

REGISTRATION REPORT

Part A

Risk Management

Product code: RLG 385

Chemical active substance:

1-Naphthylacetic acid, 30.2 g/L

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

Application for a label extension according to Art. 51

-

Minor uses

Applicant: L. Gobbi

Date: 23/01/2026

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PART A – Risk Management

The company L. Gobbi has requested a label extension in France for the RLG 385 according to article 51 Regulation (EC) no 1107/2009¹

This document describes the specific conditions of use and labelling required for extension of the registration of RLG 385 containing 1-naphthylacetic acid in France.

The conclusions of the risk assessment are based on the already existing registration of the preparation in France. Therefore, the evaluation of the current application is limited to the points not covered by the existing registration.

Appendix 1 of this document provides a copy of the French Decision.

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

1 DETAILS OF THE APPLICATION

1.1 Application background

RLG 385 is a soluble liquid (SL) product containing 30.2 g/L of 1-naphthylacetic acid, for use as a plant growth regulator for the control of thinning and fruit drop decrease on pom. The aim of this registration application is to gain a label extension for ornamental trees.

The complete GAP for the national application in France is provided below, under point 2.3.

1.2 Active substance approval

1-naphthylacetic acid

Commission Implementing Regulation (EU) No 787/2011 of 5 August 2011 approving the active substance 1-naphthylacetic acid, 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 Commission Decision 2008/941/EC.

Specific provisions of Regulation (EU) No 787/2011 were as follows:

PART A

Only uses as plant growth regulator may be authorised.

PART B

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 1-naphthylacetic acid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.

In this overall assessment Member States:

- (a) shall pay particular attention to the risk to operators and workers and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate;
- (b) shall pay particular attention to the dietary exposure situation of consumers in view of future revisions of maximum residue levels;
- (c) shall pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;
- (d) shall pay particular attention to the risk to aquatic organisms;
- (e) shall pay particular attention to the risk to birds.

¹ 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

Conditions of use shall include risk mitigation measures, where appropriate.

The applicant shall submit confirmatory information as regards:

- (1) the route and rate of degradation in soil including an assessment of the potential for photolysis;
- (2) the long-term risk to birds.

The applicant shall submit to the Commission, the Member States and the Authority such information by 31 December 2013.

An EFSA conclusion (EFSA Journal 2011;9(2):2019) was made available on 23/02/2011 and a new version regarding confirmatory data (EFSA Supporting publication 2015:EN-789) was made available on 15/04/2015.

A Review Report is available (SANCO/11269/2011 final rev 3, 19 May 2016).

1.3 Regulatory approach

The present application (n°2024-2819) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)².

The current document based on Anses' assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009, implementing regulations and French regulations.

Since the application is intended for use in France only, the draft Part A was not circulated for comments.

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

The French Order of 4th May 2017³ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 m;
- unless formally 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, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French order.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) N°546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 12 April 2021⁵ provides that:

- an authorisation granted for a « reference » crop applies also for “linked” crops unless formally stated in the decision
- the “reference” and “linked 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 “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁶ 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.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of RLG 385, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

² French Food Safety Agency, Afssa, before 1 July 2010

³ 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>

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

⁵ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

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

1.5 Letter(s) of access

Not relevant for this application.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	RLG 385
Authorisation number	21711306
Function	Plant growth regulator
Applicant	L. GOBBI
Composition	30.2 g/L 1-naphthylacetic acid
Formulation type (code)	Soluble liquid (SL)
Packaging	Not relevant for extension of authorisation according article 51.

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not relevant for extension of authorisation according article 51.

2.2.2 Classification and labelling in accordance with Regulation (EC) No1272/2008

Not relevant for extension of authorisation according article 51.

2.2.3 Other phrases in compliance with Regulation (EU) No 547/2011

Refer to the decision of product authorization.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment ⁷ : refer to the Decision in Appendix 1 of product authorisation.
Re-entry period ⁸ : refer to the decision of product authorisation.
Pre-harvest interval ⁹ : not relevant.
Other mitigation measures: refer to the decision of product authorisation.
The label must reflect the conditions of authorisation.

⁷ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

⁸ The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

⁹ According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

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: 23/01/2026

PPP (product name/code): RLG 385

Formulation type: SL ^(a, b)

Active substance 1: 1-naphthylacetic acid

Conc. of a.s. 1: 30.2 g/L ^(c)

Safener: -

Conc. of safener: - ^(c)

Synergist: -

Conc. of synergist: - ^(c)

Applicant: L. GOBBI

Professional use:

Zone(s): National ^(d)

Non-professional use:

Verified by MS: Yes

Field of use: Plant growth regulator

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or situation (crop destination/purpos e 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/K ind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
Minor uses according to Article 51 (zonal uses)													
4	FR	Tree nursery, ornamental trees, Christmas tree plantation	F	None, used as growth factor	Rolling	1st appl.: terminal shoot length= 10 cm 2nd appl.: terminal shoot length= 30-35 cm	a) 1 b) 2	7	a) 0.042 b) 0.084	a) 1.268 b) 2.537	1 L/1000 trees 6 L/6000 trees 6 L/ha	NA	Acceptable for Christmas tree (PIEAB)

Remarks table heading:	<ul style="list-style-type: none"> (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 	<ul style="list-style-type: none"> (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.
Remarks columns:	<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> 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 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The physico-chemical properties of the formulation have been evaluated taken into account the concentration of uses (concentration of 0.083% v/v) and considered acceptable during the registration of this formulation.

The concentrations of uses claimed for this extension of uses (concentration of 0.7% v/v) are not covered by the previous assessment. Physico-chemical tests (persistent foaming and dilution stability) were carried out at 0.083% v/v according to the studies provided for the first authorization. The level of foam was 33 mL and stability of the dilution showed no residue (clear solution). However, results cannot be extrapolated to the new claimed use rate (0.7% v/v). Hence, the following physico-chemical tests at the highest concentration (0.7% v/v) are missing and should be provided at the renewal of the preparation:

- Persistent foam test using MT 47.3 method
- Dilution stability test using MT 41.1 method

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical method for the determination of the active substance in the preparation has already been provided and deemed acceptable for the first authorization.

3.1.2.2 Analytical methods for residues

The claimed use is non-food. Therefore, no method is required for the determination of residues in plant-based and animal-based products.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute toxicity

RLG 385 has a low toxicity in respect to oral, dermal and acute inhalation toxicity. RLG 385 has no sensitising properties, is not irritating to the skin and eyes.

3.1.3.2 Operator exposure

The detailed operator exposure assessment is presented in the registration report B3.

In conclusion, according to the exposure assessment performed with the EFSA model 2022¹⁰, the operator exposure to RLG 385 is below the AOEL value of 1-NAA, with a workwear and gloves during mixing/loading and application.

3.1.3.3 Worker exposure

The detailed worker exposure assessment is presented in the registration report B3.

In conclusion, according to the exposure assessment performed with the EFSA model 2022¹¹, the worker exposure to RLG 385 is below the AOEL value of 1-NAA, without workwear and gloves.

¹⁰ Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products (EFSA Journal 2022;20(1):7032)

¹¹ Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products (EFSA Journal 2022;20(1):7032)

3.1.3.4 Bystander exposure

For the active substance 1-NAA, only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2022;20(1):7032):

“When an acute risk assessment is not triggered (i.e. for PPPs containing active substances that are not acutely toxic, and for which the setting of an AAOEL was not necessary), no bystander risk assessment is required. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure”.

3.1.3.5 Resident exposure

The detailed resident exposure assessment is presented in the registration report B3.

In conclusion, according to the exposure assessment performed with the EFSA model 2022¹², the resident exposure to RLG 385 is below the AOEL value of 1-NAA, with a buffer zone 10 meters and without drift reduction technology.

3.1.4 Residues and Consumer Exposure

Ornamental trees are not intended for human or animal food, the assessment of consumer exposure was not considered necessary for these uses.

3.1.5 Environmental fate and behaviour

Considering the mode of application for the product RLG 385 (roller application), exposure of environmental compartments to the active substance is considered negligible. Consequently, no risk assessment for environment and non-target organisms is deemed necessary for use on ornamental trees (Christmas trees).

3.1.6 Ecotoxicology

Considering the mode of application for the product RLG 385 (roller application), exposure of environmental compartments to the active substance is considered negligible. Consequently, no risk assessment for environment and non-target organisms is deemed necessary for use on ornamental trees (Christmas trees).

3.1.7 Efficacy

According to Article 51 of Regulation (EC) No 1107/2009, the efficacy assessment and the absence of any phytotoxicity risk on the crop is not necessary.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted as proposed in Appendix 1 – Copy of the product Decision.

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

No further information is required.

¹² Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products (EFSA Journal 2022;20(1):7032)

Appendix 1 – Copy of the French Decision



RLG385_PMIN_2024
-2819_D.pdf

Appendix 2 – Copy of the draft product label as proposed by the applicant

FRUIT AUXIN 30 SL® - AMM n° 2171306
Contient : 30,2 g/L d'acide 1-naphtylacétique (1-NAA) - UFI : 4QGO-J0T4-100R-QJ0Y

H412 - Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme.
P101 - En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette.
P102 - Tenir hors de portée des enfants.
P273 - Eviter le rejet dans l'environnement.
P501 - Eliminer le conteneur/ récipient en accord avec les réglementations nationales.

EUH401 - Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.
SP1 - Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.
SPe3 - Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

Le produit FRUIT AUXIN 30 SL® étant un régulateur de croissance, des risques de phytotoxicité différents peuvent être attendus selon les variétés.
Délai de rentrée : 6 heures.

EN CAS D'URGENCE

Composer le 15 ou le 112, ou contacter le Centre Antipoison le plus proche

Puis signaler vos symptômes au réseau Phyl'altitude, N° vert 0800 887 887 (appel gratuit depuis un poste fixe).

PREMIERS SOINS

S'éloigner de la zone dangereuse.

En cas de contact cutané : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet avec du savon.

En cas de projection dans les yeux : rincer immédiatement pendant 15 minutes sous un filet d'eau paupières ouvertes. Retirer les lentilles de contact après quelques minutes et rincer abondamment de nouveau. Consulter un spécialiste.

En cas d'inhalation : Déplacer la victime à l'air frais. Si la victime ne respire plus, la placer sous respiration artificielle. Contacter les secours.

En cas d'ingestion : rincer immédiatement la bouche avec de l'eau si la victime est consciente. Contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

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.

En cas d'intoxication animale, contactez votre vétérinaire.

Fiche de Données de Sécurité disponible sur www.quickfds.com

STOCKAGE A L'ABRI DU GEL ET DE LA CHALEUR

DE SANGOSSE 

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