

WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES

ISOCYCLOSERAM



WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

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DISCLAIMER¹

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.

WHO disclaims any and all liability for any injury, death, loss, damage or other prejudice of any kind that may be arise as a result of, or in connection with, the manufacture, sale, transportation, storage, handling, preparation and/or use of pesticides which are found, or are claimed, to have been manufactured to comply with these specifications.

Additionally, WHO wishes to alert users to the fact that improper storage, handling, preparation and/or use of pesticides can result in either a lowering or complete loss of safety and/or efficacy.

WHO is not responsible, and does not accept any liability, for the testing of pesticides for compliance with the specifications, nor for any methods recommended and/or used for testing compliance. As a result, WHO does not in any way warrant or represent that any pesticide claimed to comply with a WHO specification actually does so.

¹ This disclaimer applies to all specifications published by WHO.

INTRODUCTION

WHO establishes and publishes specifications¹ 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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ISOCYCLOSERAM INFORMATION

ISO common name: Isocycloseram

Synonyms: SYN547407

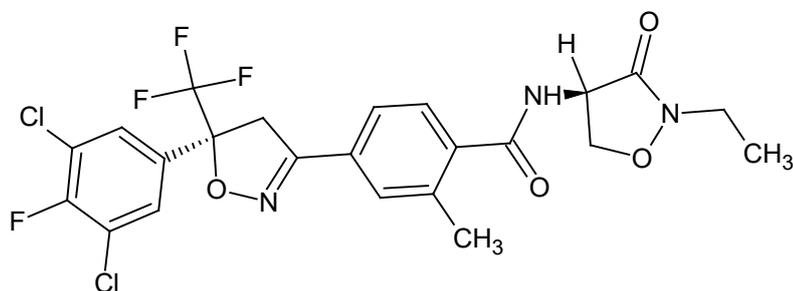
Chemical names:

IUPAC (PIN): mixture comprised of 80–100% 4-[(5*S*)-5-(3,5-dichloro-4-fluorophenyl)-5-(trifluoromethyl)-4,5-dihydro-1,2-oxazol-3-yl]-*N*-[(4*R*)-2-ethyl-3-oxo-1,2-oxazolidin-4-yl]-2-methylbenzamide and 20–0% of the (5*R*,4*R*), (5*R*,4*S*) and (5*S*,4*S*) isomers

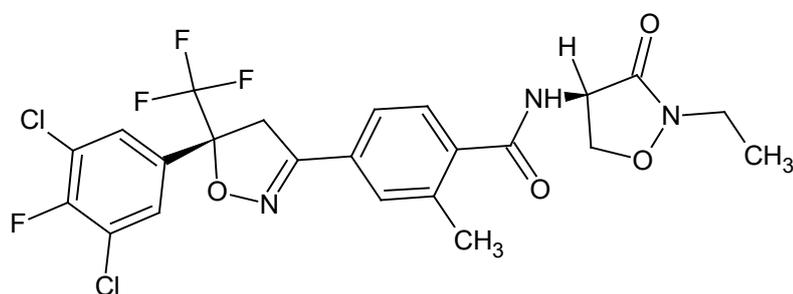
CA: 4-[5-(3,5-dichloro-4-fluorophenyl)-4,5-dihydro-5-(trifluoromethyl)-3-isoxazolyl]-*N*-(2-ethyl-3-oxo-4-isoxazolidinyl)-2-methylbenzamide

Structural formulae:

5*S*,4*R*-isomer

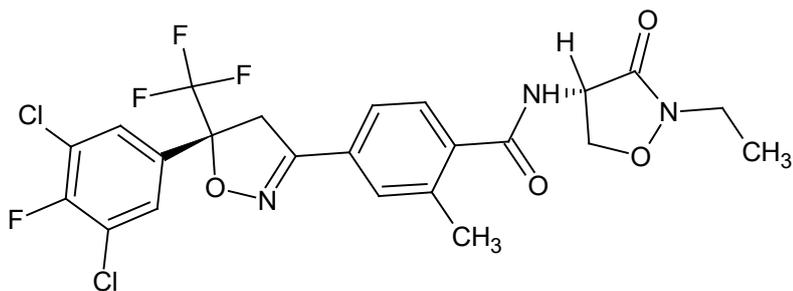


5*R*,4*R*-isomer

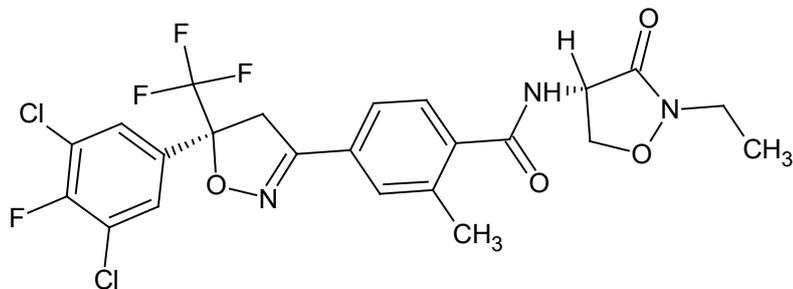


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5R,4S-isomer



5S,4S-isomer



Molecular formula:

$C_{23}H_{19}Cl_2F_4N_3O_4$

Relative molecular mass:

548.3

CAS Registry number:

2061933-85-3

CIPAC number:

1025

Identity tests:

HPLC retention time, UV spectrum, IR spectrum.

ISOCYCLOSERAM TECHNICAL MATERIAL

WHO Specification 1025/TC (April 2025*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (1025/2025). This specification should be applicable to TC produced by these manufacturers, 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 reports (1025/2025), as PART TWO, form an integral part of this publication.

1 Description

The material shall consist of isocycloseram together with related manufacturing impurities, in the form of a white to beige powder, and shall be free from visible extraneous matter and added modifying agents, except stabilizers if required.

2 Active ingredient

2.1 Identity tests (1025/TC/M/2, CIPAC Handbook Q, p.86, 2024)

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 Isocycloseram content (1025/TC/M/3, CIPAC Handbook Q, p.89, 2024)

The isocycloseram content shall be declared (not less than 960 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

2.3 Isocycloseram isomer ratio (1025/TC/M/2.2, CIPAC Handbook Q, p.86, 2024)

The isocycloseram 5*S*,4*R*-isomer content shall be at least 80% of the total isocycloseram content as measured under 2.2.

* 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>

PART TWO: EVALUATION REPORTS

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FAO/WHO EVALUATION REPORT 1025/2025

Recommendations

The Meeting recommended that the specification for isocycloseram TC, proposed by Syngenta Crop Protection AG, should be adopted by WHO.

