Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

# PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

TERMIGARD PLUS

Product type 18

Diflubenzuron as included in the Union list of approved active substances

Case Number in R4BP: BC-BN014745-39

Evaluating Competent Authority: SPAIN

August 2020

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| **Application type** | **Ref MS** | **Case number/Asset number in the ref MS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
|---|---|---|---|---|
| NA-MIC | ES | BC-JN054596-20 | August 2020 | Add the packaging size. |

# 1 CONCLUSION

The assessment presented in this report has shown that, TERMIGARD PLUS, with the active substance diflubenzuron, at a level of 0,25% w/w, may be authorised for use as an insecticide (product-type 18) for the control against termites by trained professional users.

An acceptable risk to humans, following primary and secondary exposure to the active substance diflubenzuron, has been identified for all uses assessed.

The applicant has submitted 18 essays to support the efficacy of the product. 6 trials against *Reticulitermes flivipes*, 8 trials against *Reticulitermes grassei* and 2 trials against *Reticulitermes banyulensis.*
The description off the trials have been summarized in annex 3. Section 3.5.

The biocidal product TERMIGARD PLUS is cellulose bait impregnated in diflubenzuron (0.25%). No animal or human data on toxicological properties has been generated, but a calculation of toxicological properties according to Regulation (EC) No 1272/2008 (CLP Regulation) criteria taking into account the amount of each ingredient in the product has been done instead.
The applicant has submitted a justification for non-submission data and Spanish-CA accepts these justifications.

Considering that in one day the worker can treat different houses, a reverse scenario is performed in order to determine the maximum quantity of product that can be manipulated by the operator to reach 100% of the long term AEL during a day.

This maximum quantity of product is closed to 45 Kg or biocial product, corresponding to place 900 baits per day. If the maximun number of baits per house is 21, the manipulation of 45 kg a day would lead to the treatment of 43 houses considering the maximum quantity presented in the efficacy data. The duration of the task (checking of each bait station, replacing of the consumed bait…) can be estimated to more than one hour, so the treatment of more than 43 houses by the same opetator is very unlikely.

Therefore, the risk is considered as acceptable providing the use PPE (protective gloves) by the trained professional user during handling of the product.

The environmental risk assessment. No harmonized exposure scenario is available for treatment against termites. Based on a previous approach validated at European level for hexaflumuron active substance approval, indoor and outdoor uses lead to unacceptable risk for the soil and no data in the dossier is available to refine the risk assessment. Due to the use pattern of diflubenzuron in the bait stations, diflubenzuron-containing baits will only be dissiminated when and where termite activity is detected (treated area).

According to the data available for the amount of product that could be applied (10 places in 1 ha), the risk for groundwater is acceptable for 5 of 8 scenario locations. Howecer, the risk should be acceptable when less places are treated in the areas where unacceptable risk has bee found. No data are available in the dossier nor provided by the applicant during the PAR commenting period to refine the risk assessment or to conclude on the relevance of a number of sites treated to consider the risk for groundwater as acceptable. Therefore, the risk assessment is not finalized for groundwater due to the lack of data about the maximum number of treated sites per hectare.

The risk of secondary poisoning is acceptable.

We considers that the product should be authorized, despite unacceptable risk ins soil and groundwater, in applicaction of article 19(5) of the Biocidal product Regulation 528/2012.

The following risk mitigation measures must be followed when using the product, notably to limit risk for the consumers and the environment:

- Remove bait and bait stations at the end of the treatment.
- Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste.
- Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations
- Code the waste according to Decision 2014/955 / EU.

Do not release to soil, ground, surface water or any kind of sewer.

# 2 ASSESSMENT REPORT

## 2.1 Summary of the product assessment

### 2.1.1 Administrative information

#### 2.1.1.1 Identifier of the product

| Identifier | Country |
|---|---|
| TERMIGARD PLUS | SPAIN |

#### 2.1.1.2 Authorisation holder

| | | |
|---|---|---|
| **Name and address of the authorisation holder** | **Name** | QUÍMICA DE MUNGUÍA, S.A. |
| | **Address** | Derio Bidea, 5148100 Munguía – Bilbao.<br>Spain |
| **Authorisation number** | ES/APP(NA)-2019-18-00596 | |
| **Date of the authorisation** | 26/03/2019 | |
| **Expiry date of the authorisation** | 26/03/2029 | |

#### 2.1.1.3 Manufacturer of the product.

| | |
|---|---|
| **Name of manufacturer** | QUÍMICA DE MUNGUÍA, S.A. |
| **Address of manufacturer** | Derio Bidea, 5148100 Munguía – Vizcaya<br>Spain |
| **Location of manufacturing sites** | Derio Bidea, 5148100 Munguía – Vizcaya<br>Spain |

#### 2.1.1.4 Manufacturer of the active substance.

| | |
|---|---|
| **Active substance** | Diflubenzuron |
| **Name of manufacturer** | Chemtura Europe Limited |
| **Address of manufacturer** | Kennet House, 4 Langley Quay, Slough,<br>Berkshire SL3 6EH<br>United Kingdom |
| **Location of manufacturing sites** | See confidential annex |

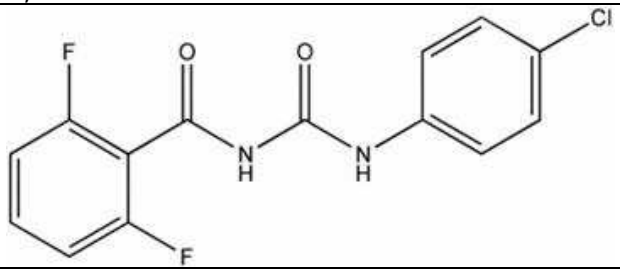
### 2.1.2 Product composition and formulation

NB: the full composition has been provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☒
No ☐

### 2.1.2.1 Identity of the active substance

| Main constituent(s) | |
|---|---|
| **ISO name** | Diflubenzuron |
| **IUPAC or EC name** | 1-(4-chlorophenyl)-3-(2,6-diflurobenzoyl)urea |
| **EC number** | 252-529-3 |
| **CAS number** | 35367-38-5 |
| **Index number in Annex VI of CLP** | |
| **Minimum purity / content** | 0,25% |
| **Structural formula** |  |



### 2.1.2.2 Candidate(s) for substitution

Diflubenzuron is not a candidate for substitution.

### 2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product.

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|---|---|---|---|---|
| Diflubenzuron | 1-(4-chlorophenyl)-3-(2,6-diflurobenzoyl)urea | Active substance | 35367-38-5 | 252-529-3 | 0,25 |
| - | - | Non-active substance | - | - | - |

### 2.1.2.4 Information on technical equivalence

The source of diflubenzuron is the same that considered for inclusion in the Union list of approved active substances.

### 2.1.2.5 Information on the substance(s) of concern

No substance of concern was identified.

### 2.1.2.6 Type of formulation

| |
|---|
| Granular bait (cellulose granules impregnated in diflubenzuron) |

## 2.1.3 Hazard and precautionary statements

**Classification and labelling of the product according to the Regulation (EC) 1272/2008**

| **Classification** | |
|---|---|
| Hazard category | Aquatic Acute 1<br>Aquatic Chronic 1 |
| Hazard statement | H400<br>H410 |
| | |
| **Labelling** | |
| Pictogram |  <br>GHS09 |
| Signal words | Warning |
| Hazard statements | H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P273: Avoid release to the environment.<br>P391: Collect spillage.<br>P501: Dispose of content/container as hazardous waste to a register establishment or undertaking, in accordance with current regulations. |

## 2.1.4 Authorised uses

### 2.1.4.1 Use description Table 1

**Table 1. Use # 1 – Insecticide against termites - indoors - trained professional users.**

| | |
|---|---|
| **Product Type** | PT18: insecticides, acaricides and products to control other arthropods |
| **Where relevant, an exact description of the authorised use** | Insecticidal. The product, supplied in plastic bag, has to be mixed with water before its introduction in the bait stations. |

| | |
|---|---|
| **Target organism (including development stage)** | • *Reticulitermes spp.* |
| **Field of use** | Indoors in the pathways of termites in industrial, domestic and public buildings. |
| **Application method.** | Bait system. |
| **Application rates and frequency** | Dose: Depends on the number of connections established between the outdoor bait stations and on the number of points inside the building where termites appear. The total amount of bait will be always function of the consumption.<br>Frequency of application: The bait is reviewed every 30-45 days and replaced when the bait is consumed. In the case of pest persist repeat the procedure. |
| **Category of user** | Trained professional users |
| **Pack sizes and packaging material** | Sachets of high density polyethylene (HDPE) of 50, 75, 500 and 1000g. Box of board containing 10 sachets. |

2.1.4.1.1 Use-specific instructions for use

| |
|---|
| See the point 2.1.5.1 |

2.1.4.1.2 Use-specific risk mitigation measures.

| |
|---|
| See the point 2.1.5.2 |

2.1.4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

| |
|---|
| See the point 2.1.5.3 |

2.1.4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

| |
|---|
| See the point 2.1.5.4 |

2.1.4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

| |
|---|
| See the point 2.1.5.5 |

### 2.1.4.2 Use description. Table 2.

**Table 2. Use #2 – Insecticide against termites - outdoors - trained professional users.**

| | |
|---|---|
| **Product Type** | PT18: insecticides, acaricides and products to control other |

| | |
|---|---|
| | arthropods |
| **Where relevant, an exact description of the authorised use** | Insecticidal cellulose powder bait (product PT18) used to control termites (*Reticulitermes spp.*) in and around industrial, domestic and public buildings. The product, supplied in plastic bag, has to be mixed with water before its introduction in the bait stations. |
| **Target organism (including development stage)** | • *Reticulitermes spp.* |
| **Field of use** | Outdoors in the pathways of termites |
| **Application method.** | Bait system. |
| **Application rates and frequency** | Dose: Depends on the number of connections established between the outdoor bait stations and on the number of points inside the building where termites appear. The total amount of bait will be always function of the consumption.<br>Frequency of application: The bait is reviewed every 30-45 days and replaced when the bait is consumed. In the case of re-infestación repeat the procedure. |
| **Category(ies) of users** | Trained professional users |
| **Pack sizes and packaging material** | Sachets of high density polyethylene (HDPE) of 50, 75, 500 and 1000g. Box of board containing 10 sachets. |

2.1.4.2.1 Use-specific instructions for use

| |
|---|
| See the point 2.1.5.1 |

2.1.4.2.2 Use-specific risk mitigation measures.

| |
|---|
| See the point 2.1.5.2 |

2.1.4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

| |
|---|
| See the point 2.1.5.3 |

2.1.4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

| |
|---|
| See the point 2.1.5.4 |

2.1.4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

| |
|---|
| See the point 2.1.5.5 |

## 2.1.5 General directions for use

### 2.1.5.1 Instructions for use

Dispose the baits on the bear-baits in direct contact with the attacked wood or perforated tubes to introduce inside the ground, in order to reach all the colonies which may exist in your environment.

The application patern of TERMIGARD PLUS (both indoors and outdoors) comprises different stages:

-Stage 1: Survey. In order to obtain the maximum performance of the product is necessary to know with the maximum accuracy where the termites are identified their pathways. This step is performed with precision equipment.

-Stage 2: Testing placement. Once termite's pathway are identified, it is required to place a testing piece of cellulose (moistened cardboard or a piece of wood) in order to attract and check the level of infestation. The testing bait is introduced into a bait station which is placed inside the soil in the sorrounding of the building (outdoor use) or which is placed in the walls or floor inside the building in middle of termites pathway.

-Stage 3: Bait application. When the testing bait shows the presence of termites (the termites attack directly the carboard or the piece of wood), the product is added replacing the testing bait. TERMIGARD PLUS is placed into the bait station inside a plastic bag or by refilling the bait station (only outdoor). When it is applied inside a bag, the bag is drilled or cut in the bait station with a small punch or knife and the bait station is closed again, allowing the termites to enter through the small slits in the bait station or through the testing bait itself.

Do not mix with other chemicals.

-Check the efficacy of the product on site: if need be, causes of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance.

-The users should inform if the treatment is ineffective and report straightforward to the registration holder.

### 2.1.5.2 Risk mitigation measures

Before use the product, read carefully the label.

In order to avoid risks for the people and the environment, follow the instructions of use.

Do not use on foods nor utensils of kitchen.

Do not perform the operation in the presence of children and / or pets.

Do not apply on surfaces or utensils likely to be in direct contact with food, feed or livestock.
Do not eat food and do not feed livestock with crops grown on land at and near bait stations.
Decontaminate and/or demonstrate the non-residue situation before any reimplantation of edible crops in vicinity of treated points

Wear waterproof gloves.

This product should be used in alternation with other products not containing the same a.s. to avoid resistant populations'.

The product should be reapplied only until the pest is controlled.

Use products at recommended doses and intervals.

Areas where barrier type termiticides may have been previously applied, such as within half meter of the foundation wall, must be avoided if possible.

- Remove bait and bait stations at the end of the treatment.
- Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste.
- Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations
- Code the waste according to Decision 2014/955 / EU.

Do not release to soil, ground, surface water or any kind of sewer

### 2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment.

**First aid measures:**

- In case of eye exposure; check for and remove contact lenses, wash eyes with plenty of water maintaining eye lids open for at least 15 minutes.
- Skin contact; wash affected area with plenty of water and soap, without scrubbing.
- If necessary take the affected individual to a healthcare center and bring packaging or label whenever possible.

**NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED!**

**Advice for medical and healthcare personnel:**

- Provide symptomatic and supportive treatment.

**WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER ☎ [*INSERT LOCAL NUMBER HERE*].**

### 2.1.5.4 Instructions for safe disposal of the product and its packaging

Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste.

Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations.

Code the waste according to Decision 2014/955 / EU.

Do not release to soil, ground, surface water or any kind of sewer.

### 2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

| |
|---|
| Keep in the original recipents.<br><br>Store in a dry place in the shelter.<br><br>Keep out of the reach children.<br><br>Shelf life of 24 months. |

### 2.1.6 Other information

| |
|---|
| Trained professional: pest control operators, having received specific training in insecticide control according to the national legislation in force. |

### 2.1.7 Packaging of the biocidal product

| Type of packaging | Size/volume of the packaging | Material of the packaging | Type and material of closure(s) | Intended user (e.g. professional, non-professional) | Compatibility of the product with the proposed packaging materials (Yes/No) |
|---|---|---|---|---|---|
| Sachet | 50, 75, 500 and 1000g | Plastic: HDPE | - | Trained Professional | Yes |

### 2.1.8 Documentation

### 2.1.8.1 Data submitted in relation to product application

No new data in support of the active substance or substances of concern have been submitted.

### 2.1.8.2 New data submitted in support of the evaluation of the biocidal product are listed in Annex 3.1.Access to documentation

Chemtura Europe Limited owns the active substance dossier has provided the applicant (Química De Munguía, S.A) with a letter of access to these data and therefore no further consideration is required from a chemistry perspective.

## 2.2 Assessment of the biocidal product

### 2.2.1 Intended use(s) as applied for by the applicant

Table 2. Intended use # 1.

| | |
|---|---|
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Bait system for termite control. Use only by trained professionals for treatment of underground termites in soils, foundation and walls. |
| Target organism (including development stage) | Reticulitermes sp. |
| Field of use | Indoor, outdoor |
| Application method(s) | Bait application. |
| Application rate(s) and frequency | The application dose will depend on the numer of connetions established between the ooutdorr bait stations and on the number of points inside the building where termites appear. The total amount of bait will be always function of the consumption. In the case of re-infestación repeat the procedure. The bait is reviewed every 30-45 days and replaced when the bait is consumed. |
| Category(ies) of user(s) | Trained Professional users |
| Pack sizes and packaging material | Sachets of high density polyethylene (HDPE) of 50, 75, 500 and 1000g. Box of board containing 10 sachets. |

### 2.2.2 Physical, chemical and technical properties

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Physical state at 20 °C and 101.3 kPa | EPA 712-C-96-020 | Diflubenzuron (0,25%) | Fibrous dust | *See Confidential Annex* |
| Colour at 20 °C and 101.3 kPa | EPA 712-C-96-019 | Diflubenzuron (0,25%) | White | *See Confidential Annex* |
| Odour at 20 °C and 101.3 kPa | EPA 712-C-96-021 | Diflubenzuron (0,25%) | Odourless | *See Confidential Annex* |
| Acidity / alkalinity | - | - | Not required (4<pH<10) | *See Confidential Annex* |
| | Standard Methods for the Examination of Water and Wastewater | Diflubenzuron (0,25%) | pH= 6,10 (1%, p/p) | *See Confidential Annex* |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | (ALPHA-AWWA-WPCF).<br><br>Determination of pH values. CIPAC MT 75 | | | |
| Relative density / bulk density | Pour and tap bulk density of granular materials. CIPAC MT 159<br>Bulk density. CIPAC MT 186 | Diflubenzuron (0,25%) | Pour density= 0,061 g/ml<br><br>Bulk density= 0,105 g/ml | *See Confidential Annex* |
| Storage stability test – **accelerated storage** (8 weeks at 40ºC) | CIPAC MT 46.3<br>NF X 41-580-10:2006 | Diflubenzuron (0,25%) | Pack tested: 20g in an inert and closed packaging (glass flask, PTFE cap)<br><br>Active content<br>Initial: 0,207% w/w<br>4 weeks: 0,209% w/w<br><br>Initial: 0,213% w/w<br>8 weeks: 0,212% w/w<br><br>Physical stability: No change of appearance | *See Confidential Annex* |
| Storage stability test – **long term storage at ambient temperature** | OPPTS<br>830.6303<br>830.6302<br>830.6304 | Diflubenzuron (0,25%) | t=0 days<br>Concentration (% w/w)<br>E-13/12-001S<br>0.187<br><br>t=12 months<br>Concentration (% w/w)<br>E-13/12-003S<br>0.183<br><br>t=24 months<br>Concentration (% w/w)<br>E-13/12-004S<br>0.190 | *See Confidential Annex* |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | Packaging test: 50 g. of polyethylene bag<br><br>Impurity PCA content:<br>t=0: <0,005%<br>t=6 months: <0,005%<br>t=12 months: <0,005%<br><br>Appearance: No changes have been observed before and after storage<br><br>pH<br>Before storage: 6,10<br>After storage: 7,02 | |
| Storage stability test – **low temperature stability test for liquids** | - | - | This study is not needed as the product is a solid. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | This study is not needed as the product may be kept out of sun exposure during storage | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | No changes has been observed | *See Confidential Annex* |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | No changes has been observed | *See Confidential Annex* |
| Wettability | - | - | Not relevant | - |
| Suspensibility, spontaneity and | - | - | Not relevant | - |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| dispersion stability | | | | |
| Wet sieve analysis and dry sieve test | - | - | Not relevant | - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant | - |
| Disintegration time | - | - | Not relevant | - |
| Particle size distribution, content of dust/fines, attrition, friability | Dust content and apparent density of granular pesticide formulations. CIPAC MT 58.2<br><br>Dry sieve analysis of water dispersible granules CIPAC MT 170 | Diflubenzuron (0,25%) | Fraction of granular material= 14,9% w/w<br><br>Fraction of dust >150 µm= 29,3% w/w<br><br>Fraction of dust <150 µm= 55,8% w/w | *See Confidential Annex* |
| Persistent foaming | - | - | Not relevant | - |
| Flowability/Pourability/Dustability | - | - | Not relevant | - |
| Burning rate — smoke generators | - | - | Not relevant | - |
| Burning completeness — smoke generators | - | - | Not relevant | - |
| Composition of smoke — smoke generators | - | - | Not relevant | - |
| Spraying pattern — aerosols | - | - | Not relevant | - |
| Physical compatibility | - | - | Not relevant | - |
| Chemical compatibility | - | - | Not relevant | - |
| Degree of dissolution and dilution stability | - | - | Not relevant | - |
| Surface tension | - | - | Not relevant | - |
| Viscosity | - | - | Not relevant | - |

**Conclusion on the physical, chemical and technical properties of the product**

TERMIGARD PLUS is a white, fibrous and odourless powder. The pH value for the product is 6.1 (between 4.0-10.0) so the acidity/alkalinity test is not applicable. The bulk density value for the product is ca. 0.061 g/cm$^3$ and the tap density is 0.105 g/cm$^3$. The formulation exhibited stability under accelerated storage 8 weeks at 40ºC, and the long term storage data for this product were acceptable.

Post-authorization requirement:

- Due a shelf-life of 24 months is set, the PCA impurity content after 24 months in Termigard plus should be required through an analytical method (LOQ<0,0000075%) for its determination in the biocidal product at 0,25% Diflubenzuron.

### 2.2.3 Physical hazards and respective characteristics

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Explosives | - | - | TERMIGARD is not considered to be potentially explosive. The preparation is not intended for use in combination with other products | - |
| Flammable gases | - | - | Diflubenzuron is not highly flammable and celullose is not flammable | - |
| Flammable aerosols | - | - | Diflubenzuron is not highly flammable and celullose is not flammable | - |
| Oxidising gases | - | - | TERMIGARD does not contain any oxidising agente. The preparation is not intended for use in combination with other products. | - |
| Gases under pressure | - | - | Not relevant | - |
| Flammable liquids | - | - | Not relevant | - |
| Flammable solids | Method A10. Regulation (EC) Nº 440/2008 | Diflubenzuron (0,25%) | Time of burning > 45s | *See Confidential Annex* |
| Self-reactive substances and mixtures | - | - | Not relevant | - |
| Pyrophoric liquids | - | - | Not relevant | - |
| Pyrophoric solids | - | - | Not relevant | - |
| Self-heating substances and mixtures | - | - | Not relevant | - |
| Substances and mixtures which in contact with water | - | - | Not relevant | - |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| emit flammable gases | | | | |
| Oxidising liquids | - | - | Not relevant | - |
| Oxidising solids | - | - | Not relevant | - |
| Organic peroxides | - | - | Not relevant | - |
| Corrosive to metals | - | - | Not relevant | - |
| Auto-ignition temperatures of products (liquids and gases) | - | - | Not relevant | - |
| Relative self-ignition temperature for solids | Method A15. Regulation (EC) Nº 440/2008 | Diflubenzuron (0,25%) | T= 279,6ºC | *See Confidential Annex* |
| Dust explosion hazard | - | - | Not relevant. | - |

| **Conclusion on the physical hazards and respective characteristics of the product** |
|---|
| TERMIGARD PLUS is not considered to be potentially explosive and does not contain an oxidising or reducing agent. It is not flammable, showing a burning time > 45 s and a relative self-ignition temperature of 279.6ºC. |

### 2.2.4 Methods for detection and identification

| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | Range | Mean | RSD | | |
| Active substance in biocidal product: Diflubenzuron | HPLC-UV | Six measurements | $R^2$=0,9996 | No interference at the wave length of the active ingredient to quantify or no interference greater than 3% of the active ingredient to quantify in HPLC-UV | 96,69-102,21 | 99,28 | 0,6312 | Not relevant | *See Confidential Annex* |

| **Conclusion on the methods for detection and identification of the product** |
|---|
| The contents of diflubenzuron and the relevant metabolites CPU and DFBA in soil are determined by LC-MS/MS using one transition, with a LOQ of 0.05 mg/kg for all species. The content of diflubenzuron in air is quantified by means of LC-MS/MS using two ion transitions, with a LOQ of 0.6 µg/m3 , which is considered acceptable with respect to the AEL of 0.0066 mg/kg bw/day.<br>In accordance with results of the analytical method validation, all acceptance criteria have been satisfied: the applied method is consistent with the requirements of the validation for the quantitative analysis of active ingredients in solid formulations.The analytical methods (AGQ Internal Procedure PE-857 "Determinación de Diflubenzuron por cromatografía y Validación del método") are found to be specific, linear, precise and accurate for the Diflubenzuron content determination. The results obtained during the validation were totally correct. Therefore, the method was assumed as validated.<br>No method is required for the analysis of diflubenzuron residues in food and feeding stuffs of plant origin as the intended use pattern does not result in contact with these matrices.<br>A Method for body fluids and tissues is not required since diflubenzuron is not classified as toxic or highly toxic.<br>Regarding an available method to determine residues of Diflubenzuron in water, theses studies have been obtained throught a letter of access of the technical Diflubenzuron. |

## 2.2.5 Efficacy against target organisms

### 2.2.5.1 Function and field of use

Mains group 03: Pest Control.
Product Type 18: Insecticides, acaricides and products to control other arthropods.

TERMIGARD PLUS is baits system for termite control (*Reticulitermes spp*) for trained professional user only. Treatment is applied in soils, foundations and walls. Indoor and outdoors.

### 2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

TERMIGARD PLUS provides an effective control against termites *Reticulitermis flavipes* (formely R. santonensis), *Reticulitermes grassei* and *reticulitermes banyulensi* and thus preserving the wood of industrial, domestic and public buildings.

### 2.2.5.3 Effects on target organisms, including unacceptable suffering

The s.a. Diflubenzuron belong to the chemical family of benzoilureas. These act by inhibition of chitin biosynthesis. It’s a growth regulation but target protein responsible for biological activity is unknown, or uncharacterized. (IRAC).

The workers ingest the bait and take it back to the colony. The whole colony will be contaminated through trophallaxis, all developmental stages able to moult will die.There is no direct ovicide effect in this case but when all workers are dead, there is no care for the eggs, so the whole colony dies.

It is not known whether there is an unacceptable suffering for termites.

### 2.2.5.4 Mode of action, including time delay

Diflubenzuron is a growth regulator. It acts as an endocrine disruptor in species that synthesize chitin, causing alterations in the moult or metamorphosis. It influences the chain of reactions caused by the hormone ecdysone. Diflubenzuron affects the hatching of eggs, molt of larvae and even the fertility of adults.
It does not cause a direct death but causes alterations in the larvae, which causes them not to reach adults.

Diflubenzuron is an insecticide which acts by ingestion and contact. Because all the termites in a colony do not moult at the same time, the effect of diflubenzuron on the colony as a whole progressive.

### 2.2.5.5 Efficacy data

| Experimental data on the efficacy of the biocidal product against target organism(s) | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Function** | **Test substance** | **Field of use envisaged** | **Test organisms** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| *Insecticide* | *Diflubenzuron 0.25%* | *Laboratory test* | *R. flavipes* | *XP X41-543-1 Test A* | *Exposure time: 9 weeks. 4 replicates. 4 controls. N: 100 workers* | *Mortality: 96.5%. te= 20 days.* | III.5.10.1 |
| | | | | *XP X41-543-1 Test B* | *Exposure time: 20 days step 1 and 42 weeks, step 2. . 4 replicates. 4 controls. N: 200 workers* | *Moratlity: 100% Control mortality was 100%. Test no valid. Justification accept.* | III.5.10.2 |
| | | | | *Xp X41-543-1 Test C* | *Exposure time: 33 weeks. 6 replicates and 2 controls. N: 500 workers.* | *Moratlity: 100% within 11-33 weeks (25 weeks in average) Control mortality was 24.01% in average.* | III.5.10.3 |
| | | | *R. grassei* | *XP X41-543-1 Test A* | *Exposure time: 12 weeks. 4 replicates. 4 controls. N: 100 workers* | *Mortality: 100%. te= 26 days.* | III.5.10.7 |
| | | | | *Justification. Test B* | *Justification of non submission.* | *Accept.* | III.5.10.8 |
| | | | | *XP X41-543-1 Test C* | *Exposure time: 28 weeks. 6 replicates and 2 controls. N: 500 workers. 20 nymphs, 10 soldiers.* | *Moratlity: 100% within 14-28 weeks (19 weeks in average) Control mortality was 20% in average.* | III.5.10.9 |
| | | *Field test* | *R. grassei* | *XP X41-543-2* | *Site: Church on Abaigar, Navarra, Spain. Indoor and outdoor. Conection phase: 5 weeks. Intoxication phase: 42 weeks.* | *All device were inactive at the end of the trial. Confirmation of elimination: YES.* | III.5.10.10 |
| | | | | *XP X41-543-2* | *Site: Private house on Bizkaia, Spain. Indoor and outdoor. Conection phase: 5 weeks. Intoxication phase: 43 weeks.* | *All device were inactive at the end of the trial. Confirmation of elimination: YES.* | III.5.10.11 |
| | | | | *XP X41-543-2* | *Site: Private house on Galdeano, Navarra, Spain.* | *All device were inactive at the end of the trial.* | III.5.10.12 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | *Indoor and outdoor.*<br>*Conection phase: 5 weeks.*<br>*Intoxication phase: 43 weeks* | *Confirmation of elimination: YES.* | |
| | | | | *CTBA-BIO-E-03* | *Site: Private house on Valence sur Baïse, France.*<br>*Indoor and outdoor.*<br>*Conection phase: 8 weeks.*<br>*Intoxication phase: 52 weeks.* | *All device were inactive at the end of the trial.*<br>*Confirmation of elimination: YES.* | III.5.10.13 |
| | | | | *CTBA-BIO-E-03* | *Site: Private house on le Haillan, France.*<br>*Indoor and outdoor.*<br>*Conection phase: 13 weeks.*<br>*Intoxication phase: 16 weeks.* | *All device were inactive at the end of the trial.*<br>*Confirmation of elimination: YES.* | III.5.10.14 |
| | | | *R. flavipes* | *CTBA-BIO-E-03/ XP X41-543-2* | *Site: Private house on Thouars, France.*<br>*Indoor and outdoor.*<br>*Conection phase: 6 weeks.*<br>*Intoxication phase: 63 weeks.* | *11 indoors devices, 5 devices were still actives.*<br>*The only one outdoor device was still active.*<br>*Confirmation of elimination: NO.* | III.5.10.4 |
| | | | | *CTBA-BIO-E-03/ XP X41-543-2* | *Site: Two private houses on Angoulême, France.*<br>*Conection phase: 4 weeks.*<br>*Intoxication phase: 40 weeks* | *All device were inactive at the end of the trial.*<br>*Confirmation of elimination: YES.* | III.5.10.5 |
| | | | | *CTBA-BIO-E-03/ XP X41-543-2* | *Site: Private house on Thouars, France.*<br>*Indoor and outdoor*<br>*Conection phase: 6 weeks.*<br>*Intoxication phase: 59 weeks* | *All device were inactive at the end of the trial.*<br>*Confirmation of elimination: YES.* | III.5.10.6 |
| | | | *R. Banyulensis* | *CTBA-BIO-E-03* | *Site: Private house on Corneilla-la-Rivière, France.*<br>*Indoor and outdoor.*<br>*Conection phase: 3 weeks.*<br>*Intoxication phase: 26 weeks* | *All device were inactive at the end of the trial.*<br>*Confirmation of elimination: YES.* | III.5.10.15 |
| | | | | *CTBA-BIO-E-03* | *Site: Private house on St Cyprien Plage, France.*<br>*Indoor and outdoor.*<br>*Conection phase: 5 weeks.*<br>*Intoxication phase: 8 weeks* | *All device were inactive at the end of the trial.*<br>*Confirmation of elimination: YES.* | III.5.10.16 |

| **Conclusion on the efficacy of the product** |
|---|
| The applicant has submitted 18 essays to support the efficacy of the product. 6 trials against *Reticulitermes flivipes*, 8 trials against *Reticulitermes grassei* and 2 trials against *Reticulitermes banyulensis.*<br>The description of the trials have been summarized in annex 3. Section 3.5.<br>Concusions about efficacy trials:<br>*Reticulitermes flavipes*:<br>The applicant has submitted three laboratory test (A, B and C tests) and three field trials indoors and outdoors. All the trials demonstrate the product is efficacy and they are according to TNsG, except test B. The applicant has provided a justification of why there is no transmission between termites. Spain CA accepts it.<br>*Resticulitermes grassei*:<br>The applicant has submitted two laboratory test (A and C tests), a justification for non-submission of test B and five field trials indoors and outdoors. All the trials demonstrate the product is efficacy and they are according to TNsG. The applicant has provided a justification of why ther ir no transmission between termites and Spain CA accepts it.<br>*Reticulitermes banyulensis*:<br>The applicant has submitted two field trials that demostrate the efficacy of the product against this termite. |

### 2.2.5.6 Occurrence of resistance and resistance management

No resistant strains have been shown in the efficacy laboratory/field trials conducted with termites. No other studies on the resistance of diflubenzuron were available to the applicant.

In the final CAR of Diflubenzuron, the RMS was aware of the potential for the development of resistance against the a.s. and suggested to further address this issue. A literature review concluded that there is no evidence of resistance and cross-resistance case to diflubenzuron in mosquito larvae and in houseflies under field conditions. (CAR Diflubenzuron). However studies on specific resistance against termites were not presented during the a.s. approval.

A study The Impact of Selection with Diflubenzuron, a Chitin Synthesis Inhibitor, on the Fitness of Two Brazilian Aedes aegypti Field Populations (2015) show that only a few generations of diflubenzuron selection were sufficient to change the susceptible status of both populations to this compound and the conclusion was that diflubenzuron resistance acquisition is associated with a fitness cost.

Benzoylurea insecticide resistance of termites to diflubenzuron was searched for in the literature during the evaluation of TERMIGARD PLUS but no updated references and documentation was found about.

Diflubenzuron acts by contact and ingestion. It belongs to the benzoylurea family. They are growth regulators that inhibit the chitin synthesis, which is responsible for the moults. The moults allow the insect to increase in size, during which it renews the cuticle composed mainly of chitin. As a consequence, the moult does not end and the insect

develops with malformations and dies. The product acts mainly against workers and larvae, because they are the castes that moult. Diflubenzuron is listed by IRAC (Insecticide Resistance Action Committee): Group 15. Inhibition of chitin biosynthesis, type 0. Benzoylureas, along with other actives substances such as triflumuron.

In conclusion we do not have evidences about insecticide resistance of diflubenzuron of termites but we do not consider particular problems. Nevertheless, to minimise the chances of resistance developing in the future, it is advisable to avoid using products containing diflubenzuron exclusively and continuously as the sole agent for termite control. Therefore diflubenzuron containing products should be used as one component of an integrated pest management program which features products from alternative chemical classes.

The IRAC group (Insecticide Resistance Action Committee) provides guidelines on resistance management in agricultural settings. These also may be used for a resistance management strategy for biocidal products (insecticides used in urban environments).
The proposed resistance management strategy includes the following actions:

- The incorporation of a label warning: 'this product should be used in alternation with other products not containing the same a.s. to avoid resistant populations'.
- The label warning: 'the product should be reapplied only until the pest is controlled".
- The incorporation of a label warning: 'Use products at recommended doses and intervals'.

### 2.2.5.7 Known limitations

These known limitations should be followed for the safe use of this biocidal product and therefore they should be incorporated in the product label:

- Do not mix with other chemicals.
- Do not perform the operation in the presence of children and / or pets.
- To avoid risks to man and the environment follow the instructions.

### 2.2.5.8 Evaluation of the label claims

The label claims reflected the expected use of the products (insecticide) for the specific target organisms and the kind of use, but above all they must be supported by efficacy trials.

- The product is effective against subterranean termites (*Reticulitermes flavipes, reticulitermes grassei* and *Reticulitermes banyulensis).*
- The product eliminates the termite colony.

### 2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product.

This product in not to be authorised for use with other biocidal product.
Areas where barrier type termiticides may have been previously applied, such as within half meter of the foundation wall, must be avoided if possible.

## 2.2.6 Risk assessment for human health

The biocidal product TERMIGARD PLUS is cellulose bait impregnated in diflubenzuron (0.25%). No animal or human data on toxicological properties has been generated, but a calculation of toxicological properties according to Regulation (EC) No 1272/2008 (CLP Regulation) criteria taking into account the amount of each ingredient in the product has been done instead.
The applicant has submitted a justification for non-submission data and Spanish-CA accepts these justifications.

### 2.2.6.1 Assessment of effects on Human Health

#### *Skin corrosion and irritation*

| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
|---|---|
| Value/conclusion | Not irritant to skin |
| Justification for the value/conclusion | Based on the classification of the diflubenzuron and the coformulants and, their respective content in the final formulation. |
| Classification of the product according to CLP | TERMIGARD PLUS is not classified as irritant to skin. |

| **Data waiving** | |
|---|---|
| Information requirement | Skin corrosion/irritation study |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. None of the components present in the formulation is irritant to skin. So this study does not need to be conducted. |

#### *Eye irritation*

| **Conclusion used in Risk Assessment – Eye irritation** | |
|---|---|
| Value/conclusion | Not irritant to eyes |
| Justification for the value/conclusion | Based on the classification of the diflubenzuron and the coformulants and, their respective content in the final formulation |
| Classification of the product according to CLP | TERMIGARD PLUS is not classified as irritant to eyes. |

| **Data waiving** | |
|---|---|
| Information requirement | Eye irritation study |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP |

| | |
|---|---|
| | Regulation), and synergistic effects between any of the components are not expected. None of the components present in the formulation is irritant to eyes. So this study does not need to be conducted. |

### *Respiratory tract irritation*

| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
|---|---|
| Justification for the conclusion | Based on the classification of the diflubenzuron and the coformulants and, their respective content in the final formulation |
| Classification of the product according to CLP | TERMIGARD PLUS is not classified as irritant to respiratory tract |

| **Data waiving** | |
|---|---|
| Information requirement | Respiratory tract irritation data |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. None of the components present in the formulation is irritant to respiratory tract. |

### *Skin sensitization*

| **Conclusion used in Risk Assessment – Skin sensitisation** | |
|---|---|
| Value/conclusion | Not skin sensitizer |
| Justification for the value/conclusion | Based on the classification of the diflubenzuron and the coformulants and, their respective content in the final formulation |
| Classification of the product according to CLP | TERMIGARD PLUS is not classified as skin sensitizer |

| **Data waiving** | |
|---|---|
| Information requirement | Skin sensitisation study |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. None of the components present in the formulation is skin sensitizer. So this study does not need to be conducted. |

### *Respiratory sensitization (ADS)*

| **Conclusion used in Risk Assessment – Respiratory sensitisation** | |
|---|---|
| Value/conclusion | Not respiratory sensitizer. |
| Justification for the value/conclusion | Based on the classification of the diflubenzuron and the coformulants and, their respective content in the final formulation. |

| | |
|---|---|
| Classification of the product according to CLP | TERMIGARD PLUS is not classified as respiratory sensitizer |

| **Data waiving** | |
|---|---|
| Information requirement | Respiratory sensitization data |
| Justification | TERMIGARD PLUS has not skin respiratory sensitizing properties and none of the components of the mixture shows respiratory sensitisation effects. |

### *Acute toxicity*

The assessment of all acute toxicological properties of TERMIGARD PLUS is derived from the classification of the active substance and co-formulants as agreed in the Annex VI of the CLP regulation or, when not available, as agreed in the Classification and Labelling notification at ECHA. This information is included in their safety data sheets.

According to Regulation (EC) No 1272/2008 classification of mixtures based on ingredients of the mixture is determined by calculation from the ATE values ($ATE_{mix}$):

$$\frac{100}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

or

$$\frac{100\text{-}(\sum C_{unknown} if > 10\%)}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

where:
$C_i$ = concentration of ingredient i (% w/w or % v/v)
i = the individual ingredient from 1 to n
n = the number of ingredients
$ATE_i$ = Acute Toxicity Estimate of ingredient i.

*Acute toxicity by oral route*

| **Value used in the Risk Assessment – Acute oral toxicity** | |
|---|---|
| Value | $ATE_{mix}$>2000mg/kg bw |
| Justification for the selected value | Calculation of $ATE_{mix}$ for oral toxicity results in >2000 mg/Kgb.w and no classification is triggered. |
| Classification of the product according to CLP | TERMIGARD PLUS is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation). |
| **Data waiving** | |
| Information requirement | Acute oral toxicity study |

| | |
|---|---|
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. None of the components present in the formulation is toxic by oral route. Diflubenzuron is of low acute toxicity $LD_{50}$ oral (rat) >4640 mg/kg bw/day and the co-formulants are not acute toxic. Therefore this study is not deemed necessary. |

*Acute toxicity by inhalation*

| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
|---|---|
| Value | $ATE_{mix}$>5mg/l |
| Justification for the selected value | Calculation of $ATE_{mix}$ for inhalatory toxicity results in >5mg/l and no classification is triggered. |
| Classification of the product according to CLP | TERMIGARD PLUS is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation). |

| **Data waiving** | |
|---|---|
| Information requirement | Acute inhalation toxicity study |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Diflubenzuron is of low acute toxicity $LC_{50}$ inhalation (rat) >2.5 mg/L/4h (nose-only, dust) and the co-formulants are not acute toxic. Moreover, TERMIGARD PLUS is a solid (granular bait) and the vapor pressure of Diflubenzuron is $\leq 1.2 \times 10^{-7}$ Pa which indicates that volatilization is not expected. Therefore this study is not deemed necessary. |

*Acute toxicity by dermal route*

| **Value used in the Risk Assessment – Acute dermal toxicity** | |
|---|---|
| Value | $ATE_{mix}$>2000mg/kg bw |
| Justification for the selected value | Calculation of $ATE_{mix}$ for dermal toxicity results in >2000 mg/Kgb.w and no classification is triggered. |
| Classification of the product according to CLP | TERMIGARD PLUS is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation). |

| **Data waiving** | |
|---|---|
| Information requirement | Acute dermal toxicity study |
| Justification | There are valid data available on each of the components in the |

| | |
|---|---|
| | mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. None of the components present in the formulation is toxic by dermal route. Diflubenzuron is of low acute toxicity $LC_{50}$ dermal (rabbit) >2000 mg/kg bw/day and the co-formulants are not acute toxic. Therefore this study is not deemed necessary. |

### *Information on dermal absorption*

No new data have been provided for TERMIGARD PLUS.

