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)



TECHNIVERT

Product type 18

Acetamiprid

Case Number in R4BP: BC-NM056842-23

Evaluating Competent Authority: France

Date: November 2022

Table of Contents

[Table of Contents 2](#_Toc118447517)

[*1* CONCLUSION 4](#_Toc118447518)

[*2* ASSESSMENT REPORT 7](#_Toc118447519)

[2.1.1 Packaging of the biocidal product 7](#_Toc118447520)

[2.2 Summary of the product assessment 7](#_Toc118447521)

[2.2.1 Administrative information 7](#_Toc118447522)

[**2.2.1.1** Identifier of the product 7](#_Toc118447523)

[**2.2.1.2** Authorisation holder 7](#_Toc118447524)

[**2.2.1.3** Manufacturer(s) of the products 7](#_Toc118447525)

[**2.2.1.4** Manufacturer(s) of the active substance(s) 7](#_Toc118447526)

[2.2.2 Product composition and formulation 8](#_Toc118447527)

[**2.2.2.1** Identity of the active substance 8](#_Toc118447528)

[**2.2.2.2** Candidate(s) for substitution 8](#_Toc118447529)

[**2.2.2.3** Qualitative and quantitative information on the composition of the biocidal product 10](#_Toc118447530)

[**2.2.2.4** Information on technical equivalence 10](#_Toc118447531)

[**2.2.2.5** Information on the substance(s) of concern 10](#_Toc118447532)

[**2.2.2.6** Assessment of endocrine disruption (ED) properties of the biocidal product 10](#_Toc118447533)

[**2.2.2.7** Type of formulation 11](#_Toc118447534)

[2.2.3 Hazard and precautionary statements 11](#_Toc118447535)

[2.2.4 Authorised use(s) 11](#_Toc118447536)

[**2.2.4.1** Use description 11](#_Toc118447537)

[**2.2.4.2** Use-specific instructions for use 12](#_Toc118447538)

[**2.2.4.3** Use-specific risk mitigation measures 12](#_Toc118447539)

[**2.2.4.4** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 12](#_Toc118447540)

[**2.2.4.5** Where specific to the use, the instructions for safe disposal of the product and its packaging 12](#_Toc118447541)

[**2.2.4.6** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 12](#_Toc118447542)

[2.2.5 General directions for use 12](#_Toc118447543)

[**2.2.5.1** Instructions for use 12](#_Toc118447544)

[**2.2.5.2** Risk mitigation measures 13](#_Toc118447545)

[**2.2.5.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 13](#_Toc118447546)

[**2.2.5.4** Instructions for safe disposal of the product and its packaging 13](#_Toc118447547)

[**2.2.5.5** Conditions of storage and shelf-life of the product under normal conditions of storage 13](#_Toc118447548)

[2.2.6 Other information 13](#_Toc118447549)

[2.2.7 Documentation 14](#_Toc118447550)

[**2.2.7.1** Data submitted in relation to product application 14](#_Toc118447551)

[**2.2.7.2** Access to documentation 14](#_Toc118447552)

[2.3 Assessment of the biocidal product 15](#_Toc118447553)

[2.3.1 Intended use(s) as applied for by the applicant 15](#_Toc118447554)

[2.3.2 Physical, chemical and technical properties 15](#_Toc118447555)

[2.3.3 Physical hazards and respective characteristics 23](#_Toc118447556)

[2.3.4 Methods for detection and identification 31](#_Toc118447557)

[2.3.5 Efficacy against target organisms 40](#_Toc118447558)

[**2.3.5.1** Function and field of use 40](#_Toc118447559)

[**2.3.5.2** Organisms to be controlled and products, organisms or objects to be protected 40](#_Toc118447560)

[**2.3.5.3** Effects on target organisms, including unacceptable suffering 40](#_Toc118447561)

[**2.3.5.4** Mode of action, including time delay 40](#_Toc118447562)

[**2.3.5.5** Efficacy data 41](#_Toc118447563)

[**2.3.5.6** Occurrence of resistance and resistance management 48](#_Toc118447564)

[**2.3.5.7** Known limitations 48](#_Toc118447565)

[**2.3.5.8** Evaluation of the label claims 48](#_Toc118447566)

[**2.3.5.9** Relevant information if the product is intended to be authorised for use with other biocidal product(s) 48](#_Toc118447567)

[2.3.6 Risk assessment for human health 49](#_Toc118447568)

[**2.3.6.1** Assessment of effects on Human Health 49](#_Toc118447569)

[**2.3.6.2** Exposure assessment 54](#_Toc118447570)

[**2.3.6.3** Risk characterisation for human health 61](#_Toc118447571)

[2.3.7 Risk assessment for animal health 65](#_Toc118447572)

[2.3.8 Risk assessment for the environment 65](#_Toc118447573)

[**2.3.8.1** Effects assessment on the environment 65](#_Toc118447574)

[**2.3.8.2** Exposure assessment 69](#_Toc118447575)

[**2.3.8.3** Risk characterisation 72](#_Toc118447576)

[2.3.9 Measures to protect man, animals and the environment 76](#_Toc118447577)

[2.3.10 Assessment of a combination of biocidal products 76](#_Toc118447578)

[2.3.11 Comparative assessment 76](#_Toc118447579)

[*3* Annexes 77](#_Toc118447580)

[3.1 List of studies for the biocidal product 77](#_Toc118447581)

[3.2 Output tables from exposure assessment tools 78](#_Toc118447582)

[3.3 New information on the active substance 78](#_Toc118447583)

[3.4 Residue behaviour 78](#_Toc118447584)

[3.5 Summaries of the efficacy studies (B.5.10.1-xx) 78](#_Toc118447585)

[3.6 Confidential annex 78](#_Toc118447586)

[3.7 Other 78](#_Toc118447587)

# CONCLUSION

The biocidal product TECHNIVERT, based on 0.2 % acetamiprid, is a ready-to-use fluid to be used as a preventive protection of constructions against termites by professional users.

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

Physical and chemical properties of the product TECHNIVERT are described and considered acceptable in the conditions of use.

Analytical methods were considered as validated.

**Conclusion on Efficacy**

Efficacy of the product TECHNIVERT, used as a physico-chemical barrier (peripheral application and singular areas (pipes, ducts…)) to protect buildings is demonstrated against subterranean termites (*Reticulitermes sp*.).

The field test in progress is planned for a duration of 10 years. The interim reports at 6, 8 and 10 years available at the renewal of the product TECHNIVERT should be provided.

**Conclusion on Human health**

Risks are deemed acceptable for Human Health during the handling and the application of the product considering wearing appropriate PPE (such as gloves, protective coverall and facial protection), and appropriate RMMs (such as avoid splashes and spills during the loading phase).

**Conclusion on risk for consumers via residues in food**

No specific residue data were submitted in the context of this dossier. However, no dietary exposure is expected considering the intended use.

**Conclusion on environmental risk assessment**

The environmental risk assessment of the product TECHNIVERT is based on the active substance and two environmentally relevant substances of concern, CMIT/MIT and MIT.

The product TECHNIVERT poses a risk to the aquatic and terrestrial compartment during the application of the product.

Indeed, following indirect releases to the environment via the STP (urban area), RCR values are > 1 for the surface water and sediment, indicating unacceptable risk for these environmental compartments. Following direct releases to the environment (rural area), calculated RCR values were > 1 for the exposure of soil. Thus, the risk for this environmental compartment is unacceptable.

As the product is always covered by masonry elements and is completely contained once the construction process is complete, the service-life phase was considered not relevant.

Then, the following risk mitigation measures are proposed to prevent the exposure of the soil and STP during the application step:

* Apply the product only on surfaces that will be completely contained once the construction process is complete
* Once treated surfaces are dried, they must be totally protected as long as they are not covered by masonry or protected from rain (ducts, pipes...).
* Due to the high toxicity of acetamiprid to water living and soil organisms, prevent any releases to soil, sewer or water. Any losses of the product, including contaminated water/soil must be collected for disposal in accordance with local/national/international requirements
* The area where the product is handled for preparation or application must be done on hard surfaces not connected to a sewer system.
* Do not apply the product in case rain is expected within 24 hours.

The application of these risk mitigation measures preventing emissions to the environment would achieve acceptable risks.

**Substances of concern**

The biocidal product contains two non-active substances (so called “co-formulant(s)”) which are considered as substances of concern (for human health and environment).

**Endocrine disruptor**

The biocidal product contains the active substance acetamiprid, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

**Active Substance candidate for substitution**

The biocidal product contains acetamiprid which meets the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is considered as a candidate for substitution based on the following criteria: persistent (P) and toxic (T). Therefore, a comparative assessment has been performed in accordance with Article 23(1) of Regulation (EU) No 528/2012 and following the Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a – Final)[[1]](#footnote-2). The assessment is presented under section 3.10 of the PAR.

The competent authority concluded that there is currently no products with significantly lower overall risks for human health, animal health or the environment to substitute the product TECHNIVERT.

**Overall conclusion**

The conformity to the uniform principles, as defined in the Regulation (EU) n°528/2012, for the biocidal product TECHNIVERT is reported in the table below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Users** | **Target organism** | **Application rate validated** | **Field of use** | **Conclusions** |
| Professionals | Termites  *Reticulitermes sp* | Ready-to-use  400-500g of product/m² | Outdoor: Preventive treatment to be applied during the construction of the building | Acceptable |

# ASSESSMENT REPORT

### 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)** |
| **Bucket** | 25 kg | Tin with LDPE liner in contact with the product | Metal | professional | Yes |

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| TECHNIVERT |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | SAPA |
| **Address** | 224, rue Eugène Biraud  17 700, Saint Georges du Bois  France |
| **Authorisation number** | FR-2022-0092 | |
| **Date of the authorisation** | **30/11/2022** | |
| **Expiry date of the authorisation** | **29/11/2027** | |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | KWIZDA |
| **Address of manufacturer** | 30 Avenue de l’Amiral Lemonnier  78160 Marly le Roi  France |
| **Location of manufacturing sites** | OLERON STP  Petit Port des Seynes  17320 Marennes  France |

#### Manufacturer(s) of the active substance(s)

|  |  |
| --- | --- |
| **Active substance** | 1235 - N-((6-chloro-3-pyridinyl)méthyl)-N′-cyano-N-méthyléthanimidamide (acetamiprid) |
| **Name of manufacturer** | Nisso Chemical Europe GmbH |
| **Address of manufacturer** | Berliner Allee 42  40212 Düsseldorf  Germany |
| **Location of manufacturing sites** | Nihongi Plant, Nippon Soda Co., Ltd.  950 Fujisawa  Nagakoh-Ku 949-2392 Johetsu  Niigata  Japan |
| Liling Fine Chemicals Co., Ltd.  698 Xing Gang Rd., Riverside Industry Park, Changshu, Economic Development Zone.  215537 Jiangsu  China |
| The origins of the active substance are those authorised at EU level in the confidential CAR. | |

### Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be 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

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Acetamiprid |
| **IUPAC or EC name** | (E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamide |
| **EC number** | / |
| **CAS number** | 135410-20-7 |
| **Index number in Annex VI of CLP** | PT18 |
| **Minimum purity / content** | 99.55 % |
| **Structural formula** |  |

#### Candidate(s) for substitution

The biocidal product contains acetamiprid which meets the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is considered as a candidate for substitution based on the following criteria: persistent (P) and toxic (T). Therefore, a comparative assessment has been performed in accordance with Article 23(1) of Regulation (EU) No 528/2012 and following the Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a – Final)[[2]](#footnote-3). The assessment is presented under section 3.10 of the PAR.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Technical Content (%)** | **Content**  **(pure)**  **(% w/w)** |
| --- | --- | --- | --- | --- | --- | --- |
| Acetamiprid | (E)-N1-[(6-chloro-3-  pyridyl)methyl]- N2-  cyano- N1-  methylacetamide | Active substance | 135410-20-7 | - | 0.200 | 0.199\* |
| MIT | 2-methyl-2H-isothiazol-3-one | Preservative | 2682-20-4 | - |  | 0.006 |
| C(M)IT MIT | Reaction mass of: 5-chloro-2-methyl-2H-isothiazol-3-one [EС No. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EС No. 220-239-6] (3:1) | Preservative | 55965-84-9 | - |  | 0.0007 |

\* Taking into account a minimum purity of 99.55% in the technical active substance indicated in the Assement report (August 2018)

#### Information on technical equivalence

Not relevant

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

Two substances of concern (SoC) are identified for environment: C(M)IT-MIT (CAS 55965-84-9) and MIT (CAS 2682-20-4). Indeed, there are active substances from other PT for which a draft final CAR is available and participate to the toxicity of the product.

Please see the confidential annex for further details.

MIT (CAS 2682-20-4) is also considered a SoC for Human Health following the same reasons presented above and its contribution to classify of the product for skin sensitization.

#### Assessment of endocrine disruption (ED) properties of the biocidal product

The biocidal product contains the active substance “acetamiprid”, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

The biocidal product does not contain any non-active substances having endocrine-disrupting properties.

Based on the available information, none of the co-formulants contained in the TECHNIVERT product are regulatory identified as endocrine disruptors or have significant ED properties.

For further information, please refer to the Confidential Annex.

