

CTPA Decision Tree for Borderline Assessment

January 2023

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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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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Introduction

Products must be correctly classified before being placed on the market. Article 2 of the UK Cosmetics Regulation (UKCR) and EU Cosmetic Products Regulation (CPR) includes the legal definition of a cosmetic product. However, it may sometimes be unclear whether a product is a cosmetic and therefore falls under the scope of the UKCR or CPR, depending on the market where the product is sold.

If a product is not a cosmetic, it may fall under another regulatory regime such as that for foods, biocides or general product safety. However, care must be taken to ensure that what is, at first sight, a cosmetic does not become another product type by virtue of its presentation, its claims or its composition.

The legal framework for cosmetics sets boundaries for product classification with regards to other legislations, giving origin to the terminology of cosmetic borderlines. "Borderlines" are not a product classification in itself, as a product must be classified under the legislation for the appropriate product type. However, it is a common way of describing products where classification is not readily apparent, and where a given product could be, intentionally or unintentionally, classified as one or more product type.

Borderline products, therefore, denote those products which require a careful assessment for classification. There are a lot of possible borderlines for cosmetics: medicines (including traditional herbal medicines), biocides, medical devices, toys, food or general products. Borderline products are those that require further examination for classification, due to their composition and/or their overall presentation and claims, but a classification decision must ultimately be taken.

A company that classifies and markets a product incorrectly may face enforcement actions by UK competent authorities.

This document is intended to provide companies with clarity on the process to product classification.

Legal Definitions

Article 2 of the UK and EU Cosmetics Regulations outline the legal definition of a cosmetic product:

*"cosmetic product shall mean any **substance or mixture** intended to be placed in contact with the various **external parts of the human body** (skin, hair, 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 **clean, perfume, change the appearance, correct body odours, protect or keep in good condition**"*

Article 3 of the UK Biocidal Products Regulation outlines the legal definition of a biocide.

*"any **substance or mixture**, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of **destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action**"*

Article 1 of the UK The Human Medicines Regulations 2012 outlines the legal definition of a medicinal product:

- *"Any **substance or combination of substances** presented as having properties for **treating or preventing disease in human beings**;*
- *Any **substance or combination of substances** which may be used in, or administered to, human beings, either with a view to **restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.***

STEP 1: 5 Key Questions

The first step in the classification process is determining if the product and its intended use fulfils the criteria established in the cosmetic product definition. To help in this determination, the following key questions can be used as a guide:

QUESTION	PRODUCT
Is the product a substance or mixture?	
What is the site of application? ¹	
What is the function of the product? ²	
Is the product formulated according to the requirements of the UK cosmetics regulation? ³	
Does the product look like a cosmetic?	

¹ The UKCR includes the following sites of application for cosmetic products: (skin, hair, nails, lips, oral cavity, teeth, external genital organs)

² The UKCR considers the following functions as pertaining to cosmetics: clean, perfume, change the appearance, correct body odours, protect or keep in good condition

³ It possible to classify the product based on the presence ingredients which could have a medicinal effect (by pharmacological, immunological or metabolic action) even in the absence of medicinal-type claims, and where the ingredient licensed for medicinal purposes and has no cosmetic function

If all criteria are met, the product may be reasonably classed as a cosmetic. However, where there are further considerations, such as claims which may introduce additional non-cosmetic characteristics or functions, a more in-depth assessment may be required.

STEP 2: List of Product Claims and Context for Borderline Assessment

The primary function of a cosmetic must fit within the cosmetic definition. Primary or secondary claims may change the classification of the product by presenting to the consumer a claim that could be interpreted outside of the scope of the cosmetic definition. A cosmetic product may have a secondary preventative, but not curative function however this needs to be interpreted with a degree of caution. Secondary non-cosmetic claims may be allowed in certain instances, but these should be taken into context and indeed, remain secondary and not supersede the cosmetic definition.

