Case study for a BP - PT8

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MG1 or MG2?

Is the treatment intended to protect the material/article or its functionality from biological deterioration during storage or in service, extend its durability or prevent odour? Is the active substance/product intended for curative treatment of wood, industrial liquids, solutions, dispersions or processes?

Is the treatment intended to protect humans or animals?

Disinfectant – MG1

Preservative – MG₂

Preservatives in main group 2 are intended to prevent the biodeterioration of a material or a matrix

directed towards the protection of a *material*.

If the material itself is not affected by the target organisms, the claim does not belong in main group 2.

PT8 sect/BPR is mainly based on

- \checkmark EN 599-1 for preventive uses
- \checkmark EN 14128 for curative uses.

For product already on the market before entering into force of the standards (1990 and 2004):

- Efficacy data on the product should be provided.
- The assessment of the product efficacy should be based on expert judgement;
- Some data taken from the literature or used in certification could be accepted on case by case basis.



GUIDANCE

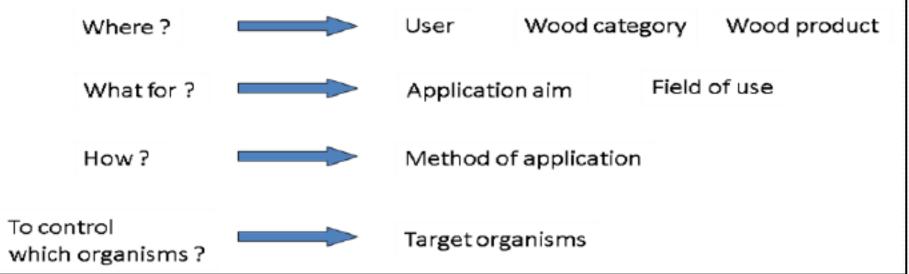
Guidance on the Biocidal Products Regulation

Volume II Efficacy - Assessment and Evaluation (Parts B+C)

Version 3.0 April 2018 Update to PT8 (version 2.0 Dec 2017) <u>To add a new Appendix 12;</u> To revise section 5.5.8.3 to remove temporary footnote re. the new Appendix 12; To add a new footnote to section 5.5.8.2.2.3, Use Class 2, Test Species; To re-number Appendices after the new Appendix 12 and revise all cross references to these Appendices.

Update to PT8 (version 3.0 Apr 2018) Section, 5.5.8.2.2.3: the footnote added in version 2.0, (footnote 28) has been moved to the beginning of the section because it applies to Use Class 1 as well as Use Class 2. It is now footnote 24

- Where is the product used?
- What is the product used for?
- How is the product used? To control which organisms?



Categories	Code for product
User category	A.xx
Wood category	B.xx
Wood product	C.xx
Application aim & Field of use	D.xx & E.xx
Method of application and rate	F.xx
Target organisms	G.xx

Where/by whom?

Users: professional/industrial/general public.

Wood category: softwood / hardwood

Wood product: solid wood wood-based panels

What for?

Application aim: preventive / curative

Field of use: i.e. service conditions

Field of use (service conditions)

- Use Class 1: not exposed to weathering agents
- Use Class 2: not directly exposed to weather but occasional (non persistent) wetting may occur
- Use Class 3: above ground and exposed to weather
- Use Class 4: direct contact with ground and fresh water
- Use Class 5: permanently of regularly submerged in salt water

How?

Method & rate of application:

- superficial treatment
- penetrating treatment
- other (i.e. fumigation)