#### Type of formulation

|  |
| --- |
| AL : Any other liquid, ready to use |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Skin Sens 1  Aquatic chronic 3 |
| Hazard statement | H317: may cause an allergic reaction  H412: Harmful to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H317: may cause an allergic reaction  H412: Harmful to aquatic life with long lasting effects |
| Precautionary statements | P261: Avoid breathing vapours.  P272: Contaminated work clothing should not be allowed out of the workplace.  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P302 + P352: IF ON SKIN: Wash with plenty of water/…  P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.  P321: Specific treatment (see … on this label).  P362 + P364: Take off contaminated clothing and wash it before reuse.  P273: Avoid release to the environment.  P501: Dispose of the contents/container in an approved hazardous waste collection centre, in accordance with local, regional, national and/or international regulations. |
|  | |
| Note | Contains 1,2-benzisothiazol-3(2H)-on (BIT) and Reaction mass of: 5-chloro-2-methyl-2Hisothiazol-3-one and 2-methyl-2H-isothiazol-3-one (C(M)IT/MIT). |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Protection of buildings – Preventive treatment – Professionals

|  |  |
| --- | --- |
| **Product Type** | PT 18 Insecticides, acaricides and products to control others arthropods |
| **Where relevant, an exact description of the authorised use** | The product TECHNIVERT is a ready-to-use anti-termites physico-chemical barrier used in pre-construction, for protection of buildings. |
| **Target organism (including development stage)** | Subterranean termites : *Reticulitermes spp*. |
| **Field of use** | Preventive treatment during the construction of buildings  Outdoor |
| **Application method(s)** | TECHNIVERT is used between buildings layers as an internal perimeter lining. It is applied by brushing (paintbrush/brush/roller) on masonry surfaces and singular areas (pipes, ducts…). |
| **Application rate(s) and frequency** | One application of 400 g to 500 g product/m² at the construction of the building |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Tin bucket containing a LDPE liner, in contact with the product (25kg)  Metal closure |

#### Use-specific instructions for use

|  |
| --- |
| - |

#### Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

### General directions for use

#### Instructions for use

|  |
| --- |
| * Comply with the instructions for use. * Inform the registration holder if the treatment is ineffective. |

#### Risk mitigation measures

|  |
| --- |
| * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during product handling and application phases ; * Wear a protective coverall (at least type 6) (coverall material to be specified by the authorisation holder within the product information) during product handling and application phases ; * Use facial protection during product handling and application phases ; * Avoid splashes and spills during the loading phase; * Do not rinse used equipment with water. Reuse or dispose of in a safe way. * Apply the product only on surfaces that will be completely contained once the construction process is complete. * Once treated surfaces are dried, they must be totally protected as long as they are not covered by masonry or protected from rain (ducts, pipes...). * Due to the high toxicity of acetamiprid to water living and soil organisms, prevent any releases to soil, sewer or water. Any losses of the product, including contaminated water/soil must be collected for disposal in accordance with local/national/international requirements * The area where the product is handled for preparation or application must be done on hard surfaces not connected to a sewer system. * Do not apply the product in case rain is expected within 24 hours. * Do not expose the treated surfaces to rain. |

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

|  |
| --- |
| * IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice. * IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor. * IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. * IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor. |

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

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

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

|  |
| --- |
| * Shelf life: 2-years |

### Other information

|  |
| --- |
| * Efficacy has only been demonstrated on European subterranean termites (*Reticulitermes spp.*). * The label of the product shall indicate that it contains silicone dioxide (nano). |

### Documentation

#### Data submitted in relation to product application

A letter of access was provided by Nisso (Applicant of the active substance in the CAR) for SAPA (Holder of the product).

A letter of access was provided by KWIZDA (Manufacturer of the product) for SAPA (Holder of the product).

#### Access to documentation

**Efficacy data**

New data have been submitted in the purpose of product authorisation. All documents are available in section 13 of IUCLID and are listed in annex.

## Assessment of the biocidal product

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

Table 2. Intended use # 1 – Film – surface application

|  |  |
| --- | --- |
| Product Type(s) | PT18 Insecticides |
| Where relevant, an exact description of the authorised use | Ready-to-use anti-termites physico-chemical barrier used during construction, for protection of buildings. |
| Target organism (including development stage) | Subterranean termites: Reticulitermes spp.  Workers, soldiers, nymphs |
| Field of use | Preventive treatment, during the construction  Outdoor use |
| Application method(s) | Brushing (paintbrush/brush/roller) on masonry surfaces and singular areas (pipes, ducts…). |
| Application rate(s) and frequency | The application rate is 400 g to 500 g product/m².  One application at the construction of the building |
| Category(ies) of user(s) | Professionals |
| Pack sizes and packaging material | Please see the relevant section (paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file). |

### Physical, chemical and technical properties

Use concentration: liquid ready to use

Claimed packaging: 25kg tin bucket containing LDPE liner. The product TECHNIVERT is in contact with the LDPE liner but not with the metal (tin).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| Physical state at 20 °C and 101.3 kPa | Organoleptic and  visual  observations  No guideline  required | Product Technivert  Batch number:  944-029 containing  0.194% w/w  acetamiprid | Homogeneous green opaque liquid with a characteristic odour. | Acceptable | Halbwachs P., 2020  Section 3.1. in the IUCLID file |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa |
| Acidity / alkalinity | CIPAC MT 75.3 | Product Technivert  Batch number:  944-029 containing  0.194% w/w  acetamiprid | At initial time, the pH of the pure test item of Technivert was 6.63 at 20.7°C after 2 min. | Acceptable | Halbwachs P., 2020  Report n°: No.19-919073-003  Section 3.2. in the IUCLID file |
| Relative density / bulk density | EU Method A.3,  OECD Guideline  No.109 (2012)  (pycnometric  method) | Product Technivert  Batch number:  944-029 containing  0.194% w/w  acetamiprid | The mean relative density of the test item was 1.024 ± 0.001 at 21.6 °C. | Acceptable | Halbwachs P., 2020,  Report n°: 19-919073-002  Section 3.3. in the IUCLID file |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  method (storage  stability)  (A.S. method: HPLC/UV (validated method from No.402/12/1113F/de-e and No.19-919073-005 studies) | Product Technivert  Batch number:  944-029 containing  0.194% w/w | Packaging tested: 25kg tin bucket containing LDPE liner.   |  |  |  | | --- | --- | --- | |  | T0 | T14d / T2w | | Acetamiprid (% w/w) | 0.194 | 0.191  (-1.5 %) | | pH (pure)  (CIPAC MT 75.3)  After 1 min  After 2 min | 6.66 (20.8°C)  6.63 (20.7 °C) | 5.35 (19.9°C)  5.34 (20.1°C) | | Apparence | Homogeneous green opaque liquid with a characteristic odour. | | | Packaging  (25 kg tin bucket containing a LDPE liner) | The packaging material  showed some slight signs of corrosion after the accelerated storage  procedure. However, no change of weight was observed (26.96 g). | | | Acceptable  The variation of the active substance and of the pH after accelerated storage (14 days at 54°C) is considered acceptable.  The commercial packaging is stable after accelerated storage. | Halbwachs P., 2020  Report n°: No.19-919073-003  Section 3.4.2. in the IUCLID file |
| Storage stability test – **long term storage at ambient temperature** | Technical  Monograph  No.17, 2nd  edition, CropLife  (A.S. method: HPLC/UV (validated method from No.402/12/1113F/de-e and No.19-919073-005 studies) | Product Technivert  Batch number:  944-029 containing  0.194% w/w  acetamiprid | The results at ambient temperature after 6, 12 and 24 months of  storage related to the appearance of the test item, the appearance and  weight of the commercial packaging (25 kg tin bucket containing a  LDPE liner), the analytical quantifications of the active substance and the  pH of the pure test item were provided and summarised below:  The   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | T0 | T6 months at 20 ± 2°C | T12 months at 20 ± 2°C | T12 months at 20 ± 2°C | | Appearance | homogeneous green opaque  liquid with a characteristic odour | | | | | Acetamiprid content (%w/w) | 0.194 | 0.190  (-2.1%) | 0.200 (+3.1%) | 0.194  (-0.0%) | | pH (pure test item)  After 1 min  After 2 min  (CIPAC MT 75.3) | 6.66 at 20.8 °C  6.63 at 20.7 °C | - | - | -  5.35 at 18.4°C  5.35 at 18.4°C | | Packaging (25 kg tin bucket containing a LDPE liner)  Appearance  Weight (g) | No change  27.22 | No change  27.24 | No change  27.24 |  |   The test item Technivert and its commercial packaging were considered to be stable after 24 months of storage at 20 ± 2°C. The results after 24 months of storage related to the appearance of the test item, the appearance and weight of the commercial packaging (25 kg tin bucket containing a LDPE liner), the analytical quantifications of the active substance, the pH of the pure test item are considered acceptable. | Content of the active substance , the commercial packaging and the pH are stable after 24 months storage at 20 °C.  The final report should be included in IUCLID under the point 3.4.1.2. | Halbwachs P., 2019,  Report n°: 19-919073-004  Section 3.4.1.2 in the IUCLID file  Halbwachs P., 2022,  Report n°: 19-919073-004 |
| Storage stability test – low temperature stability test for liquids | CIPAC MT 39.3  method (2000) | Product Technivert  Batch number:  944-029 containing  0.194% w/w  acetamiprid | |  |  |  | | --- | --- | --- | | At 0°C | T0 | T7d | | Appearance | homogeneous green opaque  liquid with a characteristic odour | | | Acceptable | Halbwachs P., 2020,  Report n°: 19-919073-002  Section 3.4.1. in the IUCLID file |
| Effects on content of the active substance and technical characteristics of the biocidal product - light | - | - | Not required according to the Assessment Report of acetamiprid  (Product Type 18, August 2018): this active substance does not absorb  at wavelengths >290 nm which indicates that the molecule is not susceptible to breakdown by light. | - | Section 3.4.2. in the IUCLID file |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | See the storage stability tests | Data on temperature have been provided in the accelerated storage stability study and in the low temperature stability study. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | See the accelerated stability test | Acceptable  No significant change was observed on the commercial packaging after storage for 14 days at 54°C. | Section 3.4.1. in the IUCLID file |
| Wettability | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Suspensibility, spontaneity and dispersion stability | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Wet sieve analysis and dry sieve test | CIPAC MT 185  method (2003) | Product Technivert  Batch number: 944-029 containing  0.194% w/w  acetamiprid | As the test item Technivert is a liquid formulation, a wet sieve test was carried out after the low temperature stability test.  No residue of the test item was held on a 75-μm sieve | Acceptable | Halbwachs P., 2020,  Report n°: 19-919073-002  Section 3.5.1. in the IUCLID file  - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Disintegration time | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Persistent foaming | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Flowability/Pourability/Dustability | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Burning rate — smoke generators | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Burning completeness — smoke generators | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Composition of smoke — smoke generators | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Spraying pattern — aerosols | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Physical compatibility | - | - | The product is not intended to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of Technivert with other biocidal products, chemicals or active substances is required. | Acceptable | Section 3.6. in the IUCLID file |
| Chemical compatibility |  |  | The product is not intended to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of Technivert with other biocidal products,  chemicals or active substances is required | Acceptable | / |
| Degree of dissolution and dilution stability | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Surface tension | EU Method A.5,  OECD Test  Guideline115 | Product Technivert  Batch number:  944-029 containing  0.194% w/w  acetamiprid | The mean surface tension of the neat test item Technivert at a temperature of 20.3°C was 17.2 mN/m. The test item was considered as surface active. | Acceptable | Halbwachs P., 2020,  Report n°: 19-919073-002  Section 3.8. in the IUCLID file |
| Viscosity | OECD Test  Guideline 114  ISO Standard  3219 (rotational  viscometer) | Product Technivert  Batch number:  944-029 containing  0.194% w/w  acetamiprid | The test item was considered to have non-newtonian properties.  The dynamic viscosity varied as following:  At 20 ± 0.2°C, from h(0.0025 s-1) = 1452815 mPa.s to h(1.5000 s-1) =  14825 mPa.s.  At 40 ± 0.2°C, from h(0.0250 s-1) = 157466 mPa.s to h(5.0000 s-1) =  4091 mPa.s. | Acceptable | Halbwachs P., 2020,  Report n°: 19-919073-002  Section 3.9. in the IUCLID file |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The product TECHNIVERT is an other liquid (AL) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  The product is an homogeneous green opaque liquid with a characteristic odour. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54° C in the commercial packaging (tin bucket containing a LDPE liner 25 kg), neither the active ingredient content nor the technical properties were changed. This showing that the product is stable for two years at ambient temperature. The stability data indicate that the product is stable for 24 months at 20 ± 2°C when stored in the commercial packaging material.  After 7 days at 0°C, the appearance and the wet sieve test have not significantly changed. The product is stable at 0°C.  Its technical characteristics are acceptable for an AL formulation.  **Implication concerning labelling**:  Shelf life: 2 years  **Post authorisation requirement:** none  / |

### Physical hazards and respective characteristics

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| Explosives | Statement | - | The product Technivert contains 0.20% w/w of acetamiprid (CAS No. 135410-20-7), which is not explosive according to its Assessment Report (Product-Type 18, August 2018).  Based on the structural formulae of each co-formulate and based on the MSDS, no chemical group associated with explosive properties is observed. It is not expected an explosive reaction. | DSC test has been performed, See below. | Section 4.1. in  the IUCLID file |
| Calorimetry method (DSC) | Product Technivert Batch number: 944-029 containing 0.194% w/w acetamiprid | In the temperature range used (25-600°C), no exothermic reaction was observed. This thermodynamic information allows knowing that the test item shall not be classified as explosive and that the tests on explosive properties according to EC A14 method and UN test series 1 to 3 described in Part I of UN Manual of Tests and Criteria should not be performed. | Acceptable  The product is not explosive. | DEMANGEL B., 2021  Report: o.21-919073-001  Section 4.1. in  the IUCLID file |
| Flammable gases | - | - | The product Technivert is not concerned by the physical hazard “flammable gases” as it is a liquid product. | - | - |
| Flammable aerosols | - | - | The product Technivert is not concerned by the physical hazard “flammable  aerosols” as it is not conditioned in aerosols. | - | Section 4.2. in  the IUCLID file |
| Oxidising gases | - | - | The product Technivert is not concerned by the physical hazard “oxidising gases” as it is a liquid product. | - | - |
| Gases under pressure | - | - | The product Technivert is not concerned by the physical hazard “gases under  pressure” as it is a liquid product. | - | Section 4.5. in  the IUCLID file |
| Flammable liquids | EC A.9. method (2008) (equilibrium method closed cup) | Product Technivert Batch number: 944-029 containing 0.194% w/w acetamiprid | The flash point of the product Technivert was higher than 140.0°C.  Therefore, the product Technivert is not classified as a flammable liquid according to the CLP Regulation. | Acceptable  The product is not flammable according to the CLP regulation. | DEMANGEL B., 2021  Report: o.21-919073-001  Section 4.6. in  the IUCLID file |
| Flammable solids | - | - | The product Technivert is not concerned by the physical hazard “flammable solid” as it is a liquid product. | - | Section 4.2. in  the IUCLID file |
| Self-reactive substances and mixtures | Differential Scanning Calorimetry method (DSC) | Product Technivert Batch number: 944-029 containing 0.194% w/w acetamiprid | An endothermic peak was observed from approximately 70°C to 120°C which may correspond to a loose of solvent. However, no exothermic peak was observed no exothermic reaction was observed in the temperature range from 25°C to 600°C. Therefore, the product Technivert is unlikely to be self-reactive and the test on self-reactive properties according to UN Test series A to H described in Part II of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria should not be performed. | Not relevant for liquid product as this hazards classification is only applied to solid product. | DEMANGEL B., 2021  Report: o.21-919073-001  Section 4.8. in  the IUCLID file |
| Pyrophoric liquids | Statement | - | Based on the composition, the product Technivert is not a pyrophoric liquid.  Test is not required as the product Technivert does not contain any components classified as pyrophoric. Moreover, experience in manufacture and handling shows that the product Technivert do not ignite spontaneously on coming into contact with air at normal temperature. The product  Technivert is not expected to be a pyrophoric liquid and test is not required. | Acceptable | Section 4.17. in  the IUCLID file |
| Pyrophoric solids | - | - | The product Technivert is not concerned by the physical hazard “pyrophoric solids” as it is a liquid product | - | Section 4.17. in  the IUCLID file |
| Self-heating substances and mixtures | Statement | - | Tests are considered as unnecessary regarding these physical hazards. Indeed, as mentioned in section 4 of the IUCLID file, the product Technivert contains 0.20% w/w of acetamiprid (CAS No. 135410-20-7), which has no flammable, self-reactive, and oxidising properties according to its Assessment Report (Product-Type 18, August 2018). This active substance also has no self-ignition temperature up to 450 °C.  The main constituents of the product Technivert are:  - an “aqueous dispersion of a polymer based on acrylic ester and styrene” (around 50% w/w of the composition); this ingredient has no flammable, self-reactive and oxidising properties and is not self-flammable according to its safety datasheet and/or to the chemical structures of its components,  - water (more than 45% w/w of the composition), which is an inert component.  The other components (less than 5% w/w of the formulation), are not classified as flammable, self-reactive and oxidising according to their safety datasheets, and due to their low contents in the product, they are not considered as being able to lead to a classification of the product Technivert. They are also not expected to present a significant hazard for auto-flammability according to their safety data sheets.  Therefore, the product Technivert is not expected to have flammable, self-reactive and oxidising properties and to present a significant hazard for auto-flammability and no tests are deemed necessary. | Not relevant for liquid product as this hazards classification is only applied to solid product. | Section 4.17. in  the IUCLID file |
| Substances and mixtures which in contact with water emit flammable gases | - | - | According to the composition (45 % water) the test is not required as the product Technivert.  It does not contain any components classified as substances which in contact with water emit flammable gases. Therefore, the product Technivert is not expected to emit flammable gases in contact with water and test is not required. | Acceptable | Section 4.17. in  the IUCLID file |
| Oxidising liquids | Statement | - | The product Technivert contains 0.20% w/w of acetamiprid (CAS No. 135410-20-7), which has no oxidising properties according to its Assessment Report (Product-Type 18, August 2018). The main constituents of the product Technivert are: - an “aqueous dispersion of a polymer based on acrylic ester and styrene” (around50% w/w of the composition); based on the substances mentioned in sections 2 and 3 of the safety datasheet of this mixture, it does not contain any substance with **oxygen, fluorine or chlorine atoms bonded to atoms other than carbon and hydrogen**. In addition, the absence of oxidising properties of this mixture is clearly indicated in section 9 of the safety datasheet. - water (more than 45% w/w of the composition), which is an inert component. The other components (less than 5% w/w of the composition), are not classified as oxidising according to their safety datasheets, and due to their low contents in the product, they are not considered as being able to lead to a classification of the product Technivert. Therefore, the product Technivert is not expected to have oxidising properties and test is considered as unnecessary. | Acceptable | Section 4.4. in  the IUCLID file |
| Oxidising solids | - | - | The product Technivert is not concerned by the physical hazard “oxidising solids” as it is a liquid product. | - | Section 4.4. in  the IUCLID file |
| Organic peroxides | - | - | The product Technivert is not concerned by the physical hazard “organic peroxides” as its components are not expected to form or contains organic peroxides | - | Section 4.15. in  the IUCLID file |
| Corrosive to metals | C.1 UN Test of  UN Manual of  Tests and  Criteria | Product Technivert  Batch number:  944-029 containing  0.194% w/w  acetamiprid | The product Technivert is not considered to be corrosive to steel and aluminium.  The maximal recorded loss of mass recorded was 0.10% (steel) for one of the plate which is lower than 13.5% for an exposure time of 7 days. No localised corrosion was observed on plates; thus the test is then considered negative. See the table below for more details:   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | Initial weight (g) | Weight after treatment (g) | Loss of mass (%) | Loss of mass (%) | | Steel plate  (immersed plate after treatment) | 14.8573 | 14.8444 | 0.0129 | 0.09 | | Steel plate  (Half way immersed plate after treatment) | 14.8041 | 14.7899 | 0.0142 | 0.10 | | Steel plate  (Non immersed plate after treatment) | 14.6228 | 14.6216 | 0.0012 | 0.0 | | Aluminum plate  (immersed plate after treatment) | 5.4914 | 5.4901 | 0.0013 | 0.02 | | Aluminum plate  (Half way immersed plate after treatment) | 5.5729 | 5.5718 | 0.0011 | 0.02 | | Aluminum plate  (Non immersed plate after treatment) | 5.4674 | 5.4674 | 0.000 | 0.000 | | Acceptable | Halbwachs P., 2020,  Report n°: 19-919073-002  Section 4.16. in  the IUCLID file |
| Auto-ignition temperatures of products (liquids and gases) | EEC A.15. | Product Technivert Batch number: 944-029 containing 0.194% w/w acetamiprid | The auto-ignition temperature of the test item was 448 ± 3°C (corrected temperature). | Acceptable | DEMANGEL B., 2021  Report: o.21-919073-001  Section 4.8. in  the IUCLID file  Section 4.17.1.  in the IUCLID  file |
| Relative self-ignition temperature for solids | - | - | The product Technivert is not concerned by the physical hazard “relative self-ignition temperature for solids” as it is a liquid product. | - | Section 4.17.1.  in the IUCLID  file |
| Dust explosion hazard | - | - | The product Technivert is not concerned by the physical hazard “dust explosion” as it  is a liquid product. | - | Section 4.2. in  the IUCLID file |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is not classified for physical properties.  Implication concerning labelling: None. |

### Methods for detection and identification

**2.2.4.1 Method of the determination of the active substance in the product:**

Acetamiprid is analysed after extraction from the formulation and quantified by liquid chromatography using a UV detector (248 nm). Quantification is performed using external standard calibration.

This analytical method for the determination of acetamiprid content in the product LIGNOSAN 2 CSXX (having the same composition as the product Technivert) was validated in the lab.1 test facility by definition of the specificity, the linearity, the accuracy and the precision of the method.

However, as the stability studies are performed in another test facility (lab 2 instead lab 1), the method has been adapted to the materials of this laboratory and was validated by definition of the linearity, the accuracy, the precision and the reproducibility of the method.

Validation results are presented below.

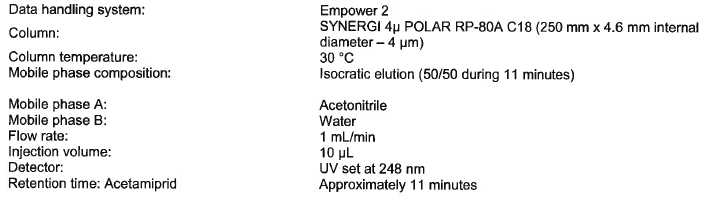
***Determination of acetamiprid content in the product Technivert (Lab. 1 confidential)***

Reference: Raphalen E., 2013, Validation of analytical method according to SANCO 3030/99 rev.4 and chemical analysis of active substance declared in the test item LIGNOSAN 2 CSXX, Testing laboratory: Lab 1; confidential

Report no.: 402/12/11113F/de-e, Company owner: Kwizda France SAS, Report Date: 2013-12-20, GLP compliance: yes (including certificate)

**Principle of the method**

About 0.250 g of the product LIGNOSAN 2 CSXX (0.2 % w/w (2 g/kg)) is accurately weighed (to the nearest 0.01 mg) into a 10-mL volumetric flask and the volume was made up with the acetonitrile. Acetamiprid is analysed by Liquid Chromatography with UV detection (248 nm) by external standard calibration, at retention time of about 4.6 min.



**Results**

Specificity

Specificity was studied by analysis of the matrix without any active substance (blank formulation), the acetamiprid reference item, the blank formulation spiked with a known amount of acetamiprid reference item, and the test item. The specificity was assessed by checking for any interference in HPLC-UV at the retention time of the peak of acetamiprid (about 4.6 min).

No peak appears in the blank formulation. In the solutions of acetamiprid reference item, the spiked blank formulation, and the test item, the peak at the retention time around 4.6 min represents acetamiprid.

No additional peak appears near the retention time of the acetamiprid peak in the reference item, the spiked blank formulation and in the test item.

Therefore, the analytical method showed a good specificity for analysis of acetamiprid in the product.

Linearity

To define the linearity of the detector answer of acetamiprid, five concentrations taken between 80% and 120% (from 40 mg/L to 60 mg/L) of the acetamiprid reference item were analysed (one determination for each concentration). Two analyses were performed.

The response of the detector during the two analyses of acetamiprid was linear:

- within the range of 80% and 120% (40.00 mg/L to 60.18 mg/L) (y = 5.071192 \* 104 \* x + 3.616533 \* 104 (y = acetamiprid peak area, x = acetamiprid amount (in mg/L), r = 0.9998),

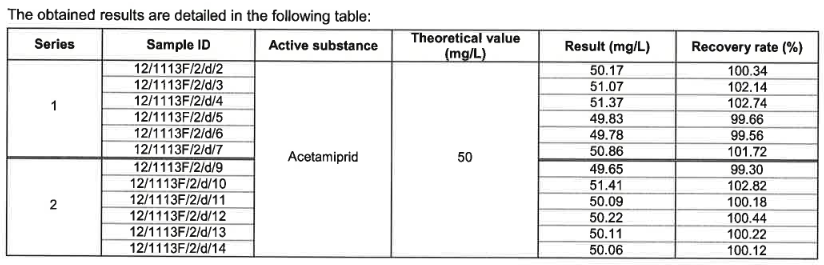
- and within the range of 39.80 mg/L to 59.84 mg/L (y = 4.991287 \* 104 \* x + 6.735593 \* 104 (y = acetamiprid peak area, x = acetamiprid amount (in mg/L), r = 0.9998).

The correlation coefficients r were > 0.99, showing a good linearity.

Accuracy/ precision

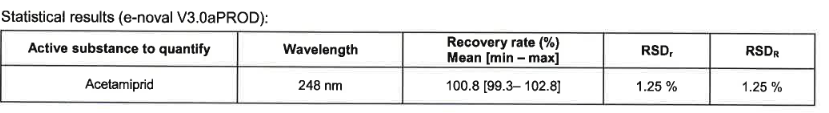
Accuracy and precision were carried out by two operators and on two analytical series. The validation conditions were obtained by using the same method and the same equipment, on two analytical series.

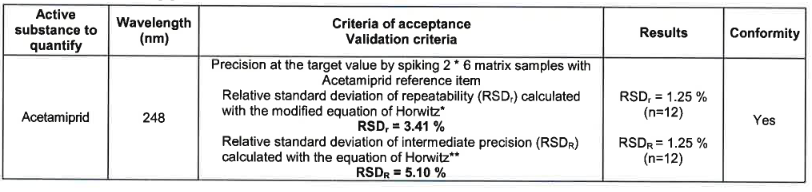
The accuracy results of acetamiprid were in conformity with the Guidelines requirements for formulations containing between 0.1% and 1% of an active substance. Indeed, the recovery results should be in the range 95% - 105% and they were experimentally equal to 99.30% and 102.82%. Mean recovery rate = 100.8% (n = 12). Data are summarized in the table below.



