate cosmetic claims support and further reinforce the need to classify the product as a medicine.

Q. Can products that penetrate the skin, such as microneedle patches, be classified as cosmetics?

A. Cosmetic patches may be classed as cosmetics, however, the patch itself might be considered a special applicator or an article, with the substance or mixture applied through the patch being classed as a cosmetic product. Microneedle patches may be presented as patches that intend to puncture or break the skin layer or those that present dissolvable crystals from ingredients that are not intended to penetrate the skin.

A microneedle patch therefore may present or claim to have a cosmetic benefit; however, if the needles on the patch break the surface of the skin and the substance or mixture penetrates the deeper layers of skin, the site of application will be outside of the scope of a cosmetic product.

Q. Can a massage candle be a cosmetic?

A. Massage candles are understood to be oil that is solidified into a candle shape, which then must be burned to melt again into a liquid oil that can be used for massage.

In general, a massage oil can be classified as a cosmetic only if it has a clear cosmetic function. If it doesn't have a clear cosmetic function, such as oils only intended to reduce friction when massaging the skin, a massage oil cannot be classified as a cosmetic product. It is important to highlight that this applies to all massage products, as clarified in the EU Borderline Products Manual. If the massage oil is classified as a cosmetic, it will have to comply with the cosmetic regulations.

Candles are outside of CTPA remit but are subject to the requirements under the General Product Safety Regulations to place only safe products on the marketplace, and the Consumer Protection Act

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1987. They also may need to fulfil the CLP (Classification, Labelling and Packaging) requirements. It is essential to label the product carefully with appropriate warning statements.

The safety of the product particularly regarding the directions for use and the temperature of the melted candle oil must be taken into consideration if the melted oil is being applied to the skin.

Q. Is a cooling cream or a cooling eye gel a cosmetic?

A. The claim "cooling" itself does not specifically mention a cosmetic property, and therefore this would have to be taken into account with the overall presentation of the product.

If the product contains anti-inflammatory, anti-bacterial or anti-viral ingredients to treat an "adverse condition" it will likely be classified as medicinal. Likewise, even if it does not contain a pharmaceutical ingredient, if the product claims to be able to treat or alleviate a medical condition, this would also be classified as a medical device or medical product.

Q. When would a physiological effect go beyond a cosmetic definition?

A. Cosmetic products may, to some extent, affect the physiology of the tissues to which they have been applied. In the case of products such as antiperspirants, this is how they exert their cosmetic efficacy.

In 2001, the European Commission issued Guidance Document on the demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83. In the document, clarification regarding physiological activity is provided by pointing out that the sentence as a whole must be read whereby a medicinal product is defined as: "*any substance… used or administered… with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological immunological or metabolic action…".* The words 'with a view to' indicate there must be an intent to restore, correct or modify physiological functions through the mechanisms described, not just that such modification may occur as a consequence of the application of the product.

The ASA have guidance and examples of cosmetic claims that have extended beyond more than insignificant physiological effect which can be accessed here.

Q. Would a nipple balm for breastfeeding mothers be a cosmetic, even if it is not removed before feeding and may be ingested by the baby?

A. Firstly, the function of the nipple balm must be cosmetic. If the intention is to sooth or relieve the sore or broken skin after breastfeeding, then the product would likely be classified as a medicine or medical device.

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If the product has a cosmetic function and be classified as a cosmetic, a safety assessment must be carried out. The safety assessor would need to assess if there is a potential issue with the product being accidentally ingested by the baby, and if any specific cautions or instructions for use should be provided to the consumer.

Q. Are claims for "healing" and intensively moisturising very dry itchy skin and eczema allowed for cosmetics?

A. Eczema, psoriasis, dermatitis, rosacea, acne, spots, nappy rashes are all adverse medical conditions. They will generally exhibit as dry, inflamed, scaly and itchy skin or scalp.

Any product claiming to treat or prevent eczema, psoriasis, rosacea or other types of dermatitis, or their symptoms, will not be considered cosmetics; they will be regarded as medicinal products. However, it is recognised that consumers suffering from one of these adverse conditions may wish to know whether the product is appropriate for them to use. Which means that companies can communicate that the product would not make a condition worse, without implying that it would exacerbate it. Where the overall presentation of a product is clearly intended for a cosmetic function, the MHRA and CTPA have aligned on a specific claim that companies can use to communicate exactly this, which is: '*Also suitable for people who may be prone to eczema*' or other adverse skin conditions.

It is important to highlight that a claim specifically targeting consumers with adverse skin conditions who may therefore expect the products to treat, prevent or at least soothe the symptoms of adverse conditions would be considered a medicinal claim and the product would be regarded as a medicine. An example of this is the claim 'for eczema-prone skin'. More information can be found in the CTPA Guide on Eczema Claims.

Q. Can a moisturiser have claims surrounding leaving the skin feeling less irritated and calmer, and reducing the appearance of redness be used for cosmetics?

A. Redness, in the view of the MHRA, may be a sign or consequence of skin damage or irritation, which are considered adverse skin conditions and are also related to adverse conditions. Therefore, products claiming to calm or relieve from redness or irritation would likely be considered medicines.

However, claims such as 'helps prevent redness/itchiness associated with dry skin' may, in context, be considered cosmetic, as long as a product has a clear cosmetic function and overall presentation - so this claim would communicate on the secondary preventative benefit of a cosmetic.

Q. Can claims for soothing and reducing inflammation be used as secondary claims for cosmetics?

A. According to the MHRA Guidance Note 8, references to treatment or alleviation of adverse conditions including reducing inflammation are likely medicinal claims.

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