# HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

## 1. BESLUIT

Op 25 september 2014 is van

BASF Nederland B.V.
Postbus 1019
6801 MC ARNHEM

een aanvraag tot wijziging van de toelating als bedoeld in artikel 45, eerste lid Verordening 1107/2009 van het gewasbeschermingsmiddel

**Opus Team**

op basis van de werkzame stoffen epoxiconazool en fenpropimorf.

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

Alle bijlagen vormen een onlosmakelijk onderdeel van dit besluit.

Voor nadere gegevens over deze toelating wordt verwezen naar de bijlagen:
- Bijlage I voor details van de aanvraag en toelating.
- Bijlage II voor de etikettering.
- Bijlage III voor wettelijk gebruik.
- Bijlage IV voor de onderbouwing.

### 1.1 Wijziging toelating

De toelating van het middel Opus Team is laatstelijk bij besluit d.d. 4 juli 2014 verlengd tot 1 juli 2024. De toelating van het middel Opus Team wordt gewijzigd en is met ingang van datum dezes toegelaten voor de in bijlage III genoemde toepassingen. De wijziging betreft het opnemen van een toepassing in granen met een lagere dosering van 1 liter middel per hectare waarvoor minder stringente driftbeperkende maatregelen van toepassing zijn. Voor de gronden van dit besluit wordt verwezen naar bijlage IV bij dit besluit.

### 1.2 Samenstelling, vorm en verpakking

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

### 1.3 Gebruik

Het middel mag slechts worden gebruikt volgens het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in bijlage III van dit besluit.

### 1.4 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 bij dit besluit.
- Het toelatingsnummer met een cirkel met daarin de aanduiding van de W-codering zoals vermeld onder “toelatingsinformatie” in bijlage I bij dit besluit.
- De etikettering zoals opgenomen in bijlage II bij dit besluit.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in bijlage III bij dit besluit.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.

### 1.5 Aflever- en opgebruiktermijn (respijtperiode)

Aangezien de wijziging niet leidt tot een inperking van de toelating met toelatingsnummer 11407 en volgnummer w.7, is het niet noodzakelijk om het afleveren en opgebruik van verpakkingen met volgnummer W.7 te beperken middels respijttermijnen

Het nieuwe gebruiksvoorschrift en de nieuwe etikettering dienen bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. De te hanteren w-coderingen en aflever- en opgebruiktermijnen voor oude verpakkingen staan vermeld onder “toelatingsinformatie” in bijlage I.

## 2. WETTELIJKE GRONDSLAG

| | |
|---|---|
| Besluit | Artikel 45, eerste lid Verordening 1107/2009. |
| Classificatie en etikettering | artikel 31 en artikel 65 van de Verordening (EG) 1107/2009 |
| Gebruikt toetsingskader | RGB (Hoofdstuk 2); en de Evaluation Manual 1.1. |

## 3. BEOORDELINGEN

### 3.1 Fysische en chemische eigenschappen

Dit aspect is niet beoordeeld aangezien de gevraagde wijziging binnen de risicobeoordeling van de oorspronkelijke toelating van Opus Team valt.

### 3.2 Analysemethoden

Dit aspect is niet beoordeeld aangezien de gevraagde wijziging binnen de risicobeoordeling van de oorspronkelijke toelating van Opus Team valt.

### 3.3 Risico voor de mens

Dit aspect is niet beoordeeld aangezien de gevraagde wijziging binnen de risicobeoordeling van de oorspronkelijke toelating van Opus Team valt.

### 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.

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***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 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.*

Wageningen, 6 februari 2015

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

| | |
|---|---|
| *Aanvraagnummer:* | 20146230 NLWG |
| *Type aanvraag:* | aanvraag tot wijziging van nationaal addendum |
| *Middelnaam:* | Opus Team |
| *Verzenddatum aanvraag:* | 11 september 2014 |
| *Formele registratiedatum: ** | 6 oktober 2014 |
| *Datum in behandeling name:* | 10 december 2014 |
| *Datum compliance check:* | n.v.t. |

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

## 2.2 Stofinformatie

| Werkzame stof | Gehalte |
|---|---|
| epoxiconazool | 84G/L |
| fenpropimorf | 250G/L |

De werkzame stof epoxiconazool is bij Richtlijn 2008/107/EG, d.d. 25 november 2008, van de Europese Commissie van de Europese Gemeenschappen opgenomen in Bijlage I van Richtlijn 91/414/EEG en goedgekeurd krachtens Verordening (EG) No 1107/2009 (Uitvoeringsverordening (EU) No 540/2011 d.d. 25 mei 2011).

De werkzame stof fenpropimorf is bij Richtlijn 2008/107/EG, d.d. 25 november 2008, van de Europese Commissie van de Europese Gemeenschappen opgenomen in Bijlage I van Richtlijn 91/414/EEG en goedgekeurd krachtens Verordening (EG) No 1107/2009 (Uitvoeringsverordening (EU) No 540/2011 d.d. 25 mei 2011).

## 2.3 Toelatingsinformatie

| | |
|---|---|
| Toelatingsnummer: | 11407 N |
| Expiratiedatum: | 1 juli 2024 |
| Biocide, gewasbeschermingsmiddel of toevoegingsstof: | Gewasbeschermingsmiddel |
| Gebruikers: | Professioneel |

W-coderingen en aflever- en opgebruiktermijnen:

- *W-codering professioneel gebruik:* W.8
- *Vorige w-codering professioneel gebruik:* W.7.
- *Aflevertermijn professioneel gebruik:* onbeperkt
- *Opgebruiktermijn professioneel gebruik:* onbeperkt

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**HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN**

**BIJLAGE II Etikettering van het middel Opus Team**

Professioneel gebruik
de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel: epoxiconazool, fenpropimorf

| | |
|---|---|
| Pictogram | GHS07<br>GHS08<br>GHS09 |
| Signaalwoord | GEVAAR |
| Gevarenaanduidingen | H332 Schadelijk bij inademing.<br>H351 Verdacht van het veroorzaken van kanker.<br>H360Df Kan het ongeboren kind schaden. Wordt ervan verdacht de vruchtbaarheid te schaden.<br>H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen. |
| Voorzorgsmaatregelen | P201 Alvorens te gebruiken de speciale aanwijzingen raadplegen.<br>P273 Voorkom lozing in het milieu.<br>P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen.<br>P391 Gelekte/gemorste stof opruimen.<br>SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.<br>SPo 2 Was alle beschermende kleding na gebruik. |
| Aanvullende etiketelementen | EUH205 Bevat epoxyverbindingen. Kan een allergische reactie veroorzaken.<br>EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen. |
| Kinderveilige sluiting verplicht | Nee |
| Voelbare gevaarsaanduiding verplicht | Nee |

**HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN**

**BIJLAGE III** bij het besluit d.d. 6 februari 2015 tot wijziging van de toelating van het middel Opus Team, toelatingnummer 11407 N

**Wettelijk Gebruiksvoorschrift**
Toegestaan is uitsluitend het professionele gebruik als schimmelbestrijdingsmiddel door middel van een bespuiting in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden

| Toepassings-gebied | Te bestrijden organisme | Dosering (middel) per toepassing | Maximaal aantal toepassingen per teeltcyclus | Minimum interval tussen toepassingen in dagen | Veiligheidstermijn in dagen |
|---|---|---|---|---|---|
| Suikerbiet | Bladvlekkenziekten [1,2]<br>Roest [3]<br>Echte meeldauw [4] | 1,0 L/ha | 2 | 21 | 46 |
| Wintertarwe, | Bruine roest [5]<br>Gele roest [6]<br>Echte meeldauw [9] | 1,0 L/ha* | 2 | 21 | 35 |
| | Bruine roest [5]<br>Gele roest [6]<br>Bladvlekkenziekten [7,13]<br>Kafjesbruin [8]<br>Echte meeldauw [9] | 1,5 L/ha* | | | |
| Wintergerst | Gele roest [6]<br>Dwergroest [10]<br>Bladvlekkenziekten [11]<br>Echte meeldauw [9] | 1,0 L/ha* | 2 | 21 | 35 |

| Toepassings-gebied | Te bestrijden organisme | Dosering (middel) per toepassing | Maximaal aantal toepassingen per teeltcyclus | Minimum interval tussen toepassingen in dagen | Veiligheidstermijn in dagen |
|---|---|---|---|---|---|
| | Gele roest [6]<br>Dwergroest [10]<br>Bladvlekkenziekten [11,14]<br>Netvlekkenziekte [12]<br>Echte meeldauw [9] | 1,5 L/ha* | | | |
| Winterrogge | Bruine roest [5]<br>Gele roest [6]<br>Bladvlekkenziekten [11,13]<br>Echte meeldauw [9] | 1,5 L/ha | 2 | 21 | 35 |
| Triticale | Bruine roest [5]<br>Gele roest [6]<br>Echte meeldauw [9] | 1,0 L/ha* | 2 | 21 | 35 |
| | Bruine roest [5]<br>Gele roest [6]<br>Bladvlekkenziekten [7,13]<br>Kafjesbruin [8]<br>Echte meeldauw [9] | 1,5 L/ha* | | | |
| Spelt | Bruine roest [5]<br>Gele roest [6]<br>Echte meeldauw [9] | 1,0 L/ha* | 2 | 21 | 35 |
| | Bruine roest [5]<br>Gele roest [6]<br>Bladvlekkenziekten [7,13]<br>Kafjesbruin [8]<br>Echte meeldauw [9] | 1,5 L/ha* | | | |
| Zomertarwe | Bruine roest [5]<br>Gele roest [6]<br>Echte meeldauw [9] | 1,0 L/ha* | 2 | 21 | 35 |

| Toepassings-gebied | Te bestrijden organisme | Dosering (middel) per toepassing | Maximaal aantal toepassingen per teeltcyclus | Minimum interval tussen toepassingen in dagen | Veiligheidstermijn in dagen |
|---|---|---|---|---|---|
| | Bruine roest [5]<br>Gele roest [6]<br>Bladvlekkenziekten [7,13]<br>Kafjesbruin [8]<br>Echte meeldauw [9] | 1,5 L/ha* | | | |
| Zomergerst | Gele roest [6]<br>Dwergroest [10]<br>Bladvlekkenziekten [11]<br>Echte meeldauw [9] | 1,0 L/ha* | 2 | 21 | 35 |
| | Gele roest [6]<br>Dwergroest [10]<br>Bladvlekkenziekten [11,14]<br>Netvlekkenziekte [12]<br>Echte meeldauw [9] | 1,5 L/ha* | | | |
| Zomerrogge | Bruine roest [5]<br>Gele roest [6]<br>Bladvlekkenziekten[11,13]<br>Echte meeldauw [9] | 1,5 L/ha | 2 | 21 | 35 |
| Haver | Echte meeldauw [9] | 1,5 l/ha | 2 | 21 | 35 |

* Maximale dosering is mede afhankelijk van de technische inzetbaarheid van driftreducerende maatregelen, zie hiervoor de toepassingsvoorwaarden.

[1] Bladvlekkenziekte (*Cercospora beticola* )

[2] Bladvlekkenziekte *(Ramularia beticola* )

[3] Roest (*Uromyces betae)*

[4] Echte meeldauw (*Erysiphe betae* )

[5] Bruine roest (*Puccinia recondita)*

[6] Gele roest (*Puccinia striiformis*)

[7] Bladvlekkenziekte *(Mycosphaerella graminicola (Septoria tritici* ))

[8] Kafjesbruin (*Phaeosphaeria nodorum (Septoria Nodorum))*

[9] Echte meeldauw (*Blumeria graminis* (*Erysiphe graminis*))

[10] Dwergroest (*Puccinia hordei* )

[11] Bladvlekkenziekte *(Rynchosporium secalis)*
[12] Netvlekkenziekte *(Pyrenophora teres* )
[13] Bladvlekkenziekte (*Pyrenophora tritici-repentis)*
[14] Bladvlekkenziekte *(Ramularia collo-cygni)*

Het gebruik in de teelt van vezelvlas en ter bestrijding van kroonroest in de teelt van haver is beoordeeld conform de “vereenvoudigde uitbreidingsprocedure”. Er is voor deze toepassingen geen werkzaamheids- en fytotoxiciteitonderzoek uitgevoerd. Er wordt daarom aangeraden een proefbespuiting uit te voeren, voordat het middel gebruikt wordt. Gebruik van dit middel in deze toepassingsgebieden, komt voor risico en verantwoordelijkheid van de gebruiker.

| Toepassings-gebied | Te bestrijden organisme | Dosering (middel) per toepassing | Maximaal aantal toepassingen per teeltcyclus | Minimum interval tussen toepassingen in dagen | Veiligheidstermijn in dagen |
|---|---|---|---|---|---|
| Haver | Kroonroest [15] | 1,0 -1,5 L/ha* | 2 | 21 | 35 |
| Vezelvlas | Echte meeldauw [16] | 1,0 -1,5 L/ha* | 2 | 21 | - |

* Maximale dosering is afhankelijk van de technische inzetbaarheid van driftreducerende maatregelen, zie hiervoor de toepassingsvoorwaarden.
[15] Kroonroest (*Puccinia coronata*)
[16] Echte meeldauw (*Oidium lini*)

**Toepassingsvoorwaarden**

Opus Team mag in de teelt van haver maximaal 2 keer per teeltcyclus worden toegepast.

Het loof en de koppen van met Opus Team behandelde suikerbieten mogen niet voor dierlijke vervoedering worden aangewend.

Stro van met Opus Team behandeld graan mag niet voor dierlijke vervoedering worden aangewend.

Vlas en lijnzaad van behandeld vezelvlas mag niet voor dierlijke vervoedering worden aangewend.

Om in het water levende organismen te beschermen is toepassing van het middel in de teelt van suikerbiet, granen en vezelvlas, uitsluitend toegestaan wanneer in percelen die grenzen aan oppervlaktewater gebruik wordt gemaakt van één van de volgende driftreducerende maatregelen.
Let op: de voorgeschreven driftreducerende maatregelen zijn afhankelijk van de dosering.

- Dosering tot maximaal 1,0 l/ha,
  - minimaal 90% driftreducerende spuitdoppen.
- Dosering tot maximaal 1,5 l/ha
  - minimaal 75% driftreducerende spuitdoppen in combinatie met luchtondersteuning;
  - minimaal 50% driftrecuderende spuitdoppen in combinatie met Hardi TwinForce luchtondersteuning;
  - Lage spuitboomhoogte (30 cm boven de top van het gewas) met minimaal 50% driftreducerende spuitdoppen in combinatie met luchtondersteuning;
  - Sleepdoek.

Opus Team mag in de teelt van vezelvlas alleen toegepast worden vanaf gewasstadium BBCH 40.

Om het grondwater te beschermen mag dit product niet worden gebruikt in grondwaterbeschermingsgebieden.

Resistentiemanagement
Dit middel bevat de werkzame stoffen epoxiconazool en fenpropimorf. Epoxiconazool behoort tot de ‘demethylation inhibitors’ (DMI fungiciden), subgroep triazolen, de Frac code is 3. Fenpropimorf behoort tot de morfolineverbindingen, de FRAC code is 5. 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.

**HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN**

**BIJLAGE IV** bij het besluit d.d. 6 februari 2015 tot wijziging van de toelating van het middel Opus Team, toelatingnummer 11407 N

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# 1 Identity of the plant protection product

## 1.1 Applicant

BASF Nederland BV
Groningensingel 1
6835 EA ARNHEM

## 1.2 Identity of the active substance

### 1.2.1 Epoxiconazole

| | |
|---|---|
| Common name | Epoxiconazole |
| Name in Dutch | Epoxiconazool |
| Chemical name | (2*RS*, 3*SR*)-1-[3-(2-chlorophenyl)-2,3-epoxy-2-(4-fluorophenyl)propyl]-1*H*-1,2,4-triazole [IUPAC] |
| CAS no | 135319-73-2<br>(formerly 106325-08-0) |
| EC no | 406-850-2 |

The active substance was included in Annex I of Directive 91/414/EEC on 1 May 2009. From 25 May 2011 forward, according to Reg. (EU) No 540/2011 the substance is approved under Reg. (EC) No 1107/2009, repealing Directive 91/414/EEC.

### 1.2.2 Fenpropimorph

| | |
|---|---|
| Common name | Fenpropimorph |
| Name in Dutch | Fenpropimorf |
| Chemical name | (RS)-cis-4-[3-(4-tert-butylphenyl)-2-methylpropyl]-2,6-Dimethylmorpholine [IUPAC] |
| CAS no | 67564-91-4 |
| EC no | 266-719-9 |

The active substance was included in Annex I of Directive 91/414/EEC on 1 May 2009. From 25 May 2011 forward, according to Reg. (EU) No 540/2011 the substance is approved under Reg. (EC) No 1107/2009, repealing Directive 91/414/EEC.

## 1.3 Identity of the plant protection product

| | |
|---|---|
| Name | Opus Team |
| Formulation type | SE |
| Content active substance | 84 g/L pure Epoxiconazole<br>250 g/L pure Fenpropimorph |

The formulation is not part of the assessment of the active substance for inclusion in Annex I of Directive 91/414/EEC.

## 1.4 Function

Fungicide.

## 1.5 Uses applied for

| New uses | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 12 | NL | Winter wheat | F | Puccinia recondita<br>Puccinia striiformis<br>Mycosphaerella graminicola<br>Septoria nodorum<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.0 | 84 *<br>250 ** | 150-400 | 35 | |
| 13 | NL | Spring wheat | F | Puccinia recondita<br>Puccinia striiformis<br>Mycosphaerella graminicola<br>Septoria nodorum<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.0 | 84 *<br>250 ** | 150-400 | 35 | |
| 14 | NL | Winter barley | F | Puccinia striiformis<br>Puccinia hordei<br>Rhynchosproium secalis<br>Pyrenophora teres<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.0 | 84 *<br>250 ** | 150-400 | 35 | |
| 15 | NL | Spring barley | F | Puccinia striiformis<br>Puccinia hordei<br>Rhynchosproium secalis<br>Pyrenophora teres<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.0 | 84 *<br>250 ** | 150-400 | 35 | |
| 16 | NL | Spelt | F | Puccinia recondita<br>Puccinia striiformis<br>Mycosphaerella graminicola<br>Septoria nodorum<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.0 | 84 *<br>250 ** | 150-400 | 35 | |
| 17 | NL | Triticale | F | Puccinia recondita<br>Puccinia striiformis<br>Mycosphaerella graminicola<br>Septoria nodorum<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.0 | 84 *<br>250 **. | 150-400 | 35 | |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 18 | NL | Flax | F | Oidium lini | Spray | May-June<br>BBCH 40-69 | 2 / 21 | 1.0 | 84 *<br>250 ** | 200-400 | nr | |
| | | | | | | | | | | | | |
| * = epoxiconazole<br>** = fenpropimorph<br><br>**Minor uses according to article 51** | | | | | | | | | | | | |
| 19 | NL | oats | F | Puccinia coronata | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.0 | 84 *<br>250 ** | 150-400 | 35 | Mitigation measures:<br>90% drift reducing nozzles |

* = epoxiconazole

** = fenpropimorph

### 1.6 Background to the application

It concerns an application for a reduction of the dose in the use of Opus Team in cereals, in order to offer users an alternative use with less strict drift reduction prescriptions.

### 1.7 Packaging details

| | |
|---|---|
| **Material:** | HDPE/PA coex containers |
| **Capacity:** | 0.15; 0.25; 0.5; 1; 3; 5 and 10L |
| **Type of closure and size of opening:** | Sealed by foil HF seals (0.15; 0.25 and 0.5L) or by polyamide laminated PE-foam gaskets, protected by screw caps of polyethylene. |
| **Other information** | ADR/RID compliant |

### 1.7.2 Detailed instructions for safe disposal

No particular recommendations.

