

#### COSMETIC SKINCARE PRODUCTS CLAIMS

The following is a guide to the regulation of claims for cosmetic skin care products; it is intended to reflect generally accepted scientific opinion rather than a guide to skincare. This document should not be considered as legal advice; please consult your own legal advisors if you require legal advice.

The basic principle is that vendors must hold robust documentary evidence to substantiate any claims they wish to make for their products.

While QVC accepts your product may be able to achieve results beyond those documented here, you cannot refer to, or imply, these results for your product unless you can demonstrate them with robust evidence.

#### **THE REGULATORY BODIES**

Where the claim is made affects which Government or Self-regulatory body regulates it and how it is regulated.

Claims made on-air or in marketing literature that accompanies products will

Type of claim	Regulatory Body	Most relevant regulations
On-air	ASA	BCAP Code
Internet	Trading Standards	Cosmetic Products (Safety) Regulations 1994
Literature	ASA	CAP Code
Product (including packaging)	Trading Standards	Cosmetic Products (Safety) Regulations 1994
Medicinal	MHRA	Various Legislation

be regulated by the Advertising Standards Authority (ASA). Not only do the ASA investigate consumer complaints, they also have a monitoring team reviewing the media, including teleshopping channels, to ensure claims adhere to their rules. Consequently, claims that are commonplace in the high street are not found in advertising, because non-removable point of sale advertising does not fall within the ASA's remit.

Any direct claim, or implication, that features on-air will fall within the ASA remit, regardless of how it is made – on-air graphic, claims on the product itself, press, testimonials, opinions, personal experience, beliefs etc are all assessed against the BCAP Code.

Most other claims will be regulated by Trading Standards. While they do not enforce the regulations as vigilantly as the ASA, the requirement to substantiate claims is similar.



Within QVC, On-air claims must be approved by the Advertising Standards Compliance Officer while claims featuring on the product, accompanying packaging and literature must be approved by the Quality Assurance (QA) department.

It is QVC policy that our vendors must substantiate their claims to the standard required by the relevant regulator.



#### **COSMETIC OR MEDICINAL?**

Another factor that will affect how claims are regulated is whether they are considered cosmetic or medicinal.

#### A cosmetic product is defined as:

# "Any substance or preparation intended to be placed in contact with the various 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 and/or correcting body odours and/or protecting them or keeping them in good condition."

#### A medicinal product is defined as:

(a) Any substance or combination of substances presented for treating or preventing disease in human beings.

#### and/or

(b) 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."

A product may have a principal cosmetic purpose and also a secondary purpose to maintain health. A secondary preventive purpose does not necessarily make the product a medicine.

e.g. a product offered to conceal a spot but having a secondary purpose of preventing the formation of further spots is a cosmetic. A product can therefore be medicinal by:

- presentation (e.g. "this pill will get rid of headaches")
- function (e.g. it contains paracetamol)

While there is no written definition of disease a good working definition is "any adverse condition that would not be found in a healthy human being"

So diseases include conditions such as spots, sun burn and even razor burn

#### More info<sup>1</sup>

#### TYPICAL COSMETIC CLAIMS: Clean, Protect, Cover, Mask, Perfume

#### More info

TYPICAL MEDICINAL CLAIMS: Treat, Restore, Cure, Rejuvenate, Repair, Lift, Prevent, Fix

Please note: context is important in the above given examples

COSMETIC CLAIMS CAN FEATURE ON QVC IF SUBSTANTIATED

TO MAKE MEDICINAL CLAIMS WITHOUT A PRODUCT LICENCE IS A CRIMINAL OFFENCE

 $Medicines: \ http://www.mhra.gov.uk/home/idcplg?IdcService=SS\_GET\_PAGE\&nodeId=91$ 

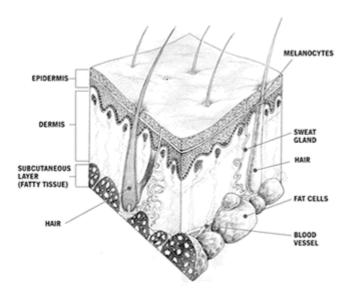
<sup>&</sup>lt;sup>1</sup> If you viewing a hard copy of this document the links are as follows: Cosmetics: http://www.ctpa.org.uk/page.asp?section=3&page=1



