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**AUTHORISATION AND REGISTRATION OF A BIOCIDAL PRODUCT
GUIDANCE DOCUMENT**

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1. Initial Administrative Procedure

According to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998, concerning the placing of biocidal products on the market, upon receiving an application for the authorization and registration of a biocidal product, the competent authority must check if the product/active substance:

1. is a biocidal product, as defined by the Directive; (also refer to Borderline Guidelines and Scope of products)
2. is covered by a current Annex I (authorized) or Annex IA (registered);
3. has a complete dossier (which also include the checking of format and other studies which include toxicology and ecotoxicology studies);


After establishing the product as a Biocide, the applicant's proposed conditions of use are checked to see if they are permitted under Annex I or IA. If the applicant's proposed conditions are not permitted or the product consists of a new active substance, Annex I / IA entry is revised according to procedures defined in Annex I / IA. Also, the proposed use is checked to see if it conforms to any other conditions imposed by other commission legislations.

A complete dossier is an important asset in the authorization and registration of biocides. A Letter of Access is the most important piece of document, giving legitimate access to the data provided by the applicant (since the data is subject to protection). This Letter of Access is the industry's responsibility. For the Letter of Access to be acceptable, the authority must check that it contains:

- name of data holder;
- name of applicant to which data access is granted;
- name of applicant product;
- product type;
- nature of data package (active substance or product) and description;
- authority having original data package.

A checklist is also used to check completeness of the dossier and the authority evaluates the dossier by checking if the dossier meets the standards, notes any deviations, assesses overall scientific integrity of the study and/or report, describes routine and unusual observations and summarizes the result. All relevant test reports are the responsibility of the applicant.

The competent authority should consider all of the above information and on judging that the application is within scope of the Directive, the active substances

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are included in Annex I or IA and the dossier is sufficiently complete and suitable for evaluation, the procedure should continue on to the main scientific evaluation.

2. Main Scientific Evaluation


When the administrative evaluation is adequate, the application for authorization and registration is passed on within 60 days.

When an applicant holds an authorization/registration for a particular biocidal product in one Member State (provided there is a suitable entry into Annex I or IA for the active substance), they can apply to competent authorities in other Member States for that authorisation (or registration) to be mutually recognised so that the product can also be placed on the market there. Mutual recognition should be based on harmonised models and established evaluation procedures. The applications for mutual recognition should be approved by the second Member State under the provisions laid down in Article 4 of Directive 98/8/EC. The receiving competent authority must therefore assess the application in relation to conditions in its own territory (Article 4).

Risk Assessments on various characteristics are then carried out. A risk assessment for physico-chemical properties is always needed before a biocidal product can be authorised. No specific risk assessment is normally required for registration of low-risk biocidal products. This assessment is done qualitatively, taking into consideration normal occasions and worst case scenarios. Physico-chemical properties include intrinsic properties (flammability and explosivity), chemical incompatibility, environmental conditions and reactions with any post-treatment residues.

The process of estimating the magnitude and probability of effects is defined as Risk Characterisation and Risk Characterisation is considered when authorizing and registering substances susceptible to (see Flow Chart Fig. 1):

- oxidizing;
- flammable (or self-ignites at a temperature below 250°C);
- explosivity;
- compatibility and reactivity of biocidal product with other products;
- viscosity and surface tension (liquid) (aspiration hazard);
- combustible dusts;
- storage stability.

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Authorization and registration may only be given to substances with no unacceptable risk to humans, even in realistic worst case scenarios. Human health effects considered which could result in adverse effects include:

- acute, repeated dose and chronic toxicity;
- irritation or corrosivity;
- sensitisation;
- genotoxicity;
- carcinogenicity;
- reproduction toxicity
- neurotoxicity;
- other.

An Exposure Assessment is also carried out, which is an assessment for each human population that will encounter the biocide. Three types of exposure assessments take place:


1. Primary, having direct application (professional use);
2. Secondary, bystanders and people not aware of themselves being exposed (non-professional use);
3. environment, consumer exposure (environment).

A Risk Assessment for the environment also takes place and this takes into account the fate and distribution in the environment of the active substance, contamination of surface waters, impact on non-target organisms and proves that it has no unacceptable effects on human/animal health through drinking water/food (see Hazard Identification procedure Fig. 2). Possible additive, synergistic or other effects are also included in the risk assessment if the product contains 2 or more active substances (PEC / PNEC* ratios; if less than 1, acceptable; if more than 1, authority must obtain more information but if still remains more than 1, product fails for authorisation). Efforts should be made to refine the PEC before further data from vertebrate animal studies are requested to refine PNEC.

