



P23. TOXICITY TESTS APPLIED TO THE BIOCIDAL PRODUCTS

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Biocides are defined as chemical substances used to suppress, destroy, deter, render harmless, or exert a controlling effect on any harmful organism to human or animal health, or that cause damage to natural or manufactured materials. Biocidal products (BPs) containing biocides are disinfectants, products related to human and veterinary hygiene, products used for pests such as insects, rodents etc., repellents and industrial chemicals like anti-fouling paints for ship and material preservatives. They are commonly used in medicine, agriculture, forestry and industry. BPs and their active substances fall into 4 categories and 23 product-types which are all regulated by the Ministry of Health compliance with European Union under the Biocidal Products Directive (published in the official gazette, 31.12.2009 date, 27449 number). These products are highly regulated because of health and performance concerns. They first have to be legally regulated, and all products or substances are on the market also had to be tested and approved.

Before marketing the biocidal products, it is necessary to assess the risks related to humans, animal and environmental health. To registration of a biocidal product, while the product is expected to have sufficient activity upon the target pests, it is desirable to have no adverse effect on non-target organisms. Therefore, characteristics of the active ingredient in biocidal products, amount and all kinds of significant toxicological or ecotoxicological impurities and adjuvant formulas and toxic residue resulting from the use must be required to comply with relevant regulations. In order to use the public biocidal products classified as a very toxic, toxic, carcinogenic, mutagenic or toxic to the reproductive systems will not be licensed. Thus, the analysis required to be made for the registration of biocidal products by the Ministry of Health are physical and chemical analyses, microbiological efficacy tests, biological activity testing of the insecticide, acaricide, repellent and rodenticide, and skin irritation test which is mandatory test for products of human hygiene. Skin irritation tests are used in evaluation of local toxicity in dermal toxicity studies.

Skin irritation tests of biocidal products used for human hygiene and classified as Product Type 1 in the scope of "Biocidal Products Directive" can be performed in vivo and in vitro. In the tests, Draize method (Draize et al., 1944), OECD Guideline No. 404, EN ISO 10993 methods or internationally recognized standards are used. These methods were developed with the purpose of evaluation in animal models of acute dermal toxicity of the product prior to use safely by humans. Rabbits are usually used as the test animals because of having high skin permeability. Such tests are similarly designed to the way exposed to humans. Skin irritation tests are carried out in laboratories with required permission to work under the "Regulation for Welfare and Protection of Animals used for Experimental and other Scientific Purposes" (published in the official gazette, 13.12.2011 date, 28141 number) with the approval of Local Ethics Committee of Animal Experiments.