

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (repealed)

Article 1	Scope
Article 2	Definitions
Article 3	Authorisation for placing on the market of biocidal products
Article 4	Mutual recognition of authorisations
Article 5	Conditions for issue of an authorisation
Article 6	Review of an authorisation
Article 7	Cancellation or modification of an authorisation
Article 8	Requirements for authorisation
Article 9	Placing on the market of active substances
Article 10	Inclusion of an active substance in Annexes I, IA or IB
Article 11	Procedure for inclusion of an active substance in Annex I, IA or IB
Article 12	Use of data held by competent authorities for other applicants
Article 13	Cooperation in the use of data for second and subsequent applications for authorisation
Article 14	New information
Article 15	Derogation from the requirements
Article 16	Transitional measures
Article 17	Research and development
Article 18	Information exchange
Article 19	Confidentiality
Article 20	Classification, packaging and labelling of biocidal products
Article 21	Safety-data sheets
Article 22	Advertising
Article 23	Poison control
Article 24	Compliance with requirements
Article 25	Charges
Article 26	Competent authorities
Article 27	Commission procedures
Article 28	Committees and procedures
Article 29	Adaptation to technical progress
Article 30	Modification or adaptation of Annexes V and VI
Article 31	Civil and criminal liability
Article 32	Safeguard clause
Article 33	Technical notes for guidance
Article 34	Implementation of the Directive
Article 35	This Directive shall enter into force on the 20th day...
Article 36	This Directive is addressed to the Member States.

ANNEX I

LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL FOR INCLUSION IN BIOCIDAL PRODUCTS

ANNEX IA

LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL FOR INCLUSION IN LOW-RISK BIOCIDAL PRODUCTS

ANNEX IB

LIST OF BASIC SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL

ANNEX IIA

COMMON CORE DATA SET FOR ACTIVE SUBSTANCES

1. Dossiers on active substances are required to address at least...
2. Information which is not necessary owing to the nature of...

Dossier requirements

- I. Applicant
 - II. Identity of the active substance
 - III. Physical and chemical properties of the active substance
 - IV. Methods of detection and identification
 - V. Effectiveness against target organisms and intended uses
 - VI. Toxicological profile for man and animals including metabolism
 - VII. Ecotoxicological profile including environmental fate and behaviour
 - VIII. Measures necessary to protect man, animals and the environment
 - IX. Classification and labelling
 - X. Summary and evaluation of Sections II to IX
- I. APPLICANT
 - 1.1. Name and address, etc.
 - 1.2. Active substance manufacturer (name, address, location of plant)
 - II. IDENTITY
 - 2.1. Common name proposed or accepted by ISO and synonyms
 - 2.2. Chemical name (IUPAC nomenclature)
 - 2.3. Manufacturer's development code number(s)
 - 2.4. CAS and EC numbers (if available)

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- 2.5. Molecular and structural formula (including full details of any isomeric...
 - 2.6. Method of manufacture (syntheses pathway in brief terms) of active...
 - 2.7. Specification of purity of the active substance in g/kg or...
 - 2.8. Identity of impurities and additives (e.g. stabilisers), together with the...
 - 2.9. The origin of the natural active substance or the precursor(s)...
 - 2.10. Exposure data in conformity with Annex VIIA to Directive 92/32/EEC....
- III. PHYSICAL AND CHEMICAL PROPERTIES
- 3.1. Melting point, boiling point, relative density (1)
 - 3.2. Vapour pressure (in Pa) (1)
 - 3.3. Appearance (physical state, colour) (2)
 - 3.4. Absorption spectra (UV/VIS, IR, NMR), and a mass spectrum, molar...
 - 3.5. Solubility in water including effect of pH (5 to 9)...
 - 3.6. Partition coefficient n-octanol/water including effect of pH (5 to 9)...
 - 3.7. Thermal stability, identity of relevant breakdown products
 - 3.8. Flammability including auto-flammability and identity of combustion products
 - 3.9. Flash-point
 - 3.10. Surface tension
 - 3.11. Explosive properties
 - 3.12. Oxidising properties
 - 3.13. Reactivity towards container material
- IV. ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION
- 4.1. Analytical methods for the determination of pure active substance and,...
 - 4.2. Analytical methods including recovery rates and the limits of determination...
- V. EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES
- 5.1. Function, e.g. fungicide, rodenticide, insecticide, bactericide
 - 5.2. Organism(s) to be controlled and products, organisms or objects to...
 - 5.3. Effects on target organisms, and likely concentration at which the...
 - 5.4. Mode of action (including time delay)
 - 5.5. Field of use envisaged
 - 5.6. User: industrial, professional, general public (non-professional)
 - 5.7. Information on the occurrence or possible occurrence of the development...
 - 5.8. Likely tonnage to be placed on the market per year...
- VI. TOXICOLOGICAL AND METABOLIC STUDIES
- 6.1. Acute toxicity
 - 6.1.1. Oral
 - 6.1.2. Dermal
 - 6.1.3. Inhalation
 - 6.1.4. Skin and eye irritation (3)
 - 6.1.5. Skin sensitisation
 - 6.2. Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption...
 - 6.3. Short-term repeated dose toxicity (28 days)
 - 6.4. Subchronic toxicity 90-day study, two species, one rodent and one...
 - 6.5. Chronic toxicity (4)
 - 6.6. Mutagenicity studies
 - 6.6.1. In-vitro gene mutation study in bacteria