* predicted environmental concentration / predicted no effect concentration

Other Risk Assessments include those for:

- Resistance;
- Humaneness (degree of pain, distress and discomfort to target organism) against vertebrates and for vertebrates to control non-vertebrate target organisms;
- Any other effects if directly linked to human, animal or environmental safety.

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An Efficacy Assessment based on Quality Assurance procedures is carried out. This is taken by the authority to assess authorisation in their territory. Screening tests, stimulation tests, field studies are carried out as performance standards.

An evaluation of label claims then takes place. By these labels, efficacy claims can be substantiated; the efficacy assessment is made against the claims made on the product label for the effectiveness of the product. The label should consist of product type, spectrum of biological activity and function, mode of action, area of use/site of application, duration of control/effect, directions for use, time and duration, efficacy of product.

Efficacy assessment ensures that the proposed use of a biocidal product is supported by adequate scientific information.


The Adequacy of a test is examined on Reliability (test methodology and the way in which result tests are described) and on Relevance (extent to which data/tests are appropriate for assessment against label claims, contrasted against elements of label claims).

When used in accordance with the label instructions, the use of biocidal product will result in a measurable beneficial effect in relation to a performance standard. Finally, the overall balanced view for the product is established, having considered the proposed conclusions from each of the effects on humans, animals and the environment, the possibility of unacceptable effects and the efficacy.

To grant authorisation / registration the product must:

- Contain only the active substances listed on Annex I / IA and all the Annex's requirements are fulfilled;
- No unacceptable risk to humans, animals, environment or other and is efficacious;
- Determine significant properties e.g. toxicology;
- Possess appropriate information that it can be properly used;
- Contain labelling and data sheet;
- Possess packaging, destruction, decontamination procedures.

After authorisation, authority identifies the data owner, any other companies which have the right to use the data on their behalf (Letters of Access), if data is new or existing and if any data protection already applies under existing national rules in their territory.

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Summary Data protection periods are implemented as shown below:

Data on	Purpose of submission	Time period
New active substance	First entry to Annex I/IA	15 years
Existing active substance	Following its entry onto Annex I/IA	Up to 10 years
Additional data on existing or new active substance	To maintain/vary the active substance's Annex I/IA entry	At least 5 years
New biocidal product	For the first authorisation of a biocidal product	10 years
Existing biocidal product	Following the product's authorisation	Up to 10 years
Additional data on existing and new biocidal product	To vary the conditions of a biocidal product's authorisation	At least 5 years

After data protection period has expired, no letters of access are required and any applicant can use this data.

