



HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. **BESLUIT**

Op 22 maart 2016 is van

W. Neudorff GmbH KG
An der Muhle 3
D-31860 EMMERTHAL
Germany

een zonale aanvraag tot verlenging van de toelating ontvangen als bedoeld in artikel 43 van Verordening (EG) 1107/2009 (verder te noemen: de Verordening) voor het gewasbeschermingsmiddel

Derrex

op basis van de werkzame stof ijzer(III)fosfaat. Nederland is in deze een betrokken lidstaat, als bedoeld in artikel 36, tweede lid; de beoordelend lidstaat is Denemarken.

HET COLLEGE BESLUIT tot toelating van bovenstaand middel.

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

1.1 Samenstelling, vorm en verpakking

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

1.2 Gebruik

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

1.3 Classificatie en etikettering

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

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

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Bij de verlenging is het WG/GA omgezet naar WG2.0. Daarom wordt het volgnummer van het etiket verhoogd van W0 naar W1 en dient respijt te worden vastgelegd voor het oude etiket. Omdat er geen beperking van het etiket plaatsvindt, kunnen de maximale respijttermijnen van 6 maanden voor afleveren en 12 maanden aansluitend voor opgebruik van verpakkingen met het oude etiket worden toegekend.

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 vastgesteld volgens het besluit beleidsregel respijttermijnen voor gewasbeschermingsmiddelen staan vermeld onder “toelatingsinformatie” in bijlage I.

2. WETTELIJKE GRONDSLAG

| | |
|-------------------------------|---|
| Besluit | artikel 43 Verordening (EG) Nr. 1107/2009 van het Europees Parlement en de Raad |
| Classificatie en etikettering | artikel 31 en artikel 65 van de Verordening (EG) 1107/2009 |
| Gebruikt toetsingskader | De beoordeling van deze aanvraag is conform Bgb en Rgb d.d. 16 december 2011 en Evaluation Manual Zonaal 2.0. |

3. BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

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

3.2 Analysemethoden

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

3.3 Risico voor de mens

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

3.4 Risico voor het milieu

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

3.5 Werkzaamheid

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

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

Bezwaarmogelijkheid

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

Ede, 2 juni 2017

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING**2.1 Aanvraaginformatie**

| | |
|------------------------------------|--|
| <i>Aanvraagnummer:</i> | 20160454 NLRG |
| <i>Type aanvraag:</i> | Zonale aanvraag tot verlenging van gewasbeschermingsmiddeltoelating met Nederland als betrokken lidstaat |
| <i>Middelnaam:</i> | Derrex |
| <i>Verzenddatum aanvraag:</i> | 21 maart 2016 |
| <i>Formele registratiedatum: *</i> | 14 april 2016 |
| <i>Datum in behandeling name:</i> | 30 januari 2017 |

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

2.2 Stofinformatie

| Werkzame stof | Gehalte |
|-------------------|-----------|
| ijzer(III)fosfaat | 29,7 G/KG |

- De stof ijzer(III)fosfaat is per 1 januari 2016 opnieuw goedgekeurd (renewal) volgens Verordening (EG) No 1107/2009 (Uitvoeringsverordening (EU) 2015/1166 d.d. 15 juli 2015). De goedkeuring van deze werkzame stof expireert op 31 december 2030.

2.3 Toelatingsinformatie

| | |
|---|-------------------------|
| <i>Toelatingsnummer:</i> | 13507 N |
| <i>Expiratiedatum:</i> | 31 december 2031 |
| <i>Afgeleide parallel of origineel:</i> | n.v.t. |
| <i>Biocide, gewasbeschermingsmiddel of toevoegingsstof:</i> | Gewasbeschermingsmiddel |
| <i>Gebruikers:</i> | Professioneel |

W-coderingen en aflever- en opgebruiktermijnen:

| | |
|---|-----------------|
| ▪ <i>W-codering professioneel gebruik:</i> | 1 |
| ▪ <i>Vorige w-codering professioneel gebruik:</i> | 0 |
| ▪ <i>Aflevertermijn professioneel gebruik:</i> | 1 december 2017 |
| ▪ <i>Opgebruiktermijn professioneel gebruik:</i> | 1 december 2018 |

2.4 Verpakkingsinformatie

| | |
|--------------------------------|-------------------------|
| <i>Aard van het preparaat:</i> | Lokmiddel in korrelvorm |
|--------------------------------|-------------------------|

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II Etikettering van het middel Derrex

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

Pictogram

Signaalwoord

Gevarenaanduidingen

Voorzorgsmaatregelen P280C Beschermende handschoenen en beschermende kleding dragen.

SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.

Aanvullende etiketelementen EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.

Kinderveilige sluiting verplicht Nee

Voelbare gevaarsaanduiding verplicht Nee

**REGISTRATION REPORT
Part A**

Risk Management

Product name: Derrex

Product code: NEU 1280 M

**Active Substance: 29.7 g pure active/kg ferric
phosphate (30 g technical/kg)**

**Central Zone
Zonal Rapporteur Member State: Denmark**

NATIONAL ASSESSMENT - NETHERLANDS

Applicant: W. Neudorff GmbH KG

Date: May 2017

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PART A – Risk Management

1 Details of the application

This application is made to fulfil the requirements of Article 43(2) of Regulation (EC) No 1107/2009 for the renewal of authorisation of the product Derrex following renewal of the approval of the active substance, ferric phosphate. The representative product for active substance renewal was NEU 1165 M which contains 9.9 g pure active/kg (10 g technical/kg) ferric phosphate, and is similar in formulation to Derrex.

Ferric phosphate is the only active substance in Derrex.

This part of the draft Registration Report (dRR) describes the acceptable use conditions required for the re-registration of the plant protection product, Derrex.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-8 and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national re-registration/registration by the EU review. It also includes assessment of data and information relating to NEU 1280 M where that data has not been considered in the EU review.

This document describes the specific conditions of use and labelling required for the Netherlands for the re-registration of Derrex.

Appendix 1 of this document is a copy of the product label.

Appendix 2 of this document contains information on letters of access to the protected data / third party data that was needed for evaluation of the formulation.

Appendix 3 provides a list of data in support of the evaluation

1.1 Application background

This application was submitted by W. Neudorff GmbH KG in March 2016.

The application is for approval of Derrex, a granular bait containing 29.7 g pure active/kg (30g technical/kg) ferric phosphate for use as a molluscicide (ground application bait) applied up to four times per year in the field and greenhouses. The product is for professional use only.

The products contains 29.7 g pure active/kg (30g technical/kg) ferric phosphateM for professional uses.

1.2 Annex I inclusion

Ferric phosphate was listed for renewal of approval in Commission Regulation (EU) No 1141/2010 (the second stage, 'AIR-2', of the renewal programme for active substances). The active substance approval was renewed by Commission Implementing Regulation (EU) No 2015/1166 and the renewal of approval entered into force on 1 January 2016.

No restrictions or requirements for confirmatory information were detailed in the specific provisions of the Implementing Regulation. There are no "Category 4" studies (as defined in the Guidance Document on Renewal of Authorisations – SANCO/2010/13170) missing at the time of this application.

The active substance is not a candidate for substitution.

Reference is made to the conclusions reached in the EU renewal of the active substance. The agreed endpoints are listed in the EFSA Conclusion on ferric phosphate published in January 2015 and these have been used throughout this dossier where necessary.

Ferric phosphate has been included in Annex IV of Parliament and Council Regulation 396/2005¹ as being exempt from the establishment of MRLs in food crops as listed in Commission Regulation (EC) No 839/2008².

1.3 Regulatory approach

To obtain re-authorisation the product Derrex must meet the conditions of approval under Regulation (EC) No. 1107/2009 and be supported by dossiers satisfying the data requirements of Regulation (EU) No. 283/2013 and Regulation (EU) No. 284/2013, with an assessment to Uniform Principles, using recently agreed end-points.

This application was submitted in order to allow the re-registration of an already approved product in accordance with the above

¹ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. Official Journal of the European Union L 70/1 – 16. 16 March 2005.

² Commission Regulation (EC) No 839/2008 of 31 July 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products. Official Journal of the European Union L 234/1 – 216. 30 August 2008.

1.4 Data protection claims

All data are owned by W Neudorff GmbH and regarded as being data protected.

1.5 Letters of Access

W. Neudorff GmbH KG is the confirmed owner of all the submitted data, no access is needed for protected studies and no third party data requiring a letter of access has been presented.

2 Details of the authorisation

2.1 Product identity

| | |
|---|--|
| Product Name | Derrex |
| Authorization Number (for re-registration) | 13507N |
| Function | Molluscicide |
| Applicant | W.Neudorff GmbH KG |
| Composition | 29.7 g pure active/kg (30 g technical/kg) ferric phosphate |
| Formulation type | Ready to use bait [Code : RB] (previously identified as a (Granular Bait) |
| Packaging | The packaging is polypropylene bags 2.5 kg to 1000 kg. The material thickness varies depending on size of bag. |

2.2 Classification and labelling

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

Proposal for the classification and labelling of the formulation

Based on the profile of the substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessment for the operator, as mentioned above, the following labeling of the preparation is proposed:

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

| | | | |
|---------------------------------------|--------|---|----------------|
| - | | | |
| Pictogram: | - | Signal word: | - |
| H-statements: | - | | |
| P-statements: | P280c | Wear protective gloves and protective clothing. | |
| Supplemental Hazard information: | EUH401 | To avoid risks to human health and the environment, comply with the instructions for use. | |
| | SP1 | Do not contaminate water with the product or its container. | |
| Child-resistant fastening obligatory? | | | Not applicable |
| Tactile warning of danger obligatory? | | | Not applicable |

Explanation:

Pictogram: -

H-statements: -

P-statements: P280c has to be assigned based on the operator exposure assessment.

Other: -

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

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

Not applicable.

2.2.3 Other phrases

Not applicable.

