

## **Consumerism gone mad?**

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### **Introduction**

It is understandable that a company should want to be as attractive and enticing to the consumer as possible, but it would seem that there are some manufacturers who are prepared to take their chances and go over the strict barriers and guidelines that are clearly defined by law. There is also a trend to tell us what it does not contain and by so doing imply that their product is safer, but nothing could be further from the truth.

### **Definitions**

The EEC have Council Directive 76/768/EEC up to the 27<sup>th</sup> amending Directive 2003/15/EC and including the previous 26 amendments and this has to be translated into the language of each member state, in the UK the law is Statutory Instrument 2004 No. 2152 The Cosmetic Products (Safety) Regulations 2004 (107 pages)

In addition, products must not infringe the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994, a very common infringement with today's eagerness to have 'alluring' pack copy. The Regulations provide that, unless exempt, any "medicinal product" to which Chapters II to V of Directive 2001/83/EEC apply must not be placed on the UK market unless it has a marketing authorisation (product licence) granted by the European Commission or by the UK Licensing Authority. The Act similarly provides that, unless exempt, any other "medicinal product" must not be sold or supplied without a marketing authority. A marketing authorisation or product licence is only granted for a product which meets statutory standards of safety, quality and efficacy.

The status of many products on the "borderline" between medicinal products and food supplements, cosmetic or medical devices can be difficult to determine. The MHRA have produced a Guidance Note 8 document to explain how and on what basis the MCA decides whether products are medicines or not. It includes guidance on the statutory procedures in Regulation 3A of the Regulations introduced by the Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2000 (S.I. 2000/292).

There is also the requirement to ensure that claims made on the packaging comply with the Trade Descriptions Act 1968, Control of Misleading Advertising Regulations 1988 (as amended)

Products must also comply with the Weights and Measures Act 1985.

Certain categories (e.g. insect repellants and products that contain this property) may also be subject to the Statutory Instrument 2003 No. 429 The Biocidal Products (Amendment) Regulations 2003.

Compliance with these laws is mandatory in Europe and many countries have adopted them with little alteration. It will be way of things to come and most countries are in the process of harmonizing and adopting these legal safeguards. Any company that does not react ahead of the inevitable is going to find it an arduous and almost impossible task to implement in the time frames that are normally allowed for full compliance.

## **The MHRA or Medicines and Healthcare products Regulatory Agency (formerly the MCA or Medicines Control Agency)**

### *A guide to what is a medicinal product*

The MHRA have issued a booklet that may be obtained freely from their internet site ([www.mhra.gov.uk](http://www.mhra.gov.uk)). It is called Guidance Note 8 and this document is used as a basis for discussion.

The following paragraphs are taken from this excellent publication.

“The Cosmetics Directive 76/768/EC, as amended (implemented in the UK by the Cosmetic Products (Safety) Regulations 2004 (SI 2004/2152) as amended, harmonises the requirements for cosmetics in the European Community to achieve free trade in cosmetics whilst ensuring that the products are safe and consumers are not misled. It prohibits, or places restrictions on, certain ingredients and defines a cosmetic product. The definition envisages that a cosmetic product may have a secondary preventative (but not curative), purpose. When deciding whether or not a product on the borderline between cosmetics and medicines is a medicinal product, the MHRA will apply the tests set out in Directive 2001/83/EC. If a product falls within the definition of a cosmetic and within the definition of a medicinal product it will be classified as a medicinal product (*Delattre* 1991, C-369/88). The regulatory status of products in other Member States will also be taken into account”.

Article 1 of Directive 2001/83/EC *as amended* defines a “medicinal product” as:

“(a) Any substance or combination of substances presented **as having properties** for treating or preventing disease in human beings; [*“the first limb”*]

(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**” [*“the second limb”*]

*The paragraph identifications (a) and (b) are not part of the definition and are added here solely for ease of reference later on. Changes to the definition which came into effect from 30 October 2005 are shown in **bold** to aid identification.*

Medicinal products may well fall under both limbs of the definition but the European Court of Justice (“ECJ”) has confirmed that falling under either limb is sufficient to classify a product as a medicinal product. [*Upjohn* 1989 C-112/89]: **“Directive 65/65 (now Directive 2001/83) provides two definitions of the term “medicinal product”: one relating to presentation, the other to function. A product is medicinal if it falls within either of those definitions.”**

It is these infringements that cause problems for the consumer and the Borderline Substances division of the MHRA. The proliferation of products that clearly intend to mislead the consumer into believing that a product will exert a physiological effect is on the increase. There are elements of the industry that are determined to jeopardize a sane consumer's credibility with product suggestions that are so ludicrous as to be lamentable.

### **The Cosmetic Products (Safety) Regulations 2004**

Let us refresh our memories with the exact wording of the law in relation to the definition of a cosmetic, toiletry or skin care product.

"cosmetic product" means any substance or preparation intended to be placed in contact with any part of the external surfaces of the human body (that is to say, the 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, protecting them, keeping them in good condition or correcting body odours except where such cleaning, perfuming, protecting, changing, keeping or correcting is wholly for the purpose of treating or preventing disease.