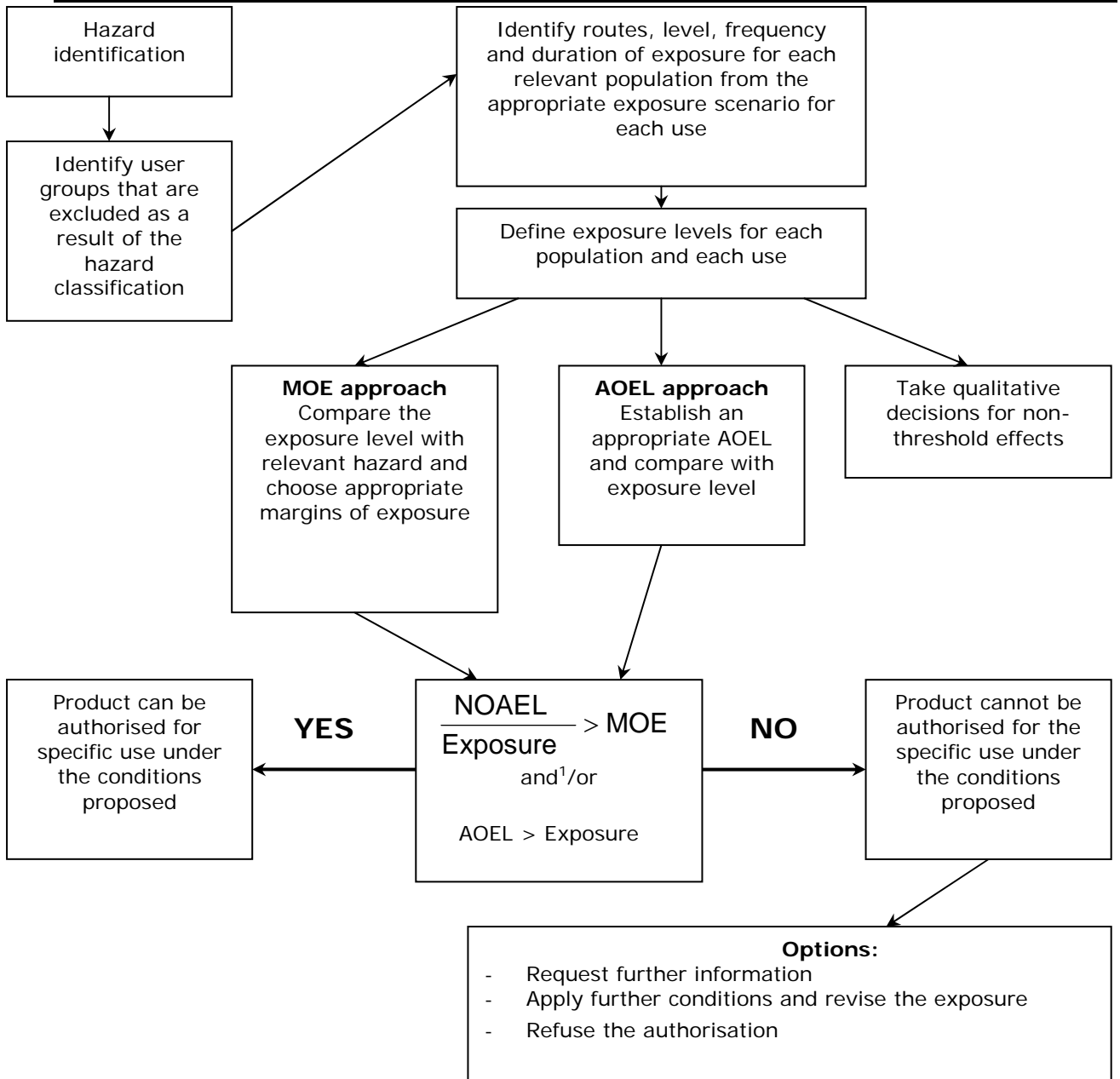



Figure 1: Summary Flow Chart of Risk Characterisation procedure

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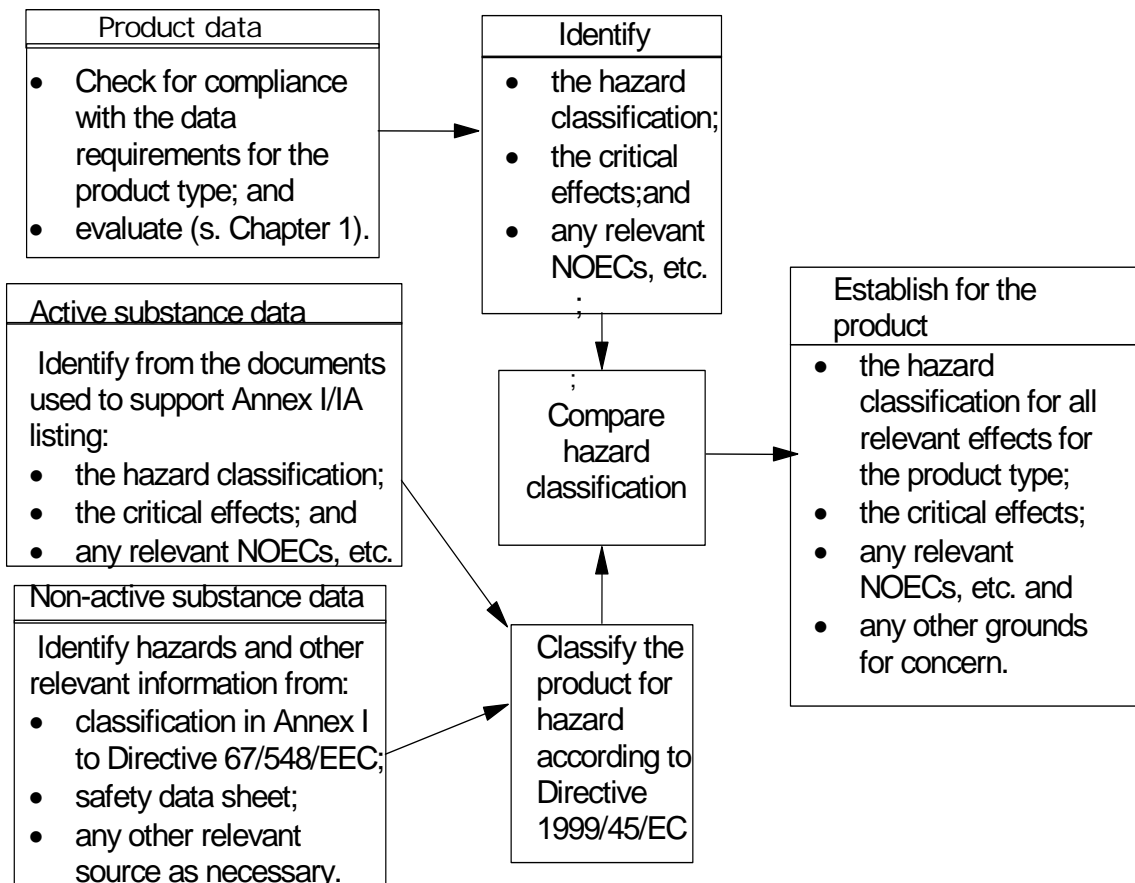



