

# **The Role of Cosmetics and Toiletries in Society**

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## **Introduction**

Cosmetics and Toiletries have benefit to the consumer, not only do they provide a safe and effective means to cleanse, perfume and decorate the skin, but they also provide a safe and trusted way to protect the skin from dryness and the effects of external influences, such as ultraviolet rays from the sun. Thus if a pharmaceutical is for diseased or damaged skin, then a skin care product is for the protection of healthy skin.

This paper will try and address some of the more frequently asked questions and compare the answers to common practice in the pharmaceutical industry.

## **Legal requirements**

The cosmetic and toiletry industry is regulated by the Cosmetic Products (Safety) Regulations 1989 and the four additional Statutory Instruments leading up to 1996, as well as by the EEC Cosmetic Directive including the 18 different Commission Directives that have modified and tightened those regulations to the present day.

In addition, we must be within the scope of the Trade Descriptions Act and not make claims which we cannot substantiate, unless we wish to be visited by our friendly Trading Standards officer. We must also be careful that we do not make any physiological claims to our product that would infringe the recommendations of the Medicines Advice Leaflet (MAL 8), pursuant to the Medicines Act of 1968 and its various amendments.

Companies producing cosmetics and toiletries will be required to keep dossiers of data on the products that they produce. This information package must include safety data on each of the raw materials, the formula, specification, method of manufacture, microbiological standards of both raw material and finished product, microbiological challenge testing results, proof of efficacy, proof of safety assessment, dermatological reports, toxicology report and any other data or

instrumental data that may be required to substantiate the product's safety or efficacy. The differences between a pharmaceutical and a cosmetic product are becoming much less.

### **Comparison between the effect of a medicine and the effect of a skin care product.**

A medicine carries a PL number, which identifies it as a pharmacologically active preparation that has a physiological action on the skin and makes medicinal claims for its action, or refers to medical conditions and their cures. It has a batch number and a *use before* date.

A skin care product should only refer to the physical nature of the skin benefits, which could be wrinkles, softness, skin texture, elasticity, smoothness, hydration, moisturisation, or beauty. The marketers always try to say more, but these are the legal limits (regardless of the flowery language that may be read on the pack.). Prevention against a skin condition or protection from an outside influence is the borderline area that separates the two categories and is the greatest area of concern to the MCA (The Medicines Control Agency). The products have a batch code, but do not require a *use by* or *sell by* date, however, they must be demonstrated to have a shelf life of at least 30 months or else a *sell by* date **is** required.

### **Composition of skin care products versus salves, ointments and skin creams.**

The medicinal product will contain an active, which will be declared on the outside of the pack. The composition of the drug delivery vehicle will more than likely be formulated exclusively with excipients that appear in the British Pharmacopoeia. By cosmetic standards, the base is crude, organoleptically and aesthetically very poor. The absorption is usually awful, the skin feel is greasy, the base odour is smelly and the packaging utilitarian and old fashioned.

The excipients are not necessarily safe, indeed, the cosmetic industry does not allow the use of 85% pure triethanolamine and will only allow 99% grade purity to be used. In aqueous cream, it is common to see sodium lauryl sulphate being used as the emulsifier, in the cosmetic industry we recognise this material to be so potentially irritant, that we will not even use it in rinse-off products such as shower gels or foam baths. The pharmaceutical industry can use many other materials that would be frowned upon by a cosmetic scientist.

The cosmetic product not only declares the active material, but also every single material used in the preparation of that product in descending order of use (this will be a legal requirement in 1997). This means that any person experiencing a

reaction to a product, will be able to go to their GP or dermatologist and look for the potential irritant.

However, reactions to skin care products are extremely rare. In almost all cases, especially with reputable producers, the product will have been screened by a toxicologist, probably tested on healthy human volunteers and also tested by a dermatologist on eczema-prone patients. All of the materials used in our industry have to appear in the European Inventory, and most of us insist that the materials also appear in the CTFA (Cosmetic Toiletry and Fragrance Association) Cosmetic Ingredient Dictionary of USA. All of these materials either have a long history of use in cosmetic products or have satisfied various committees as to their safety and skin compatibility. Monographs exist for many of these materials, and of course we also use BP grade materials where their use is appropriate.

### **Animal Testing**

People are very concerned about animal testing. The pharmaceutical industry does use animals for legitimate and justified reasons (the legal requirement for products intended for human use). The number of cosmetic products tested on animals is now virtually nil, and most would agree that it is somewhat barbaric to sacrifice an animal for the sake of vanity. In 1997, the use of animals for cosmetic and toiletry testing will legally become a thing of the past. There are already a large number of non-animal testing protocols and human tests that have been in use for many years now, and it should be said that the animal liberation protesters are on a band wagon that lost its wheels years ago (having won a good battle).

### **Botanical extracts**

The one area that is very difficult to formulate is in that of plant extracts. There is a list of some 35 or so prohibited botanical materials as might be expected, such as *Datura stramonium*, *Digitalis purpurea*, *Hyoscyamus niger*, *Cephaelis ipecacuanha* etc.

The real problem is how to decide when a plant ceases to be an excipient or have simple protective addition and when does it begin to exhibit a real physiological action? A typical example would be German Chamomile or *Matricaria recutita*, which has been used for many years in shampoos and skin products without any concerns. However, what happens if one increases the apigenin (a flavonoid) content of the aqueous extract by making stronger infusions and using them at higher doses, and what if we were also to include the essential oil (which is rich in alpha-bisabolol, matricin and chamazulene) at an active level? There already exists a pharmaceutically licensed product which contains Chamomile, called

Kamillosan. At real levels, the product would take on anti-inflammatory and wound healing benefits, it would also be anti-erythematous and useful in conditions like eczema and nappy-rash. None of these attributes could be claimed, but could still be present as part of the product's unsung benefits.

This is a moral dilemma for the cosmetic scientist, who wants to deliver real skin benefit to his customer and at the same time be able to more than substantiate his product's claims. It is more than likely, that there are many products on the market that are in possession of real physiological benefits, but which are hiding their true value under a cloak of marketing pack copy 'double-talk', because to do otherwise would infringe the Medicines Act.

## **Conclusions**

A cosmetic product will do what it says. A sun care product will most certainly have a sun protection factor in excess of that shown on the label. A moisturiser will increase the skin moisture balance and so reduce dry skin. A beauty product will make you (more) beautiful. A nail varnish will colour your nails and a hardener will strengthen them. A modern shaving foam will leave your skin softer, smoother and less inflamed than a strop and cut throat with soap and water, and I would like to bet that the shave will be closer and last longer than the old traditional method.

Most of all, a cosmetic or toiletry product will bring pleasure, it will make the simple task of washing, shaving, or cleaning of the hair a delight. The fragrance will create moods (scientifically proven for many essential oils), allow time for dreaming and contemplation - bringing a psychological benefit in addition to the more practical considerations of personal hygiene.

A beautiful woman, her eyes highlighted with a tinge of colour, her cheeks gently flushed with the slightest kiss of blusher, her perfumed hair flowing like shining silk in the mildest of breezes captures a tantalising trace of her glorious perfume and envelopes you in her aura. Her lips are full and rich with colour, her skin is soft and baby-like, she is absolutely magnificent and she knows it.

Someone once said that the cosmetic industry sold only dreams, if this is the case, please do not wake me up.