-
- 6.6.2. In-vitro cytogenicity study in mammalian cells
 - 6.6.3. In-vitro gene mutation assay in mammalian cells
 - 6.6.4. If positive in 6.6.1, 6.6.2 or 6.6.3, then an in-vivo...
 - 6.6.5. If negative in 6.6.4 but positive in-vitro tests then undertake...
 - 6.6.6. If positive in 6.6.4 then a test to assess possible...
 - 6.7. Carcinogenicity study (4)
 - 6.8. Reproductive toxicity (5)
 - 6.8.1. Teratogenicity test — rabbit and one rodent species
 - 6.8.2. Fertility study — at least two generations, one species, male...
 - 6.9. Medical data in anonymous form
 - 6.9.1. Medical surveillance data on manufacturing plant personnel if available
 - 6.9.2. Direct observation, e.g. clinical cases, poisoning incidents if available
 - 6.9.3. Health records, both from industry and any other available sources...
 - 6.9.4. Epidemiological studies on the general population, if available
 - 6.9.5. Diagnosis of poisoning including specific signs of poisoning and clinical...
 - 6.9.6. Sensitisation/allergenicity observations, if available
 - 6.9.7. Specific treatment in case of an accident or poisoning: first...
 - 6.9.8. Prognosis following poisoning
 - 6.10. Summary of mammalian toxicology and conclusions, including no observed adverse...
- VII. ECOTOXICOLOGICAL STUDIES
- 7.1. Acute toxicity to fish
 - 7.2. Acute toxicity to *Daphnia magna*
 - 7.3. Growth inhibition test on algae
 - 7.4. Inhibition to microbiological activity
 - 7.5. Bioconcentration
 - 7.6. Degradation
 - 7.6.1. Biotic
 - 7.6.1.1. Ready biodegradability
 - 7.6.1.2. Inherent biodegradability, where appropriate
 - 7.6.2. Abiotic
 - 7.6.2.1. Hydrolysis as a function of pH and identification of breakdown...
 - 7.6.2.2. Phototransformation in water including identity of the products of transformation...
 - 7.7. Adsorption/desorption screening test
 - 7.8. Summary of ecotoxicological effects and fate and behaviour in the...
- VIII. MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT
- 8.1. Recommended methods and precautions concerning handling, use, storage, transport or...
 - 8.2. In case of fire, nature of reaction products, combustion gases,...
 - 8.3. Emergency measures in case of an accident
 - 8.4. Possibility of destruction or decontamination following release in or on...
 - 8.5. Procedures for waste management of the active substance for industry...
 - 8.5.1. Possibility of reuse or recycling
 - 8.5.2. Possibility of neutralisation of effects

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- 8.5.3. Conditions for controlled discharge including leachate qualities on disposal
- 8.5.4. Conditions for controlled incineration
- 8.6. Observations on undesirable or unintended side-effects, e.g. on beneficial and...
- IX. CLASSIFICATION AND LABELLING
- X. SUMMARY AND EVALUATION OF SECTIONS II TO IX
 - Notes
 - (1) These data must be submitted for the purified active substance...
 - (2) These data must be submitted for the active substance of...
 - (3) Eye irritation test shall not be necessary where the active...
 - (4) The long-term toxicity and carcinogenicity of an active substance may...
 - (5) If, in exceptional circumstances, it is claimed that such testing...

ANNEX IIB

COMMON CORE DATA SET FOR BIOCIDAL PRODUCTS

1. Dossiers on biocidal products are required to address at least...
2. Information which is not necessary owing to the nature of...
3. Information may be derived from existing data where a justification...

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...
- VI. Toxicology data for the biocidal product (additional to that for...
- VII. Ecotoxicology data for the biocidal product (additional to that for...
- VIII. Measures necessary to protect man, animals and the environment
- IX. Classification, packaging and labelling
- X. Summary and evaluation of Sections II to IX
- I. APPLICANT
 - 1.1. Name and address, etc.
 - 1.2. Formulator of the biocidal product and the active substance(s) (names,...
- II. IDENTITY
 - 2.1. Trade name or proposed trade name, and manufacturer's development code...
 - 2.2. Detailed quantitative and qualitative information on the composition of the...
 - 2.3. Physical state and nature of the biocidal product, e.g. emulsifiable...
- 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...
 - 3.8. Technical characteristics of the biocidal product, e.g. wettability, persistent foaming,...
 - 3.9. Physical and chemical compatibility with other products including other biocidal...
 - IV. METHODS OF IDENTIFICATION AND ANALYSIS
 - 4.1. Analytical method for determining the concentration of the active substance(s)...
 - 4.2. In so far as not covered by Annex IIA, paragraph...
 - 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...
 - 5.4. Number and timing of applications, and where relevant, any particular...
 - 5.5. Function, e.g. fungicide, rodenticide, insecticide, bactericide
 - 5.6. Pest organism(s) to be controlled and products, organisms or objects...
 - 5.7. Effects on target organisms
 - 5.8. Mode of action (including time delay) in so far as...
 - 5.9. User: industrial, professional, general public (non-professional)
 - 5.10. The proposed label claims for the product and efficacy data...
 - 5.11. Any other known limitations on efficacy including resistance
 - VI. TOXICOLOGICAL STUDIES
 - 6.1. Acute toxicity
 - 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...
 - 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....
 - 6.6. Information related to the exposure of the biocidal product to...
 - VII. ECOTOXICOLOGICAL STUDIES
 - 7.1. Foreseeable routes of entry into the environment on the basis...
 - 7.2. Information on the ecotoxicology of the active substance in the...
 - 7.3. Available ecotoxicological information relating to ecotoxicological relevant non-active substances (i.e....
 - VIII. MEASURES TO BE ADOPTED TO PROTECT MAN, ANIMALS AND THE...
 - 8.1. Recommended methods and precautions concerning handling, use, storage, transport or...
 - 8.2. Specific treatment in case of an accident, e.g. first-aid measures,...
 - 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...

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- 8.6. Possibility of destruction or decontamination following release in or on...
- 8.7. Observations on undesirable or unintended side-effects, e.g. on beneficial and...
- 8.8. Specify any repellents or poison control measures included in the...
- IX. CLASSIFICATION, PACKAGING AND LABELLING
- X. SUMMARY AND EVALUATION OF SECTIONS II TO IX
 - Notes
 - (1) Eye-irritation test shall not be necessary where the biocidal product...