2.3 Product uses

PPP (product name/code) /NEU 1280 M
 active substance 1 Ferric phosphate
 safener -
 synergist -
 Applicant: W. Neudorff GmbH KG
 Zone(s): EU
 Verified by MS: N

GAP rev. , date: 2014-11-11
 Formulation type: RB (Ready to use bait) (previously identified as a
 GB (Granular Bait)
 Conc. of as 1: 29.7 g pure active/kg (30 g technical/kg)
 Conc. of safener: -
 Conc. of synergist: -
 professional use
 non professional use

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 12 | 13 | 14 |
|-------------|--------------------|--|-------------------|---|---|--|---|--|---|-------------------------|---------------|---|
| Use- No. | Member state(s) | Crop and/ or situation (crop destination / purpose of crop) | F G or I | Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) | Application | | | Application rate | | | PHI (days) | Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number (min. interval between applications) a) per use b) per crop/ season | kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season | g, as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min / max | | |
| 1 | NL | All edible and non- edible crops, amenity vegetation | F, G | Slugs | Strew Agriculture crops: Broadcast application Horticulture crops: Between plants | BBCH 0-99 Prefer application in early BBCH stages at beginning of infestation Jan-Dec | b) 4 (7days) | a) 7 b) 28 | a) 207.9 b) 831.6 | Not applicable | - | ready-to-use formulation |
| 2 | NL | Fodder plants | F, | Slugs | Strew: Broadcast application | BBCH 0-99 Prefer application in early BBCH stages at beginning of infestation March-November | b) 4 (7days) | a) 7 b) 28 | a) 207.9 b) 831.6 | Not applicable | - | ready-to-use formulation |

Applicant: W Neudorff GmbH KG

Evaluator:Ctgb, NL
Date: May 2017

3 Risk management

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

3.1.1 Physical and chemical properties

Overall Summary: The product Derrex is a ready to use granular bait formulation. All physical chemistry studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. The appearance of the product is that of a pale blue granule, with no odour. It is not explosive, has no oxidising properties, and is not flammable. It has a self-ignition temperature of 372°C. In 1% aqueous solution, it has a pH value of 3.50 and a free acidity of 3.02%. The pour density was 0.8 g/mL and a tap density of 0.85 g/mL. The product is nearly dust free, and has a nominal size range of $\geq 90\%$ that was retained on the 2000 μm and $\leq 10\%$ that was retained on the 3350 μm sieve. The product is flow able after test under pressure and the attrition resistance of granules was 99.92%. The stability data for 14 days at 54°C and 2 year at ambient temperature show a shelf life of 2 years at ambient temperature PE packaging. However, the packaging used for the formulation are 2.5 – 1000 kg PP bags. Nevertheless, this has been accepted as the formulation is a solid granule and the composition of the granule is not to be expected to negatively interact with the PP bags. Its technical characteristics are acceptable for a RB formulation.

Implications for labelling: None.

Compatibility of mixtures: Not applicable - the bait is not intended for use with other products.

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

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

3.1.2 Methods of analysis

Adequate methodology exists for the determination of iron in the plant protection product. Details are provided in Part B Section 2 of this dRR.

Relevant residues of ferric phosphate in food of plant and animal origin are not expected to occur. Therefore, residue analytical methods for the determination of the active substance in food of plant and animal origin for enforcement purposes are not required and are not presented.

3.1.2.1 Analytical method for the formulation

The determination of the iron and phosphorus content in the plant protection product is determined using a method incorporating inductively coupled plasma mass spectrometry (ICP-MS). The analytical method is fully validated according SANCO/3030/99 rev. 4, however with a different formulation (NEU 1186 M). Nevertheless, based on the composition of the two formulations it can be considered that they are identical and therefore it is found acceptable.

3.1.2.2 Analytical methods for residues

Relevant residues of ferric phosphate in food of plant and animal origin are not expected to occur. The setting of MRL is not necessary and a residue relevant to MRL is not defined. Therefore, residue analytical methods for the determination of the active substance in food of plant and animal origin for enforcement purposes are not required and were not presented in the Renewal Assessment Report prepared by RMS Germany and co-RMS Poland or in the Review Report for ferric phosphate.

As additional information and completeness, the accepted protocol for analysis of soil samples via Atomic Absorption was presented in the Renewal Assessment Report prepared by RMS Germany and co-RMS Poland or in the Review Report for ferric phosphate and is taken from the United States EPA Digestion Method 3050 "Acid digestion of sediments, sludges and soils" (see Reference). As this method is accepted and proven by the United States regulatory authority, further analysis as to specificity, repeatability, validation, limits of determination and recovery, were deemed unnecessary.

