EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Safety of the Food Chain
Pesticides and Biocides

Insert Active substance name

MRL application form

(SANCO 4044/2008 rev. 10.2)

Insert applicant's name

Part A

1	**Purpose of the application[1]:**	
1.1	Set specific maximum residue level(s) (new active substance not mentioned in Annex II/III/IV of Regulation (EC) No 396/2005)	☐
1.2	Set specific maximum residue level(s) (changing current EU MRL listed in Annex II or III of Regulation (EC) No 396/2005	☐
1.3	Set import tolerance(s) (new active substance not mentioned in Annex II/III/IV of Regulation (EC) No 396/2005)	☐
1.4	Set import tolerance(s) (changing current EU MRL listed in Annex II or III of Regulation (EC) No 396/2005)	☐
1.5	Delete maximum residue level(s)	☐
1.6	Include an active substance in Annex IV	☐
1.7	Amend existing residue definition	☐
1.8	Include active substance/product combinations into Annex VII as referred to in Article 18 (3) of Regulation (EC) No 396/2005	☐
1.9	Evaluation of confirmatory data following review according to Article 12 of Regulation (EC) No 396/2005	☐

Evaluating Member State (EMS)	
Rapporteur Member State (RMS)	

2	**Applicant**	
2.1	Party requesting an authorisation or a provisional authorisation under Regulation (EC) No 1107/2009 (Art. 6.1 of Regulation (EC) No. 396/2005).	☐
2.2	Parties demonstrating through adequate evidence a legitimate interest in health, including organisations of civil society (Article 6.2 of Regulation (EC) No. 396/2005)	☐
2.3	Parties concerned with a commercial interest such as manufacturers, growers, importers and producers of products covered by Annex I of Regulation (EC) No. 396/2005 (Article 6.2 of Regulation (EC) No. 396/2005)	☐
2.4	Member State of the European Community (Article 6.3 of Regulation (EC) No 396/2005)	☐
2.5	Party requesting an import tolerance (Art. 6.4 of Regulation (EC) No. 396/2005)	☐

[1] **Please tick all relevant boxes.**

3	Details on the status of evaluation	Date
3.1	Evaluation under Regulation (EC) No 1107/2009 pending[2]	/ / (date of confirmed receipt of dossier by RMS)
3.2	Evaluation under Regulation (EC) No 1107/2009 scheduled[2]	/ / (scheduled date of submission to RMS)
3.3	Evaluation under Regulation (EC) No 844/2012 pending[3]	/ / (date of confirmed receipt of dossier by RMS)
3.4	Evaluation under Regulation (EC) No 844/2012 scheduled[3]	/ / (scheduled date of submission to RMS)

4	Details Concerning Applicant	
4.1	Company code (if known)	
4.2	Company/organisation/Member State	
4.3	Contact person Title First name Surname	
4.4	Address Street Street number Addition to street number Town/city Postcode Country	
4.5	Telephone Dialling code Telephone number	
4.6	Telefax Dialling code Telephone number	

[2] MRL applications to be submitted in accordance with the approval procedure of Regulation 1107/2009 (Art. 8(1) g. According to that Article 8(1)g a copy of an application for a MRL as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information should be included.

[3] MRL applications to be submitted in accordance with the renewal procedure Reg. 844/2012. According to Art. 7(1)(i) of Reg. 844/2012, a copy of an application for a MRL as referred to in Article 7 of Regulation (EC) No 396/2005 should be included 2005 or a justification for not supplying such information should be included.

4	**Details Concerning Applicant**	
4.7	E-mail	

5	**Information on the Plant Protection Product Used**	
5.1	Trade name for the plant protection product	
5.2	Type of formulation	

6	**Active Substance for which the MRL Application is to be Submitted**	
6.1	Active substance number	
6.2	Active substance (ISO common name) English	
6.3	IUPAC name	
6.4	CAS no.	**- -**
6.5	Use category/categories (eg. insecticide)	
6.6	Is the active substance also used in biocides?	
6.7	Is the active substance also used in veterinary drugs?	

