

CTPA Tool for Claim Substantiation

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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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Introduction

This CTPA tool has been created to help companies build their approach to claim substantiation following the principles of the [building blocks of claim support](#), putting industry best practice into application in relation to the review, examination and rationalisation of claim substantiation.

The CTPA Claim Substantiation Tool takes into account the factors that have to be considered when building robust claim substantiation. While the columns represent a step-by-step approach, they should not be taken in isolation. There must be a clear connection between the rationale, the evidence and each of the following factors: the wording and context of the claim, and how the consumer perceives or understands the claim.

Companies can:

- use the Tool for each claim made on a specific product, whether they are featured on product labels, online, advertising, etc.;
- use the Tool to guide the thought process to ensure claims are robustly substantiated;
- use the Tool to ensure all key factors are taken into consideration for claim substantiation, including the context in which the claim is made and the expected understanding of the reasonably well informed, reasonably observant and circumspect consumer;
- use the Tool to guide compilation of the claim support dossier that must be part of the Product Information File (PIF) as per Article 11 of the UK Cosmetics Regulation.

This resource is not intended to introduce mandatory requirements or to replace individual company practices. Companies with an internal template in place to support the claim substantiation process may, however, use the CTPA Claim Substantiation Tool to ensure that these include all relevant considerations as per industry best practice.

By using the tool's suggested thought process for claim substantiation, companies will be able to ensure that the evidence/data is presented in the best possible way within the Product Information File and is readily available in the event of an external investigation from regulators or relevant stakeholders in claims and advertising.

The correct application of the tool will not guarantee that the claim will be sufficiently substantiated or be accepted by regulators and stakeholders but will enable companies to present the information in the best possible way in order to showcase the available substantiation in place.

CTPA Tool for Claim Substantiation

CLAIM MADE AND CONTEXT	CONSUMER EXPECTATION OF THE CLAIM ¹	CLASS OF CLAIM ²	LEVEL OF SUBSTANTIATION EXPECTED ³	TYPE OF SUPPORTING INFORMATION		
				FORMULA RATIONALE	LITERATURE INFORMATION	TESTING- BASED EVIDENCE
Include the exact wording of the claim or the description of the visual representation (logo, images, etc.) alongside the information on how it has been presented. Include information such as where the claim is being made (product label, printed ad,) and provide the context in which the claim is made (e.g. any image/ visual, model used, symbols, etc.).	Evaluate and explain the expected consumer understanding of the claim, taking into account the context in which the claim is made.	Define the class of the claim as per the available list of classes of claims.	Determine the level of substantiation required for the claim. Assess and decide which amount of data/tests or combination of data/tests might be required to fully substantiate the claim. There should be a correct balance between qualitative and quantitative data appropriate to the claim.	Explain how the product, formulation or combination of ingredients contribute to delivering the claimed benefit.	Collate the information from literature reviews and scientific papers that help build up the support for the claim made.	Provide a summary of the test(s) performed to substantiate the claimed benefit including the overview of the test methodology as well as the results obtained. The test methodology must reflect the directions for use as well as real use conditions of the product, as related to the claim, context and targeted consumer.
NARRATIVE LINKING THE AVAILABLE SUBSTANTIATION TO THE CLAIM MADE	Connect all the information from the previous steps and build the narrative that overall substantiates the claim made. Any data will need to be assessed for relevance against the target consumer expected lifestyle.					

¹ Consumer research can be conducted to gather insight on what the consumer expectation of the claim is based on the wording, to help determine the relevance of the claim for the targeted audience. However, this data might not be representative of the views of the average well-informed consumer and therefore may not be suitable to justify consumer expectation of the claim.

² Class of claims include sensory/aesthetic claim, performance claims, ingredient claims, product aesthetics claims, combination claim and comparison claim; as explained in the [CTPA Guide to Advertising Claims](#), Part 2, Section 3 – Nature of a Claim

³ Level of evidence for supporting claims include: claims widely accepted to be established; claims with established rationale but requiring product of ingredient specific evidence; and claims that are based upon a significant advance in science or technology, as explained in the [CTPA Guide to Advertising Claims](#), Part 2, Section 2 – Supporting information.

Practical examples

The following tables provide examples of how the CTPA Claims Substantiation Tool can be used in practice. The given examples have been provided with different wording or context for the same claim to highlight different levels of substantiation and different ways of substantiating, and how the tool remains applicable and highlights the evidence provided.

Please note the proposed ways in which the following examples have been substantiated are not prescriptive and do not represent agreed industry best practice. Claims and claim substantiation can only be assessed on a case-by-case basis, taking into account the wording and context in which the claim is made. It is the responsibility of the Responsible Person to ensure the right substantiation is in place for the claims made. The below examples shall not be taken as an agreed way of substantiating the claims used, but as a way to portray the use and practical application of the CTPA Claim Substantiation Tool.

Examples for general performance claims

CLAIM MADE AND CONTEXT	CONSUMER EXPECTATION OF THE CLAIM	CLASS OF CLAIM	LEVEL OF SUBSTANTIATION EXPECTED	TYPE OF SUPPORTING INFORMATION		
				FORMULA RATIONALE	LITERATURE INFORMATION	TESTING BASED EVIDENCE
Moisturising (1) Product is displayed with this claim on front of pack, no significant accompanying visuals. (2) Product is a leave-on day cream	Skin is moisturised	Performance claim	Widely accepted	<p>The formulation is a competently formulated⁴ leave-on product with a blend of ingredients known to improve/remove skin dryness (see literature information) for moisturisation.</p>	<p>Literature shows that the skin can lose moisture, environmental effects (low humidity, cold temperature, UV incidence), or low water intake, and therefore become visibly dry and taut. There are several ways to improve/remove skin dryness, which are generally accepted to be provided for by the inclusion on ingredients to:</p> <ul style="list-style-type: none"> - Temporarily reinforce the skin barrier with intercellular lipids, (e.g., ceramides) - Coat the skin with a protective seal (e.g., glycerin emollient) - Add extra moisture-holding ingredients into the skin (e.g., hyaluronic acid) <p>Here, the correct literature proving the assumptions made with regards to moisture levels on the skin, as well as the suggested properties of the ingredients in the formulation should be summarised and cited.</p>	<p>The claim has been regarded as widely accepted and therefore testing evidence may not be required, provided there is sufficient evidence from formula rationale and literature information.</p>
NARRATIVE LINKING THE AVAILABLE SUBSTANTIATION TO THE CLAIM MADE		<p>The claim is an inherent benefit of the formulation type (leave-on cream), therefore able to be substantiated by the formula rationale and ingredient selection at demonstrably functional levels, as well as literature review. As the claim is widely accepted, it does not need further substantiation to meet the requirements and the consumer expectation.</p>				

⁴ A competently formulated product has been purposefully designed and formulated with the understanding that the formulation is expected to deliver the claimed benefit when used as instructed.

CLAIM MADE AND CONTEXT	CONSUMER EXPECTATION OF THE CLAIM	CLASS OF CLAIM	LEVEL OF SUBSTANTIATION EXPECTED	TYPE OF SUPPORTING INFORMATION		
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<p>“Your skin will feel moisturised”</p> <p>(1) Product is displayed with this claim on front of pack, alongside a visual of running water.</p> <p>(2) Product is a rinse-off day product</p>	Skin will feel more moisturised after use	Performance claim	Established rationale but requiring specific product or ingredient evidence due to the nature of the product and intended method for use.	The formulation is a competently formulated rinse-off product with a blend of ingredients for short-term moisturisation.	<p>Literature shows that the skin can lose moisture through an impaired skin barrier, environmental effects (low humidity, cold temperature, UV incidence), or low water intake, and therefore become visibly dry and taut. There are several ways to improve/remove skin dryness, which are generally accepted to be provided for by the inclusion on ingredients to:</p> <ul style="list-style-type: none"> - Reinforce the skin barrier with intercellular lipids, (e.g., ceramides) - Coat the skin with a protective seal (e.g., glycerin emollient) - Add extra moisture-holding ingredients into the skin (e.g., hyaluronic acid) <p>Here, the correct literature proving the assumptions made with regards to moisture levels on the skin, as well as the suggested properties of the ingredients in the formulation should be summarised and cited.</p>	Consumer use test on a relevant number of panellists. Agreement with question assessed for consumer noticeability and relevance by achieving positive agreement for skin feeling and looking moisturised, and statistical significance ($P < 0.05$) is determined using relevant methods, at a time point in line with directions for use/ expected duration of use.
NARRATIVE LINKING THE AVAILABLE SUBSTANTIATION TO THE CLAIM MADE		The claim is not an automatic inherent benefit of the formulation type (it is a rinse-off product), and it is therefore not widely accepted for this type of formulation. Despite having a strong formula rationale and widely accepted ingredient selection, as well as literature information, the claim needs a higher level of substantiation from consumer use test and because the claim is worded in a subjective way (skin feels moisturised).				

