Kemikalieinspektionen
Swedish Chemicals Agency

REPORT

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Our reference
5.1.3-B15-00284

Comparative assessment report

X6122B1

Authorisation No: 5596

Type of application Authorisation	Product type PT 8 – wood preservative
Active substances Cypermethrin (CAS: 52315-07-8) ; Propiconazole (CAS: 60207-90-1) ; Tebuconazole (CAS: 107534-96-3) ; IPBC (CAS: 55406-53-6)	User category Class 2 – Products that can be used for preventive and curative treatment by professional users. Class 3 – Products that can be used for preventive treatment by non-professional users.
Case number in R4BP3 BC-NC017438-47	
Reference Member state France	
Asset number (Reference Member state) FR-0012538-0000	

Swedish Chemicals Agency

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1 Background

The Swedish competent authority has been processing an application for a biocidal product (X6122B1) which contains the active substances cypermethrin, propiconazole, tebuconazole and IPBC. Tebuconazole meets the criteria for substitution under Article 10.1.d of the Biocidal Products Regulation (528/2012), and should consequently be regarded as candidate for substitution. Products that contain an active substance, which is a candidate for substitution can only be authorised in accordance with Article 23 in Regulation (EU) No 528/2012.

Member States (MS) are encouraged to restrict or prohibit the use of a biocidal product subject to comparative assessment, even when the alternative biocidal product is only authorised in other MS or the non-chemical alternative is only available in other MS. However, at the moment, detailed information about products authorised in other MS is not easily obtained from the R4BP3 database. Also there is no information available on non-chemical alternatives. Such information shall be available, according to Article 10.3 in Regulation (EU) No 528/2012, through the public consultation carried out by ECHA in connection with the approval or renewal of an active substance that is a candidate for substitution. Separate from the assessment by the Reference Member State (France), the Swedish Chemicals Agency is therefore required to perform a comparative assessment restricted to products authorised in Sweden.

According to the guidance document "Technical Guidance Note on comparative assessment of biocidal products", CA-May15-Doc.4.3.a – Final, (hereinafter – the Guidance document) a tiered approach, preceded by a screening phase, should be followed when carrying out a comparative assessment.

2 Screening phase of the comparative assessment

The screening phase allows the competent authority to perform a simple assessment to judge whether a comprehensive comparative assessment is required or not. Article 23.3(b), Regulation (EU) No 528/2012, refers to the adequate chemical diversity of the available active substances within a given product type/use/target organism combination as one of the two *sine qua non* conditions to be met in order to allow a restriction or prohibition of a biocidal product subject to comparative assessment. During the screening phase, it shall be checked whether the diversity of the active substance, product type and mode of action combination in biocidal products authorised under the Directive 98/8/EC or Regulation (EU) No 528/2012, is adequate to minimise the occurrence of resistance in the target organisms. According to the Guidance document, adequate chemical diversity means that at least three different active substances - mode of action combinations should remain available of the authorised biocidal products. If not, a conclusion could be reached that there is not adequate chemical diversity available and it is therefore not pertinent to conduct further investigations. The comparative assessment could therefore be finalised at this stage.

2.1 Intended use of the biocidal product and properties of active substances

Article 23(3) and the Guidance document focus the comparative assessment on the uses specified in the application of the biocidal product, as the comparative assessment has to be product specific.

Table 2. Intended uses of the biocidal product

	X6122B1
Product Type	8, Wood preservative
Active substances	• Cypermethrin – a synthetic pyrethroid that acts by preventing the transmission of impulses along the nervous system of the insect. • Propiconazole - a DMI (DeMethylation Inhibitor) that inhibits the C14 demethylation step in the ergosterol biosynthesis of fungi. • Tebuconazole - a DMI (DeMethylation Inhibitor) that inhibits the C14 demethylation step in the ergosterol biosynthesis of fungi. • IPBC (3-iodo-2-propynylbutylcarbamate) - a carbamate targeting fatty acids and cell membrane permeability of fungi.
Where relevant, an exact description of the authorised use	Professionals (Class 2) - Preventive and curative treatment for wood in use class 1, 2 and 3.1 (superficial treatment). Non-professionals (Class 3) - Preventive treatment for wood in use class 1, 2 and 3.1 (superficial treatment).
Target organism (including, where relevant)	Wood rotting fungi (brown and white rot fungi) Wood boring beetles: - House longhorn beetle (*Hylotrupes bajulus*) - Common furniture beetle (*Anobium punctatum*) - Powder post beetles (*Lyctus brunneus*)

development stage)	Termites (*Reticulitermes spp)*
Field(s) of use	Preventive and curative treatment for wood in use classes 1, 2 and 3.1.
Application method(s)	Superficial application / short dipping treatment Superficial application / spray treatment Superficial application / brush / roller / pad treatment Injection (combined with a superficial application)
Category(ies) of users	Industrial users Professional users Non-professional users

2.2 Chemical diversity of the active substances in Sweden

In Sweden, 94 wood preservatives have been authorised under the Directive 98/8/EC or Regulation (EU) No 528/2012. Five of the 94 authorised wood preservatives are against both wood rotting fungi and wood-damaging insects. Of these five wood preservatives, one product have the same fungicide constituents as X6122B1. However, this single product is the only authorized preservative against wood-damaging insects that contains the insecticide thiacloprid (neonicotinoid) and that would make X6122B1 the only product containing cypermethrin (pyrethroid) as the active substances against wood-damaging insects. In total, there are four active substances with different mode of actions against wood-damaging insects authorized in a total of seven products on the Swedish market. However, only one of the seven products contains a pyrethroid like X6122B1 and this product is limited to treatment of wood-damaging insects in user class 1 and 2.

2.3 Conclusion of the comparative assessment

In the Guidance document on comparative assessment of biocidal products, it is stated that:

- a suitable number of available active substances having different modes of action on the harmful organism would be necessary to minimise resistance development or selection;
- as a general rule, at least three different and independent "active substance/mode of action" combinations should remain available through authorized BPs for a given use in order to consider that chemical diversity is adequate.

The Swedish Chemicals Agency considers therefore, in line with the Guidance document, that the chemical diversity, concerning active substances against wood boring beetles and termites is not adequate in order to minimise the occurrence of resistance in the target organisms. This is based on the fact that there are less than three different active substances - mode of action combinations in Swedish authorised products against wood-damaging insects that are relevant to compare with X6122B1.

The comparative assessment on X6122B1 can therefore be finalised at the screening stage and the conclusion is that the criteria in Article 23.3 are not met. The Swedish Chemicals Agency shall therefore not prohibit or restrict the making available on the market or the use of the biocidal product X6122B1.