

HEALTH, ENVIRONMENTAL & REGULATORY SERVICES

UNDERSTANDING & ATTAINING COMPLIANCE TO THE EU DETERGENT REGULATION

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White Paper



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INTRODUCTION

Many cleaning products are on the market with the majority being what are referred to as “detergents”. A detergent, as defined in the current European legislation, means “any substance or preparation containing soaps and/or other surfactants intended for washing and cleaning processes”. ‘Washing’ means cleaning of laundry fabrics, dishes and other hard surfaces and ‘cleaning’ has the meaning defined by Part 7.1 of EN ISO 846. Detergents may be in any physical form (e.g. powder, unit dose tablet, concentrated liquid, liquid capsule, paste, cake, bar, moulded piece, shape etc.) and marketed for or used in household, or institutional or industrial purposes. These may come in a range of variants to meet consumers’ needs on cleaning, skin care, fabric care and fragrances.

Other products to be considered as detergents and covered by the EU Regulation are:

- ‘Auxiliary washing preparation’ - soaking (pre-washing), rinsing or bleaching (e.g. specialist stain removers, pre-treater);
- ‘Laundry fabric - softener’ - modify the feel of fabrics in processes which are to complement the washing of fabrics (e.g. fabric conditioners, Ironing aids);
- ‘Cleaning preparation’ - domestic all purposes cleaners and /or other cleaning of surfaces (e.g. materials, products, machinery, mechanical appliances, instruments, apparatus etc.);
- ‘Other cleaning and washing preparations’ - any other washing and cleaning processes.

This definition of ‘detergent’ means that all products claiming a ‘cleaning’ function whether it be on textiles or hard surfaces, and which may or may not contain surfactants, need to comply with the requirements of regulation (EC) No 648/2004. Personal hygiene products such as shampoos, shower gels, bubble baths etc. by definition are categorised as cosmetic products and do not fall within the scope of the detergent regulation. In addition, pet cleaning products currently do not fall within the scope of the detergent regulation.

BACKGROUND

The EU detergents legislations evolved from widespread water pollution in Western Europe in the 1960s caused by poorly biodegradable detergents, resulting in the formation of large quantities of foams in rivers; this had adverse impacts on the environment and waste water plants. A seminal moment for the detergent industry and consequently the environment was the introduction of Directive 1973/404/EEC as the response to the damaging effects from "foaming rivers" caused by the accumulation of surfactants. The directive required surfactants used in detergents to be biodegradable to 90% measured by the loss of surfactant properties (i.e. primary biodegradation). This covered only two categories of surfactant (anionics and non-ionics) which at the time left approximately 10% of the total surfactants on the EU market outside the scope of the legislation. The current detergent legislation, regulation (EC) No 648/2004, has now been in force since 8 October 2005, when it replaced various earlier legislative measures (five directives and recommendation). It was designed to achieve the free movement of detergents and surfactants used for detergents on the EU internal markets whilst ensuring a high degree of protection of the environment and public health. The regulation imposes a two-tier testing regime on the biodegradability of the surfactants.

The scope is now wider, covering all surfactants including anionics, non-ionics, cationics and amphoteric. It is applicable to the manufacturing, sale and use of detergents; as such any natural or legal person responsible for placing a detergent or a surfactant for a detergent on the EU market must comply with this regulation.

These include:

- Manufacturers/producers of detergents;
- Importers of detergents;
- Any person changing the characteristics of a detergent;
- 'Any person changing the labelling or packaging of a detergent;
- Packager i.e. a person working on its own account; for example Company A purchases a detergent in bulk form from Company B and then repackages the detergent with its "own" name on the box.

KEY ELEMENTS OF REGULATION (EC) 648/2004

Biodegradability

Regulation (EC) No. 648/2004 tightens the biodegradability testing requirements for surfactants in detergents. It required 'ultimate' aerobic biodegradability for all surfactants used in detergents. The biodegradability control methods are outlined in Annex III of the Regulation. The biodegradability test is made on the raw materials, and must be conducted in GLP- or EN ISO/IEC 17025 compliant laboratories.

A 'surfactant' is defined as II 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 micro-emulsions and/or micelles, and
- of adsorption at water-solid interfaces. 11

Surfactants which failed the ultimate biodegradability, but pass the less stringent primary biodegradable test may, by way of derogation from the Commission, be placed on the market. However, this derogation is only applicable to industrial and institutional detergents and only the manufacturer(s) of these products can apply to the European Commission for derogation. Surfactants granted EU derogations are listed in Annex V of the Regulation.

