

**HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN**

**BIJLAGE II** bij het besluit d.d. 1-9-2017 tot toelating van het middel Quick Bayt WG / Quick Bayt Spray, toelatingnummer NL-0017633-0000

# **Evaluation Report Mutual Recognition**

## **Quick Bayt WG Quick Bayt Spray**

1-9-2017

Biocidal product assessment report related to product authorisation under (EU) Regulation 528/2012

# Contents

<b>1</b>	<b>General information about the product application .....</b>	<b>1</b>
<b>2</b>	<b>Summary of the product assessment.....</b>	<b>1</b>
2.1	Classification and labelling .....	1
2.2	Packaging and shelf-life .....	1
2.3	Physico/chemical properties and analytical methods .....	2
2.4	Effectiveness against target organisms .....	2
2.5	Risk assessment for human health .....	2
2.6	Risk assessment for the environment .....	4
2.7	Measures to protect man, animals and the environment .....	5
2.8	Substitution/exclusion criteria and comparative assessment.....	5
<b>3</b>	<b>Decision.....</b>	<b>5</b>

# 1 General information about the product application

<b>Name and address of the authorisation holder</b>	<b>Name</b>	Bayer CropScience SA-NV
	<b>Address</b>	Energieweg 1 Postbus 231 3640 AE Mijdrecht The Netherlands
<b>Authorisation number</b>	NL-0017633-0000	
<b>Date of the authorisation</b>	01-09-2017	
<b>Expiry date of the authorisation</b>	07-07-2022	

<b>Trade names</b>	Quick Bayt WG Quick Bayt Spray
Evaluating member state	UK
Name of the product in RMS	QuickBayt WG10
Active substance	Imidacloprid Cis-Tricos-9-ene (Muscalure)
PT	18
User category	Professional use

## 2 Summary of the product assessment

### 2.1 Classification and labelling

The proposed classification and labelling of the preparation is identical to that proposed in the Product Assessment Report by the competent authority UK:

Pictogram:	GHS09	Signal word:	Warning
H-statements:	H410	Very toxic to aquatic life with long lasting effects.	
P-statements:	P273	Avoid release to the environment.	
	P391	Collect spillage.	
Supplemental Hazard information:	P501	Dispose of contents/container in accordance with local regulation.	
Child-resistant fastening obligatory?			-
Tactile warning of danger obligatory?			-

### 2.2 Packaging and shelf-life

In accordance with the authorisation of RMS UK, the following packagings are authorised:

HDPE bottle – 250g to 1Kg

Polyfoil film bag - 250 g

The shelf-life is 2 years.

## 2.3 Physico/chemical properties and analytical methods

For the assessment of the physical and chemical properties, analytical methods and risk assessment regarding physical and chemical properties we refer to the Product Assessment Report of the original authorisation.

## 2.4 Effectiveness against target organisms

For the assessment of the effectiveness against target organisms we refer to the Product Assessment Report of the original authorization by the RMS United Kingdom (Quick Bayt WG10, Quick Bayt WG, Final PAR). The conclusions of the RMS are acceptable.

A post-authorization condition with regard to efficacy was postulated by the RMS: "further laboratory-based data will be required demonstrating the intrinsic palatability of the product to *M. domestica* and demonstrating > 95 % mortality at a given time point. In the palatability test, the alternative food source should be available to the flies throughout the period of the test. The palatability/knock down/mortality data can be submitted post-authorisation." The Ctgb agrees that these data should be provided as soon as possible to the UK CA post-authorization.

### 2.4.1 Authorised uses and use instructions

The applicant has provided a Dutch SPC. This has been adapted to our standards.

## 2.5 Risk assessment for human health

For the risk assessment for human health we refer to the Product Assessment Report of the original authorisation.

The formulation Quick Bayt WG10 is a bait which needs to be mixed with warm water. For a floor area of 100m<sup>2</sup> 250g bait should be mixed with up to 200mL of warm water and apply to 2m<sup>2</sup> of discrete surface, such as cardboard sheets (5.56 % w/w of imidacloprid and 0.047% w/w of cis-tricos-9-ene). These sheets should be hanged up in areas frequented by flies.

Reapplication may occur after a minimum of 28 days but it should not be repeated more than 5 times within a 12 month period. The product is intended for professional use. The Product Assessment Report (PAR) was prepared by the refMS United Kingdom (UK).

An *in vivo* skin sensitisation study with the product has been submitted and based on the study outcome no classification is warranted for sensitising properties. No study was submitted for acute oral, acute dermal toxicity, and acute inhalation or for skin and eye irritation. The classification of Quick Bayt WG10 was performed by the calculation method detailed in the Guidance on the Application of the CLP Criteria. The conclusions of UK on formulation toxicity are accepted by Ctgb.

No dermal absorption study is provided. However, a comparative *in vitro* dermal absorption study performed with an oil-based formulation of imidacloprid 0.5% in rat and human skin, submitted for the active substance approval assessment of imidacloprid has been considered (Assessment Report, EC, 2011). Dermal absorption values of < 1% for concentrate and 8% for dilution were agreed. In the CAR the value of 8% dermal absorption is considered to be a conservative approach for "Imidacloprid WG 10" granular formulation (concentrate and dilution). The concentrations of Imidacloprid present in the concentrate (10%) and diluted Quick Bayt product (5.5%) are far higher in comparison to diluted product Confidor 200 OD (0.07 %; presented in the CAR) therefore the dermal absorption for Quick Bayt are likely to be lower than 8% (EFSA Guidance on Dermal Absorption, 2012). Quick Bayt WG10 does not contain a high content in surfactants and is not

classified for skin irritation nor sensitisation likely to enhance absorption via the skin. This is accepted by Ctgb.

For cis-tricos-9-ene no dermal absorption data are available. Therefore the EFSA default values for dermal absorption should be used (25% for neat substances, 75% for solutions  $\leq 5\%$ ). Thus a dermal absorption of 75% of cis-tricos-9-ene is considered as default absorption. However, this is very likely an overestimation since cis-tricos-9-ene has a log Po/w far above 4 and is not soluble in water ( $< 7 \times 10^{-6}$  g/L). Therefore, additional testing of Quick Bayt WG10 is not scientifically justified.

For professional exposure, mixing 'Quick Bayt WG10' into a paintable slurry, adult applying the paintable slurry by brush or roller, adult hanging treated timber, sheets of cardboard or fabric and adult cleaning application equipment (i.e. paintbrush or roller) after use were considered by UK.

Mixing and loading model 5 has been used to model the scenario of mixing (TNSG 2007, p.65). TNSG 2002, part 2, p110 informs us that equipment used for insect control is portable, so the "granule" indicative values for "professional pouring formulation from a container into a portable receiving vessel" have been used. The model is developed for the loading of agricultural pesticides and covers relatively large amounts. Only exposure to the hands is involved.

The consumer product painting model 3 has been used to estimate exposure during 'paint-on' application (TNSG 2002, Part 2, p. 202). This model is based on brush painting of sheds and fences and is thought to best represent the painting of 'Quick Bayt WG10' using a brush or a roller onto pieces of timber, sheets of cardboard or fabric. A survey of pest controllers estimated that the median duration of using pesticides was 120 minutes with a range of 40 to 330 minutes (TNSG 2002, part 2, p111).

It is assumed that the user treating the timber or sheets of cardboard or fabric will also hang the treated material themselves. As such, the user would be aware of where the product has been applied and it can be assumed that they would avoid these areas. Exposure can therefore be considered negligible for this scenario.

For water based paint, the brush will often be cleaned under a running tap; the running water washing both the paint from the brush and any contamination from the hands (HEEG opinion 11). It is therefore concluded that exposure during the cleaning of the brushes is negligible.

Since the worst case for the combined professional exposure is 1090% of the AEL-long-term for imidacloprid and 211% of the AEL-medium/long-term for cis-tricos-9-ene, UK concluded that adverse effects from exposure to imidacloprid or cis-tricos-9-ene are expected for the unprotected professional user during the application of Quick bayt WG. Risk for professional users is demonstrated to be acceptable providing users wear appropriate PPE and taken into account a more realistic figure for duration of application from 330 to 120 mins (41% of the AEL-long-term imidacloprid and 9% of AEL-medium/long-term cis-tricos-9-ene). This is accepted by the Ctgb.

For bystanders (general public) exposure following application of the product the inhalation of volatilised imidacloprid was considered by UK. The HEEG opinion 13 on the assessment of inhalation exposure to volatilised biocides provided the screening tool.

Since the risk from inhalation exposure to imidacloprid can be excluded, UK concluded that no adverse effects from exposure to imidacloprid are expected for the bystanders (general public) during the application of Quick Bayt WG10. This is accepted by the Ctgb.

The imidacloprid exposure by the professional user could be considered as worst case. Further consideration was only necessary for bystander inhaling volatilised cis-tricos-9-ene after the application of 'Quick Bayt WG10'. The first tier vapour exposure assessment has been modelled in ConsExpo. The instantaneous release mode has been used. Since the exposure is less than the long-term AEL (0.024 mg/kg bw/day) UK concluded that no adverse effects from exposure to cis-tricos-9-ene are expected for the bystanders (general public) during the application of Quick bayt WG. This is accepted by the Ctgb.