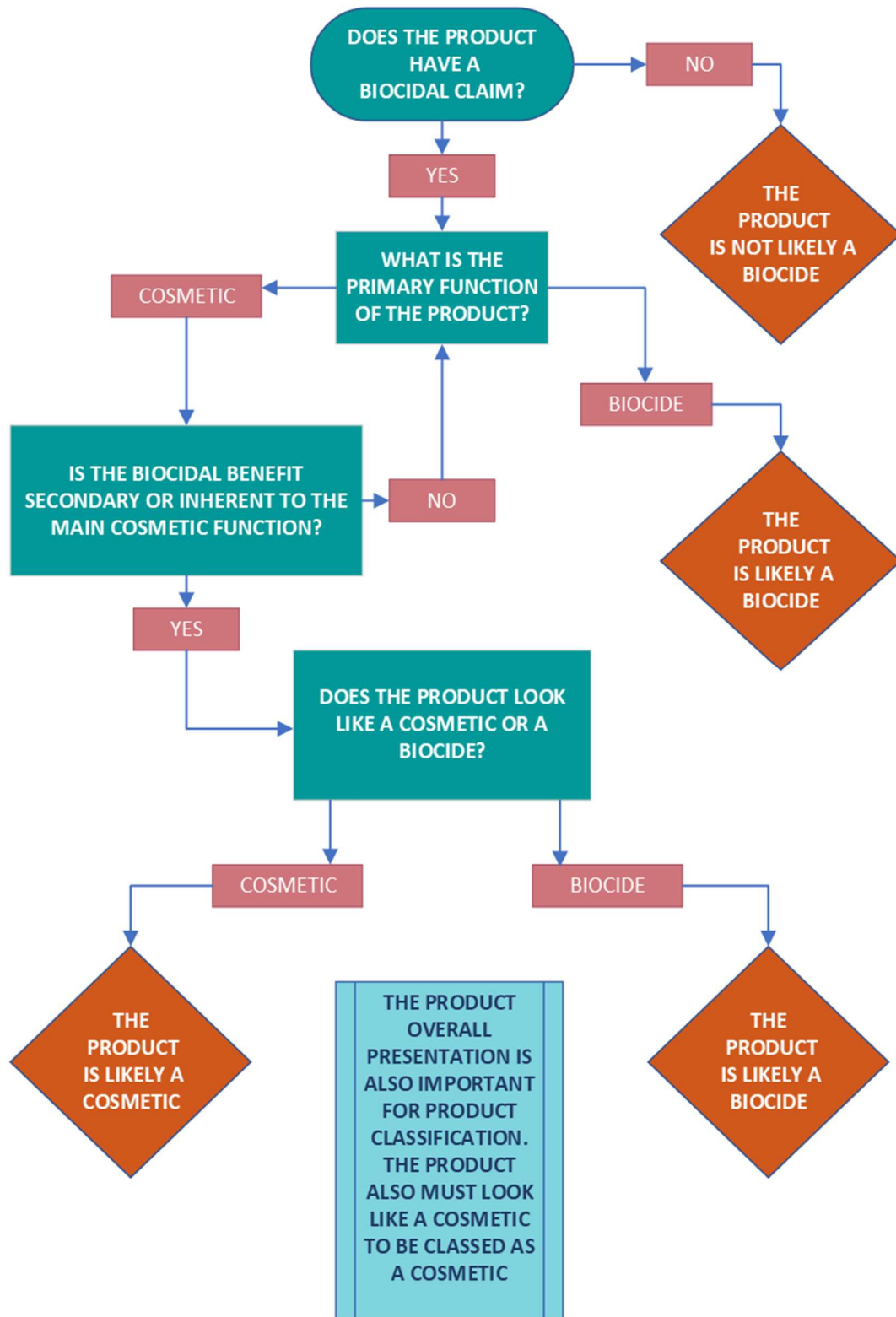
To conduct the assessment, we recommend listing all the claims, whether text or visual representation, that may have an implication on the product classification. For example, “moisturising” might not be relevant for this section, but “antibacterial” or a sentence with the word “eczema” would likely require a careful evaluation.

