

After consultation of the regions, the need for this authorisation was not confirmed. It will hence not be evaluated nor granted.

Advice of the regions :

Only try to resolve this problem on the succeeding crops with treatment of plant protection products is not a “Good agricultural practice”

The “Good agricultural practice” is to avoid/limit the potatoes in the succeeding crops by:

- **Limiting the potato losses;**
- **Ensuring that potatoes losses can freeze. So no deep tillage after potatoes harvesting**
- **To have better rotation. The succeeding crops who can have a problem of potatoes storage don't have to follow potatoes within the next two years.**
- **The use of products based on maleic hydrazide to reduce the formation of potato sprouts in the succeeding crops**

N(23341P/B) – CORAGEN (9822P/B)

Type of product	Insecticide
Formulation type	SC
Active substance(s) and content	200 g/L chlorantraniliprole
Formulation code	(development code)

Application for authorization for 120 days (Art. 53 – Emergency situations in plant protection products – Regulation 1107/2009)

Requested application period 120-days: from **1/7/2018 till 28/10/2018**

Destination Professional use

Status of active substance Chlorantraniliprole is on annex I, [Reg. \(EU\) No 1199/2013](#), [Reg. \(EU\) No 540/2011](#)
expiration of approval 30/04/2024

Problem description (all sections below should be completed by the applicant):

In attachment:

Note of FAVV about the control of Colorado beetle: <http://www.afsca.be/plantaardigeproductie/ziekten/aardappelen/coloradokever/>

PCA (potato research centre) – www.pcainfo.be - <https://www.pcainfo.be/Home/PCANieuws/de-coloradokever-in-beeld>

Altacor (35 % chlorantraniliprole) is already authorized in France:


2010: evaluation report: <https://www.anses.fr/fr/system/files/DPR2009ha0641.pdf>

2015: Efsa: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4216>

2018: actual label in France: <https://ephy.anses.fr/ppp/altacor>

Remark: Chlorantraniliprole is on the Belgian market as commercial product Altacor and Coragen. Altacor is authorized in crops under protection and Coragen is authorized in crops in open field.

Notwithstanding, Altacor is authorized in beans in France, it's more logic to have an authorization for Coragen in outdoor crops. And it's more likely that growers are already in possession of Coragen, because of other crops in rotation with peas and beans.

<p>Danger (<i>pest name EPPO, English and scientific</i>) <i>Group names only acceptable in case of approved substances</i>)</p>	<p>Colorado beetle - <i>Leptinotarsa decemlineata</i> – LPTNDE</p>  <p>Source: PCA, Kruishoutem (www.pcainfo.be)</p>
<p>Crop, plants or situation (<i>crop or plant name EPPO, English; no group names</i>)</p>	<p>Peas (with pods) (outdoor) (<i>Pisum sativum</i>) - PIBSX</p> <p>Beans (with pods) (outdoor) (<i>Phaseolus vulgaris</i>) - PHSVX</p>
<p>Minor or major use (<i>Indicate if the use is considered to be minor</i>)</p>	<p>Minor use for the requested crops</p>
<p>Further limitations (<i>e. g. amount of product, restriction to certain regions or individual sites, conditions to be checked by regional plant protection service</i>)</p>	<p>Law of 19 November 1987: obligation to control Colorado beetle in potatoes. Note of FAVV of 10/08/2017: http://www.afsca.be/plantaardigeproductie/ziekten/aardappelen/coloradokever/</p>
<p>MRL: Reference to product code number in Annex I of regulation (EC) No 396/2005</p>	<p>0260010 Beans (with pods) 0260030 Peas (with pods)</p>

