Guidance for Waiving of Data Requirements for Pheromones for Inclusion in Annex I/IA of Directive 98/8/EC

This document was endorsed at the 18th meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (29-30 March 2005).

Disclaimer: This document attempts to provide guidance to Member States and industry on the data requirements for pheromones. It does not, intend to produce legally binding effects, nor does it pre-empt the outcome of discussions between participants and Rapporteur Member States regarding data requirements or the verification of completeness of submitted dossiers.

I. Introduction

This document provides guidance for waiving of data requirements for the four pheromones (one dipteran and three lepidopteran pheromones) for which a notification was received under Commission Regulation (EC) No 1896/2000.

The draft Guidance is based on the *OECD Monograph 12 (OECD ENV/JM/MONO(2001)12)*, the *UK document (TMIII04GEN-ITEM1B-UKCOMMENTS-IBMA AND TSGE.DOC)* and on comments received from other Member States. It takes into consideration the inherent differences between pheromones and conventional chemical biocides. Pheromones act by modifying the behaviour of the pest species rather than killing, are more target specific than conventional insecticides, are used at concentrations close to those in nature, and dissipate rapidly. For these reasons it is expected that most pheromones pose lower potential risk to human health and the environment than conventional biocides. Experience from the Plant Protection Products based on environmental and health studies has demonstrated that pheromones may provide effective pest control at low volumes, and at minimal risk. This draft Guidance, furthermore, takes into account that the exposure patterns for biocidal use of these four substances is different from the standard use of pheromones under the plant protection legislation, meaning that, among others, the OECD Monograph 12 does not specifically address all issues related to the biocidal use of the four pheromones.

In order for an active substance to be included in Annex I/IA of the Directive 98/8/EC a dossier on the active substance and an associated biocidal product dossier should be provided. The product dossier is required to ensure that the active substance can be used safely and is effective against the target organism in a biocidal product. The data requirements are laid down in Annexes IIA/IIIA and IIB/IIIB of Directive 98/8/EC for chemical biocides. These data requirements may be reduced for the family of chemicals that comprises the Straight-Chained Lepidopteran Pheromones (SCLPs), under the condition that sound scientific arguments are provided by the applicant. Similarly, for the dipteran pheromone certain data may not be required on scientific grounds. Table 1 and Table 2 in Appendix 1 provide a proposal for the core data set (Annexes IIA and IIB of Directive 98/8/EC) for the four pheromones, both for the active substance and for the product.

Additional data requirements according to the Annexes IIIA and IIIB of Directive 98/8/EC which are conditionally required depending on the hazard profile of the active substance, the exposure and use pattern are not specifically addressed in Appendix 1, but may need to be considered.

Table 1 and Table 2 in Appendix 1 also show how the data requirements considered by this draft Guidance differs from the OECD approach, which deals mainly with the outdoor use of pheromones as agricultural pesticides. Additional data may be required if the review of the data suggests that the use of the active substance through an associated biocidal product could pose a risk to human health or the environment.

While this specific Guidance document is especially prepared for waiving of data requirements for pheromones for inclusion in Annex I/IA according to Directive 98/8/EC, it might be also applicable in a modified form to other semiochemicals, e.g. allochemicals. It is important to note, in this context, that the main argument for the non-submission of a number of data

requirements is based on low exposure, so the first issue to confirm when checking if the applicability of the current guidance is if the exposure profile is similar.

II. Definitions

- *Semiochemicals* (SC) are chemicals emitted by plants, animals, and other organisms - and synthetic analogues of such substances - that evoke a behavioural or physiological response in individuals of the same or other species. They include pheromones and allelochemicals. This report pertains only to SCs that affect the behaviour of arthropods.
- *Pheromones* are semiochemicals produced by individuals of a species that modify the behaviour of other individuals of the same species (*i.e*. an intraspecific effect).
- *Straight-chained lepidopteran pheromones (SCLPs)* are a group of pheromones consisting of unbranched aliphatics having a chain of nine to eighteen carbons, containing up to three double bonds, ending in an alcohol, acetate or aldehyde functional group. This structural definition encompasses the majority of known pheromones produced by insects in the order Lepidoptera, which includes butterflies and moths.
- *Allelochemicals* are semiochemicals produced by individuals of one species that modify the behaviour of individuals of a different species (*i.e.* an interspecific effect). They include allomones (emitting species benefits), kairomones (receptor species benefits) and synomones (both species benefit).

III. Guidance for Reduced Data Requirements

Arthropod and other pheromones are inherently different from conventional biocides in their non-toxic, target-specific mode of action and natural occurrence. They are generally effective at very low rates, comparable to levels that occur naturally. They are generally volatile and usually dissipate rapidly in the environment. In addition, many end use products are formulated mainly in passive dispensers (hollow fibres, tapes) that present little direct exposure to humans and non-target organisms. All these factors minimise the risk of adverse effects from the use of pheromones.

The low exposure potential of arthropod pheromones in general and of SCLPs in particular are recorded e.g. in the *OECD Monograph 12* for their outdoor use as agricultural pesticides. It is further reported that

- the application rate is typically low and probably comparable to naturally efficacious concentrations
- volatility and rapid environmental transformation minimise residues in crops and exposure of non-target organisms for outdoor use
- SCLPs are of low toxicity to mammals.

IV. Data Requirements

1. Physical Chemistry

The draft Guidance considers that chemistry data should, wherever practicable, be provided in order to confirm the structure and characteristics of the active substance notified and supported under the Directive 98/8/EC. All the core data requirements for physico-chemical properties should be addressed by data or by a robust argument for waiving, which should always be based on sound science and may include theoretical data or calculated values with supporting arguments. General 'not applicable' statements are not considered robust and should not be considered as fulfilling a data requirement.

Where an applicant agrees to submit data for any physico-chemical endpoint to be evaluated, the designated Rapporteur Member State (RMS) should evaluate these data on a case-by-case basis and inform the applicant if it believes that further data are required in order to satisfy a particular endpoint.

The draft Guidance considers where appropriate, that data may be used to read across from the active substance to the biocidal product or *vice versa* as long as robust arguments can be presented to show that this is valid.

The draft Guidance understands that provision of all data on every active substance within the group SCLPs claimed could be difficult. However, the draft Guidance considers that representative data are required from studies or published literature for physico-chemical endpoints in order to aid the characterisation of the active substance involved and therefore enable an informed decision as to waiving of data for other end-points.

