**Regulation (EC) No. 648/2004 of the European Parliament and of the Council on Detergents.**

**Background**

The provision of information provided to the consumer via the labelling of ingredients and websites.

Information to be held by manufacturers and to be supplied to Medical Professionals and competent authorities on request

**Detergent ‘Scope’**

The term "detergents" can be summarised as applying to all products to clean textiles or to clean hard surfaces, in other words, any ‘detergent / cleaning product’ claiming a cleaning function.

***‘Detergent’*** *means any substance or preparation containing soaps and/or other surfactants intended for washing and cleaning processes. Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and marketed for or used in household, or institutional or industrial purposes.*

***Other products to be considered as detergents are:***

***‘Cleaning preparation’****, intended for domestic all purposes cleaners and/or other cleaning of surfaces (e.g.: materials, products, machinery, mechanical appliances, means of transport and associated equipment, instruments, apparatus, etc.);*

***‘Other cleaning and washing preparations’****, intended for any other washing and cleaning processes.*

***‘Surfactant’*** *means any organic substance and/or preparation used in detergents, which has surface-active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing the surface tension of water, and of forming spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or microemulsions and/or micelles, and of adsorption at water-solid interfaces.*

## **8.2. New Ingredient Datasheet for Medical Personnel**

Article 9(3) requires that manufacturers placing Detergent products on the market shall, upon request, make available without delay and free of charge, to any medical personnel, an ingredient datasheet as stipulated in Annex VII C, to be used for medical purposes only. Annex VII(C) reads:

*“The following provisions shall apply to the listing of ingredients on the datasheet referred to in Article 9(3).*

*The datasheet shall list the name of the detergent and of the manufacturer.*

*All ingredients shall be listed; in order of decreasing abundance by weight, and the list shall be sub-divided into the following weight percentage ranges:*

*— 10 % or more,*

*— 1 % or over, but less than 10 %,*

*— 0,1 % or over, but less than 1 %,*

*— less than 0,1 %.*

*Impurities shall not be considered to be ingredients.*

*The common chemical name or IUPAC2) name, the CAS number, and, where available, the INCI3 name, and the European Pharmacopoeia name, shall be given for each ingredient.”*

Additionally Article 11.2 requires that information required to locate the source of the ingredient datasheet appears “on the packaging in which the detergents are put up for sale to the consumer”.

## 2 International Union of Pure and Applied Chemistry

3 International Nomenclature Cosmetic Ingredient

### 8.2.1. Ingredient Datasheet Guidance

• The ‘Consumer’ should be considered as the ‘User’ and the required information is thus required on both the packaging of products sold to the general public and to Institutional & Industrial products.

• The ingredient datasheet should list all ingredients, except impurities, present in the marketed product. The ingredients will normally be those added by the manufacturer to produce the final product. However, where it is known that interactions between ingredients occur during the manufacture of the product, then any resultant chemicals should be taken into account and identified in the list of ingredients.

• The inclusion of ingredients such as perfumes and colorants in a product should be listed in the datasheet as such, i.e. their presence should be indicated by the terms “perfume” and/or “colorant(s)”. Any of the allergenic fragrances that are subject to package labelling requirements under Annex VII.A (i.e. if at concentrations exceeding 0,01% by weight) should also be listed in the ingredient datasheet if they are included in the product.

• It should be emphasised that the obligation to provide an ingredient datasheet to medical personnel is intended to provide product information for medical purposes only. ‘Medical personnel’ is defined as meaning ‘a registered medical practitioner, or a person working under the direction of a registered medical practitioner, acting to provide patient care, make a diagnosis or administer treatment, and who is bound by professional confidentiality’.

• The manufacturer is entitled to require evidence confirming the medical credentials of the requesting party. Whilst credentials are checked, the manufacturer will supply the publicly available data (See 8.3.1).

• Making available ‘without delay’ should be interpreted as making available as quickly as is practically possible.

## **8.3. Publication of list of ingredients**

Annex VII (D) requires that;

*“Manufacturers shall make available on a website the ingredient datasheet mentioned above except for the following information:*

*— weight percentage ranges*

*— constituents of perfumes and essential oils,*

*— constituents of colouring agents.*

*This obligation shall not apply to industrial or institutional detergents containing surfactants, or to surfactants for industrial or institutional detergents, for which a technical data sheet or safety data sheet is available.”*

### 8.3.1. Ingredient Publication Guidance:

• The manufacturer is required to make available to the public at large, on a website, a simplified version of the ingredient datasheet, as described above. In this case it is recommended that ingredients be listed in the order of their concentration in the product, e.g. highest to lowest ingredient concentration. Any allergenic fragrances that are subject to package labelling requirements under Annex VII.A (i.e. if at concentrations exceeding 0,01% by weight) should also be listed on the website if they are included in the product.

• For each ingredient listed the INCI name should be given, if available. Where not available, then the European Pharmacopoeia name, if available, should be given. If neither name is available, then the common chemical or the IUPAC name should be used.

(This guidance assumes a future amendment to the current wording of Annex VII D).

• Manufacturers must make available on a website the public list of ingredients. The location of the website is not prescribed and the manufacturer is free to choose. It is recommended that the choice is made on the basis of logical access, e.g. via a website dedicated to the product or the manufacturer. The manufacturer can also consider making joint arrangements with other manufacturers, e.g. via their trade association, with a view to producing a general detergent product ingredient database website.

• A website is required and not optional. Its address should appear on the label. This last point is not strictly required at this stage, but it is strongly recommended in view of a foreseen future amendment along those lines that will be discussed after entry into force of this regulation. The information on the website must be kept up-to-date. However, when a website is in the course of development or being upgraded, consumers should be able to acquire the information by enquiring from the telephone number that is on the label.

• That manufacturers must ‘make available’ on a website should be interpreted as ‘display’ on a website (free of charge) the public list of ingredients.

• In view of a foreseen future amendment to the current wording of Annex VII D that will be discussed after entry into force of the Regulation and that will confirm the possibility to use only the INCI names for each ingredient, a link must be provided to the Commission’s website on cosmetics that provides a correspondence table between INCI names and CAS numbers. This website address is: http://pharmacos.eudra.org/F3/inci/index.htm.

• Information regarding a product should be retained on the website for two years following the last production of that product. The manufacturer should also consider the means by which products and their variants will be linked to the website information.