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<p>“Moisturises for 24 hours”</p> <p>(1) Product is displayed with this claim on front of pack with a visual of a running clock, with prominent “24h” in the centre.</p> <p>(2) Product is a leave-on product intended for day use.</p>	Skin will feel moisturised, even after 24 hours of normal activity.	Performance claim	Established rationale but requiring specific product or ingredient evidence	<p>The formulation is a competently formulated leave-on product with a blend of ingredients known to improve/remove skin dryness (see literature information) for both short-term and long term (at least 24 hours) moisturisation</p>	<p>Literature shows that the skin can lose moisture through an impaired skin barrier, environmental effects (low humidity, cold temperature, UV incidence), or low water intake, and therefore become visibly dry and taut. There are several ways to improve/remove skin dryness, which are generally accepted to be provided for by the inclusion on ingredients to:</p> <ul style="list-style-type: none"> - Reinforce the skin barrier with intercellular lipids, (e.g., ceramides) - Coat the skin with a protective seal (e.g., glycerin emollient) - Add extra moisture-holding ingredients into the skin (e.g., hyaluronic acid) <p>Here, the correct literature proving the assumptions made with regards to moisture levels on the skin, as well as the suggested properties of the ingredients in the formulation should be summarised and cited.</p>	<p>Instrumental test on a relevant number of panellists using corneometer / DPM on relevant target site, with agreement with statistically significant (P<0.05) increase in measures vs control after 24 hours.</p>
NARRATIVE LINKING THE AVAILABLE SUBSTANTIATION TO THE CLAIM MADE		The moisturising benefit is inherent of the formulation type. Therefore, a strong the formula rationale and widely accepted ingredient selection, as well as literature information, can substantiate this attribute. However, the claim needs a higher level of substantiation as it calls out a specific time point in relation to the duration of the effect. Specific substantiation is needed to demonstrate that the product leaves skin moisturised over the period of 24 hours; in this example, the time reference is substantiated by an instrumental test performed over 24 hours.				

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<p>“Clinically proven moisturisation”</p> <p>(1) Product is displayed with this claim on front of pack, with no direct visual references.</p> <p>(2) It is a leave-on product</p>	Skin will feel significantly more moisturised, as well as that the product has undergone a more specific testing regime	Performance claim	Established rationale but requiring specific product or ingredient evidence	<p>The formulation is a competently formulated leave-on product with a blend of ingredients known to improve/remove skin dryness (see literature information) for both short-term and long term</p>	<p>Literature shows that the skin can lose moisture through an impaired skin barrier, environmental effects (low humidity, cold temperature, UV incidence), or low water intake, and therefore become visibly dry and taut. There are several ways to improve/remove skin dryness, which are generally accepted to be provided for by the inclusion on ingredients to:</p> <ul style="list-style-type: none"> - Reinforce the skin barrier with intercellular lipids, (e.g., ceramides) - Coat the skin with a protective seal (e.g., glycerin emollient) - Add extra moisture-holding ingredients into the skin (e.g., hyaluronic acid) <p>Here, the correct literature proving the assumptions made with regards to moisture levels on the skin, as well as the suggested properties of the ingredients in the formulation should be summarised and cited.</p>	<p>Expert grading study in a clinical setting with trained expert(s) oversight of a panel of subjects representative of the target consumer, with:</p> <ul style="list-style-type: none"> - validated and reproducible assessment method (expert grading /instrumental) - high repeatability (>80%) through repeat scoring - statistically significant benefits from baseline and versus a control group, with a consumer relevant/noticeable magnitude of change
NARRATIVE LINKING THE AVAILABLE SUBSTANTIATION TO THE CLAIM MADE		<p>The moisturising benefit is inherent of the formulation type. Therefore, a strong the formula rationale and widely accepted ingredient selection, as well as literature information, can substantiate this attribute. However, the claim needs a higher level of substantiation as it calls out a specific way in which the moisturising benefit was investigated (clinically proven). Specific substantiation is needed to demonstrate that the product was tested in the specifically claimed conditions, under the supervision of a relevant and appropriate clinical expert.</p>				

