

SAFEGUARDS

SGS CONSUMER TESTING SERVICES

HARDGOODS, COSMETICS, PERSONAL CARE AND HOUSEHOLD

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NEW EUROPEAN REGULATION ON BIOCIDAL PRODUCTS

On June 27, 2012, the European Commission has published the new biocidal product regulation (EU) No 528/2012. The purpose of this Regulation is to administer the making available on the market and the use of biocidal products and to ensure a high level of protection of both human and animal health and environmental protection.

A biocidal product is a substance or a mixture with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism by any means other than mere physical or mechanical action.

Through this regulation, biocidal products and their active substances are separated in 4 groups and in 22 product-types (PT). Different PTs are listed in Table 1.



TABLE 1.

GROUP	PRODUCT-TYPE	SOME PRODUCT
Group 1: Disinfectants	PT 1: Human hygiene PT 2: Disinfectants and algacides not intended for direct application to humans or animals PT 3: Veterinary hygiene PT 4: Food and feed area PT 5: Drinking water	PT 1 : Soap with antibacterial claim PT 2 : Disinfectant for swimming pool Detergent with antibacterial claim
Group 2: Preservatives	PT 6: Preservatives for products during storage PT 7: Film preservatives PT 8: Wood preservatives PT 9: Fiber, leather, rubber and polymerised materials preservatives PT 10: Construction material preservatives PT 11: Preservatives for liquid-cooling and processing systems PT 12: Slimicides PT 13: Working or cutting fluid preservatives	PT 6: Preservative in paint, ink, detergent, etc. PT 8: Wood varnish with insecticide properties

References:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:EN:PDF>

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GROUP	PRODUCT-TYPE	SOME PRODUCT EXAMPLES
Group 3: Pest control	PT 14: Rodenticides PT 15: Avicides PT 16: Molluscicides, vermicides and products to control other invertebrates PT 17: Piscicides PT 18: Insecticides, acaricides and products to control other arthropods PT 19: Repellents and attractants PT 20: Control of other vertebrates	PT 14: Rat poison paste PT 19: Mosquito repellent wristband
Group 4: Other biocidal products	PT 21: Antifouling products PT 22: Embalming and taxidermist fluids	

Biocidal products and their active substances have to be authorized before use or placing on the EU market. All treated product shall contain only authorized biocidal active substances.

To be authorized, the EU manufacturer or importer shall submit a technical dossier in IUCLID format to ECHA. Highlights of the requirements for technical dossiers are summarized in Table 2.

**TABLE 2.**

Active substance	<ul style="list-style-type: none"> • ID of manufacturer or importer • ID of substance (including manufacture) • Physico-chemical properties of the active substance • Methods of detection and identification • Effectiveness against target organisms • Intended uses and exposure • Toxicological properties • Ecotoxicological properties • Measures necessary to protect humans, animals and the environment • Classification, labelling and packaging • Summary and evaluation (risk assessment)
Biocidal product	<ul style="list-style-type: none"> • ID of manufacturer or importer • ID of biocidal product • Physico-chemical properties of the active substance • Methods of detection and identification • Effectiveness against target organisms • Intended uses and exposure • Toxicological properties • Ecotoxicological properties • Environmental fate and behaviour • Measures necessary to protect humans, animals and the environment • Classification, labelling and packaging • Summary and evaluation (risk assessment)

One of major modifications of this new legislation concerns treated articles. A treated article is a substance, a mixture or an article which has been treated with, or intentionally incorporates, one or more biocidal products. Treated articles shall be labeled, if:

- there is a claim on biocidal properties,
- there is a possibility of contact with humans or release into the environment
- it is required as a condition of an active substance authorisation

The label should contain:

- a statement that the treated article incorporates biocidal products;
- where substantiated, the biocidal property attributed to the treated article;
- the name of all active substances contained in the biocidal products;
- the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets ;
- any relevant instructions for use, including any precautions to be taken because of the biocidal products with which a treated article was treated or which it incorporates.



SGS will follow up and inform interested parties as developments on REACH and other legislation occur. Our REACH expertise combined with consultancy services and experience in consumer product supply chains provides a central point of contact for global solutions. If you would like to learn more about how SGS can support your REACH compliance activities please contact us:

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