WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES

BROFLANILIDE

N-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(*N*-methylbenzamido)benzamide

World Health Organization

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DISCLAIMER[1]

WHO specifications are developed with the basic objective of promoting, as far as practicable, the manufacture, distribution and use of pesticides that meet basic quality requirements.

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.

Furthermore, pesticides which are manufactured to comply with these specifications are not exempted from any safety regulation or other legal or administrative provision applicable to their manufacture, sale, transportation, storage, handling, preparation and/or use.

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

INTRODUCTION

WHO establishes and publishes specifications[1] for technical material and related formulations of public health 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 WHO specifications follows the **New Procedure**, described in the "Manual on the development and use of FAO and WHO specifications for chemical pesticides." This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by WHO and the experts of the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS).

WHO specifications now only apply to products for which the technical materials have been evaluated. Consequently, from the year 2002 onwards, the publication of WHO 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 8 of the above-mentioned manual.

Part Two: The Evaluation Report(s) of the pesticide, reflecting the evaluation of the data package carried out by WHO and the JMPS. The data are provided by the manufacturer(s) according to the requirements of chapter 3 of the above-mentioned manual and supported by other information sources. Evaluation reports include 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 chronological order to this report.

WHO specifications 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. WHO 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.

[1] Publications available on the WHO Prequalification Unit – Vector Control Product Assessment Team (PQT/VCP) website: https://extranet.who.int/prequal/vector-control-products

PART ONE: SPECIFICATIONS

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BROFLANILIDE INFORMATION

ISO common name

Broflanilide (ISO 1750 approved)

Chemical names

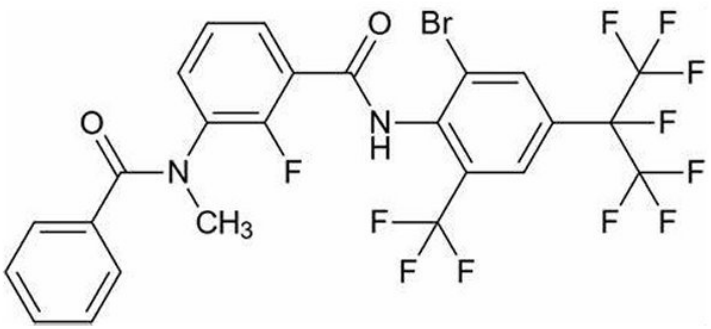
IUPAC *N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(*N*-methylbenzamido)benzamide

CA 3-(benzoylmethylamino)-*N*-[2-bromo-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-6-(trifluoromethyl)phenyl]-2-fluorobenzamide

Synonyms

TENEBENAL™, MCI-8007, BAS 450 I, MLP-8607, Reg. No. 5672774, LS5672774, LSP5672774, MAI-7316

Structural formula



Molecular formula

$C_{25}H_{14}BrF_{11}N_2O_2$

Relative molecular mass

663.3

CAS Registry number

1207727-04-5

CIPAC number

994

Identity tests

HPLC retention time, IR, UV/Vis, ^{13}C-NMR, ^{1}H-NMR, Mass Spectrum

BROFLANILIDE TECHNICAL MATERIAL

WHO specification 994/TC (September 2023)

This specification, which is PART ONE of this publication, is based on evaluations of data submitted by the manufacturer whose name is listed in the evaluation report (994/2022). This specification 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 (994/2022), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of broflanilide together with related manufacturing impurities and shall be a white to beige powder free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 Identity tests (994/TC/M/2, CIPAC Handbook P, p.22, 2021)

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 Broflanilide content (994/TC/M/3, CIPAC Handbook P, p.22, 2021)

The broflanilide content shall be declared (not less than 990 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

BROFLANILIDE ULTRA LOW VOLUME LIQUID

WHO specification 994/UL (November 2024*)

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 (994/2024). It should be applicable to relevant products of this manufacturer and those of any other formulators who use only TC from the evaluated sources. 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 (994/2024), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of technical broflanilide, complying with the requirements of WHO specification 994/TC, in the form of a slightly pale to light yellow organic liquid, together with any necessary formulants. It shall be in the form of a stable homogeneous liquid free from visible suspended matter and sediment.

2 Active ingredient

2.1 **Identity tests** (994/UL/M/2, Note 1)

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 **Broflanilide content** (994/UL/M/3, Note 1)

The broflanilide content shall be declared (g/kg or g/L at 20 ± 2°C, Note 2) and, when determined, the average measured content shall not differ from that declared by more than the following tolerance:

Declared content, g/kg or g/l at 20 ± 2ºC	Tolerance
up to 25 Note: the upper limit is included in each range	± 15% of the declared content

3 Storage stability

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

After storage at 0 ± 2°C for 7 days, the volume of solid and/or liquid which separates shall not be more than 0.3 ml.

3.2 **Stability at elevated temperature** (MT 46.4, CIPAC Handbook P, p.232, 2021)

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 3).

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* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at the WHO Prequalification Unit – Vector Control Product Assessment Team (PQT/VCP) website: https://extranet.who.int/prequal/vector-control-products/specifications-new-procedure

Note 1 The extension of the reversed phase HPLC method 994/TC/M3 (CIPAC/5388) for the determination of broflanilide in UL formulations was accepted as provisional CIPAC method in 2024. Prior to its publication in the next Handbook, copies of the method can be obtained through the CIPAC website, https://www.cipac.org/index.php/m-p/pre-published-methods

Note 2 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 3 Samples of the formulation taken before and after the storage stability test may be analysed concurrently after the test in order to reduce the analytical error.

PART TWO: EVALUATION REPORTS

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FAO/WHO EVALUATION REPORT 994/2024

Recommendations

The Meeting recommended that the specification for broflanilide UL, proposed by Clarke Mosquito Control Products, Inc., as amended, should be adopted by WHO.

Appraisal

The Meeting considered data and information submitted by Clarke Mosquito Control Products, Inc. (Clarke) in December 2023 and May 2024 to support a new WHO specification for broflanilide UL.

The data submitted met the requirements of the Manual on the development and use of FAO and WHO specifications for chemical pesticides – Second edition (FAO/WHO, 2022). A data package on the physical-chemical properties of the formulation was provided to the Meeting. It included:

- The analytical method used for the active ingredient content and a GLP method validation study (Ref. AN 1102);
- A GLP study on the product properties where the colour, physical state, pH, viscosity and density were determined on one batch of CMP132-022 ULV (Ref. AN1103);
- A GLP accelerated storage stability study where the colour, physical state, pH, viscosity, density and active ingredient content were determined on three batches of the product before storage and after storage at 54°C for 14 days in four different types of commercial packaging (Ref. AN1110);
- A GLP low temperature storage stability study where the colour, physical state, pH, viscosity, density and active ingredient content were determined on three batches of the product stored at 0°C for 7 days (Ref. AN1111);
- A GLP long-term storage stability study where the colour, physical state and active ingredient content were determined on three batches of the product stored at 30°C for 3, 6, 9 and 12 months in commercial packaging (Ref. AN1105).