The information provided from the physico-chemical endpoints may also be used in some of the environmental and occupational exposure modelling programs for risk assessment. The information potentially required for these programs would include water solubility, volatility, vapour pressure, partition co-efficient and probably also relative density.

Specific Physico-chemical Endpoints

Melting point, boiling point and probably also relative density are properties that provide information on the physico-chemical characteristics of an active substance. It is accepted that the physical state of a chemical e.g. liquid, solid can be seen at room temperature however the required characteristic properties such as the melting point and boiling point cannot. Therefore, this information is required. The draft Guidance is in agreement with the *OECD Monograph 12* that suitable data or waiving arguments resp. should be submitted where appropriate for these endpoints. Applicants should also note sublimation/decomposition points may be more appropriate for certain active substances; it is up to the applicant to determine how to address these endpoints.

With respect to vapour pressure, water solubility, and partition coefficient endpoints again the draft Guidance concurs with the requirements listed in the *OECD Monograph 12* that these endpoints should be addressed for an active substance. As previously mentioned this information may also be required to complete the human and environmental risk assessments.

For the endpoint of surface tension the draft Guidance accepts that depending on the active substance this information is not always necessary or practicable and not listed as a requirement within the *OECD Monograph 12*. However, this is a core data requirement under the Directive 98/8/EC and the draft Guidance would suggest that in line with *OECD Monograph 12* justification should be provided rather than a 'not necessary' statement for fulfilment of this endpoint. The applicant should also consider when compiling any waiving argument whether these data would be required for the environmental risk assessment.

2. Efficacy

The applicant has to provide either efficacy data including the mode of action, the target organism, field of use or arguments against submitting data on the grounds that the "information is not necessary due to the nature of the biocidal product or its proposed uses need not be supplied. In such cases, a justification, acceptable to the competent authority must be submitted."

3. Mammalian Toxicology

The possibility of a reduction in toxicity data requirements in *OECD Monograph 12* is based on a number of arguments: low application rate and exposure, use of exposure controls (e.g. micro encapsulation), low toxicity with no reports of human toxicity and read-across to a well-characterised chemical group (notably straight-chained lepidopteran pheromones (SCLPs)).

These arguments are consistent with options for addressing toxicology data requirements described in the *TNsG on data requirements* and therefore can be applied to product specific guidance under the Directive 98/8/EC. The draft Guidance notes and agrees with the OECD concerns about active substances with potentially reactive moieties e.g. epoxides and substances with indications of toxic concerns in existing studies; i.e. that such concerns should be considered on a case-by-case basis, but should in general require a fuller toxicological consideration.

The *OECD Monograph 12* specifically mentions a 'well-characterised' group of substances, the SCLPs. The data package consists of a range of studies that includes a 90-day feeding study and a developmental toxicity study involving inhalation exposure. If this data package is to be referred to as bridging data on a generic basis by companies wishing to put SCLPs on the market under the biocides regulations then the draft Guidance suggests:

- For consistency of interpretation and efficiency, the suitability and interpretation of the package should be agreed by Member States once. It can then be referred to in multiple applications
- The chemical characteristics that an active substance must meet in order to be considered an SCLP or any other chemical group should be carefully defined and discussed.

In conclusion, the draft Guidance considers that in the context of the demonstration of negligible levels of exposure and duration of exposure of low concern, the data requirements detailed by the OECD i.e. acute toxicity, irritation, sensitisation and mutagenicity are in general sufficient and that the minimum data requirement for longer duration studies i.e. 90-day study detailed in the *TNsG on data requirements*, and other repeated dose studies, can be waived. With regard to read across to a 'well-characterised group' (e.g. SCLPs), the draft Guidance would consider each active substance on a case-by-case basis, assessing the size and quality

of the available data before accepting a read across argument. In addition, it should be noted that the provision of a dermal penetration assay would be considered on a case-by-case basis as discussed in the Human Exposure Assessment Section.

With regard to the exposure argument, it should be noted that if negligible levels of exposure cannot be demonstrated, e.g. in case of indoor use, then toxicology end points must be addressed by the options detailed in the *TNsG on data requirements*.
The draft Guidance agrees that medical data such as any reports on the effects (particularly adverse effects) of the substance on human health should be required, if available.

The *TNsG on data requirements* (chapter 1.4) offers a number of additional points that could be used to waive or address all data requirements without actual testing of the substance e.g. the test is scientifically not necessary, it is technically impossible to supply the information or the use of published literature. To offer the fullest options in the guidance these should be mentioned. In all these cases a justification needs to be written for the approach.

4. Human Exposure Assessment

There is agreement with the *OECD Monograph 12* for reduced data requirements, which is based on the following precepts:

- the application rate is typically low and probably comparable to natural emissions, if used outdoors
- volatility and rapid environmental transformation minimise residues in crops and exposure of non-target organisms, if used outdoors and
- SCLPs (Straight-Chained Lepidopteran Pheromones) are of low toxicity to mammals,

However it should be taken into consideration that – in case of use of pheromones as biocides – there are mainly indoor applications.

For occupational exposure – although applicators are mostly non-professionals– and for bystander exposure there should be sufficient information available to characterise this exposure potential. This would include consideration of application method and rate, and appropriate physico-chemical properties. For those active substances with significant exposure potential and/or those active substances with toxicological concerns, additional exposure data would be required.

The fundamental concept underlying the approach for human exposure assessment under the EU regime is the need to establish the full range of human exposure situations that could occur from the use of a biocidal product and therefore to consider all routes of exposure. The exposure assessment process requires determination of the patterns of use, identification of the exposed population, establishment the pathways of exposure and quantification of potential chemical intake. To this end, the *TNsG on human exposure* proposes a tiered approach to exposure assessment whereby, initially, an assessment is based on realistic ‘worst case’ assumptions. If the outcome of this risk assessment, based on worst-case exposure assumptions, is that the biocides is ‘not of concern’, then the risk assessment for that human population can be stopped and no further refinement of the exposure estimate is required. However, if the outcome is that a biocide is ‘of concern’, the assessment must, if possible, be refined using additional data and/or reasoned arguments based on expert judgment to allow a more informed decision. This tiered approach is a logical stepwise process to risk assessment and

uses the available information to the optimum extent while reducing unnecessary requirements for human exposure surveys or studies. The *TNsG on human exposure* should be consulted to check if relevant exposure scenarios and data are available in this source of information.