## 2 Physical and chemical properties

No changes.

## 3 Methods of analysis

No changes.

## 4 Mammalian toxicology

No changes.

## 5 Residues

No changes.

## 6 Environmental fate and behaviour

Epoxiconazole is an existing active substance and is included in Annex I since 01/05/2009 (directive 2008/107/EC d.d. 25/11/2008). The underlying risk assessment is based on the final list of endpoints from the EFSA Conclusion for epoxiconazole (26 March 2008). Additional information is given in *italics*.

Fenpropimorph is an existing active substance and is included in Annex I since 01/05/2009 (directive 2008/107/EC d.d. 25/11/2008). The underlying risk assessment is based on the final list of endpoints from the EFSA Conclusion for fenpropimorph (14 April 2008). Additional information is given in *italics*.

Only the parts relevant to the surface water exposure and aquatic risk assessment have been provided, as the requested change only concerns that aspect.
In fact the assessment is based purely on the risk of fenpropimorph, however for completeness and to appropriately address combination toxicology the epoxiconazole assessment is also included.

### LoEP fate and behaviour (sorption and degradation in water-sediment systems)

## List of Endpoints Epoxiconazole (26 March 2008, EFSA conclusion)

**Soil adsorption/desorption** (Annex IIA, point 7.1.2)

| | |
|---|---|
| $K_f$ /$K_{oc}$ ‡ [L/kg] | Epoxiconazole: $K_{foc}$ 280 – 2647 (2 studies), arithmetic mean 1073 (n=5):<br>soil / pH / $K_{foc}$ / $K_f$ / 1/n<br>2.1, sand / 6.0 / 957 / 4.79 / 0.766<br>(90,9 % sand, 3.8 % silt, 5.3 % clay, 0.5 % org.C.)<br>Les.EV, sandy loam / 4.75 / 2647 / 19.59 / 0.813<br>(53,7 % sand, 29.3 % silt, 17 % clay, 0.74 % org.C.)<br>Itingen, clay/clay loam / 6.87 / 1100 / 21.78 / 0.808<br>(33.6 % sand, 24.8 % silt, 41.6 % clay, 1.98 % org.C.)<br>Sandy silty loam / 7.1 / 280 / 7.25 / 0.882<br>(40.4 % sand, 43 % silt, 16.9 % clay, 2.6 % org.C.)<br>Clayey loam / 6.8 / 380 / 7.50 / 0.910<br>(19.1 % sand, 40.2 % silt, 41 % clay, 2.0 % org.C.)<br><br>no correlation of $k_f$ with parameters oc, clay and pH was observed<br><br>metabolite 1,2,4-triazole<br>$K_{foc}$: 43-120, arithmetic mean 89 (n=4)<br>soil / pH / $K_{foc}$ / $K_f$ / 1/n<br>Sandy loam / 6.9 / 89 / 0.720 / 1.016<br>(62 % sand, 21 % silt, 17 % clay, 1.4 % org. matter, Corg 0.812 %.)<br>Clay loam / 6.9 / 43 / 0.748 / 0.827<br>(26 % sand, 46 % silt, 28 % clay, 3.0 % org. matter, Corg 1.74 %.)<br>Silty clay / 8.8 / 120 / 0.833 / 0.897<br>(11 % sand, 44 % silt, 45 % clay, 1.2 % org.C matter, Corg 0.696)<br>Silty clay loam / 7.0 / 104 / 0.722 / 0.922<br>(9 % sand, 62 % silt, 29 % clay, 1.2 % org. matter, Corg 0.696) |
| pH dependence (yes / no) (if yes type of dependence) ‡ | no (for 1,2,4-triazole agreed by PRAPeR 12). |

**Route and rate of degradation in water** (Annex IIA, point 7.2.1)

| | |
|---|---|
| Hydrolysis of active substance and relevant metabolites ($DT_{50}$) (state pH and temperature) ‡ | pH 3: parent: 65 % decrease at 70 ℃ after 20 d |
| | pH 5: parent: stable at 25 ℃, stable at 75 ℃ for 29 d, 20 % decrease at 90 ℃ after 29 d<br>1,2,4-triazole: stable at 25 ° |
| | pH 7: parent: stable at 25 ℃, 75 ℃, 90℃<br>1,2,4-triazole: stable at 25 ° |
| | pH 9: parent: stable at 25 ℃, 75 ℃, 12 % decrease at 90 ℃ |

| | |
|---|---|
| | 1,2,4-triazole: stable at 25 ° |
| Photolytic degradation of active substance and relevant metabolites ‡ | Active substance<br>- absorption coefficient < 10 L/mol x cm.<br>- no photolysis in sterile buffer solution after 31 days, 3 mg as/L, pH 7, 25 °C, natural sunlight mimic, 1800 µEinstein (SUN-TEST apparatus), 12 h cycle light/dark. $^{14}$C-labelled as.<br>- 20 % degradation in natural water after 15 days, 3.3 mg as/L, pH 8.2, DOC 11.7, TOC 11.2 mg/L; nitrate 0.84 mg/L. 22 °C, natural sunlight mimic, 3 mW/cm² (SUNTEST-apparatus), constant light. As not labelled.<br>Epoxiconazole: slow photolysis, $DT_{50}$ 52 d, 1$^{st}$ order.<br>No metabolites investigated<br><br>Metabolite: 1,2,4-triazole, $^{14}$C-labelled<br>- 80 mg/L triazole in distilled water containing humic acid (Fluka). No photochemical loss after 30 days (natural sun light).<br>absorption coefficient < 10 L/mol x cm |
| Readily biodegradable (yes/no) ‡ | no (OECD 301F) |
| Dissipation in water/sediment | Water/sediment, 2 systems, $^{14}$C-U-chlorophenyl and $^{14}$C-U-fluorophenyl labelled epoxiconazole, application rate 125 g as/ha. 2 systems (A = Millstream Pond, sediment: clayey loam; B = Swiss lake, sediment: sand) |
| Active substance | Epoxiconazole as: (ModelMaker 3.0.4, 1$^{st}$ order) |

| | system A | system B |
|---|---|---|
| Degradation in water/sediment - $DT_{50}$ water ‡ - $DT_{90}$ water ‡ | | |
| $DT_{50,water}$ | 38.4 d | 93.1 d |
| $DT_{90,water}$ | 127.6 d | 309.4 d |
| $r^2$ | 0.987 | 0.975 |
| - $DT_{50}$ whole system ‡ - $DT_{90}$ whole system ‡ | | |
| $DT_{50,system}$ | 172 d | 67.5 d |
| $DT_{90,system}$ | 573 d | 224 d |
| $r^2$ | 0.997 | 0.989 |
| - $DT_{50}$ sediment ‡ - $DT_{90}$ sediment ‡ | | |
| $DT_{50,sediment}$ | - | 61.4 d |
| $DT_{90,sediment}$ | - | 204 d |
| $r^2$ | - | 0.975 |

Dissipation - $DT_{50}$ water ‡

| ModelMaker 4.0 | system A | system B | |
|---|---|---|---|
| $DT_{50,water\ degradation}$ | 2.8 d | 6.4 d | best fit |

Metabolite

Metabolite: BAS 480-entriazole

| Degradation in water/sediment - $DT_{50}$ sediment ‡ - $DT_{90}$ sediment ‡ | system A | system B |
|---|---|---|
| $DT_{50,sediment}$ | -/-* | 65.2 d |
| $DT_{90,sediment}$ | -/-* | 216 d |
| $r^2$ | 0.987 | 0.975 |

* no reliable fit in ModelMaker calculations

| | |
|---|---|
| Mineralisation | after 100 days (study end) in % TAR:<br>$^{14}$C-U-chlorophenyl / $^{14}$C-U-fluorophenyl labelled epoxiconazole<br>system A: 4.2 / 3.3<br>system B: 3.8 / 3.2 |
| Non-extractable residues | after 100 days (study end) in % TAR:<br>$^{14}$C-U-chlorophenyl / $^{14}$C-U-fluorophenyl labelled epoxiconazole<br>system A: 21.9 / 21.6<br>system B: 19.7 / 19.2 |
| Distribution in water / sediment systems (active substance) ‡ | Maximum values: (as in % TAR) epoxiconazole, $^{14}$C-U-chlorophenyl / $^{14}$C-U-fluorophenyl label |

System A: 71.0/67.7 % in sediment after 30 days
System B: 48.3/50.0 % in sediment after 13 days

BAS 480 F in % total applied radioactivity (TAR)

| days after applicat. | (as: chloro-/fluorophenyl-$^{14}$C label) (A) **water** | (B) | (A) **sediment** | (B) |
|---|---|---|---|---|
| 0 | 93.6/91.1 | 93.4/91.1 | < LOD/3.2 | 2.0/2.7 |
| 1 | 66.7/67.5 | 76.8/78.1 | 26.9/26.0 | 18.1/15.8 |
| 3 | 49.4/43.0 | 64.4/62.5 | 45.4/48.6 | 31.2/30.3 |
| 7 | 24.9/25.7 | 47.8/49.9 | 65.7/62.2 | 42.8/41.0 |
| 13 | 12.9/22.7 | 37.7/32.3 | 69.9/60.3 | 48.3/50.0 |
| 30 | 8.0/9.6 | 21.6/15.2 | 71.0//67.7 | 36.4/40.7 |
| 59 | 4.5/4.7 | 12.8/12.8 | 66.4/63.8 | 38.5/35.0 |
| 100 | 3.6/4.5 | 6.3/6.6 | 64.0/58.5 | 33.6/37.2 |

Distribution in water / sediment systems (metabolites) ‡

Maximum values: (BAS 480 entriazole in % TAR)
System A: 6.1/6.6 % in sediment after 30/59 days
System B: 32.7/34.0 % in sediment after 100/59 days

BAS 480 entriazole in % TAR

| days after applicat. | (as: chloro-/fluorophenyl-$^{14}$C label) (A) **water** | (B) | (A) **sediment** | (B) |
|---|---|---|---|---|
| 0 | < LOD/1.4 | < LOD/1.7 | < LOD | < LOD |
| 1 | < LOD/0.7 | < LOD/0.9 | < LOD/0.4 | < LOD |
| 3 | < LOD | < LOD/0.8 | < LOD/0.8 | < LOD/0.9 |
| 7 | < LOD | < LOD | 1.3/2.6 | 2.5/2.4 |
| 13 | < LOD | < LOD | 3.9/5.7 | 6.4/7.0 |
| 30 | < LOD | < LOD | 6.1/5.6 | 27.0/27.4 |
| 59 | < LOD | < LOD | 3.1/6.6 | 30.6/34.0 |
| 100 | < LOD | < LOD | 3.7/5.7 | 32.7/28.1 |

other unknown metabolites:
water A: max. 0.8/1.7 %TAR at day 0
water B: max. 1.4/1.3 %TAR at day 0
sediment A: max. 2.3/2.5 %TAR after 30 resp. 100 d sediment B: max. 2.1/1.8 % TAR after 100 d

**List of Endpoints Fenpropimorph (14 April 2008, EFSA conclusion)**

**Soil adsorption/desorption** (Annex IIA, point 7.1.2)

| | |
|---|---|
| $K_f$ /$K_{oc}$ ‡ | **Fenpropimorph**<br>High adsorption $C_{org}$ dependent:<br>pH $K_f$(mL/g) 1/n $K_{oc}$ (mL/g)<br>Loam 7.3 34.47 1.340 5943<br>($C_{org}$ 0.58 %; 13 CEC (mVal/100 g dry soil)<br>Loamy sand 7.2 73.73 0.867 2772<br>($C_{org}$ 2.66 %; 10 CEC (mVal/100 g dry soil)<br>Sand 7.0 22.60 0.949 4432<br>($C_{org}$ 0.51 %; 3.7 CEC (mVal/100 g dry soil)<br><br>Worst case $K_{Foc}$ 2772 L/kg with 1/n = 0.867 to be used for FOCUS modelling.<br><br>**BF 421-2**<br>pH $K_f$(mL/g) 1/n$K_{foc}$ (mL/g)<br>LUFA 2.2 5.6 1.45 0.882 68.6<br>($C_{org}$ 2.12 %; 10.6 CEC (mVal/100 g dry soil)<br>Birnbaum 6.1 0.443 0.955 55.4<br>($C_{org}$ 0.8 %; 13.0 CEC (mVal/100 g dry soil)<br>Sora 6.4 0.883 0.890 46.2<br>($C_{org}$ 1.91 %; 16.6 CEC (mVal/100 g dry soil)<br>Bruch West 7.4 0.403 0.851 17.5<br>($C_{org}$ 2.3 %; 20.9 CEC (mVal/100 g dry soil)<br>LUFA 3A 7.5 0.833 0.835 29.9<br>($C_{org}$ 2.79 %; 21.4 CEC (mVal/100 g dry soil)<br><br>**BF 421-7 (non-GLP study)**<br>Data gap identified. |
| $K_d$ ‡<br><br>pH dependence (yes / no) (if yes type of dependence) ‡ | Fenpropimorph: no<br>BF 421-2: yes, lowest value was selected for use in FOCUS modelling |

## Route and rate of degradation in water (Annex IIA, point 7.2.1)

| | |
|---|---|
| Hydrolysis of active substance and relevant metabolites ($DT_{50}$) (state pH and temperature) ‡ | pH 3, 5, 7 and 9 (25 °C): stable |
| Photolytic degradation of active substance and relevant metabolites ‡ | stable, no UV adsorption above 290 nm |
| Readily biodegradable (yes/no) ‡ | No data submitted, none required |
| Dissipation in water/sediment - $DT_{50}$ water ‡<br>- $DT_{90}$ water ‡<br>- $DT_{50}$ whole system ‡<br>- $DT_{90}$ whole system ‡ | Fenpropimorph as: (ModelMaker 3.0.4)<br>system A / system B<br>$DT_{50,water}$ 3.4 d / 1.9 d<br>$DT_{90,water}$ 11.1 d / 6.4 d<br>$DT_{50,system}$ 54 d / 18 d<br>$DT_{90,system}$ > 2 x study duration (>200 d) |
| Dissipation in water/sediment - $DT_{50}$ water ‡<br>- $DT_{90}$ water ‡<br>- $DT_{50}$ whole system ‡<br>- $DT_{90}$ whole system ‡ | BAS 421-2 metabolite:<br>system A / system B<br>$DT_{50,water}$ - / 38.7 d<br>$DT_{90,water}$ > 2 times study duration (>200 d)<br>$DT_{50,system}$ no data given / no data given<br>$DT_{90,system}$ no data given / no data given |
| - $DT_{50}$ (only degradation) ‡ | Fenpropimorph as (ModelMaker 4.0):<br>system A / system B / geom.. mean<br>$DT_{50,water\ degradation}$ 11.7 d / 4.0 d / 6.8 d<br>$DT_{50,sediment\ degradation}$ 102.2 d / 63.4 d / 80.5 d<br>BAS 421-2 metabolite (ModelMaker 4.0):<br>system A / system B / geom.. mean<br>$DT_{50,water\ degradation}$ 555 d / 31.9 d / 133 d |
| Mineralisation | water/sediment, 2 systems after 100 days (study end):<br>System A 6.3 % and system B 8.5 %<br>(mean of phenyl and morpholine radiolabel) |
| Non-extractable residues | water/sediment, 2 systems after 100 days (study end):<br>System A 20.0 % and system B 36.8 %<br>(mean of phenyl and morpholine radiolabel) |

Distribution in water / sediment systems (active substance) ‡

| days after application | BAS 421 F in % total applied radioactivity (as phenyl- and morpholine-$^{14}$C label) | | | |
|---|---|---|---|---|
| | (A) water | (B) | (A) sediment | (B) |
| 0 | 70.1 | 73.5 | 13.2 | 11.5 |
| 0.25 | 73.5 | 68.9 | 9.3 | 11.7 |
| 1 | 60.1 | 48.6 | 20.9 | 28.8 |
| 2 | 43.4 | 36.1 | 30.0 | 33.3 |
| 7 | 19.8 | 9.1 | 46.9 | 44.8 |
| 14 | 7.6 | 4.5 | 48.2 | 44.6 |
| 29 | 4.5 | 2.0 | 46.2 | 32.0 |
| 63 | 3.0 | 0.7 | 34.7 | 25.7 |
| 100 | 2.7 | 1.0 | 28.2 | 27.4 |

Distribution in water / sediment systems (metabolites) ‡

| days after application | BAS 421-2 in % total applied radioactivity (as phenyl- and morpholine-$^{14}$C label) | | | |
|---|---|---|---|---|
| | (A) water | (B) | (A) sediment | (B) |
| 0 | 0 | 0 | 0 | 0 |
| 0.25 | 0 | 0 | 0 | 0 |
| 1 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 | 0 |
| 7 | 1.7 | 7.5 | 0 | 0 |
| 14 | 6.5 | 10.9 | 0 | 0 |
| 29 | 9.3 | 16.9 | 0.2 | 4.3 |
| 63 | 20.5 | 14.0 | 4.1 | 5.2 |
| 100 | 22.6 | 8.6 | 7.7 | 5.7 |

## LoEP Ecotoxicology (aquatic organisms)

**List of Endpoints Epoxiconazole (26 March 2008, EFSA conclusion)**

**Effects on aquatic organisms (Annex IIA, 8.2 & Annex IIIA, 10.2)**

| Group | Test substance | Time-scale | Endpoint | Toxicity (mg/l) * |
|---|---|---|---|---|
| *Pseudokirchneriella subcapitata* | epoxiconazole | 72 h acute | $E_bC_{50}$ biomass<br>$E_rC_{50}$ growth rate NOEC<br>biomass NOEC | 1.19 ><br>10<br>0.007<br>8 |
| *Daphnia magna* | epoxiconazole | 48 h acute | $EC_{50}$ immobilisation | 8.69 |
| *Oncorhynchus* | epoxiconazole | 96 h acute | $LC_{50}$ | 3.14 |
| *Lemna gibba* | epoxiconazole | 7 d | $E_bC_{50}$ biomass<br>$E_rC_{50}$ growth rate<br>$E_bCio$ biomass | 0.0043**<br>0.0138**<br>0.00098* |
| | | | | |
| *Daphnia magna* | epoxiconazole | 21 d | NOEC reproduction | 0.63 |
| *Oncorhynchus* | epoxiconazole | 28 d | NOEC juvenile | 0.01 |
| *P. promelas* | epoxiconazole | FLC | NOEAEC growth F2 | 0.01 |
| *Danio rerio, 3 different life stages,* | epoxiconazole | FLC | NOEAEC ($EC_{10}$) sex ratio | 0.030 |
| *Danio rerio* | epoxiconazole | FLC | NOEAEC reproduction FI | 0.012 |
| *Chironomus riparius* | epoxiconazole | 28 d | NOEC emergence | 0.0625 > |
| | | | | |
| *Pseudokirchneriella subcapitata* | formulated product | 72 h | $E_bC_{50}$ biomass<br>$E_rC_{50}$ growth rate NOEC<br>biomass NOEC | 0.81 (0.1 as)<br>-<br>0.02 (0.0024 as) |
| *Daphnia magna* | formulated | 48 h | $EC_{50}$ immobilisation | 1.8 (0.22 |
| *Daphnia magna* | formulated | 21 d | NOEC reproduction | 0.625 (0.08 |
| *Oncorhynchus* | formulated | 96 h | $LC_{50}$ | 0.50 (0.059 |
| *Oncorhynchus* | formulated | 28 d | NOEC feed | 0.1 (0.012 |
| | | | | |
| *Pseudokirchneriella subcapitata* | metabolite 1,2,4-triazole | 72 h | $E_bC_{50}$ biomass<br>$E_rC_{50}$ growth rate NOEC<br>biomass NOEC | 14<br>31<br>3.1<br>6.8 |
| *Daphnia magna* | metabolite 1,2,4-triazole | 48 h | $EC_{50}$ immobilisation | > 100 |
| *Oncorhynchus mykiss* | metabolite 1,2,4-triazole | 96 h | $LC_{50}$ | 760 |
| *Oncorhynchus mykiss* | metabolite 1,2,4-triazole | 28 d | NOEC juvenile growth | 3.2 |
| *Chironomus riparius* | metabolite BF480- | 28 d | NOEC emergence | 0.03<br>1.55 |