Description

The supporting data showed that the colour of the Clarke's broflanilide UL formulation is slightly pale yellow, pale yellow or light yellow and does not change after storage at low and elevated temperatures. The Meeting proposed to add the colour range "slightly pale to light yellow" in the description clause of the specification in order to clearly describe the product for checking by simple visual inspection.

Active ingredient identity and content and analytical methods

The nominal content of broflanilide in the submitted UL formulation is 10 g/kg. The supporting data showed that the broflanilide content is within the tolerance of ± 10% of the declared content in all the batches analysed. Broflanilide content was determined by reversed phase HPLC with UV detection at 230 nm after solubilisation of the UL formulation in methanol. The in-house method was successfully validated on its specificity, linearity, accuracy and precision.

An extension of the reversed phase HPLC method 994/TC/M/3 (CIPAC/5388) for the determination of broflanilide in UL formulations was accepted as a provisional CIPAC method at the June 2024 CIPAC meeting.

The Meeting noted significant differences between the extended CIPAC method and the in-house method used in the supporting studies, as regards the dilution solvent, the chromatographic column and the detector wavelength, and requested the proposer to provide an analytical bridging study. The analytical bridging study performed on three batches of broflanilide UL using both the CIPAC method and the in-house method demonstrated that the results are comparable.

Relevant impurities

The are no relevant impurities identified in the WHO specification for broflanilide TC. The Meeting therefore agreed that no relevant impurities need to be specified for the broflanilide UL formulation.

Physical-chemical properties

The pH of a 1% dilution in water was measured in the supporting studies and showed consistent results for all batches tested. As broflanilide is stable to hydrolysis at pH 4, 7 and 9, the Meeting concluded that a pH clause is not necessary.

The viscosity was also measured in the supporting studies and showed consistent results for all batches tested. The Meeting concluded that a clause for viscosity is not necessary.

Storage stability

The low temperature storage stability study showed that the broflanilide UL formulation remains homogeneous after storage at 0°C for 7 days using the CIPAC method MT 39.3. Moreover, the colour and the active ingredient content of the formulation are not adversely affected by the storage. The Meeting therefore agreed with the proposed specification clause that the volume of solid and/or liquid which separates shall not be more than 0.3 ml.

The accelerated storage stability study at elevated temperature showed that the Clarke's broflanilide UL formulation remains homogeneous and stable after storage at 54°C for 14 days using the CIPAC method MT 46.4 in different types of commercial packaging, with an active ingredient content above 95% of the content before storage. The additional long-term storage stability study showed that the broflanilide UL formulation remains homogeneous and stable after storage at 30°C up to at least 12 months. The Meeting therefore agreed with the proposed specification clause.

Annex 1: References

Study number	Author(s)	Year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study
BROF-001	Moncada C.	2021	HPLC Determination of Broflanilide Content. Method BROF-001. Clarke Mosquito Control Products, Inc.
AN1102	Moncada C.	2021	Method validation of BROF-001. Study No. AN1102. GLP. Clarke Mosquito Control Products, Inc.
AN1103	Moncada C.	2021	Product properties of CMP132-022. Study No. AN1103. GLP. Clarke Mosquito Control Products, Inc.
AN1110	Moncada C.	2022	Accelerated Storage Stability and Corrosion Characteristics of CMP132-022. Study No. AN1110. GLP. Clarke Mosquito Control Products, Inc.
AN1111	Moncada C.	2022	Low temperature Storage Stability of CMP132-022. Study No. AN1111. GLP. Clarke Mosquito Control Products, Inc.
AN1105	Moncada C.	2023	Long-term Storage Stability of CMP132-022. Study No. AN1105. GLP. Clarke Mosquito Control Products, Inc.
-	Moncada C.	2024	Broflanilide CIPAC / Clarke analytical method bridging study. Clarke Mosquito Control.

BROFLANILIDE

FAO/WHO Evaluation Report 994/2022

Recommendations

The Meeting recommended that the specification for broflanilide TC proposed by Mitsui Chemicals Crop & Life Solutions, Inc. should be adopted by WHO.

Appraisal

The Meeting considered a data package submitted by Mitsui Chemicals Crop & Life Solutions, Inc. in 2021 in support of a new WHO specification for broflanilide TC.

Broflanilide is the ISO common name for *N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(*N*-methylbenzamido)benzamide (IUPAC).

Broflanilide is used in non-agricultural settings for general insect control and for vector control as a public health pesticide. It is also intended for use in agriculture as well as in feed and food-handling establishments. It is a meta-diamide insecticide and is the pro-insecticide that is metabolized to the des-methyl form. Des-methyl broflanilide is the active substance that binds to an inter-subunit allosteric site on the GABA receptor, resulting in a block of inhibitory neurotransmission, convulsions and death of target insects. Due to its unique site of action, the Insecticide Resistance Action Committee has assigned it to a new classification (Group 30: GABA-gated chloride channel allosteric modulators).

Broflanilide is under patent until June 2029.

Broflanilide has been evaluated by JMPR in 2022, the US EPA in 2021 and JMAFF in 2020.

The data submitted were in accordance with the requirements of the Manual on Development and Use of FAO and WHO specifications for Pesticides (2016-third revision of the First Edition) and support the proposed specification.

The Meeting was provided with commercially confidential information on the manufacturing process, GLP 5-batch analysis data on all impurities present below or above 1 g/kg and their manufacturing limits in the TC. Data were provided for both pilot and full-scale material. Mass balances were 99.58–100.03% in the 5-batch data. The confidential data provided on the manufacturing process of broflanilide and the batch analysis data are the same as those submitted for registration in several countries.

The proposer declared the minimum purity of the broflanilide TC as 990 g/kg, which is statistically justified (mean value - 3 standard deviation = 992 g/kg for full-scale production). The levels of the other manufacturing impurities were proposed based on the analytical batch data from pilot and full-scale material. The Meeting considered that sufficient analytical data had been provided to support the declared manufacturing specification.

