Evaluation Manual for the Authorisation of plant protection products and biocides

EU part

Biocides

Chapter 2 Physical and chemical properties

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Authors:
Ing. Tjaart-Jan Huizing & Drs. Ing. Marion Sanders
Coordination:
Dr. Janhendrik Krook

Lay-out:
Jiske de Wolf

ctgb

Board
for the authorisation
of plant protection products and biocides

Chapter 2 Physical and chemical properties

Category: biocides

GENERAL INTRODUCTION

This chapter describes the data requirements for the aspect physical-chemical properties and how these are evaluated in the EU framework.

1. EU FRAMEWORK

The procedure for inclusion of active substances in Annex I to the Biocides Directive 98/8/EC [1] is described under EU framework where only the procedure laid down in the EU is described. The NL procedure for evaluation of a substance is reverted to where no EU procedure has been laid down.

1.1. Introduction

Composition and physical-chemical properties are evaluated to prevent products being placed on the market which:

1. are of insufficient quality resulting in reduced applicability or reduced efficacy
2. may cause risks to user, public health and environment. This in particular concerns properties of the product that are relevant for the field of use and efficacy so that no undesirable effects occur during application of the product, such as precipitation of the product in the spray tank, excessive foam formation, or poor water-miscibility.

Properties of the formulation are also important from the point of view of safety and human health for which aspects such as flammability of the product and the presence of undesirable impurities are relevant.

A number of data regarding the physical-chemical properties of the product and the active substance are also used for evaluation of (eco)toxicological and/or environmental studies. For the aspect environment these are properties of the active substance such as n-octanol/water partition coefficient, pKa, water-solubility, vapour pressure and Henry coefficient. Relevant for the aspect toxicology are, e.g., composition, viscosity and surface tension of the product.
Another example is the attrition of granules and the particle size distribution of powders in the context of the operator risk evaluation.

The most important guidance documents for this chapter are:
- Technical notes on guidance (TNsG) on data requirements [2].
- Technical notes on guidance (TNsG) on product evaluation [3].
- Technical notes on guidance (TNsG) on Annex 1 inclusion [4].

1.2. Data requirements

In order to qualify for inclusion of an active substance in Annex I to 98/8/EC a dossier that meets the provisions laid down in Annex IIA, IIB, IIIA and IIIB to 98/8/EC must be submitted for the active substance as well as for the product.
The data requirements have been elaborated in the TNsG (Technical Notes of Guidance) on data requirements [2].
The data requirements in EU framework are first subdivided into data on the active substance and data on the product. These are then subdivided into ‘common core data’, i.e., data required for each product type and ‘additional data’, data that must be submitted in certain situations (e.g. depending on the field of use, expected exposure, toxicological properties and physical-chemical properties of the substance/product).
This is elaborated in the sections below.

The texts mainly originate from documents that have been drawn up in the context of 98/8/EC.

Good Laboratory Practice (GLP)
Directive 98/8/EC (Article 8, sub 8) stipulates that studies that are submitted with an application for authorisation should meet the methods described in Annex V to Directive 67/548/EEC. If a study has not been carried out according to one of the described methods, a study of equivalent quality may also be accepted.
The applicant must demonstrate the equivalence of the quality. The text of Article 8, sub 8 of Directive 98/8/EC reads as follows:

As a general principle, tests must be conducted according to the methods 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. Where appropriate, tests must be conducted in accordance with the provisions laid down in Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (1) and Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (2).

Directive 87/18/EC has meanwhile been replaced by 2004/10/EC.
The TNsG on data requirements reads as follows:

6.3 General principles
The general GLP principles are aimed at the chemicals defined in Council Directive 67/548/EEC. Thus, the laboratory studies on active substances or other substances (substances of concern) of a biocidal product must have been performed in accordance with the GLP Directive if the study was started after 30 June 1988. Laboratory studies on biocidal products performed later than 13 May 2000 must be conducted in compliance with the GLP Directive.

GLP is applied to the organisational processes and conditions under which the studies are planned, performed, recorded, archived and reported. The regulations are not concerned with the interpretation and evaluation of test results.

All physical-chemical studies and non-clinical health and environmental safety studies, i.e. toxicological, ecotoxicological, the analysis of the specimens of tests, field studies and residue trials have to be performed in accordance with the principles of GLP. The GLP principles, however, need not be applied to the efficacy and exposure studies. These studies should be done to an appropriate protocol and suitable QA (Quality Assurance) standards.

Exemptions of this general wish are given in section 6.3 of the same guidance document:

6.4 Exemptions
In general, the Biocidal Products Directive does not provide any flexibility for the acceptance of studies that have not been performed to GLP if they were started after 30 June 1988. Where a study was started before 30 June 1988, or a study did not require GLP certification before 13 May 2000 (e.g. physico-chemical studies on products) repeat testing will not normally be necessary provided the study is scientifically valid. The acceptance of other studies that have not been performed to GLP but were started after 30 June 1988 must always be decided on a case-by-case basis (see Chapter 1.3, point 4). In particular, in accordance with Article 8(8) of the Biocidal Products Directive needless repetition of testing on animals should be avoided.Article 16(1) in the Biocidal Products Directive provides that Member States may continue to apply their national regulations for data requirements of existing active substances until those substances have been included in Annex I.

In the Manual of decisions [5] the Member States arrives at the conclusion that the studies must be carried out in accordance with GLP but that deviations can be accepted if the studies meet the same quality standard. The EU Member States have subsequently agreed that the studies must have been prepared in accordance with to the GLP method.

Justification of the non-submission of data
Where the applicant holds the view that a certain study is not necessary, a relevant scientific justification can be provided for the non-submission of the particular study.
The TNsG on data requirements [2] reads as follows:

1.4 Guidance on non-submission on data
The basic principle is that the applicant must address all the data specified in the common core data set and in the additional data requirements in accordance with the detailed guidance given in Chapter 2, Chapter 2.5 and Chapter 3. In certain cases, waiving of data requirements is possible, but the applicant must always be able to justify the suggested exemptions from the data requirements.

The methods/guidelines form the table in Annex 1 should be observed in the performance of the required tests. If a different method is used a complete description of the method used must be given with a description of the differences in comparison with the required method. The reason for using an own method instead of the required method must be justified.

1.2.1 Data requirements active substance
Common core data
The text below in grey frames has been taken from the TNsG on data requirements [2]. The numbering in these grey frames follows the numbering of the TNsG on data requirements [2].
EEC methods are frequently mentioned in the text below, these can also be obtained via internet [6]

Identification of the active substance

1 APPLICANT [Ann IIA, I.]
1.1 Name and address, etc. [Ann IIA, I. 1.1]
- Names, address, telephone and fax numbers, e-mail, and other contact information of the applicant.

- The applicant shall be required to have a permanent office with a legally responsible representative within the European Community.

1.2 Active substance manufacturer [Ann IIA, I. 1.2.]
- Name, address and location of manufacturing plant.

In case the active substance is produced at more than one location the complete address of each location should be given.

2 IDENTITY [Ann IIA, II.]
- The information must be sufficient to identify the active substance, to define it on terms of its specification and to characterise it as to its nature. Chapter One gives the definition of “active substance as manufactured”.

2.1 Common name proposed or accepted by ISO and synonyms [Ann IIA, II. 2.2.]
- The name of the active substance must be given as registered in the list in Annex I to Directive 67/548/EEC or, if the name is not included therein, as given in EINECS or in ELINCS and the ISO common name of the substance, if available.
- Generally known names, trade names, abbreviations, etc. must be included.

If the active substance is a derivative of a substance with an assigned specified name, this should be clearly stated. Example: 2,4-D is the assigned ISO name, and the used active substance is the sodium salt or the methyl ester. This data requirement, however, has not yet been elaborated in EU framework; for this we refer to §2.2.1 of the NL part.

2.2 Chemical name [Ann IIA, II. 2.2.]
- The chemical name must be given according to IUPAC nomenclature and CAS-name, if different.
- For substances that may exist as isomers each isomer, if available, should be given correct designation.
- For substances of undefined or variable composition (UVCB), identity and proportion of compounds in reaction mixture should be given.

2.3 Manufacturer’s development code number(s) [Ann IIA, II .2.3.]
- Company(ies) code number(s) or internal name(s).

2.4 CAS- and EC-numbers [Ann IIA, II. 2.4.]
- The CAS-number, EC number (EINECS, ELINCS or No Longer Polymer List) and other numbers (e.g. CIPAC-number) must be given, if available.
- For mixture of isomers the CAS- and/or EC-numbers of the mixture and individual isomers should be given, if available.

The CIPAC number of a substance can be found on http://www.cipac.org/.
It is possible that different CAS and/or EC numbers apply to the active substance. In that case they should all be given.

2.5 Molecular and structural formula, molecular mass [Ann IIA, II. 2.5.]
- The molecular formula should be given according to the traditional Hill system and, where different, to the CAS-system.
- Full details of any isomeric composition must be included.
- An empirical formula should be determined for substances of undefined or variable composition, if possible.
- For polymers the number average molecular weight and the molecular weight distribution are required.
- OECD test guideline 118.

2.6 Method of manufacture of the active substance [Ann IIA, II. 2.6.]
- A description of the synthesis pathway in brief terms; the chemical reactions taking place, initial products and substances generated in the synthesis etc. must be presented.
- The method of extraction should be provided, where relevant.
- When relevant, where the data refers to a pilot plant production system, the information required must be re-submitted when the industrial scale production plant comes on stream and production procedures have stabilised.
- Chemical engineering data is not required as a rule, but submission may be required, where necessary.