No analytical method for the determination ferric phosphate residues in water (drinking water, surface water and ground water) and air are provided, as ferric phosphate is not soluble in water and not volatile to air and is not applied as a spray or a dust. Therefore, analytical methods for residues in water and air are not considered necessary.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

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

Toxicity data are provided for NEU 1181 M containing 29.7 g pure active/kg (30 g technical/kg) ferric phosphate. Based on the similarity of the compositions, studies performed with NEU 1181 M are considered applicable to Derrex, containing 29.7 g pure active/kg (30 g technical/kg) ferric phosphate. NEU 1181 M has a low toxicity in respect to acute oral and dermal toxicity and is not irritating to the skin or eyes of treated rabbits. No investigation of inhalation toxicity was appropriate based on the physical properties of the non-inhalable granules. It was also found not to be a skin sensitiser to the guinea pig, based on a maximisation test conducted with the final product. On the basis of these findings, Derrex does not require classification in accordance with Regulation (EC) No 1272/2008.

3.1.3.2 Operator Exposure

Operator exposure to ferric phosphate following the use of Derrex was not evaluated as part of an EU review for the proposed critical use rate/crop. Therefore, all relevant data were reviewed and risk assessments provided where required.

Operator exposure was assessed against the AOEL value agreed in the EU Review (0.4 mg/kg bw/d; EFSA Journal 2015;13(1):3973). No relevant dermal absorption of ferric phosphate from Derrex is expected, however a value of 10% was proposed in the EU Review as a worst-case scenario. Exposure of professional operators was estimated according to PHED Surrogate Exposure Guide (75th percentile) included in the EFSA Opex model in the core dossier.

According to the model calculations, it can be concluded that the risk for the professional operator applying Derrex using vehicle-mounted or hand-held equipment is acceptable with the use of personal protective equipment (gloves and coverall).

3.1.3.3 Bystander Exposure

The risk assessment for operator exposure demonstrates that there is no risk for the operator when handling the product. Since Derrex is a solid, non-dusty, non-volatile granule and the active substance is non-volatile and practically insoluble in water and lipids, no relevant exposure by the dermal, oral or inhalation route is expected for bystanders.

Exposure of child residents was estimated in the core dossier, considering the potential risk of a small child ingesting applied granules. The ADI is not exceeded, therefore no unacceptable risk is anticipated. In addition to this, resident exposure for adults and children was assessed in the core dossier using the EFSA Opex model. Exposure was <0.01% for adults and 0.02% for children, indicating there is no unacceptable risk to residents.

3.1.3.4 Worker Exposure

The risk assessment for operator exposure revealed that there is no risk for the operator when handling the product and during application. The main route of exposure for re-entry into treated crops is via dislodgeable foliar residues. Since Derrex is a solid, non-dusty, non-volatile granule, that is not applied to foliage (the product is applied directly to the soil) no relevant exposure by the dermal, oral or inhalation route is expected for re-entry workers.

3.1.4 Residues and Consumer Exposure

Ferric phosphate needs to be broken down into iron and phosphate before being utilised by plants. As ferric phosphate is tightly bound and practically insoluble it is not readily available to plants and is only broken down slowly. It is, therefore, expected that only trace amounts of the iron and phosphate from ferric phosphate will be found in plants. Both iron and phosphorous occur naturally in the soil and are essential nutrients to plants. Plants which utilise these break down products will merely be performing a natural metabolic function which occurs whether Derrex is applied to the soil or not.

3.1.4.1 Residues

According to Commission Regulation (EC) No 149/2008 amending Reg. (EC) 396/2005, no MRLs are required (ferric phosphate is included in the Annex IV of the Reg. 396/2005). Iron and phosphate ions are considered ubiquitous in the environment and are also essential for animal and plant functions.

No supplementary supervised residue studies are submitted within this application nor considered necessary for ferric phosphate or for Derrex. During the peer review, no residue studies were evaluated and no data gaps or critical areas of concern were identified in the area of residues and consumer exposure (EFSA Journal 2015;13(1):3973). Hence, no harmful effects on human or animal health is expected from the proposed uses.

3.1.4.2 Consumer exposure

The potential exposure through diet of the ferric phosphate from plants protected by Derrex would be minimal. As ferric phosphate is approved by the Food Chem Codex as a nutritional supplement of foods, it could be expected that there would be some dietary exposure to it due to the intentional addition in to food. However, as ferric phosphate does not represent a concern for residues(Annex IV of the Reg. 396/2005), estimations of the potential and actual exposure through diet and other means are not necessary.

The allocation of an ARfD was not considered necessary by the Rapporteur Member State (Anonymous, 1999). NESTI calculations are therefore not required.

3.1.5 Environmental fate and behaviour

The Renewal Assessment Report prepared by RMS Germany and co-RMS Poland concluded that ferric phosphate presents a low risk to the environment. This conclusion was based on: the natural occurrence of ferric phosphate in soil; the insolubility and stability of ferric phosphate; the low rate of application; the use pattern of the end-use product NEU 1280 M, which does not include marine or any other aquatic uses; the lack of toxicity to animals; the use of ferric phosphate as a nutrient and dietary supplement in foods; ferric phosphate (or its components) may already be present in the food/nutrient sources of plants, wild birds and other animals; and the inherent function (as essential nutrients) of the components of ferric phosphate in the metabolic pathways of animals and plants. On the basis of the above, the Renewal Assessment Report concluded that no further data were required. However, The EFSA Conclusion (January 2015) expressed some potential concerns over the aquatic risk assessment, based on the possibility of ferric phosphate pellets directly entering water courses via spinning disc spreaders and via surface water runoff through a high rainfall event. This concern has been fully addressed in the Section B5 of the Core Assessment and is not considered to result in any further information being required for the aquatic exposure assessment of ferric phosphate.

