[F1ANNEX IVB

DATA SET FOR BIOCIDAL PRODUCTS MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI

Textual Amendments

F1 Substituted by Commission Directive 2006/50/EC of 29 May 2006 amending Annexes IVA and IVB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (Text with EEA relevance).

1. For the purposes of this Annex, the term micro-organisms shall be understood as including also viruses and fungi. This Annex provides data requirements for the authorisation of a biocidal product based on preparations of micro-organisms. For all biocidal products based on preparations containing micro-organisms that are subject to application, all available relevant knowledge and information in literature should be provided. The information related to the identification and characterisation of all components in a biocidal product is particularly important and must be entered in sections I to IV and provides the basis for an assessment of possible impacts on human health and the environment.

2. Where, information is not necessary owing to the nature of the biocidal product Article 8(5) shall apply.

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 67/548/EEC and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[(1)] shall be used wherever possible to minimise animal testing.

4. Where testing is done, a detailed description (specification) of the material used and its impurities, according to the provisions of Section II, must be provided. Where necessary, data as established in Annexes IIB, IIIB shall be required for all the toxicologically/eco-toxicologically relevant chemical components of the biocidal product, in particular if the components are substances of concern as defined in Article 2(1)(e).

5. In cases where a new preparation is to be dealt with, extrapolation from Annex IVA, could be acceptable, provided that all the possible effects of the components, especially on pathogenicity and infectiveness, are evaluated.

Dossier requirements

SECTIONS:

I. Identity of the biocidal product

II. Physical, chemical and technical properties of the biocidal product

III. Data on application

IV. Further information on the biocidal product

V. Analytical methods

VI. Efficacy data

VII. Effects on human health

VIII. Residues in or on treated materials, food and feed

IX. Fate and behaviour in the environment

X. Effects on non-target organisms

XI. Classification, packaging and labelling of the biocidal product

XII. Summary and evaluation of sections I to XI including conclusions of the risk assessment and recommendations

The following data will be required to support submissions on the above points.

I. IDENTITY OF THE BIOCIDAL PRODUCTS

1.1. Applicant

1.2. Manufacturer of the biocidal product and the micro-organism(s)

1.3. Trade name or proposed trade name, and manufacturer's development code number of the biocidal product

1.4. Detailed quantitative and qualitative information on the composition of the biocidal product

1.5. Physical state and nature of the biocidal product

1.6. Function

II. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT

2.1. Appearance (colour and odour)

2.2. Storage stability and shelf-life

2.2.1. Effects of light, temperature and humidity on technical characteristics of the biocidal product

2.2.2. Other factors affecting stability

2.3. Explosivity and oxidising properties

2.4. Flash point and other indications of flammability or spontaneous ignition

2.5. Acidity, alkalinity and pH value

2.6. Viscosity and surface tension

2.7. Technical characteristics of the biocidal product

2.7.1. Wettability

2.7.2. Persistent foaming

2.7.3. Suspensibility and suspension stability

2.7.4. Dry sieve test and wet sieve test

2.7.5. Particle size distribution (dustable and wettable powders, granules), content of dust/ fines (granules), attrition and friability (granules)

2.7.6. Emulsifiability, re-emulsifiability, emulsion stability

2.7.7. Flowability, pourability (rinsability) and dustability

2.8. Physical, chemical and biological compatibility with other products including biocidal products with which its use is to be authorised or registered

2.8.1. Physical compatibility

2.8.2. Chemical compatibility

2.8.3. Biological compatibility

2.9. Summary and evaluation of physical, chemical and technical properties of the biocidal product

III. DATA ON APPLICATION

3.1. Field of use envisaged

3.2. Mode of action

3.3. Details of intended use

3.4. Application rate

3.5. Content of micro-organism in material used (e.g. in the application device or bait)

3.6. Method of application

3.7. Number and timing of applications and duration of protection

3.8. Necessary waiting periods or other precautions to avoid adverse effects to human and animal health and the environment

3.9. Proposed instructions for use

3.10. Category of users

3.11. Information on the possible occurrence of the development of resistance

3.12. Effects on the materials or products treated with the biocidal product

IV. FURTHER INFORMATION ON THE BIOCIDAL PRODUCT

4.1. Packaging and compatibility of the biocidal product with proposed packaging materials

4.2. Procedures for cleaning application equipment

4.3. Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment

4.4. Recommended methods and precautions concerning: handling, storage, transport or fire

4.5. Measures in the case of an accident

4.6. Procedures for destruction or decontamination of the biocidal product and its packaging

4.6.1. Controlled incineration

4.6.2. Others

4.7. Monitoring plan to be used for the active micro-organism and other micro-organism(s) contained in the biocidal product including handling, storage, transport and use

V. ANALYTICAL METHODS

5.1. Methods for the analysis of the biocidal product

5.2. Methods to determine and quantify residues

VI. EFFICACY DATA

VII. EFFECTS ON HUMAN HEALTH

7.1. Basic acute toxicity studies

7.1.1. Acute oral toxicity

7.1.2. Acute inhalation toxicity

7.1.3. Acute percutaneous toxicity

7.2. Additional acute toxicity studies

7.2.1. Skin irritation

7.2.2. Eye irritation

7.2.3. Skin sensitisation

7.3. Data on exposure

7.4. Available toxicological data relating to non-active substances

7.5. Supplementary studies for combinations of biocidal products

7.6. Summary and evaluation of effects on human health

VIII. RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED

IX. FATE AND BEHAVIOUR IN THE ENVIRONMENT

X. EFFECTS ON NON-TARGET ORGANISMS

10.1. Effects on birds

10.2. Effects on aquatic organisms

10.3. Effects on bees

10.4. Effects on arthropods other than bees

10.5. Effects on earthworms

10.6. Effects on soil micro-organisms

10.7. Additional studies on additional species or higher tier studies such as studies on selected non-target organisms

10.7.1. Terrestrial plants

10.7.2. Mammals

10.7.3. Other relevant species and processes

10.8. Summary and evaluation of effects on non-target organisms

XI. CLASSIFICATION, PACKAGING AND LABELLING OF THE BIOCIDAL PRODUCT

As established in Article 20, proposals including justification for the classification and labelling of the biocidal product in accordance with the provisions set in Directive 67/548/EEC and Directive 1999/45/EC must be submitted. The classification comprises of the description of the category/categories of danger and qualifying risk phrases for all dangerous properties. On the basis of the classification, a proposal for labelling including the hazard symbol(s) and indications of danger, risk phrases and safety phrases should be given. The classification and labelling shall be in regard to the chemical substances contained in the biocidal product. If necessary, specimens of proposed packaging shall be submitted to the competent authority of a Member State.

The dossier shall be accompanied by a reasoned proposal for allocation to one of the risk groups specified in Article 2 of Directive 2000/54/EC together with indications on the need for products to carry the biohazard sign specified in Annex II to that Directive.

XII. SUMMARY AND EVALUATION OF SECTIONS I TO XI INCLUDING CONCLUSIONS OF THE RISK ASSESSMENT AND RECOMMENDATIONS**]**

(1) [F1OJ L 200, 30.7.1999, p. 1. Directive as last amended by Commission Directive 2006/8/EC (OJ L 19, 24.1.2006, p. 12).]

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