**Bioconcentration**

| | |
|---|---|
| Bioconcentration factor (BCF) ‡ | whole fish (trout): highest mean value 70 (steady state) |
| Annex VI Trigger for the bioconcentration factor | 100 |
| Clearance time ($CT_{50}$)<br>($CT_{90}$) | whole fish: 0.72 days<br>whole fish: 1.6 days |

| | |
|---|---|
| Level of residues (%) in organisms after the 14 day depuration phase | after 7 days depuration phase:<br>5 µg/L 5.7 % TAR in whole fish, 4.8 % in inedible tissue, 11.3 % in edible tissue<br>1 µg/L: 6.8 % TAR in whole fish, 5.4 % in inedible tissue, 11.5 % in edible tissue |

**List of Endpoints Fenpropimorph (14 April 2008, EFSA conclusion)**

**Effects on aquatic species** (Annex IIA, point 8.2, Annex IIIA, point 10.2)

| Group | Test substance | Time-scale | Endpoint | Toxicity (mg/L) |
|---|---|---|---|---|
| Laboratory tests | | | | |
| *Pseudokirchneriella subcapitata* | fenpropimorph | 72 h acute | $E_bC_{50}$ biomass $E_rC_{50}$ growth rate NOEC biomass NOEC growth rate | 0.327 > 1 0.005 0.058 |
| *Daphnia magna* | fenpropimorph | 48 h acute | $EC_{50}$ immobilisation | 2.24 |
| *Lepomis macrochirus* | fenpropimorph | 96 h acute | $LC_{50}$ | 2.30 |
| *Oncorhynchus mykiss* | fenpropimorph | 21 d | NOEC behaviour NOEC mortality, young fish | 0.1 1.1 |
| *Oncorhynchus* | fenpropimorph | 94 d | NOEC early life stage | 0.00016 |
| *Chironomus riparius* | fenpropimorph | 20 d | NOEC (nominal initial) | 0.13 |
| | | | | |
| *Pseudokirchneriella subcapitata* | metabolite BAS 421-2 | 72 h | $EC_{50}$ biomass NOEC biomass | > 100 25 |
| *Daphnia magna* | metabolite BAS | 48 h | $EC_{50}$ immobilisation | > 100 |
| *Oncorhynchus* | metabolite BAS | 96 h | $LC_{50}$ | > 100 |
| | | | | |
| *Scenedesmus subspicatus* | product RO 14-3169/002 | 72 h | $EC_{50}$ biomass $EC_{50}$ growth rate NOEC biomass and growth rate based on measured conc. at test end | 0.17 (0.13 as) 0.28 (0.21 as) 0.058 (0.044 as) |
| *Daphnia magna* | product RO 14-3169/002 | 48 h | $EC_{50}$ immobilisation | 1.5 (1.13 as) |
| *Daphnia magna* | product RO 14-3169/002 | 21 d | NOEC reproduction | 0.032 (0.024 as) |
| *Oncorhynchus mykiss* | product RO 14-3169/002 | 96 h | $LC_{50}$ | 2.20 (1.65 as) |
| *Oncorhynchus mykiss* | product RO 14-3169/002 | 28 d | NOEC mortality, young fish NOEC other symptoms | 0.18 (0.14 as) 0.056 (0.042 as) |
| *Oncorhynchus mykiss* | product BAS 421 12 F | 49 d | NOEC early life stage (growth young fish) | 0.0026 (0.00195 as) |

**Bioconcentration**

| | |
|---|---|
| Bioconcentration factor (BCF)‡ | Study 1: $BCF_{ss}$ mean (plateau): 1096 (phenyl label)<br>Study 2: $BCF_{ss}$ mean (plateau): 942 (morpholine label)<br>Study 3: $BCF_{ss}$ mean (plateau): 968 – 1145 based on % TAR<br>$BCF_k$: 1169 – 1220 based on % TAR<br>$BCF_{ss}$ mean (plateau): 421 – 605 based on % parent |

| | |
|---|---|
| Annex VI Trigger for the bioconcentration factor | 100 |
| Clearance time ($CT_{50}$)<br>($CT_{90}$) | Study 1: 4.8 days<br>Study 2: 5.9 days<br>Study 3: 1.7 – 2.8 days<br>Study 1 & 2: -<br>Study 3: 15.5 – 31 days |
| Level of residues (%) in organisms after the 14 day depuration phase | Study 1: -<br>Study 2: 25.6 & 32% after 14 days<br>Study 3: 10.7 & 14.1% after 16 days,<br>3.3 & 5.3% after 56 days |

## 6.2 Fate and behaviour in water

### 6.2.1 Rate and route of degradation in surface water

Article 2.10c of the *Plant Protection Products and Biocides Regulations* (RGB) prescribes the use of Dutch specific drift percentages.
The exposure concentrations of the active substances epoxiconazole (and its metabolite BAS 480-entriazole) and fenpropimorph (and its metabolite BF 421-2) in surface water have been estimated for the various proposed uses using calculations of surface water concentrations (in a ditch of 30 cm depth), which originate from spray drift during application of the active substance. The spray drift percentage depends on the use.

In the new directions for use proposed by the applicant the following drift reduction measures are requested for the use on cereals and flax in combination with a reduced dose rate of 1 L product/ha:
*Om in het water levende organismen te beschermen is toepassing in de teelt van suikerbiet, winter- en zomertarwe, winter- en zomerrogge, winter- en zomergerst, triticale, spelt, haver en vlas uitsluitend toegestaan wanneer in percelen die grenzen aan oppervlaktewater gebruik wordt gemaakt van 90% driftreducerende doppen.*

Please note that the restriction sentence also refers to the use in sugar beet which is already authorised.

Concentrations in surface water are calculated using the model TOXSWA. The following input data are used for the calculation:

**TOXSWA:**
<u>epoxiconazole:</u>
Geomean $DT_{50}$ for degradation in water at 20°C: 107.7 days (geomean of 2 systems)
$DT_{50}$ for degradation in sediment at 20°C: 1000 days (default)

Arithmetic mean $K_{om}$ for suspended organic matter: 719.9 L/kg (n=8)
Arithmetic mean $K_{om}$ for sediment: 719.9 L/kg (n=8)
Arithmetic mean 1/n: 0.85

Saturated vapour pressure: $3.5 \times 10^{-7}$ Pa (20 ℃) (Addendum 7, April 2005)
Solubility in water: 7.1 mg/L at 20 ℃
Molecular weight: 329.76 g/mol

<u>BAS 480-entriazole:</u>
Geomean $DT_{50}$ for degradation in water at 20°C: 1000 days (default)
$DT_{50}$ for degradation in sediment at 20°C: 65.2 days (*n*=1, as the metabolite is only found in sediment, the use of this sediment dissipation half-life is considered acceptable)

<u>$K_{om}$ for suspended organic matter: 1000 L/kg (estimation)</u>

$K_{om}$ for sediment: 1000 L/kg (estimation)
1/n: 1.0 (default)

Saturated vapour pressure: 3.5 x $10^{-7}$ Pa (20 °C) (parent value)
Solubility in water: 7.1 mg/L at 20 °C (parent valu e)
Molecular weight: 313.76 g/mol
Correction factor: 0.34 (max. % observed) x 0.95 (relative molar ratio = M metabolite/ M parent) = 0.32
Q10: 2.2

<u>fenpropimorph:</u>
Geometric mean $D_{eg}T_{50}$ for degradation in water at 20°C: 6.8 days (EFSA agreed endpoint)
Geometric mean $D_{eg}T_{50}$ for degradation in sediment at 20°C: 80.5 days (EFSA agreed endpoint)

$K_{om}$ for suspended organic matter: 1608 L/kg (lowest value conform EU. Less than minimum dataset available)
$K_{om}$ for sediment: 1608 L/kg (lowest value conform EU. Less than minimum dataset available)
1/n: 0.867 (lowest value conform EU. Less than minimum dataset available)

Saturated vapour pressure: 3.9 x $10^{-3}$ Pa (20°C)
Solubility in water: 4.32 mg/L (20°C)
Molecular mass: 303.5 g/mol
Q10: 2.2

<u>BF 421-2:</u>
Geometric mean $DT_{50}$ for degradation in water at 20°C: 1000 days (conservative assumption conform EU, Addendum 1)
$DT_{50}$ for degradation in sediment at 20°C: 1000 days (default).

$K_{om}$ for suspended organic matter: 10.2 L/kg (lowest value conform EU due to pH dependency)
$K_{om}$ for sediment: 10.2 L/kg (lowest value conform EU due to pH dependency)
Arithmetic mean 1/n: 0.851 (value corresponding to lowest Kfoc conform EU)

Saturated vapour pressure: 3.9 x $10^{-3}$ Pa (20°C) (parent value)
Solubility in water: 9300 mg/L (20°C)
Molecular mass: 333.5 g/mol
Correction factor: 0.226 (max. % observed) * 1.10 (relative molar ratio = M metabolite/ M parent) = 0.25
Q10: 2.2

Other parameters: standard settings TOXSWA

When no separate degradation half-lives (DegT50 values) are available for the water and sediment compartment (accepted level P-II values), the system degradation half-life (DegT50-system, level P-I) is used as input for the degrading compartment and a default value of 1000 days is to be used for the compartment in which no degradation is assumed. This is in line with the recommendations in the FOCUS Guidance Document on Degradation Kinetics.

For metabolites, the level M-I values are used (system DegT50 value) only, since level M-II criteria have not been fully developed under FOCUS Degradation Kinetics.

In Table M.1, the drift percentages and calculated surface water concentrations for the active substances epoxiconazole (and its metabolite BAS 480-entriazole) and fenpropimorph (and its metabolites BF 421-2 and BF 421-7) for each intended use are presented.

**Table M.1 Overview of surface water concentrations for active substances epoxiconazole (and its metabolite BAS 480-entriazole) and fenpropimorph (and its metabolites BF 421-2 and BF 421-7) in the edge-of-field ditch following spring/autumn application**

| Use | Substance | Rate a.s. [kg/ha] | Freq./ interval [days] | Drift [%] | PIEC [µg/L] * | | PEC7 [µg/L] ** | | PEC21 [µg/L] * | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Spring | autumn | spring | autumn | spring | autumn |
| Cereals and flax (reduced dose rate) | Epoxiconazole | 0.084 | 2/21 | 0.2 | 0.131 | 0.079 | | | 0.092 | 0.011 |
| | 480-entriazole | 0.027 | | | 0.043 | 0.026 | | | 0.031 | 0.004 |
| | Fenpropimorph | 0.25 | | | 0.271 | 0.235 | 0.128 | 0.085 | 0.111 | 0.030 |
| | BF 421-2 | 0.062 | | | 0.112 | 0.059 | | | 0.081 | 0.009 |

* calculated according to TOXSWA

** a PECsw TWA over 7 days was reported as this value is needed in the ecotoxicological assessment (Section 7). As this value is not routinely reported by TOXSWA, the value was calculated separately in Excel based on adapted TOXSWA output (time step for output was set to 0.07 d) using a moving-average approach

The exposure concentrations in surface water are compared to the ecotoxicological threshold values in section 7.2.

# 7 Ecotoxicology

## 7.2 Effects on aquatic organisms

### 7.2.1 Aquatic organisms

The risk for aquatic organisms is assessed by comparing toxicity values with surface water exposure concentrations from section 6.2. Risk assessment is based on toxicity-exposure ratios (TERs).

Toxicity data for aquatic organisms are presented in Table E.1. For epoxiconazole, the effects on macrophytes (aquatic plants) are evaluated, as they are the most sensitive organism for epoxiconazole.

**Table E.1 Overview toxicity endpoints for aquatic organisms**

| Substance | Organism | Lowest | | Toxicity value |
|---|---|---|---|---|
| | | $L(E)C_{50}$ [mg as/L] | NOEC [mg as/L] | [µg as/L] |
| epoxiconazole | *Acute* | | | |
| | Algae | 1.19 | | 1190 |
| | Invertebrates | 8.69 | | 8690 |
| | Fish | 3.14 | | 3140 |
| | Macrophytes | 0.0081 | | 8.1 |
| | *Chronic* | | | |
| | Invertebrates | | 0.63 | 630 |
| | Fish | | 0.01 | 10 |
| 1,2,4 - triazole | *Acute* | | | |
| | Algae | 3.1 | | 3100 |
| | Invertebrates | >100 | | > 100000 |
| | Fish | 760 | | 760000 |
| | *Chronic* | | | |
| | Fish | | 3.2 | 3200 |
| fenpropimorph | *Acute* | | | |
| | Algae | 0.327 | | 327 |
| | Invertebrates | 2.24 | | 2240 |

| Substance | Organism | Lowest | | Toxicity value |
|---|---|---|---|---|
| | | $L(E)C_{50}$ [mg as/L] | NOEC [mg as/L] | [µg as/L] |
| | Fish | 2.30 | | 2300 |
| | *Chronic* | | | |
| | Invertebrates | | 0.0022 | 2.2 |
| | Fish | | 0.00016 | 0.16 |
| metabolite BAS 421-2 | *Acute* | | | |
| | Algae | > 100 | | > 100000 |
| | Invertebrates | > 100 | | > 100000 |
| | Fish | > 100 | | > 100000 |
| BAS 481 08F (Opus Team) | *Acute* | | | |
| | Algae | 1.6 | | 1600 |
| | Invertebrates | 1.51 | | 1510 |
| | Fish | 0.19 | | 190 |

These toxicity values are compared to the surface water concentrations calculated in section 6.2. Trigger values for acute exposure are 100 for invertebrates and fish (0.01 times the lowest $L(E)C_{50}$-value) and 10 for algae and macrophytes (0.1 times the lowest $EC_{50}$-value). Trigger values for chronic exposure are 10 for invertebrates and fish (0.1 times the lowest NOEC-values).

For both acute and chronic risk, the initial concentration is used (PIEC) for TER calculation. In Table E.2 TER values for aquatic organisms are shown.

**Table E.2a TER values: acute**

| Use | Substance | PECsw [µg a.s./L] | | $TER_{st}$ (trigger 10) Algae | | $TER_{st}$ (trigger 100) Invertebrates | | $TER_{st}$ (trigger 100) Fish | | $TER_{st}$ (trigger 10) Macrophytes | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | spring | autumn | spring | autumn | spring | autumn | spring | autumn | spring | autumn |
| Cereals and flax (reduced dose rate) | epoxiconazole | 0.131 | 0.079 | 9084 | 15063 | 66336 | 110000 | 23969 | 39747 | 61.8 | 102.5 |
| | 1,2,4-triazole | 0.043 | 0.026 | 72093 | 119231 | 2325581 | 3846154 | 17674419 | 29230769 | NA | NA |
| | fenpropimorph | 0.271 | 0.235 | 1207 | 1391 | 8266 | 9532 | 8487 | 9787 | NA | NA |
| | BAS 421-2 | 0.112 | 0.059 | 892857 | 1694915 | 892857 | 1694915 | 892857 | 1694915 | NA | NA |
| | combination | | | 1065 | 8772 | 7350 | 8772 | 6268 | 7853 | NA | NA |
| | Opus Team | 0.402 | 0.314 | 3980 | 5096 | 3756 | 4809 | 473 | 605 | NA | NA |

**Table E.2b TER values: chronic**

| Use | Substance | PECsw [µg a.s./L] | | $TER_{lt}$ (trigger 10) Invertebrates | | $TER_{lt}$ (trigger 10) Fish | |
|---|---|---|---|---|---|---|---|
| | | spring | autumn | spring | autumn | spring | autumn |
| Cereals and flax (reduced dose rate) | epoxiconazole | 0.131 | 0.079 | 4809 | 7975 | 92 | 152 |
| | 1,2,4-triazole | 0.043 | 0.026 | NA | NA | 74419 | 123077 |
| | fenpropimorph | 0.271 | 0.235 | **8.1** | **9.4** | **0.59** | **0.68** |
| | combination | 0.402 | 0.314 | **8.1** | **9.4** | **0.59** | **0.68** |

Taking the results in Table E.2a and b into account, a chronic risk for aquatic organisms cannot be excluded. Therefore, an adequate risk assessment should be provided.

*Higher tier risk assessment (refinement of the risk assessment)*:
A chronic risk to fish and Daphnia was found for the proposed application. This risk is mainly caused by the active substance fenpropimorph. First the refined assessment for fish is presented, followed by the refinement for Daphnia.

**Fenpropimorph - Risk assessment for fish**
A risk to fish was also identified in the EU process and an additional modified ELS study was submitted (addendum 1). This was also discussed in the PRAPeR meeting (PRAPeR 13, Jan 2007) and finalized in addendum 4 (07/01/2008). In the modified ELS test with *Oncorhynchus mykiss* under more realistic conditions, a NOEC of 1.95 µg a.s./L was determined.

Table E.2c shows the refined risk assessment for fish using the PRAPeR endpoint.

**Table E.2c Refined risk assessment for fish**

| Use | Substance | PECsw [µg a.s./L] | | $TER_{lt}$ (trigger 10) Fish | |
|---|---|---|---|---|---|
| | | spring | autumn | spring | autumn |
| Cereals and flax (reduced dose rate) | epoxiconazole | 0.131 | 0.079 | 92 | 152 |
| | 1,2,4-triazole | 0.043 | 0.026 | 74419 | 123077 |
| | fenpropimorph | 0.271 | 0.235 | **7** | **8** |
| | combination | 0.402 | 0.314 | **6.7** | **7.9** |

The refined risk assessment using the agreed upon endpoint for fish still does not reach the trigger value. Further refinement is needed and presented below.

Fenpropimorph is moderately toxic in acute studies with LC/EC50 values above 1 mg/L. For fish a number of different species (*n =6)* have been tested to address potential species sensitivity differences . The results demonstrate, that there is hardly a difference at all between fish species in their sensitivity towards fenpropimorph. All results are within a factor of two, which is roughly within the range of experimental error. These data reduce significantly uncertainties with respect to potential species sensitivity differences and a factor of two to account for it appears appropriate.

Chronic exposure to fenpropimorph causes significantly higher toxicity, particularly if very long-term constant chronic exposure is maintained in standard laboratory studies under flow-through conditions.

| Test species | Test system | LC50 [µg/L] | NOEC [µg/L] |
|---|---|---|---|
| *Oncorhynchus mykiss* | 4 d, semi-static | 4600 | 464 |
| *Oncorhynchus mykiss* | 21 day, flow-through | 1200 | 90 |
| *Oncorhynchus mykiss* | 94 d, flow-through | 50 | 0.16 |

Obviously, long-term constant exposure to the substance is needed to cause an effect. In the 21 day study, 60% mortality was reached after 3 days at 5.5 mg/L, 50% mortality at 3.1 mg/L occurred after 5 days (these results are in good agreement with the acute test) and 9 days were needed to cause 50% impact at 1.7 mg/L. No mortality was found after 21 days of constant exposure at a concentration of 0.9 mg/L (however, sublethal effects were observed).

