Technical Notes for Guidance on

Dossier Preparation including preparation and evaluation of study summaries

under Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market

28 March 2002

Short Title: TNsG on Preparation of Dossiers and Study Evaluation

PART I
DOSSIER PREPARATION

ECB, February 2008

The Technical Notes for Guidance on Dossier Preparation including preparation and evaluation of study summaries that were previously published as individual chapters on the ECB website were formatted and edited in three individual parts in pdf format.

Part I: Technical Notes for Guidance for the Preparation and Presentation of Complete Dossiers for the Inclusion of Active Substances in Annex I, IA or IB of Directive 98/8/EC or for Authorisation or Registration of Biocidal Products

(Dossier Preparation)

Contents

1 GENERAL INTRODUCTION

This Dossier Guidance focuses primarily on applications for the inclusion of active substances in Annex I, IA or IB. For information relating to applications for authorisation (or registration) of biocidal products, see chapter 9.

1.1 BACKGROUND

In order to meet the requirements set out in Article 33 of the Biocidal Products Directive 98/8/EC (BPD), the European Commission has prepared, in co-operation with the Member States, Technical Notes for Guidance (TNsG) to facilitate the day-to-day implementation of this Directive. As described below (chapter 1.4), there are a number of TNsG intended to provide guidance on what is required for both the applicant and the competent authorities in terms of the submission and assessment of studies and all information required by the BPD. This TNsG is intended to give guidance on how the documentation to be submitted by the applicant should be prepared and presented.

Regarding study summaries, sample formats have been prepared and are presented in Part III of the TNsG. All required data have to be addressed and must be presented in this type of format.

1.2 OBJECTIVE OF THE GUIDANCE ON DOSSIER PREPARATION

1.2.1 Whom the guidance is for

The Dossier Guidance only refers to chemical substances and not to biocidal fungi, micro-organisms and viruses (some guidance relating to these may be found in documents prepared for Directive 91/414/EC) , and is intended for use by:

- those making applications for the inclusion of active substances in Annex I, IA or IB to the BPD;

- other interested parties wishing to submit information for the review or renewal of any Annex I inclusion.

The approach aims at a uniform structure of the documentation of both the applicant's dossier and the competent authorities' report as further outlined in chapter 2.2.1. Hence, the Dossier Guidance should also be consulted by the competent authorities.

1.2.2 Standardisation of dossier preparation

The objective of this TNsG on Dossier Preparation is to provide guidance on how the requirements given by the BPD are to be fulfiled in a harmonised and, as far as possible, standardised procedure. Thus, this guidance aims at:

- supporting the applicant in preparing the complete documentation required for a dossier including a check for completeness and quality;
- supporting the applicant in summarising and evaluating the tests and studies and other data submitted or, if necessary, in justifying the non-submission of data;
- advising the applicant to report and justify, if necessary, any deviations from standard study protocols as well as deficiencies;
- facilitating the evaluation of the dossier to be performed by the Rapporteur Member State and Competent Authorities and hence, the decision-making by the the regulatory authorities.

Notwithstanding this standardisation, the use of expert judgement is required.

1.3 PRINCIPLES OF GUIDANCE

The TNsG on Dossier Preparation gives guidance on the following items:

- General structure and content of the documentation required for a complete dossier which consists of a summary dossier and the test and study reports. Some of this information may be confidential;
- Structure, format and lay-out of the individual document types.

The applicants are guided through the preparation of the dossier. For each dossier document required the purpose is explained and the format to be used is proposed.

In some cases, fixed forms are provided, for example the Application Form, Justification Form or Check for Completeness. Particularly for summarising individual tests and studies, standard formats are provided which should be used by the applicant to the extent that is practicable and feasible, keeping in mind that modifications, particularly in the form of additions, should be undertaken (see chapter 4).

1.4 REFERENCE DOCUMENTS TO BE CONSULTED

1.4.1 Technical notes for guidance concerning the Biocidal Products Directive

A number of specific Technical Notes for Guidance drafted for the European Commission should be thoroughly consulted by the applicant when preparing dossiers. The TNsGs are intended to explain the requirements laid down in the BPD, including the principles of evaluation and assessment. This TNsG on Dossier Preparation has been based on these TNsG, particularly on the TNsG on data requirements.

The TNsG addresses only active substances and biocidal products defined as chemical substances. Fungi, microorganisms and viruses (Annex IV of the BPD) are not addressed. The scope and objectives of the TNsG are briefly described as follows.

1.4.1.1 Technical notes for guidance on data requirements

TNsG <u>on data requirements</u>: Technical Notes for Guidance in Support of the Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market - Guidance on Data Requirements for Active Substances and Biocidal Products

- This TNsG provides detailed and practical guidance particularly to the applicants, but also to competent authorities, on which studies or other data are required in accordance with the BPD.

- The data requirements for the common core data and the product type-specific additional data are given in detail.
- Guidance is given on the data requirements for substances of concern and in consideration of the simplified procedures.
- Guidance is given on documenting the non-submission of data.

This TNsG is available from the web site of the ECB at http://ecb.jrc.it/biocides/

1.4.1.2 Technical notes for guidance on Annex I inclusion

TNsG on Annex I inclusion: Technical Notes for Guidance on the Inclusion of Active Substances in Annexes I, IA and IB of the Biocidal Products Directive

- This TNsG proposes a rationale for the inclusion of active chemical substances in Annexes I, IA and IB.
- The guidance is primarily for the competent authorities of the Member States designated to assess the active substances and biocidal products, but is also for the applicant.
- Little emphasis is placed on efficacy of the active substance itself as this is more relevant at the product level.
- Guidance is given on relevant aspects concerning risk characterisation.
- Guidance on the assessment of the potential for resistance is also given.

This TNsG is available from the web site of the ECB at http://ecb.jrc.it/biocides/

1.4.1.3 Technical notes for guidance on product evaluation

TNsG on product evaluation: Technical Notes for Guidance in Support of Annex VI of the Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market

- This TNsG is intended to explain the Common Principles laid down in Annex VI of the BPD. Guidance is given on the risk and efficacy assessment of individual biocidal products, assuming that all active substances present in the product are already included in Annex I of BPD.

- The TNsG is intended for use by the competent authorities, but also for the applicant.
- The document focuses on how to use study results to reach an authorisation decision, but does not cover how to appraise data for every end point listed in Annexes II and III of the BPD.

This TNsG is expected to be available from the web site of the ECB at http://ecb.jrc.it/biocides/

1.4.1.4 Technical notes for guidance on human exposure

- The TNsG on human exposure lists the models available for estimating the human exposure to active substances in the biocidal products, and where possible it also gives measured data. The document is in preparation (2002) and when a final draft is available it will be placed on the ECB web site.

This TNsG is expected to be available from the web site of the ECB at http://ecb.jrc.it/biocides/

1.4.1.5 Technical notes for guidance for environmental emissions

- The environmental emission scenarios are integrated as part of the TGD on Risk Assessment. Further development of scenarios is on-going (year 2002-2003) and when a final draft of a scenario is available it will be placed on the ECB web site.

1.4.2 Guidelines and criteria for the preparation of plant protection products dossiers

Many elements of this Dossier Guidance are similar to the corresponding PPP approach. Some have even been adopted. The following Guidelines give guidance on how to prepare dossiers for PPP:

EU (1998a): European Commission: Guidelines and criteria for the preparation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EC (Article 5.3 and 8,2). Document 1663/VI/94 Rev 8, 22 April 1998

1.4.3 Technical guidance document on risk assessment for new and existing chemicals, and biocidal active substances

The following Technical Guidance Document (TGD) gives guidance on how to prepare risk assessments for new and existing substances and biocidal active substances.

The version available while drafting this TNsG was: **European Chemicals Bureau, ECB (1996) Technical Guidance Documents in support of the Commission Directive 93/67/EEC on risk assessment for new notified substances and the Commission Regulation (EC) 1488/94 for existing substances**

The updated version is **European Chemicals Bureau, ECB (2002) Technical Guidance Documents in support of the Commission Directive 93/67/EEC on risk assessment for new notified substances and the Commission Regulation (EC) 1488/94 for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.** The following parts of the TGD will be used for Biocides : the full environmental part, and the hazard assessment part for the toxicological assessment. Where an assessment of exposure during manufacture is relevant for Biocides the TGD should be followed.

2 DOCUMENTATION REQUIRED TO APPLY FOR THE ANNEX I, IA OR IB INCLUSION OF AN ACTIVE SUBSTANCE

2.1 INTRODUCTION

The data required, as set out in the BPD and specified in the TNsG on data requirements, are to be summarised by the applicant to form the basis for the evaluation and the decision-making process of the regulatory authorities. The applicant's preliminary risk assessment should result in a proposal for a decision, the rationale of which should be given in an overall summary and assessment. All this information comprises the so-called **summary dossier** of an application which, together with copies of the original test and study reports, form the **complete dossier** to be submitted to the Rapporteur Member State.

After the receiving competent authority has accepted the dossier, the applicant has, according to Article 11.1(b) of the BPD, to forward a "summary of the dossiers" to the Commission and the other Member States. Hence, all dossier documents except for the original test and study reports are to be forwarded (see also chapter 8).

2.2 DOSSIER STRUCTURE AND CONTENT

The production of a full dossier requires the preparation of a number of different documents, as depicted in Fig. 2-1a.

Fig. 2-1. Structure of (a) applicant's dossier and (b) CAs' report

Fig. 2-1a

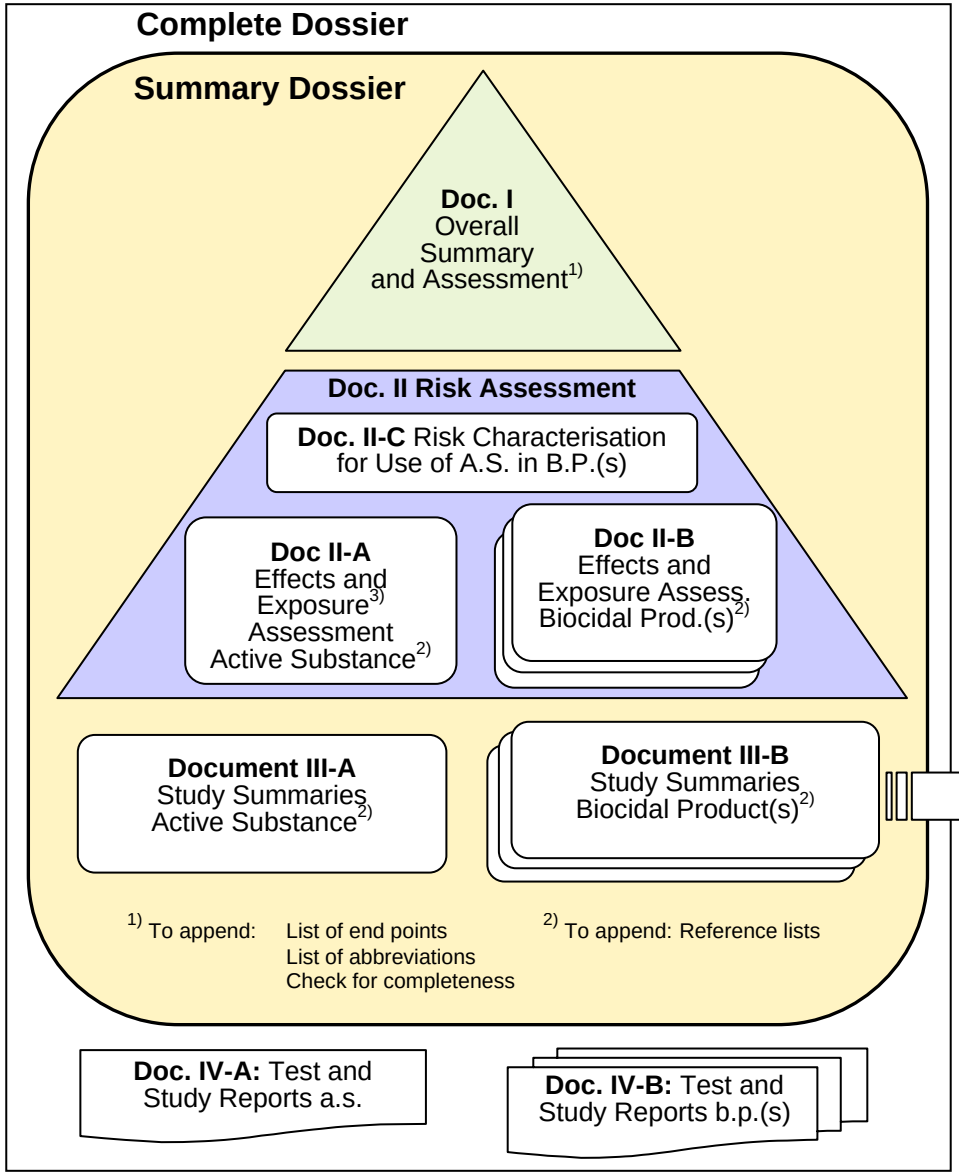
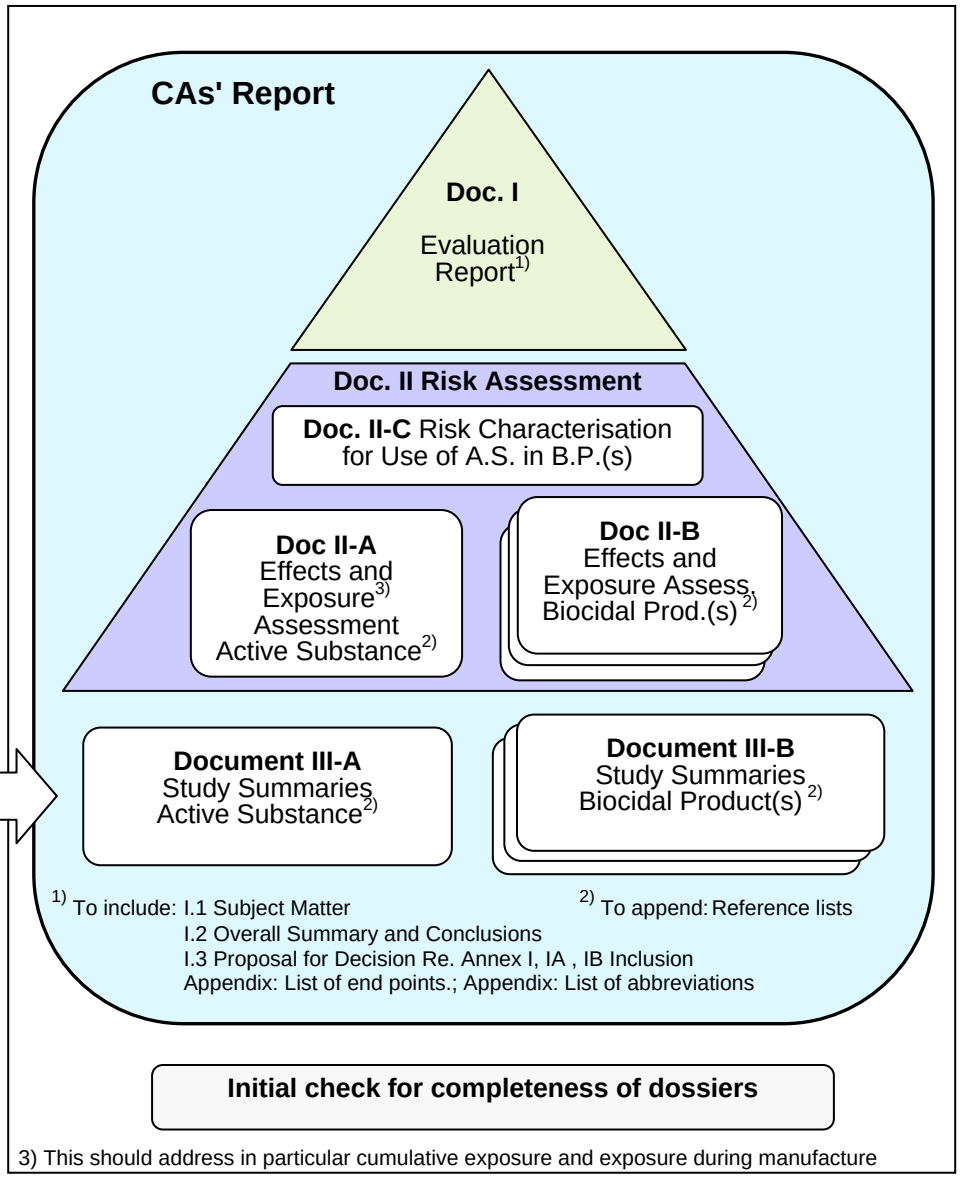


Fig. 2-1b



Because the report to be prepared by the competent authorities is an overall evaluation of the applicant's dossier, the elements of the dossier and the CAs' report are principally the same, except for specific statements given by the authorities, e.g. the proposed decision regarding the inclusion of an active substance in Annex I to the BPD. Therefore a uniform overall structure of documentation has been developed, as shown in Fig. 2-1a and Fig. 2-1b. This structure offers the advantage that:

- the number of main documents is reasonably small;
- the corresponding documents of both dossier and CAs' report have the same numbers and, except for DOCUMENT I, the same nomenclature;
- for the distinction between documents on the active substance (AS) and those on biocidal products (BP) the suffixes "A" and "B" are continuously used and correspond to those used in the BPD itself;
- for the distinction between proposed uses of biocidal products e.g. in different product types, the B documents can be assigned suffixes "B1", "B2" etc.

2.2.1 Detailed structure of dossiers

The detailed structure of the dossier documentation is shown in Table 2-1. The purpose, structure and format of the different documents, subdocuments and appendices are further described in the following chapters 3 to 6, in the order of dossier preparation and not in the order appearing in Table 2-1.

Table 2-1: Detailed structure of dossier documentation

Document type	Subdocument
DOCUMENT I OVERALL SUMMARY AND ASSESSMENT	I.1 Application form Appendices, if relevant: - Documentation relating to the joint submission I.2 Overall summary and conclusions Appendices: - Listing of end points - List of terms and abbreviations - Check for completeness - Active substance - Check for completeness - Biocidal product(s) I.3 Proposal for decision regarding Annex I, IA or IB inclusion
DOCUMENT II RISK ASSESSMENT	II-A Effects and exposure assessment - Active substance II-B Effects and exposure assessment - Biocidal product II-C Risk characterisation for the use of the active substance in biocidal product(s) Appendices: - Reference lists
DOCUMENT III STUDY SUMMARIES	III-A Study summaries - Active substance III-B Study summaries - Biocidal product(s) Appendices: - Reference lists - Confidential data and information (if applicable)
DOCUMENT IV ORIGINAL TEST AND STUDY REPORTS	IV-A Original test and study reports - Active substance IV-B Original test and study reports - Biocidal product*) Appendices, if applicable: - Profile and results of literature search

3 DOCUMENT IV - ORIGINAL TEST AND STUDY REPORTS

3.1 LITERATURE SEARCH

The applicant has to compile the data and information required in accordance with the BPD. If they are of adequate quality, unpublished test and study reports available to the applicant, other non published data or published data may be used to fulfil the BPD data requirements.

The applicant should conduct a detailed literature search to ensure that all relevant data and information can be provided with the dossier. It is recommended to append copies of the profile and the results of such literature searches to Document IV-A and IV-B. This can avoid duplication of work by the competent authorities of the Rapporteur Member State, who can then limit their own literature search to specific data gaps, if appropriate.

3.2 TEST AND STUDY REPORTS INCLUDING PUBLISHED DATA

DOCUMENT IV-A (for the active substance) and DOCUMENT IV-B (for biocidal products) should contain copies of all original test and study reports and of any other information compiled and summarised in the entire dossier.

For the submission of these documents in electronic format see chapter 8.

3.2.1 Use of literature data

Tt is agreed that in principle literature data may be used under the following conditions:

- Literature data may be used if they comply with the rules of article 8 of Directive 98/8/EC.
- Furthermore, the identity, purity and the impurities of the substance have to be defined in the publication and to be comparable with the notified substance.

- The test must have been conducted according to international guidelines (e.g. EU or OECD) and GLP is also an important issue. Deviations should be justified (cf Art. 8 (8) and (9) of Directive 98/8/EC).
- The reporting of the study should allow evaluation of the quality of the study.

The final decision on acceptance of literature data will be taken by the Rapporteur Member State after consultation with the other Member States and the Commission.

3.3 CONFIDENTIAL DATA AND INFORMATION

An applicant may indicate commercially sensitive information as confidential. This information should be included as Appendices to Document III-A and/or III-B. Information accepted by the receiving Rapporteur as being confidential will be treated as such by the competent authorities and the European Commission.

The criteria applying on whether data can be claimed as confidential are given in Article 19 of the BPD. For further guidance see TNsG on Product Evaluation.

4 DOCUMENT III - STUDY SUMMARIES

4.1 PURPOSE

The applicant has to summarise the data and information provided with Document IV-A and IV-B. These STUDY SUMMARIES provide the general basis for the further evaluation and assessment of the data submitted.

The objective of the STUDY SUMMARIES is:

- to present comprehensive summaries of test and key studies and any other information required according to the BPD;
- to evaluate the data provided as to their validity, i.e. acceptability of the quality, in order to facilitate the checking of dossiers for completeness, compliance with standard test guidelines and, where relevant, GLP or, in the case of tests not conducted according to accepted guidelines, the suitability of test methods;
- to allow the competent authorities to use the applicant's study summaries in a so-called **all-in-one approach** (see chapter 4.4.3).

As stated in the BPD, the different sections should be summarised and evaluated. As explained in chapter 5, there is a clear-cut distinction between the STUDY SUMMARIES (Doc. III level), which do not contain any summaries of the end points or sections and the hazard and risk assessment parts. Hence, any summaries of the end points or sections are covered by the hazard identification part (Doc. II-A and II-B) of the RISK ASSESSMENT documentation.

4.2 KEY STUDIES

The Biocidal Products Directive requires that at least for the endpoints given in Annex IIA and IIB of the BPD at least one acceptable study or a justification for non-submission of data should be available. This common core data set is regarded to be the minimum required for all substances and

product types. Some of the toxicological and ecotoxicological data requirements may be waived.

Studies for the endpoints in Annex IIIA and IIIB of the BPD may also be relevant. These additional data requirements are triggered by of the (eco)toxicological properties of a substance and the Product Type and the expected exposure (estimation of potential or actual exposure of the active substance to humans or the environment, or animals through food and feeding stuffs and other means).

In addition to the core and additional data required, the applicant must submit any additional available data, which is relevant to the risk assessment. This means that normally all valid studies per endpoint should be submitted.

A key study is a study regarded as sufficient and adequate to use for the risk assessment, and a key study must be summarised according to the study formats given in the TNsG on Dossier Preparation and Study Evaluation.

If no key study for any endpoint of the core data set and the relevant additional data requirements can be identified, then an additional study has to be performed (if no satisfactory justification for waiving of these (eco)toxicological data is given).

4.2.1 Purpose of Selection of key studies

When several reports are available on a specific endpoint (maybe using different species or routes of exposure), they can be used together to derive a more sound risk assessment. However, they can also originate from different periods of time and laboratories, they can be of different qualities and can be performed according to different guidelines and so each study's value to the risk assessment has to be judged individually. This range of studies occurs more commonly for existing substances. Making detailed study summaries for all these studies could, therefore, be unnecessary and cause a tremendous amount of work not only for the applicant but also for the Competent

Authority. For risk assessment normally only studies compliant with GLP, where relevant, and test guidelines are taken into account, whereas the other studies may either serve only to confirm the assessment or may not be used because they are not relevant or adequate.

In view of the above, a key study concept may be useful to distinguish the studies that need summarising in detail from those that do not, thereby reducing the workload at least for the preparation of dossiers and evaluations.

4.2.2. Criteria for key studies

The prerequisites for a key study concept related to toxicological and ecotoxicological studies are that it:

a) is in accordance with principles laid down in the relevant Test-Guidelines, including GLP wherever possible, the Technical Notes for Guidance on Data Requirements and the Technical Guidance Document on Risk Assessment;

b) is a tiered, transparent approach that ensures that at least one reliable study is defined as key study for each relevant endpoint;

c) has a certain flexibility to allow for special data conditions and risk assessment requirements following consultations with a Competent Authority.

Identifying the key study is an iterative procedure where the study reports available are pre-evaluated, the most critical one is chosen and if it cannot be used as key study then the next study is scrutinised to assess if this would then be a key study.

If in a *non-key study* the results are more critical than in the *key study*, then a robust study summary with full description of the method should be prepared.