Appraisal

The Meeting considered data and information submitted in 2022–2024 by Syngenta Crop Protection AG ("Syngenta") in support of development of a new WHO specification for isocycloseram TC. The data submitted met the requirements of the Manual on development and use of FAO and WHO specifications for chemical pesticides (2022, second edition). Isocycloseram consists of four stereoisomers, with 80–100% 5*S*,4*R*-isomer and 20–0% of the (5*R*,4*R*), (5*R*,4*S*) and (5*S*,4*S*) isomers.

The toxicology of isocycloseram was evaluated by the FAO/WHO JMPR in 2023.

Isocycloseram TC has been registered in Australia. A notice of approval has been received (APVMA, Nov 2021). Registration is being pursued in the USA.

Isocycloseram is a white to beige powder. It has a low vapour pressure. The compound has no potentially dissociating functional groups, possesses low water solubility and the octanol/water partition coefficient at pH 5-6 at 20°C is 5. The active ingredient undergoes rapid degradation by hydrolysis at pH 9 at 25°C. In simulated sunlight, there is degradation with half-life of 38.4 days at pH 4.

The manufacturer submitted confidential data on the manufacturing process, together with the manufacturing specification and 5-batch analysis data on isocycloseram TC purity and all detectable impurities at or above 1 g/kg.

The batches analyzed in the 5-batch study were produced over 3 months in 2018. The mass balance in the 5 batches ranged from 991 to 993 g/kg. The specified minimum purity of isocycloseram in the TC is 960 g/kg. The minimum purity, the isomer ratio, and the maximum limits for the impurities were supported by the 5-batch data and are statistically justified. The 5-batch study report indicates that no other significant impurities (each at or above 1 g/kg) were found in any of the 5 batches.

Based on available toxicological information, *in silico* modelling and the criteria of the Manual, the Meeting concluded that no impurities should be considered as relevant at the specified limits.

The identity of isocycloseram is confirmed by comparing the retention time in the HPLC method and by IR spectroscopy. The 5-batch analysis study was performed according to GLP guidelines. Validated in-house methods were used for the determination of isocycloseram content (reversed-phase UHPLC with UV detection) and isomer ratio (chiral UHPLC with UV detection) in the technical material. GLP analytical bridging studies were submitted, which demonstrated that in-house methods led to comparable results as CIPAC methods 1025/TC/M/3 and 1025/TC/M/2.2, respectively. Validated in-house methods (reversed-phase UHPLC with UV detection, or GC with flame ionization detection) were used for the determination of organic manufacturing impurities. Water was determined using the CIPAC method MT 30.6 (Karl Fischer

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titration). All the analytical methods used in the 5-batch analysis study were adequately validated with their specificity, linearity of response, accuracy, repeatability and limits of detection and quantification (for impurities).

Test methods for determination of physical-chemical properties of the technical active ingredient were essentially OECD and CIPAC methods, as indicated in the supporting data.

Isocycloseram is of low toxicity following acute exposure. The acute oral median lethal dose (LD₅₀) is greater than 4500 mg/kg bw in female rats and the dermal LD₅₀ is greater than 5000 mg/kg bw in female rats under the experimental conditions employed. Acute inhalation exposure was conducted for 4 hours nose-only in male and female rats. The combined median lethal concentration (LC₅₀) value was above 1.15 mg/L in one study (Biró, 2022) and 4.62 mg/L in another study (JMPR, 2023), the highest attainable concentration in the study. Isocycloseram was not a skin irritant to rabbits but was minimally irritating to rabbit eyes. Finally, isocycloseram obtained a positive result in a skin sensitizer murine local lymph node assay (LLNA) in mice but a negative result in the less sensitive Buehler test in guinea pigs.

JMPR selected a point of departure (POD) to derive an acute reference dose (ARfD) from an acute neurotoxicity study in rats with a NOAEL of 50 mg/kg and a LOAEL of 200 mg/kg based on decreased body weight gain, reduced food consumption and transiently depressed activity. This study was considered appropriate by JMPR for the route of duration of exposure and for the population of concern. An uncertainty factor of 100X (10X for interspecies extrapolation and 10X for intraspecies variation) is applied to establish the ARfD of 0.5 mg/kg bw (JMPR, 2023).

JMPR reported on an 18-month carcinogenicity study in mice and a chronic (24-month) carcinogenicity study in rat that support establishing a POD of 2 mg/kg/day to derive the acceptable daily intake (ADI). The mouse carcinogenicity study review identified a NOAEL of 1.7 mg/kg/day from the LOAEL of 6.7 mg/kg/day based on increased plasma cell infiltration in the mesenteric lymph nodes. The rat carcinogenicity study review identified a NOAEL of 2.3 mg/kg/day from the LOAEL of 7.0 mg/kg/day based on histopathological findings in the testes and epididymis in males. JMPR considered these studies appropriate for the route of exposure and duration and for the population of concern. JMPR has established an ADI at 0 – 0.02 mg/kg bw/day from the two chronic carcinogenicity studies in mice and rats and the safety factor of 100X (10X for interspecies extrapolation and 10X for intraspecies variation) (JMPR, 2023).

Isocycloseram was not considered carcinogenic in mice or rats and is unlikely to be genotoxic based on the chronic carcinogenicity and genotoxic studies according to JMPR (2023). Furthermore, JMPR also concluded that isocycloseram is not teratogenic (2023).

The Meeting concluded that the specifications for isocycloseram TC, proposed by Syngenta Crop Protection AG, should be adopted by WHO.

**Supporting Information
for
Evaluation Report 1025/2025**

Uses

Isocycloseram is a new broad spectrum insecticide belonging to the chemical group of isoxazolines. Isocycloseram binds to a site on the GABA receptor, resulting in a block of inhibitory neurotransmission, hyperexcitation, and death of target insects, and the mode of action is classified by the Insecticide Resistance Action Committee as a Group 30 insecticide (GABA-gated chloride channel allosteric modulators). It is used in public health against mosquitos.

Identity of the active ingredient*ISO common name*

Isocycloseram

Synonyms

SYN547407

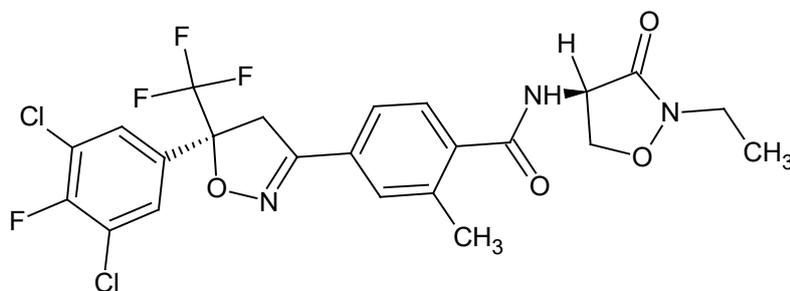
Chemical names

IUPAC (PIN)

mixture comprised of 80–100% 4-[(5*S*)-5-(3,5-dichloro-4-fluorophenyl)-5-(trifluoromethyl)-4,5-dihydro-1,2-oxazol-3-yl]-*N*-[(4*R*)-2-ethyl-3-oxo-1,2-oxazolidin-4-yl]-2-methylbenzamide and 20–0% of the (5*R*,4*R*), (5*R*,4*S*) and (5*S*,4*S*) isomers

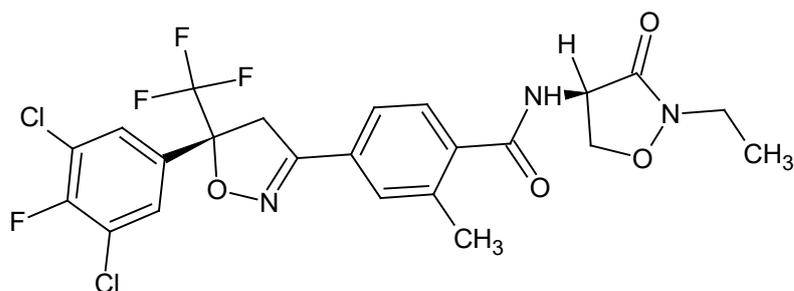
CA

4-[5-(3,5-dichloro-4-fluorophenyl)-4,5-dihydro-5-(trifluoromethyl)-3-isoxazolyl]-*N*-(2-ethyl-3-oxo-4-isoxazolidinyl)-2-methylbenzamide

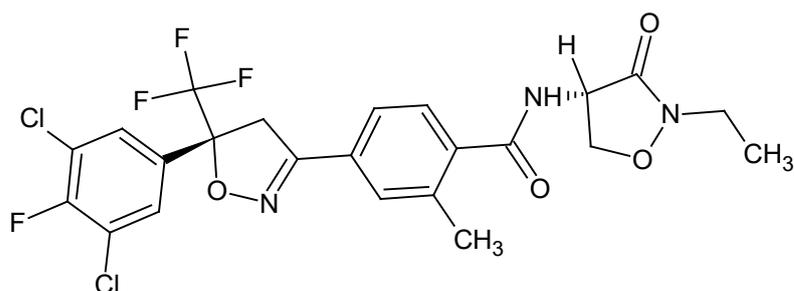
*Structural formulae*5*S*,4*R*-isomer

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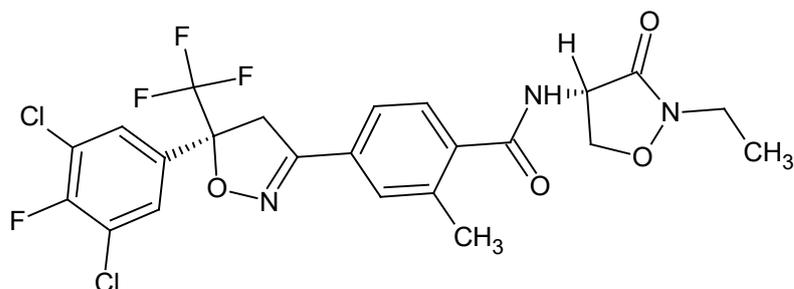
5R,4R-isomer



5R,4S-isomer



5S,4S-isomer



Molecular formula



Relative molecular mass

548.3

CAS Registry number

2061933-85-3

CIPAC number

1025

Identity tests

HPLC retention time, UV spectrum, IR spectrum.

Physico-chemical properties of isocycloseram**Table 1. Physico-chemical properties of pure isocycloseram**

Parameter	Value(s) and conditions	Purity %	Method reference (and technique if the reference gives more than one)	Study number
Vapour pressure	< $6.2 \cdot 10^{-6}$ Pa at 20 °C < $6.2 \cdot 10^{-6}$ Pa at 25 °C	98.4	OECD 104 (2006) gas saturation method	Vijayakumar (2017) SMG14076, GLP
Melting point.	138.9 °C, at 100.1 to 103.0 kPa	98.4	OECD 102 (1995) differential scanning calorimetry (DSC)	O'Connor (2017) QD17QM, GLP
Temperature of decomposition	The test item was determined to decompose from approximately 212°C (485 K) at 102.0 to 103.0 kPa. Decomposition was observed both in air and under a nitrogen atmosphere	98.4	OECD 103 (1995) differential scanning calorimetry (DSC)	O'Connor (2017) SG92NR, GLP
Solubility in water	1.2 mg / l (pure water, pH=6) at 20°C No Potential dissociating functional groups. Therefore, no other pH ranges measured	98.4	OECD 105 (1995) column elution method	Halarnakar (2017) SMG14120, GLP
Octanol/water partition coefficient	$\log P_{ow} = 5.0$ (pH=5.4) at 20°C	98.4	OECD 107 (1995) shake-flask method	Halarnakar (2017) SMG14121, GLP
Hydrolysis characteristics	At pH 4, SYN547407 was relatively stable with DegT ₅₀ values of 1290, 759, 350 and 140 days at 25, 50, 60 and 70°C, respectively. Degradation of SYN547407 was slightly faster at pH 7 than pH 4. DegT ₅₀ values of 262, 9.81, 3.14 and 1.03 days were obtained at 25, 50, 60 and 70°C, respectively. Degradation at pH 9 was rapid resulting in DegT ₅₀ values of 5.41, 1.36 and 0.348 days at 10, 25 and 35°C, respectively.	97.4- 99.7 (chemical purity); 97.4- 99.3 (radioc hemical purity)	OECD 111 (2004)	Adam (2019) 20160233, GLP
Photolysis characteristics	Photo-degradation of SYN547407 in pH 4 buffer solution was slow as a result of direct photolysis. A half-life (DegT ₅₀) of 38.4 days was determined in continuously irradiated samples under the light of the Suntest. This was calculated to be equivalent to 233.9 days of Tokyo spring sunlight at 35°N and of 72.4 days of summer sunlight at 30 to 50°N.	98.9- 99.2 (chemical purity); 97.5- 99.1 (radioc hemical purity)	OECD 316 (2008)	Wijnties, (2021) 20160284, GLP

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Dissociation characteristics	No Potential dissociating functional groups No experimental evaluation due to low water solubility	98.4	OECD 112 (1981)	O'Connor (2017) YJ47SY, GLP
Solubility in organic solvents	See for technical grade			

Table 2. Chemical composition and properties of isocycloseram technical materials (TC and/or TK)

Manufacturing process, maximum limits for impurities ³ 1 g/kg, 5 batch analysis data		Confidential information supplied and held on file by WHO. Mass balances were 99.1 -99.3 % and percentages of unknowns were 0.7 - 0.9 %.		
Declared minimum isocycloseram content		960 g/kg		
Relevant impurities ³ 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 and/or TK	135.3°C	96.9	OECD 102 DSC	B J O'Connor (2017) VV-466832
Solubility in organic solvents	at 25°C: acetone 270 g/l methanol 75 g/l dichloromethane 400 g/l octanol 17 g/l ethyl acetate 190 g/l toluene 33 g/l hexane 39 mg/l	96.9	Similar to CIPAC MT 157.3 flask method	C Vijayakumar (2017) VV-466922

Hazard summary

The toxicology of isocycloseram was evaluated by the FAO/WHO JMPR in 2023.

The JMPR concluded that the results of the long-term studies in rats and mice and a series of studies designed to evaluate genotoxicity indicated that isocycloseram is unlikely to pose a carcinogenic hazard to humans. An ADI of 0-0.02 mg/kg bw was allocated on the basis of the NOAEL using a 100-fold safety factor.

Formulations

The main formulation type available is WP.

Methods of analysis and testing

The analytical methods for the active ingredient in TC are validated in-house methods. Isocycloseram content is determined by reversed-phase UHPLC with UV detection, while the isomer ratio is determined by chiral UHPLC with UV detection. GLP analytical

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bridging studies were submitted, which demonstrated that in-house methods led to comparable results as CIPAC methods 1025/TC/M/3 and 1025/TC/M/2.2, respectively.

The methods for determination of impurities are based on reversed-phase UHPLC with UV detection, or GC with flame ionization detection, and are adequately validated.

Test methods for determination of physico-chemical properties of the technical active ingredient were essentially OECD and CIPAC methods, as indicated in the supporting data.

Containers and packaging

No special requirements for containers and packaging have been identified.

Expression of the active ingredient

The active ingredient is expressed as isocycloseram.

Annex 1: Hazard Summary Provided by the Proposer

Notes.

- (i) The proposer has confirmed that the toxicological and ecotoxicological data included in the summary below were derived from isocycloseram having impurity profiles similar to that referred to in the table above.
- (ii) The conclusions expressed in the summary below are those of the proposer, unless otherwise specified.

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

Species	Test	Purity %	Guideline, duration, doses and conditions	Result [(isomer/form)]	Study number
Rat (CrI:WI); (female)	oral	96.9	OECD425 (2008), GLP Dose levels: 1750 or 5000 mg/kg 14 day observation period	LD ₅₀ >5000 mg/kg bw	Tarcai (2016) VV-466679
Rat (SD); (males and females)	oral	96.9	P.R. of China GB/T 15670.3-2017 Dose levels: 464, 1000, 2150, 4640 or 5000 mg/kg 14 day observation period	LD ₅₀ = 4569 mg/kg bw	Xue (2021) VV-924284
Rat (CrI:WI); (males and females)	dermal	96.9	OECD402 (1987), GLP Dose levels: 5000 mg/kg 14 day observation period	LD ₅₀ >5000 mg/kg bw	Tarcia (2016) VV-466714
Rat (SD); (males and females)	dermal	96.9	P.R. of China GB/T 15670.5-2017 Dose levels: 5000 mg/kg 14 day observation period	LD ₅₀ >5000 mg/kg bw	Xue (2021) VV-937895
Rat (CrI:WI); (males and females)	inhalation	96.9	OECD403 (2009), GLP 4h nose only exposure, MMAD approx.3.38 µm 14 day observation period	LC ₅₀ = >4.62mg/L	Rosos-Matting (2016) VV-467437
Rabbit (NZW); (male)	skin irritation	98.4	OECD404 (2002), GLP Dose levels: 0.5g per animal 72hr observation period	Not irritating	Matting (2015) VV-413103
Rabbit (JW); (male)	skin irritation	96.9	P.R. of China GB/T 15670.7-2017 Dose levels: 0.5g per animal 72hr observation period	Not irritating	Xue (2021) VV-937896
Rabbit (NZW); (male)	eye irritation	98.4	OECD405 (2012), GLP Dose levels: 0.1g per left eye 72hr observation period	Minimal irritant	Matting (2015) VV-413102
Chicken eye	eye irritation	98	OECD438 (2013), GLP Dose levels: 30mg per eye 4hr observation period	Not classified as a severe irritant and not classified as non-irritant	Váliczkó (2014) VV-410146
Rabbit (JW); (male)	eye irritation	96.9	P.R. of China GB/T 15670.8-2017 Dose levels: 0.1g per right eye 72hr observation period	Slight irritant	Xue (2021) VV-937897
Mouse (CBA/Ca); (Female)	skin sensitisation	96.9	OECD429 (2010), GLP Dose levels: 10, 25, 50% (w/w) in acetone/olive oil 4:1	Skin sensitization potential	Pooles (2016) VV-466882
Guinea Pig (Dunkin Hartley); (male)	skin sensitisation	96.9	P.R. of China GB/T 15670.9-2017 Dose levels: 50% w/w in corn oil	Not a skin sensitiser	Xue (2021) VV-937898

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

Species	Test	Purity %	Guideline, duration, doses and conditions	Result [(isomer/form)]	Study number
Rat (CrI:WI), (males and females)	Short term toxicity	98	OECD407 (2008), GLP 28 day dietary oral Dose levels: 0, 50, 200, 350 or 500 ppm (males) or 0, 50, 700, 800 or 1000 ppm (females) 5/sex/group	NOAEL = 50 ppm (4.3mg/kg (male), 4.5mg/kg (female))	Dymarkowska (2017) VV-467799
Mouse (CrI:CD-1); (males and females)	Short term toxicity	98	OECD407 (2008); GLP 28 day dietary oral Dose levels: 0, 100, 300, 700 or 1000 ppm 5/sex/group	NOAEL = 100 ppm (17.4mg/kg (male), 20.9mg/kg (female))	Dymarkowska (2015) VV-467980
Dog (Beagle); (males and females)	Short term toxicity	98	OECD409 (1998), GLP 28 day capsule oral Dose levels: 0, 10, 50 and 150/80 mg/kg (males) or 0, 10, 35 and 70 mg/kg (females) 3/sex/group	NOAEL = 10mg/kg	Robertson (2019) VV-719063
Rat (CrI:WI); (males and females)	Short term toxicity	98.4	OECD408 (1998), GLP 13 week dietary oral Dose levels: 0, 50, 150 or 300 ppm (equivalent to 0, 3.9, 11.2, and 22.0 mg/kg in males and 0, 4.4, 13.4, and 24.0 mg/kg in females) 10/sex/group	NOAEL = 50 ppm in males (3.9mg/kg), 150ppm in females (13.4mg/kg)	Laidlaw (2019) VV-472306
Mouse (CRL:CD-1); (males and females)	Short term toxicity	98.4	OECD408 (1998), GLP 13 week dietary oral Dose levels: 0, 50, 300 or 700 ppm (equivalent to 0, 8.0, 48.8	NOAEL = 50 ppm equating to 8.0 mg/kg bw/day in males and 9.9 mg/kg bw/day in females	Laidlaw (2019) VV-472418

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Species	Test	Purity %	Guideline, duration, doses and conditions	Result [(isomer/form)]	Study number
			and 117 mg/kg in males and 0, 9.9, 51.6 and 140 mg/kg in females) 10/sex/group		
Dog (Beagle); (males and females)	Short term toxicity	96.9	OECD409 (1998), GLP 13 week capsule oral Dose levels: 0, 5, 15 and 35/25 mg/kg 4/sex/group	NOAEL = 15 mg/kg	Robertson (2019) VV-718750
Rat (RccHan™:WIST); (males and females)	Short term dermal toxicity	96.9	OECD410 (1981), GLP 4 week dermal Dose levels: 0, 100, 300 and 1000 mg/kg 10/sex/group	NOAEL = 100 mg/kg	Cooper (2019) VV-619265
Rat (CrI:WI); (males and females)	Carcinogenicity	96.9	OECD453 (2009), GLP 104 Week dietary oral Dose levels: 0, 20, 50 or 150 ppm (equivalent to 0, 0.9, 2.3 and 7.0 mg/kg in males and 0, 1.2, 3.0 and 9.2 mg/kg for females) 52/sex/group	NOAEL = 50 ppm (2.3/3.0 mg/kg for males/females respectively)	Strepka (2019) VV-716659
Mouse (CRL:CD-1); (males and females)	Carcinogenicity	96.9	OECD451 (2009) 80 Week dietary oral Dose levels: 0, 15, 60 or 200 ppm (equivalent to 0, 1.7, 6.7 and 23.1 mg/kg in males and 0, 1.8, 7.1 and 24.4 mg/kg for females) 50/sex/group	NOAEL = 15 ppm (1.7/1.8 mg/kg for males/females respectively)	Strepka (2019) VV-716634
Rat (CrI:WI); (males and females)	Reproductive toxicity, enhanced 1-generation	98.4	OECD415 (1983) Oral gavage Dose levels: 0, 7.5, 15, and 45/60 mg/kg (males), 0, 3.5,	NOAEL: <u>Reproductive</u> 45/60 mg/kg (males) and 15 mg/kg (females) <u>Systemic</u>	Penn (2018) VV-471049

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Species	Test	Purity %	Guideline, duration, doses and conditions	Result [(isomer/form)]	Study number
			7.5, and 15 mg/kg (females) 24/sex/group	7.5 mg/kg (males and females)	
Rat (CrI:WI); (males and females)	Reproductive toxicity, 2-generation	96.9	OECD416 (2001) Dietary oral Dose levels: 0, 1.5, 4, and 12 mg/kg 24/sex/group	NOAEL: <u>Reproductive</u> 12 mg/kg <u>Systemic</u> 4 mg/kg	Britton, King (2019) VV-471790
Rat (CrI:WI); (female)	Developmental toxicity dose ranger finding	96-97	No guideline Oral gavage Dose levels: 0, 3.5, 7.5, and 15 mg/kg 10/group	NOAEL: Not assigned in this study type	Britton (2015) VV-411304
Rat (CrI:WI); (female)	Developmental toxicity	96.9	OECD414 (2001), GLP Oral gavage Dose levels: 0, 3.5, 7.5, and 15 mg/kg 22/group	NOAEL: <u>Maternal</u> 15 mg/kg <u>Embryo-Fetal</u> 15 mg/kg	Blunt, Fincher (2019) VV-472253 Wolton, French (2020) VV-882864 DeSesso, Williams (2019) VV-882865
Rabbit (NZW); (female)	Developmental toxicity dose ranger finding	>96	No guideline Oral gavage Dose levels: 0, 7.5, 15, and 30 mg/kg 10/group	NOAEL: Not assigned in this study type	Blunt (2015) VV-411667
Rabbit (NZW); (female)	Developmental toxicity	96.9	OECD414 (2001) Oral gavage Dose levels: 0, 3.5, 7.5, and 15 mg/kg 22/group	NOAEL: <u>Maternal</u> 15 mg/kg <u>Embryo-Fetal</u> 15 mg/kg	Pottle (2017) VV-468197
Rat (RccHan™: WIST); (males and females)	Acute neurotoxicity	98.4	OECD424 (1997) Oral gavage Dose levels: 0, 50, 200, and 1000 mg/kg 10/sex/group	NOAEL: <u>General Toxicity</u> 50 mg/kg <u>Neurotoxicity</u> 1000 mg/kg	Cocker (2016) VV-466670
Rat (RccHan™: WIST); (males and females)	90 day neurotoxicity	96.9	OECD424 (1997) Dietary oral Dose levels: 0, 50, 150, 300 ppm 10/sex/group	NOAEL: General Toxicity and Neurotoxicity 300ppm (24.8 and 32.7 mg/kg for males and	Froud (2019) VV-619064

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Species	Test	Purity %	Guideline, duration, doses and conditions	Result [(isomer/form)]	Study number
				females respectively)	

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

Species	Test	Purity %	Guideline, duration, doses and conditions	Result [(isomer/form)]	Study number
Salmonella typhimurium strains TA1535, TA1537, TA98, and TA100, and the Escherichia coli strains WP2 uvrA pKM101 and WP2 pKM101	Bacterial Reverse Gene Mutation (in vitro)	96.9	3-5000 µg/plate ±S9-mix (Exp I&II) DMSO OECD471 (1997), GLP	Negative	Chang (2016) VV-465073
Salmonella typhimurium strains TA1535, TA1537, TA98, and TA100, and the Escherichia coli strains WP2 uvrA pKM101 and WP2 pKM101	Bacterial Reverse Gene Mutation (in vitro)	96.1	3-5000 µg/plate ±S9-mix (Exp I) 33-5000 µg/plate ±S9-mix (Exp II) 33-5000 µg/plate -S9-mix (Exp III) DMSO OECD471 (1997), GLP	Negative	Chang (2019) VV-619413
Mouse lymphoma L5178Y Tk +/- cells	Mammalian Gene Mutation (in vitro)	96.9	1-125 µg/mL ±S9-mix (Exp I) 1.9-77.5 µg/mL ±S9-mix (Exp II) DMSO OECD490 (2015)	Non-mutagenic	Wollny (2016) VV 465417
Mouse lymphoma L5178Y Tk +/- cells	Mammalian Gene Mutation (in vitro)	96.1	0.9-80 µg/mL ±S9-mix (Exp I) 3.13-80 µg/mL +S9-mix (Exp II) 3.2-75 µg/mL +S9-mix (Exp III) DMSO OECD490 (2016)	Non-mutagenic	Sokolowski (2019) VV-719550
Human lymphocytes	Chromosomal aberration (in vitro)	96.9	4.3-5160 µg/mL ±S9-mix (Exp I) 2.1-322.5 µg/mL -S9 mix (Exp II) DMSO OECD473 (2014)	Non-clastogenic	Chang (2016) VV-465554
Rat (CRL:WI); (male)	Micronucleus formation (in vivo)	96.9	500, 1250, 2000 mg/kg bw/day 0.5% (w/v) CMC with 0.1% (v/v) Tween 80 OECD474 (1997)	Neither clastogenic nor aneugenic	Dunton (2016) VV 465063

