REGISTRATION REPORT

Part A

Risk Management

Product name: MODDUS

Active substance:

trinexapac-ethyl 250 g/L

COUNTRY:

FRANCE

NATIONAL ASSESSMENT

Application for a label extension according to Art. 51

-

Minor uses

Applicant: Syngenta France SAS

Date: 28/03/2018

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PART A – Risk Management

The company Syngenta France SAS, has requested a label extension according to Article 51 in France for the product MODDUS.

This document describes the specific conditions of use and labelling required for extension of the registration of MODDUS containing trinexapac-ethyl in France.

The risk assessment conclusions 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.

Appendix 3 of this document is a copy of the letter(s) of access.

1 DETAILS OF THE APPLICATION

1.1 Application background

MODDUS is a micro-emulsion containing 250 g/L of trinexapac-ethyl, for use as a growth regulator for lodging control. The aim of this registration application is to gain a label extension for poppy.

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

1.2 Active substance approval

Trinexapac-ethyl

Regulations Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. (extension of the approval period – Reg. (EU) No 678/2014)
Specific provisions of regulation 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 trinexapac, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of birds and mammals. Conditions of authorisation should include risk mitigation measures, where appropriate.
An EFSA conclusion is available (EFSA Scientific Report (2005) 57, 1-70). A Review Report is available (SANCO/ 10011 /06 final, 4 April 2006).

1.3 Regulatory approach

The present application (No 2014-2572) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1].

The current document based on Anses' assessment of the application submitted for this product is in compliance with Regulation (EC) No 1107/2009[2], 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 2017[3] 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) No 546/2011[4], and are expressed as "acceptable" or "unacceptable" in accordance with those criteria.

Last, the French Order of 26 March 2014[5] 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 this French order. .

Then, at FR level, possible extrapolation of submitted data and corresponding assessment from "reference" crops to linked ones are assessed even if not clearly intended by applicant in the dRR, and a conclusion is reached on acceptability of intended uses on those linked crops. The aim of this order, mainly based on EU document on residue data extrapolation [6] is to supply minor crops with registered PPP.

Then, GAPs table (§2.3.) and decision may include uses on crops not clearly intended by applicant.

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

1.4 Data protection claims

[1] French Food Safety Agency, Afssa, before 1 July 2010
[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] 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
[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] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo
[6] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

There is no new data submitted with this application.

1.5 Letter(s) of access

Not relevant for this application.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name	MODDUS
Authorisation number	9100046
Function	plant growth regulator
Applicant	Syngenta France SAS
Composition	250 g/L trinexapac-ethyl
Formulation type (code)	micro-emulsion (ME)
Packaging	Not relevant for extension of authorization according to Article 51.

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not relevant for extension of authorization according to Article 51.

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

Not relevant for extension of authorization according to Article 51.

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

N/A : no label extension grantedOther phrases linked to the preparation

Wear suitable personal protective equipment[7]: N/A : no label extension granted
Re-entry period[8] : N/A : no label extension granted
Pre-harvest interval[9] : N/A : no label extension granted
Other mitigation measures: N/A : no label extension granted

[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 2017concerning 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:
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

PPP (product name/code):	**MODDUS**	**Formulation type:**	**ME**
active substance:	**trinexapac-ethyl**	**Conc. of as:**	**250 g/L**
Applicant:	**Syngenta France SAS**	**professional use**	☒
Zone:	**France**	**non-professional use**	☐

Verified by MS: **yes**

Crop and/ or situation (a)	**Zone**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)** (l)	**Remarks:** (m)
				Type (d-f)	**Conc. of as** (i)	**method kind** (f-h)	**growth stage & season** (j)	**number min max** (k)	**interval between applications (min)**	**L product/ha min max**	**water L/ha min max**	**kg as/ha min max**		
poppy (PAPSO)	FR	F	plant growth regulator	ME	250 g/L	spraying	BBCH 39 used as a foliar treatment during the stem elongation, before the first flower bud becomes visible, in May-June	1	-	1.5	200 - 400	0.375	> 45 (BBCH 39 max)	**Not acceptable** Unacceptable risks for operators, and workers (not covered by previous assessments).

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at 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
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) 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

Not relevant for extension of authorization according to Article 51.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Not relevant for extension of authorization according to Article 51.

3.1.2.2 Analytical methods for residues

Further data for this application are not necessary.

3.1.3 Mammalian Toxicology

The risks to operators, and workers related to this extension of claimed use (poppy at 1.5 L/ha) are not covered by previous assessments at 0.5 L/ha, 0.6 L/ha and 0.8 L/ha.

3.1.4 Residues and Consumer Exposure

The residue behaviour of the active substance trinexapac has been recently evaluated in the framework of the review of the existing MRLs for trinexapac (EFSA, 2012). Metabolism of this active substance was sufficiently investigated to define residue for enforcement and risk assessment in poppy seed and to evaluate the intended cGAPs on this crop.

3.1.4.1 Residues

The intended cGAPs for the plant protection product MODDUS on poppy seed is based on the available EU residue data on rape seed which support the authorised GAPs in NL (EFSA, 2012). The EU MRL on rape seed is derived from this GAP.

Residue trials

Table 3.1.4.1-1. Comparison between intended GAP and authorised GAP

Crop	Type of GAP	Number of applications	Application rate per treatment (g sa/ha)	Interval between application	Growth stage at last application	PHI (days)
Poppy seed	Intended FR	1	375 g/ha	-	BBCH 39	45
Rape seed	Registered GAP in NL Article 12, EFSA 2012	1	380 g/ha	-	BBCH 51-55	F

The EU registered GAP on rape seed is comparable to the intended FR GAP on poppy seed. According to EU guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (SANCO 7525/VI/95 – rev.9, extrapolation from rape seed to poppy seed is possible. Therefore reference is made to residue assessment achieved in the framework of the EU review of the existing MRLs for trinexapac.

A total of 20 trials performed in Northern Europe have been considered suitable to support the authorised GAP in NL and to derive MRL as well as risk assessment values. In France, only trials performed in Northern EU are required to support use on poppy seed, so it is considered that enough residue data are available to support the GAP

of MODDUS on this crop.

Residue levels in those trials are summarised in the table below.

Commodity	Poppy seed	
Source	Article 12 (EFSA, 2012)	
EU zone	North (20)	South
Evaluation GAP Residue levels (mg/kg)	**Trials on rape seed compliant with the GAP : 1x 380 g/ha, BBCH 51-55** 0.04, 0.12, 0.13, 2x0.15, 0.16, 0.19, 2x0.24, 0.26, 0.27, 2x0.29, 0.31, 0.33, 3x0.64, 0.90, 1.0	No data available
STMR (mg/kg)	0.27	-
HR (mg/kg)	1	-
Rber (mg/kg)	1.13	-
Rmax (mg/kg)	0.99	-
OCDE	1.42	-
Data resulting MRL (mg/kg)	1.5	-
In force EU MRL (mg/kg) (1)	2	
MRL compliance resulting / in force	Y	

On the basis of the available supporting residue data it is possible to conclude that the in force MRL on poppy seed of 2 mg/kg (Reg. (EU) No 87/2014) will not be exceeded according to the intended GAP.

Furthermore 15 analytical residue data are available on poppy seed. These data are derived from poppy seed treated with 1 application at 375 g trinexapac/ha, BBCH 39, PHI 59-63 days. In these conditions the residue level in poppy seed at harvest ranging from 0.21 to 0.41 mg/kg. These analytical data confirms that when poppy seed are treated according to the intended cGAPs the in force MRL on this crop will not be exceeded.