Examples for ingredient claims

CLAIM MADE AND CONTEXT	CONSUMER EXPECTATION OF THE CLAIM	CLASS OF CLAIM	LEVEL OF SUBSTANTIATION EXPECTED	TYPE OF SUPPORTING INFORMATION		
				FORMULA RATIONALE	LITERATURE INFORMATION	TESTING BASED EVIDENCE
With ingredient X, where there is no well-known implied benefit (e.g. hand wash with banana extract)	The consumer would expect the product to contain that ingredient, and the product to have certain sensory characteristics related to the ingredient (e.g. banana smell)	Ingredient claim	Widely accepted	The ingredient is deliberately added and declared in the INCI	There is no obvious or implied claim through claiming the inclusion of an ingredient. No further substantiation required	There is no obvious or implied claim through claiming the inclusion of an ingredient. No further substantiation required
NARRATIVE LINKING THE AVAILABLE SUBSTANTIATION TO THE CLAIM MADE		The claim only states that the product contains a specific ingredient, without relating to any specific benefit. Demonstrating that the ingredient is included in the formulation and can be identified in the INCI list is enough.				
With ingredient X, where there is a well-known implied benefit or it is explicitly called out (e.g. known to do A, B, C/helps to do A, B, C)	The consumer would expect the product to contain that ingredient and to identify it in the ingredients list. The consumer would also expect the product to deliver benefits A, B, C with the ingredient partially contributing to the full effect	Ingredient claim	Established rationale but requiring specific product or ingredient evidence	The ingredient is deliberately added and declared in the INCI	Literature information and raw material supplier information to demonstrate that the ingredient is widely known to have the claimed benefits	Perform a consumer use test or an instrumental test (as relevant) to demonstrate that the product delivers benefits A, B, C
NARRATIVE LINKING THE AVAILABLE SUBSTANTIATION TO THE CLAIM MADE		The claim states that the product contains a specific ingredient, which is known to or partly contributing to provide specific benefits. The explicit benefit, as well as the implied benefit that the consumer would understand are substantiated by a combination of evidence from formula rationale, literature information, as well as testing on the finished product.				

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With ingredient X to do A, B, C	The consumer would expect the product to contain that ingredient and to identify it in the ingredients list. The consumer would also expect the product to deliver benefits A, B, C entirely because of the presence of ingredient X.	Ingredient claim linked to a specific performance	Established rationale but requiring specific product or ingredient evidence	The ingredient is deliberately added and declared in the INCI	Literature information and raw material supplier information to demonstrate that the ingredient delivers the claimed benefits	Perform a consumer use test or an instrumental test (as relevant) to demonstrate that the product with ingredient X delivers benefits A, B, C vs the same product without ingredient X does not deliver A, B, C
NARRATIVE LINKING THE AVAILABLE SUBSTANTIATION TO THE CLAIM MADE		The claim states that the product contains a specific ingredient, which is entirely contributing to provide specific benefits. The must be substantiated by a combination of evidence from formula rationale, literature information, as well as testing on the finished product with and without the claimed ingredient, to demonstrate that it is exactly the claimed ingredient that delivers the benefits.				
Our formula, with ingredient X, does A, B, C	The consumer would expect the product to contain that ingredient and to identify it in the ingredients list. The presence of the ingredient is disconnected from the benefits, which are claimed in relation to the final formula.	Ingredient claim	Established rationale but requiring specific product or ingredient evidence	The ingredient is deliberately added and declared in INCI. The combination of ingredients can also support that the formula delivers benefits A, B, C	Literature information demonstrating that the formula containing a combination of ingredients provides benefits A, B, C	Perform a consumer use test or an instrumental test (as relevant) to demonstrate that the product delivers benefits A, B, C
NARRATIVE LINKING THE AVAILABLE SUBSTANTIATION TO THE CLAIM MADE		The claim states that the product contains a specific ingredient, which is known to or partly contributing to provide specific benefits. The explicit benefit, as well as the implied benefit that the consumer would understand are substantiated by a combination of evidence from formula rationale, literature information, as well as testing on the finished product.				

Other resources

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](#).

For claims referring to the absence of an ingredient (e.g. free from, without, 0%, no added, no, etc.), CTPA has published specific resources including the [CTPA Position Paper on the use of 'Free From' Claims](#). CTPA members can access all guidance on the ['Free From' Claims Reference Zone](#). Non-members can find further information in:

- [CTPA Confidence in Cosmetics booklet](#): consumer-facing information that explains to consumers the safety of key ingredients, many of which are currently targeted by 'free from' claims. The booklet also encourages consumers not to look for products free from certain ingredients, whilst explaining how ingredients can be easily identified on the ingredients list if they have a known allergy or sensitivity to certain ingredients.
- [CTPA Help Note on 'Free From' Claims](#): explains in detail how the Common Criteria apply to 'free from' claims, also providing examples, and the results from the 2018 Cosmetics Europe survey of anticipated/known enforcement positions by the EU Member States.

The www.thefactsabout.co.uk displays the consumer-facing information that can be used to explain to consumers the safety of key ingredients targeted by 'free from' claims.

