



## HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

### 1. **BESLUIT**

Op 31 december 2015 is van

Certis Europe B.V.  
Postbus 1180  
3600 BD MAARSSEN

een aanvraag tot wijziging van de toelating met Nederland als Europees rapporteur ontvangen als bedoeld in artikel 33 Verordening (EG) 1107/2009 (verder te noemen: de Verordening) voor het gewasbeschermingsmiddel

#### **Frupica SC**

op basis van de werkzame stof mepanipyrim.

**HET COLLEGE BESLUIT** tot toelating van de wijziging van bovenstaand middel.

Alle bijlagen, waaronder registratierapport deel A en deel B, vormen een onlosmakelijk onderdeel van dit besluit.

De nieuwe toegelaten gebruiken zijn opgenomen in het Wettelijk Gebruiksvoorschrift van het besluit onder aanvraag 20171719 WGF, welke is ondertekend op 15 december 2017 en een ingangsdatum heeft van 1 januari 2019.

Het besluit van 15 december 2017 komt te vervallen.

#### **1.1 Samenstelling, vorm en verpakking**

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

#### **1.2 Gebruik**

Het middel mag slechts worden gebruikt volgens het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.

### 1.3 Classificatie en etikettering

Mede gelet op de onder “wettelijke grondslag” vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen conform de geldende regelgeving op of bij de verpakking te worden vermeld:

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder “verpakkingsinformatie” in bijlage I.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.
- De classificatie die overeenkomstig het toelatingsbesluit is vastgesteld, moet volgens de voorschriften op de verpakking worden vermeld, zoals beschreven in bijlage II en in hoofdstuk 2 van deel A van het registratierapport.

### 1.4 Aflever- en opgebruiktermijn (respijperiode)

De aflever- en opgebruiktermijnen van het WG besluit op aanvraag 20171719 WGF zijn van toepassing op deze toelating.

## 2. WETTELIJKE GRONDSLAG

Besluit	artikel 28 Verordening (EG) Nr. 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Conform Bgb en Rgb d.d. 16 december 2011 en Evaluation Manual Zonaal 2.0.

## 3. BEOORDELINGEN

### 3.1 Fysische en chemische eigenschappen

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

### 3.2 Analysemethoden

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

### 3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

### 3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

### 3.5 Werkzaamheid

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

Voor nadere onderbouwing van de beoordelingen verwijzen wij u naar deel A en B van het registration report als toegevoegd aan de bijlagen van dit besluit overeenkomstig Besluit beleidsregel bekendmaken delen A en B van het Registration Report.

***Bezwaarmogelijkheid***

*Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 8030, 6710 AA, EDE. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opgesteld.*

Ede, 6 april 2018

HET COLLEGE VOOR DE TOELATING VAN  
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw  
Voorzitter

## BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

### 2.1 Aanvraaginformatie

<i>Aanvraagnummer:</i>	20131642 ZEWTG
<i>Type aanvraag:</i>	Aanvraag tot wijziging van de toelating van een gewasbeschermingsmiddel met Nederland als Europees rapporteur
<i>Middelnaam:</i>	Frupica SC
<i>Verzenddatum aanvraag:</i>	23 december 2015
<i>Formele registratiedatum: *</i>	15 januari 2016

\* Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

### 2.2 Stofinformatie

Werkzame stof	Gehalte
mepanipyrim	440 G/L

- De stof is per 1 oktober 2004 geplaatst op Annex I van Richtlijn 91/414/EEG (2004/62/EC) en vervolgens bij Uitvoeringsverordening (EU) [540/2011](#) d.d. 25 mei 2011 goedgekeurd). De goedkeuring van deze werkzame stof expireert op 30 april 2018.

### 2.3 Toelatingsinformatie

<i>Toelatingsnummer:</i>	12229 N
<i>Expiratiedatum:</i>	30 april 2019
<i>Afgeleide parallel of origineel:</i>	Origineel
<i>Biocide, gewasbeschermingsmiddel of toevoegingsstof:</i>	Gewas
<i>Gebruikers:</i>	Professioneel

W-coderingen en aflever- en opgebruiktermijnen:

- *W-codering professioneel gebruik:* W.3
- *Vorige w-codering professioneel gebruik:* W.2
- *Aflevertermijn professioneel gebruik:* 1 juli 2019
- *Opgebruiktermijn professioneel gebruik:* 1 juli 2020

