

REGISTRATION REPORT

Part A

Risk Management

Product code: AKD 2023 SC

Product name(s): KANEMITE

Chemical active substance(s):

Acequinocyl, 164 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(label extension)

Applicant: CERTIS Europe B.V.

Date: 29/08/2024

Table of Contents

1	Details of the application	4
1.1	Application background	4
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Details of the authorisation decision	5
2.1	Product identity	5
2.2	Conclusion DAMM	5
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011	6
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	6
2.5	Risk management	6
2.5.1	Restrictions linked to the PPP	7
2.5.2	Specific restrictions linked to the intended uses	8
2.6	Intended uses (only NATIONAL GAP)	9
3	Background of authorisation decision and risk management	11
3.1	Physical and chemical properties (Part B, Section 2)	11
3.2	Efficacy (Part B, Section 3)	11
3.3	Methods of analysis (Part B, Section 5)	11
3.3.1	Analytical method for the formulation	11
3.3.2	Analytical methods for residues	11
3.4	Mammalian toxicology (Part B, Section 6)	11
3.4.1	Acute toxicity	11
3.4.2	Operator exposure	11
3.4.3	Worker exposure	12
3.4.4	Bystander exposure	13
3.4.5	Resident exposure	13
3.4.6	Combined exposure	14
3.5	Residues and consumer exposure (Part B, Section 7)	14
3.6	Environmental fate and behaviour (Part B, Section 8)	15
3.7	Ecotoxicology (Part B, Section 9)	15
3.8	Relevance of metabolites (Part B, Section 10)	16
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	16

5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation.....	16
5.1.1	Post-authorisation monitoring.....	16
5.1.2	Post-authorisation data requirements	16
Appendix 1	Copy of the product authorisation DAMM	17
Appendix 2	Copy of the product label	22

PART A

RISK MANAGEMENT

1 Details of the application

The company CERTIS Europe B.V. has requested a marketing authorisation in France for the product KANEMITE (formulation code: AKD 2023 SC), containing 164 g/L acequinocyl¹ as an acaricide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report concerns the evaluation of CERTIS Europe B.V.'s application submitted on 29/06/2021 to market KANEMITE (AKD 2023 SC) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the label extension of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2021-1812) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of KANEMITE (AKD 2023 SC) has been made using endpoints agreed in the EU peer review of acequinocyl. It also includes assessment of data and information related to KANEMITE (AKD 2023 SC) where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

¹ Commission Implementing Regulation (EU) No 496/2014 of 14 May 2014 approving the active substance acequinocyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

² REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

³ SANCO document "risk envelope approach", European Commission (14 March 2011). [Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5](#)

⁴ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

AKD 2023 SC / KANEMITE
Part A - National Assessment
FRANCE

This document also describes the specific conditions of use and labelling required for France for the registration of KANEMITE KANEMITE (AKD 2023 SC).

1.2 Letters of Access

The applicant has provided a letters of access for active substance acequinocyl and KANEMITE (AKD 2023 SC) data. This letters of access is available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: « All tests and studies were prepared and submitted in support of the assessment as required according to 284/2013 EU. ».

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 3.

2 Details of the authorisation decision

2.1 Product identity

Product code	AKD 2023 SC
Product name in MS	KANEMITE
Authorisation number	2100183
Kind of use	Professional use
Low risk product (article 47)	No
Function	Insecticide
Applicant	CERTIS Europe B.V.
Active substance(s) (incl. content)	acequinocyl, 164 g/L
Formulation type	Concentrate suspension [SC]
Packaging	Packaging not changed
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion DAMM

AKD 2023 SC / KANEMITE
Part A - National Assessment
FRANCE

The evaluation of the application for KANEMITE (AKD 2023 SC) resulted in **the decision to grant the authorisation.**

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

Classification not changed.

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
	For other restrictions refer to 2.5

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁵ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Moreover, the French Order of 12 April 2021⁶ provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision

⁵ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

⁶ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

AKD 2023 SC / KANEMITE
Part A - National Assessment
FRANCE

- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁷ is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

Finally, the French Order of 20 November 2021⁸ on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop⁹ when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 20 meters ¹⁰ to surface water bodies for uses on citrus.
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 50 meters ⁸ to surface water bodies for uses on peach.
	The unsprayed buffer zone to aquatic systems can be reduced from 50 to 20 meters by the use of an application device with a minimal efficacy of drift reduction of 75%

⁷ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

⁸ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

⁹ List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

¹⁰ in consistency with French Order of 4 May 2017 (Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime), modified by the French Order of 27 December 2019.