7	**Content of that Active Substance in the Formulation**	
7.1	Declared content of pure active substance Unit	
7.2	Is the active substance available as a variant (e. g. ethyl ester, sodium salt)?	
7.3	Active substance variant (code)	
7.4	Active substance variant (name)	
7.5	Remarks	

8	**Name and content of other active substances** ***(repeat data for each additional active substance)***	
8.1	Active substance number	
8.2	Active substance (ISO common name) English	
8.3	IUPAC name	
8.4	CAS no.	**- -**

8.5	Declared content of pure active substance	

9	**Residue definitions for[4]**	
9.1	Active substance number	
9.2	Active substance (ISO common name) English	
9.3	Monitoring purposes (plant)	
9.4	Risk assessment (plant)	
9.5	Monitoring purposes (animal)	
9.6	Risk assessment (animal)	

[4] In case the applicant asked to check the impact of a new residue definition existing (first line) and new (second line) definition should be stated in each case.

10	Product(s) of Plant or Animal Origin as listed in Annex I of regulation (EC) No 396/2005		Proposed MRL NB: Footnote to be added in case of application for import tolerance(s)	Current EU MRL
	Code	Name		
			mg/kg:[5]	mg/kg:
			mg/kg:	mg/kg:
			mg/kg:	mg/kg:
			mg/kg:	mg/kg:
			mg/kg:	mg/kg:
			mg/kg:	mg/kg:
			mg/kg:	mg/kg:
			mg/kg:	mg/kg:
			mg/kg:	mg/kg:
			mg/kg:	mg/kg:

Additional lines to be added if necessary

[5] **In case of import tolerances insert for each tolerance reference to the corresponding national legislation of the exporting country concerning the MRL or a clarification should be given if no MRLs are established in the originating country**

11	**Enclosed Documents According to Regulation (EC) No. 396/2005**	
11.1	A summary of the application (Article 7.1.b.i)	☐
11.2	The main substantive arguments (Article 7.1.b.ii) [applicant's conclusions]	☐
11.3	An index of the documentation enclosed (Article 7.1.b.iii)	☐
11.4	A copy of the relevant Good Agricultural Practice applying to the specific use of the active substance (Article 7.1.b.iv) [see Annex I for template]	☐
11.5	A comprehensive overview of relevant concerns raised in the available scientific literature about the plant protection product and/or its residue (Article 7.1.c)	☐
11.6	The data listed in Commission Regulation (EU) No 544/2011[6] and Commission Regulation (EU) No 545/2011[7] relating to data requirements for the setting of maximum residue limits for pesticides including, where appropriate, toxicological data and data on routine analytical methods for use in control laboratories, as well as plant and animal metabolism data (Article 7.1.d)	☐

Part B

1	**Further information requested by MS to cover requirements on national procedures**	
1.1	In addition to point 4: - Details concerning leading company - Details concerning authorisation holder - Details concerning representative in the entire MS	☐
1.2	Connection between application for MRL and national authorisation/approval	☐
1.3	In addition to point 5: Further information on the plant protection product like authorisations in other MS, authorisation number in that MS	☐
1.4	In addition to point 6: Further information on the approved and/or pending MRLs for biocides and/or veterinary products	☐
1.5	In addition to point 11: - In addition other description of GAP (having the same elements as Annex I) - Additional documentation like residue summary form - Spraying intervals	☐
1.6	Summary Form Supervised Residue Trials	☐
1.7	Remarks, if necessary	☐

[6] Data requirements for active substances in the version in place at time of application
[7] Data requirements for plant protection products in the version in place at time of application

Part C

For evaluating Member States only.

1	Details on the status of evaluation	Date
1.1	Request to change current EU MRL under Regulation (EC) No. 396/2005	/ / (date of receipt of MRL application in MS)

Date Signature of the applicant

Annex I (GAP Form)

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Use Pattern

Crop and/or situation (a)	**Member State or Country For Import Tolerance**	**Product name**	**NEU SEU or G** (b)	**Pests or Group of pests controlled** (c)	**Preparation**		**Application**				**Application rate per treatment**			**PHI (days)** (m)	**Remarks**
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) NEU: outdoor field use in Northern EU, SEU: outdoor field use in Southern EU, State: Member state (MS) or country for Import tolerance, G: glasshouse or indoor application
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(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 plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to 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) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval