

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

NL part

Plant protection products

Chapter 2 Physical and chemical properties

version 2.1; October 2016



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

Chapter 2 Physical and chemical properties

Category: Plant protection products

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Important changes with the last version of the E.M.

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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 25th 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.

2.1 Introduction

With respect to the physical and chemical properties, the NL national data requirements for active substance and plant protection products and the evaluation methodology do not differ from the EU framework. The NL procedure is only described if no EU procedure is available.

2.2 Data requirements

2.2.1 Data requirements for the active substance

For the active substance the same requirements apply as described under EU framework.

2.2.2 Data requirements for the plant protection product

Requirements for the plant protection product are the same as described under EU framework. Please refer to the EU part of the Evaluation Manual for details. Supplemental requirements or exceptions considered by the Ctgb are included in the text below.

1.1.1.1.**1.1.1.2. Material Safety Data Sheet (284/2013: 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 should not have been prepared or amended longer than 5 years prior to submission, to ensure it is sufficiently representative for current legislation and scientific knowledge.

In addition, safety data sheets are only accepted if CLP classification is included in the safety data sheet.

1.1.1.3. Storage tests (284/2013: 2.7)

Within the EU, extrapolation of packaging types in storage stability studies is not harmonised.

NL specific evaluation allows packaging extrapolation (suitability of packaging to its contents) as follows:

Worst case	Extrapolation to
HDPE	HDPE co-extruded packaging with additional barrier made of e.g. polyamide (PA), ethylvinylalcohol (EV, EVAL, EVOH) or fluorination (F).
LDPE	Additional barriers like paper, aluminium as long as LDPE is the layer in contact with the formulation, e.g. LDPE/Aluminium/paper.

Other packaging types cannot be extrapolated unless a solid argumentation is provided.

1.1.1.4. 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.

1.1.1.5. Supplementary data requirements on technical characteristics

Specific data requirements for tablets, smoke generators and aerosols are not yet included in the European evaluation, whereas they are stated in the Uniform Principles as described in Commission Regulation [\(EU\) 546/2011](#).

There is no agreement on these data requirements because these types of products are not included in the European substance evaluation.

Data for these types of products are however requested in the Netherlands; the Dutch evaluation therefore reverts to the [FAO manual](#).

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.

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.

1.1.1.6. Packaging

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).

The methods for testing and requirements are given in [Directive \(EU\) 2008/47/EC](#).

Restrictions for non-professional use

According to the [2^e Nota duurzame gewasbescherming](#) (2nd memo sustainable plant protection), the contents of products intended for non-professional use must not exceed the amount needed for treatment of a 500m² area.

2.3 Risk assessment

The evaluation methodologies for chemical crop protection products comply with the description under EU framework.