It is worth noting that detergents (surfactants) that also have active biocidal activity within the meaning of the Biocides Product Directive (BPD, 98/8/EC) (replaced by Regulation 528/2012 (BPR) from September, 2013) and are used as disinfectants are exempted from the biodegradability test requirements if they fulfil the following proviso - the active is listed in Annex I of the BPR, is a constituent of an authorised Biocidal Product or has been allowed under the 10-year transitional measure.

Specific labelling requirements

Detergent regulation (EC) No 648/2004 also placed more stringent labelling requirements on detergent manufacturers / formulators. The responsibility and labelling of packaging for detergents are specified in Article 11 of the Regulation. Furthermore, the labelling requirements apply whether the surfactant or mixture (detergent) is classified as non-hazardous or otherwise. The label information on packaging of detergent products which are for sale to the general public must contain the following information:

- Name and trade name of product
- Name or trade name or trademark, full address and telephone number of the party responsible for placing the product on the EU market. "Placing on the market" means "the first making available of the product on EU market" and refers to "any supply for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge". Hence, an import into the Union customs territory shall be deemed to be placing on the market.
- The address, e-mail address (where available) and telephone where an Ingredient Datasheet (for medical personnel) may be obtained.
- Website address where the list of ingredients of the detergent product is provided.



- For some specific constituents (e.g. surfactants, solvents, builders etc. ... total of 18 are listed in the Regulation) if added to the detergent product at greater than 0.2 % (w/w) must be stated on the label. Precise details of formulation are not required and only types or categories need to be listed in percentage ranges (< 5%; ≥ 5% < 15%; ≥ 15% < 30%; ≥ 30%).
- Additionally, enzymes, disinfectant, optical brighteners, preservatives or perfumes should be stated irrespective of their concentration.
- Names of allergenic fragrance ingredients (e.g. citral, Linalool, d-Limonene etc.) as listed in Annex III of the Cosmetics Regulation (1223/2009) must be included on the label if present at greater than 0.01 % (w/w) (or at a replacement limit).
- In addition, for laundry detergents sold to the general public, the label must include the recommended quantities and/or dosage instructions (in ml/grams) per wash for different water hardness as well as the number of standard washes possible with the content (i.e. using medium water hardness).

Note: It is also referenced that industrial detergent products (solely intended for professional use) may not have to fulfil the above labelling criteria if the equivalent information is provided by other means for example, in a technical data sheet or safety data sheet.

In addition, all detergents which are classified as hazardous must be labelled and packaged in accordance with the requirements of the Dangerous Preparation Directive (applicable till 1st June, 2015) and/or the EU CLP Regulation (1272/2008).

Provision of data

The detergent regulation mandates manufacturers of detergents to give more detailed information on datasheets that must be made available to medical personnel on request. The datasheet which is treated as confidential must include the name of the detergent and manufacturer listing all the ingredients by the chemical name, CAS number and INCI name by percentage ranges (10% or more; 1% ≤ 10%; 0.1% ≤ 1%; < 0.1%).

A less detailed version of the data sheet must be made available in the public domain on a website.

Restriction on phosphates in domestic laundry and dishwasher detergents

Regulation (EU) No 259/2012 published on 14 March 2012 amends Regulation (EC) 648/2004 as regards the use of phosphates and other phosphorus compounds in domestic laundry and dishwasher detergents. From 30 June 2013, it placed a ban on detergents for non-professional use with the total content of phosphorus ≥ 0.5 g in the recommended quantity/dose per wash. The restriction level of ≥ 0.3 g phosphorus for the standard dose of automatic dishwasher detergents will become applicable from 1 January 2017.

COMPLIANCE: WHAT DO I NEED TO DO?

There is no over-arching requirement in the European Union for the registration of detergent products. However, manufacturers of detergents must ensure that their products meet the requirements discussed above. A dossier proving that the detergent product complies with the regulation must be held at the disposal of the Competent Authorities and made available to them upon request by the manufacturer/importer. In some EU, some Member States there is also requirement for registration with a poisons centre (or similar central information point). The person responsible for placing the detergent on the market must include on a website that is freely accessible, a data sheet listing the ingredients in the detergents without the percentage ranges and there is no requirement to declare the constituents of perfumes, essential oils or colouring agents.