Figure 1 gives a decision tree for defining a key study and its level of detail.

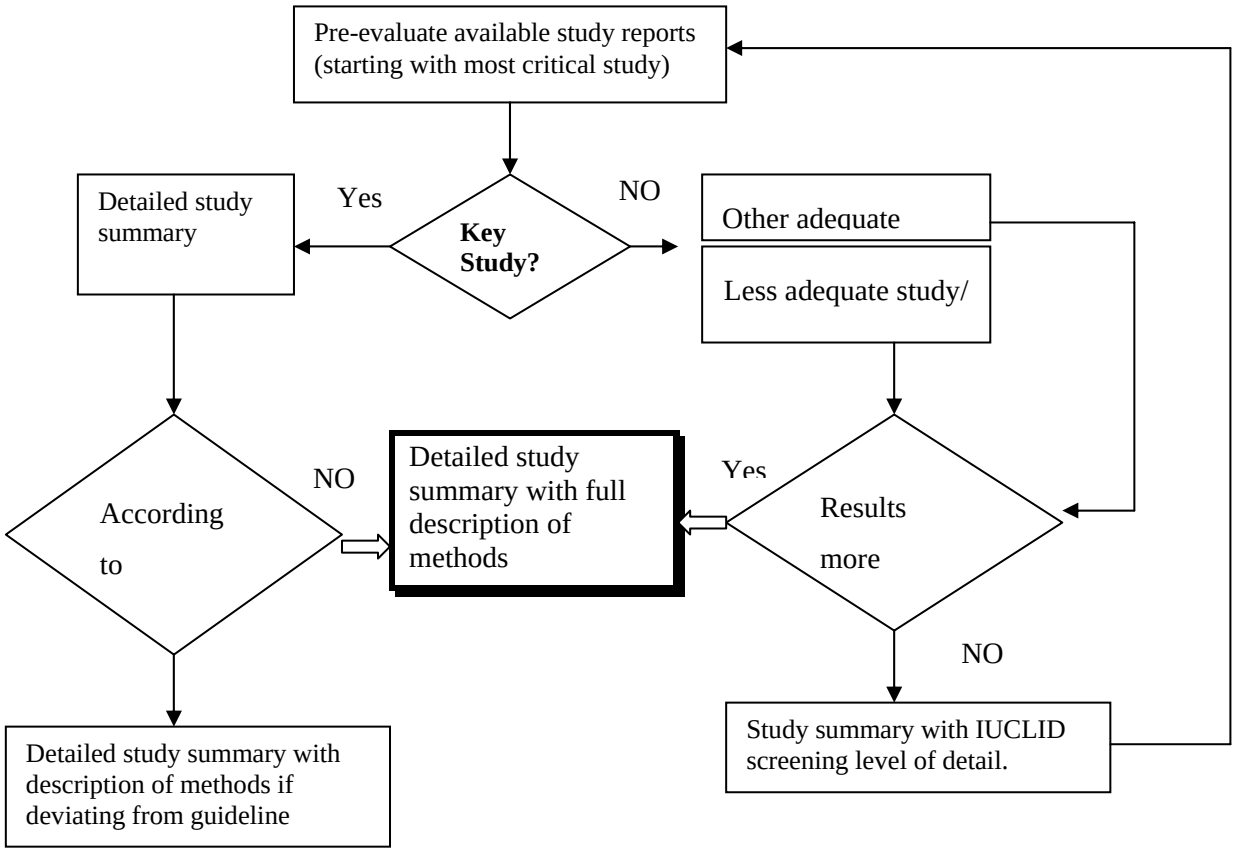


Fig. 1.-Decision tree for defining level of detail for studies (adapted from *Joint Final Project Report on the Pilot evaluations on existing biocidal active substance, Sept 2001*)

4.2.3 Toxicological studies

1) If there are several reliable tests (for example, for acute oral toxicity testing on the same species), the most appropriate test should be summarised as key study. The key study for a specific endpoint is normally defined as *the study*, which results in the lowest no-effect value (below which no effects were seen for that endpoint in that or any other similar study) and/or the lowest effect dose (e.g. LD_{50} or LC_{50} indicating highest toxicity) except where scientific evidence and the characteristic signs of toxicity for

the substance in the relevant species indicates the contrary. The most sensitive species, among the relevant species, should normally be used.

2) A short summary (including the key results and an indication of the validity) of all studies performed must be provided in the IUCLID database. Based on the IUCLID study summaries (and a table comparing studies if this is useful), the key study should be selected, justified and summarised in greater detail according to the TNsG on Dossier Preparation and Study Evaluation. If there are several reliable studies based on different test guidelines on the same endpoint, the key study should be selected from the method with the highest sensitivity (for example, a Magnusson and Kligman test instead of a Buehler test). It might be necessary for several studies to be considered as key studies for the same endpoint (for example, when data is available on several species or different routes of exposure or if different results are observed in valid tests).

In any case, all studies with "positive" findings for the endpoints mutagenicity, carcinogenicity and teratogenicity must be summarised using the format given in the TNsG on Dossier Preparation and Study Evaluation.

3) All data for key studies should be of an acceptable quality. However, flexibility is also necessary. If they are crucial or supporting special risk assessment aspects some studies with deficiencies may also be regarded as key studies and require a study summary as given in the TNsG on Dossier Preparation and Study Evaluation. For example this could apply to non-guideline studies, to studies on endpoints which are not specifically required by the BPD, or even to literature data if their result is crucial for risk assessment. This would particularly apply to all carcinogenicity, mutagenicity and reproductive toxicity studies with "positive" results, but could also be relevant for studies on sensitive sub-populations or mechanisms of action. The relevance of these results to the final risk assessment and the proposals for classification and labelling can then be fully assessed and their use or exclusion justified in the evaluation.

The data submitted by the applicant must be sufficient for a proper risk assessment and decision making. Therefore, the applicant should consult a Competent Authority at an early stage on which data should be submitted as key studies. The selection of key studies should be also indicated for the Completeness check.

4.2.4 Eoctoxicological studies

1) A short summary (including the key results and an indication of the validity) of all studies performed must be provided in the IUCLID database. Based on the IUCLID study summaries (and a table comparing studies if this useful), the key study should be selected, justified and summarised in greater detail according to the format given in the TNsG Dossier on Preparation and Study Evaluation. If there are several reliable studies based on different test guidelines on the same endpoint, the key study should be selected from the method with the highest sensitivity. It might be necessary for several studies to be considered as key studies for the same endpoint (for example, when data is available on several species or if different results are observed in valid tests).

2) All data for key studies should be of an acceptable quality. However, flexibility is also necessary. If they are crucial or supporting special risk assessment aspects some studies with deficiencies may also be regarded as key studies and require a study summary given in the TNsG on Dossier Preparation and Study Evaluation. For example this could apply to non-guideline studies, to studies on endpoints which are not specifically required by the BPD, or even to literature data if their result is crucial for risk assessment.

In the field of ecotoxicity the TGD principles of environmental risk assessment focus on the most critical value for each endpoint. That means for choosing the key study when more than one LC_{50}/EC_{50} values is available that the lowest data from a valid study has to be chosen for PNEC derivation. The key study is therefore defined as the study, which results in this lowest value.

When using statistical extrapolation techniques in deriving the NOEC value for the environmental risk assessment of a substance according to the TGD on Risk Assessment, all the results used in this extrapolation should be summarised at least as studies which are not key studies. For large ecotoxicological data sets mean values can only be used according to the rules given in the TGD.

3) Flexibility is important in many cases for which examples are given below:

Divergent data

Divergent data can occur if only a qualitative result of a test is given (e.g. readily biodegradable) and tests with different evaluations occur, or if one or two quantitative data (if one LC_{50} is considerably below the other one). In the case of divergent data at least one of each has to be covered by a detailed study summary according to the TNsG on Dossier Preparation and Study Evaluation, looking for the validity of the data. Decision-making if both data are valid goes beyond the scope of this paper.

Large (and homogenous) data sets for one endpoint

For large and not divergent data sets other approaches than to choose the lowest value can be taken into account. Normally this requires that all studies are summarised in detail; however in some cases one detailed study summary of a representative and "foreseeable good quality" (e.g. a recent GLP and Guideline study) can be sufficient. Data sets mean values can also be used according to the rules given in the TGD on Risk Assessment.

Supportive studies for risk assessment purposes

If they are crucial or supporting special risk assessment aspects, studies are, in any case, regarded as key studies and require a detailed study summary according to the TNsG on Dossier Preparation and Study Evaluation. This can for example apply also to non-guideline studies, to studies on endpoints

which are not required by the BPD, or even to literature data, if they are used instead of own studies or their result is crucial for risk assessment.

4.2.5 Studies which are not key studies

These studies have to be summarised in the IUCLID database and more detailed summaries using the TNsG on Dossier Prepartion and Study Evaluation must be made available if necessary, for example if the results are more critical than in the key study.

The IUCLID summaries must at least include:

- Name of the study (headline of the literature or unpublished documents)
- Substance (origin and impurities of substance used in test)
- Year of origin (start and finalization of the study, if given in the study report)
- Source (e.g. Company name, report no., performing lab., or quotation of the literature)
- Acceptability and test method (including GLP-status and test guideline, if appropriate)
- Results/threshold dose levels (measured or nominal data; key results, including LD_{50}, LC_{50}, NOAEL, LOAEL). If certain information is not available this should be flagged by the statement " not available".
- Results ecotoxicology (key results, including both $LC/EC/IC_{50}$ and NOEC where available).
- Analytical techniques and limit of determination

4.3 NUMBERING SYSTEM OF DATA REQUIREMENTS

The numbering system in the document type STUDY SUMMARIES is equivalent to that used in the TNsG on data requirements because this TNsG is to serve as a basis document for the applicant. In some (sub)sections a further substructuring is required, for example in the section on identity of active substance. However, this does not affect the overall numbering system or the cross-referencing to the TNsG on data requirements.

Table 1 and Table 2 preceding the standard formats given in **Part III** of this TNsG give an overview of the sections and section numbers used for DOCUMENT III-A and DOCUMENT III-B. For comparison, the corresponding BPD Annex Points are listed in these tables. Corresponding to the TNsG on data requirements, data from the common core data set (BPD Annex IIA or IIB) and the additional data set (BPD Annex IIIA or IIIB) are integrated in Doc. III-A and Doc. III-B, respectively.

Table 1 and Table 2 in **Part III** also give guidance on which standard formats are available or, if not available for a specific subsection, are recommended to be used or adapted.

4.4 FORMAT

4.4.1 Use of standard formats for the preparation of study summaries

The standardised formats provided in **Part III** of this TNsG should be used as far as possible for the preparation of the required summaries of individual test and study reports for the key studies. It should be stressed that these formats are not to be considered as fixed forms, but should be adapted and expanded if necessary. Sections 4.4 and 4.5 give technical guidance (section 4.4) and examples (section 4.5 and appendix 4.1) on formats. Unless a justification for non-submission is given (see chapter 4.4.2), the applicant must provide data and information for each subsection of Doc. III-A or III-B:

- by means of a standard format or several standard formats, if more than one test or study is presented for a specific end point;

- by means of creating new formats taking into account the overall structure and format of the standard formats given in this Dossier Guidance, if no specific standard formats are available;
- by including data in an informal way, if no specific standard formats can be used.

Many standard formats can be used for different subsections as indicated in the overview tables Table 1 and Table 2 in **Part III**. For example, the same standard format can be used for short-term repeated dose toxicity, subchronic toxicity and chronic toxicity.

The standard formats are intended to facilitate the checks to be carried out to ensure a high quality and the completeness of all required information and thus, to facilitate the evaluation process by the competent authorities. Where necessary, the applicant should deviate from the proposed schemes. A special study design may also require special presentation. If relevant items are not addressed in the standard formats, the applicant should add those as appropriate. In addition, tables should be created as far as possible to present detailed information in a concise form.

Much time and effort can be saved if the test laboratories are asked to produce their study reports directly in the standard formats.

In principle two different types of standard formats are provided for summarising test and study reports and any other data required.

4.4.1.1 Standard formats for combining several subsections

This type is provided particularly for the presentation of data from sections 2 (identity) and 3 (physical and chemical properties) and combines several subsections.

This appears to be appropriate as each subsection consists of names, short statements or figures only. Standard methods are widely applied for the determination of the physical and chemical properties of substances, which do not require an in-depth description. In addition, this condensed format gives an quick overview of the substance's identity and physico-chemical properties.

4.4.1.2 Standard formats for individual tests and studies

As shown in the standard format presented in Table 4-1, this type has the following lay-out and structure:

- Section heading (with consecutive number of reference concerning the same section number in parentheses)
- Cross-reference to BPD Annex Point
- Cross-reference to TNsG(s) (only if other than TNsG on data requirements)
- Structured form covering the main items such as:
  - REFERENCE (including data protection)
  - GUIDELINES AND QUALITY ASSURANCE (including GLP status)
  - MATERIALS AND METHODS
  - RESULTS AND DISCUSSION
  - APPLICANT'S SUMMARY AND CONCLUSION
- Fields and subfields common to most standard formats, e.g. field "2.1 Guideline study"
- End point specific fields and subfields with specific guidance and, where appropriate illustration by means of example texts or default options
- Separate areas for official use by competent authorities of the Rapporteur Member State and to track comments from other Members States:
  - Commentary column for indicating any discrepancies or deficiencies
  - Evaluation box: EVALUATION BY COMPETENT AUTHORITIES

Table 4-1: Standard format for summarising individual tests and studies where appropriate

Section xyz (Ref. no) **Annex Point/TNsG**	**(Sub)heading** *(specify where appropriate, e.g. species)*	
	1 REFERENCE	Official use only
1.1 Reference	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)* *If necessary, copy field and enter other reference(s).*	
1.2 Data protection	Yes/No *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company*	
1.2.3 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* A note on data protection is under preparation by the Competent Authorities (June 2002). When published it should be followed Data on new [a.s. / b.p.] for [first entry to Annex I/IA / authorisation] Data on existing [a.s. / b.p.] submitted under national legislation [entry into Annex I/IA / authorisation] Data on existing [a.s. / b.p.] submitted for the first time for [entry into Annex I/IA / authorisation] Data on existing or new [a.s. / b.p.] to [maintain or vary a.s. Annex I/IA entry / vary conditions of a b.p.'s authorisation] No data protection claimed	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes/No *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP *(only where required)*	Yes/No *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	Yes/No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3 MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material		
3.1.1 Lot/Batch number	*List lot/batch number where relevant*	

Section xyz (Ref. no) **Annex Point/TNsG**	**(Sub)heading** *(specify where appropriate, e.g. species)*	
3.1.2 Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially 2.7 and 2.8 of Annex IIA. Deviating from specification above as follows *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
3.1.3 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)*	
3.1.4 Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance*	
3.1.5 Stability	*Describe stability of test material*	
3.2 xxx	*Headings and subheadings study type-specific*	
	4 RESULTS	
4.1 xxx	*Headings and subheadings study type-specific*	
4.2 yyy		
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.*	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate*	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4*	
5.3.2 Deficiencies	No/Yes *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Materials and Methods	*Adopt applicant's version or include revised version. If necessary, discuss relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*	
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*	

Section xyz (Ref. no) **Annex Point/TNsG**	**(Sub)heading** *(specify where appropriate, e.g. species)*	
Conclusion	*Adopt applicant's version or include revised version*	
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator (the text in section 4.4.2.5.1 gives guidance on this point)*	
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)*	
Remarks		
	COMMENTS FROM	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

4.4.2 Standard form for justification for non-submission of data

Article 8.5 of the BPD regulates the possible non-submission of data. If supported by an acceptable justification, information need not be supplied if it is not necessary "owing to the nature of the biocidal product or of its proposed uses" or in cases "where it is not scientifically necessary or technically possible". For guidance on the possible non-submission of data see the TNsG on data requirements.

For the sake of clarity, all (sub)sections referring to the BPD Annex II or III Points should be addressed in the STUDY SUMMARIES either by:

- providing data and information as outlined above or by
- providing a justification form as given in Table 4-2, if the non-submission of specific data can be reasonably justified.

The justification forms should substitute the standard formats designated for particular subsections and take their position in Document III.

This approach offers the advantage that both the applicant and the competent authorities can easily check the data base without having to look up different files. In addition, the check for completeness (see chapter 4.7) will be facilitated.

For the case where the applicant has charged a test laboratory to conduct a missing test or study, please refer to section 4.6.3.

A justification will not be sufficient if it only states that information for a particular endpoint is not required or not relevant. While the justification should be concise and to the point, it should also be long and detailed enough for the reader to be able to decide the case for themselves. Supporting information can be provided in annexes if necessary.

Table 4-2: Standard form for justification of the non-submission of data

Section x.y **Annex Point x.y**	**(Sub)heading** *(specify where appropriate)*	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:		
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

4.4.3 All-in-one approach: use of applicant's study summaries by the competent authorities

The applicant's dossier will be evaluated by the Competent Authorities (CA) of the Rapporteur Member State. The CAs' report will be commented on by other Member States. A final report will then be prepared by the Rapporteur Member State. Although both the dossier and the CAs' report have most document types in common, as discussed in chapter 2.2.1, the regulatory authorities will summarise the data base provided by the applicant and perform evaluations and risk assessments independently of the applicant's view. However, parts of the applicant's dossier can be synergetically used by the authorities. This pertains mainly to document type III - STUDY SUMMARIES. The standard formats given in this document type were designed in such a way that allows the authorities to:

- annotate on the applicant's version and/or to amend and change applicant's entries;
- mark and comment on any deficiencies of tests and studies or of their reporting;
- comment on the applicant's summary and conclusion;
- include comments on the evaluation of the individual tests and studies submittted to the Rapporteur Member State by other Member States.

Separate space is reserved for the CAs' entries in the form of:

- a separate comment area (shaded column); where the CAs can mark fields, e.g. with an X, in the case of reporting errors, study deficiencies or any other reason;
- a separate part "Evaluation by Competent Authorities", in which the CAs can either enter an adopted or revised version of the applicant's summary and conclusion. In the fields "Materials and methods" and "Results and discussion" the CAs can indicate any errors found in the applicant's study summaries or discuss relevant discrepancies and deficiencies referring to the corresponding (sub)heading number(s).

This so-called all-in-one approach aims at minimizing the duplication of work, as the rapporteur has to annotate only in the case of discrepancies with the applicant's entries. The lay-out of these standard formats guarantees a high transparency of the comments and evaluation carried out by the regulatory authorities. In addition, the

rapporteur can adopt the annotated and revised STUDY SUMMARIES from the applicant's dossier to form the corresponding CAs' report.

4.5 TECHNICAL GUIDANCE ON THE CREATION OF STUDY SUMMARIES USING STANDARD FORMATS

4.5.1 Principles

As far as possible, guidance notes written in *italics* are directly included in the standard formats. These notes are intended to provide guidance to the applicant preparing summaries of tests and studies, but also to the regulatory authorities evaluating the completed formats submitted by the applicant, with a view to:

- explaining the specific data inputs expected in the fields or sections of the standard formats;
- giving guidance on whether a field is to be filled in compulsory or conditionally;
- giving default entries, where appropriate (e.g. Yes/No or test parameters);
- giving guidance on particular relevance of specific parameters;
- referring to example tables attached to the standard formats;
- giving examples where appropriate;
- giving guidance on which aspects should be covered in summary and evaluation fields

The guidance notes given in the standard formats generally address technical items. As recommended above, the applicant should consult the Technical Notes for Guidance, particularly the TNsG on data requirements (see chapter 1.4.1), where further explanations on the data requirements are provided.

The development of the sample formats, given in **Part III,** concerning (sub)headings and appropriate guidance notes was, inter alia, based on:

- EC and OECD guidelines;
- US EPA guidelines and ISO standards;
- preliminary OECD templates from the PMRA, Health Canada;

- examples given in the guidelines for plant protection products;
- fields covered by the IUCLID chapters;
- proformas used in the New Substances scheme;
- experience with reporting toxicological and ecotoxicological data in chemical risk assessment reports.

The standard format related to environmental and human exposure should be used in a very flexible way, depending on the peculiarities of the different product types. The exposure information submitted should reflect also the results from the Projects on Human Exposure to Active Substances in Biocidal Products[1] and the EUBEES Projects[2] and the OECD biocides activities[3]. Possibly the product type-related requirements on exposure data have to be specified. Further research in this field is being carried out. The results of these activities should be taken into consideration for revising this standard format.

4.5.2 Explanations of main entry fields

4.5.2.1 Reference (including data protection claim)

References

In the standard formats for individual tests and studies, the reference(s) used to compile the data of a test or study is/are to be included under the main heading "1. REFERENCE", in subfield "1.1 Reference". The following rules should be followed:

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[1] (1998) Assessment of human exposures to biocides. Report to DG XI. Project 97/505/3040/DEB/E2. ECB web site at http://ecb.jrc.it/biocides

[2] EUBEES I. European Union Biocdal Environmental Emission Scenarios. Results published at the ECB web site at http://ecb.jrc.it/biocides. (A follow-up study has been undertaken [2002]) the Emission scenarios for biocides will be integrated in the TGD on Risk Assessment.

[3] OECD (2000) Wood preservation and human exposure. http://www1.oecd.org/ehs/Biocides/Fin_Report_12102000_2.pdf

- All authors' names and initials; initial letters capitalized
- Year of report or publication
- Full title of article or study report
- In the case of study report: laboratory name, laboratory report number
- In the case of published article: name of journal (abbreviated according to the International Serials Data System, ISDS), volume number (in bold print), first and last page numbers
- In the case of book, conference proceedings or similar: editor(s), full title of the conference (if any), place and date of the conference (if any), place of publication, the volume number (if any), page numbers
- In parentheses: "(published)" or "(unpublished)"
- If more than one reference applies, the subfield "1.1 Reference" should be copied and each additional reference should be entered into a separate Reference subfield, thus facilitating the creation of a reference list.
- All references should be transferred from the standard formats to create a reference list, ordered by author (see chapter 6.6).

Examples:

Watanabe I, Parker KL, Paul JP (1990) Residue analysis of synthetic pyrethroids. Pure Appl. Chem. **62:** 522-526 (published)

Parker EM, Smiles HP, Miller P (1989) Substance x: test of sensitizing effect on guinea pig (Maximization test according to Magnusson and Kligman). General Laboratories Inc., Report No: 2778 (unpublished)

Budavari S, ed. (1986) The Merck Index: an encyclopedia of chemicals, drugs and biologicals. 12th ed., Merck Co. Inc., New Jersey, p. 577 (published)

Indication of data protection claim

In the case of unpublished reports the applicant can indicate if data protection is claimed in accordance with Article 12 of the BPD. A guidance for data protection is in preparation. Because the CAs have to monitor the periods of data protection, the

following subfields under "1.2 Data protection" should be filled in by the applicant, if applicable:

- 1.2.1 Data owner: The name of company should be given.
- 1.2.3: Criteria for data protection: One of the following criteria should be selected and the criteria being not applicable should be deleted (further guidance on data protection is being elaborated):
  - Data on new [a.s. / b.p.] for [first entry to Annex I/IA / authorisation]
  - Data on existing [a.s. / b.p.] submitted for the first time [entry into Annex I/IA / authorisation]
  - Data on existing [a.s. / b.p. submitted under national legislation for [entry into Annex I/IA / authorisation]
  - Data on existing or new [a.s. / b.p.] to [maintain or vary a.s. Annex I/IA entry / vary conditions of a b.p.'s authorisation]
  - No data protection claimed

The criteria concerning both the active substance and biocidal products are given because many standard formats developed for study summaries on active substances can also be used for study summaries on biocidal products.

4.5.2.2 Guidelines and quality assurance

In the standard formats for individual tests and studies the applicant should state whether or not a test or study was conducted in accordance with standard test guidelines and which test guidelines were applied (subfield "2.1 Guideline study") and whether the principles of GLP were complied with, if applicable (subfield "2.2 GLP").

It should be noted that compliance with standard test guidelines or GLP is indicative of acceptable quality of individual tests and studies, but does not necessarily equate with good science. On the other hand "non-guideline" studies may be useful for risk assessment if they were conducted in accordance with generally accepted scientific principles (see chapter 4.5.2.5.1).

4.5.2.3 Materials and methods

According to the general principle stated in Article 8.8 of the BPD, "tests must be conducted according to the method described in Annex V to Directive 67/548/EEC. In the event of a method being inappropriate or not described, other methods used should, whenever possible, be internationally recognised and must be justified ...". For detailed guidance see TNsG on data requirements. The use of OECD test guidelines does not need to be justified.