"cosmetic product intended to come into contact with the mucous membranes" means a cosmetic product intended to be applied in the vicinity of the eyes, on the lips, in the oral cavity or to the external genital organs, and does not include any cosmetic product which is intended to come into only brief contact with the skin.

There is no degree of freedom and there is no possible scope for interpretation, the law is precise and specific. You may only protect the body with your product. It might be suitable for those with eczema-prone skin and it may be helpful for those liable to get spots and pimples, but it is never allowed to be a treatment for medicinal conditions, because that would be achieved using drugs or medicines.

Once again this is a huge stumbling block and the helpful MHRA say "again in context, and particularly in the case of products on the borderline between food and medicinal products, claims to **"protect"** or **"avoid"** may be perceived by consumers as having much the same meaning as **"prevent"**". For example, a product may be presented to **"protect"** a consumer against a specific disease or adverse condition in such a way that consumers would believe that the product could **"prevent"** it".

You may see words like "kills the bacteria responsible for producing spots" or "moisturizes the skin to stop it from becoming dry and itchy (pruritic)". Any product that uses the word 'heal' or states that a product will be a remedy or treatment for any disease is breaking the law. The MHRA say that "claims to relieve symptoms, or to cure, remedy or heal a specific disease or adverse condition of body or mind will also be regarded as medicinal claims".

The beauty industry targets the population in areas of stress, obesity, lifestyle and being healthy. Beauty requires a good diet, plenty of exercise, low alcohol consumption, no smoking policy and plenty of sleep. All of these things in combination would give all of us a good start of the looking good, feeling good trail.

Sadly one should also stay out of the sun altogether, even safe tanning will age the skin faster than those who dwell in the shade under the trees or umbrellas!

The MHRA does not consider claims to “*maintain*” or “*help to maintain*” or “*support*” health or a healthy lifestyle, as medicinal in themselves. Nor, if such claims are made in relation to *healthy bodily functions or organs*, is the MHRA likely to consider them as presenting the product for treating or preventing disease. In general, the MHRA is only likely to consider “*health maintenance*” claims as medicinal if they suggest or imply that a product, perhaps targeted on a vulnerable section of the population, may *restore*, or *help to restore*, a specific bodily function or organ to a normal healthy state.

The balance of common sense seems to be thrown over by unbelievable promises using magical products that will reduce weight in a single application and there are even products that will suck toxins out through the skin by strapping on to the soles of the feet a giant Japanese tea bag full of saw dust and other herbal detritus. How so many people are taken in by the blatant mumbo jumbo remains a mystery that beggars either belief or explanation.

We show a few strap lines as examples

“The body wrap is an advanced development that works on shrinking the adipose tissue of fat called cellulite that is found directly below the surface of the skin. Body Wrapping eliminates toxins and impurities that have built up in the body plus helps to rid the body of cellulite. It detoxifies your body, tightens loose tissue, exfoliates, smoothes and softens your skin”. “Lose 5-15 Inches in One Body Wrap! Schedule 3 or more wraps for better results within 7-10 days of each other. Reduce the appearance of cellulite and stretch marks.”

The System is an all-natural detox and inch loss program, which draw out toxins and tighten the skin. The bandages are soaked in a solution and applied warm, allowing the solution to open pores and draw out toxic accumulations from the lymph system which can be caused by stress, metabolic waste, medication and pollution. Proven wrapping techniques tightens the skin, compacts tissue and firms-up the body quickly. Will the lost inches return? Clients have kept off the inches as long as long as you maintain your weight. Are there any medical considerations? If you are on medication or have any physical conditions you should obtain your doctor's permission. How long does it take? The entire process takes approximately 3 hours.

Toxins are removed from the body by the liver and kidneys with some contribution being afforded by the exhalation of gases through the lungs and expectoration of damaging phlegm that may have accumulated in the lungs by the act of coughing. Lymph nodes act as filters, with an internal honeycomb of reticular connective tissue filled with lymphocytes that collect and destroy bacteria and viruses. When the body is fighting an infection, lymphocytes multiply rapidly and produce a characteristic swelling of the lymph nodes.

The idea that a bandage soaked in colloidal clay can remove toxins is non-factual, dangerous drivel that could be dangerous to anyone who believes that it could sort out a truly dangerous medical problem where toxins are involved.

When at school we used to measure weight in pounds and ounces or grams and kilograms, now it would seem that educational standards have dropped and some would have us believe that we now measure weight in inches? It is nonsense and a physiological impossibility.

The thought that one can lose weight by squashing it up with a few bandages in an hour or so is so ridiculous. The idea that we can drag toxins through the skin is the height of stupidity. It is hard to believe that the Trading Standards Office have not prosecuted already. Maybe they will when they are presented with the evidence (or lack of it).

## **THE WHAT IS “DOES NOT CONTAIN” TREND**

Scientists go to huge lengths to include wonderful things in their products but the trend now seems to be to tell the consumer what is not in there and most of the time the thing left out is safer than what has been put in as a replacement!

