FAO SPECIFICATIONS AND EVALUATIONS FOR AGRICULTURAL PESTICIDES

CYAZOFAMID

4-chloro-2-cyano-*N,N*-dimethyl-5-*p*-tolylimidazole-1-sulfonamide

FOOD AND AGRICULTURE ORGANIZATION of THE UNITED NATIONS

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CYAZOFAMID

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

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

INTRODUCTION

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

From 2002, the development of WHO specifications follows the **New Procedure**, described in the November 2010 - second revision of the First Edition of "Manual for Development and Use of FAO and WHO Specifications for Pesticides" (2010) (the Manual) and amended with the supplements of this Manual, which is available only on the internet through the FAO and WHO web sites. This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by FAO and the Experts of the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS). [Note: prior to 2002, the Experts were of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent, which now forms part of the JMPS, rather than the JMPS.]

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

PART ONE: **The Specification** of the technical material and the related formulations of the plant protection product in accordance with chapter 4, 5 and 6 of the Manual.

PART TWO: **The Evaluation Report(s)** of the plant protection product reflecting the evaluation of the data package carried out by FAO and the JMPS. The data are to be provided by the manufacturer(s) according to the requirements of Chapter 3 of the Manual and supported by other information sources. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical material has been evaluated. Evaluation reports on specifications developed subsequently to the original set of specifications are added in a chronological order to this report.

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

Specifications bear the date (month and year) of publication of the current version. Dates of publication of the earlier versions, if any, are identified in a footnote. Evaluations bear the date (year) of the meeting at which the recommendations were made by the JMPS.

* NOTE: PUBLICATIONS ARE AVAILABLE ON THE INTERNET AT (http://www.fao.org/ag/agp/agpp/pesticid/) OR IN HARDCOPY FROM THE PLANT PROTECTION INFORMATION OFFICER.

PART ONE

SPECIFICATIONS

CYAZOFAMID

INFORMATION

ISO common name

Cyazofamid (ISO 1750 published)

Synonyms

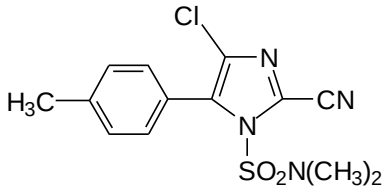
IKF-916

Chemical names

IUPAC 4-chloro-2-cyano-*N,N*-dimethyl-5-*p*-tolylimidazole-1-sulfonamide

CA 4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1*H*-imidazole-1-sulfonamide

Structural formula



Empirical formula

$C_{13}H_{13}ClN_4O_2S$

Relative molecular mass

324.8

CAS Registry number

120116-88-3

CIPAC number

653

Identity tests

Retention time in HPLC and UV spectrum

CYAZOFAMID TECHNICAL MATERIAL

FAO Specification 653 / TC (February 2015[*])

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 (653/2014). It should be applicable to TC produced by this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for TC produced by other manufacturers. The evaluation report (653/2011), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of cyazofamid together with related manufacturing impurities, in the form of an ivory, odourless solid powder, free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 **Identity tests** (653/TC/M/2, CIPAC/4833/m) (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 **Cyazofamid content** (653/TC/M/3, CIPAC/4833/m) (Note 1)

The cyazofamid content shall be declared (not less than 935 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

Note 1 The method of analysis for identification and determination of cyazofamid content in TC and SC was adopted as CIPAC Method in 2011 and became a full method in 2012. Prior to its publication in CIPAC Handbook O, copies of the method may be obtained via the CIPAC pre-published methods scheme http://www.cipac.org/cipacpub.htm

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

CYAZOFAMID AQUEOUS SUSPENSION CONCENTRATE

FAO Specification 653 / SC (February 2015*)

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 (653/2014). It should be applicable to SC produced by this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for SC produced by other manufacturers. The evaluation report (653/2011), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of a suspension of fine particles of technical cyazofamid, complying with the requirements of FAO specification 653/TC (February 2015), in the form of a beige liquid with musty latex paint odour, in an aqueous phase together with suitable formulants. After gentle agitation the material shall be homogeneous (Note 1) and suitable for further dilution in water.

2 Active ingredient

2.1 Identity tests (653/SC/M/2, CIPAC/4833/m) (Note 2)

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 Cyazofamid content (653/SC/M/3, CIPAC/4833/m) (Note 2)

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

Declared content in g/l at 20 ± 2°C	Tolerance
above 250 up to 500 Note: the upper limit is included in each range.	± 5% of the declared content

3 Physical properties

3.1 Pourability (MT 148.1, CIPAC Handbook F, p.348, 1995)

Maximum "residue": 5 %.

