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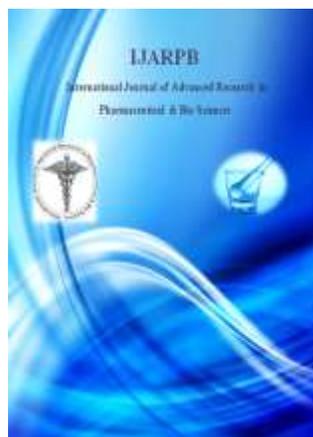
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A Report on Quality, Safety & Legislation of Cosmetics

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ABSTRACT

With a broad development study in chemical supply legislation (notification, classification, risk assessment, etc.), and regulatory chemistry and toxicology we are also able to produce dossiers to support inclusion of colouring agents, preservatives, and UV filters in Annexes IV, VI and VII of the Cosmetics directive. To control quality product the international organization of standardization in ISO:9000 has defined Quality control system.

KEY WORDS: Safety assessment, Quality control, Legislation

(Review Article)**INTRODUCTION****Cosmetic Product**

Any substance or preparation intended to be placed in contact with the various external parts of the human body with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, correcting body odours, protecting them, or keeping them in good condition.

Quality control: The operational techniques & activities that are used to fulfill requirements for quality¹.

Quality control tests for cosmetic products:**Quality control of Compact Powder:**

Shade control & lighting: This is to control & determine the variation of color shade from batch to batch & with the standard one such method is comparison of the appearance of the body of the powder with a standard when it is spread out & flattened on a white paper background. Artificial lighting is used for color evaluation.

Dispersion of color: Color should be homogeneously distributed in the powder base. There should be no segregation or bleeding of the color. Spreading the powder on a white paper & checking it with magnifying glass can test this.

Pay-off: The pay-off character, i.e. adhesion with the puff, of a compact or pressed powder should be tested on the skin.

Pressure testing: Pressure applied to compact powder should be uniform to prevent air pocket & thus breaking or cracking. Uniformity of hardness

can be tested by penetrometer. Reading of hardness is checked at various points of compact tablet to see the uniformity of hardness.

Breaking test: This is carried out by dropping tablet of powder on a wooden surface several times from a height 8-10 inches & checking the breakage or clipping of the compact. If the cake is unbroken it is indication of the resistance against travel & normal handling.

Flow property: This is very important, particularly for body powders, as they should come out easily from the container for easy application. Measuring the angle of repose of powder product by allowing falling on a plate from a funnel & measuring the height radius of heap formed can study this.

Particle size & abrasiveness: Particle size can be determined by microscope, sieve analysis or by using sophisticated instruments & techniques. Rubbing the powder on a smooth surface & then studying the effect on the surface-using microscope can study abrasiveness.

Moisture content & limits for color: These can be estimated by using suitable analytical methods².

Lipsticks

Melting point: Determination of melting Point & is determined by capillary tube method by keeping the size of capillary, length of fill & rate of heating constant.

Breaking point: This test is done to determine the strength of the lipstick.

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Thixotropy character: This is done by using penetrometer.

Perfume stability: how much time the fragrance long lasted is measured?

Oxidative stability: It is predicted by standard determination of peroxide value after exposure to oxygen under given condition.

Surface anomalies

Accelerated stability test; It can be studied at higher temperature or alternatively keeping at 45c and 0c and observing the changes^{3,4}.

Nail lacquers and removers

Drying rate: This can be done by taking the product on a flat surface and touching the tip of finger at short intervals of time of feel the tackiness. Time taken for disappearance of tackiness is noted. The time by IS - 6min (minimum)

Smoothness: The film is applied on a surface and the surface characteristics of the film are studied microscopically

Hardness: Film is applied on flat surface and the hardness is measured by applying pressure mechanically.

Adhesion: This is done by applying the film and then measuring the adhesion character by trying to remove the film mechanically and the force required for that.

Water resistance: This is done by applying a continuous film on a surface and immersing in weight, is calculated. Higher the increase in weight lowers the resistance^{9,10}.

Quality control of shampoos

Foam & foam Stability test for foam stability: - 200ml. of a surfactant solution is dropped into a glass column containing 50 ml of same solution.