<p>Compliance with MRL set in Regulation (EC) No 396/2005 (<i>yes/no; if no, complete attached GAP table and provide proposal for tMRL and consumer risk assessment</i>)</p>	<p>YES</p>
<p>Value of tMRL if needed, including information on the measures taken in order to confine the commodities resulting from the treated crop to the territory of the notifying MS pending the setting of a tMRL on the EU level. (PRIMO EFSA model to be attached)</p>	<p>/</p>
<p>Validated analytical method for monitoring of residues in plants and plant products.</p>	<p><i>Source:</i> Conclusion on the peer review of the pesticide risk assessment of the active substance chlorantraniliprole - EFSA Journal 2013;11(6):3143 - https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2013.3143</p> <p>1. Identity, physical/chemical/technical properties and methods of analysis The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000) and SANCO/825/00 rev. 8.1 (European Commission, 2010).</p> <p>The minimum purity of the active substance is 950 g/kg. No FAO specification exists.</p> <p>The specification is based on industrial scale production. The impurities acetonitrile, 3-picoline and methanesulfonic acid are relevant impurities from the toxicological point of view, although at the level found in the technical specification they are considered to be of no concern. The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of chlorantraniliprole or the representative formulation. The main data regarding the identity of chlorantraniliprole and its physical and chemical properties are given in appendix A.</p> <p>Adequate analytical methods are available for the determination of chlorantraniliprole in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material. Appropriate LC-MS/MS methods are available for the post-registration monitoring of chlorantraniliprole in food of plant and animal origin with LOQs of 0.01 mg/kg.</p> <p>Validated analytical methods based on HPLC-MS/MS or GC-ECD exist for the determination of chlorantraniliprole in soil with LOQs of 0.5 µg/kg or 0.01 mg/kg respectively. Residues of chlorantraniliprole</p>

	<p>in ground water and surface water can be monitored by HPLC-MS/MS method with LOQ of 0.1 µg/L. Pending on the final residue definition for monitoring, additional information might be required. LC-MS/MS method is available for the determination of chlorantraniliprole in air with LOQ of 0.5 µg/m³. A method for residues in body fluids and tissues is not required as the active substance is not classified as toxic or very toxic</p>
<p>Function of the product(<i>E.g. systemic long acting insecticide; foliar fungicide, used for regular control, elimination scenario etc</i>)</p>	<p>Insecticide to control Colorado beetle - <i>Leptinotarsa decemlineata</i> - LPTNDE</p>
<p>Type of danger to plant production or ecosystem. (<i>Provide reasoning for what category the 120 day authorisation is given: quarantine pest; emergent pest, either invading non-native, or native; emerging resistance in a pest, etc. Whereas reference to the EU quarantine legislation may suffice for quarantine pests elaborate reasoning should be provided for the category 'any harmful pest'</i>)</p>	<p>Colorado beetle - <i>Leptinotarsa decemlineata</i> - LPTNDE</p> <p>Colorado beetles are a known pest in potatoes, but can also be a problem in other crops because of the presence of potato storage.</p> <p>If potato storage is a problem in fields with crops like peas (with pods) and beans (with pods) and the Colorado beetle is present, not the damage on the peas and beans is the problem, but afterwards. Because of the mechanical harvest of peas and beans, a lot of Colorado beetles are within the harvested product. And it's very difficult to sort the beetles out during a sorting process. Companies of processing vegetables like peas and beans are working with optical sorting machines but even with these type of machines it's not possible to guarantee processed product (frozen or canned) without a Colorado beetle.</p> <p>In the harvest season of 2017, was the harvest of some fields with a known presence of Colorado beetle sent twice true the process of optical sorting, but even in that case, the processing industry couldn't guarantee product free of Colorado beetle.</p> <p>Colorado beetles overwinter in the soil as adults. In spring, depending on the soil temperature they become active and begin to feed on potato storage and weeds on the field. If the beetles have enough feed, they go through a complete life cycle (eggs and the 4 larval stages) on the same field. If no action is taken to control the Colorado beetle, in summer a multitude of beetles will hatch and move to potato fields. To avoid problems it's necessary to control potato storage and to control the beetles in the first or second larval stage, when they are not capable to migrate to other (potato) fields.</p> <p>The control of Colorado beetle is necessary for the processing crops, but also to control the population to anticipate to a next season. Because females can lay 500 or more eggs over a period of 4-5 weeks.</p>
<p>Size and effect of danger (<i>Describe shortly the area affected, the development over time of the infestation, and the agronomic and</i></p>	<p>Production area in Belgium: Peas 10.400 ha, with a production of 65 to 80.000 ton and beans 8.200 ha, with a production of 105.000 ton.</p>