Figure 2: Summary Flow Chart of Hazard Identification procedure

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PREPARATION OF SUMMARY OF AUTHORISATION OR REGISTRATION


Article 8(10) of the Directive requires competent authorities to keep:

- a file containing a copy of the application;
- a copy of the summary of the dossiers submitted; and
- details of the administrative decisions taken for each application.

The summary produced should contain sufficient information to allow other Member States to trace how the decision to authorise or not to authorise a product was reached. In any case other Member States may require to receive the full information both on the product and the active substance(s), cf. Article 8(10) of the Directive.

The summary for each product evaluated should contain information to such detail to prove that the data requirements according to Annex II and III have been fulfilled. At least the following information is required:


1. Details of the applicant (authorisation/registration holder) and the formulator company, e.g. names, addresses and telephone numbers, etc.
2. Identity of the biocidal product, e.g. product name, name and percentage of active substance(s), formulation details, etc.
3. Identity of the product type to which the product belongs.
4. Procedure for evaluation (authorisation or registration) and date on which authorisation/registration were granted.
5. Summary of both the physical and chemical properties of the product and the methods of identification and analysis.
6. Summary of the risk assessment for human health including specific toxicological endpoints, potential for exposure and an overall integration of human health risk characterisation.
7. Summary of the risk assessment for the environment including effects assessment, exposure assessment and risk characterisation.
8. Unacceptable effects of the biocidal product e.g. resistance, unacceptable suffering of the target organisms, other effects.
9. Summary of the efficacy of the biocidal product including function of the product, evaluation of label claims, pests controlled, effects on target organisms, known limitations.
10. Summary of the final decision taken; in case of a negative decision a summary of the justifications leading to the decision must be taken.

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In addition, on each product authorised/registered, the following information is required:

- Classification, packaging and labelling for the biocidal product, e.g. hazard symbols, indications of danger, proposals for safety data sheets.
- Conditions of authorisation of the biocidal product, e.g. method of application, application rate, product type, field of use, user, proposed limits on residues (where appropriate), any other restrictions.

Where letters of access and/or reasoned cases are used to satisfy data requirements or specific data are not provided for a justifiable reason, sufficient explanation must be presented in the summary to ensure that Member States can fully comprehend the decisions made with respect to the application.