The height of the foam generated is measured immediately and again after specific time interval. It is measured in volume

Detergency & coloring action: 1) Effect on water hardness 2) Surfactension and wetting:- The measurement of surface and interfacial tension is a guide for effectiveness of a surfactant solution to surround, to break up and solubilize the soil. 3) Surfactant analysis:

Eye Irritation: 0.1 ml of test soln is instilled I eye of rabbit. Keep one eye for control test. After 4sec both eye are washed with saline and observation made after 1 hour

Oral toxicity: It is given in terms of LD₅₀ .if LD₅₀ is 5 or more the toxicity is considered as low ^{5,6}.

Safety assessment for Cosmetics

Unlike other chemical products (new industrial chemicals, biocides, medicines, etc.), the CD achieves this aim without a pre-market procedure (authorisation, registration, or notification), although there are provisions for informing the authority of the place of manufacture, or importation, and some national requirements to file the composition with Poison Information Centres^{7,8}.

The safety assessment is part of a package of information, the TIF (or PIP), which the manufacturer or importer must keep up-to-date and available for inspection by the Authorities. The content of the TIF is as follows:

Composition of the cosmetic product

Physico-chemical and microbiological specifications of raw materials and finished product

(Review Article)**Method of manufacture**

Cosmetic safety assessment and details of the safety assessor

Existing data on the undesirable effects on human health (eg from customer complaints)

Proof of the effect (only for certain products, such as sunscreens)

Data on animal testing performed by the manufacturer, his agents, or suppliers relating to the development or safety evaluation of the product or its ingredients

The cosmetic safety assessment has to be carried out by a suitably qualified person, such as a chartered toxicologist, dermatologist, or chemist. The safety assessment uses available test reports, literature data, structure–activity relationships, and regulatory texts to determine safe levels of cosmetic ingredients in a new formulation^{13, 14}.

Safety assessment

It is recommended that this should generally be in the form of a signed statement of opinion by an appropriately qualified and suitably experienced person or persons. A specific safety assessment is also required for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.

The safety assessor should take into account all support information such as:

The general toxicological profile of each ingredient used;

The chemical structure of each ingredient;

The level of exposure of each ingredient;

The specific exposure characteristics of the areas on which the cosmetic product will be applied;

The specific exposure characteristics of the class of individuals for whom the cosmetic product is intended^{11, 12}.

The safety assessor

In the UK Regulations, the person responsible for the health assessment is called a qualified person. The name and address of the qualified person or the person responsible for the assessment under Regulation (16) (1)(d) and (e) must be provided.

Safety Assessment and Product Information Pack:

The assessment will form part of the product information pack which should also include details of the qualitative and quantitative composition of the product, specifications of raw materials and finished products and the purity and microbiological controls, details of 2 methods of manufacture in accordance with good manufacturing practice, data on undesirable effects on human health, and where appropriate, proof of any claimed effect.

Restrictions on Ingredients

All ingredients, natural or not, need to be in line with the Regulations (which are the same as EU Council Directive 76/768 EEC). There are lists of banned substance which may not be used in any cosmetic product, lists of products which are restricted by percentage use in a particular product, and also positive lists for colours, uv-

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filters and preservatives – meaning only those on the list may be used.

Labelling

There are very specific requirements for labelling, which must include an address within the European Union from where the product information is available, and a full ingredients listing amongst other items. A product manufactured outside of the EU must also include country of origin^{15, 16}.

Cosmetic legislation and the product safety assessment

Cosmetic legislation in Europe is based on the Cosmetics Directive (CD; 76/768/EC, as amended). This has been transcribed in the UK into the Cosmetic Products (Safety) Regulations 1996. Its two key objectives are:

Ensuring a high level of protection for consumers of cosmetic product

Allows the free circulation of safe cosmetic products within the EU

In current cosmetic legislation, colouring agents (with the exception of hair dyes) (Annex IV), preservatives (Annex VI), and sunscreens (Annex VII) can only be used in cosmetic formulations if they are listed in the Annexes and used according to the conditions given therein. All other ingredients may be used, unless specifically banned or restricted according to Annexes II and III²¹.

Fragrance ingredients

Fragrances are regulated as industrial chemicals, but there is a separate code of practice (CoP) issued by the International Fragrance Association (IFRA). Interestingly, copyright laws usually apply only to visual or aural works, and fragrance formulations cannot generally be protected this way, so that the industry is often highly secretive about the composition of its products. .

For existing fragrances, the CoP advocates a safety evaluation of the substance before marketing occurs. The evaluation follows guidelines given in a published paper (Regulatory Toxicology and Pharmacology, 2000, 31, 166-181)^{17, 18}.