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Table 6. Ecotoxicology profile of the isocycloseram technical material

Species	Test	Purity %	Guideline, duration, doses and conditions	Result [(isomer/form)]	Study number
<i>Colinus virginianus</i> [Bobwhite quail]	Acute toxicity	96.9	OECD Guideline 223. 2000 mg/kg bw limit dose	LD50 > 2000 mg/kg bw	VV-465340
<i>Anas platyrhynchos</i> [Mallard duck]	Acute toxicity	96.9	OECD Guideline 223. 2000 mg/kg bw limit dose	LD50 > 2000 mg/kg bw	VV-465876
<i>Serinus Canaria</i> [Canary]	Acute toxicity	96.9	OECD Guideline 223. 1500 mg/kg bw limit dose	LD50 > 1500 mg/kg bw	VV-470612
<i>Colinus virginianus</i> [Bobwhite quail]	Short term dietary	96.9	U.S. EPA 850.2200, OECD Guideline 205. 5-day dietary study, 562, 1000, 1780, 3160, 5620 mg/kg	LC50 > 5620 mg/kg	VV-465340
<i>Anas platyrhynchos</i> [Mallard duck]	Short term dietary	96.9	U.S. EPA 850.2200, OECD Guideline 205. 5-day dietary study, 562, 1000, 1780, 3160, 5620 mg/kg	LC50 = 2000 mg/kg	VV-468375
<i>Colinus virginianus</i> [Bobwhite quail]	Chronic toxicity	96.9	U.S. EPA 850.2300, OECD Guideline 206. 21-week reproductive study, 100, 320, 1000 mg/kg	NOEC = 320 mg/kg equivalent to 21.6 mg/kg bw/d	VV-470611
<i>Anas platyrhynchos</i> [Mallard duck]	Chronic toxicity	96.9	U.S. EPA 850.2300, OECD Guideline 206. 21-week reproductive study, 100, 320, 1000 mg/kg	NOEC = 100 mg/kg equivalent to 14.6 mg/kg bw/d	VV-470610
<i>Oncorhynchus mykiss</i> [rainbow trout]	Acute toxicity	96.9	U.S. EPA 850.1075, OECD Guideline 203, 96 hr acute test 0.066, 0.12, 0.23, 0.42 and 0.94 mg/L	LC50 = 0.13 mg/L	VV-470111
<i>Pimephales promelas</i> [fathead minnow]	Acute toxicity	96.9	U.S. EPA 850.1075, OECD Guideline 203, 96 hr acute test 0.058, 0.14, 0.23, 0.48 and 0.62 mg/L	LC50 = 0.33 mg/L	VV-469970
<i>Cyprinodon variegatus</i> [sheepshead minnow]	Acute toxicity	96.9	U.S. EPA 850.1075, OECD Guideline 203, 96 hr acute test 0.064, 0.14, 0.27, 0.54 and 0.94 mg/L	LC50 = 0.29 mg/L	VV-470108
<i>Cyprinus carpio</i> [carp]	Acute toxicity	96.9	U.S. EPA 850.1075, OECD Guideline 203, 96 hr acute test 0.057, 0.12, 0.24, 0.47 and 0.97 mg/L	LC50 = 0.37 mg/L	VV-470076
<i>Pimephales promelas</i> [fathead minnow]	Chronic toxicity	96.9	U.S. EPA 850.1400, OECD Guideline 210, 28-day early life-stage toxicity test, 0.013, 0.027, 0.048, 0.11 and 0.22 mg/L	NOEC = 0.11 mg/L	VV-470291
<i>Cyprinodon variegatus</i>	Chronic toxicity	96.9	U.S. EPA 850.1400, OECD Guideline 210, 28-day early	NOEC = 0.0081 mg/L	VV-469971

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[sheepshead minnow]			life-stage toxicity test, 0.0037, 0.0081, 0.018, 0.052 and 0.13 mg/L		
<i>Daphnia magna</i> [water flea]	Acute toxicity	96.9	U.S. EPA 850.1010, OECD Guideline 202, 48 hr acute toxicity 0.0035, 0.0089, 0.021, 0.052, 0.14, 0.53 and 0.91 mg/L	EC50 = 0.52 mg/L	VV-470284
<i>Crassostrea virginica</i> [Eastern oyster]	Acute toxicity	96.9	U.S. EPA 850.1025, 96 hr acute toxicity 0.0057, 0.016, 0.031, 0.056, 0.19 and 0.50 mg/L	EC50 = 0.083 mg/L	VV-469923
<i>Mysidopsis bahia</i> [mysid shrimp]	Acute toxicity	96.9	U.S. EPA 850.1035, 96 hr acute toxicity 0.003, 0.0064, 0.013, 0.026, 0.053 and 0.12 ug/L	LC50 = 0.018 ug/L	VV-846361
<i>Hyalella azteca</i> [freshwater amphipod]	Acute toxicity	96.9	U.S. EPA 850.1020, OECD Guideline 202, JMAFF 2-7-5, 96 hr acute toxicity 0.032, 0.095, 0.27, 0.82, 2.5 and 9.2 ug/L	LC50 = 0.041 ug/L	VV-868235
<i>Chironomus riparius</i> [midge]	Acute toxicity	96.9	OECD Guideline 235, 48 hr acute toxicity 0.0011, 0.0023, 0.0056, 0.014, 0.038 and 0.096 ug/L	LC50 = 0.015 ug/L	VV-866777
<i>Caecidotea communis</i> [water louse]	Acute toxicity	96.9	U.S. EPA 850.1020, U.S. EPA 850.1000, 96 hr acute toxicity 0.038, 0.058, 0.099, 0.170 and 0.26 ug/L	EC50 = 0.15 ug/L	VV-890842
<i>Brachionus calyciflorus</i> [freshwater rotifer]	Acute toxicity	96.9	U.S. EPA 850.1000, ASTM E 1440-91, 24 hr acute toxicity 1.3, 1.8, 7.2, 20, 66, 220 and 810 ug/L	EC50 > 810 ug/L	VV-889418
<i>Hexagenia limbata</i> [mayfly]	Acute toxicity	96.9	U.S. EPA 850.1000, OECD Guideline 235, 48 hr acute toxicity <0.015, 0.032, 0.084, 0.23, 0.60 and 1.5 ug/L	EC50 = 0.32 ug/L	VV-888013
<i>Pycnopsyche gentilis</i> [caddisfly]	Acute toxicity	96.9	U.S. EPA 850.1000, OECD Guideline 235, 48 hr acute toxicity <0.015, 0.027, 0.071, 0.19, 0.51 and 1.4 ug/L	EC50 = 0.49 ug/L	VV-878602
<i>Faxonius virilis</i> [Northern crayfish]	Acute toxicity	96.9	U.S. EPA 850.1000, 96 hr acute toxicity 0.22, 0.49, 0.98, 2.1 and 3.6 ug/L	EC50 = 1.6 ug/L	VV-888912
<i>Palaemonetes paludosus</i> [grass shrimp]	Acute toxicity	96.9	U.S. EPA 850.1000, U.S. EPA 850.1045, 96 hr acute toxicity 0.058, 0.14, 0.37, 0.91 and 2.2 ug/L	EC50 = 0.25 ug/L	VV-889404
<i>Thamnocephalus platyurus</i> [Fairy shrimp]	Acute toxicity	96.9	U.S. EPA 850.1000, U.S. EPA 850.1035, 96 hr acute toxicity 0.028, 0.074, 0.22, 0.69, 2.3, 6.9 and 21 ug/L	EC50 = 0.26 ug/L	VV-892711
<i>Daphnia magna</i> [water flea]	Chronic toxicity	96.9	U.S. EPA 850.1300, OECD Guideline 211, 21-day static	NOEC = 0.063 ug/L	VV-740015