A description of the production process is always required, also in case the substance is produced outside Europe.
The method according to which this must be evaluated has not yet been elaborated in EU framework. For this we refer to §2.2.1 of the NL part.

2.7 Specification of purity of the active substance, as appropriate [Ann IIA, II. 2.7.]
- Give typical concentration and upper and lower limits for typical commercial batches of the active substance in g/kg, g/l or % w/w (v/v).
- For substances of undefined or variable composition the purity is 100% minus unreacted starting materials.
- When relevant, where the data refers to a pilot plant production system, the information required must be re-submitted when the industrial scale production plant comes on stream and production procedures have stabilised and if production changes result in a changed specification and purity.

The draft guidance document on equivalence is used for evaluation of the equivalence of the active substance [7]. At this moment it is still unclear in EU framework when a 5-batch analysis must be submitted. For this we refer to §2.2.1 of the NL part.

The data requirements for specification of the active substance have not yet been elaborated in EU framework. For this we refer to the elaboration of the data requirements as described in §2.2.1 of the NL part.

2.8 Identity of impurities and additives, as appropriate [Ann IIA, II.2.8.]

- The following information on impurities and additives, including by-products of synthesis, optical isomers, degradation products (if the substance is unstable), unreacted and endgroups etc. of polymers and unreacted starting materials of UVC-substances, must be provided, where possible:
- common name and chemical name in conformity with 2.1. and 2.2.,
- CAS- and EC-numbers, if available,
- molecular and structural formula, molecular mass,
- the typical concentration and the range of concentrations expressed as g/kg, g/l or % w/w (v/v),
- the maximum content of active isomer and the ratio of the content isomer/ diastereoisomers, where relevant.
- An indication of the functions of the components added to the active ingredient (additives) prior to the formulation of the biocidal product (e.g. stabiliser, antifreeze, antifoaming agent, dispersing agent, and inhibitors) must be given.
- When relevant, where the data refers to a pilot plant production system, the information required must be re-submitted when the industrial scale production plant comes on stream and production procedures have stabilised and if production changes result in changed specification and purity. Substances present in quantities 1 g/kg or higher must be stated. Furthermore, quantities of substances below the concentration limit 1 g/kg, specified in Directive 67/548/EEC, Annex I, or which may be of toxicological or ecotoxicological significance (i.e. substances of concern) must be stated.

The data requirements for the nature of the impurities and additives have not yet been elaborated in EU framework. For this we refer to the elaboration of the data requirements as described in §2.2.1 of the NL part.

2.9 The origin of the natural active substance or the precursor(s) of the active substance [Ann IIA, II.2.9.]

- E.g. an extract of a flower.
- The scientific name of species, common name and strain, and polymer starting material should be given, if relevant.

The point above has not been elaborated in EU framework. The best possible agreement is therefore sought with the guidance document “concerning the data requirements for active substances of plant protection products made from plants or plant extracts”[8].

2.10 Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L154, 5.6.1992, p.1) amending Council Directive 67/548/EEC [Ann IIA, II.2.10.]

- Information should be sufficient to allow an approximate but realistic estimation of human (occupational and consumer) and environmental exposure associated with the production process, the proposed/expected uses and disposal of an active substance. Precise details of the production process, particularly those of a commercially sensitive nature, are not required. Substances manufactured outside the EU do not need a description of the manufacturing process for exposure estimation purposes. The prediction of the exposure levels should also describe a reasonable worst case situation, excluding accidental exposure and abuse. Exposure levels or concentrations need to be derived based on available measured data and/or modelling. A starting point is the report ‘Assessment of human exposures to biocides’, see reference EC 1998.

Information about the exposure during the production process only needs to be provided if the substance is exclusively manufactured as biocide and its production takes place within the 'European Economic Area' [9].

3 PHYSICAL AND CHEMICAL PROPERTIES [Ann IIA, III.]

Chapter 1, §1.3 sub 5 of the TNsG on data requirements [2] indicates the required purity of the active substance that must be used for the various tests, e.g. for the physical-chemical properties:

As a general rule, tests on a active substance should be carried out on the substance as it is to be supplied for formulation of the product for which the approval is applied for, including any essential additives (stabilisers etc.) and impurities. The "Active substance as manufactured" should be understood to mean the active substance in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product(s) and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. (cf. Directive 67/548/EC) A substance listed as an active substance in Annex I, IA or IB should be connected to what is active in the formulation. This means that a case-by-case decision must be taken by the competent authority on what to list e.g. simple ions or different molecular structures, precursor/activator, or unstable/breakdown active components, or multiple component products. A detailed description (specification) of the material used (i.e. a brief composition description for all batches used in tests), as provided for under paragraph A2.8 must be given. Where testing is done using an active substance the material used should be of the same specification as that which would be used in the manufacture of preparations to be authorised except where radio labelled material is used. All batches of a substance or a product used for testing should be representative of typical commercial material for which the approval is applied for and within the production concentration range. If for any test the composition of the substance or product is different from that quoted for commercial material, full details must be provided. Certain exceptions on this general rule are given in the Technical Note. When the long-term stability is in doubt, the composition should be measured before testing. Where appropriate, details of the stability of the substance in any vehicle used during testing should also be specified. For certain tests (e.g. some physico-chemical tests) there are specific requirements for purity of the active substance.

This is supplemented by the following in Chapter 2 of the TNsG on data requirements [2]:

- The information provides direct input parameters for assessing physical, chemical and technical hazards, as well as prerequisites for performing and guidance information for optimising other tests.
- Ideally, one batch of substance of stated specification should be used for all tests. If for any test the composition of the substance is different from that quoted in sections 2.7. - 2.8. then full details must be provided.

3.1 Melting point, boiling point, relative density [Ann IIA, III. 3.1.]

- These data must be studied for a purified active substance of stated specification.
- If the melting point or boiling point cannot be determined, the sublimation or decomposition temperature should be given.
- Measurements of the melting point and boiling point should be taken up to 360 °C.

- The boiling point should be measured at normal atmospheric pressure unless decomposition occurs, in which case reduced pressure can be used.
- Usually the freezing point of liquid substances should be determined if above –20 °C. An indication that no freezing has occurred during preliminary tests is also acceptable. For viscous liquids the pour point is an acceptable alternative.
- The density of gas should be calculated from its molecular weight and the Ideal Gas Laws. Polymer density should be determined by buoyancy methods, where appropriate.
- EC methods A.1 (Melting/freezing temperature), A.2 (Boiling temperature) and A.3 (relative density) based on OECD guidelines 102, 103 and 109.

3.2 Vapour pressure [Ann IIA, III. 3.2.]

- Vapour pressure at two temperatures (at 20 °C and 25 °C) or as a vapour pressure curve must be studied for the purified substance of stated specification. The unit is the Pascal (Pa).
- Where the vapour pressure is less than 10^{-5} Pa, the vapour pressure at 20 °C and 25°C may be estimated by a vapour pressure curve.
- The vapour pressure needs not to be measured, if calculations indicate that the value is significantly less than 10^{-5} Pa.
- The study needs not to be conducted (unless there are minor volatile impurities or degradation products etc. in the substance) if the melting point is above 300 °C. A limit value based on measurement or a recognised calculation method is sufficient where the melting point is between 300 °C and 200 °C.
- EC method A.4 based on OECD guideline 104.
- The Henry's law constant must be always stated for solids and liquids if it can be calculated. The Henry's law constant depends on the water solubility and vapour pressure of a substance, and expresses the tendency of a substance to evaporate from aqueous solutions. The unit should be stated as Pa x m^3 x mol^{-1}.

3.3 Appearance [Ann IIA, III. 3.3.]

- Physical state, colour and odour at 20 °C and 101,3 kPa.
- These data must be submitted both for a purified active substance of a stated specification and the active substance as manufactured, if different.
- A description of the odour associated with the active substance as manufactured and of a purified active substance as noted during the handling of the materials in laboratories or production plants, must be reported.

A description of the odour is only required if this can be noticed during safe use. It is not necessary to smell at the active substance to answer this question.

3.4 Absorption spectra (UV/VIS, IR, NMR), and a mass spectrum, molar extinction at relevant wavelengths, where relevant [Ann IIA, III. 3.4.]

- These data must be submitted for a purified active substance of stated specification.
- Absorption spectra and mass spectrum must be determined and reported for the identification of impurities of concern, where necessary.

The document Guidance on Spectral Analysis [10] can be used for making the spectra. Spectra must also be submitted for any relevant impurities that are included in the specification of the active substance.

The identity must be determined with all spectra and these spectra must be taken from the purified active substance of the applicant; a copy from a spectra handbook is not acceptable.
The data requirements for the absorption spectra (UV/VIS, IR, NMR), and mass spectrum and molecular extinction have not yet been elaborated in European framework. For this we refer to the elaboration of the data requirements as described in §2.2.1, NL part.

3.5 Solubility in water [Ann IIA, III. 3.5.]
- These data must be submitted for a purified active substance of stated specification.
- The studies must include the effect of pH (5 to 9) and temperature on solubility.
- Should be studied at or near 20 °C and for a substance the solubility of which is temperature dependent solubility at 10 °C and 30 °C should be reported, if relevant
- Must be studied when relevant. Water solubility should be measured unless the substance is hydrolytically unstable. Phrases such as “insoluble in water” are not sufficient; instead a limit test should be performed so that a positive statement can be made (e.g. until analytical limit). For complex mixtures, a mass balance may be the only practical method. However, the extract should be compared (e.g. HPLC) with the mixture to check for differential solubilities of components.
- Where the stability of the active ingredient in aqueous media is such that the water solubility cannot be determined, a justification based on test data must be submitted.
- Colloid and micelle formation and other possible observations must also be reported.
- EC method A.6 or the corresponding OECD guideline 105.

