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Swedish Chemicals Agency

REPORT

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5.1.3-B13-00244

Comparative assessment report

Myrr Extra

Authorisation No: 5382

Type of application Authorisation	Product type PT 18
Active substances Imidacloprid	User category Class 3 – Non-professional users
Case number in R4BP3 BC-UL012454-33	
Reference Member state United Kingdom	
Asset number (Reference Member state) UK-0009263-0000	

Swedish Chemicals Agency

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Table of Contents

1 Background

The Swedish competent authority has been processing an application for the biocidal product Myrr Extra which contains the active substances Imidacloprid. Imidacloprid 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. Under Article 23(1) of Regulation 528/2012, Member States evaluating biocidal product containing an active substance that is a candidate for substitution in accordance with Article 10(1) are required to perform a comparative assessment.

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 R4BP database. Also there is no available information concerning available non-chemical alternative. 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 of the approval or renewal of an active substance which is a candidate for substitution. Separate from the assessment by the Reference Member State (UK), 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) should a tiered approach, preceded by a screening phase, be followed when carrying out a comparative assessment.

2 Screening phase of the comparative assessment

The screening phase shall allow through a simple assessment to judge whether it is required or not to perform a comprehensive comparative assessment. 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 through authorised biocidal products. If not, a conclusion could be reached that there is not an adequate chemical diversity and that 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

According the Guidance document each intended use included in the product SPC should be part of the comparative assessment.

Table 2. Intended uses of the biocidal product

	Myrr Extra
Product Type	18, insecticide
Active substance	The active substance imidacloprid is a neonicotinoid that acts on organisms by ingestion. It acts on the central nervous system as an agonist at the nAChRs in the insects. Imidacloprid has a killing effect.
Where relevant, an exact description of the authorised use	Bait granules against ants (incl. black garden ant) for outdoor use, around buildings. To be used by non-professionals.
Target organism (including, where relevant) development stage)	Ants (*Formicinae*) including black garden ant (*L. niger*)
Field(s) of use	Outdoor use around buildings
Application method(s)	Application of bait granules along ant trails, in cracks and crevices and/or in the nest entrance
Category(ies) of users	Non-professional

2.2 Chemical diversity of the active substances in Sweden

In Sweden, nine insecticides have been authorised under Regulation (EU) No 528/2012 for the same target organisms and within the same area of use. These products cover three different active substances but only two different mode of actions.

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 ants (including *L. niger*) 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 authorised Swedish insecticides which are relevant to compare with Myrr Extra.

The Swedish Chemicals Agency is not aware of any eligible non-chemical alternative which is likely to meet the required criteria of Article 23.3 of the BPR. ECHA will collect information for non-chemical alternatives during the public consultation in the context of the approval or renewal of an active substance that is a candidate for substitution (Article 10.3 of the BPR).

The comparative assessment concerning Myrr Extra could be finalised at the screening stage and could not demonstrate that any of the criteria in Article 23.3 are met. The Swedish Chemicals Agency shall therefore not prohibit or restrict the making available on the market or the use of the product based on the comparative assessment.