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			renewal, 0.031, 0.063, 0.13, 0.24, and 0.5 ug/L		
<i>Daphnia magna</i> [water flea]	Chronic toxicity	96.9	U.S. EPA 850.1300, OECD Guideline 211, 21-day static renewal, 0.0092, 0.015, 0.03, 0.064, 0.13 and 0.24 ug/L	NOEC = 0.03 ug/L	VV-869410
<i>Mysidopsis bahia</i> [mysid shrimp]	Chronic toxicity	96.9	U.S. EPA 850.1350, 28-day flow-through, 0.00052, 0.001, 0.0023, 0.0042 and 0.0074 ug/L	NOEC = 0.001 ug/L	VV-846373
<i>Hyalella azteca</i> [freshwater amphipod]	Chronic toxicity	96.9	U.S. EPA 100.4, US EPA 850.1770 (in preparation), 42-day intermittent-renewal, 0.019, 0.051, 0.13, 0.31, 0.77 and 2.1 ug/kg dw	NOEC = 0.77 ug/kg dw	VV-869054
<i>Leptocheirus plumulosus</i> [estuarine amphipod]	Chronic toxicity	96.9	U.S. EPA 600/R-01/020, 21-day intermittent-renewal, 0.21, 0.38, 0.79, 1.7 and 3.0 ug/kg dw	NOEC = 1.7 ug/kg dw	VV-846384
<i>Chironomus dilutus</i> [midge]	Chronic toxicity	96.9	U.S. EPA 100.5, US EPA 850.1760 (in preparation), 60-day intermittent-renewal, 0.018, 0.046, 0.12, 0.39 and 1.1 ug/kg dw	NOEC = 0.39 ug/kg dw	VV-890854
<i>Chironomus riparius</i> [midge]	Chronic toxicity	96.9	OECD 218, 28-day static, 0.085, 0.18, 0.34, 0.68, 1.5 and 2.7 ug/kg dw	NOEC = 0.68 ug/kg dw	VV-893580
<i>Pseudokirchneriella subcapitata</i> [green algae]	Chronic toxicity	96.9	U.S. EPA 850.4500, OECD 201; 96 hr algal growth inhibition assay. 0.041, 0.061, 0.11, 0.24 and 0.78 mg/L	96hr ErC50 > 0.78 mg/L	VV-469976
<i>Navicula pelliculosa</i> [freshwater diatom]	Chronic toxicity	96.9	U.S. EPA 850.4500, OECD 201; 96 hr algal growth inhibition assay. 0.023, 0.042, 0.090, 0.21 and 0.61 mg/L	96hr ErC50 > 0.61 mg/L	VV-469967
<i>Skeletonema costatum</i> [marine diatom]	Chronic toxicity	96.9	U.S. EPA 850.4500, OECD 201; 96 hr algal growth inhibition assay. 0.023, 0.044, 0.093, 0.21 and 0.54 mg/L	96hr ErC50 = 0.29 mg/L	VV-469997
<i>Anabaena flos-aquae</i> [freshwater cyanobacterium]	Chronic toxicity	96.9	U.S. EPA 850.4550, OECD 201; 96 hr freshwater cyanobacterium growth inhibition assay. 0.033, 0.050, 0.11, 0.29 and 0.69 mg/L	96hr ErC50 > 0.69 mg/L	VV-470238
<i>Lemna gibba</i> [Duckweed]	Chronic toxicity	96.9	U.S. EPA 850.4400, OECD 221; 7-day static renewal. 0.080, 0.13, 0.24, 0.50 and 1.2 mg/L	7d ErC50 > 1.2 mg/L	VV-469969
<i>Eisenia andrei</i> [earthworm]	Acute toxicity	96.9	OECD 207; 14d acute toxicity test	LC50 > 1000 mg/kg dw	VV-466604