AKD 2023 SC / KANEMITE
Part A - National Assessment
FRANCE

SPe8	SPe 8:To protect bees and pollinating insects do not apply to crop plants when in flower or during the exsudate production period./Do not use where bees are actively foraging. /Do not apply when flowering weeds are present.
Other specific restrictions	
Re-entry period	3 days for uses on peach. 2 days for uses on citrus.
Storage	-
Risk mitigation measures	According to available data, the following specific mitigation measures are recommended: Citrus and peaches are considered as melliferous crops and according to the intended cGAP, application of acequinocyl should be performed at BBCH 51-89 and BBCH 35-89 for citrus and peaches, respectively. Although acequinocyl is a non-systemic substance, it is applied during the flowering stage of a melliferous crop and no residue data on honey were submitted. Therefore, the product should not be applied during the flowering stage (BBCH 60-69).
Risk mitigation measures	-

The other conditions of use specified in the previous evaluations are not changed.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

AKD 2023 SC / KANEMITE
Part A - National Assessment
FRANCE

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

When the conclusion is “not finalised”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: [29/08/2024](#)

PPP (product name/code): KANEMITE (AKD 2023 SC)
Active substance 1: Acequinocyl
Safener: No
Synergist: No
Applicant: Certis Europe B.V.
Zone(s): Southern
Verified by MS: yes

Formulation type: Suspension Concentrate (SC)
Conc. of as 1: 164 g/L
Conc. of safener: -
Conc. of synergist: -
Professional use:
Non professional use:

Field of use: Acaricide (Miticide)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & sea- son	Max. num- ber a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.i./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1-5	FR	Citrus (oranges, lemons, grape- fruits, limes, man- darins, ...)	F	Spider mites	Foliar spray	51-89 51-59 and 70- 89	a) 1 b) 1	--	a) 1.8 b) 1.8	a) 295.2 b) 295.2	1000- - 3000	28	Acceptable, except between 60-69 <i>Efficacy only demon- strated on acarids.</i>

AKD 2023 SC / KANEMITE
Part A - National Assessment
FRANCE

6	FR	Peach and similar	F	Spider mites	Foliar spray	35-89 35-59 and 70-89 spring – autumn	a) 1 b) 1	--	a) 1.6 b) 1.6	a) 262.4 b) 262.4	1000- - 1500	30	Acceptable, except between 60-69 <i>Efficacy only demonstrated on acarids.</i>
---	----	-------------------	---	--------------	--------------	---	--------------	----	------------------	----------------------	-----------------	----	--

Remarks table heading:	<p>(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008</p> <p>(c) g/kg or g/l</p>	<p>(d) Select relevant</p> <p>(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1</p> <p>(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.</p> <p>(g) Compliant after publication of the MRLs for acequinocyl. in an implementing regulation, currently adopted in document SANTE/11314/2021</p>	
1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		13	PHI - minimum pre-harvest interval
		14	Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

The physico-chemical properties of the formulation have been evaluated and considered acceptable during the registration of this formulation. The intended concentrations claimed for the extension use(s) (concentrations from 0.06% to 0.18% v/v or w/v) are covered by the concentrations authorized during the registration of this formulation.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of KANEMITE (AKD 2023 SC) is considered satisfactory for all the requested uses.
- The phytotoxicity level of KANEMITE (AKD 2023 SC) is considered negligible for all the requested uses.
- The risks of negative impact on yield, quality, propagation and adjacent crops are considered negligible
- There is a risk of resistance to acequinocyl for *Panonychus sp.* and *Tetranychus urticae* requiring a monitoring.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical method for the determination of active substance in the formulation is available and validated.