ANNEX IIIA

ADDITIONAL DATA SET FOR ACTIVE SUBSTANCES

- 1. Dossiers on active substances are required to address at least...
 - 2. Information which is not necessary owing to the nature of...
 - III. PHYSICAL AND CHEMICAL PROPERTIES
 - 1. Solubility in organic solvents, including effect of temperature on solubility...
 - 2. Stability in organic solvents used in biocidal products and identity...
 - IV. ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION
 - 1. Analytical methods including recovery rates and the limits of determination...
 - VI. TOXICOLOGICAL AND METABOLIC STUDIES
 - 1. Neurotoxicity study
 - 2. Toxic effects on livestock and pets
 - 3. Studies related to the exposure of the active substance to...
 - 4. Food and feedingstuffs
 - 5. If any other tests related to the exposure of the...
 - 6. If the active substance is to be used in products...
 - 7. Mechanistic study — any studies necessary to clarify effects reported...
 - VII. ECOTOXICOLOGICAL STUDIES
 - 1. Acute toxicity test on one other, non-aquatic, non-target organism
 - 2. If the results of the ecotoxicological studies and the intended...
 - 3. If the result of the test in paragraph 7.6.1.2 of...
 - 4. Any other biodegradability tests that are relevant from the results...
 - 5. Phototransformation in air (estimation method), including identification of breakdown products(1)...
 - 6. If the results from paragraphs 7.6.1.2 in Annex IIA or...
 - VIII. MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT
 - 1. Identification of any substances falling within the scope of List...
- Notes
- (1) These data must be submitted for the purified active substance...
 - (2) These data must be submitted for the active substance of...

-
- XI. FURTHER HUMAN HEALTH-RELATED STUDIES
1. Food and feedingstuffs studies
 - 1.1. Identification of degradation and reaction products and of metabolites of...
 - 1.2. Behaviour of the residue of the active substance, its degradation...
 - 1.3. Overall material balance for the active substance. Sufficient residue data...
 - 1.4. Estimation of potential or actual exposure of the active substance...
 - 1.5. If residues of the active substance remain on feedingstuffs for...
 - 1.6. Effects of industrial processing and/or domestic preparation on the nature...
 - 1.7. Proposed acceptable residues and the justification of their acceptability
 - 1.8. Any other available information that is relevant
 - 1.9. Summary and evaluation of data submitted under 1.1 to 1.8...
 2. Other test(s) related to the exposure to humans
- XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT
1. Fate and behaviour in soil
 - 1.1. Rate and route of degradation including identification of the processes...
 - 1.2. Absorption and desorption in at least three soil types and,...
 - 1.3. Mobility in at least three soil types and where relevant...
 - 1.4. Extent and nature of bound residues
 2. Fate and behaviour in water
 - 2.1. Rate and route of degradation in aquatic systems (as far...
 - 2.2. Absorption and desorption in water (soil sediment systems) and, where...
 3. Fate and behaviour in air
 4. Summary and evaluation of parts 1, 2 and 3
- XIII. FURTHER ECOTOXICOLOGICAL STUDIES
1. Effects on birds
 - 1.1. Acute oral toxicity — this need not be done if...
 - 1.2. Short-term toxicity — eight-day dietary study in at least one...
 - 1.3. Effects on reproduction
 2. Effects on aquatic organisms
 - 2.1. Prolonged toxicity to an appropriate species of fish
 - 2.2. Effects on reproduction and growth rate on an appropriate species...
 - 2.3. Bioaccumulation in an appropriate species of fish
 - 2.4. *Daphnia magna* reproduction and growth rate
 3. Effects on other non-target organisms
 - 3.1. Acute toxicity to honeybees and other beneficial arthropods, e.g. predators....
 - 3.2. Toxicity to earthworms and to other soil non-target macro-organisms
 - 3.3. Effects on soil non-target micro-organisms
 - 3.4. Effects on any other specific, non-target organisms (flora and fauna)...
 4. Other effects
 - 4.1. Activated sludge respiration inhibition test
 5. Summary and evaluation of parts 1, 2, 3 and 4...