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			62.5, 125, 250, 500 and 1000 mg/kg dry soil		
<i>Eisenia fetida</i> [earthworm]	Chronic toxicity	96.9	OECD 222; 28d chronic toxicity test 0.625, 1.25, 2.5, 5.0 and 10.0 mg/kg dry soil	NOEC = 10 mg/kg dw	VV-412931
Soil Microflora	Nitrogen and Carbon Transformation	96.9	OECD 216, OECD 217; 28d chronic transformation test 0.5 and 4.95 mg/kg dry soil	NOEC = 4.95 mg/kg dw	VV-466609
Activated sludge	Respiration inhibition test	96.9	OECD 209, ISO 8192; 3-h inhibition test 10, 32, 100, 320 and 1000 mg/L	NOEC = 100 mg/L	VV-467858
<i>Folsomia candida</i> [Collembola]	Chronic toxicity	96.9	OECD 232; 28-day toxicity test 0.009, 0.016, 0.029, 0.053, 0.095, 0.171, 0.309, 0.556 and 1.0 mg/kg dw	NOEC = 0.095 mg/kg dw	VV-412444
<i>Hypoaspis aculeifer</i> [predatory mite]	Chronic toxicity	96.9	OECD 226; 14-day toxicity test 0.009, 0.016, 0.029, 0.053, 0.095, 0.171, 0.309, 0.556 and 1.0 mg/kg dw	NOEC = 0.171 mg/kg dw	VV-412437
<i>Apis mellifera</i> [honeybee]	Acute toxicity	96.9	OECD 213, OECD 214; 96h acute oral and contact toxicity test. 0.04, 0.09, 0.21, 0.47 and 0.99 ug/bee (oral test). 0.04, 0.09, 0.20, 0.45 and 1.0 ug/bee (contact test).	72-h oral LD50 = 0.28 ug/bee 96-h contact LD50 = 0.26 ug/bee	VV-466340
<i>Bombus terrestris</i> [bumblebee]	Acute toxicity	96.9	OECD 246, OECD 247; 48h acute oral and contact toxicity test. 0.16, 0.32, 0.64, 1.35 and 2.57 ug/bee (oral test). 1.3, 2.2, 3.6, 6.0 and 10 ug/bee (contact test).	48-h oral LD50 = 0.35 ug/bee 48-h contact LD50 >10 ug/bee	VV-900003
<i>Apis mellifera</i> [honeybee]	Chronic toxicity	96.9	Based on OECD guideline proposal (2016); 10-day laboratory adult feeding test. 0.07, 0.13, 0.25, 0.5 and 1.0 mg/kg feeding solution	NOEC = 0.13 mg/kg diet NOEDD 0.0034 ug/bee/day	VV-462082
<i>Apis mellifera</i> [honeybee]	Larval toxicity test (single exposure)	96.9	OECD 237; 7-day larval toxicity test (single exposure). 0.02, 0.07, 0.22, 0.67 and 2.0 mg/kg diet	LD50 = 0.08 ug/larvae LC50 = 2.42 mg/kg diet	VV-467266
<i>Apis mellifera</i> [honeybee]	Larval toxicity test (repeat exposure through adult emergence)	96.9	OECD Draft guidance 20 July 2015; 22-day repeat exposure through feeding larval toxicity test. 0.0123, 0.0370, 0.111, 0.333 and 1.0 mg/kg diet	22d NOEC = 0.111 mg/kg diet 22d NOED = 0.0171 ug/larvae per developmental period	VV-467145

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Annex 2: References

Study number	Author(s)	year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study.
Physical Chemistry			
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VV-466821	B J O'Connor	2017	SYN547407 - Determination of Melting Temperature, GLP Testing Facility Envigo Research Limited Shardlow Business Park, Shardlow Derbyshire, DE72 2GD, UK, QD17QM, 14 February 2017, GLP. unpublished
VV-466830	B J O'Connor	2017	SYN547407 - Determination of Boiling Temperature, GLP Testing Facility Envigo Research Limited Shardlow Business Park, Shardlow Derbyshire, DE72 2GD, UK, SG92NR, 13 February 2017, GLP. unpublished
VV-466832	B J O'Connor	2017	SYN547407 - Determination of Melting Temperature using Technical Grade Material, GLP Testing Facility Envigo Research Limited Shardlow Business Park, Shardlow Derbyshire, DE72 2GD, UK, CF74TF, 20 February 2017, GLP. Unpublished
VV-466922	C. Vijayakumar	2017	SYN547407 - Solubility in Organic Solvents, GLP Testing Facility GOA Syngenta Biosciences Pvt. Ltd, Santa Monica Works, Corlim, Ilhas Goa 403 110, India, SMG14077, 3 February 2017 GLP. Unpublished
VV-466958	R. Halarnakar	2017	SYN547407 – Solubility in Water, GLP Testing Facility GOA Syngenta Biosciences Pvt. Ltd, Santa Monica Works, Corlim, Ilhas Goa 403 110, India, SMG14120, 3 March 2017. GLP. unpublished
VV-467214	C. Vijayakumar	2017	SYN547407 - Vapour Pressure, GLP Testing Facility GOA Syngenta Biosciences Pvt. Ltd, Santa Monica Works, Corlim, Ilhas Goa 403 110, India, SMG14076, 23 February 2017. GLP. unpublished
VV-467222	R. Halarnakar	2017	SYN547407 - 1-Octanol / Water Partition Coefficient, GLP Testing Facility GOA Syngenta Biosciences Pvt. Ltd, Santa Monica Works, Corlim, Ilhas Goa 403 110, India, SMG14121, 22 February 2017. GLP. unpublished
VV-732925	Dr D. Adam	2019	SYN547407 - Hydrolysis of 14C-SYN547407, Innovative Environmental Services (IES) Ltd Benkenstrasse 260 4108 Witterswil Switzerland, 20160233. 28 November 2019. GLP. unpublished
VV-733294	C. Wijntjes	2021	SYN547407 - Photolysis of 14C-SYN547407 in pH 4 Buffer Solution, Innovative Environmental Services (IES) Ltd Benkenstrasse 260 4108 Witterswil Switzerland, 20160284. 17 May 2021 GLP. unpublished
Toxicology			
SYN547407_10132	Hutton E	2017	SYN547407 – Pharmacokinetics of [Methylphenyl 14C] SYN547407 Following Single Oral and Intravenous Administration in the Rat. Charles River Laboratories Edinburgh Ltd, Tranent, East Lothian, EH33 2NE, UK. Charles River Report No. 38010. Issue date 02 October 2017. Unpublished

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VV 465417	Wollny H	2016	SYN547407 - Cell Mutation Assay at the Thymidine Kinase Locus (TK +/-) in Mouse Lymphoma L5178Y Cells. Envigo CRS GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany. Laboratory Report No. 1740700 issue date: 02 June 2016. Unpublished.
VV-230077	Thibaut, R	2019	SYN547407 – In Vitro Comparative Metabolism of [Methylphenyl-U-14C]-SYN547407, [Halophenyl-U-14C]-SYN547407 and [Oxoisoxazolidinyl-4,5-14C]-SYN547407 in Human and Rat Liver Microsomes. Innovative Environmental Services (IES) Ltd, Benkenstrasse 260, 4108 Witterswil, Switzerland. Report No. 20180274, issue date 11 April 2019. Unpublished.
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VV-411667	Blunt, H	2015	SYN547407 - Oral (Gavage) Dose Range-Finding Prenatal Developmental Toxicity Study in the Rabbit. Sequani Limited, Bromyard Road, Ledbury, Herefordshire, HR8 1LH, United Kingdom. Laboratory Report No. BFI0190, 11 March 2015. Unpublished.
VV-413102	Matting E	2015	SYN547407 - Acute Eye Irritation Study in Rabbits. CiToxLAB Hungary Ltd. H-8200 Veszprém, Szabadságpuszta Hungary, Laboratory Report No. 15/031-005N, 23 July 2015. Unpublished.
VV-413103	Matting E	2015	SYN547407 - Primary Skin Irritation Study in Rabbits. CiToxLAB Hungary Ltd. H-8200 Veszprém, Szabadságpuszta Hungary, Laboratory Report No. 15/031-006N, 23 July 2015. Unpublished.
VV-465073	Chang S	2016	SYN547407 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay. Envigo CRS GmbH GmbH, In den Leppsteinswiesen 19, 64380 Rossdorf Germany. Laboratory Report No. 1737001, issue date: 25 May 2016. Unpublished.
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