The proposer indicated that none of the impurities in broflanilide TC should be considered as relevant impurities. Based on a (Q)SAR analysis with DEREK (Program version Derek Nexus: 6.2.1, Nexus: 2.5.2) and SARAH (Program version Sarah Nexus: 3.2.1, Model Version 1.10), the Meeting agreed that the impurities in broflanilide TC are non-relevant. In addition, a process solvent present in broflanilide TC was considered not to be relevant at the level declared in the manufacturing

specification. The Meeting therefore concluded that none of the manufacturing impurities in broflanilide TC need to be considered as relevant.

The analytical method for the active ingredient (including identity tests) is the CIPAC method 994/TC/M/2 & 3 published in Handbook P. The broflanilide content is determined by reversed phase HPLC, using UV detection at 254 nm and external standardization. The analytical method used for the determination of broflanilide in the TC was reverse phase HPLC/UV with detection at 226 nm, using internal standardization, which was acceptably validated. Additional bridging data were provided for the analysis of 5 batches of broflanilide TC using both the CIPAC method and the in-house method, and the results were in good agreement.

Other impurities were determined by in-house methods using HPLC-MS or GC-FID. These methods were considered acceptably validated.

The Meeting was provided with data on the melting point, temperature of decomposition, vapour pressure, octanol/water partition coefficient, solubility in water and organic solvents, dissociation content, hydrolysis and photolysis characteristics for pure broflanilide; data on the melting point and solubility in organic solvents for broflanilide TC were also reported. Test methods for determination of physico-chemical properties of the active ingredient were OECD test methods or equivalent.

Broflanilide is a white solid. It has a low vapour pressure and pKA of 8.8. Broflanilide is only slightly soluble in water; however, the solubility in water and the octanol/water partition coefficient are both pH-dependent. The active ingredient is stable to hydrolysis at pH 4, 7 and 9 at 50°C. Photochemical degradation is pH-dependent with half-lives from 3 days in basic condition to greater than 60 days in neutral conditions.

Hazard Profile

Broflanilide has been evaluated by FAO/WHO JMPR (2022) and has not been evaluated by the WHO IPCS.

Supporting Information
for
Evaluation Report 994/2022

USES

Broflanilide is an insecticide. Broflanilide is a meta-diamide insecticide and is the pro-insecticide that is metabolized to the des-methyl form. Des-methyl broflanilide is the active substance that binds to an inter-subunit allosteric site on the GABA receptor, resulting in a block of inhibitory neurotransmission, convulsions and death of target insects. Due to its unique site of action, the Insecticide Resistance Action Committee has assigned it to a new classification (Group 30: GABA-gated chloride channel allosteric modulators).

Broflanilide is used in non-agricultural settings for general insect control, vector control and also for agricultural uses in feed and food-handling establishments. Broflanilide is currently registered in Australia, Canada, China, Japan, Korea and the USA [since 2021] for agricultural and/or non-crop uses.

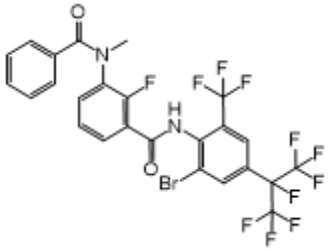
IDENTITY OF THE ACTIVE INGREDIENT

ISO common name
Broflanilide (ISO approved)

Chemical name(s)
IUPAC *N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(*N*-methylbenzamido)benzamide
CA 3-(benzoylmethylamino)-*N*-[2-bromo-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-6-(trifluoromethyl)phenyl]-2-fluorobenzamide

Synonyms
TENEBENAL™, MCI-8007, BAS 450 I, MLP-8607, Reg. No. 5672774, LS5672774, LSP5672774, MAI-7316

Structural formula



Molecular formula
$C_{25}H_{14}BrF_{11}N_2O_2$

Relative molecular mass
663.3

CAS Registry number
1207727-04-5

CIPAC number
994

Identity tests
HPLC retention time, IR, UV/Vis, ^{13}C-NMR, ^{1}H-NMR, Mass Spectrum

PHYSICO-CHEMICAL PROPERTIES OF BROFLANILIDE

Table 1. Physico-chemical properties of pure broflanilide

Parameter	Value(s) and conditions	Purity %	Method reference (and technique if the reference gives more than one)	Study number
Vapour pressure	9 x 10^{-9} Pa at 25 °C (extrapolated)	99.7	EEC A.4 OECD 104 OCSPP 830.7950 Using a vapour pressure balance	MUY0026
Melting point	154.0 to 155.5 °C	99.7	EEC A.1 OECD 102 OCSPP 830.7200 Metal block method	MUY0026
Temperature of decomposition	>180 °C	99.7	EEC A.2 OECD 103 OCSPP 830.7220 Siwoloboff method	MUY0026
Solubility in water	0.71 mg/l at 20 °C in purified water 0.28 mg/l at 20 °C at pH 4 0.51 mg/l at 20 °C at pH 7 3.6 mg/l at 20 °C at pH 10	99.7	EEC A.6 OECD 105 OCSPP 830.7840 Column elution method	MUY0011
Octanol/water partition coefficient	log P_{OW} = 5.2 at 20 °C at pH 4 log P_{OW} = 5.2 at 20 °C at pH 7 log P_{OW} = 4.4 at 20 °C at pH 10	99.7	EEC A.8 OECD 107 OCSPP 830.7550 Flask method	MUY0026
Hydrolysis characteristics	<10% degradation after 5 days at 50°C incubated at pH 4, 7, and 9 broflanilide is considered hydrolytically stable	98.1	OECD 111 OPPTS 835.2120 JMAFF 8147	2499W-1
Photolysis characteristics	In pH 7 buffer solution at 25°C DT_{50} = 845 - 1216 hours (69 - 89 OECD days, 79 -123 US-EPA days, 222 -287 JMAFF days) No major metabolites	99.7 (B-ring label) >99.9 (C-ring label)	OECD 316 OCSPP 835.2240 JMAFF 8147	2579W
Photolysis characteristics	In pH 5 buffer solution at 25°C DT_{50} = 136 - 204 hours (14 - 20 OECD days, 15 -22 US-EPA days, 44 - 64 JMAFF days) In pH 9 buffer solution at 25°C DT_{50} = 39 - 73 hours (3 - 6 OECD days, 4 - 7 US-EPA days, 11 - 21 JMAFF days)	99.7 (B-ring label) >99.9 (C-ring label)	OECD 316 OCSPP 835.2240 JMAFF 8147	2914W
Dissociation characteristics	pKa = 8.8 at 20°C	99.7	OECD 112 OCSPP 830.7370 Spectrophoto-metric method	MUY0026
Solubility in organic solvents	0.096 g/l heptane at 20 °C 6.0 g/l xylene at 20 °C 110 g/l 1,2-dichloroethane at 20 °C >250 g/l acetone at 20 °C >250 g/l methanol at 20 °C 7.4 g/l n-octanol at 20 °C >250 g/l ethyl acetate at 20 °C	99.7	EEC A.6 Flask shake method	MUY0026