3.1.5.1 Predicted Environmental Concentration in soil (PEC_{SOIL})

The GAP for NEU 1280 M is within the risk envelope use of NEU 1165 M. In addition, the supported use for NEU 1165 M is the same as that used for the active substance review for renewal of approval under EC Regulation 1107/2009, and consequently PECs are within those calculated in the Renewal Assessment Report.

3.1.5.2 Predicted Environmental Concentration in groundwater (PEC_{GW})

The predicted environmental concentration of the active substance ferric phosphate and any degradation components in groundwater was considered during the renewal of approval under EC Regulation 1107/2009. No further information was deemed necessary in the Renewal Assessment Report prepared by RMS Germany and co-RMS Poland or in the Review Report for ferric phosphate. The Renewal Assessment Report concluded that the use of ferric phosphate according to the intended use pattern is highly unlikely to trigger concerns regarding the risk for a potential groundwater contamination. The GAP proposed for NEU 1280 M lies within the risk envelope assessed in the Renewal Assessment Report.

Consequently, predicted environmental concentrations of the active substance ferric phosphate and any degradation components in groundwater have not been determined.

In the light of the above, no calculations have been performed for this Addendum as Dutch national requirements using FOCUSPELMO and the Kremsmünster scenario will not fundamentally alter this conclusion.

3.1.5.3 Predicted Environmental Concentration in surface water (PEC_{SW})

For the intended application as slug pellet (granular application), drift is not considered in the Dutch National Addendum. Consequently, Dutch specific surface water calculations are not needed.

3.1.5.4 Predicted Environmental Concentration in air (PEC_{AIR})

The predicted environmental concentration of the active substance ferric phosphate and any degradation components in air was evaluated during the renewal of approval under EC Regulation 1107/2009. No

further information was deemed necessary in the Renewal Assessment Report prepared by RMS Germany and co-RMS Poland or in the Review Report for ferric phosphate. No additional field testing is indicated. No additional testing has been conducted.

The Renewal Assessment Report concluded that the active substance ferric phosphate is a non-volatile salt and that no further data regarding the fate and behaviour of the active substance are required.

Monitoring data

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

There are no data available in the Pesticide Atlas regarding the presence of the substance Ferric phosphate in surface water.

The standards for surface water destined for the production of drinking water are met.

3.1.6 Ecotoxicology

The active substance ferric phosphate is an inorganic salt, which occurs naturally in terrestrial and aquatic ecosystems. Iron and phosphate are released from ferric phosphate by the activity of microorganisms and are then available for uptake by plants. Both ferric and phosphate ions are natural constituents of soils and serve as essential nutrients in plant and animal physiology. The amount of ferric phosphate added by the proposed applications of NEU 1280 M in accordance with Good Agricultural Practice may be expected to be small compared to the natural content in soil. No specific ecotoxicological concerns arise from the proposed use of NEU 1280 M molluscicide granules.

The mode of action of the active substance is specific to the target organisms. Following ingestion of the granular bait, ferric phosphate accumulates in the calcium spherules of the digestive gland of terrestrial slugs and snails, where it interferes with their calcium metabolism. This in turn disrupts feeding and mucus production and ultimately results in mortality.

According to the Renewal Assessment Report of April 2013 prepared on ferric phosphate by RMS Germany and co RMS Poland, a literature search was conducted on the active substance in accordance with EFSA (2011) guidance. No evidence of negative influence of ferric phosphate on the environment or adverse impact on non-target species was found. Accordingly, RMS Germany and co RMS Poland have proposed that ferric phosphate be considered a low-risk active substance.

3.1.6.1 Effects on Terrestrial Vertebrates

The EFSA conclusion indicated that use of the representative product NEU 1165 M posed a low acute and long-term risk for birds and mammals. Due to its similarity to NEU 1165 M, NEU 1280 M can be considered to pose an acceptable risk to birds and mammals. Acute oral toxicity studies in quail and rat were conducted with NEU 1181 M, a similar product to NEU 1280 M.

The risk assessment for birds and mammals exposed to NEU 1280 M is only relevant for the acute time scale. A long-term risk assessment for ferric phosphate is not considered relevant based on a) the natural occurrence of ferric phosphate in the soil, b) the known effect of ferric phosphate on living organisms, c) the lack of toxicity of the end-use product NEU 1280 M, d) the use of ferric phosphate as a nutrient and dietary supplement in foods, e) ferric phosphate may already be present in the food sources of the living organisms in the environment, f) the inherent function of ferric phosphate in the metabolic pathways of living organisms, both iron and phosphorous are essential nutrients for plants and animals, g) the practical

insolubility of ferric phosphate and fact that it adsorbs to the soil, and is thus rendered immobile and h) the use pattern of the product which will not lead to contamination of sources of water.