STEP 3: Use of the Appropriate Decision Tree

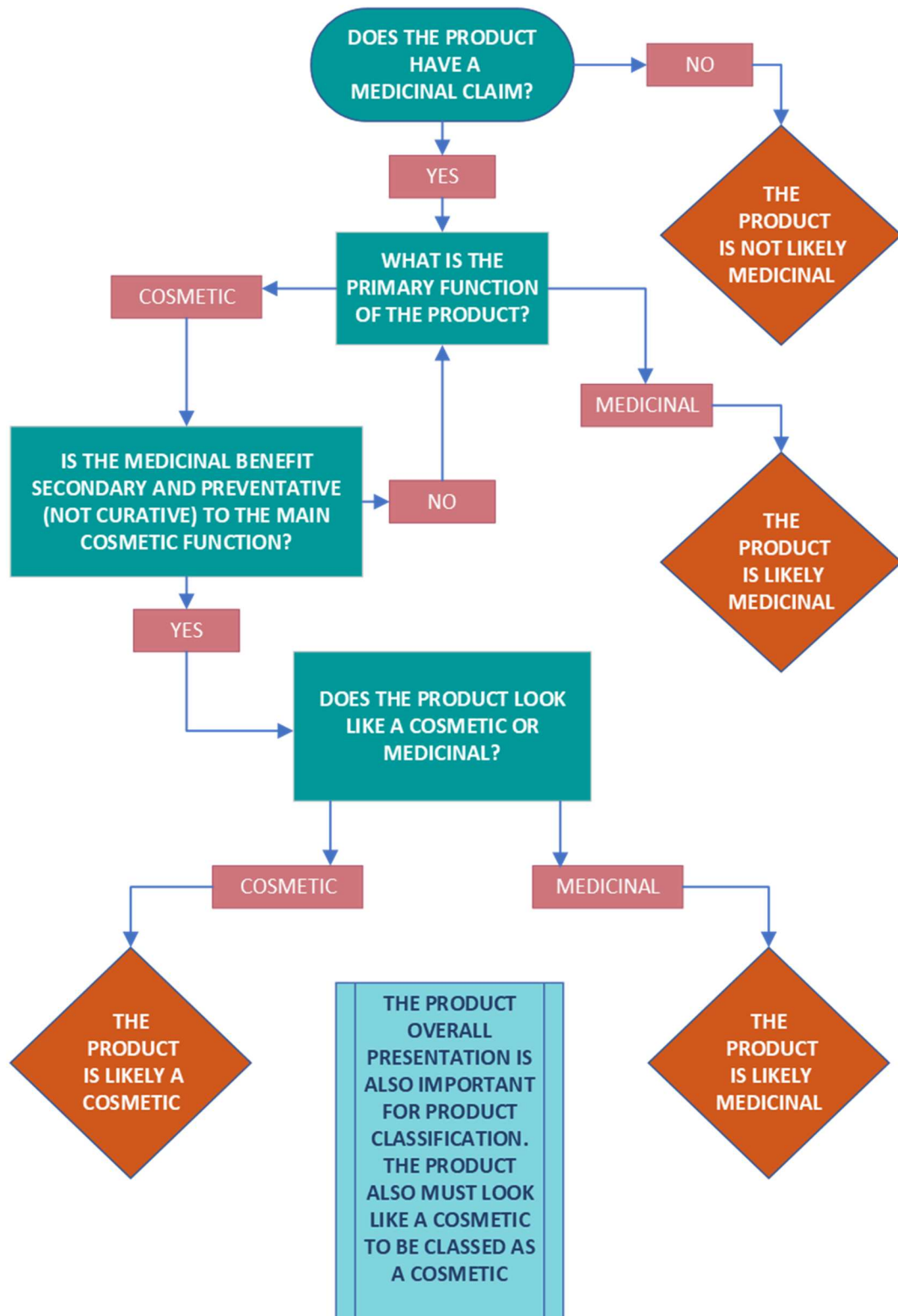
CTPA has created two decision trees to facilitate in the evaluation and decision-making processes: one for biocidal products and one for medicinal products.

Please note that these decision trees are intended as guidance only, and do not constitute a formal classification decision. They are intended to provide a likely outcome of the process, but the final determination will require all the information about the product and must be done on a case-by-case basis. Ultimately, the Competent Authorities responsible for the product classifications will have final say and have the powers to act should an incorrect classification been reached.

Borderline with Biocides Assessment Decision Tree



Borderline with Medicines Assessment Decision Tree



Biocide Decision Tree – Example 1

5 Key Questions

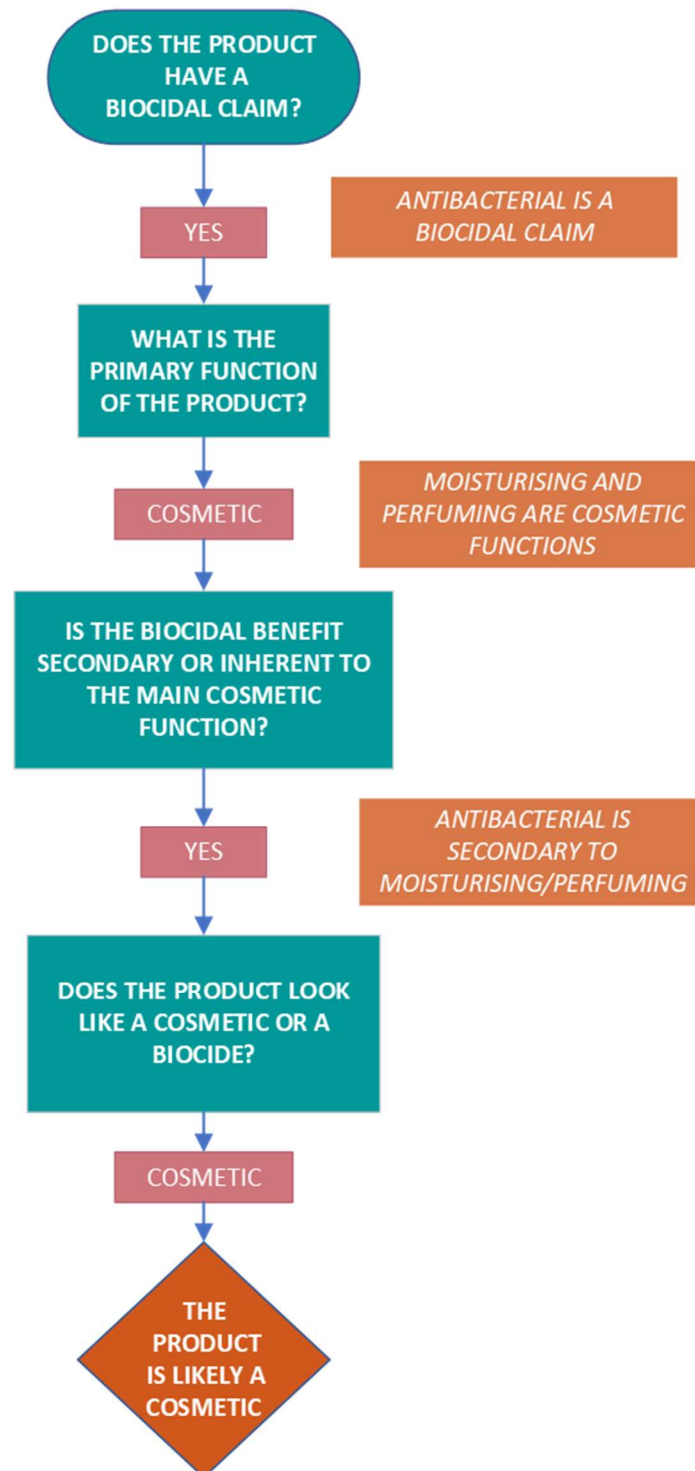
QUESTION	PRODUCT
Is the product a substance or mixture?	Mixture
What is the site of application? ¹	Hands
What is the function of the product? ²	Hand soap
Is the product formulated according to the requirements of the UK cosmetics regulation? ³	Yes
Does the product look like a cosmetic?	Yes