Table 2. Chemical composition and properties of broflanilide 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 and or WHO. Mass balances were were 99.58 – 100.03 % and percentages of unknowns were 0.0 – 0.42%.
Declared minimum Broflanilide content	990 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

Parameter	**Value and conditions**	**Purity %**	**Method reference**	**Study number**
Melting temperature range of the TC	152.5 to 154.8 °C	97.95	OECD 102 Liquid bath method	15890.005.026.18
Solubility in organic solvents	331 g/l (acetone at 20 °C) 9.64 g/l (n-octanol at 20 °C)	98.67	OECD 105 OCSPP 830.7840 Shake Flask method	86316

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 broflanilide 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 the broflanilide technical material, based on acute toxicity, irritation and sensitization

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Rat, female	oral	99.7	OECD 425, OCSPP 870.1100. Single dose, 550, 1750 or 5000 mg/kg bw by gavage.	LD_{50} >5000 mg/kg bw	8257210
Rat, male/female	dermal	99.7	OECD 402, OCSPP 870.1200. 24 hours, 5000 mg/kg bw. At least 10% of the total body surface on the dorsum.	LD_{50} >5000 mg/kg bw	8257211
Rat, male/female	inhalation	98.7	OECD 403, OCSPP 870.1300. 4 hours, 2.20 mg/L. Nose only.	LC_{50} >2.20 mg/L	B121285
Rabbit, male	skin irritation	99.7	OCSPP 870.2500, OECD 404. 4 hours, 500 mg. 30 x 20 mm on the dorsal side.	Non-irritant	8257216
Rabbit, male	eye irritation	99.7	OCSPP 870.2400, OECD 405. Single dose, 100 mg. Left eye.	Non-irritant	8257217
Mouse, female	skin sensitisation	99.7	OPPTS 870.2600, OECD 429, (EC) No 440/2008. 3 consecutive days, 25 µL of 50% w/v solution in methyl ethyl ketone in each ear.	Does not exhibit skin sensitizing potential	58V0219/10A210
Mouse, female	skin sensitisation	99.7	OPPTS 870.2600, OECD 429. 3 consecutive days, 0, 10, 25, and 50% in dimethylformamide. Dermal.	Does not exhibit skin sensitizing potential	8257218
Guinea pig, female	skin sensitisation, range finding	98.7	OPPTS 870.2600, OECD 406, Japan MAFF 8147. Intradermal injection of 1 or 0.5% in liquid paraffin or 50:50 (v:v) FCA/saline or 24 hour topical exposure to 50, 25, 10 and 5% (w/w) in white petrolatum.	Not applicable	IET 14-0027
Guinea pig , female	skin sensitisation	98.7	OPPTS 870.2600, OECD 406, Japan MAFF 8147. Intradermal induction, topical induction and topical application challenge at 1% (w/v), 50 and 50% (w/w) for the test substance.	Negative	IET 14-0028

Table 4. Toxicology profile of the technical material based on repeated administration (subacute to chronic)

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Dog, male	Oral, range-finding	98.7	Non-guideline. 14 days, 1000 mg/kg body weight/day. Capsule.	The male Beagle dogs tolerated the administration of broflanilide via capsules at a dose level of 1000 mg/kg body weight over a period of 2 weeks.	10D0219/10D163
Dog, male/female	Oral, 28-day	98.7	OECD 407, OECD 409, Japan MAFF 8147, EC 440/2008. 4 weeks, 0, 100, 300 and 1000 mg/kg body weight per day. Capsule	NOAEL =1000 mg/kg bw/d LOAEL not established	30D0219/10D164
Mouse, male/female	Feeding, range finding, 28-day	99.5	OCSPP 870.3100, OECD 407. 28 days, 0, 200, 700, 2000 or 7000 ppm. Dietary	NOAEL =7000 ppm LOAEL not established	8262274
Rat, male/female	Feeding, combined repeated dose toxicity study with the reproduction/ developmental toxicity screening test.	99.7	OECD 422. Two weeks prior to pairing, during the pairing period and until day 22 *post partum* for the females, and until the day before necropsy for the males (Week 6). 5000, 10,000 or 15,000 ppm. Dietary.	NOAEL =15,000 ppm LOAEL not established	8222156
Rat, male/female	Feeding, maximum Tolerated Dose (MTD) Study	99.8	Non-Guideline. 20,000 ppm for three days (Days 1-3), after a 3-day non-administration period, the same animals were then fed at 10,000 ppm for three days (Day 6-8) and after a 4-day non-administration period beginning on day 12 fed at 15,000 ppm for three days (Days 12-14). Dietary.	The maximum tolerated dose (MTD) of Broflanilide following 3 days of dietary administration was concluded to be 15,000 ppm.	8222155
Mouse, male/female	Feeding, range finding, 90-day	99.5	OCSPP 870.3100, OECD 408. 13 weeks, 0, 200, 1500 or 7000 ppm. Dietary.	NOAEL =7000 ppm LOAEL not established	8262273
Rat, male/female	Feeding, 90-day	99.6	Non-Guideline. 72 days, 0, 500, 1500, 5000 and 15,000 ppm. Dietary.	NOAEL =5000 ppm LOAEL = 15,000 ppm based on lower body weight and body weight gain in male animals and lower body weight gains in female Dietary exposure to Broflanilide resulted in measurable plasma	430013

