FAO SPECIFICATIONS AND EVALUATIONS
FOR AGRICULTURAL PESTICIDES

# CLOTHIANIDIN

(*E*)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine


FOOD AND AGRICULTURE ORGANIZATION of THE UNITED NATIONS

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# CLOTHIANIDIN

## DISCLAIMER[1]

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Compliance with the specifications does not constitute an endorsement or warranty of the fitness of a particular pesticide for a particular purpose, including its suitability for the control of any given pest, or its suitability for use in a particular area. Owing to the complexity of the problems involved, the suitability of pesticides for a particular purpose and the content of the labelling instructions must be decided at the national or provincial level.

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[1] This disclaimer applies to all specifications published by FAO.

## INTRODUCTION

FAO establishes and publishes specifications* for technical material and related formulations of agricultural pesticides, with the objective that these specifications may be used to provide an international point of reference against which products can be judged either for regulatory purposes or in commercial dealings.

From 2002, the development of FAO specifications follows the **New Procedure**, described in the 1st edition of the "Manual on Development and Use of FAO and WHO Specifications for Pesticides" (2002) - currently available as 3rd revision of the 1st edition (2016) - , which is available only on the internet through the FAO and WHO web sites.

This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by FAO and the Experts of the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS). [Note: prior to 2002, the Experts were of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent, which now forms part of the JMPM, rather than the JMPS.]

FAO Specifications now only apply to products for which the technical materials have been evaluated. Consequently from the year 2000 onwards the publication of FAO specifications under the **New Procedure** has changed. Every specification consists now of two parts namely the specifications and the evaluation report(s):

**Part One**: **The Specification** of the technical material and the related formulations of the pesticide in accordance with chapters 4 to 9 of the "Manual on development and use of FAO and WHO specifications for pesticides".

**Part Two**: The Evaluation Report(s) of the pesticide, reflecting the evaluation of the data package carried out by FAO and the JMPS. The data are provided by the manufacturer(s) according to the requirements of chapter 3 of the "FAO/WHO Manual on Pesticide Specifications" and supported by other information sources. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical material has been evaluated. Evaluation reports on specifications developed subsequently to the original set of specifications are added in a chronological order to this report.

FAO specifications developed under the **New Procedure** do not necessarily apply to nominally similar products of other manufacturer(s), nor to those where the active ingredient is produced by other routes of manufacture. FAO has the possibility to extend the scope of the specifications to similar products but only when the JMPS has been satisfied that the additional products are equivalent to that which formed the basis of the reference specification.

**Specifications bear the date (month and year) of publication of the current version. Evaluations bear the date (year) of the meeting at which the recommendations were made by the JMPS.**

* NOTE: PUBLICATIONS ARE AVAILABLE ON THE INTERNET AT (http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmps/ps-new/en/) OR IN HARDCOPY FROM THE PLANT PROTECTION INFORMATION OFFICER.

# PART ONE

# SPECIFICATIONS

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## CLOTHIANIDIN

INFORMATION

*ISO common name*

Clothianidin (ISO 1750, published)

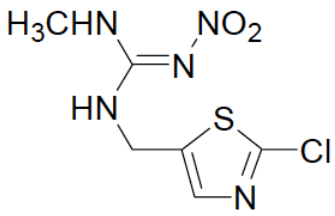
*Chemical name*

IUPAC (*E*)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine

CA [*C*(*E*)]-*N*-[(2-chloro-5-thiazolyl)methyl]-*N'*-methyl-N''-nitroguanidine

*Synonym* TI-435

*Structural formula*




*Molecular formula*

$C_6H_8ClN_5O_2S$

*Relative molecular mass*

249.7 g/mol

*CAS Registry number*

210880-92-5

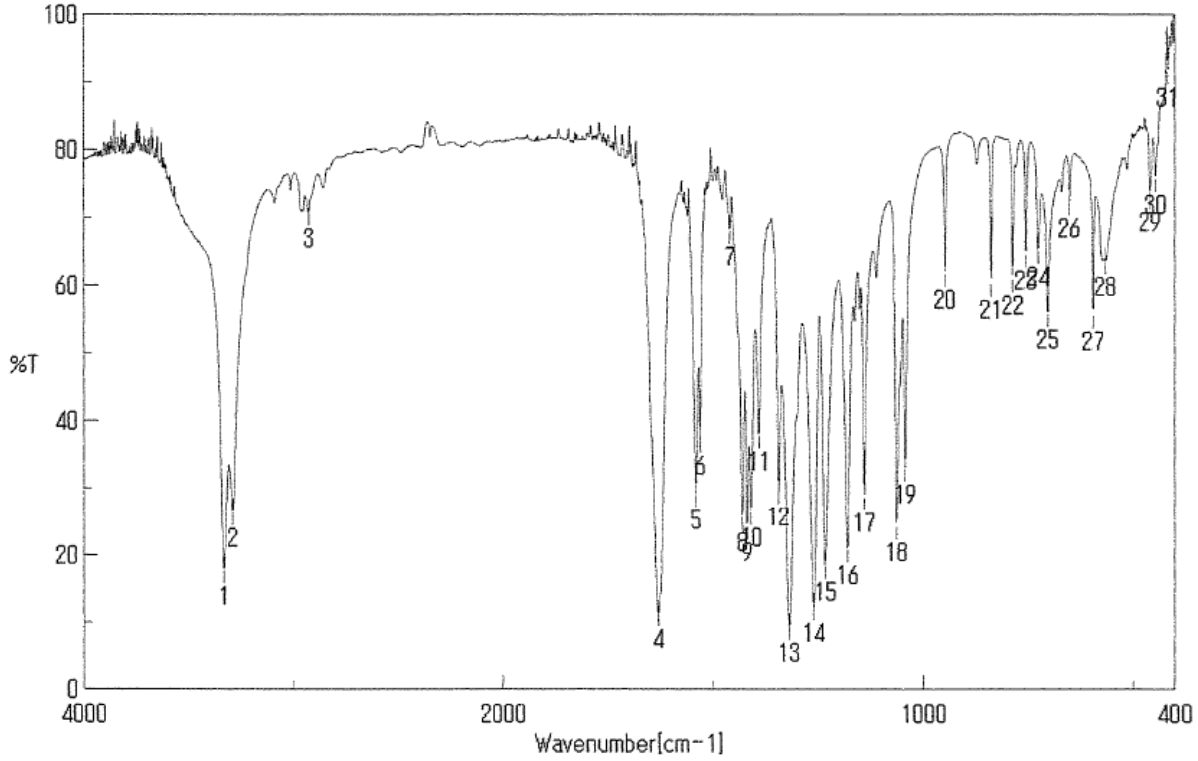
*CIPAC number*

738

*Identity tests*

Retention time in reversed phase HPLC, IR spectrum

Figure 1. IR spectrum of clothianidin



# CLOTHIANIDIN TECHNICAL MATERIAL

FAO Specification 738 / TC (October 2016*)

*This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (738/2015). It should be applicable to TC produced by this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for TC produced by other manufacturers. The evaluation report (738/2015) as PART TWO, forms an integral part of this publication.*

## 1 Description

The material shall consist of clothianidin together with related manufacturing impurities, and shall be white to pale yellow crystalline powder free from visible extraneous matter and added modifying agents.