If all criteria are met, the product may be classed as a cosmetic.

List of Product Claims for Borderline Assessment:

1. Moisturises hands
2. Antibacterial
3. Hands feel refreshed
4. Lemon scent

Biocide Decision Tree – Example 1



Biocide Decision Tree – Example 2

5 Key Questions

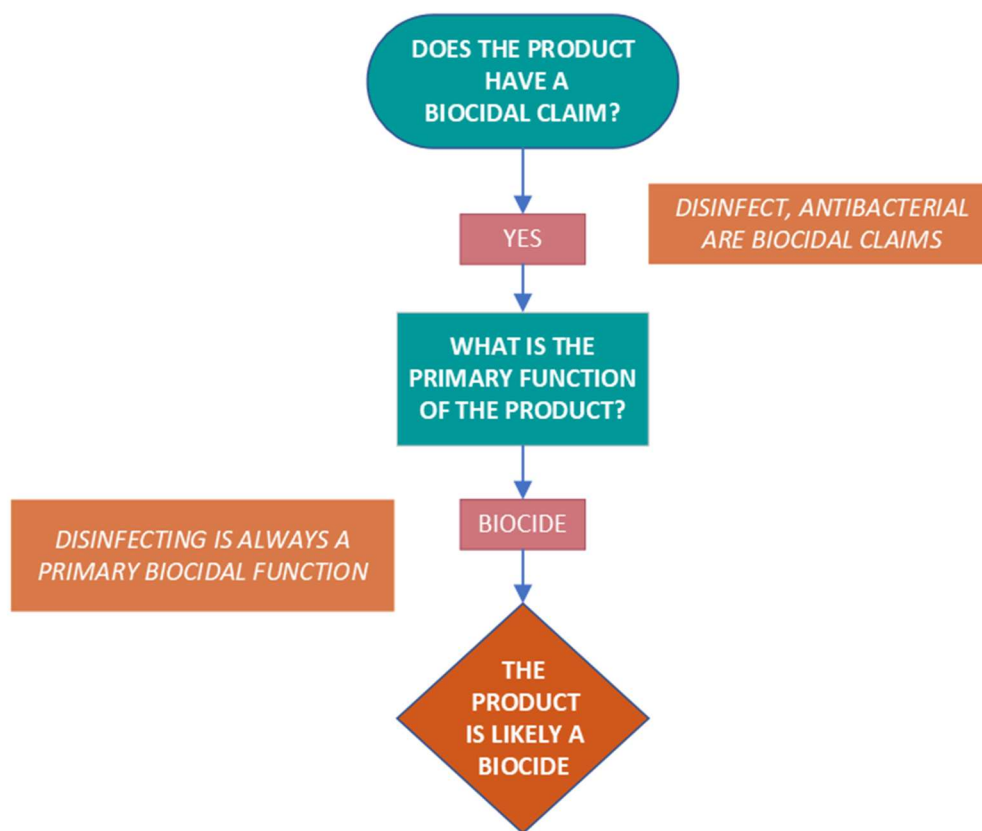
QUESTION	PRODUCT
Is the product a substance or mixture?	Mixture
What is the site of application? ¹	Hands
What is the function of the product? ²	Hand soap
Is the product formulated according to the requirements of the UK cosmetics regulation? ³	Yes
Does the product look like a cosmetic?	Yes

If all criteria are met, the product may be classed as a cosmetic.

List of Product Claims for Borderline Assessment:

1. Disinfects hands
2. Moisturising
3. Antibacterial
4. Hands feel refreshed
5. Lemon scented

Biocide Decision Tree – Example 2



Biocide Decision Tree – Example 3

5 Key Questions

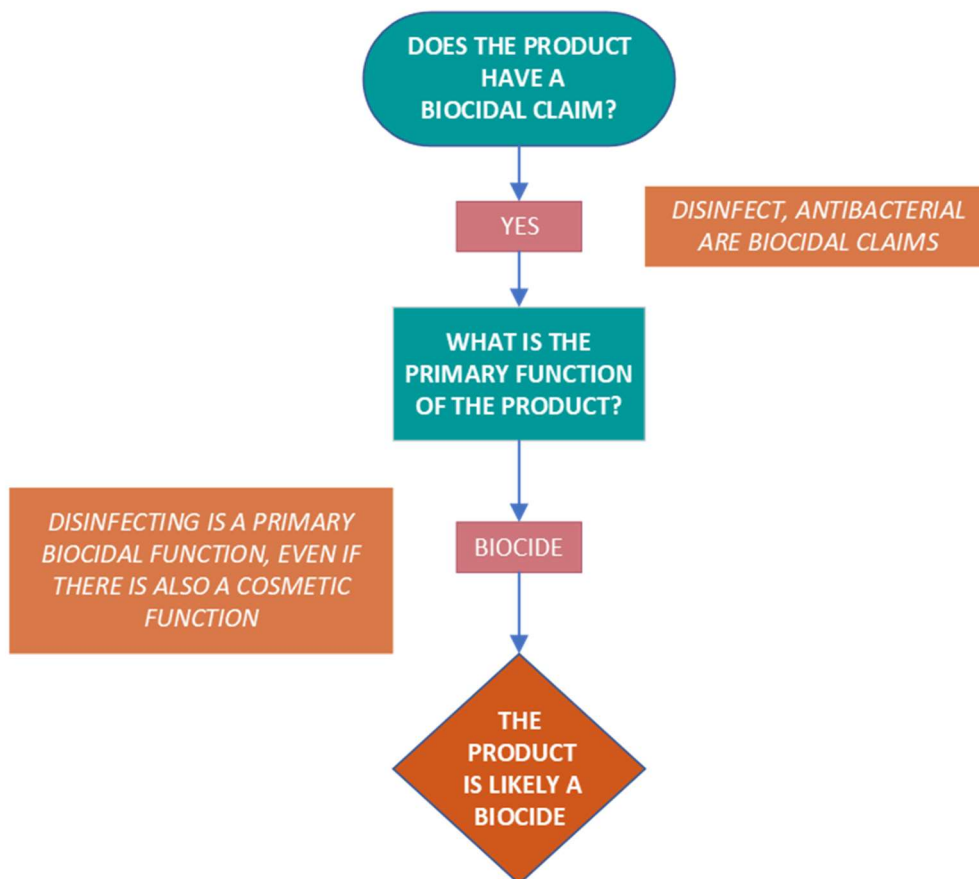
QUESTION	PRODUCT
Is the product a substance or mixture?	Mixture
What is the site of application? ¹	Hands
What is the function of the product? ²	Hand soap
Is the product formulated according to the requirements of the UK cosmetics regulation? ³	Yes
Does the product look like a cosmetic?	Yes

If all criteria are met, the product may be classed as a cosmetic.

List of Product Claims for Borderline Assessment:

1. Moisturising
2. Refreshing
3. Disinfectant
4. Antibacterial
5. Lemon scented

Biocide Decision Tree – Example 3



Medicine Decision Tree – Example 1

5 Key Questions

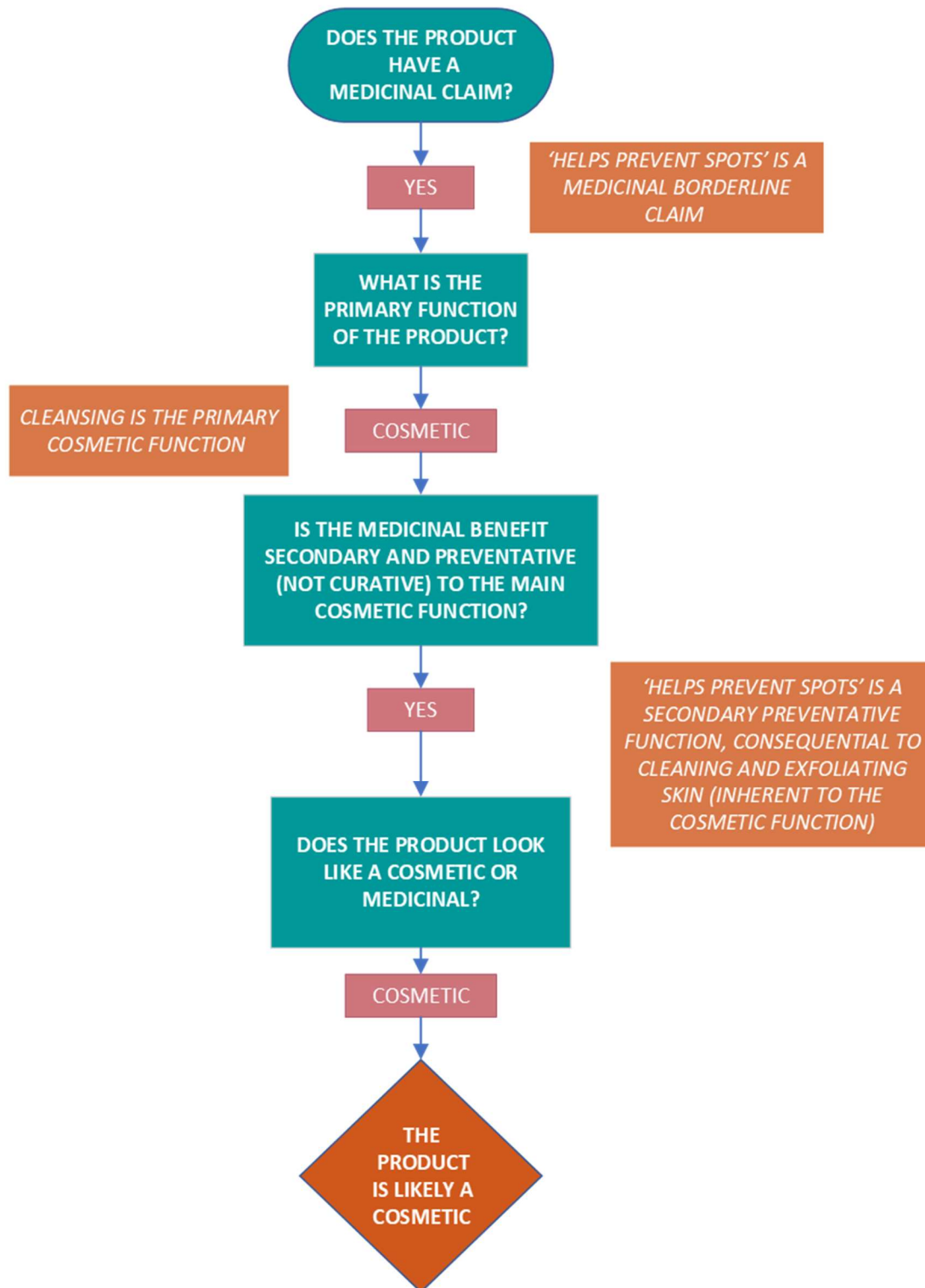
QUESTION	PRODUCT
Is the product a substance or mixture?	Mixture
What is the site of application? ¹	Face
What is the function of the product? ²	Facial cleanser
Is the product formulated according to the requirements of the UK cosmetics regulation? ³	Yes
Does the product look like a cosmetic?	Yes

If all criteria are met, the product may be classed as a cosmetic.

List of Product Claims for Borderline Assessment:

1. Cleanses skin
2. Exfoliates
3. Help prevent spots
4. For all skin types

Medicine Decision Tree – Example 1



Medicine Decision Tree – Example 2

5 Key Questions

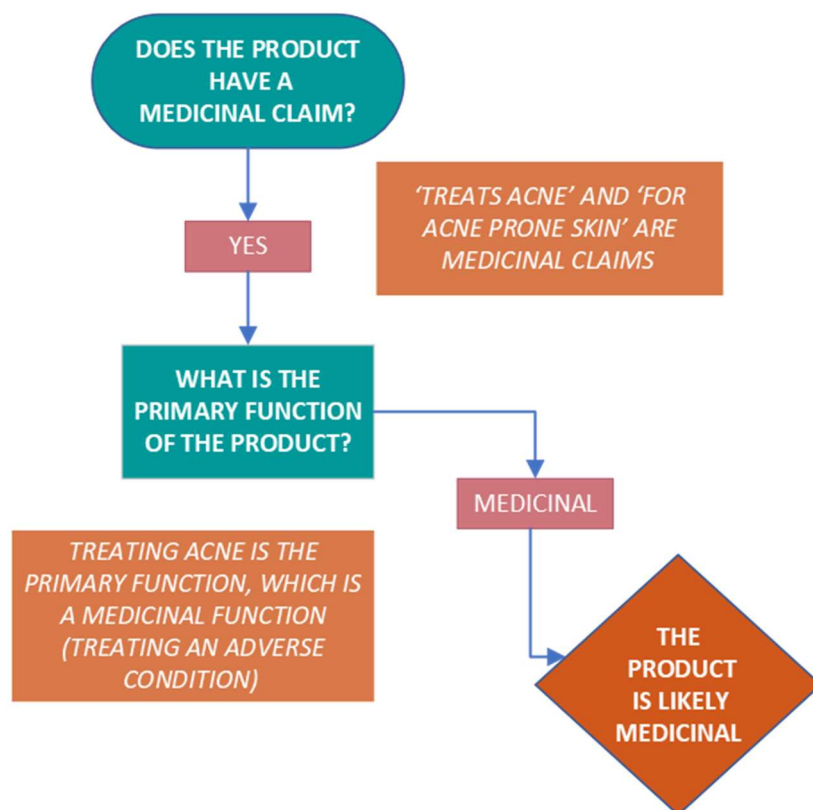
QUESTION	PRODUCT
Is the product a substance or mixture?	Mixture
What is the site of application? ¹	Face
What is the function of the product? ²	Facial moisturiser
Is the product formulated according to the requirements of the UK cosmetics regulation? ³	Yes
Does the product look like a cosmetic?	Yes

If all criteria are met, the product may be classed as a cosmetic.