Natural ingredients are often held up as being a lot safer than their synthetic counterparts and although nature is a wonderful provider it is wrong to make any assumptions on their being benign. Indeed many chemotherapy drugs are derived from plant sources like taxol, vincristine, vinblastine and podophyllotoxin, as well as a good number of deadly poisons like strychnine, colchicines, nicotine and rotenone. See the drug list appended.

### **1. DOES NOT CONTAIN PARABENS**

The first exclamation has to be “Why not?” Parabens are found in nature, they are extremely safe and occur in the food we eat, could it be that the poor science supplied in the name of breast cancer is to blame?

In the plant world 4-hydroxybenzoic acid and its derivatives are commonly found in various vegetable foods, such as barley, strawberries, blackcurrants, peaches, carrots, onions, cocoa-beans, vanilla; further in foods prepared from fruit plants such as grapes and fruit juices, yeast extract, wine vinegar and also in cheeses. 122 plant species were investigated and the acid was found present in all of them. 4-hydroxybenzoic acid is the most widely distributed aromatic organic acid in the vegetable kingdom. The Scandinavian cloudberry contained benzoic acid, sorbic acid, salicylic acid, 2-hydroxybenzoic acid, as well as methyl and propyl parabens, which accounted for the superior resistance of cloudberry to microbial spoilage.

Well informed brands like Liz Earle says “Parabens occur naturally in many fruits and are used as preservatives in some of our products, but only in very small quantities”.

**In Australia, NICNAS (National Industrial Chemicals Notification and Assessment Scheme).**

[http://www.nicnas.gov.au/search/search.cgi?query=paraben&collection=nicnas-web&num\\_ranks=10](http://www.nicnas.gov.au/search/search.cgi?query=paraben&collection=nicnas-web&num_ranks=10)

This independent and horribly thorough organization has reviewed the publication and other available data on the health effects of parabens. The study by Darbre et al (2004) utilized a small sample (20), no healthy breast tissue (or other tissues from affected women) was analysed and the source(s) of the parabens found in the breast tumours and routes of exposure were not identified. This paper however, notes the need for further research to establish the significance of the presence of parabens in these tumours and to establish any link between parabens in underarm cosmetics and the development of breast cancer.

Data from published sources indicates that parabens demonstrate weak oestrogenic activity in some experimental animals and that enzymes present in skin cells and subcutaneous fat cells are capable of breaking down topically applied parabens. Following analysis of all available data, NICNAS believes that further research is required before a causal link between parabens in cosmetic products and breast cancer can be established.

Parabens in cosmetic products are considered safe to use when the products are used as directed.

**In Europe, Scientific Committee on Consumer Products (SCCP)** reporting on “Parabens, underarm cosmetics and breast cancer” on 28<sup>th</sup> January 2005 looked at a series of questions:

*Do the data provided within the requests indicate a potential risk for the development of breast cancer in past users of underarm cosmetics?*

There are insufficient data to establish a clear link between the use of underarm cosmetics and breast cancer. The authors of the studies that led to the suggestion of a connection between the use of underarm cosmetics and breast cancer, clearly state that they did not have the intention to prove such a link. Two recent epidemiological studies on the use of underarm cosmetics in relation to breast cancer exist. The authors of these studies could not establish a relationship between the use of underarm deodorants and antiperspirants and the occurrence of breast cancer [Mirick et al. 2002, McGrath 2003].

Moreover, according to current knowledge in this field, age is the major risk factor with regard to the incidence of breast tumours, followed by family history of breast cancer [De Grève 2004].

The effect of hormones has been acknowledged, but not all cancers are estrogen receptor positive. In fact, it is strongly suggested that for the pathogenesis of a significant proportion of all breast cancers, hormones do not play a significant role. It is true, however, that estrogens might have a role through their mitogenic action to further stimulate the malignant transformation of premalignant cells [De Grève 2004].

For this reason, exposure to potent estrogens should be avoided whenever possible.

Further important clinical data are:

- breast cancer tumours occur most frequently in the upper quadrant of the breast (closest to the armpit). A clear relationship, however, has been found with the amount of gland tissue present at that location;

- it is clinically well-established that the circulation of blood/lymph goes from the breast towards the armpit and further towards different organs and tissues and not vice-versa, making an exchange process from the armpit towards the breast tissue highly speculative.

***It is the opinion of the SCCP that, viewing the current knowledge, there is no evidence of demonstrable risk for the development of breast cancer caused by the use of underarm cosmetics.***

*In particular, do the data provided indicate a potential risk for the development of breast cancer in past users of underarm cosmetics containing parabens?*

With regard to their general toxicological profile, acute, subacute and chronic toxicity studies in rats, dogs and mice, have proven parabens to be practically non-toxic, not carcinogenic, not genotoxic or co-carcinogenic, and not teratogenic. Parabens are not expected to accumulate in tissues and the ester linkage of the parabens is expected to be readily hydrolyzed [SCF 1994].