#### **STRUCTURE**

The skin is composed of three distinct layers:

- Epidermis;
- · Dermis, and
- Hypodermis (or subcutaneous)



You will note from the diagram that the top layer, the **epidermis**, makes up only a small part of the skin typically between 75 micrometres and millimetres thick. This is the only layer in which can claim you cosmetic product has effect. There currently no research accepted by the ASA to show that cosmetic

products can have a significant effect any deeper in the skin.

Collagen and Elastin are found in the dermis; this is one reason why claims that refer or imply that your product can affect them in some way are not permitted.

#### **FUNCTION OF THE EPIDERMIS**

The epidermis has three major functions:

- protecting the body from the environment, particularly the sun
- preventing excessive water loss from the body
- protecting the body from infection.

# 1. Protection from the environment

Our skin acts our defensive barrier against various threats, most notably UV rays. It is estimated that 90% of all the visible signs of ageing are a result of Ultra Violet exposure. As the primary source of skin damage, it is fair to say that consumers will naturally assume that when you claim to protect their skin, the product will



protect them from UV exposure. Therefore, to use the word "protect" unqualified your product must contain an SPF.

A product that contains a SPF15+ can claim to "temporary delay premature ageing" as this is generally accepted as the level of protection needed to have a significant effect.

UV exposure is one of the causes of the formation of free radicals; therefore by reducing the amount of UV exposure will help to reduce, not remove, the amount of free radical molecules created due to UV exposure.

The skin also offers protection against other factors: e.g. pollution, bacteria and inclement weather. Products can claim to protect against these conditions if they reinforce the skin's natural barrier but they must qualify what they will protect against.

e.g. "help protect skin during cold spells" or "protect against pollution by reinforcing the skin's natural barrier"

# **Summary of protection claims:**

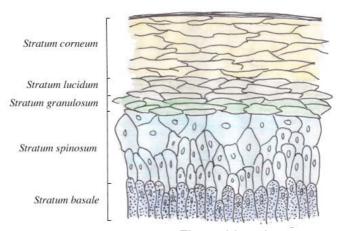
Rejected Claims:	Accepted Claims:
Sun block	Sunscreen
Improves the skin's natural barrier	Reinforces the skin's natural barrier
Protects skin (if no SPF contained)	Protects skin (if SPF contained)
	Help protect against further age spots
Temporary delays premature ageing (if <spf15 contained)<="" td=""><td>. 3 3 .</td></spf15>	. 3 3 .
Protect skin against sunburn (medicinal claim)	_
Reduces free radicals	Helps to prevent the formation of free radicals caused by UV exposure



#### 2. Preventing Excessive Water Loss

For skin to remain in good condition, it is important to maintain an adequate level of moisture. Skin moisture is affected more by

external factors such as humidity rather than the amount of water drunk. Moisture constantly lost from the (Transepidermal skin Water Loss) effective moisturisers should replace this lost moisture and/or help skin protect from further dehydration.



Please note that the

The epidermis

top layer of skin is dead so it can't not be nourished (nourish typically means feed). Therefore if you use the claim "nourish", you must qualify that you are nourishing by replacing lost moisture/via moisturisation.

As previously stated, the only proven preventative cosmetic measure against premature ageing is applying an SPF. Furthermore, no cosmetic product can claim to remove/reduce fines lines and wrinkles. Evidence suggests that retonoic acid could be of benefit here, but if your product has enough of this to be effective, it is likely to be considered a medicine and can therefore not be sold without a product licence from the MHRA.

Through the process of moisturisation however, the stratum corneum will swell which can **reduce the appearance of fine lines and wrinkles**. A moisturiser can also smooth the skin, by flattening the loose surface skin cells. Furthermore, as the stratum corneum becomes more hydrated it becomes more translucent. This enhances the skin's colour as more light is reflected from the skin's melanin.



