cerfa
No. 15722*01

FORM RELATING TO A MARKETING AUTHORISATION FOR A PLANT PROTECTION PROJECT, ADJUVANT OR MIXED PRODUCT

Under Regulation (EC) No 1107/2009 and Chapter III, Title V in Book II of the French Rural and Maritime Fishing Code

To fill out this form and prepare the dossier, refer to the explanatory note (CERFA No. 52173#01)

This translation into English is provided for information only. The form Cerfa 15722*01 must be completed in French and only that version is officially valid".

anses

Please send to:
ANSES-DAMM-UIA
14 rue Pierre et Marie Curie
ACI-COP-3-043
94701 MAISONS-ALFORT Cedex
FRANCE

BOX RESERVED FOR THE ADMINISTRATION – LEAVE BLANK

REGISTRATION NO.: |__|__|__|__|__|__|__|__|__| DATE RECEIVED: |__|__|/|__|__|/|__|__|__|__|

1. IDENTIFICATION OF THE APPLICATION:

1.1. PRODUCT TYPE: ☐ Plant protection product ☐ Adjuvant ☐ Mixed product

1.2. RANGE OF USES: ☐ Professional ☐ Amateur

1.3. APPLICATION TYPE:

1.3.1. Marketing authorisation (MA) application:
- ☐ New authorisation *(1)*[i]
- ☐ New authorisation by mutual recognition *(2)*
- ☐ New authorisation for a generic product *(3)*
- ☐ New authorisation for a resale product *(4)*
- ☐ New authorisation for a second-range product *(5)*

1.3.2. Authorisation renewal application:
- ☐ Ten-year renewal (adjuvant) *(6)*
- ☐ Renewal following the re-approval or approval of an active substance *(7)*

1.3.3. Application to totally or partially withdraw an MA:
- ☐ MA withdrawal *(8)*
- ☐ Use withdrawal *(9)*

1.3.4. Claim for:
1.3.4.1. bee notation *(10)*
- ☐ Application authorised during flowering
- ☐ Application authorised during exudate-production periods

1.3.4.2. Product type:
- ☐ biocontrol
- ☐ low risk

1.3.5. Other application *(15)*
- ☐ Post-authorisation monitoring

1.3.6. Application to amend an authorisation with scientific assessment:
- ☐ Extension of major uses *(11a)*
- ☐ Extension of minor uses *(11a) (other than Article 51*[ii]*)*
- ☐ Extension of minor uses *(11b) (according to Article 51)*
- ☐ Extension of uses by mutual recognition *(11c)*
- ☐ Minor change of composition *(12)*
- ☐ Change of classification *(13)*
  - ☐ By calculation ☐ With studies
- ☐ Another MA amendment case *(14)*

Specify the requested amendment type:
_____
_____

1.3.7. Application to amend an authorisation with administrative examination:
- ☐ Change of trade name *(16)*
- ☐ Addition of a new trade name *(17)*
- ☐ MA transfer to another holder *(18)*
- ☐ Classification amendment notification *(19)*
- ☐ Another MA amendment case *(20)*

Specify the requested amendment type:
_____
_____

1.3.8. Amendment of an application currently being assessed:
- ☐ Amendment of information declared in a ongoing application *(21)*

Specify the number of the pending application: _____

Specify the requested amendment type:
_____
_____

1.4. CHARACTERISATION OF THE APPLICATION:

1.4.1. Characterisation of the assessment of the application:
☐ South Zone ☐ All zones ☐ National

1.4.2. Member State status for France:
- ☐ Rapporteur Member State for the South Zone assessment
- ☐ Rapporteur Member State for the all-zone assessment
- ☐ Concerned Member State

  Specify the Rapporteur Member State:
  For the South Zone assessment: _____
  For the all-zone assessment: _____
- ☐ Co-Rapporteur Member State

1.4.3. Clarification relating to the application:
- ☐ The application has been notified to ANSES

Specify the notification number: _____

- ☐ Application submitted for a product with an identical formulation *(22)*

[i] The numbers in italics refer to Annex I "Preparation of dossiers" of the explanatory note for filling-out the application form (Cerfa 52173#01).
[ii] Article of Regulation (EC) No 1107/2009

Specify the Co-Rapporteur Member State For the South Zone assessment: _____ For the all-zone assessment: _____	

