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European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (repealed)

ANNEX I

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

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
- 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)
- 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

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
- 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, professsional, 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

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

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...

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. Dossiers on active organisms are required to address at least...

2. Information which is not necessary owing to the nature of...

Dossier requirements

I. APPLICANT
- 1.1. Applicant (name, address, etc.)
- 1.2. Manufacturer (name, address, plant location)

II. IDENTITY OF THE ORGANISM
- 2.1. Common name of organism (including alternative and superseded names)
- 2.2. Taxonomic name and strain indicating whether it is a stock...
- 2.3. Collection and culture reference number where the culture is deposited...
- 2.4. Methods, procedures and criteria used to establish the presence and...

III. SOURCE OF THE ORGANISM
- 3.1. Occurrence in nature or otherwise
- 3.2. Isolation methods for organism or active strain
- 3.3. Culture methods
- 3.4. Production methods including details of containment and procedure to maintain...
- 3.5. Composition of the final active organism material i.e. nature, purity,...
- 3.6. Methods to prevent contamination of seed stock and loss of...
- 3.7. Procedures for waste management

IV. METHODS OF DETECTION AND IDENTIFICATION
- 4.1. Methods for establishing the presence and identity of the organism...
- 4.2. Methods for establishing the identity and purity of seed stock...
- 4.3. Methods to show the microbiological purity of the final product...
- 4.4. Methods used to show that there are no human or...
- 4.5. Methods to determine viable and non-viable (e.g. toxins) residues in...

V. BIOLOGICAL PROPERTIES OF THE ORGANISM
- 5.1. History of the organism and its uses including as far...
- 5.2. Relationship to existing pathogens of vertebrates, invertebrates, plants or other...
- 5.3. Effects on target organism. Pathogenicity or kind of antagonism to...
- 5.4. Transmissibility, infective dose and mode of action including information on...
- 5.5. Possible effects on non-target organisms closely related to the target...
- 5.6. Transmissibility to other non-target organisms
- 5.7. Any other biological effects on non-target organisms when properly used...
- 5.8. Infectivity and physical stability when properly used
- 5.9. Genetic stability under environmental conditions of proposed use
- 5.10. Any pathogenicity and infectivity to man and animals under conditions...

5.11. Pathogenicity and infectivity for known parasites/predators of the target species...

VI. EFFECTIVENESS AND INTENDED USES

6.1. Harmful organisms controlled and materials, substances, organisms or products to...

6.2. Uses envisaged (e.g. insecticide, disinfectant, anti-fouling product, etc.)

6.3. Information or observations on undesirable or unintended side effects

6.4. Information on the occurrence or possible occurrence of the development...

6.5. Effects on target organisms

6.6. Category of user

VII. TOXICOLOGICAL AND METABOLIC STUDIES

7.1. Acute toxicity

7.2. Sub-chronic toxicity

7.3. Chronic toxicity

7.4. Carcinogenicity study

7.5. Mutagenicity studies

7.6. Reproductive toxicity

7.7. Metabolism studies

7.8. Neurotoxicity studies: required where there is any indication of anticholinerterase...

7.9. Immunotoxicity studies (e.g. allergenicity)

7.10. Incidental exposure studies: required where the active substance will be...

7.11. Human exposure data including:

7.12. Summary of mammalian toxicology — conclusions (including NOAEL, NOEL and...

VIII. ECOTOXICOLOGICAL STUDIES

8.1. Acute toxicity to fish

8.2. Acute toxicity to Daphnia magna

8.3. Effects on algae growth (inhibition test)

8.4. Acute toxicity on one other, non-aquatic, non-target organism

8.5. Pathogenicity and infectivity for honeybees and earthworms

8.6. Acute toxicity and/or pathogenicity and infectivity for other non-target organisms...

8.7. Effects (if any) on other flora and fauna

8.8. In cases where toxins are produced, data as outlined in...

8.9. Spread, mobility, multiplication and persistence in air, soil and water...

8.10. In cases where toxins are produced, data as outlined in...

IX. MEASURES NECESSARY TO PROTECT HUMANS, NON-TARGET ORGANISMS AND THE ENVIRONMENT...

9.1. Methods and precautions to be taken for storage, handling, transport...

9.2. Any circumstances or environmental conditions under which the active organism...

9.3. The possibility of rendering the active organism non-infective and any...

9.4. Consequences of the contamination of air, soil and water, particularly...

9.5. Emergency measures in case of accident

9.6. Procedures for waste management of the active organism including leachate...

9.7. Possibility of destruction or decontamination following release in or into...

X. CLASSIFICATION AND LABELLING
XI. SUMMARY AND EVALUATION OF SECTIONS II TO X

ANNEX IVB

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
- 1.1. Name and address, etc.
- 1.2. Manufacturers of biocidal products and active organisms including location of...