## 2 Active ingredient

2.1 **Identity tests** (738/TC/M/2, CIPAC Handbook N, p. 15, 2012)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 **Clothianidin content** (738/TC/M/3, CIPAC Handbook N, p. 15, 2012)

The Clothianidin content shall be declared (not less than 975 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

## 3 Relevant impurities

3.1 By-products of manufacture or storage (Note 1)

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Note 1 There are no relevant impurities to be controlled in the TC of the manufacturer identified in the evaluation report 738/2015. However a compound (TI-triazan, IUPAC name: (*Z*)-5-benzyl-1-methyl-*N*-nitro-1,3,5-triazinan-2-imine, CAS Nr. 141856-57-7) may occur as a result of certain manufacturing processes. If this impurity could occur at > 3 g/kg (of clothianidin) in the products of other manufacturers, it would be designated as a relevant impurity and a clause would be required to limit its concentration.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/en/

# CLOTHIANIDIN SUSPENSION CONCENTRATE FOR SEED TREATMENT

FAO Specification 738 / FS (October 2016*)

*This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (738/2015). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated source. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation report (738/2015) as PART TWO, forms an integral part of this publication*

## 1 **Description**

The material shall consist of a suspension of fine particles of technical clothianidin, complying with the requirements of FAO specification 738/TC (October 2016), in an aqueous phase together with suitable formulants, including colouring matter (Note 1). After gentle stirring or shaking, the material shall be homogeneous (Note 2) and suitable for further dilution with water if necessary.

## 2 **Active ingredient**

### 2.1 **Identity tests** (738/FS/M/2 CIPAC Handbook N, p. 20, 2012)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

### 2.2 **Clothianidin content** (738/FS/M/3 CIPAC Handbook N, p. 21, 2012)

The clothianidin content shall be declared (g/kg or g/l at 20 ± 2ºC, Note 3) and, when determined, the average content measured shall not differ from that declared by more than the appropriate tolerances.

| Declared content in g/kg or g/L at 20 ± 2°C | Tolerance |
|---|---|
| above 100 up to 250<br>above 250 up to 500<br>above 500 | ± 6% or of the declared content<br>± 5% or of the declared content<br>± 25 g/kg or g/L of the declared content |
| Note: the upper limit is included in the range | |

## 3 **Relevant impurities**

### 3.1 By-products of manufacture or storage (Note 4)

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/en/

## 4 **Physical properties**

4.1 **Pourability** (MT 148.1, CIPAC Handbook J, p. 133, 2000)

Maximum "residue": 4 %.

4.2 **Wet sieve test** (MT 185, CIPAC Handbook K, p.149, 2003) (Note 5)

Maximum: 0.5 % retained on a 75 µm test sieve.

4.3 **Persistent foam** (MT 47.3) (Notes 6 & 7)

If the product is intended to be used after dilution, persistent foam is to be measured at a concentration of 30% w/v in water. In those conditions, the maximum is 60 mL after 1 min. This clause is not applicable where the product is used without dilution.

4.4 **Suspensibility** (MT 184, CIPAC Handbook K, p.142, 2003) (Notes 8 & 9)

If the product is intended to be used after dilution, suspensibility is to be measured at the highest and lowest concentration provided they are within the scope of the method. In those conditions, a minimum of 85 % of the clothianidin content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C. This clause is not applicable where the product is used without dilution.

4.5 **Adhesion to seeds** (MT 194, CIPAC Handbook N, p.145, 2012)

| | |
|---|---|
| Wheat: | Min.: 90% |
| Sugar beet: | Min.: 98% |
| Rape seed: | Min.: 95% |
| Maize: | Min.: 90% |

## 5 **Storage stability**

5.1 **Stability at 0°C** (MT 39.3, CIPAC Handbook J, p.126, 2000)

After storage at 0 ± 2°C for 7 days, the formulation shall continue to comply with the clause for:

- wet sieve test (4.2).

5.2 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p.128, 2000)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 95 % relative to the determined average content found before storage (Note 10) and the formulation shall continue to comply with the clauses for:
- pourability (4.1),
- wet sieve test (4.2),
- suspensibility (4.4)

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Note 1 The influence of treatment on germination is of major importance but it is not the subject of a specification clause because no test method is applicable to all types of seeds. To avoid adverse effects, users should apply the formulation strictly according to the recommendations of the manufacturer and should not treat seeds for which effect on germination is not known. Treated seeds

should be stored in a suitable container and should be protected from excessive temperature and moisture.

The formulation shall contain a dye or pigment that permanently colours the seed after treatment (red is recommended, but other colours are possible). In some countries, there may be a legal requirement that a specific colour shall be used. The same colour must not be used for denaturing seeds intended for use as livestock feeding stuffs.

Note 2 Before sampling to verify the formulation quality, inspect the commercial container carefully. On standing, suspension concentrates usually develop a concentration gradient from the top to the bottom of the container. This may even result in the appearance of a clear liquid on the top and/or sediment on the bottom. Therefore, before sampling, homogenize the formulation according to the instructions given by the manufacturer or, in the absence of such instructions, gently shake the commercial container (for example by inverting the closed container several times, large containers must be opened and stirred adequately). After this procedure, the container should not contain a sticky layer of non-dispersed matter at the bottom. A suitable and simple method of checking for a non-dispersed sticky layer ("cake") is by probing with a glass rod or similar device adapted to the size and shape of the container. All the physical and chemical tests must be carried out on a laboratory sample taken after the recommended homogenization procedure.

Note 3 Unless homogenization is carried out carefully, it is possible for the sample to become aerated. This can lead to errors in the determination of the mass per millilitre, and in calculation of the active ingredient content (in g/l) if methods other than MT 3.3 are used. If the buyer requires both g/kg and g/l at 20°C, then in case of dispute the analytical results shall be calculated as g/kg.

Note 4 There are no relevant impurities to be controlled in the TC of the manufacturer identified in the evaluation report 738/2015. However a compound (TI-triazan, IUPAC name: (*Z*)-5-benzyl-1-methyl-*N*-nitro-1,3,5-triazinan-2-imine, CAS Nr. 141856-57-7) may occur as a result of certain manufacturing processes. If this impurity could occur at > 3 g/kg (of clothianidin) in the products of other manufacturers, it would be designated as a relevant impurity and a clause would be required to limit its concentration.

Note 5 This test should detect coarse particles (e.g. caused by crystal growth) or extraneous materials which could cause blockage of spray nozzles or filters of the application equipment.

Note 6 The mass of sample to be used in the test should correspond to the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

Note 7 MT 47.3 is a revised version of MT 47.2 using a standard measuring cylinder. This new method was accepted as a full CIPAC method in 2013. Prior to publication of the method in a Handbook, copies of the method may be obtained through the CIPAC website, http://www.cipac.org/index.php/methods-publications/pre-published-methods

Note 8 Suspensions are to be tested at the highest and lowest recommended rates of use, provided that they are within the scope of MT 184. Whereas the test defines a lower limit of 0.2 %, the upper limit is only implicitely defined by the remaining 1/10 of 250 ml. The mass of sample used must therefore result in a sedimentation volume that is below 25 ml. This is usually the case with formulations that are diluted in the low % range. However, FS formulations - if diluted before use - have such high use concentrations that they are not in line with the implicit upper limit of MT 184 and the suspensibility should not be tested.