3.3.2 Analytical methods for residues

The analytical methods for the determination of the active substance residues in matrices (plants origin) submitted at European level and in the dossier of the preparation meet the regulatory requirements. The intended uses are not used in animal feed. So, no analytical method is necessary for the determination of residues in these matrices.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

3.4.2 Operator exposure

AKD 2023 SC / KANEMITE
Part A - National Assessment
FRANCE

Model data	Level of PPE	Acequinocyl	
		Total absorbed dose [mg/kg bw/day]	% of systemic AOEL
Citrus			
Spray application Vehicle-mounted Upward spraying 10 ha/day 60 kg bodyweight	Work wear (arms, body and legs covered)	0.1689116	1206.51
	Work wear (arms, body and legs covered) + gloves M/L and A + hood at A	0.0015081	82.20
	Work wear (arms, body and legs covered) + gloves M/L and A + closed cabin at A.	0.0020617	14.73
Peaches			
Spray application Vehicle-mounted Upward spraying 10 ha/day 60 kg bodyweight	Work wear (arms, body and legs covered)	0.1032	737.42
	Work wear (arms, body and legs covered) + gloves M/L and A	0.0118	84.26%
	Work wear (arms, body and legs covered) + closed cabin at A	0.0014	9.97%
	Work wear (arms, body and legs covered) + gloves M/L and A + Hood at A	0.0075	53.22%

According to the model calculations, for the citrus uses (n°1-5), it can be concluded that the operator exposure using KANEMITE (AKD 2023 SC) is below the AOEL with workwear and gloves during mixing/loading and application additionally **hood during application, or closed cabin** is necessary.

For the peach use (n°6), it can be concluded that the risk for the operator exposure KANEMITE (AKD 2023 SC) is below the AOEL with workwear and gloves during mixing/loading and application (84.26% of AOEL); and is lowered when either closed cabin during application or hood is worn during application (respectively 9.97% of AOEL and 53.22% of AOEL).

3.4.3 Worker exposure

Acequinocyl			
Model data	Level of PPE	Total absorbed dose [mg/kg bw/day]	% of systemic AOEL
Citrus (0.2952 kg a.i./ha)			
Hand harvesting Outdoor Work rate: 8 hrs/day, DT ₅₀ : 2.72 days DFR: 0.816 µg/cm ² /kg a.i./ha Body weight: 60 kg	No delayed re-entry period		
	Potential TC: 22500 cm ² /person/h	0.1871	1336.90
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0374	267.38
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0187	133.69
	Re-entry period of 2 days		
	Potential TC: 22500 cm ² /person/h	0.1124	803.07
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0225	160.61
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.01124	80.31
Peaches (0.2624 kg a.i./ha)			
Hand harvesting Outdoor Work rate: 8 hrs/day, DT ₅₀ : 4.1 days	No delayed re-entry period		
	Potential TC: 22500 cm ² /person/h	0.4015	2867.66
	Work wear (arms, body and legs covered)	0.0803	573.53

AKD 2023 SC / KANEMITE
Part A - National Assessment
FRANCE

Acequinocyl			
Model data	Level of PPE	Total absorbed dose [mg/kg bw/day]	% of systemic AOEL
DFR: 1.548 µg/cm ² /kg a.i./ha Body weight: 60 kg	TC: 4500 cm ² /person/h		
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0401	286.77
	Re-entry period of 3 days		
	Potential TC: 22500 cm ² /person/h	0.1248	891.1
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0249	178.21
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.01248	89.11

According to the model calculations, it can be concluded that worker exposure reentering into treated crops with KANEMITE (AKD 2023 SC) is below the AOEL of acequinocyl with workwear and gloves and after a **re-entry period of 2 days** for the citrus uses (n°1-5) or **3 days** for the peach use (n°6).

3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established of the active substances, i.e. no acute operator or bystander exposure assessments can be performed with the EFSA model where no AAOEL has been set¹¹.

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): “No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.”

3.4.5 Resident exposure

Model data		Acequinocyl	
		Total absorbed dose [mg/kg bw/day]	% of systemic AOEL
Citrus upward application, vehicle mounted (0.2952 kg a.i./ha) , refined values for DFR			
Resident child Body weight: 10 kg Buffer strip: 10 m Drift reduction technology: no DFR: 0.816 µg/cm²/kg a.i./ha DT50 = 2.72 days	Spray drift (75 th perc.)	0,0106	75.98
	Vapour (75 th perc.)	0,0011	7.64
	Surface deposits (75 th perc.)	0,0019	13,49%
	Entry into treated crops (75 th perc.)	0,0035	25,07%
	All pathways (mean)	0,0121	86,76%
Resident adult Body weight: 60 kg Buffer strip: 10 m Drift reduction technology: no DFR: 0.816 µg/cm²/kg a.i./ha DT50 = 2.72 days	Spray drift (75 th perc.)	0,0059	42.09
	Vapour (75 th perc.)	0,0002	1.64
	Surface deposits (75 th perc.)	0,0008	5,95%
	Entry into treated crops (75 th perc.)	0,0019	13,93%
	All pathways (mean)	0,0062	44,31%

¹¹ Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

AKD 2023 SC / KANEMITE
Part A - National Assessment
FRANCE

Model data		Acequinocyl	
		Total absorbed dose [mg/kg bw/day]	% of systemic AOEL
Peaches upward application, vehicle mounted (0.2624 kg a.i./ha), refined values for DFR			
Resident child Body weight: 10 kg Buffer strip: 10 m Drift reduction technology: no DFR: 1.548 µg/cm²/kg a.i./ha	Spray drift (75 th perc.)	0,0062	44,44%
	Vapour (75 th perc.)	0,0011	7,64%
	Surface deposits (75 th perc.)	0,0011	8,10%
	Entry into treated crops (75 th perc.)	0.0039	27.74%
	All pathways (mean)	.0090	64.51%
Resident adult Body weight: 60 kg Buffer strip: 10 m Drift reduction technology: no DFR: 1.548 µg/cm²/kg a.i./ha	Spray drift (75 th perc.)	0,0034	24,58%
	Vapour (75 th perc.)	0,0002	1,64%
	Surface deposits (75 th perc.)	0,0005	3,47%
	Entry into treated crops (75 th perc.)	0,0022	15.41
	All pathways (mean)	0,0061	32.36%

According to the model calculations, it can be concluded that resident exposure (adult and child) is below to the AOEL of acequinocyl.

3.4.6 Combined exposure

Not applicable (1 active substance only)

3.5 Residues and consumer exposure (Part B, Section 7)

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.6 mg/kg and 0.1 mg/kg for Acequinocyl in citrus and peaches, respectively, as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of Acequinocyl residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the intended use(s).

Data gaps

Noticed data gaps are:

Data gaps were identified by EFSA (EFSA, 2020). In the framework of the Article 12 (EFSA Journal 2020;18(1):5983), confirmatory data about representative storage stability of residues in high oil content commodities and hops have already been required to confirmed tentative MRLs.

Data gaps were identified by EFSA (EFSA, 2020). In the framework of the Article 12 (EFSA Journal 2020;18(1):5983), confirmatory data about the nature of residues under standard processing conditions of pasteurisation, boiling and sterilisation have already been required to confirmed tentative MRLs.

Information on KANEMITE (AKD 2023 SC) (KCA 6.8)

Crop	PHI for KANEMITE (AKD 2023 SC) proposed by applicant	PHI sufficiently supported for	PHI for KANEMITE (AKD 2023 SC) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Acequinocyl		
Citrus	28 d	Yes		
Peach	30 d	Yes		

NR: not relevant

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of acequinocyl and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC_{soil} and PEC_{sw} derived for the active substance and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC_{gw} for acequinocyl and its metabolites do not occur at levels exceeding those mentioned in regulation EU No 546/2011. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and its metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals, aquatic organisms, non-target arthropods other than bees and terrestrial plants are acceptable for the intended uses. Mitigation measures are required for aquatic organisms.

For bees, the acute risk to adult honeybees can be considered acceptable.

Adult chronic toxicity study is available, however in absence of analytical verification the study cannot be considered reliable. Moreover the test on larvae do not cover emergence and is therefore considered not

appropriate to fulfill requirements of Reg. No. 284/2013. Thus, the risk assessment for bees can not be finalized.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance acequinocyl is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

It should be put in place monitoring of resistance to acequinocyl (one monitoring for all products based on acequinocyl) for *Panonychus sp.* and *Tetranychus urticae*, on fruit crops.