In a number of *in vitro* studies, such as the recombinant yeast estrogen screen, parabens have proven to be able to bind to the estrogen receptor, to activate genes controlled by these receptors, and to stimulate cell growth and increase the level of immune reactive estrogen receptor protein. The estrogenic potency increases with increasing length and branching of the alkyl side chains (methyl < ethyl < propyl < butyl < isobutyl), but remains at all times 1000 to 1,000,000 times below the potency of 17 $\beta$ -estradiol. Hydroxybenzoic acid, the common metabolite of all parabens, appeared to be inactive in the *in vitro* assays. The *in vivo* estrogenic activities of parabens have been tested in uterotrophic assays employing either immature female rodents or adult ovariectomized female rodents after oral, subcutaneous or dermal administration. Again, butyl paraben appeared being more potent than propyl, ethyl and methyl paraben, and again the values remained several magnitudes of order below the potency of 17 $\beta$ -estradiol. Conflicting results have been reported for p-hydroxybenzoic acid tested *in vivo*. One study claimed that it has no estrogenic effect; another study gives potency values 1000-fold below the 17 $\beta$ -estradiol level [EFSA 2004, Anonymous 2004, Paulsen and Alexander 2003].

*Taking into consideration the answer to the question 2.2 and viewing the fact that the estrogenic potential of parabens has been found to be very low, it is the opinion of the SCCP that, in the light of the present knowledge, there is no evidence of demonstrable risk for the development of breast cancer caused by the use of paraben-containing underarm cosmetics.*

**In the UK, the CTPA (Cosmetic, Toiletry and Perfumery Association)**

<http://www.ctpa.org.uk/page.asp?section=4&page=60&term=paraben>

The following quotations were found

## **Expert comment regarding latest reports on parabens and breast cancer**

*“The findings of parabens in tumour samples are additional results in line with the general hypothesis that there may be a link between oestrogenic compounds commonly used in underarm cosmetics and other consumer products and breast cancer. The results alone, however, do not suggest that these chemicals caused the tumours in these patients. Darbre et al.’s findings invite several questions: how did the parabens get into the breast, are they persistent and could they do harm? The answers require further research.”*

### **Philip W. Harvey and David J. Everett**

General considerations and conclusion from the Editorial of the Journal of Applied Toxicology where the research was published

*“We are all exposed to all kinds of chemicals but it doesn’t mean that they all cause cancer. The question is here whether the chemicals would have an impact on the hormones, and also what level you would see in a healthy breast tissue. A causal link has by no means been proved.”*

### **Karol Sikora, Professor of Oncology at Imperial College London**

The Observer

Sunday, 11<sup>th</sup> January 2004

*“Although this is an interesting study the sample size is very small. No causal link has been found between underarm cosmetics containing parabens and breast cancer. There is also no robust population-based evidence to suggest a link. Should any notional risk exist it would be insignificant when compared to other avoidable environmental risks for the disease, such as obesity.”*

### **Dr Richard Sullivan, Head of Clinical Programmes at Cancer Research UK**

The Sun, The Star, Daily Mail, The Independent, The Observer

Monday, 12<sup>th</sup> January 2004

*“This extremely small study does not demonstrate a direct or causal link between deodorant or anti-perspirant use and developing breast cancer. Further research is needed to establish the source of the chemicals found in the breast tumour samples and what, if any, the relationship is to breast cancer.”*

### **Delyth Morgan, Breakthrough Breast Cancer**

Daily Mail, Daily Mirror

Monday, 12<sup>th</sup> January 2004

*“We conclude from our results that the above mentioned paraben esterase III of keratinocytes (a skin enzyme that breaks down parabens) is sufficient to completely hydrolyse the traces of parabens that may enter the skin from topically applied ointments.”*

### **C. Lobermeier, C. Tschötschel, S. Westie and E. Heymann.**

Hydrolysis of parabens by extracts from differing layers of human skin.

Biol.Chem. 377(1): 647-651 (1996)

Even Breakthrough the Breast Cancer Awareness Organisation decry the risks  
[http://www.breakthrough.org.uk/what\\_we\\_do/breakthrough\\_publications/deodorant.html](http://www.breakthrough.org.uk/what_we_do/breakthrough_publications/deodorant.html)

### **In the USA, the FDA (Food and Drug Administration)**

The following comments were made (<http://www.cfsan.fda.gov/~dms/cos-para.html>)

#### ***Are there health risks associated with the use of parabens in cosmetics?***

The Cosmetic Ingredient Review (CIR) reviewed the safety of methylparaben, propylparaben, and butylparaben in 1984 and concluded they were safe for use in cosmetic products at levels up to 25%. Typically parabens are used at levels ranging from 0.01 to 0.3%.

On November 14, 2003, the CIR began the process to reopen the safety assessments of methylparaben, ethylparaben, propylparaben, and butylparaben in order to offer interested parties an opportunity to submit new data for consideration. In September 2005, the CIR decided to re-open the safety assessment for parabens to request exposure estimates and a risk assessment for cosmetic uses. In December 2005, after considering the margins of safety for exposure to women and infants, the Panel determined that there was no need to change its original conclusion that parabens are safe as used in cosmetics. (The CIR is an industry-sponsored organization that reviews cosmetic ingredient safety and publishes its results in open, peer-reviewed literature. FDA participates in the CIR in a non-voting capacity.)