Due to the nature of moisturisation, **all benefits should be seen immediately**. If you consider your products have a cumulative, persistent or long-term effect, we would need to see product specific evidence.



# **Summary of moisturisation claims:**

Rejected Claims:	Accepted Claims:	Notes:
Reduce/remove/correct lines and wrinkles	Reduce the appearance of lines and wrinkles	
	Lines and wrinkles appear diminished	
Helps prevent/reduce ageing/premature ageing	Helps prevent/reduce the signs of ageing/premature ageing	The addition of "the signs of" is what makes the claims acceptable
Permanently fills in wrinkles/ long lasting wrinkle filler	Filling effect Fill/ fills in wrinkles	Must be clear it is a short term, rather than permanent/long term, effect
Nourishes your skin	Nourishes your skin by replacing lost moisture	
	Nurture/take care of your skin	
Increases elasticity/suppleness	Promotes elasticity/suppleness	
Permanent/long lasting plumping/firming of the skin	Firm/plump up your skin	Must be clear it is a short term, rather than permanent/long term, effect
Anti-wrinkle/anti- ageing effect	Anti-wrinkle/anti-ageing product	Claim acceptable when used as a noun but not an adjective so fine to call a product an "antiageing" cream but not claim it has an "antiageing" effect
Rejuvenate skin/ increase cell turnover	Exfoliate/stimulate/renew your skin	Product must have an exfoliating effect to make these claims
See results within 3 days/2 weeks	Instant results	Cumulative/Persistent effects can not be
Long lasting results	Benefits last with continued/regular use	made unless product specific evidence is held
See benefits even after you've stopped using the product	See results as long as you are using the product	An independent expert will need to verify the evidence
Lifting effect/ combats sagging skin	Tightens and tones/ temporary lifting effect/tauten	A long term lifting effect can not be achieved by a cosmetic product



#### 3. Protection from infection

The stratum corneum and the covering layer of moisture provide the skin's first barrier against micro-organisms. While cosmetic products can reinforce the skin's natural barrier, they cannot be said to increase the skin's protection against infection.

It is acceptable to claim that a product is anti-bacterial or antiseptic (as long as you hold evidence that it is). To state, however, that the product can be used to treat spots, bites, cuts or wounds etc. would be a medicinal claim and would therefore be illegal without a product licence from the MHRA.

Claiming a product is anti-biotic, anti-fungal or anti-inflammatory will always be considered medicinal.

# **Summary of Infection claims**

Rejected Claims:	Accepted Claims:
Anti-fungal/Anti- biotic/Anti-inflammatory	Anti-bacterial/Anti-septic
Treats/heals/restores etc spots/bites/cuts/wounds etc	
Helps prevent infection	Reinforces the skin's natural barrier

#### **APPEARANCE OF THE SKIN**

#### 1. Comparisons to Cosmetic surgery

No cosmetic product should compare its effect to any form of cosmetic surgery or medicinal product. As previously stated, no cosmetic product will lift the skin or fix sagging skin.

It is acceptable, however, to claim that a consumer may be so happy with the results of using a particular product that they may consider that surgery isn't necessary yet.

#### 2. Cellulite

Cellulite occurs when fat lobules swell to excess creating a dimpled pattern on the skin. General scientific opinion is that cellulite is not



a distinct type of fat and so it follows that there are no cosmetic products that are proven to reduce cellulite.

Massaging may temporarily smooth the appearance but there is also no proof that this effect can be increased with cosmetic products.

No direct, or implied, claims can be made that indicate a product can reduce cellulite, or the appearance of cellulite, on-air.

#### 3. Blemishes

#### (i) Dark Circles

Dark Circles under the eyes occur when the veins and/or bone shadowing under the skin become visible.

Claims to reduce dark circles are unlikely to be acceptable but claims can be made to reduce the appearance of them.

## (ii) Puffiness

Puffiness can be caused by a number of factors, most notably fluid retention and the natural aging process.