To control

Target organism

Target organisms				
Common English term	Code F forproduct	Target organisms according to EN 1001	Classification	Scientific name
Fungi		-	Fungi	
Wood rotting fungi				
Wood rotting	G.10	Brown rot fungi	Basidiomycetes	e.g. Gloeophyllum trabeum
basidiomycetes	G.11	White rot fungi	Basidiomycetes	e.g. Coriolus versicolor
Soft rot fungi	G.12	Soft rot fungi	Ascomycetes, Deuteromycetes	e.g. Chaetomium globosum
	G.21.1	Sapstain fungi (bluestain	Ascomycetes,	e.g. Ophiostoma piliferum
		mainly)	Deuteromycetes	(Ceratocystis pilifera)
Wood	G.21.2	Bluestain in service	Ascomycetes,	e.g. Aureobasidium pullulans
discolouring fungi			Deuteromytcetes	e.g. Aureobasidium pundians
	G.22	Mould fungi	Ascomycetes,	e.g. Aspergilus niger
	0.22	Deuteromycetes		c.g. Aspergilas higer
Insects			Insecta	
G	G.30	Wood boring beetles	Coleoptera	
	G.31	House longhorn beetle		e.g. Hylotrupes bajulus.
Beetles	G.32	Common furniture beetle		e.g. Anobium punctatum
	G.33	Powder post beetles		e.g. Lyctus brunneus
	G.40	Fresh wood insect	Coleoptera	e.g. Scolytus spp
	G.50	Termites (genus claimed)	Isoptera	
G.!	G.51	Subterranean termites (genus	·	e.g. Reticulitermes spp, e.g.
		claimed)		Coptotermes spp
	G.52	Drywood termites		
		(genus claimed)		e.g. Cryptotermes spp
	G.53	Tree termites		o a Nacutitarmas ana
		(genus claimed)		e.g. Nasutitermes spp
	G.60	Marine borers		
Wood destroying		(genus claimed)		
marine organisms	G.61	Mussels	Teneridae, Pholadidae	e.g. Toredo sp, Martesia sp
-	G.62	Crustaceans	Isopoda, Amphipoda	e.g. Limnoria spp, Chelura spp

Note

CAs should evaluate the available data to determine whether they are sufficient for label claims as follows:

a) for general claims against "wood boring beetles"²⁶

All relevant beetle species (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*) should be tested except if data (relevant and robust literature data where the materials and methods are detailed; certification data²⁷ on a case by case basis) are provided which demonstrate that one of the targets is the less sensitive or that the product has an equivalent activity against all beetle species (refer to EN599-1:2014, section 5.2.3)

b) for claims against a specific beetle species

If claims against individual beetle species are detailed on a product label, then suitable efficacy data against those named target pests will be required.

c) for claims against termites

Some data on efficacy against termites will only be required when the product is to be marketed for use as a termiticidal product or where local requirements demand such activity.

For a product claiming activity against termites, suitable data demonstrating preventive efficacy against a European *Reticulitermes* species will be required.

For a product claiming efficacy against overseas tropical termites, suitable data demonstrating preventive efficacy against relevant species will be required.

Note

The CAs evaluate the available data to determine if they are sufficient for label claims as follows:

a) For claims against wood rotting fungi the following data have to be available:

Suitable laboratory data demonstrating efficacy against brown rot fungi after ageing test in accordance with EN 73.

b) For claims against wood discolouring fungi the following data have to be available:

- Suitable laboratory data on the protective efficacy of the product against blue stain in service after ageing test in accordance with EN 73 or after a natural or artificial weathering cycle as given in EN 152;
- The application process used in the tests (i.e. whether by superficial or penetrative

treatment) has to be in accordance with label claims.

c) For claims against insect pests the following data have to be available:

As outlined in Use Class 1.

Note

The CAs should evaluate the available data to determine if they are sufficient for claims matrix as follows:

a) For claims against wood rotting fungi, the following data have to be available:

 Suitable laboratory tests as outlined for Use Class 2 and in addition, the efficacy will be demonstrated following preconditioning of the treated test blocks by a suitable leaching procedure according to EN 84

b) For claims against wood discolouring fungi the following data have to be available:

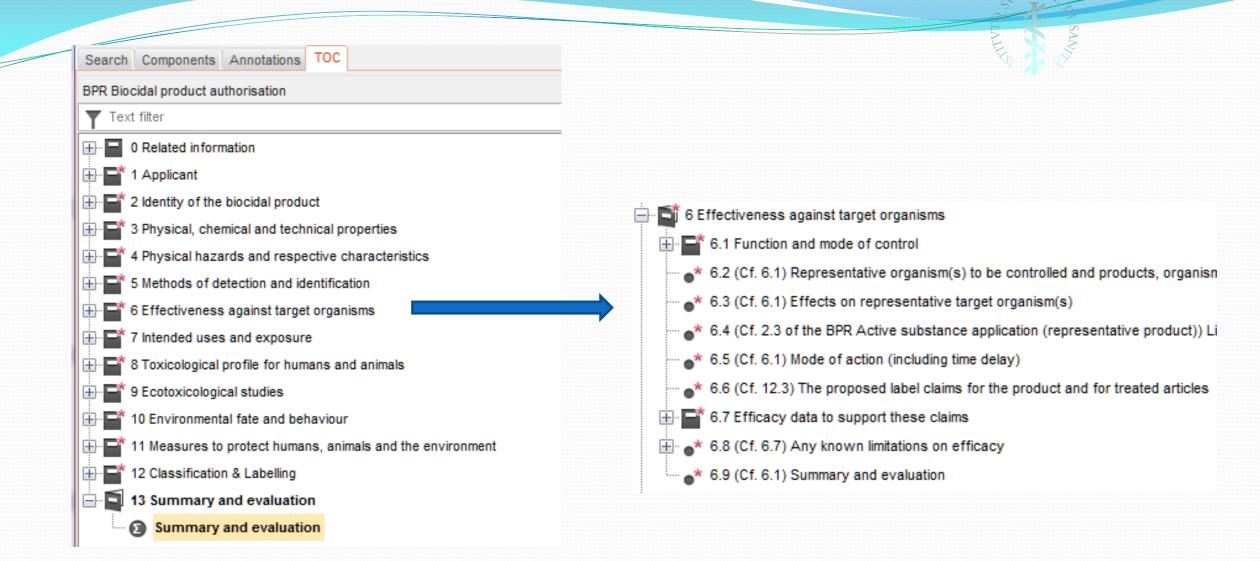
- Suitable laboratory data on the protective efficacy of the product against blue stain in service after a natural weathering or an artificial weathering as given in EN 152.
- The application process used in the tests (i.e. whether by superficial or penetrative treatment) should be in accordance with label claims.

c) For claims against insect pests (if relevant) the following data have to be available:

As outlined in Use Class 1, and in addition the efficacy will be demonstrated following preconditioning of the treated test blocks by a suitable leaching procedure according to EN 84 if technically possible (i.e. this is not the case for EN 20-1 and 20-2 due to methodological constraints).

According to EN599-1 field test results, according to EN330 may be used by the applicant instead of certain EN 113 test results, after EN 84 leaching test to derive the brown rot fungi. They are not needed to derive the minimum retention requirements.

Moreover EN 330 may be used as an alternative to basidiomycetes laboratory tests (EN 113 + EN 84) for product under coating.



Pest / target organisms to be controlled 🔨

Target organisms

Scientific name	Common name	Developmental stage
Hylotrupes bajulus L.	house longhorn beetle	larvae
other: Reticulitermes santonensis	termites	adults / and nymphs
Aureobasidium pullulans spp.	blue stain fungi	hyphae
other: Sydowia polyspora	blue stain fungi	hyphae

V Move down

🕀 Add... 🧪 View

Products, organisms or objects to be protected / under study 🔨

X Delete

Organisms (to be protected) or treated materials

Suitable for treatment of all elements in new or already impregnated wood outside as: balconies, shutters, fences, pergolas, doors, wooden beams, boardings. Not ... to be used for the timber which can come into direct contact with the ground.

↑ Move up

Information on intended use and application A

Function addressed	
▼ fungicide	
insecticide	
termiticide	
Product type	
EU BPR Product type 8: Wood preservatives (F 🔻 Other	
Field of use envisaged / User	
Intended to protect the wood from insects (including termites) and blue stain fungi. For outdoor applications. To be used by professional users and amateurs.	

Information on application of biocidal product A

Method of application

▼ open system: brush treatment

Details on application

AIX.

DESCRIPTION OF APPLICATION SYSTEM USED

The wood must be dry and free of dust, wax, grease, etc.

New or already impregnated wood: apply directly, distribute the product evenly over the entire surface. For a better absorption lightly sand the surface before

General information on effectiveness 🔨

Effects on target organisms

By disrupting the nervous system of insects, Cypermethrin may cause paralysis or death. The product acts by contact and by ingestion at very low doses. The product provides residual efficacy.

IPBC acts by altering the cell membrane permeability.

Mode of action

other:

Cypermethrin: acute toxin (contact and ingestion);



Details on mode of action

AIX

Cypermethrin is a synthetic pyrethroid with contact and stomach action. It acts by preventing the transmission of impulses along the nervous system of the insect. It is thought that this is achieved by blocking the sodium channels in nerve membranes, thus preventing action potentials passing down the nerve axon. IPBC has a carbamate structure. The target sites of carbamates in fungi are cell membrane permeability and fatty acids (according to the information provided

(Possible) Occurrence of resistance

IPBC:

The risk of resistance formation against carbamate fungicides is regarded to be low to medium by FRAC (Fungicide Resistance Action Committee). This applies to the use of carbamate fungicides in agriculture, where yearly applications to the same fields are possible (even more than one application per season is possible).