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
				levels of the parent compound and its metabolite, DM-8007. Plasma levels of DM-8007 were approximately 100-fold higher than those of the parent compound. The increase in plasma level with administered dose was sub-proportional for both parent broflanilide and its DM-8007 metabolite	
Rat, male/female	Feeding, 90-day	98.7	Non-guideline. 90 days, 0 and 30 ppm. Dietary	NOAEL =30 ppm LOAEL not established	50C0219/10S173
Rat, male/female	Feeding, 90-day	99.6	OECD 408, OPPTS 870.3100, Japan MAFF 8147, Commission Regulation (EC) No 440/2008. 90 days, 0 ppm, 500 ppm, 1500 ppm, 5000 ppm and 15,000 ppm. Dietary	NOAEL =5000 ppm LOAEL = 15,000 ppm based on lower body weight and body weight gain in male animals and lower body weight gains in female	50C0219/10S117
Dog, male/female	Oral, 90-day	98.7	OECD 409, OCSPP 870.3150, Japan MAFF 8147, (EC) No. 440/2008, B.27. 3 months, 0, 100, 300 and 1000 mg/kg body weight per day. Capsule.	NOAEL =1000 mg/kg bw/day LOAEL not established	31D0219/10D165
Dog, male/female	Oral, 1 year	98.7	OECD 452, OCSPP 870.4100, Japan MAFF 8147, (EC) No. 440/2008, B.30. 12 months, 0, 100, 300 and 1000 mg/kg body weight per day. Capsule.	NOAEL (M) =1000 mg/kg/day LOAEL not established NOAEL (F) = 300 mg/kg/day LOAEL =1000 mg/kg/day based on lower body weight	34D0219/10D177
Rat, male/female	Inhalation, range finding	98.7	Non-Guideline. 5 days, 100 mg/m³, 300 mg/m³ and 1000 mg/m³. Aerosol dust inhalation.	NOAEC = 300 mg/m³ LOAEC not established.	30I0219/10I179
Rat, male/female	Inhalation, 28-day	98.7	OPPTS 870.3465, OECD 412, EC No. 440/2008. 6 hours a day, 5 days per week for 4 weeks (20 exposures). 30 mg/m³, 200 mg/m³ and 1000 mg/m³. Aerosol dust inhalation.	NOAEC = 30 mg/m³ LOAEC = 200 mg/m³ based on minimal regenerative hyperplasia of the bronchial epithelium and cellular debris in bronchial lumina in the lungs and extramedullary hematopoiesis in the	46I0219/10I043

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
				spleen of the male and female animals	
Rat, male/female	Dermal, 28-day	98.7	OECD 410, OPPTS 870.3200. 6 hours per day on 5 days a week during a period of 4 weeks. 0, 100, 300 and 1000 mg/kg body weight/day	NOAEL =1000 mg/kg bw/day LOAEL not established	33C0219/10S178
Rat, male/female	Feeding, Combined Chronic Toxicity/Carcinogenicity	98.7	OECD 453, OPPTS 870.4300, Japan MAFF 8147, Commission Regulation (EC) No 440/2008. 104 weeks, 0, 100, 300, 1500 or 15,000 ppm. Dietary	Chronic phase (12 months) NOAEL (M) = 15,000 ppm LOAEL not established. NOAEL (F) = 1,500 ppm (F) LOAEL = 15,000 ppm based on changes in clinical chemistry parameters Carcinogenicity phase (24 months) NOAEL (M) = 300 ppm LOAEL = 1,500 ppm NOAEL (F) = 100 ppm LOAEL = 300 ppm At the LOAEL and above (carcinogenicity phase) Leydig cell hyperplasia was observed in males and an increased incidence of uterine glandular hyperplasia in females. The carcinogenic threshold (LOAEL) is considered to be 1500 ppm in males and 300 ppm in females (Leydig cell tumors and ovarian tumors in males and females, respectively).	80C0219/10S142
Mouse, male/female	Feeding, Combined Chronic Toxicity/Carcinogenicity	98.7	OCSPP 870.4200, OECD 451, Japan MAFF 8147. 78 weeks, 0, 200, 1500 or 7000 ppm. Dietary	NOAEL = 7,000 ppm LOAEL not established. There was no evidence for carcinogenicity of Broflanilide in male or female mice.	8263556

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Rat, male/female	Feeding, 2 generation reproduction	98.7	OECD 416, OPPTS 870.3800, Japan MAFF 8147, EC No. 440/2008. 0, 30, 100, 300, 1500 and 15,000 ppm. Dietary	Systemic NOAEL = 300 ppm LOAEL = 1,500 ppm Fertility and reproductive (F0 and F1) NOAEL =15,000 ppm Developmental (F1 and F2) NOAEL = 15,000 ppm Developmental toxicity did not occur in the absence of parental toxicity. Therefore, neither signs of selective developmental toxicity nor evidence for increased susceptibility of the offspring were noted in this 2-generation reproduction toxicity study	76R0219/10R167
Rat, pregnant female	Teratogenicity and developmental toxicity, range finding	99.1	OECD 414, OPPTS 870.3700, (EC) No 440/2008, No L142 Gestation day(GD) 6 through GD 19. Broflanilide: 100, 300 and 1000 mg/kg body weight/day Gavage	The oral administration of broflanilide to pregnant Wistar rats from implantation to one day prior to the expected day of parturition (GD 6-19) did not cause any test substance related adverse effects at dose levels up to the limit dose of 1000 mg/kg bw/day.	10R0219/10R066
Rat, female	Teratogenicity and developmental toxicity	99.7	OECD 414, OPPTS 870.3700, Japan MAFF 8147, EC No. 440/2008. Gestation days 6 through 19, 100, 300 and 1000 mg/kg body weight/day. Aqueous suspension gavage.	There were no test substance-related adverse effects on dams, gestational parameters or fetuses. The NOAEL for maternal toxicity and prenatal developmental toxicity is 1000 mg/kg body weight/day. There were no toxicologically relevant adverse maternal or fetal findings.	30R0219/10R080
Rabbit, pregnant female	Teratogenicity and developmental	99.6	Non-guideline. From day 6-28 of gestation. 0, 100,	Oral administration of broflanilide up to the limit dose of 1000	20R0219/10R137

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
	toxicity, range finding		300 and 1000 mg/kg bw/day. Gavage.	mg/kg bw/day from gestational day 6 to 28 was well tolerated by pregnant rabbits.	
Rabbit, non-pregnant female	Teratogenicity and developmental toxicity, range finding	99.6	Non-guideline. 14 days, . 0, 100, 300 and 1000 mg/kg bw/day. Gavage.	The non-pregnant rabbits used in this study tolerated the administration of Broflanilide up to the limit dose of 1000 mg/kg bw/day over 14 days.	01R0219/10R135
Rabbit, female	Teratogenicity and developmental toxicity	98.7	OECD 414, OPPTS 870.3700, Japan MAFF 8147, EC No. 440/2008. Day 6 to 28 of gestation, 0, 100, 300 and 1000 mg/kg bw/day. Gavage.	There were no effects on maternal reproductive parameters or signs of toxicity. There were no effects on fetal parameters or visceral and skeletal malformations and variations considered to be treatment related. The maternal and developmental no-observable-adverse-effect-level (NOAEL) of broflanilide are both 1000 mg/kg/day.	40R0219/10R166
Rat, male/female	Acute neurotoxicity, range finder	98.7	Non-guideline. Single dose, 2000 mg/kg bw. Gavage.	The single administration of broflanilide by gavage to male and female Wistar rats at a dose level of 2000 mg/kg body weight did not cause any test substance-related adverse signs of toxicity during the observation period.	60C0219/10S015
Rat, male/female	Acute neurotoxicity	98.7	OECD 424, OPPTS 870.6200, (EC) No 440/2008. Single dose of0, 200, 600 and 2000 mg/kg body weight. Gavage.	The no observed adverse effect level (NOAEL) was 2000 mg/kg body weight (highest dose tested; HDT) for male and female animals with regard to systemic toxicity or neurotoxicity. There were no indications of structural damage to the neurons at dose levels of up to and including 2000 mg/kg body weight.	61C0219/10S040

