

Guidance document for the extrapolation of packaging materials of plant protection products in Belgium



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DOCUMENT INFORMATION

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<https://phytowebe.be/en/guide/crop-protection/guidance-physico-chemistry>

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General requirements for packaging materials

A detailed description of the packaging in which the product will be marketed is required. Information should comprise of the following:

- the content of the product and specifically for liquid containers, the ullage/headspace
- packaging material (e.g. HDPE, PP, epoxy phenolic coating, etc.). If packaging consists of multiple layers or is co-extruded, the various materials should be specified as well.
- packaging size and dimensions
- size of the opening
- Type and material of the closure
- Type, material and dimensions of the seal
- Manner of construction
- Compliance to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)¹

A shelf-life study should be conducted in the proposed commercial packaging. However, if packaging is not identical, the shelf-life study must represent a **worst-case**.

For products for non-professional use, additional information needs to be provided. Details can be found in the guidance document *Check-list "Conformity and precision of packaging and measuring device for home and garden products submitted for registration in Belgium"*²

Extrapolation of packaging materials

Depending on the formulation type of the product, different criteria are used to extrapolate different packaging materials.

¹ 2017 edition (ECE/TRANS/257, Vol. I and II). More info: https://www.unece.org/trans/danger/publi/adr/adr_e.html

² <http://fytoweb.be/sites/default/files/guide/attachments/checklist.pdf>

Containers for powders and granules.

- Extrapolation is possible between all container types (with the exception of water-soluble packaging, e.g. PVA packs) providing that the new packaging is **not more flexible**. The material used must be waterproofed or have a waterproof lining.
- When authorization is sought for a flexible container, the issue of compaction or loss of granule integrity potentially caused by stacking containers in a pile such as in a store or warehouse must be addressed.

Rigid containers for liquid preparations

- For aqueous SL and SC formulations extrapolation between any plastic (not metal) material types is acceptable **with acceptable seepage data** (see below). Extrapolation from plastic material to metals is not acceptable.
- For organic solvent containing formulations e.g. EC, EW, SE extrapolation from HDPE to HDPE co-extruded with any of the following: HDPE/EVOH, fluorinated HDPE and HDPE/polyamide is acceptable. Extrapolation between plastic material types e.g. HDPE to PET is not acceptable.
- There are additional requirements for the larger containers - companies need to address any sedimentation & settling that may occur as this may be a problem for larger containers particularly as it is difficult to “shake well before use”. You may not always see these issues in a 1 L storage tests.

Packaging used in shelf life study	Acceptable extrapolations
Water based formulations (SC, SL,...)	
Any plastic (PET, LDPE, HDPE,...; no metal!)	All plastic packaging types will be supported by <u>seepage data</u> in the required packaging
Solvent based formulations (EC, EW, SE,...)	
HDPE	HDPE/EVOH, HDPE/F, HDPE/PA packs will be supported without further data
HDPE/EVOH HDPE/F HDPE/PA	Data generated in one of these three packaging materials will be supported for any of the three packaging materials with <u>seepage data</u> HDPE packs will be supported with acceptable <u>seepage data</u>

Seepage data

Data are only required to demonstrate that the required packaging is stable for the required shelf life (e.g. no leakage, no ballooning, no paneling of the packaging, no deformations) rather than a new shelf life study in which all chemical and physical properties are investigated prior to and after storage. The **weight change** on storage should also be determined.

Where seepage is observed then the new packaging cannot be authorized. Any paneling and/or ballooning in the new packaging is an indication of the new packaging not being fully resistant to the product and/or air entrainment. In such cases to ensure no adverse effects on the physical and chemical properties of the product then a complete shelf life study conducted in the new packaging will be required.