

Evaluation Manual for the Authorisation of plant protection products and biocides

EU part

Biocides

Chapter 7 Efficacy

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**Board
for the Authorisation
of plant protection products and biocides**

Chapter 7 Efficacy

Category: biocides

Main group 2 Preservatives

PT10 Masonry preservatives

Contents

general introduction 3

GENERAL INTRODUCTION

This chapter describes the data requirements for the assessment of the efficacy of a biocide and the active substance within PT 10, and which evaluation methodologies are applied for the EU framework. This chapter is derived from the TNSG on product evaluation (appendix to chapter 7 on Product Type 10 Masonry preservatives).

In December 2012 a new chapter of the TNSG was endorsed describing requirements for the main group of preservatives (PT6 to PT13). See this chapter for more recent requirements. Where the chapter below is in contradiction with the general chapter the general chapter will prevail.

PRODUCT TYPE 10 - MASONRY BIOCIDES

1 LABEL CLAIMS

1.1 Spectrum of biological activity (including target organisms)

Possible target organisms to be considered are confined to several broad groups. These are dependent on the intended use of the candidate product (i.e. either as a general surface biocide or for specific use as a dry rot treatment) and are shown in Figure 1.

1.2 Mode of action/effect

There are a number of possible 'effects' on target organisms derived from the proposed use of a masonry biocide and the actual effectiveness of products will depend on a number of variables such as substrate, target organism, persistence and penetration, concentration used and desired effect. Commonly these effects can be described as either kill or prevention of re-growth of organism.

1.3 Areas of use & sites of application

With respect to label claims for masonry biocide product applications, a distinction between two use patterns may be made when evaluating a data package.

- **Masonry biocides intended specifically for the control of dry rot**

In this situation the product is applied to masonry (or other mineral construction materials) in order to prevent the growth of dry rot fungi through or over the treated material.

- **Products intended for general surface biocide use**

In this situation the product (sometimes known as a toxic wash) is applied to a wide variety of hard and/or soft surfaces to control organisms such as algae, yeasts, fungi, lichens, mosses and liverworts.

The possible efficacy label claims for both use patterns are depicted in Figure 2.

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2 AVAILABLE DATA

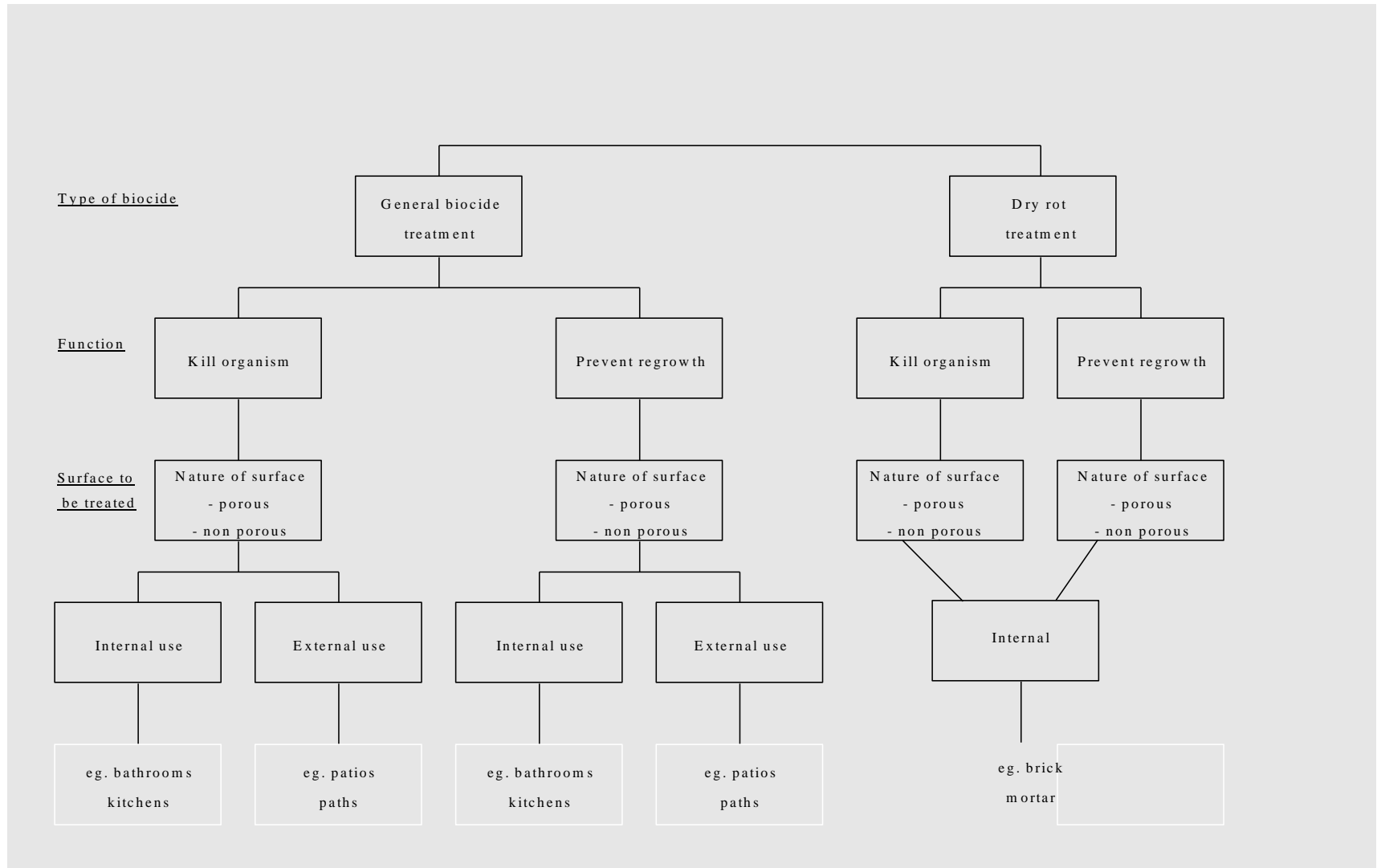
2.1 Standard test methods

Very few international standard test methods currently exist for masonry biocide products. Those recognised standards that are available are presented in Appendix 1 to this document.

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61**Dry rot fungus***Serpula lacrymans***Algae***Pleurococcus spp.*
Stichococcus bacillaris (green algae)
Gloeocapsa alpicola (green algae)
Nostoc commune (Blue-green algae)**Fungi/yeasts***Aspergillus versicolor*
Aureobasidium pullulans
Cladosporium caldosporioides
Penicillium purpurogenum
Phoma violacea
Rhodotorula rubra
Sporbolomyces roseus
Stachybotrys atra
*Ulocladium atrum***Lichens***Lecanora dispersa*
Caloplaca spp.
Candelariella spp.
*Buellia canescens***Mosses and liverworts**Mosses*Tortula muralis*
Barbula cylindrica
Grimmia pulvinata
Camptothecium sericenum
*Rhynchostegiella tenella*Liverworts*Lunularia cruciata*
Marchantia polymorpha

N.B. The above is not intended to be an exhaustive list of possible target organisms nor is intended to be prescriptive with respect to data generation, it gives some examples only from the major biological groups.

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64**Figure 1:** *Target organisms*



66 **Figure 2:** *Examples of efficacy claims for masonry biocide products: Breakdown of the information that may be required when*
67 *considering efficacy testing strategies and the evaluation of data.*

2.2 Specific data to support label claims

In assessing the efficacy for a masonry biocide product competent authorities should in particular take the following parameters into account:

- The toxicity (and permanence) of the product itself towards the target organism(s)
- The intended use pattern for the candidate product
- The method of application (and dose rate)

In considering an assessment for a masonry biocide product the claimed target organism(s) will depend on the intended use pattern; and since particular organisms will predominate in certain situations, the treatment environment.