With regard to the use of carbamates in wood preservation, resistance formation constitutes an even smaller problem. The number of treatments to wooden Management strategies to avoid resistance

Strategies such as alteration of insecticides with different modes of action and avoidance of over frequent use are standard practises in agriculture and should be applied also to biocide uses of cypermethrin. It is recommended to watch out for the apparition of any resistance to pyrethroids such as cypermethrin. In case of apparition of resistance phenomena in wood preservative context, active substances with other mode of action should be used.

Efficacy tests

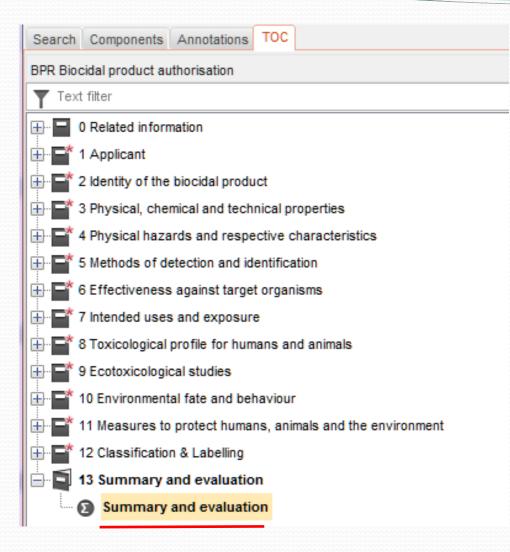
- Determination of the preventive action against recently hatched larvae of *Hylotrupes bajulus* (L.) according to EN 46 1(2009) after evaporative ageing procedure according to EN 73
- Determination of the preventive action against recently hatched larvae of *Hylotrupes bajulus* (L.) according to EN 46 1(2009) after leaching procedure according to EN 84
- Determination of the preventive action against *Reticulitermes santonensis de Feytaud* according to EN 118 in combination with evaporative ageing procedure according to EN 73
- Determination of the preventive action against *Reticulitermes santonensis de Feytaud* according to EN 118 in combination with leaching procedure according to EN 84

Function addressed	
✓ fungicide	
insecticide	
termiticide	



Efficacy tests

- Protective effectiveness of preservative treatment of *Pinus sylvestris* against blue stain fungi (*A.pullulans* and *S.polyspora*) after a 4 week artificial weathering period according to EN152(2011).
- From note to UC2: for claim vs wood discoloring fungi, suitable laboratory data on the protective efficacy of the product against blue stain in service after ageing test in accordance with EN 73 or after a natural or artificial weathering cycle as given in EN 152;
- From note to UC3: For claims against insect pests, as outlined in UC1 (all relevant beetle species). In addition the efficacy will be demonstrated following pre-conditioning of the treated test blocks by a suitable leaching procedure according to EN 84 if technically possible
- From note to UC1: For a claim against termites, test vs European *Reticulitermes*



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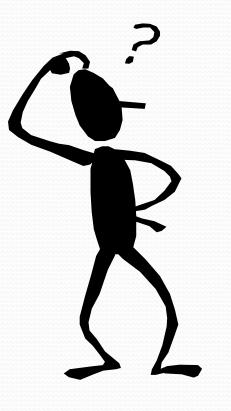
- <u>1</u> <u>General product information</u>
- **<u>1.1</u>** Identification of the Biocidal product
- **<u>1.2</u>** Identity of ingredients of the biocidal product
- **1.3** Physical-chemical properties
- **<u>1.4</u>** Analytical methods for detection and identification 1.4.1 Formulation analysis
- 1.5 Classification. packaging and labelling
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- 1.5.2 Proposed classification
- 1.5.3 Packaging

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- 3.2.1 Identification of main paths of human exposure towards active substance from its use in the biocidal product
- 3.2.2 Professional or non-professional exposure

- 3.2.3 Indirect exposure as a result of use of the active substance in biocidal product
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- 5 Environmental effects assessment of the product
- 6 Hazard identification for physico-chemical properties

7 <u>References</u>



Thanks for your patience!