

Packaging : harmonised approach on how to report the packaging size and packaging materials of PT14 products in the SPC

During the renewals of the PT 14 products, it appeared that the packagings reported in SPCs were quite diverse in the level of description. The aim of this document is to harmonise the level of detail/description of the packagings to be reported in SPC for the most “classical” PT14 products, i.e. baits in the form of grains, pellets, blocks or paste (other forms of PT14 products such as foam, liquids, and other PT 14 products are not covered by this document).

In the SPC, the packaging is described in the part “Pack sizes and packaging material”. According to the agreed PT14 SPC template, the minimum pack size, the number of packed bags per packaging, the grams/kg of bait per packed bag and packaging material should be reported.

A clear description of the biocidal product packaging is necessary for enforcement purposes but also for the assessment of stability of the product during storage, and for the assessment of human health and environmental exposure.

Two types of packaging should be considered, especially in the frame of PT14 products:

- The first type corresponds to the packaging of the biocidal product itself. It is as a closed packaging that preserves the biocidal product, prevents leakage during storage and is removed or opened before use. For example, a cardboard or plastic box containing grains (individually packed or in loose). This type of packaging is referred here after as “primary packaging”
- The second type corresponds to packagings intended to be used to prevent human exposure and facilitate the use of the product. They are not intended to be removed or opened before use.
For example, sachets of small doses of biocidal products (so-called individual sachets in PE, or tea paper).

The primary packagings should be sufficiently described by the applicant to ensure that they are fully covered by the PC assessment. It must be verified that it is efficient enough to prevent leakage and preserve the biocidal product. Therefore, following details should be provided:

- The specification of the material of all parts of the packaging: container, inner liner closure (lid, stopper ...) ...); the specification of the plastic material such as :PET, HDPE etc... ,
- The type of each packagings (bottle, bag, ...),
- The range of size volume.

Other characteristics that apply to the packaging should also be described:

- The whole list of possible quantity of product in an individual sachet (20-25-30g...).

- Whether the biocidal product is individually packed or not. When the biocidal product is individually packed, the compatibility of the sachet with the product must be demonstrated in the storage stability studies¹.
 - o For block or paste, the weights of individual products and whether they are individually packed or not, and the material of the sachet should be indicated.
 - o For grains or pellets, whether they are individually packed or in loose, the chemical nature of the sachet, the minimum and maximum quantity in an individual sachet must be indicated
- Pack size restriction that applies to the primary packaging (for example 10 kg limitation for grain in loose) or to the products as they are sold (pack size restriction for non-professional users) should also be indicated in the SPC.

On the contrary, the following information on the packaging is not considered as necessary in the SPC: Packagings that aim at grouping the primary packagings (a cardboard with several cartridges containing paste , or a cardboard containing several large bags of grains)

Here are some examples of sufficient description of packagings:

<p>Block/ professional users 20; 50; 100; 200 g Blocks packed in individual sachets (PE or PP) or in bulk. Blocks are then packed in:</p> <ul style="list-style-type: none"> - HDPE buckets (1,5-10 kg) - Carton box with HDPE inner liner 1.5-20 kg. - Metal box in Al with or without lacquer (epoxyphenolique lacquer) with a closure in PP² (3 kg)
<p>Grain/ professional users Minimum quantity of bait per unit sold : 5 kg</p> <p>PE sachets (20; 30; 50; 100g) packed in:</p> <ul style="list-style-type: none"> - Bags (paper or PE) (5-25 kg) - Bucket (PE) (525kg) - Carton box (carton) (5-50 kg) <p>Loose baits packed in:</p> <ul style="list-style-type: none"> - Bags (paper or PE) (5-10 kg) - Sachets (PE or PP) (100 ; 200 ; 500 ; 1000g) - Bucket (PE) (5 ;10 kg) - Carton box (carton) (5 kg) <p>For loose grain baits, the packaging is restricted to 10 kg.</p>
<p>Grain / non professional users</p>

¹ BPR Guidance Vol I PartA+B+C: 3.3.7

² Polypropylen

Maximum quantity of bait per unit sold : 150g (product for mouse only) of 300g (product for rates and mouse)

Paper or PE or PP sachets (20; 30; 50; 100g) packed in:

- Bags (paper or PE) (100-300g)
- Carton box (carton) (20-300g)
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Block/ professional users

HPDE cartridge with PP stopper containing 1 kg paste

Specific case of product for non-professional users against mice AND rats

In case a product is to be used against rats and mice by non-professional users, uses against each target are separated in the agreed TP14 SPC template. However, in accordance with renewal approval conditions, the maximal quantity of bait per pack indicated in all tables of use for the general public should be the one proposed “for rats, only or mice and rats”. In MSs where some use against rats are not allowed for the general public, maximum pack size can be adjusted pursuant to article 37.

Specific case of pre-filled bait boxes

Two cases could be encountered for prefilled bait boxes:

- Pre-filled bait boxes where the openings are already open before use. The pre-filled bait boxes are considered as packagings to prevent from exposure and facilitate the use but it is not intended to preserve the biocidal product (and should therefore not be considered as a primary packaging) . In those cases, the packaging should be described as follows:

Block/ professional users

PET pre-filled bait boxes (20-200g product) packed in bags (paper/PE) (100 – 300g)

- Pre-filled bait boxes where the openings are closed and that should be opened before use. These pre-filled bait boxes are thus considered as packagings intended to prevent from exposure and to facilitate the use and also to preserve the biocidal product. In those cases, the packaging should be described as follows:

Block/ professional users

PET pre-filled bait boxes (20-200g product) with openings to be opened before use