A report on the results of the monitoring put in place should be provided at the time of the demand of renewal for the product.

5.1.2 Post-authorisation data requirements

None.

-

Appendix 1 Copy of the product authorisation DAMM

DocuSign Envelope ID: D60E679E-2BBC-42C7-A198-0D666F906DC1



Décision relative à une demande d'extension d'usages d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) n° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et réglementaire,

*Vu la demande d'extension d'usages majeurs du produit phytopharmaceutique **KANEMITE***

de la société CERTIS BELCHIM B.V.

enregistrée sous le n° 2021-1812

Vu les conclusions de l'évaluation de l'Anses du 4 juillet 2024,

L'autorisation de mise sur le marché du produit référencé ci-après **est étendue** aux usages décrits dans la présente décision.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

DocuSign Envelope ID: D60E679E-2BBC-42C7-A198-0D666F906DC1



Informations générales sur le produit	
Noms du produit	KANEMITE WENO
Type de produit	Produit de référence
Titulaire	CERTIS BELCHIM B.V.5 rue Galilée 78280 GUYANCOURT France
Formulation	Suspension concentrée (SC)
Contenant	164 g/L - acéquinocyle
Numéro d'intrant	2090113
Numéro d'AMM	2100183
Fonction	Acaricide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

La présente décision peut être retirée ou modifiée si des éléments le justifient.

A Maisons-Alfort, le 29/08/2024

DocuSigned by:

 AE281A955A42454
 Directrice générale déléguée
 en charge du pôle produits réglementés
 Agence nationale de sécurité sanitaire de
 l'alimentation, de l'environnement et du travail (ANSES)

DocuSign Envelope ID: D60E679E-2BBC-42C7-A198-0D666F906DC1



ANNEXE : Modalités d'autorisation du produit

Liste des nouveaux usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
12053103 Agrumes*Trt Part.Aer.*Acariens et phytoptes	1,8 L/ha	1/an	entre les stades BBCH 51 et BBCH 89	28	20	-	-	Emploi interdit
	Efficacité montrée sur acariens.							
12553113 Pêcher - Abricotier*Trt Part.Aer.*Acariens et phytoptes	1,6 L/ha	1/an	entre les stades BBCH 35 et BBCH 89	30	50	-	-	Emploi interdit
	Efficacité montrée sur acariens.							

Emploi possible ou interdit = usage autorisé ou interdit durant la floraison et sur les zones de butinage, pour les cultures attractives en plein champ ou sous abri ouvert, dans les conditions fixées par l'arrêté du 20/11/2021

DocuSign Envelope ID: D60E679E-2BBC-42C7-A198-0D666F906DC1



Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles ;
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage) ;
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application avec un pulvérisateur pneumatique ou un atomiseur

Les équipements de protection individuelle ci-après sont applicables à tous les usages autorisés du produit utilisant ce mode d'application.

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

• pendant l'application

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- Combinaison de protection de catégorie III type 4 avec capuche ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 et, en cas de contact avec la culture traitée, des gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A).

Délai de rentrée :

- 3 jours sur "pêcher-abricotier".
- 2 jours sur "agrumes".

KANEMITE
AMM n° 2100183

Page 4 sur 5

DocuSign Envelope ID: D60E679E-2BBC-42C7-A198-0D666F906DC1



Protection des personnes présentes et des résidents (au sens du règlement (UE) N°284/2013)

Respecter une distance d'au moins 10 mètres entre le dernier rang traité et :

- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

Respect des limites maximales de résidus (LMR)

Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

Protection de l'environnement (milieux, faune et flore)

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 50 mètres par rapport aux points d'eau pour l'usage "pêcher-abricotier".
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau pour l'usage "agrumes".
- SPe 8: Pour protéger les abeilles et autres insectes pollinisateurs, ne pas utiliser en présence d'abeilles et autres pollinisateurs, ne pas appliquer lorsque des adventices en fleur sont présentes.

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Réurrence (mois)
Poursuivre le suivi de la résistance à l'acéquinocyle. Fournir, aux autorités compétentes, toute nouvelle information susceptible de modifier l'analyse du risque de résistance.	-	-
Fournir les éléments permettant de garantir le respect des limites maximales de résidus d'acéquinocyle fixées dans le miel (consulter le document guide SANTE/11956/2016).	A fournir lors du renouvellement de l'AMM	-

Les autres modalités d'autorisation du produit restent inchangées.