If a test was not conducted according to a standard protocol, a full and detailed description of the method used is compulsory.

A bibliographic reference may be sufficient for tests that were conducted according to a method described in Annex V to Directive 67/548/EEC as required by the BPD or the corresponding OECD methods. In all cases, those parts of the method which are not covered by or deviate from the methodology described in the guideline given as reference are to be described in detail. However, to avoid the risk of deviations and deficiencies not being reported and to facilitate the evaluation of the study summaries by the CAs, it is highly recommended to also describe in full detail those methods used in studies conducted in compliance with EC and OECD test guidelines.

Particularly in the toxicology sections the effort required to fill in the subfields given under the main heading "Materials and Methods" in the standard formats is minimized, because a number of parameters or values from the respective test guidelines is given as "default" data. The applicant is required to adopt, change or delete these default values depending on the actual parameters.

It should be noted that the default values given in the standard formats may change if test guidelines are updated. In all cases, the applicant must change the default values in such a way that only the data from the test or study being summarised remain in the subfields.

4.5.2.4 Results and discussion

In the standard formats for individual tests and studies the applicant should report the findings concisely but comprehensively. As far as possible the results of the different examinations should be given in tabular form. Sample tables are appended to most standard formats. Supporting text including any further explanation and discussion should be entered in the designated subfields under the heading "Results and discussion".

4.5.2.5 Applicant's summary and conclusion

Under the heading "Applicant's summary and conclusion" an executive summary should be given in which the relevant aspects of the individual tests and studies including the conclusions reached should be briefly presented. Where appropriate, these executive summaries or part of them can be transferred to the HAZARD AND EFFECTS ASSESSMENT part (Doc. II-A or II-B), in which the (sub)sections of the STUDY SUMMARIES are summarised and discussed.

The "Applicant's summary and conclusion" contains concise summaries of:

- Materials and methods: giving a concise description of the method used
- Results and discussion: summarising relevant results and discussing dose- or concentration-response relationships where relevant

In addition the conclusions reached should be included in the following subfields:

- Conclusion: this is further broken down to:
  - Subfields designated for no effect levels or other conclusions, e.g. regarding the biodegradabilty of a substance
  - Subfield "Reliability" (see below)
  - Subfield "Deficiencies" (see below)

4.5.2.5.1 Reliability indicators

The STUDY SUMMARIES also include a check as to the inherent quality of the test methodology and study documentation. Before the regulatory authorities evaluate

the data provided, the applicant should conduct a quality check. To standardise this check as far as possible, the following reliability indicators are introduced:

0) Not applicable (Reasons to be given in the reliability field)

1) Study conducted in compliance with agreed protocols, with no or minor deviations from standard test guidelines and/or minor methodological deficiencies, which do not affect the quality of relevant results

2) Study conducted in accordance with generally accepted scientific principles, possibly with incomplete reporting or methodological deficiencies, which do not affect the quality of relevant results

3) Study with major methodological and/or reporting deficiencies

4) Unsuitable test system or conditions and/or insufficient reporting of methods and/or results data

Based on the assessment of materials and methods, the applicant should derive the appropriate reliability indicator and include it in the corresponding field in the standard formats.

Reliability scores 1 and 2 indicate that the results from such studies can be considered for risk assessment. Studies with reliability scores 3 or 4 are of limited or no value with regard to risk assessment. However, there may be reasons to use even those data, if for example the test results are supportive for other data.The reliability indicators can be transferred to the completeness check list, as decribed in chapter 4.7.2.

4.5.2.5.2 Deficiencies

The applicant can discuss the impact of any methodological deficiencies and implications on results and, if relevant, justify the acceptability of a study. This subfield corresponds to the subfield "Acceptability" in the Evaluation box of the CAs, in which the CAs indicate whether the tests and studies submitted by the applicant are acceptable and if unacceptable, have to be repeated or not.

4.6 EXAMPLES OF STUDY SUMMARIES

Examples of study summaries are given in **Appendix 4.1** to demonstrate the use of standard formats. The examples were taken from the corresponding PPP guidelines (EU Document 1663/VI/94 Rev 8, 22 April 1998), but modified by e.g. adding additional data, to demonstrate how the formats should be ideally filled in.

4.7 CHECK FOR COMPLETENESS AND QUALITY

The competent authorities of the Rapporteur Member State have to check:

- the completeness of the documentation submitted and
- the completeness and quality of the data submitted.

The applicant should perform these checks before submitting the dossier. **The applicant should discuss any gaps, problems or points of uncertainty with the Rapporteur Member State at the earliest opportunity. This is especially crucial for the review of an existing active substance where the timetable for evaluation is short once the dossier is officially submitted**.

4.7.1 Check for completeness of documentation

In the APPLICATION FORM (Document I.1, see **Appendix 6.1**), the applicant should confirm that all documents required are included in the dossier documentation.

In the case that a collective dossier for an active substance has not been achieved, explanations of the efforts made to provide a collective dossier should be submitted with each dossier.

4.7.2 Check for completeness and quality of data

For each dossier the applicant should carry out a completeness check covering the data requirements for DOCUMENT III. Check list forms are provided in **Appendix**

4.2 and **Appendix 4.3**. The extent of documentation is determined by the nature of the active substance, any non-active substances of concern regularly used in products and the exposure scenarios in which they will be used. Guidance is available in the TNsG on data requirements, beginning at section 1.2.

These forms should be used in checking, for each data requirement, whether the criteria described below (4.7.2.1 to 4.7.2.4) are fulfiled or not. The lists should be filed as an Appendix of Document I and will be used by the receiving competent authority to conduct their initial evaluation. The "official use only" columns in the forms are reserved for the competent authorities.

The following items should be indicated in these evaluation forms:

4.7.2.1 Information, test or study provided

The applicant should indicate whether the data required have been provided in the dossier:

- Yes (Y); number of studies in parentheses if more than one study, e.g. "Y(2)"
- No (N)
- In part (P) (relevant if a section heading includes more than one possible study type, e.g. as in section 6.5).

When an animal study has been conducted for an endpoint where an equivalent one already existed, an explanation for the repetition of the study should be provided with the study report.

4.7.2.2 Justification

The applicant should indicate whether a justification form has been provided in the case of non-submission of data.

4.7.2.3 Confidential data

The applicant should indicate whether data are considered as confidential.

4.7.2.4 Reliability indicator

The applicant should indicate the outcome of the preliminary quality check regarding the reliability and relevance of data.

4.7.3 When the dossier is not yet complete

The dossier should be complete. Early planning and discussions with the Rapporteur Member State (RMS) should ensure that the dossier is complete, especially in view of the applicant's unique knowledge of the nature of the active substance and its uses. However, if a dossier is not complete due to force majeure, an applicant must provide an explanation, with appropriate evidence, of why it was not possible to submit the information by the deadline, to the RMS.

In the event that a study is under way the applicant should inform the RMS of its current status and when the draft and final reports should be available.

In the event that a study is not begun, the RMS may establish a new deadline for the submission of the information. The applicant must then provide evidence that the lacking information has been commissioned in order to fulfil the requirement within 3 months of receiving the new deadline.

In the event that the RMS identifies information as necessary that the applicant had not identified as such, the above process of setting deadlines and providing evidence of commissioning work shall also apply.

The validity of justifications will be evaluated as far as possible during the completeness check in order to identify inadequacies and allow for timely action by the applicant. However, there will be time constraints on the RMS for reviews and a detailed evaluation of relevant submitted data (for example, in cases of read-across) is not likely at that stage. For this reason among others (such as differing interpretations of data), there is the potential for a data gap to be identified at later stages either by the RMS or other Member States. In this case the time frame for commissioning new data will apply as above.

In any of the above cases, the RMS will inform the applicant as soon as a data gap is confirmed.

4.8 REFERENCE LISTS

To each STUDY SUMMARIES document (Doc. III-A and III-B) the following types of reference lists should be provided:

- Reference list, by section number

- Reference list, by author (in alphabetical order)

In addition:

- a listing of the test and study reports and other documentation not submitted as part of the dossier should be provided and this should be arranged in alphabetical order by author.

Formats for these lists are shown in Table 4-3 and Table 4-4. The following information should be included:

- for each study summary or any other information included in Doc. III-A or Doc. III-B, its author(s), title, source, company and report number;
- the section number covered by the test or study, and the consecutive reference number
- for each study summary or any other information, an indication as to whether it is published or not;
- for each study summary or any other information, an indication as to whether it has been conducted in compliance with the principles of GLP, where relevant;
- in the case of unpublished reports, an indication of the identity of the owner of the test or study concerned, if different from the person or organisation that submitted it;
- in the case of unpublished reports, an indication as to whether or not data protection is claimed in accordance with Article 12 of the BPD and as further explained in the TNsG on Product Evaluation.
  If data protection is claimed, one of the following conditions can be given in parentheses:
  New/First = Data on new a.s. for first entry to Annex I/IA
  Exist./First = Data on existing a.s. following its entry into Annex I/IA
  Variation = Data on existing or new a.s. to maintain/vary Annex I/IA entry

Note: In the case of applications for the authorisation or registration of a biocidal product, the following conditions can be given for product data:
New/First = Data on new b.p. for first authorisation

Exist./First = Data on existing b.p. following its authorisation

Variation = Data on existing or new b.p. to vary conditions of authorisation

Table 4-3: Format for reference list, by section number[4]

Section No / Reference No	**Author(s)**	**Year**	**Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
A6.1/01	Flucke W, Thyssen J	1980a	XXX 1111 / acute toxicity studies. Organics Inc Report No: 8800 Not GLP, Unpublished	N	ORG
A6.1/02	Bomann W	1991	XXX 1111 / study for acute oral toxicity in rats. Organics Inc Report No: 19852 GLP, Unpublished	Y (New/First)	ORG
A6.2/01	Casida JE, Gaughan LC, Ruzo LO	1979	Comparative metabolism of pyrethroids derived from 3-phenoxybenzyl and α-cyano-3-phenoxybenzyl alcohols. Advances in pesticide science, Fourth International Congress of Pesticide Chemistry, Zürich, Switzerland, July 24-38, 1978, part 2, 182-189 Not GLP, Published	N	-
A6.2/02	Eben A, Thyssen J	1981	Thiocyanate excretion in rats' urine after intraperitoneal administration of XXX 1111 and decamethrin in comparable doses and after exposure to defined XXX 1111 concentrations in the inhalation air. Organics Inc Report No: 10130 Not GLP, Unpublished	N	ORG
A6.2/03	Rensor D, Ekneb A, Frodslegnam I, Reiem I, Rekennek G,	1985	Metabolism of XX in the rat. Generics Unlimited, Report No: PH 2802 Not GLP, Unpublished	N	GEN
A6.3.1/01	Watanabe I, Parker KL, Paul JP	1990	Short-term toxicity studies with synthetic pyrethroids. Toxicol. Letters 22: 42-46 Not GLP, Published	N	-
A6.3.1/02	Flucke W, Schilde B	1980b	XXX 1111 / subacute oral toxicity study	N	ORG

[4] Adapted from: EU (1998): European Commission: Guidelines and criteria for the preparation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EC (Article 5.3 and 8,2). Document 1663/VI/94 Rev 8, 22 April 1998

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			on rats. Organics Inc Report No: 9039 Not GLP, Unpublished		

Table 4-4: Format for reference list, by author[5]

Author(s)	Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Bomann W	A6.1/02	1991	XXX 1111 / study for acute oral toxicity in rats. Organics Inc Report No: 19852 GLP, Unpublished	Y (New/First)	ORG
Casida JE, Gaughan LC, Ruzo LO	A6.2/01	1979	Comparative metabolism of pyrethroids derived from 3-phenoxybenzyl and α-cyano-3-phenoxybenzyl alcohols. Advances in pesticide science, Fourth International Congress of Pesticide Chemistry, Zürich, Switzerland, July 24-38, 1978, part 2, 182-189 Not GLP, Published	N	-
Eben A, Thyssen J	A6.2/02	1981	Thiocyanate excretion in rats' urine after intraperitoneal administration of XXX 1111 and decamethrin in comparable doses and after exposure to defined XXX 1111 concentrations in the inhalation air. Organics Inc Report No: 10130 Not GLP, Unpublished	N	ORG
Flucke W, Schilde B	A6.3.1/02	1980b	XXX 1111 / subacute oral toxicity study on rats. Organics Inc Report No: 9039 Not GLP, Unpublished	N	ORG
Flucke W, Thyssen J	A6.1/01	1980a	XXX 1111 / acute toxicity studies. Organics Inc Report No: 8800 Not GLP, Unpublished	N	ORG
Rensor D, Ekneb A,	A6.2/03	1985	Metabolism of XX in the rat.	N	GEN

[5] Adapted from: EU (1998): European Commission: Guidelines and criteria for the preparation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EC (Article 5.3 and 8,2). Document 1663/VI/94 Rev 8, 22 April 1998

Author(s)	Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Frodslegnam I, Reiem I, Rekennek G,			Generics Unlimited, Report No: PH 2802 Not GLP, Unpublished		
Watanabe I, Parker KL, Paul JP	A6.3.1/01	1990	Short-term toxicity studies with synthetic pyrethroids. Toxicol. Letters 22: 42-46 Not GLP, Published	N	-

5 DOCUMENT II - RISK ASSESSMENT

5.1 PURPOSE

The preparation of DOCUMENT II - RISK ASSESSMENT is in accordance with the BPD Annex IIA/IIB Points X "Summary and Evaluation of Sections II to IX".

The risk assessment should in principle follow the common risk assessment paradigm given in the Technical Guidance Document (TGD) on risk assessment for new and existing chemicals, and active biocidal substances (see chapter 1.4.3) and includes the following elements:

- Exposure assessment
- Hazard identification
- Dose-response assessment

} Health / Environmental effects assessment

- Risk characterisation

Guidance on risk assessment is spread over several documents: for the environment, including the marine environment, the methodology is given in the TGD and further environmental exposure scenarios are under development; for the human toxicology the hazard identification and the dose-response guidance is given in the TGD, an exposure guidance is under development, and the risk characterisation is given in the guidance for Annex I inclusion. The documents will all be placed at the ECB web page at http://ecb.jrc.it/biocides/

Depending on the purpose of the application, the emphasis on active substance or product data with respect to risk assessment will differ:

- For an Annex I or Annex IA entry a risk assessment of the active substance related to its use in specific product types is most important since, once listed in Annex I or IA, no reassessment should be necessary for this particular substance with respect to its specific product type.

  To carry out the risk assessment, product data are required to assess the exposure to the active substance at the envisaged normal use and at a realistic worst-case scenario.

- For the product authorisation in one of the Member States, the hazard identification and dose-response assessment of the active substance(s) will be used for the risk assessment, together with further data on the biocidal product itself (see chapter 9).

An effects assessment for both the active substance and the biocidal product, including possible substances of concern, is needed. For the active substance the exposure assessment is based on typical uses of the products in which it is present, as data on application of the product are required. A TNsG on human exposure to an active substance via the products is being elaborated, and environmental emission scenario documents are being drafted to have a tool box for exposure estimation. Any data on use and exposure as compiled on Doc. III-A level are to be combined with data on the application of the product and evaluated in Doc. II-B. Doc II-A should in any case include an exposure assessment.

For basic substances to be included on Annex IB only data on the substances is required, there being no associated product; however, information relating to simple diluents is to be given. Following from Article 10(3) of the BPD the inclusion in Annex IB of an active substance will be restricted to those product types for which relevant data have been submitted. Hence, for the risk characterisation, use pattern and exposure data are required.

5.2 STRUCTURE AND FORMAT

The mutual dependency of elements of the risk assessment for the active substance and the product implies the implementation of a modular structure of the risk assessment documentation, as also shown in Fig. 1a.
Doc. II – RISK ASSESSMENT is based on three modules:

- Doc. II-A: Effects and exposure assessment – active substance
- Doc. II-B: Effects and exposure assessment – biocidal product
- Doc. II-C: Risk characterisation for the use of the active substance in biocidal products

5.2.1 Document II-A: Effects and exposure assessment – active substance

The general format in which the Doc. II-A type could be presented is depicted in Table 5-1. For comparison it is indicated in which sections of Doc. II-A the different (sub)sections of the STUDY SUMMARIES (Doc. III-A) are summarised and evaluated. Cross-references to the respective (sub)section number in the STUDY SUMMARIES should be given.

In **Appendix 5.1** a reporting format for Doc. II-A is provided including samples of summary tables. This format should be considered as general guidance. The introduction of additional subheadings may be required.

The relevant data included for hazard identification should be summarised and discussed as concisely as possible. The text should focus on the the most important information which should be summarised in tabular form. It is proposed that the applicant's summaries and conclusions compiled in the STUDY SUMMARIES be used as far as practicable and feasible, in order to minimize duplication of work. The relevant results and conclusions can be easily transferred to summary tables such as the sample tables provided in **Appendix 5.1**.

The human exposure assessment for the active substance relates to cumulative exposure and exposure during production and formulation of the product(s) and should be carried out separately for the different groups of people exposed according to the TNsG on exposure, being elaborated (2002). For the Environmental exposure Emission Scenario Documents are being elaborated.

With regard to the effectiveness against target organism, the BPD requires only a general overview of the data compiled in Doc. III-A.

5.2.2 Document II-B: Effects and exposure assessment – biocidal product

The general format in which the Doc. II-B type could be presented is depicted in Table 5-2, and a reporting format is given in **Appendix 5.2**. This format should be considered as general guidance. The introduction of additional subheadings may be required.

The human health and environmental effects assessment for a product is mainly based on data from the active substance and any substance of concern contained. Information relating to the active substance need not be repeated here. A short description of the relevant aspects could be given, with cross-referencing to the corresponding Doc. II-A sections, where appropriate.

The exposure assessment should be carried out separately for the different groups of people described in chapter 3.1 of the TNsG on Annex I Inclusion; furthermore that chapter introduces the concept of primary and secondary exposure which should also be taken into account. Further guidance on exposure is given in the TNsG on human exposure, being elaborated (2002).

In addition, quantitative information is required on the exposure to substances of concern contained in the product or released as degradation product(s).

With regard to the effectiveness against target organisms, an efficacy assessment is required for the product only in the case of the subsequent application for authorisation or registration.

5.2.3 Document II-C: Risk characterisation for the use of the active substance in biocidal products

The general format in which the Doc. II-C type could be presented is depicted in Table 5-3, and a reporting format is given in In **Appendix 5.3**. This format should be considered as general guidance. The introduction of additional subheadings may be required.

5.3 REFERENCE LIST

A list of the studies cited, ordered by author, should be appended to each document, i.e. Doc. II-A, Doc. II-B and, if references are given, also to Doc. II-C.

Table 5-1: Standard format of Doc. II-A - Effects and exposure assessment for the active substance

Sec. No.	Section heading	Data on a.s. (Doc. III-A section no.)
1	**GENERAL SUBSTANCE INFORMATION**	**2-4, 9**
1.1	Identification of the substance	2 except 2.10
1.2	Purity/impurities, additives	2.8
1.3	Physico-chemical properties	3
1.4	Analytical methods for detection and identification and determination	4
1.4.1	Analysis of active substance	4
1.4.2	Formulation analysis (may be covered in product section)	4
1.4.3	Residue analysis	4
1.5	Classification and labelling	9
1.5.1	Current classification	9
1.5.2	Proposed classification	9
2	**EFFECTIVENESS AGAINST TARGET ORGANISMS**	
2.1	Function	5.1
2.2	Field of use envisaged	5.5
2.3	Effects on target organisms	5.3
X	**EXPOSURE ASSESSMENT**	
x.1	Intended uses	5.1, 5.5, 5.6
x.2	Human exposure assessment during manufacture of active substance and product formulation	2.10, 5.8, 6.15, 6.17, 6.18
x.2.1	Identification of main paths of human exposure towards active substance	
x.3	Environmental exposure assessment (emission scenarios)	2.10, 5.8, 7.1-7.3
x.3.5	Non compartment specific exposure relevant to the food chain (secondary poisoning)	
3	**HUMAN HEALTH EFFECTS ASSESSMENT**	**6 except 6.15, 6.16, 6.17**
3.1	Toxicokinetics, metabolism and distribution	6.2
3.2	Acute toxicity	6.1
3.3	Irritation and Corrosivity	6.1.4
3.4	Sensitisation	6.1.5
3.5	Repeated dose toxicity	6.3, 6.4, 6.5
3.6	Genotoxicity	6.6
3.6.1	In vitro	6.6.1-6.6.3
3.6.2	In vivo	6.6.4-6.6.7
3.7	Carcinogenicity	6.7

Sec. No.	Section heading	Data on a.s. (Doc. III-A section no.)
3.8	Reproductive toxicity	6.8
3.8.1	Teratogenicity	6.8.1
3.8.2	Fertility	6.8.2
3.9	Neurotoxicity	6.9
3.10	Human data	6.12
4	**ENVIRONMENTAL EFFECTS ASSESSMENT**	**7.4, 7.5**
4.1	Fate and distribution in the environment	7.1, 7.2, 7.3
4.1.1	Degradation	7.1, 7.2, 7.3
4.1.1.1	Biodegradation	7.1, 7.2
4.1.1.2	Abiotic degradation	7.1, 7.2, 7.3
4.1.2	Distribution	7.1, 7.2, 7.3
4.1.3	Accumulation	7.1, 7.2
4.2	Effects on environmental organisms	7.4, 7.5
4.2.1	Aquatic compartment	7.4
4.2.2.	Atmosphere	
4.2.3	Terrestrial compartment	7.5
4.2.4	Non compartment specific effects relevant to the food chain (secondary poisoning)	
5	**HAZARD IDENTIFICATION FOR PHYSICO-CHEMICAL PROPERTIES**	**3**

Table 5-2: General format of Doc. II-B - Effects and exposure assessment for biocidal products

Sec. No.	Section heading	Data on b.p. (Doc. III-B section no.)	Data on a.s. (Doc. III-A section no.)
1	**GENERAL PRODUCT INFORMATION**	**2-4, 9**	
1.1	Identification of the product	2	
1.2	Identity of ingredients of the biocidal product	2.2	
1.3	Physico-chemical properties	3	
1.4	Analytical methods for detection and identification	4	
1.4.1	Formulation analysis	4	
1.5	Classification, packaging and labelling	9	
1.5.1	Current classification	9	
1.5.2	Proposed classification	9	
2	**EFFICACY**	**5.5 to 5.8, 5.10,**	

Sec. No.	Section heading	Data on b.p. (Doc. III-B section no.)	Data on a.s. (Doc. III-A section no.)
		5.11	
2.1	Function	5.5	
2.2	Organism(s) to be controlled and products, organisms or object to be protected	5.6	
2.3	Effects on target organisms and efficacy	5.7, 5.10	
2.4	Mode of action including time delay	5.8	
2.5	Occurrence of resistance	5.11	
3	**EXPOSURE ASSESSMENT**		
3.1	Intended uses	5.1, 5.5, 5.9	5.1, 5.5, 5.6
3.2	Human exposure assessment	5.9, 6.6	2.10, 5.8, 6.15, 6.17, 6.18
3.2.1	Identification of main paths of human exposure towards active substance from its use in biocidal product		
3.2.2	Professional exposure		
3.2.3	Non-professional exposure		
3.2.4	Indirect exposure as a result of use of the active substance in biocidal product		
3.3	Environmental exposure assessment	5.9, 7.1, 7.5, 7.7.2	2.10, 5.8, 7.1-7.3
3.3.1	Fate and distribution in the environment		7.1 to 7.3
3.3.2	PEC in surface water, ground water and sediment		
3.3.3	PEC in air		
3.3.4	PEC in soil		
3.3.5	Non compartment specific exposure relevant to the food chain (secondary poisoning)		
4	**HUMAN HEALTH EFFECTS ASSESSMENT**	**6 except 6.5, 6.6**	
4.1	Percutaneous absorption	6.4 (6.5)	
4.2	Acute toxicity	6.1 (6.5)	
4.3	Irritation and corrosivity	6.2 (6.5)	
4.4	Sensitisation	6.3 (6.5)	
4.5	Other	6.7 (6.5)	
5	**ENVIRONMENTAL EFFECTS ASSESSMENT**	**7 except 7.1, 7.5, 7.7.4**	
5.1.	Aquatic compartment	7.2, 7.7 (7.3)	
5.2	Atmosphere		
5.3	Terrestrial compartment	7.2, 7.6, 7.8 (7.3)	
5.4	Non compartment specific effects relevant to the food chain		

Sec. No.	Section heading	Data on b.p. (Doc. III-B section no.)	Data on a.s. (Doc. III-A section no.)
	(secondary poisoning)		
6	**HAZARD IDENTIFICATION FOR PHYSICO-CHEMICAL PROPERTIES**	**3**	**3**

Table 5-3: General format of Doc. II-C - Risk characterisation for the use of the active substance in biocidal product(s)

Sec. No.	Section heading	Data from Doc. II-A	Data from Doc. II-B
1	**Risk Characterisation for Human Health**		
1.1	General aspects	X	X
1.2	Professional users	X	X
1.2.1	Production / formulation of active substance		X
1.2.1.1	Critical endpoint(s)	X	X
1.2.1.2	Relevant exposure paths	X	X
1.2.1.3	Risk characterisation for production / formulation of a.s.		
1.2.2	Application product type x		X
1.2.2.1	Critical end point(s)	X	X
1.2.2.2	Relevant exposure paths		X
1.2.2.3	Risk characterisation for product type x		
1.2.3	Application product type y		X
1.2.4	Overall assessment of the risk for the use of the active substance in biocidal products		
1.3	Non-professional users including the general public	X	X
1.4	Indirect exposure as a result of use	X	X
1.5	Combined exposure		X
2	**Risk Characterisation for the Environment**		
2.1	Aquatic compartment (incl. sediment)	X	X
2.2	Atmosphere	X	X
2.3	Terrestrial compartment	X	X
2.4	Non compartment specific effects relevant to the food chain (secondary poisoning)	X	X
3	**Risk Characterisation for the Physico-chemical Properties**	**X**	**X**
4	**Measures to Protect Man, Animals and the Environment**	**X**	**X**

6 DOCUMENT I - OVERALL SUMMARY AND ASSESSMENT

6.1 PURPOSE

The dossier should, as Document I.1, contain the APPLICATION FORM with several subdocuments referring to the purpose of the dossier submission, the joint submission and confidentiality of data, proposed labels of the substance and information on the intended uses etc. The purpose of these documents is to provide an overview of the context in which the dossier is submitted. In addition, the applicant is to confirm that the documentation is complete.