3.2 Spontaneity of dispersion (MT 160, CIPAC Handbook F, p.391, 1995) (Note 4)

A minimum of 95 % of the cyazofamid content found under 2.2 shall be in suspension after 5 min in CIPAC Standard Water D at 30 ± 2°C.

3.3 Suspensibility (MT 184, CIPAC Handbook K, p.142, 2003) (Note 4)

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

A minimum of 98 % of the cyazofamid content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C.

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

Maximum: 0.1 % of the formulation shall be retained on a 75 µm test sieve.

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

Maximum: 25 ml after 1 min.

4 Storage stability

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

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

- suspensibility (3.3),
- wet sieve test (3.4)

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

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 95% relative to the determined average content found before storage (Note 8) and the formulation shall continue to comply with the clauses for:

- pourability (3.1),
- spontaneity of dispersion (3.2),
- suspensibility (3.3),
- wet sieve test (3.4)

Note 1 Before sampling to verify the formulation quality, inspect the commercial container carefully. On standing, suspension concentrates usually develop a concentration gradient from the top to the bottom of the container. This may even result in the appearance of a clear liquid on the top and/or of sediment on the bottom. Therefore, before sampling, homogenize the formulation according to the instructions given by the manufacturer or, in the absence of such instructions, by gentle shaking of the commercial container (for example by inverting the closed container several times). Large containers must be opened and stirred adequately. After this procedure, the container should not contain a sticky layer of non-dispersed matter at the bottom. A suitable and simple method of checking for a non-dispersed sticky layer "cake" is by probing with a glass rod or similar device adapted to the size and shape of the container. All the physical and chemical tests must be carried out on a laboratory sample taken after the recommended homogenization procedure.

Note 2 The method of analysis for identification and determination of cyazofamid content in TC and SC was adopted as CIPAC Method in 2011 and became a full method in 2012. Prior to its publication in CIPAC Handbook O, copies of the method may be obtained via the CIPAC pre-published methods scheme http://www.cipac.org/cipacpub.htm

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

Note 4 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of the chemical assay method. In case of dispute, the chemical method shall be the referee method.

Note 5 This test detects coarse particles (e.g. caused by crystal growth) or agglomerates (crust formation) or extraneous materials which could cause blockage of spray nozzles or filters in the spray tank.

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

Note 7 MT 47.3 is a revised version of MT 47.2 using a standard measuring cylinder. Prior to publication of the method in a Handbook, copies of the method may be obtained through the CIPAC website, http://www.cipac.org/cipacpub.htm

Note 8 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

PART TWO

EVALUATION REPORTS

CYAZOFAMID

CYAZOFAMID

FAO/WHO EVALUATION REPORT 653/2011

Recommendations

The Meeting recommended that the specifications for cyazofamid TC and SC formulations, proposed by ISK Bioscience, as amended, should be adopted by FAO.

Appraisal

The data for cyazofamid were evaluated in support of new FAO specifications based on the draft specifications and the supporting data for TC and SC formulations provided by ISK Bioscience (Belgium) in May 2011. The data submitted were in accordance with the requirements of the "Manual on development and use of FAO and WHO specifications for pesticides, November 2010 revision of the First Edition." [FAO/WHO Manual, 2010]

Cyazofamid is not under patent. At the date of submission it was under patent in Japan, Korea, UK, France, Italy, The Netherland, Switzerland, Belgium, Sweden, Spain, Luxemburg, Denmark, Portugal and Czech Republic (until March, 2013), in Ukraine (until June, 2013) and in Canada (until July, 2014).

The data package for the manufacturing process, the analyses of five lots of samples from the manufacturing site(s) for the active ingredient and impurities, and the certification of limits is similar to that submitted to France and the EU. [Venant, 2011]

Mass balances were in the range of 97.8% - 101%. Limits for minimum purity were supported by data on five typical batches from each of several manufacturing sites.

Cyazofamid has not been evaluated by the JMPR or IPCS.

The TC is an ivory, odourless solid powder, no data has been submitted for its melting point. The melting point of the pure material is 152.7^{o} C.