3.6 An additional data requirement.
3.7 An additional data requirement.
3.8 An additional data requirement.

Questions 3.6, 3.7 and 3.8 are discussed under *additional data*.

3.9 Partition coefficient n-octanol/water including effect of pH (5 to 9) and temperature [Ann IIA, III. 3.6.]
- These data must be submitted for the purified substance of stated specification.
- Where the stability of the active ingredient in aqueous media is such that the partition coefficient cannot be determined a justification based on test data must be submitted.
- For those substances which are extremely soluble in one of the phases a limit value should be provided. If necessary it can be based on the individual solubilities in n-octanol and water.
- If the test cannot be performed a calculated value should be provided, if relevant.
- EC method A.8. corresponding partly to OECD guideline number 107 and is partly similar to OECD guideline 117.
- A draft OECD guideline (pH metric) is planned to be finalised during spring 2000.

According to the description, the EEC method (or in fact: the HPLC method as well as the shake-flask method as described in EEC method A8) cannot be used for determination of the logPow of surface-active agents. The shake-flask method may nevertheless be accepted if it is clear that no problems (such as, e.g., a phase partition) have been observed during the test (and this has as such been included in the report) . The column-elution method is certainly not acceptable for surface-active agents.

For surface-active agents the report of the determination of the octanol-water partition coefficient should contain information about a phase partition, if any, to enable evaluation. The result may be supported by calculations on the basis of the structure (estimation method) and/or on the basis of the solubility in water and n-octanol separately.

3.10 Thermal stability, identity of relevant breakdown products [Ann IIA, III. 3.7.]
- Data on thermal stability to the point of melting, sublimation or decomposition is to be identified.
- If possible, the thermal breakdown compounds are to be evaluated and the possibility of formation of dangerous substances is to be considered.
- OECD guideline 113.

The identity of relevant breakdown products is only required if heating is used when using the active substance which may cause the breakdown, such as, e.g., smoke generators.

3.11 Flammability including auto-flammability and identity of combustion products [Ann IIA, III. 3.8.]
- The flammability of active substances which are solids, gases or substances which evolve highly flammable gases must be determined and reported according to EC methods A.10 (solids), A.11. (gases) and A.12 (contact in water) and pyrophoric properties according to EC method A.13. (solids and liquids)
- Substances with very low melting point (<50 °C) should be tested according to method A15 (Auto-ignition temperature, liquids and gases) and the test can be terminated at 400 °C.
- Test A12/A13 can be omitted if experience in use indicates that negative results would be obtained or if a substance is expected to react violently under the test conditions.
- The auto-flammability of the active ingredient must be determined and reported according to EC methods A.15 (liquids and gases) and A.16 (solids). A9 can be used for substances with a melting point below 100 °C.
- Considerations on further testing of substances with melting point less than 100 °C should be done on a case-by-case basis (UN transport classification methods are available).

3.12 Flash-point [Ann IIA, III. 3.9.]
- The flash-point must be provided for liquids whose vapours can be ignited.
- The closed cup method is the only acceptable procedure in general. If an open cup method has been used and the flash-point is above 70 °C, it may be acceptable.
- EC method A.9.

3.13 Surface tension [Ann IIA, III. 3.10.]
- The surface tension should be measured using an aqueous solution of sufficient concentration such that any surface activity potential is expressed; i.e. at 90% of saturation (the concentration must be quoted) to maximum concentration of 1 g/l (where viscosity permits). Inconsistencies between the water solubility result and the solubility reported should be fully addressed.
- EC method A.5 based on OECD guideline 115.

3.14 An additional data requirement.

Question 3.14 is discussed under *additional data*.

3.15 Explosive properties [Ann IIA, III. 3.11.]

- The test can be exempted when available thermodynamic information (heat of formation/decomposition) or absence of certain reactive groups in the structural formula or its “oxygen balance” establishes beyond reasonable doubt that the substance is incapable of decomposing, forming gases or releasing heat very rapidly.
- EC method A.14.

3.16 Oxidising properties [Ann IIA, III. 3.12.]

- In cases where an examination of structural formula establishes beyond reasonable doubt that the active ingredient is incapable of reacting exothermically with combustible material, it is acceptable to provide such information as justification for the non-determining of oxidising properties.
- EC method A.17. (solids)

EEC method A21 is meanwhile accepted and available for determination of the oxidising properties of liquids.

3.17 Reactivity towards container material [Ann IIA, III. 3.13.]

- Suitable container materials which are resistant against corrosion and do no react with the substance in question, and/or container materials that cannot be used with the substance, must be specified taking into consideration the properties of the chemicals (e.g. pH and impurities) and storage conditions (e.g. pressure and temperature).
- The information can be obtained from experience in use and the chemical structure.

8 MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

- Reference can be made to the corresponding data submitted for the product when it is also applicable to the active substance.

8.1 Recommended methods and precautions concerning handling, use, storage, transport or fire [Ann IIA, VIII. 8.1.]

- The guidance given for the corresponding data requirement for the product (paragraph B8.1) also applies here.

8.2 In case of fire, nature of reaction products, combustion gases, etc. [Ann IIA, VIII. 8.2.]

- The guidance given for the corresponding data requirement for the product (paragraph B8.4) also applies here.

8.3 Emergency measures in case of an accident [Ann IIA, VIII. 8.3.]

- The guidance given for the corresponding data requirement for the product (paragraph B8.2) also applies here.

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

- The guidance given for the corresponding data requirement for the product (paragraph B8.6) also applies here.

8.5 Procedures for waste management of the active substance for industry or professional users [Ann. IIA, VIII.8.5.]

- Information necessary for safe disposal including treated material must be given. If preliminary treatment of the waste is necessary, information about this must also be given. If the waste from the substance is classified as hazardous waste (e.g. according to Council Decision 94/904/EC1), this has to be mentioned separately and appropriate handling according to the related legislation indicated.
- More information is given in Part B section 8.5 (product specific guidance).

8.5.1 Possibility of re-use or recycling [Ann. IIA, VIII.8.5.1.]

- The possibility of recovery or recycling should be given for both normal uses of the substance and quantities involved in spills.

8.5.2 Possibility of neutralisation of effects [Ann. IIA, VIII.8.5.2.]

- Neutralisation procedures (e.g. by reaction with an alkali to form less toxic compounds) for use, for instance, in the event of accidental spillage must be described where they are feasible. Details to be given: proposed procedures for small and large quantities, evaluation of products of neutralisation (in small and large quantities), procedures for disposal of neutralised waste (in small and large quantities).

8.5.3 Conditions for controlled discharge including leachate qualities on disposal [Ann. IIA, VIII.8.5.3.]

- E.g. controlled landfill or extensive dilution (to be specified) before discharge to surfacewater.
- If a controlled landfill is recommended for use as a disposal sight, information about the necessary preliminary treatment, the fate of the waste in the landfill, the release of active substances or breakdown products from the waste etc. must be given.

8.5.4 Conditions for controlled incineration [Ann. IIA, VIII.8.5.4.]

- If the waste disposal method suggested is incineration, the compounds generated by burning (e.g. whether polychlorinated dioxins and furans or other halogen compounds can be formed), recommended burning conditions (temperature, reaction time and oxygen content) and other information needed for the safe incineration of the waste must be given.

More information about incineration of dangerous compounds is given in Directive 2000/76/EC[11].

8.6 Observations on undesirable or unintended side-effects, for example, on beneficial and other non-target organisms [Ann. IIA, VIII.8.6.]

- The guidance given for the corresponding data requirement for the product (paragraph B8.7) applies also here.

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 (OJ No L 20, 26.1.1980, p. 43.) [Ann. IIIA, VIII.1.]

- All biocides and their derivatives are classed in either List I or II. In addition other substances (additives, impurities) in the active substance as manufactured may fall within the scope of the Lists. Specify which substances are classed in List I and which in List II.

Additional data

The text below in grey frames has been taken from the TNsG on data requirements [2]. The numbering in these grey frames follows the section numbering of the TNsG on data requirements [2]. The additional questions below must always be answered for all product types, except question 3.7, 3.8 and 3.14 for product type 5.

3.6 Dissociation constant
- The acid-base constant (pKa, pKb) or another such constant should always be given if it can be determined.
- E.g. OECD guideline number 112 (Dissociation constant in water) only if water solubility cannot be measured.

In the example above “cannot” should be read as “can”. The identity of the dissociation products formed as determined on the basis of theoretical considerations should be reported. The pKa value of the active component should be given in case the active substance is a salt.

3.7 Solubility in organic solvents, including the effect of temperature on solubility [Ann. IIIA, III. 1.]
- Must be submitted for a purified active substance of stated specification.
- Must be examined using at least two common solvents with different polarities.
- Results should be given as mg/l of solvent.
- This data is usually not required for the product type 5.

CIPAC method MT 181 ‘solubility in organic solvents’ can be used if the solubility is higher than 10 g/l. CIPAC method MT 157 (water solubility) can be adjusted and used for lower concentrations.

3.8 Stability in the organic solvents used in biocidal products and the identity of relevant breakdown products [Ann. IIIA, III. 2.].
- Must be stated if the active substance as manufactured includes an organic solvent.
- Must be submitted for the active substance of stated specification.
- This data is usually not required for the product type 5.

3.14 Viscosity
- This data is always required for liquid substances, excluding product type 5.
- E.g. OECD guideline 114

Only the rotation viscometer can be used for determination of the (dynamic) viscosity of non-Newtonian liquids.

Where viscosity is required for classification of the active substance (assignment risk phrase R65; required if the active substance contains more than 10% hydrocarbons or is itself a hydrocarbon) viscosity must have been determined at least at a temperature of 40°C.

1.2.2 Data requirements product

Common core data

The text below in grey frames has been taken from the TNsG on data requirements [2]. The numbering in these grey frames follows the TNsG on data requirements.

For the evaluation of the substance in the context of 98/8/EC it is possible to submit a product dossier based on a dummy product.

1 APPLICANT [Ann IIB, I.]

1.1 Name and address, etc. [Ann IIB, I. 1.1.]

- Name, address, telephones and faxes numbers, e-mail and other contact information of the applicant.
- Applicant shall be required to have a permanent office with a legally responsible representative within the European Community.

1.2 Manufacturer/formulator of the biocidal product and the active substance(s) [Ann IIB, I. 1.2.]

- Name, address, telephone number including location of formulating plant(s).
- Contact information of formulator if other than the manufacturer.

2 IDENTITY [Ann IIB, I.]

- The information must be sufficient to identify each substance, to define it on terms of its specification and to characterise it as to its nature. The definition of “active substance as manufactured” is given in Chapter 1.

2.1 Trade name or proposed trade name, and manufacturer’s development code number of the preparation, if appropriate [Ann IIB, I. 2.1.]

- If different trade names are used in different Member States, all of those have to be cited.

2.2 Detailed quantitative and qualitative information on the composition of the biocidal product e.g. active substance(s), impurities, adjuvants, and inert components. [Ann IIB, I. 2.2.]

The following information must be given:

- The information on individual ingredients before mixing and the final composition of product shall be given. If a non-active ingredient is a preparation, full quantitative and qualitative specification of this preparation has to be given.
- The chemical name of each ingredient according to IUPAC or CA and their content in the product (g/kg). Trade names shall also be mentioned.
- CAS number and EC number (EINECS, ELINCS or No Longer Polymer List number).
- Structure or structural formula.
- Functions of the ingredients must be given (e.g. solvent, stabiliser).
- Classification of components according to Directive 67/548/EEC for the components or classification of preparations according to Directive 88/379/EEC amended by 1999/45/EC, as appropriate.

The applicant should indicate whether the product contains *substances that give cause for concern*. What these are, and any additional requirements, is extensively discussed in Chapter 4 of the TNsG on data requirements [2].

It has not yet been elaborated in European framework how the composition of a product must be stated. For this we refer to the elaboration described in §2.2.2.

2.3 Physical state and nature of the biocidal product [Ann IIB, I. 2.3.]
- E.g. emulsifiable concentrate, wettable powder, solution.

Here the classification made by FAO and WHO can be used, as described in Annex E of the FAO/WHO manual [12] or Appendix 2.

3 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES [Ann IIB, III.]
- The information shall provide direct input parameters for assessing physical, chemical and technical hazards, prerequisites for performing and guidance information for optimising other tests.

3.1 Appearance [Ann IIB, III. 3.1.]
- Physical state, colour and description of odour.
- For substances with intense odour or taste in water, a description of the substance(s) in question must be given, together with a threshold concentration for air or water, if available.

A description of odour or taste in water is only required if this can be noticed during safe use.

3.2 Explosive properties [Ann IIB, III. 3.2.]
- An acceptable justification for non-performance of a test for explosive properties is where none of the components are classified as explosive and where available thermodynamic information establishes beyond reasonable doubt that the product is incapable of exothermic reaction.
- EC method A.14.

3.3 Oxidising properties [Ann IIB, III. 3.3.]
- Oxidising properties do not have to be determined if it can be shown without reasonable doubt on the basis of thermodynamic information that the preparation is incapable of reacting exothermically with combustible materials.
- An acceptable justification for non-performance of a test for oxidising properties is where none of the components are classified as oxidising and where available thermodynamic information establishes beyond reasonable doubt that the product is incapable of exothermic reaction.
- EC method A.17.

EEC method A21 is available for determination of the oxidising properties of liquids.

3.4 Flash-point and other indications of flammability or spontaneous ignition [Ann IIB, III. 3.4]
- An acceptable justification for non-performance of a test for flammability properties is where none of the components are classified as flammable and where available thermodynamic information establishes beyond reasonable doubt that the product is incapable of exothermic reaction.

- The flash-point of liquids must be determined and reported according to EC method

A.9 and the flammable properties of solids and gases according to EC methods A.10 (solids), A.11 (gases), and A.12 (contact with water), as appropriate. The auto-flammability of preparations must be determined and reported according to A.15 (liquids and gases) or A.16 (solids), as appropriate.

3.5 Acidity/alkalinity and, if necessary, pH value (1 % in water) [Ann IIB, III. 3.5.]
- The product pH should be determined and if found to be acidic or alkaline, the quoted test method used.
- In cases where preparations are acidic (pH<4), the acidity and pH must be determined and reported e.g. according to CIPAC method MT31 (MT is Material Test) and where preparations are alkaline (pH>10) the alkalinity must be determined and reported e.g. according to CIPAC method MT 75. The pH of a 1% aqueous dilution, emulsion or dispersion of preparation must be determined e.g. according to CIPAC method MT 75, where relevant.

CIPAC methods can be requested via the website http://www.cipac.org/. CIPAC MT 75.3 is a revised method for pH determination and is therefore preferred.
For formulations intended for dilution with water, CIPAC method MT 191 can be used as well. For an aqueous product, the pH of the undiluted preparation must always be determined as well.

3.6 Relative density [Ann IIB, III. 3.6.]
- The relative density of liquid materials must be determined and reported according to EC method A.3. Preparations which are powders or granules must be determined e.g. according to CIPAC methods MT 33, MT 159, or MT 169, as appropriate.

3.7 Storage stability - stability and shelf-life [Ann IIB, III. 3.7.]
- Effects of light, temperature and humidity on technical characteristics of the biocidal product; reactivity towards container material.
- E.g. CIPAC methods MT 46, MT 39, MT 48, MT 51, or MT 54, as appropriate.

It has in EU framework not yet been elaborated how storage stability should be investigated. For this we refer to the elaboration as described in the NL part of the evaluation manual.

3.8 Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability [Ann IIB, III. 3.8.]
- The wettability of solid preparations which are diluted for use must be determined and reported e.g. according to CIPAC method MT 53.3.
- The persistence of foaming of preparations to be diluted with water must be determined and reported e.g. according to CIPAC method MT 47.
- The flowability of granular preparations must be determined and reported e.g. according to CIPAC method MT 172.
- The pourability of suspensions must be determined and reported e.g. according to CIPAC method MT 148.
- The dustability of dustable powders must be determined and reported e.g. according to CIPAC method MT 34.

The exact requirements for the technical characterisation of a product strongly depend on the field of use and product type. The FAO/WHO manual [12] can be used as guidance, or the requirements laid down per product type for the evaluation of plant protection products according to 91/414/EC.

3.9 Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised [Ann IIB, III. 3.9.]

- Those products and active ingredients with which the product will be used. Possible incompatibility with any products or active ingredients should be mentioned.

It has in EU framework not yet been elaborated how physical and chemical compatibility with other products should be investigated. For this we refer to the elaboration as described in the NL part of this evaluation manual.

3.10 An additional data requirement.
3.11 An additional data requirement.

Questions 3.10 and 3.11 are discussed under *additional data*.

8 MEASURES TO BE ADOPTED TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

8.1 Recommended methods and precautions concerning handling, use, storage, transport or fire. [Ann. IIB, VIII.8.1.]

- Provide technical safety precautions, including personal protective equipment when handling the product, e.g. during different stages of the process, to minimise the risk of exposure to humans and the environment. Appropriate precautions for substances/products which are flammable, oxidising, etc., should be given. Handling, storage and transport must take into account any surface which could directly or indirectly come in contact with the product, including for example: processing equipment, piping, ventilators, transport vehicles and their washing and cleaning, as well as protective clothing and shower areas for workers. Storage precautions should include ventilation system to be used for storerooms (in general terms and other conditions for storage, e.g. temperature regime). Precautionary measures during service should especially be considered in addition to the prevention of environmental effects and measures to be taken when the product is released to the environment due to an accident and misuse.
- Materials which are incompatible with the product, e.g. substances and products which may react with the active substance evolving toxic gases, and also other dangers such as reactions resulting in a large increase in volume, aggressive acidity, the possibility of dust explosions, etc., should be indicated.
- The precise type of fire-fighting equipment (i.e. both the type of extinguishing agent, including those to be avoided and any protective equipment), e.g. water or carbon dioxide, should be noted.

8.2 Specific treatment in case of an accident, for example, first aid measures following accidental eye or skin contact, ingestion or inhalation, antidotes, medical treatment if available; emergency measures to protect the environment; in so far as not covered by paragraph A8.3 (data set for the active substance) [Ann. IIB, VIII.8.2.]

- Provide precise medical data regarding first aid, proven antidotes, and proven medical treatment. This should detail the effectiveness of first aid, suggested antidote doses, etc. and include full documentation of reference sources. The information here is intended for the purpose of immediate first-aid treatment. It is not intended to replace definitive diagnosis and treatment, which can only be undertaken by a qualified medical doctor.
- Measures and courses of action in response to different kinds of accident scenarios (e.g. threat of release of the biocidal product, the product is actually being released

and release has already occurred) should be described. In addition actions to avert or stop release, minimise impacts of release, protect human life and property and recover the product and by-products should be indicated.