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Rat, male/female	90-day oral neurotoxicity	98.7	OECD 424, OPPTS 870.6200, Commission Regulation (EC) No 440/2008, B43. 90 days, 0, 1500, 5000 or 15,000 ppm. Dietary.	NOAEL = 15,000 ppm LOAEL not established	63C0219/10S169

Table 5. Mutagenicity profile of the technical material based on in vitro and in vivo tests

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Salmonella typhimurium/ Escherichia coli	Genotoxicity	99.7	OECD 471, OCSPP 870.5100, EC 440/2008 B.13/B.14. 48-72 hours, 33 to 10,000 µg/plate in DMSO in the presence and absence of an induced rat liver metabolic activation using the pre-incubation procedure	Broflanilide is not mutagenic in the *Salmonella typhimurium/Escherichia coli* reverse mutation assay	40M0219/10M041
Chinese hamster lung fibroblast cell line (CHL/IU)	Genotoxicity	99.7	OCSPP 870.5375, OECD 473, Japan MAFF 8147. 6 hours at exposure concentrations of 72.0 to 5000 µg/mL with and without S9 metabolic activation.	Broflanilide does not induce chromosome aberrations in cultured mammalian cells	C138 (077-093)
Chinese hamster ovary (CHO) cells	Genotoxicity	98.7	OECD 476, OCSPP 870.5300, Commission Regulation (EC) No 440/2008, B17. 4 hours, 1st Experiment: Without S9-mix: 39.1, 78.1, 156.3, 312.5, 625.0, 1250.0, 2500.0, and 5000.0 µg/mL exposure medium. With S9-mix: 39.1, 78.1, 156.3, 312.5, 625.0, 1250.0, 2500.0, and 5000.0 µg/mL exposure medium. 2nd Experiment: Without S9-mix: 10.0, 20.0, 40.0, 80.0, 160.0, 320.0, 640.0 and 128.0 µg/mL exposure medium. With S9-mix: 10.0, 20.0, 40.0, 80.0, 160.0, 320.0, 640.0 and 128.0 µg/mL exposure medium.	Broflanilide is not mutagenic in the HPRT locus assay using CHO cells.	50M0219/10M213
Mouse, male	Genotoxicity	98.7	OCSPP 870.5395, OECD 474, EC No.440/2008 B.12. Single dose of 0, 500, 1000, and 2000 mg/kg bw	Broflanilide does not induce the formation of micronuclei in mouse polychromatic erythrocytes	26M0219/10M100

Table 6. Ecotoxicology profile of the technical material

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Daphnia magna (water flea)	Acute toxicity	98.7	OCSPP 850.1010, OECD 202. 48 hours. Static renewal. 21, 40, 68, 148 and 332 µg a.i./L.	EC_{50} >0.332 mg/L	236A-171
Crassostrea virginica (eastern oyster)	Acute toxicity	98.7	OCSPP 850.1025. 96 hours. Flow through. 0.030, 0.069, 0.14, 0.22 and 0.43 mg a.i./L	LC50 > 0.43 mg a.i./L NOEC = 0.43 mg a.i./L	986.6304
Americamysis bahia (saltwater mysis)	Acute toxicity	98.7	OCSPP 850.1035. 96 hours. Flow through. 0.024, 0.043, 0.077, 0.14 and 0.25 µg a.i./L	LC50 = 0.000024 mg a.i./L NOEC = 0.000012 mg a.i./L	147A-306B
Daphnia magna (water flea)	Chronic toxicity	98.7	OECD 211, OCSPP 850.1300. 21 days. Semistatic. 1.41, 2.86, 5.84, 11.31, 21.55 and 37.73 µg a.i./L.	NOEC = 0.00584 mg a.i./L	706454
Americamysis bahia (saltwater mysis)	Chronic toxicity	98.7	OCSPP 850.1350. 28 days. Flow through. 1.8, 3.0, 6.3, 13 and 28 ng a.i./L	NOEC = 0.0063 mg a.i./L	147A-309A
Chironomus dilutus (freshwater midge)	Sub-chronic toxicity	99.9	OCSPP 850.1735. 10 days. Static renewal.	LC50/EC50 = 0.01 mg a.i./kg dry sediment NOEC = 0.0048 mg a.i./kg dry sediment	986.6243
Hyalella Azteca (freshwater amphipod)	Sub-chronic toxicity	98.7	OCSPP 850.1735. 10 days. Static renewal.	LC50/EC50 = 0.015 mg a.i./kg dry sediment NOEC = 0.0095 mg a.i./kg dry sediment	986.6244
Leptocheirus plumulosus (estuarine amphipod)	Sub-chronic toxicity	98.7	EPA 850.1740, EPA 850.1735. 10 days.	LC50 = 0.014 mg a.i./kg dry sediment NOEC = 0.0096 mg a.i./kg dry sediment	986.6245
Hyalella Azteca (freshwater amphipod)	Chronic toxicity	98.7	EPA 100.4. 42 days. Static renewal	NOEC = 0.0066 mg a.i./kg dry sediment, 0.0002 mg a.i./L (28 d) NOEC = 0.0032 mg a.i./kg dry sediment, 0.000099 mg a.i./L (42 d)	986.6282
Chironomus dilutus (freshwater midge)	Chronic toxicity	99.9	EPA 100.5, OPPTS 850 (supplemental). 60 days. Static renewal	NOEC = 0.0015 mg a.i./kg dry sediment, 0.000028 mg a.i./L (17 d) NOEC = 0.0015 mg a.i./kg dry sediment, 0.000028 mg a.i./L (60 d)	986.6246
Leptocheirus plumulosus	Chronic toxicity	98.7	EPA/600/R-01/020. 28 days. Static renewal	NOEC = 0.0085 mg a.i./kg dry	986.6283