Then, the Relative Standard Deviation (R.S.D.) was calculated.

In the case of acetamiprid, the precision was acceptable as the R.S.D. was lower than the result of the modified Horwitz equation: 1.25% < 3.41% (C = 0.002). Data are summarized in the tables below.





Limit of quantification:

The limit of quantification can be set at the lowest acceptable concentration tested for the accuracy test 0.1%.

Quantitative analysis

A quantitative analysis was carried out on the test item in six replicates.

Then, the average value of the content and the Relative Standard Deviation (R.S.D.) were calculated.

The concentration of acetamiprid in the test item was equal to 0.18% w/w or 1.8 g/kg.

In the case of acetamiprid, the precision was acceptable as the R.S.D. was lower than the result of the modified Horwitz equation: 2.78% < 3.41% (C = 0.002).

***Determination of acetamiprid content in the product Technivert (Lab 2: confidential )***

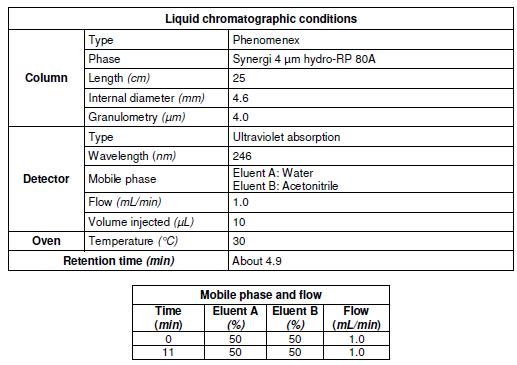
Reference type: Ricau H., 2020, Validation of the analytical method for the determination of acetamiprid in TECHNIVERT In compliance with SANCO/3030/99 rev.5 from 22/03/2019, Testing laboratory: Lab 2 confidential , Report no.: 19-919073-005, Company owner: SAPA SAS, Report Date: 2020-01-24

GLP compliance: yes (including certificate)

Acetamiprid is analysed after extraction from the formulation and quantified by liquid chromatography using a reverse phase column and a UV detector following the method developed in the study No.402/12/1113F/de-e provided by the Study Sponsor. This method was slightly adapted.

**Principle of the method**

About 0.250 g of the product Technivert is accurately weighed (to the nearest 0.01 mg) into a 10-mL volumetric flask, a few volume of acetonitrile was added and the solution was vigorously manually stirred. The volume was made up with acetonitrile and the solution was treated with ultrasounds for 10 minutes. The solution was vigorously manually stirring then treated again with ultrasounds for 10 minutes. The solution was filtered on 0.45-μm nylon filter before analysis. Acetamiprid is analysed by Liquid Chromatography with UV detection (248 nm) and C18 column by external standard calibration, at retention time of about 4.9 min.



**Results**

Specificity

No chromatograms have been provided in this report, nevertheless, as the specificity of the method was validated in the report Raphalen E., 2013, on the product LIGNOSAN 2 CSXX, identical to Technivert according to the Applicant, no more data required.

A declaration indicating that LIGNOSAN 2 CSXX has the same composition as Technivert was be provided.

Linearity

To define the linearity of the detector answer of acetamiprid, five concentrations taken between 50% and 150% (from 22.96 mg/L to 73.80 mg/L) of the acetamiprid reference item were analysed (two determinations for each concentration).

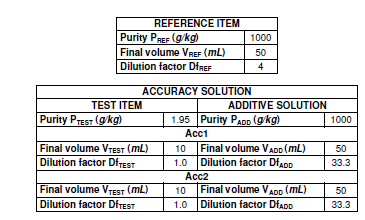
The response of the detector during the analysis of acetamiprid was linear within the range of 22.96 mg/L to 73.80 mg/L (y = 3.25 \* 105 \* x + 1.35 \* 106 (y = acetamiprid peak area, x = acetamiprid amount (in mg/L), r = 0.9957).

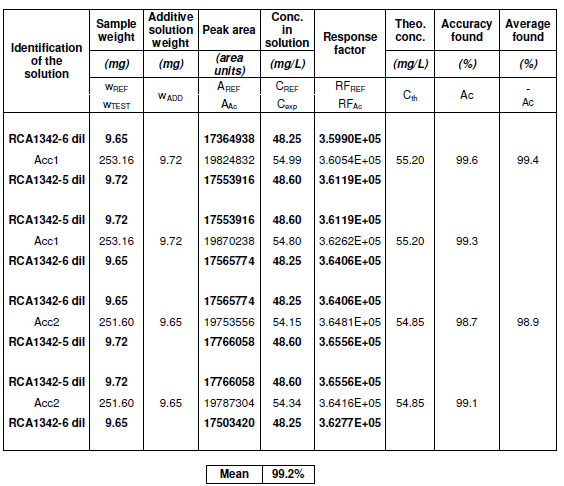
The correlation coefficient r was > 0.99 showing a good linearity.

Accuracy

The accuracy was determined by the standard addition method comparison of the acetamiprid reference item and two test items spiked with a known amount of acetamiprid reference item and analysed in duplicate.

The accuracy results of acetamiprid were in conformity with the Guidelines requirements for formulations containing between 0.1% and 1% of an active substance. Indeed, the recovery results should be in the range 80% - 120% and they were experimentally equal to 98.9% and 99.4%.





Limit of quantification:

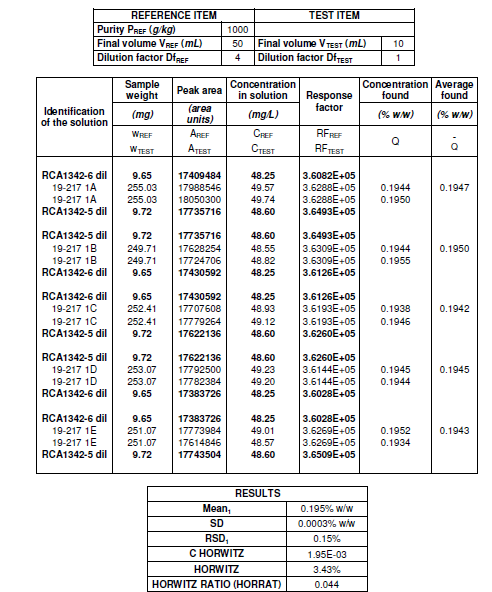
The limit of quantification can be set at the lowest acceptable concentration tested for the accuracy test 0.1%.

Precision

The precision was determined by analysing twice five test item solutions. The content of acetamiprid for each analysis was calculated with the average value of the response factor of the two calibration solutions bracketing the test item. Then, the average value of the content, the standard deviation and the Relative Standard Deviation (R.S.D.) were calculated.

The concentration of acetamiprid in the test item was equal to 0.195% w/w or 1.95 g/kg.

In the case of acetamiprid, the precision was acceptable as the R.S.D. was lower than the result of the modified Horwitz equation: 0.15% < 3.43% (C = 0.00195) with Horwitz ratio (Horrat) equal to 0.044.



Reproducibility

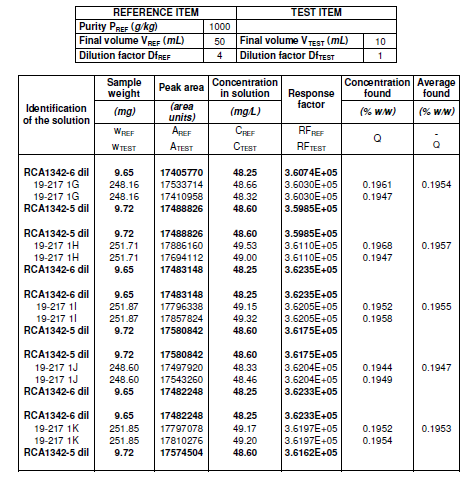
The reproducibility was determined by analysing preparations (twice n = 5) carried out at two different days by two different analysts. The content of acetamiprid for each analysis was calculated then the average value of the content, the standard deviation and the Relative Standard Deviation (R.S.D.) were calculated.

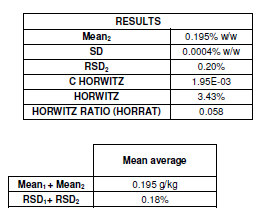
For the second series, the concentration of acetamiprid in the test item was equal to 0.195% w/w (corresponding to 1.95 g/kg).

And the precision was acceptable as the R.S.D. was lower than the result of the modified Horwitz equation: 0.20% < 3.43% (C = 0.00195) with Horwitz ratio (Horrat) equal to 0.058.

The mean average content of acetamiprid for the two reproducibility tests was equal to 0.195% w/w (corresponding to 1.95 g/kg).

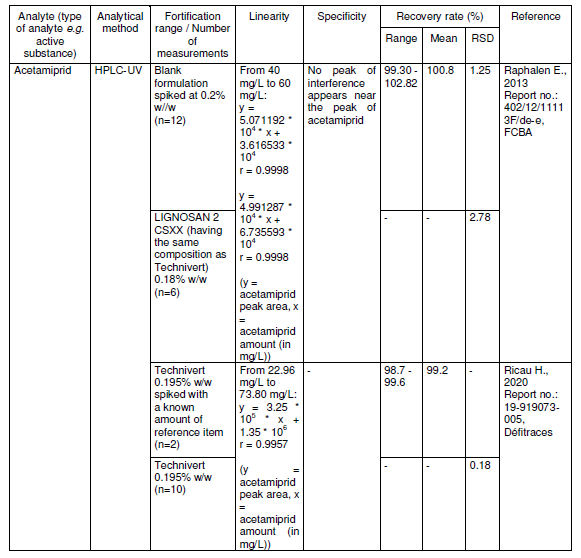
The mean Relative Standard Deviation of acetamiprid for the two reproducibility tests was equal to 0.18%.





**Summary HPLC/UV validation data:**

The HPLC-UV methods Raphalen E., 2013 and Ricau H. 2020 were used for the determination of the active substance Acetamiprid in the biocidal product Technivert. The following validation data were provided and are considered acceptable.



**2.2.4.2 Substances of Concern determination**

The product TECHNIVERT contains the following substances of concerns:

* MIT (2-methyl-2H-isothiazol-3-one) (CAS No. 2682-20-4)
* CMIT-MIT (CAS 55965-84-9)

These SoCs were not determined in the product, however an acceptable justification was provided by the Applicant:

The preservatives CMIT-MIT and MIT are biocidal substances approved for PT06, 11, 12 and 13 that are present in several co-formulants of the product TECHNIVERT. Their content are expected to be less than 0.01% (0.00075 and 0.00675% w/w respectively) in the final product TECHNIVERT and these substances are not expected to be formed during the storage of the final product. It does not appear necessary to monitor the evolution of the contents of these substances in the product during the storage studies.

No analytical methods for the determination of the 2-methyl-2H-isothiazol-3-one (CAS No. 2682-20-4) and CMIT-MIT (CAS 55965-84-9) in the product are available in the dossier. However, as this substance is not expected to be formed during the storage no further data is required.

**2.2.4.3 Methods for the determination of residues:**

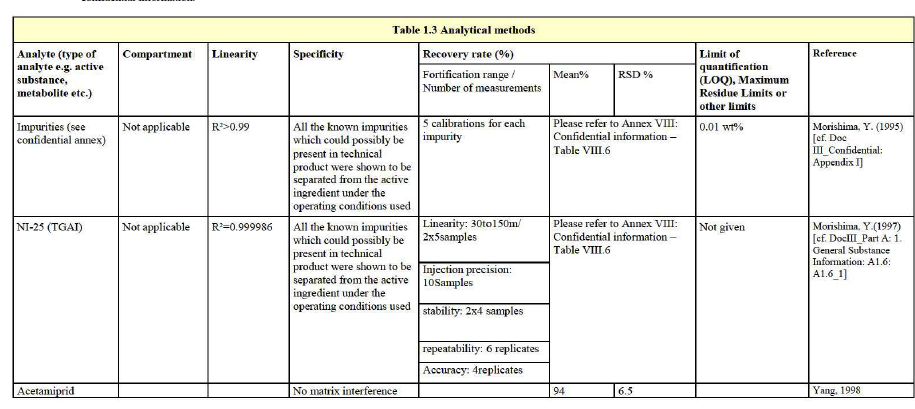
A letter of access was provided by Nisso (Applicant of the active substance in the CAR) for SAPA (Holder of the product).

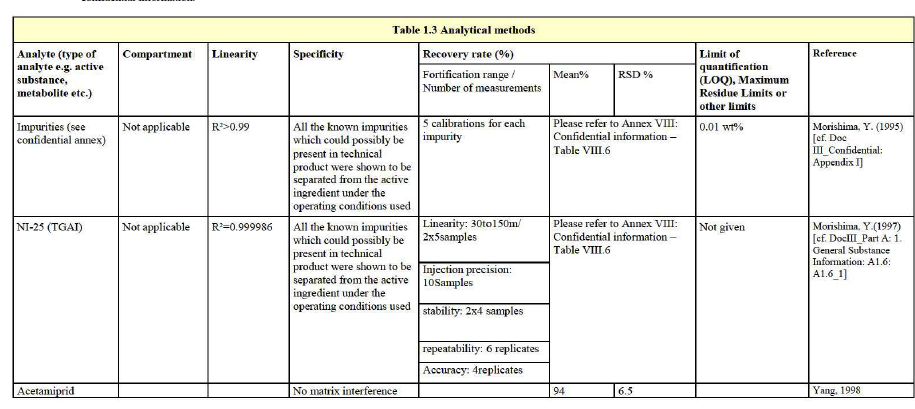
A letter of access was provided by KWIZDA (Manufacturer of the product) for SAPA (Holder of the product).