When talking about puffiness without qualifying its cause, you will only be able to refer to reducing the appearance of puffiness. It may be permissible to talk about reducing puffiness caused by fluid retention as long as you attribute the efficacy to a massage effect rather than the product itself.

#### (iii) Acne

Acne is considered a disease and therefore any claims to treat acne, even if someone only has a few spots, are considered medicinal.

There are three major contributing factors to acne: the overproduction of sebum, improper shedding of dead skin, and the over colonisation of the bacterium Propionibacterium acnes.

While treating acne is considered medicinal, correcting any of the above factors isn't necessarily so. Claims can be made to reduce excess sebum, slough off dead skin cells and kill



bacteria. It would be acceptable to claim that reducing any of the above factors **may**, **not will**, help to reduce spots.

Furthermore, if a cosmetic has a main primary benefit that is not to treat acne (e.g. cover-up), a secondary claim to **prevent further spots** would be acceptable (as long as it has the necessary effect).

### (iv) Age spots

Age spots, also known as liver spots, are only of cosmetic concern.

Products to remove them, however, should normally be recommended by a GP or dermatologist; most products that have the required efficacy to remove age spots are not considered cosmetics. If you consider that your product can reduce age spots you will need to present evidence to QVC to demonstrate that effect.

Claims should be limited to covering up age spots or helping to prevent them with an SPF (although the role an SPF can play should not be overstated).

#### (v) Other Blemishes

A general rule of thumb is that it is acceptable to claim to cover up blemishes but removing them will often not be an acceptable claim for a cosmetic.

Claims in regards to blemishes caused by medical conditions (e.g. Eczema, Psoriasis) will always need to be assessed by QVC before being made on air.

# **Summary of appearance claims**

Rejected Claims:	Accepted Claims:	Notes:
Botox in a bottle Facelift in a jar Non surgical facelift Lift the face Tighten and contour your skin without surgery	Temporary lifting effect Look visibly younger Let surgery wait	
Reference to improving, removing, reducing cellulite or even the appearance of cellulite	Skin feels/appears smoother	This includes references to cellulite by another name e.g. orange peel skin



Removes/Reduces/Treats dark circles/ /puffiness	Reduces the appearance of dark circles/puffiness	Reduction of puffiness caused by water retention may be acceptable if efficacy is attributed to massage
Treat/remove/reduce spots or acne	Cover up/conceal spots  Ideal for those with oily/greasy skin  Reduce excess oil/reduce bacteria/exfoliate dead skin cells which MAY help to prevent further spots	If the products primary function is cosmetic (e.g. concealer) it is permissible to say it has a secondary function of preventing further spots.
Reduce/Remove Age spots	Cover up/conceal age spots  Help prevent further age spots (if SPF present)	

#### **OTHER SKIN CARE REGULATORY CONCERNS**

#### Claims-in-names

The name of a cream may in itself be regarded as a claim and therefore subject to the substantiation requirements outlined above. In some cases, the ASA will allow a little leeway: for example, describing a product as an "anti-wrinkle cream" in an ad that clarifies that it reduces the appearance of wrinkles is unlikely to trigger the 'body of evidence' substantiation requirement, but stating a product has an anti-wrinkle effect is.

#### **Professional Recommendation**

The BCAP Code states that, in relation to health and beauty products, references to approval, recommendation of, or preference for, any product or its ingredients by professionals (e.g. doctors, nurses, dermatologists, pharmacists, vets etc) is not allowed. This includes the name of the product. This rule would equally apply to professional institutions.

No references to professionals are to be made on QVC without consent from the Advertising Standards Compliance Officer. The only time a professional should be mentioned is if you are recommending viewers seek advice from their doctor before using the product although this is unlikely to be relevant to cosmetic products.



## **Ingredients**

Many efficacy claims are based on an ingredient contained within the product rather than the finished product itself. While this can be acceptable for some established cosmetic ingredients it is likely to be problematic for new or more unusual ingredients.

While a raw ingredient may have a certain effect when applied individually, when combined with other ingredients that constitute the rest of the product it will not necessarily have the same effect. Furthermore, a number of ingredients have had efficacy applied to them by the cosmetic industry that have never been proven, to a standard accepted by the Advertising Standards Authority, in a final product. Examples include antioxidants and peptides.