The CIPAC method for the determination of cyazofamide in TC and SC formulations is based on reversed phase HPLC with UV detection. The method has not been published yet, however it is available as a pre-published method. [653]

The Meeting concluded that the several sites use the same manufacturing process, that they produce comparable technical materials, and that none of the impurities should be considered relevant. The Meeting confirmed that the minimum limit for cyazofamid and the maximum limits for impurities in the TC are same as submitted to France.

The Meeting concluded that the ISK Bioscience source is a suitable reference profile, as the physical/chemical properties and toxicity data presented were generated on this material.

The following issues were addressed by the Meeting (2011): the Meeting requested clarifications on the origin of the batches used for toxicological tests and on the GHS interpretation of the eye and dermal irritation and the dermal sensitization studies.

Explanation was also requested for the concentrations used in the fish and daphnia toxicity studies. The explanation for the concentrations above the limit of water solubility was that for the purpose of the tests different solvents were used. The Meeting concluded that the clauses for pH, particle size distribution and viscosity are not justified and should be removed from the proposed specification of the SC formulation.

SUPPORTING INFORMATION
FOR
EVALUATION REPORT 653/2011

USES

Cyazofamid is a foliar contact and protective fungicide. The mode of action of cyazofamid according to the Fungicide Resistance Action Committee classification (FRAC, 2014) is by inhibiting the complex III: cytochrome bc1(ubiquinone reductase) at Qi site in the mitochondria of *Oomycetes* fungi (such as *Phytophthora*, *Plasmopara*, *Pseudoperonospora* and *Pythium*). It is used in agriculture on e.g. on potatoes and tomatoes especially against *Phytophtora infestans*. It also controls downy mildew (*Pseudoperonospora humuli*) in cucurbit vegetables and grapes.

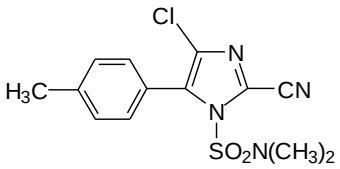
IDENTITY OF THE ACTIVE INGREDIENT

ISO common name
Cyazofamid (ISO published)

Synonyms
IKF-916

Chemical name(s)
IUPAC 4-chloro-2-cyano-*N,N*-dimethyl-5-*p*-tolylimidazole-1-sulfonamide
CA 4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1*H*- imidazole-1-sulfonamide

Structural formula



Empirical formula
$C_{13}H_{13}ClN_4O_2S$

Relative molecular mass
324.8

CAS Registry number
120116-88-3

CIPAC number
653

Identity tests
HPLC retention time; UV spectrum

Table 1. Physico-chemical properties of pure cyazofamid

Parameter	Value(s) and conditions	Purity %	Method reference (and technique if the reference gives more than one)	Study number
Vapour pressure	$<1.33x10^{-5}$ Pa at 35°C	99.1%	EEC A.4 Gas Saturation Method	4561-95-0213-AS-001
Melting point.	152.7°C	99.1%	EEC A.1 Differential Scanning Calorimetry Method	4561-96-0015-AS-001
Temperature of decomposition	No decomposition or chemical transformation was found below 150°C and no weight loss (>5%) was observed below 150°C	99.1%	OECD 113 Differential Scanning Calorimetry and thermogravi-metric analysis	4561-98-0116-AS-001
Solubility in water	0.107-0.121 mg/l at 20°C at pH 5, 7 and 9	99.0%	EEC A.6 Column Elution Method	4561-95-0212-AS-001
Octanol/water partition coefficient	log P_{OW} = 3.2 at 25°C	99.0%	US EPA Guidelines OPPTS 830.7570 according to EEC A.8 HPLC Method	4561-95-0211-AS-001
Hydrolysis characteristics	The half-lives (DT_{50} values = $t_{½}$ values) of the hydrolysis of cyazofamid (IKF-916) in sterile conditions and the absence of light at different temperatures: Half-life = 24.6 days at 20°C at pH 4 Half-life = 27.2 days at 20°C at pH 5 Half-life = 24.8 days at 20°C at pH 7 Half-life = 24.8 days at 20°C at pH 9	[14C-Bz] IKF - 916 ≥ 99.5% [^{14}C-Im] IKF- 916 ≥ 97.5%	EPA Guideline § 161-1 EEC C.7	6578-95-0181-EF-001
Photolysis characteristics	pH 5 (25°C): DT50 0.5 h (artificial light 12 h photoperiod)	[^{14}C-Bz] IKF - 916 ≥ 99.5% [^{14}C-Im] IKF - 916 ≥ 97.5%	EPA Guideline 161-2	6794-96-0063-EF-001
Dissociation characteristics	no dissociation constant in the pH range from 2-12	99.0%	OECD 112 UV spectra method	4561-96-0014-AS-001