A study published in 2004 (Darbre, in the *Journal of Applied Toxicology*) detected parabens in breast tumors. The study also discussed this information in the context of the weak estrogen-like properties of parabens and the influence of estrogen on breast cancer. However, the study left several questions unanswered. For example, the study did not show that parabens cause cancer, or that they are harmful in any way, and the study did not look at possible paraben levels in normal tissue.

FDA is aware that estrogenic activity in the body is associated with certain forms of breast cancer. Although parabens can act similarly to estrogen, they have been shown to have much less estrogenic activity than the body's naturally occurring estrogen. For example, a 1998 study (Routledge et al., in *Toxicology and Applied Pharmacology*) found that the most potent paraben tested in the study, butylparaben, showed from 10,000- to 100,000-fold less activity than naturally occurring estradiol (a form of estrogen). Further, parabens are used at very low levels in cosmetics. In a review of the estrogenic activity of parabens, (Golden et al., in *Critical Reviews in Toxicology*, 2005) the author concluded that based on maximum daily exposure estimates, it was implausible that parabens could increase the risk associated with exposure to estrogenic chemicals.

FDA believes that at the present time there is no reason for consumers to be concerned about the use of cosmetics containing parabens. However, the agency will continue to evaluate new data in this area. If FDA determines that a health hazard exists, the agency will advise the industry and the public, and will consider its legal options under the authority of the FD&C Act in protecting the health and welfare of consumers.

In conclusion on the parabens. It is unbelievable that any company could make mileage and a unique sales proposition from saying that parabens are unsafe, when in reality the opposite is true. Clearly any company trying to make a strong case for not using parabens is uninformed and technically incompetent. Stupidity deserves tough words.

## 2. CONTAINS NO CHEMICALS

This is too silly to warrant any comment – everything is a chemical in one form or another.

## 3. CONTAINS NO PRESERVATIVES

This is another way of saying that the product contains no preservatives listed in Annex V1 of the legislation and so in law would be viewed as illegal. However, there are some raw materials which when added to our products reduce the level of preservative required to protect our product and may even offer sufficient preservative action to allow a product to pass the BP or USP microbiological challenge test.

These materials may be perfumery ingredients as in the Dr Straetmans Dermofeel range, Naticide from Sinerga, or Neopein and Biopein from Bio-Botanica, etc. There are a whole raft of botanical extracts based on Grapefruit Seed Extract but be careful because on one web site we found the following statement

*“Grapefruit Extract is made by first converting grapefruit seeds and pulp into a very acidic liquid. This liquid is loaded with polyphenolic compounds, including quercetin, helperidin, campherol glycoside, neohelperidin, naringin, apigenin, rutinoid, poncirin, etc. The polyphenols themselves are unstable but are chemically converted into more stable substances that belong to a diverse class of products called quaternary ammonium compounds.*

*Some quaternary compounds, benzethonium chloride and benzalkonium chloride, for example, are used industrially as antimicrobials, but are toxic to animal life. The B vitamin choline is also a quaternary compound, but is non-toxic and even essential for maintaining healthy neurological function and fat metabolism.*

*This material features the best of both worlds: the quaternary compounds derived from grapefruit exhibit broad-spectrum antimicrobial activity, while evidencing none of the toxic side-effects of chemically-derived quaternaries”.*

By its own admission this material is a synthetic (albeit a natural source) **derivative** and could not be called “Citrus Paradisi (Grapefruit) Seed Extract as shown in the CTFA Cosmetic Ingredient Dictionary. How many natural cosmetics use this material, which by admitted definition is not a natural preservative?

High levels of alcohol, glycols and sugars may also give a high level of self-preservation.

## 4. CONTAINS NO PETROCHEMICALS

Britannica Concise Encyclopaedia defines petrochemical as “strictly, any of a large class of chemicals (as distinct from fuels) derived from petroleum and **natural gas**. The category has been broadened to include a much larger range of organic compounds and a few inorganic compounds (including carbon black, sulfur, and ammonia). Some materials cannot be classified unequivocally because they have alternative sources (benzene from coal, ethanol from fermentation). Like crude oil and natural gas, most petrochemicals consist mainly of carbon and hydrogen and are called hydrocarbons. Petrochemicals used as raw materials (feedstocks) include ethylene, propylene, butadiene, benzene, toluene, xylene, and naphthalene.

The word “natural” in natural gas demanded us to seek a source for these petrochemicals.

“Crude oil, natural gas and coal are fossil fuels and were formed from the fossilized remains of dead plants and animals that once lived millions of years ago. Oil and natural gas are the products of the deep burial and decomposition of dead plants and animals. Heat and pressure, in the absence of oxygen, transform the decomposed material into tiny pockets of gas and crude oil. The oil and gas then migrates through the pores in the rocks to eventually collect in reservoirs. Coal comes mainly from dead plants which have been buried and compacted beneath sediments. Most coal originated as peat in ancient swamps created many millions of years ago”. Source <http://www.moorlandschool.co.uk/earth/earthresources.htm>) – even a child knows where coal and oil come from!