According to the Guidance on the BPR (Volume III: Human health Part A: Information Requirements), *"before new studies are commenced, it should be checked whether the intended use is safe when the appropriate default value is applied. If no experimental data are available, studies with similar formulations should be looked for or further information used that may give at least a rough estimate."*

According to EFSA Guidance Document on Dermal Absorption (EFSA, 2012), a default value of 75% should be used for products containing ≤ 5% of active substance.

| **Value(s) used in the Risk Assessment – Dermal absorption** | |
|---|---|
| Substance | Diflubenzuron |
| Value(s)* | 75% |
| Justification for the selected value(s) | There are no experimental data available on the dermal absorption of the product TERMIGARD PLUS since no study has been conducted thus far. Therefore, according to the EFSA guidance document on dermal absorption (EFSA Journal, 2012;10(4):2665), a default value of 75% should be used for products or in use dilutions containing ≤ 5% active substance. |

| **Data waiving** | |
|---|---|
| Information requirement | Dermal absoption study of TERMIGARD PLUS |
| Justification | There is no experimental data available on the dermal absorption of the product TERMIGARD PLUS Moreover, no access has been requested to the available dermal absorption data from the current notifier due to some uncertainty of its suitability for this product. As a result, risk assessment calculations for human exposure have been made according to the EFSA guidance on dermal absorption (EFSA Journal, 2012;10(4):2665) and a default value of 75% dermal absorption has been used for this product (products or in use dilutions containing ≤ 5% active substance). |

### *Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)*

Not relevant. TERMIGARD PLUS does not contain substances of concern.

### *Available toxicological data relating to a mixture*

Not relevant. Substances of concern in the formulation are not in the form of mixtures.

***Other***

Not relevant.

### 2.2.6.2 Exposure assessment

**Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product**

| Summary table: relevant paths of human exposure | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| | **Industrial use** | **Trained professional use** | **Non-professional use** | **Industrial use** | **Trained Professional use** | **General public** | **Via food** |
| Inhalation | NA | Yes | NA | No | No | No | No |
| Dermal | NA | Yes | NA | No | No | No | No |
| Oral | NA | No | NA | No | No | No | No |

***List of scenarios***

| Summary table: scenarios | | | |
|---|---|---|---|
| **Scenario number** | **Scenario** (e.g. mixing/ loading) | **Primary or secondary exposure Description of scenario** | **Exposed group** (e.g. professionals, non-professionals, bystanders) |
| 1. | Placing the product in the bait stations and further disposal | Primary exposure | Trained Professionals |

***Trained professional exposure***

*Scenario [1]*

The application pattern of TERMIGARD PLUS (both indoors and outdoors) comprises different stages:

- Stage 1: Survey:
In order to obtain the maximum performance of the product is necessary to know with the possible accuracy where the termites are, identifying their pathways. This step is performed with precision equipment.

- Stage 2: Testing placement.
Once the termite's pathways are identified, it is required to place a testing piece of cellulose (moistened cardboard or a piece of wood) in order to attract and check the level of infestation. The testing bait is introduced into a bait station which is placed inside the soil in the surrounding of the building (outdoor use) or which is placed in the walls or floor inside the building in middle of termites pathway. In any way the bait must be put out in specially designed feeding stations, in such a way that bait which is pre-packed in a sealed bag, it is not within the reach of children, pets or birds.

- Stage 3: Bait application:
When the testing bait shows the presence of termites (the termites attack directly the cardboard or the piece of wood), the product is added replacing the testing bait. The TERMIGARD PLUS bait which is inside a plastic bag is placed into the bait station. The bag is drilled or cut in the bait station with a small punch or knife and the bait station is closed again, allowing the termites to enter through the small slits in the bait station or through the product itself. Primary exposure is likely at this stage.

- Stage 4: Use phase:
It is the period when the biocidal product is waiting to be consumed by the target organism. This means that no primary exposure of humans is intended and should not take place. However, secondary exposure of bystanders may take place. This could be a human working or living in the treated area or personnel working in storage rooms where TERMIGARD PLUS is applied.

- Stage 5: Bait disposal:
When the activity is stopped the remains of TERMIGARD PLUS must be collected and disposed of as small chemical waste. Primary exposure of humans is likely at this stage.

A treated placed is visited every 2 months. Testing bait stations and treated bait stations are checked and the operator adapts the placement of the treated stations. So visiting a house take at least 1 hour to several hours for big houses or for high infestations.
Once the treatment is finished (absence of termites activities in all the devices during 3 months), the remaining baits are removed and a testing piece of cellulose is placed in the station

**Description of Scenario [1]**

Exposure can take place during plastic bag drilling/cutting and during product disposal.
Cellulose bait is in a plastic bag and no leakage is likely. Small incisions are done in the product's bag, it is sprayed with water by a hand-sprayer and then it is introduced into the bait station. The product is sufficiently compact inside the bag to avoid spilling outside.
The applicant QUIMUNSA has obtained a Letter of Access (henceforth LoA) from ENSYSTEX. This LoA brings access to the confidential report nº 2015/05/EE -2015/08/20 from ENSYSTEX EUROPE (henceforth Report 2015/05/EE), which summarizes different efficacy field tests that have been developed in France with an identical product of TERMIGARD PLUS.
In this field study and depending on the species of termites, different data are obtained on the treatment for the termite eradication in several places, such as, the duration of the treatment, the amount of product used and the number of bait station refilling visits made,etc.
By studying this data, and due to the high variability between the outputs, it is considered reasonable to use the values obtained from the percentile 75th as a real value to take in account in the Human Risk Assessment. Therefore, the maximum amount of product considered to be placed by the trained professional users in a refilling visit is 1719 grams.
No model exists to take into account the phase of loading and mixing into the bag and for the disposal of the bag. The exposure model "mixing and loading model 5, powder" from the TNsG 2007 has been taken into account to evaluate the operator exposure during these two phases. To take into account these two phases, the dermal contamination from the model has been doubled from 10.2 mg a.s. /kg a.s. to 20.4 mg a.s. /kg a.s, and on a first approach it has been considered that for one day, one trained professional users makes one refilling visit appliying 1719 g product.

| | Parameters[1] | Value |
|---|---|---|
| Tier 1 | Frecuency | Diary |
| | Duration | No relevant |
| | Dermal absorption | 75% |
| | Inhalation absorption | 100% |
| | Glove´s protection factor for solids | 95% |
| | Concentration of active substance | 0,25% |
| | Amount of biocidal product in a refilling visit | 1719g |
| | Potential dermal exposure | 10.2 mg/kg a.s. |
| | Potential inhalation exposure | 0.66 mg/kg a.s. |
| | Body weight of an adult | 60 Kg |
| | | |

**Calculations for Scenario [1]**

| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/day)** | **Estimated dermal uptake (mg/kg bw/day)** | **Estimated total uptake (mg/kg bw/day)** |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| Scenario [1] | Tier 1/ Without PPE | 4,73E-05 | 1,09E-3 | 1,14E-03 |
| Scenario [1] | Tier 2/ With PPE | 4,73E-05 | 5,48E-05 | 1,02E-04 |

**Further information and considerations on scenario [n]**

### *Non-professional exposure*

TERMIGARD PLUS will only be used by professionals. Therefore the assessment of non-professional exposure is not relevant.

### *Exposure of the general public*

The product is applied in sealed bait station fixed to walls and/or the floor or burried into the ground at more than 20 cm deep. Therefore, exposure to general population via environment or as a consequence of secondary exposure is not likely.

### *Monitoring data*

### *Dietary exposure*

No specific residue data were submitted in the context of this dossier. The product TERMIGARD PLUS is intended to be applied by professional users inside bait stations by indoor application in the walls and floor of buildings and outdoor applications buried around the buildings.
However, an indirect release of active substance in soil *via* the termites' activity is relevant. A contamination of crops growing in vicinity of bait stations cannot be excluded. Regarding the lack of data on resulted residues in soil following the use of diflubenzuron, dietary risk cannot be assessed.

Consequently, the risk mitigation measures below are required :

- Do not apply on surfaces or utensils likely to be in direct contact with food, feed or livestock.
- Do not eat food and do not feed livestock with crops grown on land at and near bait stations.
- Decontaminate and/or demonstrate the non-residue situation before any reimplantation of edible crops in vicinity of treated points

As underlined in the opinion for products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council or Regulation (EC) No 396/2005 of the European Parliament and of the Council shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. MRLs under Regulation (EC) No 396/2005 and 37/2010 exist for diflubenzuron. With the proposed risk mitigation measures these applicable MRLs should not be exceeded.

### *Aggregated exposure*

### *Summary of exposure assessment*

| Scenarios and values to be used in risk assessment | | | |
|---|---|---|---|
| **Scenario number** | **Exposed group (e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake (mg/kg bw/day)** |
| 1. | Trained professional users | 1 | 1,14E-03 |
| 1. | Trained professional users | 2 | 1,02E-04 |

## 2.2.6.3 Risk characterisation for human health

**Reference values to be used in Risk Characterisation**

| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF[1]** | **Correction for oral absorption** | **Value** |
|---|---|---|---|---|---|
| AELshort-term | 28days rat study | 81mg/kgbw/day | 200[a] | 33% | 0.13mg/kgbw/day |
| AELmedium-term | 1year dog study | 2mg/kgbw/day | 100 | 33% | 0.0066mg/kgbw/day |
| AELlong-term | 91week mouse study | 1.2mg/kgbw/day | 100 | 33% | 0.004mg/kgbw/day |
| ARfD | No value in CAR: Does not need to be set | | | | |
| ADI | 91week mouse study | 1.2mg/kgbw/day | 100 | 100 | 0.012mg/kgbw/day |

[1]safety factor of 100 was applied taking into account a factor for inter- and intraspecies differences of 100 (10 x 10).
[a]200 (from LOAEL).

**Maximum residue limits or equivalent**

Residue definitions

| **MRLs or other relevant reference values** | **Reference** | **Relevant commodities** | **Value** |
|---|---|---|---|
| **MRL** | COMMISSION REGULATION (EU) No 37/2010 of 22 December 2009 | Salmonidae<br>- | 1 000 µg/kg |

| | | | |
|---|---|---|---|
| **MRL** | COMMISSION REGULATION (EU) 2019/91 of 18 January 2019 | FRUITS, FRESH or FROZEN; TREE NUTS<br>VEGETABLES, FRESH or FROZEN<br>PULSES<br>OILSEEDS AND OIL FRUITS<br>SUGAR PLANTS<br>PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS | 0.01mg/kg* |
| | COMMISSION REGULATION (EU) 2019/91 of 18 January 2019 | TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS<br>HOPS<br>SPICES | 0.05mg/kg* |

**Specific reference value for groundwater**

### *Risk for trained professional users*

**Systemic effects**

| Task/ Scenario | Tier | Systemic NOAEL mg/kg bw/d | AEL mg/kg bw/d | Estimated uptake mg/kg bw/d | Estimated uptake/ AEL (%) | Acceptable (yes/no) |
|---|---|---|---|---|---|---|
| 1 | 1 | | 0.004 | 1,14E-03 | 28,6 | yes |
| 1 | 2 | | 0.004 | 1,02E-04 | 2,6 | yes |

**Conclusion**
Considering that in one day the worker can treat different houses in different visits, a reverse scenario is performed in order to determine the maximum quantity of product that can be manipulated by the operator to reach 100% of the long term AEL during a day.

Without PPE: This maximum quantity of product is closed to 6 Kg of biocial product, corresponding to make 3.5 visits per day.

Using PPEs: This maximum quantity of product is closed to 66 Kg of biocial product, corresponding to make 38.5 visits per day. The duration of the visit (checking of each bait station, replacing of the consumed bait…) can be estimated to more than one hour, so the treatment of more than 38 houses in one day by the same opetator is very unlikely.

Therefore, the risk is considered as acceptable providing the use PPE (protective gloves) by the trained professional user during handling of the product.

## 2.2.7 Risk assessment for the environment

The applicant has not provided any study with the biocidal product. The environmental risk assessment for TERMIGARD PLUS has been done using the Competent Authority Report on the active substance diflubenzuron. The whole assessment submitted by the applicant has been included and reviewed by the ES CA.

According to the applicant TERMIGARD PLUS is formulated as an insecticide, it is a granular bait (cellulose granules impregnated in diflubenzuron). It is effective against termites. It is to be used by trained professional users by indoor applications of bait stations in the walls and floor of buildings and outdoor applications inside proper bait station buried in the perimeter of the building. The Annex I assessment of this active substance, diflubenzuron, was supported by the biocidal product "Dimilin GR-2", containing 2 % of the active substance, it is a granular formulation. This product is use to control mosquito larvae (belonging to genera *Aedes*, *Anopheles* and *Culex*) in water and fly larvae (*Musca domestica* (housefly), *Stomoxys calcitrans* (stable fly), *Haematobia irritans* (horn fly and *Musca autumnalis* (face fly)) in animal houses by professional users. Thus, the product TERMIGARD PLUS is not similar to the product evaluated during Annex I inclusion so cannot be addressed by the assessment of the active substance, diflubenzuron. The applicant has calculated the exposure level in each environmental compartment and compared this to the most sensitive PNEC value. The applicant has used the OECD Emission Scenario Document for Insecticides, Acaricides and Products to control other Arthropods for household and professional users (July 2008).

The applicant has a letter of access to all data to support the original Annex I listing of diflubenzuron.

Further comments on this assessment are included in the relevant sections below.

### 2.2.7.1 Effects assessment on the environment

The applicant has been granted with access to the data of the active substance by the original EU notifier of the active substance diflubenzuron (Chemtura Netherlands B.V.). Therefore all environmental studies referred to in this assessment are property of the original notifier of the active substance and have been agreed during the revision of the active substance diflubenzuron (Assessment Report of Diflubenzuron November 2007).

**ES CA**: the risk assessment of the active substance diflubenzuron has been updated in March of 2013; these new values have been taken into account for ES CA to perform the environmental risk assessment:

Summary of PNECs:

| **PNEC** | **VALUE** |
|---|---|
| $PNEC_{water}$ | 0.004 µg/l |
| $PNEC_{microorganisms}$ (STP) | 100 mg/l |
| $PNEC_{sediment}$ | 0.4 µg/kg |
| $PNEC_{soil}$ | 0.33 µg/$kg_{ww}$ |

As it is stated in the CAR of diflubenzuron is of low toxicity to birds with four oral $LD_{50}$ values of >2000 mg a.s./$kg_{bw}$, dietary $LC_{50}$ values of >1206 and >1323 mg/kg $_{bw}$/day for bobwhite and mallard duck, respectively, and NOECs (reproduction) of 42.7 and 59.4 mg a.s./kg diet for bobwhite and mallard duck, respectively.