Cosmetic ingredient

A cosmetic ingredient is any substance or preparation of synthetic or natural origin used in the composition of a cosmetic product. Note, however, that for ingredient labelling purposes perfume and aromatic compositions, i.e. flavours, are subject to special rules and these are explained in the paragraphs dealing with ingredients listings^{19, 20}.

Common ingredient nomenclature

The labelling nomenclature referred to in Regulation 12(2) (a) is published by the European Commission as part of the inventory of cosmetic ingredients. This nomenclature shall be used for products supplied in European Union. There are over 7000 ingredients on the current list published in 1996, amended in 2006, and it must be used for ingredient labelling purposes. This nomenclature, developed by a Colipa (European Cosmetics Association) working

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group, has been approved by Member States and will be updated from time to time. It is now known as the INCI nomenclature (International Nomenclature of Cosmetic Ingredients) with the objective of satisfying the need for a truly international system of labelling. For example: water is known as aqua

These refer to the various groups of ingredients contained in Schedules 3 to 7 of the Regulations that list prohibitions and restrictions.

Schedule 3, Part I lists ingredients prohibited in all cosmetics unless otherwise specified.

Schedule 4, Part I lists ingredients that may only be used subject to the restrictions specified. It includes certain ingredients commonly but not exclusively used in fragrances and which must be labelled individually if they exceed a certain threshold level regardless of the function they perform in the product²³.

Ban on animal testing

The Cosmetics Directive banned the testing of finished cosmetic products on animals in any territory of the EU from 11th September 2004 and the testing of ingredients, or combinations of ingredients, from 11th March 2009, where the testing is undertaken in order to satisfy the requirements of the Directive. The UK Government already had a ban in place for a number of years that has a similar effect.

The Regulations contain a ban on the testing of finished cosmetic products on animals where the testing is undertaken to ensure compliance with Directive 76/768/EEC or with the Regulations. This prohibition had effect from 11th September 2004. The Regulations also maintain a 2-stage

ban on the testing of cosmetic ingredients on animals.

After 11th March 2009 (or 2013 in the case of tests concerning repeated dose toxicity, reproductive toxicity or toxicokinetics) it is illegal to supply any cosmetic product which contains any ingredient or combination of ingredients which have been tested on animals using a method other than an alternative test method irrespective of whether an appropriate alternative test method exists²².

List of ingredients

A full list of ingredients must be given on the outer packaging headed or preceded by the word INGREDIENTS. Where there is no outer packaging, the list must appear on the container (see also paragraphs 64 to 80 on Labelling Difficulties). This listing must:

Show all ingredients added to the product;

use the name given in the Common Ingredients Nomenclature known as the INCI name (International Nomenclature for Cosmetic Ingredients). See paragraph 13. There is no requirement to use either upper or lower case text;

In the absence of an INCI name¹⁰, use an alternative as listed in Appendix 1 of this guidance note;

For colouring agents, use the INCI names as detailed above²⁴.

Name and address

The name and address required are those of the manufacturer or supplier established within a Member State of the Community or European Economic Area.

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The name and address must be sufficient to identify the undertaking. The address may be abbreviated to a well-known city or town such that the normal postal service will deliver a letter to that address.

Best before date

A product which is likely to deteriorate up to and including 30 months from the date of manufacture so that it:

Ceases to satisfy the general safety requirement in Regulation 4; or

Ceases to fulfil its intended function;

Must have a date of minimum durability using the words “Best before” immediately followed by either:

The earliest date, in the form month, year, in which one of these may occur; or

An indication of where that date appears on the labelling.

The minimum durability date must appear on both the primary container and outer packaging in English. Best before November 2010, Best before Nov 10 and Best before 11/10 is all acceptable forms. It is generally accepted practice to be able to abbreviate the words best before to Exp and Best Before End to BBE²⁵.

“Period after Opening” (PAO)

Any cosmetic product, subject to certain exceptions detailed below, that does not require a date of minimum durability must be marked with a “Period after Opening” (PAO). It must appear on both the primary container and outer packaging.

Opening of the product may be considered as occurring when the consumer opens the product for use for the first time²⁴.

Batch number or lot codes

A code which enables the manufacturer or supplier to identify the batch in which the product was manufactured must be marked on both the primary container and outer packaging. If the product is not made in a batch, then the code should enable the date and place of manufacture to be identified.

Where it is impossible for reasons of size for the lot code to appear on both the primary container and outer packaging, it may appear on the outer packaging alone²⁵.

