

ANNEX IIB

COMMON CORE DATA SET FOR BIOCIDAL PRODUCTS CHEMICAL PRODUCTS

1. Dossiers on biocidal products are required to address at least all the points listed under 'Dossier requirements'. Responses are required to be supported by data. The dossier requirements must be in line with technical development.
2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.
3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 88/379/EEC should be used wherever possible to minimise animal testing.

Dossier requirements

- I. Applicant
- II. Identity of the biocidal product
- III. Physical and chemical properties of the biocidal product
- IV. Methods for identification and analysis of the biocidal product
- V. Intended uses of the biocidal product and efficacy for these uses
- VI. Toxicology data for the biocidal product (additional to that for the active substance)
- VII. Ecotoxicology data for the biocidal product (additional to that for the active substance)
- VIII. Measures necessary to protect man, animals and the environment
- IX. Classification, packaging and labelling
- X. Summary and evaluation of Sections II to IX

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

- I. **APPLICANT**
 - 1.1. Name and address, etc.
 - 1.2. Formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s))
- II. **IDENTITY**
 - 2.1. Trade name or proposed trade name, and manufacturer's development code number of the preparation, if appropriate
 - 2.2. Detailed quantitative and qualitative information on the composition of the biocidal product, e.g. active substance(s), impurities, adjuvants, inert components
 - 2.3. Physical state and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution

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III. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES

- 3.1. Appearance (physical state, colour)
- 3.2. Explosive properties
- 3.3. Oxidising properties
- 3.4. Flash-point and other indications of flammability or spontaneous ignition
- 3.5. Acidity/alkalinity and if necessary pH value (1 % in water)
- 3.6. Relative density
- 3.7. Storage stability — stability and shelf-life. Effects of light, temperature and humidity on technical characteristics of the biocidal product; reactivity towards container material
- 3.8. Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability
- 3.9. Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised

IV. METHODS OF IDENTIFICATION AND ANALYSIS

- 4.1. Analytical method for determining the concentration of the active substance(s) in the biocidal product
- 4.2. In so far as not covered by Annex IIA, paragraph 4.2, analytical methods including recovery rates and the limits of determination for toxicologically and ecotoxicologically relevant components of the biocidal product and/or residues thereof, where relevant in or on the following:
 - (a) Soil
 - (b) Air
 - (c) Water (including drinking water)
 - (d) Animal and human body fluids and tissues
 - (e) Treated food or feedingstuffs

V. INTENDED USES AND EFFICACY

- 5.1. Product type and field of use envisaged
- 5.2. Method of application including description of system used
- 5.3. Application rate and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used, e.g. cooling water, surface water, water used for heating purposes
- 5.4. Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals
- 5.5. Function, e.g. fungicide, rodenticide, insecticide, bactericide

- 5.6. Pest organism(s) to be controlled and products, organisms or objects to be protected
- 5.7. Effects on target organisms
- 5.8. Mode of action (including time delay) in so far as not covered by Annex IIA, paragraph 5.4
- 5.9. User: industrial, professional, general public (non-professional)

Efficacy data

- 5.10. The proposed label claims for the product and efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate
- 5.11. Any other known limitations on efficacy including resistance

VI. TOXICOLOGICAL STUDIES

6.1. Acute toxicity

For studies 6.1.1 to 6.1.3, biocidal products other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the product and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route

6.1.1. Oral

6.1.2. Dermal

6.1.3. Inhalation

6.1.4. For biocidal products that are intended to be authorised for use with other biocidal products, the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate

6.2. Skin and eye irritation⁽¹⁾

6.3. Skin sensitisation

6.4. Information on dermal absorption

6.5. Available toxicological data relating to toxicologically relevant non-active substances (i.e. substances of concern)

6.6. Information related to the exposure of the biocidal product to man and the operator

Where necessary, the test(s) described in Annex IIA, shall be required for the toxicologically relevant non-active substances of the preparation

VII. ECOTOXICOLOGICAL STUDIES

7.1. Foreseeable routes of entry into the environment on the basis of the use envisaged

7.2. Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information on the active substance itself

7.3. Available ecotoxicological information relating to ecotoxicological relevant non-active substances (i.e. substances of concern), such as information from safety data sheets

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VIII. MEASURES TO BE ADOPTED TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

- 8.1. Recommended methods and precautions concerning handling, use, storage, transport or fire
- 8.2. Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment; in so far as not covered by Annex IIA, paragraph 8.3
- 8.3. Procedures, if any, for cleaning application equipment
- 8.4. Identity of relevant combustion products in cases of fire
- 8.5. Procedures for waste management of the biocidal product and its packaging for industry, professional users and the general public (non-professional users), e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration
- 8.6. Possibility of destruction or decontamination following release in or on the following:
 - (a) Air
 - (b) Water, including drinking water
 - (c) Soil
- 8.7. Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms
- 8.8. Specify any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms

IX. CLASSIFICATION, PACKAGING AND LABELLING

- Proposals for packaging and labelling
- Proposals for safety-data sheets, where appropriate
- Justification for the classification and labelling according to the principles of Article 20 of this Directive
 - Hazard symbol(s)
 - Indications of danger
 - Risk phrases
 - Safety phrases
 - Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials to be included

X. SUMMARY AND EVALUATION OF SECTIONS II TO IX

Notes

- (¹) Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.