The OVERAL SUMMARY AND CONCLUSIONS (DOC. I.2) and the applicant's PROPOSAL FOR THE DECISION REGARDING ANNEX I, IA OR IB INCLUSION (Doc. I.3) are intended to give a concise overview of the data base and the conclusions derived in the RISK ASSESSMENT documents. A listing of those end points used for the risk assessment and relevant to the proposed decision should be appended to Doc. I.

6.2 INDIVIDUAL SUBDOCUMENTS

6.2.1 Application form (Doc. I.1)

A specimen application form is presented in **Appendix 6.1** which can be used for either:

- application for first inclusion of a new active substance in Annex I, IA or IB or
- application for first inclusion of an existing active substance in Annex I, IA or IB
- application for prolongation/amendment.

The purpose of the application, i.e. the statement concerning the dossier submission, is to be specified in the main heading of the form.

The application form contains information enabling an unambigous identification of the substance in question in terms of its identity, intended uses, effectiveness and proposed classification and labelling requirements. In addition, the applicant is to

formally confirm that the documentation provided is complete, as required by the BPD.

The following documents should be appended to the application form if applicable:

- Documentation relating to the joint submission (in the case of existing active substances)
  The applicant should indicate that all reasonable steps have been taken to present the dossiers collectively with all notifiers of an existing active substance.
- Copies of notifications (in the case of existing active substances)
  A copy of the notification submitted to the European Commission should be appended.
- Safety data sheet for active substance
- Safety data sheet(s) for substance(s) of concern
- Safety data sheet(s) for formulant(s) of representative products.

6.2.2 Overall summary and conclusions (Doc. I.2)

Depending on the purpose of the application, Document I.2 - OVERALL SUMMARY AND CONCLUSIONS should establish the rationale for the envisaged Annex I, IA or IB entry of an active substance. It summarises the preceding risk assessment for the active substance for its use in biocidal product in a concise form including conclusions derived. For each product type for which a dossier is provided, subheadings should be included.

In general, the order of summarising the relevant aspects and conclusions should follow the order used in the RISK ASSESSMENT documents. Part of the conclusions may be transferred from these documents.

6.2.3 Proposal for decision regarding Annex I, IA or IB inclusion (Doc. I.3)

The applicant's proposal for a decision regarding the possible Annex I, IA or IB inclusion should be supported by a statement as to the rationale used in coming to the respective conclusions.

6.2.4 Listing of end points

The critical end points which are used in or are relevant to the decision proposal should be summarised in data sheets, as proposed for dossiers of PPP by the EU Commission and in the respective OECD and WHO guidance documents.

In **Appendix 6.2** the reporting format of the listing of end points is given. This format has been adapted from the corresponding PPP guidelines.

7 STANDARD UNITS, CODES, TERMS AND ABBREVIATIONS

7.1 STANDARD UNITS

The English language version of Standard International (SI) Units must be used in reporting and summarising tests and studies, although other units, if desired or considered relevant, may be used in parentheses. Particular attention is drawn to the requirement to use metric units - for example in the case of application rates, grams of active substance per square metre (g/m^2); content of active substance in formulations (g/kg or g/l); doses in feeding studies (mg/kg body weight).[6]

7.2 STANDARD TERMS AND ABBREVIATIONS

In the interest of avoiding confusion, standard technical terms and abbreviations should be used. A list of STANDARD TERMS AND ABBREVIATIONS, adapted from the already existing list in the corresponding EU guidelines for the preparation of PPP dossiers (see chapter 1.4.2) and slightly modified, is presented in **Appendix 7.1**. A list of ORGANISATIONS AND PUBLICATIONS, also adapted from these EU guidelines, is compiled in **Appendix 7.2**.It should be emphasised that these lists are not exhaustive and can be further developed as required.

Where terms and abbreviations not listed in **Appendix 7.1** and **Appendix 7.2** are used, they should be explained by the applicant (i) at the place where they are used for the first time, (ii) in corresponding lists appended to Doc. I.

[6] Adapted from: EU (1998) Guidelines and criteria for the preparation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EC (Article 5.3 and 8,2). European Commission, Document 1663/VI/94 Rev 8, 22 April 1998

7.3 APPLICATION CODES

To standardise and harmonise the terminology, standard terms are considered useful, examples for wood preservatives are given in Appendix 7.3. The introduction of such terms facilitates:

- the unequivocal and transparent definition of the authorisation / registration conditions,
- a harmonised inclusion of active substances in Annex I between the member states,
- the compilation of data concerning different products containing the same active substance and belonging to the same product type,
- the setting of limitations of use,
- electronic data processing and
- further agreements between the member states.

Preliminary lists of standard terms are available currently, but need to be further developed.

8 SUBMISSION OF DOSSIERS

Copies of the dossier documentation should be submitted to the responsible competent authority (CA) of a Member State as follows:

8.1 HARD COPIES

A number of hard copies, as requested by Competent Authorities of the individual Rapporteur Member States, of the entire dossier including copies of the individual test and study reports and any other information referred to in the dossier, should be submitted.

8.2 ELECTRONIC SUBMISSION

Those parts of the dossier prepared using a word processing or spread sheet system should be submitted as such, i.e. saved on a diskette or a CD-ROM. An electronic submission system is under development.

8.3 SUBMISSION TO OTHER MEMBER STATES

After the dossier has been accepted by the RMS following a satisfactory completeness check, the applicant should forward hard or electronic copies of the summary dossier, i.e. all documents except for the test and study reports (Doc. IV-A and IV-B), to the European Commission and the other Member States.

The details for submission will be laid down in the (future) second Review Regulation, which is expected to be published in year 2003.

9 DOCUMENTATION REQUIRED TO APPLY FOR THE AUTHORISATION OR REGISTRATION OF BIOCIDAL PRODUCTS

9.1 INTRODUCTION

The authorisation or registration of biocidal products falls under the responsibility of the individual Member States. Prerequisite for the authorisation of biocidal products is the preceding inclusion of the active substances contained in these products in Annex I of the BPD. Annex I inclusion requires that at least one product is likely to be authorised and thus the dossier for the Annex I inclusion of an active substance must include a dossier on at least one product. The following guidance concentrates on the product information needed for the Annex I inclusion of an active substance. For the registration of low-risk products, a reduced data set is required according to Article 8(3) of the BPD, provided the respective active substance(s) are listed in Annex IA of the BPD.

According to Article 8 of the BPD, a person applying for the first placing on the market of a biocidal product has to submit to the competent authority of the Member State in which the first placing on the market is intended:

- "a dossier or a letter of access for the biocidal product satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex IIB and, where specified, the relevant parts of Annex IIIB" (Article 8(2a) BPD) (In the case of application for the registration of low-risk products, limited requirements on the dossier apply as set out in Article 8(3) BPD);
- "for each active substance in the biocidal product, a dossier or a letter of access satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex IIA and, where specified, the relevant parts of Annex IIIA".

A dossier submission can be a mixture of letter(s) of access and test reports ansd summaries.

Guidance on common principles and practical procedures for the authorisation and registration of products, including the Letter of Access system, is given by the TNsG on Products Evaluation.

9.2 DOSSIER STRUCTURE

In principle, the scheme described for the application for Annex I inclusion of an active substance can be applied to the application for authorisation / registration of biocidal products. However, some modification is required to account for the fact that no reassessment of the human health and environmental effects should be carried out for active substances already listed in Annex I or IA of the BPD (see chapter 5.1). Thus, the structure of the dossier documentation to be submitted by a company applying for the authorisation of a biocidal product could follow the scheme shown in Fig. 9-1.

The major differences compared to the structure of dossiers required for the application for Annex I inclusion of active substances are:

- A dossier or parts of a dossier does not need to be submitted if a letter of access (LoA) can be provided.
- A biocidal product can contain more than one active substance, for which dossiers or letters of access have to be provided.
- An efficacy assessment is to be provided.

Independent of which documents are replaced by letters of access, the applicant should provide at least a risk characterisation and an overall summary and assessment.

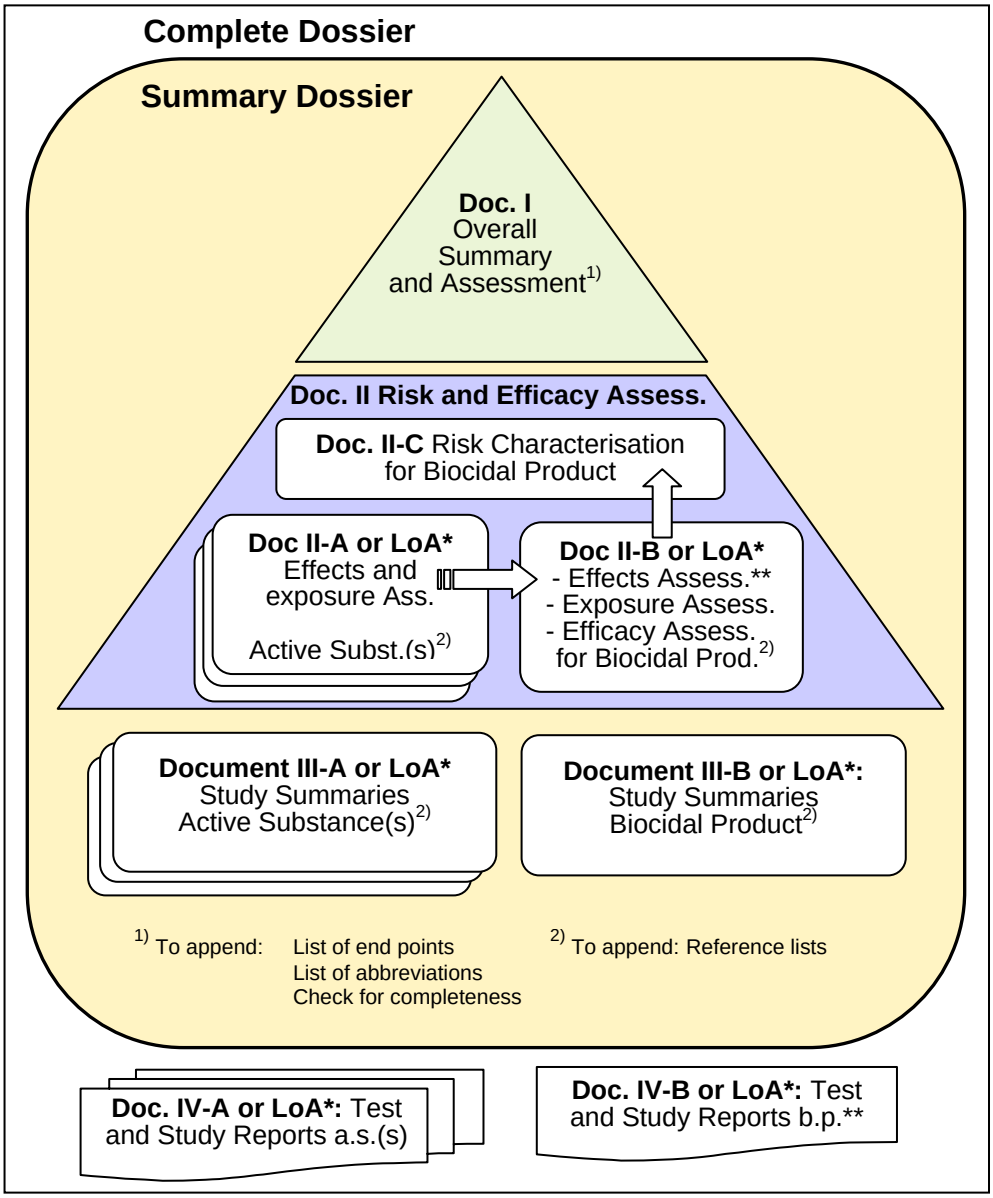
9.3 RISK ASSESSMENT FOR BIOCIDAL PRODUCTS

The TNsG on data requirements imply that the applicant has to carry out a preliminary risk assessment for the product. To carry out such a risk assessment, the applicant must have access to all data required for an application even if letters of access are provided to the RMS.

The preliminary risk assessment for a product is to be based on:

- **the effects assessment for all active substances contained in a product:** As outlined in chapter 5.1, no reassessment of the human health and environmental effects should be carried out for active substances already included in Annex I or IA of the BPD. Hence, the documents (Doc. II-A) provided with such applications should be used as basis for the effects assessment for the product.
- **the effects assessment for the biocidal product including substances of concern:** Product-specific data as required by Annex IIB and IIIB of the BPD have to be provided and summarised and evaluated by the applicant.
- **the exposure assessment for the biocidal product including substances of concern:** Where appropriate, the applicant can adopt or adapt parts from the Doc. II-B submitted with the application(s) for Annex I inclusion of the active substance(s).
- **the risk characterisation for the biocidal product:** Where appropriate, the applicant can adopt or adapt parts from the Doc. II-C submitted with the application(s) for Annex I inclusion of the active substance(s). In any case, the risk characterisation must address all product types for which the product in question is intended to be used.

Fig. 9-1. Structure of the dossier documentation required for the application for authorisation or registration of a biocidal product, provided that the active substance is listed in Annex I or IA or IB



* LoA = Letter of access

** In the case of applications for registration of low-risk products, the effects assessment is confined to data on the active substance(s) only. In general, the data to be provided in Doc. IV-B and III-B are limited.

List of Appendices

Appendix 4.1

Examples of study summaries

Section A6.1.5 (01) **Skin sensitisation**

Annex Point IIA6.1.5 Guinea pig maximisation test (GPMT)

1 REFERENCE

Official use only

1.1 REFERENCE

M. Drew, J. Kerr (1992); XXX-YYY - Skin sensitising effect in guinea pigs (Maximization Test according to Magnusson and Klingman); Organics Inc, unpublished report No.: 21687 (August 21, 1994; report) and 21644A (July 07, 1996; addendum); Organics Inc, Institute of Toxicology, Castlebar, Ireland; dates of experimental work: April 1991 - May 1991.

[**Note:** The fictitious data, text and tables of this example have been adopted from the corresponding PPP Guidelines, EU Document 1663/VI/94 Rev 8, and partly modified or supplemented with additional (*) example text.]

1.2 DATA PROTECTION

Yes (*)

1.2.1 Data owner

Organics Inc (*)

1.2.2 Companies with letter of access

1.2.3 Criteria for data protection

Data on new a.s. for first entry to Annex IA (*)

2 GUIDELINES AND QUALITY ASSURANCE

Section A6.1.5 (01) **Skin sensitisation**

Annex Point IIA6.1.5 Guinea pig maximisation test (GPMT)

2.1 GUIDELINE STUDY	Yes OECD 406 (equivalent to EEC method B.6 - Directive 92/69/EEC)
2.2 GLP	Yes
2.3 DEVIATIONS	No

3 MATERIALS AND METHODS

3.1 TEST MATERIAL	As given in section 2 (*)
3.1.1 Lot/Batch number	FL 921658
3.1.2 Specification	As given in section 2 (*)
3.1.2.1 Description	
3.1.2.2 Purity	95.6 % (*)
3.1.2.3 Stability	
3.1.2.4 Preparation of test substance for application	in 0.9 % NaCl/Cremophor
3.1.2.5 Pretest performed on irritant effects	Yes

Section A6.1.5 (01)	**Skin sensitisation**
Annex Point IIA6.1.5	Guinea pig maximisation test (GPMT)
3.2 TEST ANIMALS	Non-entry field
3.2.1 Species	Guinea pigs
3.2.2 Strain	BOR:DHPW
3.2.3 Source	
3.2.4 Sex	
3.2.5 Age/weight at study initiation	
3.2.6 Number of animals per group	10
3.2.7 Control animals	Yes
3.3 ADMINISTRATION/ EXPOSURE	State study type:
	Adjuvant
3.3.1 Application	Non-entry field
3.3.1.1 Induction schedule	day 0 – day –21 – day 28
	see table A6.1.5(01)-1
3.3.1.1.1 Way of Induction	Intradermal
	+ topical
	Occlusive
3.3.1.1.2 Concentrations used for induction	Intradermal application: 5 %
	topical application: 6 %
3.3.1.1.3 Concentration Freunds Complete Adjuvant (FCA)	10 % in water

Section A6.1.5 (01)	**Skin sensitisation**
Annex Point IIA6.1.5	Guinea pig maximisation test (GPMT)

3.3.1.2 Challenge schedule	first challenge: after 3 weeks second challenge: after 4 weeks
3.3.1.2.1 Concentrations used for challenge	first challenge 0.5, 1 % second challenge 0.05, 0.1 %
3.3.1.3 Rechallenge	Yes
3.3.1.4 Removal of the test substance	
3.3.1.5 Scoring schedule	24h, 48h after challenge or other
3.3.2 Positive control substance	α-hexylcinnamaldehyde, benzothiazole-2-thiole, or benzocaine or other
3.4 EXAMINATIONS	Non-entry field
3.4.1 Results of pilot studies	3 % maximum non irritant concentration
3.4.2 Induction phase	no effects
3.4.3 Challenge phase	no effects
3.5 FURTHER REMARKS	

RESULTS AND DISCUSSION

3.6 RESULTS OF TEST	first challenge: 1 % solution: 14/20 animals positive reaction 0.5 % solution: 5/20 animals positive reaction second challenge: 0.05, 0.1 % solution: no reaction

4 APPLICANT'S SUMMARY AND

Section A6.1.5 (01) **Skin sensitisation**

Annex Point IIA6.1.5 Guinea pig maximisation test (GPMT)

CONCLUSION

4.1	**MATERIALS AND METHODS**	Guinea pig maximisation Test, OECD 406
4.2	**RESULTS AND DISCUSSION**	XXX-YYY has skin sensitizing potential under the conditions of the Maximization Test. Skin sensitization was not provoked following the second challenge.
4.3	**CONCLUSION**	sensitizing
4.3.1	**Reliability**	1
4.3.2	**Deficiencies**	No

Evaluation by Competent Authorities

Section A6.1.5 (01) **Skin sensitisation**

Annex Point IIA6.1.5 Guinea pig maximisation test (GPMT)

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
DATE	25 Feb 2000
MATERIALS AND METHODS	Guinea pig maximisation Test, OECD 406
RESULTS AND DISCUSSION	XXX-YYY has skin sensitizing potential under the conditions of the Maximization Test. Skin sensitization was not provoked following the second challenge.
CONCLUSION	
RELIABILITY	1
ACCEPTABILITY	acceptable
REMARKS	

Table A6.1.5(01)-1. Detailed information including induction/challenge/scoring schedule for skin sensitisation test

	Concentration of solution	**Day of treatment**	**Application** *intradermal/ topical*	**Observations** *number of animal positive/ total number of animals tested*
induction 1	5 %	0	intradermal	
induction 2	6 %	7	topical	
challenge	1 %	21	topical	14/20 positive
	0.5 %	21	topical	5/20 positive
controls	0 %	21	topical	0/9
rechallenge	0.05 %	28	topical	0/20
	0.1 %	28	topical	0/20

5 REFERENCE

Official use only

5.1 REFERENCE

Elbers R, Hagen E (1992): XXX-YYY - Subchronic toxicity in Wistar rats (13-week administration in the diet with a four-week recovery period). Organics Inc, unpublished report No.: 21627 No. (July 07, 1996); Organics Inc, Institute of Toxicology, Castlebar, Ireland, (Dates of experimental work: April 1991 - May 1991).

[**Note:** The fictitious data, text and tables of this example have been adopted from the corresponding PPP Guidelines, EU Document 1663/VI/94 Rev 8, and partly modified or supplemented with additional (*) example text.]