It is quite obvious then that petrochemicals are totally and unequivocally natural. Maybe the marketers should look at specific materials like the low molecular weight mineral oils that were a concern in some food packaging as a potential source of carcinogenic materials. Perhaps they are thinking of the aniline hair dyes? Whatever they are thinking cannot be generalized in such sweeping and irrational statements that exclude wonderfully protective, safely moisturising and an effective skin barrier like petrolatum (petroleum jelly) beloved by dermatologists for decades.

## **5. CONTAINS NO ANIMAL DERIVATIVES**

The majority of us eat meat (it would not be fair to point at vegetarians anymore than it would be fair of them to point at us). Man was designed a meat eater and his dentition is set up for tearing and chewing at meat with a digestive system tailored to the processing of that energy source. However, man no longer eats every scrap of the kill and so a lot of waste products remain that go the pet food industry and to the soap makers. The fat renderers produce tallow which can then be saponified into tallowate soap, which was an excellent way to use up much of the fatty waste. Other waste – particularly hooves and horns was used to extract the gelatin used in jellies and other food stuffs as a thickener. The skin and other tissue were used as a valuable source of proteins, keratin, stearic acid and other useful cosmetic derivatives.

Now there is a move against these animal derivatives, which seems daft, since these materials are useful and functional. The animal was going to be used for food anyway and it was not as if the animal was being sacrificed for its raw materials. So the demand for these slaughter house products has gone into decline, the previously valuable resource is now being burnt or is destined for a land fill site. This is hardly

the green, caring for the environment promise made on the natural label. It is positively wasteful contributing a massive and potentially toxic selection of waste gases as it is burnt or some foul decomposition products if thrown to valuable land fill.

## 6. CONTAINS NO SYNTHETIC FRAGRANCE

This is a shame, because the synthetic fragrances are unlikely to have the 26 allergens that need to be legally declared on the packaging. Those on the table marked in green are found in natural essential oils. **This file is included in the files sent to you.**

Ingredients	
1	Amyl Cinnamyl Alcohol (Amyl Cinnamic Alcohol)
2	Amyl Cinnamal
3	Anisyl Alcohol (Anise Alcohol)
4	Benzyl Alcohol
5	Benzyl Benzoate
6	Benzyl Cinnamate
7	Benzyl Salicylate
8	Cinnamyl Alcohol
9	Cinnamal
10	Citral
11	Citronellol
12	Coumarin
13	Eugenol
14	Farnesol
15	Geraniol
16	Hexyl Cinnamaldehyde (Hexyl Cinnamal) CTFA
17	Hydroxycitronellal
18	Isoeugenol
19	2-(4-tert-Butylbenzyl) Propionaldehyde (Lilial) Butylphenyl methylpropional (CTFA)
20	Limonene
21	Linalool
22	Hydroxymethylpentylcyclohexene-carboxaldehyde (Lyal) Hydroxyisohexyl-3-cyclohexene carboxaldehyde (CTFA)
23	Methyl Heptin Carbonate
24	3-Methyl-4(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one (Methyl Ionone) Alpha-isomethyl ionone (CTFA)
25	Oakmoss Extract
26	Treemoss Extract

Not found in essential oils

As an example Lavender contains linalool at about 45%, Lemon contains around 73% limonene, Lemongrass about 93% of citral and Clove has 92% eugenol. Clearly those that advocate the safety of natural fragrances over synthetic are neither chemists nor perfumers.

## 7. CONTAINS NO SULFATES

Thankfully this claim is rarely seen, because it is idiotic and meaningless. There are so many wonderful sulfates (US spelling) or sulphates

Alum or potassium aluminium sulphate is astringent and very useful in some weeping skin conditions and also makes a reasonable styptic. Glauber's salts or sodium sulphate is a good choice for sitz baths. White vitriol, white copperas or zinc sulphate is used in treating stubborn skin conditions. Epsom salts or magnesium sulphate is another excellent additive to the bath for problematic skin conditions. The Roman spa ethic used *Sal polychrestum* or sulphurated potash which is potassium sulphate and *Sal enixum* which is potassium bisulphate. Gypsum salts are calcium sulphate (as is plaster of Paris). Not many hazards to be seen within the list of sulfates. Perhaps the marketer in this case meant Sodium Lauryl Sulfate (SLS)?

## 8. CONTAINS NO SLS

The joke on the green brigade is that this is one of the most natural detergents produced from nature by man. It is chemically simple in structure and the process to make SLS is relatively unsophisticated while giving a detergent that is close to the starting coconut fatty acids.

Any mention that SLS is a carcinogen is without any fact or substance.