Accordingly, in the 94 day study first mortalities in the highest concentration of 0.2 mg/L were seen at 69 days of exposure (i.e. approx. 35-40 days after hatch). It took eight more days of constant exposure to cause mortality also at lower concentrations, the onset of toxic signs generally increasing in strength with concentration and exposure duration. Similarly, indications of impaired growth such as reduced feed uptake at low concentrations were observed only at the later stages of the 94 day study.

The differences in effects observed with different exposure durations may be explained largely by a build up of critical body burdens (critical target burdens) over time, and potential overloading of detoxification mechanisms following long term high body burdens. Although detailed information on toxicodynamics for this compound in fish is not available, fenpropimorph has a log Pow of about 4 and a bioconcentration study (Hafemann, C., 2003, BASF DocID 2003/1009213) resulted in a maximum BCF at steady state of about 1000 (942 - 1145 for total residues, respectively 421 - 605 based on parent compound).

However, fenpropimorph is not stable in the environment, and dissipates rapidly from water with DT50 values of about 2 to 3 days. In addition, toxicokinetic information from the fish BCF study demonstrates a very rapid depuration from fish with half-lifes of about 1 - 2 days (see BCF study, Hafemann, 2003). It is therefore highly unlikely that situations which would allow the long term build up of target concentrations to an extent causing the observed toxicity within the 94 day constant exposure study would exist in the real world exposure scenario.

To investigate this theory, a higher tier fish study has been conducted in small outdoor ponds (Dohmen G. P., 2002; BASF DocID 2002/1011545), conducted under realistic worst-case exposure conditions (simulation of two applications of a fenpropimorph containing formulation with a 14 day interval). *Leuciscus idus* was chosen in this study as test organism. Besides the practical reasons (e.g. behavioural effects are easier to observe in this more 'visible' fish), this species was selected because it is generally rather sensitive and has higher demands on water quality than other cyprinids, and in addition it feeds both on pelagic and benthic food items, thus ensuring maximum exposure via water, sediment and potentially contaminated feed. The results of this study showed that under these more realistic exposure conditions initial fenpropimorph concentrations up to 12 µg a.s./L have no harmful effect on juvenile fish.

Under the realistic conditions of the above study, fenpropimorph showed the expected rapid dissipation from water. To address also potential situations causing longer exposure times and covering other fish species and potentially most sensitive life stages, another higher tier fish study was performed with trout, which considered both the critical points mentioned above and at the same time tried to simulate a more realistic worst case exposure (Zok, 2005, BASF DocID 2005/1005782). This study was conducted as a modified ELS study. The test substance was applied twice: first at the start of swim up, and again 14 days later. This time span was identified as the most sensitive life stage according to the results of the other fish studies and specifically of the standard ELS study. The test was terminated 60 days after end of hatch and 49 days after the start of the first exposure. The concentrations followed a realistic worst case exposure pattern for static surface water systems assuming a DT50 of 3.4 days (reflecting the upper range of fenpropimorph DT50 values).

The type of effects and time of occurrence was similar to the standard ELS study, however, at an order of magnitude higher concentration. The NOEC with respect to mortality was 9 µg a.s./L, the growth of young fish was the most sensitive parameter again with a NOEC of 3 µg a.s./L and a LOEC of 9 µg a.s./L where small, but statistically significant differences were observed in fish length and wet weight (resulting in an MATC of 5.2 µg a.s./L). If the NOEC is based on the time weighted average concentration during the sensitive life stages, this results in an endpoint of 1.9 µg a.s./L. However, if this endpoint is used, it was argued that this value should also be compared to the $PEC_{twa}$, leading to the conclusion that no effect on fish will be observed under realistic worst case conditions at initial maximum concentrations of 3 µg a.s./L or time weighted average concentrations of 1.9 µg a.s./L. Due to the amount of information available - i.e. a species sensitivity distribution with 6 fish species demonstrating a very small - if any - difference in sensitivity by a factor of two, and four chronic studies with two fish species, the standard assessment factor based on chronic studies may be reduced (according to the "unless" clause in 91/414 for not meeting the standard triggers, additional data and the refined assessment have been provided demonstrating the lack of an unacceptable impact at the levels shown below with a high level of certainty).

The relevant chronic endpoint, NOEC = 3 µg a.s./L, is in itself is a rather conservative endpoint, as the impact at the next higher concentration (LOEC = 9 µg a.s./L) was very minor and may be considered to be of negligible ecological impact. It has therefore suggested to use as relevant MPC a $PEC_{ini}$ of 1.5 µg a.s./L (i.e. the conservative chronic NOEC divided by a factor of two related to the negligible species sensitivity differences, respectively taking the MATC and an assessment factor of 3) or a $PEC_{twa}$ (14 days) of 1 µg a.s./L (1.9 µg a.s./L divided by two).

The Ctgb agrees that assessment based on long-term continuous exposure and a PIEC is, in this case, very worst-case.

In the Elink workshop several situations are described in which the use of an TWA is not appropriate:

(1) when the risk assessment is based on laboratory tests with algae or studies in which exposure is not maintained and the loss of the active substance other than uptake from the organisms is fast.
(2) when the endpoint in a chronic test is based on developmental process in a sensitive lifecycle stage.
(3) when there is evidence of endocrine disruption.
(4) when the endpoint in the chronic test is based on mortality occurring early in the test or if the acute to chronic ratio is < 10.
(5) if latency of effects has been demonstrated or might be expected due to the mode of action.

When it is possible to use a TWA concentration, it is proposed to use a $PEC_{twa}$ of 7 days as a default.

For fish testing with fenpropimorph, none of the 5 situations mentioned above are true (the NOEC is based on growth of young fish). Therefore a $PEC_{twa}$ of 7 days can be used for risk assessment.

The applicant submitted additional justifications for the use of PECtwa values for the aquatic long-term risk assessment for fenpropimorph by delivering a 50-d time to effect / pulsed dose rainbow trout ELS study. The test was conducted with 3 concentrations, 9, 27 and 81 µg a.s./L, to which *Oncorhynchus mykiss* larvae (from the day after the first larval swim-up) were exposed for different exposure durations, in a flow-through test system. The 9 µg/L exposure was for 4 days or 4+4 days. For the 27 µg/L treatment group, the exposure lasted 1, 1+1, 4 or 4+4 days. The 81 µg/L exposure was for 1 day or 1+1 day. The second exposure period was for all treatment groups at 14 days after start of first exposure period.
The test was performed without a reference item. Four replicates with 25 larvae per replicate were exposed. Assessment of clinical effects and mortality was performed daily. Body length and weight were determined at the end of the test, on day 50 (= 60 days after the end of hatch).
The study shows that two 24 hour pulses of up to 67.3 µg a.s./L (first application) / 61.7 µg a.s./L (second application) have no statistical significant effects, covering any theoretically possible delayed, latent effects, too. Similarly, two 96 hour pulses of up to 7.09 µg a.s./L (first application) / 7.21 µg a.s./L (second application) did not cause any statistical significant effects.

Ctgb is of the opinion that the results of the pulsed exposure study with fish show that the use of a default PEC twa over 7 days is bonafied (relatively short term exposure to fenpropimorph is tolerated at higher levels than constant concentrations over longer periods). Ctgb will not use the NOEC of the pulsed exposure study as such, because the exposure in the test, even in the case of two 96 hour pulses, is not considered long enough in view of the DT50 in water of fenpropimorph.

Based on what is mentioned above Ctgb will use the nominal NOEC of 3 µg/L from the higher tier fish study conducted in small outdoor ponds together with the PIEC, or the mean measured NOEC of 1.9 µg/L from the same study with the $PEC_{twa, 7d}$. The standard safety factor will be maintained.

The resulting risk assessment for fenpropimorph in fish is given below:

**Table E.2d Further refined risk for fish from fenpropimorph using refined NOEC of 3 µg/L with the PIEC**

| Use | Substance | PECsw [µg a.s./L] | | $TER_{lt}$ (trigger 10) Fish | |
|---|---|---|---|---|---|
| | | spring | autumn | spring | autumn |
| Cereals and flax (reduced dose rate) | epoxiconazole | 0.131 | 0.079 | 92 | 152 |
| | 1,2,4-triazole | 0.043 | 0.026 | 74419 | 123077 |
| | fenpropimorph | 0.271 | 0.235 | 11 | 13 |
| | combination | 0.402 | 0.314 | **9.9** | 11.8 |

Using the refined NOEC of 3 µg/L and the PIEC, it appears that the risk to fish from the uses in cereals and flax (reduced dose rate in combination with 90% reducing nozzles) is not acceptable.
See Table E.2e for further refined assessment of the NOEC of 1.9 µg/L against the PEC,twa7days.

**Table E.2e Further refined risk for fish from fenpropimorph using the NOEC of 1.9 µg/L with the $PIEC_{TWA}$ with a default TWA of 7 days**

| Use | Substance | PECsw [µg a.s./L] | | $TER_{lt}$ (trigger 10) Fish | |
|---|---|---|---|---|---|
| | | spring | autumn | spring | autumn |
| cereals and flax (reduced dose rate) | epoxiconazole | 0.131 | 0.079 | 92 | 152 |
| | 1,2,4-triazole | 0.043 | 0.026 | 74419 | 123077 |
| | fenpropimorph | 0.128 | 0.085 | 15 | 22 |
| | combination | 0.259 | 0.164 | 13 | 19 |

Using the mean measured NOEC with the PECtwa over 7 days, the risk to fish from uses in cereals and flax (reduced dose rate in combination with 90% reducing nozzles) is acceptable.

**Fenpropimorph - Risk assessment for Daphnia**
Also a refinement for the chronic risk to invertebrates is required.

The applicant submitted additional justifications for the use of PECtwa values for the aquatic long-term risk assessment for fenpropimorph. In support of these justifications, the applicant also submitted a pulsed exposure chronic study with *Daphnia magna* .

Chronic daphnia study
Two concentrations were tested, 9 and 27 µg/L, under semi-static test conditions with different exposure durations. For 9 µg/L exposure times of 24, 48 and 96 hours, and 2x 24, 2x 48 and 2x 96 hours were used. For 27 µg/L the exposure time was set to 24 hours, but tested at two different developmental stages: as neonates on day 0 (24 hours) and as adults on day 8 (at the beginning of their reproductive phase). The test was performed with 10 replicates in each treatment and control group, with one (parent) daphnia in each vessel. No reference item was tested. Assessment of parent mortality, numbers of live offspring, dead offspring, egg production and visual assessments of the daphnids were performed daily. Body length of the parent daphnids was only determined at test end. Analysis of the test item showed initial mean measured concentrations of ≥ 93% and mean measured concentrations

at the end of ≥ 58%. The time weighted concentration as % of nominal was ≥ 74%. Although some treatments demonstrated significant variations from the control group, no exposure (dose and duration)-effect relationship could be established.
The lowest NOEC from the Daphnia study is 6.7 µg a.s./L (2 x 96h). At 6.7 µg a.s./L there were observed some significant effects, none of them showing a dose-response effect.

Ctgb is of the opinion that also this study shows that short term exposure to fenpropimorph is tolerated at higher levels than constant concentrations over longer periods. And that therefore also for fish a default PECtwa over 7 days can be applied.
Ctgb will not use the NOEC of the pulsed exposure study as such, because the exposure in the test, even in the case of two 96 hour pulses, is not considered long enough in view of the DT50 in water of fenpropimorph.

In the table below the PECtwa over 7 days is compared with the NOEC from the standard chronic study.

**Table E.12f Further refined risk for dapnia from fenpropimorph using the NOEC of 2.2 µg/L with the $PEC_{TWA}$ with a default TWA of 7 days**

| Use | Substance | $PECsw_{,TWA}$ [µg a.s./L] | | $TER_{lt}$ (trigger 10) Daphnia | |
|---|---|---|---|---|---|
| | | spring | autumn | spring | autumn |
| Cereals and flax (reduced dose rate) | epoxiconazole | 0.131 | 0.079 | >1000 | >1000 |
| | fenpropimorph | 0.128 | 0.085 | 17.2 | 25.9 |
| | combination | 0.259 | 0.164 | 17.0 | 25.2 |

As the table above shows, the risk to invertebrates/daphnia is acceptable for the use in cereals and flax (reduced dose rate in combination with 90% reducing nozzles) using the PECtwa over 7 days.

**Based on the current assessment, the following has to be stated in the GAP/legal instructions for use:**

**In the WG (legal instructions):**

*Om in het water levende organismen te beschermen is toepassing met een dosis tot 1 l/ha in de teelt van winter- en zomertarwe, winter- en zomergerst, triticale, spelt, haver en vlas uitsluitend toegestaan wanneer in percelen die grenzen aan oppervlaktewater gebruik wordt gemaakt van minimaal 90% driftreducerende spuitdoppen.*

### 7.9 Overall conclusions regarding the environment

It can be concluded that:

1. the proposed applications of the product meet the standards for aquatic organisms as laid down in the RGB, provided that drift reduction measures are applied.

## 8 Efficacy

This evaluation is partly based on the summary and evaluation of Opus Team prepared by Linge agroconsultancy on behalf of the applicant. (report number Lds14basf04).

The product is authorised for control of fungi in cereals, flax and beets. The old uses remain unchanged, but the applicant wants to include a label claim for control of cereal diseases and flax diseases at a lower dose rate in addition to the already existing claim, for this new dose rate, restriction sentences are likely to be less strict. The current restrictions are impractical under certain conditions.

**Pathogen and cultivation**
Plant diseases are often major factors in limiting the development and yield potential of cereal crops and often cause reductions in grain quality.

The following diseases were present in the trials:

| EPPO | Scientific name | Common name |
|---|---|---|
| PUCCRE | *Puccinia recondita* | Brown rust |
| PUCCST | *Puccinia striiformis* | Yellow rust |
| PUCCHD | *Puccinia hordei* | Brown rust |
| RHYNSE | *Rhynchosporium secalis* | Leaf blotch |
| ERYSGR | *Erysiphe graminis / Blumeria graminis* | Powdery mildew |
| SEPTTR | *Septoria tritici / Mycosphaerella graminicola* | Leaf spot |
| PYRNTE | *Pyrenophora teres* | Net blotch |

**Data requirements**
For the new uses it concerns the dose lowering of a registered product based on fenpropimorph and epoxiconazole. Trials are required to demonstrate the effectiveness of the lower dose rate. No additional data on adverse effects is required. No data on the unchanged uses is required.

**Location and period**
Data to support the product label and which are summarized in this biological dossier were generated in a total of 52 effectiveness trials conducted in the Maritime EPPO Zone in the period from 1997 to 2013 in the following crops:

| Crop | Location | Year | Number of trials |
|---|---|---|---|
| winter wheat | Denmark | 2003 | 1 |
| | France | 2003 | 2 |
| | | 2010 | 2 |
| | the Netherlands | 2006 | 1 |
| | | 2007 | 6 |
| | | 2008 | 1 |
| | | 2009 | 5 |
| | | 2010 | 7 |
| | | 2011 | 4 |
| | | 2012 | 2 |
| | | 2013 | 3 |
| | **Total** | | **34** |
| spring barley | Denmark | 2004 | 1* |
| | | 2005 | 2* |
| | | 2006 | 1* |
| | | 2007 | 1* |
| | **Total** | | **5*** |
| winter barley | Germany | 1997 | 3 |
| | | 1998 | 6 |
| | | 2006 | 1 |
| | the United Kingdom | 2006 | 1 |
| | France | 2009 | 1 |
| | | 2010 | 1 |

| | | |
|---|---|---|
| | **Total** | **13** |
| **Total** | | **53** |

* Proposed dose rate was not applied in these trials

All trials were carried out by officially recognized organisations and conducted either in accordance with the Principles of Good Experimental Practice (GEP), or design of the trials, the application methods used and the assessments conducted were properly documented and reported making the trials useful for support of the claim.

The trials were conducted with the following crop-pest combinations:

| **Pest** | **Crop** | **Location** | **Year** | **Number of trials** |
|---|---|---|---|---|
| PUCCRE | winter wheat | the Netherlands | 2007 | 3 |
| | | | 2008 | 1 |
| | | | 2009 | 3 |
| | | | 2011 | 2 |
| | | **Total** | | **9** |
| PUCCST | winter wheat | the Netherlands | 2011 | 1 |
| | | | 2013 | 1 |
| | | **Total** | | **2** |
| PUCCHD | spring barley | Denmark | 2005 | 1* |
| | | | 2006 | 1* |
| | | | 2007 | 1* |
| | | **Total** | | **3*** |
| | winter barley | Germany | 1998 | 3 |
| RHYNSE | winter barley | Germany | 1997 | 1 |
| | | | 1998 | 5 |
| | | | 2006 | 1 |
| | | the United Kingdom | 2006 | 1 |
| | | France | 2009 | 1 |
| | | **Total** | | **9** |
| ERYSGR | winter wheat | Denmark | 2003 | 1 |
| | | France | 2003 | 2 |
| | | | 2010 | 2 |
| | | the Netherlands | 2007 | 1 |
| | | | 2009 | 2 |
| | | | 2010 | 1 |
| | | **Total** | | **9** |
| | spring barley | Denmark | 2005 | 2* |
| | | | 2006 | 1* |
| | | | 2007 | 1* |
| | | **Total** | | **4*** |
| | winter barley | Germany | 1998 | 1 |
| SEPTTR | winter wheat | Denmark | 2003 | 1 |
| | | France | 2003 | 1 |
| | | the Netherlands | 2006 | 1 |
| | | | 2007 | 5 |
| | | | 2009 | 5 |
| | | | 2010 | 4 |
| | | | 2011 | 3 |
| | | | 2012 | 1 |
| | | | 2013 | 3 |
| | | **Total** | | **24** |
| PYRNTE | winter barley | Germany | 1997 | 3 |
| | | | 1998 | 6 |

| Pest | Crop | Location | Year | Number of trials |
|---|---|---|---|---|
| | | | 2006 | 1 |
| | | France | 2009 | 1 |
| | | | 2010 | 1 |
| | | **Total** | | **12** |
| | spring barley | Denmark | 2004 | 1* |
| | | | 2005 | 3* |
| | | | 2007 | 1* |
| | | **Total** | | **5*** |

* Proposed dose rate was not applied in these trials

**Sites**
The trials were carried out in the field at sites selected on the basis of a history of infection and in areas representative of those where the crops are grown commercially, or at fields of testing facilities.

**Experimental details**

*Winter wheat*
A total of 34 trials were conducted in Denmark (1), France (4) and the Netherlands (29) in the period from 2003 to 2013. All trials were conducted in accordance to GEP. EPPO guideline PP 1/26(3): Foliar and ear diseases on cereals, was followed in the majority of trials. In some trials in France guideline CEB 189 was followed.
Trials were set up in a randomized block design with 4 replicates. Plot size varied between 21 and 30 $m^2$.

*Spring barley*
A total of 5 trials were conducted in Denmark from 2004 to 2007. All trials were conducted in accordance to GEP. EPPO guideline PP 1/26(3): Foliar and ear diseases on cereals, was followed.
Trials were set up in a randomized block design with 4 replicates. Plot size varied between 22.5 and 25 $m^2$.

*Winter barley*
A total of 13 trials were conducted in Germany (10), the United Kingdom (1) and France (2) in the period from 1997 to 2010. With exception of the trials conducted in 1997 and 1998 in which GEP status was not reported, all trials were conducted in accordance to GEP. EPPO guideline PP 1/26(3): Foliar and ear diseases on cereals, was followed in the majority of trials conducted after 1998. In trials in France guideline CEB 189 was followed.

**Application methods**
The products were applied by foliar spraying in water volumes of 190-400 L/ha at crop growth stages BBCH 31-57 but generally between BBCH 31-33.

**Assessment methods – crop yield**
The majority of trials was taken to yield. Next to total grain yield, thousand grain weight and hectolitre weight was assessed in the majority of trials.