Language

The following must be in English for products supplied in the UK, but the additional use of other languages is allowed:

Any warnings or information required

Precautionary information;

“Best before” when used to indicate the date of minimum durability;

“Months” and “years” when used to indicate “Period after Opening”;

Product function.

Warning statements and precautionary information

Information relating to substances, preservatives and UV filters, and any particular precautions to be observed in use will normally appear on both the primary container and outer packaging.

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Where it is impossible, for reasons of size, for details of the batch code to appear on both the primary container and outer packaging, the details may be given on the outer packaging.

Ingredient listing

An ingredient listing is required on the outer packaging only or, in its absence, on the primary container. Where it is impossible for practical reasons for the list to appear on the packaging (or container), it must be given on a leaflet, label, tag, tape or card enclosed with the product or attached to it²¹.

Ingredient labelling - colours and associated ingredients

Colour ingredients which do not have a CI number, as listed in Schedule 5 to the Regulations, but are closely associated with colour might only be present in some products within the decorative range. The industry interpretation is to list these items under the +/- (may contain) section of the ingredient listing. Examples are mica and tin oxide, both used as opacifiers.

Free samples

Free samples, whether they are provided in-store, by direct mail or in magazines e.g. shampoo samples, are considered to be within the definition of supply contained in the Regulations. Compliance with all of the requirements of the Regulations is, therefore, required.

Off-Pack Labelling - Responsibilities of Manufacturers, Retailers & Suppliers

Manufacturers must provide a list of ingredients relating to the products in question. It is advisable to include information which refers to the retailer's responsibility, for example 'To comply with the Cosmetic Products (Safety) Regulations 2008, a list of ingredients as given above must be displayed in immediate proximity to the container in which the product is exposed for sale'.

Contents of the Product Information

The information which must be present in the PI is detailed in the following sections. It may be the case that a competent authority would like to see supporting documentation, in which event adequate time is likely to be given to the company for this to be obtained. Supporting documentation may be in a language of the Community which is not English.

Product composition

This should be a statement of the complete quantitative composition of the product covering all raw materials added. This will also meet the specified requirement for qualitative composition.

It will be useful to link the names of the raw materials used to the equivalent INCI names used for ingredient labelling.

In the case of perfumes and perfume compositions used as ingredients, only the name and code number of the composition and the identity of the supplier have to be provided²².

(Review Article)**Offences**

Any contravention of the Cosmetic Products (Safety) Regulations 2008 (as amended) is treated as a contravention of the safety regulations made under the Consumer Protection Act 1987. Please refer to the Regulations themselves for full details.

Where the product concerned is for export to a state outside the European Economic Area, that is the European Union, Iceland, Norway and Liechtenstein, enforcement action will not be taken on regulations concerning:

The general safety requirement
 Substances prohibited in cosmetics
 Restrictions on ingredients
 Coloring agents, preservatives & UV filters
 labelling requirements
 Product information
 Notification of manufacture or import
 Qualified persons

The enforcement powers available for all these responsibilities are contained in the Consumer Protection Act 1987. If there are reasonable grounds to suspect an offence, the officer of the competent authority (normally a Local Authority Trading Standards Officer) has the power to require companies or individuals to produce any records relating to their business and to seize and detain goods or records which the Officer has reasonable grounds for believing may be required as evidence in court proceedings²¹.

Penalties

Penalties for contravention of the Regulations 16, 17 and 19 are, on summary conviction, imprisonment for not more than 6 months or a

fine not exceeding £5000, or both. For Regulations 10, 11, 14 and 16 (1) (i), the maximum fine is the same, but imprisonment cannot exceed 3 months²⁶.

CONCLUSION

The cosmetic safety assessment has to be carried out by a suitably qualified person, such as a chartered toxicologist, dermatologist, or chemist. The safety assessment uses available test reports, literature data, structure–activity relationships, and regulatory texts to determine safe levels of cosmetic ingredients in a new formulation. Combined with exposure values for particular types of cosmetic use, this risk assessment process can give margins of safety for individual components and an overall conclusion regarding the safety of the new cosmetic product.

The assessment will form part of the product information pack which should also include details of the qualitative and quantitative composition of the product, specifications of raw materials and finished products and the purity and microbiological controls, details of methods of manufacture in accordance with good manufacturing practice, data on undesirable effects on human health, and where appropriate, proof of any claimed effect.

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