An article published in the Journal of the American College of Toxicology, Volume 2, Number 7, pp. 127- 181, 1983 states that Sodium Lauryl Sulfate and Ammonium Lauryl Sulfate appear to be safe in formulations designed for discontinuous, brief use followed by thorough rinsing from the surface of the skin. In products intended for prolonged contact with skin, concentrations should not exceed 1%.

**CTFA Response Statement: Internet-Spread Rumors About Sodium Lauryl Sulfate (SLS) and Sodium Laureth Sulfate (SLES) are false and unsubstantiated**

[http://www.ctfa.org/Template.cfm?Section=Internet\\_Rumors&Template=/ContentManagement/ContentDisplay.cfm&ContentID=867](http://www.ctfa.org/Template.cfm?Section=Internet_Rumors&Template=/ContentManagement/ContentDisplay.cfm&ContentID=867)

July 12, 2000

*It has come to our attention that an e-mail is currently circulating on the Internet which falsely states that Sodium Lauryl Sulfate (SLS) and Sodium Laureth Sulfate (SLES), ingredients used primarily in some cosmetic "rinse off" products, are unsafe. The story relayed via e-mail is an unsubstantiated story. It is typical of Internet rumors notorious for inaccurate and false information.*

*There is no evidence of harm from the use of either SLS or SLES as used in cosmetic products. Both ingredients were reviewed in 1983 by the Cosmetic Ingredient Review (CIR) Expert Panel and found to be safe. Complete reports on both ingredients are available from CIR.*

*The Canadian Health Protection Branch (part of the Canadian government) has branded SLS e-mail stories as a hoax. On its web site ([www.hc-](http://www.hc-sc.gc.ca)*

[sc.gc.ca/ehp/ehd/psb/cosmetics/sls.htm](http://sc.gc.ca/ehp/ehd/psb/cosmetics/sls.htm)), Health Canada goes on to say “Health Canada considers SLS safe for use in cosmetics. Therefore, you can continue to use cosmetics containing SLS without worry.”

*(CIR was established in 1976 by CTFA. CIR is a unique endeavor to assess the safety of ingredients used in cosmetics in an unbiased, expert manner. Its findings have established a public record of the safety of cosmetic ingredients. The heart of the CIR program is the Independent Expert panel consisting of world-renowned physicians and scientists. Expert Panel members must be free of any conflicts of interest, and must meet the same conflict of interest requirements as outside experts to the Food and Drug Administration (FDA).*

The American Cancer Society totally debunks the views that SLS is carcinogenic.  
[http://www.cancer.org/docroot/NWS/content/NWS\\_2\\_1x\\_Debunking\\_the\\_Myth.asp](http://www.cancer.org/docroot/NWS/content/NWS_2_1x_Debunking_the_Myth.asp)

NICNAS in Australia have prepared a useful summary of all the factual published data.

[http://www.nicnas.gov.au/Publications/Information\\_Sheets/Existing\\_Chemical\\_Information\\_Sheets/ecis\\_SLS\\_PDF.pdf](http://www.nicnas.gov.au/Publications/Information_Sheets/Existing_Chemical_Information_Sheets/ecis_SLS_PDF.pdf)

The OECD report (1997) concluded that, “The human health hazard assessment for SLS shows that at present the substance is of no concern for the general public (consumers) and for workers” and similarly the CIR report (1983) concluded, “SLS [and ALS] appear to be safe in [cosmetic] formulations designed for discontinuous, brief use followed by thorough rinsing from the surface of the skin. In products intended for prolonged contact with skin, concentrations should not exceed 1%.” Overall, there are no data in the OECD and CIR reports on SLS and their formulations to indicate SLS to be a skin sensitizer, genotoxic, carcinogenic, or a reproductive toxicant. The toxicity of SLS appears to be restricted to acute toxicity and skin and eye irritation. Indeed, for chronic toxicity, an oral study in the rat indicates that the primary health effect of SLS appears to be local irritation. However, these health effects are primarily based on the effects of SLS at high doses in studies in laboratory animals. The risk to humans from SLS will depend on the amount of exposure to the chemical. The amounts of SLS used in cosmetics, and hence the potential human exposure, is significantly smaller than that used in animal studies. Consequently, considering the human health effects associated with SLS together with data indicating potentially extensive use in both industrial and consumer areas, it appears that for consumers and workers, the human health hazards are low.

There can be no excuse for the claims made against SLS, the risk or irritation in a leave on product is no worse than any other concentrated and powerful detergent. There would be no instance when SLS would be left on the skin, it is a detergent and in all cases would be rinsed off anyway. It is a fabulous foaming agent, with masses of bubbles and leaves squeaky clean hair.

## **9. CONTAINS NO PEGS / CONTAINS NO ETHOXYLATES**

Sadly more nonsense written by those who would wish to create a marketing opportunity based on ignorance and/or intention to deceive. The truth is that ethylene

oxide is used to produce an ethoxylate by grafting an ethylene oxide unit onto a carbon chain backbone. The fully reacted ethylene oxide (which is a carcinogen in its raw state) is totally reacted and the resultant molecule is left milder as a result of this reaction. Thus sodium lauryl sulfate (SLS) when reacted with ethylene oxide becomes sodium lauryl ether sulfate (SLES) or sodium laureth sulfate (some ignoramuses consider SLS and SLES to be the same which is totally incorrect). The interesting result of this transformation is that the new SLES is about one eighth of the irritancy of the original SLS, furthermore, if one adds more ethoxylation to the SLES and go to higher than a normal 2 mole ethoxylate then the irritancy decreases still further. So much for the scare stories.