Solubility in organic solvents	In g/L at 20°C: acetone 41.92 dichloromethane 101.84 ethyl acetate 15.63 hexane 0.03 methanol 1.54 n-octanol 0.25 toluene 5.28 acetonitrile 29.42 propan-2-ol 0.39	99.1%	Pesticide Assessment Guidelines, Subdivision D : Product Chemistry Guidelines 63-8 Flask Method	4561-98-0122-AS-001

Table 2. Chemical composition and properties of cyazofamid technical material (TC)

Manufacturing process, maximum limits for impurities ≥ 1 g/kg, 5 batch analysis data	Confidential information supplied and held on file by FAO. Mass balances were 98.2 – 101.0 % for the manufacturing plant 1, 97.8 – 100.0 % for the manufacturing plant 2 and 99.8 – 100.2 % for the manufacturing plant 3.
Declared minimum cyazofamid content	935 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	Not available	-	-	-
Solubility in organic solvents	Solubility at 21.2 ± 1 °C acetone 45.64 g/L ethyl acetate 16.49g/L dichloromethane 102.12 g/L acetonitrile 30.59 g/L methanol 1.74 g/L toluene 6.0 g/L hexane 0.03 g/L n-octanol 0.04 g/L 2-propanol 0.43 g/L	95.5%	40 CFR 158.190 Pesticide Assessment Guidelines, Subdivision D: Product Chemistry Guidelines 63-8, EC Annex II Section 2.7	4561-95-0214-AS-001

HAZARD SUMMARY

Cyazofamid has not been evaluated by the WHO IPCS or by the FAO/WHO JMPR.

The IPCS hazard classification of cyazofamid is: there is no hazard classification for cyazofamid.

The following classification was set in 2003 by the European Commission based on acute toxicity, irritation, sensitization and acute ecotoxicity:
- Symbol: N – Dangerous for the environment
- Risk phrase: R50/53 – Highly toxic to aquatic organisms

The US EPA has established an acute reference dose for females (13 – 50 years of age) of 1.0 mg/kg bw based on a LOAEL of 1000 mg/kg in a rat prenatal developmental toxicity study, with a finding of increase incidence of bent ribs. The US EPA also established a chronic reference dose (equivalent of ADI) of 0.95 mg/kg bw/day based on an 18 month oral carcinogenicity study with a LOAEL of 985 mg/kg/day with the finding of increased skin lesions [D292390], [D376500]. The EC completed its review of ISK cyazofamid in 2002 (10379/2002). It established an ADI of 0.17 mg/kg bw/day based on the 2 year rat study. The EC also considered that an acute reference dose (ARfD) is not required [EC, 2002].

FORMULATIONS AND CO-FORMULATED ACTIVE INGREDIENTS

The main formulation type available is a suspension concentrate (SC) at 400 g cyazofamid/L.
Cyazofamid may be co-formulated with other fungicide active ingredients.
These formulations are registered and sold in many countries in Europe, USA, Mexico, Brazil and Chile.

METHODS OF ANALYSIS AND TESTING

The method for the technical material and SC formulations has been adopted by CIPAC and will be published in the next Handbook. Cyazofamid is determined by isocratic reversed phase HPLC (column: Phenomenex SphereClone ODS-2, 5 µm, 250 x 4.6 mm i.d. or equivalent with the same selectivity) with water (pH 4 with acetic acid) – acetonitrile – methanol (43-32-25 v/v) as mobile phase, ultra-violet detection at 280 nm and external standardization.

The methods for determination of impurities are based on HPLC-UV and on ion chromatography.

Test methods for determination of physical-chemical properties of the technical active ingredient were EPA while those for the formulations were CIPAC, as indicated in the specifications.

PHYSICAL PROPERTIES

The physical properties, the methods for testing them and the limits proposed for the 400SC formulation, comply with the requirements of the FAO/WHO Manual (2010 edition).

CONTAINERS AND PACKAGING

No special requirements for containers and packaging have been identified.

EXPRESSION OF THE ACTIVE INGREDIENT

The active ingredient is expressed as cyazofamid.