List of Product Claims for Borderline Assessment:

1. Moisturises skin
2. Softens skin
3. Treats acne
4. For acne prone skin

Medicine Decision Tree – Example 2



Medicine Decision Tree – Example 3

5 Key Questions

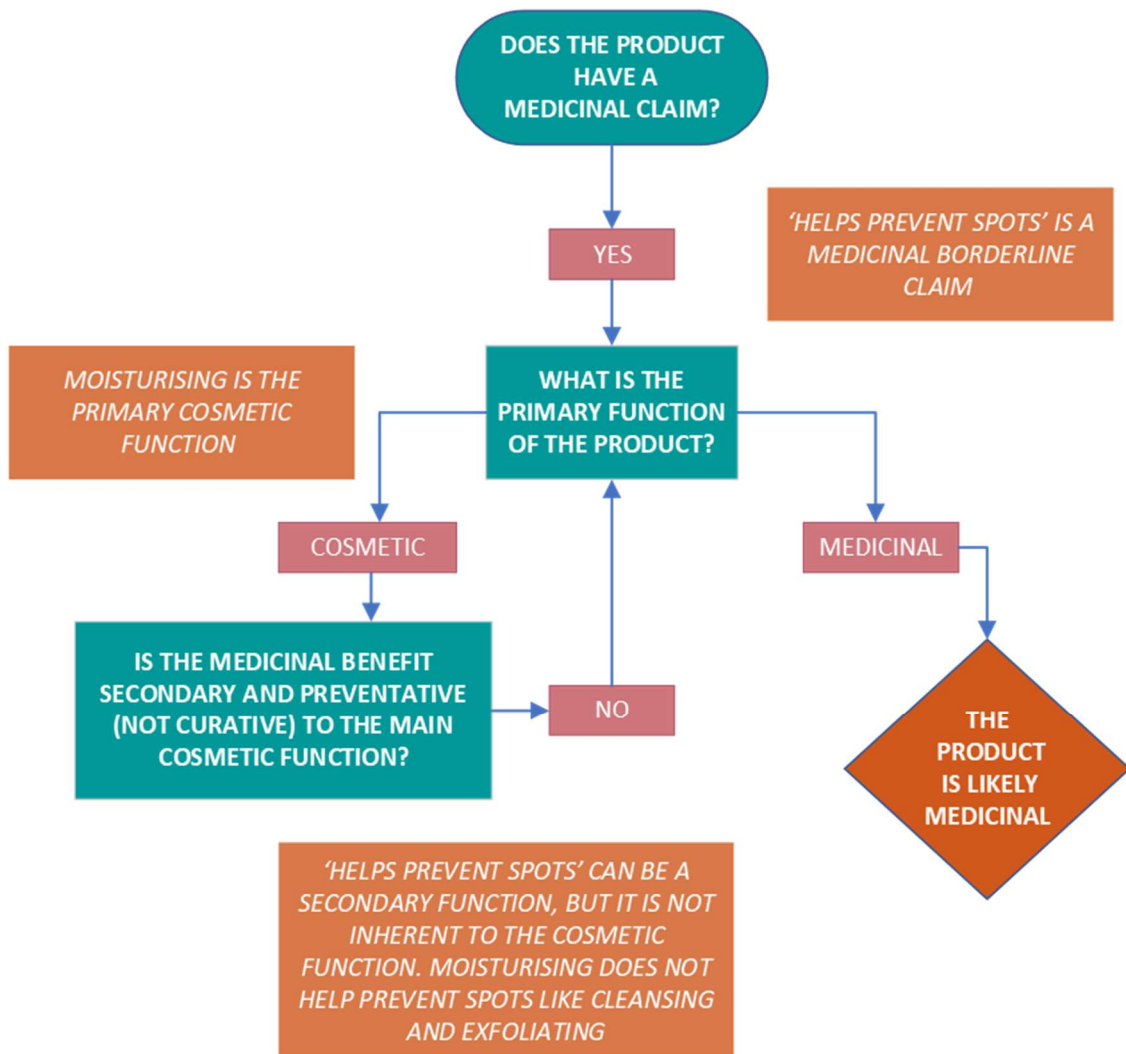
QUESTION	PRODUCT
Is the product a substance or mixture?	Mixture
What is the site of application? ¹	Face
What is the function of the product? ²	Facial moisturiser
Is the product formulated according to the requirements of the UK cosmetics regulation? ³	Yes
Does the product look like a cosmetic?	Yes

If all criteria are met, the product may be classed as a cosmetic.