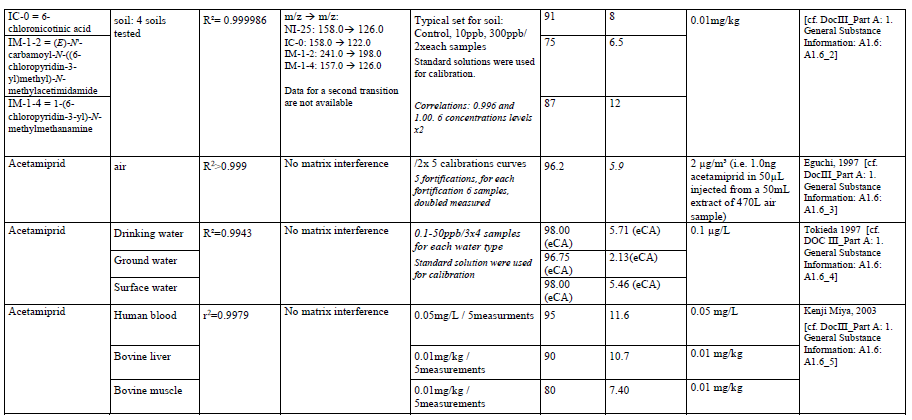
As the product TECHNIVERT is not intended to be used with surface in contact with food/feed of plant and animal origin, analytical method for the determination of acetomiprid residue in food/feed of plant and animal origin is unnecessary.

Analytical methods for acetamiprid residues in soil, air, water, and human body fluids and tissues are available in the Assessment Report acetamiprid Product-type 18 (Insecticides, acaricides and products to control others arthropods), August 2018 (CAR).

See the table below from the assessment report (August 2018):







|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The analytical methods HPLC/ UV (248 nm) are fully validated for the determination of the active substance acetamiprid in the product with an LOQ of 0.1 %.  No analytical method was provided for the determination of SoCs as they are not expected to increase after storage.  The product is not intended to be used on surface in contact with food/feed of plant and animal origin, an analytical method for the determination of acetamiprid in food/feed of plant and animal origin is not required.  Analytical methods were provided at EU level for the determination of acetamiprid residue in soil, water and air with respectively LOQ = 0.01 mg/kg, 0.1 µg/L and 2 µg/m3.  Acetamiprid is not toxic (T) or very toxic (T+) active substance. Nevertheless, an analytical method for the determination of acetamid in blood, liver and muscle is available in the CAR and is validated with an LOQ of 0.05 mg/L in blood and 0.01 mg/kg in liver and muscle. |

### Efficacy against target organisms

#### Function and field of use

Main Group 3: Pest control

Product Type 18: Insecticides

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

According to the use claimed by the applicant, the product TECHNIVERT is a ready-to-use fluid coating containing 0.2% w/w acetamiprid to be used as a physico-chemical barrier.

The product is designed for the preventive protection of buildings against termites.

The application is performed by brushing to cover localized surfaces between foundations and masonry elements (peripheral application) that leads to an amount recommended of 400 - 500 g per m² of product (0.2 % of acetamiprid w/w).

The application takes place during the building construction.

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

The product TECHNIVERT forms a physico-chemical barrier against termites that kill termites after contact. The dry film also acts as a barrier.

#### Mode of action, including time delay

According to the Assessment Report (August 2018), acetamiprid is a neonicotinoid insecticide which acts on harmful organisms by contact and ingestion. The neonicotinoids are a class of insecticides with a common mode of action that affects the central nervous system of insects, causing paralysis and death.

The product is effective as soon as it has dried and has formed a continuous film.

#### Efficacy data

All the efficacy trials have been conducted with the product AMP 2 CS XX, identical to the product TECHNIVERT, according to the requirements of the BPR Efficacy guidance Volume II part B/C.

Efficacy is demonstrated in lab tests according to XP X 41-550 method, after ageing.

A field test has been performed in France. Nevertheless, it should be noted that the field trial has not been performed according to the test method FCBA BIO E008 but according to FCBA BIO E045 method. The FCBA BIO E045 is an update of the method FCBA BIO E008, where the product application is more representative of the application method in real situation. Indeed, in this new method, the product is not in contact with the soil. FR CA is of the opinion that this updated method is more suitable for the demonstration of the product TECHNIVERT taken into account its mode of application (liner between foundations and masonry elements). The duration of the test is expected on 10 years, and the applicant has submitted a 2 and 4 years interim report.

After 2 years, termites have not penetrated any test control device even if presence of termites is observed around control and test devices.

After 4 years, in two control devices, degradations of the bait wood was noted. It validated the test.

In the test devices treated no degradation nor presence of termites was observed that demonstrate the efficacy of the product 4 years after its application.

Based on the data presented, FR CA considers that the efficacy of the product TECHNIVERT as a physicochemical barrier as perimeter lining against subterranean termites (Reticulitermes spp.) is demonstrated.

The field test in progress is planned for a duration of 10 years. The interim reports at 6, 8 and 10 years available at the renewal of the product TECHNIVERT should be provided.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisa- ged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide | Outdoor | AMP 2 CS XX  acetamiprid 0.2% w/w | *Reticulitermes*  *flavipes*  50 workers per replicate | CTBA-BIO-E- 004 | Each test device is a Petri dish containing 5 mm of mortar which surface has been treated with the test product.  Application rate: 300-302 g/m², then 8 days drying  Exposure: 48 hours  Replicates: 5  Controls: 5 (non-treated mortar)  Mortality is assessed after 48 hours exposure. | Survival rate in the control higher than 70 % (90 %),  Mortality of workers: 88%. The remaining living termites, transferred into clean Petri dishes, also died within the following 48 hours.  Efficacy criterion matched. | Ansard D and Paulmier I.  2012  S6.7\_01  R. I.: 1 |
| Insecticide | Outdoor | AMP 2 CS XX  acetamiprid  0.2% w/w | *Reticulitermes*  *flavipes*  150 workers, 3  nymphs and 2  soldiers per replicate | XP X 41-550 | Each test device is composed of the lower part of sand with a pine sapwood bait wood block and on the higher part of floral foam, with a polystyrene block between these two parts.  The product is applied on the upper part of the  polystyrene, in contact with the floral foam.  At the beginning of exposure, the termites are disposed on the floral foam.  Application rate: 300 g/m²  Exposure: 4 weeks  Replicates: 4  Controls: 4, with a heat-sealable film applied on  the polystyrene instead of the product.  Recovery of insects and mortality assessed after the 4 weeks exposure.  Visual observation of the penetration through the film.  Visual observation of the bait wood block and rating (0- no attack, 1- traces of gnawing, 2- slight attack, 3- medium attack, 4- heavy attack).  Validity criteria:  More than 50% of alive termites in the control sample.  All the control blocks are ranked 4 | Survival rate in the control higher than 50% (50.2%), all the control blocks are ranked 4.  Damages rate in the test blocks: 0  No passing through the film in all the test devices.  Efficacy criterion is matched. | Ansard D and  Paulmier I.  2012  S6.7\_02  R. I.: 1 |
| Insecticide | Outdoor | AMP 2 CS XX  acetamiprid  0.2% w/w | *Reticulitermes*  *flavipes*  150 workers, 3  nymphs and 2  soldiers per replicate | XP X 41-550  after XP ENV  1250-2  adapted  (FCBA-BIO-  E-046) | Each test device is composed of the lower part  of sand with a pine sapwood bait wood block  and of the higher part of floral foam, with a  polystyrene block between these two parts. The  product is applied on the upper part of the  polystyrene, in contact with the floral foam.  Before exposure, product applied on polystyrene is aged by immersion in water.  At the beginning of exposure, the termites are disposed on the floral foam.  Application rate: 300 g/m²  Exposure: 4 weeks  Replicates: 4  Controls: 4, with a heat-sealable film applied on the polystyrene instead of the product.  Recovery of insects and mortality assessed after the 4 weeks exposure.  Visual observation of the penetration through the film.  Visual observation of the bait wood block and rating (0- no attack, 1- traces of gnawing, 2- slight attack, 3- medium attack, 4- heavy attack).  Validity criteria:  More than 50% of alive termites in the control sample.  All the control blocks are ranked 4 | Survival rate in the control higher than 50% (69.75%), all the control blocks are ranked 4.  Damages rate in the test blocks: 0  No passing through the film in all the test devices.  Efficacy criterion is matched. | Ansard D and  Paulmier I.  2012  S6.7\_03  R. I.: 1 |
| Insecticide | Outdoor | AMP 2 CS XX  acetamiprid  0.2% w/w | *Reticulitermes*  *flavipes*  150 workers, 3  nymphs and 2  soldiers per replicate | XP X 41-550  after FCBA-  BIO-E-016 | Each test device is composed of the lower part of sand with a pine sapwood bait wood block and on the higher part of floral foam, with a polystyrene block between these two parts.  The product is applied on the upper part of the polystyrene, in contact with the floral foam.  Before exposure, product applied on polystyrene is aged by horizontal exposure to solar radiation during 17 days.  At the beginning of exposure, the termites are disposed on the floral foam.  Application rate: 300 g/m²  Exposure: 4 weeks  Replicates: 4  Controls: 4, with a heat-sealable film applied on the polystyrene instead of the product.  Recovery of insects and mortality assessed after the 4 weeks exposure.  Visual observation of the penetration through the film.  Visual observation of the bait wood block and rating (0- no attack, 1- traces of gnawing, 2- slight attack, 3- medium attack, 4- heavy attack).  Validity criteria:  More than 50% of alive termites in the control sample.  All the control blocks are ranked 4 | Survival rate in the control higher than 50 % (75.25%), all the control blocks are ranked 4.  Damages rate in the test blocks: 0  No passing through the film in all the test devices.  Efficacy criterion is matched. | Ansard D and  Paulmier I.  2013  S6.7\_04  R. I.: 1 |
| Insecticide | Outdoor | AMP 2 CS XX | *Reticulitermes*  *flavipes*  150 workers, 3  nymphs and 2  soldiers per replicate | XP X 41-550  after CTBA-  BIO-E-016 | Each test device is composed of the lower part of sand with a pine sapwood bait wood block and on the higher part of floral foam, with a polystyrene block between these two parts.  The product is applied on the upper part of the polystyrene, in contact with the floral foam.  Before exposure, product applied on polystyrene is aged by vertical exposure to solar radiation during 96 days.  At the beginning of exposure, the termites are disposed on the floral foam.  Application rate: 300 g/m²  Exposure: 4 weeks  Replicates: 4  Controls: 4, with a heat-sealable film applied on the polystyrene instead of the product.  Recovery of insects and mortality assessed after the 4 weeks exposure.  Visual observation of the penetration through the film.  Visual observation of the bait wood block and rating (0- no attack, 1- traces of gnawing, 2- slight attack, 3- medium attack, 4- heavy attack).  Validity criteria:  More than 50% of alive termites in the control sample.  All the control blocks are ranked 4 | Survival rate in the control higher than 50 % (75.75%), all the control blocks are ranked 4.  Damages rate in the test blocks: 0  No passing through the film in all the test. Efficacy criterion) is matched. | Ansard D and  Paulmier I.  2013  S6.7\_05  R. I.: 1 |
| Insecticide | Outdoor | AMP 2 CS XX  acetamiprid 0.2% w/w | *Reticulitermes*  *flavipes*  150 workers, 3  nymphs and 2  soldiers per replicate | XP X 41-550  after CTBA- BIO-E-007 | Each test device is composed of the lower part of sand with a pine sapwood bait wood block and on the higher part of floral foam, with a polystyrene block between these two parts.  The product is applied on the upper part of the polystyrene, in contact with the floral foam.  Before exposure, a block of mortar (= alkaline pH), with passages for termites, is poured on the test product applied on polystyrene.  At the beginning of exposure, the termites are disposed on the floral foam.  Application rate: 300 g/m² Exposure: 4 weeks  Replicates: 4  Controls: 4, with a heat-sealable film applied on the polystyrene instead of the product.  Recovery of insects and mortality assessed after the 4 weeks exposure.  Visual observation of the penetration through the film.  Visual observation of the bait wood block and rating (0- no attack, 1- traces of gnawing, 2- slight attack, 3- medium attack, 4- heavy attack).  Validity criteria:  More than 50% of alive termites in the control sample.  All the control blocks are ranked 4 | Survival rate in the control higher than 50 % (64.50%), all the control blocks are ranked 4.  Damages rate in the test blocks: 0  No passing through the film in all the test.  Efficacy criterion is matched. | Ansard D and Paulmier I. 2013  S6.7\_06  R. I.: 1 |
| Insecticide | Outdoor | Technivert acetamiprid 0.2% w/w | *Reticulitermes*  *flavipes*  150 workers, 3  nymphs and 2  soldiers per replicate | FCBA-BIO-E- 045 | Study area: Saint-Trojan-Les Bains (Charente- Maritime, France) – 10 years duration  Each test device is composed of susceptible bait wood, shut up in a concrete manhole riser (40\*40\*40 cm) half-buried and closed by a cover.  The concrete manhole riser is set on a concrete slab, which surface, not in contact with the soil, is treated with the test product. "Sensitive" areas, which would be easily overcome by termites, are created in the devices.  10 concrete slabs were cracked, and cracks were kept opened during the reformation of the slabs.  On these 10 cracked slabs, the treatment was applied on 5 slabs without filling the crack (EF devices). On the other 5 slabs, the crack was filled with polystyrene before treatment with the product, so there is a continuous and homogeneous layer of the test product (EP devices).  The mean application rate was 400 g/m² (393-417)  On 5 of these 10 slabs (3 EF + 2 EP devices), there was also a 4.5 cm dimeter hole made in the slab, to insert a 4 cm diameter PVC pipe (clogged with mortar). The space between the pipe and the slab was filled with polystyrene and the test product applied on the surface and also on a few centimeters along the pipe.  5 control devices (T devices), 3 without any treatment and 2 treated with AMP 0 XX, similar to the test product but without active substance. All the T devices also contained a PVC pipe  These 15 devices are disposed on the test site as 5 sets of 3 devices: one control + one cracked slab not filled + one cracked slab filled.  Exposure: 10 years, from November 2017  Assessments 1, 2, 4, 6, 8 and 10 years after installation.  Controls inside the devices (examination of mud tunnels done by termites, of damages on wood blocks…) and in the vicinity of the tests devices. | First interim report after 2 years, termite activity has been recorded in the vicinity of 4 out of 5 sets of devices. Termites have not penetrated in any device (treated or control)  Second interim report after 4 years, termite degradation have been recorded in 2 control devices.  In the treated device, no presence nor degradation has been observed in the device despite the presence of thermites of the vicinity of 3 out of 5 sets of devices.  Interim reports at 6, 8 and 10 years should be provided at the renewal of the product TEHCNIVERT | Ansard D and Paulmier I. 2020  Brunet C and Paulmier I. 2021  S6.7\_07  S6.7\_08  R. I.: 1 |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| In accordance with the submitted tests and the requirements of the efficacy guidance Vol II part B/C, the efficacy of the ready to use product TECHNIVERT as physico-chemical barrier (peripheral application and singular areas (pipes, ducts…)) to protect buildings is demonstrated against European subterranean termites (*Reticulitermes sp.).*  For the field trial in progress and planned for a duration of 10 years, the interim reports at 6, 8 and 10 years available at the renewal of the product TECHNIVERT should be provided. |