5.2 DATA PROTECTION

Yes (*)

5.2.1 Data owner

Organics Inc

5.2.2 Companies with letter of access

no (*)

5.2.3 Criteria for data protection

Data on new active substance for first entry to Annex I/IA (*)

6 GUIDELINES AND QUALITY ASSURANCE

Section A6.4.1 (02)	Subchronic oral toxicity test with rodent (rat)	
Annex Point IIA6.4		
6.1 GUIDELINE STUDY	OECD 408 » FIFRA § 83-1 » 67/548/EEC	
6.2 GLP	Yes	
6.3 DEVIATIONS	Yes: T3, T4 and thyroxine in the blood were measured in excess of Guideline requirements. In addition P450 levels in the blood were measured.	X
	7 MATERIALS AND METHODS	
7.1 TEST MATERIAL	As given in section 2 (*)	
7.1.1 Lot/Batch number	17002/88 (*)	
7.1.2 Specification	Deviating from specification given in section 2 as follows: (*)	
7.1.2.1 Description		
7.1.2.2 Purity	93.6% (*)	X
7.1.2.3 Stability		
7.2 TEST ANIMALS		
7.2.1 Species	rat	
7.2.2 Strain	Wistar	
7.2.3 Source		
7.2.4 Sex	male and female	
7.2.5 Age/weight at study initiation		
7.2.6 Number of animals per group	10	

Section A6.4.1 (02) Subchronic oral toxicity test with rodent (rat)

Annex Point IIA6.4

7.2.7 Satellite group(s)	10 rats/sex treated at levels of 0 or 111 ppm over a period of 13 weeks, and then observed for four weeks.
7.2.8 Control animals	Yes
7.3 ADMINISTRATION/ EXPOSURE	Oral
7.3.1 Duration of treatment	90 days
7.3.2 Frequency of exposure	daily
7.3.3 Postexposure period	4 weeks
	Oral
7.3.1 Type	in food
7.3.2 Concentration	food 0, 11, 111 or 611 ppm food consumption per day ad libitum
7.3.3 Vehicle	
7.3.4 Concentration in vehicle	
7.3.5 Total volume applied	
7.3.6 Controls	
7.4 EXAMINATIONS	
7.4.1 Observations	
7.4.1.1 Clinical signs	Yes
7.4.1.2 Mortality	Yes
7.4.2 Body weight	Yes

Section A6.4.1 (02) **Subchronic oral toxicity test with rodent (rat)**

Annex Point IIA6.4

7.4.3 Food consumption	Yes	
7.4.4 Water consumption	Yes	
7.4.5 Ophthalmoscopic examination	Yes	
7.4.6 Haematology	Yes number of animals: all animals time points: 5, 13 weeks and 17 weeks (recovery groups) Parameters: see table A6.4.1(02)-1	
7.4.7 Clinical Chemisty	Yes number of animals: time points: 5, 13 weeks and 17 weeks (recovery groups) Parameters: total cholesterol, alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, P-450	
7.4.8 Urinalysis	Yes number of animals: time points: Parameters:	
7.5 SACRIFICE AND PATHOLOGY		
7.5.1 Organ Weights		X
7.5.2 Gross and histopathology	Yes: all dose groups organs examined: oesophagus, stomach, small and large intestines, liver, urinary bladder, eyes	
7.5.3 Other examinations		
7.5.4 Statistics		

Section A6.4.1 (02) **Subchronic oral toxicity test with rodent (rat)**

Annex Point IIA6.4

7.6	**FURTHER REMARKS**		

8 RESULTS AND DISCUSSION

8.1	**OBSERVATIONS**		
8.1.1	**Clinical signs**	At 611 ppm, several animals exhibited a depressed general condition and an ungroomed coat. These findings were reversible.	
8.1.2	**Mortality**		X
8.2	**BODY WEIGHT GAIN**	The retarded body weight gains observed at the high-dose level were not fully reversible within a post observation period of four weeks (Fig.: A6.4.1(02)-1 and A6.4.1(02)-2).	
8.3	**FOOD CONSUMPTION AND COMPOUND INTAKE**	Food intake was not affected at levels up to 611 ppm. Animals drank slightly less water at 611 ppm. In order of increasing doses the treated rats ingested the equivalent of: males: 1.1, 11.1, and 11.1 mg/kg bw/day; females: 1.1, 11.1 and 11.1 mg/kg bw/day of XXX-YYY.	
8.4	**OPHTALMOSCOPIC EXAMINATION**	No effects	
8.5	**BLOOD ANALYSIS**		
8.5.1	**Haematology**	White blood cell numbers: no effects Evidence of impaired blood coagulation (transiently lower thrombocyte counts (THRO) and elevated Hepato-Quick readings (HQUICK) in the high-dose group, but reversible following the recovery period	
8.5.2	**Clinical chemistry**	See table A6.4.1(02)-1	

Section A6.4.1 (02) **Subchronic oral toxicity test with rodent (rat)**

Annex Point IIA6.4

	Cytochrome P-450 levels (P 450): statistical significant increase at 111 ppm and above in males. Liver enzyme activities in the serum (aspartate- and alanine-aminotransferase, alkaline phosphatase) elevated in both sexes at 611 ppm. Blood cholesterol (CHOL) levels: depressed to a statistically significant extent in both sexes at 611 ppm.	
8.5.3 Urinalysis	No effects	
8.6 SACRIFICE AND PATHOLOGY		
8.6.1 Organ weights		X
8.6 and thology	Slight degenerative liver changes (hyaline droplets) in three of ten males in the high dose group. These effects were no longer manifest or were observed to a lesser degree after 4 weeks recovery.	
	The urinary bladder epithelia of several 611 ppm animals exhibited hyperplastic change. This change turned out to be reversible.	X
	Hyperkeratosis in the superficial epithelium was determined at 111 ppm and above (in oesophagus and forestomach) and at 611 ppm (in the tongue) (Table A6.4.1(02)-2). The changes could no longer be observed, or were only seen at a considerably lower incidence, at the end of the recovery period.	
8.7 OTHER		

Demo

9 APPLICANT'S SUMMARY AND CONCLUSION

Section A6.4.1 (02) Subchronic oral toxicity test with rodent (rat)

Annex Point IIA6.4

9.1	**MATERIALS AND METHODS**	In accordance with method OECD 408 » FIFRA § 83-1 » 67/548/EEC, groups of 10 male and 10 female Wistar rats were administered XXX-YYY (purity 93.6 %) at levels of 0, 11, 111 or 611 ppm in their diet over a period of 90 days. Additional recovery groups made up of ten rats of each sex were treated at levels of 0 or 111 ppm over a period of 13 weeks, and then observed for four weeks. In order of increasing doses the treated rats ingested the equivalent of: males: 1.1, 11.1, and 11.1 mg/kg bw/day; females: 1.1, 11.1 and 11.1 mg/kg bw/day of XXX-YYY.
9.2	**RESULTS AND DISCUSSION**	Reversible findings in the high-dose group include a depressed general condition and an ungroomed coat, retarded body weight gains (not fully reversible) transiently lower thrombocyte counts (THRO) and elevated Hepato-Quick readings (HQUICK), slight degenerative liver changes and hyperplastic change in the urinary bladder epithelia. The relevant end points are histopathological changes: In both sexes hyperkeratosis in the superficial epithelium was determined at 111 ppm and above (in oesophagus and forestomach) and at 611 ppm (in the tongue), and was also accompanied by hyperplastic changes and hypertrophy in the oesophagus of the affected animals. Hyperkeratosis, which also occurred in a few control rats, could no longer be observed, or was only seen at a considerably lower incidence, at the end of the recovery period.
9.3	**CONCLUSION**	

Section A6.4.1 (02)	Subchronic oral toxicity test with rodent (rat)	
Annex Point IIA6.4		
9.3.1 LO(A)EL		
9.3.2 NO(A)EL	11 ppm, equivalent to: 1.1 mg/kg bw/day (males), 1.1 mg/kg bw/day (females), based on histopathological findings in the liver at 111 ppm	
9.3.3 Other		
9.3.4 Reliability	1	
9.3.5 Deficiencies	No	

Evaluation by Competent Authorities

Section A6.4.1 (02) Subchronic oral toxicity test with rodent (rat)

Annex Point IIA6.4

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
DATE	14 Feb. 2000
MATERIALS AND METHODS	In accordance with method OECD 408 » FIFRA § 83-1 » 67/548/EEC, groups of 10 male and 10 female Wistar rats were administered XXX-YYY (purity 93.6 %) at levels of 0, 11, 111 or 611 ppm in their diet over a period of 90 days. Additional recovery groups made up of ten rats of each sex were treated at levels of 0 or 111 ppm over a period of 13 weeks, and then observed for four weeks. In order of increasing doses the treated rats ingested the equivalent of: males: 1.1, 11.1, and 11.1 mg/kg bw/day; females: 1.1, 11.1 and 11.1 mg/kg bw/day of XXX-YYY. **Comments:** The purity of the test substance (see 3.1.2.2) is much lower than that given in section 2. No further specification is given in 3.1.2. However, a check of the original study report revealed that the impurities are not of toxicological relevance.

Section A6.4.1 (02) Subchronic oral toxicity test with rodent (rat)

Annex Point IIA6.4

RESULTS AND DISCUSSION	Reversible findings in the high-dose group include a depressed general condition and an ungroomed coat, retarded body weight gains (not fully reversible), transiently lower thrombocyte counts (THRO), elevated Hepato-Quick readings (HQUICK), slight degenerative liver changes and hyperplastic change in the urinary bladder epithelia. Demo The relevant end points are histopathological changes: In both sexes hyperkeratosis in the superficial epithelium was determined at 111 ppm and above (in oesophagus and forestomach) and at 611 ppm (in the tongue), and was also accompanied by hyperplastic changes and hypertrophy in the oesophagus of the affected animals. **Comments:** Hyperkeratosis was claimed to be (partly) reversible, but no statistical data were given in 4.6.2. Organ weights and mortality (see 4.12. and 4.6.1) and results of additional determinations, i.e. T3, T4 and thyroxine in the blood (see 2.3), were not reported by the applicant. A check of the original report showed no adverse effects.
CONCLUSION	NO(A)EL: 11 ppm, equivalent to: 1.1 mg/kg bw/day (males), 1.1 mg/kg bw/day (females), based on histopathological findings in the liver at 111 ppm
RELIABILITY	1
ACCEPTABILITY	acceptable
REMARKS	

Fig. A6.4.1(02)-1: Results of a 13-week feeding study in rats: Mean Body weights [g] - males*)

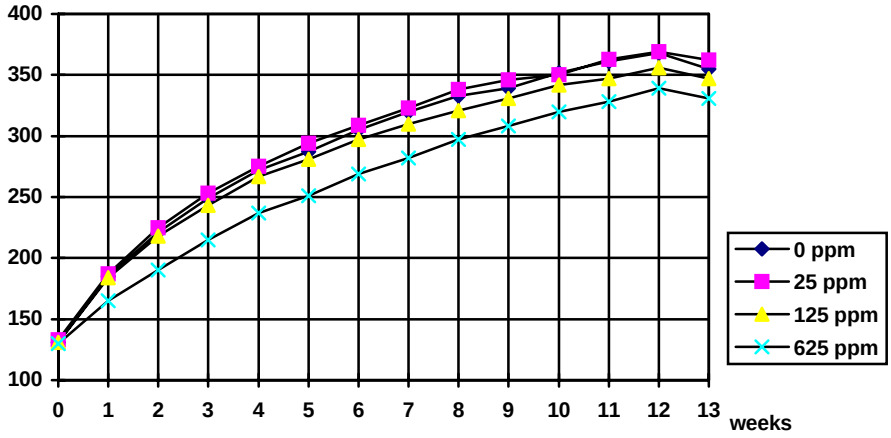
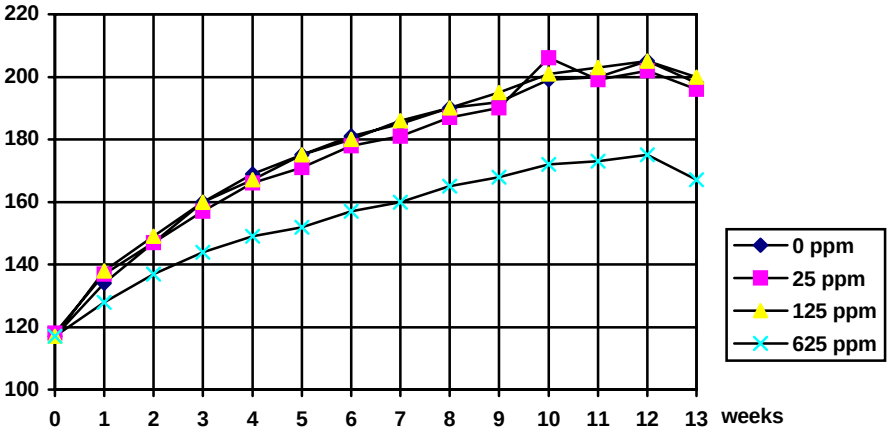


Fig. A6.4.1(02)-2: Results of a 13-week feeding study in rats: Mean Body weights [g] - females*)



*) Adopted from: EU (1998): European Commission: Guidelines and criteria for the preparation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EC (Article 5.3 and 8,2). Document 1663/VI/94 Rev 8, 22 April 1998

Table A6.4.1(02)-1: Results of clinical chemistry and haematology

parameter changed	**ppm**	**0**			**11**			**111**			**611**		
weeks after start of treatment		**5**	**13**	**17**	**5**	**13**	**17**	**5**	**13**	**17**	**5**	**13**	**17**
Males													
THRO [10^9/l]													
HQUICK [sec]													
P 450 [nmol/g]													
ASAT [U/l]													
ALAT [U/l]													
SAP [U/l]													
CHOL [mmol/l]		2.28	2.46	2.42 re	2.29	2.53		2.32	2.50		1.68 ++	2.00+	1.95 re+
Females													
THRO [10^9/l]													
HQUICK [sec]													
P 450 [nmol/g]													
ASAT [U/l]													
ALAT [U/l]													
SAP [U/l]													
CHOL [mmol/l]		2.44	2.14	2.19 re	2.35	2.13		2.20	2.04		1.60 ++	1.51 ++	1.87 re++

re recovery groups; + U-test, 1 %; ++ U-test, 5 %

Table A6.4.1(02)-2: Incidence of treatment related histopathological findings

Parameter	**Control**		**low dose**		**medium dose**		**high dose**		**dose-response +/-**	
	m[a]	**f[a]**	**m[a]**	**f[a]**	**m[a]**	**f[a]**	**m[a]**	**f[a]**	**m**	**f**
number of animals examined	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	-	-
BLADDER UROTHEL - hyperplasia (multifocal)	0	0	0	0	0	0	3	4	-	-
TONGUE - hyperkeratosis	0	0	0	0	0	0	7	10	-	-
OESOPHAGUS - hyperkeratosis - hyperplasia/ hypertrophy	 1 1	 0 0	 0 0	 0 0	 9 9	 5 5	 10 10	 10 10	-	-
FORESTOMACH - hyperkeratosis	0	0	0	0	1	0	3	8	-	-
LIVER - hyaline droplets	0	0	0	0	0	0	3	0	-	-

Section A7.1.3 (01) **Adsorption / Desorption screening test**

Annex Point IIA7.7

1 REFERENCE

Official use only

1.1 REFERENCE

Bond, B (1995a): Adsorption/desorption of XXX-YYY in soil Organics Inc, unpublished report No.: 27566

[**Note**: The fictitious data, text and tables of this example were adopted from the corresponding PPP Guidelines, EU Document 1663/VI/94 Rev 8, and partly modified or supplemented. Fictitious data added are indicated with an asterisk (*).]

1.2 DATA PROTECTION

Yes

1.2.1 Data owner

Organics Inc (*)

1.2.2 Companies with letter of access

No (*)

1.2.3 Criteria for data protection

Data on new active substance for first entry to Annex I (*)

2 GUIDELINES AND QUALITY ASSURANCE

Section A7.1.3 (01) **Adsorption / Desorption screening test**

Annex Point IIA7.7

2.1	**GUIDELINE STUDY**	Yes US EPA-guideline § 163-1 of October 18, 1982
2.2	**GLP**	Yes
2.3	**DEVIATIONS**	No

3 MATERIALS AND METHODS

3.1	**TEST MATERIAL**	As given in section 2 (Annex IIA of Directive 98/8/EC, section 2.7 and 2.8)
3.1.1	**Lot/Batch number**	
3.1.2	**Specification**	As given in section 2 (Annex IIA of Directive 98/8/EC, section 2.7 and 2.8)
3.1.3	**Purity**	92.4 % (v/v) (*)
3.1.4	**Further relevant properties**	
3.1.5	**Method of analysis**	Analysis by standard HPLC method as described in section A4 (*)
3.2	**DEGRADATION PRODUCTS**	Degradation products tested: No (*) At any time during the test all degradation products account for < 10 % of the a.s. added. (*)
3.2.1	**Method of analysis for degradation products**	No degradation products were tested (*)
3.3	**REFERENCE SUBSTANCE**	Yes, Naphtalene (0.01 – 5 mg/ml) (*)

Section A7.1.3 (01) Adsorption / Desorption screening test

Annex Point IIA7.7

3.3.1	**Method of analysis for reference substance**	Analysis by standard HPLC method as described in section A4 (*)
3.4	**SOIL TYPES**	Available data are given in table A7.1.3.1(01)-1
3.5	**TESTING PROCEDURE**	Non-entry field
3.5.1	**Test system**	Adsorption and desorption of XXX-YYY was measured using a batch equilibrium procedure (based on EPA guideline § 163-1) to determine the Kd and Koc values of [cyclopropyl-1-^{14}C]XXX-YYY in three soils, including one subsoil.
3.5.2	**Test solution and Test conditions**	The test substance XXX-YYY was tested in a concentration range of 0.01 to 5 mg/ml
3.6	**TEST PERFORMANCE**	Non-entry field
3.6.1	**Preliminary test**	According to the OECD guideline 106 (*) Degree of saturation: 2.5 mg/l (*) Equilibration: as given in guideline (*)
3.6.2	**Screening test: Adsorption**	According to the OECD guideline 106 (*)
3.6.3	**Screening test: Desorption**	Not performed because no significant adsorption, approx. < 25%, in 3.6.2 occurred (*)
3.6.4	**HPLC-method**	According to the OECD method (*) OECD (1999) OECD-Guidelines for the Testing of Chemicals. Proposal for a new guideline 121: Estimation of the adsorption coefficient (K_{OC}) on soil and on sewage sludge using High Performance Liquid Chromatography (HPLC), Draft Document (August 1999)

3.6.5 Other test

No other test (*)

4 RESULTS

4.1 PRELIMINARY TEST

The obtained solution is acceptable, the applicability of the method to the test substance XXX-YYY is given.(*)

4.2 SCREENING TEST: ADSORPTION

Solid volume: 2 ml (*)

Supernatant volume: 10 ml(*)

Degree of adsorption: 10 %(*)

4.3 SCREENING TEST: DESORPTION

No test performed, see 3.6.3 (*)

CALCULATIONS

Non-entry field

Section A7.1.3 (01) Adsorption / Desorption screening test

Annex Point IIA7.7

4.3.1 Ka , Kd

Soil type	Ka (mg/g)	Kd (mg/g)
Loamy sand (0-30 cm)	9.07	12.23
Loamy sand (30-60 cm)	11.89	10.14
Silty loam	9.89	10.62

4.3.2 Ka_{oc} , Kd_{oc}

Soil type	Ka_{oc} (mg/g)	Kd_{oc} (mg/g)
Loamy sand (0-30 cm)	1084	963
Loamy sand (30-60 cm)	990	932
Silt loam	974	1054

DEGRADATION PRODUCT(S)

No degradation product(s) occur in a significant amount (> 10 % of a.s.) (*)

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 MATERIALS AND METHODS	The test system is described in 3.5.1 (batch equilibrium procedure), the EPA guideline is given in 2.1. No relevant deviations from the guideline occurred.	X
5.2 RESULTS AND DISCUSSION	The test material-specific properties (e.g. solubility, stability, volatility, specific activity, radiochemical purity) are not expected to have any impact on results. The obtained results underline the known properties of the test substance XXX-YYY as found in the literature and prior testing. With regard to its low soil leaching behaviour, the results confirm the immobility of the test substance in soils.	X
5.2.1 Adsorbed a.s. [%]	The percentage adsorption of test substance varied between 11.1 and 11.1 % of the applied a.i. depending on soil type and concentration.	
5.2.2 K_a	10.22 mg/g	
5.2.3 K_d	10.88 mg/g	
5.2.4 Ka_{oc}	1019 mg/g	
5.2.5 Ka/Kd	1 (*)	
5.2.6 Degradation products (% of a.s.)	All degradation products revealed are < 5 % and were not identified due to their short half-life in soil. (*)	
5.3 CONCLUSION	On the basis of these findings XXX-YYY should be classified as being of low mobility to immobile in soils.	X
5.3.1 Reliability	1 (*)	X

Section A7.1.3 (01) Adsorption / Desorption screening test

Annex Point IIA7.7

5.3.2 Deficiencies	No (*)	X

Evaluation by Competent Authorities

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
DATE	25.02.2002
MATERIALS AND METHODS	Generally, the used test method (based on EPA guideline) can be considered valid. The data submitted by the applicant are not sufficient especially concerning the soil data (see table). Furthermore, regarding subfield “Test performance (3.6)” the applicant submitted also a reduced data set. Therefore, it is recommended to obtain more data/information.
RESULTS AND DISCUSSION	The applicants argumentation may be acceptable but it must be mentioned that the given statement concerning known properties is without any scientific evidence. Also no data regarding relevant test substance properties (especially the n-octanol/water coefficient) are submitted. The low content of degradation products indicate a high stability or a very fast degradation/volatilisation. It is recommended to obtain more data/information.
CONCLUSION	In principle, the test results revealed a low to immobile character of the test substance in soils.
RELIABILITY	3

Section A7.1.3 (01) **Adsorption / Desorption screening test**

Annex Point IIA7.7

ACCEPTABILITY	not acceptable A decision on whether the test can be accepted can only be made, when relevant data on test substance properties (n-octanol/water coefficient) and the missing specification of the used soils (table A7.1.3.1(01)-1) are submitted by the applicant
REMARKS	

COMMENTS FROM ...

DATE	
MATERIALS AND METHODS	
RESULTS AND DISCUSSION	
CONCLUSION	
RELIABILITY	
ACCEPTABILITY	
REMARKS	

Table A7.1.3.1(01)-1: Classification and physico-chemical properties of soils used as adsorbents

	Soil 1	**Soil 2**	**Soil 3**
Soil order	Loamy sand	Loamy sand	Silt loam
Soil series			
Classification			
Location	Location 1	Location 1	Location 2
Horizon	0 – 30 cm	30 – 60 cm	
Sand [%]			
Silt [%]			
Clay [%]			
Organic carbon [%]	1.8	0.3	2.4
Carbonate as $CaCO_3$ [%]			
insoluble carbonates [%]			
pH (1:1 H_2O)			
Cation exchange capacity (MEQ/100 g)			
Extractable cations (MEQ/100 g)			
Ca			
Mg			
Na			
K			
H			

Special chemical/mineralogical features			
Clay fraction mineralogy			

Section A7.4.1.1 (04) **Acute toxicity to fish**

Annex Point IIIA7.4

1 REFERENCE

Official use only

1.1 REFERENCE

Dorgerloh, M. (1996); XXX-YYY – Acute toxicity (96 hours) to rainbow trout (*Oncorhynchus mykiss*) in a semi-static test Organic Ltd., unpublished report No. 99999-9, 14.07.1996, Organics Ltd., Institute of Ecotoxicology, Castlebar, Ireland Dates of experimental work: March 1996

[**Note:** The fictitious data, text and tables of this example have been adopted from the corresponding PPP Guidelines, EU Document 1663/VI/94 Rev 8, and partly modified or supplemented with additional (*) example text.]

1.2 DATA PROTECTION

Yes (*)

1.2.1 Data owner

Control & Cleaning Ltd., London, UK (*)

1.2.2 Companies with letter of access

No companies with letter of access (*)

1.2.3 Criteria for data protection

Data on new active substance for first entry to Annex I (*)

2 GUIDELINES AND QUALITY ASSURANCE

Section A7.4.1.1 (04) Acute toxicity to fish

Annex Point IIIA7.4

2.1	**GUIDELINE STUDY**	Yes OECD guideline 203
2.2	**GLP**	Yes
2.3	**DEVIATIONS**	No

3 MATERIALS AND METHODS

3.1	**TEST MATERIAL**	As given in section 2
3.1.1	**Lot/Batch number**	Batch No. 0111 based on 0531/335510
3.1.2	**Specification**	As given in section 2
3.1.3	**Purity**	49 % (v/v)
3.1.4	**Composition of Product**	44.7 % active substance XYZ (*) 3.5 % ZYX (isomer) (*) 0.3 % www (*) 0.5 % water (*)
3.1.5	**Further relevant properties**	
3.1.6	**Method of analysis**	Analysis by standard HPLC method as described in section A4 (*)
3.2	**PREPARATION OF TS SOLUTION FOR POORLY SOLUBLE OR VOLATILE TEST SUBSTANCES (*)**	log Pow = 1.3 (*) Henry's law constant: 2.8 x 10^{-9} atm x m^3 x mol^{-1} (*) The test material is highly soluble in water and not volatile. The preparation of a test material solution is not necessary. (*)

Section A7.4.1.1 (04) Acute toxicity to fish

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3.3 REFERENCE SUBSTANCE	Yes (XXX av 500) (*)
3.3.1 Method of analysis for reference substance	Standard HPLC method, comparable to test material (*)
3.4 TESTING PROCEDURE	Non-entry field
3.4.1 Dilution water	Details are given in table A7.4.1.1(04)-1 (*)
3.4.2 Test organisms	Rainbow trout (*Oncorhynchus myciss*), details are given in table A7.4.1.1(04)-2
3.4.3 Test system	Details are given in table A7.4.1.1(04)-3
3.4.4 Test conditions	Details are given in table A7.4.1.1(04)-4 (*)
3.4.5 Duration of the test	96 hours
3.4.6 Test parameter	Mortality (*)
3.4.7 Sampling	Sampling intervals: daily (*) Sample storage: dark at 4 °C (*)
3.4.8 Monitoring of TS concentration	Yes (*) Intervals: 24 h (*)
3.4.9 Statistics	

4 RESULTS

LIMIT TEST	Performed (*)
4.1.1 Concentration	10 mg/L, 20 mg/L, 50 mg/L, 100 mg/L (*)
4.1.2 Number/ percentage of	10 mg/L (*) 20 mg/L (*) 50 mg/L (*) 100 mg/L (*)

Section A7.4.1.1 (04) Acute toxicity to fish

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	animals showing adverse effects	0	3 animal (5 %)	32 animal (53.4 %)	57 animal (95 %)
4.1.3	**Nature of adverse effects**	Mortality and abnormal behaviour (erratic swimming, changes in appearance, lethargy) (*)			
RESULTS TEST SUBSTANCE					
4.1.4	**Initial concentrations of test substance**	2 / 4 / 8 / 16 / 32 / 64 mg/L (*)			
4.1.5	**Actual concentrations of test substance**	See enclosed table A7.4.1.1(04)-5 (*)			
4.1.6	**Effect data (Mortality)**	The mortality data as absolute numbers of immobile fish and as percent of exposed animals are given in table A7.4.1.1(04)-6 (*) The LC_0, LC_{50}, and LC_{100} values for at least 48 and 96 h are given in table A7.4.1.1(04)-7			
4.1.7	**Concentration / response curve**	Graph of the concentration-mortality curve at test termination in the summary and assessment part (*)			
4.1.8	**Other effects**	No other observations differentiating organisms in tests and controls were realised. (*)			
RESULTS OF CONTROLS					
4.1.9	**Number/ percentage of animals showing adverse effects**	One animal died during the 96 hour test period. Other adverse effects did not occur. (*)			
4.1.10	**Nature of adverse effects**	Mortality, no other adverse effects (*)			
TEST WITH REFERENCE SUBSTANCE		Performed (*)			

Section A7.4.1.1 (04) Acute toxicity to fish

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4.1.11 Concentrations	0.5 / 1.0 / 2.0 / 4.0 / 8.0 mg/L (*)
4.1.12 Results	LC_{50} (48 h): 2.3 mg/L, LC_{50} (96 h): 0.9 mg/L (*)

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 MATERIALS AND METHODS	The test was conducted according to OECD guideline 203. The test system was semistatic and rainbow trout was used as test organism. (*)
5.2 RESULTS AND DISCUSSION	The test substance has a high water solubility and a good stability in water. No vehicle was used. The volatility from water was low. The properties of the test substance give no indications to assume any relevant influences on the test results. (*)
5.2.1 LC_0	8 mg/L (*)
5.2.2 LC_{50}	48 h : 55 mg/L (*) 96 h : 38 mg/L (*)
5.2.3 LC_{100}	> 64 mg/L (*)
5.3 CONCLUSION	The validity criteria as given in table A7.4.1.1(04)-8 can be considered as fulfilled. The dose-response relationship revealed a low toxicity level to fish, especially concerning the high dosage concentrations used. (*)
5.3.1 Other Conclusions	No other conclusions (*)
5.3.2 Reliability	1 (*)
5.3.3 Deficiencies	No (*)

Section A7.4.1.1 (04) Acute toxicity to fish

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Evaluation by Competent Authorities

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
DATE	23 Feb 2000
MATERIALS AND METHODS	In accordance with method OECD 203, 21 fish (Rainbow trout [*Oncorhynchus myciss*], lot F3/ 96) per test concentration were tested for 96 h under semistatic conditions. A limit test was conducted before to determine the toxicologically relevant range. Reference groups and control groups were used in the test. The test conditions (oxygen, pH, temperature) were within the demanded ranges, also the volume per fish used. The test equipment used was acceptable. **Comment**: The adsorption behaviour of the test substance (e.g. to the test container material) was not determined. Due to the high water solubility an influence of the adsorption behaviour on the test result is not expected. This assumption is underlined by the measured concentration values which are comparable to the nominal values.
RESULTS AND DISCUSSION	Nominal test substance concentrations ranged from 2.0 to 64.0 mg/L. Analytical data showed mean measured levels from 98 – 100 % (24 h) of the nominal values, so nominal vales were used in reporting results. The 96-hour LC_0, LC_{50} and LC_{100} values were 8 mg/L, 38 mg/L and > 64 mg/L test substance technical/L. **Comment**: The limit test where test concentrations higher than 64 mg/L were used (up to 100 mg/L) revealed abnormal behaviour like erratic swimming, changes in appearance, lethargy. Such effects were not observed in the main test.