ANNEX IIIB

ADDITIONAL DATA SET FOR BIOCIDAL PRODUCTS

1. Dossiers on biocidal products are required to address at least...
 2. Information which is not necessary owing to the nature of...
 3. Information may be derived from existing data where a justification...
- XI. FURTHER HUMAN HEALTH-RELATED STUDIES
1. Food and feedingstuffs studies
 - 1.1. If residues of the biocidal product remain on feedingstuffs for...
 - 1.2. Effects of industrial processing and/or domestic preparation on the nature...
 2. Other test(s) related to the exposure to humans
- XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT
1. Where relevant all the information required in Annex IIIA, Section...
 2. Testing for distribution and dissipation in the following:
- XIII. FURTHER ECOTOXICOLOGICAL STUDIES
1. Effects on birds
 - 1.1. Acute oral toxicity, if not already done in accordance with...
 2. Effects on aquatic organisms
 - 2.1. In case of application on, in, or near to surface...
 - 2.1.1. Particular studies with fish and other aquatic organisms
 - 2.1.2. Residue data in fish concerning the active substance and including...
 - 2.1.3. The studies referred to in Annex IIIA, Section XIII, parts...
 - 2.2. If the biocidal product is to be sprayed near to...
 3. Effects on other non-target organisms
 - 3.1. Toxicity to terrestrial vertebrates other than birds
 - 3.2. Acute toxicity to honeybees
 - 3.3. Effects on beneficial arthropods other than bees
 - 3.4. Effects on earthworms and other soil non-target macro-organisms, believed to...
 - 3.5. Effects on soil non-target micro-organisms
 - 3.6. Effects on any other specific, non-target organisms (flora and fauna)...
 - 3.7. If the biocidal product is in the form of bait...
 - 3.7.1. Supervised trials to assess risks to non-target organisms under field...
 - 3.7.2. Studies on acceptance by ingestion of the biocidal product by...
 4. Summary and evaluation of parts 1, 2, and 3

ANNEX IVA

DATA SET FOR ACTIVE SUBSTANCES

1. For the purposes of this Annex, the term micro-organisms shall...
2. Where information is not necessary owing to the nature of...

3. A dossier within the meaning of Article 11(1) shall be...
4. Where the micro-organism has been genetically modified within the meaning...
5. If the biocidal product action is known to be partly...

Dossier requirements

- I. IDENTITY OF THE MICRO-ORGANISM
 - 1.1. Applicant
 - 1.2. Manufacturer
 - 1.3. Name and species description, strain characterisation
 - 1.3.1. Common name of the micro-organism (including alternative and superseded names)...
 - 1.3.2. Taxonomic name and strain indicating whether it is a stock...
 - 1.3.3. Collection and culture reference number where the culture is deposited...
 - 1.3.4. Methods, procedures and criteria used to establish the presence and...
 - 1.4. Specification of the material used for manufacturing of formulated products...
 - 1.4.1. Content of the micro-organism
 - 1.4.2. Identity and content of impurities, additives, contaminating micro-organisms
 - 1.4.3. Analytical profile of batches
- II. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM
 - 2.1. History of the micro-organism and its uses. Natural occurrence and...
 - 2.1.1. Historical background
 - 2.1.2. Origin and natural occurrence
 - 2.2. Information on target organism(s)
 - 2.2.1. Description of the target organism(s)
 - 2.2.2. Mode of action
 - 2.3. Host specificity range and effects on species other than the...
 - 2.4. Development stages/life cycle of the micro-organism
 - 2.5. Infectiveness, dispersal and colonisation ability
 - 2.6. Relationships to known plant or animal or human pathogens
 - 2.7. Genetic stability and factors affecting it
 - 2.8. Information on the production of metabolites (especially toxins)
 - 2.9. Antibiotics and other anti-microbial agents
 - 2.10. Robustness to environmental factors
 - 2.11. Effects on materials, substances and products
- III. FURTHER INFORMATION ON THE MICRO-ORGANISM
 - 3.1. Function
 - 3.2. Field of use envisaged
 - 3.3. Product type(s) and category of users for which the micro-organism...
 - 3.4. Method of production and quality control
 - 3.5. Information on the occurrence or possible occurrence of the development...
 - 3.6. Methods to prevent loss of virulence of seed stock of...
 - 3.7. Recommended methods and precautions concerning handling, storage, transport or fire...
 - 3.8. Procedures for destruction or decontamination
 - 3.9. Measures in case of an accident
 - 3.10. Procedures for waste management