8.3 Procedures, if any, for cleaning application equipment. [Ann. IIB, VIII.8.3.]
- The procedures should be such that the likelihood of accidental contamination of water or its sediments is minimised.

8.4 Identity of relevant combustion products in cases of fire. [Ann. IIB, VIII.8.4.]
- It should be stated what gases are evolved, either by experiment or on the basis of structure, when the substance burns or when heated in the absence of air so that it simply decomposes, e.g. nitrogen oxides, phosgene or soot. Especially the identity of dangerous substances formed should be given (e.g. analysed according to the ISO standard 9122, Part 3, ISO 1993).

8.5 Procedures for waste management of the biocidal product and its packaging for industry, professional users and the general public (non-professional users), for example, the possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration [Ann. IIB, VIII.8.5.] Product-type-specific guidance is given here.
- Information necessary for safe disposal must be given. If preliminary treatment of the waste is necessary, information about this must also be given. If any waste generated is classified as hazardous waste (e.g. according to Council Decision 94/904/EC2), this has to be mentioned separately and appropriate handling according to the related legislation indicated.
- The possibility of recovery or recycling should be indicated for both normal uses of the substance and quantities involved in spills.
- A chemical or other disposal method for the product. Disposal methods for the waste generated when using the product (e.g. precipitates generated, instruments for spreading, residues treated with the product).
- Information must be given on how the package is to be emptied and cleaned and on the recycling or disposal method for empty packages.
- Recycling or disposal methods for the waste generated from a treated product, and in the processing of the treated product (e.g. shavings, cuttings or other waste from the treated product) and for treated products no longer in use (e.g. impregnated wood), if applicable.
- The guidance given for the corresponding data requirement for the active substance (paragraph A8.5) applies also here.
- When the product is applied to a system with water which is to be released into surface water with or without pre-treatment, as may be for product type 11 and 12, information on the necessary waste water treatment methods and times and/or the on minimum dilution for the active substance in waste water in order to assure a sufficient decree of degradation or dilution before being released into a water course to protect aquatic organisms from harmful effects.
- Recycling or disposal methods for the waste generated from a treated material (e.g. for chips from metal-cutting where the product is used), and in the processing of the possible treated material (e.g. waste from treated paper pulp or porous sand strata for product type 12) and for treated material or treated process water or metal working fluid no longer used, if applicable.

8.6 Possibility of destruction or decontamination following release in or on the following: (a) Air, (b) Water, including drinking water, and (c) Soil [Ann. IIB, VIII.8.6.]
- Prevention of health and environmental effects and measures to be taken when the product is released to the environment due to an accident or misuse. Provide details of measures necessary to quickly limit the consequences of accidental release to the environment, and to decontaminate areas affected by the accidental release. These may include neutralisation, destruction and removal procedures.

8.7 Observations on undesirable or unintended side-effects, for example, on beneficial and other non-target organisms [Ann. IIB, VIII.8.7.]
- E.g. unnecessary suffering and pain for vertebrates or effects on wildlife.
- Additionally, observations such as on adverse reaction to fastenings and fittings used in wood following the application of a wood preservative. It should also be reported if the substance is anticipated to have adverse effects on the air compartment, for example, which may contribute to the depletion of ozone layer, tropospheric ozone building, acidification, warming the atmosphere or degrading air quality.

8.8 Specify any repellents or poison control measures included in the preparations that are present to prevent action against non-target organisms. [Ann. IIB, VIII.8.8.]

Packaging
According to 98/8/EC, Article 20, biocides must be packed in accordance with Article 6 of Directive 88/379/EEC. This Directive has meanwhile been included in Directive 99/45/EC [13].

Material Safety Data Sheets
A Material Safety Data Sheet (MSDS or SDS) should be provided for each co-formulant for evaluation of the product. These must have been drawn up in accordance with Directive 91/155/EC [14] and its amendments 93/112/EC and 01/58/EC.

Directive 98/8/EC, Article 21, reads as follows about Material Safety Data Sheets:

The safety-data sheets shall be prepared:
– for biocidal products classified as dangerous and in accordance with Article 10 of Directive 88/379/EEC,
– for active substances used exclusively in biocidal products in accordance with the requirements of Article 27 of Directive 67/548/EEC.

In 98/8/EC a biocide is the active substance as well as the product; this means that a Safety Data Sheet must be provided for the product as well as the active substance. The Safety Data Sheets are used for labelling and to investigate whether the product contains relevant co-formulants.

Furthermore, Annex VI, the Common Principles for evaluation of dossiers for biocides to 98/8/EC reads:

66. The Member State shall take the necessary measures to ensure that the applicant proposes a label, and, where relevant, the safety-data sheet, for the biocidal product which:
– fulfils the requirements of Articles 20 and 21 of this Directive,
– contains the information on the protection of users required by Community legislation on worker protection,
specifies in particular the conditions or restrictions under which the biocidal product may or may not be used.
– Before issuing an authorisation the Member State shall confirm that these requirements must be satisfied.

Annex IIB to 98/8/EC stipulates that a Safety Data Sheet is also required for all relevant co-formulants for evaluation of the ecotoxicology:

7.3. Available ecotoxicological information relating to exotoxicological relevant non-active substances (i.e. substances of concern), such as information from safety data sheets

Additional data
The additional questions below must always be answered for all product types, except question 3.10 for product type 5, while question 3.11 is only applicable for granular products (usually from product types 16, 18 and 19).

3.10 Surface tension and viscosity
- Information is usually not required for product type 5.
- EC method A.5 or the corresponding OECD guideline 115 (Surface tension) and e.g. OECD guideline 114 (Viscosity).

Only the rotation viscometer can be used for determination of the (dynamic) viscosity of non-Newtonian liquids.

Where viscosity is required for classification of the formulation (assignment risk phrase R65; necessary if the product contains more than 10% hydrocarbons) viscosity must have been determined at least at a temperature of 40°C.

3.11 Particle size distribution
- Must be determined and reported for products that are supplied as powders or granules.
- Size, weight, shape (qualitative description as grit, cylindrical shape or precise dimensions of granules) should be produced for granular products, e.g. for product types 16, 18 and 19.
- E.g. OECD guideline 110.

CIPAC methods MT 178 (for granules general) and MT 178.2 (for water dispersible granules) can be used to determine attrition and friability characteristics of granules. CIPAC method MT 193 must be used for the attrition of tablets.

For the particle size distribution of powders, method CIPAC MT 187 can be used as well. The questions above may not be sufficient for a complete risk assessment. Additional questions may therefore be possible, provided that they can be justified in view of the properties of the active substance or the expected exposure [2]. Annex VI to 98/8/EC, the Common Principles for the evaluation of biocides, sub 5 of the introduction reads:

5. In order to carry out a risk assessment data are required. These data are detailed in Annexes II, III and IV and, recognising that there are a wide variety of product types, are flexible according to the product type and associated risks. The data required shall be the minimum necessary to carry out an appropriate risk assessment. Member States should take due consideration of the requirements of Articles 12 and 13 of this Directive in order to avoid duplication of data submissions. The minimum set of data required for an active substance in any biocidal product type, however, shall be that detailed in Annex VIIA to Directive 67/548/EEC; these data will already have been submitted and assessed as part of the risk assessment required for entry of the active substance into Annex I, IA or IB to this Directive. Data may also be required on a substance of concern present in a biocidal product.

Aerosol
If a product is placed on the market in the form of an aerosol, the guidelines for aerosols [15], with the corresponding data requirements, apply as well.
For the European assessment NL uses the elaboration as described in the NL part of the evaluation manual.

1.3. Risk assessment
An endpoint (such as, e.g., melting point, boiling point, vapour pressure etc) is derived from each study.

Evaluation methods to be followed
Chapter 1 of the TNsG on data requirements [2] sub 1.3 reads:

If new tests are performed in order to fulfil the data requirements, the following principles have to be followed:
1. According to Article 8(8), as a general principle, tests must be conducted according to the methods described in Annex V of Council Directive 67/548/EEC, according to the most recent adaptation to the technical progress. These are based on those recognised and recommended by international bodies in particular OECD. In the event of a method being inappropriate or not described, other methods used should, whenever possible, be internationally recognised and must be justified. Sources of recommended test methods are given in Chapter 1.6.

4. *Where test data exist that have been generated before the adoption of the Biocidal Products Directive by methods other than those laid down in Annex V to Council Directive 67/548/EEC, the adequacy of such data for the purposes of this Directive and the need to conduct new tests according to Annex V must be decided on a case-by-case basis, taking into account, amongst other factors, the need to minimise testing on vertebrate animals (Article 8(9))*. Such a decision should be first proposed by the applicant when collecting data for the application and then evaluated by the competent authority when checking the completeness of the application and approving the justification given for such a case. If a non-Annex V test has been performed, the nature of the differences must be indicated and justified (the same applies to deviations from the test protocol used). The test protocol should be provided in full unless there is sufficient detail in the test report. In certain cases, testing can be replaced by modelling using (Q)SAR, Quantitative Structure Activity Relation.
The guidance document for risk assessment for new notified substances and existing substances contains further information on this.

The following guidance documents are relevant for the evaluation:
– Croplife International (formerly GIFAP): Technical Monograph No. 17 [16]
– TNsG on data requirements [2].
– TNsG on product evaluation [3].