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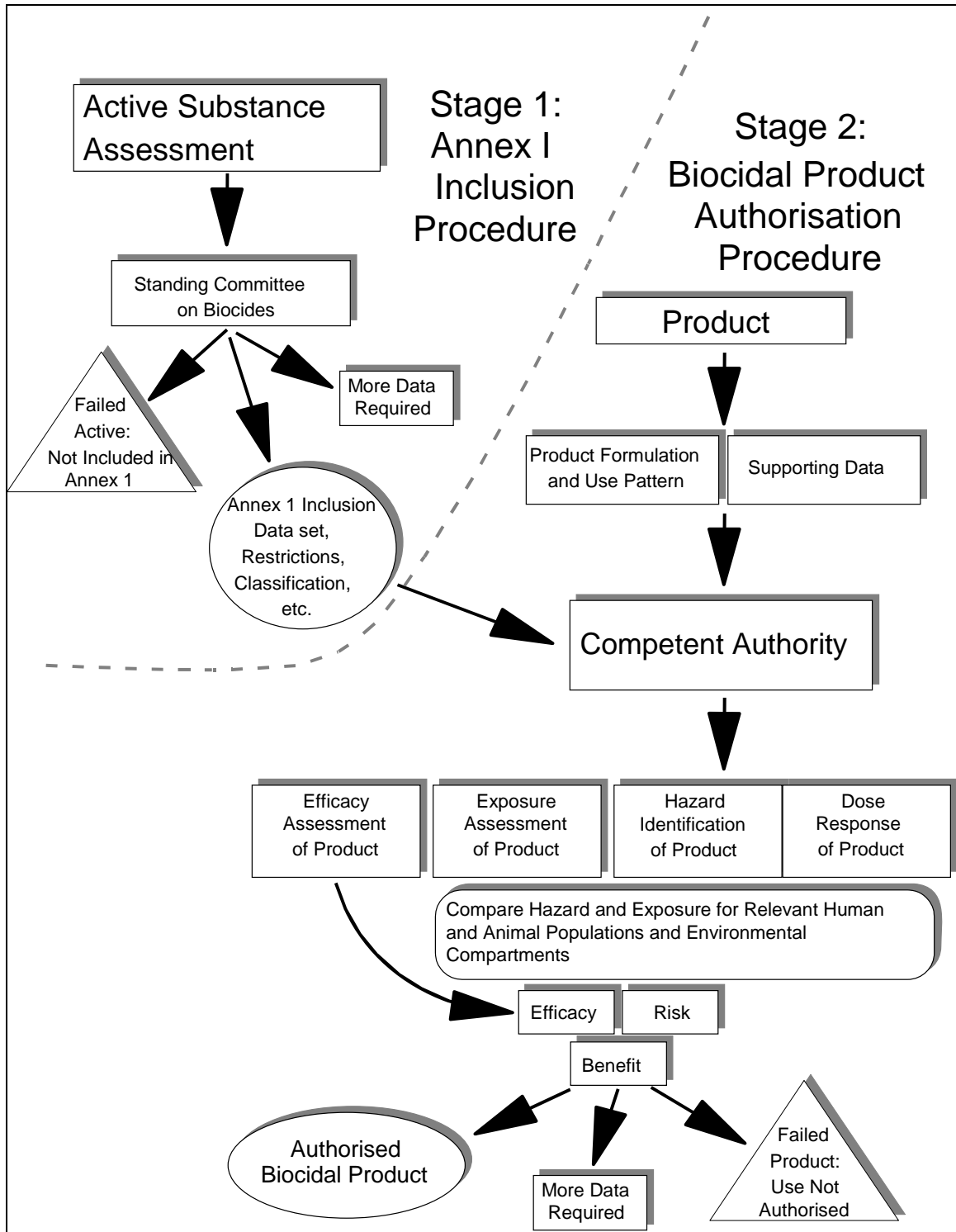



Figure 3: Overview of the authorisation process

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The checklist is not exhaustive and the items necessary will vary between product types and types of test as appropriate.	<p>Table: Summary of details that should be included in an efficacy study report</p> <p>The test Study/method The objective of the particular efficacy study The name, number and reference of any standard protocol used (if appropriate) Any deviations from standard protocols (if standard protocols were used) Validity criteria of the test Quality assurance</p> <p>Test Organism(s) The names (and where relevant, the strains and national collection numbers), origin and culture conditions of the organism(s) used Stage of the life cycle Age of the stadia (where relevant) Any selection pressure Numbers used in the test Sex of those used in the test (where appropriate)</p> <p>Active Substance and Formulation The identity, nature and full details of the formulation(s) used (where relevant) The solvent or diluent used The identity and concentration(s) of the active substance(s) present in the material tested Control and reference substance/product</p> <p>Study details Pre-conditioning of test species Application/delivery method used Application/dosage rate Test chamber construction/measurements Temperature, relative humidity and lighting during the test Number of replicates Controls Nutrient supply conditions Any additions or alterations to the test environment during the study Duration of the exposure to the biocide (contact time) Post monitoring of the test organism</p> <p>Results Dates of assessment Scoring or other assessment system used in the test Presentation of all results data including tabulation or graphical presentation of the summarised results Performance evaluation including fulfilment of validity criteria, interpretation, discussion and conclusions that relate to label claims</p> <p>Test reference Test reference including author(s), title, test house, test study number, year of publication/report, location of raw data and a statement on whether these results have been published (if so a full journal reference should be included where possible)</p>
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