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- 3.11. Monitoring plan to be used for the active micro-organism including...
- IV. ANALYTICAL METHODS
 - 4.1. Methods for the analysis of the micro-organism as manufactured
 - 4.2. Methods to determine and quantify residues (viable or non-viable)
- V. EFFECTS ON HUMAN HEALTH
 - TIER I
 - 5.1. Basic information
 - 5.1.1. Medical data
 - 5.1.2. Medical surveillance on manufacturing plant personnel
 - 5.1.3. Sensitisation/allergenicity observations
 - 5.1.4. Direct observation, e.g. clinical cases
 - 5.2. Basic studies
 - 5.2.1. Sensitisation
 - 5.2.2. Acute toxicity, pathogenicity, and infectiveness
 - 5.2.2.1. Acute oral toxicity, pathogenicity and infectiveness
 - 5.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness
 - 5.2.2.3. Intraperitoneal/subcutaneous single dose
 - 5.2.3. In vitro genotoxicity testing
 - 5.2.4. Cell culture study
 - 5.2.5. Information on short-term toxicity and pathogenicity
 - 5.2.5.1. Health effects after repeated inhalatory exposure
 - 5.2.6. Proposed treatment: first aid measures, medical treatment
 - 5.2.7. Any pathogenicity and infectiveness to humans and other mammals under...
 - END OF TIER I
 - TIER II
 - 5.3. Specific toxicity, pathogenicity and infectiveness studies
 - 5.4. Genotoxicity — In vivo studies in somatic cells
 - 5.5. Genotoxicity — In vivo studies in germ cells
 - END OF TIER II
 - 5.6. Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation...
- VI. RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED
 - 6.1. Persistence and likelihood of multiplication in or on treated materials,...
 - 6.2. Further information required
 - 6.2.1. Non-viable residues
 - 6.2.2. Viable residues
 - 6.3. Summary and evaluation of residues in or on treated materials,...
- VII. FATE AND BEHAVIOUR IN THE ENVIRONMENT
 - 7.1. Persistence and multiplication
 - 7.1.1. Soil
 - 7.1.2. Water
 - 7.1.3. Air
 - 7.2. Mobility
 - 7.3. Summary and evaluation of fate and behaviour in the environment...
- VIII. EFFECTS ON NON-TARGET ORGANISMS
 - 8.1. Effects on birds
 - 8.2. Effects on aquatic organisms

- 8.2.1. Effects on fish
- 8.2.2. Effects on freshwater invertebrates
- 8.2.3. Effects on algae growth
- 8.2.4. Effects on plants other than algae
- 8.3. Effects on bees
- 8.4. Effects on arthropods other than bees
- 8.5. Effects on earthworms
- 8.6. Effects on soil micro-organisms
- 8.7. Further studies
 - 8.7.1. Terrestrial plants
 - 8.7.2. Mammals
 - 8.7.3. Other relevant species and processes
- 8.8. Summary and evaluation of effects on non-target organisms
- IX. CLASSIFICATION AND LABELLING
- X. SUMMARY AND EVALUATION OF SECTIONS I TO IX INCLUDING CONCLUSIONS...

ANNEX IVB

DATA SET FOR BIOCIDAL PRODUCTS

1. For the purposes of this Annex, the term micro-organisms shall...
2. Where, information is not necessary owing to the nature of...
3. Information may be derived from existing data where a justification...
4. Where testing is done, a detailed description (specification) of the...
5. In cases where a new preparation is to be dealt...

Dossier requirements

- 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...
 - 1.4. Detailed quantitative and qualitative information on the composition of the...
 - 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...
 - 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

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- 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...
 - 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...
 - 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...
- 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...)
 - 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...
 - 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...
- IV. FURTHER INFORMATION ON THE BIOCIDAL PRODUCT
 - 4.1. Packaging and compatibility of the biocidal product with proposed packaging...
 - 4.2. Procedures for cleaning application equipment
 - 4.3. Re-entry periods, necessary waiting periods or other precautions to protect...
 - 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...
 - 4.6.1. Controlled incineration
 - 4.6.2. Others
 - 4.7. Monitoring plan to be used for the active micro-organism and...
- 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...
 - 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
- XII. SUMMARY AND EVALUATION OF SECTIONS I TO XI INCLUDING CONCLUSIONS...

ANNEX V

BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN ARTICLE 2(1)(a) OF THIS DIRECTIVE

These product-types exclude products where they are covered by
the...