**Assessment methods – crop safety**
Assessments on crop safety (crop condition, phytotoxicity) were made in all trials. Phytotoxicity was assessed as a percentage.

**Statistical analysis**
Data were statistically analysed. The mean separation test used was Student-Newman-

Keuls. When P has a value of 0,05 or less, the difference between two treatments is statistically significant. The least significant difference (lsd) is the smallest difference between significant different treatments at 95% (P = 0,05).

**Treatments relevant to the claim**

**Table 6.1.3-2: Treatments efficacy trials in winter wheat**

| Authorisation No. - Country | Treatments | Active ingredient | | Rate | |
|---|---|---|---|---|---|
| | | name | content | product | active ingredient |
| Claim | | | | | |
| 11407 NL<br>570-43 DK | Opus Team*<br>/ Opus Top* | epoxiconazole /<br>fenpropimorph | 84 g/L<br>250 g/L | 1.0 L/ha | 84 g/ha<br>250 g/ha |
| 11407 NL<br>570-43 DK | Opus Team*<br>/ Opus Top* | epoxiconazole /<br>fenpropimorph | 84 g/L<br>250 g/L | 0.5 L/ha | 42 g/ha<br>125 g/ha |
| | | | | 1.0 L/ha | 84 g/ha<br>250 g/ha |
| | | | | 1.5 L/ha | 126 g/ha<br>375 g/ha |
| Reference products | | | | | |
| 12747 NL | Allegro Plus | kresoxim-methyl /<br>epoxiconazole /<br>fenpropimorph | 125 g/L<br>125 g/L<br>150 g/L | 1.0 L/ha | 125 g/ha<br>125 g/ha<br>150 g/ha |
| 12725 NL | Proline | prothioconazole | 250 g/L | 0.8 L/ha | 200 g/ha |
| 13908 NL | Osiris | epoxiconazole<br>/ metconazole | 37.5 g/L<br>27.5 g/L | 3.0 L/ha | 112.5 g/ha<br>82.5 g/ha |
| 8158 NL<br>8000045 FR | Corbel | fenpropimorph | 750 g/L | 1.0 L/ha | 750 g/ha |
| 8800124 FR | Boscor | fenpropidine /<br>fenpropimorph | 188 g/L<br>562 g/L | 1.0 L/ha | 188 g/ha<br>562 g/ha |
| 12781 NL | Venture | epoxiconazole<br>/ boscalid | 67 g/L<br>233 g/L | 1.5 L/ha | 100 g/ha<br>155 g/ha |

* identical products

**Table 6.1.3-3: Treatments efficacy trials in winter barley**

| Authorisation No. - Country | Treatments | Active ingredient | | Rate | |
|---|---|---|---|---|---|
| | | name | content | product | active ingredient |
| Claim | | | | | |
| 11407 NL<br>570-43 DK | Opus Team*<br>/ Opus Top* | epoxiconazole /<br>fenpropimorph | 84 g/L<br>250 g/L | 1.0 L/ha | 84 g/ha<br>250 g/ha |
| 11407 NL<br>570-43 DK | Opus Team*<br>/ Opus Top* | epoxiconazole /<br>fenpropimorph | 84 g/L<br>250 g/L | 0.5 L/ha | 42 g/ha<br>125 g/ha |
| | | | | 1.0 L/ha | 84 g/ha<br>250 g/ha |
| | | | | 1.5 L/ha | 126 g/ha<br>375 g/ha |
| Reference products | | | | | |
| 11826 NL | Allegro | kresoxim-methyl /<br>epoxiconazole | 125 g/L<br>125 g/L | 1.0 L/ha | 125 g/ha<br>125 g/ha |
| 025625-00 DE | Input Classic | spiroxamine /<br>prothioconazole | 300 g/L<br>160 g/L | 1.25 L/ha | 375 g/ha<br>200 g/ha |
| 12276 UK | Fandango | fluoxastrobin /<br>prothioconazole | 100 g/L<br>100 g/L | 1.25 L/ha | 125 g/ha<br>125 g/ha |
| 11408 NL | Opus | epoxiconazole | 125 g/L | 1.0 L/ha | 125 g/ha |
| 12509 NL | Opera | epoxiconazole / | 50 g/L | 1.5 L/ha | 75 g/ha |

| | | | | | |
|---|---|---|---|---|---|
| | | pyraclostrobin | 133 g/L | | 199.5 g/ha |

* identical products

**Table 6.1.3-4: Treatments efficacy trials in spring barley**

| Authorisation No. - Country | Treatments | Active ingredient | | Rate | |
|---|---|---|---|---|---|
| | | name | content | product | active ingredient |
| Claim | | | | | |
| 11407 NL<br>570-43 DK | Opus Team*<br>/ Opus Top* | epoxiconazole /<br>fenpropimorph | 84 g/L<br>250 g/L | 1.0 L/ha | 84 g/ha<br>250 g/ha |
| 11407 NL<br>570-43 DK | Opus Team*<br>/ Opus Top* | epoxiconazole /<br>fenpropimorph | 84 g/L<br>250 g/L | 0.375 L/ha | 31.5 g/ha<br>93.75 g/ha |
| | | | | 0.75 L/ha | 63 g/ha<br>187.5 g/ha |
| | | | | 1.5 L/ha | 126 g/ha<br>375 g/ha |
| Reference products | | | | | |
| 12781 NL | Venture | epoxiconazole<br>/ boscalid | 67 g/L<br>233 g/L | 1.5 L/ha | 100 g/ha<br>155 g/ha |
| 2090173FR<br>- DK | Capalo | epoxiconazole /<br>fenpropimorph /<br>metrafenone | 62.5 g/L<br>200 g/L<br>75 g/L | 2.0 L/ha | 125 g/ha<br>400 g/ha<br>150 g/ha |

* identical products

### 8.1.1 Preliminary studies

Data not included due to a sufficient number of GEP trials / registration trials.

### 8.1.2 Dose justification

Different dose rates of Opus Team were laid out in all 52 efficacy trials conducted in the Maritime EPPO Zone (Germany, Denmark, France, the Netherlands and the United Kingdom) in the period from 1997 to 2013. The trials were conducted in winter wheat (34), spring barley (5) and winter barley (13). In all trials, with exception of the trials in spring barley, the newly proposed dose rate of 1.0 L/ha was compared to the currently registered rate of 1.5 L/ha. In a small number of trials, also dose rates lower than 1.0 L/ha were tested. In the trials in spring barley dose rates of 0.375, 0.75 and 1.5 L/ha were applied.
Opus Team was applied in 1-2 applications. Assessment was made on the percentage infection over the total plot or was specified per leaf level (1st, 2nd, 3rd leaf).

An overview of results is presented in Table IIIA1 6.1.2-1.

Brown rust (*Puccinia recondita*, PUCCRE)
Opus Team was not applied at lower dose rates than 1.0 L/ha in presence of brown rust. In 9 efficacy trials in winter wheat Opus Team was also applied at the currently registered rate of 1.5 L/ha.. The trials were conducted in the Maritime EPPO Zone in the period from 2007 to 2011.

Overall the dose rate of 1.5 L/ha achieved comparable to slightly higher control compared to the proposed dose rate of 1.0 L/ha. However the effect was not significant at any of the assessment timings.

Yellow rust (*Puccina striiformis*, PUCCST)
Opus Team was not applied at lower dose rates than 1.0 L/ha in presence of yellow rust. In 2 trials in winter wheat conducted in the Netherlands in 2011 and 2013, Opus Team was also applied at the currently registered rate of 1.5 L/ha.

The higher dose rate of 1.5 L/ha was comparably to slightly more effective compared to the dose rate of 1.0 L/ha especially at the 1st leaf level. However no significant differences were observed.

Brown rust (*Puccinia hordei*, PUCCHD)
In winter barley Opus Team was not applied at lower dose rates than 1.0 L/ha in presence of brown rust. In 3 trials conducted in Germany in 1998 Opus Team was also applied at the currently registered rate of 1.5 L/ha.
In one trial with low infection (1.5%) all treatments (Opus Team at dose rates of 1.0 and 1.5 L/ha, and reference) achieved low and non-significant control (33%). In the 2 remaining trials the higher dose rate of 1.5 L/ha achieved slightly higher control compared to the proposed dose rate of 1.0 L/ha. However the effect was not significant at any of the assessment timings.

In 3 trials in spring barley conducted in Denmark from 2005 to 2007 Opus Team was applied at dose rates of 0.375, 0.75 and 1.5 L/ha. The higher dose rates of 0.75 and 1.5 L/ha achieved comparable control levels (means of respectively 72 and 66%), which were higher than those achieved at a dose rate of 0.375 L/ha (mean of 55%), resulting in a significant difference in 1 trial at 1 assessment.

Leaf blotch (*Rhynchosporium secalis*, RHYNSE)
Opus Team was applied at lower dose rates in 1 trial in winter barley conducted in Germany in 2007. At assessment timings 26 and 40 DAA1 a dose related effect was observed in which the control levels achieved at the higher dose rates of 1.0 and 1.5 L/ha were higher than those achieved at the lower dose rate of 0.5 L/ha. However the effect was not significant and had disappeared at 44 DAA1 at which time all dose rates achieved high control.

Opus Team was applied at the currently registered rate of 1.5 L/ha in 9 trials in winter barley. All trials were conducted in the Maritime EPPO Zone (Germany, the United Kingdom and France) in the period from 1997 to 2009).
Over the trials the higher dose rate of 1.5 L/ha achieved slightly higher control compared to the proposed dose rate of 1.0 L/ha.

Powdery mildew (*Erysiphe graminis*, ERYSGR)
In 2 trials in winter wheat conducted in Denmark and France in 2003 Opus Team was applied at dose rates of 0.5, 1.0 and 1.5 L/ha. A dose related effect on control was observed in both trials. The proposed dose rate of 1.0 L/ha achieved a mean control of 88% (range of 74-96%), which was higher than that achieved at a dose rate of 0.5% (mean of 78%, range of 68-79%) and slightly lower than that achieved at a dose rate of 1.5% (mean of 92%, range of 86-97%). However no significant effects were observed.
In the remaining 7 trials in winter wheat Opus Team was not applied at lower dose rates than 1.0 L/ha. However in all 9 trials conducted in the Maritime EPPO Zone (Denmark, France, the Netherlands) in the period from 2003 to 2010, the currently registered rate of 1.5 L/ha was applied. Over the 9 trials the dose rate of 1.5 L/ha achieved comparable to higher control of powdery mildew compared to the proposed dose rate of 1.0 L/ha. However the effect was not significant in any of the trials.

In the 4 trials in spring barley conducted in Denmark from 2005 to 2007, Opus Team was applied at dose rates of 0.375, 0.75 and 1.5 L/ha. A dose related effect on control was observed over the trials. The higher dose rates of 0.75 L/ha (mean of 79%, range of 71-90%) and 1.5 L/ha (mean of 83%, range of 77-91%) achieved consistently higher control of powdery mildew compared to the lower dose rate of 0.375 L/ha (mean of 55%, range of 14-84%).

In the trial in winter barley conducted in Germany in 1998, Opus Team was not applied at lower dose rates than 1.0 L/ha, yet was applied at the currently registered rate of 1.5 L/ha.

Over the 2 assessments the dose rate of 1.5 L/ha achieved a higher control compared to the proposed dose rate of 1.0 L/ha. However infection levels in this trial were low and the effect was not significant.

Leaf spot (*Septoria tritici*, SEPTTR)
In 2 trials in winter wheat conducted in Denmark and France in 2003 Opus Team was applied at dose rates of 0.5, 1.0 and 1.5 L/ha. No clear dose related effect on control was observed and differences in control levels were slight. At 23-28 DAA, the proposed dose rate of 1.0 L/ha was most effective with a mean control of 80% (range of 78-81%), followed by the dose rate of 1.5 L/ha (mean of 78%, range of 77-80%) and the dose rate of 0.5 L/ha (mean of 75%, range of 73-76%).
In the remaining 22 trials in winter wheat no lower those rates than 1.0 L/ha were applied, yet in all trials the currently registered rate of 1.5 L/ha was applied. Over the 24 trials conducted in the Maritime EPPO Zone (Denmark, France and the Netherlands) in the period from 2003 to 2013 a more consistent and higher control was observed at the higher dose rate of 1.5 L/ha.

Net blotch (*Pyrenophora teres*, PYRNTE)
In 3 trials in winter barley conducted in Germany in 1997, Opus Team was applied at dose rates of 0.5, 1.0 and 1.5 L/ha. A dose related effect on control was observed. At 26-40 DAA, the proposed dose rate of 1.0 L/ha achieved a mean control of 59% (range of 56-62%), which was higher than that achieved at the dose rate of 0.5 L/ha (mean of 47%, range of 43-49%) and lower than that achieved at the dose rate of 1.5 L/ha (mean of 67%, range of 62-71%).
In the remaining 9 trials in winter barley Opus Team was not applied at dose rates lower than 1.0 L/ha, yet was applied at the currently registered rate of 1.5 L/ha. Over 12 trials conducted in Germany and France in the period from 1997 to 2010 a consistently higher control was achieved at the dose rate of 1.5 L/ha.

In 5 trials in spring barley conducted in Denmark from 2004 to 2007, Opus Team was applied at dose rates of 0.375, 0.75 and 1.5 L/ha. The higher dose rates of 0.75 L/ha (mean control of 59%, range of 35-76%) and 1.5 L/ha (mean control of 62%, range of 32-79%) achieved higher control compared to the lower dose rate of 0.375 L/ha (mean of 45%, range of 0-69%).

**Table IIIA1 6.1.2-1 Dose justification data for Opus Team**

| Pest | Crop | # trials | DAA | Assess-ment | Untreated % infection | Control of brown rust (%) Opus Team | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 0.375 L/ha | 0.5 L/ha | 0.75 L/ha | 1.0 L/ha | 1.5 L/ha |
| PUCCRE | Winter wheat | 9 | 39-74 | total | 20.0 (3.3-70.0) | | | | 79 (50-99) | 80 (50-100) |
| PUCCST | Winter wheat | 2 | 52-90 | total | 44.4 (23.0-75.0) | | | | 95 (83-100) | 97 (91-100) |
| | | | | 1st leaf | 34.7 (29.3-40.0) | | | | 91 (83-98) | 95 (91-99) |
| | | | | 2nd leaf | 46.5 (23.0-70.0) | | | | 96 (92-100) | 98 (96-99) |
| | | | | 3rd leaf | 52.2 (29.3-75.0) | | | | 99 (98-100) | 100 (99-100) |
| PUCCH | Winter | 3 | 45-56 | total | 5.5 | | | | 68 | 71 |

| Pest | Crop | # trials | DAA | Assess-ment | Untreated % infection | Control of brown rust (%) Opus Team | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 0.375 L/ha | 0.5 L/ha | 0.75 L/ha | 1.0 L/ha | 1.5 L/ha |
| D | barley | | DAA1/ 28-35 DAA2 | | (1.5-10.0) | | | | (33-100) | (33-100) |
| | Spring barley | 3 | 37-40 | total | 3.9 (0.8-8.5) | 55 (40-76) | | 72 (56-85) | | 66 (48-87) |
| RHYNSE | Winter barley | 9 | 29-51 DAA1 | total | 16.2 (5.8-41.8) | | | | 77 (43-98) | 81 (52-94) |
| | | 1 | 44 DAA1 | total | 13.8 | | 96 | | 98 | 94 |
| ERYSGR | Winter wheat | 9 | 14-64 | total | 11.4 (2.8-29.8) | | | | 69 (21-100) | 77 (29-100) |
| | | 2 | 14-23 | total | 5.6 (2.8-8.5) | | 78 (68-89) | | 88 (74-96) | 92 (86-97) |
| | Spring barley | 4 | 28-37 | total | 7.3 (3.5-13.0) | 55 (14-84) | | 79 (71-90) | | 83 (77-91) |
| | Winter barley | 1 | 42 DAA1 | total | 1.8 | | | | 83 | 100 |
| SEPPTR | Winter wheat | 24 | 23-115 | total | 15.2 (6.7-50.0) | | | | 64 (34-82) | 71 (35-91) |
| | | 12 | | 1st leaf | 4.6 (0.3-17.5) | | | | 75 (11-100) | 80 (34-100) |
| | | 11 | | 2nd leaf | 11.4 (2.8-20.3) | | | | 57 (29-84) | 70 (41-88) |
| | | 12 | | 3rd leaf | 26.7 (0.8-57.5) | | | | 51 (32-100) | 57 (34-100) |
| | | 2 | 23-28 | total | 10.5 (9-11.9) | | 75 (73-76) | | 80 (78-81) | 78 (77-80) |
| PYRNTE | Winter barley | 12 | 26-49 | total | 11.0 (3.2-27.5) | | | | 60 (34-88) | 68 (49-88) |
| | | 3 | 26-40 | total | 11.9 (7.5-18.0) | | 47 (43-49) | | 59 (56-62) | 67 (62-71) |
| | Spring barley | 5 | 30-41 | total | 14.3 (5.6-25.0) | 45 (0-69) | | 59 (35-76) | | 62 (32-79) |

**Conclusion minimum effective dose**

The claim concerns the addition of a lower dose rate of 1.0 L/ha, next to the existing dose rate of 1.5 L/ha. The lower dose rate is expected to have less severe restrictions on the method of application. Current restrictions at 1.5 L/ha make it hard to use the product under practical conditions.

Different dose rates of Opus Team were laid out in all 52 efficacy trials conducted in the Maritime EPPO Zone (Germany, Denmark, France, the Netherlands and the United Kingdom) in the period from 1997 to 2013. The trials were conducted in winter wheat (34), spring barley (5) and winter barley (13). In all trials, with exception of the trials in spring barley, the newly proposed dose rate of 1.0 L/ha was compared to the currently registered rate of 1.5 L/ha. In a small number of trials, also dose rates lower than 1.0 L/ha were tested. In the trials in spring barley dose rates of 0.375, 0.75 and 1.5 L/ha were applied.

Over the majority of trials a dose related effect on control was observed. In trials were the newly proposed dose rate of 1.0 L/ha and the currently registered dose rate of 1.5 L/ha were compared, though differences were often only slight, a consistently higher control was observed for the higher dose rate. This effect was most pronounced against leaf blotch (*Rhynchosporium secalis*, RHYNSE), powdery mildew (*Erysiphe graminis*, ERYSGR) and leaf spot (*Septoria tritici,* SEPPTR).
In the trials were the newly proposed dose rate of 1.0 L/ha was compared to a dose rate of 0.5 L/ha generally a higher control was observed for the higher dose rate. In the trials in spring barley were dose rates of 0.375, 0.75 and 1.5 L/ha were compared a clear dose related effect was observed.

The dose rate of 1.5 L/ha achieved a consistently higher control compared to the lower rate of 1.0 L/ha, and was chosen in the past as the minimum effective dose rate. This rate will remain on the label. The lower additionally proposed dose rate of 1.0 L/ha still provides reasonable control, a real decrease of efficacy only seems to occur at still lower dose rates, while differences between 1.0 L/ha and 1.5 L/ha are relatively small. There is a need for the addition of the lower dose rate because of the restrictions that are placed on the 1.5 L/ha rate.

The dose justification results imply that the 1.0 L/ha rate seems to provide sufficient efficacy to be considered as an additional dose rate option.

### 8.1.3 efficacy

The effectiveness of Opus Team against foliar and ear diseases in cereals was tested in a total of 52 trials in winter wheat (34), spring barley (5) and winter barley (13). The trials were conducted in the Maritime EPPO Zone (Germany, Denmark, France, the Netherlands and the United Kingdom) in the period from 1997 to 2010.
Opus Team was applied at its proposed dose rate of 1.0 L/ha in 1-2 applications. In the trials in spring barley the proposed dose rate was not tested, yet a lower dose rate of 0.75 L/ha was applied.
Assessment was made on the percentage infection over the total plot or was specified per leaf level (1$^{st}$, 2$^{nd}$, 3$^{rd}$ leaf).