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 cyazofamid 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 technical cyazofamid based on acute toxicity, irritation and sensitization

Species	Test	Purity % Note[2]	Guideline, duration, doses and conditions	Result	Study number
Rat (males/ females)	acute oral	95.5%	Guidance of US EPA, Subdivision F, 81-1; 14-day observation period; 5000 mg/kg bw; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	LD_{50} > 5000 mg/kg	6563-95-0162-TX-002
Mice (males/ females)	acute oral	95.7%	Guidance of Japan MAFF, US EPA OPPTS 870.1100, OECD 401; 14-day observation period; 5000 mg/kg bw; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	LD_{50} > 5000 mg/kg	7712-98-0209-TX-001
Rat (males/ females)	dermal	95.5%	Guidance of US EPA, Subdivision F, 81-2; 14-day observation; 2000 mg/kg; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	LD_{50} > 2000 mg/kg	6563-95-0163-TX-001
Rat (males/ females)	inhalation	95.5%	Guidance of US EPA, Subdivision F, 81-3; 14-day observation period; 5.5 mg/l; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	LC_{50} > 5.5 mg/l	6563-95-0164-TX-001
Rabbit (males/ females)	skin irritation	95.5%	Guidance of US EPA, Subdivision F, 81-5; 72 hours; 0.5 g; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	Non-irritant	6563-95-0166-TX-001
Rabbit (males/ females)	eye irritation	95.5%	Guidance of US EPA, Subdivision F, 81-4 (1984); 72 hours; 0.09 g; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	Non-irritant	6563-95-0165-TX-001
Guinea pigs (males/ females)	skin sensitization (maximization test)	95.5%	Guidance of US EPA, Subdivision F, 81-6 (1984); 72 hours; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	No dermal sensitization	6563-95-0167-TX-002

[2] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

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

Species	Test	Purity % Note[3]	Guideline, duration, doses and conditions	Result	Study number
Rats (males / females)	Oral subacute	97.3%	Not required under U.S. EPA FIFRA Guideline (dose range finding study). 4 weeks; (M) 0. 3.8, 38.5, 370, 1488 and (F) 0. 3.6, 37.1, 389, 1535 mg/kg bw/day; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	NOEL = 38.5 mg/kg/day or 37.1 mg/kg/day	IET 95-0077
Dog (males / females)	Oral subacute	96.4%	Guidance of OPPTS 870.3150; 28 days; 0,10, 100, 1000 mg/kg bw/day; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1992)	NOEL= 1000 mg/kg/day	6756-96-0043-TX-001
Mouse (males / females)	Oral subacute feeding	95.5%	Not a guideline study (dose range finding study); 6 weeks; (M) 0, 8, 38, 193, 653, 1419 and (F) 0, 9, 47, 248, 854, 1796 mg/kg bw/day; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	NOAEL = 1419 mg/kg day or 1796 mg/kg day	6599-95-0193-TX-002
Rats (males / females)	Oral subchronic	95.5%	Guidance of U.S. EPA FIFRA, Subdivision F, 82-1; 90 days; (M) 0, 0.60, 2.91, 29.5, 295 and (F) 0, 3.30, 33.3, 338, 1359 mg/kg bw/day ; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	NOEL= 29.5 mg/kg/day or 33.3 mg/kg/day	
Dog (males / females)	Oral subchronic	96.2%	Guidance of OPPTS 870.3150; 90 days; 0, 40, 200,1000 mg/kg bw/day; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	NOEL= 1000 mg/kg/day	6898-96-0141-TX-002

[3] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Species	Test	Purity % Note[3]	Guideline, duration, doses and conditions	Result	Study number
Dog (males / females)	Oral subchronic	96.4%	Guidance of OPPTS 870.4100; 1 year ; 0, 40, 200,1000 mg/kg bw/day; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	NOEL= 1000 mg/kg/day	7055-96-0273-TX-002
Rats (males / females)	Dermal subacute	95.5%	92/69/EEC Method B9, Guidance of OECD 410, FIFRA 82-2; 28 days; 0, 250, 500,1000 mg/kg bw/day; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	NOEL= 500 mg/kg/day	6717-96-0023-TX-002
Rats (male/ female)	Oral chronic and oncogenicity	95.5%	Guidance of U.S. EPA FIFRA, Subdivision F, 83-5; 24 months; 0, 10, 50, 500, 5000 ppm and 0, 50, 500, 5000, 20 000 ppm; GLPs US EPA (1989), Japan MAFF (1984), OECD (1981)	NOAEL = 500 ppm, equivalent to 17.1 (M) and 20.2 (F) mg/kg/day no carcinogenic potential	IET 95-0079
Mice (male/ female)	Oncogenicity	95.5%	Guidance of OECD 451 and FIFRA 83-2; 18 months; 0, 70, 700, 7000 ppm; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	NOAEL = 7000 ppm equivalent to 985 (M) and 1203 (F) mg/kg/day no carcinogenic potential	6785-96-0071-TX-003
Rats (male/ female)	Reproductive one generation	95.5%	Not a guideline study (dose range finding study); 0, 1000, 3000, 7000, 20 000 ppm; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1992)	NOEL = 20 000 ppm equivalent to 1327 (M) and 1613 (F) mg/kg/day	6754-96-0041-TX-001