Appendix I contains a list of ingredient and approved effects. If you wish to attribute an efficacy claim to an individual ingredient not contained in the list, you will need to clear it with either QA's Health and Beauty Engineer or the Advertising Standards Compliance Officer. You must be able to demonstrate that the ingredient still has this effect as part of your finished product.

# <u>Cumulative/Persistent/Long Term Effects</u>

As previously mentioned cumulative, persistent or long term effects cannot be made on QVC without product specific evidence. The level of evidence required by the ASA is very high; please refer to Appendix II to view the types of issues that will need to be addressed when testing products.

Without proof to substantiate otherwise, the effects of all cosmetic products must be said to happen immediately, with continued use, with regular use or whilst using the product.

# Homeopathy/Aromatherapy

Put simply, a homeopathic product is considered a medicine and can therefore not be sold on QVC.

Aromatherapy is purported to use essential oils to promote spiritual, physical and emotional health and well-being. Plant extracts, which are usually ingested, massaged or inhaled, are intended to induce relaxation and restore balance to the body and mind. Although the claims that you can make about its benefits are limited, it is accepted that aromatherapy might help people to relax, sleep and



de-stress. You should not, however, claim that aromatherapy can be used to treat the causes or symptoms of serious or prolonged ailments

You can also claim that the use of essential oils combined with massage might help muscle strains or muscle tension but emphasis should be placed on the massage and not on the action of the oils.

In short, you can claim that aromatherapy can be used for beauty, relaxation or 'feel good' purposes.

# Summary of regulatory concerns

Rejected Claims:	Accepted Claims:	Notes:
Designed/Used/ Approved by doctors/ dermatologists/hospitals	Designed/Used/Approved by skin experts/ professional make up artists	Claims of use/design by individuals or certain professions need to be substantiated
Vitamins/anti- oxidants/peptides/ "exotic" ingredient reduce the appearance of lines and wrinkles  Claims that topically applied anti-oxidants reduce free radicals	Fortified with/containing vitamins/anti-oxidants/ peptides, this product reduces the appearance of lines and wrinkles	Evidence must be held that the product achieves an effect unless it is an established claim as listed above
See results within 3 days/2 weeks  Long lasting results  See benefits even after you've stopped using the product	Instant results  Benefits last with continued/regular use  See results as long as you are using the product	Cumulative/Persistent effects can not be made unless product specific evidence is held  An independent expert will need to verify the evidence
Any reference to homeopathy	References to aromatherapy with regards to cosmetic beauty, relaxation or 'feel good' claims	

#### **FURTHER CLAIMS**

As previously stated the above is the generally accepted scientific opinion amongst regulators. It does not, however, mean that claims will always be limited to the above advice. It should be noted that the industry has been trying to demonstrate that cosmetic products



have benefits further to those stated above with very little success as of yet.

To make claims above and beyond you would be required to produce a robust package of evidence to substantiate them. That package would most likely have to contain an explanation of how the product could achieve the desired effect, a review of relevant clinical trials and a product specific clinical trial. While there is no guarantee as to what would be accepted as evidence, Appendix II lists the types of considerations that need to be considered when developing a clinical trial.

QVC would recommend that you contact the Advertising Standards Compliance Officer before undertaking clinical trials to substantiate a claim you intend to feature on QVC. We would also recommend you contact the Cosmetic Toiletry and Perfumery Association (CTPA) who have been working with the ASA on claims substantiation.



# <u>APPENDIX I – ACCEPTABLE INGREDIENT CLAIMS</u>

Examples of ingredient specific claims that can be made without further substantiation if the product contains the ingredient in an acceptable amount and formulation.