The surfactant(s) in the detergent product are required to pass the ultimate biodegradability test as outlined in Annex III of the Regulation. The test methods which are based on the EN ISO standard 14593: 1999 (CO₂ headspace test) and are taken from Council Directive 67/548/EEC measured the ultimate biodegradation to carbon dioxide (CO₂) and oxygen over 28 days. A surfactant achieving above 60% yield is considered to have passed the test and may be used in detergents. Either the results of the actual tests on the surfactant(s) or published data obtained from reliable source with adequate description of the testing conditions may be used to prove compliance. Furthermore, "read-across" using data generated from tests on similar surfactant(s) (i.e. family/group approach) supported with scientifically reasoned justification could be provided as evidence.

The compliance of the surfactant(s) to the biodegradability criteria is communicated by the manufacturer to the detergent formulator(s) by means of the Safety Data Sheet (SDS) using the CESIO recommended standard phrase. In addition, the SDS must indicate the name, e-mail address and the telephone number of the person or a specific service which must be contacted at the surfactant supplier for requesting the biodegradability data and which is responsible for ensuring that these would be provided to the Competent Authorities (CA) on request. The surfactant supplier is expected to provide the biodegradability data to the CAS within three weeks from the date of the request by the detergent manufacturer.

For surfactant(s) which are intended for use in industrial/institutional detergents which failed the ultimate biodegradation test but scored above 80% on the primary biodegradation test, the manufacturer may apply to the EU Commission (through the Member States Competent Authorities) for derogation. Methods for the testing of primary biodegradability of surfactants in detergents are listed in Annex II of the Regulation. The application for derogation must be supported by a technical file which includes a risk assessment report. There is no definition for "industrial and institutional" application as such; however, the product would be for professional use only and not available to the general public. Examples given in the technical guidance document include - bottle washing, Cleaning in Place (CIP - food, cosmetics & pharmaceuticals contacting equipment, tanks etc.).



CONCLUSIONS

The manufacturer/importer must ensure that the actives (i.e. surfactants) meet the criteria laid down in Regulation (EC) No 648/2004 and fulfil the information/data provision requirements. Before placing on the market, the manufacturer must ensure that the correct hazard classification, labelling and packaging information is applied on the detergent. In addition, it should be noted that although the detergent regulation contains no specific requirements for toxicological risk or safety assessment of detergent products, there are other supplementary regulations and directives which may be applicable to the product; e.g. the Biocides Product Regulation (528/2012), REACH (1907 /2006) and the General Product Safety Directive (GPSD 2001/95/EC). In particular, the latter Directive requires that all products for general consumer use must be safe for the purpose for which it is intended.

HOW CAN INTERTEK HELP?

Intertek can support you to bring your product to the marketplace with the confidence that you have met all regulatory requirements of a complex and important regulation. Our experts can provide advice on EU Eco labelling, a voluntary scheme that shows commitment to environmental sustainability.

In addition, our detergent and household product experts can provide services on any of the following category of products:

- Bleaching products;
- Dishwashing products;
- Laundry care products;
- General surface cleaners e.g. wipe, multipurpose cleaners, household disinfectants, etc.
- Toilet care products e.g. tablets, rim blocks, etc.

Our core services are:

- Classification and Labelling
- Safety data sheets
- Detergent ingredient data sheets
- Toxicological risk assessment (GPSD, BPR or REACH compliance)
- Preparation of technical file for derogation application which includes full toxicological risk assessment (ecotoxicity/ exposure/ human health)
- Poison centre notification
- EU Eco labelling evaluation

REFERENCES

EEC, (1973). Council Directive 73/404/EEC of 22 November 1973 on the approximation of the laws of the Member States relating to detergents, Official Journal L 34 7, 17 December 1973, pp. 51 and 52.

EC, (2004). Regulation (EC) No 648/2004 of the European parliament and of the council of 31 March 2004 on detergents. Official Journal of the European Union. European Commission 2004 Brussels.

EC, (2012). Regulation (EU) No 259/2012 of the European parliament and of the council of 14 March 2012 amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents. Official Journal of the European Union. European commission, 2012 Brussels.

A.I.S.E. / CESIO / EC OSOL/ FECC (2008): A Joint Guideline on Implementation of the Detergent Regulation with regard to the Biodegradability of Surfactants and Transmission of information for Surfactants Biodegradability. Final version published on January 25 2008.



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