PBT assessment

Diflubenzuron should not be regarded as a PBT substance, since it cannot be considered as fulfilling the criteria for persistence or bioaccumulation.

### *Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required*

The following classification/labelling have been proposed for TERMIGARD based on the calculation method according to Regulation (EC) 1272/2008 (CLP).

| **Classification** | **According to Regulation 1272/2008/EC** |
|---|---|
| Hazard symbol | GHS09 |
| Signal word | Warning |
| Hazard statements | H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P273: Avoid release to the environment<br>P391: Collect spillage<br>P501: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations |

### *Further Ecotoxicological studies*

No data is available

### *Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)*

No data is available

### *Supervised trials to assess risks to non-target organisms under field conditions*

No data is available

### *Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk*

No data is available

### *Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)*

### *Foreseeable routes of entry into the environment on the basis of the use envisaged*

According with the OECD Emission Scenario Document for Insecticides, Acaricides and Products to control other Arthropods (PT 18) for household and professional users (July 2007) systems, intended for termite control baits containing an insecticide and an attractant such as cellulose are enclosed in bait stations. These bait stations are buried in the soil or fixed in the wall surface on termites pathways. Termite traps are usually contained in plastic bags inside the bait stations where access to children and animals is not likely. In addition, releases to the environment are considered negligible during use. In this report, it is considered that both indoor and outdoor uses do not lead to releases of the biocidal product to the environment. However, diflubenzuron is classified as R50/53 (Very toxic for the aquatic environment. May cause long term adverse effects to the aquatic environment) and its use is of environmental concern even if it is used in low concentrations. Therefore, in order to provide the most accurate situation, the worst possible scenario for the environmental risk assessment has been considered: outdoor application of bait buried in the ground.

The environmental risk assessment for the use of the product TERMIGARD PLUS has been performed according with the "Technical Guidance Document on Risk Assessment in Support of the Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market".

Relevant application patterns are summarised below in Table 2.2.8.1-1.

**Table 2.2.7.1-1: Summary of the application patterns used in the environmental risk assessment.**

| | |
|---|---|
| **Use** | Outdoor (bait buried in the ground in the perimeter of a building) |
| **Formulation** | Bait |
| **Application dose** | 250 g per treatment |
| **Relevant treated surfaces** | Typically a building of 100 $m^2$ surface is considered |

TERMIGARD PLUS is a product based on 0.25% diflubenzuron in the form of cellulose bait impregnated in the active substance. Cellulose acts as termite attractant, as it is a common food source of the termites. Then, termites carry the food to the termite nest, contaminating the other termites and killing the whole population.

This environmental risk assessment has been performed taking into account the properties agreed in the diflubenzuron revision as insecticide product (November 2007). QUÍMICA DE MUNGUÍA, S. A. has been granted with a letter of access to the active substance data. Please refer to Section 13 of IUCLID dossier for this letter. The following properties have been considered in the risk assessment for diflubenzuron:

**Table 2.2.7.1-2: Physical-chemical properties of diflubenzuron.**

| | |
|---|---|
| **Molecular weight (g/mol)** | 310.7 |
| **Melting point (ºC)** | 227.6 |
| **Vapour pressure (Pa, 25ºC)** | $1.2\times10^{-7}$ |
| **Water solubility (mg/l, pH7, 25ºC)** | 0.08 |
| **Log Kow (pH 3)** | 3.89 |
| **Koc (mg/l)** | 4609 |
| **Henry's Law constant (Pa $m^3$/mol)** | $4.7\times10^{-4}$ |

No specific Exposure Scenario has been developed for this kind of products. In this assessment it was considered the treatment of a 100 $m^2$ surface corresponding to a typical building. Bait stations are placed outdoors, buried at a distance of 1 m of the building's walls and with a distance of 4 m between bait stations. This accounts for a total of 12 bait stations in the perimeter of the building, where the testers are placed. Considering a typical average rate of termite attack to the testers of 10 - 15 %, this leads to a maximum of 2 bait stations to be filled with the product.

The average amount of product required to kill all the termites in the nest ranges from 150 – 250 g. Due to termite behaviour and typical size of the termite nests, we can consider that termite's activities comprise a distance of 35 m radius around the nest. Therefore, activity area is equivalent to 3848 $m^2$. Considering that the activity of termites takes place at a maximum deep of 40 cm, this leads to a total ground volume of 1539 $m^3$ likely to be contaminated by the termites by scattering the product in the ground.

TERMIGARD PLUS is typically buried at a deep of 20-40 cm in the ground and therefore, it is assumed that no direct or indirect discharge is likely to any sign or drainage system and therefore, surface water contamination is not likely. For this reason, the application of TERMIGARD PLUS does not represent any risk to the aquatic environment (either in the water or in the sediment) and to the STP systems, which are not affected by the application of TERMIGARD PLUS. In addition, due to the low volatility of diflubenzuron (vapour pressure = $1.2\times10^{-7}$ Pa) it is not likely the contamination of the air as consequence of TERMIGARD PLUS application.

The relevant exposure compartments are summarised in Table 2.2.8.1-3 below:

**Table 2.2.7.1-3: Relevant compartments exposed to diflubenzuron after indoor and outdoor application.**

| **Use** | **Relevant exposure compartment** | | | | | |
|---|---|---|---|---|---|---|
| | **Air** | **Soil** | **STP** | **Surface water** | **Ground water** | **Secondary poisoning** |
| **Indoor application** | - | - | - | - | - | - |
| **Outdoor application** | - | Primary exposure | - | - | Secondary exposure | Secondary exposure |

Outdoor application is considered the worst-case situation.

TERMIGARD PLUS is buried in the ground inside bait stations with small slits in order to allow the entry of termites inside. Therefore, soil contamination for direct product contact with the soil is likely. Furthermore, as consequence of the presence of diflubenzuron in the soil the contamination of ground water due to leeching is also likely. Finally, other no-target insects can be also exposed to diflubenzuron.

No harmonized approach for the Environmental Risk Assessment (ERA) of biocidal products against termites is available in the ESD. This approach is based on the data available in the ESD PT18 and the assessment report validated at European level for the substance hexaflumuron approval[1] with a product used as bait against termites.

***Indoor use***

Direct emissions into environmental compartments will be negligible. In contrast, an indirect release *via* the termites' activity is relevant for an indoor use. The estimation of emissions in the environment *via* the termites' activity is developed below, for the outdoor use.

***Outdoor use***

*Application dose*

It is indicated that the average amount of product required killing all the termites in the nest ranges from 150 – 250 g. An application dose of **250 g** is proposed by the applicant. This value appears to be largely underestimated. The amount of product per sachet can

1 CAR of Hexaflumuron (PT18) June 2014- RMS: Portugal

go up to 1 050 g. Moreover and based on the fields trials supplied in the efficacy section (Report n° 2015/05/EE, confidential), a maximum of **5850 g** of the maximum quantities used per application and for one site is observed. From an analysis of this field studies, a value of **1719 g** is estimated, corresponding to the 75$^{th}$ percentile of the product quantities applied at each applicator visit. According to the same report, it also be considered that the reloading of the baits stations is done every two months on average. In conclusion, for the TERMIGARD PLUS, application doses of **250 g** and **1719** g were used.

*Relevant environmental compartments*

The relevant compartments for the use of TERMIGARD PLUS are soil and groundwater, from two ways of release:

- Direct release from the bait box

TERMIGARD PLUS, enclosed in a bait station, is buried at a deep of 20-40 cm in the ground. According to the ESD PT18 about termite's traps buried in soil, "releases from flooding are considered negligible". Consequently, direct releases from the bait box are considered **negligible**.

- Indirect release *via* the termites' activity

Information gathered during a survey from the ESD PT18 indicates that about 80 % of the product is consumed by the insects ($\mathbf{F_{soil,\ termites}}$ =0.8) whereas 20% remain in the bait station. Thus, the fraction that might be, as a worst case, released towards soil *via* termites' activity is:

**$F_{soil,\ termites}$ = 0.8**

*Spatial distribution of foraging territories*

No default values are available to characterize the spatial distribution of foraging territories. In accordance with the approval of the active substance hexaflumuron for product type 18 where a similar use has been adopted, same proposed default values have been taken into account.

- Soil depth (**DEPTH**)

Termites live in tunnels underneath the ground and leave at various depth depending on soil moisture and depth of ground water. As indicated in the hexaflumuron dossier, it is very conservative to use a deep of 25 cm to derive a local soil concentration A depth of **50 cm** is proposed.

- Surface of the foraging area ($\mathbf{S_{foraging}}$)

According to the report "Biology of subterranean termites of the genus Reticulitermes" by Barbara Thorne, National Pest Control Association, the foraging range of Reticulitermes flavipes is 7-79 meters, with an estimated foraging area of 18-2,360 m². Most of the data based on literature used by the applicant deal with the depth of foraging but assessing a harmonized surface of foraging is not possible. The value proposed by the applicant, 3848 m², is not covered by the validated approach proposed in the CAR of Hexaflumuron.

In order to be consistent with the hexaflumuron approach, a value for the foraging area of **1 000 m²** is proposed.

### *Further studies on fate and behaviour in the environment (ADS)*

No data is available

### *Leaching behaviour (ADS)*

No data is available

### *Testing for distribution and dissipation in soil (ADS)*

No data is available

### *Testing for distribution and dissipation in water and sediment (ADS)*

No data is available

### *Testing for distribution and dissipation in air (ADS)*

No data is available

### *If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)*

No data is available

### *If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)*

## 2.2.7.2 Exposure assessment

**General information**

| | |
|---|---|
| Assessed PT | PT 18 |
| Assessed scenarios | No scenario for termites treatment is available |
| ESD(s) used | Emission Scenario Document for Product Type 18:Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses, Jul 2008 |
| Approach | No Scenario is available |
| Distribution in the environment | Calculated based on TGD 2003 (alternative: based on measured data) |
| Groundwater simulation | |
| Confidential Annexes | NO |

| | |
|---|---|
| Life cycle steps assessed | Scenario n:<br>Production: No<br>Formulation No<br>Use: Yes<br>Service life: Yes |
| Remarks | |

No specific Exposure Scenario has been developed for this kind of products. In this assessment it was considered the treatment of a 100 $m^2$ surface corresponding to a typical building. Bait stations are placed outdoors, buried at a distance of 1 m of the building's walls and with a distance of 4 m between bait stations. This accounts for a total of 12 bait stations in the perimeter of the building, where the testers are placed. Considering a typical average rate of termite attack to the testers of 10 - 15 %, this leads to a maximum of 2 bait stations to be filled with the product.

The average amount of product required to kill all the termites in the nest ranges from 150 – 250 g. Due to termite behaviour and typical size of the termite nests, we can consider that termite's activities comprise a distance of 35 m radius around the nest. Therefore, activity area is equivalent to 3848 $m^2$. Considering that the activity of termites takes place at a maximum deep of 40 cm, this leads to a total ground volume of 1539 $m^3$ likely to be contaminated by the termites by scattering the product in the ground.

TERMIGARD PLUS is typically buried at a deep of 20-40 cm in the ground and therefore, it is assumed that no direct or indirect discharge is likely to any sign or drainage system and therefore, surface water contamination is not likely. For this reason, the application of TERMIGARD PLUS does not represent any risk to the aquatic environment (either in the water or in the sediment) and to the STP systems, which are not affected by the application of TERMIGARD PLUS. In addition, due to the low volatility of diflubenzuron (vapour pressure = $1.2\times10^{-7}$ Pa) it is not likely the contamination of the air as consequence of TERMIGARD PLUS application.

**ES CA**: as it is stated in the MOTA vs-6, a surface of a standard house of 130 $m^2$ is considered as a default for general treatment. So for this area 325 g of product would be used. We agree with the applicant about the termite's activities. According to the scientific literature "A termite's colony can mature to the massive size of one million individuals, foraging for food up to 150 feet from the nest".

## *Emission estimation*

### Scenario [1]

| **Input parameters for calculating the local emission** | | | |
|---|---|---|---|
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Control of termites (no scenario has been developed) | | | |
| Application rate of biocidal product *[alternative: annual tonnage in the EU]* | 325 | g | 350 g for treatment |
| Concentration of active substance in the product | 0.25 | % | |
| Relevant treated surfaces | 130 | $m^2$ | |

Calculations for Scenario [*n*]

The average of the amount product required to kill all termites is 325 g, so the local emission should be 0.81 g

| **Resulting local emission to relevant environmental compartments** | | |
|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$) [kg/d]** | **Remarks** |
| Freshwater | - | |
| Freshwater sediment | - | |
| Seawater | - | |
| Seawater sediment | - | |
| STP | - | |
| Air | - | |
| Soil | 0.81 g | |
| Groundwater | | |

## *Fate and distribution in exposed environmental compartments*

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Scenario 1 | No | No | No | No | No | No | Yes | Yes | |

| Input parameters (only set values) for calculating the fate and distribution in the environment | | | |
|---|---|---|---|
| Input | Value | Unit | Remarks |
| Molecular weight | 310.7 | | |
| Melting point | 227.6 | °C | |
| Boiling point | 257 | °C | |
| Vapour pressure (at XC) | $1.2*10^{-7}$ | Pa | |
| Water solubility (at X°C) | 0.08 | mg/l | |
| Log octanol/water partition coefficient | 3.89 | Log 10 | |
| Organic carbon/water partition coefficient (Koc) | 4609 | l/kg | |
| Henry's Law Constant (at X C)*[if measured data available]* | $4.7*10^{-4}$ | $Pa/m^3/mol$ | |
| Biodegradability | Not Ready biodegradable | | |
| $DT_{50}$ for photolysis in surface water | 32.5 | d (at 25ºC, pH 9) | |

## *Calculated PEC values*

### PEC in soil

The adsorption of diflubenzuron was tested in different soils. Koc values ranged from 1983 to 6918, with a mean value of 4609, indicating a low potential of mobility of diflubenzuron in soil. Other metabolites showed weaker potential of adsorption to the soil compared with the parent compound (Please, refer to Assessment Report for Diflubenzuron, November 2007).