### 2.4 Verpakkingsinformatie

*Aard van het preparaat:*  
Suspensie concentraat



## HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

### BIJLAGE II Etikettering van het middel Frupica SC

Professioneel gebruik

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:  
mepanipyrim

Pictogram	GHS08 GHS09
Signaalwoord	Waarschuwing
Gevarenaanduidingen	H351 Verdacht van het veroorzaken van kanker. H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt. P201 Alvorens te gebruiken de speciale aanwijzingen raadplegen. P202 Pas gebruiken nadat u alle veiligheidsvoorschriften gelezen en begrepen heeft. P273 Voorkom lozing in het milieu. P280C Beschermende handschoenen en beschermende kleding dragen. P302 + P352 BIJ CONTACT MET DE HUID: Met veel water/... wassen. P308 + P313 Na (mogelijke) blootstelling: een arts raadplegen. P405 Achter slot bewaren.
Aanvullende etiketelementen	EUH208 Bevat 1,2-benzisothiazool-3(2H)-on . Kan een allergische reactie veroorzaken. EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

**REGISTRATION REPORT  
Part A**

**Risk Management**

**Product code:** Frupica SC  
**Active Substance:** Mepanipyrim 440 g/l

**COUNTRY:** The Netherlands  
**All Zones**  
**Zonal Rapporteur Member State:** The Netherlands

**NATIONAL ASSESSMENT**

**Applicant:** Certis Europe B.V.  
**Date:** March 2018

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## **PART A – Risk Management**

This document describes the acceptable use conditions required for the extension of the label of Frupica SC containing the active substance mepanipyrim in The Netherlands. This evaluation is required subsequent to the inclusion of mepanipyrim on Annex 1.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C and where appropriate the addendum for The Netherlands. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national re-registration/registration by the EU review. It also includes assessment of data and information relating to Frupica SC where that data has not been considered in the EU review. Otherwise assessments for the safe use of Frupica SC have been made using endpoints agreed in the EU review of mepanipyrim.

This document describes the specific conditions of use and labelling required for The Netherlands for the re-registration/registration of Frupica SC.

Appendix 1 of this document provides a copy of the final product authorisation in The Netherlands.

Appendix 2 of this document is a copy of the approved product label for The Netherlands.

Appendix 3 of this document contains copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation.

Appendix 4 of this document provides a list of data in support of the evaluation.

### **1 Details of the application**

#### **1.1 Application background**

This application was submitted by Certis Europe B.V. on 23 December 2015.

The application was for extension of the uses for Frupica SC, a suspension concentrate containing 440g mepanipyrim/l, for use as a fungicide used in protected cultivation of tomato, aubergine, cucumber and zucchini by foliar spray application for the control of powdery mildew. In addition the PHI for strawberries is changed from 3 days to 1 day.

#### **1.2 Annex I inclusion**

Mepanipyrim was included on Annex I Directive 91/414 by means of 2004/62/EC and which was approved under Regulation 1107/2009 by means of Regulation (EC) 540/201.

The Annex I Inclusion Directive for mepanipyrim (**2004/62/EC**) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on mepanipyrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 30-03-2004, shall be taken into account. In this overall assessment:

Member States should/must/may pay particular attention to the protection of aquatic organisms. Risk mitigation measures should be applied where appropriate.

These concerns have been addressed within the current submission.

### 1.3 Regulatory approach

To obtain approval of the new uses for the product, Frupica SC must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in order to allow a label extension of an already approved product in the Netherlands in accordance with the above.

### 1.4 Data protection claims

Certis Europe B.V. claims protection of plant protection product data supporting the application for authorizing a label extension for Frupica SC according to the provisions set in Articles 33.4 and 59 of Regulation EC No. 1107/2009.

### 1.5 Letters of Access

Please refer to appendix 3.

## 2 Details of the authorisation

### 2.1 Product identity

Product Name	KIF-3535SC - Frupica SC
Authorization Number	12229 N
Function	fungicide
Applicant	Certis Europe B.V.
Composition	440 g/L mepanipyrin
Formulation type	Suspension concentrate [Code: SC]
Packaging	1 L HDPE-F-flask

### 2.2 Classification and labelling

#### 2.2.1 Classification and labelling under EG Nr. 1272/2008

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The identity of all substances in the mixture that contribute to the classification of the mixture \*:

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mepanipyrin

Pictogram:

GHS08

Signal word:

Warning

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		GHS09	
H-statements:		H351	Suspected of causing cancer.
		H410	Very toxic to aquatic life with long lasting effects.
P-statements:		P201	Obtain special instructions before use.
		P202	Do not handle until all safety precautions have been read and understood.
		P273	Avoid release to the environment.
		P280C	Wear protective gloves and protective clothing.
		P302+P352	IF ON SKIN: Wash with plenty of water/...
		P308+P313	IF exposed or concerned: Get medical advice/attention.
		P405	Store locked up.
Supplemental information:	Hazard	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.
		EUH208	Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction.
		SP1	Do not contaminate water with the product or its container.
		Child-resistant fastening obligatory?	Not applicable
		Tactile warning of danger obligatory?	Not applicable

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**Explanation:**

Pictogram: -

H-statements: Under the former DPD classification criteria R38 was assigned. However, under the CLP criteria the formulation Frupica SC does not have to assigned with H315.

P-statements: P280 is assigned based on the assigned hazard statement. P280 (gloves and coverall) is also required based on the risk assessment.

The other P-statements were proposed by the applicant and are accepted.

Other: EUH208 has to be assigned, since 1,2-benzisothiazolin-3-one is present in the formulation above 10% of its SCL.

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**2.2.2 R and S phrases under Directive 2003/82/EC (Annex IV and V)**

None.

**2.2.3 Other phrases**

None.

**2.3 Product uses (only those uses part of the label extension/ label change are provided here)**

PPP (product name/code):	Frupica SC
Active substance(s):	Mepanipyrim, 440 g/l
Formulation type:	Suspension concentrate (SC)

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks:  e.g. safener/synergist per ha  e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use  b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		

**New major uses (existing uses without GAP changes are not included in this GAP)**

1	NL	Tomato and aubergine	G	Powdery mildew (OIDILY)	Spraying	At beginning of infection  BBCH 11 – 89 (January – December)	2 / (7 days)	0.45-0.9	0.396	200 – 2000	1	In combination with a surfactant  0.045-0.09% spray solution
2	NL	Cucumber and zucchini (including bush pumpkin)	G	Powdery mildew SPHRFU	Spraying	At beginning of infection  BBCH 11 – 89 (January – December)	2 / (7 days)	0.45-0.9	0.396	200 – 2000	1	In combination with a surfactant  0.045-0.09% spray solution  2 applications per crop cycle. In the cucumber culture are up to 3 crop cycles per year. In the courgette culture up to 2 crop cycles per year.

**Changed major uses**

1	NL	Strawberry	F	<i>Botrytis</i> (BOTRCI) <i>Sphaerotheca aphans</i> (PODOAP)	Spraying	From stretching of the flower stems  BBCH 10-91 (January- December)	2 / (7 days)	0.9	0.396	200 – 1200	1	In combination with a surfactant  Change of PHI from 3 to 1 day. Changed spraying volumes.  Max. number of applications per year: 2
1	NL	Strawberry	G	<i>Botrytis</i> (BOTRCI)	Spraying	From stretching of the flower stems  BBCH 10-91 (January- December)	2 / (7 days)	0.9	0.396	200 – 1200	1	In combination with a surfactant  Change of PHI from 3 to 1 day. Changed spraying volumes.  Max. number of applications per year: 4

### **3 Risk management**

#### **3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles**

##### **3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)**

**Overall Summary:** The product Frupica SC is a suspension concentrate. All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. The appearance of the product is that of opaque and light viscous, off-white liquid with an organic odour. It is not explosive and has no oxidising properties. It has a self-ignition temperature of 465 °C. In aqueous solution, it has a pH value around 6.56. Its technical characteristics are acceptable for a suspension concentrate formulation.

In fluorinated HDPE (HDPE-F), the product is stable for 2 years when stored at ambient conditions.

**Implications for labelling:** *None*

**Compliance with FAO specifications:** The product Frupica SC complies with FAO specifications.

**Compatibility of mixtures:** Frupica SC is not claimed for use in tank mixes in this application.

**Nature and characteristics of the packaging:** Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

**Nature and characteristics of the protective clothing and equipment:** Information regarding the required protective clothing and equipment for the safe handling of Frupica SC has been provided and is considered to be acceptable.

##### **3.1.2 Methods of analysis (Part B, Section 2, Point 5)**

###### **3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)**

Adequate analytical methods were provided to enable the determination of the active substance in the product.

In addition, pre-registration methods were provided and validated to support the shelf-life study and the determination of the suspensibility.

###### **3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)**

All analytical methods are active substance data and were provided in the EU review of mepanipyrim and were considered adequate.