Section A7.4.1.1 (04) Acute toxicity to fish

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CONCLUSION	The tested substance XXX-YYY has a low to moderate toxicological effect on the fish species Rainbow trout.
RELIABILITY	1
ACCEPTABILITY	acceptable
REMARKS	

COMMENTS FROM ...

DATE	
MATERIALS AND METHODS	
RESULTS AND DISCUSSION	
CONCLUSION	
RELIABILITY	
ACCEPTABILITY	
REMARKS	

Table A7.4.1.1(04)-1: Dilution water (*)

Criteria	Details
Source	Institute of Fishery standard drinking water quality
Alkalinity (pka)	No data available
Hardness	100 mg $CaCO_3$ / L
pH	6.8
Oxygen content	80 % of air saturation value
Conductance	No data available
Holding water different from dilution water	No

Table A7.4.1.1(04)-2: Test organisms

Criteria	Details
Species/strain	Rainbow trout *(Oncorhynchus myciss)* / lot F3 / 96
Source	Fishery Institute of Hamburg (*)
Wild caught	No (*)
Age **Size** **Weight**	10 weeks, mean body length 4.7 cm, mean body weight 1.2 g
Kind of food	Standard food of Fishery Institute of Hamburg (*)
Amount of food	0.5 g per day/fish (*)
Feeding frequency	Once per day (*)

Pretreatment	Acclimation period: 2 weeks (*) No other pre-treatment (*)
Feeding of animals during test	No feeding during the test (last feeding: 24 hours before test started) (*)

Table A7.4.1.1(04)-3: Test system

Criteria	**Details**
Test type	Semistatic
Renewal of test solution	Intervals of renewal: daily (*)
Volume of test vessels	14 L (*)
Loading	1.0 g fish / L (*)
Volume/animal	2 L/animal (*)
Total number of tested animals	126 (*)
Number of animals/vessel	7 animals/vessel (*)
Number of vessels/concentration	3 vessels/concentration (*)
Apparatus	Normal laboratory equipment including (*) - oxygen meter, - equipment for determination of water hardness, - adequate apparatus for temperature control, - vessels made of chemical inert material
Test performed in closed vessels due to significant volatility of TS	No (*)

Table A7.4.1.1(04)-4: Test conditions (*)

Criteria	Details
Test temperature	15 °C
Dissolved oxygen	Average value during test: 75 % of air saturation value Min: 70 % Max: 80 %
pH	Average pH value during test: 7.0 Min: 6.5 Max: 7.5
Adjustment of pH	No adjustment of pH was performed
Aeration of dilution water	Aeration was performed with standard apparatus
Intensity of irradiation	30 - 100 lm at water surface
Photoperiod	12 h photoperiod daily

Table A7.4.1.1(04)-5: Actual concentrations of test substance (*)

Time	Nominal concentrations of test substance (mg/L)					
	2	4	8	16	32	64
	Actual concentrations (mg/L)					
24 h	1.98	4.05	7.97	16.10	31.22	63.55
48 h	1.96	3.92	7.90	15.82	31.03	63.59
72 h	1.88	3.85	7.69	15.77	30.59	62.49
96 h	1.76	3.71	7.62	15.34	30.11	61.85

Table A7.4.1.1(04)-6: Mortality data (*)

Test-Substance Concentration (~~nominal~~/measured) [1] **[mg/l]**	**Mortality (total number)**							
	Number				**Percentage**			
	24 h	**48 h**	**72 h**	**96 h**	**24 h**	**48 h**	**72 h**	**96 h**
2	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0
8	0	0	0	1	0	0	0	0.8
16	0	2	5	9	0	1.6	4.0	7.2
32	7	11	20	31	5.6	8.8	16	24.8
64	55	71	78	94	44.0	56.8	62.4	75.2
Temperature [°C]	14.0	14.5	14.0	15.0				
pH	6.5	7.0	7.5	7.0				
Oxygen [mg $CaCO_3$/l]	80	90	100	100				

[1] specify, if TS concentrations were nominal or measured

Table A7.4.1.1(04)-7: Effect data (*)

	48 h [mg/l][1]	**95 % c.l.**	**96 h [mg/l][1]**	**95 % c.l.**
LC_0	8 mg/L (m)		8 mg/L (m)	
LC_{50}	55 mg/L (m)		38 mg/L (m)	
LC_{100}	> 64 mg/L (m)		> 64 mg/L (m)	

[1] indicate if effect data are based on nominal (n) or measured (m) concentrations

Table A7_4_1_1-8: Validity criteria for acute fish test according to OECD Guideline 203 (*)

	Fulfilled	**Not fulfilled**
Mortality of control animals <10%	**yes**	---
Concentration of dissolved oxygen in all test vessels > 60% saturation	**yes**	---
Concentration of test substance ≥80% of initial concentration during test	**yes**	---

Criteria for poorly soluble test substances	**Not applicable**	**Not applicable**

Appendix 4.2

Check for completeness and quality of data compiled in Doc. III-A

Appendix 4.2 Format for check for completeness and quality of data compiled in **Doc. III-A** (BPD Annex IIIA data in *italics*)

Y(n) = Yes (number of tests/studies); P = in part; N = No; n.a. = not applicable;
Reliability indicators: 0, 1, 2, 3 or 4)

Doc. III-A Section No.	**Information, test or study required for active substance** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justification prov'd. Y/N**	**Confidential data Y/N**	**Reliability indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
1	APPLICANT (only headline)	-	-	-	-	-
1.1	Name and address, etc.					
1.2	Active substance manufacturer (name, address, location of plant)					
2.	IDENTITY (only headline)	-	-	-	-	-
2.1	Common name proposed or accepted by ISO and synonyms					
2.2	Chemical name					
2.3	Manufacturer's development code number(s)					
2.4	CAS and EC numbers (only headline)	-	-	-	-	-
2.4.1	CAS number					
2.4.2	EC numbers					
2.4.3	Other substance No.					
2.5	Molecular and structural formula, molecular mass (only headline)	-	-	-	-	-
2.5.1	Molecular formula					
2.5.2	Structural formula					
2.5.3	Molecular mass					
2.6	Method of manufacture of the active substance					
2.7	Specification of purity of the active substance, as appropriate					
2.8	Identity of impurities and additives, as appropriate (only headline)	-	-	-	-	-
2.8.1	Common name and function					
2.8.2	IUPAC name					
2.8.3	CAS No.					
2.8.4	EC No.: EINECS					
2.8.5	Other					
2.8.6	Molecular formula					
2.8.7	Structural formula					

Doc. III-A Section No.	**Information, test or study required for active substance** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justifi-cation prov'd. Y/N**	**Confi-dential data Y/N**	**Relia-bility indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
2.8.8	Molecular mass					
2.2.9	Concentration of the impurity or additive					
2.9	The origin of the natural active substance or the precursor(s) of the active substance					
2.10	Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L 154, 5.6.1992, p.1) amending Council Directive 67/548/EEC.					
2.10.1	Human exposure towards active substance					
2.10.1.1	Production					
2.10.1.2	Intended use(s)					
2.10.2	Environmental exposure towards active substance					
2.10.2.1	Production					
2.10.2.2	Intended use(s)					
3.	PHYSICAL AND CHEMICAL PROPERTIES (only headline)	-	-	-	-	-
3.1	Melting point, boiling point, relative density (only headline)	-	-	-	-	-
3.1.1	Melting point					
3.1.2	Boiling point					
3.1.3	Bulk density/relative density					
3.2	Vapour pressure					
3.2.1	Henry's law constant					
3.3	Appearance (only headline)	-	-	-	-	-
3.3.1	Physical state					
3.3.2	Colour					
3.3.3	Odour					
3.4	Absorption spectra (UV/VIS, IR, NMR), and a mass spectrum, molar extinction at relevant wavelengths, where relevant (only headline)	-	-	-	-	-
3.4.1	UV/VIS					
3.4.2	IR					
3.4.3	NMR					
3.4.4	MS					
3.5	Solubility in water					
3.6	*Dissociation constant*					

Doc. III-A Section No.	**Information, test or study required for active substance** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justifi-cation prov'd. Y/N**	**Confi-dential data Y/N**	**Relia-bility indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
3.7	*Solubility in organic solvents, including the effect of temperature on solubility*					
3.8	*Stability in organic solvents used in biocidal products and identity of relevant breakdown products*					
3.9	Partition coefficient n-octanol/water including effect of pH (5 to 9) and temperature					
3.10	Thermal stability, identity of relevant breakdown products					
3.11	Flammability including auto-flammability and identity of combustion products					
3.12	Flash-point					
3.13	Surface tension					
3.14	*Viscosity*					
3.15	Explosive properties					
3.16	Oxidizing properties					
3.17	Reactivity towards container material					
4.	ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION (only headline)	-	-	-	-	-
4.1	Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their 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 (d) Animal and human body fluids and tissues					
4.3	*Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, in/on food or feedstuffs and other products where relevant*					
5.	EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES (only headline)	-	-	-	-	-
5.1	Function, for example fungicide, rodenticide, insecticide, bactericide					

Doc. III-A Section No.	**Information, test or study required for active substance** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justifi-cation prov'd. Y/N**	**Confi-dential data Y/N**	**Relia-bility indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
5.2	Organism(s) to be controlled and products, organisms or objects to be protected					
5.2.1	Organism(s) to be controlled					
5.2.2	Products, objects or organisms to be protected					
5.3	Effects on target organisms, and likely concentration at which the active substance will be used					
5.3.1	Effects on target organisms					
5.3.2	Likely concentrations at which the active substance will be used					
5.4	Mode of action (including time delay) (only headline)	-	-	-	-	-
5.4.1	Mode of action					
5.4.2	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					
5.7.1	Development of resistance					
5.7.2	Management strategies					
5.8	Likely tonnage to be placed on the market per year					
6.	TOXICOLOGICAL AND METABOLIC STUDIES (only headline)	-	-	-	-	-
6.1.	Acute toxicity					
6.1.1.	Oral					
6.1.2.	Dermal					
6.1.3.	Inhalation					
6.1.4.	Skin and eye irritation					
6.1.5.	Skin sensitisation					
6.2.	Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study					
6.3.	Short-term repeated dose toxicity (28 days)					
6.3.1	Repeated dose toxicity (oral)					
6.3.2	Repeated dose toxicity (dermal)					

Doc. III-A Section No.	**Information, test or study required for active substance** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justification prov'd. Y/N**	**Confidential data Y/N**	**Reliability indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
6.3.3	Repeated dose toxicity (inhalation)					
6.4	Subchronic toxicity					
6.4.1	Subchronic oral toxicity test					
6.4.2	Subchronic dermal toxicity test					
6.4.3	Subchronic inhalation toxicity test					
6.5	Chronic toxicity					
6.6.	Genotoxicity 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					
6.6.7	If the results are negative for the three tests 6.6.1, 6.6.2 and 6.6.3, then further testing is normally only required if metabolites of concern are formed in mammals					
6.7.	Carcinogenicity study					
6.8.	Reproductive toxicity					
6.8.1.	Teratogenicity test					
6.8.2.	Two generations reproduction study					
6.9	*Neurotoxicity study*					
6.10	*Mechanistic study - any studies necessary to clarify effects reported in toxicity studies*					
6.11	*Studies on other routes of administration (parenteral routes)*					
6.12	Medical data in anonymous form					
6.12.1	Medical surveillance data on manufacturing plant personnel if available					

Doc. III-A Section No.	**Information, test or study required for active substance** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justifi-cation prov'd. Y/N**	**Confi-dential data Y/N**	**Relia-bility indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
6.12.2	Direct observation, e.g. clinical cases, poisoning incidents if available					
6.12.3	Health records, both from industry and any other available sources					
6.12.4	Epidemiological studies on the general population, if available					
6.12.5	Diagnosis of poisoning including specific signs of poisoning and clinical tests, if available					
6.12.6	Sensitisation/allergenicity observations, if available					
6.12.7	Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known					
6.12.8	Prognosis following poisoning					
6.13	*Toxic effects on livestock and pets*					
6.14	*Other test(s) related to the exposure of humans*					
6.15	Food and feedingstuffs					
6.15.1	*Identification of the residues (identity and concentrations), degradation and reaction products and of metabolites of the active substance in contaminated foods or feedingstuffs*					
6.15.2	*Behaviour of the residues of the active substance, its degradation and reaction products and where relevant, its metabolites on the treated or contaminated food or feedingstuffs including the kinetics of disappearance*					
6.15.3	*Estimation of potential or actual exposure of the active substance to humans through diet and other means*					
6.15.4	*Proposed acceptable residues and the justification of their acceptability*					
6.15.5	*Any other available information that is relevant*					
6.15.6	*Summary and evaluation of data submitted under point 6.15*					
6.16	*Any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, that are considered necessary may be required*					

Doc. III-A Section No.	**Information, test or study required for active substance** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justification prov'd. Y/N**	**Confidential data Y/N**	**Reliability indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
6.17	*If the active substance is to be used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required*					
6.18	Summary of mammalian toxicology and conclusions (in Doc. II-A)					
7.	ECOTOXICOLOGICAL PROFILE INCLUDING ENVIRONMENTAL FATE AND BEHAVIOUR					
7.1	Fate and behaviour in water (only headline)	-	-	-	-	-
7.1.1	Degradation, initial studies (only headline)	-	-	-	-	-
7.1.1.1	Abiotic (only headline)	-	-	-	-	-
7.1.1.1.1	Hydrolysis as a function of pH and identification of breakdown products					
7.1.1.1.2	Phototransformation in water including identity of the products of transformation					
7.1.1.2	Biotic (only headline)	-	-	-	-	-
7.1.1.2.1	Ready biodegradability					
7.1.1.2.2	Inherent biodegradability, where appropriate					
7.1.1.2.3	*Biodegradation in seawater*					
7.1.2	*Rate and route of degradation in aquatic systems including identification of metabolites and degradation products*					
7.1.2.1	*Biological sewage treatment (only headline)*	-	-	-	-	-
7.1.2.1.1	*Aerobic biodegradation*					
7.1.2.1.2	*Anaerobic biodegradation*					
7.1.2.2	*Biodegradation in freshwater(only headline)*	-	-	-	-	
7.1.2.2.1	*Aerobic aquatic degradation study*					
7.1.2.2.2	*Water/sediment degradation study*					
7.1.3	Adsorption/desorption screening test					
7.1.4	*Further studies on adsorption and desorption in water/sediment systems and, where relevant, on the adsorption and desorption of metabolites and degradation products where the preliminary risk assessment indicates that it is necessary*					
7.1.4.1	*Field study on accumulation in the sediment*					
7.2	*Fate and behaviour in soil (only headline)*	-	-	-	-	-

Doc. III-A Section No.	**Information, test or study required for active substance** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justification prov'd. Y/N**	**Confidential data Y/N**	**Reliability indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
7.2.1	*Aerobic degradation in soil, initial study*					
7.2.2	*Aerobic degradation in soil, further studies*					
7.2.2.1	*The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions*					
7.2.2.2	*Field soil dissipation and accumulation*					
7.2.2.3	*Extent and nature of bound residues*					
7.2.2.4	*Other soil degradation studies*					
7.2.3	*Adsorption and mobility in soil, further studies*					
7.2.3.1	*Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products*					
7.2.3.2	*Mobility in at least three soil types and where relevant mobility of metabolites and degradation products*					
7.3	*Fate and behaviour in air (only headline)*	-	-	-	-	-
7.3.1	*Phototransformation in air (estimation method), including identification of breakdown products*					
7.3.2	*Fate and behaviour in air, further studies*					
7.4	Effects on aquatic organisms					
7.4.1	Aquatic toxicity, initial tests (only headline)	-	-	-	-	-
7.4.1.1	Acute toxicity to fish					
7.4.1.2	Acute toxicity to invertebrates					
7.4.1.3	Growth inhibition test on algae					
7.4.1.4	Inhibition to microbiological activity					
7.4.2	Bioconcentration					
7.4.3	*Effects on aquatic organisms, further studies*					
7.4.3.1	*Prolonged toxicity to an appropriate species of fish*					
7.4.3.2	*Effects on reproduction and growth rate on an appropriate species of fish*					
7.4.3.3	*Bioaccumulation in an aquatic organism (only headline)*	-	-	-	-	-

Doc. III-A Section No.	**Information, test or study required for active substance** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justification prov'd. Y/N**	**Confidential data Y/N**	**Reliability indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
7.4.3.3.1	*Bioaccumulation in an appropriate species of fish*					
7.4.3.3.2	*Bioaccumulation in an appropriate invertebrate species*					
7.4.3.4	*Effects on reproduction and growth rate with an appropriate invertebrate species*					
7.4.3.5	*Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk*					
7.4.3.5.1	*Effects on sediment dwelling organisms*					
7.4.3.5.2	*Aquatic plant toxicity*					
7.5	Effects on terrestrial organisms (only headline)	-	-	-	-	-
7.5.1	Terrestrial toxicity, initial tests (only headline)	-	-	-	-	-
7.5.1.1	Inhibition to microbiological activity					
7.5.1.2	*Acute toxicity test to earthworms or othersoil non-target organisms*					
7.5.1.3	*Acute toxicity to plants*					
7.5.2	*Terrestrial tests, long-term tests (only headline)*	-	-	-	-	-
7.5.2.1	*Reproduction study with other soil non-target macro-organisms*					
7.5.2.2	*Long-term test with terrestrial plants*					
7.5.3	*Effects on birds (only headline)*	-	-	-	-	-
7.5.3.1.1	*Acute oral toxicity*					
7.5.3.1.2	*Short-term toxicity*					
7.5.3.1.3	*Effects on reproduction*					
7.5.4	*Effects on honeybees (only headline)*	-	-	-	-	-
7.5.4.1	*Acute toxicity to honeybees and other beneficial arthropods, for example predators*					
7.5.5	Bioconcentration, terrestrial					
7.5.5.1	Bioconcentration, further studies					
7.5.6	*Effects on other terrestrial non-target organisms*					
7.5.7	*Effects on mammals(only headline)*	-	-	-	-	-

Doc. III-A Section No.	**Information, test or study required for active substance** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justifi-cation prov'd. Y/N**	**Confi-dential data Y/N**	**Relia-bility indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
7.5.7.1	*For some product types, direct and/or indirect exposure for mammals is possible and some tests with mammals may be required in rare cases on the basis of concern for severe risk for the terrestrial environment*					
7.5.7.1.1	*Acute oral toxicity*					
7.5.7.1.2	*Short term toxicity*					
7.5.7.1.3	*Effects on reproduction*					
7.6	Summary of ecotoxicological effects and fate and behaviour in the environment					
8.	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 re-use 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					
8.7	*Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of ground water against pollution caused by certain dangerous substances*					
9.	CLASSIFICATION AND LABELLING					
10.	SUMMARY AND EVALUATION OF SECTIONS 2 TO 9 (in Doc. II-A)					

Doc. III-A Section No.	**Information, test or study required for active substance** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justifi-cation prov'd. Y/N**	**Confi-dential data Y/N**	**Relia-bility indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
Evaluation by Competent Authorities						
Doc. III-A Section No.	**Information, test or study required for biocidal product** *(list data gaps identified in the official-use column)*	**Explanation**			**Action**	

Appendix 4.3

Check for completeness and quality of data compiled in Doc. III-B

Appendix 4.3 Form for check for completeness and quality of data compiled in **Doc. III-B** (BPD Annex IIIB data in *italics*)

Y(n) = Yes (number of tests/studies); P = in part; N = No; n.a. = not applicable; Reliability indicators: 0, 1, 2, 3 or 4)

Doc. III-B Section No.	**Information, test or study required for biocidal product** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justification prov'd. Y/N**	**Confidential data Y/N**	**Reliability indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
1	APPLICANT (headline only)	-	-	-	-	-
1.1	Name and address, etc.					
1.2	Manufacturer/formulator of the biocidal product and the active substance(s)					
2.	IDENTITY (headline only)	-	-	-	-	-
2.1	Trade name or proposed trade name, and manufacturer's development code number of the preparation, if appropriate					
2.1.1	Trade name					
2.1.2	Manufacturer's development code number(s)					
2.2	Detailed quantitative and qualitative information on the composition of the biocidal product, e.g. active substance(s), impurities, adjuvants, inert components					
2.2.1	Trade name					
2.2.2	IUPAC name					
2.2.3	CAS No.					
2.2.4	EC No.: EINECS					
2.2.5	Other					
2.2.6	Molecular formula					
2.2.7	Structural formula					
2.2.8	Classification according to Directive 67/548/EEC					
2.3	Physical state and nature of the biocidal product					
2.3.1	Physical state					
2.3.2	Nature					
3.	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES (headline only)	-	-	-	-	-
3.1.	Appearance					
3.1.1	Physical state					
3.1.2	Colour					

Doc. III-B Section No.	**Information, test or study required for biocidal product** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justifi-cation prov'd. Y/N**	**Confi-dential data Y/N**	**Relia-bility indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
3.1.3	Odour					
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					
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					
3.10	*Surface tension and viscosity (headline only)*	-	-	-	-	-
3.10.1	*Surface tension*					
3.10.2	*Viscosity*					
3.11	*Particle size distribution*					
4.	METHODS OF IDENTIFICATION AND ANALYSIS (headline only)	-	-	-	-	-
4.1	Analytical method for determining the concentrations of the active substance(s) in the biocidal product					
4.2	In so far as not covered by paragraph A4.2 (data set for the active substance), 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					
5.	INTENDED USES AND EFFICACY (headline only)	-	-	-	-	-
5.1	Product type and field of use envisaged (headline only)	-	-	-	-	-
5.1.1	Product type					
5.1.2	Overall use pattern					