- Oral and Dermal Exposure

In the natural environment, it is unlikely humans would have direct oral or dermal contact with appreciable quantities of the active substance. However when used indoors as a biocide, humans could be exposed to quantities of the active substance which may have toxicological significance. Therefore, the potential exposure *via* oral and dermal routes for those handling and applying the product under normal working practices (primary exposure) will need to be addressed, as will the exposure of others who might come into contact with the active substance following application (secondary exposure). The form in which the product is packaged for marketing and use may determine the need to assess oral and/or dermal exposures to the product. For active substances which are volatile and unlikely to deposit on surfaces, the need to assess exposure to the active substance's residues may be unnecessary and therefore, residue data requirements might be waived (Please see also subchapter "Other Exposure Issues including Inhalation Exposure by indoor use").

In the absence of data derived from actual measurements of exposure during use of the active substance, generic model or surrogate data (published or unpublished, if accessible) can be used to estimate potential dermal exposure for comparison to appropriate toxicological end point(s). Alternatively, a 'reverse reference scenario' assessment could be undertaken, whereby the amount of active substance a person would need to be exposed to achieve a toxicologically significant dose can be calculated. If the 'reverse reference scenario' assessment shows that the person would need to be exposed to an unrealistic amount of the active substance then, in terms of dermal exposure, the proposed use of the biocidal product could be considered acceptable.

- Inhalation Exposure by outdoor use

The active substance acts by dispersal in the air; therefore human exposure *via* inhalation must be addressed.

There will be existing emissions of pheromones to which human beings could be exposed outdoors. The concentration of this emission can be estimated by simple calculation from data on the population density of emitting insects and the amount of substance emitted by individual insects per hour. Such a calculation would not take into account weather conditions e.g. air currents, and the consequent effect these conditions may have on the reduction in concentration of the substance in the air. The population density used in these calculations should be explained.

During outdoor use of the product, if the emission rates and resultant concentrations for the substance are at or below those that could occur via the emitting insect population then, providing there are no toxicological concerns, the product could be considered acceptable in terms of inhalation risk.

If the emission rates and resultant concentrations for the substance are above those that could occur via the emitting insect population, it will be necessary to estimate the contribution the artificially introduced pheromones makes to the outdoor exposure levels. This should then be added to an estimate of the exposure via the emitting insect population and compared to a toxicological end point, which is appropriate to an inhalation risk.

- Other Exposure Issues including Inhalation Exposure by indoor use

Exposure assessments will usually need to be made for an adult and, depending on use pattern, an infant or child, and any groups of people who might be considered particularly susceptible to the active substance, especially in case of indoor use. In some circumstances, exposure to livestock and/or companion animals may also have to be considered.

If food or animal feedstuffs are likely to become contaminated with the active substance in non-negligible amounts, residue data will usually be required. A scientific rationale, based on the low potential risk of any residues in food/feedstuffs would be required to waive the residue requirement.

To carry out a suitable and sufficient assessment of the risks to health, the draft Guidance considers sound information should be submitted to characterize and, if required, to quantify potential exposure for primary and secondary exposure scenarios. This includes details of:

- the biocidal product as marketed and in-use;
- where the biocidal product is to be used (including whether or not there is a potential for food/feedingstuffs to be contaminated);
- the method and rate of application (if diluted, the diluent(s) will need to be identified);
- for users and bystanders, the predicted frequency, the level and the duration of exposure and
- relevant physico-chemical data, such as vapour pressure for the active substance, the nature and probably the density of the biocidal product as marketed and the product as applied.

For active substances with toxicological concerns, additional exposure data may be required. Reasoned cases would have to be submitted in order to waive the need to estimate exposures, or undertake ‘reverse reference scenario’ assessments.

5. Environmental assessment

Directive 98/8/EC has a limited data requirement for environmental core data, and the general opinion of the Competent Authorities for implementing Directive 98/8/EC is that these core data cannot be waived. However, as the four pheromones are claimed to be highly target specific and not bioaccumulative and the emissions to environment could be so low that an argument not to perform all the core tests could be brought forward. Nevertheless, sufficient information has to be provided by the applicant to enable the evaluation of any risk arising to the environment from the use of pheromones.

The *OECD Monograph 12* provides guidance for a reduced set of data requirements with the general precursor that pheromones are inherently different from conventional pesticides in that they work by a non-toxic mode of action. This has been assessed for its applicability to the waiving of environmental data for pheromones as biocides.

Compared to agricultural pheromones the wide range of target organisms results in a greater diversity of use areas and patterns of biocidal pheromones. For example: ant or beetle attractants or repellents could be used in contact with ground unlike lepidopteran pheromones, which are generally dispersed at height. It is also possible to have repellents and attractants for use in water. Pheromones against clothes moths and moth that effect different foodstuffs are especially used indoor.

The draft Guidance's assessment of possible waiving arguments for environmental data describes a logical sequence to address data requirements and develop waiving arguments that might be acceptable for these actives substances. Each data requirement must be addressed and will be assessed on a case-by-case basis, this flexibility of approach is required for environmental assessment because of the diversity of biocidal products and exposure scenarios that are possible.

As data required for classification and labelling cannot be generated solely to satisfy this purpose, this evaluation considers only the data that would be required to satisfy biocidal data requirements and does not consider the classification and labelling requirements.

- Environmental core data requirements

According to *OECD Monograph 12*, for environmental data there is an all-encompassing proposal that if exposure – in case of outdoor use - is comparable to natural levels then the assessment of the active substance's fate in the environment and its ecotoxicity can be waived. The draft Guidance considers this to be an acceptable principle for data waiving.

With regard to the data to support the rationale that release of pheromones is comparable to natural emissions, the draft Guidance agrees, that as the effectiveness of pheromones is often dependent on olfactory systems that are tuned to natural emission rates, levels above this will not be effective. The *OECD Monograph 12* suggests that the application rate threshold of up to 375 g SCLP/ha/year, used by US-EPA as the threshold for not requiring an experimental permit for field trials as agricultural pesticides under 250 acres, can be used to represent natural emissions for SCLPs. Outdoor application rates of up to 375[1] g SCLP/ha/year are generally understood to result in exposure levels which are comparable to natural emissions and safe for non-target species. Therefore, environmental test data on arthropod pheromones will only be required if their use will result in environmental contamination exceeding natural environmental levels.

The draft Guidance considers that estimating emissions is an acceptable approach to show how comparable application rates are to natural levels for pheromones. To consider waiving of data requirements will depend on whether the applicant's argument that exposure is comparable to natural emissions is sufficiently robust.

- Environmental fate

[1] This value is taken directly from the OECD Monograph 12, and if used in a Biocide dossier documentation should be provided that this is a relevant value. A simple reference to the OECD Monograph, or US-EPA documents that just cite the value without explaining how it is derived and how it can be converted to an air concentration, is not sufficient.

The *OECD Monographs 12* states that pheromones generally dissipate rapidly in the environment, primarily by volatilisation and degradation. This is partly attributed to persistence being counterproductive to communication. But it has to be noted that while this may be generally applicable to insect pheromones, repellency, for example, is often communicated with persistence.

Studies referred to in *OECD Monograph 12* show that once active substances are volatilised in the field they are said to undergo photo-oxidation. Tests of dissipation of SCLPs occurring naturally or applied outdoors on moistened soil and in water indicate that degradation/removal can be rapid, with half-lives of 29 h and 30 h for (Z)-9-tetradecenal at 22^{o}C and 24^{o}C respectively. However, some SCLPs have been shown to have slight persistence in water (e.g. mixture of Z, Z and Z, E 7, 11-hexadecadien-1-ol acetate, with a half life of 7 d at 32^{o}C.).

The draft Guidance agrees that the limited persistence described above might make read-across arguments between SCLPs appropriate, provided the active substance contains no structural groups of concern. However, it is considered that while these data are applicable to lepidopteran pheromones, extrapolation to biting fly repellents or fly attractants, for example, would not be appropriate, as these products act by producing longer lived signals.

A further argument for rapid dissipation/non persistence of the active substance could be based on/supported by food residue data. While the draft Guidance accepts this approach, it would be dependent on the relevance of the time interval between application and sampling.

In accordance with the *OECD Monograph 12*, the draft Guidance considers that information about emission rates/locations and transport properties (volatility, vapour pressure, and water solubility) would be necessary to establish the compartments of concern. The draft Guidance considers that basic fate data, including read-across data, would be required for the compartment of concern. The data required would be triggered by the exposure assessment (e.g. a hydrolysis study or read-across data would need to be submitted where there is exposure to the aquatic compartment).

- <u>Ecotoxicity</u>

The *OECD Monograph 12* proposes that aquatic testing would only be required if the product was applied by air or directly to water or at rate exceeding natural levels, and it would not be required if the product was applied via a fixed dispenser on land. The draft Guidance considers that exposure from fixed dispensers on land would need to be assessed to indicate whether aquatic toxicity testing is necessary. Reasoned cases including mitigation measures such as placing the dispenser at a suitable distance away from water might be acceptable. Acute ecotoxicity data requirements could be addressed with basic fate if rapid degradation in the compartment of concern can be demonstrated.

- <u>Toxicity to honeybees and other beneficial arthropods</u>

The draft Guidance states that information/discussion to address whether behaviour or reproduction would be affected in bees is required as a minimum if the exposure is likely to exceed natural levels. The product-type 19 (repellents and attractants) specific data requirements for acute toxicity testing to bees or other beneficial arthropods are triggered by outdoor use.

However, if it could be demonstrated that pheromone exposure does not exceed natural levels, waiving is possible, depending on the robustness of the supporting data.

It considers that for potential effects on non-target insects, a discussion of available information may be sufficient, particularly if target specificity can be demonstrated, as with pheromones. Information on the mode of action provided for efficacy may also be useful for determining target specificity.

For biocides, the suggestion of using efficacy data where studies have exposed non-target species and reported the effects would be a suitable approach.

This has also been supported by the UK-Advisory Committee on Pesticides for Plant Protection Products. If there are species related to the target for which Biodiversity Action Plans (BAPs) exist, this must be taken into consideration.

The draft Guidance considers that basic fate data or read-across data would be required for the compartment of concern. If these data indicate rapid degradation, even in less toxic metabolites then this could be used to support a reasoned case to reduce some of basic ecotoxicity data in the same compartment.

If initial hazard studies indicate any persistence or ecotoxicity then further testing would be required.

6. Overall conclusions

In general, the draft Guidance considers that the basic principles of the *OECD Monograph 12* can be applied to the data requirements for pheromones according to Directive 98/8/EC. However, due to the wide range and the use pattern of biocides, fewer generalisations can be made. Each data requirement will need to be considered by the applicant and evaluated on a case-by-case basis by the RMS when an individual application is received. Also, when using read-across arguments from data on related active substances the draft Guidance considers that the original data on which the arguments are based should be submitted.

The draft Guidance considers also that all data including bridging arguments, where justified, have to be submitted that are necessary to undertake risk assessments for the biocidal uses of pheromones and to demonstrate biocidal efficacy.

APPENDIX 1

Guidance for Waiving of Data Requirements for Pheromones

for Inclusion in Annex I/IA of Directive 98/8/EC

The requirements for data or information are listed in the left column of the following table. Each requirement has been assigned a status of "R" or "CR" based on the APPENDIX 1 of the OECD Monograph 12[1] (ENV/JM/MONO(2001)12).

Waiving not possible (**R)** means that information is required; the requirement may be satisfied:

1. by data on the active substance;
2. by published information;
3. by surrogate information or bridging data to another substance, if both substances belong to a well-known group of substances, *e.g*. Straight-Chained Lepidopteran Pheromones (SCLPs); or
4. by a rationale based on scientific principles for non submission of data because it is unnecessary or technically impractical.

Waiving conditionally possible (**CR)** means that the information is required under the following conditions and in most cases further specified in the "Comments" column:

A scientific justification is required based on any of the following criteria on a case by case basis.

- Many of the data points marked CR represent types of information that are only required for high exposure scenarios, or if hazards are noted from other data points.
- Information in the "Comments" column further details the requirements or specifies particular cases for requesting a waiver.
- The following categories may be applicable for conditional waiving:
  - SCLP
  - Indoor use and/or only Outdoor use
  - Food contact and/or non-Food Contact
  - High human exposure, low human exposure or negligible human exposure to the active substance/biocidal product.

Table 1: Annex IIA (COMMON CORE DATA SET FOR ACTIVE SUBSTANCES (CHEMICAL SUBSTANCES))

Annex IIA Section No.	Dossier requirements	R/CR[ii]	Comments[ii]	OECD Monograph 12: requirements, conditions and comments[i]
I.	APPLICANT			
1.1.	Name and address, etc.	R		Required*
1.2.	Active substance manufacturer (name, address, location of plant)	R		Required*
II.	IDENTITY			
2.1.	Common name proposed or accepted by ISO and synonyms	R		Required
2.2.	Chemical name (IUPAC nomenclature)	R		Not directly addressed
2.3.	Manufacturer's development code number(s)	R	If available	Not directly addressed
2.4.	CAS and EC numbers (if available)	R	If available	Not directly addressed
2.5.	Molecular and structural formula (including full details of any isomeric composition), molecular mass	R		Not directly addressed but inferred from spectral identification
2.6.	Method of manufacture (syntheses pathway in brief terms) of active substance	R		Required
2.7.	Specification of purity of the active substance in g/kg or g/l, as appropriate	R		Required
2.8.	Identity of impurities and additives (e.g. stabilisers), together with the structural formula and the possible range expressed as g/kg or g/l, as appropriate	R		Required
2.9.	The origin of the natural active substance or the precursor(s) of the active substance, e.g. an extract of a flower	R	If relevant	Not directly addressed, but see also point 2.6.
2.10.	Exposure data in conformity with Annex VIIA to Directive 92/32/EEC	R	Exposure measurements (e.g. dosimetry) or exposure models based on phys.-chem. properties, e.g. saturated vapour concentration	Not addressed for the formulation process
III.	PHYSICAL AND CHEMICAL PROPERTIES			
3.1.	Melting point/ boiling point/ relative density	R/R/CR		Required
3.2.	Vapour pressure (in Pa)	R	Necessary for exposure estimation	Required
3.3.	Appearance (physical state, colour)	R		Required

Annex IIA Section No.	Dossier requirements	R/CR[ii]	Comments[ii]	OECD Monograph 12: requirements, conditions and comments[i]
3.4.	Absorption spectra (UV/VIS, IR, NMR), and a mass spectrum, molar extinction at relevant wavelengths, where relevant	R	To identify components	To extent necessary to identify components
3.5.	Solubility in water including effect of pH (5 to 9) and temperature on solubility, where relevant	CR	For one relevant pH and one relevant temperature for outdoor use / indoor water bodies	Not explicitly required for different pHs and temperatures
3.6.	Partition coefficient n-octanol/water including effect of pH (5 to 9) and temperature	R	At least for one relevant pH and one relevant temperature	Required, but may be waived if component hydrolyses in water or is soluble in water in all proportions
3.7.	Thermal stability, identity of relevant breakdown products	CR	To identify major mechanisms of degradation	Only thermal stability addressed
3.8.	Flammability	CR	Depending on the molecular structure[2]	Not directly addressed
3.9.	Flash point	CR	Depending on the molecular structur[1]e	Not directly addressed
3.10.	Surface tension	CR	Depending on the molecular structure	Not directly addressed
3.11.	Explosive properties	CR	Depending on the molecular structure	Not directly addressed
3.12.	Oxidising properties	CR	Depending on the molecular structure	Not directly addressed
3.13.	Reactivity towards container material	CR	Depending on the molecular structure[1]	Not directly addressed
IV.	ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION			
4.1.	Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of the active substance and additives (e.g. stabilises)	R		Analytical data and methodology (including spectral confirmation of identity required; also for impurities of toxicological concern, if indicated
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			Relevant if residue data are required
	(a) Soil	CR	Normally not required	

[2] There is no structural alerts that can be used to deduct this end-point; however it may be possible to provide scientific arguments for not performing the test

Annex IIA Section No.	Dossier requirements	R/CR[ii]	Comments[ii]	OECD Monograph 12: requirements, conditions and comments[i]
	(b) Air	CR	See point 3.2.; vapour pressure > 0,01 Pa;	
	(c) Water	CR	Normally not required	
	(d) Animal and human body fluids and tissues	CR	Normally not required	
V.	EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES			
5.1.	Function	R		Not directly addressed
5.2.	Organism(s) to be controlled and products, organisms or objects to be protected	R		Not directly addressed
5.3.	Effect on target organisms and likely concentration at which the active substance will be used	R	Concentration also needed for exposure calculations	Not directly addressed
5.4.	Mode of action (including time delay)	R		May be addressed by qualitative descriptions
5.5.	Field of use envisaged	R		Not directly addressed
5.6.	User: industrial, professional, general public (non- professional)	R		Not directly addressed
5.7.	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies	CR		Not directly addressed
5.8.	Likely tonnage to be placed on the market per year	R	Average amount if below 10 kg/year	Not directly addressed
VI.	TOXICOLOGICAL AND METABOLIC STUDIES			
6.1.	Acute toxicity. For studies 6.1.1 to 6.1.3, substances other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the substance and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route.			
6.1.1.	Oral	R		Required, but data may be waived if substance is a member of a well characterised group e.g. SCLPs and the acute toxicity of that group is described and especially when used only outdoor
6.1.2.	Dermal	CR	Depending on potential skin contact	As above
6.1.3.	Inhalation	R		As above

Annex IIA Section No.	Dossier requirements	R/CR[ii]	Comments[ii]	OECD Monograph 12: requirements, conditions and comments[i]
6.1.4.	Skin and eye irritation	R		As above
6.1.5.	Skin sensitisation	R		As above; but reporting of hypersensitivity incidences necessary
6.2.	Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study. For the following studies, 6.3 (where necessary), 6.4, 6.5, 6.7 and 6.8, the required route of administration is the oral route unless it can be justified that an alternative route is more appropriate	CR	Conditionally required, i.e. only when triggered by adverse effects or toxicolog. concerns arising from other data points (as OECD)	Conditionally required, i.e. only when triggered by adverse effects or toxicity concerns arising from other data points for health risk
6.3.	Short-term repeated dose toxicity (28 days). This study is not required when a sub-chronic toxicity study is available in a rodent	CR	Agree with OECD but also depending on the level, frequency and duration of exposure	Conditionally required if there is a significant exposure potential e.g. above background levels or if a tolerance/MRL will be set. Data may be waived if substance is a member of a well characterised group e.g. SCLPs and the repeated dose toxicity of that group is described
6.4.	Subchronic toxicity 90-day study, two species, one rodent / one non-rodent	CR/CR	Normally not required if there is no concern from toxicological profile and depending on the level, frequency and duration of exposure	Not directly addressed
6.5.	Chronic toxicity: One rodent / one other mammalian species	CR/CR	Normally not required if there is no concern from toxicological profile and depending on the level, frequency and duration of exposure	Conditionally required, i.e. only when triggered by adverse effects in mutagenicity or short term studies. Waived if long term exposure above background can be excluded
6.6.	Mutagenicity studies			Required but data may be waived if substance is a member of a well characterised group e.g. SCLPs and the mutagenicity of that group is described
6.6.1.	*In-vitro* gene mutation study in bacteria	R		As above
6.6.2.	*In-vitro* cytogenicity study in mammalian cells	R		As above
6.6.3.	*In-vitro* gene mutation assay in mammalian cells	R		As above
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)	CR		As above

Annex IIA Section No.	Dossier requirements	R/CR[ii]	Comments[ii]	OECD Monograph 12: requirements, conditions and comments[i]
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	CR		Not directly addressed
6.6.6.	If positive in 6.6.4 then a test to assess possible germ cell effects may be required	CR		Not directly addressed
6.7.	Cancerogenicity study; one rodent / one other mammalian species. These studies may be combined with those in 6.5	CR/CR	Agree with OECD, the trigger for cancerogenicity studies are adverse effects in mutagenictiy or repeated dose studies	Triggered by adverse effects in mutagenicity or short term studies; waiving if long term exposure above background can be excluded
6.8.	Reproductive toxicity			
6.8.1.	Teratogenicity test — rabbit / one rodent species	CR/CR	Agree with OECD and also depending on the level, frequency and duration of exposure	Required in one species if there is a significant exposure potential or if a tolerance/MRL will be set. Data may be waived if the substance is a member of a well characterised group, e.g. SCLPs and the repeated dose toxicity of that group is described. The teratogenicity study in the 2. species is triggered by adverse effects or toxicity concerns arising from other data points for health risks
6.8.2.	Fertility study — at least two generations, one species, male and female	CR	Agree with OECD and if there is no concern from toxicological profile and depending on the level, frequency and duration of exposure	Triggered by adverse effects or toxicity concerns arising from other data points for health risks
6.9.	Medical data in anonymous form			Medical data, available information required
6.9.1.	Medical surveillance data on manufacturing plant personnel if available	R		
6.9.2.	Direct observation, e.g. clinical cases, poisoning incidents if available	R		
6.9.3.	Health records, both from industry and any other available sources	CR	If available	
6.9.4.	Epidemiological studies on the general population, if available	CR	Normally not necessary	
6.9.5.	Diagnosis of poisoning including specific signs of poisoning and clinical tests, if available	CR	Normally not necessary	

Annex IIA Section No.	Dossier requirements	R/CR[ii]	Comments[ii]	OECD Monograph 12: requirements, conditions and comments[i]
6.9.6.	Sensitisation/allergenicity observations, if available	R		Data on hypersensitivity incidences
6.9.7.	Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known	CR		Not directly addressed
6.9.8.	Prognosis following poisoning	CR		Not directly addressed
6.10.	Summary of mammalian toxicology and conclusions, including no observed adverse effect level (NOAEL), no observed effect level (NOEL), overall evaluation with regard to all toxicological data and any other information concerning the active substances. Where possible any suggested worker protection measures should be included in summary form	R		Required
VII.	ECOTOXICOLOGICAL STUDIES			
7.1.	Acute toxicity to fish	R	Required unless exposure to surface water is not expected[3]	Testing of end-use product preferred
7.2.	Acute toxicity to *Daphnia magna*	R	Required unless exposure to surface water is not expected[3]	Not required for affixed dispensers on land, but data may be required for labelling; preferred to end-use product
7.3.	Growth inhibition test on algae	R	Required unless exposure to surface water is not expected[3]	EU permits waivers; preferred to end-use product
7.4.	Inhibition to microbiological activity	CR	If used outdoor and exposure assessment indicates concern	Required, but may be waived in case volatility, dissipation and degradation are rapid*
7.5.	Bioconcentration, Fate and behaviour in the environment	R	Calculation based on the log Pow	Required, but may be waived only if exposure is unlikely to exceed natural background levels (e.g. at > 375g/ha/year for SCLPs)
7.6.	Degradation			Required on a case-by-case basis, e.g. if ecotoxicity data or public literature indicate a hazard to biota
7.6.1.	Biotic			As above
7.6.1.1.	Ready biodegradability	R	If used outdoors and the exposure assessment indicates con-	As above

[3] Under the Directive 98/8/EC these are core data and the chapter 1.4 of the TNsG on data requirements clearly states that the environmental core data cannot be waived under normal circumstances. However, for the four pheromones notified under Directive 98/8/EC e.g. quantitative structure/activity – relationships combined with other relevant high quality, data may be sufficient to predict the acute ecotoxicology.

Annex IIA Section No.	Dossier requirements	R/CR[ii]	Comments[ii]	OECD Monograph 12: requirements, conditions and comments[i]
			cern[3]	
7.6.1.2.	Inherent biodegradability, where appropriate	R	If used outdoors and the exposure assessment indicates concern[3]	As above
7.6.2.	Abiotic			As above
7.6.2.1.	Hydrolysis as a function of pH and identification of breakdown products	CR	If used outdoors and the exposure assessment indicates concern	As above
7.6.2.2.	Phototransformation in water including identity of the products of transformation	CR	If used outdoors and the exposure assessment indicates concern	As above
7.7.	Adsorption/desorption screening test Where the results of this test indicate the need to do so, the test described in Annex IIIA Part XII.1 paragraph 1.2 shall be required, and/or the test described in Annex IIIA Part XII.2 paragraph 2.2	CR	Normally not required	As above
7.8.	Summary of ecotoxicological effects and fate and behaviour in the environment	R		Required
VIII.	MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT			
8.1.	Recommended methods and precautions concerning handling, use, storage, transport or fire	R		Not directly addressed
8.2.	In case of fire, nature of reaction products, combustion gases, etc.	CR		Not directly addressed
8.3.	Emergency measures in case of an accident	CR		Not directly addressed
8.4.	Possibility of destruction or decontamination following release in or on the following: (a) air (b) water, including drinking water (c) soil	CR		Not directly addressed
8.5.	Procedures for waste management of the active substance for industry or professional users			Not directly addressed
8.5.1.	Possibility of reuse or recycling	CR	Normally not required if not classified according to the principles of 67/548/EEC	Not directly addressed
8.5.2.	Possibility of neutralisation of effects	CR	Normally not required if not classified according to the principles of 67/548/EEC	Not directly addressed

Annex IIA Section No.	Dossier requirements	R/CR[ii]	Comments[ii]	OECD Monograph 12: requirements, conditions and comments[i]
8.5.3.	Conditions for controlled discharge including leachate qualities on disposal	CR	Normally not required if not classified according to the principles of 67/548/EEC	Not directly addressed
8.5.4.	Conditions for controlled incineration	CR	Normally not required	Not directly addressed
8.6.	Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms[4]	CR	See biocidal product	Preferred for end-use product
IX.	CLASSIFICATION AND LABELLING			Required by EU according to Directives 67/548/EEC and 99/45/EE
	Proposals including justification for the proposals for the classification and labelling of the active substance according to Directive 67/548/EEC Hazard symbol(s), Indications of danger, Risk phrases, Safety phrases	R		Required by EU according to Directives 67/548/EEC and 99/45/EE
X.	SUMMARY AND EVALUATION OF SECTIONS II TO IX	R		Not directly addressed

Annex IIIA (ADDITIONAL DATA SET FOR ACTIVE SUBSTANCES (CHEMICAL SUBSTANCES))

Data requirements regarding e.g. neurotoxicity, residues in food and feed, effects on life stock and pets, acute toxicity on other non target organisms, photo transformation in air are conditionally required depending on the hazard profile of the active substance, the exposure and use pattern.

Please note: For the consideration of the relevant dossier requirements, the elaborations of the *TNsG on data requirements* (e.g. chapter 2.5 and 3) are of special importance.

[4] For the four pheromones notified under Directive 98/8/EC data regarding effects on honey bees may not be needed if the applicant provides a scientifically sound argumentation as to why no effects on honey bees would be expected. Should the current Guidance be used to develop the data set for other active substances within product type 19 (Attractants and Repellents) this need for data on honey bees will be a case-by-case decision and must always be supported by scientifically sound arguments

Table 2: ANNEX IIB (COMMON CORE DATA SET FOR BIOCIDAL PRODUCTS (CHEMICAL PRODUCTS))

Annex IIB Section No.	Dossier requirements	R/CR[ii]	Comments[ii]	OECD Monograph 12: requirements, conditions and comments[i]
I.	APPLICANT			
1.1.	Name and address, etc.	R		Required*
1.2.	Formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s))	R		Required*
II.	IDENTITY			
2.1.	Trade name or proposed trade name, and manufacturer's development code number of the preparation, if appropriate	R		Required*
2.2.	Detailed quantitative and qualitative information on the composition of the biocidal product, e.g. active substance(s), impurities, adjutants, inert components	R		Data required on composition regarding: TGAI (technical grade of the active ingredient) as g/kg or g/l and regarding all other ingredients exceeding 1 g/kg. Where the manufacturing process is such that impurities and by-products which are particularly undesirable could be present in the TGAI, the content of each such compound must be determined and reported even if below 1g/kg (0.1% w/w)
2.3.	Physical state and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution	R		Required
III.	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES			
3.1.	Appearance (physical state, colour)	R		Required
3.2.	Explosive properties	CR	Depending on the chemical structure of the components of the biocidal product	To be addressed, where applicable
3.3.	Oxidising properties	CR	Depending on the chemical structure of the components of the biocidal product	Not directly addressed
3.4.	Flash-point and other indications of flammability or spontaneous ignition	CR	Depending on the chemical structure of the components of the biocial product	Not directly addressed
3.5.	Acidity/alkalinity and if necessary pH value (1% in water)	CR	Depending on the chemical structure of the components of	Not directly addressed

Annex IIB Section No.	Dossier requirements	R/CR[ii]	Comments[ii]	OECD Monograph 12: requirements, conditions and comments[i]
			the biocidal product	
3.6.	Relative density	CR	Depending on the chemical structure of the components of the biocidal product	To be addressed, where applicable
3.7.	Storage stability — stability and shelf-life. Effects of light, temperature and humidity on technical characteristics of the biocidal product; reactivity towards container material	CR	Depending on the chemical structure of the components of the biocidal product	Required
3.8.	Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability	CR	Depending on the chemical structure of the components of the biocidal product	Not directly addressed
3.9.	Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised	CR	Depending on the chemical structure of the components of the biocidal product	Not directly addressed
IV.	METHODS OF IDENTIFICATION AND ANALYSIS			
4.1.	Analytical method for determining the concentration of the active substance(s) in the biocidal product	R		Analytical methodology required for post-registration monitoring
4.2.	In so far as not covered by Annex IIA, paragraph 4.2, 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	CR	See active substance	Not directly addressed
	(b) Air	CR	See active substance	Not directly addressed
	(c) Water (including drinking water)	CR	See active substance	Not directly addressed
	(d) Animal and human body fluids and tissues	CR	See active substance	Not directly addressed
	(e) Treated food or feedingstuffs	CR	If relevant	Required, if a tolerance/MRL is required, i.e. if a pheromone is for use on food/feed crops and if a toxicity concern is raised by toxicity data
V.	INTENDED USES AND EFFICACY			
5.1.	Product type and field of use envisaged	R		Required
5.2.	Method of application including description of system used	R		Required

Annex IIB Section No.	Dossier requirements	R/CR[ii]	Comments[ii]	OECD Monograph 12: requirements, conditions and comments[i]
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	R		Required
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	R		Required
5.5.	Function, e.g. fungicide, rodenticide, insecticide, bactericide	R		Required
5.6.	Pest organism(s) to be controlled and products, organisms or objects to be protected	R		Required
5.7.	Effects on target organisms	R	See active substance	Qualitative description of the active ingredient's action is only required
5.8.	Mode of action (including time delay) in so far as not covered by Annex IIA, paragraph 5.4	R	See active substance	As above
5.9.	User: industrial, professional, general public (non-professional)	R		Not directly addressed but information on handling is required
5.10.	Efficacy data 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	R		Required including reporting of adverse effects to site (e.g. phytotoxicity)
5.11.	Any other known limitations on efficacy including resistance	CR		Not directly addressed
VI.	TOXICOLOGICAL STUDIES			
6.1.	Acute toxicity. For studies 6.1.1 to 6.1.3, biocidal products other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the product and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route			
6.1.1.	Oral	R	Can be calculated according to	Data may be waived if toxic potential of formu-

Annex IIB Section No.	Dossier requirements	R/CR[ii]	Comments[ii]	OECD Monograph 12: requirements, conditions and comments[i]
			the principles of the 1999/45/EEC in case the acute toxicity potential of formulant(s) are well known.	lant(s) are well known
6.1.2.	Dermal	CR	Depending on the potential skin contact. Can be calculated according to the principles of the 1999/45/EEC in case the acute toxicity potential of formulant(s) are well known	As above
6.1.3.	Inhalation	R	Can be calculated according to the principles of the 1999/45/EEC in case the acute toxicity potential of formulant(s) are well known	Required, but data may be waived: i.) for TGAI, if substance is a member of a well charactereised group e.g. SCLPs, and the acute toxicity of that group is described and ii.) for end-use product if toxic potential of formulant(s) are well known
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	CR		Not directly addressed
6.2.	Skin / eye irritation	R/R	Can be calculated according to the principles of the 1999/45/EEC in case the irritant potential of formulant(s) are well known	Required, but data may be waived: i.) for TGAI, if substance is a member of a well charactereised group e.g. SCLPs, and the toxicity of that group is described and ii.) for end-use product if toxic potential of formulant(s) are well known
6.3.	Skin sensitisation	R	Can be calculated according to the principles of the 1999/45/EEC in case the sensitising potential of formulant(s) are well known	As above
6.4.	Information on dermal absorption	CR	Normally not necessary	Conditionally required
6.5.	Available toxicological data relating to toxicologically relevant non-active substances (i.e. substances of concern)	R		Not directly addressed
6.6.	Information related to the exposure of the biocidal product to man and the operator Where necessary, the test(s) described in Annex IIA, shall be required for the toxicologically relevant	R	Estimation of exposure based on the necessary information (e.g. application method, rate, physical-chemical properties)	Estimation of exposure required based on available information (application method, rate, physical-chemical properties). Measurement by passive dosimetry or biological monitoring are condition-

Annex IIB Section No.	Dossier requirements	R/CR[ii]	Comments[ii]	OECD Monograph 12: requirements, conditions and comments[i]
	non-active substances of the preparation			ally required if the use description information and/or if toxicity tests or published data indicate concerned. Solid-matrix dispensers are unlikely to present significant exposure, but some sprayed applications might. Ambient air samples and data on clothing penetration, package integrity and on epidemiology are conditionally required
VII.	ECOTOXICOLOGICAL STUDIES			
7.1.	Foreseeable routes of entry into the environment on the basis of the use envisaged	R		Not directly addressed but addressed as stability and persistence in the environment (air, water and soil)*
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	CR		Not directly addressed
7.3.	Available ecotoxicological information relating to ecotoxicological relevant non-active substances (i.e. substances of concern), such as information from safety data sheets	R		Not directly addressed
VIII.	MEASURES TO BE ADOPTED TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT			
8.1.	Recommended methods and precautions concerning handling, use, storage, transport or fire	R		Required as precautionary measures
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 Annex IIA, paragraph 8.3	CR		Required as precautionary measures
8.3.	Procedures, if any, for cleaning application equipment	CR		Required as procedures to clean equipment and spills
8.4.	Identity of relevant combustion products in cases of fire	CR		Not directly addressed
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 con-	CR	Normally not required if not classified	Required as procedures to dispose unused products

Annex IIB Section No.	Dossier requirements	R/CR[ii]	Comments[ii]	OECD Monograph 12: requirements, conditions and comments[i]
	trolled discharge, and incineration			
8.6.	Possibility of destruction or decontamination following release in or on the following:			Not directly addressed
	(a) Air	CR	Normally not required	As above
	(b) Water, including drinking water	CR	Normally not required	As above
	(c) Soil	CR	Normally not required	As above
8.7.	Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms	CR	Only relevant for outdoor use	Conditionally required
8.8.	Specify any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms	CR	Normally not relevant	Not directly addressed
IX.	CLASSIFICATION, PACKAGING AND LABELLING	R		Required by EU according to Directives 67/548/EEC and 99/45/EC
	— Proposals for packaging and labelling			
	— Proposals for safety-data sheets, where appropriate			
	— Justification for the classification and labelling according to the principles of Article 20 of this			
	Directive			
	— Hazard symbol(s)			
	— Indications of danger			
	— Risk phrases			
	— Safety phrases			
	— Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging			
	materials to be included			
X.	SUMMARY AND EVALUATION OF SECTIONS II TO IX	R		Not directly addressed

Annex IIIB (ADDITIONAL DATA SET FOR BIOCIDAL PRODUCTS (CHEMICAL PRODUCTS)

Data requirements regarding e.g. acute toxicity on other non target organisms, other test(s) related to the exposure of humans are conditionally required depending on the hazard profile of the biocidal product, the exposure and use pattern

Please note: For the consideration of the relevant dossier requirements, the elaborations of the *TNsG for data requirements* (e.g. chapter 2.5 and 3) are of special importance.

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[i] For reasons of comparison, the conditions and comments laid down in APPENDIX 1 of the OECD Monograph 12 to each data requirements are listed in the right column of the table. In some cases* a short interpretation of these conditions and comments are used instead, developed by experts of the EU-drafting group on pheromones (Meeting in Vienna on 24./25.1.2005).

[ii] In both tables – concerning data requirements for the active substance and the biocidal product – the status of **R** or **CR** signed to each requirement including **Comments** are recommendation of the experts of the group mentioned above.