ANNEX IIA

COMMON CORE DATA SET FOR ACTIVE SUBSTANCES
CHEMICAL SUBSTANCES

1. Dossiers on active substances 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.

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

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

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 composition), molecular mass

2.6. Method of manufacture (syntheses pathway in brief terms) of active substance

2.7. Specification of purity of the active substance in g/kg or g/1, as appropriate

2.8. Identity of impurities and additives (e.g. stabilisers), together with the structural formula and the possible range expressed as g/kg or g/1, as appropriate

2.9. The origin of the natural active substance or the precursor(s) of the active substance, e.g. an extract of a flower

2.10. Exposure data in conformity with Annex VIIA to Directive 92/32/EEC[(1)].

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 extinction at relevant wavelengths, where relevant ([1])

3.5. Solubility in water including effect of pH (5 to 9) and temperature on solubility, where relevant ([1])

3.6. Partition coefficient n-octanol/water including effect of pH (5 to 9) and temperature([1])

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, where appropriate, for relevant degradation products, isomers and impurities of the active substance and additives (e.g. stabilisers)

4.2. Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following:

(a) Soil

(b) Air

(c) Water: the applicant should confirm that the substance itself and any of its degradation products which fall within the definition of pesticides given for parameter 55 in Annex I to Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption[(2)] can be estimated with adequate reliability at the MAC specified in that Directive for individual pesticides

(d) Animal and human body fluids and tissues

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 be protected

5.3. Effects on target organisms, and likely concentration at which the active substance will be used

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 of resistance and appropriate management strategies

5.8. Likely tonnage to be placed on the market per year

VI. TOXICOLOGICAL AND METABOLIC STUDIES

6.1. Acute toxicity

For studies 6.1.1 to 6.1.3, substances 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 substance 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. Skin and eye irritation ([3])

6.1.5. Skin sensitisation

6.2. Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study

For the following studies, 6.3 (where necessary), 6.4, 6.5, 6.7 and 6.8, the required route of administration is the oral route unless it can be justified that an alternative route is more appropriate

6.3. Short-term repeated dose toxicity (28 days)

This study is not required when a sub-chronic toxicity study is available in a rodent

6.4. Subchronic toxicity

90-day study, two species, one rodent and one non-rodent

6.5. Chronic toxicity ([4])

One rodent and one other mammalian species

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* mutagenicity study will be required (bone marrow assay for chromosomal damage or a micronucleus test)

6.6.5. If negative in 6.6.4 but positive *in-vitro* tests then undertake a second *in-vivo* study to examine whether mutagenicity or evidence of DNA damage can be demonstrated in tissue other than bone marrow

6.6.6. If positive in 6.6.4 then a test to assess possible germ cell effects may be required

6.7. Carcinogenicity study ([4])

One rodent and one other mammalian species. These studies may be combined with those in 6.5

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 and female

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 tests, if available

6.9.6. Sensitisation/allergenicity observations, if available

6.9.7. Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known

6.9.8. Prognosis following poisoning

6.10. Summary of mammalian toxicology and conclusions, including no observed adverse effect level (NOAEL), no observed effect level (NOEL), overall evaluation with regard to all toxicological data and any other information concerning the active substances. Where possible any suggested worker protection measures should be included in summary form

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

Fate and behaviour in the environment

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 products

7.6.2.2. Phototransformation in water including identity of the products of transformation ([1])

7.7. Adsorption/desorption screening test

Where the results of this test indicate the need to do so, the test described in Annex IIIA Part XII.1 paragraph 1.2 shall be required, and/or the test described in Annex IIIA Part XII.2 paragraph 2.2

7.8. Summary of ecotoxicological effects and fate and behaviour in the environment

VIII. MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

8.1. Recommended methods and precautions concerning handling, use, storage, transport or fire

8.2. In case of fire, nature of reaction products, combustion gases, etc.

8.3. Emergency measures in case of an accident

8.4. Possibility of destruction or decontamination following release in or on the following: (a) air (b) water, including drinking water (c) soil

8.5. Procedures for waste management of the active substance for industry or professional users

8.5.1. Possibility of reuse or recycling

8.5.2. Possibility of neutralisation of effects

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 other non-target organisms

IX. CLASSIFICATION AND LABELLING

Proposals including justification for the proposals for the classification and labelling of the active substance according to Directive 67/548/EEC

Hazard symbol(s)

Indications of danger

Risk phrases
Safety phrases

X. SUMMARY AND EVALUATION OF SECTIONS II TO IX

Notes

([1]) These data must be submitted for the purified active substance of stated specification.

([2]) These data must be submitted for the active substance of stated specification.

([3]) Eye irritation test shall not be necessary where the active substance has been shown to have potential corrosive properties.

([4]) The long-term toxicity and carcinogenicity of an active substance may not be required where a full justification demonstrates that these tests are not necessary.

([5]) If, in exceptional circumstances, it is claimed that such testing is unnecessary, that claim must be fully justified.

(**1**) OJ L 154, 5.6.1992, p. 1.

(**2**) OJ L 229, 30.8.1980, p. 11. Directive as last amended by Directive 91/692/EEC (OJ L 377, 31.12.1991, p. 48).