Brown rust (*Puccinia recondita*, PUCCRE)
The effectiveness of Opus Team against brown rust (*Puccinia recondita*, PUCCRE) was tested in 9 trials in winter wheat. The trials were conducted in the Maritime EPPO Zone in the period from 2007 to 2011.

Opus Team was applied at the proposed dose rate of 1.0 L/ha in 1 application.

*Winter wheat*

In a total of 9 trials conducted in the Netherlands in the period from 2007 to 2011, the mean infection at 39-74 DAA was 20.0% (range of 3.3-70.0%). An overview of results is presented in Table IIIA1 6.1.3-1. Opus Team achieved a mean control of 79% (range of 50-99%), which was comparable to higher to that achieved by the reference product containing prothioconazole (9 trials) and comparable to that achieved by the reference product containing epoxiconazole + metconazole (2 trials).
In 1 of these trials assessment was made per leaf. Opus Team achieved 64 and 74% control (respectively 1st and 3rd leaf) at 39 DAA, which was comparable to higher to that achieved by the reference products containing prothioconazole and epoxiconazole + metconazole.

**Table IIIA1 6.1.3-1 Effectiveness of Opus Team against PUCCRE in winter wheat**

| # trials | DAA | Assessment | Untreated % infection | Control of brown rust (%) | | |
|---|---|---|---|---|---|---|
| | | | | Opus Team 1.0 L/ha | Reference prothioconazole | Reference epoxiconazole metconazole |
| 9 | 39-74 | total | 20.0 (3.3-70.0) | 79 (50-99) | 71 (21-99) | |
| 2 | 39-64 | total | 7.4 (3.3-11.4) | 76 (69-82) | 65 (64-67) | 77 (65-88) |
| 1 | 39 | 1st leaf | 13.8 | 64 | 53 | 58 |
| | | 3rd leaf | 9.0 | 74 | 74 | 72 |

Yellow rust (*Puccina striiformis*, PUCCST)
The effectiveness of Opus Team against yellow rust (*Puccinia striiformis*, PUCCST) was tested in 2 trials in winter wheat conducted in the Netherlands in 2011 and 2013.

Opus Team was applied at the proposed dose rate of 1.0 L/ha in 1 application.

*Winter wheat*
In the 2 trials conducted in the Netherlands in 2011 and 2013, the infection in the untreated objects at 52 and 90 DAA ranged between 29.3-40.0% on the 1st leaf, 23.0-70.0% on the 2nd leaf and 29.3-75.0% at the 3rd leaf. An overview of results is presented in Table IIIA1 6.1.3-2.
Opus Team achieved a mean overall control of 95% (range of 83-100%), which was comparable to that achieved by reference products containing prothioconazole and epoxiconazole + metconazole.

**Table IIIA1 6.1.3-2 Effectiveness of Opus Team against PUCCST in winter wheat**

| # trials | DAA | Assessment | Untreated % infection | Control of yellow rust (%) | | |
|---|---|---|---|---|---|---|
| | | | | Opus Team 1.0 L/ha | Reference prothioconazole | Reference epoxiconazole metconazole |
| 2 | 52-90 | total | 44.4 (23.0-75.0) | 95 (83-100) | 96 (91-99) | 97 (91-100) |
| | 52-90 | 1st leaf | 34.7 (29.3-40.0) | 91 (83-98) | 94 (91-97) | 94 (91-97) |
| | 52-90 | 2nd leaf | 46.5 (23.0-70.0) | 96 (92-100) | 95 (94-96) | 97 (96-98) |
| | 52- | 3rd leaf | 52.2 | 99 | 98 | 100 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | 90 | | (29.3-75.0) | (98-100) | (97-99) | (99-100) |

Brown rust (*Puccinia hordei*, PUCCHD)

The effectiveness of Opus Team against brown rust (*Puccinia hordei*, PUCCHD) was tested in a total of 6 trials in spring barley (3) and winter barley (3). All trials were conducted in the Maritime EPPO Zone (Denmark and Germany) in the period from 1998 to 2007.

*Winter barley*

In 3 trials conducted in Germany in 1998 Opus Team was applied at the proposed dose rate of 1.0 L/ha in 2 applications. An overview of results is presented in Table IIIA1 6.1.3-3a.

The mean infection in the untreated objects was 5.5% (range of 1.5-10.0%). In the trial with low infection (1.5%) all treatments (Opus Team at dose rates of 1.0 and 1.5 L/ha, and the reference product containing kresoxim-methyl + epoxiconazole) achieved low and non-significant control (33%). In the remaining 2 trials Opus Team achieved 70 and 100% control at 46-56 DAA1, which was comparable to lower (not significant) than that achieved by the reference product.

**Table IIIA1 6.1.3-3a Effectiveness of Opus Team against PUCCHD in winter barley**

| # trials | DAA | Assessment | Untreated % infection | Control of brown rust (%) | |
|---|---|---|---|---|---|
| | | | | Opus Team 1.0 L/ha | Reference kresoxim-methyl epoxiconazole |
| 3 | 46-56 DAA1/ 28-35 DAA2 | total | 5.5 (1.5-10.0) | 68 (33-100) | 73 (33-100) |

*Spring barley*

In 3 trials conducted in Denmark from 2005 to 2007 Opus Team was not applied at the proposed dose rate, yet at a lower dose rate of 0.75 L/ha.in 1 application. An overview of results is presented in Table IIIA 6.1.3-3b.

The mean infection in the untreated objects was 3.9% (range of 0.8-8.5%). Over the 3 trials at 37-40 DAA the dose rate of 0.75 L/ha achieved a mean control of 72% (range of 56-85%). In 1 of these trials, with the highest disease pressure (8.5% infection at 39 DAA) Opus Team was compared to the reference product containing epoxiconazole + fenpropimorph + metrafenone. Opus Team at a dose rate of 0.75 L/ha achieved 85% control at 39 DAA which was slightly higher (not significant) than that achieved by the reference product.

**Table IIIA1 6.1.3-3b Effectiveness of Opus Team against PUCCHD in spring barley**

| # trials | DAA | Assessment | Untreated % infection | Control of brown rust (%) | |
|---|---|---|---|---|---|
| | | | | Opus Team 0.75 L/ha | Reference epoxiconazole fenpropimorph metrafenone |
| 3 | 37-40 | total | 3.9 (0.8-8.5) | 72 (56-85) | |
| 1 | 39 | total | 8.5 | 85 | 79 |

Leaf blotch (*Rhynchosporium secalis*, RHYNSE)

The effectiveness of Opus Team against leaf blotch (*Rhynchosporium secalis*, RHYNSE) was tested in 9 trials in winter barley. All trials were conducted in the Maritime EPPO Zone (Germany, the United Kingdom and France) in the period from 1997 to 2009).

Opus Team was applied at the proposed dose rate of 1.0 L/ha in 1-2 applications.

*Winter barley*

Over 9 trials conducted in the Maritime EPPO Zone (Germany, the United Kingdom and France) in the period from 1997 and 2009, the mean infection in the untreated objects was 16.2% (range of 5.8-41.8%). An overview of results is presented in Table IIIA 6.1.3-4.
At 29-51DAA1 Opus Team achieved a mean control of 77% (range of 43-98%).
Opus Team was comparably to somewhat less effective than the reference product containing kresoxim-methyl + epoxiconazole (6 trials), less effective than the reference product containing spiroxamine + prothioconazol (1 trial), comparably to less effective than the reference product containing fluoxastrobin + prothioconazole (1 trial) and less effective than the reference products containing epoxiconazole and epoxiconazole + pyraclostrobin (1 trial).

**Table IIIA1 6.1.3-4 Effectiveness of Opus Team against RHYNSE in winter barley**

| # trials | DAA | Assessment | Untreated % infection | Control of leaf blotch (%) | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Opus Team 1.0 L/ha | Reference kresoxim-methyl epoxiconazole | Reference spiroxamine prothioconazol | Reference fluoxastrobin prothioconazole | Reference epoxiconazole | Reference epoxiconazole pyraclostrobin |
| 9 | 29-51 DAA 1 | total | 16.2 (5.8-41.8) | 77 (43-98) | | | | | |
| 6 | 39-51 DAA 1/ 14-33 DAA 2 | total | 18.8 (7.0-41.8) | 81 (71-98) | 88 (79-100) | | | | |
| 1 | 49 | total | 5.8 | 43 | | 66 | | | |
| 1 | 29 | 1st leaf | 3.8 | 92 | | | 100 | | |
| | | 2nd leaf | 17.5 | 86 | | | 98 | | |
| | | 3rd leaf | 42.5 | 79 | | | 98 | | |
| 1 | 34 | 2nd leaf | 3.6 | 82 | | | | 92 | 97 |
| | | 3rd leaf | 8.3 | 72 | | | | 82 | 93 |

Powdery mildew (*Erysiphe graminis*, ERYSGR)
The effectiveness of Opus team against powdery mildew (*Erysiphe graminis*, ERYSGR) was tested in a total of 14 trials conducted in winter wheat (9), spring barley (4) and winter barley (1). All trials were conducted in the Maritime EPPO Zone (Germany, Denmark, France and the Netherlands) in the period from 1998 to 2010.

*Winter wheat*
In 9 trials conducted in the Maritime EPPO Zone (Denmark, France, the Netherlands) in the period from 2003 to 2010, Opus Team was applied at the proposed dose rate of 1.0 L/ha in 1-2 applications. An overview of results is presented in Table IIIA1 6.1.3-5a.
The mean infection in the untreated objects was 11.4% (range of 2.8-29.8%). At 14-64 DAA1 Opus Team achieved a mean control of 69% (range of 21-100%). Opus Team was comparably effective to reference products containing kresoxim-methyl + epoxiconazole + fenpropimorph (2 trials), prothioconazole (4 trials) and fenpropidine + fenpropimorph (1 trial) and comparably to less effective than the reference product containing fenpropimorph (3 trials).

**Table IIIA1 6.1.3-5a Effectiveness of Opus Team against ERYSGR in winter wheat**

| # trials | DAA | Assessment | Untreated % infection | Control of powdery mildew (%) | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Opus Team 1.0 L/ha | Reference prothioconazole | Reference fenpropimorph | Reference kresoxim-methyl epoxiconazole fenpropimorph | Reference fenpropidine fenpropimorph |
| 9 | 14-64 | total | 11.4 (2.8-29.8) | 69 (21-100) | | | | |
| 2 | 14-23 | total | 5.6 (2.8-8.5) | 88 (74-96) | | | 86 (74-99) | |
| 3 | 23-48 | total | 14.9 (6.3-29.8) | 75 (59-86) | | 85 (77-97) | | |
| 4 | 35-64 | total | 12.0 (3.5-27.5) | 57 (21-86) | 55 (24-77) | | | |
| 1 | 14 | 1st leaf | 0.2 | 100 | | | 100 | |
| 4 | 14-48 | 2nd leaf | 11.0 (2.5-29.8) | 75 (59-91) | | | | |
| 2 | 23-34 | 3rd leaf | 5.0 (3.2-6.7) | 88 (85-91) | | | | |
| 1 | 34 | 2nd leaf | 2.5 | 62 | | | | 73 |
| | | 3rd leaf | 3.2 | 91 | | | | 82 |

*Spring barley*

In 4 trials conducted in Denmark from 2005 to 2007 Opus Team was not applied at the proposed dose rate, yet at a lower dose rate of 0.75 L/ha in 1 application. An overview of results is presented in Table IIIA1 6.1.3-5b.

The mean infection in the untreated objects was 7.3% (range of 3.5-13.0%) at 28-37 DAA. Opus Team at a dose rate of 0.75 L/ha achieved a mean control of 79% (range of 71-90%). Opus Team was less effective (not significant) than the reference product containing fenpropimorph (1 trial).

**Table IIIA1 6.1.3-5b Effectiveness of Opus Team against ERYSGR in spring barley**

| # trials | DAA | Assessment | Untreated % infection | Control of powdery mildew (%) | |
|---|---|---|---|---|---|
| | | | | Opus Team 0.75 L/ha | Reference epoxiconazole fenpropimorph metrafenone |
| 4 | 28-37 | total | 7.3 (3.5-13.0) | 79 (71-90) | |
| 1 | 30 | total | 13.0 | 77 | 99 |

*Winter barley*

In 1 trial conducted in Germany in 1998, Opus Team was applied at the proposed dose rate of 1.0 L/ha in 2 applications. An overview of results is presented in Table IIIA1 6.1.3-5c.

Infection in the untreated objects was low with 1.8% at 42 DAA1. Opus Team achieved 83% control at 42 DAA1, which was lower (not significant) compared to that achieved by the reference product containing kresoxim-methyl + epoxiconazole.

**Table IIIA1 6.1.3-5c Effectiveness of Opus Team against ERYSGR in winter barley**

| # trials | DAA | Assessment | Untreated % infection | Control of powdery mildew (%) | |
|---|---|---|---|---|---|
| | | | | Opus Team 1.0 L/ha | Reference kresoxim-methyl epoxiconzole |
| 1 | 42 DAA1/ 14 DAA2 | total | 1.8 | 83 | 100 |

Leaf spot (*Septoria tritici*, SEPTTR)

The effectiveness of Opus Team against leaf spot (*Septoria tritici*, SEPTTR) was tested in 24 trials in winter wheat conducted in the Maritime EPPO Zone (Denmark, France and the Netherlands) in the period from 2003 to 2013.

*Winter wheat*

Opus Team was applied at the proposed dose rate of 1.0 L/ha in 1 application. An overview of results is presented in Table IIIA1 6.1.3-6.

Over the 24 trials, the mean infection in the untreated objects was 15.2% (range of 6.7-50.0%). Opus Team achieved a mean control of 64% (range of 34-82%), which was comparable to that achieved by the reference product containing kresoxim-methyl + epoxiconazole + fenpropimorph (5 trials) and lower than that achieved by reference products containing prothioconazole (17 trials), epoxiconazole + metconazole (7 trials) and epoxiconazole + boscalid (5 trials).

Opus Team achieved useful control of leaf spot on the 1st leaf (mean of 75%, range of 11-100%) (12 trials) and moderate control on the 2nd leaf (mean of 57%, range of 29-84%) and 3rd leaf (mean of 51%, range of 32-100%).

| # trials | DAA | Assessment | Untreated % infection | Control of leaf spot (%) | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Opus Team 1.0 L/ha | Reference kresoxim-methyl epoxiconazole fenpropimorph | Reference prothioconazole | Reference epoxiconazole metconazole | Ref epo bo |
| 24 | 23-115 | total | 15.2 (6.7-50.0) | 64 (34-82) | | | | |
| 12 | | 1st leaf | 4.6 (0.3-17.5) | 75 (11-100) | | | | |
| 11 | | 2nd leaf | 11.4 (2.8-20.3) | 57 (29-84) | | | | |
| 12 | | 3rd leaf | 26.7 (0.8-57.5) | 51 (32-100) | | | | |
| 5 | 23-60 | total | 13.8 (9.0-16.1) | 67 (49-81) | 72 (61-87) | | | |
| 17 | 27-115 | total | 15.3 (6.7-50) | 64 (34-82) | | 73 (43-89) | | |
| 7 | 39-115 | total | 12.6 (6.7-26.9) | 57 (45-69) | | | 68 (52-81) | |
| 5 | 41-60 | total | 16.9 (9.2-26.9) | 57 (48-73) | | | | (6 |

Net blotch (*Pyrenophora teres*, PYRNTE)

The effectiveness of Opus Team against net blotch (*Pyrenophora teres*, PYRNTE) was tested in a total of 17 trials in winter barley (12 trials) and spring barley (5 trials). The trials

were conducted in the Maritime EPPO Zone (Germany, France and Denmark) in the period from 1997 to 2010.

*Winter barley*

In 12 trials conducted in Germany and France in the period from 1997 to 2010 Opus Team was applied at the proposed dose rate of 1.0 L/ha in 1-2 applications. An overview of results is presented in Table IIIA1 6.1.3-8a.

The mean infection in the untreated objects was 11.0% (range of 3.2-27.5%) at 26-49 DAA1. Opus Team achieved a mean control of 60% (range of 34-88%). Opus Team was less effective than reference products containing kresoxim-methyl + epoxiconazole (8 trials), epoxiconazole (2 trials), epoxiconazole + pyraclostrobin (2 trials) and spiroxamine + prothioconazol (1 trial).

**Table IIIA1 6.1.3-8a Effectiveness of Opus Team against PYRNTE in winter barley**

| # trials | DAA | Assessment | Untreated % infection | Control of net blotch (%) | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Opus Team 1.0 L/ha | Reference kresoxim-methyl epoxiconazole | Reference spiroxamine prothioconazol | Reference epoxiconazole | Referen epoxico zole pyraclo obin |
| 12 | 26-49 DAA1 | total | 11.0 (3.2-27.5) | 60 (34-88) | | | | |
| 8 | 26-49 DAA1 | total | 13.2 (6.8-27.5) | 65 (51-88) | 83 (76-95) | | | |
| 2 | 34 DAA1 | total | 5.1 (2.4-10.9) | 50 (44-61) | | | 65 (47-82) | 92 (87-96 |
| 1 | 39 | total | 3.5 | 34 | | 71 | | |
| 1 | 34 | 1st leaf | 3.1 | 48 | | | 55 | 94 |
| 2 | 34 | 2nd leaf | 6.7 (2.4-10.9) | 53 (44-61) | | | 65 (47-82) | 92 (87-96 |
| 1 | 34 | 3rd leaf | 3.9 | 46 | | | 74 | 91 |

*Spring barley*

In 5 trials conducted in Denmark from 2004 to 2007, Opus Team was not applied at the proposed dose rate of 1.0 L/ha, yet at a lower dose rate of 0.75 L/ha in 1 application. An overview of results is presented in Table IIIA1 6.1.3-8b.

The mean infection in the untreated objects was 14.3% (range of 5.6-25.0%) at 30-41 DAA. Opus Team at a dose rate of 0.75 L/ha achieved a mean control of 59% (range of 35-76%). Opus Team was less effective (not significant) than the reference product containing epoxiconazole + boscalid (1 trial) and comparably effective to the reference product containing epoxiconazole + fenpropimorph + metrafenone (1 trial).

**Table IIIA1 6.1.3-8b Effectiveness of Opus Team against PYRNTE in spring barley**

| # trials | DAA | Assessment | Untreated % infection | Control of net blotch (%) | | |
|---|---|---|---|---|---|---|
| | | | | Opus Team 0.75 L/ha | Reference epoxiconazole boscalid | Reference epoxiconazole fenpropimorph metrafenone |
| 5 | 30-41 | total | 14.3 (5.6-25.0) | 59 (35-76) | | |
| 1 | 41 | 1st leaf | 1.8 | 83 | 100 | |
| | | 2nd leaf | 9.3 | 69 | 93 | |
| 1 | 30 | total | 21.0 | 71 | | 72 |

**Extrapolation possibilities**

According to the extrapolation document “Possibilities for extrapolation of efficacy and crop safety of crop protection products” (CTB, May 2004), extrapolation of effectiveness data against foliar and ear diseases is possible from winter wheat to spring wheat, triticale and spelt.

According to the extrapolation document “Possibilities for extrapolation of efficacy and crop safety of crop protection products” (CTB, May 2004), extrapolation of effectiveness data against leaf blotch (*Rhynchosporium* secalis, RHYNSE), powdery mildew (*Erysiphe graminis*, ERYSGR), yellow rust (*Puccinia striiformis*, PUCCST) and brown rust (*Puccinia hordei*, PUCCHD) is possible from winter barley to spring barley and vice versa.