1.4. Approval

According to the Directive of the European Parliament and the Council of 16 February 1998 concerning the placing of biocides on the market (98/8/EC) it should be investigated whether biocides have, when approved, no unacceptable effect on the environment and in particular the health humans and animals (consideration 8) if used properly for the envisaged purpose, in the light of the current scientific and technical knowledge.
Article 5, 1, c and d stipulates that Member States only authorise a biocide if the product

Article 5, 1, c) and d):
(c) the nature and quantity of its active substances and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants, and its residues of toxicological or environmental significance, which result from authorised uses, can be determined according to the relevant requirements in Annex IIA, IIB, IIIA, IIIB, IVA or IVB;
(d) its physical and chemical properties have been determined and deemed acceptable for purposes of the appropriate use, storage and transport of the product.

Restrictions (co)formulants from Directive 76/769/EC

According to Directive 76/769/EC [17] certain substances are forbidden or are subjected to restrictions. Directive 03/53/EC, e.g., restricts the use of nonylphenol (NP) and nonylphenolethoxylates (NPE). The provisions of this Directive particular apply as from 17 January 2005. This means that as from that date the concentration NP and NPE in pesticides must be lower than 0.1% (m/m). For products that already had an authorisation on 17 July 2003 this means that the composition (if applicable) must be adjusted at the moment of re-evaluation (this thus also applies for products with an administrative authorisation and for extensions, except simplified extensions). Products for new authorisations must as from 17 July 2003 meet the new requirements.

1.4.1 Evaluation

The principles for the evaluation as regards the effects on humans, animals and the environment are presented in the Uniform Principles (Annex VI to 98/8). These concern the relevant sections of the introductory principles, the general principles and the specific principles for effects on humans and the environment.

The specific principles Physical and chemical properties are in the text below printed in a grey frame. This text, including numbering, is the verbatim text from Annex VI to Directive 98/8/EC.

Effects on humans
32. The exposure assessment shall be based on the information in the technical dossier provided in conformity with Article 8 of this Directive and on any other available and relevant information.
Particular account shall be taken, as appropriate, of:
– adequately measured exposure data,
– the form in which the product is marketed,
– the type of biocidal product,
– the application method and application rate,
– the physico-chemical properties of the product,
– the likely routes of exposure and potential for absorption,
– the frequency and duration of exposure,
– the type and size of specific exposed populations where such information is available.

Effects on the environment
44. The PEC, or qualitative estimation of exposure, shall be determined taking account of, in particular, and if appropriate:
– adequately measured exposure data,
– the form in which the product is marketed,
– the type of biocidal product,
– the application method and application rate,
– the physico-chemical properties,
– breakdown/transformation products,
– likely pathways to environmental compartments and potential for adsorption/desorption and degradation,
– the frequency and duration of exposure.

Directive 98/8/EC and the TNsGs contain no criteria for the tolerance of the concentration of the active substance in the product. For the European evaluation the Netherlands uses the elaboration as described in §2.4.1.

1.4.2 Decision making
The principles for decision making as regards the effects on humans, animals and the environment are presented in the Uniform Principles (Annex VI to 98/8/EC). These concern the relevant sections of the introductory principles, the general principles and the specific principles for effects on humans and the environment.
The specific principles Physical and chemical properties are in the text below printed in a grey frame. This text, including numbering, is the verbatim text from Annex VI to Directive 98/8/EC.

Uniform Principles
63. In the decision-making process the Member State shall take into consideration the following:
– the results of the risk assessment, in particular the relationship between exposure and effect,
– the nature and severity of the effect,
– the risk management which can be applied,
– the field of use of the biocidal product,
– the efficacy of the biocidal product,
– the physical properties of the biocidal product,
– the benefits of using the biocidal product.

66. The Member State shall take the necessary measures to ensure that the applicant

proposes a label, and, where relevant, the safety-data sheet, for the biocidal product which:
– fulfils the requirements of Articles 20 and 21 of this Directive,
– contains the information on the protection of users required by Community legislation on worker protection,
– specifies in particular the conditions or restrictions under which the biocidal product may or may not be used.
Before issuing an authorisation the Member State shall confirm that these requirements must be satisfied.

67. The Member State shall take the necessary measures to ensure that the applicant proposes packaging and, where appropriate, the procedures for destruction or decontamination of the biocidal product and its packaging or any other relevant material associated with the biocidal product, which conforms to the relevant regulatory provisions.

Effects on the environment
70. The Member State shall examine the relationship between the exposure and the effect, and use this in the decision-making process. A number of factors need to be considered when examining this relationship and one of the most important is the nature of the adverse effect of the substance. These effects include acute toxicity, irritancy, corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, neurotoxicity, reproduction toxicity together with physico-chemical properties, and any other adverse properties of the active substance or substance of concern.

The text in grey frames below has been taken from Chapter 2 and 5 of the TNsG on annex I inclusion. The numbering follows the numbering of the TNsG on annex I inclusion.

2.1 Hazard Assessment for Physico-Chemical Properties
The hazards should be assessed from each of the physico-chemical properties of an active substance according to the data requirements described in the TNsG on Data Requirements. The assessment can be carried out to the same principles described in chapter 3 of the TNsG on Product Evaluation.

And 5.1 also reads:

Composition of the Active Substance and Physico-Chemical Properties
- The minimum degree of purity must be defined.
- The identity of the impurities and their maximum content, and where relevant identity and content of isomers / diastereo-isomers and additives.
- Impurities of toxicological or environmental concern are within acceptable limits.
- The specification is within FAO specification where relevant.

1.5. Developments
The first biocidal products are now being evaluated in EU framework.
The activities in this context will result in amendments of the existing TNsGs and new documents will be drawn up.
The guidance document on equivalence is under development.

3. APPENDICES

Appendix 1: Requirements regarding the active substance

EU 98/8/EC	EU TNsG	description	explanatory notes	Method / guideline
IIA II 1.1	1.1	Applicant (name, address, etc.)		
IIA II 1.2	1.2	Manufacturer (name, address, including location of plant)	New data should be submitted as soon as possible after a change of location and/or manufacturer.	
IIA II 2.1	2.1	Common name proposed or ISO-accepted, and synonyms		
IIA II 2.2	2.2	Chemical name (IUPAC nomenclature)	Name of the compound as included in 67/548/EC or, if not included there, the corresponding (proposed) IUPAC and CA name.	
IIA II 2.3	2.3	Manufacturer's development code active substance		
IIA II 2.4	2.4	CAS, EEC and CIPAC number (if available)	CAS (Chemical Abstracts), EEC (EINECS or ELINCS) and CIPAC number should be given where they exist. If different numbers are applicable, they should all be given.	
IIA II 2.5	2.5	Molecular and structural formula, with complete data about isomer composition, where applicable, and molecular mass	Also, where relevant, for each stereo isomer and optical isomer of the active substance. Molecular mass is used by toxicology for evaluation of dermal absorption.	OECD 118
IIA II 2.6	2.6	Method of manufacture (synthesis pathway) of the active substance	It should be indicated for each plant which manufacturing method is used, including identity and purity raw materials, chemical synthesis routes, identity of the byproducts and impurities present in the end product. Where data originate from a pilot installation the required data must be re-submitted once industrial scale production methods and procedures have stabilised.	
IIA II 2.7	2.7	Specification of purity of the active substance in g/kg or g/l	Minimum purity active substance. If data originate from a pilot installation the required data must be re-submitted once industrial scale production methods and procedures have stabilised.	
IIA II 2.8	2.8	Identity of impurities and additives (e.g. stabilisers), together with the structural formula and its concentration interval in g/kg or g/l	The maximum content inactive isomers and the ratio between isomer and diastereo isomer content must, where relevant, be stated. The maximum content of each component, including byproducts and impurities, should be stated as well. It should be indicated whether impurities may occur in the active substance as produced.	
IIA II 2.9	2.9	Origin of the natural active substance or the starting	State with::	

EU 98/8/EC	EU TNsG	description	explanatory notes	Method / guideline
		material for the active substance, e.g., a flower extract	- Latin name of the plant, with common name. - genus, family, sub-family, variet/chemotype (if relevant) - geographical origin. - natural status; cultivated or wild; growth stage; growing conditions (if relevant) - parts of the plant that are used (if relevant) If the biocide is obtained by processing of the plant, state process as well.	
IIA II 2.10	2.10	Exposure data in accordance with Annex VIIA to Directive 92/32/EEC (*)	Not required if the active substance is produced outside the EU	
IIA II 3.1	3.1	Melting point, boiling point, relative density	Melting point: Measurements should be carried out up to 360 °C with the purified a.s. For a liquid the freezing point should be determined if this is higher than –20°C.	EEC methodA1 OECD 102
			Boiling point: Measurements should be carried out up to 360 °C under normal pressure with the purified a.s. This measurement is not necessary if the melting point is higher than 360°C.	EEC method A2 OECD 103
			If the melting point and/or the boiling point cannot be determined as result of decomposition or sublimation it should be indicated at which temperature this decomposition or sublimation takes place. This measurement is not necessary if the melting point is higher than 360°C	OECD 113
			Relative density: Necessary for liquid and solid active substances. (remark: *Relative density* has no unit)	EEC method A3 OECD 109
IIA II 3.2	3.2	Vapour pressure (in Pa)	Measurements should be carried out with the purified active substance at 20 and 25°C or with a vapour pressure curve. Where the estimated vapour pressure is lower than 10^{-5} Pa or if the melting point is higher than 300°C measurement is not required. This parameter is used for evaluation of environmental behaviour and for the toxicological evaluation of the respiratory risk.	EEC method A4 OECD 104