List of Product Claims for Borderline Assessment:

1. Moisturises skin
2. Softens skin
3. Helps prevent spots
4. For all skin types

Medicine Decision Tree – Example 3



Medicine Decision Tree – Example 4

5 Key Questions

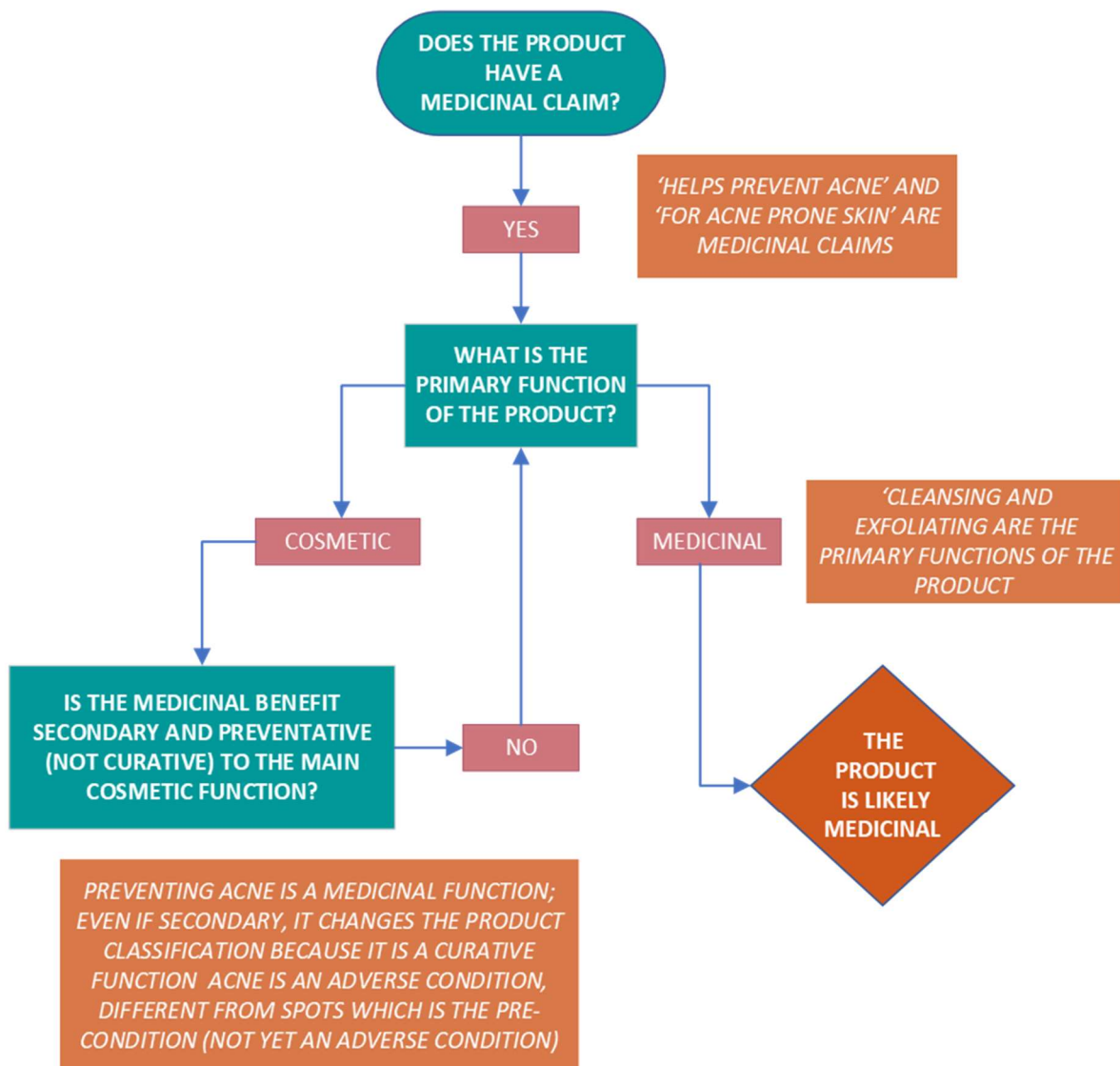
QUESTION	PRODUCT
Is the product a substance or mixture?	Mixture
What is the site of application? ¹	Face
What is the function of the product? ²	Facial cleanser
Is the product formulated according to the requirements of the UK cosmetics regulation? ³	Yes
Does the product look like a cosmetic?	Yes

If all criteria are met, the product may be classed as a cosmetic.

List of Product Claims for Borderline Assessment:

1. Cleanses skin
2. Exfoliates skin
3. Helps prevent acne
4. For acne prone skin

Medicine Decision Tree – Example 4



Other Resources

CTPA has specific resources on this topic. Members can access the [Borderlines Reference Zone](#) for further information.

There is also information on borderlines available for non-members [here](#).

Members can access all CTPA information on claims including guidance documents, Reference Zone pages, webinars and decision trees in the [Cosmetic Claims Resource Inventory](#).

There is also information on claims and guidance documents available for non-members [here](#).

The Medicines and Healthcare products Regulatory Agency (MHRA) is the regulator and enforcement body for medicinal products and medical devices. The MHRA has extensive guidance on product classification in [Guidance Note 8](#).

The Health and Safety Executive (HSE) is the regulator and enforcement body for biocidal products.