Note 9 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of the chemical assay method. In case of dispute, the chemical method shall be the referee method.

Note 10 Samples of the formulation taken before and after the storage stability test may be analyzed concurrently after the test in order to reduce the analytical error.

# PART TWO

# EVALUATION REPORTS

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## CLOTHIANIDIN

# CLOTHIANIDIN

FAO/WHO EVALUATION REPORT 738/2015

## Recommendation

The Meeting recommended that the specifications for clothianidin TC and FS proposed by Bayer CropScience, as amended, should be adopted by FAO.

## Appraisal

The Meeting considered data on clothianidin submitted by Bayer CropScience (BCS) in support of FAO specifications for the technical material and a FS formulation.

The insecticide clothianidin was developed by Takeda Chemical Industries in Japan in the 1990. This also explains the code number allocated to that compound - TI-435 - , with "TI" standing for Takeda Industries. Takeda was later incorporated into Sumitomo, and clothianidin was further developed jointly by Sumitomo Chemical Company (SCC) and Bayer CropScience (BCS). Therefore, some of the nonpublished studies referenced in the hazard summary are owned by Sumitomo, some by Bayer. This may explain the unusual situation, that two reference specifications for the same compound were developed and published - the first one for Sumitomo in 2009, and the second for Bayer in 2015 due to the fact that two slightly different specifications each with supporting data were evaluated and adopted by FAO and WHO (see below).

Clothianidin is a neonicotinoid insecticide that controls insects by acting as an agonist at the nicotinic acetylcholine receptor, affecting the synapses in the insect central nervous system. Clothianidin is not under patent.

Clothianidin was evaluated by the FAO/WHO JMPR in 2010 [JMPR, 2010] and JMPR agreed to re-evaluate the clothianidin residue definition in 2011.

It was evaluated by US EPA, the results were published in the US Federal Register [EPA, 2011]. Clothianidin was evaluated by the European Commission as part of the EU review of existing active substances for inclusion in Annex I of the Council directive 91/414/EEC in 2006. It was included in Annex I with a minimum purity of 960 g/kg [CR, 2011].

The data for clothianidin were evaluated in support of FAO specifications based on the draft specifications and the supporting data provided by Bayer CropScience in 2008 and a revised submission was received in November 2011 and April 2015. The FAO specifications for clothianidin were first published in 2011 and last modified in 2015 for TC, SC, GR, SG, FS and WG based on submission of data by Sumitomo Chemical Co., Ltd. [FAO, 2015].

The supporting data on clothianidin TC, WS and FS formulations were in accordance with the requirements of the second revision of the first edition of the Manual on development and use of FAO and WHO specifications for pesticides [FAO/WHO Manual] and supported the proposed specifications. In the updated submission BCS no longer supported the WS specification [Bascou, 2012].

A statement was provided by the German pesticides regulatory authority confirming that the confidential data on the manufacturing process and declaration of composition submitted to the FAO were the same as those submitted to the national regulatory authority [Hänel, 2015].

Clothianidin is a white to cream coloured crystalline powder. It is not volatile and has a melting point of 176.8 °C. It is slightly soluble in water at 0.33 g/l at 20°C. It is not fat soluble and is not likely to bioaccumulate with a log $P_{ow}$ of circa 0.9. It is considered to be stable to hydrolysis at all environmentally relevant pHs. It undergoes rapid photolysis with a half lifehalf-life of 3.3 hours at pH 7 at 25°C. Clothianidin is a strong base with a $pK_a$ of 11.

The Meeting was provided with commercially confidential information on the manufacturing process and batch analysis data on all impurities present below or above 1 g/kg and their manufacturing limits in the TC. Mass balances were 99.57-100.24% in the 5-batch data.

At the 2009 JMPS Meeting it was discussed whether or not there are two reference sources of clothianidin or if Sumitomo is the reference source and Bayer should be considered equivalent on the basis of the additional toxicological data on their impurities. As Sumitomo and BCS utilize different manufacturing processes leading to different minimum content of the active ingredient, and, more importantly, the two TC have entirely different impurity profiles, the Meeting considered that two separate specifications should therefore be developed for the TC produced by Sumitomo and BCS. The minimum content of the TC produced by BCS is 975 g/kg, however based on the submitted data an even higher minimal purity could have been specified.

In the submission Bayer CropScience proposed that there are no impurities of toxicological relevance. The impurity TI-435-triazan was reported to be sensitizing [M-020895-01-1] and according to the criteria defined in the FAO/WHO Manual, (Determination of the relevance or non-relevance of impurities and Appendix J) it would be relevant. The 2009 JMPS meeting considered that the impurities, with the exception of TI-435-triazan are not relevant. To decide on the relevance of this impurity a study using OECD 406 (Directive 92/69/EC, Method B.6) on the Bayer technical material was requested. The Meeting noted that BCS had tested the impurity only, however a test is needed on the TC with a representative content of the impurity. In order to demonstrate the non-relevance of the impurity TI-435-triazan contained in the clothianidin batches at the specified maximum concentration of 0.3%, BCS conducted a skin sensitization study, that has proved that under the conditions of the maximization test, clothianidin TC is not a sensitizer [M-424556-01-2]. As a consequence there is no need to consider TI-435-triazan as a relevant impurity. Nevertheless this impurity may be potentially relevant in other products where the concentration would be higher. The Meeting agreed to add a footnote in the specification to reflect that and a method should be available for the determination of the impurity. The HPLC method for the determination of the impurity was submitted in May 2015 [AM025915MP1].

The recent submission of April 2015 contained one new impurity in comparison to the data submitted in 2011. Additional data were requested about the relevance of this impurity.

BCS confirmed that the new impurity identified was present in BCS clothianidin TC in batches used in nontoxicity studies, in batches used in genotoxicity studies as well as in skin sensitization study. It has been identified only recently due to the improvement of the

analytical method. Quantification of this formerly unspecified impurity with reference standard resulted in its specification as significant impurity.

The extension of the scope of the HPLC method for the determination of clothianidin in TC and FS formulations was accepted as a full CIPAC method in 2011. [CIPAC Handbook N].

The proposed specifications for TC and FS were essentially in accordance with the requirements of the FAO/WHO Manual. If the FS formulation is to be used diluted, the clause for persistent foam is given on the basis of a 30% w/v concentration which may be the used concentration and it was already agreed in the published specification, too. The clause for suspensibility is given on basis on the highest and lowest concentration of use which means that the reference to the CIPAC method in the specification may exceed the upper range of concentration which is broadly speaking about 10 %. The test for suspensibility is based on the sedimentation of formulation particles in a water column and determination of a possible accumulation of particles in the lowest 10 % after a given time. Any use concentration that is near or greater than the lower 10 % is not within the scope of the method.

The Meeting considered the differences in the descriptions and in the clauses of the previously published specifications for clothianidin FS proposed by Sumitomo and BCS. The Meeting concluded that the description clauses and limits in the clauses for ‘Persistent foam’, ‘Suspensibility’ and ‘Adhesion to seeds’ in the published and proposed specifications justify two different FS specifications.

# SUPPORTING INFORMATION

# FOR

# EVALUATION REPORT 738/2015

## USES

Clothianidin is a systemic insecticide which acts as acute contact and stomach poison. Clothianidin belongs to the chemical class of neonicotinoid insecticides. The mode of action is by agonizing the insect nicotinic acetylcholine receptors in the nervous system of pest insects.