For surface water, the LOQ of the GC-MS method, evaluated during the substance review, is 0.1µ/L, which satisfies the Dutch national requirements.

### **3.1.3 Mammalian Toxicology (Part B, Section 3, Point 7)**

#### **3.1.3.1 Acute Toxicity (Part B, Section 3, Point 7.1)**

Acute toxicity studies for Frupica SC were not evaluated as part of the EU review mepanipyrin. Therefore, all relevant data were provided and are considered adequate.

Frupica SC containing 440 g/L mepanipyrin, has a low toxicity in respect to acute oral and dermal toxicity and is not irritating to the rabbit eye. It was not a skin irritant and is not a skin sensitiser to the guinea pig.

#### **3.1.3.2 Operator Exposure (Part B, Section 3, Point 7.3)**

Operator exposure to Frupica SC was not evaluated as part of the EU review of mepanipyrin for this submitted rate/crop. Therefore all relevant data and risk assessments have been provided and are considered to be adequate.

Operator exposure was assessed against the AOEL agreed in the EU review (0.07 mg/kg bw/day). Data on dermal absorption of Frupica SC was provided and considered acceptable. Operator exposure was modelled using the Dutch Greenhouse Model for the greenhouse uses and the EFSA OPEX model for the field use.

According to the model calculations, it can be concluded that the risk for the operator using Frupica SC on strawberry, tomatoes, courgettes and cucurbitaceae is acceptable with the use of personal protective equipment (gloves and coverall during mixing/loading and application).

#### **3.1.3.3 Bystander Exposure (Part B, Section 3, Point 7.4)**

Bystander exposure to Frupica SC was not evaluated as part of the EU review of mepanipyrin. Therefore, all relevant data and risk assessments have been provided and are considered adequate. It is concluded that there is no undue risk to any bystander due to no estimated exposure of bystanders arising from the greenhouse application of Frupica SC.

For the greenhouse application resident exposure was estimated with the Lee side turbulence model. The calculations show that the exposure amounts to 0.07% of the AOEL. Therefore the risk to residents near glasshouses is considered negligible.

For the field application resident exposure was estimated with the EFSA OPEX model. The calculations show that the exposure amount to a maximum of 47% of the AOEL. Therefore the risk to residents is considered acceptable.

#### **3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)**

Worker exposure to Frupica SC was not evaluated as part of the EU review of mepanipyrin. Therefore, all relevant data and risk assessments have been provided and are considered adequate. It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing (but no PPE), when re-entering fruiting vegetable crops treated with Frupica SC. The requested change in the application in strawberry does not affect the worker exposure and therefore this is covered by the current authorization.

### 3.1.4 Residues and Consumer Exposure (Part B, Section 4, Point 8)

#### 3.1.4.1 Residues (Part B, Section 4, Points 8.3 and 8.7)

Subsequent to the EU review of mepanipyrim an evaluation of all uses has been made to establish EU MRLs ([EFSA Journal 2011;9\(8\):2342](#)). MRLs have been set according to Regulation (EC) 396/2005. An amendment of MRLs for strawberry, tomato, aubergine and cucumber was performed (EFSA Journal 2015;13(3):4037) Results of this recent MRL review are given in the table below

**Table 3.1.4.1-1.(Proposed) MRLs for mepanipyrim in strawberry, tomato, aubergine, cucumber**

Commodity	MRL (mg/kg)	Remark
residue definition for monitoring: mepanipyrim		
Strawberries	3	<a href="#">EFSA Journal 2015;13(3):4037</a>
Tomatoes	1.5	<a href="#">EFSA Journal 2015;13(3):4037</a>
Aubergines	1.5	<a href="#">EFSA Journal 2015;13(3):4037</a>
Cucumber	0.5	<a href="#">EFSA Journal 2015;13(3):4037</a>
courgette, patisson	0.6	<a href="#">current</a> EU MRL

#### 3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)

The TMDI calculation revealed that maximal 12% of the ADI will be used for the FR all population. All other EU diets use less of the ADI. The NESTI calculation resulted in maximal 17% of the ARfD for the product tomato for the Belgian children. All other products use less of the ARfD.

Taking into account the properties of mepanipyrim in soil, residues in succeeding crops are not expected. New processing studies indicate that residues will be diluted in strawberry jam and preserves. In tomato, residues of mepanipyrim will be diluted in juice and preserves, and slight concentration (factor 1.3) was found in tomato ketchup and puree. Taking into account the TMDI and NESTI calculations, these processing factors do not significantly influence the outcome of the consumer risk assessment.