The value of PECs was calculated only for the parent metabolite according with the following equation:

Where:

$$PEC_{soil} = \frac{C_{prod} \times F_{a.s.} \times F_{em.soil}}{M_{soil}}$$

$PEC_{soil}$: Predicted Environmental Concentration in soil

$C_{prod}$: Amount of product applied

$F_{a.s.}$: Fraction of active substance in the product

$F_{em.soil}$: Fraction emitted to the soil

$M_{soil}$: Mass of soil affected

Average soil density is 1700 Kg/$m^3$ as described in the guidelines for environmental risk assessment. The volume of soil treated was agreed to be 1539 $m^3$. Therefore, the mass of soil affected is 2,616,640 kg.

Values used in the calculation of $PEC_{soil}$ are summarized in the Table 2.2.8.2-1 below:

**Table 2.2.7.2-1: Values used in the calculation of $PEC_{soil}$.**

| Property | Value |
|---|---|
| $C_{prod}$ | 325 |
| $F_{a.s.}$ | 0.0025 |
| $F_{em.soil}$ | 1* |
| $M_{soil}$ | 2616640 kg |
| $PEC_{soil}$ | 0.31 µg/kg |

Termites' activity is considered as the only relevant way of release towards soil for TERMIGARD PLUS.

Parameters used for the PEC calculation are discussed in this section and above. The first approach does not take into account the degradation in soil of the diflubenzuron (low $DT_{50}$) and consequently overestimates the soil concentration.

In a second approach, a TWA is proposed for the parent substance. The hypothesis is that the entire quantity of the product is not consumed in one day. Consequently, it is considered that the foraging area will not be contaminated in one day but in 30 days.

The $PEC_{soil}$ for the active substance and its relevant metabolites are presented in the table below:

| **Parameters** | **Diflubenzuron** | **CPU 4-chlorophenylurea** | **DFBA 2.6-difluorobenzoic acid** |
|---|---|---|---|
| Scenario: **250 g** of TERMIGARD PLUS applied per treatment (dose claimed by the applicant). | | | |
| INPUT | | | |
| Fraction in the product | 2.50E-03 | / | / |
| Molar mass (g/mol) | 310.70 | 170.60 | 158 |
| Amount of substance in the product (g), considering for the metabolites a worst case (100% of the parent substance give 100% of each metabolite) | 0.625 | 0.343 | 0.318 |
| Density of soil (kg/m$^3$) | 1700 | | |
| Ways of release towards soil compartment | *via* termite's activity | | |
| Depth of soil (m) | 0.5 | | |
| Contaminated surface (m²) | 1000 | | |
| Volume of soil contaminated (m$^3$) | 500 | | |
| Amount of contaminated soil (Kg) | 850000 | | |
| $F_{soil,\ termites}$ | 0.8 | | |
| Amount of substance released to soil (g) | 1 | | |

| | | | |
|---|---|---|---|
| $DT_{50}$ soil (d) | 7.5 | / | / |
| Averaging time (d) | 30 | / | / |
| ksoil ($d^{-1}$) | 9.24E-02 | / | / |
| OUTPUT | | | |
| PEC soil (mg/kg) | 5.88-04 | 3.23E-04 | 2.99E-04 |
| TWA concentration in soil after 30 days (mg/kg) | 1.99E-04 | / | / |
| Scenario: **1719 g**, "realistic" dose application of TERMIGARD PLUS (according to efficacity data) | | | |
| INPUT | | | |
| Amount of substance in the product (g), considering for the metabolites a worst case (100% of the parent substance give 100% of each metabolite) | 4.29 | 2.38 | 2.18 |
| OUTPUT | | | |
| PEC soil (mg/kg) | 4.04E-03 | 2.22E-03 | 2.06E-03 |
| TWA concentration in soil after 30 days (mg/kg) | 1.36E-03 | / | / |

**$PEC_{ground\ water}$**

The presence of diflubenzuron in the soil can lead to contamination to ground water through leaching. No emission to STP is expected and therefore no contamination will occur due to STP sludge deposition, and the only process that may lead to contamination to ground water is the leaching of the diflubenzuron remaining in the soil after application. The $PEC_{GW}$ was calculated according with the Emission scenario document for insecticides, acaricides, and products to control other arthropods for household and professional uses (2008):

$$PEC_{GW\ (leeching)} = \frac{PEC_{soil} \times Density_{soil}}{K_{soil-water} \times 1000}$$

Where:

$PEC_{GW\ (leaching)}$: Predicted environmental concentrations in ground water due to leaching

$PEC_{soil}$: Predicted environment concentrations in soil

$Density_{soil}$: Soil volumetric density

$K_{soil\text{-}water}$: Soil-water partition coefficient

Values used in the calculation of $PEC_{GW}$ are summarized in the Table 2.2.8.2-2 below:

**Table 2.2.7.2-1: Values used in the calculation of $PEC_{GW}$.**

| Property | Value |
|---|---|
| $PEC_{soil}$ | 0.31 µg/Kg |
| $Density_{soil}$ | 1700 Kg/$m^3$ |
| $K_{soil\text{-}water}$ | 138 |
| $PEC_{GW}$ | 3.81x$10^{-3}$ µg/l |

Soil-water partition coefficient has been calculated from the Koc value agreed during the revision of diflubenzuron (Koc= 4609 l/Kg). Estimated concentration of diflubenzuron in water was estimated in 3.81×$10^{-3}$ µg/l, which is below the maximum admissible concentration (0.1 µg/l).

**ES CA positon:**
According to the assessment report of the diflubenzuron, the calculation of $PEC_{gw}$ was done for the diflubenzuron and the metabolite CPU, as CPU has a considerably longer half-life than the parent substance. The $PEC_{GW}$ was calculated according to the guidance for the biocidal product assessment[2].

| **Parameter** | **Diflubenzuron** | **CPU 4-chlorophenylurea** |
|---|---|---|
| Scenario: **250 g** of TERMIGARD PLUS applied per treatment (dose claimed by the applicant). | | |
| $PEC_{soil}$ (µg/kg) | 5.88 E-01 | 3.23E-01 |

[2] Guidance on the BPR: Volume IV Environment, Part B Risk Assessment, ECHA (2015)

| | | |
|---|---|---|
| $Density_{soil}$ ($kg/m^3$) | 1700 | 1700 |
| $K_{soil-water}$ (m3/m3) | 138.47 | 7.55 |
| $PEC_{GW}$ (µg/L) | 7.22E-03 | 7.27E-02 |
| Scenario: **1719 g** of TERMIGARD PLUS, "realistic" dose (according to efficacity data). | | |
| $PEC_{soil}$ (µg/kg) | 4.04 | 2.22 |
| $PEC_{GW}$ (µg/L) | 4.96E-02 | **5.00E-01** |

In the first approach and at the the realistic dose 1719 g, the threshold value of 0.1 µg/L is reached for the metabolite, CPU.

Therefore, FOCUS groundwater calculations are run for diflubenzuron and for the metabolite CPU.
According to the PAR de biotic degradation in the terrestrial compartment for diflunbenzuron is:

- Aerobic degradation

The half-life of diflubenzuron in aerobic conditions is DT50=7.5 days at 12°C (geometric). Only DFBA (2,6-difluorobenzoic acid) and CPU (4-chlorophenylurea) were detected, at a maximum of 13.3 % and 30.8 %), respectively. The geometric mean DT50 is 42 days for CPU and 12 days for DFBA (both normalized to 12°C).

- Anaerobic degradation

In anaerobic conditions, the half-life of diflubenzuron is DT50 = 84 days at 12 °C and is, hence, slower than under aerobic conditions.

According to the degradation data in soil indicated above, a maximum of 30.8 % CPU is formed by diflubenzuron degradation. 1719 g of product per application is considered ( $75^{th}$ percentile of the product quantities applied at each applicator visit) considering an incorporation at a deep of 50 cm and 5 applications per year. It is based on the fields trials supplied in the efficacy section. A reloading of the baits stations is realised every two months (considering five applications between Februarys to November, activity period of termites). Finally, Focus considers 26 years of simulation.

For each FOCUS scenario, PEC values for groundwater are estimated considering the maximum number of sites of treatment per hectare for which concentrations are below the groundwater threshold value of 0.1 $\mu g.L^{-1}$.

**Relevant input variables in PEARL**

| **Input parameter** | **Unit** | **Value** | | **Reference** |
|---|---|---|---|---|
| **Product name : TERMIGARD PLUS** | | | | |
| **Substance active: Diflubenzuron & metabolite : CPU (fraction transformed of 0.308)** | | | | |
| | | **Diflubenzuron** | **CPU** | **References** |
| **Physicochemical parameters** | | | | |
| Molecular weight | $g.mol^{-1}$ | 310.7 | 170.6 | AR |

| | | | | |
|---|---|---|---|---|
| Water solubility (25 °C) | $mg.L^{-1}$ | 0.08 | 1773 | AR |
| Molar enthalpy of dissolution | $kJ.mol^{-1}$ | 27 | 27 | Default |
| Saturated vapour pressure (25 °C) | Pa | 1.2E-07 | 0.022 | AR |
| Molar enthalpy of vaporisation | $kJ.mol^{-1}$ | 95 | 95 | Default |
| Diffusion coefficient in water (20 °C) | $m^2.d^{-1}$ | $4.3 \times 10^{-5}$ | $4.3 \times 10^{-5}$ | Default |
| Diffusion coefficient in air (20 °C) | $m^2.d^{-1}$ | 0.43 | 0.43 | Default |
| **Degradation parameters** | | | | |
| Half-life (20°C, pF2) | d | 3.5 | 19.8 | AR |
| Arrhenius activation energy | $kJ.mol^{-1}$ | 65.4 | 65.4 | Default |
| Exponent of moisture correction function | - | 0.7 | 0.7 | Default |
| **Sorption parameters** | | | | |
| $K_{oc}$ value | $L.kg^{-1}$ | 4609 | 245.25 | AR |
| $K_{om}$value (20°C) | $mL.g^{-1}$ | 2.67E+03 | 142.3 | AR |
| Freundlich exponent 1/n | - | 1 | 1 | Default |
| Method of subroutine description | - | pH independent | pH independent | - |
| **Crop related parameters** | | | | |
| Crop uptake factor | - | 0 | / | Default |
| **Application Schemes** | | | | |
| Dosage | $Kg.ha^{-1}$ | =[number of treated sites per hectare *(1719*0.005)]/1000=0.0429 | | |
| Application type | - | Incorporation | | |
| Depth | m | 0.5 | | |
| Repeat interval for years | - | 1 | | |
| Date | - | 01/02/1901 | | |
| | | 01/04/1901 | | |
| | | 01/06/1901 | | |
| | | 01/08/1901 | | |
| | | 01/10/1901 | | |
| **Crops Application** | | | | |
| Crop(s) | - | Grassland | | |
| Selected Locations | | CHATEAUDUN | | |
| | | HAMBURG | | |
| | | JOIKIONEN | | |
| | | KREMSMUENSTER | | |
| | | OKEHAMPTON | | |
| | | PIACENZA | | |
| | | PORTO | | |
| | | SEVILLA | | |

| | | |
|---|---|---|
| | | THIVA |

*It is considered that 10 sites maximum per hectare can be treated simultaneously:

| **Maximum of treated sites per hectare leading to $PEC_{gw}$< 0.1µg/L** | **DOSAGE (kg/ha)** | **Diflubenzuron concentration in groundwater (µg/L)** | **CPU concentration in groundwater (µg/L)** | **LOCATION** |
|---|---|---|---|---|
| 10 | 0.0429 | >> 0.000 | 0.0053 | CHATEAUDUN |
| 10 | 0.0429 | >> 0.000 | 0.112 | HAMBURG |
| 10 | 0.0429 | >> 0.000 | 0.168 | JOKIOINEN |
| 10 | 0.0429 | >> 0.000 | 0.105 | KREMSMUENSTER |
| 10 | 0.0429 | >> 0.000 | 0.099 | OKEHAMPTON |
| 10 | 0.0429 | >> 0.000 | 0.13 | PIACENZA |
| 10 | 0.0429 | >> 0.000 | 0.0017 | PORTO |
| 10 | 0.0429 | >> 0.000 | 0.00001 | SEVILLA |
| 10 | 0.0429 | >> 0.000 | 0.0002 | THIVA |

| **Summary table on calculated PEC values** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **$PEC_{STP}$** | **$PEC_{water}$** | **$PEC_{sed}$** | **$PEC_{seawater}$** | **$PEC_{seased}$** | **$PEC_{soil}$** | **$PEC_{GW}$[1]** | **$PEC_{air}$** |
| | [$mg/m^3$] | [mg/l] | [$mg/kg_{wwt}$] | [mg/l] | [$mg/kg_{wwt}$] | [mg/kg] | [µg/l] | [$mg/m^3$] |
| Scenario 1 | - | - | - | - | - | $0.31*10^{-3}$ | $3.81*10^{-3}$ | - |

[1] If the $PEC_{GW}$ was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table.

***Primary and secondary poisoning***

Primary poisoning

The exposure through primary poisoining was not assessed.

Secondary poisoning

No specific studies were carried out to determine whether diflubenzuron residues have an impact on secondary poisoning.

**ES CA positon:**

*Primary poisoning*

As the bait boxes are buried and closed, no primary poisoning risk is identified for the intended uses of TERMIGARD PLUS.

*Secondary poisoning*

Mammals and birds may consume contaminated worms from the contaminated soil. The concentration of the active substance in earthworms is calculated according to the guidance for the biocidal product assessment (2015).

PEC local $_{soil}$ and PEC local $_{soil\ porewater}$ is based on a quantity of product of 1719 g.

**Calculation of the predicted environmental concentration in earthworms (cf. TGD, Equation 82b-d)**

| Parameter | Definition | Unit | Value |
|---|---|---|---|
| Scenario: 250 g of TERMIGARD PLUS applied per treatment (dose claimed by the applicant). | | | |
| INPUT | | | |
| Bioconcentration factor for earthworm on wet weight basis | BCF | $L:kg^{-1}_{wet\ earthworm}$ | 94 |
| Fraction of gut loasing in worm | $F_{gut}$ | $kg_{dwt}.kg^{-1}_{wwt}$ | 0.1 |
| Conversion factor for soil concentration wet-dry weight soil | $CONV_{soil}$ | $kg_{wwt}.kg^{-1}_{dwt}$ | 1.13 |
| Predicted environmental concentration in groundwater | $PEClocal_{groundwater}$ | $mg.L^{-1}$ | 7.20E-06 |
| Predicted environmental concentration in soil | $PEClocal_{soil}$ | $mg.kg^{-1}_{wwt}$ | 5.88E-04 |
| OUTPUT | | | |
| Predicted Environmental Concentration in earthworms | $C_{earthworm} = \frac{BCF_{earthworm} \times C_{porewater} + C_{soil} \times F_{gut} \text{ x } CONV_{soil}}{1 + F_{gut} \text{ x } CONV_{soil}}$ | $mg.kg^{-1}_{wet\ earthworm}$ | 6.67E-04 |
| Scenario: 1719 g, "realistic" dose application of TERMIGARD PLUS according to efficacity data | | | |
| INPUT | | | |
| Predicted environmental concentration in groundwater | $PEClocal_{groundwater}$ | | 4.96E-05 |
| Predicted environmental concentration in soil | $PEClocal_{soil}$ | | 4.04E-03 |
| OUTPUT | | | |
| Predicted Environmental Concentration in earthworms | $C_{earthworm}$ | | 4.59E-03 |

The $C_{earthworm}$ has to be replaced by the estimated theoretical exposure (ETE). For the food chain from earthworm to earthworm-eating mammals and birds, the estimated residues in earthworm is converted to daily dose by multiplying a factor that relates the food intake rates and the body weight (FIR/bw). This factor corresponds to 1.4 for mammals and 1.1 for birds and it is derived from the exposure scenario established for plant protection products in the EU.

**Calculation of the estimated theoretical exposure (ETE) for earthworm-eating mammals and birds**

| Parameter | Definition | Unit | Value | |
|---|---|---|---|---|
| | | | Mammals | Birds |
| Scenario: 250 g of TERMIGARD PLUS applied per treatment (dose claimed by the applicant). | | | | |
| INPUT | | | | |
| Predicted Environmental Concentration in earthworms | $C_{earthworm}$ | $mg.kg^{-1}_{wwt}$ | 6.67E-04 | |
| Food intake rates per body weight | FIR /BW | $kg_{food}.d^{-1}.kg^{-1}_{bw}$ | 1.4 | 1.1 |
| Avoidance factor of contaminated food (AV=1, no avoidance) | AV | - | 1 | |
| Proportion of diet obtained in treated area | PT | - | 1 | |
| Proportion of food type (vegetation or insects) in the diet of species of concern | PD | - | 1 | |
| OUTPUT | | | | |
| Estimated theoretical exposure | ETE= $C_{earthworm}$ x (FIR/BW) x AV x PT x PD | $mg.kg^{-1}_{bw}.d^{-1}$ | 9.34E-03 | 7.34E-04 |
| Scenario: 1719 g, "realistic" dose application of TERMIGARD PLUS according to efficacity data | | | | |
| INPUT | | | | |
| Predicted Environmental Concentration in earthworms | $C_{earthworm}$ | $mg.kg^{-1}_{wwt}$ | 4.59E-03 | |
| OUTPUT | | | | |
| Estimated theoretical exposure | ETE= $C_{earthworm}$ x (FIR/BW) x AV x PT x PD | $mg.kg^{-1}_{bw}.d^{-1}$ | 6.42E-03 | 5.05E-03 |

### 2.2.7.3 Risk characterisation

#### *Atmosphere*

According to the TGD on Risk Assessment (ECB Part II, 2003) there is currently no appropriate guidance to calculate a $PNEC_{air}$. Diflubenzuron has very low vapour pressure ($1.2 \times 10^{-7}$ Pa at 25 ºC) and no significant losses are anticipated through evaporation as a result of the proposed use of diflubenzuron. The atmospheric half-life of diflubenzuron, due to gas-phase hydroxyl radical reactions, was estimated to be 3.08 hours. Therefore, it is not expected that diflubenzuron will be present in air for extended periods and the long range transport and re-deposition of diflubenzuron is expected to be negligible, therefore, release or dispersal of diflubenzuron into the atmosphere is highly unlikely.

#### *Terrestrial compartment*

| **Calculated PEC/PNEC values** | |
|---|---|
| | **$PEC/PNEC_{soil}$** |
| Scenario 1 | 0.94 |

Conclusion: PEC/PNEC ratios results in values below 1, which indicates a safe use of TERMIGARD PLUS for terrestrial organisms according with recommended use pattern.

#### *Groundwater*

Conclusion: Estimated concentration of diflubenzuron in water was estimated in $3.81 \times 10^{-3}$ µg/l, which is below the maximum admissible concentration (0.1 µg/l).

**ES CA positon:**

***Risk assessment for soil***

For indoor/outdoor use of the TERMIGARD PLUS, termites' activity is considered as the only relevant way of release towards soil.

**PEC/PNEC ratio for soil**

| | **PECsoil (µg/kg)** | **PNECsoil (µg/kg)** | **PEC/PNEC** |
|---|---|---|---|
| Scenario: 250 g of TERMIGARD PLUS applied per treatment (dose claimed by the applicant). | | | |
| Diflubenzuron | 5.88E-01 (initial) | 0.33 | **1.78** |

| | | | |
|---|---|---|---|
| | 1.99E-01 (TWA-30d)) | | 0.603 |
| CPU 4-chlorophenylurea | 3.23E-01 | 952 | 3.39E-04 |
| DFBA 2.6-difluorobenzoic acid | 2.99E-01 | 1390 | 2.15E-04 |
| Scenario: 1719 g, dose application of TERMIGARD PLUS according to efficacity data | | | |
| Diflubenzuron | 4,37 (initial) | 0,33 | **12.24** |
| | 1,48 (TWA-30d) | | **4.12** |
| CPU 4-chlorophenylurea | 2.40 | 952 | 2.50E-03 |
| DFBA 2.6-difluorobenzoic acid | 2.22 | 1390 | 1.56E-03 |

For the first case, using the dose claimed by the applicant (250 g), the risk for soil is acceptable for both metabolites. For diflubenzuron, the risk is unacceptable using initial concentration by not using the TWA concentration (over 30 days). For the second case, the dose of the product according to efficacity data (1719 g) the risk for soil is acceptable for both metabolites. However, for diflubenzuron, the risk is unacceptable in using initial or TWA concentrations (over 30 days).

Therefore a risk for the terrestrial compartment is identified for indoor and outdoor use of the TERMIGARD PLUS. Due to the use pattern of diflubenzuron in the bait stations, diflubenzuron-containing baits will only be disseminated when and where termite activity is detected (treated area).

***Risk assessment for groundwater***

The groundwater compartment is affected from both in- and outdoor use of the product. Estimated concentrations in groundwater are compared to the general drinking water limit of 0.1 µg/L set for pesticides.

The soil is indirectly exposed via termites' activites. The PEC/PNEC ratio of the highest leachate concentration of diflubenzuron and the relevant metabolite, CPU 4-cholorphenylurea was calculated from FOCUS PEARL 4.4.4. .For each scenario, PEC values for groundwater are estimated for 10 treatments, the worst case. PEC values are presented in Table below.

| **FOCUS scenario** | **Location** | **Diflubenzuron [µg.L$^{-1}$]** | **CPU [µg.L$^{-1}$]** | **Nb of treated sites per hectare** |
|---|---|---|---|---|
| GRASS | CHATEAUDUN | >> 0.000 | 0.0053 | 10 |
| | HAMBURG | >> 0.000 | 0.112 | 10 |
| | JOIKIONEN | >> 0.000 | 0.168 | 10 |

| | | | | |
|---|---|---|---|---|
| | KREMSMUENSTER | >> 0.000 | 0.105 | 10 |
| | OKEHAMPTON | >> 0.000 | 0.099 | 10 |
| | PIACENZA | >> 0.000 | 0.130 | 10 |
| | PORTO | >> 0.000 | 0.001 | 10 |
| | SEVILLA | >> 0.000 | 0.00001 | 10 |
| | THIVA | >> 0.000 | 0.0002 | 10 |

The risk assessment is dependent on the number of sites treated per hectare.

JOIKIONEN is not considered relevant for the termite's scenario due to the climate conditions (frozen soils).

According to the data available for the amount of product that could be applied, and considering that up to 10 sites can be treated simultaneously per hectare, the risk for groundwater is acceptable for 5 of 8 scenario location, whereas for 3 scenarios, the concentrations of diflubenzuron metabolite are above the threshold value when less that 10 sites are treated.

No data are available in the dossier to refine the risk assessment or to conclude on the relevance of a number of sites treated to consider the risk for groundwater as acceptable. Therefore, the risk is unacceptable for groundwater, due to the lack of data about the maximum number of treated sites per hectare.

### *Primary and secondary poisoning*

Primary poisoning

The exposure through primary poisoining was not assessed.

Secondary poisoning

Conclusion: uptake routes such as intake of contaminated food or sediment are considered to be of importance for substances with a log Kow ≥ 4.5. As diflubenzuron has a log Kow of 3.89, an assessment of the potential for secondary poisoning in birds and mammals through the consumption of aquatic and terrestrial biota exposed to diflubenzuron is not deemed necessary. Due to the proposed use patterns of TERMIGARD PLUS, no significant exposure is expected in the terrestrial compartment.

**ES CA positon:**

The PNEC value is compared to the corresponding PEC (ETE) values.

**PEC/PNEC ratio concerning predators**

| Compartment | Value | PEC/PNEC | Risk |
|---|---|---|---|
| Scenario: 250 g of TERMIGARD PLUS applied per treatment (dose claimed by the applicant). | | | |
| **Worm eating mammals** | | | |
| $ETE_{mammals}$ | 9.34E-04 $mg.kg^{-1}_{bw} \times d^{-1}$ | 2.33E-02 | Acceptable |
| $PNEC_{mammal}$ mg.kg $diet^{-1}$ | 0.04 $mg.kg^{-1}_{bw} \times d^{-1}$ | | |
| **Worm eating birds** | | | |
| $ETE_{birds}$ | 7.34E-04 $mg.kg^{-1}_{bw} \times d^{-1}$ | 5.17E-04 | Acceptable |
| $PNEC_{bird}$ | 1.42 $mg.kg^{-1}_{bw} \times d^{-1}$ | | |
| Scenario: 1719 g, "realistic" dose application of TERMIGARD PLUS according to efficacity data | | | |
| **Worm eating mammals** | | | |
| $ETE_{mammals}$ | 6.42E-03 | 1.60E-01 | Acceptable |
| $PNEC_{mammal}$ mg.kg $diet^{-1}$ | 0.04 | | |
| **Worm eating birds** | | | |
| $ETE_{birds}$ | 5.05E-03 | 3.55E-03 | Acceptable |
| $PNEC_{bird}$ | 1.42 | | |

The PEC/PNEC ratios for secondary poisoning are below 1. Results indicate that the risk of secondary poisoning to worm-eating birds and mammals can be considered acceptable.

Conclusions

No harmonized exposure scenario is available for treatment against termites. Based on a previous approach validated at European level for hexaflumuron active substance approval, indoor and outdoor uses lead to unacceptable risk for the soil and no data in the dossier is available to refine the risk assessment. Due to the use pattern of diflubenzuron

in the bait stations, diflubenzuron-containing baits will only be dissiminated when and where termite activity is detected (treated area).

According to the data available for the amount of product that could be applied (10 places in 1 ha), the risk for groundwater is acceptable for 5 of 8 scenario locations. However, the risk should be acceptable when less places are treated in the areas where unacceptable risk has bee found. No data are available in the dossier nor provided by the applicant during the PAR commenting period to refine the risk assessment or to conclude on the relevance of a number of sites treated to consider the risk for groundwater as acceptable. Therefore, the risk assessment is not finalized for groundwater due to the lack of data about the maximum number of treated sites per hectare.

The risk of secondary poisoning is acceptable.

However, ESCA considers that the product should be authorized despite unaceptable risk for soil and groundwater compartments since there is not many products containing active substances with different modes of action available for curative treatment of buildings against termites. Hence the unauthorisation of the product TERMIGARD PLUS would have disporporcionate negative consequences for the society against the risk of the soil around termite mound.

We consider that the product should be authorized, despite unacceptable risk ins soil and groundwater, in applicaction of article 19(5) of the Biocidal product Regulation 528/2012.

The following risk mitigation measures must be followed when using the product, notably to limit risk for the consumers and the environment:

- Remove bait and bait stations at the end of the treatment.
- Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste.
- Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations
- Code the waste according to Decision 2014/955 / EU.
- Do not release to soil, ground, surface water or any kind of sewer.

### 2.2.8 Measures to protect man, animals and the environment

Before using the product, read the label carefully. Follow the instructions.

Do not apply on surfaces or utensils likely to be in direct contact with food, feed or livestock.

Do not eat food and do not feed livestock with crops grown on land at and near bait stations.

Decontaminate and/or demonstrate the non-residue situation before any reimplantation of edible crops in vicinity of treated points

Avoid discharge into drains, water courses, wells and the natural environment.

### 2.2.9 Assessment of a combination of biocidal products

Not relevant. TERMIGARD PLUS is not intended to be used in combination with other biocidal products.

### 2.2.10 Comparative assessment

Not relevant. Diflubenzuron is not a candidate for substitution.