When considering the overall evaluation of a proposed label claim competent authorities should ensure that the data presented are relevant not only to biological challenge and treatment environment but also that the method of application and application/dose rate used in the test(s) are appropriate to the label claims and proposed use of the product.

Examples of the types of data that would likely to be available for evaluation of biocidal products intended for use as general surface biocides and those products specifically intended for the control of dry rot are presented in Figures 3 and 4.

Competent authorities should evaluate the available data to determine whether they are sufficient to support the label claim.

For claims made for products intended for use as general surface biocides

Available data

For products intended for general surface biocide use the test organisms used will depend upon the label claims made. Examples of the type of data that may be available when considering the efficacy of products intended for general surface biocide use are shown in Figure 3.

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98**Figure 3: General surface biocide use****Simulated use studies**

Laboratory tests employing aged mortar, which is treated with various concentrations or application rates of the test product and then exposed to challenge by *Serpula lacrymans* to determine the ability of the test fungus to grow over or through the treated substrate. One suitable method is described in ENV 12404:1997. See Appendix 1

Field Studies (see note)

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Note

At present there is no laboratory method for determining the efficacy of surface biocides against lichens, mosses and liverworts. These organisms are likely to colonise building materials placed on exposure racks but only after several years.

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Figure 4: Masonry biocides intended for the control of dry rot

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Note

Field trials for dry rot control are difficult to establish because each outbreak is unique.

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Laboratory/screening tests: (see note)

Application of a range of concentrations of the active ingredient, absorbed onto assay discs applied to a suitable nutrient agar medium seeded with either fungal or algae and following a suitable incubation period, determination of the zone of growth inhibition.

Simulated use studies

Laboratory tests employing actual building materials as substrates and permitting full substrate/organism/biocide interaction during testing, e.g. use of moist vermiculite-bed techniques to evaluate the efficacy of a biocide on a range of substrates.

Field studies

Natural exposure trials using samples from actual building material supported on an exposure rack in a region known to be vulnerable to establishment of biological growths, weathered and colonised by the organisms can be used to evaluate the efficacy of a biocide. Application of surface biocides to walls and other structures already colonised with lichens, mosses etc. may be used.

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Thus it is not possible to have "untreated controls". In treatments used to effect dry rot eradication, treatment requires major site works and the implementation of a "package" of measures which together effect control. It is therefore difficult to design a field test which

110 conclusively demonstrates that a product is efficacious, given that the level of actual
111 biological challenge it is required to resist will be altered so much by the associated works
112 and will vary greatly from building to building. The provision of a suitable simulated use test
113 (e.g. one conducted to CEN DD ENV 12404 or an equivalent) will normally be sufficient to
114 give a good indication of field performance.

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116 **Available data**

117 For products intended for the control of dry rot the test organism used will be *Serpula*
118 *lacrymans*. Examples of the types of data that may be available when considering the
119 efficacy of a masonry biocide intended for the control of dry rot fungi are shown in Figure 4.

1.1.1.1. APPENDIX 1

There are at present only two standardised test methods which are relevant to this area of

1. British Standards Institution (1989). Methods of test for paints. Part G6. Assessment of resistance to fungal growth. British Standard BS 3900. Part G6, BSI, London, UK.¹

2. Durability of wood and wood-based products - assessment of the effectiveness of a masonry fungicide to prevent growth into wood of dry rot *Serpula lacrymans* - Laboratory Method. ENV 12404:1997

pesticides efficacy evaluation.

¹ The BS test has been published but only provides a methodology for production of a test surface for exposure by inoculation with mould growth. Therefore this BS has to be modified to be used as a test method for assessing interior surface biocides.

6. References

- 1 Biocidal directive (BPD) (98/8/EC)
- 2 Technical Notes for Guidance: TNSG on Product Evaluation; Common principles and practical procedures for the authorisation and registration of products. Available at: <http://ecb.jrc.it/biocides/>