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
(estuarine amphipod)				sediment, 0.000034 mg a.i./L	
Cyprinodon variegatus (sheepshead minnow)	Acute toxicity	98.7	OCSPP 850.1075, OECD 203. 96 hours. Flow through. 0.08, 0.15, 0.32, 0.65 and 1.3 mg a.i./L	LC50 > 1.3 mg a.i./L NOEC = 0.15 mg a.i./L	147A-307
Oncorhynchus mykiss (rainbow trout)	Acute toxicity	98.7	OCSPP 850.1075, EEC C.1, OECD 203, JMAFF Guideline 2-7-1-1, ASTM Standard E 729-96. 75, 150, 300, 600 and 1200 µg a.i./L (nominal). 96hour static renewal.	LC50 = 0.359 mg a.i./L NOEC = 0.132 mg a.i./L	236A-168
Cyprinus carpio (common carp)	Acute toxicity	98.7	OECD 203, OCSPP 850.1075, JMAFF 2-7-1-1, ASTM E 729-96. 75, 150, 300, 600 and 1200 µg a.i./L (nominal). 96hour static renewal.	LC50 > 0.498 mg a.i./L NOEC = 0.241 mg a.i./L	236A-169
Lepomis macrochirus (bluegill)	Acute toxicity	98.7	OECD 203, OCSPP 850.1075, JMAFF 2-7-1-1, ASTM E 729-96. 75, 150, 300, 600 and 1200 µg a.i./L (nominal). 96hour static renewal.	LC50 > 0.246 mg a.i./L NOEC = 0.158 mg a.i./L	236A-167
*Pimephales promelas (*Fathead Minnow)	Acute toxicity	98.7	OECD 203, OCSPP 850.1075. 96-hour flow-through. 63, 125, 250, 500 and 1000 µg a.i./L (nominal).	LC50 > 0.511 mg a.i./L NOEC = 0.511 mg a.i./L	147A-326
Cyprinodon variegatus (sheepshead minnow)	Early life stage toxicity	98.7	OPPTS 850.1400, OECD 210. 34-day flow-through. 9.0, 18, 35, 70 and 140 µg a.i./L (nominal)	NOEC = 0.010 mg a.i./L	147A-310B
Pimephales promelas (fathead minnow)	Early life stage toxicity	98.7	OPPTS 850.1400, OECD 210. 33-day flow-through. 9.5, 31, 98, 313 and 1000 µg a.i./L	NOEC = 0.051 mg a.i./L	147A-330
Oncorhynchus mykiss (rainbow trout)	Bioconcentration potential of the active substance in fish	Radiolabeled test substance radiochemical purity >98 Non-radiolabeled test substance 99.7	OECD 305, OPPTS 850.1730, 28-days exposure, 10-days post-exposure. Flow through at 1 µg a.i./L and 10 µg a.i./L (nominal).	BCF_{SS} = 102-123 BCF_{KGL} = 189-234	MUY0012
Oncorhynchus mykiss (rainbow trout)	Bioconcentration potential of the active substance in fish, Screening test	Radiolabeled test substance 99.3	OECD 305, OPPTS 850.1730, 28-days exposure. Flow through at 0.2 µg a.i./L (nominal).	BCF_{KGL} = 181-303	236A-137
Lemna gibba (duckweed)	Acute toxicity	98.7	OCSPP 850.4400, OECD 221. 7 days. Static renewal.	EyC50 >0.63 mg a.i./L	147P-120A

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
				ECr50 > 0.63 mg a.i./L NOEC = 0.63 mg a.i./L	
Anabaena flos-aquae (cyanobacteria)	Acute toxicity	98.7	OCSPP 850.4500, OECD 201, EEC C.3. 96 hours.	EyC50 > 0.66 mg a.i./L ErC50 > 0.66 mg a.i./L EbC50 > 0.66 mg a.i./L NOEC = 0.66 mg a.i./L	147P-118A
Navicula pelliculosa (freshwater diatom)	Acute toxicity	98.7	OCSPP 850.4500, OECD 201, EEC C.3. 96 hours.	EyC50 > 0.40 mg a.i./L ErC50 > 0.40 mg a.i./L EbC50 > 0.40 mg a.i./L NOEC = 0.14 mg a.i./L	147P-119A
Pseudokirchneriella subcapitata (freshwater alga)	Acute toxicity	98.7	OECD 201. 72 hours.	EyC50 >0.60 mg a.i./L ErC50 >0.60 mg a.i./L EbC50 >0.60 mg a.i./L NOEC = 0.60 mg a.i./L	236P-105
Raphidocelis subcapitata (freshwater alga)	Acute toxicity	98.7	OCSPP 850.4500, OECD 201, EEC C.3. 96 hours.	ErC50 > 0.71 mg a.i./L NOEC = 0.12 mg a.i./L	236P-108
Skeletonema costatum (marine diatom)	Acute toxicity	98.7	OCSPP 850.4500, OECD 201. EEC C.3. 96 hours. 0.063, 0.13, 0.25, 0.50, 1.0 mg a.i./L	EyC50 = 0.31 mg a.i./L ErC50 > 0.33 mg a.i./L NOEC = 0.25 mg a.i./L	147P-114B
Eisenia fetida (earthworm)	Acute toxicity	98.7	OECD 207, ISO 11268-1, OPPTS 850 Supplemental	LC_{50} > 1000 mg a.i./kg dry soil NOEC ≥ 1000 mg/kg dry soil	15 10 48 156 S
Eisenia fetida (earthworm)	Sublethal toxicity	98.7	OECD 222. 56 days. 5.29, 9.53, 17.15, 30.86, 55.56 and 100 mg a.i./kg dry soil.	28-d NOEC ≥ 100 mg ai/kg dry soil 56-d NOEC = 30.86 mg ai/kg dry soil	15 10 48 155 S
Apis mellifera (honeybee)	Adult acute contact toxicity	98.7	OECD 213 and 214. 96 hours Single application at 30.0, 15.0, 7.5, 3.7 and 1.9 ng a.i./bee. Temperature: 24.7 °C – 25.2 °C; relative humidity: 55 % - 62 %.	LD_{50} = 10.3 ng a.i./bee	15 10 48 096 B
Apis mellifera (honeybee)	Adult acute oral toxicity	98.7	OECD 213 and 214. 96 hours at 30.0, 18.0, 10.8, 6.5 and 3.9 ng a.i./bee. Temperature: 24.7 °C – 25.2 °C; relative humidity: 55 % - 62 %.	LD_{50} = 15.2 ng a.i./bee	15 10 48 096 B,