II. IDENTITY OF BIOCIDAL PRODUCT
- 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 (emulsifiable concentrate,...
- 2.4. Concentration of active organism in material used

III. TECHNICAL AND BIOLOGICAL PROPERTIES
- 3.1. Appearance (colour and odour)
- 3.2. Storage — stability and shelf-life. Effects of temperature, method of...
- 3.3. Methods for establishing storage and shelf-life stability
- 3.4. Technical characteristics of the biocidal product
- 3.4.1. Wettability
- 3.4.2. Persistent foaming
- 3.4.3. Suspensibility and suspension stability
- 3.4.4. Wet sieve test and dry sieve test
- 3.4.5. Particle size distribution, content of dust/fines, attrition and friability
- 3.4.6. In the case of granules, sieve test and indications of...
- 3.4.7. Content of active substance in or on bait particles, granules...
- 3.4.8. Emulsifiability, re-emulsifiability, emulsion stability
- 3.4.9. Flowability, pourability and dustability
- 3.5. Physical and chemical compatibility with other products including biocidal products...
- 3.6. Wetting, adherence and distribution following application
- 3.7. Any changes to biological properties of the organism is a...

IV. METHOD FOR IDENTIFICATION AND ANALYSIS
- 4.1. Analytical methods for determining the composition of the biocidal product...
- 4.2. Methods for determining residues (e.g. biotest)
- 4.3. Methods used to show microbiological purity of the biocidal product...
- 4.4. Methods used to show the biocidal product to be free...
- 4.5. Techniques used to ensure a uniform product and assay methods...

V. INTENDED USES AND EFFICACY FOR THESE USES
- 5.1. Use
- 5.2. Details of intended use, (e.g. types of harmful organism controlled,...
- 5.3. Application rate
- 5.4. Where necessary, in the light of the test results, any...
- 5.5. Method of application
- 5.6. Number and timing of applications
- 5.7. Proposed instructions for use
- 5.8. Preliminary range-finding tests
- 5.9. Field experimentation
- 5.10. Information on the possible occurrence of the development of resistance...
- 5.11. Effects on the quality of materials or products treated

VI. TOXICITY INFORMATION ADDITIONAL TO THAT REQUIRED FOR THE ACTIVE ORGANISM...
- 6.1. Oral single dose
- 6.2. Percutaneous single dose
- 6.3. Inhalation
- 6.4. Skin and where relevant eye irritation
- 6.5. Skin sensitisation
- 6.6. Available toxicological data relating to non-active substances
- 6.7. Operator exposure
- 6.7.1. Percutaneous absorption/inhalation depending on formulation and method of application
- 6.7.2. Likely operator exposure under field conditions, including where relevant quantitative...

VII. ECOTOXICITY INFORMATION ADDITIONAL TO THAT REQUIRED FOR THE ACTIVE ORGANISM...
- 7.1. Observations concerning undesirable or unintended side-effects, e.g. on beneficial and...

VIII. MEASURES TO BE ADOPTED TO PROTECT MAN, NON-TARGET ORGANISMS AND...
- 8.1. Recommended methods and precautions concerning handling, storage, transport and use...
- 8.2. Re-entry periods, necessary waiting periods or other precautions to protect...
- 8.3. Emergency measures in case of an accident
- 8.4. Procedures for destruction or decontamination of the biocidal product and...

IX. CLASSIFICATION, PACKAGING AND LABELLING
- 9.1. Proposals including justification for the classification, packaging and labelling
- 9.2. Packaging (type, materials, size, etc.), compatibility of the biocidal product...
- 9.3. Specimens of proposed packaging

X. SUMMARY OF SECTIONS II to IX

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 other biocidal...
- 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
- 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 Products used...
- 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

(**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.