MAIN GROUP 1: Disinfectants and general biocidal products

- Product-type 1: Human hygiene biocidal products
- Product-type 2: Private area and public health area disinfectants and...
- Product-type 3: Veterinary hygiene biocidal products
- Product-type 4: Food and feed area disinfectants
- Product-type 5: Drinking water disinfectants

MAIN GROUP 2: Preservatives

- Product-type 6: In-can preservatives
- Product-type 7: Film preservatives
- Product-type 8: Wood preservatives
- Product-type 9: Fibre, leather, rubber and polymerised materials preservatives
- Product-type 10: Masonry preservatives
- Product-type 11: Preservatives for liquid-cooling and processing systems
- Product-type 12: Slimicides

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

Product-type 13: Metalworking-fluid preservatives

MAIN GROUP 3: Pest control

Product-type 14: Rodenticides

Product-type 15: Avicides

Product-type 16: Molluscicides

Product-type 17: Piscicides

Product-type 18: Insecticides, acaricides and products to control other arthropods...

Product-type 19: Repellents and attractants

MAIN GROUP 4: Other biocidal products

Product-type 20: Preservatives for food or feedstocks

Product-type 21: Antifouling products

Product-type 22: Embalming and taxidermist fluids

Product-type 23: Control of other vertebrates

ANNEX VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

CONTENTS

Definitions

Introduction

Evaluation

Decision-making

Overall integration of conclusions

DEFINITIONS

(a) Hazard identification

(b) Dose (concentration) — response (effect) assessment

(c) Exposure assessment

(d) Risk characterisation

(e) Environment

INTRODUCTION

1. This Annex lays down principles to ensure that evaluations made...
2. In order to ensure a high and harmonised level of...
3. A risk assessment on the active substance or substances present...
4. Additional risk assessments shall be carried out, in the same...
5. In order to carry out a risk assessment data are...
6. The results of the risk assessments carried out on an...
7. When making evaluations and taking decisions concerning the authorisation of...
8. The Member State shall comply with the requirements of mutual...
9. It is known that many biocidal products present only minor...
10. It is known that certain biocidal products are considered as...
11. The application of these common principles shall lead to the...
12. During the process of evaluation and decision-making, Member States and...
13. The judgments made by the Member State during the evaluation...

EVALUATION

General principles

14. The data submitted in support of an application for authorisation...
15. A risk assessment on the active substance present in the...
16. For each active substance and each substance of concern present...
17. The results arrived at from a comparison of the exposure...
18. The risk assessment shall determine:
19. In certain cases it may be concluded that further data...

Effects on humans

20. The risk assessment shall take account of the following potential...
21. The effects previously mentioned result from the properties of the...
22. The populations previously mentioned are:
23. The hazard identification shall address the properties and potential adverse...
24. In those cases where the test appropriate to hazard identification...
25. The Member State shall apply paragraphs 26 to 29 when...
26. For repeated dose toxicity and reproductive toxicity the dose response...
27. For acute toxicity, corrosivity and irritation, it is not usually...
28. For mutagenicity and carcinogenicity it shall be sufficient to determine...
29. With respect to skin sensitisation and respiratory sensitisation, in so...
30. Where toxicity data derived from observations of human exposure, e.g....
31. An exposure assessment shall be carried out for each of...
32. The exposure assessment shall be based on the information in...
33. Where adequately measured, representative exposure data are available, special consideration...
34. Where, for any of the effects set out in paragraph...

Effects on animals

35. Using the same relevant principles as described in the section...

Effects on the environment

36. The risk assessment shall take account of any adverse effects...
37. The hazard identification shall address the properties and potential adverse...
38. In those cases where the test appropriate to hazard identification...
39. A dose (concentration) — response (effect) assessment shall be carried...
40. The PNEC shall be determined from the data on effects...
41. An assessment factor is an expression of the degree of...
42. For each environmental compartment an exposure assessment shall be carried...
43. A PEC, or where necessary a qualitative estimate of exposure,...
44. The PEC, or qualitative estimation of exposure, shall be determined...
45. Where adequately measured, representative exposure data are available, special consideration...
46. For any given environmental compartment, the risk characterisation shall, as...
47. If it has not been possible to derive a PEC/PNEC...