Species	Test	Purity % Note[3]	Guideline, duration, doses and conditions	Result	Study number
Rats (male/ female)	Reproductive two generations	95.5%	Guidance of FIFRA 83-4,OECD 416; 0, 200, 2000, 20 000 ppm; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1992)	-Parental NOAEL = 20 000 (M) and 2000 (F) ppm equivalent to 936 (M) and 134 (F) mg/kg/day - Reproductive NOAEL = 20 000 ppm equivalent to 1338 mg/kg/day (F) - Neonatal NOAEL= 2000 ppm	6755-96-0042-TX-003
Rats (female)	Teratogenicity	95.5%	Guidance of US EPA OPPTS 870.3700 and OECD 414; 20 days; 0, 30, 100 ,1000 mg/kg; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1981)	NOAEL = 1000 mg/kg/day	7664-98-0130-TX-000
Rabbits (female)	Teratogenicity	95.5%	Guidance of US EPA OPPTS 870.3700 and OECD 414; 29 days; 0, 30, 100 ,1000 mg/kg/day; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1997)	NOAEL = 1000 mg/kg/day	7665-98-0128-TX-000
Rats (female)	Teratogenicity	95.5%	Guidance of US EPA OPPTS 870.3700 and OECD 414 (dose range finding study); 20 days; 0, 20, 100, 500, 1000 mg/kg/day; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1997)	NOEL = 1000 mg/kg/day	7323-97-0168-TX-000
Rabbits (female)	Teratogenicity	95.5%	Guidance of US EPA OPPTS 870.3700 and OECD 414 (dose range finding study); 29 days; 0, 20, 100, 500, 1000 mg/kg/day; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1997)	NOEL = 1000 mg/kg/day	7324-97-0169-TX-000

Species	Test	Purity % Note[3]	Guideline, duration, doses and conditions	Result	Study number
Rabbits (female)	Teratogenicity	95.5%	No guidelines (dose range finding study); 21 days; 0, 250, 500, 1000 mg/kg/day; GLPs EPA FIFRA 160 of 40 CFR, OECD Annex 2 C (81) 30 (Final)	NOEL = 1000 mg/kg/day	7324-97-0225-TX-000

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

Species	Test	Purity % Note[4]	Guideline, duration, doses and conditions	Result	Study number
Bacteria (*Salmonella typhimurium)* and *Escherichia coli)*	*In vitro* bacterial mutation assay	95.5%	Guidance of EEC Annex to 92/69/EEC B 13 and B14, OECD 471 and 472, US EPA, US EPA (TSCA) 799.9510 and Japan MAFF 59 NohSan No. 4200; 5, 15, 50, 150, 500, 1500, 5000 µg/plate; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1992)	No mutagenic activity	RIA 005/982367
Human Lymphocytes	*In vitro* aberration test	95.5%	Guidance of OECD 473, US EPA (TSCA) 798.5375 and Japan MAFF 59 NohSan No. 4200; 50, 100 and 150 µg/ml (with and without S9 mix); GLPs US EPA (1989), Japan MAFF (1984) and OECD (1997)	No clastogenic activity	RIA/006/982370
Mouse lymphoma cells	*In vitro* cell mutation assay	95.5%	Guidance of OECD 476, US EPA and EEC 88/302/EEC; Preliminary toxicity: 0.5, 1, 5, 10, 25, 50, 75,100 µg/ml, without and with S9 mix: 1, 5, 10, 25, 50, 75, 100 µg/ml; GLPs UK (1997), EEC (1986), US EPA (1989), Japan MAFF (1984) and OECD (1992)	No mutagenic potential	RIA 008/982368
Bacillus subtilis	DNA repair test – Rec-Assay (*in vitro*)	95.5%	Guidance of Japan MAFF 59 NohSan No. 4200, US EPA FIFRA Subdivision F; 250, 500, 1000, 2000, 4000, 8000 µg/disk; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1998)	Negative	IET 98-0053
Mice	*In vivo* micronucleus test	95.5%	Guidance of OECD 474, EEC B12, US EPA, Japan EPA No 237, MOHW No 306 and MITI No 303; 500, 1000, 2000 mg/kg bw; GLPs UK (1997), EEC (1986), US EPA (1989), Japan MAFF (1984) and OECD (1992)	No clastogenic or aneugenic activity	RIA-007/983715