<p><i>economic effects it has)</i></p>	<p>It's estimated that potato storage with the presence of Colorado beetle is a problem on 50% of the fields of peas and beans. Producers are strongly advised to remove manually as much as possible the potato storage on the fields, but that's only realistic for smaller fields and if not much potato storage is present in the field.</p> <p>The presence of Colorado beetles in harvested peas and beans is a problem for the processing industry. Because of the extra time needed to go at least two times through an optical sorting machine, to slow down the sorting process, and still no guarantee to have at the end a product free of Colorado beetle. It would be very inconvenient for a consumer to find a Colorado beetle in a package of frozen/canned peas or beans.</p> <p>And on the other hand, it's important to reduce the population of Colorado beetle. See also note of FAVV. http://www.afsca.be/plantaardigeproductie/ziekten/aardappelen/coloradokever/</p>
<p>Absence of any other reasonable means <i>(Describe the alternative control measures (chemical, non-chemical and cultural) and indicate why they do not (in combination) suffice. Describe which, if any, authorisations for the pest to be controlled exist in other Member States.</i></p>	<p>Against Colorado beetle are no active substances authorized in crops like peas and beans. In Belgium are only products against Colorado beetle authorized in potatoes.</p> <p>In Belgium, active substances authorized in potatoes against Colorado beetle are pyrethroids, spinosad, chlorantraniliprole and azadirachtine.</p> <p>Some pyrethroids have also an authorization in peas or beans against another enemy, but the efficacy against Colorado beetle is too low. Specially at higher temperatures as in summer. For azadirachtine are no data available for peas and beans.</p> <p>The active substance chlorantraniliprole is already authorized in potatoes (Coragen; 8922P/B)) against Colorado beetle and has already an authorization in beans (with pods) indoor against caterpillars. And chlorantraniliprole is in France (Altacor) also authorized in beans (with pods) outdoor.</p> <p>Altacor (35% chlorantraniliprole) is already authorized in France in beans (with pods): 2010: evaluation report: https://www.anses.fr/fr/system/files/DPR2009ha0641.pdf - note that the MRL of 0,8 mg/kg, was applicable from 24/06/2015, Reg. (EU) 2015/845. 2015: Efsa: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4216 2018: actual label in France: https://ephy.anses.fr/ppp/altacor</p> <p>And extrapolation is possible to peas (with pods), which is supported by the Lundehn-document vs. 10.3.</p>

	<p>An advantage of use of chlorantraniliprole is the low impact on other beneficials in beans. Spinosad is also an option, but is in a lot of case already needed against thrips, caterpillars and miner flies. To avoid resistance it's necessary to have also an active substance of another resistance group available. Spinosad [5], pyrethroids [3A] and chlorantraniliprole [28].</p> <p>This 120 days authorization is needed to control Colorado beetle - <i>Leptinotarsa decemlineata</i> as much as possible on the field, to avoid problems with the presence of Colorado beetle during the sorting process and to avoid population growth.</p> <p>See also note of:</p> <ul style="list-style-type: none"> - FAVV of 10/08/2017 – The control of Colorado beetle is mandatory. - PCA (potato research centre) – www.pcainfo.be
<p>Rationale (<i>Reason the risk management decision based on the findings of 15 to 18, containing especially a description of measures taken to ensure consumer protection</i>).</p>	/
<p>Mitigation measures (<i>Describe what mitigation measures are taken if needed for minimising risk to humans, animals, and the environment, attach summary risk assessment. Describe what measures are taken to limit and control use</i>)</p>	<p>This request is only for use in beans and peas (with pods), because of the mechanical harvest and processing steps.</p> <p>Producers are strongly advised to destroy manually the potato storage as much as possible. But chemical control is also needed to control the problem of Colorado beetle in beans and peas.</p>
<p>Applications in progress (<i>The use notified may have been applied for already, or a suitable alternative PPP may be in the process of authorisation. Describe such applications, including a possible date of authorisation</i>)</p>	<p>Actually, no authorisations are available to control Colorado beetle in beans and peas.</p> <p>But because of the problems in season 2017 and the first findings in May of Colorado beetle in potato storage in fields with beans and peas are growers and the processing industry very concerned about season 2018.</p> <p>Because of the timing to control Colorado beetle it's necessary to ask for an emergency use for chlorantraniliprole.</p> <p>The time line for a request for a regular extension is in this case too long, but an authorization is possible because data are available.</p>

	<p>Chlorantraniliprole is authorized in France in beans (with pods) and extrapolation is possible to peas (with pods).</p> <p>2010: evaluation report: https://www.anses.fr/fr/system/files/DPR2009ha0641.pdf - note that the MRL of 0,8 mg/kg, was applicable from 24/06/2015, Reg. (EU) 2015/845.</p> <p>2015: Efsa: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4216</p> <p>2018: actual label in France: https://ephy.anses.fr/ppp/altacor</p>
<p>Research activities (<i>Describe the research efforts undertaken and/or in progress, their aims, their funding, and their expected date of results. This is needed for all categories of dangers, except quarantine pests that can still be eliminated, or infrequent pests, for which no official application for a normal authorisation or extension of use of the plant protection product exists.</i> <i>In case of a repeated notification: indicate the state of works of the research projects.</i>)</p>	<p>There is a lot of experience to control Colorado beetle in potatoes available at the research station PCA. Chlorantraniliprole is one of the active substances with a good efficacy against Colorado beetle and with the advantage of having a low impact on other beneficials.</p> <p>And the processing industry had very bad experiences with the harvest of season 2017.</p> <p>An insecticide is needed to control Colorado beetles next to potato fields also in fields with beans and peas (with pods).</p>

1. PHYSICAL/CHEMICAL PROPERTIES AND METHODS OF ANALYSIS

Advice of the expert concerning physical-chemical analysis and analysis methods:


2. TOXICOLOGY

Applicant proposal for labelling:

Classified as:	Dangerous for the environment
Hazard symbol:	N
Risk phrases:	R50/53
Safety phrases:	S2-S13-S20/21-S35-S61

CLP proposal for labelling:

Proposed Classification:

Classification:	
Symbol(s):	GSH09
Pictograms	
Signal words:	WARNING
H-statement(s):	H410
P-statement(s):	P391
Other mentions:	EUH208, EUH401, SP1, SPo, SPe3

*Advice of the expert concerning toxicology :***3. EFFICACY**Requested usage

GAP rev. , date: 2018-06-13

PPP (product name/code) CORAGEN
active substance 1 chlorantraniliprole

Formulation: Type: SC type
Conc. of as 1: 200 g/L

safener: /
synergist: /

Conc. of safener: n.a.
Conc. Of synergist: n.a.

Applicant: KDT

company: FMC CHEMICAL S.P.R.L.

1	2	3	4	5	6	7	8	9	10	11	12
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Use- No.	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
				Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	Beans (with pods) (outdoor) 0260010	F	Colorado beetle - <i>Leptinotarsa decemlineat - LPTNDEa</i>	Spray application		2 applications Interval: 7 days	0,15 kg/ha	0,03 kg as/ha		1 day	
2	Peas (with pods) (outdoor) 0260030	F	Colorado beetle - <i>Leptinotarsa decemlineat - LPTNDEa</i>	Spray application		2 applications Interval: 7 days	0,15 kg/ha	0,03 kg as/ha		1 day	