#### Occurrence of resistance and resistance management

According to the Assessment Report (August 2018), with a mono-site activity the development of resistance to acetamiprid may occur. And it could be likely that cross-resistance with nicotinic insecticide could also appear.

Resistant German cockroach strains have already been found (Fardisi *et al.*; 2017), and cross resistance to acetamiprid of an imidacloprid resistant house fly strain has been demonstrated (Kavi *et al*., 2014).

Also, acetamiprid is classified by IRAC in mode of action group 4A insecticide (nicotinic acetylcholine receptor competitive modulators, neonicotinoids). And resistance to insecticide from group 4A has been confirmed for many agricultural pests (IRAC 2014).

However, no specific data has been found in the literature regarding occurrence of resistance to acetamiprid among wood-boring insects and termites. There are no reported cases of development of resistance involving the use of acetamiprid for this specific use in physico-chemical barriers against termites.

To ensure a satisfactory level of efficacy and avoid the development of the recommendations proposed in the SPC have to be implemented.

#### Known limitations

None

#### Evaluation of the label claims

In accordance with the submitted tests and the requirements of the efficacy guidance Vol II part B/C, the efficacy of the ready to use product TECHNIVERT as physico-chemical barrier (peripheral application and singular areas (pipes, ducts…)) to protect buildings is demonstrated against European subterranean termites (*Reticulitermes spp.).*

In the laboratory trials, the amount of product applied was 300 g/m² and 400 g/m² in the field trial. The amount of product to be applied recommended by the applicant is 400 g to 500 g product/m².

#### Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Not relevant

### Risk assessment for human health

#### Assessment of effects on Human Health

Neither skin and eye irritation study, nor skin sensitisation study, nor acute toxicity study (oral, dermal and inhalation), have been performed on the product TECHNIVERT.

Classification of the product has been carried out according to the calculation rules laid down in the CLP regulation.

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not irritant to skin |
| Justification for the value/conclusion | The product TECHNIVERT contains several ingredients classified for skin corrosion or irritation but all at contents < 1%.  The application of the calculation rules do not trigger any classification for skin irritation. |
| Classification of the product according to CLP | Not classified. |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Not irritant to eye |
| Justification for the value/conclusion | The product TECHNIVERT contains several ingredients classified for eye irritation but all at contents < 1%.  The application of the calculation rules do not trigger any classification for skin irritation. |
| Classification of the product according to CLP | Not classified. |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Value/conclusion | Not irritant to the respiratory tract |
| Justification for the conclusion | The product TECHNIVERT contains 0.064% of ingredient classified as STOT SE 3, H335 which is less than the threshold value of 20% to classify the product as STOT SE 3, H335. |
| Classification of the product according to CLP | Not classified |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Skin sensitizer |
| Justification for the value/conclusion | The product TECHNIVERT contains more than 0.0015% w/w of 2-methyl-2H-isothiazol-3-one (MIT), which is the specific concentration limit of this substance. A classification H317 is therefore required.  Moreover, the content of 1,2-benzisothiazol-3(2H)-one (BIT) is of 0.031% which is below the SCL value of 360 ppm (RAC 49) but above the threshold for elicitation of 36 ppm.  In the same way, the content of C(M)IT/MIT is above the elicitation threshold of 1.5 ppm (= 0.00015%)  The product being already classified H317, the statement “Contains 1,2-benzisothiazol-3(2H)-one (BIT) and Reaction mass of: 5-chloro-2-methyl-2Hisothiazol-3-one and 2-methyl-2H-isothiazol-3-one (C(M)IT/MIT)” has to be added. |
| Classification of the product according to CLP | Skin sens. 1 – H317.  Contains 1,2-benzisothiazol-3(2H)-one (BIT) and Reaction mass of: 5-chloro-2-methyl-2Hisothiazol-3-one and 2-methyl-2H-isothiazol-3-one (C(M)IT/MIT). |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not respiratory sensitizing |
| Justification for the value/conclusion | The product TECHNIVERT contains 0.06% of ingredient classified as Resp. Sens. 1, H334, which is less than the threshold value of 1% to classify the product as Resp. Sens. 1, H334. |
| Classification of the product according to CLP | Not classified |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | No toxicity by oral route |
| Justification for the selected value | The product TECHNIVERT contains several ingredients classified for acute toxicity by orale route.  ATEmix, oral is greater than 2000 mg/kg b.w., no classification is required.  For details, please refer to confidential PAR. |
| Classification of the product according to CLP | Not classified |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | No toxicity by inhalation |
| Justification for the selected value | The product TECHNIVERT contains several ingredients classified for acute toxicity by inhalation.  ATEmix, inhalation is greater than 2000 mg/kg b.w., no classification is required.  For details, please refer to confidential PAR. |
| Classification of the product according to CLP | Not classified |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | No toxicity by dermal route |
| Justification for the selected value | The product TECHNIVERT contains several ingredients classified for acute toxicity by inhalation.  ATEmix, dermale is greater than 2000 mg/kg b.w., no classification is required.  For details, please refer to confidential PAR. |
| Classification of the product according to CLP | Not classified |

***Information on dermal absorption***

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Value(s)\* | 50% |
| Justification for the selected value(s) | According to the information provided by the applicant, the product TECHNIVERT contains > 70% water and can be considered as a water-based product.  Following the EFSA guidance 2017 on dermal absorption and considering an active substance content < 5%, the default dermal absorption value of 50% (water-based) is retained to perform the risk assessment. |

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

The product TECHNIVERT contains the active substance 2-methyl-2H-isothiazol-3-one (MIT) (CAS No. 2682-20-4) which content in the product is < 0.1%.

However, this substance contributes to the classification Skin Sens 1, H317 of the product.

It is therefore considered as a SoC.

According to the Guidance on BPR Part B+C, page 422/427, this substance is in Band B and a qualitative risk assessment must be done.

Some European Occupational Exposure Limits (OELs) exist for ingredients present in the product TECHNIVERT. However, taking into account the very low contents of these ingredients, no inhalatory toxicological concern expected and limited exposure of the professional during application step (outdoor application), it can reasonably be concluded that no inhalation exposure concern is expected.

In this context and following the document from CG-45 on “Harmonized approach to consider a co-formulant as a substance of concern (SoC) based on its workplace exposure limits”, they are not considered SoC.

For details please refer to the confidential PAR.

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

None

***Other***

One of the components of the product TECHNIVERT is classified as Carc. 2, H351.

The content is 0.94%, which is less than the threshold value of 1% to classify the product as Carc. 2, H351. Therefore, the product TECHNIVERT is not classified for carcinogenicity.

According to the RAC opinion (date 2020), acetamiprid is proposed to be classified also Repr. 2 H361d.

The content of the a.s of 0.2% being below the threshold value of 3% to classify the product as Repr.2, H361d, no classification is required.

#### 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** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | No | Yes | No | No | No | No |  |
| Dermal | No | Yes | No | No | No | No |  |
| Oral | No | No | No | 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. | Mixing and loading | **Primary exposure**  Loading of the RTU product into a receiving vessel | Professionals |
| 2. | Application | **Primary exposure**  Application of the product with a long nap roller or a brush | Professionals |
| 3. | Post-application | **Primary exposure**  Cleaning of the roller or the brush | Professionals |

***Industrial exposure***

Not applicable

***Professional exposure***

**Scenario [1]: Loading of the product into a receiving vessel**

| **Description of Scenario [1]** | | | |
| --- | --- | --- | --- |
| According to the information provided by the applicant, the product TECHNIVERT is supplied in bucket of 25 kg.  The product is intended to be applied by brushing to cover localised surfaces between foundations and masonry elements.  It is assumed that the professional applying the product will not carry the whole bucket to perform the task.  A loading phase is considered to transfer the product from the bucket to a more transportable receiving vessel.  Potential exposure is predominantly to the hands.  Inhalation exposure is considered negligible due to the low volatility of the a.s (< 1x10-6 Pa). No formation of aerosols is expected during the task.  To assess exposure during this task, the *Mixing and loading model 4* has been used as recommended in HEEG opinion 1.  Considering a density value of 1.024 for the product, a bucket of 25 kg is equivalent to 24L. In this context, the M&L model 4 is considered suitable since it is aimed for packaging of 10 and 20L.  The indicative exposure value from the model is as follows :   * 0.5 mL produit/loading (hands)   Two loading tasks are assumed per day. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 0.2% | Applicant’s data |
| Exposure value from the model | 0.5 mL/loading | M&L model 4 |
| Product density (g/cm3) | 1.024 | Applicant’s data |
| Number of event per day | 2 | RMS assomption |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEAd Hoc recommendation 14 |
| Dermal absorption | 50% | See above |
| **Tier 2** | Gloves penetration factor | 10% | HEEG Opinion 9 |

**Calculations for Scenario [1]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [1] | Tier 1/No PPE | negligible | 1.71 x 10-2 | - | 1.71 x 10-2 |
| Tier 2/ Gloves | negligible | 1.71 x 10-3 | - | 1.71 x 10-3 |

**Scenario [2]: Application of the product using a long nap roller or a brush**

| **Description of Scenario [2]** | | | |
| --- | --- | --- | --- |
| The product TECHNIVERT is a ready-to-use fluid to be used as a physico-chemical barrier for the protection of constructions against termites (PT18).  It is intended to be applied by brushing to cover localized surfaces between foundations and masonry elements. It forms a continuous and regular film on horizontal and vertical surfaces after drying.  The product is only intended to be applied by a roller or a brush on localised surfaces between foundations and masonry, and not on the entire surface of the ground foundation. It can also be used on singular areas (pipes, ducts…).  To assess exposure during this task, the *HEAd Hoc Recommendation 10* has been used.  The indicative exposure value from the model for water-based product is as follows :   * 4.07 μL/min (hands) ; * 1.7 μL/min (body) ; * 1.63 mg/m3 (inhalation).   As a worst-case approach, an exposure duration of 240 min is proposed. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 0.2% | Applicant’s data |
| Exposure value from the model | 4.07 μl/min (hands) ;  1.7 μl/min (body) ;  1.63 mg/m3 (inhalation) | HEAd Hoc Recommendation 10 |
| Product density | 1.024 | Applicant’s data |
| Exposure duration (min) | 240 | RMS assumption |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEAd Hoc recommendation 14 |
| Dermal absorption | 50% | See above |
| **Tier 2** | Gloves penetration factor | 10% | HEEG Opinion 9 |

**Calculations for Scenario [2]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| **Scenario [2]** | Tier 1/No PPE | 2.72 x 10-4 | 2.36 x 10-2 | - | 2.39 x 10-2 |
| Tier 2/Gloves | 2.72 x 10-4 | 8.63 x 10-3 | - | 8.90 x 10-3 |

**Combined scenarios**

| **Summary table: combined systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| **Scenarios [1+2]/Tier 1** | 2.72 x 10-4 | 4.07 x 10-2 | - | 4.1 x 10-2 |
| **Scenarios [1+2]/Tier 2** | 2.72 x 10-4 | 1.03 x 10-2 | - | 1.06 x 10-2 |

**Scenario [3]: Cleaning of the roller/brush**

According to the HEEG Opinion 11, for water-based paints, the brush will often be cleaned under a running tap; the running water washing both the paint from the brush and any contamination from the hands. In this context, exposure to the product water-based product TECHNIVERT during this task is considered negligible.