**Conclusion effectiveness**
The claim concerns the addition of a lower dose rate of 1.0 L/ha to the label of the product. The old dose rate will also remain on the label.

Over 9 trials in winter wheat, Opus Team at the proposed dose rate of 1.0 L/ha achieved sufficient control of brown rust (*Puccinia recondita*, PUCCRE) and was comparably to more effective than the reference product containing prothioconazole. Based on the presented data and extrapolation, Opus Team is concluded to be effective in the control of brown rust (*Puccinia recondita*, PUCCRE) in winter and spring wheat, triticale and spelt at a dose rate of 1.0 L/ha..

Over 2 trials in winter wheat, Opus Team at the proposed dose rate of 1.0 L/ha achieved high control of yellow rust (*Puccinia striiformis*, PUCCST) from 1$^{st}$ leaf to 3$^{rd}$ leaf, and was comparably effective to reference products containing prothioconazole and epoxiconazole + metconazole.
Though only 2 trials in winter wheat are available, it is known from experience in the field that Opus Team is particularly effective against rusts in cereals as is underlined by the results of the 2 available trials against yellow rust and results of the trials against brown rust (*Puccinia recondita*, PUCCRE) in winter wheat and brown rust (*Puccinia hordei*, PUCCHD) in barley. Based on the experience with Opus Team in practice and the effectiveness of the product observed against other rusts, Opus Team is expected to be sufficiently effective against yellow rust (*Puccinia striiformis*, PUCCST) in winter wheat and through extrapolation in spring wheat, triticale and spelt and spring and winter barley at a dose rate of 1.0 L/ha..

Over 3 trials in winter barley, Opus Team at the proposed dose rate of 1.0 L/ha achieved sufficient efficacy against brown rust (*Puccinia hordei,* PUCCHD) and was comparably effective to the reference product containing kresoxim-methyl + epoxiconazole. Also, over 3 trials in spring barley, Opus Team at the lower rate of 0.75 L/ha achieved sufficient efficacy against brown rust. Based on the presented data and extrapolation Opus Team is concluded to be effective against brown rust (*Puccinia hordei,* PUCCHD) in winter and spring barley at a dose rate of 1.0 L/ha..

Over 9 trials in winter barley, Opus Team at the proposed dose rate of 1.0 L/ha achieved good control levels of leaf blotch (*Rhynchosporium secalis*, RHYNSE). Opus Team was comparably to slightly less effective compared to the reference product containing kresoxim-methyl + epoxiconazole. Based on the presented data and extrapolation Opus Team is concluded to be effective against leaf blotch (*Rhynchosporium secalis*, RHYNSE) winter barley and through extrapolation in spring barley at a dose rate of 1.0 L/ha..

Over a total of 10 trials in winter wheat (9) and winter barley (1), Opus Team at the proposed dose rate of 1.0 L/ha achieved sufficient efficacy against powdery mildew (*Erysiphe graminis*, ERYSGR) and was comparably effective to reference products containing kresoxim-methyl + epoxiconazole + fenpropimorph and prothioconazole, and was less effective than the reference product containing fenpropimorph. Also, over 4 trials in spring barley, Opus Team at the lower rate of 0.75 L/ha achieved sufficient efficacy against powdery mildew.

Based on the presented data and extrapolation Opus Team is concluded to be effective against powdery mildew (*Erysiphe graminis*, ERYSGR) in spring and winter wheat, triticale, spelt and spring and winter barley at a dose rate of 1.0 L/ha..

Over 24 trials in winter wheat, Opus Team at the proposed dose rate of 1.0 L/ha only gave a reduction to moderate control of *Septoria tritici* (SEPTTR).
Opus Team was slightly less effective to the reference product containing kresoxim-methyl + epoxiconazole + fenpropimorph, and less effective compared to reference products containing prothioconazole, epoxiconazole + metconazole and epoxiconazole + boscalid. In general the product was less effective than reference products. From results in the dose justification section it is known that the dose rate of 1,5 L/ha provides a more consistent control of Septoria tritici, that compares better to the reference products. In the light of resistance management issues (please refer to paragraph 8.3) it is undesirable that an inefficient dose rate is applied when control of septoria tritici is intended. The dose rate of 1.5 L/ha will remain on the label, and this dose rate should be applied when control of Septoria tritici is intended.
Based on the presented data and extrapolation it is concluded that a dose rate of 1.0 L/ha is insufficiently effective against leaf spot (*Septoria tritici*, SEPTTR) and glume blotch (*Phaeosphaeria nodorum*, LEPTNO) in spring and winter wheat, triticale and spelt.

Over 12 trials in winter barley, Opus Team at the proposed dose rate of 1.0 L/ha achieved moderate to useful control of net blotch (*Pyrenophora teres,* PYRNTE) and was less effective than the reference products containing kresoxim-methyl + epoxiconazole, epoxiconazole and epoxiconazole + pyraclostrobin. Also, over 5 trials in spring barley, Opus Team at the lower rate of 0.75 L/ha achieved moderate to useful control of net blotch. . From results in the dose justification section it is known that the dose rate of 1,5 L/ha provides a more consistent control of *Pyrenophora teres*, that compares better to the reference products. In the light of resistance management issues (please refer to paragraph 8.3) it is undesirable that an inefficient dose rate is applied when control of *Pyrenophora tritici* is intended. The dose rate of 1.5 L/ha will remain on the label, and this dose rate should be applied when control of Septoria tritici is intended.
Based on the presented data and extrapolation it is concluded that a dose rate of 1.0 L/ha is insufficiently effective against net blotch (*Pyrenophora teres,* PYRNTE) in spring and winter barley.

The evaluation complies with the Uniform Principles, article 2.1.

At a dose rate of 1.0 L/ha, opus team controls:
-yellow rust (*Puccinia striiformis*, PUCCST) in winter wheat,spring wheat, triticale and spelt and spring and winter barley
-brown rust (*Puccinia recondita*, PUCCRE) in winter and spring wheat, triticale and spelt.
-brown rust (*Puccinia hordei,* PUCCHD) in winter and spring barley
- powdery mildew (*Erysiphe graminis*, ERYSGR) in spring and winter wheat, triticale, spelt and spring and winter barley.

*Septoria tritici*, *Septoria nodorum* and *Pyrenophora teres* are insufficiently controlled at a dose rate of 1.0 L/ha. Application has withdrawn these claims from the application.

### 8.1.4 Yield

In a total of 42 efficacy trials in winter wheat (26 trials), winter barley (11) and spring barley (5) assessments on quality were made after harvest. The trials were conducted in the Maritime EPPO Zone (Denmark, France, Germany, the Netherlands and the United Kingdom) in the period from 1997-2013.

An overview of results is presented in Table 8.1.4.1-1 for assessments on thousand grain weight and Table 8.1.4.1-2 for assessments on hectolitre weight.

*Winter wheat*

In 3 trials conducted in Denmark and France in 2003 and 2010 thousand grain weight was assessed. Opus Team was applied at the proposed dose rate of 1.0 L/ha and at the currently registered rate of 1.5 L/ha in 1 application.
The mean thousand grain weight in the untreated objects was 34.0 g (range of 31.2-38.1 g). Opus Team at a dose rate of 1.0 L/ha did not affect thousand grain weight with a mean of 102% (range of 99-106%) in relation to the untreated objects, as compared to a mean of 108% (range of 99-119%) for the dose rate of 1.5 L/ha.

In 25 trials conducted in Germany, the United Kingdom and France in the period from 1997 to 2010 hectolitre weight was assessed. Opus Team was applied at the proposed dose rate of 1.0 L/ha and at the currently registered rate of 1.5 L/ha in 1-2 applications.
The mean hectolitre weight in the untreated objects was 73.5 kg (range of 61.3-83.2 kg). Opus Team at a dose rates of 1.0 and 1.5 L/ha did not affect hectolitre weight with means of respectively 101% (range of 99-111%) and 101% (range of 99-113%) in relation to the untreated objects.

*Winter barley*
In 9 trials conducted in Germany and the United Kingdom in the period from 1997 to 2006 thousand grain weight was assessed. Opus Team was applied at the proposed dose rate of 1.0 L/ha and at the currently registered rate of 1.5 L/ha in 1-2 applications.
The mean thousand grain weight in the untreated objects was 41.3 g (range of 33.3-55.9 g). Opus Team at dose rates of 1.0 and 1.5 L/ha did not affect thousand grain weight with means of respectively 102% (range of 94-110%) and 102% (range of 98-110%) in relation to the untreated objects.

In 11 trials conducted in Germany, the United Kingdom and France in the period from 1997 to 2010, hectolitre weight was assessed. Opus Team was applied at the proposed dose rate of 1.0 L/ha and at the currently registered rate of 1.5 L/ha in 1-2 applications.
The mean hectolitre weight in the untreated objects was 67.2 kg (range of 63.3-70.8 kg). Opus Team at dose rates of 1.0 and 1.5 L/ha did not affect thousand grain weight with means of respectively 101% (range of 99-106%) and 101% (range of 100-106%) in relation to the untreated objects.

*Spring barley*
In 4 trials conducted in Denmark from 2005 to 2007 thousand grain weight was assessed. Opus Team was applied at dose rates of 0.75 and 1.5 L/ha in 1 application.
The mean thousand grain weight in the untreated objects was 41.1 g (range of 37.8-43.0 g). Opus Team at dose rates of 0.75 and 1.5 L/ha did not have negative effects on thousand grain weight with means of 105% (range of 103-108%) and 104% (range of 101-107%) in relation to the untreated objects.

In 5 trials conducted in Denmark from 2004 to 2007 hectolitre weight was assessed. Opus Team was applied at dose rates of 0.75 and 1.5 L/ha in 1 application.
The mean hectolitre weight in the untreated objects was 67.1 kg (range of 65.1-70.3 kg). Opus Team at dose rates of 0.75 and 1.5 L/ha did not affect thousand grain weight with means of respectively 101% (range of 100-102%) and 101% (range of 100-102%) in relation to the untreated objects.

**Table 8.1.4.1-1 Thousand grain weight for Opus Team**

| Crop | # trials | Thousand grain weight (g) Untreated | Thousand grain weight (% relative) | | |
|---|---|---|---|---|---|
| | | | Opus Team | | |
| | | | 0.75 L/ha | 1.0 L/ha | 1.5 L/ha |
| Winter wheat | 3 | 34.0 (31.2-38.1) | | 102 (99-106) | 108 (99-119) |
| Winter barley | 9 | 41.3 (33.3-55.9) | | 102 (94-110) | 102 (98-110) |

| | | | | | |
|---|---|---|---|---|---|
| Spring barley | 4 | 68.9 | 102 | | 101 |

**Table 8.1.4.1-2 Hectolitre weight for Opus Team**

| Crop | # trials | Hectolitre weight (kg) Untreated | Hectolitre weight weight (% relative) | | |
|---|---|---|---|---|---|
| | | | Opus Team | | |
| | | | 0.75 L/ha | 1.0 L/ha | 1.5 L/ha |
| Winter wheat | 25 | 73.5 (61.3-83.2) | | 101 (99-111) | 101 (99-113) |
| Winter barley | 11 | 67.2 (63.3-70.8) | | 101 (99-106) | 101 (100-106) |
| Spring barley | 5 | 67.1 (65.1-70.3) | 101 (100-102) | | 101 (100-102) |

**Conclusion quality**

In a total of 42 efficacy trials in winter wheat (26 trials), winter barley (11) and spring barley (5) assessments on quality were made after harvest. The trials were conducted in the Maritime EPPO Zone (Denmark, France, Germany, the Netherlands and the United Kingdom) in the period from 1997-2013.

With exception of the trials in spring barley Opus Team was applied at dose rates of 1.0 and 1.5 L/ha in 1-2 applications. In the trials in spring barley Opus Team was applied at dose rates of 0.75 and 1.5 L/ha in 1 application.

Overall treatment with Opus Team did not have negative effects on the thousand grain weight or hectolitre weight in winter wheat, winter barley or spring barley.

Based on the presented data and practical experience it is concluded that Opus Team when applied as proposed does not have negative effects on quality.

### 8.1.4.2 Effects on the processing procedure.

No new data is available. Opus Team has been used commercially in cereals for several years without complaints at a dose rate of 1.5L/ha, it is therefore considered highly unlikely that application of Opus Team at the lower rate of 1.0 L/ha will have an impact on the processing procedure.

### 8.1.4.3 Effects on the yield of treated plants and plant products

In a total of 46 efficacy trials in winter wheat (29 trials), winter barley (12) and spring barley (5) assessments on yield were made. The trials were conducted in the Maritime EPPO Zone (Denmark, France, Germany, the Netherlands and the United Kingdom) in the period from 1997-2013.

An overview of results is presented in Table 8.1.4.3.

*Winter wheat*

Yield was assessed in 29 trials conducted in Denmark, France and the Netherlands in the period from 2003 to 2013. Opus Team was applied at the proposed dose rate of 1.0 L/ha and at the currently registered rate of 1.5 L/ha in 1-2 applications.

The mean yield in the untreated objects was 9.0 ton/ha (range of 5.6-11.9 ton/ha). Opus Team at a dose rate of 1.0 L/ha achieved an increase in yield with a mean relative yield of 107% (range of 98-149%), which was comparable to that achieved at the dose rate of 1.5 L/ha (mean of 108%, range of 100-149%). Opus Team achieved comparable increases in yield to reference products containing fenpropimorph (3 trials), prothioconazole (20 trials) and epoxiconazole + metconazole (9 trials) and comparable to slightly lower increases in yield to reference products containing kresoxim-methyl + epoxiconazole + fenpropimorph (5 trials) and epoxiconazole + boscalid (7 trials).

*Winter barley*

Yield was assessed in 12 trials conducted in Germany, the United Kingdom and France in the period from 1997 to 2010. Opus Team was applied at the proposed dose rate of 1.0 L/ha and at the currently registered rate of 1.5 L/ha in 1-2 applications.
The mean yield in the untreated objects was 7.5 ton/ha (range of 5.7-9.7 ton/ha). Opus Team at a dose rate of 1.0 L/ha achieved an increase in yield with a mean relative yield of 109% (range of 100-127), which was comparable to that achieved at the dose rate of 1.5 L/ha (mean of 111%, range of 104-127%). Opus Team achieved comparable increases in yield to the reference product containing epoxiconazole (2 trials) and lower increases in yield compared to the reference product containing kresoxim-methyl + epoxiconazole (8 trials) and comparable to lower increases in yield compared to the reference product containing epoxiconazole + pyraclostrobin (2 trials).

*Spring barley*
Yield was assessed in 5 trials conducted in Denmark from 2004 to 2007. Opus Team was applied at dose rates of 0.75 and 1.5 L/ha.
The mean yield in the untreated objects was 5.8 ton/ha (range of 4.8-6.8 ton/ha). Opus Team at a dose rate of 0.75 L/ha achieved an increase in yield with a mean relative yield of 107% (range of 98-118%), which was comparable to that achieved at the dose rate of 1.5 L/ha (mean of 109%, range of 102-123%).

**Table 8.1.4.3 Yield data for Opus Team**

| Crop | # trials | Yield (to/ha) Untreated | Yield (% relative) Opus Team | | | Reference product* |
|---|---|---|---|---|---|---|
| | | | 0.75 L/ha | 1.0 L/ha | 1.5 L/ha | |
| Winter wheat | 29 | 9.0 (5.6-11.9) | | 107 (98-149) | 108 (100-149) | |
| | 5 | 7.8 (5.6-9.7) | | 110 (101-123) | 112 (102-127) | 114 [1)] (101-130) |
| | 3 | 8.5 (6.7-9.5) | | 105 (103-109) | 108 (106-112) | 105 [2)] (103-107) |
| | 20 | 9.3 (5.7-11.9) | | 108 (98-149) | 107 (100-149) | 109 [3)] (97-145) |
| | 7 | 9.0 (7.4-10.0) | | 104 (100-123) | 105 (100127) | 108 [4)] (101-127) |
| | 9 | 9.3 (7.8-11.6) | | 105 (101-114) | 105 (101-115) | 106 [5)] (102-114) |
| Winter barley | 12 | 7.5 (5.7-9.7) | | 109 (100-127) | 111 (104-127) | |
| | 8 | 7.4 (5.7-9.7) | | 110 (100-127) | 113 (104-127) | 119 [6)] (109-141) |
| | 2 | 7.3 (6.5-8.0) | | 108 (107-108) | 108 (105-111) | 108 [7)] (106-110) 112 [8)] (111-113) |
| Spring barley | 5 | 5.8 (4.8-6.8) | 107 (98-118) | | 109 (102-123) | |

*Reference products:
1) kresoxim-methyl + epoxiconazole + fenpropimorph
2) fenpropimorph
3) prothioconazole
4) epoxiconazole + boscalid
5) epoxiconazole + metconazole
6) kresoxim-methyl + epoxiconazole
7) epoxiconazole
8) epoxiconazole + pyraclostrobin

**Conclusion yield**

In a total of 46 efficacy trials in winter wheat (29 trials), winter barley (12) and spring barley (5) assessments on yield were made. The trials were conducted in the Maritime EPPO Zone (Denmark, France, Germany, the Netherlands and the United Kingdom) in the period from 1997-2013.

With exception of the trials in spring barley Opus Team was applied at dose rates of 1.0 and 1.5 L/ha in 1-2 applications. In the trials in spring barley Opus Team was applied at dose rates of 0.75 and 1.5 L/ha in 1 application.

Overall trials treatment with Opus Team resulted in an increase in yield in relation to the untreated objects, reflecting the effectiveness of Opus Team in the control of foliar and ear diseases in cereals.

### 8.2.1 Phytotoxicity

Assessments on crop safety were made in a total of 29 efficacy trials in winter wheat (17), winter barley (11) and spring barley (1). The trials were conducted in the Maritime EPPO Zone (Germany, the Netherlands, Denmark, France and the United Kingdom) in the period from 1997 to 2013.
Opus Team was applied at dose rates of 1.0 and 1.5 L/ha in 1-2 applications in the trials in winter wheat and winter barley and at dose rates of 0.75 and 1.5 L/ha in 1 application in the trial in spring barley.
No symptoms of phytotoxicity were observed in any of the trials.

Considering the fact that Opus Team has been used commercially in wheat, triticale, spelt, barley, rye and oats for several years without complaints at a dose rate of 1.5 L/ha, it is considered highly unlikely that a lower dose rate of 1.0 L/ha would cause damage to the crop.

### 8.2.2 Yield

Please refer to paragraph 8.1.4.

### 8.2.3 Effects on succeeding crops or substitution crops

Opus Team has been used commercially for several years without complaints at a dose rate of 1.5 L/ha, it is considered highly unlikely that a lower dose rate of 1.0 L/ha would lead to adverse effects on succeeding crops.

### 8.2.4 Effects on plants or plant products to be used for propagation

Opus Team has been used commercially for several years without complaints at a dose rate of 1.5 L/ha, it is considered highly unlikely that a lower dose rate of 1.0 L/ha would lead to adverse effects on parts of plants used for propagating purposes.

### 8.2.5 Effects on adjacent crops

Opus Team has been used commercially for several years without complaints at a dose rate of 1.5 L/ha, it is considered highly unlikely that a lower dose rate of 1.0 L/ha would lead to adverse effects on adjacent crops.

**Conclusion**
The evaluation complies with the Uniform Principles, article 2.2.

The product does not induce any unacceptable side effects on plants or plant products, when used and applied in accordance with the proposed label.

### 8.3 Resistance

Opus Team is a fungicide containing 250 g/L fenpropimorph and 84 g/L epoxiconazole.