Often you will notice that cocamidopropyl betaine (CAB) has been added to an SLES formula. Blending CAB (25%) and SLES (75%) give an irritancy value far less than if either of these materials were used alone – this is a synergistic effect.

In order to make an emulsion there is a need to stabilize the oil and water, which as everybody will know are not miscible. The way to keep these two phases in a stable emulsion is to use an emulsifier and it is in these cases where the use of ethoxylated materials is most prevalent. The long chain carbon part of the molecule wants to dissolve in the oil phase, and the inclusion of an ethoxylated part gives a water loving end to the molecule. The emulsifier acts as a bond between the two and so helps to form a stable colloid.

There is another use for these ethoxylated materials and that is as a solubiliser for the perfume in an Eau de Toilette or Aftershave. Alcohol may partially dissolve some of the oily perfume, but the addition of an ethoxylated material makes the product crystal clear and far more stable and resistant to the cold (when the product might otherwise go cloudy as the perfume comes out of solution as the temperature drops).

In conclusion for ethylene oxide, we agree it is a carcinogen in its raw state, but not when it is reacted out to form an ethoxylated compound (anymore than concentrated sulphuric acid is dangerous when reacted with a strong alkali to form a salt and water).

## **10. CONTAINS NO DIMETHICONE**

This was a recent discovery on a label and we were puzzled as to why this inert and wonderful material that is so lubricious on the skin should be a target for marketing rejection. After much thinking we decided it could only be because of the complications caused from very old prosthetic breast implants that used silicon oil that had burst or leaked. Hardly a problem in topical skin products, just another case of misinformation.

## **11. CONTAINS NO PESTICIDES**

We have not managed to find any product formulated with a pesticide and we hope that the marketer that came up with this suggestion was well rewarded for such an inane strap line.

## **ORGANIC**

The Organic Certification scheme was designed for foods and it is perfectly understandable that a product would want to use an oil or material that had been produced under organic conditions so that the ingredient could be highlighted as coming from organic conditions. However, to certify a product as organic does not make quite so much sense. Water is not considered organic - this is surprising since it falls out of the heavens as a pure substance and is then purified by distillation or demineralization to remove anything it might have picked up on its journey to the factory tap. To get around this somebody had the clever (but very expensive idea) of using a distilled floral water (the steam condensate from producing essential oil from an organic feedstock). Strangely, the Soil Association say that this does not count and only 30% of the floral water can be considered as organic (mystified? You are not alone). The alternative is to use 1:1 Aloe vera gel (organic of course), but what would happen if we shipped the 10:1 organically certified concentrate and then replaced the 90% of water taken out to reduce shipping costs when it arrived at our factory? The truth is that nobody knows the answer yet!

The question of whether organic is any different to non-organic remains another mystery. We have examined organically grown extracts versus non-organic, and we have also looked at organic fixed oils versus non organic. The overall opinion is that in the most part the organic oils are of inferior quality as the colour is often considerably worse, the rancidity is more developed and therefore the odour is poorer. A molecule does not know it is organic and so *gamma* linolenic acid found in organic Evening Primrose Oil is identical to that found in regular Evening Primrose Oil (*Oenothera biennis*). To use organic material is a very good way of paying four times the price per kilogram for an inferior product.

### **FAIR TRADED**

A wonderful idea that helps the poorer countries to make a living, but do make sure that the scheme has been vetted, audited and is genuine, because there are those that would exploit the idea, charge the higher prices but not reward the workers as promised.

### **ECO FRIENDLY**

A future topic that is worthy of discussion.

## **Conclusions**

It would be refreshing to see a return to the truth confirmed by science rather than the drivel that is being generated and perpetrated by non scientific lay people. The cosmetic and toiletry industry is well regulated and the laws are fierce and robust, supported by independent safety assessors, toxicologists, the SCCP (Scientific Committee for Consumer products), CIR (Cosmetic Ingredient Review), IFRA (International Fragrance Research Association), and independent researchers. Basing a range of products on farcical and untruthful facts is a trend that should be stopped immediately by prosecuting those companies for unfair trading and misleading the consumer.

The industry is in danger of going out of control and there needs to be a stand taken against the ridiculous statements made on some of the products being sold in our industry. Some claims are so ludicrous that it is only a matter of time before the consumers realize that some of those in our industry are not only dishonest but spouting a lot of meaningless mumbo-jumbo. If we want to remain respected and to be taken seriously, then it is the duty of each of us to stamp out this type of product. Tough words perhaps, but we either regulate ourselves or be totally legislated out of any degrees of freedom and damned to a life of even more bureaucracy.