***Non-professional exposure***

The product is intended to be used by professional only.

***Exposure of the general public***

For the general public, as the product is applied on construction site prohibited to the public and on surfaces intended to be covered (between foundations and masonry elements), no exposure is expected.

***Monitoring data***

None

***Dietary exposure***

Regulation (EU) No 528/2012 specifies that biocidal products containing active substances that, as a result of their use, may lead to residues in food shall only be authorised if these residues do not have unacceptable effects on human health.

TECHNIVERT is a ready-to-use fluid coating to be used as a physical-chemical barrier for the protection of constructions against termites (PT18). The product shall not be used in areas where food/feed, food utensils or food processing surfaces may come into contact with or be contaminated by it. In addition, the product is not intended to be used inside the housings of food-producing animals.

Therefore, an investigation of residues in food does not appear to be justified.

Furthermore, considering the intended use, no risk mitigation measures are required.

*Information of non-biocidal use of the active substance*

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use1** | **Intended use** | **Reference value(s) 2** |
| 1. | Plant protection products | All plant and animal commodities | MRLs are set in Reg. (EU) 2019/88 |

1 e.g. plant protection products, veterinary use, food or feed additives

2 e.g. MRLs. Use footnotes for references.

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

Not relevant.

*Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)*

Not relevant.

*Estimating transfer of biocidal active substances into foods as a result of non-professional use*

Not relevant.

***Exposure associated with production, formulation and disposal of the biocidal product***

Not relevant

***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/d)** |
| 1. | Professionals | Tier 1/ no PPE | 1.71 x 10-2 |
| Tier 2/ Gloves | 1.71 x 10-3 |
| 2. | Professionals | Tier 1/ no PPE | 2.39 x 10-2 |
| Tier 2/ Gloves | 8.9 x 10-3 |

#### Risk characterisation for human health

Reference values to be used in Risk Characterisation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term | Oral developmental Toxicity | 2.5 mg/kg bw/d | 100 | 100 | 0.025 mg/kg bw/d |
| AELmedium-term |
| AELlong-term | Oral developmental Toxicity | 2.5 mg/kg bw/d | 100 | 100 | 0.025 mg/kg bw/d |
| ARfD | Oral developmental Toxicity | 2.5 mg/kg bw/d | 100 | - | 0.025 mg/kg bw/d |
| ADI | Oral developmental Toxicity | 2.5 mg/kg bw/d | 100 | - | 0.025 mg/kg bw/d |

**Maximum residue limits or equivalent**

Not relevant

**Specific reference value for groundwater**

Not relevant

***Risk for industrial users***

Not applicable

***Risk for professional users***

*Systemic effects*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** |
| **Scenario [1]** | 1/no PPE | 0.025 | 1.7 x 10-2 | 68.3 |
| 2/Gloves | 0.025 | 1.7 x 10-3 | 6.83 |
| **Scenario [2]** | 1/no PPE | 0.025 | 2.39 x 10-2 | 95.6 |
| 2/Gloves | 0.025 | 8.9 x 10-3 | 35.6 |

*Combined scenarios*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** |
| **Scenario [1+2]** | 1/no PPE | 0.025 | 4.10 x 10-2 | **164** |
| 2/Gloves | 0.025 | 1.06 x 10-2 | 42.4 |

*Local effects*

* Qualitative risk assessment (dermal exposure)

The Ready To Use product TECHNIVERT is classified for skin sensitizing properties (category 1, H317) due to the presence of the substance of concern MIT.

Please refer to the tables below for the PPE and RMMs required.

**Outcome of qualitative local risk assessment –** Handling of concentrated product classified H317 – Professional users

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **High** | **H317** | **18** | Mixing and loading + application using a roller or a brush | **Skin** | **Loading task:**  Frequency:  2/day  **Application**  Frequency:  Once a day  Duration :  240 min | **Loading and application**:  Direct dermal contact and potential splashes or spills during the manual loading task. | Use of appropriate personal protective equipment:  Hand protection: gloves  Facial protection[[3]](#footnote-4)  Body protection: Protective clothing | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency  (**↓**) Avoid splashes and spills during the loading phase |

**Conclusion**

Risks are considered acceptable for the use of TECHNIVERT for PT 18 application considering the following PPE and RMMs:

* Wear protective chemical resistant gloves and protective coverall during product’s handling and application phases (gloves and coverall material to be specified by the authorisation holder within the product information) ;
* Use facial protection during product’s handling and application phases;
* Avoid splashes and spills during the loading phase.

***Risk for non-professional users***

The product is intended to be used by professionals only.

***Risk for the general public***

No exposure is foreseen, therefore no risk assessment is performed.

***Risk for consumers via residues in food***

Not relevant.

See details in the paragraph above ”Dietary exposure”.

***Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product***

Not relevant

### Risk assessment for animal health

As the product is applied on construction site prohibited to the public and on surfaces intended to be covered (between foundations and masonry elements), no exposure of pets is expected.

### Risk assessment for the environment

The product TECHNIVERT is a ready-to-use fluid coating containing 0.2% w/w acetamiprid as technical active substance, intended to be used as a physico-chemical barrier for the protection of constructions against termites (PT18). According to the CAR of acetamiprid, it is considered that the risk assessment performed for the active substance also covers the risk for metabolites since it is assumed that the metabolites are less toxic that the parent compound. Two substances of concern, CMIT-MIT (0.00075%) and MIT (0.006%), were identified (cf. confidential PAR) and an assessment has been conducted for these two SoC in the STP compartment only as for the other compartments the active substance brings 99% of the product toxicity. In the C(M)IT/MIT (3:1) Assessment Reports (France, April/May/June 2015), it is stated that in an STP simulation test no C(M)IT was detected in the effluent phase or in the sludge. It was concluded that C(M)IT is totally degraded in the STP or after mechanical/chemical treatment and will not be released to the environment. Thus, it was concluded that only MIT needs to be considered for the environmental risk assessment when assessing the emission pathway via STP. Therefore, based on the mixture ratio of C(M)IT and MIT of 3:1, ¼ of the total C(M)IT/MIT (3:1) emission accounts to MIT.

#### Effects assessment on the environment

An overview of the PNECs for the active substance Acetamiprid and for MIT as a SoC for the STP is given in the table below:

|  |  |  |
| --- | --- | --- |
| **Compartment** | **PNEC (Acetamiprid)** | **Remarks** |
| STP microorganisms | 32 mg/L | CAR |
| Surface water | 2.00E-04 mg/L | CAR |
| Sediment (EPM) | 6.20E-04 mg/kg wwt | CAR |
| Soil (EPM) | 3.99E-04 mg/kg wwt | CAR |

|  |  |  |
| --- | --- | --- |
| **Compartment** | **PNEC (MIT)** | **Remarks** |
| STP microorganisms | 2.30E-01 mg/L | CAR MIT PT 11 |

***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***

|  |  |
| --- | --- |
| **Classification of the Active Substance Acetamiprid** | |
| Value/conclusion | Very toxic to aquatic life – H400 with M-factor= 10  Very toxic to aquatic life with long-lasting effects – H410 with M-factor = 10 |

|  |  |
| --- | --- |
| **Classification and labelling of the Product TECHNIVERT** | |
| Value/conclusion | **Aquatic Chronic Cat 3; H412**  None of the coformulants contributes to the product classification. |

***Further Ecotoxicological studies***

No new data is available.

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

No new data is available.

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

No new data is available.

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

No new data is available.

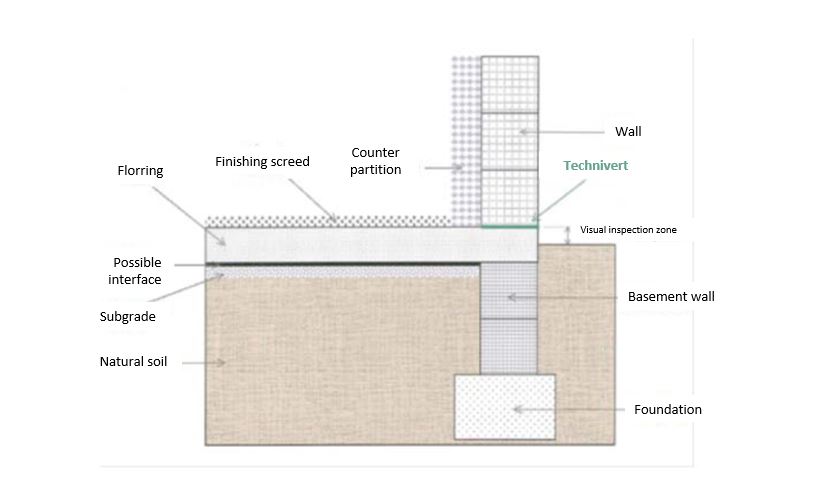
***Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)***

No new data is available.

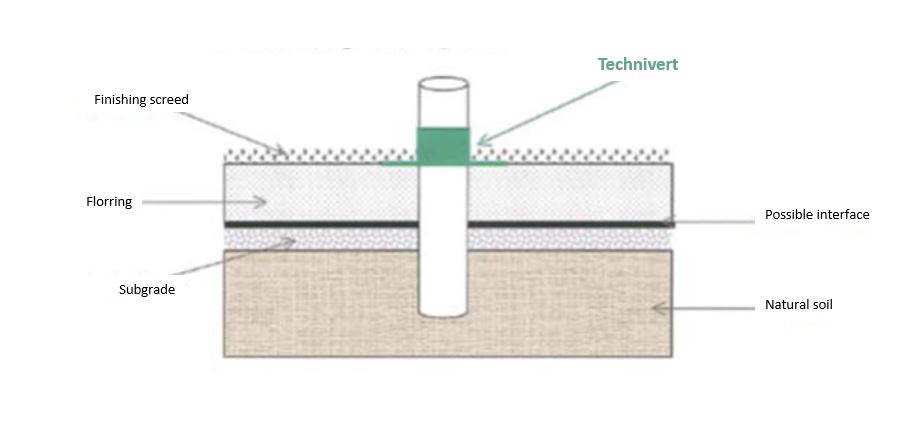
***Foreseeable routes of entry into the environment on the basis of the use envisaged***

The product is intended to be applied by brushing, to cover localized surfaces on masonry (figure 1) and singular areas like pipes and ducts (figure 2). It is always applied after the pouring of the slab, between foundations and masonry elements.

**Figure 1: Application of the product TECHNIVERT on localized surfaces on masonry**



**Figure 2: Application of the product TECHNIVERT one singular areas like pipes and ducts**



According to the intended uses, the environment might be exposed to the product **during the application** at the edge of the slab. Emission to STP or surface water **during the service-life** of the product is considered as not relevant*.* Indeed, this product is not used directly on soil but to cover localised surfaces between foundations and masonry elements (see figures above). The product is therefore always covered by masonry elements and is completely contained once the construction process is complete.

Therefore, the foreseeable routes of entry into the environment **during the application** of the biocidal product are:

- In urban area, the aquatic compartment (including sediment) after releases to the sewage treatment plant and the terrestrial compartment via spreading of the STP sludge onto soil.

- In rural area, the terrestrial compartment via direct emissions to bare soil.

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

No new data is available.

***Leaching behaviour (ADS)***

No new data is available.

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

No new data is available.

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

No new data is available.

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

No new 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)***

The biocidal product is a fluid coating intended to be used as a physico-chemical barrier for the protection of constructions, applied by brushing between foundations and masonry elements. The product is not intended to be sprayed near to surface waters. Therefore a risk assessment for spray application is not relevant.

***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)***

The biocidal product is a fluid coating intended to be used as a physico-chemical barrier for the protection of constructions, applied by brushing between foundations and masonry elements. Therefore a risk assessment for spray application is not relevant.

#### Exposure assessment

General information

|  |  |
| --- | --- |
| Assessed PT | PT18 |
| Assessed scenarios | Scenario 1: Application phase in urban area – direct releases to STP  Scenario 2: Application phase in rural area – direct releases to soil |
| ESD(s) used | Specific scenario adapted from Emission Scenario Document for Product Type 18: Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses, July 2008 |
| Approach | Consumption based approach |
| Distribution in the environment | Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C)  Simple Treat 4.0 |
| Groundwater simulation | No |
| Confidential Annexes | Yes |
| Life cycle steps assessed | Scenario 1 and 2:  Production: No  Formulation No  Use: Yes  Service life: No |
| Remarks | No |

***Emission estimation***

The product is applied by professional users by brushing to cover localised surfaces on masonry and singular areas (pipes, ducts…). It is always applied after the pouring of the slab, between foundations and masonry elements. The application rate is 400 g to 500 g product/m². It is considered as a conservative assumption that 100% of the product is released to the STP or to the soil through run-off at the edge of the slab considering a house dimension of 17.5 x 7.5 m and a band of treatment around the building of 50 cm leading to an edge surface of 24 m2 ((17.5 x 7.5) – ((17.5 - (2 x 0.5)) x (7.5 - (2 x 0.5)))).

There is only one application phase of the product at the construction of the building. As the product is always covered by masonry elements and is completely contained once the construction process is complete, **the service-life phase is considered not relevant**.