[4] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Table 6. Ecotoxicology profile of technical cyazofamid

Species	Test	Purity % Note[5]	Guideline, duration, doses and conditions	Result	Study number
Bobwhite quail *(Colinus virginianus)*	Acute oral	95.5%	Guidance of US EPA (TSCA) 797.2175 and US EPA (FIFRA) 71-1; 14-day observation period; 2000 mg/kg bw; GLPs OECD (1997), Japan MAFF (1984), Switzerland (1986) and US EPA (1989)	LD_{50} > 2000 mg as/kg bw	182789
Mallard duck *(Anas platyrhynchos)*	Acute oral	95.5%	Guidance of OECD 423, US EPA OPPTS 870.1100; 14-day observation period; 2000 mg/kg bw; GLPs US EPA (1989), Japan MAFF (1984) and OECD (1997)	LD_{50} > 2000 mg as/kg bw	728886
Bobwhite Quail *(Colinus virginianus)*	Dietary	95.5%	Guidance of OECD 205, US EPA (TSCA) 797.2050, US EPA (FIFRA) 71-2; 5 days; 5000 ppm; GLPs OECD and US EPA	LC_{50} > 5 000 ppm as (equivalent to 1278 mg as/kg bw)	182813
Mallard duck *(Anas platyrhynchos)*	Dietary	95.5%	Guidance of OECD 205, US EPA (TSCA) 797.2050, US EPA (FIFRA) 71-2; 5 days; 5000 ppm; GLPs OECD and US EPA	LC_{50} > 5 000 ppm as (equivalent to 1533 mg as/kg bw)	218521
Japanese Quail *(Coturnix coturnix japonica)*	Reproduction Test	95.5%	Guidance of OECD 206, US EPA OPPTS 850.2300; 20½ weeks; 28, 167,1000 mg/kg diet (ppm); GLP OECD (1986)	NOEC = 1000 ppm as (nominal concentration	729314
Rainbow Trout (*Oncorhynchus mykiss)*	Acute flow-through test	95.5%	Guidance of EEC 92/69 C.1, OECD 203; 96 hours; 0.14, 0.25, 0.45, 0.80, 1.4 mg/L; GLPs OECD and US EPA	LC_{50} > 0.14 mg as/l (limit of the water solubility of the as)	182857
Bluegill *(Lepomis macrochirus)*	Acute flow-through test	95.5%	Guidance of EEC 92/69 C.1, OECD 203; 96 hours; 0.14, 0.25, 0.45, 0.80, 1.4 mg/L; GLPs OECD and US EPA	LC_{50} > 0.14 mg as/l (limit of the water solubility of the as)	182846
Carp *(Cyprinus carpio)*	Acute flow-through test	95.5%	Guidance of EEC 92/69 C.1, OECD 203; 96 hours; 0.14, 0.25, 0.45, 0.80, 1.4 mg/L; GLPs OECD and US EPA	LC_{50} > 0.14 mg as/l (limit of the water solubility of the as)	182881