2. PRODUCT IDENTIFICATION:

2.1. Trade name: _____

2.2. If the product is already authorised in France, specify:

2.2.1. Authorisation number: _____

2.3. If the product is administratively related to a reference product, specify:

2.3.1. Name of the reference product: _____

2.3.2. Authorisation number of the reference product: _____

3. APPLICANT IDENTIFICATION:

Company name: _____

SIRET No.: _____ *(assigned by INSEE during registration in the national directory of businesses)*

☐ Registration pending (evidence of the request must be provided when submitting the application)

Intra-Community VAT No.: _____

Address: _____

_____

Post code: _____ Municipality: _____ Country: _____

E-mail address: _____

4. DETAILS OF THE CONTACT PERSON (FOR MONITORING THE DOSSIER):

SURNAME: _____ First name: _____

Company name: _____

Address: _____

_____

Post code: _____ Municipality: _____ Country: _____

Landline phone: _____ ;

Mobile phone: _____ ;

E-mail address: _____

Decisions and other final documents related to the application will be sent to the person and address indicated in Section 4.

5. ACTIVE SUBSTANCE(S) / SAFENER(S) / SYNERGIST(S) IN THE PRODUCT:

		Active substance(s) / Safener(s) / Synergist(s)			**Content of active substance**	**Unit (g/L, g/kg, CFU/g, OB/g, IU/g, etc.)**
5.1.	a)	*Active substance in French as mentioned in its approval Regulation*			*Content of pure A.S.*	*Unit*
	b)	*If applicable, active substance in French (expressed if necessary in its acid, salt, ester form, etc.)*			*Content of pure A.S.*	*Unit*
	Status	☐ pending approval or re-approval	☐ approved		☐ candidate for substitution	☐ low risk
	Type	☐ synthetic substance		☐ micro-organism		
		substance of natural origin	☐ of mineral origin			
			☐ of animal origin			
			☐ of plant origin	☐ not subject to chemical conversion ☐ with chemical conversion		
		chemical mediator	☐ pheromone	☐ other: please specify:		
5.2.	a)	*Active substance in French as mentioned in its approval Regulation*			*Content of pure A.S.*	*Unit*
	b)	*If applicable, active substance in French (expressed if necessary in its acid, salt, ester form, etc.)*			*Content of pure A.S.*	*Unit*
	Status	☐ pending approval or re-approval	☐ approved	☐ candidate for substitution		☐ low risk
	Type	☐ synthetic substance		☐ micro-organism		
		substance of natural origin	☐ of mineral origin			
			☐ of animal origin			
			☐ of plant origin	☐ not subject to chemical conversion ☐ with chemical conversion		
		chemical mediator	☐ pheromone	☐ other: please specify:		
5.3.	a)	*Active substance in French as mentioned in its approval Regulation*			*Content of pure A.S.*	*Unit*

	b)	*If applicable, active substance in French (expressed if necessary in its acid, salt, ester form, etc.)*		*Content of pure A.S.*	*Unit*
	Status	☐ pending approval or re-approval ☐ approved		☐ candidate for substitution	☐ low risk
	Type	☐ synthetic substance	☐ micro-organism		
		substance of natural origin	☐ of mineral origin		
			☐ of animal origin		
			☐ of plant origin	☐ not subject to chemical conversion ☐ with chemical conversion	
		chemical mediator	☐ pheromone	☐ other: please specify:	

6. PRODUCT DESCRIPTION:

6.1. PRODUCT FUNCTION:

☐ Herbicide ☐ Insecticide ☐ Fungicide ☐ Acaricide ☐ Molluscicide ☐ Elicitor of the crop's self-defence mechanisms ☐ Growth regulator ☐ Adjuvant ☐ Other: please specify:

_____

6.2. PHYSICAL STATE/FORMULATION TYPE:

Formulation type (CropLife International code[iii]): |__|__| name: _____

6.3. PRODUCT PACKAGING:

6.3.1. Case of a liquid product	Requested volume (L):	Nature of the packaging material:	System limiting (operator) exposure:
☐ Bottle (0 to 2L)			
☐ Can (above 2L to 20L)			
☐ Barrel (above 20L to 200L)			
☐ Tank (above 200L)			
☐ Other			
6.3.2. Case of a solid product	Requested mass (kg):	Nature of the packaging material:	System limiting (operator) exposure:
☐ Bag/pouches			
☐ Box			
☐ Cardboard box			
☐ Tube			
☐ Other			