# 3 ANNEXES

## 3.1 List of studies for the biocidal product

| Section No. | **Authors** | **Year** | **Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published** | **Data Protection Claimed (Yes/No)** | **Owner** |
|---|---|---|---|---|---|
| III.5.10.1 | [redacted] | 2012 | Title: TERMIGARD Anti-termite efficacy delayed effect. Test A. Against R. Flavipes.<br>Test facility: FCBA Institut technologiche. 10, Avenue de Saint-Mandé 75012. Paris.<br>N Report: 401/10/200F/1 et 2/d-e | YES | QUIMICA DE MUNGUIA |
| III.5.10.2 | [redacted] | 2013 | Title: TERMIGARD. Transmission of an active ingredient. TEST B. Against R. flavipes.<br>Test facility: FCBA Institut technologiche. 10, Avenue de Saint-Mandé 75012. Paris.<br>Nº report: 401/10/200F/1 and 2/e-e | YES | QUIMICA DE MUNGUIA |
| III.5.10.3 | [redacted] | 2012 | Title: TERMIGARD. Anti-termite efficacy. Choice test. TEST C. Against R. flavipes.<br>Test facility: FCBA Institut technologiche. 10, Avenue de Saint-Mandé 75012. Paris.<br>Nº report: 401/10/200F/1 and 2/f-e | YES | QUIMICA DE MUNGUIA |
| III.5.10.4 | [redacted] | 2004 | Title: LABYRINTH. "Bait trap" techniche. Checking of effectiveness against termintes on experimental sites. Against R. Flavipes.<br>Test facility: CTBA. Entomolgy laboratory<br>Nº report: PC/66/084/00F/f1/s4/e | YES | ENSYSTEX |
| III.5.10.5 | [redacted] | 2004 | Title: LABYRINTH *Techniche de type piege-appat. Verification l´efficacite anti-termite sur site experimental*. Against R. Flavipes.<br>Test facility: CTBA. Entomolgy laboratory<br>Nº report: PC/66/241/03F/b | YES | ENSYSTEX |
| III.5.10.6 | [redacted] | 2004 | Title: LABYRINTH. Bait trap" | YES | ENSYS |

| | | | | | |
|---|---|---|---|---|---|
| | | | techniche. Checking of effectiveness against termintes on experimental sites. Against R. Flavipes. Against R. Flavipes.<br>Test facility: CTBA. Entomolgy laboratory<br>Nº report: PC/66/084/00F/f1/s3/e | | TEX |
| III.5.10.7 | [redacted] | 2016 | Title: TERMIGARD.Delayed-effect and efficacy of insecticidal formulation against termites (R. Grassei). TEST A.<br>Test facility: FCBA Institut technologiche. 10, Rue Galileé. 77420 Champs-sur-Marne.<br>Nº Report: 401/15/217F/a/1 and 2. | YES | QUIMICA DE MUNGUIA |
| III.5.10.9 | [redacted] | 2016 | Title: TERMIGARD.Choice test. (R. Grassei). TEST C.<br>Test facility: FCBA Institut technologiche. 10, Rue Galileé. 77420 Champs-sur-Marne.<br>Nº Report: 401/15/217F/c/1 and 2-e | YES | QUIMICA DE MUNGUIA |
| III.5.10.10 | [redacted] | 2016 | Title: TERMIGARD PLUS. Experimental Site nº·3. (R. Grassei).<br>Test facility: FCBA Institut technologiche. 10, Rue Galileé. 77420 Champs-sur-Marne.<br>Nº report: 401/10/200F/3/i-e | YES | QUIMICA DE MUNGUIA |
| III.5.10.11 | [redacted] | 2016 | Title: TERMIGARD PLUS. Experimental Site nº·5. (R. Grassei).<br>Test facility: FCBA Institut technologiche. 10, Rue Galileé. 77420 Champs-sur-Marne.<br>Nº report: 401/10/200F/3/k-e. | YES | QUIMICA DE MUNGUIA |
| III.5.10.12 | [redacted] | 2016 | Title: TERMIGARD PLUS. Experimental Site nº·4. (R. Grassei).<br>Test facility: FCBA Institut technologiche. 10, Rue Galileé. 77420 Champs-sur-Marne.<br>Nº report: 401/10/200F/3/j-e | YES | QUIMICA DE MUNGUIA |
| III.5.10.13 | [redacted] | 2003 | Title: LABYRINTH. *Techniche de type piege-appat. Verification l´efficacite anti-termite sur site experimental.* Against *R. Grassei*.<br>Test facility: CTBA. Entomolgy laboratory<br>Nº report: PC/66/084/00F/f/1/g2/f | YES | ENSYSTEX |
| III.5.10.1 | [redacted] | 2002 | Title: LABYRINTH. Bait trap" | YES | ENSYS |

| | | | | | |
|---|---|---|---|---|---|
| 4 | | | techniche. Checking of effectiveness against termintes on experimental sites. Against *R. Grassei*.<br>Test facility: CTBA. Entomolgy laboratory.<br>Nº report: PC/66/084/00F/f/1/g1/e | | TEX |
| III.5.10.15 | [redacted] | 2015 | Title: TERMIGARD PLUS. Experimental Site nº·1. (*R. bayulensis*).<br>Test facility: FCBA Institut technologiche. 10, Rue Galileé. 77420 Champs-sur-Marne.<br>Nº report: 401/10/200F/3/g | YES | QUIMICA DE MUNGUIA. |
| III.5.10.16 | [redacted] | 2015 | Title: TERMIGARD PLUS. Experimental Site nº·2. (*R. bayulensis).*<br>Test facility: FCBA Institut technologiche. 10, Rue Galileé. 77420 Champs-sur-Marne.<br>Nº report: 401/10/200F/3/h | YES | QUIMICA DE MUNGUIA. |
| | [redacted] | 2015 | Title: Detailed analysis of the efficacy of 0.25% and 0.50% Diflubenzuron termite baits on European Reticulitermes species<br>2015/05/EE - 2015/08/20 | YES | ENSYSTEX europe |

## 3.2 Output tables from exposure assessment tools

## 3.3 New information on the active substance

No new information about active substance has been provided in support of this biocidal product

## 3.4 Residue behaviour

## 3.5 Summaries of the efficacy studies (B.5.10.1-16)

**III.5.10.1: TERMIGARD Anti-termite efficacy delayed effect. Test A. Against R. Flavipes**

Laboratory test A against *Reticulitermes flavipes* has been performed.
4 replicates have been done with 100 workers each one. A control trial has been done also to validate the trial.Termites are put in contact with TERMIGARD PLUS and mortality is check every week up to nine weeks.
The mortality becomes different from that of the control between th $16^{th}$ and $20^{th}$, so the time of exposure of termites "te" is 20 days.
Mortality of termites is 96,5% in 9 weeks.

**III5.10.2. TERMIGARD. Transmission of an active ingredient. TEST B. Against R. flavipes**

Laboratory test B against *Reticulitermes flavipes* has been performed.

4 replicates and 4 controls have been done with 200 workers each one. Termites was exposed to the product 20 days (te) with 20 grams of cellulosic matrix. A group of termites was separated from the colony and put in contact with an healthy uncontaminated group.

The time of test was 42 weeks. 100% mortality was achieved in 42 weeeks, but the control reached almost 100% in the same time. According to the standar, the test is not valid.

The test has not demostrated the transmission of diflubenzuron between termites.
The applicant and the responsable technique of laboratory have submitted this justification :
*„[...] our long experience allows us to say that the test method developed in order to demostrate the transmission of an active ingredient between termites (French standard XP X41-543-1, test B), is not relevant for formulation conaining diflubenzuron*.
*[...] The test method described in the Frencj Standard doesn´t take into accpunt this specificity of diflubenzuron in its current version. We are currently definin and validating the necessary modification of the existing test protocol wich will allow the identification of the active ingredient transmission between termites in any case*"

Spain CA accepts this justificaction

**III.5.10.3 TERMIGARD. Anti-termite efficacy. Choice test. TEST C. Against R. flavipes**

Laboratory test C against *Reticulitermes flav*ipes has been performed.
6 replicates and 2 controls have been done with 500 worker each one. Sap-wood of *Pinus silvestri* was used to alternative food. The 6 replicates of termites were eliminated within 11 to 33 weeks (25 weeks in average) depended the level of consumption. Control mortality were 28.4 and 19.8%, so the test is valid.

**III.5.10.4. LABYTINTH. Checking of effectiveness against termites on experimentali sites. „Bait-Trap" Techniche.**

Field trial test against *Reticulitermes flavipes*.
13 indoors devices and 12 outdoors devices to check the infestation of termites on January were placed. 8 week later, 11 indoors devices and 1 outdoor device were only actives.
63 weeks later, 5 indoors devices and the outdoor device were still active. Therefore the confirmation of elimination is negative according to TNsG.

**III.5.10.5. LABYTINTH. Checking of effectiveness against termites on experimentali sites. „Bait-Trap" Techniche.**

Field trial test against *Reticulitermes flavipes*.
23 indoors devices and 19 outdoors devices to check the infestation of termites on August were placed. 25 days later, 14 indoors devices and 3 outdoors device were only actives.
40 weeks later, all devices were inactive and no termite activity were reported in six following months. Therefore the confirmation of elimination is positive according to TNsG.

**III.5.10.6. LABYTINTH. Checking of effectiveness against termites on experimentali sites. „Bait-Trap" Techniche**

Field trial test against *Reticulitermes flavipes*.
10 indoors devices and 11 outdoors devices to check the infestation of termites on july were placed. 6 weeks later, 9 indoors devices and 1 outdoor device were only actives.

59 weeks later, all devices were inactive and no termite activity were reported in 39 following days. The confirmation of elimination is positive, but not according to TNsG.

**III.5.10.7: TERMIGARD Anti-termite efficacy delayed effect. Test A. Against R. Grassei**

Laboratory test A against *Reticulitermes grassei* has been performed.
4 replicates have been done with 100 workers each one. A control trial has been done also to validate the trial.Termites are put in contact with TERMIGARD PLUS and mortality is check every week up to twelve weeks.
The time of exposure of termites "te" is 26 days.
Mortality of termites is 100% in 12 weeks.

**III.5.10.8. Justification of non submission of test B. (*Reticulitermes grassei*)**

Due to the test B against R. Flavipes, the applicant and the responsable technique of laboratory have submitted a justification of non-submission of test B. Againt *R. grassei*.
This justification is the same as that provided for *R. flavipes*.
Spain CA accepts the justification.

**III.5.10.9 TERMIGARD. Anti-termite efficacy. Choice test. TEST C. Against R. Grassei**

Laboratory test C against *Reticulitermes grassei* has been performed.
6 replicates and 2 controls have been done with 500 worker, 20 nymphs and 10 soldiers each one. Sap-wood of *Pinus silvestri* was used to alternative food. The 6 replicates of termites were eliminated within 14 to 28 weeks (19 weeks in average) depended the level of consumption. Control mortality were 0%, so the test is valid

**III.5.10.10. TERMIGARD PLUS. Checking of effectiveness against termites on experimentali sites.**

Field trial test against *Reticulitermes Grassei*.
6 indoors devices and 24 outdoors devices to check the infestation of termites on August were placed. During the intoxication phase, 1 indoors device and 4 outdoor devices were only actives.
42 weeks later, all devices were inactive and no termite activity were reported in four following months. Therefore the confirmation of elimination is positive acording to TNsG.

**III.5.10.11. TERMIGARD PLUS. Checking of effectiveness against termites on experimentali sites**

Field trial test against *Reticulitermes Grassei*.
6 indoors devices and 24 outdoors devices to check the infestation of termites on August were placed. The beginninf of stage of intoxication started 35 days later and during the intoxication phase 3 outdoor devices were only actives.
43 weeks later, all devices were inactive and no termite activity were reported in four following months. Therefore the confirmation of elimination is positive acording to TNsG.

**III.5.10.12. TERMIGARD PLUS. Checking of effectiveness against termites on experimentali sites**

Field trial test against *Reticulitermes Grassei*.
12 indoors devices and 12 outdoors devices to check the infestation of termites on August were placed. The beginninf of stage of intoxication started 35 days later and during the intoxication phase 5 indoors devices and 3 outdoor devices were only actives.
43 weeks later, all devices were inactive and no termite activity were reported in four following months. Therefore the confirmation of elimination is positive acording to TNsG.

**III.5.10.13. LABYTINTH. Checking of effectiveness against termites on experimentali sites. „Bait-Trap" Techniche**

Field trial test against *Reticulitermes Grassei*.
7 indoors devices and 34 outdoors devices to check the infestation of termites on August were placed. The beginninf of stage of intoxication started 56 days later and during the intoxication phase 5 indoors devices and 2 outdoor devices were only actives.
53 weeks later, all devices were inactive and no termite activity were reported in ten following months. Therefore the confirmation of elimination is positive acording to TNsG

**III.5.10.14. LABYTINTH. Checking of effectiveness against termites on experimentali sites. „Bait-Trap" Techniche**

Field trial test against *Reticulitermes Grassei*.
7 indoors devices and 5 outdoors devices to check the infestation of termites on August were placed. The beginninf of stage of intoxication started 91 days later and during the intoxication phase 4 indoors devices were only actives.
16 weeks later, all devices were inactive and no termite activity were reported in nine following months. Therefore the confirmation of elimination is positive acording to TNsG

**III.5.10.15. TERMIGARD PLUS. Checking of effectiveness against termites on experimentali sites**

Field trial test against *Reticulitermes banyulensis*.
6 indoors devices and 6 outdoors devices to check the infestation of termites on August were placed. The beginninf of stage of intoxication started 22 days later and during the intoxication phase 4 indoors devices and 2 outdoor devices were only actives.
26 weeks later, all devices were inactive and no termite activity were reported in seven following months. Therefore the confirmation of elimination is positive acording to TNsG.

**III.5.10.16. TERMIGARD PLUS. Checking of effectiveness against termites on experimentali sites**

Field trial test against *Reticulitermes banyulensis*.
3 indoors devices and 14 outdoors devices to check the infestation of termites on August were placed. The beginninf of stage of intoxication started 35 days later and during the intoxication phase 4 indoors devices and 2 outdoor devices were only actives.
26 weeks later, all devices were inactive and no termite activity were reported in seven following months. Therefore the confirmation of elimination is positive acording to TNsG.

## 3.6 Addendum (August 2020)

Add the packaging size of 2000 g to the authorized packaging size (50, 75, 500 and 1000 g). Amendment applied in Spanish authorisation.