Fenpropimorph belongs to the morpholine group of fungicides, classified under FRAC code 5. According to FRAC (2014) the morpholines in general are low to moderate risk compounds to resistance.
Epoxiconazole belongs to the demethylation inhibitors (DMI), classified under FRAC code 3. According to FRAC (2014) the DMI fungicides in general are medium –risk compounds to resistance.

The newly proposed uses include applications at lower dose rates compared to the authorised uses, the claim for control remains the same. A lower dose rate implies that there will be a higher risk of selection for (partially) resistant isolates. This is especially relevant for *Pyrenophora teres* and *Septoria tritici,*where contol at 1.0 L/ha is lower than control for reference products, and the currently authorised dose rate. From a resistance management point of view the higher dose rate of 1,5 L.ha should be used if control of *Pyrenophora teres* and *Septoria tritici* is intended.

The following resistance management sentence is included on the label:

| |
|---|
| Resistentiemanagement<br>Dit middel bevat de werkzame stoffen epoxiconazool en fenpropimorf. Epoxiconazool behoort tot de 'demethylation inhibitors' (DMI fungiciden), subgroep triazolen, de Frac code is 3. Fenpropimorf behoort tot de morfolineverbindingen, de FRAC code is 5. 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. |

**Conclusion**
The evaluation complies with the Uniform Principles, article 2.1.3. The level of control on the long term is not influenced by the use of this product because of the possible build up of resistance.

### 8.4 For vertebrate control agents: impact on target vertebrates
Because no vertebrates are controlled, this point is not relevant.

### 8.5 Any other relevant data / information / Data requirements

**Data requirements**
None.

**Restriction sentences**

| |
|---|
| Resistentiemanagement<br>Dit middel bevat de werkzame stoffen epoxiconazool en fenpropimorf. Epoxiconazool behoort tot de 'demethylation inhibitors' (DMI fungiciden), subgroep triazolen, de Frac code is 3. Fenpropimorf behoort tot de morfolineverbindingen, de FRAC code is 5. 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. |

## 9 Conclusion

The product does comply with the Uniform Principles.
The evaluation is in accordance with the Uniform Principles laid down in appendix VI of Directive 91/414/EEC. The evaluation has been carried out on basis of a dossier that meets the criteria of appendix III of the Directive.

## 10 Classification and labelling
No changes with regard to the CLP classification.

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The following warning and restriction sentences should be added to the existing label:

*Om in het water levende organismen te beschermen is toepassing met een dosis tot 1 l/ha in de teelt van winter- en zomertarwe, winter- en zomergerst, triticale, spelt, haver en vlas uitsluitend toegestaan wanneer in percelen die grenzen aan oppervlaktewater gebruik wordt gemaakt van minimaal 90% driftreducerende spuitdoppen.*

Resistentiemanagement
Dit middel bevat de werkzame stoffen epoxiconazool en fenpropimorf. Epoxiconazool behoort tot de ‘demethylation inhibitors’ (DMI fungiciden), subgroep triazolen, de Frac code is 3. Fenpropimorf behoort tot de morfolineverbindingen, de FRAC code is 5. 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.

## Appendix 1 Authorised uses

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Use-No.** | **Member state(s)** | **Crop and/ or situation** | **F G or I** | **Pests or Group of pests controlled** | **Application** | | | **Application rate per treatment** | | | **PHI** (days) | **Remarks:**<br>a) max. no. of applications per crop and season<br>b) Maximum product rate per season<br>c) additional remarks |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Number / (min. Interval between applications) | kg, L product / ha | g, kg as/ha | Water L/ha<br>min / max | | |
| **Existing (unchanged) uses** | | | | | | | | | | | | |
| 1 | NL | Beet | F | Cercospora beticola<br>Ramularia beticola<br>Uromyces beate<br>Erysiphe betae | Spray | June-Sept<br>BBCH 39-49 | 2 / 21 | 1.0 | 84 *<br>250 ** | 150-400 | 46 | Mitigation measures:<br>90% drift reducing nozzles |
| 2 | NL | Winter wheat | F | Puccinia recondita<br>Puccinia striiformis<br>Pyrenophora tritici-repentis<br>Mycosphaerella graminicola<br>Septoria nodorum<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.5 | 126 *<br>375 ** | 150-400 | 35 | Mitigation measures:<br>- 75% drift recucing nozzles icw air support<br>- 50% drif reducing nozzles icw Hardi Twin Force air support<br>- Low boom (30 cm above the crop) icw at least 50% drift reducing nozzles icw air support<br>- Släpduk |
| 4 | NL | Spring wheat | F | Puccinia recondita<br>Puccinia striiformis<br>Pyrenophora tritici-repentis<br>Mycosphaerella graminicola<br>Septoria nodorum<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.5 | 126 *<br>375 ** | 150-400 | 35 | Mitigation measures:<br>- 75% drift recucing nozzles icw air support<br>- 50% drif reducing nozzles icw Hardi Twin Force air support<br>- Low boom (30 cm above the crop) icw at least 50% drift reducing nozzles icw air support<br>- Släpduk |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 5 | NL | Winter barley | F | Puccinia striiformis<br>Puccinia hordei<br>Rhynchosproium secalis<br>Pyrenophora teres<br>Blumeria graminis<br>Ramularia collo-cygni | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.5 | 126 *<br>375 ** | 150-400 | 35 | Mitigation measures:<br>- 75% drift recucing nozzles icw air support<br>- 50% drif reducing nozzles icw Hardi Twin Force air support<br>- Low boom (30 cm above the crop) icw at least 50% drift reducing nozzles icw air support<br>- Släpduk |
| 6 | NL | Spring barley | F | Puccinia striiformis<br>Puccinia hordei<br>Rhynchosproium secalis<br>Pyrenophora teres<br>Blumeria graminis<br>Ramularia collo-cygni | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.5 | 126 *<br>375 ** | 150-400 | 35 | Mitigation measures:<br>- 75% drift recucing nozzles icw air support<br>- 50% drif reducing nozzles icw Hardi Twin Force air support<br>- Low boom (30 cm above the crop) icw at least 50% drift reducing nozzles icw air support<br>- Släpduk |
| 7 | NL | Triticale | F | Puccinia recondita<br>Puccinia striiformis<br>Pyrenophora tritici-repentis<br>Mycosphaerella graminicola<br>Septoria nodorum<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.5 | 126 *<br>375 ** | 150-400 | 35 | Mitigation measures:<br>- 75% drift recucing nozzles icw air support<br>- 50% drif reducing nozzles icw Hardi Twin Force air support<br>- Low boom (30 cm above the crop) icw at least 50% drift reducing nozzles icw air support<br>- Släpduk |
| 8 | NL | Spelt | F | Puccinia recondita<br>Puccinia striiformis<br>Pyrenophora tritici-repentis<br>Mycosphaerella graminicola<br>Septoria nodorum<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.5 | 126 *<br>375 ** | 150-400 | 35 | Mitigation measures:<br>- 75% drift recucing nozzles icw air support<br>- 50% drif reducing nozzles icw Hardi Twin Force air support<br>- Low boom (30 cm above the crop) icw at least 50% drift reducing nozzles icw air support<br>- Släpduk |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 9 | NL | Winter rye | F | Puccinia recondita<br>Puccinia striiformis<br>Pyrenophora tritici-repentis<br>Rhynchosporium secalis<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.5 | 126 *<br>375 ** | 150-400 | 35 | Mitigation measures:<br>- 75% drift recucing nozzles icw air support<br>- 50% drif reducing nozzles icw Hardi Twin Force air support<br>- Low boom (30 cm above the crop) icw at least 50% drift reducing nozzles icw air support<br>- Släpduk |
| 10 | | Spring rye | F | Puccinia recondita<br>Puccinia striiformis<br>Pyrenophora tritici-repentis<br>Rhynchosporium secalis<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.5 | 126 *<br>375 ** | 150-400 | 35 | Mitigation measures:<br>- 75% drift recucing nozzles icw air support<br>- 50% drif reducing nozzles icw Hardi Twin Force air support<br>- Low boom (30 cm above the crop) icw at least 50% drift reducing nozzles icw air support<br>- Släpduk |
| 11 | NL | oats | F | Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.5 | 126 *<br>375 ** | 150-400 | 35 | Mitigation measures:<br>- 75% drift recucing nozzles icw air support<br>- 50% drif reducing nozzles icw Hardi Twin Force air support<br>- Low boom (30 cm above the crop) icw at least 50% drift reducing nozzles icw air support<br>- Släpduk |
| **New uses** | | | | | | | | | | | | |
| 12 | NL | Winter wheat | F | Puccinia recondita<br>Puccinia striiformis<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.0 | 84 epox.<br>250 fenpr. | 150-400 | 35 | |
| 13 | NL | Spring wheat | F | Puccinia recondita<br>Puccinia striiformis<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.0 | 84 epox.<br>250 fenpr. | 150-400 | 35 | |
| 14 | NL | Winter barley | F | Puccinia striiformis | Spray | Marc h-June | 2 / 21 | 1.0 | 84 epox. | 150-400 | 35 | |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Puccinia hordei<br>Rhynchosproium secalis<br>Blumeria graminis | | BBCH 30-69 | | | 250 fenpr. | | | |
| 15 | NL | Spring barley | F | Puccinia striiformis<br>Puccinia hordei<br>Rhynchosproium secalis<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.0 | 84 epox.<br>250 fenpr. | 150-400 | 35 | |
| 16 | NL | Spelt | F | Puccinia recondita<br>Puccinia striiformis<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.0 | 84 epox.<br>250 fenpr. | 150-400 | 35 | |
| 17 | NL | Triticale | F | Puccinia recondita<br>Puccinia striiformis<br>Blumeria graminis | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.0 | 84 epox.<br>250 fenpr. | 150-400 | 35 | |
| | | | | | | | | | | | | |
| * = epoxiconazole<br>** = fenpropimorph<br><br>**Minor uses according to article 51** | | | | | | | | | | | | |
| 18 | NL | oats | F | Puccinia coronata | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.5 | 126 *<br>375 ** | 150-400 | 35 | Mitigation measures:<br>- 75% drift recucing nozzles icw air support<br>- 50% drif reducing nozzles icw Hardi Twin Force air support<br>- Low boom (30 cm above the crop) icw at least 50% drift reducing nozzles icw air support<br>- Släpduk |
| 19 | NL | oats | F | Puccinia coronata | Spray | Marc h-June<br>BBCH 30-69 | 2 / 21 | 1.0 | 84 *<br>250 ** | 150-400 | 35 | Mitigation measures:<br>90% drift reducing nozzles |
| 20 | NL | Flax | F | Oidium lini | Spray | May-June<br>BBCH 40-69 | 2 / 21 | 1.5 | 126 *<br>375 ** | 150-400 | | Mitigation measures:<br>- 75% drift recucing nozzles icw air support<br>- 50% drif reducing nozzles icw Hardi Twin Force air support<br>- Low boom (30 cm above the |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | crop) icw at least 50% drift reducing nozzles icw air support<br>- Släpduk |
| 21 | NL | Flax | F | Oidium lini | Spray | May-June<br>BBCH 40-69 | 2 / 21 | 1.0 | 84 *<br>250 ** | 150-400 | nr | Mitigation measures:<br>90% drift reducing nozzles |

* = epoxiconazole

** = fenpropimorph

## Appendix 2 Referencelist

| Annex point | | Year | Title<br>Source Company,<br>Report No.<br>GEP status, (un)published | Data protection claimed Y/N | Owner |
|---|---|---|---|---|---|
| IIIA 6.0 | | 2014 | Biological Assessment Dossier for Opus Team in cereals<br>BASF<br>-<br>-, unpublished | Y | BASF |
| Winter wheat | | | | | |
| IIIA 6.1 | | 2003 | BAS 549 F, BAS 565 F / FOLIAR DISEASES / WHEAT<br>BASF<br>DEV-F-2003-DK-DK1-035<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2003 | BAS 560 F /BLE/OIDIUM<br>BASF<br>DEV-F-2003-FR-FR7-760<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2003 | BAS 549 F (DA)/BLE/MALADIES FOLIAIRES<br>BASF<br>DEV-F-2003-FR-FR7-754<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2006 | INTRODUCTION BAS 549 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2006-NL-NL1-105<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2007 | INTRODUCTION BAS 549 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2007-NL-NL1-108<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2007 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2007-NL-NL1-109<br>GEP, unpublished | Y | BASF |

| Annex point | | Year | Title<br>Source Company,<br>Report No.<br>GEP status, (un)published | Data protection claimed Y/N | Owner |
|---|---|---|---|---|---|
| IIIA 6.1 | | 2007 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2007-NL-NL4-408<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2007 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2007-NL-NL4-409<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2007 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2007-NL-NL4-410<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2008 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2008-NL-NL4-411<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2009 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2009-NL-NL1-109<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2009 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2009-NL-NL1-110<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2009 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2009-NL-NL4-407<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2009 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2009-NL-NL4-408<br>GEP, unpublished | Y | BASF |

| Annex point | | Year | Title<br>Source Company,<br>Report No.<br>GEP status, (un)published | Data protection claimed Y/N | Owner |
|---|---|---|---|---|---|
| IIIA 6.1 | | 2009 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2009-NL-NL4-409<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2010 | AFPP/BLE/OIDIUM<br>BASF<br>DEV-F-2010-FR-803-738<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2010 | HOMOMOLOGATION BAS 702 F, BAS 712 F / BLE / OIDIUM<br>BASF<br>DEV-F-2010-FR-C03-E36<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2010 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2010-NL-810-110<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2010 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2010-NL-810-111<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2010 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2010-NL-810-112<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2010 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2010-NL-810-122<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2011 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2011-NL-810-113<br>GEP, unpublished | Y | BASF |

| Annex point | | Year | Title<br>Source Company,<br>Report No.<br>GEP status, (un)published | Data protection claimed Y/N | Owner |
|---|---|---|---|---|---|
| IIIA 6.1 | | 2011 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2011-NL-810-114<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2011 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2011-NL-810-408<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2011 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2011-NL-810-665<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2012 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2012-NL-810-111<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2012 | INTRODUCTION BAS 565 AT T1 IN THE NETHERLANDS<br>BASF<br>DEV-F-2012-NL-810-112<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2013 | MOGELIJKHEDEN BASF PRODUCTEN OP T1<br>BASF<br>DEV-F-2013-NL-810-112<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2013 | MOGELIJKHEDEN BASF PRODUCTEN OP T1<br>BASF<br>DEV-F-2013-NL-810-113<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2013 | MOGELIJKHEDEN BASF PRODUCTEN OP T1<br>BASF<br>DEV-F-2013-NL-810-409<br>GEP, unpublished | Y | BASF |
| Winter barley | | | | | |

| Annex point | | Year | Title<br>Source Company,<br>Report No.<br>GEP status, (un)published | Data protection claimed Y/N | Owner |
|---|---|---|---|---|---|
| IIIA 6.1 | | 1997 | BEKAEMPFUNG VON BLATTKRANKHEITEN AN GERSTE<br>BASF<br>DEV-F-1997-DE-D04-064<br>n.r., unpublished | Y | BASF |
| IIIA 6.1 | | 1997 | BEKAEMPFUNG VON BLATTKRANKHEITEN AN GERSTE<br>BASF<br>DEV-F-1997-DE-D05-123<br>n.r., unpublished | Y | BASF |
| IIIA 6.1 | | 1997 | BEKAEMPFUNG VON BLATTKRANKHEITEN AN GERSTE<br>BASF<br>DEV-F-1997-DE-D14-016<br>n.r., unpublished | Y | BASF |
| IIIA 6.1 | | 1998 | DEV-F-1998-ZX-023-A-01.0-DE-D05-133<br>BASF<br>DEV-F-1998-DE-D05-133<br>n.r., unpublished | Y | BASF |
| IIIA 6.1 | | 1998 | BEKAEMPFUNG VON BLATTKRANKHEITEN AN GERSTE<br>BASF<br>DEV-F-1998-DE-D07-028<br>n.r., unpublished | Y | BASF |
| IIIA 6.1 | | 1998 | PRODUKTVERGLEICH WINTERGERSTE<br>BASF<br>DEV-F-1998-DE-D08-123<br>n.r., unpublished | Y | BASF |
| IIIA 6.1 | | 1999 | BEKAEMPFUNG VON BLATTKRANKHEITEN AN GERSTE<br>BASF<br>DEV-F-1998-DE-D13-819<br>n.r., unpublished | Y | BASF |
| IIIA 6.1 | | 1998 | BEKAEMPFUNG VON BLATTKRANKHEITEN AN GERSTE<br>BASF<br>DEV-F-1998-DE-D14-015<br>n.r., unpublished | Y | BASF |

| Annex point | | Year | Title<br>Source Company,<br>Report No.<br>GEP status, (un)published | Data protection claimed Y/N | Owner |
|---|---|---|---|---|---|
| IIIA 6.1 | | 2001 | BEKAEMPFUNG VON BLATTKRANKHEITEN AN GERSTE<br>BASF<br>DEV-F-1998-DE-D15-020<br>n.r., unpublished | Y | BASF |
| IIIA 6.1 | | 2006 | NEW OPUS TEAM FORMULATIONS / RHYNSE, PYRNTE / BARLEY<br>BASF<br>DEV-F-2006-DE-D04-G03<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2006 | NEW OPUS TEAM FORMULATIONS / RHYNSE, PYRNTE / BARLEY<br>BASF<br>DEV-F-2006-UK-UK4-W06<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2009 | REHOMOLOGATION / ORGE / FOLIAIRES<br>BASF<br>DEV-F-2009-FRF-F25<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2010 | REHOMOLOGATION / ORGE / RHYNCHOSPORIOSE<br>BASF<br>DEV-F-2010-FR-C3E-754<br>GEP, unpublished | Y | BASF |
| Spring barley | | | | | |
| IIIA 6.1 | | 2004 | EFFICACY OF BAS 549 F AND BAS 562 F IN SPRINGBARLEY<br>BASF<br>DEV-F-2004-DK-852-DK1-118<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2005 | CONTROL OF LEAFDISEASES IN BARLEY WITH BAS 600 F AND 601 F<br>BASF<br>DEV-F-2005-DK-339-DK0-001<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2005 | CONTROL OF LEAFDISEASES IN BARLEY WITH BAS 600 F AND 601 F<br>BASF<br>DEV-F-2005-DK-339-DK0-002<br>GEP, unpublished | Y | BASF |

| Annex point | | Year | Title<br>Source Company,<br>Report No.<br>GEP status, (un)published | Data protection claimed Y/N | Owner |
|---|---|---|---|---|---|
| IIIA 6.1 | | 2005 | CONTROL OF LEAFDISEASES IN BARLEY WITH BAS 562 F AND 565 F<br>BASF<br>DEV-F-2005-DK-347-DK0-002<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2006 | REGISTRATION TRIAL BAS 562 F AND BAS 565 F SPRINGBARLEY<br>BASF<br>DEV-F-2006-DK-364-DK0-001<br>GEP, unpublished | Y | BASF |
| IIIA 6.1 | | 2007 | EFFICACY OF BAS 602 F AGAINST LEAFDISEASES HORVS<br>BASF<br>DEV-F-2007-DK-339-DK0-001<br>GEP, unpublished | Y | BASF |

Deze appendix geeft een indicatief overzicht van de gegevens die voor het eerst gebruikt zijn ten behoeve van een besluit; het kan echter voorkomen dat (onder andere) door een samenloop van aanvragen, de hier opgenomen gegevens al eens eerder gebruikt zijn. Aan dit overzicht kunnen dan ook geen rechten ontleend worden.This appendix serves only to give an indication of which data have been used for decision making for the first time; as a result of concurring applications for authorisations, the data mentioned here may have been used for an earlier decisions as well. Therefore, no rights can be derived from this overview.”