The EU Renewal Assessment Report and the peer review conclusion (EFSA 2015) of ferric phosphate conclude that the use of slug granules containing the active substance should be considered safe for birds and mammals. The GAP for NEU 1280 M in NL (total application rate 0.8316 kg a.s./ha) is covered by the GAP considered in the EFSA conclusion (total application rate of 2 kg a.s./ha). In accordance with the EFSA conclusion (2015), TER values were not calculated.

Ferric phosphate presents low toxicity to birds and mammals and it has negligible potential to accumulate in the tissues of earthworms or fish. Studies to investigate the effects of secondary poisoning in birds and mammals following the use of NEU 1181 M are therefore unnecessary and have not been performed.

3.1.6.2 Effects on Aquatic Species

NEU 1280 M will not pose a concern for aquatic toxicity. In the NL, exposure of surface water following the use of slug pellets is not relevant, as this application does not result in drift. Therefore, endpoints for the product were not considered needed. The risk to aquatic organisms from the proposed use of NEU 1180 M is acceptable.

3.1.6.3 Effects on Bees and Other Arthropod Species

EFSA concluded that ferric phosphate and the representative product NEU 1165 M posed a low risk to bees and non-target arthropods. NEU 1280 M is similar in formulation to NEU 1165 M. As the application rate of NEU 1181 M is lower than that considered in the EFSA conclusion, the risk assessment by EFSA (2015) covers the risk assessment for the current application. The risk to bees and other non-target arthropods is concluded to be acceptable.

Bees

NEU 1280 M is a solid, non-dusty, non-volatile granule and the active substance is practically insoluble in water and lipids and is not volatile. As a granular bait and with the same use pattern as NEU 1165M, there should be no significant exposure of honey bees.

A study was conducted with NEU 1181 M, a product similar to NEU 1280 M. HQ values were not calculated, which is in accordance with the EFSA conclusion (2015): a quantitative risk assessment is not required because of the negligible potential for exposure following the use of NEU 1280 M granules and the low intrinsic toxicity of ferric phosphate to bees.

No specific mitigating measures are considered necessary to protect bees under growing conditions in the Netherlands.

Other non-target arthropods

The endpoints establishing the toxicity of NEU 1280 M to non-target arthropods are presented in Section B6.

The results of these studies indicate low risk at the proposed rates and so no further semi-field studies, field studies or higher tier risk assessments are required.

Risks to non-target arthropods are adequately addressed by the core assessment for the Central Zone and no specific mitigating measures are considered necessary to protect non-target arthropods under growing conditions in the Netherlands.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

NEU 1280 M is formulated as a solid granule that does not release significant quantities of dust or vapour and it is not applied by spraying. The granules are scattered on the ground at a rate of 7 kg/ha (equivalent to 207.9 g a.s./ha) to control slugs and snails in edible and non-edible crops like ornamental garden plants, potatoes, fruits and vegetables. Up to four such applications may be made per year, representing a cumulative annual rate of 28 kg NEU 1280 M/ha, equivalent to 831.6 g a.s./ha.

The risk assessment was based on the calculation of TER values using EU agreed endpoints and PECsoil values for the intended application. All TER values exceeded the trigger values, indicating acceptable acute and long-term risk to earthworms and other soil macro-organisms.

3.1.6.5 Effects on organic matter breakdown

No specific studies to establish the effects of NEU 1280 M on organic matter breakdown are required as the quantities of iron and phosphate added to the soil through the use of NEU 1280 M are negligible compared to the amounts the soil already contains.

3.1.6.6 Effects on Soil Non-target Micro-organisms

As for point 3.1.6.5, no specific studies to establish the effects of NEU 1280 M on soil micro-organisms are required as the quantities of iron and phosphate added to the soil through the use of NEU 1280 M are negligible compared to the amounts the soil already contains. Soil non-target micro-organisms are in contact with both substances in higher concentrations in the environment, which does obviously not affect their populations.

The risk assessment was based on the calculation of TER values using EU agreed endpoints and PECsoil values for the intended application. All TER values exceeded the trigger values, indicating acceptable risk to soil non-target micro-organisms.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna)

NEU 1280 M does not pose a significant risk to plants or other non-target organisms. The product is applied as ready-for-use bait. Drift to non-target areas generally does not occur and a specific risk assessment for possible impact on non-target crops is not required. Furthermore, Ferric phosphate is included in the Food and Agriculture Organization of the United Nations list of permitted nutrient supplements in food as made in an amendment in March 2002³. In fact, both the iron and the phosphate ions occur in foods naturally because they are an inherent part of plant and animal metabolism, as discussed below.