Doc. III-B Section No.	**Information, test or study required for biocidal product** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justifi-cation prov'd. Y/N**	**Confi-dential data Y/N**	**Relia-bility indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
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 (headline only)	-	-	-	-	-
5.6.1	Pest organism(s) to be controlled					
5.6.2	Products, objects or organisms to be protected					
5.7	Effects on target organisms					
5.8	Mode of action (including time delay) in so far as not covered by paragraph A5.4					
5.9	User: industrial, professsional, general public (non-professional)					
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 (headline only)	-	-	-	-	-
5.10.1	Proposed label claims for the product					
5.10.2	Efficacy data					
5.11	Any other known limitations on efficacy including resistance (headline only)	-	-	-	-	-
5.11.1	Use-related restrictions					
5.11.2	Prevention of the development of resistance					
5.11.3	Concomittant use with other (biocidal) products					
6.	TOXICOLOGICAL STUDIES (headline only)	-	-	-	-	-
6.1	Acute toxicity					
6.1.1	Oral					

Doc. III-B Section No.	**Information, test or study required for biocidal product** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justification prov'd. Y/N**	**Confidential data Y/N**	**Reliability indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
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					
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					
6.7	*Further human health-related studies*					
6.7.1	*Food and feedingstuffs studies*					
6.7.1.1	*If residues of the biocidal product remain on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin*					
6.7.1.2	*Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product*					
6.7.2	*Other test(s) related to the exposure to humans* *Suitable test(s) and a reasoned case will be required for the biocidal product*					
7.	ECOTOXICOLOGICAL DATA FOR THE BIOCIDAL PRODUCT (headline only)	-	-	-	-	-
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 exotoxicological relevant non-active substances (i.e. substances of concern), such as information from safety data sheets					

Doc. III-B Section No.	**Information, test or study required for biocidal product** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justification prov'd. Y/N**	**Confidential data Y/N**	**Reliability indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
	Further studies on fate and behaviour in the environment					
7.4	*Where relevant all the information required in accordance with paragraph A7.1 and A7.2 (data set for the active substance)*					
7.5	*Testing for distribution and dissipation in the following:* *(a) Soil* *(b) Water* *(c) Air*					
7.6	*Effects on birds (headline only)*	-	-	-	-	-
7.6.1	*Acute oral toxicity, if not already done in accordance with Annex IIB, section VII*					
7.7	*Effects on aquatic organisms(headline only)*	-	-	-	-	-
7.7.1	*In case of application on, in, or near to surface waters*					
7.7.1.1	*Particular studies with fish and other aquatic organisms*					
7.7.1.2	*Residue data in fish concerning the active substance and including toxicologically relevant metabolites*					
7.7.1.3	*The studies referred to in Annex IIIA, section XIII parts 2.1, 2.2 and 2.3 may be required for relevant components of the biocidal product*					
7.7.2	*If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms under field conditions*					
7.8	*Effects on other non-target organisms (headline only)*	-	-	-	-	-
7.8.1	*Toxicity to terrestrial vertebrates other than birds*					
7.8.2	*Acute toxicity to honeybees*					
7.8.3	*Effects on beneficial arthropods other than bees*					
7.8.4	*Effects on earthworms and other soil non-target macro-organisms, believed to be at risk*					
7.8.5	*Effects on soil non-target micro-organisms*					
7.8.6	*Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk*					

Doc. III-B Section No.	**Information, test or study required for biocidal product** (for compulsory or conditional requirements, see TNsG on data requirements)	**Information, test/study provided Y(n)/P/N/n.a.**	**Justification prov'd. Y/N**	**Confidential data Y/N**	**Reliability indic. 0-4/n.a.**	**Official use only Data Gap Y/N**
7.8.7	*If the biocidal product is in the form of bait or granules(headline only)*	-	-	-	-	-
7.8.7.1	*Supervised trials to assess risks to non-target organisms under field conditions*					
7.8.7.2	*Studies on acceptance by ingestion the biocidal product is in by any non-target organisms thought to be at risk*					
7.9	*Summary and evaluation of ecotoxicological data (in Doc. II-B)*					
8.	MEASURES TO BE ADOPTED TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT (headline only)	-	-	-	-	-
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 the paragraph 8.3 (data set for active substance)					
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					

Doc. III-B Section No.	**Information, test or study required for biocidal product** (for compulsory or conditional requirements, see TNsG on data requirements)	Information, test/study provided Y(n)/P/N/n.a.	Justifi-cation prov'd. Y/N	Confi-dential data Y/N	Relia-bility indic. 0-4/n.a.	Official use only Data Gap Y/N
9.	CLASSIFICATION, PACKAGING AND LABELLING					
10.	SUMMARY AND EVALUATION OF SECTIONS 2 TO 9 (in Doc. II-B)					

Evaluation by Competent Authorities			
Doc. III-B Section No.	**Information, test or study required for biocidal product** *(list data gaps identified in the official-use column)*	**Explanation**	**Action**

Appendices 5.1 to 5.3

Reporting Formats for Document II - Risk Assessment

Appendix 5.1: Reporting format for Document II-A – Effects Assessment for the Active Substance

1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS-No.	
EINECS-No.	
Other No. (CIPAC, ELINCS	
IUPAC Name	
Common name, synonyma	
Molecular formula	
Structural formula	
Molecular weight (g/mol)	

1.2 PURITY/IMPURITIES, ADDITIVES

	CAS-No.	**Common name**	**Typical concentration or concentr.range (% w/w)**	**Remarks**
Purity of a.s.				
Impurities				*origin of impurity (e.g. manufacturing process, starting material)*
Additives				*function of additive*

1.3 PHYSICO-CHEMICAL PROPERTIES

1.4 ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

See example table below

1.4.1 Analysis of active substance as manufactured

1.4.2 Formulation analysis

1.4.3 Residue analysis

1.5 CLASSIFICATION AND LABELLING

1.5.1 Current classification

Classification according to Annex I of Council Directive 67/548/EEC

Current classification of a.s.

Classification	as in Directive 67/548/EEC
Class of danger	
R phrases	
S phrases	

1.5.2 Proposed classification

If deviating from current classification

2 EFFECTIVENESS AGAINST TARGET ORGANISMS

Summarise data presented in Doc. III-A Section 5.1 and 5.3. Report relevant details in summary tables as far as possible. Indicate any data gaps.

2.1 FUNCTION

2.2 FIELD OF USE ENVISAGED

2.3 EFFECTS ON TARGET ORGANISMS

Experimental data on the effectiveness of the active substance against target organisms (*See example table below)*

Analytical methods for the determination of residues of a.s. and relevant metabolites

Sample	Test substance	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of determination	Reference
						Range	Mean	St. dev.		

Experimental data on the effectiveness of the active substance against target organisms

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test results: effects, mode of action, resistance	Reference

3 HUMAN HEALTH EFFECTS ASSESSMENT

In all subsections, where appropriate, give summary and evaluation of data presented in Doc. III-A 6 (give cross-references). Report relevant details in summary tables as far as possible (see examples below).

Indicate any data gaps and give reasons of whether selected data are considered reliable and relevant for risk assessment.

3.1 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

3.2 ACUTE TOXICITY

Route	**Method Guideline**	**Species Strain Sex no/group**	**dose levels duration of exposure**	**Value LD50/LC50**	**Remarks**	**Reference**

3.3 IRRITATION AND CORROSIVITY

Skin irritation

Species	**Method**	**Aaverage score 24, 48, 72 h**		**Reversibility yes/no**	**Result**	**Reference**
		Erythema	Edema			

Eye irritation

Species	**Method**	**Average Score**				**Result**	**Reversibility yes/no**	**Reference**
		Cornea		Iris	Redness Conjunctiva	Chemosis		

3.4 SENSITISATION

Species	**Method**	**Number of animals sensitized/total number of animals**	**Result**	**Reference**

3.5 REPEATED DOSE TOXICITY

Route	duration of study	Species Strain Sex no/group	dose levels frequency of application	Results	LO(A)EL	NO(A)EL	Reference
				low dose:* medium dose:* high dose:*			

3.6 GENOTOXICITY

3.6.1 In vitro

Test system Method Guideline	organism/ strain(s)	concentra-tions tested *(give range)*	Result		Remark *give information on cytotoxicity and other*	Reference
			+ S9	- S9		
			+/-/+	+/-/+		

3.6.2 In vivo

Type of test Method/ Guideline	Species Strain Sex no/group	frequency of application	sampling times	dose levels	Results ***give dose, sampling time and result* +/-/+**	Remarks	Reference
					dose x, sampling time y:		

3.7 CARCINOGENICITY

Route	Species Strain Sex no/group	dose levels frequency of application	Tumours	Reference
			organ x, type of tumour controls:* low dose:* medium dose:* high dose:* other effects in organ x	

3.8 REPRODUCTIVE TOXICITY

3.8.1 Teratogenicity

Route of exposure	Testtype Method Guideline	Species Strain Sex no/group	Exposure Period	Doses	Critical effects dams fetuses	NO(A)EL maternal toxicity	NO(A)EL Teratogenicity Embryotoxicity	Reference

3.8.2 Fertility

Route of exposure	Testtype Method Guideline	Species Strain Sex no/group	Exposure Period	Doses	critical effect	NO(A)EL Parental		NO(A)EL F1		NO(A)EL F2		Reference
						m	f	m	f	m	f	

3.9 NEUROTOXICITY

only if relevant

3.10 HUMAN DATA

4 ENVIRONMENTAL EFFECTS ASSESSMENT

Where appropriate, give summary and evaluation of data presented in Doc. III-A 7 (give cross-references). Report relevant details in summary tables as far as possible (see examples below).

Indicate any data gaps and give reasons of whether selected data are considered reliable and relevant for risk assessment.

4.1 FATE AND DISTRIBUTION IN THE ENVIRONMENT

4.1.1 Degradation

4.1.1.1 Biodegradation

Guideline / Test method	Test type[1]	Test para-meter	Inoculum			Additional substrate	Test substance concentr.	Degradation		Reference
			Type	Concen-tration	Adap-tation			Incubation period	Degree [%]	

[1] Test on *inherent* or *ready* biodegradability according to OECD criteria

4.1.1.2 Abiotic degradation

Hydrolysis

Guideline / Test method	pH	Temperature [°C]	Initial TS concentration, C_0 [mol/l]	Reaction rate constant, K_h [1/s x 10^5]	Half-life, DT_{50} [h]	Coefficient of correlation, r_2	Reference

Photolysis in water

Guideline / Test method	Initial molar TS concen-tration	Total recovery of test substance [% of appl.a.s.]	Photolysis rate constant (k^c_p)	Direct photolysis sunlight rate constant (k_{pE})	Reaction quantum yield (ϕ^c_E)	Half-life ($t_{1/2E}$)	Reference

to be adapted for photo-oxidation in air

4.1.1.3 Distribution

Adsorption onto / desorption from soils

Guideline / Test method	Adsorbed a.s. [%]	K_a [1]	K_{aOC} [2]	K_d [3]	K_{dOC} [4]	K_a / K_d [5]	Degradation products		Reference
							Name	[%] of a.s.	
Soil 1 Soil 2 Soil 3 Soil n							*Product 1* *Product n*		
Soil 1 Soil 2 Soil 3 Soil n									

[1] K_a = Adsorption coefficient

[2] K_{aOC} = Adsorption coefficient based on organic carbon content

[3] K_d = Desorption coefficient

[4] K_{dOC} = Desorption coefficient based on organic carbon content

[5] K_a / K_d = Adsorption / Desorption distribution coefficient

4.1.2 Accumulation

Measurements of aquatic bioconcentration

Guideline / Test method	Expo-sure	Log P_{OW} of a.s.	Initial concentr. of a.s.	Steady-state BCF	Uptake rate constant	Depuration rate constant	Depuration time (DT_{50})	Metabo-lites	Reference

Estimations on aquatic bioconcentration

Basis for estimation	log P_{OW} (measured)	Estimated BCF for fish (freshwater)	Estimated BCF for fish eating bird/predator	Reference

Estimations on terrestrial bioconcentration

Basis for estimation	log P_{OW} (measured)	Estimated BCF for				Reference
		Terrestrial food chain I		Terrestrial food chain II		
		Soil dwelling species	Predatory bird / vertebrate	Terrestrial plant	Grazing non-target organism	

4.2 EFFECTS ON ENVIRONMENTAL ORGANISMS

4.2.1 Aquatic compartment

Acute toxicity to fish

Guideline / Test method	Species	Endpoint / Type of test	Exposure		Results			Remarks	Reference
			design	duration	LC_0	LC_{50}	LC_{100}		

Acute toxicity to invertebrates

Guideline / Test method	Endpoint / Type of test	Exposure		Results			Remarks	Reference
		design	duration	LC_0	LC_{50}	LC_{100}		

Growth inhibition on algae

Guideline / Test method	Species	Endpoint / Type of test	Exposure		Results			Remarks	Reference
			design	duration	NOE_rC	E_bC_{50} [1]	E_rC_{50} [2]		

[1] calculated from the area under the growth curve; [2] calculated from growth rate

Inhibition of microbial activity (aquatic)

Guideline / Test method	Species / Inoculum	Endpoint / Type of test	Exposure		Results			Remarks	Reference
			design	duration	EC_{20}	EC_{50}	EC_{80}		

4.2.2 Atmosphere

4.2.3 Terrestrial compartment

Toxicity to terrestrial organisms, initial tests

Guideline / Test method	Species	Endpoint / Type of test	Exposure		Results			Remarks	Reference
			design	duration	NOEC	LOEC	EC/LC_{50}		

4.2.4 Non compartment specific effects relevant to the food chain (secondary poisoning)

5 HAZARD IDENTIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

Give summary of data presented under Doc. III-A sections 3.10-3.12 and 3.15-3.17.

Appendix 5.2 Reporting Format for Document II-B – Effects and Exposure Assessment for the Biocidal Product

6 GENERAL PRODUCT INFORMATION

6.1 IDENTIFICATION OF THE PRODUCT

Trade name		
Manufacturer´s development code number(s)		
Ingredient of preparation	Function	Content
Physical state of preparation		
Nature of preparation		

6.2 IDENTITY OF INGREDIENTS OF THE BIOCIDAL PRODUCT

See example table below

6.3 PHYSICO-CHEMICAL PROPERTIES

Give summary and evaluation of data presented under Doc. III-B 3.1 to 3.12

6.4 ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

Give cross reference to Doc IIA if appropriate (Effects Assessment for active substance)

6.4.1 Formulation analysis

If appropriate use example table in Doc IIA (Effects Assessment for active substance)

Trade name	**IUPAC Name**	**CAS-No.**	**EC-No.**	**Molecular formula**	**Structural formula**	**Classification according to Directive 67/548/EEC**
Ingredient 1						
Ingredient n						

6.5 CLASSIFICATION, PACKAGING AND LABELLING

6.5.1 Current classification

Classification according to Annex I of Council Directive 67/548/EEC in tabular form (example see below):

Current classification of b.p.

Classification	as in Directive 67/548/EEC
Class of danger	
R phrases	
S phrases	

6.5.2 Proposed classification

If deviating from current classification

7 EFFICACY

In all subsections, where appropriate, give summary and evaluation of data presented in Doc. III-B 5. Report relevant details in summary tables as far as possible (see example below). Indicate any data gaps.

7.1 FUNCTION

7.2 ORGANISM(S) TO BE CONTROLLED AND PRODUCTS, ORGANISMS OR OBJECTS TO BE PROTECTED

7.3 EFFECTS ON TARGET ORGANISMS AND EFFICACY

7.4 MODE OF ACTION INCLUDING TIME DELAY

7.5 OCCURRENCE OF RESISTANCE

Efficacy of the active substance from its use in the biocidal product *)

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference

**) fill in one table for each MG/PT and/or field of use envisaged*

8 EXPOSURE ASSESSMENT

Where appropriate, give summary and evaluation of use and exposure related data presented in Doc. III-A and Doc. III-B. Report relevant details in summary tables as far as possible (see examples below). Indicate any data gaps and give reasons of whether selected data are considered reliable and relevant for risk assessment. Consider substances of concern where appropriate.

8.1 INTENDED USES

Give summary and evaluation of use data presented under Doc. III-B 5

MG/PT	**Field of use envisaged**	**Likely concentr. at which a.s. will be used**

8.2 HUMAN EXPOSURE ASSESSMENT

8.2.1 Identification of main paths of human exposure towards active substance from its use in biocidal product

Exposure path	**Industrial use**	**Professional use**	**General public**	**Via the environment**
Inhalation				
Dermal				
Oral				

8.2.2 Professional exposure

Intended use (MG/PT)	**Exposure scenario**	**PPE**	**Inhalational uptake**	**Dermal uptake**
			Exposure concentration (mg/m^3)	Exposure concentration (mg/m^2)

8.2.3 Non-professional exposure

Intended use (MG/PT)	Exposure scenario	Inhalational uptake	Dermal uptake	Oral uptake
		Exposure concentr. (mg/m^3)	Exposure concentr. (mg/m^2)	Exposure concentr. (mg/event)

8.2.4 Indirect exposure as a result of use of the active substance in biocidal product

8.3 ENVIRONMENTAL EXPOSURE ASSESSMENT

8.3.1 Fate and distribution in the environment

For the assessment of the environmental fate and behaviour of the active substance contained in biocidal product(s), refer to the chapter on Fate and distribution in the environment Doc. II-A.

8.3.2 PEC in surface water, ground water and sediment

8.3.3 PEC in air

8.3.4 PEC in soil

8.3.5 Non compartment specific exposure relevant to the food chain (secondary poisoning)

9 HUMAN HEALTH EFFECTS ASSESSMENT

Where appropriate, give summary and evaluation of data presented in Doc. III-B 6 (give cross-references). Use summary tables as those given in Doc. II-A. Indicate any data gaps and give reasons of whether selected data are considered reliable and relevant for risk assessment. Consider substances of concern where appropriate

9.1 PERCUTANEOUS ABSORPTION

9.2 ACUTE TOXICITY

9.3 IRRITATION AND CORROSIVITY

9.4 SENSITISATION

9.5 OTHER

10 ENVIRONMENTAL EFFECTS ASSESSMENT

Where appropriate, give summary and evaluation of data presented in Doc. III-B 7 (give cross-references). Use summary tables as those given in Doc. II-A. Indicate any data gaps and give reasons of whether selected data are considered reliable and relevant for risk assessment. Consider substances of concern where appropriate.

10.1.1 Aquatic compartment

10.1.2 Atmosphere

10.1.3 Terrestrial compartment

10.1.4 Non compartment specific effects relevant to the food chain (secondary poisoning)

11 HAZARD IDENTIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

Give summary and evaluation of data presented under Doc. III-B sections 3.2-3.4, 3.7 and 3.9.

Appendix 5.3 Reporting Format for Document II-C - Risk Characterisation for the Use of the Active Substance in Biocidal Product(s)

12 RISK CHARACTERISATION FOR HUMAN HEALTH

Based on the effects assessment document (Doc. II-A) and the effects and exposure assessment document (Doc. II-B or, if more than one product is concerned, Doc. II-B1, II-B2, etc.), the applicant should carry out a preliminary risk characterisation for each product type. This should cover the proposed normal use of the active substance in the biocidal product(s). In addition, a realistic worst case scenario should be applied. If substances of concern are to be considered, a risk characterisation should be included for each of these. For each area where risk characterisation is carried out, an overall assessment for the active substance should be included (see BPD Annex VI, TNsG on data requirements).

12.1 GENERAL ASPECTS

12.2 PROFESSIONAL USERS

Present the most relevant results of the risk characterisation in tabular form (see sample table below); identify data gaps and demands for further tests and studies.

Subheadings should be added if appropriate, for example:

12.2.1 Production / formulation of active substance

12.2.1.1 Critical endpoint(s)

12.2.1.2 Relevant exposure paths

12.2.1.3 Risk characterisation for production / formulation of a.s.

12.2.2 Application product type x

12.2.2.1 Critical end point(s)

The relevant effects should be briefly summarised and, if possible, dose-response relationships (NOAEL, LOAEL) should be given for the active substance (based on the effects assessment in Doc. II-A). If data are provided for relevant end points in Doc. II-B indicating a higher toxicity of the active substance used in a product, e.g. due to synergistic effects with ingredient , the critical end points for the product should be identified as well.

12.2.2.2 Relevant exposure paths

The relevant exposure paths should be briefly summarised (based on the exposure assessment in Doc. II-B) and, if data are provided also for substances of concern. On the basis of data and/or assumptions on exposure frequency

and amount and anthropometric data (e.g. body weight, body surface) body doses should be calculated from the exposure concentrations given in Doc. II-B.

Give reasonable justification if certain exposure paths are not considered.

12.2.2.3 Risk characterisation for product type x

Comparison of critical endpoint data with expected body doses, calculation of MOS, MOE, ARfD, TER (see sample table below)

12.2.3 Application product type y

see above

12.2.4 Overall assessment of the risk for the use of the active substance in biocidal products

12.3 NON-PROFESSIONAL USERS

see above

12.4 INDIRECT EXPOSURE AS A RESULT OF USE

see above

12.5 COMBINED EXPOSURE

summarise the above mentioned exposure scenarios giving expected lifetime doses from the different applications and the respective health risks

TER and MOS values for the critical effects concerning the workplace exposure towards active substance *)

Workplace operation	**PPE**	**Exposure path**	**Body dose (mg/kg bw/d)**	**Acute toxicity (NOAEL =...)**		**Repeated dose toxicity (LOAEL = ...)**		**Sensitization (NOAEL = ...)**	
				TER	MOS	TER	MOS	TER	MOS

*) *to be adjusted depending on the outcome of the discussion concerning the AOEL vs. TER approach*

13 RISK CHARACTERISATION FOR THE ENVIRONMENT

13.1 AQUATIC COMPARTMENT (INCL. SEDIMENT)

Summarise the relevant results in tabular form if appropriate (see sample table below)

PEC/PNEC ratios for different exposure situations concerning the hydrosphere

Exposure scenario	PEC	PEC/PNEC
	Water/local ($PNEC_{water}$ = ...)	

13.2 ATMOSPHERE

13.3 TERRESTRIAL COMPARTMENT

13.4 NON COMPARTMENT SPECIFIC EFFECTS RELEVANT TO THE FOOD CHAIN (SECONDARY POISONING)

14 RISK CHARACTERISATION FOR THE PHYSICO-CHEMICAL PROPERTIES

Characterise the potential risk of the properties flammability, explosivity, thermal stability for users and recommendations concerning e.g. storage, PPE

15 MEASURES TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

Data from Doc. III-A, section 8, should be transferred and inserted here.