Livestock feeding studies

Intended use on poppy seed do not modify dietary burden, further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Industrial Processing and/or Household Preparation

In processed commodities, trinexapac-ethyl was shown to be stable during pasteurisation, boiling, brewing, baking and sterilisation. A study conducted with trinexapac however showed that at the end of incubation, trinexapac had degraded and represented 51-59% of the total radioactivity and that two main metabolites are formed. One of them was not of toxicological concern but for the other metabolite the complete toxicology package has not been submitted. Nevertheless, since the TMDI represents less than the trigger value of 10% ADI processing studies are not mandatory. Therefore further data are currently not considered essential.

Residues in representative succeeding crops

Residues in succeeding crops have been sufficiently investigated; it is very unlikely that residues of trinexapac will be present in succeeding crops.

3.1.4.2 Consumer exposure

An assessment of residue uptake by consumers (TMDI calculation, EFSA PRIMo) results in the following maximum ADI consumptions:

Trinexapac (0.32 mg/kg bw/d) – 3.2 % ADI for UK Tolder.

An ARfD was not deemed necessary for trinexapac therefore acute exposure calculations were not carried out for this active substance.

Then, no chronic or acute risk is expected from the consumption of poppy seed treated according to the intended GAPs.

3.1.5 Environmental fate and behaviour

According to previous risk assessments performed by Anses, no unacceptable risk for groundwater and for non-target organisms is expected. Similar mitigation measures as defined for previous risk assessment apply.

3.1.6 Ecotoxicology

According to previous risk assessments performed by Anses, no unacceptable risk for groundwater and for non-target organisms is expected. Similar mitigation measures as defined for previous risk assessment apply.

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, considering that risk for operators and workers are not covered by already registered uses,, an authorization **cannot 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.

Appendix 1 – Copy of the French Decision

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Décision relative à une demande d'extension d'usage 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'extension d'usage mineur du produit phytopharmaceutique ***MODDUS***

de la société *SYNGENTA FRANCE SAS*

enregistrée sous le *n°2014-2572*

Vu les conclusions de l'évaluation de l'Anses du 1er décembre 2017,

Considérant que les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour l'opérateur et le travailleur,

Considérant qu'en conséquence, les exigences mentionnées à l'article 51 du règlement (CE) n°1107/2009 ne sont pas remplies

L'extension d'usage du produit référencé ci-après **n'est pas accordée** en France.

MODDUS

AMM n°9100046

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Informations générales sur le produit	
Nom du produit	MODDUS CIRCLE SCITEC
Type de produit	Produit de référence
Titulaire	SYNGENTA FRANCE SAS 12 Chemin de l'Hobit 31790 Saint Sauveur FRANCE
Formulation	Micro-émulsion (ME)
Contenant	250 g/L - trinexapac-éthyl
Numéro d'intrant	9100046
Numéro d'AMM	9100046
Fonction	Régulateur de croissance
Gamme d'usages	Professionnel

A Maisons-Alfort, le 2 8 MARS 2018

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

MODDUS

AMM n°9100046

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
Pavot œillette*lutte contre la verse	1,5 L/ha	1/an	45
	Motivation du refus : L'usage est refusé au motif que les résultats d'évaluation disponibles pour l'utilisation du produit ne permettent pas d'exclure un risque d'effet nocif pour les opérateurs et les travailleurs.		

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

iteipmai
Aurélie FURET
Mars 2014

MODDUS

MODDUS
[250 g de trinexpac-éthyl/l]

Proposition d'étiquette

Conditions d'utilisation sur plantes à parfum, aromatiques et médicinales.

MODDUS peut être utilisé sur les cultures de plantes aromatiques et médicinales, dans les conditions et aux doses d'emploi mentionnées ci-dessous :

Espèce	Stade	Complément de stade	Dose	Nb. applis	DAR
Pavot œillette	En période de montaison	Avant que le premier bouton floral ne devienne visible, en mai-juin	1.5 l/ha	1	> 45 J

Renseignements complémentaires

Pour tout renseignement complémentaire sur l'utilisation de **MODDUS** sur plantes à parfum, aromatiques et médicinales, contacter de manière préférentielle l'**iteipmai** au tél : 02.41.30.30.79

Appendix 3 – Letter(s) of Access

Not applicable