[5] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Species	Test	Purity % Note[5]	Guideline, duration, doses and conditions	Result	Study number
Rainbow Trout (*Oncorhynchus mykiss*)	Acute flow-through test	95.7%	Guidance of EEC 92/69 C.1, OECD 203; 96 hours; 18, 32, 56, 100,180 µg/l; GLPs OECD and US EPA	LC_{50} > 0.10 mg as/l (mean measured concentration)	AF0381/B
Rainbow Trout (*Oncorhynchus mykiss*)	Chronic flow-through test	95.5%	Guidance of OECD 215 and 204; 28 days; 0.013, 0.029, 0.064, 0.14, 0.31 mg/L; GLP OECD (1986)	NOEC = 0.13 mg as/l (mean measured concentration)	738944
Rainbow trout (*Oncorhynchus mykiss*)	Bioaccumulation flow-through test	95.7%	Guidance of OECD Guideline 205; 6 exposure and 12 depuration days; 1.0 µg/l and 10 µg/l; GLPs UK, OECD and US EPA	BCF = 286; depuration rate 0.95 d^{-1}	AF0381/C
Daphnia magna	Acute flow-through test	95.5%	Guidance of TSCA 72-2, EEC 92/69 C2, OECD 202; 48 hours; 0.14, 0.25, 0.45, 0.80,1.4 mg/l; GLPs OECD and US EPA	EC_{50} > 0.14 mg as/l (limit of the water solubility of the as)	182868
Daphnia magna	Chronic semi-static test	95.5%	Guidance of OECD 211; 21 days; 0.0014, 0.0044, 0.014, 0.044, 0.14 mg/L; GLP OECD (1986)	NOEC = 0.11 mg as/l (mean measured concentration)	741251
Algae *(Selenastrum capricornutum)*	Growth Inhibition test (static)	95.5%	Guidance of US EPA OPPTS 850.5400, EEC 92/69 C3, OECD 201; 96 hours; 5, 10, 22, 46, 100 µg/l; GLPs OECD and US EPA	ErC_{50} > 0.1 mg as/l EbC_{50} = 0.025 mg as/l	218767
Algae *(Selenastrum capricornutum)*	Growth Inhibition test (static)	95.5%	Guidance of OECD 201; 72 hours; 0.0257, 0.154, 0.926, 5.56, 33.3, 200 mg/l; GLPs OECD	ErC_{50} = 60.9 mg as/l EbC_{50} = 0.858 mg as/l	E95-1599
Sediment dwelling organism (*Chironomus riparius*)	Spiked water test	95.5%	Guidance of OECD draft and BBA; 23 days; 100 µg/l; GLPs OECD (1997) and Switzerland (1986)	NOEC = 0.1 mg as/l	732058
Honey bee (*Apis mellifera*)	Acute contact and oral	95.5%	Guidance of EPPO 170; 96 hours; contact concentrations 6.25, 12.5, 25.0, 50.0, 100.0 µg/bee and oral 7.7, 19.4, 31.7, 63.4, 151.7 µg/bee; GLPs OECD (1992) and DE (1994/97)	LD_{50} oral > 151.7 µg as/bee LD_{50} contact > 100 µg as/bee	2915036

Species	Test	Purity % Note[5]	Guideline, duration, doses and conditions	Result	Study number
Parasitic Wasp (*Aphidius rhopalosiphi)*	Laboratory test	95.5%	Guidance of IOBC/WPRS; 13 days; 209.4 g as/ha; GLPs OECD (1992) and DE (1994/97)	mortality : 2.5 % reduction of parasitation efficiency: 0.68 %	2911001
Predatory mite (Typhlodromus pyri)	Laboratory test	95.5%	Guidance of IOBC/WPRS; 14 days; 209.4 g as/ha; GLPs OECD (1992) and DE (1994/97)	mortality: 2.5 % reduction of parasitation efficiency: 10 %	2912063
Rove Beetles *(Aleochara bilineata)*	Laboratory test	95.5%	Guidance of IOBC/WPRS; exposure 4 weeks; 210.6 g as/ha; GLPs OECD (1992) and DE (1994/97)	reduction of reproduction : 11 %	2914070
Lacewing (*Chrysoperla carnea*)	Laboratory test	95.5%	Guidance of IOBC/WPRS; exposure 15 days; 209.4 g as/ha; GLPs OECD (1992) and DE (1994/97)	mortality : 6.7 % reduction of reproduction: 19.3 %	2913046
Earthworm (*Eisenia foetida)*	Acute toxicity	95.5%	Guidance of OECD 207, EC Directive 87/302 - C; 14 days; 0.1, 1, 10, 100, 1 000 mg/kg dry soil; GLPs OECD and US EPA	LC_{50} > 1 000 mg as/kg dry soil	182892
Earthworm (*Eisenia foetida)*	Reproductive toxicity	95.5%	Guidance of ISO 11268-2 and BBA Part VI, 2-2; 8 weeks; 0.5, 1.0, 1.5, 2.0 and 4.0 mg/kg dry soil; GLPs OECD (1997) and Switzerland (1986)	NOEC = 4.0 mg as/kg dry soil	763446
Soil non-target micro-organisms	Soil respiration and nitrification	95.5%	Guidance of EEC SETAC; 28 days; 0.27 mg/kg dry soil; GLPs OECD and US EPA	No relevant effect	253081

Annex 2
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