It can be concluded that the use of the product Frupica SC does not lead to an unacceptable risk for consumers when applied according to the recommendations.

### 3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

No new studies are presented; all data were reviewed in the EU review of mepanipyrim. Appropriate endpoints from the EU review were used to calculate PECs for mepanipyrim in soil, surface water, ground water and air for the intended use patterns. As the minor change in PHI values is specified for the field application in the GAP, it is agreed that only the greenhouse uses are considered in the fate assessment.

### **3.1.5.1 Predicted Environmental Concentration in Soil (PEC<sub>soil</sub>) (Part B, Section 5, Points 9.4 and 9.5)**

Based on the GAP no exposure to soil is expected for protected crops (permanent greenhouses only) for non-persistent substance. Although the mean lab DT<sub>50</sub> of mepanipyrim is 105.4 days, the maximum field DT<sub>50</sub> of 75.1 days demonstrates that the active substance mepanipyrim is not persistent. Therefore the PEC soil is not required and was not calculated for the applied uses.

### **3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC<sub>GW</sub>) (Part B, Section 5, Point 9.6)**

The PEC of mepanipyrim in ground water has been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PEARL models and the K<sub>oc</sub> values established in the EU review or agreed in the assessment based on new data provided. No major metabolites were observed.

Mepanipyrim has a pH-dependant sorption and therefore the endpoints that were selected were from an alkaline soil (pH: 7.9) with the lowest K<sub>OC</sub> as a worst case. The predicted environmental concentration (PEC<sub>GW</sub>) at 1m depth for mepanipyrim following 26 years use on winter cereals at 6 applications of 396g a.s./ha with a 7-day interval with 15% foliar interception at the respective applications, are examined against the standard of 0.01 µg/L. This is the standard of 0.1 µg/L with an additional safety factor of 10 for vulnerable groundwater protection areas (NL-specific situation). Results of PEARL 4.4.4 using the Kremsmünster scenario show that the expected leaching for mepanipyrim is smaller than 0.01 µg/L for the proposed applications. Therefore all the proposed applications meet the standards for leaching.

### **3.1.5.3 Predicted Environmental Concentration in Surface Water (PEC<sub>SW</sub>) (Part B, Section 5, Points 9.7 and 9.8)**

The PEC of mepanipyrim in surface water (PEC<sub>sw</sub> and PEC<sub>sed</sub>) has been assessed with the Steps 1&2 in FOCUS (v3.2) model, the Dutch specific TOXSWA 1.2 model and the DT<sub>50</sub> water/sediment values established in the EU review or agreed in the assessment based on new data provided. Based on the recommended use rate of 6 applications of 396g a.s./ha with a 7-day interval, the maximum PEC values for surface water and sediment have been calculated according to FOCUS for the active substance mepanipyrim. No major metabolites were found to be of relevance. The maximum PEC<sub>sw</sub> is calculated as 0.6404 µg/L.

The results for PEC surface water for the active substance and its metabolites were used for the ecotoxicological risk assessment.

#### *Monitoring data groundwater*

There are no data available regarding the presence of the substance mepanipyrim in groundwater.

#### *Monitoring data surface water*

Data from the Pesticide Atlas are used to evaluate potential exceedances of the authorisation threshold and environmental quality standards. Monitoring data is available for the active substance mepanipyrim (most recent data from 2015). As there is no exceedance of thresholds, the monitoring data have no consequences for the proposed uses of the product.

#### *Drinking water criterion*

Mepanipyrim has been on the Dutch market for > 3 years (authorised since 21-09-2001). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. The Ctgb does under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water are met.

### **3.1.5.4 Predicted Environmental Concentration in Air (PEC<sub>Air</sub>) (Part B, Section 5, Point 9.9)**

The fate and behaviour in air of mepanipyrim was evaluated during the Annex I Inclusion and is considered to be non-volatile. No assessment is required.

### **Implications for labelling resulting from environmental fate assessment**

None

### **3.1.6 Ecotoxicology (Part B, Section 6, Point 10)**

Current risk assessment concerns the glasshouse use of Frupica SC in tomato and aubergine, and cucumber and zucchini (including bush pumpkin). Change in use for strawberry (amendment of Pre-harvest interval (PHI)) is considered not relevant for ecotoxicology and is covered in the original assessment of Frupica SC (12229 N).