Iron is a plant micronutrient and phosphorus is a macronutrient, both of which are essential to plant growth and development. Iron is required for chloroplast development and is a component of cytochromes. Phosphorus is required for formation of 'high-energy' phosphate compounds (ATP and ADP) and is a component of nucleic acids and of several essential coenzymes. In fact, plants experience

³ Food (Amendment) (No. 3) Regulations 2002, PU(A) 131/2002, 09 March 2002.

problems obtaining adequate phosphorous due to low total amount in soil and very low availability to plants, please refer to Section 5, Point 9 for additional information.

In plants and animals, iron is important for a) oxygen transport; b) electron transfer; c) DNA synthesis; d) many other cellular functions. Phosphate is a component of ATP and ADP (which are the primary energy sources of cells) nucleic acids and several essential co-enzymes. Both the ferric and phosphate ions of Ferric phosphate are, therefore, essential in plant and animal metabolism and are extremely common and abundant in soil and nature in general.

NEU 1280 M has no known herbicidal activity and is unlikely to cause phytotoxicity in terrestrial plants for the reasons given above. Further data were not considered to be required in the EFSA conclusion (2015). The risk to non-target terrestrial plants is considered to be acceptable.

3.1.7 Efficacy

It concerns an application for a renewal. A renewal is a re-registration of an unchanged product: the formulation of the product remains the same and the uses on the GAP and label are unchanged (or less claims are made compared to the authorised label).

If no resistance has developed, it can be expected that the efficacy of the product is unchanged. The evaluation for renewal focuses on the resistance section. For evaluation of efficacy reference can be made to evaluation and experience with the product in the past. Therefore efficacy does not need to be evaluated again.

Only the chapter 'Possible development of resistance or cross-resistance' has to be evaluated.

Possible development of resistance or cross-resistance

Iron phosphate is toxic to slugs and snails by damaging their digestive tissue. With enough exposure, they stop eating altogether and slowly die. The exact mode of action is not clearly understood. Because it is a molluscicide, the resistance classification of Ferric phosphate (iron (III) phosphate) is not covered by registration of HRAC, WSSA, IRAC, FRAC. Current knowledge suggests little risk of resistance development. Based on the most recent efficacy trials submitted the product provides good control against slugs.

3.1.8 Assessment of the relevance of metabolites in groundwater

In accordance with the guidance document on the assessment of the relevance of metabolites in groundwater of substance regulated under Council Directive 91/414/EEC (EC 2003⁴) an assessment of the relevance of metabolites in groundwater is triggered if the predicted environmental concentration of any metabolites in groundwater exceeds the limit of 0.1 µg/L. For the active substance ferric phosphate, as no metabolites are identified for potential concentrations in groundwater no relevance assessment is considered necessary.

3.2 Conclusions

An authorisation can be granted.

3.3.1 Substances of concern for national monitoring

None.

⁴ EC 2003. Guidance document on the assessment of the relevance of metabolites in groundwater of substance regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev.10-final, 25 February 2003.

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

Further information is not required.

Appendix 1 – Copy of the product label

Wettelijk Gebruiksvoorschrift

Het middel is uitsluitend toegelaten als slakkenbestrijdingsmiddel voor het professionele gebruik door middel van strooien in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.1 Ctgb juni 2015) onder de hierna vermelde toepassingsvoorwaarden.

Toepassingsvoorwaarden:

| Toepassingsgebied | Werkzaamheid getoetst op | Dosering* middel per toepassing | Maximaal aantal toepassingen per 12 maanden | Minimum interval tussen toepassingen in dagen |
|---------------------------------|--------------------------|---------------------------------|---|---|
| Akkerbouwgewassen | slakken ¹ | 7 kg/ha | 4 | 7 |
| Fruïtgewassen | slakken ¹ | 7 kg/ha | 4 | 7 |
| Groenteteelt | slakken ¹ | 7 kg/ha | 4 | 7 |
| Kruidenteelt (vers of gedroogd) | slakken ¹ | 7 kg/ha | 4 | 7 |
| Sierteeltgewassen | slakken ¹ | 7 kg/ha | 4 | 7 |

* Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken. Werkzaamheid is vastgesteld voor de genoemde dosering per toepassing en niet voor verlaagde doseringen.

¹ naaktslakken

Overige toepassingsvoorwaarden

Er zijn geen aanvullende toepassingsvoorwaarden.

Appendix 2 – Letter of Access

W. Neudorff GmbH KG is the confirmed owner of all the submitted data, no access is needed for protected studies and no third party data requiring a letter of access has been presented.

Appendix 3: Reference lists

| Annex point | Author | Year | Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished | Data protection claimed Y/N | Data protection granted Y/N | Studies relied on Y/N | Owner |
|--|---------------|-------------|---|------------------------------------|------------------------------------|------------------------------|--------------|
| KIIIA 2.1/01 KIIIA 2.4.1/01 KIIIA 2.4.2/01 KIIIA 2.7.5/01 KIIIA 2.8.5.1/01 KIIIA 2.8.6.2/01 KIIIA 2.8.6.3/01 KIIIA 2.8.6.5/01 | Burkhard, A. | 2012 | Physico-chemical properties of the test item NEU 1280 M over 2 years at 20 °C Eurofins Agrosience Services, EcoChem GmbH, Eutinger Str.24 D-75223 Niefern-Oschelbronn,Germany W. Neudorff GmbH KG, Emmerthal, Germany Report-no. S09-03456 GLP: yes Published: no | yes | Y | Y | NEU |
| KIIIA 2.3.2/01 KIIIA 2.3.3/01 | Smeykal, H. | 2010 | NEU 1280 M - Flammability (Solids) A.10. Autoflammability A.16. Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany W. Neudorff GmbH KG, Emmerthal, Germany Report-no. 20091081.01 GLP/GEP: no Published: no | yes | Y | Y | NEU |
| KIIIA 2.6.2/01 | Burkhard, A. | 2010 b | Pour and Tap Density of NEU 1280 M eurofins-GAB GmbH, Niefern-Öschelbronn, Germany W. Neudorff GmbH KG, Emmerthal, Germany Report-no. S09-03453 GLP: yes Published: no | yes | Y | Y | NEU |

| Annex point | Author | Year | Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished | Data protection claimed Y/N | Data protection granted Y/N | Studies relied on Y/N | Owner |
|----------------------------------|-----------------|-------------|---|--|--|--------------------------------------|--------------|
| KIIIA 2.7.1/01 KIIIA 2.7.3/01 | Burkhard, A. | 2010a | Physico-chemical properties of the formulation NEU 1280 M after accelerated storage at 54 °C for 2 weeks eurofins-GAB GmbH, Niefern-Öschelbronn, Germany W. Neudorff GmbH KG, Emmerthal, Germany Report-no. S09-03455 GLP: yes Published: no | yes | Y | Y | NEU |
| KIIIA 2.8.8.1/01 | Bar, C. | 2010 | Flowability of the formulation NEU 1280 M eurofins-GAB GmbH, Niefern-Öschelbronn, Germany W. Neudorff GmbH KG, Emmerthal, Germany Report-no. S10-01181 GLP: yes Published: no | yes | Y | Y | NEU |

| Annex point | Author | Year | Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished | Data protection claimed Y/N | Data protection granted Y/N | Studies relied on Y/N | Owner |
|--------------------|---------------|-------------|---|------------------------------------|------------------------------------|------------------------------|--------------|
| KIIIA1 5.2.1/01 | Burkhard, A. | 2012 | Development and Validation of an Analytical Method for Determination of Iron and Phosphorus in NEU 1186 M Eurofins Agrosience Services, Niefern-Öschelbronn, Germany W. Neudorff GmbH KG, Emmerthal, Germany Report-no. S12-00343 GLP: yes Published: no | Y | Y | Y | NEU |
| IIIA 5.3.1/01 | US EPA | 1986 | Metals in soils (EPA digestion method 3050), US EPA, Washington D.C., USA, GLP: no Published:Yes | N | N | Y | US EPA |

Mammalian toxicology

| Annex point | Author | Year | Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished | Data protection claimed Y/N | Owner | Data protection granted Y/N | Studies relied on Y/N |
|-----------------|--------|-------|---|-----------------------------|-------|-----------------------------|-----------------------|
| KIIIA1 7.1.1/01 | | 2007a | Acute Oral Toxicity Study of NEU 1181 M in Rats Report No: 21395 GLP-Yes Not published | Y | NEU | Y | Y |
| KIIIA1 7.1.2/01 | | 2007b | Acute Dermal Toxicity Study of NEU 1181 M in CD Rats Report No: 21396 GLP-Yes Not published | Y | NEU | Y | Y |
| KIIIA1 7.1.4/01 | | 2007a | Acute Dermal Irritation/Corrosion Test(Patch Test) of NEU 1181 M in Rabbits Report No: 21397 GLP-Yes Not published | Y | NEU | Y | Y |
| KIIIA1 7.1.5/01 | | 2007b | Acute Eye Irritation/Corrosion Test of NEU 1181 M in Rabbits Report No: 21398 GLP-Yes Not published | Y | NEU | Y | Y |

| Annex point | Author | Year | Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished | Data protection claimed Y/N | Owner | Data protection granted Y/N | Studies relied on Y/N |
|-----------------|--------|------|--|-----------------------------|-------|-----------------------------|-----------------------|
| KIIIA1 7.1.6/01 | | 2009 | Examination of NEU 1181 M in the Skin Sensitisation Test in Guinea Pigs According to Magnusson and Kligman (Maximisation Test) Report No: 24957 GLP-Yes Not published | Y | NEU | Y | Y |

Ecotoxicology

| OECD Annex point/ reference number | Year | Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not | Data protection claimed yes/no | Owner | Data protection granted Y/N | Studies relied on Y/N |
|---------------------------------------|------|---|--------------------------------|-------|-----------------------------|-----------------------|
| KIIIA1 10.1.6/01 | 2007 | Avian acute oral toxicity study of NEU 1181 M, Bobwhite quail Report-no. 21399. GLP: Yes. Published: No. | Y | NEU | Y | Y |