**Scenario [1]: Application phase in urban area – direct releases to STP and [2] Application phase in rural area – direct releases to soil**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission during application** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Application rate of the product | 0.5 | kg/m² | The application rate is 400 to 500 g/m². 500 g/m² is used as a worst case in the assessment. |
| Fraction of active substance | 2.00E-3 | - | Technical value |
| Fraction of MIT as SoC | 6.19E-05 | - | Calculated adding 0.006% of MIT and 1:4 of 0.00075% of CMIT-MIT (cf CAR of CMIT-MIT).  Only relevant for the STP compartment. |
| Leaching surface area considered | 24 | m2 | Considering 50 m house perimeter and 50 cm foundation stripe width (ESD PT8) |
| Number of treated house per day (Nhouse) | 1 | d-1 | Best case for the urban area |

Calculations for Scenario [*1&2*]

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP- Urban scenario (Scenario 1) | Acetamiprid : 2.40E-02  MIT: 7.43E-04 | MIT is relevant only for the STP compartment (cf Toxic unit calculation in confidential PAR)  ElocalSTP = Qapplic, prod \* fai \* AREA \*Nhouse |
| Soil– Rural scenario (Scenario 2) | Acetamiprid : 2.40E-02 | Elocalsoil = Qapplic, prod \* fai \* AREA |

***Fate and distribution in exposed environmental compartments***

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Freshwater | Sediment | STP | Air | Soil | Groundwater |
| Scenario 1- Urban (STP) | Yes | Yes | Yes | NR | Yes | Yes |
| Scenario 2- Rural (Soil) | No | No | No | NR | Yes | Yes |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **Acetamiprid** | | | |
| Molecular weight | 222.68 | g/mol | CAR |
| Vapour pressure (at 25°C) | 1E-06 | Pa | CAR |
| Water solubility (at 25°C) | 2950 | mg/l | CAR |
| Log Octanol/water partition coefficient | 0.8 | Log 10 | CAR |
| Organic carbon/water partition coefficient (Koc) | 106.35 | l/kg | CAR |
| Henry’s Law Constant (at 20°C) | 5.3E-08 | Pa/m3/mol | CAR |
| Biodegradability | Not biodegradable |  | CAR |
| Rate constant for STP | 0 | h-1 | CAR |
| DT50 for degradation in soil | 3.25 | d (at 12ºC) | CAR |
| **MIT (SoC)** | | | |
| Molecular weight | 115.15 | g/mol | CAR MIT PT11 |
| Vapour pressure (at 20°C) | 0.64 | Pa | CAR MIT PT11 |
| Water solubility (at 20°C) | 1.00E+06 | mg/l | CAR MIT PT11 |
| Log Octanol/water partition coefficient | -0.32 | Log 10 | CAR MIT PT11 |
| Organic carbon/water partition coefficient (Koc) | 7.5 | l/kg | CAR MIT PT11 |
| Biodegradability | Not biodegradable |  | CAR MIT PT11 |
| Rate constant for STP | 0 | h-1 | CAR MIT PT11 |
| DT50 for degradation in STP | 0.04 | d (at 20ºC) | CAR MIT PT11 |
| DT50 for degradation in soil | 0.51 | d (at 12ºC) | CAR MIT PT11 |

|  |  |  |
| --- | --- | --- |
| **Calculated fate and distribution in the STP (Simple Treat 4.0)** | | |
| Compartment | Percentage [%] | Percentage [%] |
|  | **Acetamiprid** | **MIT (SoC)** |
| Air | 0.00 | 0.00 |
| Water | 98.64 | 16.7 |
| Sludge | 1.36 | 0.07 |
| Degraded in STP | 0.00 | 87.8 |

***Calculated PEC values***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | |
|  | **PECSTP** | | **PECwater** | **PECsed** | **PECsoil** | **PECGW** |
| [mg/l] | | [mg/l] | [mg/kgwwt] | [mg/m3] | [μg/l] |
| Scenario 1- Urban (via the STP) | Acetamiprid: 1.18E-02 | MIT: 6.20E-05 | 1.18E-03 | 3.66E-03 | 9.38E-05 (1) | 7.85E-03 |
| Scenario 2- Rural (direct to Soil) | NR | | NR | NR | 1.09E+00 (2)(3) | **5.45E+02** |
| 1. PEC twa 2. PEC initial 3. For volume of soil of 13 m3 (ESD PT18) | | | | | | |

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning*, i.e.* the direct consumption of the product by birds or mammals is not considered as relevant for the product. Primary poisoning may mainly occur when a product is applied together with food attractant or is applied as granular formulation. The product is a fluid coating to be used as a barrier for the protection of constructions, applied between foundations and masonry elements. The product is then not reachable for non-target organisms such as bees, birds and mammals. Therefore, no risk is foreseen for primary poisoning when using the product TECHNIVERT.

Secondary poisoning

Due to the intended use and the formulation of the product, the physico-chemical properties and the very low BCF value for the active substance (BCFfish=-2.656 L/kgwet fish and BCFearthworms=0.8496 L/kgwet worms) and the substance of concern MIT (BCFfish=0.107 L/kgwet fish and BCFearthworms= 0.48 L/kgwet worms as well as the Log Kow (=0.8 for Acetamiprid and -0.32 for MIT) indicate that acetamiprid and MIT has a very low potential of bioaccumulation. Therefore, no risk is foreseen for secondary poisoning when using the product TECHNIVERT.

#### Risk characterisation

***Atmosphere***

Volatilization of Acetamiprid is considered to be negligible based on its vapour pressure (1.00E-06 Pa at 20°C) and Henry constant (5.30E-08 Pa.m3.mole-1 at 20°C) values. Acetamiprid would not be transported over large distances in the atmosphere in gaseous phase.

Conclusion: Emissions and PECs in air are considered as negligible. It can be concluded that the use of the product TECHNIVERT will not pose a significant risk to the atmospheric compartment.

***Sewage treatment plant (STP)***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
|  | **PEC/PNECSTP** | |
| Scenario 1 – Urban (STP) | Acetamiprid: 3.70E-04 | MIT: 2.70E-04 |
| Scenario 2 – Rural (Soil) | NR | |

Conclusion: PEC/PNEC for the STP compartment are <1. The risks are therefore acceptable.

***Aquatic compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** |
| Scenario 1 – Urban (STP) | **5.92** | **5.91** |
| Scenario 2 – Rural (Soil) | NR | NR |

Conclusion: The PEC/PNEC ratio for the freshwater and sediment are above the trigger value of 1, indicating a risk for the freshwater and sediment organisms during the application step of the product when releases are directed to STP (urban area). Therefore, risk mitigation measures are necessary to prevent releases toward surface water and sediment through STP during the application step of the TECHNIVERT product.

***Terrestrial compartment***

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values** | |
|  | **PEC/PNECsoil** |
| Scenario 1 – Urban (STP) | 2.35E-01 |
| Scenario 2 – Rural (Soil) | **2.72E+03** |

Conclusion: The PEC/PNEC ratio for terrestrial compartment are <1 in urban area, but are above the trigger value of 1 in rural area, indicating a risk for the terrestrial organisms during the application step of the product when releases are directed to adjacent bare soil. Therefore, risk mitigation measures are necessary to prevent releases to adjacent soil during the application step of the TECHNIVERT product.

***Groundwater***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values for the groundwater** | | |
|  | Triggered value [µg/l] | PEC groundwater [µg/l] |
| Scenario 1 – Urban (STP) | 0.1 | 7.85E-03 |
| Scenario 2 – Rural (Soil) | **5.45E+02** |

Conclusion: For the scenario 1 (urban area), the trigger value of 0.1 µg.L-1 is not exceeded.

For the scenario 2 (rural area), the calculated value for PEClocalGW of 545 µg.L-1 exceeds the limit value in groundwater of 0.1 μg.L-1 for biocides (Directives 2006/118/EC and 98/83/EC). Therefore, risk mitigation measures are necessary to prevent releases to adjacent soil during the application step of the TECHNIVERT product.

***Primary and secondary poisoning***

Due to the intended use and the formulation of the product, the physico-chemical properties and the very low BCF value for the active substance, it is assumed that no primary or secondary poisoning may occur. The risk is therefore not assessed.

***Mixture toxicity***

A mixture toxicity assessment was performed taking into account the simultaneous presence of active substance (Acetamiprid) and the two environmentally relevant substances of concern for the STP compartment.

|  |  |  |
| --- | --- | --- |
| Summary table on calculated ∑PEC/PNEC value | | |
| STP Emission | PEC/PNECSTP |
| **Scenario 1 –** Urban (STP) | 6.39E-04 |

Conclusion: PEC/PNEC summation are <1 for the STP compartment. The risks are therefore acceptable.

***Aggregated exposure (combined for relevant emission sources)***

The use of the product TECHNIVERT is very localised and specific. It is not a wide dispersive use. In this dossier, there is only one product for this specific use. The aggregated exposure is therefore not relevant.



*Figure 1: Decision tree on the need for estimation of aggregated exposure*

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The environmental risk assessment of the product TECHNIVERT is based on the active substance and two environmentally relevant substances of concern, CMIT/MIT and MIT.  The product TECHNIVERT poses a risk to the aquatic and terrestrial compartment during the application of the product.  Indeed, following indirect releases to the environment via the STP (urban area), RCR values are > 1 for surface water and sediment, indicating unacceptable risk for these environmental compartments. Following direct releases to the environment (rural area), calculated RCR values were > 1 for the exposure of soil. Thus, the risk for this environmental compartment is unacceptable.  As the product is always covered by masonry elements and is completely contained once the construction process is complete, the service-life phase was considered not relevant.  Overall conclusion on the risk assessment for the environment of the product is summarized in the table below:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Summary table for the risk assessment of the product TECHNIVERT | | | | | | |  | PEC/PNECSTP | PEC/PNECwater | PEC/PNECsed | PEC/PNECsoil | PEC/PNECGW | | **Scenario 1** –Urban(STP) | Acceptable | **Not acceptable** | **Not acceptable** | Acceptable | Acceptable | | **Scenario 2** –Rural (Soil) | NR | NR | NR | **Not acceptable** | **Not acceptable** |   Then, the following risk mitigation measures are proposed to prevent the exposure of the soil and STP during the application step:   * Apply the product only on surfaces that will be completely contained once the construction process is complete. * Once treated surfaces are dried, they must be totally protected as long as they are not covered by masonry or protected from rain (ducts, pipes...). * Due to the high toxicity of acetamiprid to water living and soil organisms, prevent any releases to soil, sewer or water. Any losses of the product, including contaminated water/soil must be collected for disposal in accordance with local/national/international requirements * The area where the product is handled for preparation or application must be done on hard surfaces not connected to a sewer system. * Do not apply the product in case rain is expected within 24 hours.   The application of this risk mitigation measure and instruction of use preventing emissions to the environment would achieve acceptable risks. |

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

Not relevant

### Assessment of a combination of biocidal products

Not relevant

### Comparative assessment

**Overall conclusion**

In the technical guidance note on comparative assessment of biocidal products, it is stated that :

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

Considering that only two different and independent “active substance/mode of action” combinations have been identified as potential alternatives for TECHNIVERT, FR CA concludes that there is currently no products with significantly lower overall risks for human health, animal health or the environment.

Since TECHNIVERT does not meet the exclusion criteria as outlined in Article 5(1), no further assessment is needed at this point.

**The authorization for the product TECHNIVERT can be granted in accordance with the BPR 528/2012.**

# Annexes[[4]](#footnote-5)

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| Halbwachs P.  S3.1.1, S3.2.1, S3.4.1.1 | 2020 | Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54 ± 2°C on TECHNIVERT  Reference: 19-919073-003 | Yes | SAPA SAS |
| Halbwachs P.  S3.1.2, S3.3, S3.4.1.3, S3.8, S3.9, S4.16 | 2020 | Physico-chemical tests on TECHNIVERT  Reference: 19-919073-002 | Yes | SAPA SAS |
| Halbwachs P.  S3.4.1.2 | 2019 | Study plan: Physico-chemical tests and chemical stability during and after a storage procedure for 24 months at 20 ± 2°C on TECHNIVERT  Reference: 19-919073-004 | Yes | SAPA SAS |
| Halbwachs P.  S3.4.1.2 | 2022 | Final report: Physico-chemical tests and chemical stability during and after a storage procedure for 24 months at 20 ± 2°C on TECHNIVERT  Reference: 19-919073-004 | Yes | SAPA SAS |
| Demangel B.  S4.6, S4.8, S4.17 | 2021 | Physico-chemical tests on TECHNIVERT  Reference: 21-919073-001 | Yes | SAPA SAS |
| Raphalen E.  S5 | 2013 | Validation of analytical method according to SANCO 3030/99 rev. 4 and chemical analysis of active substance declared in the test item LIGNOSAN 2 CSXX  Reference: 402/12/1113F/de-e | Yes | Kwizda France SAS |
| Ricau H.  S5 | 2020 | Validation of the analytical method for the determination of acetamiprid in TECHNIVERT  Reference: 19-919073-005 | Yes | SAPA SAS |

## Output tables from exposure assessment tools

**Human Health Exposure**

****

## New information on the active substance

Not relevant

## Residue behaviour

## Summaries of the efficacy studies (B.5.10.1-xx)[[5]](#footnote-6)

## Confidential annex

Please refer to the confidential annex

## Other

1. The document is available in CIRCABC at <https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3>. [↑](#footnote-ref-2)
2. The document is available in CIRCABC at <https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3>. [↑](#footnote-ref-3)
3. The skin sensitizer classification (Skin Sens 1 - H317) is based on the presence of isothiazolinones known to be extreme sensitizers. Therefore, PPE recommended for product classified Skin Sens 1A – H317 is applied. [↑](#footnote-ref-4)
4. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-5)
5. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-6)