#### **3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)**

Effects on birds and mammals for Frupica SC were not evaluated as part of the EU review of mepanipyrim. However further data on Frupica SC is not relevant as active substance data on toxicity to birds is used and additional formulation data are not considered essential. Therefore all relevant data were assessed in the EU review. Risk assessments for Frupica SC with the proposed use pattern have been provided and are considered adequate.

The risk assessment for effects on birds and mammals is carried out according to the European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. doi:10.2903/j.efsa.2009.1438. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

As it concerns indoor uses, only secondary poisoning through fish-eating birds and mammals was assessed, as mepanipyrim has  $\log P_{ow} > 3.0$ . The current application concerns an extension of the label and involves only indoor crops and the only CMS is The Netherlands. For glasshouse uses in The Netherlands, management practice includes regular sterilisation of the soil, which prevents the formation of a natural soil organism community within glasshouses. Exposure to natural soils is not expected. Moreover, according to Part B5 Section 9.4., active substance mepanipyrim is not persistent, and for non-persistent substances no exposure to soil is expected for protected crops (permanent greenhouses only). Therefore soil PECs were not calculated, and risk to earthworm-eating birds and mammals through earthworms was not addressed.

The TER values all exceed the trigger values of 5 for long-term risk in relation to secondary poisoning through fish, thus indicating no unacceptable risk to birds and mammals from the proposed use.

### 3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

Effects on aquatic organisms for Frupica SC were not evaluated as part of the EU review of mepanipyrim. Three studies are available in which the acute toxicity of Frupica SC is tested (on respectively *Oncorhynchus mykiss*, *Daphnia magna* and *Pseudokirchneriella subcapitata*). However further data on Frupica SC is not relevant as active substance data on toxicity to aquatic organisms is used and additional formulation data are not considered essential. Therefore all relevant data were assessed in the EU review. Risk assessments for Frupica SC with the proposed use pattern are provided and are considered adequate.

The TER using NL-specific worst-case PEC values exceed the relevant triggers, indicating that Frupica SC does not pose an unacceptable risk to aquatic organisms following applications according to the recommended use pattern.

### 3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

#### Bees

Effects on bees for Frupica SC were not evaluated as part of the EU review of mepanipyrim. However further data on Frupica SC is not relevant as active substance data on toxicity to bees is used and additional formulation data are not considered essential. Therefore all relevant data were assessed in the EU review. Risk assessments for Frupica SC with the proposed use pattern were provided and are considered adequate.

The risks of Frupica SC to honey-bees was assessed in accordance with the CTGB Evaluation Manual, estimated from acute oral and contact studies with formulation KIF-3535 50% WP (worst case values compared to active substance data), and the maximum single application rate of 396 g as/ha. The hazard quotient is considerably less than the trigger of 50 during the screening step, indicating that the active ingredient poses a low risk to bees. Therefore a low risk to bees is expected from the application of Frupica SC according to the recommended use pattern.

#### Other non-target arthropods

Effects on non-target arthropods for Frupica SC were not evaluated as part of the EU review of mepanipyrim. Risk assessments for Frupica SC with the proposed use pattern were provided and are considered adequate.

In two Tier 1 laboratory tests on respectively *Aphidius rhopalosiphi* and *Typhlodromus pyri*, no statistically significant effects on mortality or effects on reproduction were observed at dose rates up to and including 3.285 L/ha. The maximum application rate of Frupica SC is 6×0.9 L/ha, which results in exposure rate of 2.88 L product/ha (considering MAF of 3.2). Since the effects of Frupica SC on *Aphidius rhopalosiphi* and *Typhlodromus pyri* are therefore under the trigger of 30% effect at the maximum dose exposure rate of 2.88 L product/ha, However, data for more species are available. For *T. cacaoiae* 96% adverse effects on parasitism were found at a dose rate of 0.5 kg a.s./ha. For *C. carnea* 35.9% effects on reproduction were found at 0.5 kg a.s./ha. Also a test with *C. septempunctata* is available, which shows that here were more than 30% effects on mortality and reproduction (47% mortality and 55% effects on reproduction) at a dose rate of 0.5 kg a.s./ha. The tested dose rate of 0.5 kg a.s./ha is lower than the actual dose rate of 0.396 kg a.s./ha x MAF (= 3.2).

Also semi-field tests are available for *C. septempunctata*, *C. carnea* and *A. rhopalosiphi*. These studies were done at dose rates of 0.6 and 2 x 0.4 kg a.s./ha, lower than the actual application rate which is 6 times 0.396 kg a.s./ha, hence 0.396 kg a.s./ha x 3.2 (MAF), which is higher than the tested dose rates. In the semi-field tests the effects were close or higher than the trigger value of 30%. Hence, it is clear that adverse effects on beneficials cannot be excluded and for that reason a warning sentence is necessary:

*Let op: dit middel kan schadelijk zijn voor natuurlijke vijanden. Raadpleeg deskundigen (uw leverancier van natuurlijke vijanden, de producent van dit middel, uw adviseur) over het gebruik van dit middel in combinatie met het gebruik van natuurlijke vijanden.*

#### **3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms (Part B, Section 6, Point 10.6)**

The current application concerns an extension of the label and involves only indoor crops and the only CMS is The Netherlands. For glasshouse uses in The Netherlands, management practice includes regular sterilisation of the soil, which prevents the formation of a natural soil organism community within glasshouses. Exposure to natural soils is not expected. Moreover, according to Part B5 Section 9.4., active substance mepanipyrim is not persistent, and for non-persistent substances no exposure to soil is expected for protected crops (permanent greenhouses only). Therefore soil PECs are were not calculated, and soil risk assessment was not performed.

#### **3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)**

No tests are required considering the persistence trigger in accordance with the EU Guidance Document, since the field  $DT_{90}$  is <365 days for mepanipyrim, indicating that there will be no long-term exposure or accumulation of residues.

#### **3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)**

The current application concerns an extension of the label and involves only indoor crops and the only CMS is The Netherlands. For glasshouse uses in The Netherlands, management practice includes regular sterilisation of the soil, which prevents the formation of a natural soil organism community within glasshouses. Exposure to natural soils is not expected. Moreover, according to Part B5 Section 9.4., active substance mepanipyrim is not persistent, and for non-persistent substances no exposure to soil is expected for protected crops (permanent greenhouses only). Therefore soil PECs are were not calculated, and effects on soil microbial activity were not addressed.

#### **3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)**

##### **Non-Target Plants**

Not applicable as Frupica SC is not an herbicide and only greenhouse applications are of concern.

##### **Other non-target species (Flora and Fauna)**

The risk assessment for activated sludge is a Dutch specific aspect.

Exposure to activated sludge is expected from indoor uses and from outdoor uses on hardened surfaces. Models to calculate the exposure concentration in the sewage treatment plant (STP) are currently available for hardened surfaces, for indoor cultivations of mushrooms and for the potato processing industry. For other indoor uses, models are not available. For the proposed uses exposure of activated sludge may occur. However, to date there is no model available to calculate influent concentrations in the sewage treatment plant (STP) for these application types. Therefore, the proposed application cannot be

examined against the standard for activated sludge. For the time being this issue is not taken into consideration.

**Implications for labelling resulting from ecotoxicological assessment:**

H410 - Very toxic to aquatic life with long-lasting effects

**3.1.7 Efficacy (Part B, Section 7, Point 8)**

Frupica is already authorized in the Netherlands for the control of powdery mildew in strawberry, ornamentals, amenity areas and plant breeding crops and basic seed production for arable and vegetable crops. Frupica is also used for control of botrytis in flower bulb and flower tuber crops. Newly proposed uses are the control of powdery mildew in zucchini, cucumber, aubergine and tomato.

**Efficacy**

Minimum effective dose

Based on the data it should be concluded that the lowest dose tested (0,045%) performed as well as the claimed dose rate. As such it is concluded that 0,045% (45 grams per 100 L water) is the minimum effective dose for the claimed uses. The label claim has to be changed from a rate of 0.09% to a rate of 0.045-0.09%. Taking into account that for other already authorised uses a rate of 0.9 L/ha was required, the maximum spray volume is changed from 1000L/ha (when applied at 0.09%) to 2000L/ha (when applied at 0.045%).

Cucumber and zucchini

No trials were submitted for zucchini. According to extrapolation table for effectiveness of fungicides, diseases on Cucurbitaceae 14-19722 it is possible to extrapolate from cucumber to zucchini for powdery mildew. Data from cucumber can therefore be used to establish MED for zucchini.

Tomato and aubergine

With respect to controlling the species claimed in the GAP: on tomato only the upper side of the leaves was mentioned in the dRR, thus only providing information on control of *O. lycopersici* since this species is found on the outside of leaves. No information on the control of *O. lycopersici* was provided for aubergine. According to expert judgement this also possible for *O. lycopersici*

*L. taurica* is situated in the leaf and the white mycelium is visible on the underside of the leaves. Trials were mentioned in the BAD in which both *L. taurica* and *O. lycopersici* were tested. However the MED results for *L. taurica* alone was not provided.

