

**Evaluation Manual  
for the Authorisation  
of Plant protection products  
according to Regulation (EC) No 1107/2009**

**NL part**

**Plant protection products**

**Chapter 2 Physical-chemical properties and  
analytical methods**

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**Board  
for the authorisation  
of Plant protection products and Biocides**

**Chapter 2 Physical and chemical properties and analytical methods**

Category: Plant protection products

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**Changes in the Evaluation Manual**

| <b>Evaluation manual PPP NL part<br/>Chapter 2 Physical and chemical properties</b> |              |                  |  |
|---|--------------|------------------|--|
| <b>Version</b>  | <b>Date</b>  | <b>Paragraph</b> | <b>Changes</b>   |
| 2.0   | January 2014 |                  |  |
| 2.1   | October 2016 |                  | New version of the E.M.  |
| 2.2   | March 2019   | Paragraph 2      | Bgb link updated   |
|   |              | All paragraphs   | Links updated  |
| 2.3   | March 2024   | All              | The EU evaluation manual for chemistry was revised/updated. Within this process, the NL evaluation manual was amended to only include NL specific information. Also the evaluation manual part 'Analytical methods' was combined with the physical-chemical properties part. |

## GENERAL INTRODUCTION

This chapter describes the data requirements with respect to physical-chemical properties of plant protection products (2.2.2), and how these are evaluated in the NL framework.

### 2. NL FRAMEWORK

The NL framework describes the authorisation procedure for plant protection products based on existing substances included in Commission Implementing Regulation ([EU No 540/2011](#)), and new active substances.

A new substance is a substance not authorised in any of the Member States of the EU on 25<sup>th</sup> of July 1993.

The plant protection product that contains such substances may be authorised if the approval criteria laid down in [Regulation \(EC\) No 1107/2009](#) are met, also taking into account the national stipulations described in the [Bgb](#) (Plant protection products and Biocides Decree). The evaluation dossiers must meet the requirements in Commission ([EU No 283/2013](#)) and Commission Regulation ([EU No 284/2013](#)) of [Regulation \(EC\) No 1107/2009](#) (see Application Form and corresponding instructions).

A Member State may deviate from the EU evaluation on the basis of agricultural, phytosanitary and ecological, including climatological, conditions which are specific for the Netherlands.

The NL framework describes the data requirements and risk assessment methodology for which the national framework has been elaborated in more detail than the EU framework.

## **1. IDENTITY**

See EM EU-specific.

### **1.1. Identity of the active substance**

See EM EU-specific.

### **1.2. Identity of the plant protection product**

See EM EU-specific.

## 2. PHYSICAL AND CHEMICAL PROPERTIES

See EM EU-specific.

### 2.1. Physical and chemical properties of the active substance

See EM EU-specific.

### 2.2. Physical, chemical and technical properties of the plant protection product

#### *Physical and chemical compatibility (284/2013: 2.9)*

There is no European guidance for tank mixes. The Member States do, however, have regulations for addressing this data requirement in their 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 WG (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 and chemical compatibility. If a tank-mix with a specific product is recommended, technical properties should be tested for the tank mix in the appropriate concentrations. Broader claims should be supported by data with an appropriate range of mixtures.

There is no standardised test for chemical compatibility. This can be included in the test for physical compatibility by observing reactions such as gas formation, heat development or colour changes.

Because research has shown that the ASTM method shows the best correlation with the field situation, the [ASTM method E1518-05\(2012\)](#) is the preferred method.

#### *Aerosols*

The spraying pattern should be studied for homogeneousness in accordance with [FEA method 644](#). In addition, the spray diameter should be determined at 30 cm distance.

#### *Tablets*

It should be demonstrated for tablets to be dissolved in water, that they rapidly disintegrate in water. Good attrition and friability properties should be demonstrated for all tablet formulations.

#### *Smoke generators*

When used as instructed, the burning rate of a smoke generator should be even, in order for the operator to be not at risk. It should be demonstrated that the preparation releases sufficient active substance, that the residual material presents no risk to operator or environment, and that residual material - if any - can be disposed of safely and according to the instructions.

### 3. FURTHER INFORMATION

#### 3.1. Further information on the active substance

See EM EU-specific.

#### 3.2. Further information on the plant protection product

##### *Aerosols*

When the capacity of the container is at least 50 ml, this packaging (also) comes under the [Warenwetbesluit drukverpakking](#) (Food and Drug Order Pressurised Packs).

##### *Restrictions for non-professional use*

According to the [2<sup>e</sup> Nota duurzame gewasbescherming](#) (2<sup>nd</sup> memo sustainable plant protection), the contents of products intended for non-professional use must not exceed the amount needed for treatment of a 500m<sup>2</sup> area.

## **4. ANALYTICAL METHODS**

### **4.1. Active substance**

See EM EU-specific.

### **4.2. Methods used for the generation of pre-approval data**

#### **4.2.1. Methods for the analysis of the active substance as manufactured**

See EM EU-specific.

#### **4.2.2. Methods for risk assessment**

See EM EU-specific.

### **4.3. Methods for post-approval control and monitoring purposes**

For post-registration the Dutch situation is important for the analytical method in surface water. A lot of surface water and groundwater is used for drinking water production, about two thirds of the drinking water is produced from groundwater.

This has led to the requirement that in the Netherlands the maximum limit of quantification (LOQ) for groundwater and surface water must be 0.1 µg/L unless it must according the European criteria be possible to measure a lower concentration.

The maximum limit of quantification will in that case have to be equal to this lower value.



#### **4.4. Plant protection product**

See EM EU-specific.

#### **4.5. Methods used for the generation of pre-authorisation data**

##### **4.5.1. Methods for the analysis of the plant protection product**

See EM EU-specific.

##### **4.5.2. Methods for the determination of residues**

See EM EU-specific.

#### **4.6. Methods for post-authorisation control and monitoring purposes**

See EM EU-specific.