

REGISTRATION REPORT

Part A

Risk Management

Product code: DIA 104 I-S

Product name(s): Force® Neo

**Chemical active substance(s):
tefluthrin, 5 g/kg**

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: DIACHEM SpA

Date: 03/12/2025

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PART A

RISK MANAGEMENT

1 Details of the application

The company DIACHEM SpA has requested a marketing authorisation in France for the product FORCE NEO (product code: DIA 104 I-S), containing 5 g/kg tefluthrin¹ as an insecticide for professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of DIACHEM SpA's application submitted on 03/10/2023 to market FORCE NEO 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 (2023-2545) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

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

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

This document also describes the specific conditions of use and labelling required for France for the registration of FORCE NEO.

¹ Commission Implementing Regulation (EU) No 800/2011 of 9 August 2011 approving the active substance tefluthrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and amending Commission Decision 2008/934/EC

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

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

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

1.2 Letters of Access

Not necessary: active substance data are not protected any more.

1.3 Justification for submission of tests and studies

According to the applicant: « All reports submitted are needed for the authorisation of use of DIA 104 I-S in accordance to the data requirements laid down in Regulation (EC) No. 284/2013. ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of FORCE NEO 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	DIA 104 I-S
Product name in MS	FORCE NEO
Authorisation number	2250546
Kind of use	Professional use
Low risk product (article 47)	No
Function	Insecticide and fertilizer
Applicant	Diachem S.p.A.
Active substance(s) (incl. content)	tefluthrin; 5 g/kg
Formulation type	Granules [GR]
Packaging	- Bags (5, 7.5, 10 kg) made of PET/aluminium/PABX (=PEBD/nylon) / PEBD - Bags (5, 7.5, 10kg) made of white paper/avana paper/PEBD/avana paper/PEBD - Bags (15, 20, 25kg) made of white paper/avana paper/PEBD/ Avana paper/avana paper/PEBD - Bottles (1, 2, 3 kg) made of PEHD - Tank (50kg) made of PEHD
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

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The evaluation of the application for FORCE NEO resulted in the decision to **grant the authorisation**.


2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	 GHS09
Signal word:	Warning
Hazard statement(s):	H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
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

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

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4 May 2017⁵ provides that:

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

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

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

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

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

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

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

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

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	

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

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

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

⁸ Arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques - Légifrance ([legifrance.gouv.fr](https://www.legifrance.gouv.fr))

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	-
Environmental protection	
SPe 2	To protect aquatic organisms, the product must be entirely incorporated in the soil at a minimal depth of : <ul style="list-style-type: none"> - 3 cm for Sugar beet, - 4 cm for Potatoes, Sweet corn, Maize, Aubergine, Cucumber, Courgette, Pumpkin, Tomatoe Soybean and Sunflower, - 7.5 cm for Tobacco.
SPe 3	To protect aquatic organisms, respect a untreated zone of 5 meters with a 5-metre permanent planted buffer strip to surface water bodies
SPe 5	To protect birds the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.
SPe 6	To protect birds and wild mammals remove spillages.
Other specific restrictions	
Re-entry period	Not applicable.
Storage	-
Risk mitigation measures	After using FORCE NEO on crops intended for food consumption, do not plant a succeeding crops/replacement crop less than 120 days after treatment.
Risk mitigation measures	-

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.

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Intended uses (only NATIONAL GAP)

PPP (product name/code): FORCE NEO (DIA 104 I-S)
 Active substance 1: tefluthrin
 Safener: not relevant
 Synergist: not relevant
 Applicant: DIACHEM S.p.A.
 Zone(s): Southern Zone
 Verified by MS: Yes

Field of use: insecticide

Date : 03/12/2025
 Formulation type: GR
 Conc. of as 1: 5 g/kg¹
 Conc. of safener: not relevant
 Conc. of synergist: not relevant
 Professional use: X
 Non professional use:

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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, G, Gn, Gpn 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. g safener/synergist per ha ^(f)
					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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	FR	Sugar beet [BEAVA]	F	<i>Agriotes</i> sp. [AGRISP]	Seeding row distributio n.	At seeding (BBCH 00)	a,b)1 (-)	-	a,b) 12-16 Kg/ha	a,b) 60-80 g ai/ha	-	-	Acceptable
4	FR	Maize [ZEAMX]	F	<i>Agriotes</i> sp. [AGRISP], <i>Diabrotica</i> sp. [DIABSP]	Seeding row distributio n	At seeding (BBCH 00)	a,b)1 (-)		a,b)12-16 Kg/ha	a,b) 60-80 g ai/ha	-	-	Acceptable
5	FR	Maize [ZEAMX]	F	<i>Diabrotica</i> sp. [DIABSP]	Seeding row distributio n	At seeding (BBCH 00)	a,b)1 (-)		a,b)20 Kg/ha	a,b) 100 g ai/ha	-	-	Acceptable
5a	FR	Sweet corn [ZEAMS]	F	<i>Agriotes</i> sp. [AGRISP], <i>Diabrotica</i> sp. [DIABSP]	Seeding row distributio n	At seeding (BBCH 00)	a,b)1 (-)		a,b)12-16 Kg/ha	a,b) 60-80 g ai/ha	-	-	Acceptable
5b	FR	Sorghum [SORVU]	F	<i>Agriotes</i> sp. [AGRISP], <i>Diabrotica</i> sp. [DIABSP]	Seeding row distributio n	At seeding (BBCH 00)	a,b)1 (-)		a,b)12-16 Kg/ha	a,b) 60-80 g ai/ha	-	-	Acceptable
6	FR	Sunflower [HELAN]	F	<i>Agriotes</i> sp. [AGRISP]	Seeding row distributio n.	At seeding (BBCH 00)	a,b)1 (-)		a,b)12-16 Kg/ha	a,b) 60-80 g ai/ha	-	-	Not acceptable (MRL)
8	FR	Soybean [GLXMA]	F	<i>Agriotes</i> sp. [AGRISP]	Seeding row distributio n.	At seeding (BBCH 00)	a,b)1 (-)		a,b)12-16 Kg/ha	a,b) 60-80 g ai/ha	-	-	Not acceptable (MRL)

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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, G, Gn, Gpn 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. g safener/synergist per ha ^(f)
					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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
16	FR	Tomato [LYPES]	F	<i>Agriotes sp.</i> [AGRISP]	Seeding row distributio n	At seeding (BBCH 00) or transplanting (BBCH 13-14)	a,b)1 (-)		a,b)16 Kg/ha	a,b) 80 g ai/ha	-		Acceptable
16a	FR	Aubergine [SOLME] Courgette [CUUPG] Pumpkin [CUUPE]		<i>Agriotes sp.</i> [AGRISP]	Seeding row distributio n	At seeding or transplanting	a,b)1 (-)		a,b)16 Kg/ha	a,b) 80 g ai/ha			Acceptable
18	FR	Cucumber [CUMSA]	F	<i>Agriotes sp.</i> [AGRISP]	Seeding row distributio n	At seeding (BBCH 00) or transplanting (BBCH 13)	a,b)1 (-)		a,b)16 Kg/ha	a,b) 80 ai/ha	-		Not acceptable (consumer exposure)
18	FR	Zucchini	F	<i>Agriotes sp.</i> [AGRISP]	Seeding row distributio n	At seeding (BBCH 00) or transplanting (BBCH 13)	a,b)1 (-)		a,b)16-Kg/ha	a,b) 80 g ai/ha	-		Acceptable
21a	FR	Lamb's lettuce/corn salad [VLLLO], Rocket [ERUVE], Red mustard [BRSJU], Baby leaf of chard [BEAVFred mustard [BRSJU], spinach [SPQOL])	F	<i>Agriotes sp.</i> [AGRISP]	Seeding row distributio n	At seeding or transplanting	a,b)1 (-)		a,b)16 Kg/ha	a,b) 80g ai/ha	-	-	Not acceptable (MRL)
21a	FR	Cress [LEPSA], Land cress [BARVE]	F	<i>Agriotes sp.</i> [AGRISP]	Seeding row distributio n	At seeding or transplanting	a,b)1 (-)		a,b)16 Kg/ha	a,b) 80 g ai/ha	-	-	Not acceptable (MRL)

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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)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
22	FR	Potato [SOLTU]	F	<i>Agriotes sp.</i> [AGRISP]	Seeding row distributio n	At seeding (BBCH 00) or transplanting	a,b)1 (-)		a,b)12-16 Kg/ha	a,b) 60-80 g ai/ha	-	-	Acceptable
24	FR	Tobacco [NIOTA]	F	<i>Agriotes sp.</i> [AGRISP]	Seeding row distributio n	At seeding or transplanting	a,b)1 (-)		a,b)12-16 Kg/ha	a,b) 60-80 g ai/ha	-	-	Acceptable

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 authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

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)

As part of the resubmission of the dossier, a change in the composition of the product FORCE NEO was made. The physico-chemical properties of the product with its new composition (code: DIA 104 I-NW) were submitted and evaluated

The physico-chemical properties of the product with its new composition (code: DIA 104 I-NW) were submitted and evaluated. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of brownish gravel with a characteristic odour, and range about 0.5-1.6 mm of diameter. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature above 400 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content, the hexachlorobenzene content nor the technical properties were changed.

The ambient temperature shelf life study is in progress. However, since the physico-chemical properties of the old and new compositions have been shown to be similar (see confidential part C), the results obtained from the ambient temperature shelf-life study of the old composition can be extrapolated to the new composition. No further data is required.

Packaging claims:

- Bags (5, 7.5, 10 kg) made of PET/aluminium/PABX (=PEBD/nylon) / PEBD
- Bags (5, 7.5, 10kg) made of white paper/avana paper/PEBD/avana paper/PEBD
- Bags (15, 20, 25kg) made of white paper/avana paper/PEBD/ Avana paper/avana paper/PEBD
- Bottles (1, 2, 3 kg) made of PEHD
- Tank (50kg) made of PEHD

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

The effectiveness level of FORCE NEO is considered satisfactory for all the requested uses.

The phytotoxicity level of FORCE NEO is considered negligible for all the requested uses.

The risks of negative impact on yield, quality, propagation and succeeding crops are considered negligible.

The risk of resistance to tefluthrin does not require a monitoring for the requested uses.

3.3 Methods of analysis (Part B, Section 5)

Only the new methods provided as part of this resubmission were reviewed by France. The conclusions drawn by Greece during the initial application therefore remain unchanged. It was noted that the composition of the product in the application evaluated by Greece (2021_0364) and the resubmission evaluated by France (2023_2545) is not the same. This is why the new methods provided for the determination of the active substance and relevant impurities were evaluated.

3.3.1 Analytical method for the formulation

Sufficiently sensitive and selective analytical methods are not available for the active substance(s) in the plant protection product.

Noticed data gaps are:

- Lodi, M. (2023), No. 23092-01C : For the methods used to determine the SA and relevant impurities in the preparation, some deficiencies to be in accordance with the guidance SANCO/3030/99-rev.5 have been noted. However, the validation data provided are sufficient to consider these methods as fit for purpose. (see zRMS comment 5.2.1.1).

3.3.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are not available for all analytes included in the residue definitions.

Noticed data gaps are:

- Rovetto, I. (2023) : The method for the determination of residue in tomato and cucumber are not considered validated since the extraction efficiency is not demonstrated in the fruits and fruiting vegetables matrix. **An indirect cross-validation should have been provided to demonstrate the extraction efficiency.**
- The summaries of the methods for the determination of residues in oilseeds (data generated by Syngenta) were not provided in Appendix II. As a result, they could not be assessed and are considered non-validated.

3.4 Mammalian toxicology (Part B, Section 6)

Active substance(s) (incl. content)	Tefluthrin 5 g/kg
AOEL systemic	0.0015 mg/kg bw/d
Inhalation absorption	100 %
Oral absorption	30 %
Dermal absorption	Concentrate: 30 %

3.4.1 Acute toxicity

FORCE NEO containing 5 g/kg tefluthrin has a low toxicity in respect to acute oral, dermal, and inhalation toxicity. The product is not irritating to the skin or to the eyes and is not a skin sensitiser.

3.4.2 Operator exposure

Considering the proposed uses, the operator systemic exposure was estimated using the EFSA model⁹.

According to the exposure assessment using the EFSA model, the operator exposure to FORCE NEO is below the AOEL of tefluthrin with a work wear, gloves and respiratory protective equipment during

⁹ EFSA Journal 2022;20(1):7032 opex 1.0.2

mixing/loading and application.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.4.3 Worker exposure

zRMS has reassessed the worker exposure according to the the EFSA model (2022). FORCE NEO is applied directly to the ground and does not require the intervention of workers after treatment.

In conclusion, worker exposure is not relevant for granular application.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.4.4 Bystander and Resident exposure

zRMS has reassessed the bystander and resident exposure according to the the EFSA model (2022).

Considering the type of application, “application at seeding/transplanting buried in soil at 4-10 cm depth” and according to the EFSA Guidance (2022) on the exposure of bystanders and residents dust drift for in-furrow applications is considered to be negligible.

In conclusion, burial is sufficient for exposure by volatilisation to be considered negligible and consequently bystander and resident exposure are not relevant for granular application.

3.4.5 Combined exposure

Not relevant. The product contains only one active substance.

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

For all crops, sufficient data are available to conclude that results are in compliance with the in-force MRL (Reg (EU) 2021/1110) except for sunflowers, soyabean seeds, others salads and spinach.

The chronic intakes of tefluthrin residues resulting from the uses proposed in the framework of this application is unlikely to present a public health concern. The proposed uses of tefluthrin in the formulation DIA 104 I-S do not represent unacceptable acute risk for the consumer, except for cucumber.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses, except for other salads, spinaches, sunflower, soybean, aubergine and cucurbits with edible and inedible peel.

According to available data, specific mitigation measures should apply.

Information on FORCE-NEO / DIA 104 I-S (KCA 6.8)

Crop	PHI for DIA 104 I-S proposed by applicant	PHI/ Withholding period* sufficiently supported for Tefluthrin	PHI for DIA 104 I-S proposed by zRMS	zRMS Comments (if different PHI proposed)
Sugar beet	Not required ***	Yes	F**, BBCH 00	
Maize and Sorghum	Not required ***	Yes	F**, BBCH 00	

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Crop	PHI for DIA 104 I-S proposed by applicant	PHI/ Withholding period* sufficiently supported for Tefluthrin	PHI for DIA 104 I-S proposed by zRMS	zRMS Comments (if different PHI proposed)
Sweet corn	Not required ***	Yes	F**, BBCH 00	
Sunflower	Not required ***	No	-	MRL exceedance
Soybean	Not required ***	No	-	MRL exceedance
Tomato	Not required ***	Yes	F**, BBCH 00 -13	
Aubergine	Not required ***	No	F**, BBCH 00 -13	
Cucumber	Not required ***	No	-	Unacceptable acute risk
Courgette	Not required ***	No	F**, BBCH 00 -13	
Pumpkin	Not required ***	No	F**, BBCH 00 -13	
Other salads (Lamb's lettuce/corn salad, Cress, Land cress, Rocket, Red mustard, Baby leaf of chard) and spinach	Not required ***	No	-	MRL exceedance
Potato	Not required ***	Yes	F**, BBCH 00	
Tobacco	NR			

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

*** PHI is covered by duration from application to normal commercial harvest.

Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for DIA 104 I
Crop group	Led by tefluthrin	
All crops	A 120-day plant-back interval is suggested, as to avoid the presence of any residues of tefluthrin or its metabolites included in the RD-RA in succeeding crops, even after multiannual use of DIA 104 I-S.	120 days

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.

PEC soil and PECsw derived for the active substance and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

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PECgw for tefluthrin and its metabolite do not occur at levels exceeding those mentioned in regulation EU No 546/2011 and guidance document SANCO 221/2000¹⁰. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Updated modelling were provided by the notifier for some of the intended uses. However, the zRMS notices a major deviation in the selection of the default value for the parameter 'Molar enthalpy of sorption'. Additional exposure assessment for aquatic compartment were provided by the Applicant to take into account the use of diffusor for uses on maize. However, the alternative modelling are not accepted by zRMS since they were not performed according to the recommendations of the guidance documentation (EFSA, 2004¹¹ ; FOCUS, 2007¹² ; 2015¹³). Thus, the previous conditions of uses still apply.

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(s) and its/their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

New data and/or updates have been provided only for aquatic organisms and birds. For the other non-target organisms, the previous conclusions and conditions of use still apply. For birds, the new refinements are sufficient to conclude to an acceptable risk for these organisms. For aquatic organisms, the additional exposure assessment are not accepted as indicated above in 3.6. Thus, the previous conclusions and conditions of use still apply to aquatic organisms.

3.8 Relevance of metabolites (Part B, Section 10)

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

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

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

¹⁰ Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Regulation (EC) No 1107/2009. Sanco/221/2000-rev.11, 21 October 2021.

¹¹ EFSA (2004) "Opinion of the PPR Panel on a request from EFSA on the appropriateness of using the current FOCUS surface water scenarios for estimating exposure for risk assessment in aquatic ecotoxicology in the context of Council Directive 91/414/EEC", 145, 1-31.

¹² FOCUS (2007) "Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.

¹³ FOCUS (2015) Generic guidance for FOCUS surface water Scenarios, Version: 1.4, Date: May 2015

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.

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Appendix 1 Copy of the product authorisation




FORCENEO_MAMM
_2023-2545_D.pdf

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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.

	
FORCE® NEO	
Composition :	Téfluthrine 5 g/kg, soit 0.5% (m/m) Engrais minéral (NP) avec oligo-éléments (manganèse et zinc)
Formulation :	Granulés [GR]
Type de produit :	INSECTICIDE du sol pour la protection des grandes cultures et cultures légumières contre les insectes du sol
Mode d'action :	Modulateur du canal sodique (3A - Pyréthriinoïdes)
Détenteur de l'A.M.M :	DIACHEM SPA - Via Tonale 15 - ALBANO S. ALESSANDRO (BG) – ITALIE Tel. +39 0363 355611 http://diachemagro.com/
Distributeur :	Nom, adresse www.internet.com
N° de lot et date de fabrication :	voir emballage
	X kg e
RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL	

RÉEMPLOI DE L'EMBALLAGE INTERDIT.

Lire les instructions ci-jointes avant l'emploi.

FORCE® NEO – AMM N° 0000000		
 Attention	H410	Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
	EUH401	Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.
	P405+P102	Garder sous clef et tenir hors de portée des enfants.
	P103	Lire l'étiquette avant utilisation.
	P261	Eviter de respirer les poussières.
	P271	Utiliser seulement en plein air ou dans un endroit bien ventilé.
	P280	Porter des gants de protection et des vêtements de protection.
	P401	Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.
	P501	Éliminer le contenu / récipient conformément à la réglementation en vigueur sur les déchets dangereux.
		Contient de la téfluthrine, susceptible de provoquer des paresthésies. Eviter le contact avec la peau.
Délai de rentrée des travailleurs dans la zone traitée : Non applicable (granulés à épandre)		
SPe 3	Pour protéger les organismes aquatiques, mettre en place un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau pour les usages sur betteraves sucrières, salades, cressons, épinard.	

SPe 3	Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau pour les usages sur concombre, tomate, aubergine, cucurbitacées, maïs, sorgho, tournesol, pomme de terre, tabac et soja.
SPe 3	Pour protéger les organismes aquatiques, mettre en place un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau de surface pour les usages sur maïs traité à l'aide d'un diffuseur.
SPe 6	Pour protéger les oiseaux/mammifères sauvages, récupérer tout produit accidentellement répandu.
SP 1	Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. / Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

Premiers secours

En cas d'urgence, appelez le 15 ou le 112 ou contactez le centre antipoison le plus proche puis signalez vos symptômes au réseau "Phyt'attitude". N° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Conseils généraux

S'éloigner de la zone dangereuse.

En cas d'exposition ou de symptômes, appeler un CENTRE ANTIPOISON ou un médecin.

Inhalation

Transporter la victime à l'extérieur et la maintenir au repos dans une position où elle peut confortablement respirer. En cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre anti-poison.

Contact avec la peau

Enlever immédiatement tous les vêtements contaminés. Rincer immédiatement et abondamment la peau à l'eau ou se doucher. En cas d'irritation ou éruption cutanée, consulter un spécialiste.

Contact avec les yeux

Rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Consulter un spécialiste.

Ingestion

Rincer immédiatement la bouche avec de l'eau. Ne PAS faire vomir sans avis médical. Contacter sans délai les secours : le 15, le 112 ou un centre anti-poison. Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la Fiche de Données de Sécurité.

Intoxication animale

Contactez votre vétérinaire.

Fiche de données de sécurité disponible sur simple demande.

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PRECONISATIONS D'EMPLOI

Usages et doses autorisées en traitement du sol

Culture	Cibles / Usages	Dose maximum d'emploi	Dose préconisée	Nombre maximum d'applications par an	Stade d'application	Méthode d'application	ZNT aquatique
Betterave sucrière	Insectes du sol (taupins)	16 kg/ha	12-16 kg/ha	1	Au semis	Dans la raie de semis	Organismes aquatiques : 5 m dont DVP 5 m**
Mais, Mais doux, Sorgho	Insectes du sol (taupins, chrysomèles)	16 kg/ha	12-16 kg/ha	1	Au semis	Dans la raie de semis	Organismes aquatiques : 5 m*
Mais <i>En cas de forte infestation</i>	Insectes du sol (chrysomèles)	20 kg/ha	20 kg/ha	1	Au semis	Dans la raie de semis	Organismes aquatiques : 5 m*
Soja	Insectes du sol (taupins)	16 kg/ha	12-16 kg/ha	1	Au semis	Dans la raie de semis	Organismes aquatiques : 5 m*
Tournesol	Insectes du sol (taupins)	16 kg/ha	12-16 kg/ha	1	Au semis	Dans la raie de semis	Organismes aquatiques : 5 m*
Concombre, Courgette	Insectes du sol (taupins)	16 kg/ha	16 kg/ha	1	Au semis ou à la plantation	Dans la raie de semis/plantation	Organismes aquatiques : Salades, cressons, épinard : 5 m dont DVP 5 m**
Potiron							Autres légumes : 5 m*
Mâche, Moutarde brune, Roquette, Cresson alénois, Cresson de terre, Epinard, Feuilles de Blettes	Insectes du sol (taupins)	16 kg/ha	16 kg/ha	1	Au semis ou à la plantation	Dans la raie de semis/plantation	Organismes aquatiques : 5 m*
Tomate, aubergine	Insectes du sol (taupins)	16 kg/ha	16 kg/ha	1	Au semis ou à la plantation	Dans la raie de semis/plantation	Organismes aquatiques : 5 m*
Pomme de terre	Insectes du sol (taupins)	16 kg/ha	12-16 kg/ha	1	A la plantation	Dans la raie de plantation	Organismes aquatiques : 5 m*
Tabac	Insectes du sol (taupins)	16 kg/ha	12-16 kg/ha	1	Au semis ou à la plantation	Dans la raie de semis/plantation	Organismes aquatiques : 5 m*

* Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau pour les usages sur concombre, tomate, aubergine, cucurbitacées, maïs, sorgho, tournesol, pomme de terre, tabac et soja.

** Pour protéger les organismes aquatiques, mettre en place un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau pour les usages sur betteraves sucrières, salades, cressons et épinard.

Respect des limites maximales de résidus (LMR)

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

Nouveau catalogue des usages et usages mineurs

DIACHEM ne préconise l'utilisation de ce produit que sur les cultures et usages mentionnés dans le tableau ci-dessus et décline toute responsabilité concernant son utilisation pour d'autres usages tels que prévus par le catalogue des usages en vigueur.

Spectre d'action

FORCE NEO est un insecticide de la famille des pyréthrinoïdes de synthèse et est particulièrement efficace contre les coléoptères qui passent une partie de leur cycle de vie dans le sol. FORCE NEO agit par effet de vapeur et de contact au niveau du système nerveux des ravageurs. FORCE NEO a une forte action répulsive qui augmente son efficacité.

FORCE NEO est efficace à faible dose. Grâce à son mode d'action différent de celui des carbamates et produits organophosphorés, le produit peut également convenir aux recommandations techniques concernant la rotation des utilisations d'insecticides.

Grâce à sa formulation particulière, le produit stimule la germination et facilite la reprise après la plantation.

INFORMATIONS RELATIVES A L'EMPLOI

Conditions d'application

FORCE NEO s'applique au fond de la raie de semis ou de plantation à l'aide d'un microgranulateur correctement calibré aux doses indiquées dans le tableau des usages. La dose peut être augmentée lorsqu'il y a un historique d'infestations élevées les années précédentes sur la parcelle.

L'utilisation d'un diffuseur est autorisée uniquement sur maïs avec une profondeur minimale d'application de 2 cm.

La formulation de FORCE NEO contient de l'azote et du phosphore (10:44), du manganèse (3%) et du zinc (2%). Cela doit être pris en compte dans le plan de fumure pour éviter une fertilisation excessive.

FORCE NEO contient des oligo-éléments : à n'utiliser qu'en cas de besoin reconnu.

Mélanges extemporanés et compatibilités

FORCE NEO n'est pas prévu pour être utilisé en mélange.

Délais à respecter

Suite à l'utilisation du produit FORCE NEO sur des cultures destinées à l'alimentation, ne pas implanter une culture suivante/de remplacement moins de 120 jours après traitement.

MODE D'ACTION

La téfluthrine appartient à la famille des pyréthrinoïdes de synthèse.

Code IRAC : 3A

PREVENTION ET GESTION DE LA RESISTANCE

L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, l'utilisateur doit raisonner en premier lieu les pratiques agronomiques et respecter les conditions d'emploi du produit. Il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation. En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité de cette préparation liée à ces phénomènes de résistance. De ce fait, DIACHEM décline toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.

MISE EN OEUVRE RÉGLEMENTAIRE ET BONNES PRATIQUES

Stockage

Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart de tout aliment et boisson y compris ceux pour les animaux. Conserver hors de la portée des enfants et des personnes non autorisées.

Protection de l'opérateur et du travailleur

L'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections complémentaires comme les protections individuelles.

Le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage). Les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Dans le cadre d'une application effectuée à l'aide d'un tracteur équipé d'un microgranulateur

Pour l'opérateur, porter :

• **pendant le chargement du matériel d'épandage (microgranulateur)**

- Gants en nitrile réutilisables (certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A));
- EPI vestimentaire (conforme à la norme NF EN ISO 27065/A1) et EPI partiel (blouse ou tablier à manches longues) catégorie III type PB3 (certifié NF EN 14605+A1) à porter par-dessus la combinaison précitée

OU combinaison de protection chimique catégorie III type 3 ou 4 (certifiée NF EN 14605+A1).

- Protections respiratoires certifiées : demi-masque filtrant anti-aérosol (certifié NF EN 149) de classe FFP3 ou demi-masque (certifié NF EN 140) avec filtre anti-aérosol (certifié NF EN 143) de classe P3.

• **pendant l'épandage**

- Gants en nitrile à usage unique (certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C)) en cas d'intervention sur le microgranulateur;
- EPI vestimentaire (conforme à la norme NF EN ISO 27065/A1).

• **pendant le nettoyage du matériel d'épandage**

- Gants en nitrile réutilisables (certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A));
- EPI vestimentaire (conforme à la norme NF EN ISO 27065/A1) et EPI partiel (blouse ou tablier à manches longues) catégorie III type PB3 (certifié NF EN 14605+A1) à porter par-dessus la combinaison précitée

OU combinaison de protection chimique catégorie III type 3 ou 4 (conforme à la norme NF EN 14605+A1).

Élimination des équipements de protection individuelle (EPI)

Rapporter les EPI usagés dans un sac translucide à votre distributeur partenaire ECO EPI ou faire appel à une entreprise habilitée pour la collecte et l'élimination de produits dangereux.

Nettoyage du matériel d'épandage (microgranulateur et du diffuseur)

À la fin de la période d'application, l'intégralité de l'appareil doit être nettoyée avec des outils (pinceau ou brosse souple, aspirateur) spécifiquement dédiés à cet usage. Ne pas utiliser d'air comprimé (ou soufflette) pour le nettoyage du matériel afin de ne pas produire de poussières.

Si un lavage des éléments est nécessaire, il convient de le réaliser dans un endroit adapté et l'élimination des effluents doit être réalisée conformément à la réglementation en vigueur.

Elimination du produit et de l'emballage

Pour les cartons et sacs : Apporter les emballages vidés et pliés à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique.

Pour les fûts plastiques et métalliques au-delà de 25 kg et ce jusqu'à 300 kg : Apporter les emballages vidés et fermés à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique.

Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'A.D.I.VALOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

En cas de déversement accidentel

Se protéger (EPI) et sécuriser la zone.

Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens.

Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse.

Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.

AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite.

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous la responsabilité de l'utilisateur, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...

Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les autorités compétentes françaises.

Pour les denrées issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.