Clothianidin has a broad spectrum of activity, particularly against sucking insects such as aphids, leaf hoppers, thrips and white flies. Furthermore, various species of beetles (e.g. *Atomaria* spp., *Agriotes lineatus*, *Diabrotica* spp.) and some species of flies (e.g. *Oscinella* frit and *Pegomyia* spp.) and cut worm (e.g. *Agrotis* spp.) are effectively controlled. Clothianidin formulations are used in seed treatments as well as for foliar spray applications. BCS clothianidin is currently registered in the Europe, Northern and Southern America and Africa.

## IDENTITY OF THE ACTIVE INGREDIENT

*ISO common name (ISO 1750, published)*

Clothianidin

*Chemical name(s)*
IUPAC

(*E*)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine

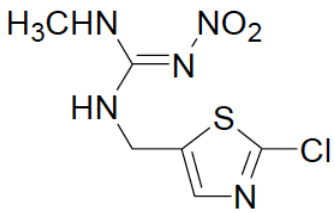
CA

[*C*(*E*)-*N*-[(2-chloro-5-thiazolyl)methyl]-*N*'-methyl-*N*''-nitroguanidine

*Synonyms*

TI-435

*Structural formula*




*Molecular formula*

$C_6H_8ClN_5O_2S$

*Molar mass*

249.7 g/mol

*CAS Registry number*

210880-92-5

*CIPAC number*

738

*Identity tests*

HPLC UV-detection and IR

**Note**: Sumitomo Chemical Company is the owner of the initial data package for clothianidin. Bayer CropScience has a commercial arrangement with Sumitomo and has a letter of access to the initial data package.

**Table 1. Physical-chemical properties of pure clothianidin**

| Parameter | Value(s) and conditions | Purity % | Method reference (and technique if the reference gives more than one) | Study reference |
|---|---|---|---|---|
| Vapour pressure | $1.3 \times 10^{-10}$ Pa at 25°C<br>$3.8 \times 10^{-11}$ Pa at 20°C<br>(extrapolated) | 99.7 | OECD 104<br>EC A.4 | M-026219-03-2 |
| Melting point, boiling point and/or temperature of decomposition | Melting point: 176.8°C<br>Boiling point: decomposes before boiling<br>Decomposition temperature: 242°C | 99.7 | OECD 102<br>EC A.1 (DSC) | M-025309-02-1 |
| Solubility in water | pH 7: 0.327 g/L at 20°C<br>determined in Milli-Q water (resistivity at least 17 megaohms) | 99.7 | OECD 105 (equivalent to EEC A.6, flask method) | M-026209-04-1 |
| Octanol/water partition coefficient | pH 4 log $P_{OW}$ = 0.89 at 25 °C<br>pH 7 log $P_{OW}$ = 0.91 at 25 °C<br>pH 10 log $P_{OW}$ = 0.87 at 25 °C | 99.7 | EEC A8 | M-041740-01-1 |
| Hydrolysis characteristics | Half-life = 14.4 days at 50°C at pH 9<br>Half-life = 3.7 days at 62°C at pH 9<br>Half-life = 0.7 days at 74°C at pH 9<br>Stable at 50ºC at pH 4 and 7 (<10% degradation after 5 days)<br>Stable at 25ºC at pH 5, 7 and 9 (<5% degradation after 33 days) | >98.0 | EPA Series 161-1 EEC method C.7 | M-048047-01-1 |

| Parameter | Value(s) and conditions | Purity % | Method reference (and technique if the reference gives more than one) | Study reference |
|---|---|---|---|---|
| Photolysis characteristics | Half-life 3.3 hours in sterile buffer pH 7 at 25ºC<br>Equivalent to 0.6 days of summer solar exposure at Pheonix, Arizona, US (40º latitude)<br>Equipment: Suntest®<br>Light source: Xenon lamp with UV cut-off filter at 290 nm.<br>Intensity (300-800 nm) = 1027 $W/m^2$ by radiometry.<br>Photonflow density = 125.86 X 1014 $s^{-1}$ $cm^{-2}$.<br>Quantum yield ($\Phi$) = 0.014 | >99.0 | EPA Series 161-2<br>SETAC | M-023549-02-1<br>M-010153-02-1 |
| Dissociation characteristics | $pK_a$ = 11.09 (at 20°C) | 99.7 | OECD 112 (spectrophoto-metric method) | M-026209-04-1 |
| Solubility in organic solvents | < 0.00104 g/l *n*-heptane at 25°C<br>1.32 g/l dichloromethane at 25°C<br>0.0128 g/l xylene at 25°C<br>0.938 g/l *n*-octanol at 25°C<br>15.2 g/l acetone at 25°C<br>2.03 g/l ethyl acetate at 25°C<br>6.26 g/l methanol at 25°C | 99.7 | OECD 105 (equivalent to EEC A.6, flask method) | M-026209-04-1 |

**Table 2. Chemical composition and properties of BCS clothianidin technical material (TC)**

| | |
|---|---|
| Manufacturing process, maximum limits for impurities ≥ 1 g/kg, 5 batch analysis data | Confidential information supplied and held on file by FAO. Mass balances were 99.57 - 100.24 % and percentages of unknowns were <0.2 %. |
| Declared minimum clothianidin content | 975 g/kg |
| Relevant impurities ≥ 1 g/kg and maximum limits for them | None |
| Relevant impurities **<** 1 g/kg and maximum limits for them | None |
| Stabilisers or other additives and maximum limits for them | None |
| Melting temperature range of the TC | 172 - 174°C (98.0%) [Smeykal 2012] |

## METHODS OF ANALYSIS AND TESTING

The analytical method for the active ingredient in TC is HPLC using UV detection at 225 nm and internal standardization. The clothianidin content of the TC and FS formulations is determined by the CIPAC method 783/TC/M/3 and 783/FS/M/3.

The method(s) for determination of impurities are based on a HPLC method using UV detection and internal standardisation.

There are no relevant impurities in clothianidin technical material.

Test methods for determination of physico-chemical properties of the technical active ingredient were OECD, EPA, and/or EC while those for the formulations were for example, CIPAC, as indicated in the specifications.

## FORMULATIONS AND CO-FORMULATED ACTIVE INGREDIENTS

The main formulation types available are FS and WS.
Clothianidin can be co-formulated with other insecticides or fungicides like *beta*-cyfluthrin, fluoxastrobin, imidacloprid, methiocarb, prothioconazole, tebuconazole, thiodicarb, thiram or triazoxide.

These formulations are registered and sold in Europe, Northern and Southern America, Africa.

## CONTAINERS AND PACKAGING

No special requirements for containers and packaging have been identified.

## EXPRESSION OF THE CONTENT OF THE ACTIVE INGREDIENT

The active ingredient is expressed and quantified as clothianidin.

## ANNEX 1

## HAZARD SUMMARY PROVIDED BY THE PROPOSER

Notes.

(i) The proposer confirmed that the toxicological and ecotoxicological data included in the summary below were derived from clothianidin having impurity profiles similar to those referred to in the table above.

(ii) The conclusions expressed in the summary below are those of the proposer, unless otherwise specified.