AKD 2023 SC / KANEMITE
Part A - National Assessment
FRANCE

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

KANEMITE – Projet étiquette pour la demande d'extension d'usages majeurs – Mai 2021
En bleu, demande d'usages mineurs (Art.51) déposés en juillet 2020 (dossier 2020-3182)

KANEMITE®		CERTIS	
Arboriculture – Tomate – Houblon – Cultures porte-graines		ACARICIDE	
KANEMITE® – A.M.M. 2100183 (contient de l'acéquinocyl, du 5-chloro-2-méthyl-4-isothiazolin-3-one et du 2-méthyl-2H-isothiazol-3-one) ATTENTION H317 Peut provoquer une allergie cutanée. H373 Risque présumé d'effets graves pour le système sanguin à la suite d'expositions répétées ou d'une exposition prolongée. H410 Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.			
Conseils de prudence P260 Ne pas respirer les brouillards/vapeurs/aérosols. P264 Se laver soigneusement les mains et le visage après manipulation. P280 Porter des gants et un vêtement de protection. P308+P311 EN CAS d'exposition prouvée ou suspectée : appeler un CENTRE ANTI-POISON ou un médecin. P314 Consulter un médecin en cas de malaise. P391 Recueillir le produit répandu. P501 Éliminer le contenu et l'emballage comme un déchet dangereux conformément à la réglementation en vigueur.			
EUH401 Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.			
SP1 Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes. Éviter le rejet direct des effluents dans l'environnement.			
SPe3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau pour l'usage « Tomate » et « Cultures porte-graines ».			
SPe3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau pour les usages pommier, agrumes et sur houblon.			
SPe8 Pour protéger les organismes aquatiques, respecter une zone non traitée de 50 mètres par rapport aux points d'eau, ou de 20 mètres assorti d'un dispositif de réduction de la dérive de 75% pour les usages pêcher.			
Pour protéger les abeilles et autres insectes pollinisateurs, ne pas utiliser en présence d'abeilles et autres pollinisateurs, ne pas appliquer durant la période de floraison, ne pas appliquer lorsque des adventices en fleurs sont présentes.			
Respecter une distance d'au moins 10 m entre le dernier rang traité et : <ul style="list-style-type: none"> - l'espace fréquenté par les personnes présentes lors du traitement, - l'espace susceptible d'être fréquenté par des résidents. 			
Délai de rentrée : 48 heures. Pour les usages sur pêcher, le délai de ré-entrée est de 3 jours. Protéger du gel. Ne pas stocker le produit dans un local où la température peut dépasser 40°C.			
KANEMITE® – A.M.M. n° 2100183 – CERTIS Europe B.V. Acéquinocyl : 164 g/L (15,8 % p/p) Suspension concentrée (SC)			
© Marque déposée Agro-Kanesho Co. Ltd.		v.03/2021	
EN CAS D'URGENCE Composer le 15 ou le 112 ou contacter le centre anti poison le plus proche.		Puis signaler vos symptômes au réseau Phyt'Attitude (n° vert 0 800 887 887 – appel gratuit depuis un poste fixe). En cas d'incident ou d'accident, appeler le 01.72.11.00.03 (Cavachem, numéro d'urgence 24h/24h). Fiche de données de sécurité disponible sur : www.quickfds.com ou sur demande à CERTIS au 01.34.91.90.00. ou en scannant le QR code avec votre téléphone mobile.	
RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL – REEMPLOI DE L'EMBALLAGE INTERDIT Lire attentivement l'étiquette avant toute utilisation.			

Distribué par : CERTIS Europe B.V. - France
 5, rue Galilée 78280 GUYANCOURT - Tél : 01.34.91.90.00 - Fax : 01.30.43.76.55
 N° Agrément : IF01808 - Distribution de produits phytopharmaceutiques à des utilisateurs professionnels.
 Conditionné en Europe pour le compte de CERTIS Europe B.V.
 N° de lot et la date de fabrication : voir indication sur l'emballage.

5 L