6.3.3. Case of a product in tablet form:
Number of tablets per package: _____ Mass of one tablet: _____

6.3.4. Case of a product in passive diffuser form:
Diffuser material: _____ Diffuser volume: _____

6.3.5. Case of a product in soluble pouch form:
Soluble pouch material: _____ Soluble pouch volume or mass: _____

6.3.6. Other packaging:

6.3.7. System limiting user exposure (for tablets, diffusers, pouches or other packaging):

6.3.8. Comments:

7. PRODUCT MANUFACTURING SITES: ☐ *CONFIDENTIAL*

☐ Information given in Part C of the draft Registration Report.

Company name: _____
Address: _____
_____
Post code: _____ Municipality: _____ Country: _____

Company name: _____
Address: _____
_____
Post code: _____ Municipality: _____ Country: _____

Company name: _____

Address: _____

_____

Post code: _____ Municipality: _____ Country: _____

8. USES:

8.1. Use number (Catalogue)	8.2. Use name (Catalogue)	8.3. List of cover crops	8.4. Maximum application rate		8.5. Number of applica-tions per year	8.6. Interval between applications (min.)	8.7. Application period		8.8. BBCH application stage		8.9. Pre-harvest interval (in day(s) or BBCH stage)	8.10. Bee notation (EX, FL or EX/FL)[iv]	8.11. Use F, G or I[v]	8.12. Recommendations/ Restrictions/Other requirements	8.13. GAP number
			rate	Unit			Min.	Max.	Min.	Max.					

[iii] EX, FL or EX/FL: EX = Application authorised during exudate-production periods; FL = Application authorised during flowering; EX/FL = Application authorised during exudate-production periods and Application authorised during flowering

[iv] I, F, and G: I = Indoor; F = Field; G = Greenhouse

9. PROPOSED CLASSIFICATION/LABELLING ACCORDING TO REGULATION (EC) NO 1272/2008:

9.1. HAZARD SYMBOLS:

☐ SGH01 ☐ SGH02 ☐ SGH03 ☐ SGH04 ☐ SGH05 ☐ SGH06 ☐ SGH07 ☐ SGH08 ☐ SGH09 ☐ No symbol

9.2. WARNING STATEMENT:

☐ No warning statement ☐ Caution ☐ Hazard

9.3. HAZARD CLASSES:

Name	Related category (1 to 4)

9.4. ADDITIONAL HAZARD STATEMENTS/PHRASES:

H/EUH code	Name

10. IN THE EVENT OF MUTUAL RECOGNITION OR IF FRANCE IS THE CONCERNED MEMBER STATE:

Identification of the authorised product or product pending authorisation in the Reference Member State:

10.1. Trade name of the product: _____

10.2. Reference Member State: _____

10.3. Code name of the product: _____

10.4. Authorisation number: _____

11. IN CASE OF A TRANSFER OF AUTHORISATION HOLDER:

Name of the authorisation holder before the transfer is processed: _____

Address: _____

_____

Post code: _____ Municipality: _____ Country: _____

Company registration no. in the business register (SIRET No. in France): _____

☐ Registration pending (evidence of the request must be provided when submitting the application)

Intra-Community VAT No.: _____

12. IN CASE OF A CHANGE OF TRADE NAME FOR THE PRODUCT:

New name: _____

13. CONFIRMATION OF THE APPLICATION:

I, the undersigned (First name and SURNAME of the person who is legally competent to sign the application):

_____

– **certify that I have power to represent the future holder in the context of this formality,**

– **certify the accuracy of all the information provided in this form and its attachments.**

Signed on _____/_____/_____

Company stamp, signature:

The information collected through this form will be subject to computer processing by ANSES intended to notify the decision on your application. In accordance with the French Data Protection Act of 6 January 1988, as amended [la loi "Informatique et libertés" du 6 janvier 1988 modifiée], you have a right to access and rectify any information that concerns you. You can exercise this right by sending an e-mail to ANSES's Market Authorisations Department at the following address: damm.uia@anses.fr. You can also, for any legitimate reason, object to the processing of any data concerning you.