Te behandelen	groengeoogste erwten (met peul) (open lucht) (<i>Pisum sativum</i>) - PIBSX stamslabonen (prinsessen-, snijboon) (groengeoogst, met peul) (open lucht) (<i>Phaseolus vulgaris</i>) - PHSVX	A traiter	pois verts (avec cosse) (mange- tout) (plein air) (<i>Pisum sativum</i>) PIBSX haricot vert (recolté frais, avec cosse)(plein air) (<i>Phaseolus vulgaris</i>) - PHSVX	To be treated	Peas (with pods) (outdoor) (<i>Pisum sativum</i>) - PIBSX Beans (with pods) (outdoor) (<i>Phaseolus vulgaris</i>) - PHSVX
Wachttijd	1 dag	Délais	1 jour	Waiting period	1 day
Vijand	coloradokever (<i>Leptinotarsa decemlineat - LPTNDEa</i>)	Ennemis	doryphore de la pomme de terre (<i>Leptinotarsa decemlineat - LPTNDEa</i>)	Enemy	Colorado beetle (<i>Leptinotarsa decemlineat - LPTNDEa</i>)
Dosis	0,15 kg/ha	Dose	0,15 kg/ha	Rate	0,15 kg/ha
Aantal toepassingen	2 toepassingen met een interval van 7 dagen	Nombre de traitements	2 applications à l'intervalle de 7 jours	Number of applications	2 applications with an interval of 7 days

Advice of the expert concerning biology:

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4. RESIDUS**4.1. End points**

Active substance	chlorantraniliprole
ADI (mg/kg bw/d) + source (Review report or JMPR*)	1,56 mg/kg bw per day – EFSA 2013
ARfD (mg/kg bw) + source (Review report or JMPR*)	Not applicable - EFSA 2013
Residue definition for products of plant origin + tested crop category	
Residue definition for products of animal origin + tested animals	

*see doc. 3010 at the following internet address: http://europa.eu.int/comm/food/plant/protection/evaluation/index_en.htm

4.2. MRL's setting

Products of plant origin						
Crop	Existing EU MRL (mg/kg) + Directive EC	Existing Belgian MRL (mg/kg)	Proposed MRL (mg/kg)	Proposed critical GAP (application rate s.a. kg/ha, application number, PHI or crop growth stage)	Residue trials complying with the critical GAP (number, north/south/indoor) or extrapolation (guideline reference)	<i>Argumentation or study reference (tile, author, year, ref n° applicant, ref n° lab). GLP: Y/N</i>
Beans with pods 0260010	0,8 mg/kg			0,03 kg as /ha, 2 applications, interval 7 days, PHI: 1 day	Gap is supported by the MRL	<i>Chlorantraniliprole is Authorised in FR</i>
Peas with pods 0260030	2 mg/kg			0,03 kg as /ha, 2 applications, interval 7 days, PHI: 1 day	Gap is supported by the MRL	<i>Extrapolation from beans with pods to peas with pods, Lundehn vs. 10.3</i>
Products of animal origin						
Product	Existing EU MRL (mg/kg) + Directive EC	Existing Belgian MRL (mg/kg)	Proposed MRL (mg/kg)	Tested animal	<i>Argumentation or study reference (tile, author, year, ref n° applicant, ref n° lab). GLP: Y/N</i>	

Chlorantraniliprole (DPX E-2Y45) (F)

Pesticide residues and maximum residue levels (mg/kg)

(*) Indicates lower limit of analytical determination

Pesticides - Web Version - EU MRLs (File created on 15/06/2018)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg. (EU) 2017/1016	Reg. (EU) 2018/687	Reg. (EU) 2016/567	Reg. (EU) 2015/845	Reg. (EU) No 36/2014
0260000	. Legume vegetables					
0260010	. Beans (with pods)	0.8	0.8	0.8	0.8	0.5
0260020	. Beans (without pods)	0.01*	0.01*	0.01*	0.01*	0.01*
0260030	. Peas (with pods)	2	2	2	0.01*	0.01*
0260040	. Peas (without pods)	0.01*	0.01*	0.01*	0.01*	0.01*

*Advice of the expert concerning residues :***5. FATE AND BEHAVIOUR***Advice of the expert concerning fate and behaviour:***6. ECOTOXICOLOGY***Advice of the expert concerning ecotoxicology:*