Ingredient Class:	Example Ingredients:	Claims
Alpha Hydroxy Acid	Glycolic Acid	Exfoliation
Beta Hydroxy Acid	Salicylic Acid	Exfoliation
Humectants	Glycerine	Moisture binding properties
Mechanical Scrub	Jojo beads	Exfoliation
SPF	Oxybenzone	<ul> <li>Protect skin</li> <li>Help prevent further age spots</li> <li>Temporarily delay premature ageing (SPF 15)</li> <li>Reduce formation of free radicals caused by UV exposure</li> </ul>
Aromatherapy	Lavender	help people to relax, sleep and de-stress
	Tea Tree Oil	Antibacterial Antiseptic
	Aloe Vera	Moisturising properties
	Collagen	Moisturising properties



#### APPENDIX II - CONSIDERATIONS FOR CLINICAL TRIALS

The nature of the study depends on the nature of the claim. But notwithstanding that, these are points to consider:

- 1. Studies should be double blind and randomised. Results must be statistically significant and show a clear consumer benefit (not just one that can be measured in a lab but unperceivable to the human eye).
- Studies must be undertaken with a suitable control, for example if you
  were testing the effect of ingredient x in formulation y, formulation y
  without ingredient x may well be considered a suitable control. If a
  placebo control were not used, a good explanation as to why would be
  required.
- 3. The number of subjects required will depend on what you are trying to prove and how likely the result is caused by chance. A statistician can advise on recommended sample sizes to detect a change of a given magnitude. The precision of the method is also important, if the method is highly reproducible, and has high precision, then this will also tend to favour smaller sample sizes.
- 4. Studies should be conducted on product (not ingredient) specific studies or present compelling evidence that results from one formulation can be extrapolated to another.
- 5. Study should ensure that appropriate concentrations of actives are used in the study. If last-minute formulation changes mean that the test product is not identical to the marketed product, evidence should be provided to demonstrate those changes would not materially affect product performance.
- 6. Study should control for time of year or record pertinent details (such as geographical location, climate conditions etc.) This may not be an issue if an internal control group is being tested at the same time of year.
- 7. Study should control for age, if appropriate, and ensure that tests are carried out on a sample that is representative of the actual audience to whom the ad is directed.
- 8. Study should involve matching test and control groups with respect to key criteria: which may include previous history of skin disease.
- 9. Study should control for skin thickening, sun-bed use and photoageing, if appropriate.



- 10. Study should control for skin type, if appropriate (unless compelling evidence demonstrates that skin type is not a confounding variable) ensuring skin types are equally distributed between the different test and control groups to avoid potentially confounding bias.
- 11. Study should avoid the use of percentages when describing non-linear changes. Or the study should clearly identify methods that are liable to have a non-linear response and explain the rationale for using percentages on a case-by-case basis.
- 12. Study should provide graphs that include error bars.
- 13. Study should provide statistical confirmation of starting group equivalence.
- 14. Study should incorporate a control, rather than be compared with baseline (however controlled the environment).
- 15. Study should ensure relevance of study to appropriate UK population. If the ASA has <u>reasonable</u> grounds for suspecting that ambient conditions might not be applicable to the audience of the claim they will probe further and perhaps ask to see evidence of transferability.
- 16. Study should ensure that normal or dry skin is tested, as appropriate.
- 17. In the absence of data showing equivalence between test sites, study should test on body sites appropriate to product usage. The ASA accepts that different sites <u>might</u> prove to be reasonable models, but the study needs to prove that.
- 18. Study should incorporate an appropriate pre-treatment 'wash-out' period, if necessary. If advertisers maintain that moisturisers can have persistent effects after cessation of treatment and if the effects can last for up to two weeks, a two week 'wash-out' period might be necessary to ensure no pre-treatment contamination of the starting groups. Without that, the ASA might find it difficult to accept that the experimental design is good. Whether a pre-treatment 'wash-out' is needed should ultimately depend on the claim.
- 19. Study should include consumer perception studies as part of its more objective testing. The ASA has been critical of consumer perception studies in the past only when they have constituted the sole support for performance claims. The benefit of carrying out consumer perception studies as part of more objective testing is that the test conditions will not vary. If the advertiser is unable to do that, the ASA strongly recommend that they be carried out under as closely comparable conditions as possible.



20. Study should ensure that consumer perception data includes a suitable control, if appropriate.