REGISTRATION REPORT

Part A

Risk Management

Product code: NEU 1143 F

Product name: NEU 1143 F

Chemical active substance:

pelargonic [nonanoic] acid, 67.56 g/L
(in the form of 81.6 g/L iron(III) pelargonate [nonanoate])

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: NEUDORFF GmbH KG

Date: 2020/03/05

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PART A

RISK MANAGEMENT

1 Details of the application

The company NEUDORFF GmbH KG has requested a marketing authorisation in France for the product NEU 1143 F (product code: NEU 1143 F), containing 67.56 g/L pelargonic acid[1] (in the form of 81.6 g/L iron(III) pelargonate), as a fungicide for non-professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of NEUDORFF GmbH KG's application submitted on 03/05/2016 to market NEU 1143 F (product code: NEU 1143 F) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2016-1222) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009, the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of NEU 1143 F (product code: NEU 1143 F) have been made using endpoints agreed in the EU peer review of pelargonic acid. It also includes assessment of data and information related to NEU 1143 F (product code: NEU 1143 F) where those data have not been considered in the EU peer review process.

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

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[3], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of NEU 1143 F (product code: NEU 1143 F).

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1 Pelargonic acid in the iron(III) pelargonate form is not approved under the Regulation (EU) No 540/2011.

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

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

1.2 Letters of Access

Not necessary: the applicant is the owner of data which support the approval of the active substance(s).

1.3 Justification for submission of tests and studies

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of NEU 1143 F (product code: NEU 1143 F), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	NEU 1143 F
Product name in MS	NEU 1143 F
Authorisation number	N/A : no marketing authorisation granted
Kind of use	Non-professional use
Low risk product (article 47)	No.
Function	Fungicide
Applicant	NEUDORFF GmbH KG
Active substance(s) (incl. content)	Pelargonic acid, 67.56 g/L (in the form of 81.6 g/L iron(III) pelargonate)
Formulation type	Suspension concenrate (SC)
Packaging	~~HDPE or PET bottles or containers (0.05 L, 0.1 L, 0.2 L, 0.25 L, 0.5 L, 0.75 L, 1 L, 1.5 L, 2 L, 2.5 L, 3 L, 4 L and 5 L).~~ All requested packaging are not acceptable by the zRMS Fr for non-professionnal users
Coformulants of concern for national authorisations	None.
Restrictions related to identity	None.
Mandatory tank mixtures	None.
Recommended tank mixtures	None.

2.2 Conclusion

The evaluation of the application for NEU 1143 F (product code: NEU 1143 F) resulted in the decision **to refuse the authorisation**.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	-
Hazard pictograms:	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
Additional labelling phrases:	-

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

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

N/A : no marketing autorisation granted:

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017[4] provides that:

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

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

Finally, the French Order of 26 March 2014[5] provides that:

[4] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

[5] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] is to supply “minor” crops with registered plant protection products.

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

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

According to French order of 30 december 2010 the packaging should minimize operator exposure when non-professional uses are intended. Considering that proposed packaging do not allow to minimize operator exposure, the product cannot be registered in France.

2.5.1 Restrictions linked to the PPP

N/A : no marketing autorisation granted :

2.5.2 Specific restrictions linked to the intended uses

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

None.

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

2.6 Intended uses (only NATIONAL GAP)

Please note:
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2020-03-05

PPP (product name/code):	NEU 1143 F / NEU 1143 F	Formulation type:	Suspension concentrate (SC) [a, b]
Active substance 1:	pelargonic [nonanoic] acid (in the form of 81.6 g/L iron(III) pelargonate)	Conc. of a.s. 1:	67.56 g/L [c]
Applicant:	NEUDORFF GmbH KG	Professional use:	☐
Zone(s):	Southern Zone [d]	Non-professional use:	☒
Verified by MS:	Yes		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group) "**Catalogue des usages**"	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] RMS conclusions
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Roses	Fn	Powdery mildew, *Sphaerotheca pannosa*	Spraying with knapsack sprayer	At beginning of infection, at first symptoms	a) 10 b) 10	7-10	~~a) 33 mL/L~~ **a) 4 mL/m² (25 mL/L)** **b) 40 mL/m²**	a) 0.326 g a.i./m² b) 3.26 g a.i./m²	120-200 mL/m²	Not necessary	**Not Acceptable** (packaging not acceptable for non-professional uses in France)
2	FR	Roses	Fn	Rust, *Phragmidium mucronatum*	Spraying with knapsack sprayer	At beginning of infection, at first symptoms	a) 10 b) 10	7-10	~~a) 33 mL/L~~ **a) 4 mL/m² (25 mL/L)** **b) 40 mL/m²**	a) 0.326 g a.i./m² b) 3.26 g a.i./m²	120-200 mL/m²	Not necessary	**Not Acceptable** (packaging not acceptable for non-professional uses in France)

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Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group) "**Catalogue des usages**"	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f) RMS conclusions
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
3	FR	Roses	Fn	Black spot, *Diplocarpon rosae*	Spraying with knapsack sprayer	At beginning of infection, at first symptoms	a) 10 b) 10	7-10	~~a) 33 mL/L~~ **a) 4 mL/m² (25 mL/L)** **b) 40 mL/m²**	a) 0.326 g a.i./m² b) 3.26 g a.i./m²	120-200 mL/m²	Not necessary	**Not Acceptable** (packaging not acceptable for non-professional uses in France)
4	FR	Woody ornamentals	Fn	Rust fungi	Spraying with knapsack sprayer	At beginning of infection, at first symptoms	a) 10 b) 10	7-10	a) 4 mL/m² (27 mL/L) b) 40 mL/m²	a) 0.326 g a.i./m² b) 3.26 g a.i./m²	150-200 mL/m²	Not necessary	**Not Acceptable** (packaging not acceptable for non-professional uses in France)
5	FR	Ornamentals	Fn	Rust fungi	Spraying with knapsack sprayer	At beginning of infection, at first symptoms	a) 10 b) 10	7-10	a) 4 mL/m² (27 mL/L) b) 40 mL/m²	a) 0.326 g a.i./m² b) 3.26 g a.i./m²	150-200 mL/m²	Not necessary	**Not Acceptable** (packaging not acceptable for non-professional uses in France)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group) "**Catalogue des usages**"	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f) RMS conclusions
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
6	FR	Woody-ornamentals	Fn	Leaf spot diseases	Spraying with knapsack sprayer	At beginning of infection, at first symptoms	a) 10 b) 10	7-10	a) 4 mL/m^2 (27 mL/L) b) 40 mL/m^2	a) 0.326 g a.i./m^2 b) 3.26 g a.i./m^2	150-200 mL/m^2	Not necessary	**Not Acceptable** (packaging not acceptable for non-professional uses in France)
7	FR	Ornamentals	Fn	Leaf spot diseases	Spraying with knapsack sprayer	At beginning of infection, at first symptoms	a) 10 b) 10	7-10	a) 4 mL/m^2 (27 mL/L) b) 40 mL/m^2	a) 0.326 g a.i./m^2 b) 3.26 g a.i./m^2	150-200 mL/m^2	Not necessary	**Not Acceptable** (packaging not acceptable for non-professional uses in France)
8	FR	Woody-ornamentals	Fn	Leaf spot diseases, *Cylindrocladium buxicola*	Spraying with knapsack sprayer	At danger of infection	a) 10 b) 10	7-10	a) 4 mL/m^2 (27 mL/L) b) 40 mL/m^2	a) 0.326 g a.i./m^2 b) 3.26 g a.i./m^2	150-200 mL/m^2	Not necessary	**Not Acceptable** (packaging not acceptable for non-professional uses in France)
9	FR	Ornamentals	Fn	Leaf spot disease, *Stagonosporopsis ajacis*	Spraying with knapsack sprayer	At danger of infection	a) 10 b) 10	7-10	a) 4 mL/m^2 (27 mL/L) b) 40 mL/m^2	a) 0.326 g a.i./m^2 b) 3.26 g a.i./m^2	150-200 mL/m^2	Not necessary	**Not Acceptable** (packaging not acceptable for non-professional uses in France)
10	FR	Woody-ornamentals	Fn	Powdery mildew	Spraying with knapsack sprayer	At danger of infection	a) 1 b) 10	7-10	a) 4 mL/m^2 (27 mL/L) b) 40 mL/m^2	a) 0.326 g a.i./m^2 b) 3.26 g a.i./m^2	150-200 mL/m^2	Not necessary	**Not Acceptable** (packaging not acceptable for non-professional uses in France)
11	FR	Ornamentals	Fn	Powdery mildew	Spraying with knapsack sprayer	At beginning of infection, at first symptoms	a) 10 b) 10	7-10	a) 4 mL/m^2 (27 mL/L) b) 40 mL/m^2	a) 0.326 g a.i./m^2 b) 3.26 g a.i./m^2	150-200 mL/m^2	Not necessary	**Not Acceptable** (packaging not acceptable for non-professional uses in France)
12	FR	Stone fruits (peaches, nectarines and apricots)	Fn	Peach leaf curl, *Taphrina deformans*	Spraying with knapsack sprayer	BBCH 01 (Beginning of bud swelling) to BBCH 54 (Inflorescence enclosed by light green scales)	a) 4 b) 4	7-35	a) 4 mL/m^2 (40 mL/L) b) 16 mL/m^2	a) 0.326 g a.i./m^2 b) 3.26 g a.i./m^2	100 mL/m^2	Not necessary	**Not Acceptable** (packaging not acceptable for non-professional uses in France)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group) "**Catalogue des usages**"	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] RMS conclusions
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
13	FR	Tomato	Fn	Late blight, *Phytophthora infestans*	Spraying with knapsack sprayer	At danger of infection	a) 10 b) 10	7-10	~~a) 33 mL/L~~ **a) 4 mL/m^2 (25 mL/L)** **b) 40 mL/m^2**	a) 0.326 g a.i./m^2 b) 3.26 g a.i./m^2	120-200 mL/m^2	Not necessary	**Not Acceptable** (packaging not acceptable for non-professional uses in France)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group) "**Catalogue des usages**"	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f) RMS conclusions
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
14	FR	Cucumber (include cucumber, zucchini, pickles and other cucurbits with edible peel)	Fn	Powdery mildew, *Sphaerotheca fuliginea*	Spraying with knapsack sprayer	At beginning of infection, at first symptoms	a) 10 b) 10	7-10	~~a) 33 mL/L~~ **a) 4 mL/m^2 (25 mL/L)** **b) 40 mL/m^2**	a) 0.326 g a.i./m^2 b) 3.26 g a.i./m^2	120-200 mL/m^2	0	**Not Acceptable** (packaging not acceptable for non-professional uses in France)
15	FR	Melon (include melon, watermelon, pumpkin and other cucurbits with inedible peel)	Fn	Powdery mildew, *Sphaerotheca fuliginea*	Spraying with knapsack sprayer	At beginning of infection, at first symptoms	a) 10 b) 10	7-10	a) 2 mL/m^2 20 mL/L b) 20 mL/m^2	a) 0.326 g a.i./m^2 b) 3.26 g a.i./m^2	100 mL/m^2	0	**Not Acceptable** (packaging not acceptable for non-professional uses in France)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

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Remarks columns:	1	Numeration necessary to allow references
	2	Use official codes/nomenclatures of EU Member States
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	8	The maximum number of application possible under practical conditions of use must be provided.
	9	Minimum interval (in days) between applications of the same product
	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
	13	PHI - minimum pre-harvest interval
	14	Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

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

NEU 1143 F is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a pink viscous liquid, with a rancid odour. It is not explosive and has no oxidising properties. The product has a flash point of 166.5 °C. It has a self-ignition temperature of 465 °C. In aqueous solution (1 % dilution), it has a pH value of 4.9 at 23.9 °C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf-life of at least two years at ambient temperature when stored in HDPE bottles. The technical characteristics are acceptable for an SC formulation. No information about the specifications of the iron salt of pelargonic acid have been supplied. On this basis the evaluation cannot be finalised.

The formulation is not classified for the physico-chemical aspect.

Rinse the packaging at least twice before its disposal.

Protect from frost.

3.2 Efficacy (Part B, Section 3)

Considering the data provided:

- NEU 1143 F's efficacy is considered acceptable for all the intended uses. **However the requested application rate of 33 mL/L was not tested for use on rose, tomato and cucumber**. For those uses, the maximum tested rate of 25 mL/L appears to provide an acceptable level of control.
- NEU 1143 F's risk of phytotoxicity to the target crop is considered acceptable.
- The risk of resistance developing to the iron salt of pelargonic acid does not require a monitoring for the requested uses.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methodology for the determination of the active substance in the formulation is available and validated. As the active substance pelargonic acid does not contain any relevant impurity, no pertinent analytical method is required.

3.3.2 Analytical methods for residues

The active substance is a naturally occurring compound and it would be impossible to distinguish between what occurs naturally and what occurs as a result of pesticide usage. So, no analytical methods are required for the determination of residues in plants, foodstuffs of animal origin, soil, water and air.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Substance: **pelargonic acid (fatty acid C_7 to C_{20})**			
ADI	NA		EU (01/09/2009)
ARfD	NA		
AOEL	As no AOEL has been set for this a.s., the figure of 821 mg/kg bw/d, for the normal dietary intakes of fatty acids, has been used as a substitute figure in the exposure calculations		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation)	Spray dilution (used in formulation)
	Dermal absorption endpoints %	**25**	**75**

(1) An acceptable operator exposure level (AOEL) for fatty acids C_7 to C_{20} was not considered necessary in Regulation (EC) n° 1107/2009.

Substance: **iron (III) chloride anhydrous**			
ADI	0.8		EFSA[1]
ARfD	NA		
AOEL	0.4		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation)	Spray dilution (used in formulation)
	Dermal absorption endpoints %	**10**	**10**

[1] Reference values for iron as defined by EFSA in its conclusion regarding iron salts (iron(II) sulfate *EFSA Journal 2012;10(1):2521* and ferric [iron(III)] phosphate *EFSA Journal 2015;13(1):3973*).

3.4.1 Acute toxicity

NEU 1143 F, containing 75.07 g/L pelargonic acid iron(III) salt, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in section 2.4.

3.4.2 Operator exposure

Summary of critical use patterns (worst case):

Crop	F/G[7]	Equipment	Application rate L NEU 1143 F /ha (g a.s./ha)	Spray dilution (L/ha)	Model
Ornamentals, high crops (> 60 cm)	Fn	Spraying with knapsack	40 L NEU 1143 F/ha (75.07 g a.s./ha)	1200 - 2000	UPJ

Crop	Equipment	PPE and/or working coverall	% AOEL pelargonic acid	% AOEL iron
Ornamentals, high crops	Spraying with knapsack	-	0.02	1.06

Exposure is estimated to be 0.02 % of the substitute AOEL of pelargonic acid and 1.06 % of the AOEL for iron. Therefore the risk for the operator (user) using NEU 1143 F is acceptable.

The proposed packaging has been described in sufficient details, and its compliance can therefore be finalised.

Compliance with the provisions of French Decree No. 2010-1755 of 30 December 2010 and Orders of 30 December 2010 relating to the use of certain plant protection products by non-professional users is considered to be not acceptable for requested packaging for non professionnal uses.

3.4.3 Worker exposure

NEU 1143 F is intended to be used by amateurs during home garden application. In this case of the non-professional user, the worker is also the user of the product. It will be necessary to ensure complete drying of the treated area or of treated plants before handling them.

3.4.4 Bystander exposure

In the context of use by non-professionals, it may be considered that the assessment for bystanders is covered by that for the operator (user).

3.4.5 Resident exposure

Residential exposure was assessed according to the EFSA model. Exposure is estimated to be 0.16 % of the substitute AOEL of pelargonic acid for adults and 0.37 % for children as well as 11.76 % of AOEL of iron for adults and 39.16 % for children. Therefore the risk for residents is acceptable.

[7] Open field or glasshouse.

3.4.6 Combined exposure

Currently no EU-harmonised guidance is available on the risk assessment of combined exposure to multiple active substances. Most assessment approaches employed up to now make use of the Hazard Index (HI) concept. It is therefore suggested to use this as a first tier assessment.

A cumulative assessment for operators (users) and residents was performed. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

Hazard quotients (HQ) for each active substance and the HI (sum of hazard quotients) are:

Population groups and PPE		**Active ingredient**	**Estimated exposure / [substitute] AOEL (HQ)**
Operators (users)	Working coverall and gloves during mixing/loading and application	**Pelargonic acid**	0.0026
		Iron	0.0106
	Cumulative risk operators (HI)		0.0132
Bystanders/Residents	Children - All pathways (mean)	**Pelargonic acid**	0.0020
		Iron	0.3916
	Cumulative risk bystanders/residents (child) (HI)		0.3953
	Adults - All pathways (mean)	**Pelargonic acid**	0.0011
		Iron	0.1173
	Cumulative risk bystanders/residents (adult) (HI)		0.1192

The Hazard Index is < 1 in each of the three cases. Thus combined exposure to all active substances in NEU 1143 F is not expected to present a risk for operators (users), workers, residents and bystanders. No further refinement of the assessment is required.

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

3.5.1 Residues

NEU 1143 F contain the iron salt of pelargonic acid.
For the iron contained in the active substance, extrapolation from available data on iron(III) phosphate and iron(II) sulfate may be made.

Table 3.5-1: Toxicological reference values for the dietary risk assessment of pelargonic acid (present as its iron salt)

Reference value	Source	Year	Value	Study relied upon	Safety factor
Pelargonic acid					
ADI	Not applicable (Dir 08/127)				
ARfD	Not applicable (Dir 08/127)				
Ferric phosphate					
ADI	0.8 mg/kg bw/d (Reg. (EU) 2015/1166)				
ARfD	Not applicable (Reg. (EU) 2015/1166)				
Iron sulfate					
ADI	0.8 mg/kg bw/d (Dir 08/127)				
ARfD	Not applicable (Dir 08/127)				

Since fatty acids and iron are common and indispensable parts of human and animal food/feeding stuffs, the use of the iron salt of pelargonic acid as a plant protection product is considered of low toxicological concern and no quantitative consumer risk assessment is needed (EFSA Journal 2013;11(1):3023).

3.5.1.1 Summary for iron salt of pelargonic acid

As fatty acids occur naturally in plants, those applied as plant protection product would be metabolised by the same routes as endogenous material. Application of ^{14}C fatty acids would result in the incorporation of radioactivity into the carbon pool and all intermediary metabolites would become labelled to some extent. A metabolism study with ^{14}C fatty acids would therefore provide no useful information (DAR, 2007, Vol 3, Annex B, part 3, B.7).

For the iron contained in the active substance, no metabolism and distribution studies in plants are necessary. Indeed, extrapolation from available data on ferric phosphate and iron sulfate could be made. Ferric phosphate and iron sulfate are listed on Annex IV to Regulation (EC) No 396/2005 and have an MRL exemption.

In addition, the fate of iron ions in soil and plants is well documented in the published literature. In plants, iron serves as a micronutrient. Iron is required for chloroplast development and is a component of cytochromes (RAR Ferric phosphate, 2013, Vol. 3, Annex B.7).

According to Commission Regulation (EC) No 149/2008, amending Reg. (EC) 396/2005, no MRLs are required (EFSA Journal 2015;13(1):3973).

Table 3.5-2: Summary for pelargonic acid (present as Iron salt)

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance**	Chronic risk for consumers identified?	Acute risk for consumers identified?
1-11	Ornamentals	Not required				Not applicable	No	No
12	Stone fruits	Not required				Not applicable		No
13-15	Fruiting vegetables	Nor required				Not applicable		No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Active substances for which no maximum residue level (MRLs) is required.

3.5.1.2 Summary for NEU 1143 F

Table 3.5-3: Information on NEU 1143 F (KCA 6.8)

Crop	PHI for NEU 1143 F requested by applicant	PHI/withholding period* sufficiently supported for pelargonic acid (present as iron salt)	PHI for NEU 1143 F proposed by zRMS	zRMS Comments (if different PHI proposed)
Ornamentals	NR	Yes	NR	-
Stone fruits	N	Yes	NR	
Fruiting vegetables	0 days	Yes	NR	

NR: not relevant;

Waiting periods before planting succeeding crops

Not relevant.

3.5.2 Consumer exposure

Selection of critical uses and justification

A list of all intended uses is given in Part B, Section 0. Identification of a cGAP for the residues section is not required.

Overall conclusion

Pelargonic acid belongs to the fatty acids family (C_7 to C_{20}), all of which are included in Annex IV of Regulation (EC) No 396/2005, containing a list of active substances for which maximum residue levels (MRLs) are not required.

For the iron contained in the active substance, extrapolation from available data on iron(III) phosphate and iron(II) sulfate could be made. Iron(III) phosphate and iron(II) sulfate are also listed in Annex IV to Regulation (EC) No 396/2005 and thus have an MRL exemption.

In addition, the fate of iron ions in soil and plants is well documented in the published literature. Indeed, in plants, iron serves as a micronutrient.

The available data are considered sufficient for risk assessment. No further assessment is required of metabolism and residues, and no safety concern to the consumer was identified regarding the uses of NEU 1143 F. France therefore agrees with the authorisation of the intended uses.

According to the available data, no specific mitigation measures should apply.

Data gaps: none.

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

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

Given the home and garden use of the preparation NEU 1143, PECsoil values are not needed for the eco-toxicological risk assessment.

PECsw values (from spray drift only) derived for the active substance are used for the ecotoxicological risk assessment.

The PEC values of pelargonic acid (present as its iron salt) in groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PECgw values for pelargonic acid (present as its iron salt) do not occur at levels exceeding those mentioned in Regulation (EC) Nº 1107/2009 solely for applications between March and August for the intended uses on roses, ornamentals, tomato, cucumber and melon. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses based on this window of application timings.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

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

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms, other soil macro- and micro-organisms and terrestrial plants are acceptable for the intended uses.

For uses on roses, flowers and ornamental plants, tomato, cucumber and melon, the risk for aquatic organisms is acceptable with mitigation measures.

For uses on ornamental trees and shrubs, and on peach, it is not possible to finalise the risk assessment for aquatic organisms.

3.8 Relevance of metabolites (Part B, Section 10)

No relevant metabolites from a toxicological perspective.

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to 3.6 for the conclusion on the risk of groundwater contamination.

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

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

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

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

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

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

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

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***NEU 1143 F***

de la société	*NEUDORFF GMBH KG*
enregistrée sous le	*n°2016-1222*

Vu les conclusions de l'évaluation de l'Anses du 19 décembre 2019,

Considérant que les emballages en PET et PEHD de 50 mL à 5 L avec des tailles d'ouverture comprises entre 2,5 et 4,4 cm du produit ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel, conformément à l'arrêté du 30 décembre 2010,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

NEU 1143 F
AMM n°-

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RÉPUBLIQUE FRANÇAISE

Informations générales sur le produit	
Nom du produit	NEU 1143 F
Type de produit	Produit de référence
Titulaire	NEUDORFF GMBH KG An der Mühle 3 D-31860 EMMERTHAL Allemagne
Formulation	Suspension concentrée (SC)
Contenant	67,6 g/L - acide pélargonique
Numéro d'intrant	336-2016.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Amateur / emploi autorisé dans les jardins

A Maisons-Alfort le, 05 MARS 2020

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

NEU 1143 F
AMM n°-

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Appendix 2 Copy of the product label

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

Draft Master Label

NEU 1143 F SC (Amateur)

For non-professional users

Naturally based concentrate against many fungicidal diseases on ornamentals, vegetables and fruits

Powdery Mildew - Roses
Rust - Roses
Black Spot – Roses
Rust – Ornamentals
Leaf spot diseases - Ornamentals
Peach leaf curl – Peaches, apricots, nectarine
Late blight – Tomatoes
Powdery mildew – Cucumbers, melons, zucchinis

/ Outside label /

NEU 1143 F
Controls many diseases on roses, ornamentals, peaches, tomatoes, cucumbers, melons and zucchinis

The active substance is pelargonic acid, formed as iron salt. Pelargonic acid occurs in nature and is quickly biodegradable in soil. No waiting time before harvest. Not harmful for bees. Not phytotoxic to plants.

Directions: Shake well before use! Unscrew measuring cap. Dilute NEU 1143 F in water.

Spray thoroughly on tops and bottoms of leaves.

Application
Spray concentration and point of time:
See inside of label. At beginning of infection when first symptoms appear, spraying several times (up to 10 applications) at intervals of 7-10 days is necessary.

Application areas stipulated by the regulating body
See inside of label.

Waiting time before harvesting
None for tomatoes, cucumbers, melons, zucchini and peaches

P101 – If medical advice is needed, have product container or label at hand.
P102 – Keep out of reach of children.
SP1 – Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
EUH401 – To avoid risks to human health and the environment, comply with the instructions for use.

Information to protect the environment:

Toxicity for bees
Not harmful to bees

Beneficial insects
Not harmful to *Chrysoperla carnea*, *Aphidius rhopalosiphi* and *Typhlodromus pyri*

Disposal of packs
Dispose only completely empty packs in the recycling materials collection.

Information to protect the user:
Avoid all unnecessary contact with the product. Misuse can lead to impairment of health.

Implementing rules fixed by the competent authority:
(To be amended after approval)

First aid measures:
GENERAL ADVICE: If you feel unwell, seek medical advice (show the label where possible).
IN CASE OF INHALATION: Ensure of fresh air.
IN CASE OF SKIN CONTACT: In case of contact with skin wash off immediately with plenty of water.
IN CASE OF EYE CONTACT: In case of contact with eyes rinse thoroughly with plenty of water. Consult a physician if symptoms appear.
IN CASE OF INGESTION: Consult a physician if symptoms appear.
No product specific symptoms known.

Note to physician: Treat symptomatically.

Net content: 250 ml
Sufficient for 12.5 litres spraying mixture

/barcode batch, Production date /

Authorisation number: XXXXX

Authorisation holder: W. Neudorff GmbH KG, An der Mühle 3, 31860 Emmerthal, Germany

READ THE ATTACHED LEAFELET BEFORE USE

Important Information – please open here!

/ Inside label /

Use areas of NEU 1143 F					
Crops	Pest	Maximum individual dose (ml product per L water)	Maximum number of treatments (per crop)	Interval between treatments	Comments
Roses	Powdery mildew rust black spot	33 ml/L	10	7 to 10 days	The dose may be reduced to 20 ml/L at light infections Application timing: see beneath
Ornamentals and woody ornamentals	Powdery mildew Rust fungi Leaf spot diseases	27 ml/L	10	7 to 10 days	
Tomatoes	Late blight	33 ml/L	10	7 to 10 days	
Cucumber, Zucchini, pickles and other cucurbits with edible peel	Powdery mildew	33 ml/L	10	7 to 10 days	
Melon, watermelons, pumpkins and other cucurbits with inedible peel	Powdery mildew	20ml/L	10	7 to 10 days	Application timing: see beneath
Stone fruits: Peaches, nectarines and apricots	Peach leaf curl	40ml/L	4	7 to 35 days	Application timing: see beneath

Maximum application rate per area: Maximum 4 ml/m^2, depending on the dose this corresponds to 120-200 ml spray solution per square metre
Application timing:
Stone fruits : Treat at the beginning of bud swelling until inflorescence enclosed by light green scales (BBCH 01 to 54)
Ornamentals and woody ornamentals: Leaf spot diseases: Treat at danger of infection or at beginning of infection when first symptoms appear.
Ornamentals and woody ornamentals: Rust fungi, powdery mildew: Treat at beginning of infection when first symptoms appear.
Other culture crops: Treat at beginning of infection when first symptoms appear.
Waiting period: no waiting periods
Re-entry period: Areas treated with NEU 1143 F can be re-entered immediately after drying of the spray. Also pets can re-enter the treated areas then.
Phytotoxicity: NEU 1143 F is highly compatible for plants in the recommended rates of application

Storage and disposal
Protect from frost.
Re-use of empty packaging is prohibited.