Unacceptable effects

48. Data shall be submitted to and evaluated by the Member...
49. The Member State shall, where relevant, evaluate the possibility of...
50. If there are indications that any other unacceptable effects may...

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

Efficacy

51. Data shall be submitted and evaluated to ascertain if the...
52. Testing should be carried out according to Community guidelines if...

Summary

53. In each of the areas where risk assessments have been...
54. For biocidal products containing more than one active substance any...

DECISION MAKING

General principles

55. Subject to paragraph 96, the Member State shall come to...
56. In making a decision concerning authorisation, the Member State shall...
57. If the conclusion arrived at by the Member State is...
58. The Member State shall comply with the principles of mutual...
59. The Member State shall apply the rules concerning the concept...
60. The Member State shall apply the rules concerning the concept...
61. The Member State shall only grant authorisation to those biocidal...
62. The Member State shall impose, where appropriate, conditions or restrictions...
63. In the decision-making process the Member State shall take into...
64. The Member State shall, when taking a decision concerning the...
65. The Member State shall prescribe that biocidal products shall be...
66. The Member State shall take the necessary measures to ensure...
67. The Member State shall take the necessary measures to ensure...

Effects on humans

68. The Member State shall not authorise a biocidal product if...
69. The Member State shall consider possible effects on all human...
70. The Member State shall examine the relationship between the exposure...
71. The Member State shall, where possible, compare the results obtained...
72. The Member State shall, if appropriate, impose, as a condition...
73. If for non-professional users the wearing of personal protective equipment...
74. If the relationship between the exposure and the effect cannot...
75. No biocidal product classified according to Article 20(1) of this...

Effects on animals

76. The Member State shall not authorise a biocidal product if...
77. Using the same relevant criteria as described in the section...

Effects on the environment

78. The Member State shall not authorise a biocidal product if...
79. The basic tool used in the decision making is the...
80. For any given environmental compartment if the PEC/PNEC ratio is...

Water

81. The Member State shall not authorise a biocidal product, if...
82. The Member State shall not authorise a biocidal product if,...
83. The Member State shall not authorise a biocidal product if...
84. The proposed instructions for use of the biocidal product, including...

Soil

85. Where unacceptable contamination of soil is likely to occur, the...

Air

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

86. The Member State shall not authorise a biocidal product where...

Effects on non-target organisms

87. The Member State shall not authorise a biocidal product where...

88. The Member State shall not authorise a biocidal product where...

89. The Member State shall not authorise a biocidal product where...

Unacceptable effects

90. If the development of resistance to the active substance in...

91. An authorisation for a biocidal product intended to control vertebrates...

Efficacy

92. Member States shall not authorise a biocidal product which does...

93. The level, consistency and duration of protection, control or other...

Summary

94. In each of the areas where risk assessments have been...

OVERALL INTEGRATION OF CONCLUSIONS

95. The Member State shall combine the individual conclusions arrived at...

96. The Member State shall then take due consideration of any...

97. The Member State shall ultimately decide whether or not the...

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- (1) OJ C 239, 3.9.1993, p. 3, OJ C 261, 6.10.1995, p. 5 and OJ C 241, 20.8.1996, p. 8.
- (2) OJ C 195, 18.7.1994, p. 70 and OJ C 174, 17.6.1996, p. 32.
- (3) Opinion of the European Parliament of 18 April 1996 (OJ C 141, 13.5.1996, p. 191), Council common position of 20 December 1996 (OJ C 69, 5.3.1997, p. 13) and Decision of the European Parliament of 13 May 1997 (OJ C 167, 2.6.1997, p. 24). Council Decision of 18 December 1997. Decision of the European Parliament of 14 January 1998.
- (4) OJ C 138, 17.5.1993, p. 1.
- (5) OJ L 398, 30.12.1989, p. 19.
- (6) OJ L 262, 27.9.1976, p. 201. Directive as last amended by Directive 97/16/EC (OJ L 116, 6.5.1997, p. 31).
- (7) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Directive 96/68/EC (OJ L 277, 30.10.1996, p. 25).
- (8) OJ L 154, 5.6.1992, p. 1.
- (9) OJ L 84, 5.4.1993, p. 1.
- (10) OJ C 102, 4.4.1996, p. 1.