**Table 3. Toxicology profile of clothianidin technical material, based on acute toxicity, irritation and sensitization**

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Rat male/female | Oral | 96.0 | JMAFF 59 NohSan No 4200; JMAFF 63-44; OECD 401; Directive 92/69/EC Method B.I.; Directive 92/18/EEC, L97; US-EPA Section 81-1; OPPTS 870. 1100 | $LD_{50}$ = > 5000 mg/kg bw | M-027393-01-1 |
| Rat male/female | Acute neurotoxicity gavage | 95.2-96.0 | US-EPA-FIFRA, Guideline 81-8(SS); US-EPA OPPTS 870.6200 0-100-200-400 mg/kg bw/d | NOELs (male / female)<br>Overall = > 60 / 100 mg/kg bw<br>Neurotoxicity = ><br>400 mg/kg bw/d<br>not neurotoxic | M-027750-03-1 |
| Mouse male/female | Oral | 96.0 | OECD 401; Directive 92/69/EC, Method B. 1.; Directive 92/18/EEC, L97; US-EPA Section 81-1; US-EPA OPPTS 870.1100 | $LD_{50}$ = 389 mg/kg bw (m)<br>465 mg/kg bw (f) | M-027394-01-1 |
| Rat male/female | Dermal | 96.0 | JMAFF 59 NohSan No 4200; JMAFF 63-44; OECD 402; Directive 92/69/EC, Method B.3.; Directive 92/18/EEC, L97; US-EPA Section 81-2; US-EPA OPPTS 870.1200<br>24 h semi-occlusive conditions | $LD_{50}$ = > 2000 mg/kg bw | M-027396-01-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Rat male/female | Inhalation | 96.0 | JMAFF 59 NohSan No 4200; JMAFF 63-44; OECD 403; Directive 92/69/EC, Method B.2.; Directive 92/18/EEC, OJEC, L97; USA-EPA Section 81-3; US-EPA OPPTS 870.1330<br>4.5 h exposure | $LC_{50}$ = > 6.141 mg/L | M-027390-01-1 |
| Rabbit male/female | Skin irritation | 96.0 | JMAFF 59 NohSan No 4200; JMAFF 63-44; OECD 404; Directive 92/69/EC, Method B.4.; Directive 92/18/EEC L97; US-EPA Section 81-5; US-EPA OPPTS 870.2500<br>4 h exposure | Non-irritating | M-027402-01-1 |
| Rabbit male | Eye irritation | 96.0 | OECD 405; Directive 92/69/EC, Method B.5.; Directive 92/18/EEC L97; US-EPA Section 81-4; US-EPA OPPTS 870.2400<br>24 h exposure | Non-irritating | M-027400-01-1 |
| Guinea pig | Skin sensitization | 96.0 | OECD 406; Directive 92/69/EC, Method B.6.; Directive 92/18/EEC L97; US-EPA Section 81-6; US-EPA OPPTS 870.2600 | Non-sensitizing | M-027406-01-1 |

**Table 4. Toxicology profile of technical clothianidin based on repeated administration (sub-acute to chronic)**

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Rat male/female | Sub-acute feeding | 97.5 | OECD 407; Directive 92/69/EEC (OJ No. L383A, 29.12.92), Part B, Method B.7.; EPA Guideline in Subdivision F. Hazard Evaluation: Human and Domestic Animals, November 1984; JMAFF 59 Nohsan No. 4200<br>4 weeks<br>0-1250-2500-5000-7500 ppm<br>(equivalent to: 0-120-249-475-602 mg/kg bw/d (male), 0-137-228-454-689 mg/kg bw/d (female)) | NOAEL = 120 / 137 mg/kg bw/d<br>LOEL = 249 / 228 mg/kg bw/d | M-027408-01-1 |
| Mouse male/female | Sub-acute feeding | 97.5 | OECD 407; Directive 92/69/EEC (OJ No. L383A, 29.12.92), Part B, Method B.7.: EPA Guideline in Subdivision F. Hazard Evaluation: Human and Domestic Animals; JMAFF Nohsan No. 4200<br>deviation: duration 4 weeks<br>0-500-1000-2000-4000 ppm<br>(equivalent to: 0-90-190-383-683 mg/kg bw/d (male)<br>0-122-248-491-619 mg/kg bw/d (female)) | NOAEL = 190 / 248 mg/kg bw/d<br>LOEL = 383 / 491 mg/kg bw/d | M-027413-01-1 |
| Dog female | Dose-range finding (palatability) feeding | 95.2 | Exposure to increasing dose levels<br>0 (for 11 days) - 3000 / 4000 / 5000 ppm (days 1-3 / 4-8 / 9-11)<br>(equivalent to: 0- 51.1/50.8/51.8 mg/kg bw/d) | NOEL = 51.8 mg/kg bw/d | M-027385-01-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Dog male/female | Dose-range finding feeding | 95.2 | Directive 88/302/EEC, Method B.27; US-EPA FIFRA Subdivision F, Section 82-1; US-EPA 870.3150; JMAFF 59 Nohsan No. 4200; mainly in accordance to OECD 409<br>4 weeks, 3 animals/sex/group<br>0-1250-2500-5000 ppm<br>(equivalent to: 0-36.3-35.8-62.4 mg/kg bw/d (male)<br>0-35.6-52.3-57.4 mg/kg bw/d (female)) | NOAEL = 36.3 / 35.6 mg/kg bw/d<br>LOEL = 35.8 / 52.3 mg/kg bw/d | M-027342-01-1 |
| Rat male/female | Sub-acute dermal | 95.2 | US-EPA OPPTS 870.3200; JMAFF 59 Nohsan No. 4200; Directive 88/302/EEC (OJEC No. L 133/27) Part B; OECD 410<br>6 hrs/day, 28 days<br>0-100-300-1000 mg/kg bw/d | NOEL = > 1000 mg/kg bw/d | M-027480-01-1 |
| Rat male/female | Sub-chronic feeding | 95.3 | FIFRA 82-1; TSCA 798.2650; US-EPA OPPTS 870.3100, OECD 408; JMAFF 59 NohSan No. 4200; Directive 87/302/EEC, part B<br>97 days<br>0-150-500-3000 ppm<br>(equivalent to: 0-9.0-27.9-202 mg/kg bw/d (male)<br>0-10.9-34.0-254 mg/kg bw/d (female)) | NOAEL = 27.9 / 34.0 mg/kg bw/d<br>LOEL = 202 / 254 mg/kg bw/d | M-027268-01-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Dog male/female | Sub-chronic feeding | 95.2 | US-EPA-FTFRA Section. 82-1; US-EPA-OPPTS OPPTS 870.3150; OECD 409; JMAFF 59 Nohsan No. 4200; Directive 88/302/EEC (OJEC No. L 133/12), Part B<br>13 weeks<br>0-325-650-1500-2250 ppm<br>(equivalent to: 0-9.2-19.3-40.9-58.2 mg/kg bw/d (male)<br>0-9.6-21.2- 42.1-61.8 mg/kg bw/d (female)) | NOAEL = 19.3 / 21.2 mg/kg bw/d<br>LOEL = 40.9 / 42.1 mg/kg bw/d | M-036499-02-1 |
| Dog male/female | Sub-chronic feeding | 95.2 | EPA-FIFRA Guideline 83-1; EPA-OPPTS Guideline Section 870.4100; OECD 452; JMAFF 59 Nohsan No. 4200, Directive 88/302/EEC, Part B<br>52 weeks<br>0-325-650-1500-2000ppm<br>(equivalent to: 0-7.8-16.6-36.3-46.4 mg/kg bw/d (male)<br>0-8.5-15.0-40.1-52.9 mg/kg bw/d (female)) | NOAEL = 36.3 / 40.1 mg/kg bw/d<br>LOEL = 46.4 / 52.9 mg/kg bw/d | M-036542-01-1 |
| Rat male/female | Chronic oncogenicity feeding | 95.2-95.5 | JMAFF 59 NohSan No. 4200; OECD 453; EEC 88/302/EEC; FIFRA F, 83-5; OPPTS 870.4300<br>104 weeks<br>0-150-500-1500-3000 ppm<br>(equivalent to: 0-8.1-27.4-82-157 mg/kg bw/d (male)<br>0-9.7-32.5-97.8-193 mg/kg bw/d (female)) | NOAEL = 27.4 / 9.7 mg/kg bw/d<br>LOEL = 82 / 32.5 mg/kg bw/d<br><br>not carcinogenic | M-031986-02-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Mouse male/female | Oncogenicity feeding | 95.2 | JMAFF 59 NohSan No. 4200; OECD 451; EEC 88/302/EEC; FIFRA F, 83-2; OPPTS 870.4200<br>78 weeks<br>0-100-350-700/2000/2500/2000/1800 (week 1-4/ 5-10/ 11-34/ 35-termination 2000 ppm (m)/ 1800 ppm (f)) -1250 ppm<br>(equivalent to: 0-13.5-47.2-171.4-251.9 mg/kg bw/d (male)<br>0-17.0-65.1-215.9-281.1 mg/kg bw/d (female)) | NOAEL = 47.2 / 65.1 mg/kg bw/d<br>LOEL = 171.4 / 215.9 mg/kg bw/d<br><br>not carcinogenic | M-032363-02-1 |
| Rat male/female | Pilot reproduction one generation | 95.2-96.0 | US-EPA-FIFRA, Section 158.340, No. 83-4: US-EPA-TSCA, 40 CFR Section 798.4700: Guideline 87/302/EEC; OECD 416; J MAFF, 59 NohSan No. 4200<br>pre-mating 8 weeks<br>0-50-100-500-1000 ppm<br>(equivalent during pre-mating to: 3.2-3.5 / 5.9-6.8 / 31.7-36.4 / 66.6 - 70.8 mg/kg bw/d) | NOEL repro. = > 66.6 mg/kg bw/d | M-027255-01-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Rat male/female | Reproduction 2-generation | 95.3-96.0 | US-EPA, OPPTS 870.3800; Directive 91/414/EEC; OECD 416; JMAFF, 59 NohSan No. 4200<br>0-150-500-2500 ppm<br>(equivalent to both generations combined:<br>0-10.2-32.7-179.6 mg/kg bw/d (male)<br>0-11.8-37.9-212.9 mg/kg bw/d (female) | Parental<br>NOEL = 32.7/11.8 mg/kg bw/d<br>LOEL = 179.6/37.9 mg/kg bw/d<br>Reproductive<br>NOEL = >179.6/ >212.9 mg/kg bw/d<br>Offspring<br>NOEL = 10.2/11.8 mg/kg bw/d<br>LOEL = 32.7/37.9 mg/kg bw/d | M-031280-02-1 |
| Rat female | Dose-range finding developmental toxicity | 96.0 | US-EPA OPPTS 870.3700<br>gestation days 6-19<br>0-125-250-500-1000 mg/kg bw/d | Maternal<br>NOAEL = not established<br>LOEL = 125 mg/kg bw/d<br>Developmental<br>NOAEL = 125 mg/kg bw/d<br>LOEL = 250 mg/kg bw/d | M-027430-02-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Rat female | Developmental toxicity | 95.2 | Guideline 88/302/EEC; OECD 414; US-EPA OPPTS 870.3700; JMAFF 59 NohSan no. 4200<br>gestation days 6-19<br>0-10-40-125 mg/kg bw/d | Maternal<br>NOEL = 10 mg/kg bw/d<br>LOEL = 40 mg/kg bw/d<br>Developmental<br>NOAEL = 125 mg/kg bw/d<br>LOEL = > 125 mg/kg bw/d<br>not teratogenic | M-027416-01-1 |
| Rabbit female | Dose-range finding developmental toxicity | 96.0 | US-EPA OPPTS 870.3700<br>gestation days 6-28<br>0-62.5-125-250-500 mg/kg bw/d | Maternal<br>NOAEL = 62.5 mg/kg bw/d<br>MTD < 125 mg/kg bw/d<br>Developmental<br>NOAEL > 62.5 mg/kg bw/d | M-027436-02-1 |
| Rabbit female | Developmental toxicity | 95.2-95.5 | Guideline 88/302/EEC, OECD 414; US-EPA OPPTS 870.3700; JMAFF 59 NohSan no. 4200<br>gestation days 6-28<br>0-10-25-75-100 mg/kg bw/d | Maternal<br>NOEL = 10 mg/kg bw/d<br>LOEL = 25 mg/kg bw/d<br>Developmental<br>NOAEL = 75 mg/kg bw/d<br>LOEL = 100 mg/kg bw/d<br>not teratogenic | M-027442-01-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Rat male/female | Sub-chronic neurotoxicity feeding | 95.3-96.0 | US-EPA-FIFRA, Guideline 82-5(b); US-EPA OPPTS 870.6200<br>0-150-1000-3000 ppm<br>equivalent to: 0-9.2-60-177 mg/kg bw/d (male)<br>0-10.6-71-200 mg/kg bw/d (female) | NOELs (male / female)<br>Overall = 60 / 71 mg/kg bw d<br>Neurotoxicity = >177 / >200 mg/kg bw/d<br>not neurotoxic | M-027986-01-1 |
| Rat male/female | Developmental neurotoxicity feeding | 95.5-95.9 | US-EPA OPPTS 870.6300; US-EPA Guideline 83-3; US-EPA Pesticide Assessment Guidelines, Subdivision F, addendum 10, neurotoxicity<br>day 0 of gestation until 22 days post partum<br>0-150-500-1750 ppm<br>(equivalent to: 0-12.9-42.9-142 mg/kg bw/d (gestation)<br>0-27.3-90.0-299 mg/kg bw/d (lactation) | NOELs (gestation / lactation)<br>Maternal = 42.9 / 90.0 mg/kg bw/d<br>Developmental = 12.9 / 27.3 mg/kg bw/d<br>Developmental neurobehavioral effects > 142 / > 299 mg/kg bw/d | M-027178-02-1 |

**Table 5. Mutagenicity profile of technical clothianidin based on *in vitro* and *in vivo* tests**

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| *Salmonella typhimurium* / *Escherichia coli* | Reverse mutation assay 'Ames test' *in vitro* | 95.2-96.0 | Guideline 92/69/EEC, Method B.I4.; OECD 471, US-EPA FIFRA section 84-2; JMAFF 59 NohSan no. 4200; Japan Ministry of Labour No. 77<br>*S. typhimurium*: TA 98, TA 100, TA 1535, TA 1537; *E. coli*: WP2uvrA$^-$<br>0-50-150-500-1500-5000 µg/plate (+/- S9 mix) | Positive (+S9 mix in TA 1535 only) | M-036520-01-1 |
| *Salmonella typhimurium* / *Escherichia coli* | Reverse mutation assay 'Ames test' *in vitro* | ≥ 99.0 | Guideline 92/69/EEC, Method B.14.; JMAFF 59 NohSan no. 4200<br>*S. typhimurium*: TA 98, TA 100, TA 1535, TA 1537; *E. coli*: WP2uvrA$^-$<br>0-313-625-1250-2500-5000 µg/plate (+/-S9 mix) | Negative | M-036420-02-1 |
| *Salmonella typhimurium* | Reverse mutation assay 'Ames test' *in vitro* | 95.2 | Directive 92/69/EEC, Method B.14.; OECD 471; US-EPA 712-C-96-219, OPPTS 870.5265<br>*S. typhimurium*: TA 98, TA 100, TA 102, TA 1535, TA 1537<br>0-16-50-158-500-1581-5000 µg/plate/tube (+/-S9 mix)<br>TA 102: 0-16-32-48-64-80-96-112 µg/plate (+/-S9 mix) | Negative | M-009777-02-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| *Salmonella typhimurium* | Reverse mutation assay 'Ames test' *in vitro* | 98.6 (batch NLL 6100-3), 96.2 (batch 30034708) | Directive 92/69/EEC, Method B.14.; OECD 471; US- EPA 712-C-96-219, OPPTS 870.5265<br>*S. typhimurium*: TA 1535<br>Batch NLL 6100-3: 0-1000-2000-3000-4000-5000 µg/plate, Batch 30034708: 3000-5000-7000 µg/plate, 0-1000-2000-4000-6000-8000 µg/tube<br>each batch +/- S9 mix, pre-incubation technique | Negative | M-009769-02-1 |
| *Bacillus subtilis* | DNA repair assay *in vitro* | ≥ 99.0 | JMAFF 59 Nohsan No. 4200<br>0-375-750-1500-3000-6000 µg/disc (+/- S9 mix) | Negative | M-036407-02-1 |
| Chinese hamster lung (CHL) cells | Chromosome aberration assay in vitro | 96.0 | OECD 473; Directive 92/69/EEC, Annex V, Part B, Method B.10.; US-EPA FIFRA section 84-2 ; JMAFF 59 Nohsan No 4200<br>1st assay: 0-156.25-312.5-625-937.5-1250-1875 µg/mL<br>2nd assay: 0- 39 to 1875 µg/mL<br>exposure 4 – 48 hrs, recovery 0 – 18 hrs, +/- S9 mix | Positive<br>(+/- S9 mix) | M-036479-02-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Chinese hamster V79 cells | Chromosome aberration assay in vitro | 98.0 | Directive 92/69/EEC, Method B.10.; OECD 473; US-EPA 712-C-98-223, OPPTS 870.5375<br>- S9 mix: 0-100-200-300-350-400-700-1000-1200-1400 µg/mL<br>+ S9 mix: 0-500-1000-1600-1800-2000 µg/mL | Weakly positive (+ S9 mix) | M-053960-01-1 |
| Mouse lymphoma cells | Gene mutation in mammalian cells in vitro | 96.0 | OECD 476; Directive 87/303/EEC no. LI 33, Method B. 14.; EPA FIFRA section 84-2; JMAFF 59 Nohsan No 4200<br>0-312.5-625-1250-1667-2500 µg/mL (+/-S9 mix)<br>0-300-600-1200-1600-2000 µg/mL (-S9 mix)<br>0-600-1200-1600-2000-2400 µg/mL (+S9 mix) | Positive | M-036462-02-1 |
| Chinese hamster lung V79 cells | Gene mutation in mammalian cells in vitro | 95.2 | Directive 88/302/EEC; OECD 476; US-EPA712-C-96-221, OPPTS 870.5300<br>0-156-313-625-1250-2500-5000 µg/mL (+/-S9 mix) | Negative | M-009761-02-1 |
| Mouse bone marrow cells | Chromosome aberration assay Micronucleus test in vivo | 96.0 | OECD 474; Directive 92/69/EEC, no. L383A, Method B.12.; EPA section 84-2; JMAFF 59 NohSan No. 4200<br>0-25-50-100 mg/kg bw (oral) | Negative | M-036435-02-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Rat hepatocytes | Unscheduled DNA synthesis in vivo | 95.2-96.2 | In accordance with OECD draft guideline 'OECD Guidelines for Testing of Chemicals, Proposal for a New Guideline, "Genetic Toxicology: DNA Damage and Repair/ Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells In Vivo' and in addition Directive 88/302/EEC; OECD 482; US-EPA PB 84-233295<br>0-2500-5000 mg/kg bw (oral) | Negative | M-009751-03-1 |

**Additional toxicity studies of technical clothianidin manufactured by Bayer CropScience**

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result [(isomer/form)] | Study Reference |
|---|---|---|---|---|---|
| *Salmonella typhimurium* | Reverse mutation assay 'Ames test'<br>*in vitro* | 99.8 | OECD 471; 2000/32/EC, Annex 4D; US EPA 712-C-98-247, OPPTS 870.5100<br>*S. typhimurium*: TA 98, TA 100, TA 102, TA 1535, TA 1537<br>0-33-100-333-1000-2500-5000 µg/plate (+/- S9) | Negative | [M-103604-02-1] |
| Chinese hamster lung V79 cells | Chromosome aberration assay<br>*in vitro* | 99.8 | OECD 473; Directive 2000/32/EC, Annex 4A; EPA 712-C-98-223, OPPTS 870.5375<br>0-200-400-600-750-1000-1500 µg/mL (-S9 mix)<br>0-500-750-1000-1500 µg/mL (+ S9 mix) | Negative | [M-103614-01-1] |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result [(isomer/form)] | Study Reference |
|---|---|---|---|---|---|
| Chinese hamster lung V79 cells | Gene mutation in mammalian cells *in vitro* | 99.8 | OECD 476; Directive 2000/32/EC, Annex 4E; US EPA 712-C-98-221, OPPTS 870.5300 0-78.1-156.3-312.5-625-1250-2500 µg/mL (+/- S9 mix) | Negative | [M-103610-01-1] |
| Mouse bone marrow cells | Micronucleus test *in vivo* | 99.8 | US-EPA 712-C-98-226, OPPTS 870.5395; OECD 474; Directive 2000/32/EC, Annex 4C 0-75-150-300 mg/kg bw (intraperitoneal) | Negative | [M-103617-01-1] |
| Rat hepatocytes | Unscheduled DNA synthesis *in vivo* | 99.8 | OECD 486, EC Directive 2000/32, B.39 0-1000-2000 mg/kg bw (oral) | Negative | [M-103622-01-1] |
| Guinea pig | Skin sensitization | 99.3 | OECD 406; Guideline 96/54/EC, Method B.6.; US-EPA 712-C-03-197, OPPTS 870.2600 | Non-sensitizing | [M-424556-01-2] |

**Table 6. Ecotoxicology profile of technical clothianidin**

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Bobwhite quail<br><br>*(Colinus virginianus)* | Acute oral | 96.0 | 14d, US EPA Subdivision E, Guideline 71-1 (1982) | LD50 > 2000 mg /kg bw | M-027064-01-1 |
| Japanese quail<br><br>*(Coturnix coturnix japonica)* | Acute oral | 97.6 | 14d, US EPA Subdivision E, Guideline 71-1 (1982) | LD50 = 430 mg /kg bw | M-027285-01-1 |
| Bobwhite quail<br><br>*(Colinus virginianus)* | dietary | 96.0 | 8d, OECD 205 (1984) | LC50 > 5200 mg/kg diet | M-027059-01-1 |
| Mallard duck<br><br>*(Anas platyrhynchos)* | dietary | 96.0 | 8d, OECD 205 (1984) | LC50 > 5200 mg/kg diet | M-027068-01-1 |
| Bobwhite quail<br><br>*(Colinus virginianus)* | Reproduction | 97.6 | 20 weeks, OECD 206 | NOEC = 500 mg/kg diet | M-027293-01-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Mallard duck<br><br>*(Anas platyrhynchos* | Reproduction | 97.6 | 20 weeks, OECD 206 | NOEC = 500 mg/kg diet | M-027289-01-1 |
| Rainbow trout<br><br>*(Oncorhynchus mykiss)* | acute | 96.0 | 96h, static, limit test, OECD 203 | LC50 > 100 mg/L | M-027029-02-1 |
| Bluegill<br><br>*(Lepomis macrochirus)* | acute | 97.6 | 96h, static, limit test, OECD 203 | LC50 > 120 mg/L | M-031285-01-1 |
| Fathead minnow<br><br>*(Pimephales promelas)* | Chronic, ELS | 97.6 | 33d, flow-through, US EPA Subdivision E, Guideline 72-4 (1982), US EPA OPPTS draft guideline 850.1400 (1996) | NOEC = 20 mg/L | M-031516-01-1 |
| Sheepshead minnow<br><br>*(Cyprinodon variegatus)* | acute | 97.6 | 96h, static, OECD 203 | LC50 > 102.5mgLl | M-027244-01-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| water flea<br><br>*(Daphnia magna*) | acute toxicity | 97.6 | 48h, static, OECD 202 | $EC_{50}$ > 120 mg/L | M-031283-01-1 |
| water flea<br><br>*(Daphnia magna*) | chronic toxicity | 96.0 | 21d, semi-static, OECD 211 | NOEC = 0.120 mg/L | M-027071-02-1 |
| Mysid shrimp<br><br>(*Mysidopsis bahia*) | acute | 97.6 | 96h, flow-through | LC50 = 0.053 mg/L | M-019551-01-1 |
| Mysid shrimp<br><br>(*Mysidopsis bahia*) | chronic, life cycle | 97.6 | 39d, flow-though, OPPTS 850.1350 | NOEC = 0.0097 mg/L | M-026384-01-1 |
| Oyster<br><br>(*Crassostrea virginica*) | acute | 97.6 | 96h, flow-through; OPPTS 850.1025 | EC50 > 129.1 mg/L | M-028515-01-1 |
| Green alga<br><br>*(Scenedesmus subspicatus)* | chronic toxicity | 96.0 | 72h, static, OECD 201 | ErC50 > 270 mg/L | M-027041-02-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Green alga<br><br>*(Selenastrum capricornutum)* | chronic toxicity | 97.6 | 72h, static, OECD 201 | ErC50 > 120 mg/L | M-026366-01-1 |
| Sediment dwelling invertebrates<br><br>*(Chironomus riparius)* | acute | 97.6 | 48h, static | EC50 = 0.029 mg/L | M-032142-01-1 |
| Sediment dwelling invertebrates<br><br>*(Chironomus riparius)* | chronic | 96.1 | 28d, static, BBA | EC15 = 0.00072 mg/L | M-011874-01-1 |
| Duckweed<br><br>*(Lemna gibba)* | chronic | 97.6 | 14d, static renewal, US EPA OPPTS guideline 850.4400 (1996) | EC50 > 121 mg/L | M-031279-01-1 |
| Honeybee<br><br>(*Apis mellifera*) | Acute oral<br><br>Acute contact | 96.0 | 48h, EPPO guideline n° 170 (1992) | Oral LD50 = 0.004 µg/bee<br><br>Contact LD50 = 0.044 µg/bee | M-027051-01-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Parasitoid<br><br>(*Aphidius rhopalosiphi*) | Laboratory | 50.3 (WG50) | 48h, tested as formulated product WG 500 g/kg<br><br>SETAC (1994) | 100 % mortality at 60 g a.s./ha | M-027182-01-1 |
| Predatory mite<br><br>(*Typhlodromus pyri*) | Laboratory | 50.3 (WG50) | 14d, tested as formulated product WG 500 g/kg<br><br>SETAC (1994) | 69 % mortality at 60 g a.s./ha<br><br>97 % effect on reproduction at 60 g a.s./ha | M-027179-01-1 |
| Ground dwelling predatory species<br><br>(*Aleochara bilineata*) | Laboratory | 50.3 (WG50) | 28d, tested as formulated product WG 500 g/kg<br><br>SETAC (1994) | 89 % corrected mortality at 75 g a.s./ha | M-027200-01-1 |
| Foliage dwelling predatory species<br><br>(*Chrysoperla carnea*) | Laboratory | 50.3 (WG50) | 28d, tested as formulated product WG 500 g/kg<br><br>SETAC (1994) | 97 % corrected mortality at 60 g a.s./ha | M-027198-01-1 |
| Earthworm<br><br>(*Eisenia fetida*) | acute | 96.0 | 14d, OECD 207 | LC50 = 13.2 mg/kg soil | M-027046-01-1 |

| Species | Test | Purity % | Guideline, duration, doses and conditions | Result | Study reference |
|---|---|---|---|---|---|
| Nitrogen transformation<br><br>Soil respiration | | 49.3 (WG50) | 28d, OECD 216 and 217 | No significant effects (<25%) at 750 g a.s./ha (equivalent to 1 mg a.s./kg soil) | M-027297-01-1 |
| Terrestrial plants (10 species) | Seedling emergence | 49.3 (WG50) | 14d, OPPTS 850.4100 and 850.4225 | NOEC = 225 g a.s./ha | M-026377-01-1 |
| Terrestrial plants (10 species) | Vegetative vigour | 49.3 (WG50) | 14d, OPPTS 850.4150 | NOEC = 225 g a.s./ha | M-026381-01-1 |

Clothianidin was evaluated by the FAO/WHO JMPR in 2010 and an acceptable daily intake (ADI) of 0–0.1 mg/kg bw per day was established and estimated the acute reference dose (ARfD) as 0.6 mg/kg bw.
Clothianidin has not been evaluated by the WHO IPCS.

In the EU the classification process is not yet finalized. In conclusion the only valid classification for the time being (September 2016) is the one proposed by the company based on the current EU regulation EC 67/548 as follows:

| | |
|---|---|
| Pictograms: |  |
| Signal word: | Warning |
| Hazard statements: | H302: Harmful if swallowed<br>H400: Very toxic to aquatic life<br>H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements: | P270: Do not eat, drink or smoke when using this product<br>P301+312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell<br>P273: Avoid release to the environment<br>P501: Dispose of contents/container in accordance with local regulations |

# ANNEX 2

# REFERENCES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