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Apis mellifera (honeybee)	Larval acute contact toxicity	98.7	OECD 237, OPPTS 850 Supplemental. 96 hour. Single	LD50 > 30 ng a.i./larva; LC50 > 0.909 mg a.i./kg-food; NOED = 11.5 ng a.i./larva; NOEC = 0.349 mg a.i./kg-food	15 10 48 036 B
Bombus terrestris (bumblebee)	Acute oral toxicity	98.7	OECD 213 and 214, OPPTS 850 supplemental. 96 hours at 80.2, 40.1, 20.0, 10.0 and 5.0 ng a.i./bee.	LD_{50} =19.5 ng a.i./bee	15 10 48 097 B
Bombus terrestris (bumblebee)	Acute contact toxicity	98.7	OECD 213 and 214, OPPTS 850 supplemental. 96 hours at 120, 60.0, 30.0, 15.0 and 7.5 ng a.i./bee.	LD_{50} > 120 ng a.i./bee	15 10 48 097 B
Apis mellifera (honeybee)	Adult chronic toxicity	98.7	Revised Proposal for a New OECD Guideline. 10 days	LDD50 = 1.329 ng a.i./bee/day; LC50 = 0.038 mg a.i./kg-food; NOED = 0.620 ng a.i./bee/day; NOEC = 0.018 mg a.i./kg-food	15 10 48 035 B
Apis mellifera (honeybee)	Larval chronic toxicity	98.7	OECD 239, OPPTS 850 Supplemental. 22 days.	Larval mortality: NOED = 0.37 ng a.i./larva NOEC = 0.0024 mg a.i./kg-food Emergence: NOED = 3.33 ng a.i./larva NOEC = 0.022 mg a.i./kg-food	15 10 48 098 B
Anas platyrhynchos (mallard duck)	Acute toxicity	98.7	OCSPP 850.2100. Single dose	LD 50 >2000 mg a.i./kg-bw NOEL ≥2000mg a.i./kg-bw	13W0219/10W019
Colinus virginianus (northern bobwhite)	Acute toxicity	98.7	OCSPP 850.2100. Single dose	LD 50 >2000 mg a.i./kg-bw NOEL >2000mg a.i./kg-bw	986.4122
Serinus canaria (canary)	Acute toxicity	98.7	OCSPP 850.2100. Single dose.	LD 50 >2000 mg a.i./kg-bw NOEL ≥2000mg a.i./kg-bw	15W0219/10W018
Anas platyrhynchos (mallard duck)	Short-term dietary	98.7	OECD 205, OCSPP 850.2200. 5 days. Dietary feeding.	LC50 > 5000 ppm (2081 mg a.i./kg-bw/day)	147B/312
Colinus virginianus (northern bobwhite)	Short-term dietary	98.7	OECD 205, OCSPP 850.2200. 5 days. Dietary feeding.	LC50 > 5000 ppm (1364 mg a.i./kg-bw/day)	147B-311
Anas platyrhynchos (mallard duck)	Subchronic and reproductive toxicity	98.7	OCSPP 850.2300, OECD 206. Dietary feeding. 250, 500 and 1000 ppm a.i.	NOEC < 250 ppm; (< 32.8 mg a.i./kg-bw/day)	147B-285

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Colinus virginianus (northern bobwhite)	Subchronic and reproductive toxicity	98.7	OCSPP 850.2300, OECD 206. Dietary feeding. 250, 500 and 1000 ppm a.i.	NOEC = 1000 ppm a.i. (88.1 mg a.i./kg-bw/day)	147B-281
Anas platyrhynchos (mallard duck)	Subchronic and reproductive toxicity	98.7	OCSPP 850.2300, OECD 206. Dietary feeding. 30, 90 and 270 ppm a.i.	NOEC = 90 ppm a.i. (13.0 mg a.i./kg-bw/day)	147B-327

Annex 2: References

Study number	Year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study
MUY0026	2017	MCI-8007 (BAS 450 I) (Pure Grade) Physico-chemical Properties. Study MUY0026. Report MUY0026. GLP. Envigo CRS Limited, United Kingdom. Unpublished.
MUY0011	2017	MCI-8007 (BAS 450 I) Water Solubility. Study MUY0011. Report MUY0011. GLP. Envigo CRS Limited, United Kingdom. Unpublished.
2499W-1	2016	Hydrolysis of [14C]MCI-8007 at pH 4, 7 and 9. Study 2499W. Report 2499W-1. GLP. PTRL West, USA. Unpublished.
2579W	2017	Direct Aqueous Photodegradation of [14C]MCI-8007 (also known as [14C]broflanilide or [14C]BAS 450 I). Study 2579W. Report 2579W-2. GLP. EAG Laboratories, USA. Unpublished.
2914W	2017	Direct Aqueous Photodegredation of [14C]Broflanilide (also known as MCI-8007 and BAS 450 I) in pH 5 and pH 9 Buffer. Study 2914W. Report 2914W-1. GLP. EAG Laboratories, USA. Unpublished.
15890.005.026.18	2019	Melting point or range of MCI-8007 (Technical grade). Study 15890.005.026.18. Report 15890.005.026.18. GLP. Bioagri Laboratórios, Brazil. Unpublished.
15890.005.026.18	2020	Melting point or range of MCI-8007 (Technical grade), Amendment nº 01 to the Final Report. Study 15890.005.026.18. Report 15890.005.026.18. GLP. Bioagri Laboratórios, Brazil. Unpublished.
86316	2020	Solubility in organic solvent of MCI-8007 (Technical grade). Study 86316. Report 86316. GLP. Chemicals Evaluation and Research Institute, Japan. Unpublished.
8257210	2012	MLP-8607: Acute Oral Toxicity Study in the Female Rat (Up and Down Method). Study 8257210. Report 8257210. Covance Laboratories, Ltd, United Kingdom. Unpublished.
8257211	2012	MLP-8607: Acute Dermal Toxicity Study in the Rat. Study 8257211. Report 8257211. Covance Laboratories, Ltd, United Kingdom. Unpublished.
B121285	2014	An Acute Inhalation Toxicity Study of MCI-8007 in Rats. Study B121285. Report B121285. GLP. Mitsubishi Chemical Medience Corporation, Japan. Unpublished.
8257216	2012	MLP-8607: Assessment of Skin Irritation. Study 8257216. Report 8257216. GLP. Covance Laboratories, Ltd, United Kingdom. Unpublished.
8257217	2012	MLP-8607: Assessment of Ocular Irritation. Study 8257217. Report 8257217. GLP. Covance Laboratories, Ltd, United Kingdom. Unpublished.
58V0219/10A210	2012	MLP-8607: Murine Local Lymph Node Assay (LLNA). Study 58V0219/10A210. Report 58V0219/10A210. GLP. BASF SE, Germany.
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