'Quick Bayt WG10' is used inside animal/agricultural housing but it is unlikely that livestock will have access to the product because the label states 'When hanging surfaces, care must be taken only to use places out of reach of food producing animals and where foodstuffs will not be contaminated'. Nevertheless, a worst case scenario (of a person consuming chicken contaminated with imidacloprid residues) has been considered associated to the consumption of dead flies and inhalation of residues by chickens. Chickens are chosen because of their low body weight compared to pigs and dairy and because hens would actively seek out dead flies for consumption leading to a higher intake of residues than other livestock. Furthermore, UK indicated that following phrases should appear on the label:

- "Do not use where food, feed or water could become contaminated"
- "When hanging surfaces, care must be taken only to use places out of reach of food producing animals and where foodstuffs will not be contaminated"
  
- "PREVENT ACCESS TO BAIT by children and animals"

Since the worst case estimated uptake for toddlers is 35% of the AEL and including the phrases that should appear on the label UK concluded that the Risk for consumers via residues in food is acceptable. This is accepted by Ctgb.

The combined exposure scenarios due to various exposure scenarios for either imidacloprid or cis-tricos-9-ene have been investigated and did not lead to another conclusion. However, the formulation Quick Bayt WG10 is a mixture of two active substances and the combined exposure to these active substances may lead to a different toxicological profile than the profiles based on the individual substances. The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity. CMS NL is of the opinion that this is justified because no repeated dose toxicity tests are available for cis-tricos-9-ene and comparable effects caused by cis-tricos-9-ene as natural food components of apples, citrus-juices, honey, olive-oil and hazelnut-oil (AELs were estimated based on human exposure to higher mono-alkenes (C17:1-C30:1)) and imidacloprid are not expected. Moreover, only 41% of the AEL-long-term imidacloprid and 9% of AEL-medium/long-term cis-tricos-9-ene has been calculated for professionals wearing appropriate PPE. Ctgb agreed with the assessment performed by the UK.

UK did not identify substances of concern. This is accepted by the Ctgb.

## 2.6 Risk assessment for the environment

QuickBayt WG is an insecticide (PT18) based on the active substances Imidacloprid and *cis*-Tricos-9-ene (Muscalure). Substances of concern regarding the environment were not identified. The product is intended to control flies in animal housing. The product is painted on boards (e.g. cardboard and wood) which are subsequently hung or attached in areas where flies tend to aggregate. The number of boards depends on the board's surface, but the applicant recommends to paint 2 m<sup>2</sup> for every 100 m<sup>2</sup> floor surface.

Considering that emission to the environment is negligible as boards are discharged as waste according to local regulations or re-used when inactive and not wetted during service life, unacceptable risks for surface water and soils cannot be expected. However, emission to the sewer or manure storage is possible when equipment is cleaned with water, but prevented by a risk mitigation measure that states that equipment and/or waste water should be collected and disposed according to national legislations. Details on the environmental risk assessment are found in the Product Assessment Report of the original authorisation.

**Overall conclusion for the aspect environment:** The conclusions in the risk assessment of the RMS are valid.

## **2.7 Measures to protect man, animals and the environment**

Based on this risk assessment, it was concluded that no adverse health effects are expected for the protected (gloves, suitable protective clothing) professional user after dermal and respiratory exposure to imidacloprid and cis-tricos-9-ene as a result of the application of Quick Bayt WG10, when used in accordance to the SPC. Furthermore, the following operator protection phrases must appear on the label:

- Wear suitable protective gloves when handling the product
- Wear suitable protective clothing (coated coveralls) and suitable protective gloves when applying the product or when handling contaminated surfaces

To exclude contamination of food/feed or water the following phrases should appear on the label :  
Do not use where food, feed or water could become contaminated  
When hanging surfaces, care must be taken only to use places out of reach of food producing animals and where foodstuffs will not be contaminated.  
PREVENT ACCESS TO BAIT by children and animals.

For the measures to protect animals and the environment a reference is made to the Product Assessment Report of the original authorisation, and to the SPC of the CMS NL.

## **2.8 Substitution/exclusion criteria and comparative assessment**

The active substance imidacloprid shall be considered a candidate for substitution using the criteria in Article 10(1) of the BPR, therefore a comparative assessment of Quick Bayt WG has been performed by RMS UK. The RMS has considered all authorised products for the relevant use, and concluded that the comparative assessment for of Quick Bayt WG can be finalized at the screening stage and that the product of Quick Bayt WG can be authorized for a period not exceeding 5 years in accordance with Article 23(6) of the BPR. As RMS UK has included in its assessment all products authorized according to the BPR in The Netherlands, an authorisation based on mutual recognition can be granted in The Netherlands.

## **3 Decision**

The authorisation of Quick Bayt WG / Quick Bayt Spray is based on mutual recognition of the authorisation of RMS UK. For the evaluation we refer to the product assessment report which has been composed by the RMS conform the Common Principles.

It is concluded that the application of Quick Bayt WG / Quick Bayt Spray according to the use instructions as stated in the SPC, will be effective and that there will be no harm for the health of humans and for the environment.