Evaluation Manual for the Authorisation of Plant protection products and Biocides

NL part

Plant protection products

Chapter 2 Physical and chemical properties

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Board
for the authorisation
of Plant protection products and Biocides

Chapter 2 Physical and chemical properties

Category: Plant protection products

GENERAL INTRODUCTION

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

2. NL FRAMEWORK

2.1 Introduction

For the aspect physical and chemical properties, the data requirements for active substance and plant protection product and the evaluation methodology do not differ from the EU framework. The NL procedure is only described if no EU procedure has been described.

2.2 Data requirements

The data requirements for chemical crop protection products are in agreement with the provisions in EU framework. A further elucidation of the EU data requirements is given in the text below.

Where GLP is required, studies carried out after 25th of July 1993 should be performed to GLP.

2.2.1 Data requirements for the active substance

For the active substance the same requirements apply as described under EU framework. Further specifications are given in Appendix 1 of the NL part of the Evaluation Manual and the text below.

The European guidelines and guidance documents do not clearly show which requirements apply where in case of the active substance as such its salt or ester are used in the product. In principle, the (physical-chemical) properties of the substance that is applied in the product are required for the risk evaluation.
It is, however, possible to submit a reasoned justification per section provided that this is acceptable. The evaluation then focuses on the purpose of the question and the reasoning of the justification.

2.2.2 Data requirements for the plant protection product

Requirements for the plant protection product are the same as described under EU framework (see § 1.2.2) and as summarised in Appendix 2. Supplements are included in Appendix 4 and in the text below.

Composition
(NL:P01.4a ; EU:AIII 1.4)

The way in which the composition must be stated has not been elaborated at EU level.
The composition information must be presented in the template attached to the application form as available on the Ctgb website.
The composition of solid products and aerosols must be given in g/kg.

To avoid confusion, the composition of liquids must be given in g/kg (and/or in %m/m) as well as in g/l.
Where the active substance is added to the product as ester or salt, the active substance content must be given as free acid as well, e.g.:

X g/kg of the ester/the salt corresponds with Y g/kg of the free acid

Where the active substance is added to the product as hydrate, the active substance content must also be given as water free, e.g.:

X g/kg of the active substance as hydrate corresponds with Y g/kg of the active substance water free

The concentration of the active substance must be stated as *pure* active substance and also as *technical* active substance.

Where co-formulants are used in diluted form, the actual concentration of the particular co-formulant in the product should be stated.

According to Articles 3 and 4 of the Regeling Samenstelling Bestrijdingsmiddelen (Regulation Composition Pesticides) [5] restrictions have been imposed on the addition of colourants or odourants to a pesticide.

Material Safety Data Sheet
(NL:P01.4a; EU:AIII 1.4)

At European level, no clear term has been agreed for a material safety data sheet being (kept) up to date. Because up-to-date information is important for the risk evaluation, a clear term has been laid down for the Dutch evaluation. The material safety data sheets may not have been prepared or amended longer than 5 years before submission.

Storage tests
(NL:P02.07a; EU:AIII 2.7)

There is yet no agreement at European level about the manner in which initial measurements must be carried out. For reasons of clarity, the Dutch requirements are given here.
To enable determination of the possible decrease in active substance concentration in the product, measurements must be carried out in the same production batch.
The concentration should also be measured prior to the test (initial measurement).
Determination of a (possible) decrease against a reference (stated) concentration is not permitted. Intermediate measurements are in principle not required for 2-year storage tests but can be useful for additional study in case there are problems with the results after 2 years storage.

In the EU, possibility of extrapolation of packaging types is not described. In Appendix 2, a general guide to extrapolation of packaging types is described

A short storage test, at 54°C for 2 weeks, is not required for the Dutch application in case the 2-year storage test has already been executed. For European authorisations the storage stability test gives additional information about the behaviour of the product in countries with a warm climate.

Physical and chemical compatibility
(NL:P02.09a; EU:AIII 2.9)

Mixing of products has not been discussed at European level because this does not, or hardly, occur in the evaluation of substances. The Member States do, however, have regulations for addressing this data requirement in the national evaluation.

For reasons of clarity, the Dutch method of evaluation is included here. There is bilateral agreement about this evaluation with other countries (England and Germany).
If it is stated in the WGGA (Statutory Use Instructions/Directions for Use) or on the label that mixing with a different product is possible or recommended (or similar phrasing), this should be justified with a test for physical compatibility.
There is no test for chemical compatibility. This can be included in the test for physical compatibility by observing reactions such as gas formation, heat development of colour changes.

Currently, two methods are described for testing physical compatibility. The procedure "EVALUATION OF THE PHYSICAL COMPATIBILITY OF TANK MIXTURE" of the BAA (British Agrochemical Association) and the ASTM method E1518-99 "standard practice for evaluation of physical compatibility of pesticides in aqueous tank mixtures by the dynamic shaker method" [1]. Because research has shown that the ASTM method shows the best correlation with the field situation the ASTM method E1518-99 is preferred.

Supplementary data requirements on technical characteristics

Three specific questions are not yet included in the European evaluation whereas they are stated in the Uniform Principles (UP). The UP refer to the FAO for this question. There is no agreement about these questions because these types of products are not covered in the European substance evaluation.
These types of products are, however, requested in the Netherlands; the Dutch evaluation therefore reverts to the FAO method. The questions are included In the review table in Appendix 6.

<u>Tablets</u>
It should be demonstrated for tablets that must be dissolved in water, that they do rapidly disintegrate in water. Good attrition and friability properties should be demonstrated for all tablets.

Smoke generators
The burning rate of a smoke generator must be so stable that the operator runs no risk when used as instructed. It should be demonstrated that the preparation releases sufficient active substance, that the remaining material presents no risk to operator or environment, and that remaining material - if any – can be disposed of safely and according to the instructions.

Aerosols
The spraying pattern should be studied for homogeneousness according to FEA method 644. In addition, the spray diameter should be determined at 30 cm distance.

Packaging

Child-proof closure
A preparation for non-professional use which must be labelled as very toxic, toxic, or corrosive (see Chapter 4 Human toxicology, toxicological dossier), or which contains more than 3% methanol or 1% dichloromethane, ór a product to which risk phrase R65 has been assigned, must be fitted with a child-proof closure in accordance with the Warenwetbesluit veilige verpakking huishoudchemicalien (Food and Drug Order Safe Packaging Household Chemicals) [2], with exception of aerosols, unless the preparation is not dangerous according to Article 15f of the Nadere regels verpakking en aanduiding milieugevaarlijke stoffen (Further Regulations Packaging and Identification Environmentally Harmful Substances) [3]. The child-proof closure should meet ISO standard 8317.

Aerosols
Where the capacity of the container is at least 50 ml, this packaging (also) comes under the Warenwetbesluit drukverpakking (Food and Drug Order Pressurised Packs) [4].
The methods for testing and requirements are given in Directive 75/324/EC.

2.3 Risk assessment
The evaluation methodologies for chemical crop protection products comply with the description under EU framework.
Further elaborations of the EU procedure are presented in the text below.

The methods/guidelines from the tables in Appendix 1, 2, 3 and 4 should be observed when executing the studies. Where a different method is used, a complete description of the method used should be given, with a description of the differences in comparison with the required method. The reason for using a different method instead of the required method must be justified.

2.4 APPENDICES

Appendix 1 Requirements regarding the active substance, NL evaluation

EU data requirement	Description	Explanatory notes	Method / guideline	GLP
AII 2.1.1	Melting point or, if applicable, freezing point of purified active substance	Freezing point should be determined down to at least –20°C	EEC method A1 OECD 102	Yes
AII 2.1.2	Boiling point of purified active substance	Measurement is not required if melting point > 150 °C	EEC method A 2 OECD 103	Yes
AII 2.2	Relative density of purified active substance	Required for liquid and solid active substances. Density at about 20°C can also be submitted instead of relative density.	EEC method A 3 OECD 109	Yes
AII 2.4.2	Odour of active substance	Only if an odour is observed during processing or manufacturing of the active substance, this should be described		No
AII 2.5.1	Spectra of purified active substance: UV/VIS, IR, MR and MS	Besides the European requirements it should be stated whether the UV spectrum shows absorption between 310 and 400 nm (UV-A region) because this information is used as indicator for assigning safety phrases as regards dermal toxicology.	For UV/VIS: OECD 101	Yes

Appendix 2 Requirements regarding the product, NL evaluation

<table>
<tr><th>EU data requirement</th><th>Description</th><th>Explanatory notes</th><th>Method / guideline</th><th>GLP</th></tr>
<tr><td>AIII 2.1</td><td>Appearance (colour and odour)</td><td>Physical form of the preparation, and colour and odour if present. Odour needs only to be described where this is observed during normal and safe use.

Requirements: Any colouring of a product should be distinct (Art 4, Regeling Samenstelling Bestrijdingsmiddelen (Regulation Composition Pesticides) [5]). For odours, Art. 3 of the Regeling Samenstelling Bestrijdingsmiddelen applies.</td><td></td><td>No</td></tr>
<tr><td>AIII 2.5.1</td><td>Kinematic viscosity ULV preparations</td><td>Where the product contains more than 10% organic solvent (see also §1.2.2, question 1.4) viscosity should be determined at at least 40°C.</td><td>ISO 3104/3105, Capillary viscometer</td><td>Yes</td></tr>
<tr><td>AIII 2.5.2</td><td>Viscosity non-newtonian liquids</td><td>See AIII 2.5.1.</td><td>ISO 31269, rotation viscometer</td><td>Yes</td></tr>
<tr><td>AIII 2.5.3</td><td>Surface tension liquid preparations</td><td>Where the product contains more than 10% organic solvent (see text for additional information) surface tension of the undiluted product must be determined at 25°C or 40°C.</td><td>EEC method A 5
OECD 115</td><td>Yes</td></tr>
<tr><td>AII 2.6.1</td><td>Relative density liquid preparations</td><td>Density at about 20°C can be submitted instead of relative density.</td><td>EEC method A 3
CIPAC MT 3
OECD 109</td><td>Yes</td></tr>
<tr><td>AIII 2.7.3</td><td>Shelf-life at ambient temperatures</td><td>The Dutch evaluation allows packaging extrapolation (suitability of packaging to its contents) as follows:
<table>
<tr><td>Worst case</td><td>Extrapolation to</td></tr>
<tr><td>HDPE</td><td>HDPE co-extruded packaging with additional barrier made of e.g. polyamide (PA), ethylvinylalcohol (EV, EVAL, EVOH) or fluorinated (F).</td></tr>
<tr><td>LDPE</td><td>Additional barriers like paper, aluminium as long as LDPE is the layer in contact with the formulation, e,g. LDPE/Aluminium/paper.</td></tr>
</table>
Other packaging types are not extrapolated unless a solid argumentation is</td><td></td><td></td></tr>
</table>

EU data requirement	Description	Explanatory notes	Method / guideline	GLP
		provided.		
AIII 2.8.3	Dispersibility tablets	It should be demonstrated that the tablets disintegrate rapidly in water and that the formulation dissolves or disperses rapidly. Test is required for all tablets that are dissolved in water before use. Requirements: not yet specified	Not yet available	Nee
AIII 2.8.6.3	Attrition and friability tablets	Tablets must remain intact to avoid risk for the operator (dust formation) or the dose becoming at risk. For separately packed tablets only friability needs to be determined. MT 193 (method based on method from pharmacy) Requirements: tablets may not break. Requirements for possible attrition have not yet been specified.	CIPAC MT 193	No
	Burning rate smoke generators	Burning rate should be determined to establish how long it takes before the preparation stops generating smoke Requirements: the burring rate should correspond with the proposed use		No
	Burning completeness smoke grantors	Burning completeness must be determined by weighing the preparation before and after use. It should be demonstrated that by far the largest part of the active substance went up in smoke. Requirements: The preparation may after use present no risk for operator or environment, and disposal should –if applicable- be possible in accordance with the instructions for use		No
	Spraying pattern aerosols	Homogeneity must be determined according FEA method 644. Spray diameter must be determined at 30 cm distance. Requirements: none	FEA 644	No

REFERENCES

1 American National Standards Institute, ASTM method E1518-99, http://webstore.ansi.org/ansidocstore/product.asp?sku=ASTM+E1518%2D99
2 Warenwetbesluit veilige verpakking Huishoudchemicaliën (Food and Drugs Order Safe Packaging Household Chemicals)
3 Nadere regels verpakking en aanduiding milieugevaarlijke stoffen (Further Regulations Packaging and Indications Environmentally Harmful Substances)
4 Warenwetbesluit drukverpakking (Food and Drugs Order Pressurised Packs)
5 Regeling samenstelling bestrijdingsmiddelen (Regulation Composition Pesticides)
NL acts, decisions, orders, etc. can be obtained via http://wetten.overheid.nl/