Frequency of application

In the trials with cucumber the number of applications was: 3 (2 trials), 4 (6 trials). And in tomato it was: 3 (2 trials) and 4 (9 trials). In the GAP however a frequency of maximum 2 applications per cropping cycle is suggested. Closer inspection of the trials shows that efficacy increases strongly with an increasing number of applications and 4 applications gives satisfactory level of control of the target pest.

Efficacy: Control of powdery mildew in Cucumber and zucchini

8 trials were carried on the control of powdery mildew in cucumber. Data after 1-4 application was provided. 7DAA2 was evaluated since mas 2 application is stated in the GAP. Frupica 0.09% demonstrated comparable or higher efficacy than reference products, with a mean curative control around 70% and a preventive control of nearly 90%. As it is explained in the minimum effective dose section, it

is concluded that the lowest dose tested 0.045% performed as well as the claimed dose rate 0.09%. The claimed use can be authorize with a dose rate range of 0.045-0.09%.

No trials were submitted for zucchini. According to the Dutch Extrapolation table and the EPPO extrapolation table for effectiveness of fungicides, diseases on Cucurbitaceae 14-19722 it is possible to extrapolate from cucumber to zucchini for powdery mildew. Thus in principle the trial reports submitted for cucumber suffice for the claim made in zucchini. And extrapolation to zucchini grown outdoors in the field is also possible according to the Dutch extrapolation table.

**Efficacy: Control of powdery mildew in tomato and aubergine**

11 trials were carried out on control of *Oidium lycopersicum* and *Leveillula taurica* on tomato. Data after 1-4 application was provided. 7DAA2 was evaluated since mas 2 application is stated in the GAP. In the control of *oidium lycopersicum*, Frupica 0.09% deomonstrated comparable or higher efficacy than reference products, with a mean curative control of 77% and a preventive control of 87%. In the control of *Leveillula taurica*, Frupica 0.09% deomonstrated lower efficacy than reference products, with a mean curative control of 55% and a preventive control of 60%. Data of minimum effective dose was also not provided for *Leveillula taurica*. Based on the submitted data only *Oidium lycopersicum* can be authorized. As it is explained in the minimum effective dose section, it is concluded that the lowest dose tested 0.045% performed as well as the claimed dose rate 0.09%. The claimed use can be authorize with a dose rate range of 0.045-0.09%.

No data on efficacy of Frupica in aubergine is provided. According to expert judgement extrapolation can be made from tomato to aubergnie possible for the use on *O. lycopersici*. **Phytotoxicity**

In the 19 effectiveness trials and 23 phytotoxicity trials (cucumber 10 trials, tomato 3 and eggplant 10) leaf wrinkling was observed in cucumber in the winter. The following warning sentence is added to the WG/the label:

In komkommer bestaat de kans op enige gewasschade (gekreukeld blad) in de wintermaanden.

According to the GAP a surfactant should be applied. No negative effect on the yield was observed.

#### **Adverse effects**

##### **Impact on parts of plant used for propagation**

The authorised label contains a warning sentence that the influence on the germination is not tested. Influence on the germination was not tested on cucumber, tomato, zucchini or aubergine. An additional warning sentence is not necessary.

##### **Impact on succeeding crops**

Tomato, eggplant and cucumber are grown on substrate. The substrate is replaced after each crop cycle. An impact on succeeding crops is therefore not expected.

##### **Impact on adjacent crops**

Tomato, eggplant and cucumber are grown as monocultures by growers. A risk for adjacent crops is therefore not expected.

#### **Resistance**

Mepaniyrim belongs to the anilinepyridimines (FRAC 9). The mode of action is inhibition of methione biosynthesis and inhibition of secretion of hydrolytic enzymes. No indication of cross resistance was found.

According to FRAC the risk for resistance is medium and resistance management is required. The following sentence was already added to the authorized WG/label:

**Resistentiemanagement**

Dit middel bevat de werkzame stof mepanipirim. Mepanipirim behoort tot de anilino-pyrimidines. De FRAC code is 9. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.

### **3.2 Conclusions**

The extension of the authorisation can be granted.

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

None.

## **Appendix 1 – Copy of the product authorisation**

The authorisation document can be found above part A.