Appendix 6.1

Application form

Dossier Document I **I.1 Application Form**	**Application for the Annex I / IA / IB inclusion of a new / existing active substance** *Delete and specify as appropriate*	**Official use* (Y / N / n.a.)**
	1 Contact Addresses	
1.1 Applicant	*Name* *address* *telephone/fax number* *e-mail address*	
1.2 Manufacturer of Active Substance (if different)	*Name* *address* *telephone/fax number* *e-mail address*	
1.3 Manufacturer of Product(s) (if different) 1) Product 1 2) Product n	*Include Name and address etc. for manufactrurer of any further products or indicate company name "as above"*	
	2 Identity of the Active Substance	
2.1 Active substance		
2.1.1 Common name		
2.1.2 Other names		
2.1.3 CAS No.		
2.1.4 EINECS No.		
2.1.5 Purity	g/kg g/l % w/w % v/v	
2.2 Impurities and additives		
2.2.1 Common name and function Substance 1 Substance n	*Include name and function (if any) for each substance, e.g. impurity of starting material, by-product of synthesis, antifoaming agent, stabilizer*	
2.2.2 CAS No. Substance 1 Substance n		
2.2.3 EINECS No. Substance 1 Substance n		
2.2.4 Concentration of impurities Substance 1 Substance n	g/kg g/l % w/w % v/v	
2.2.5 Classified as substance of concern Substance 1 Substance n	*Indicate whetherany impurities or additives are classified as substances of concern or not* *yes/no* *yes/no*	

Dossier Document I **I.1 Application Form**	**Application for the Annex I / IA / IB inclusion of a new / existing active substance** *Delete and specify as appropriate*	**Official use* (Y / N / n.a.)**
	3 Physical, chemical and technical Properties	
3.1 Physical state		
3.2 Appearance		
3.3 Vapour pressure		
3.4 Water solubility		
3.5 Surface tension		
3.6 Thermal stability		
3.7 Flammability		
3.8 Explosive properties		
3.9 Oxidizing properties		
3.10 Reactivity towards container material		
	4 Proposals for classification and labelling	
4.1 Risk phrases		
4.2 Safety phrases		
4.3 Proposal for labelling		
4.4 Existing classification and labelling	*State classification and labeling if given in Annex I of Council Directive 67/548/EEC*	
	5 Effectiveness and Field of use envisaged	
5.1 Product type and field of use envisaged	*Include code(s) and term(s) for the BPD Annex V product type(s) and the field(s) of use envisaged*	
5.2 User	*Include code(s) and term(s)*	
5.3 Function	*Include code(s) and term(s)*	
5.4 Organism(s) to be controlled and products, organisms or objects to be protected	*Include code(s) and term(s)*	
	6 Check for Completeness of Documentation	
	A full completeness check is compulsory and should always be provided as Appendix to the Application form. *Indicate whether document is provided: Yes/No*	
6.1 Document I - Overall summary and assessment		
I.2 Overall summary and conclusions		
I.3 Proposal for the		

Dossier Document I I.1 Application Form	Application for the Annex I / IA / IB inclusion of a new / existing active substance *Delete and specify as appropriate*	Official use* (Y / N / n.a.)
envisaged decision		
Appendix ….: Listing of end points		
Appendix ….: List of abbreviations		
Appendix ….: Check for completeness and quality of BPD Annex IIA/IIIA data		
Appendix ….: Check for completeness and quality of BPD Annex IIB/IIIB data		
Appendix ….: Documentation relating to the joint submission		
Appendix ….: Copies of notifications (if existing a.s.)		
Appendix ….: Copy of safety data sheet for active substance		
Appendix ….: Copies of safety data sheets for formulants / substances of concern		
6.2 Document II-A Effects assessment a.s.		
Appendix: …. Reference list Doc. II-A		
6.3 Document II-B Effects & exposure assessment b.p.		
Appendix: …. Reference list Doc. II-B		
6.4 Document II-C Risk characterisation		

Dossier Document I **I.1 Application Form**	**Application for the Annex I / IA / IB inclusion of a new / existing active substance** *Delete and specify as appropriate*	**Official use* (Y / N / n.a.)**
Appendix: …. Reference list Doc. II-C		
6.5 Document III-A Study Summaries active substance		
Appendix: …. Reference list Doc. III-A		
Appendix: …. Confidential data and information a.s.		
6.6 Document III-B Study Summaries biocidal product		
Appendix: …. Reference list Doc. III-B		
Appendix: …. Confidential data and information b.p.		
6.7 Document IV-A Original Test and Study Reports a.s.		
Appendix: …. Profile and results of literature search		
6.8 Document IV-B Original Test and Study Reports b.p.		
Appendix: …. Profile and results of literature search		
6.7 Document IV-A Original Test and Study Reports a.s.		
Appendix: …. Profile and results of literature search		
6.8 Document IV-B Original Test and Study Reports b.p.		
Appendix: …. Profile and results of literature search		
6.9 Other documentation		

Dossier Document I **I.1 Application Form**	**Application for the Annex I / IA / IB inclusion of a new / existing active substance** *Delete and specify as appropriate*	**Official use* (Y / N / n.a.)**

EVALUATION BY COMPETENT AUTHORITIES	
Documentation accepted as complete	
Documentation <u>not</u> accepted as complete	*Indicate document type missing*
Action required	

*) Official use column reserved for CAs' check (Y = Yes (accepted); N = No (not accepted); n.a. = not applicable)

Appendix 6.2

Listing of End Points

Appendix 6.2: Format for the listing of end points to be included in the document Overall Summary and Assessment - Doc. I [7]

Chapter 1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	
Function (*e.g.* fungicide)	
Rapporteur Member State	

Identity (Annex IIA, point II.)

Chemical name (IUPAC)	
Chemical name (CA)	
CAS No	
EC No	
Other substance No.	
Minimum purity of the active substance as manufactured (g/kg or g/l)	
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	
Molecular formula	
Molecular mass	
Structural formula	

[7] Other end points will be relevant in particular cases - decisions as to the additional end points to be included can only be made on a case by case basis.

Physical and chemical properties (Annex IIA, point III., unless otherwise indicated)

Melting point (state purity)	
Boiling point (state purity)	
Temperature of decomposition	
Appearance (state purity)	
Relative density (state purity)	
Surface tension	
Vapour pressure (in Pa, state temperature)	
Henry's law constant (Pa m^3 mol^{-1})	
Solubility in water (g/l or mg/l, state temperature)	pH__5____: pH__9____: pH_____:
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	
Partition coefficient (log P_{OW}) (state temperature)	pH___5___: pH___9___: pH_____:
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	pH_____: pH_____: pH_____:
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	
Quantum yield of direct phototransformation in water at Σ > 290 nm (point VII.7.6.2.2)	
Flammability	
Explosive properties	

Company Name	Name of A.S.	Month/Year

Summary of intended uses[8]

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks:
				Type	Conc. of as	method kind	number min max	interval between applications (min)	g as/L min max	water L/m^2 min max	g as/m^2 min max	
(a)			(c)	(d-f)	(i)	(f-h)	(k)					(m)

(a) *e.g.* biting and suckling insects, fungi, molds; (b) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(c) GCPF Codes - GIFAP Technical Monograph No 2, 1989 ISBN 3-8263-3152-4); (d) All abbreviations used must be explained
(e) g/kg or g/l;(f) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench;
(g) Kind, *e.g.* overall, broadcast, aerial spraying, row, bait, crack and crevice equipment used must be indicated;
(h) Indicate the minimum and maximum number of application possible under practical conditions of use;
(i) Remarks may include: Extent of use/economic importance/restrictions

[8] adapted from: EU (1998a): European Commission: Guidelines and criteria for the preparation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EC (Article 5.3 and 8,2). Document 1663/VI/94 Rev 8, 22 April 1998

Classification and proposed labelling (Annex IIA, point IX.)

with regard to physical/chemical data	
with regard to toxicological data	
with regard to fate and behaviour data	
with regard to ecotoxicological data	

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	
Air (principle of method and LOQ) (Annex IIA, point 4.2)	
Water (principle of method and LOQ) (Annex IIA, point 4.2)	
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

Rate and extent of oral absorption:	
Rate and extent of dermal absorption:	
Distribution:	
Potential for accumulation:	
Rate and extent of excretion:	
Toxicologically significant metabolite	

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	
Rat LD_{50} dermal	
Rat LC_{50} inhalation	
Skin irritation	
Eye irritation	
Skin sensitization (test method used and result)	

Repeated dose toxicity (Annex IIA, point 6.3)

Species/ target / critical effect	
Lowest relevant oral NOAEL / LOAEL	
Lowest relevant dermal NOAEL / LOAEL	
Lowest relevant inhalation NOAEL / LOAEL	

Genotoxicity (Annex IIA, point 6.6)	

Carcinogenicity (Annex IIA, point 6.4)

Species/type of tumour	
lowest dose with tumours	

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Reproduction target / critical effect	
Lowest relevant reproductive NOAEL / LOAEL	
Species/Developmental target / critical effect	
Lowest relevant developmental NOAEL / LOAEL	

Neurotoxicity / Delayed neurotoxicity (Annex IIIA, point VI.1)

Species/ target/critical effect	
Lowest relevant developmental NOAEL / LOAEL.	

Other toxicological studies (Annex IIIA, VI/XI)

.....	

Medical data (Annex IIA, point 6.9)

.....	

Summary (Annex IIA, point 6.10)	Value	Study	Safety factor
ADI (if residues in food or feed)			
AOEL (Operator/Worker Exposure)			
Drinking water limit			
ARfD (acute reference dose)			

Acceptable exposure scenarios (including method of calculation)

Professional users	
Non-professional users	
Indirect exposure as a result of use	

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water (Annex IIA, point 7.6, IIIA, point XII.2.1, 2.2)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH_____:
	pH_____:
	pH_____:
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	
Readily biodegradable (yes/no)	
Biodegradation in seawater	
Non-extractable residues	
Distribution in water / sediment systems (active substance)	
Distribution in water / sediment systems (metabolites)	

Route and rate of degradation in soil (Annex IIIA, point VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

Mineralization (aerobic)	
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic):
	DT_{90lab} (20°C, aerobic):
	DT_{50lab} (10°C, aerobic):
	DT_{50lab} (20°C, anaerobic):
	degradation in the saturated zone:
Field studies (state location, range or median with number of measurements)	DT_{50f}:
	DT_{90f}:
Anaerobic degradation	
Soil photolysis	
Non-extractable residues	
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	
Soil accumulation and plateau concentration	

Adsorption/desorption (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2)

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	

Fate and behaviour in air (Annex IIIA, point VII.3, VII.5)

Direct photolysis in air	
Quantum yield of direct photolysis	
Photo-oxidative degradation in air	Latitude: ..... Season: ..... DT_{50} .....
Volatilization	

Monitoring data, if available (Annex VI, para. 44)

Soil (indicate location and type of study)	
Surface water (indicate location and type of study)	
Ground water (indicate location and type of study)	
Air (indicate location and type of study)	

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)
(Annex IIA, point 8.2, Annex IIIA, point 10.2)

Species	Time-scale	Endpoint	Toxicity
Fish			
Invertebrates			
Algae			
Microorganisms			

Effects on earthworms or other soil non-target organisms

Acute toxicity to …….. (Annex IIIA, point XIII.3.2)	
Reproductive toxicity to …… (Annex IIIA, point XIII.3.2)	

Effects on soil micro-organisms (Annex IIA, point 7.4)

Nitrogen mineralization	
Carbon mineralization	

Effects on terrestrial vertebrates

Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	

Effects on honeybees (Annex IIIA, point XIII.3.1)

Acute oral toxicity	
Acute contact toxicity	

Effects on other beneficial arthropods (Annex IIIA, point XIII.3.1)

Acute oral toxicity	
Acute contact toxicity	
Acute toxicity to ……..	

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor (BCF)	
Depration time (DT_{50}) (DT_{90})	
Level of metabolites (%) in organisms accounting for > 10 % of residues	

Chapter 6: Other End Points

Appendix 7.1

List of standard terms and abbreviations

Appendix 7.1: List of standard terms and abbreviations

(adapted from: (i) Guidelines and criteria for the preparation of PPP dossiers[9]; (ii) TNsG on Data Requirements[10])

Stand. term / Abbreviation	**Explanation**
A	ampere
ACh	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
ADP	adenosine diphosphate
AE	acid equivalent
AF	assessment factor
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD_{50}	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
Ann.	Annex
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate

Stand. term / Abbreviation	**Explanation**
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BAF	bioaccumulation factor
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BPD	Biocidal Products Directive
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathy
BSP	bromosulfophthalein
Bt	*Bacillus thuringiensis*
Bti	*Bacillus thuringiensis israelensis*
Btk	*Bacillus thuringiensis kurstaki*
Btt	*Bacillus thuringiensis tenebrionis*
BUN	blood urea nitrogen
bw	body weight

9 EU (1998a): European Commission: Guidelines and criteria for the preparation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EC (Article 5.3 and 8,2). Document 1663/VI/94 Rev 8, 22 April 1998

10 European Chemicals Bureau, ECB (1996) Technical Guidance Documents in support of the Commission Directive 93/67/EEC on risk assessment for new notified substances and the Commission Regulation (EC) 1488/94 for existing substances

Stand. term / Abbreviation	**Explanation**
c	centi- (x 10^{-2})
°C	degrees Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DANN
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
d	day(s)
DES	diethylstilboestrol
DIS	draft international standard *(ISO)*
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation
DRP	detailed review paper *(OECD)*
$DT_{50(lab)}$	period required for 50 percent dissipation (under laboratory conditions) (define method of estimation)
$DT_{90(field)}$	period required for 90 percent

Stand. term / Abbreviation	**Explanation**
	dissipation (under field conditions) (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
EC_{50}	median effective concentration
ECD	electron capture detector
ED_{50}	median effective dose
EDI	estimated daily intake
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm
EPMA	electron probe micro-analysis
ERL	extraneous residue limit
ESPE46/51	evaluation system for pesticides
EUSES	European Union system for the evaluation of substances
F	field
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
FBS	full base set
FELS	fish early-life stage
FIA	fluorescence immuno-assay
FID	flame ionisation detector
F_{mol}	fractional equivalent of the metabolite´s molecular weight compared to the active substance
FOB	functional observation battery
f_{oc}	organic carbon factor (compartment dependent)

Stand. term / Abbreviation	**Explanation**
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram(s)
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPS	global positioning system
GSH	glutathione
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value)
ha	hectare(s)
Hb	haemoglobin
HC5	concentration which will be harmless to at least 95 % of the species present with a given level of

Stand. term / Abbreviation	**Explanation**
	confidence (usually 95 %)
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_S	Shannon-Weaver index
Ht	haematocrit
HUSS	human and use safety standard
I	indoor
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration or median inhibitory concentration 1
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
INT	2-p-iodophenyl-3-p-nitrophenyl-5-phenyltetrazoliumchloride testing method
ip	intraperitoneal
IPM	integrated pest management

Stand. term / Abbreviation	**Explanation**
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
IUCLID	International Uniform Chemical Information Database
iv	intravenous
IVF	*in vitro* fertilisation
k *(in combination)*	kilo
k	rate constant for biodegradation
K	Kelvin
Ka	acid dissociation constant
Kb	base dissociation constant
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
kg	kilogram
K_H	Henry´s Law constant (in atmosphere per cubic metre per mole)
K_{oc}	organic carbon adsorption coefficient
K_{om}	organic matter adsorption coefficient
K_{ow}	octanol-water partition coefficient
Kp	solid-water partition coefficient
kPa	kilopascal(s)
l, L	litre
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC-MS-MS	liquid chromatography with tandem mass spectrometry

Stand. term / Abbreviation	**Explanation**
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
ln	natural logarithm
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
log	logarithm to the base 10
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometre (micron)
MAC	maximum allowable concentration
MAK	maximum allowable concentration
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
MIC	minimum inhibitory concentration

Stand. term / Abbreviation	**Explanation**
min	minute(s)
MKC	minimum killing concentration
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
MMAD	mass median aerodynamic diameter
mo	month(s)
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MT	material test
MW	molecular weight
n.a.	not applicable
n-	normal (defining isomeric configuration)
n	number of observations
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometre
NMR	nuclear magnetic resonance
no, n°	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level

Stand. term / Abbreviation	**Explanation**
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OEL	occupational exposure limit
OH	hydroxide
OJ	Official Journal
OM	organic matter content
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler’s exposure data

Stand. term / Abbreviation	**Explanation**
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the acid dissociation constant
pKb	negative logarithm (to the base 10) of the base dissociation constant
PNEC	predicted no effect concentration (compartment to be added as subscript)
po	by mouth
POP	persistent organic pollutants
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PPP	plant protection product
ppq	parts per quadrillion (10^{-24})
ppt	parts per trillion (10^{-12})
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	product type
PT(CEN)	project team CEN
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QA	quality assurance
QAU	quality assurance unit
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RA	risk assessment
RBC	red blood cell
REI	restricted entry interval
RENI	Registry Nomenclature Information System
Rf	retardation factor

Stand. term / Abbreviation	**Explanation**
RfD	reference dose
RH	relative humidity
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	revolutions per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
S	solubility
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SCAS	semi-continous activated sludge
SCTER	smallest chronic toxicity exposure ratio (TER)
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
S/L	short term to long term ratio
SMEs	small and medium sized enterprises
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies

Stand. term / Abbreviation	**Explanation**
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STER	smallest toxicity exposure ratio (TER)
STMR	supervised trials median residue
STP	sewage treatment plant
t	tonne(s) (metric ton)
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
T_{25}	tumorigenic dose that causes tumours in 25 % of the test animals
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TG	technical guideline, technical group
TGD	Technical guidance document
TID	thermionic detector, alkali flame detector
TDR	time domain reflectrometry
TER	toxicity exposure ratio
TER_I	toxicity exposure ratio for initial exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake

Stand. term / Abbreviation	**Explanation**
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TNsG	technical notes for guidance
TOC	total organic carbon
Tremcard	transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TTC	2,3,5-triphenylterazoliumchloride testing method
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UR	unit risk
UV	ultraviolet
UVC	unknown or variable composition, complex reaction products
UVCB	undefined or variable composition, complex reaction products in biological material
v/v	volume ratio (volume per volume)
vis	visible
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

Appendix 7.2

Abbreviations of organisations and publications

Appendix 7.2: Abbreviations of Organisations and Publications

(adapted from: (i) Guidelines and criteria for the preparation of PPP dossiers[11]; (ii) TNsG on Data Requirements[12])

Abbreviation	**Explanation**
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
BBA	German Federal Agency of Agriculture and Forestry
CA(S)	Chemical Abstracts (System)
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe
CEC	Commission of the European Communities
CEFIC	European Chemical Industry Council
CEN	European Committee for Normalisation
CEPE	European Committee for Paints and Inks
CIPAC	Collaborative International Pesticides Analytical Council Ltd
CMA	Chemicals Manufacturers Association
COREPER	Comite des Representants Permanents
COST	European Co-operation in the field of Scientific and Technical Research
DG	Directorate General
DIN	German Institute for Standardisation
EC	European Commission
ECB	European Chemicals Bureau
ECCO	European Commission Co-ordination
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EEC	European Economic Community
EHC	Environmental Health Criteria

[11] EU (1998a): European Commission: Guidelines and criteria for the preparation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EC (Article 5.3 and 8,2). Document 1663/VI/94 Rev 8, 22 April 1998

[12] European Chemicals Bureau, ECB (1996) Technical Guidance Documents in support of the Commission Directive 93/67/EEC on risk assessment for new notified substances and the Commission Regulation (EC) 1488/94 for existing substances

Abbreviation	**Explanation**
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPAS	European Producers of Antimicrobial Substances
EPFP	European Producers of Formulated Preservatives
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organization
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
EWMP	European Wood Preservation Manufacturers
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory

Abbreviation	**Explanation**
GEMS	Global Environmental Monitoring System
GRIN	Germplasm Resources Information Network
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
ICBP	International Council for Bird Preservation
ICCA	International Council of Chemical Associations
ICES	International Council for the Exploration of the Seas
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organization for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JECFA FAO/WHO	Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
MITI	Ministry of International Trade and Industry, Japan

Abbreviation	**Explanation**
NATO	North Atlantic Treaty Organization
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Center for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Program (USA)
OECD	Organization for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
OPPTS	Office of Prevention, Pesticides and Toxic Substances (US EPA)
OSPAR	Oslo Paris Convention (Convention for the Protection of the Marine Environment of the North-East Atlantic)
PAN	Pesticide Action Network
RIVM	Netherlands National Institute of Public Health and Environmental Protection
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SETAC	Society of Environmental Toxicology and Chemistry
SI	Système International d'Unitès
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UBA	German Environmental Protection Agency
UN	United Nations
UNEP	United Nations Environment Programme
WFP	World Food Programme
WHO	World Health Organization
WPRS	West Palearctic Regional Section
WTO	World Trade Organization

Abbreviation	**Explanation**
WWF	World Wildlife Fund

Appendix 7.3

Application Codes

Appendix 7.3: Application codes

Part 1: Principles

Main Task:

Within the scope of discussion for transformation of the Directive 98/8/EEC into national law as well as the proposal of the Technical Notes of Guidance (TNsG) drafted for the European Commission, the usefulness and the principle of an application code which could be applied in course of the authorisation / registration of Biocides was intensively discussed. With regard to the structure for the Annex I entries it was proposed to add more detail (e.g. target organism, use characteristics, user category and type of formulation). A balance should be struck between a level of detail that makes simple expansions of an entry unnecessarily complicated and a structure of entry that contains all the major details needed to ensure the same level of safety in all the EU-regions where the containing product is intended to be used.

Proposal:

In a first approach a hierarchical application code has been developed by the German Federal Institute for Health Protection of Consumers and Veterinary Medicine (BGVV) in co-operation with the Federal Institute for Materials Research and Testing (BAM) for wood preservatives. Items which are especially relevant for this product type were included into the files. However, this code proposal will be in principle applicable to each product type. Items relevant for other product types can be easily added to the proposed files.

Exemplary code lists on the basis of the German application and indication codes are given for the following items: target organisms to be controlled (file 1), developmental stages of target organisms (file 2), function/mode of action, a.s./b.p. (file 3), products/objects to be protected (file 4), field of use to be envisaged (file 5), user category (file 6), method of application (file 7), application rate, a.s. (file 8), application aim (file 9), type of formulation (file 10). The present number of files is the result of intensive discussions between the German CAs and the Council of the German Chemical Industry (VCI) which proposed to add more detail as originally planned.

Benefit:

The standardisation of terms by a list of terms enables an unequivocal and trans-

parent definition of authorisation/registration conditions, use limitations as well as further harmonisation between the member states. This comprehensive information given will facilitate the authorisation/registration process in every member state and ensure the same level of safety in all EU-regions.

Also in the context of an effective electronic data processing (e.g. in the frame of the adaptation of the IUCLID database for the authorisation/registration of biocides) a hierarchical application code appears to be useful. For this purpose it is planned to develop a glossary which will be available to all member states. This glossary is intended to describe the terms in a comprehensive and scientifically justified way and can be implemented directly into IUCLID when relevant.

Part 2: Example wood preservatives

Files 1 – 10 of the Application Code for encoding wood preservatives/ proposal of the German Federal Institute for Health Protection of Consumers and Veterinary Medicine (BGVV) in co-operation with the Federal Institute for Materials, Research and Testing (BAM) . The common English term is included to help non-experts, but it should be noted that it may vary with English speaking regions.

File 1: Target organisms to be controlled

Scientific name	Common English term
Fungi	fungi
	wood rotting fungi
Basidiomycetes	wood rotting basidiomycetes
Serpula lacrymans	true dry rot fungus
Ascomycetes, Fungi imperfecti	soft rot micro-fungi
	wood disfiguring fungi
Ascomycetes, Fungi imperfecti	blue disfiguring fungi
	sapstain
	bluestain
Penicillium spec., Aspergillus spec.	mould
Insecta	insects
Coleoptera	beetles
Hylotrupes bajulus L.	house longhorn beetle
Anobium punctatum De Geer	common furniture beetle
Lyctus spec.	powder post beetles
Hymenoptera	hymenopterons
Sirex spec.	wood wasps
Isoptera	termites
Reticulitermes spec.	subterranean termites
Kalotermes spec.	dry wood termites
	marine borers
Pholadidae	mussels
Teredinidae	shipworm
Crustacea	crustaceans
Limnoriidae	ribble
Chelura spec.	-

File 2: Developmental stages of target organisms to be controlled

English term

fungi

hyphae

spores

insects

eggs and larvae

eggs

adults and larvae

adults

larvae

mussels

crustaceans

File 3: Function/Mode of action of a.s./b.p.

English term

bactericide

pheromone

fungicide

fungicide, inhibition of metabolism (mitochondria)

insecticide

contact action

stomach action

insect growth regulator

molluscicide

repellent

File 4: Products, objects and organisms to be protected

To be completed in dependence on the outcome of the discussions concerning the stepwise procedure for the introduction of code lists.

File 5: Field of use to be envisaged

English term

indoor use

wood preservative, indoor use

hazard class 1

hazard class 2

outdoor use

wood preservative, outdoor use

hazard class 2

hazard class 3

hazard class 4

hazard class 5

File 6: User category

English term

non-professional

professional

closed system
(industrial user)

open system

internal

external/
commercial

File 7: Method of application

English term

manual application

brush treatment

open technical application

spray treatment

foam application

immersion

dip treatment

injection

pressure process

mixing with glue and mortar

fumigation

closed technical application

vacuum impregnation

deluging

File 8: Application rate (active substance)

English term

value (scale unit)

% (w/w or v/v)

ml/m^2

g/m^2

kg/m^3

* it is considered appropriate to enter the nominal value

File 9: Application aim

English term

preventive treatment, preservation

control

File 10: Type of formulation

English term

emulsifiable concentrate

emulsion

gas

gas generating product

paste

water emulsifiable concentrate

others

water soluble concentrate

ready-to-use product

product for foam application

bait (ready for use)

bandages

rod / cartridge