EU 98/8/EC	EU TNsG	description	explanatory notes	Method / guideline
			Henry's Law constant: of the purified active substance of liquids and solids is required if this can be calculated or determined. For liquid or solid active substances, Henry's Law constant must be determined or calculated from water-solubility and vapour pressure. For the calculation solubility and vapour pressure values should be determined at the same temperature. When calculated, in case of dissociation of the active substance in water, solubility of the neutral form should be used. This parameter is used in the evaluation of environmental behaviour.	Determination or calculation
IIA II 3.3	3.3	Appearance (physical state, colour)	Colour, odour and physical form at 20°C of the purified active substance as well as the active substance as produced should be described. The odour only needs to be reported if this is observed during safe use, or is already known.	
IIA II 3.4	3.4	Absorption spectra (UV/VIS, IR, NMR), and mass spectrum and molar extinction at relevant wavelengths, where applicable	The spectra (ultraviolet/visible light (UV/VIS), infrared (IR), nuclear magnetic resonance (NMR) and mass spectra (MS)) should be provided with a table with signal characteristics and with the molecular extinction at relevant wavelengths of the purified active substance. For the UV/VIS spectrum, wavelength and molecular extinction should be given for each maximum above 290 nm. The UV spectrum must (if the active substance dissociates in water) be recorded at 3 pH conditions (acid, neutral and alkaline conditions). For optical isomers optical purity must be determined as well. Only spectra of the (purified) active substance of the manufacturer himself can be accepted, not a spectrum from a catalogues (or similar). Also applicable to relevant impurities.	For UV/VIS : OECD 101
IIA II 3.5	3.5	Solubility in water, including effect of pH (5-9) and temperature on solubility, where applicable	Of the purified active substance. Where the active substance is capable to form ions in water, solubility must also be determined in the acid range (pH 4-6) and in the alkaline range (pH 8-10); otherwise in the neutral pH range only. Always measure at about 20°C. The effect of temperature on solubility must also be determined where relevant. This parameter is –also- used in the evaluation of the risk of leaching to groundwater.	EEC method A6 OECD 105 CIPAC MT 157

EU 98/8/EC	EU TNsG	description	explanatory notes	Method / guideline
IIIA III0§	3.6	Dissociation constant	The dissociation constant is required if dissociation in water occurs. De acid/alkaline constant(s) (pKa, pKb) must be determined. The dissociation products that are formed must be identified, if necessary on the basis of theoretical grounds. This parameter is used for the evaluation of environmental behaviour.	OECD 112
IIIA III 1.	3.7	Solubility in organic solvents, including the effect of temperature on solubility	Solubility of the purified active substance should be determined in at least two solvents with different polarity, including the effect of temperature. Usually not required for substances that are used in PT5.	E.g. CIPAC MT 181
IIIA III 2.	3.8	Stability in organic solvents used for biocidal products and identity of the relevant breakdown products	Stability of the active substance as manufactured should be determined if the substance as produced contains an organic solvent. Usually not required for substances that are used in PT5.	No method prescribed
IIA II 3.6	3.9	Partition coefficient n-octanol/water, including effect of pH (5-9) and of temperature	If the dissociation constant (pKa) of active substance is between 2 and 12, the effect of pH must be studied between pH 5 and pH 9 of the purified active substance. The correct method must be used to determine the partition coefficient (see OECD method description) because each method has its own solubility range. If the active substance is surface active (see AII 2.14), the partition coefficient must be calculated from the solubility in n-octanol and water separately. The temperature effect on the partition coefficient must be determined as well. This parameter is used for evaluation of environmental behaviour and the toxicological evaluation of dermal absorption.	EEC method A8 OECD 107 OECD 117 Calculation (in case other methods are not possible)
IIA II 3.7	3.10	Thermal stability, identity of the relevant degradation products	The thermal stability of the active substance (purified or technical) must be determined until melting point, sublimation point or until decomposition occurs. Where possible, the degradation products must be evaluated and the formation of dangerous substances must be described.	OECD 113

EU 98/8/EC	EU TNsG	description	explanatory notes	Method / guideline
IIA II 3.8	3.11	Flammability, including auto-flammability, identity of the combustion products	The flammability of solids (if melting point is higher than 50°C) and gases (both as active substance as manufactured) must be determined. For substances developing extremely flammable gases, flammability after reaction with water must be investigated, but can be omitted if the active substance is known to show a violent reaction with water. The auto-flammability of solids and liquids must also be determined at room temperature if the active substance is known to show a violent reaction at room temperature.	EEC method A10 (solids) EEC method A11 (gases) EEC method A12 (reaction with water) EEC method A13 (pyrophoric behaviour)
			Auto-flammability: required for gases, liquids and solids that are not explosive and do not ignite spontaneously upon contact with air at room temperature.	EEC method A15 (liquids and gases) EEC method A16 and/or, the UN-Bowes-Cameron-Cage-test (solids)
IIA II 3.9	3.12	Flashpoint	Required for liquids (with a melting point below 50°C)	EEC method A9, only closed-cup methods are permitted
IIA II 3.10	3.13	Surface tension	Surface tension is an important parameter for physical behaviour of the product in aqueous solvents. Penetration through membranes and pores (skin) is, e.g., also determined by surface tension. Surface tension is determined with a concentration of 90% of the solubility, with a maximum of 1 g/l. Determination is not required if solubility is lower than 1 mg/L. Surface tension of the active substance is used to be able to establish whether the method used to determine the n-octanol/water partition coefficient (see AII 2.8) is correct. Substances with a value below 60 mN/m are considered surface active.	EEC method A5 OECD 115
IIIA III0§	3.14	Viscosity	Required for liquids (with a melting point below 50°C) except for product type 5.	OECD 114

EU 98/8/EC	EU TNsG	description	explanatory notes	Method / guideline
IIA II 3.11	3.15	Explosion risk	The explosive properties of the active substance as manufactured must be determined. The friction test is not required for liquids. The flash test is not required if a liquid has a flash point (is inflammable). If no explosive properties of the active substance and the impurities and additives are expected on theoretical grounds (based on decomposition energy, the absence of certain groups or the oxygen balance), the question can be answered in the form of a sufficiently justified expert statement.	EEC method A14 The screening methods serving as basis for the statement are described in 'Recommendations on the transport of dangerous goods' (UN) p 398
IIA II 3.12	3.16	Oxidising properties	Must be determined for the active substance as manufactured. This serves to establish whether the substance may show an exothermal reaction with combustible material. Where no oxidising properties of the active substance, and impurities and additives are expected on theoretical grounds (such as the absence of certain elements or groups) the question can be answered in the form of a sufficiently justified expert statement.	EEC method A17 (solids) EEC method A21 (liquids) The screening method serving as basis for the statement is described in 'Recommendations on the transport of dangerous goods' (UN) p 401
IIA II 3.13	3.17	Reactivity towards packaging material	It should be indicated which are (un)suitable packaging materials for the active substance in view of corrosive properties, reaction with the active substance, properties of the active substance, and storage conditions. May, where applicable, be justified on the basis of experience and structure of the active substance.	

Appendix 2: FAO/WHO 2-letter code for formulations

Code	English name	NL name	Definition / clarification
AB	Grain bait	Lokmiddel op graanbasis	Special form of bait
AE	Aerosol dispenser	Aerosol spuitbus	Formulation in a container usually dispersed by means of a carrier gas as fine droplets or particles after activation of a push button
AI	Active ingredient	Active substance	
AL	Other liquids to be applied undiluted	Andere vloeistoffen voor directe toepassing	A liquid of which the formulation type is not yet included in this list
AP	Any other powder	Ander poeder (nog niet benoemd) voor onverdund gebruik	A powder of which the formulation type is not yet included in this list
BB	Block bait	Lokmiddel in blokvorm	
BR	Briquette	Briket	Solid block designed for slow release of the active substance in water
CB	Bait concentrate	Concentraat voor lokmiddel	A solid or liquid formulation intended for dilution before use as bait
CG	Encapsulated granule	Ingekapseld granulaat	A granule with a release-regulating and/or –protecting layer
CF	Capsule suspension for seed treatment	Capsule suspensie voor zaad behandeling	A stable suspension of capsules in a liquid for use as seed treatment, directly or after dilution
CL	Contact liquid or gel	Contact vloeistof of gel	A rodenticide or insecticide in the form of a liquid or gel for direct application or after dilution in case of a gel
CP	Contact powder	Contact poeder	Rodenticide or insecticide in the form of a powder for direct application; formerly called TP
CS	Capsule suspension	Capsule suspensie	A stable suspension of capsules in a liquid, usually diluted with water before use
DC	Dispersible concentrate	Dispergeerbaar concentraat	A homogeneous liquid used as a dispersion after dilution with water
DP	Dustable powder	Stuifpoeder	A loose powder used for dusting
DS	Powder for dry seed treatment	Poeder voor droge zaadbehandeling	A powder directly used for seed treatment
DT	Tablet for direct application	Tablet voor directe toepassing (individueel)	A tablet individually and directly used without preceding dilution
EC	Emulsifiable concentrates	Emulgeerbaar concentraat	A homogeneous liquid after dilution used as emulsion in water
ED	Electrochargeable liquid	Elektrostatisch oplaadbare spuitvloeistof	Special liquid formulation for electrostatic (or electrodynamic) spraying
EG	Emulsifiable Granule	Emulgeerbaar granulaat	A granule used as oil-in-water emulsion of active substance after disintegration, may contain water-insoluble co-formulants
EO	Emulsion, water in oil	Emulsie, water in olie	A heterogenic formulation in which the active substance is dissolved in water in fine droplets that are dispersed in an organic phase

Code	English name	NL name	Definition / clarification
EP	Emulsifiable powder	Emulgeerbaar poeder	A powder, possibly with water-insoluble co-formulants, which forms an oil-in-water emulsion after application
ES	Emulsion for seed treatment	Emulsie voor zaadbehandling	A stable emulsion for seed treatment, for direct application or after dilution
EW	Emulsion, oil in water	Emulsie, olie in water	A heterogeneous formulation in which the active substance is dissolved in the organic phase in fine droplets that are dispersed in water
FD	Smoke tin	Doos met rookmiddel	Special form of a smoke generator
FG	Fine granule	Fijn granulaat	A granule with a particle size distribution between 300 and 2500 µm
FK	Smoke candle	Rookstaaf	Special form of a smoke generator
FP	Smoke cartridge	Rookpatroon	Special form of a smoke generator
FR	Smoke rodlet	Rookstaafje	Special form of a smoke generator
FS	Flowable concentrate for seed treatment	Suspensieconcentraat voor zaadbehandeling	A stable suspension for seed treatment, for direct application or after dilution
FT	Smoke tablet	Rooktablet	Special form of a smoke generator
FU	Smoke generator	Rookontwikkelaar	A combustible formulation, usually solid, which after ignition releases the active substance in the form of smoke; see also the special forms of an FU: FK, FP, FW, FR, FT, FD
FW	Smoke pellet	Rookpellet	Special form of a smoke generator
GA	Gas	Gas (onder druk)	Pressurised gas in a bottle or tank
GB	Granular bait	Lokmiddel in korrelvorm	Special form of a bait
GE	Gas generating product	Gasontwikkelend product	A formulation that produces a gas through a chemical reaction
GF	Gel for seed treatment	Gel voor zaad behandeling	A homogeneous gel-type formulation for direct seed application
GG	Macrogranule	Macrogranulaat	A granule with a particle size distribution between 2000 and 6000 µm
GL	Emulsifiable gel	Emulgeerbare gel	A gel formulation for use as an emulsion in water
GP	Flo-dust	Stuifpoeder	Very fine powder for pneumatic application in greenhouses
GR	Granule	Granulaat	A solid formulation in the form of loose size-defined granules; see also the special forms of a GR: CG, FG, GG, MG
GS	Grease	Pasta op oliebasis	Very viscous formulation based on oil or fat
GW	Water soluble gel	Wateroplosbare gel	A gel formulation for use as an aqueous solution
HN	Hot fogging concentrate	Heet vernevelbaar concentraat	A formulation suitable for hot evaporation by means of special equipment, for direct application or after dilution
KK	Combi-pack solid/liquid	Combiverpakking vast/vloeibaar	A solid and liquid formulation, packed separately but in combination, for simultaneous application in a tank mix
KL	Combi-pack liquid/liquid	Combiverpakking	Two liquid formulations, packed separately

Code	English name	NL name	Definition / clarification
		vloeibaar/vloeibaar	but in combination, for simultaneous application in a tank mix
KN	Cold fogging concentrate	Koud vernevelbaar concentraat	A formulation suitable for cold evaporation by means of special equipment, for direct application or after dilution
KP	Combi-pack solid/solid	Combiverpakking vast/vast	Two solid formulations, packed separately but in combination, for simultaneous application in a tank mix
LA	Lacquer	Filmvormer	A solvent-based lacquer-forming formulation
LS	Solution for seed treatment	Oplossing voor zaadbehandeling	A clear to opal liquid for seed treatment, for direct application or after dilution with water. The liquid may contain water-insoluble co-formulants
LV	Liquid vaporizer	Vloeibare verdamper	A liquid formulation in a cartridge/flask for a special heating unit in which the formulation is evaporated
MC	Mosquito coil	Muggen spiraal	A smouledring coil releasing the active substance into the air as vapour or smoke
ME	Micro-emulsion	Micro-emulsie	A clear oil-in-water liquid for direct use or after dilution in water under formation of a micro-emulsion or a normal emulsion
MG	Microgranule	Microgranulaat	A granule with a particle size between 100 to 600 µm
MV	Vaporizing mats	Verdampende mat	A mat manufactured of inert material impregnated with the active substance, for a special heating unit in which the active substance evaporates slowly
OD	Oil dispersion	Olie dispersie	A stable suspension of the active substance in a non-water-dissolvable liquid, possibly with other dissolved active substance(s), for dilution in water
OF	Oil miscible flowable concentrate (oil miscible suspension)	Olie dispergeerbaar concentraat	A stable suspension of active substance(s) in a liquid intended for dilution in an organic phase for use
OL	Oil miscible liquid	Olie mengbaar concentraat	A homogeneous liquid for application as a homogeneous solution after dilution with an organic phase
OP	Oil dispersible powder	Olie dispergeerbaar poeder	A powder to be applied as a suspension in an organic phase
PA	Paste	Pasta op waterbasis	A water-based film-forming formulation
PB	Plate bait	Lokmiddel in platte vorm	Special form of bait
PC	Gel or paste concentrate	Gel concentraat	A solid formulation for application as gel or paste after dilution with water
PO	Pour-on	Oplossing voor algehele huidbehandeling	A solution to pour over the skin of animals, in high volumes (usually more than 100 ml per animal)
PR	Plant rodlet	Plantenstaafje	A rodlet, usually a few cm long, with an active substance
PS	Seed coated with a pesticide	Omhuld zaad	A pesticide-covered seed

Code	English name	NL name	Definition / clarification
RB	Bait (ready for use)	Lokmiddel (klaar voor gebruik)	A formulation designed to attract target animals and make them eat it. See also special forms of bait: BB, AB, GB, PB, SB
SA	Spot-on	Oplossing voor plaatselijke huidbehandeling	Solution for application on the skin of animals in a small volume, usually less than 100 ml per animal
SB	Scrap bait	Lokmiddel in brokken	Special form of bait
SC	Suspension concentrate (= flowable concentrate)	Suspensie concentraat	A stable suspension of active substance(s) in water intended to be diluted with water before use
SD	Suspension concentrate for direct application	Suspensie concentraat for directe toepassing	A stable suspension of active substance(s) in a liquid, in which other active substances may been dissolved, for direct application
SE	Suspo-emulsion	Suspo-emulsie	A heterogeneous solution of a stable dispersion of active substance(s) in the form of solid particles and fine droplets in water
SG	Water soluble granules	Wateroplosbaar granulaat	A granule of which after dilution the active substance really dissolves in water, but which may contain water-insoluble co-formulants
SL	Soluble concentrate	Met water mengbaar concentraat	A clear to opal liquid of which after dilution the active substance really dissolves in water, but which may contain water-insoluble co-formulants
SO	Spreading oil	Spreider	A formulation designed to form a film on the water after use
SP	Water soluble powder	Wateroplosbaar poeder	A powder of which after dilution the active substance really dissolves in water, but which may contain water-insoluble co-formulants
SS	Water soluble powder for seed treatment	Wateroplosbaar poeder voor zaadbehandeling	A powder for seed treatment which is before use dissolved in water
ST	Water soluble tablet	Wateroplosbaar tablet	Formulation of which tablet(s) are individually used to obtain a solution in water. May contain water-insoluble co-formulants
SU	Ultra-low volume (ULV) suspension	Suspensie voor ULV toepassing	A suspension for direct use in ULV equipment
TB	Tablet	Tablet	A tablet in defined form. See also special forms: DT, ST, WT
TC	Technical material	Technische stof	A material after the production process with the active substance, together with the corresponding impurities, possibly with a small amount of necessary additives
TK	Technical concentrate	Technisch concentraat	A material after the production process with the active substance, together with the corresponding impurities, possibly with a small amount of necessary additives and dilution liquid

Code	English name	NL name	Definition / clarification
(TP)	*(Tracking powder)*	*(Strooipoeder)*	No longer in use: see CP formulation
UL	Ultra-low volume (ULV) liquid	Oplossing voor ULV toepassing	A homogeneous solution for direct use in ULV equipment
VP	Vapour releasing product	Damp ontwikkelend product	A formulation with one or more active substances that evaporate in the air. The evaporation rate is usually controlled by suitable co-formulants or dispensers
WG	Water dispersible granules	Water dispergeerbaar granulaat	A granule giving a dispersion after disintegration in water
WP	Wettable Powder	Spuitpoeder	A powder used as a suspension in water
WS	Water dispersible powder for slurry treatment	Water dispergeerbaar poeder voor vochtige zaadbehandeling	A powder for seed treatment, used as a slurry with a high powder concentration
WT	Water dispersible tablet	Water dispergeerbaar tablet	Formulation where tablet(s) are individually used to obtain a dispersion of active substance in water after disintegration of the tablet
XX	Others	Diversen	Temporary category for all other formulations not yet included in this list
ZC	A mixed formulation of CS and SC	Een mengsel van CS and SC formuleringen	A stable suspensie of capsules and active substance(s) in a liquid, usually intended for dilution in water
ZE	A mixed formulation of CS and SE	Een mengsel van CS and SE formuleringen	A heterogeneous liquid with a stable dispersion of active substance(s) in capsules, solid particles and fine droplets in an aqueous phase, usually intended for dilution in water
ZW	A mixed formulation of CS and EW	Een mengsel van CS and EW formuleringen	A heterogeneous liquid with a stable dispersion of active substance(s) in capsules and fine droplets in an aqueous phase, usually intended for dilution in water

4. REFERENCES

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