ctgb

Alleen voor Ctgb gebruik, niet in te vullen door aanvrager *For internal Ctgb use only; do not write in this section*		
Aanvraagnummer:	Type:	Betaling:
Aanvrager:		Connect code:

Formulier G – ZRMS (1.1)
Application Form G – ZRMS (1.1)

AANVRAAG VAN EEN TOELATING OF WIJZIGING VAN DE TOELATING VAN EEN GEWASBESCHERMINGSMIDDEL, waarbij Nederland zonaal rapporteur is.
Application for authorisation or amendment of an authorisation of a plant protection product, for which The Netherlands are the reporting Memberstate

AANVRAAG VOOR GOEDKEURING VAN EEN WERKZAME STOF
Application for approval of an active substance

Dit formulier sturen aan:
Send this form to

College voor de Toelating van gewasbeschermingsmiddelen en biociden (Ctgb)
Board for the Authorisation of Plant Protection Products and Biocides
PO Box 217
6700 AE WAGENINGEN
The Netherlands

Naam middel : **Sivanto SL 200**
Name of product

Naam werkzame stof(fen) *Active substance(s)*	**Gehalte zuiver werkzame stof (in eenheid zoals vermeld op het etiket)** *Content of pure active substance (in the same units as appear on the label)*
Flupyradifurone	200 g/L

Datum van de aanvraag : **April 23, 2012**
Date of application

Handtekening aanvrager :
Signature of applicant

Betaling
Payment

De factuur voor de aanvraagkosten moet worden voldaan voor de presubmission meeting, onder vermelding van de middelnaam, op Rabobank rekeningnummer 39.70.76.053; IBAN NL27 RABO 0397076053; SWIFT-address: RABO NL2U, ten name van Ctgb te Wageningen.
The application fee invoice is to be paid to the Ctgb before the pre-submission meeting. Please include the name of the product with the payment. Make the payment to Bank Account Number 397076053 (Rabobank, Wageningen), in the name of Ctgb in Wageningen, the Netherlands. IBAN: NL27 RABO 0397076053; SWIFT-address: RABO NL2U

Wijze van indiening
How to submit the application

Informatie over de wijze van indiening (aantal elektronische, papieren exemplaren, etc) vindt u in de algemene instructie voor het indienen van aanvragen. U wordt verzocht deze zorgvuldig door te lezen. Separaat van de te leveren middel- en stofgegevens dient u bij dit aanvraagformulier te leveren:

- Een samenvatting, evaluatie en risicobeoordeling, opgesteld conform het 'draft Registration Report (dRR)' (SANCO/5895/2009), **zie de Ctgb website**
- **Het aanmeldingsformulier voor zonale aanvragen, met o.a. de 'risk envelope' en de nationale GAP's ('Table of uses') voor alle lidstaten waarin het middel wordt aangevraagd**
- Concept Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing (WGGA) voor de toelating in Nederland in de Nederlandse taal, en concept etiketteksten voor alle lidstaten waar het middel wordt aangevraagd, in de Nederlandse of Engelse taal
- Volledige samenstelling van het middel (gebruik het Excel format dat beschikbaar is op de website)
- Referentielijst, waarin tevens wordt aangegeven naar welke reeds eerder aan het Ctgb geleverde gegevens u verwijst (gebruik het Word format dat beschikbaar is op de website). Gegevens die zijn ingediend voor het nationaal addendum moeten in een aparte referentielijst worden vermeld
- Referentielijst met de data betreffende proeven met gewervelde dieren die bij deze aanvraag worden ingediend
- Veiligheidsinformatiebladen (MSDS-en) van het middel, werkzame stoffen en alle hulpstoffen
- Letter(s) of Access (LOA) voor toegang tot gegevens van derden

You can find information about how to submit your application (the number of electronic and paper copies etc.) in the General instructions for the submission of the application form. Please ensure that you read these instructions carefully.
The following documents and data must be submitted separately from the information concerning the product and substance(s), and each document must be labelled clearly:

- *A summary, evaluation and risk assessment, according to the draft Registration Report (dRR)*(SANCO/5895/2009), **see the Ctgb website**
- *Notification form for zonal applications, with (amongst others) the 'risk envelope' and the national GAP's of each Member State where the product is applied for, in Dutch or English language*
- *Draft copy of legal conditions for use and the directions for use in Dutch, and draft label texts for all Member States where the product is applied for, in Dutch of English language*
- *Complete composition of the product (use the Excel template available from the website)*
- *A reference list which also indicates which data already held by Ctgb you refer to (use the Word template available on the website). Data submitted for the national addendum must be listed on a separate reference list*
- *Reference list which indicates which data concerning tests on vertebrate animals are submitted with this application*
- *The material safety data sheets (MSDS) relevant to the product, active substance(s) and any co-formulants*
- *Letter(s) of Access (LOA) relating to accessing data belonging to third parties*

Algemene gegevens over de aanvrager *General information about the applicant*	**Antwoord** *Answer*
Aanvrager/Applicant	[redacted]
Firma Naam/Company Name	Bayer CropScience AG
Adres/Address	Alfred-Nobel-Strasse 50
Plaats/City	Monheim/Rhein
Postcode/Postal Code	40789
Land/Country	Germany
Telefoon/Telephone	[redacted]
Fax/Fax	[redacted]
E-mail adres/E-mail address	[redacted]
Bevoegd contactpersoon/Person authorised to communicate on behalf of the applicant[1]	
Naam/Name	[redacted]
Voornaam/First name	[redacted]
Titel/Title	[redacted]
Functie/Function	[redacted]
Firma naam/Company Name	Bayer CropScience AG
Adres/Address	Alfred-Nobel-Strasse 50
Plaats/City	Monheim/Rhein
Postcode/Postal Code	40789
Land/Country	Germany
Telefoon/Telephone	[redacted]
Fax/Fax	[redacted]
E-mail adres/E-mail address	[redacted]
Wenst u via email op de hoogte te worden gebracht van de status van uw aanvraag?[2] *Do you wish to be informed by email about the status of your application?*	☒ Ja/yes

[1] Indien het formulier niet wordt ondertekend door de aanvrager, dient een machtiging te worden overlegd.
In case the form is not signed by the applicant, a mandate from the applicant should be submitted.
[2] Emailnotificaties zijn systeemberichten die enkel een wijziging weergeven die heeft plaatsgevonden met betrekking tot de status van uw aanvraag in het interne Aanvraag Behandelings Systeem (ABS) van het Ctgb. Dit bericht dient enkel als aankondiging, om u zo snel mogelijk op de hoogte te stellen van de strekking van een juridisch bindende brief die u kort erop waarschijnlijk zult ontvangen. Aan dit emailbericht kunt u derhalve geen rechten ontlenen.
Email notifications are automatically generated messages, which show changes in the status of your application. The Email notifications are only announcements (before the official letter) , from which no rights can be derived.

Aanvraagtype *Type of application*	**Antwoord** *Answer*
De aanvraag betreft een (één hokje aankruisen en doorgaan naar de volgende vragen): *Type of application (choose one type and go to the next set of questions):*	☐ aanvraag tot **zonale toelating** van een gewasbeschermingsmiddel als bedoeld in **artikel 28 Verordening 1107** *application for the **zonal authorisation** of a plant protection product* ☐ aanvraag tot **voorlopige zonale toelating** van een gewasbeschermingsmiddel als bedoeld in **artikel 30 Verordening 1107** *application for the **provisional zonal authorisation** of a plant protection product* ☐ aanvraag tot **zonale verlenging van de toelating** van een gewasbeschermingsmiddel als bedoeld in **artikel 43, Verordening 1107** *application for **zonal renewal of the authorisation** of a plant protection product* ☐ aanvraag tot **zonale uitbreiding** van het toelatingsgebied van een toegelaten gewasbeschermingsmiddel als bedoeld in **artikel 33, Verordening 1107** ***zonal application to extend the field of use** of a plant protection product* ☐ zonale aanvraag tot **wijziging van de samenstelling** van een toegelaten gewasbeschermingsmiddel als bedoeld in **artikel 33, Verordening 1107** *zonal application to modify **the composition** of an authorised plant protection product* ☐ aanvraag tot **uitbreiding van toelatingen voor kleine toepassingen** als bedoeld in **artikel 51 Verordening** *application for an extension of authorisations for minor uses*
	☒ aanvraag tot **goedkeuring van een werkzame** stof als bedoeld in **artikel 7, Verordening 1107** *application for approval of **an active substance*** ☐ aanvraag tot **verlenging van een goedkeuring van een werkzame** stof als bedoeld in **artikel 15, Verordening 1107** *application for renewal of approval of **an active substance***
Bij de aanvraag tot zonale verlenging, van een gewasbeschermingsmiddel is **tevens** sprake van een *Besides a zonal application for renewal of approval of the authorisation, this is also an*	☐ **wijziging van de samenstelling** van een toegelaten gewasbeschermingsmiddel *application to modify the **composition** of an authorised plant protection product* ☐ **uitbreiding** van het toelatingsgebied van een toegelaten gewasbeschermingsmiddel *application to extend **the field of use** of a plant protection product* ☐ aanvraag tot **uitbreiding van toelatingen voor kleine toepassingen** als bedoeld in **artikel 51 Verordening** *application for an extension of authorisations for minor uses (article 51 Verordening)*
Bij de aanvraag tot uitbreiding van het toelatingsgebied is tevens sprake van *As well as the application to extend the field of use of the product, there is also an*	☐ **wijziging van de samenstelling** van een toegelaten gewasbeschermingsmiddel *application to modify the **composition** of an authorised plant protection product*

☐ aanvraag tot **uitbreiding van toelatingen voor kleine toepassingen** als bedoeld in **artikel 51 Verordening**
application for an extension of authorisations for minor uses (article 51 Verordening)

Algemene informatie over het middel en de werkzame stof(fen) *General information about the product and the active substance(s)*	**Antwoord** Answer
Betreft de aanvraag een middel dat toegepast zal worden op voor export bestemd zaaizaad? *Is the product meant for use on sowing seed, destined for export?*	ja/*yes* ☐ nee/*no* ☒
Betreft de aanvraag een middel dat toegepast zal worden op zaaizaad, bestemd om in Nederland te worden gezaaid? *Is the product meant for use on sowing seed, destined for sowing in the Netherlands?*	ja/*yes* ☐ nee/*no* ☒
Heeft de aanvraag betrekking op gebruik in kassen (of andere gesloten ruimten voor de teelt van planten), op behandeling na de oogst of op behandeling van lege opslagruimten? *Is the product meant for use in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms?*	ja/*yes* ☐ nee/*no* ☒
Zijn er bij deze aanvraag nieuwe gegevens geleverd over dierproeven met gewervelde dieren? *Has new data been submitted with this application concerning testing on vertebrates?*	ja/*yes* ☒ nee/*no* ☐
Is er ten behoeve van het middel een verzoek om inlichtingen m.b.t. de uitvoering van dierproeven op vertebraten ingediend? **Zo ja**, dan dient u te overleggen: - een kopie van het verzoek om inlichtingen - een kopie van de reactie van het Ctgb op het inlichtingenverzoek - referentielijst van de ingediende dierproeven **Zo niet**, dan dient u in een bijlage te motiveren waarom dit niet nodig is. *Has a request been lodged for information regarding the carrying out of animal tests on vertebrates with respect to this product?* ***If so**, the following must be submitted as an appendix to the application:* - *a copy of the request for information* - *a copy of the reaction of Ctgb* - *a list of the animal tests, submitted with the application* ***if not**, you must explain in an appendix why a request was not called for.*	ja/*yes* ☐ nee/*no* ☒ bijlage informatieverzoek: - *appendix information request* bijlage reactiebrief Ctgb*:* - *appendix reaction Ctgb* bijlage referentielijst ingediende dierproeven: - *appendix reference list animal tests submitted* bijlage motivering geen inlichtingenverzoek - *appendix explanation why information-request is unnecessary.*
Is er ten behoeve van deze aanvraag een verzoek om advies aan de Helpdesk Toelatingen van het Ctgb gericht? Zo ja wat is het door het Ctgb toegekende nummer van het verzoek?	ja/*yes* ☐ nee/*no* ☒

Has a request been made to the Ctgb help desk for advice concerning this product? If so, what is the Ctgb reference number for this request?	verzoeknummer: several pre-submission meetings *request number*
Naam, adres van de fabrikant van het middel *Name, address of the manufacturer of the product*	Bayer CropScience AG Alfred-Nobel-Strasse 50 Monheim and Rheim 40789 Germany
Naam, adres van de fabrikant van de werkzame stof *Name, address of the manufacturer of the active substance*	Bayer CropScience AG Alfred-Nobel-Strasse 50 Monheim and Rheim 40789 Germany
Naam, adres van de notifier(s) van de werkzame stof *Name, address of the notifier(s) of the active substance*	BayerCropScience AG Alfred-Nobel-Strasse 50 Monheim and Rheim 40789 Germany
Is de werkzame stof goedgekeurd in de zin van art. 4 van Verordening 1107/2009? *Has the active substance been approved according to art. 4 of Regulation 1107/2009?* Zo ja, datum en nummer van EU richtlijn melden *If so, give date and number of EU Directive*	ja/*yes* ☐ nee/*no* ☒ -

Eigendom van gegevens (Ownership of data)		
Vul in voor middel en elke werkzame stof: *Fill in for the product and each active substance:*		Als nodig: *When needed:*
Naam van het middel en/of werkzame stof(fen) *Name of product and/or active substance(s)*	Naam eigenaar gegevens *Name of the owner of the data*	Datum LOA *Date of LOA*
Sivanto SL 200 (product)	Bayer CropScience AG	-
Flupyradifurone (active substance)	Bayer CropScience AG	-
.....	.....	.....

Verklaring van toegang (Letter of Access)	
Is er voor de onderhavige aanvraag een verklaring van toegang (LOA) voor gebruik gegevens van derden betreffende het middel dan wel werkzame stof(fen) noodzakelijk? Zo ja, dan dient de LOA als bijlage bij de aanvraag te worden overgelegd *Is a Letter of Access for the use of data from third parties concerning either the product or the active substances necessary for this application?* *If so, the LOA must be submitted as an appendix to the application*	ja/*yes* ☐ nee/*no* ☒ bijlage LOA: - *appendix LOA*

Gegevensbescherming en vertrouwelijke informatie (Data protection and confidential information)	
Zijn er bij de onderhavige aanvraag test- of studierapporten geleverd waarvoor u gegevensbescherming wilt aanvragen? U dient dit per studierapport aan te geven in de betreffende kolom van de referentielijst. *Did you submit test or study reports for this*	ja/*yes* ☒ nee/*no* ☐

Gegevensbescherming en vertrouwelijke informatie (Data protection and confidential information)	
application for which you claim data protection? You should indicate this on the reference list (column data protection).	
Kunt u bevestigen dat er nimmer een gegevensbeschermingsperiode voor de test- of studierapporten waarvoor gegevensbescherming wordt gevraagd zijn toegekend, en dat een eventueel al toegekende periode niet is verlopen? *Do you confirm that a period of data protection has never been granted for the test and study reports for which data protection is claimed, and that any period granted before has not expired?*	ja/*yes* ☒ nee/*no* ☐
Indien nodig kunt u een nadere toelichting met betrekking tot de gevraagde gegevensbescherming leveren. *If necessary give an explanation on the claimed data protection.*	bijlage LOA: - . Submission of new active substance *appendix LOA*
Is er bij de onderhavige aanvraag informatie geleverd waarvoor u vertrouwelijke behandeling wilt aanvragen? *Do you wish to request that information submitted for this application is to be treated confidential?* Zo ja, dan dient u hiervoor een verifeerbare verantwoording te leveren: *If so, provide verifiable evidence for this request.*	ja/*yes* ☒ nee/*no* ☐ bijlage: -. Submission of new active substance *appendix*

Gegevens over het middel *Information about the product*	**Antwoord** Answer
Is het middel reeds toegelaten als gewasbeschermingsmiddel in Nederland? *Is this product already authorised/registered as a plant protection product in the Netherlands?*	ja/*yes* ☐ nee/*no* ☒
Zo ja, onder welk toelatings/registratienummer? *If so, what is the authorisation number?*	-
Concept voorstel Wettelijk Gebruiksvoorschrift en gebruiksaanwijzing (WGGA) in de Nederlandse taal, en concept etiketteksten voor alle lidstaten waar het middel wordt aangevraagd, in de Nederlandse of Engelse taal **Het voor Nederland te gebruiken format vindt u op de Ctgb site:** **'Voorbeeld sjabloon Wettelijk gebruiksvoorschrift en gebruiksaanwijzing'.** *.Draft proposal of the Legal Conditions for Use and the Directions for Use (WGGA) in Dutch, and draft label texts for all Member States where the product is applied for, in Dutch of English language* ***See format for Dutch label on the Ctgb website: 'Voorbeeld sjabloon Wettelijk gebruiksvoorschrift en gebruiksaanwijzing'.*** Indien het middel zowel voor professioneel als voor niet-professioneel gebruik wordt geclaimd, moet	bijlage concept WGGA, en concept etiketteksten voor overige lidstaten: n.a. *appendix draft WGGA, and draft label texts for other Member States*

voor het professionele gebruik en voor het niet-professionele gebruik een apart WGGA worden geleverd, met daarbij duidelijk aangegeven voor welk type gebruik het middel geclaimd wordt. *If the use is claimed for both professional and non-professional use, two separate labels should be provided. On each label it should be clearly stated if the product is meant for professional or non-professional use.*	
Is het overzicht van details van gebruik van verleende en aangevraagde toepassingen (Tabel van toepassingen, 'table of intended uses') geleverd onder bijlage OECD Annex III A vraag 3.3 t/m 3.7.3 en 3.8 t/m 3.8.1 van deze aanvraag? **Het te gebruiken format vindt u op de Ctgb site ('Table of uses')** *Is the overview of the details of the use of the authorised and intended uses available in appendix OECD Annex III A 3.3 - 3.7.3 en 3.8 - 3.8.1 with this application?* ***See format 'Table of uses' on the Ctgb website***	ja/*yes* ☒ nee/*no* ☐ (EU format)
Is de volledige samenstelling van het middel geleverd **(gebruik het Excel format dat beschikbaar is op de website)** *Has the complete composition of the product been provided **(use the Excel template available from the website)***	ja/*yes* ☒ nee/*no* ☐ (EU format)
Material Safety Data Sheets (MSDS) van het middel, werkzame stof(fen) en alle hulpcomponenten) *Material Safety Data Sheets (MSDS) regarding the product, the active substances and the co-formulants*	bijlage MSDS: see dossier *appendix MSDS*
Het middel is bestemd voor: *The product will be used by* beroepsmatig gebruik *professional users* ☒ particulier gebruik *non-professional users* ☐	
Dient de gebruiker van het middel te beschikken over een bewijs van vakbekwaamheid ? *Should the user of the product have a certificate of competence?*	ja/*yes* ☐ nee/*no* ☒
Is het middel gebruiksgereed? *Is it a ready-to-use product?*	ja/*yes* ☐ nee/*no* ☒
Betreft de aanvraag een toepassing in een van de volgende gewassen en wilt u dat toepassing middels luchtvaartuigen wordt meegenomen in de beoordeling? (Indien u hier niets aangeeft zal het Ctgb toepassing middels luchtvaartuigen niet beoordelen en uitsluiten middels een restrictiezin in het WGGA.) - aardappelen - blauwmaanzaad - granen - koolzaad	ja/*yes* ☐ nee/*no* ☒

- peulvruchten
- spruitkool
- suikerbieten
- uien

If this application extends to the use in one of the next crops: do you want that the use by means of airplanes is taken into account for the evaluation?
(If not, applying by means of airplanes will not be taken into account and will be excluded in restriction sentences)
- *potatoes*
- *poppy seed*
- *grains*
- *oil seed rape*
- *pulses*
- *brussels sprouts*
- *beets*
- *onions*

Voor dit aanvraagformulier is het bestaande O-document van de Europese Gemeenschap gebruikt, aangevuld met de nadere specificatie voor het punt OECD Annex IIIA point 6 Efficacy data (Ctgb – part 1). Aanvullend is een formulier ter controle van de volledigheid van het dossier conform Verordening 1107/2009 toegevoegd. Tevens is aanvullende informatie benodigd voor de beoordeling van de Nederland specifieke aspecten in het nationaal addendum (Ctgb – part 2). Voor de referentielijst zijn de L documenten (Reference List: Listing of test and study reports, test guidelines and published papers relevant tot the Annex II dossier and Reference List: Listing of test and study reports, test guidelines and published papers relevant tot the Annex III dossier) als uitgangspunt genomen. Het formulier en de referentielijst moeten volledig worden ingevuld en alle documentatie moet bij de aanvraag gevoegd worden:
For this application form, the existing EU O-document has been used, together with more specific information for the OECD Annex IIIA point 6 Efficacy data (Ctgb – part 1).Also a form for checking the completeness of the dossier in line with Regulation 1107/2009 is added. Furthermore specific data is required to address the Dutch specific aspects in the national addendum (Ctgb –part 2). The L documents were used as a basis for the reference list (Reference List: Listing of test and study reports, test guidelines and published papers relevant tot the Annex II dossier and Reference List: Listing of test and study reports, test guidelines and published papers relevant tot the Annex III dossier). The form and the reference list must be filled in completely and all the documentation must be added to the application:

		Remarks
form for use in checking zonal applications for completeness (reg. (ec) 1107/2009)	To indicate that all the required information and data are in accordance with Regulation 1107/2009 and have been provided	
Document O - part 1	Supporting documentation for applications for approval of an active substance	
Document O - part 2	To indicate that all the required Annex II and Annex III dossiers have been submitted for applications for approval of an active substance	
Document O - part 3	To indicate that all the required test and study reports are in accordance with Annex IIA have been provided for applications for approval of an active substance	
Document O - part 4	To indicate that all the required test and study reports are in	

	accordance with Annex IIIA have been provided for applications for approval of an active substance	
Document Ctgb- part 1	To indicate that all the efficacy data asked for in Document O – part 4, point IIIA.6 Efficacy data on the preparation, are in accordance with IIIA and have been provided for applications for approval of an active substance	
Document Ctgb – part 2	To indicate that all the test and study reports required for the evaluation of the Dutch specific aspects in the national addendum have been provided, for zonal applications	
Reference List (available on Ctgb website)	Reference listing of the submitted tests and study reports, test guidelines and published papers must be given. Papers and reports submitted must be listed by Annex-point. List of papers and reports not submitted must be arranged by Annex-point, and if applicable the date must be given when the paper or report was submitted earlier to the Ctgb. Please note: data submitted for the national addendum must be listed on a separate reference list.	

Annex II en III bij richtlijn 91/414/EEG geven de vereisten die gesteld worden aan het dossier dat ingediend moet worden door de aanvrager in het kader van de zonale toelatingsprocedure (in lijn met Verordening 1107/2009, artikel 33, 3e lid, onder a) en b)). Richtlijn 93/71/EEG bevat gedetailleerde informatie omtrent de dossiereisen. De door het Ctgb gestelde dossiereisen zijn hierop gebaseerd, alsmede op andere, specifieke voor alle lidstaten opgestelde richtsnoeren omtrent de minimaal te stellen dossiereisen.
The Annexes II and III to 91/414/EEC lay down the requirements for the dossier to be submitted by applicant for the authorization of a plant protection product (In line with Regulation 1107/2009, article 33, under 3 a) and b)).. Commission Directive 93/71/EEC indicates to applicants the details of the required information. The Ctgb bases its data requirements on these outlines and the more specific guidelines for the setting of minimum requirements to be applied in all Member States.

Name of product: Sivanto (Flupyradifurone) SL 200

Completeness check for zonal applications

Naam werkzame stof: Flupyradifurone

Explaining notes	
Documentation provided	Two answers (yes or no) are possible. Where “no” is filled in, a short explanation is required. The location of the explanation in the dossier must be given.
Data gap	This column is for Ctgb-use only. Do not fill in.

ctgb

FORM FOR USE IN CHECKING ZONAL APPLICATIONS FOR COMPLETENESS (Reg. (EC) 1107/2009)

Product: Sivanto SL 200 Applicant: Bayer CropScience Date: April, 23. 2012

This is an application for approval of a new active substance, therefore this form is not applicable. However it has been filled in.

Requirement Regulation (EC) 1107/2009	Description of the information	Information provided (J/N; if yes: location, if no: justification)	*Data gap*
Art. 33 (2) a	List of intended uses	yes	☐
Art. 33 (2) b	Proposal as to which Member State to act as zRMS	yes	☐
Art. 33 (2) c	Copies of authorisations already granted in a Member State, where relevant	No, new a.i.	☐
Art. 33 (2) d	Copy of conclusion of the Member State assessing equivalence, where relevant	No, new a.i.	☐
Art. 33 (3) a	Complete dossier and summary dossier for the plant protection product	yes	☐
Art. 33 (3) b -1	Complete dossier and summary dossier for each active substance	yes	☐
Art. 33 (3) b -2	Complete dossier and summary dossier for each safener	No, no safeners	☐
Art. 33 (3) b -3	Complete dossier and summary dossier for each synergist	No, no synergists	☐
Art. 33 (3) c	Justifications of steps taken to avoid animal testing and duplication of such testing	No, no unnecessary animal tests conducted	☐
Art. 33 (3) d	Reasons for necessity for submission of tests and study reports	Yes, according to OECD and Reg. 1107/2009	☐
Art. 33 (3) e	Copy of the application for maximum residue levels, where relevant	yes	☐
Art. 33 (3) f	Assessment of all Annex II data submitted in accordance with Art. 8(1) point (h), where relevant for an amendment	yes	☐
Art. 33 (3) g	Draft label	yes	☐
Art. 34 (1)	Request for exemption from supplying test and study reports for the plant protection product, active substance(s), safener(s) or synergist(s)	No, new a.i.	☐
Art. 34 (2) a	Data for the identification of the plant protection product, including its composition and and declaration on co-formulants	yes	☐

Art. 34 (2) b	Data for the identification of the active substance(s), safener or synergist	yes	☐
Art. 34 (2) c	Data to demonstrate for the product to have comparable effects to the product with access to protected data, where requested	No, new a.i.	☐

Name of product Sivanto (Flupyradifurone) SL 200

DOCUMENT O - Part 1

Active substance Flupyradifurone

Explaining notes	
Documentation provided	*Please answer yes or no. In case "no" is filled in a short explanation must be given. The location of the explanation in the dossier must be given.*
Data gap	*This column is for use of the Ctgb only. Do not fill in.*

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Part 1 **Evaluation Form 1 -**
Supporting documentation, for applications for approval of active substances

Active Substance: Flupyradifurone Preparation: Sivanto SL 200
Applicant: Bayer CropScience Date: April 23, 2012

Document	Description of the document	Document provided	*Data gap*
A	Statement of the context in which the dossier is submitted	yes	☐
B	Documentation relating to the joint submission of dossiers:		
B a	* Claim that all reasonable steps were taken	yes	☐
B b	* Documentation to support the claim made	yes	☐
C a	Existing or proposed labels, and where relevant leaflets for each preparation for which an Annex III dossier is submitted	yes	☐
C b	Existing or proposed labels relevant to the uses on the basis of which existing MRLs or import tolerances are supported or new MRLs or import tolerances are proposed	yes	☐
D-1	Details of intended uses (supported by the applicant and for which data are provided or are to be provided) and the conditions of use, on food and feed crops, and on non food and feed crops, in the territory of the EU, presented using the appropriate form	yes	☐
D-2	A list of the authorized uses in the EU, an indication of whether actually used and of the extent of use, presented using the appropriate form	n.a.	☐
D-3	Details of the intended uses (supported by the applicant and for which data are provided or are to be provided) and conditions of use (GAPs) in exporting countries, for which import tolerances are required, presented using the appropriate form	yes	☐
E-1 a	Listing of EU MRLs, presented using the appropriate form	n.a.	n.a.
E-1 b	Listing of MRLs established by Member States, presented using the appropriate form	n.a.	n.a.
E-2 a	Listing of MRLs established in exporting countries, presented using the appropriate form	n.a.	n.a.
E-2 b	Listing of MRLs in non-EU OECD countries, presented using the appropriate form	n.a.	n.a.
F	A copy of each notification submitted to the Commission	n.a.	☐
G	Whether permitted in food, animal feeding stuffs, medicines or cosmetics in accordance with EU legislation	yes	☐
H	Safety data sheet prepared in accordance with Directive 67/548/EEC	yes	☐
I	Other available toxicological and environmental data on the formulant	yes	☐
J	Confidential data and information, to include:		
J a	* A listing of the data and information for which confidentiality is requested, cross referenced to the relevant test and study reports, dossier summaries and supporting documentation	yes	☐
J b	* A justification for the claim to confidentiality for each item for which confidentiality is requested	yes	☐
J c	* Highlighting of information contained in relevant study reports, dossier summaries and supporting documentation	yes	☐
J d	* File containing confidential data and information	yes	☐

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Name of product Sivanto (Flupyradifurone) SL 200

DOCUMENT O - Part 2

Active substance Flupyradifurone

Explaining notes	
Documentation provided	*Please answer yes or no. In case "no" is filled in a short explanation must be given. The location of the explanation in the dossier must be given.*
Data gap	*This column is for Ctguse of the Ctgb only. Do not fill in.*
n.a.	Not applicable

Part 2 **Evaluation Form 2 -**
for use in checking that the required Annex II and Annex III dossier summaries and an overall assessment, have been provided, for applications for approval of active substances

Active Substance: Flupyradifurone Preparation: Sivanto SL 200
Applicant: Bayer CropScience Date: April 23, 2012

Document	Description of the document	Document provided	Data gap
L-II	Annex II, *Tier I* reports as to the quality of individual test and study reports	yes	☐
L	Reference List: Listing of test and study reports, test guidelines and published papers relevant to the Annex II dossier:		
L IIa	- papers and reports submitted listed by Annex point, fill the Reference list on page 49	yes	☐
L IIb	- papers and reports submitted listed by alphabetically by author	yes	n.a.
L IIc	- list of papers and reports not submitted, arranged alphabetically by author	yes	n.a.
M-II	Annex II, *Tier II* dossier summary and overall assessment	yes	☐
L-III	Annex III, *Tier I* reports as to the quality of individual test and study reports for each Annex III dossier submitted		
L-III a	* First preparation	yes	n.a.
L-III b	* Second preparation	n.a	n.a.
L-III c	* Third preparation	n.a	n.a.
L-III d	* Fourth preparation	n.a	n.a.
L	Reference List: Listing of test and study reports, test guidelines and published papers relevant to the Annex III dossier:		
	* First preparation	yes	n.a.
L III e	- papers and reports submitted listed by Annex point, fill in the Reference list on page 49	yes	☐
L III f	- papers and reports submitted listed by alphabetically by author	yes	n.a.
L III g	- list of papers and reports not submitted, arranged alphabetically by author	yes	n.a.
	* Second preparation	n.a	n.a.
L III h	- papers and reports submitted listed by Annex point	n.a	n.a.
L III i	- papers and reports submitted listed by alphabetically by author	n.a	n.a.
L III j	- list of papers and reports not submitted, arranged alphabetically by author	n.a	n.a.
	* Third preparation	n.a	n.a.
L III k	- papers and reports submitted listed by Annex point	n.a	n.a.
L III l	- papers and reports submitted listed by alphabetically by author	n.a	n.a.
L III m	- list of papers and reports not submitted, arranged alphabetically by author	n.a	n.a.
	* Fourth preparation	n.a	n.a.
L III n	- papers and reports submitted listed by Annex point	n.a	n.a.
L III o	- papers and reports submitted listed by alphabetically by author	n.a	n.a.
L III p	- list of papers and reports not submitted, arranged alphabetically by author	n.a	n.a.
M-III	Annex III, *Tier II* dossier summary and overall assessment	yes	
M-III a	* First preparation	yes	☐
M-III b	* Second preparation	n.a	n.a.
M-III c	* Third preparation	n.a	n.a.

M-III d	* Fourth preparation	n.a	n.a.
N	An overall summary and assessment of the application	yes	☐

Naam middel:Sivanto (Flupyradifurone) SL 200

DOCUMENT O - Part 3

Naam werkzame stof: Flupyradifurone

Explaining notes	
Information test or study provided	Three answers (yes, no, not relevant) are possible. In case "no" is filled in, the application is incomplete and will not be managed
Not relevant	This means - that data and information is not necessary owing to the nature of the substance, product or its supported uses; or - the data is not scientifically necessary or technically possible to supply information and/or data
Justification provided	If Y (yes) the location in the dossier has to be mentioned
Summary provided	If a summary is submitted, fill in Y (= yes). Otherwise fill in N (= no)
Reference list	The data that was submitted or has been provided for in an earlier application and which must be available at the Ctgb must be indicated. The location on the refence list must be given bij filling in the Annex-Point.
Data gap	This column is for Ctgb-use only. Do not fill in.
OECD Annex point in brackets	Proposed new OECD point. Until further notice this item needs not to be submitted.
No EC data requirement	The OECD point concerned is no data requirement according to Council Directive 91/414/EEC. The data is therefor not required in the Netherlands.

Part 3 **Evaluation Form 3 -**
for checking that all test and study reports required in accordance with Annex IIA have been provided, for applications for approval of active substances

Active Substance: Flupyradifurone Preparation: Sivanto SL 200
Applicant: Bayer CropScience Date: April 23, 2012

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
1	Identity of the active substance	Y	Doc M-IIA Sec 1/01	Y		
1.1	Applicant (name, address, contact, telephone and telefax numbers).	Y	Doc M-IIA Sec 1/01	Y		☐
1.2	Manufacturer(s) (name, address, contact, telephone and telefax numbers)	Y	Doc M-IIA Sec 1/01	Y		☐
1.3	ISO common name proposed or accepted, and synonyms	Y	Doc M-IIA Sec 1/01	Y		☐
1.4	Chemical name as in Annex I to Directive 67/548/EEC, if not included in that Annex, in accordance with IUPAC and CA, nomenclature	Y	Doc M-IIA Sec 1/01	Y		☐
1.5	Manufacturer's code number(s)	Y	Doc M-IIA Sec 1/01	Y		☐
1.5.1	Manufacturer's code number(s), for the active substance and formulations, materials concerned, countries in which used and periods for which used	Y	Doc M-IIA Sec 1/01	Y		☐
1.5.2	Trade name(s)	No EC data requirement				
1.5.3	Patent status	No EC data requirement				
1.6	Existing CAS, CIPAC, EINECS and ELINCS numbers	Y	Doc M-IIA Sec 1/01	Y		☐
1.7	Molecular formula, molecular mass and structural formula	Y	Doc M-IIA Sec 1/01	Y		☐
1.8	Method of manufacture	Y	Doc J-II	Y		☐
1.8.1	Method of manufacture (pathways, by-products and impurities) for each plant, whether or not relevant to a pilot plant	Y	KIIA 1.8.1/01	Y		☐
1.8.2	Description of starting materials	Y	KIIA 1.8.2/01	Y		☐
1.9	Specification of purity of the active substance	Y	Doc J-II	Y		☐
1.9.1	Minimum and nominal content (g/kg) of pure active substance (excluding inactive isomers), whether or not relevant to a pilot plant	Y	Doc J-II	Y		☐
1.9.2	Certified limits of the active ingredients	No EC data requirement				
1.9.3	Control product specification form or confidential statement of formula	No EC data requirement				
1.10	Identity, content and structural formula of isomers, impurities and additives					
1.10.1	Inactive isomers – For each isomer:					
1.10.1a	* IUPAC and CA names	Y	Doc J-II	Y		☐
1.10.1b	* ISO common name proposed or accepted	Y	Doc J-II	Y		☐
1.10.1c	* CAS, CIPAC, EINECS and ELINCS numbers	Y	Doc J-II	Y		☐
1.10.1d	* molecular and structural formula	Y	Doc J-II	Y		☐
1.10.1.e	* molecular mass	Y	Doc J-II	Y		☐
1.10.1.f	* ratio of the content of isomers/diastereo-isomers	Y	Doc J-II	Y		☐

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
1.10.1.g	* maximum content in g/kg	Y	Doc J-II	Y		☐
1.10.1.h	* whether or not relevant to a pilot plant	Y	Doc J-II	Y		☐
1.10.2	Impurities and additives					
1.10.2a	* IUPAC and CA names	Y	KIIA 1.10.2/01	Y		☐
1.10.2b	* ISO common name proposed or accepted	Y	KIIA 1.10.2/01	Y		☐
1.10.2c	* CAS, CIPAC, EINECS and ELINCS numbers	Y	KIIA 1.10.2/01	Y		☐
1.10.2d	* molecular and structural formula	Y	KIIA 1.10.2/01	Y		☐
1.10.2.e	* molecular mass	Y	KIIA 1.10.2/01	Y		☐
1.10.2.f	* maximum content in g/kg	Y	KIIA 1.10.2/01	Y		☐
1.10.2.g	* whether or not relevant to a pilot plant	Y	KIIA 1.10.2/01	Y		☐
1.10.2.h	* in the case of additives, their function and trade names	Y	KIIA 1.10.2/01	Y		☐
1.10.2.i	* in the case of impurities and by-products of particular environmental concern, details of the analytical methods	Y	KIIA 1.10.2/01	Y		☐
1.10.2.j	* guidance in identifying impurities of toxicological concern	Y	KIIA 1.10.2/01	Y		
1.11	Batch analysis data	Y	Doc J-II	Y		
1.11.1	Analytical profile of batches	Y	KIIA 1.11.1/01	Y		
1.11.2	Results of analyses of batches produced in laboratory or pilot scale production systems and used in toxicological testing	Y	KIIA 1.11.2/01-02	Y		
1.12	Other/special studies	Not relevant				
2	Physcial and chemical properties of the active substance					
2.1	Melting point and boiling point					
2.1.1	Melting point, freezing point or solidification point of purified active substance	Y	KIIA 2.1.1/01 - 02	Y		
2.1.2	Boiling point of purified active substance	Y	KIIA 2.1.2/01 - 02	Y		
2.1.3	Temperature at which decomposition or sublimation occurs	Y	KIIA 2.1.3/01 - 02	Y		
2.2	Relative density of purified active substance	Y	KIIA 2.2/01 -02	Y		
2.3	Vapour pressure and volatility					
2.3.1	Vapour pressure of purified active substance	Y	KIIA 2.3.1/01	Y		☐
2.3.2	Henry's law constant	Y	KIIA 2.3.2/01	Y		☐
2.4	Appearance					
2.4.1	Description of the physical state and colour of both the purified active substance and active substance as manufactured (or technical grade active ingredient)	Y	KIIA 2.4.1/01-02	Y		☐

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
2.4.2	Description of the odour of the purified active substance and active substance as manufactured	Y	KIIA 2.4.2/01-02	Y		☐
2.5	Spectra and molecular extinction at relevant wavelengths					
2.5.1	Spectra, a table of signal characteristics and molecular extinction at relevant wavelengths for purified active substance	Y	KIIA 2.5.1.1/01-2.5.1.5/01	Y		
2.5.1.1	UV/VIS	Y	KIIA 2.5.1.1/01	Y		☐
2.5.1.2	IR	Y	KIIA 2.5.1.2/01	Y		☐
2.5.1.3	NMR	Y	KIIA 2.5.1.3/01	Y		☐
2.5.1.4	MS	Y	KIIA 2.5.1.4/01	Y		☐
2.5.1.5	Wavelengths at which UV/VIS molecular extinction occurs, where appropriate, to include a wavelength at the highest absorption above 290 nm	Y	KIIA 2.5.1.5/01	Y		☐
2.5.1.6	Optical purity	Not relevant				☐
2.5.2	Spectra for impurities	Not relevant				
2.5.2.1	UV/VIS	Not relevant				☐
2.5.2.2	IR	Not relevant				☐
2.5.2.3	NMR	Not relevant				☐
2.5.2.4	MS	Not relevant				☐
2.6.	Solubility of purified active substance in water	Y	KIIA 2.6/01	Y		☐
2.6.a	* determined in the neutral range	Y	KIIA 2.6/01	Y		☐
2.6b	* determined in the acidic range (pH 4 to 6)	Y	KIIA 2.6/01	Y		
2.6c	* determined in the alkaline range (pH 8 to 10)	Y	KIIA 2.6/01	Y		☐
2.7	Solubility in organic solvents at 15 to 25° C	Y	KIIA 2.7/01	Y		☐
2.8	Partition coefficient					
2.8.1	n-octanol/water partition coefficient	Y	KIIA 2.8.1/01	Y		☐
2.8.2	Effect of pH (4 to 10) on the n-octanol/water partition coefficient	Y	KIIA 2.8.2/01	Y		☐
2.9	Stability in water, hydrolysis rate, photochemical degradation, quantum yield and identity of breakdown products, dissociation constant					
2.9.1	Hydrolysis rate of purified active substance at pH values 4, 7 and 9 under sterile conditions, in the absence of light	Y	KIIA 2.9.1/01	Y		
2.9.1.a	* identity of hydrolysis products	Y	KIIA 2.9.1/01	Y		☐
2.9.1.b	* rate constant observed	Y	KIIA 2.9.1/01	Y		☐

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
2.9.1.c	* estimated DT_{50} value	Y	KIIA 2.9.1/01	Y		☐
2.9.2	Direct phototransformation of purified active substance in water using artificial light (simulating sunlight and excluding wavelengths λ < 290 nm) under sterile conditions, to include					
2.9.2.a	* photochemical half-life	Y	KIIA 2.9.2/01	Y		☐
2.9.2.b	* mass balance to account for 90 % of the applied radioactivity	Y	KIIA 2.9.2/01	Y		☐
2.9.2.c	* identity of breakdown products	Y	KIIA 2.9.2/01	Y		☐
2.9.3.	Quantum yield of direct phototransformation	Y	KIIA 2.9.3/01	Y		☐
2.9.4	Calculated theoretical lifetime in the top layer of aqueous systems and the real lifetime of the active substance	Y	KIIA 2.9.4/01-02	Y		☐
2.9.5	Dissociation in water of purified active substance					
2.9.5.a	* dissociation constant(s) (pKa values)	Y	KIIA 2.9.5/01	Y		☐
2.9.5.b	* identity of dissociated species formed	Y	KIIA 2.9.5/01	Y		☐
2.9.5.c	* dissociation constant(s) (pKa values) of the active principle	Y	KIIA 2.9.5/01	Y		☐
2.10	Estimated photochemical oxidative degradation	Y	KIIA 2.10/01	Y		☐
2.11	Flammability including auto-flammability					
2.11.1	Flammability of the active substance as manufactured	Y	KIIA 2.11.1/01	Y		☐
2.11.2	Auto-flammability of the active substance as manufactured	Y	KIIA 2.11.2/01-02	Y		☐
2.12	Flash point of the active substance as manufactured	Not relevant				☐
2.13	Explosive properties of the active substance as manufactured	Y	KIIA 2.13/01	Y		☐
2.14	Surface tension of the active substance as manufactured	Y	KIIA 2.14/01	Y		☐
2.15	Oxidizing properties of the active substance as manufactured	Y	KIIA 2.15/01	Y		☐
2.16	pH	No EC data requirement		Y	KIIA 2.16/01-02 Y	
2.17	Stability	No EC data requirement				
2.17.1	Storage stability	No EC data requirement		Y	KIIA 2.17.1/01 Y	
2.17.2	Stability (temperature, metals)	No EC data requirement		Y	KIIA 2.17.2/01 Y	
2.18	Other/special studies	Y	KIIA 2.18/01-07	Y		☐
3	Further information on the active substance (function, mode of action, handling)					
3.1	Function *e.g.* fungicide	Y	Doc M-IIA Sec 1/03	Y		☐
3.2	Effects on harmful organisms					
3.2.1	Nature of the effects on harmful organisms *e.g.* contact action	Y	Doc M-IIA Sec 1/03	Y		☐

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
3.2.2	Whether or not translocated in plants and if translocated whether such translocation is apoplastic, symplastic or both	Y	Doc M-IIA Sec 1/03	Y		☐
3.3	Fields of use *e.g.* forestry	Y	Doc M-IIA Sec 1/03	Y		☐
3.4	Harmful organisms controlled and crops or products protected or treated					
3.4.1	Details of existing and intended uses (crops, group of crops, plants or plant products treated or protected)	Y	KIIA 3.4.1/01-02	Y		☐
3.4.2	Details of harmful organisms against which protection is afforded	Y	Doc M-IIA Sec 1/03	Y		☐
3.4.3	Effects achieved *e.g.* sprout suppression	Y	Doc M-IIA Sec 1/03	Y		☐
3.5	Mode of action					
3.5.1	Statement of the mode of action of the active substance (in terms of biochemical and physiological mechanism(s) and biochemical pathway(s) involved	Y	Doc M-IIA Sec 1/03	Y		☐
3.5.2	Details of active metabolites and degradation products cross referenced to the toxicological and residues data provided, to include					
3.5.2.a	* IUPAC and CA names	Y	Doc M-IIA Sec 1/03	Y		☐
3.5.2.b	* ISO common name proposed or accepted	Y	Doc M-IIA Sec 1/03	Y		☐
3.5.2.c	* CAS, CIPAC, EINECS and ELINCS numbers	Y	Doc M-IIA Sec 1/03	Y		☐
3.5.2.d	* molecular and structural formula	Y	Doc M-IIA Sec 1/03	Y		☐
3.5.2.e	* molecular mass	Y	Doc M-IIA Sec 1/03	Y		☐
3.5.3	Information relative to the formation of active metabolites and degradation products, to include	Y	Doc M-IIA Sec 1/03	Y		
3.5.3.a	* the processes, mechanisms and reactions involved	Y	Doc M-IIA Sec 1/03	Y		☐
3.5.3.b	* kinetic and other data concerning the rate of conversion and if known the rate limiting step	Y	Doc M-IIA Sec 1/03	Y		☐
3.5.3.c	* environmental and other factors effecting the rate and extent of conversion	Y	Doc M-IIA Sec 1/03	Y		☐
3.6	Information on the possible occurrence of the development of resistance or cross-resistance	Y	KIIA 3.6/01	Y		☐
3.7	A material safety data sheet for the active substance	Y	KIIA 3.7/01	Y		☐
3.8	Procedures for destruction or decontamination					
3.8.1	Pyrolytic behaviour of the active substance under controlled conditions at 800 °C and the content of polyhalogenated dibenzo-p-dioxins in the products of pyrolysis	Y	KIIA 3.8.1/01	Y		☐
3.8.2	Detailed instructions for safe disposal	Y	Doc M-IIA Sec 1/03	Y		☐

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
3.8.3	Methods other than controlled incineration for disposal of the active substance, contaminated packaging and contaminated materials					
3.8.3.a	* detailed description of such methods	Y	Doc M-IIA Sec 1/03	Y		☐
3.8.3.b	* data to establish their effectiveness and safety	Y	Doc M-IIA Sec 1/03	Y		☐
3.9	Procedures for the decontamination of water in the case of an accident	Y	Doc M-IIA Sec 1/03	Y		☐
3.10	Other/special studies	Not relevant				☐
4	Analytical methods					
4.1	Analytical standards and samples					
4.1.1	Analytical standards for pure active substance	Not relevant				☐
4.1.2	Samples of the active substance as manufactured	Not relevant				☐
4.1.3	Analytical standards for relevant metabolites and other components included in the residue definition	Not relevant				☐
4.1.4	Samples of reference substances for relevant impurities	Not relevant				☐
4.2	Methods of the analysis of the active substance as manufactured					
4.2.1	Description of analytical methods for the analysis of the active substance as manufactured For each method submitted:	Y	KIIA 4.2.1/01-02	Y		☐
4.2.1.a	* specificity	Y	KIIA 4.2.1/01-02	Y		☐
4.2.1.b	* extent of interference by other substances present	Y	KIIA 4.2.1/01-02	Y		☐
4.2.1,c	* explantation of interferences which contribute more than ± 3 % of the total quantity determined	Y	KIIA 4.2.1/01-02	Y		☐
4.2.1.d	Linearity over an appropriate range:					
4.2.1.e	* equation of the calibration line	Y	KIIA 4.2.1/01-02	Y		☐
4.2.1.f	* correlation co-efficiënt	Y	KIIA 4.2.1/01-02	Y		☐
4.2.1.g	* representative labelled documentation *e.g.* chromatograms	Y	KIIA 4.2.1/01-02	Y		☐
4.2.1.h	Accuracy:					
4.2.1.i	* pure active substance	Y	KIIA 4.2.1/01-02	Y		☐
4.2.1.j	* impurities	Y	KIIA 4.2.1/01-02	Y		☐
4.2.1.k	Repeatability (at least 5 determinations):					
4.2.1.l	* % relative standard deviation (RSD)	Y	KIIA 4.2.1/01-02	Y		☐
4.2.1.m	* indication as to whether outliers identified have been discarded	Y	KIIA 4.2.1/01-02	Y		☐
4.2.1.n	* reasons for the occurrence of outliers	Y	KIIA 4.2.1/01-02	Y		☐

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
4.2.2	Applicability of existing CIPAC methods	Not relevant				☐
4.2.3	Description of analytical methods for the determination of impurities (non-active components arising from the manufacturing process or from the degradation during storage), which are of toxicological, ecotoxicological or environmental concern or which are present in quantities ≥ 1 g/kg in the active substance as manufactured For each method submitted:	Y	KIIA 4.2.3/01-08	Y		☐
4.2.3.a	* specificity	Y	KIIA 4.2.3/01-08	Y		☐
4.2.3.b	* extent of interference by other substances present	Y	KIIA 4.2.3/01-08	Y		☐
4.2.3.c	* explantation of interferences which contribute more than ± 3 % of the total quantity determined	Y	KIIA 4.2.3/01-08	Y		☐
4.2.3.d	Linearity over an appropriate range:					
4.2.3.e	* equation of the calibration line	Y	KIIA 4.2.3/01-08	Y		☐
4.2.3.f	* correlation co-efficient	Y	KIIA 4.2.3/01-08	Y		☐
4.2.3.g	* representative labelled documentation *e.g.* chromatograms	Y	KIIA 4.2.3/01-08	Y		☐
4.2.3.h	Accuracy:					
4.2.3.i	* pure active substance	Y	KIIA 4.2.3/01-08	Y		☐
4.2.3.j	* impurities	Y	KIIA 4.2.3/01-08	Y		☐
4.2.3.k	Repeatability (at least 5 determinations):					
4.2.3.l	* % relative standard deviation (RSD)	Y	KIIA 4.2.3/01-08	Y		☐
4.2.3.m	* indication as to whether outliers identified have been discarded	Y	KIIA 4.2.3/01-08	Y		☐
4.2.3.n	* reasons for the occurrence of outliers	Y	Doc J-II	Y		☐
4.2.4	Description of analytical methods for the determination of additives (*e.g*. stabilizers) in the active substance as manufactured For each method submitted:	Y	Doc J-II	Y		☐
4.2.4.a	* specificity	Y	Doc J-II	Y		☐
4.2.4.b	* extent of interference by other substances present	Y	Doc J-II	Y		☐
4.2.4.c	* explantation of interferences which contribute more than ± 3 % of the total quantity determined	Y	Doc J-II	Y		☐
4.2.4.d	Linearity over an appropriate range:					
4.2.4.e	* equation of the calibration line	Y	Doc J-II	Y		☐
4.2.4.f	* correlation co-efficient	Y	Doc J-II	Y		☐
4.2.4.g	* representative labelled documentation *e.g.* chromatograms	Y	Doc J-II	Y		☐
4.2.4.h	Accuracy:					
4.2.4.i	* pure active substance	Y	Doc J-II	Y		☐
4.2.4.j	* impurities	Y	Doc J-II	Y		☐
4.2.4.k	Repeatability (at least 5 determinations):					

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
4.2.4.l	* % relative standard deviation (RSD)	Y	Doc J-II	Y		☐
4.2.4.m	* indication as to whether outliers identified have been discarded	Y	Doc J-II	Y		☐
4.2.4.n	* reasons for the occurrence of outliers	Y	Doc J-II	Y		☐
4.2.5	Enforcement analytical methodology	No EC data requirement				
4.2.6	Inter-Laboratory analytical methodology validation	No EC data requirement				
4.2.7	Storage stability of working solutions in analytical methodology	No EC data requirement				
4.3	Description of analytical methods for the determination of residues (all components included in the residue definition proposed (see point 6) to anable compliance with MRLs to be determined or to determine dislodgeable residues) For each method and representative matrix:					
4.3.a	* specificity (using a comfirmatory method, if appropriate)	Y	KIIA 4.3/01-09	Y		☐
4.3.b	* repeatability	Y	KIIA 4.3/01-09	Y		☐
4.3.c	* validation – independent laboratory	Y	KIIA 4.3/01-09	Y		☐
4.3.d	* limit of determination	Y	KIIA 4.3/01-09	Y		☐
4.3.e	* individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level	Y	KIIA 4.3/01-09	Y		☐
4.4.	Description of methods for analysis of soil for parent compound and metabolites of toxicological, ecotoxicological or environmental concern For each method:	Y	KIIA 4.4/01	Y		☐
4.4.a	* specificity (using a comfirmatory method, if appropriate)	Y	KIIA 4.4/01	Y		☐
4.4.b	* repeatability	Y	KIIA 4.4/01	Y		☐
4.4.c	* limit of determination	Y	KIIA 4.4/01	Y		☐
4.4.d	* individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level	Y	KIIA 4.4/01	Y		☐
4.5.	Description of methods for analysis of water (drinking water, ground water and surface water) for parent compound and metabolites of toxicological, ecotoxicological or environmental concern For each method:	Y	KIIA 4.5/01	Y		☐
4.5.a	* specificity (using a comfirmatory method, if appropriate)	Y	KIIA 4.5/01	Y		☐
4.5.b	* repeatability	Y	KIIA 4.5/01	Y		☐
4.5.c	* limit of determination	Y	KIIA 4.5/01	Y		☐
4.5.d	* individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level	Y	KIIA 4.5/01	Y		☐
4.6	Method for determining pesticides in sediment For each method:	No EC data requirement				

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
4.6.a	* specificity (using a comfirmatory method, if appropriate)	No EC data requirement				
4.6.b	* repeatability	No EC data requirement				
4.6.c	* limit of determination	No EC data requirement				
4.6.d	* individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level	No EC data requirement				
4.7.	Description of methods for analysis of air for active substance and metabolites, formed during or shortly after application, of toxicological concern For each method:	Y	KIIA 4.7/01	Y		☐
4.7.a	* specificity (using a comfirmatory method, if appropriate)	Y	KIIA 4.7/01	Y		☐
4.7.b	* repeatability	Y	KIIA 4.7/01	Y		☐
4.7.c	* limit of determination	Y	KIIA 4.7/01	Y		☐
4.7.d	* individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level	Y	KIIA 4.7/01	Y		☐
4.8.	Analytical methods for parent compound and toxicologically, ecotoxicologically or environmentally significant metabolites in body fluids and tissues For each method:	Not relevant				☐
4.8.a	* specificity (using a comfirmatory method, if appropriate)	Not relevant				☐
4.8.b	* repeatability	Not relevant				☐
4.8.c	* limit of determination	Not relevant				☐
4.8.d	* individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level	Not relevant				☐
4.9	Other/special studies	Not relevant				☐
5	Toxicological and toxicokinetic studies on the active substance					
5.1	Absorption, distribution, excretion and metabolism in mammals					
5.1.1	Toxicokinetic studies - Single dose, oral route, in rats	Y	KIIA 5.1.1/01-02	Y		☐
5.1.2	Toxicokinetic studies - Second single dose, oral route, in rats	Y	KIIA 5.1.2/01-03	Y		☐
5.1.3	Toxicokinetic studies - Repeated dose, oral route, in rats	Y	KIIA 5.1.3/01-02	Y		☐
5.2	Acute toxicity					
5.2.1	Acute oral toxicity	Y	KIIA 5.2.1/01	Y		☐
5.2.2	Acute percutaneous toxicity	Y	KIIA 5.2.2/01	Y		☐
5.2.3	Acute inhalation toxicity	Y	KIIA 5.2.3/01	Y		☐
5.2.4	Skin irritation	Y	KIIA 5.2.4/01	Y		☐
5.2.5	Eye irritation	Y	KIIA 5.2.5/01	Y		☐

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
5.2.6	Skin sensitization	Y	KIIA 5.2.6/01	Y		☐
5.2.7	Potentiation/interactions of multiple active ingredients(substances) or products	No EC data requirement				
5.3	Short-term toxicity					
5.3.1	Oral 28-day toxicity	Y	KIIA 5.3.1/01-04	Y		☐
5.3.2	Oral 90-day toxicity (rodents)	Y	KIIA 5.3.2/01-02	Y		☐
5.3.3	Oral 90-day toxicity (dog)	Y	KIIA 5.3.3/01	Y		☐
5.3.4	Oral 1 year toxicity (dog)	Y	KIIA 5.3.4/01	Y		☐
5.3.5	28-day inhalation toxicity (rodents)	Not relevant				☐
5.3.6	90-day inhalation toxicity (rodents)	Not relevant				☐
5.3.7	Percutaneous 28-day toxicity (rodents)	Not relevant				☐
5.3.8	Percutaneous 90-day toxicity (rodents)	Not relevant				☐
5.4	Genotixicity					
5.4.1	*In vitro* genotoxicity testing - Bacterial assay for gene mutation	Y	KIIA 5.4.1/01-02	Y		☐
5.4.2	*In vitro* genotoxicity testing - Test for clastogenicity in mammalian cells	Y	KIIA 5.4.2/01	Y		☐
5.4.3	*In vitro* genotoxicity testing - Test for gene mutation in mammalian cells	Y	KIIA 5.4.3/01	Y		☐
5.4.4	*In vivo* genotoxicity testing (somatic cells) - Metaphase analysis in rodent bone marrow, or micronucleus test in rodents	Y	KIIA 5.4.4/01-02	Y		☐
5.4.5	*In vivo* genotoxicity testing (somatic cells) - Unscheduled DNA synthesis or a mouse spot test	Not relevant				☐
5.4.6	*In vivo* studies in germ cells	Not relevant				☐
5.5	Long-term toxicity and carcinogenicity					
5.5.1	Long-term (2 years) oral toxicity in the rat (can be a combined long-term and carcinogenicity study)	Y	See KIIA 5.5.2	Y		☐
5.5.2	Carcinogenicity study in the rat (can be a combined long-term and carcinogenicity study)	Y	KIIA 5.5.2/01	Y		☐
5.5.3	Carcinogenicity study in the mouse	Y	KIIA 5.5.3/01	Y		☐
5.5.4	Mechanism of action and supporting data	Not relevant				☐
5.6	Reproductive toxicity					
5.6.1	Two generation reproductive toxicity in the rat	Y	KIIA 5.6.1/01-02	Y		☐
5.6.2	Separate male and female studies	Y	Doc M-IIA Sec 3/01	Y		☐
5.6.3	Three segment designs	Y	Doc M-IIA Sec 3/01	Y		☐
5.6.4	Dominant lethal assay for male fertility	Y	Doc M-IIA Sec 3/01	Y		☐

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
5.6.5	Cross-matings of treated males with untreated females and *vice versa*	Y	Doc M-IIA Sec 3/01	Y		☐
5.6.6	Effect on spermatogenesis	Y	Doc M-IIA Sec 3/01	Y		☐
5.6.7	Effects on oogenesis	Y	Doc M-IIA Sec 3/01	Y		☐
5.6.8	Sperm motility, mobility and morphology	Y	Doc M-IIA Sec 3/01	Y		☐
5.6.9	Investigation of hormonal activity	Y	Doc M-IIA Sec 3/01	Y		☐
5.6.10	Teratogenicity test by the oral route in the rat	Y	KIIA 5.6.10/01-02	Y		☐
5.6.11	Teratogenicity test by the oral route in the rabbit	Y	KIIA 5.6.11/01	Y		☐
5.7	Neurotoxicity	No EC data requirement				
5.7.1	Acute neurotoxicity – rat	Y	KIIA 5.7.1/01	Y		☐
5.7.2	Delayed neurotoxicity following acute exposure	Y	Doc M-IIA Sec 3/01	Y		☐
5.7.3	28-day delayed neurotoxicity	Y	Doc M-IIA Sec 3/01	Y		☐
5.7.4	Subchronic neurotoxicity – rat – 90 day	Y	KIIA 5.7.4/01	Y		☐
5.7.5	Postnatal development neurotoxicity	Not relevant for EU	Doc M-IIA Sec 3/01	Y		☐
5.8	Toxicity studies on metabolites	Y	KIIA 5.8/01-19	Y		☐
5.9	Medical data					
5.9.1	Report on medical surveillance on manufacturing plant personnel	Y	Doc M-IIA Sec 3/01	Y		☐
5.9.2	Report on clinical cases and poisoning incidents	Y	Doc M-IIA Sec 3/01	Y		☐
5.9.3	Observations on exposure of the general population and epidemiological studies	Y	Doc M-IIA Sec 3/01	Y		☐
5.9.4	Clinical signs and symptoms of poisoning and details of clinical tests	Y	Doc M-IIA Sec 3/01	Y		☐
5.9.5	First aid measures	Y	Doc M-IIA Sec 3/01	Y		☐
5.9.6	Therapeutic regimes	Y	Doc M-IIA Sec 3/01	Y		☐
5.9.7	Expected effects and duration of poisoning as a function of the type, level and duration of exposure or ingestion	Y	Doc M-IIA Sec 3/01	Y		☐
5.9.8	Expected effects and duration of poisoning as a function of varying time periods between exposure or ingestion and commencement of treatment	Y	Doc M-IIA Sec 3/01	Y		☐
5.9.9	Dermal penetration	Y	Doc M-IIA Sec 3/01	Y		☐
5.10	Other/special studies	Y	KIIA 5.10/01-04	Y		☐
5.11	Summary of mammalian toxicity and overall evaluation	Y	Doc M-IIA Sec 3/01	Y		☐
6	Metabolism and residues data					

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
6.1	Stability of residues					
6.1.1	Stability of residues during storage of samples	Y	KIIA 6.1.1/01-02	Y		☐
6.1.2	Stability of residues in sample extracts	Y	Doc M-IIA Sec 4/01 (Refer to 6.1.1)	Y		☐
6.2.	Metabolism, distribution and expression of residues					
6.2.1	In plants, in at least three crops representative of the different crop groups (root vegetables; leafy crops; fruits; pulses and oilseed; cereals)	Y	KIIA 6.2.1/01-12	Y		☐
6.2.2	Poultry	Y	KIIA 6.2.2/01-02	Y		☐
6.2.3	Lactating ruminants (goat or cow)	Y	KIIA 6.2.3/01-02	Y		☐
6.2.4	Pigs	Y	Doc M-IIA Sec 4/01	Y		☐
6.2.5	Nature of residue in fish	No EC data requirement See also Doc M-IIA Sec 04				
6.2.6	Chemical identity (emphasis on impurities of residual concern)	No EC data requirement				
6.3	Residue trials (supervised field trials) for crops or plant products used as food or feed on which use is proposed or where residues from soil can be taken up					
6.3.1	Pre-harvest use on major crops	Y	KIIA 6.3.1.1/01-06 (lettuce) 6.3.1.2/01-02 (hops)	Y		☐
6.3.2	Pre-harvest use on minor crops	Not relevant				☐
6.3.3	Post-harvest uses	Not relevant				☐
6.3.4	Tobacco	No EC data requirement				
6.4	Livestock feeding studies					
6.4.1	Poultry	Y	KIIA 6.4.1/01	Y		☐
6.4.2	Lactating ruminants (goat or cow)	Y	KIIA 6.4.2/01	Y		☐
6.4.3	Pigs	Y	Doc M-IIA Sec 4/01	Y		☐
6.4.4	Fish	No EC data requirement				
6.5	Effects of industrial processing and/or household preparation (representative processing situations) on					
6.5.1	The nature of residue	Y	Doc M-IIA Sec 4/01	Y		☐
6.5.2	Distribution of the residue in peel/pulp	Y	Doc M-IIA Sec 4/01	Y		☐
6.5.3	Residue levels - balance studies on a core set of representative processes	Y	Doc M-IIA Sec 4/01	Y		☐
6.5.4	Residue levels - follow-up studies to determine concentration or dilution factors	Y	KIIA 6.5.4/01-02	Y		☐
6.6	Residues in succeeding crops					

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
6.6.1	Theoretical consideration of the nature and level of the residue	Y	Doc M-IIA Sec 4/01	Y		☐
6.6.2	Metabolism and distribution studies on representative crops	Y	KIIA 6.6.2/01-02	Y		☐
6.6.3	Field trials on representative crops	Y	KIIA 6.6.3/01	Y		☐
6.7	Proposed residue definition and maximum residue levels					
6.7.1	Proposed residue definition	Y	Doc M-IIA Sec 4/01	Y		☐
6.7.2	Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed, including details of statistical analyses used. If new MRLs are proposed, applicant also has send in 'Application form MRL'	Y	Doc M-IIA Sec 4/01	Y		☐
6.8	Proposed pre-harvest intervals, re-entry intervals or withholding periods to minimize residues in crops, plants, plant products, treated areas or spaces and a justification for each proposal					
6.8.1	Pre-harvest interval (in days) for each relevant crop	Y	Doc M-IIA Sec 4/01	Y		☐
6.8.2	Re-entry period (in days) for livestock, to areas to be grazed	Y	Doc M-IIA Sec 4/01	Y		☐
6.8.3	Re-entry period (in hours or days) for man to crops, buildings or spaces treated	Y	Doc M-IIA Sec 4/01	Y		☐
6.8.4	Withholding period (in days) for animal feeding stuffs	Y	Doc M-IIA Sec 4/01	Y		☐
6.8.5	Waiting period (in days) between last application and sowing or planting the crop to be protected	Y	Doc M-IIA Sec 4/01	Y		☐
6.8.6	Waiting period (in days) between application and handling treated products	Y	Doc M-IIA Sec 4/01	Y		☐
6.8.7	Waiting period (in days) between last application and sowing or planting succeeding crops	Y	Doc M-IIA Sec 4/01	Y		☐
6.9	Estimation of the potential and actual exposure through diet and other means					
6.9.1	TMDI calculations	Y	Doc M-IIA Sec 4/01	Y		☐
6.9.2	NEDI calculations	Y	Doc M-IIA Sec 4/01	Y		☐
6.9.3	NESTI calculations	Y	Doc M-IIA Sec 4/01	Y		☐
6.10	Other/special studies	Not relevant				☐
6.11	Summary and evaluation of residue behaviour	Y	Doc M-IIA Sec 4/01	Y		
6.11.a	Summary and evaluation of residue behaviour	Y	Doc M-IIA Sec 4/01	Y		☐
6.11.b	Reasonable grounds in support of the petition	No EC data requirement				
7	Fate and behaviour in the environment					
7.1	Route of degradation in soil – laboratory studies					

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
7.1.1	Aerobic degradation	Y	KIIA 7.1.1/01-06	Y		☐
7.1.2	Anaerobic degradation	Y	KIIA 7.1.2/01-03	Y		☐
7.1.3	Soil photolysis	Y	KIIA 7.1.3/01	Y		☐
7.2	Rate of degradation in soil(s) - laboratory studies	Y	Doc M-IIA Sec 5/01	Y		
7.2.1	Aerobic degradation of the active substance in soils at 20 °C	Y	KIIA 7.2.1/01-10	Y		☐
7.2.2	Aerobic degradation of the active substance in soil at 10 °C	Y	Doc M-IIA Sec 5/01	Y		☐
7.2.3	Aerobic degradation of relevant metabolites, degradation and reaction products in soils at 20 °C	Y	KIIA 7.2.3/01-05	Y		☐
7.2.4	Anaerobic degradation of the active substance in soil	Y	Doc M-IIA Sec 5/01	Y		☐
7.2.5	Anaerobic degradation of relevant metabolites, degradation and reaction products in soil	Y	Doc M-IIA Sec 5/01	Y		☐
7.3	Field studies	Y	Doc M-IIA Sec 5/01	Y		
7.3.1	Soil dissipation testing in a range of representative soils – (normally 4 soils)	Y	KIIA 7.3.1/01	Y		☐
7.3.2	Soil residue testing	Y	Doc M-IIA Sec 5/01	Y		☐
7.3.3	Soil accumulation testing on relevant soils	Y	Doc M-IIA Sec 5/01	Y		☐
7.4	Mobility studies					
7.4.1	Adsorption and desorption of the active substance	Y	KIIA 7.4.1/01-04	Y		☐
7.4.2	Adsorption and desorption of all relevant metabolites, degradation and reaction products in 3 soils	Y	KIIA 7.4.2/01-02	Y		☐
7.4.3	Column leaching studies with the active substance	Y	KIIA 7.4.3/01	Y		☐
7.4.4	Column leaching studies with relevant metabolites, degradation and reaction products	Y	Doc M-IIA Sec 5/01	Y		☐
7.4.5	Aged residue column leaching	Y	Doc M-IIA Sec 5/01	Y		☐
7.4.6	Leaching (TLC)	No EC data requirement				
7.4.7	Lysimeter studies	Y	Doc M-IIA Sec 5/01	Y		☐
7.4.8	Field leaching studies	Y	Doc M-IIA Sec 5/01	Y		☐
7.4.9	Volatility – laboratory studies	Y	Doc M-IIA Sec 5/01 And KIIIA 7.4.9/01-02	Y		☐
7.5	Hydrolysis rate of relevant metabolites, degradation and reaction products at pH values 4, 7 and 9 under sterile conditions, in the absence of light	Y	KIIA 7.5/01	Y		
7.5.a	* identity of hydrolysis products	Y	KIIA 7.5/01	Y		☐
7.5.b	* rate constant observed (for metabolites)	Y	KIIA 7.5/01	Y		☐

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
7.5.c	* estimated DT_{50} value	Y	KIIA 7.5/01	Y		☐
7.6	Direct phototransformation of relevant metabolites, degradation and reaction products in water using artificial light (simulating sunlight and excluding wavelengths λ < 290 nm) under sterile conditions, to include	Y	KIIA 7.6/01-03	Y		
7.6.a	* photochemical half-life	Y	KIIA 7.6/01-03	Y		☐
7.6.b	* mass balance to account for 90 % of the applied radioactivity	Y	KIIA 7.6/01-03	Y		☐
7.6.c	* identity of breakdown products	Y	KIIA 7.6/01-03	Y		☐
7.6.d	* quantum yield of direct phototransformation	Y	KIIA 7.6/01-03	Y		☐
7.6.e	* calculated theoretical lifetime in the top layer of aqueous systems and the real lifetime of the substance added	No EC data requirement				
7.7	Ready biodegradability of the active substance	Y	Doc M-IIA Sec 5/01	Y		☐
7.8	Degradation in aquatic systems					
7.8.1	Aerobic biodegradation in aquatic systems, including identification of breakdown products and metabolites	No EC data requirement				
7.8.2	Anaerobic biodegradation in aquatic systems, including identification of breakdown products and metabolites	No EC data requirement	Y	KIIA 7.8.2/01	Y	
7.8.3	Water/sediment study	Y	KIIA 7.8.3/01-04	Y		☐
7.9	Degradation in the saturated zone of the active substance, metabolites, degradation and reaction products	Y	Doc M-IIA Sec 5/01	Y		☐
7.10	Rate and route of degradation in air	Y	KIIA 7.10/01	Y		☐
7.11	Definition of the residue	Y	Doc M-IIA Sec 5/01	Y		☐
7.12	Monitoring data concerning fate and behaviour of the active substance and of relevant metabolites, degradation and reaction products	Y	Doc M-IIA Sec 5/01	Y		☐
7.13	Other/special studies	Y	KIIA 7.13/01-16	Y		☐
8	Ecotoxicological studies on the active substance					
8.1	Avian toxicity					
8.1.1	Acute oral toxicity to a quail species (Japanese or Bobwhite), mallard duck, or other bird species	Y	KIIA 8.1.1/01-03	Y		☐
8.1.2	Avian dietary toxicity (5-day) test in a quail species or in mallard duck	Y	KIIA 8.1.2/01-02	Y		☐
8.1.3	Avian dietary toxicity (5-day) test in a second unrelated species	Y	Doc M-IIA Sec 6/01	Y		☐
8.1.4	Subchronic and reproductive toxicity to birds	Y	KIIA 8.1.4/01-02	Y		☐
8.2	Fish toxicity					

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
8.2.1	Acute toxicity of the active substance to fish	Y	Doc M-IIA Sec 6/01	Y		
8.2.1.1a	Rainbow trout (*Oncorhynchus mykiss*)	Y	KIIA 8.2.1.1/01-02	Y		☐
8.2.1.1b	Analytical data on concentrations in the test media	Y	KIIA 8.2.1.1/01-02	Y		☐
8.2.1.2a	Warm water fish species	Y	KIIA 8.2.1.2/01-02	Y		☐
8.2.1.2b	Analytical data on concentrations in the test media	Y	KIIA 8.2.1.2/01-02	Y		☐
8.2.1.3a	Acute toxicity of metabolites,degradation or reaction products to the more sensitive of the fish species used to test the acute toxicity of the active substance	Y	KIIA 8.2.1.3/01-02	Y		☐
8.2.1.3b	Analytical data on concentrations in the test media	Y	KIIA 8.2.1.3/01-02	Y		☐
8.2.3.a	Chronic toxicity (28 day exposure) to juvenile fish growth and behaviour	Y	Doc M-IIA Sec 6/01	Y		☐
8.2.3.b	Analytical data on concentrations in the test media	Y	Doc M-IIA Sec 6/01	Y		☐
8.2.4.a	Fish early life stage toxicity test	Y	KIIA 8.2.4/01	Y		☐
8.2.4.b	Analytical data on concentrations in the test media	Y	KIIA 8.2.4/01	Y		☐
8.2.5.a	Fish life cycle test	Y	Doc M-IIA Sec 6/01	Y		☐
8.2.5.b	Analytical data on concentrations in the test media	Y	Doc M-IIA Sec 6/01	Y		☐
8.2.6.1	Bioconcentration potential of the active substance in fish	Y	Doc M-IIA Sec 6/01	Y		☐
8.2.6.2	Bioconcentration potential of metabolites, degradation and reaction products	Y	Doc M-IIA Sec 6/01	Y		☐
8.2.7	Aquatic bioavailability/biomagnification/ depuration	No EC data requirement Y Doc M-IIA Sec 6				
8.3	Toxicity to aquatic species other than fish and aquatic species field testing					
8.3.1	Acute toxicity to aquatic invertebrates					
8.3.1.1a	Acute toxicity (24 and 48 hour) for *Daphnia* preferably (*Daphnia magna)*	Y	KIIA 8.3.1.1/01-03	Y		☐
8.3.1.1b	Analytical data on concentrations in the test media	Y	KIIA 8.3.1.1/01-03	Y		☐
8.3.1.2a	Acute toxicity (24 and 48 hour) for representative species of aquatic insects	Y	KIIA 8.3.1.2/01-04	Y		☐
8.3.1.2b	Analytical data on concentrations in the test media	Y	KIIA 8.3.1.2/01-04	Y		☐
8.3.1.3a	Acute toxicity (24 and 48 hour) for representative species of aquatic crustaceans (species unrelated to *Daphnia*)	Y	Doc M-IIA Sec 6/01	Y		☐

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
8.3.1.3b	Analytical data on concentrations in the test media	Y	Doc M-IIA Sec 6/01	Y		☐
8.3.1.4a	Acute toxicity (24 and 48 hour) for representative species of aquatic gastropod molluscs	Y	Doc M-IIA Sec 6/01	Y		☐
8.3.1.4b	Analytical data on concentrations in the test media	Y	Doc M-IIA Sec 6/01	Y		☐
8.3.2	Chronic toxicity to aquatic invertebrates					
8.3.2.1a	Chronic toxicity in *Daphnia magna* (21-day)	Y	KIIA 8.3.2.1/01-02	Y		☐
8.3.2.1b	Analytical data on concentrations in the test media	Y	KIIA 8.3.2.1/01-02	Y		☐
	Chronic toxicity for at least one representative species from each of the following groups					
8.3.2.2a	Chronic toxicity for representative species of aquatic insects	Y	KIIA 8.3.2.2/01-03	Y		☐
8.3.2.2b	Analytical data on concentrations in the test media	Y	KIIA 8.3.2.2/01-03	Y		☐
8.3.2.3a	Chronic toxicity for representative species of aquatic gastropod mollusc	Y	Doc M-IIA Sec 6/01	Y		☐
8.3.2.3b	Analytical data on concentrations in the test media	Y	Doc M-IIA Sec 6/01	Y		☐
8.3.3	Aquatic field testing	No EC data requirement Y Doc M-IIA Sec 06/01				
8.4	Toxicity to algae	Y	KIIA 8.4/01-04	Y		☐
8.4.a	Effects on algal growth and growth rate (2 species)					
8.4.b	Analytical data on concentrations in the test media	Y	KIIA 8.4/01-04	Y		☐
8.5	Effects on sediment dwelling organisms	Y	Doc M-IIA Sec 6	Y		
8.5.1a	Acute test	Y	KIIA 8.5.1/01	Y		☐
8.5.1b	Analytical data on concentrations in the test media	Y	KIIA 8.5.1/01	Y		☐
8.5.2a	Chronic test	Y	KIIA 8.5.2/01	Y		☐
8.5.2b	Analytical data on concentrations in the test media	Y	KIIA 8.5.2/01	Y		☐
8.6	Toxicity to aquatic plants	Y	KIIA 8.6/01	Y		
8.6a	Effects on aquatic plants					☐
8.6b	Analytical data on concentrations in the test media	Y	KIIA 8.6/01	Y		☐
8.7	Effects on bees					
8.7.1	Acute oral toxicity	Y	KIIA 8.7.1/01-06	Y		☐
8.7.2	Acute contact toxicity	Y	Doc M-IIA Sec 6/01 (Refer to 8.7.1)	Y		☐
8.7.3	Toxicity of residues on foliage to honey bees	No EC data requirement Refer to Annex III; Doc KIIIA1 10.4.3/01				

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
8.7.4	Bee brood feeding test	Y	Refer to Annex III, KIIIA 10.4.7/06	Y		☐
8.8	Effects on non-target terrestrial arthropods					
8.8.1	Effects on non-target terrestrial arthropods using artificial substrates (in laboratory tests)					
8.8.1.1	Parasitoid	Y	KIIA 8.8.1.1/01	Y		☐
8.8.1.2	Predatory mites	Y	KIIA 8.8.1.2/01	Y		☐
8.8.1.3	Ground dwelling predatory species (selected to be relevant to the intended uses of preparations)	Y	Doc M-IIA Sec 6/01	Y		☐
8.8.1.4	Foliage dwelling predatory species (selected to be relevant to the intended uses of preparations)	Y	Doc M-IIA Sec 6/01	Y		☐
8.8.2	Effects on non-target terrestrial arthropods in extended laboratory/semi field tests	Y Refer to Annex III, KIIIA1 10.5.2 and 10.5.3				
8.8.2.1	Parasitoid	Y	See 8.8.2	Y		☐
8.8.2.2	Predatory mites	Y	See 8.8.2	Y		☐
8.8.2.3	Ground dwelling predatory species (selected to be relevant to the intended uses of preparations)	Y	See 8.8.2	Y		☐
8.8.2.4	Foliage dwelling predatory species (selected to be relevant to the intended uses of preparations)	Y	See 8.8.2	Y		☐
8.8.2.5	Other terrestrial invertebrates	Y	See 8.8.2	Y		☐
8.9	Effects on earthworms					
8.9.1	Acute toxicity to earthworms	Y	KIIA 8.9.1/01-03	Y		☐
8.9.2	Sublethal effects on earthworms	Y	KIIA 8.9.2/01-03	Y		☐
8.10	Impact on soil microbial activity					
8.10.1	Nitrogen transformation	Y	KIIA 8.10.1/01-02	Y		☐
8.10.2	Carbon mineralization	Y	KIIA 8.10.2/01	Y		☐
8.10.3	Rates of recovery following treatment	Y	Doc M-IIA Sec 6/01	Y		n.a.
8.11	Effects on marine and estuarine organisms	No EC data requirement				
8.11.1	Marine or estuarine organisms - Acute toxicity LC_{50}/EC_{50}	No EC data requirement Y KIIA 8.11.1/01-04				
8.11.2	Marine/estuarine fish - Salinity challenge	No EC data requirement				
8.12	Effects on terrestrial vascular plants	Y	KIIA 8.12/01-02	Y		☐
8.13	Effects on terrestrial vertebrates other than birds/wild mammal toxicity	No EC data requirement				
(8.14)	Available preliminary data	Y	KIIA 8.14/01-06	Y		☐

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
8.14.1	Summary of all available data from preliminary tests used to assess biological activity and dose range finding, which may provide information on other non-target species (flora and fauna)	Y	KIIA 8.14.1/01	Y		☐
8.14.2	A critical assessment as to the relevance of the preliminary test data to potential impact on non-target species	Y	See Annex III dossier	Y		☐
8.15	Effects on biological methods for sewage treatment	Y	KIIA 8.15/01	Y		☐
(8.16)	Other/special studies (for instance for deriving a MPC-soil)					
8.16.1	Other/special laboratory studies	Y	KIIA 8.16.1/01-07	Y		☐
8.16.2	Other/special field studies	Y	KIIA 8.16.2/01-02	Y		☐
8.17	Summary and evaluation of points 7 and 8	Y	Doc M-IIA Sec 6/01	Y		☐
9	Justified proposals for the classification and labelling of the active substance according to Directive 67/548/EEC	Y	KIIA 9/01	Y		
9a	* Hazard symbol(s)	Y	Doc M-IIA Sec 1/04	Y		☐
9.b	* Indications of danger	Y	Doc M-IIA Sec 1/04	Y		☐
9.c	* Risk phrases	Y	Doc M-IIA Sec 1/04	Y		☐
9.d	* Safety phrases	Y	Doc M-IIA Sec 1/04	Y		☐

Naam middel:Sivanto (Flupyradifurone) SL 200

DOCUMENT O - Part 4

Explaining notes	
Information test or study provided	Three answers (yes, no, not relevant) are possible. In case "no" is filled in, the application is incomplete and will not be managed
Not relevant	This means - that data and information is not necessary owing to the nature of the substance, product or its supported uses; or - the data is not scientifically necessary or technically possible to supply information and/or data
Justification provided	If Y (yes) the location in the dossier has to be mentioned
Summary provided	If a summary is submitted, fill in Y (= yes). Otherwise fill in N (= no)
Reference list	The data that was submitted or has been provided for in an earlier application and which must be available at the Ctgb must be indicated. The location on the refence list must be given bij filling in the Annex-Point.
Data gap	This column is for use of the Ctgb only. Do not fill in.
OECD Annex point in brackets	Proposed new OECD point. Until further notice this item needs not to be submitted.
No EC data requirement	The OECD point concerned is no data requirement according to Council Directive 91/414/EEC. The data is therefor not required in the Netherlands.

Part 4 **Evaluation Form 4 -**
for checking that all test and study reports required in accordance with Annex IIIA have been provided, for applications for approval of active substances

Active Substance: Flupyradifurone Preparation: Sivanto SL 200

Applicant: Bayer CropSCience Date: April, 23, 2012

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
1	Identity of the plant protection product	Y	Doc M-IIIA1 Sec 1/01	Y		
1.1	Applicant (name, address, contact, telephone and telefax numbers)	Y	Doc M-IIIA1 Sec 1/01	Y		☐
1.2	Manufacturer of the preparation, manufacturer and purity of the active substance(s)					
1.2.1	Manufacturer(s) of the preparation (name, address, contact, telephone and telefax numbers)	Y	Doc M-IIIA1 Sec 1/01	Y		☐
1.2.2	Manufacturer of the active substance(s) (name, address, contact, telephone and telefax numbers)	Y	Doc M-IIIA1 Sec 1/01	Y		☐
1.2.3	Statement of purity (and detailed information on impurities) of the active substance	Y	Doc M-IIIA1 Sec 1/01	Y		☐
1.3	Trade name or proposed trade name and manufacturers code number(s), for the preparation and similar preparations (differences to be specified)	Y	Doc M-IIIA1 Sec 1/01	Y		☐
1.4	Detailed quantitative and qualitative information on the composition of the preparation					
1.4.1	Contents of:	Y	Doc J-III	Y		☐
1.4.1a	* technical active substance	Y	Doc J-III	Y		☐
1.4.1b	* pure active substance	Y	Doc J-III	Y		☐
1.4.1c	* formulants	Y	Doc J-III	Y		☐
1.4.2	Certified limits of each component	No EC data requirement				
(1.4.3)	Names and codes identifying the active substance	Y	Doc M-IIIA1 Sec 1/01	Y		
1.4.3.1	ISO common name proposed or accepted for active substances, and synonyms	Y	Doc M-IIIA1 Sec 1/01	Y		☐
1.4.3.2	Existing CIPAC, EINECS and ELINCS numbers for the active substance	Y	Doc M-IIIA1 Sec 1/01	Y		☐
1.4.3.3	Salt, ester, anion or cation present for each active substance	Y	Doc M-IIIA1 Sec 1/01	Y		☐
1.4.4	For each formulant, or component in formulants					
1.4.4a	* chemical name as in Annex I to Directive 67/548/EEC, if not included in that Annex, in accordance with IUPAC and CA nomenclature	Y	Doc M-IIIA1 Sec 1/01	Y		☐
1.4.4b	* structure or structural formula	Y	Doc M-IIIA1 Sec 1/01	Y		☐
1.4.4c	* existing CAS, CIPAC, EINECS and ELINCS numbers	Y	Doc M-IIIA1 Sec 1/01	Y		☐
1.4.4d	* trade name	Y	Doc M-IIIA1 Sec 1/01	Y		☐
1.4.4e	* specification of the formulant	Y	Doc M-IIIA1 Sec 1/01	Y		☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
1.4.4f	* function of each formulant	Y	Doc M-IIIA1 Sec 1/01	Y		☐
(1.4.5)	Formulation process	No EC data requirement				
1.4.5.1	Description of formulation process	No EC data requirement				
1.4.5.2	Discussion of the formation of impurities of toxicological concern	No EC data requirement				
1.5	Type of preparation (formulation) and code	Y	Doc M-IIIA1 Sec 1/01	Y		☐
1.6	Function (herbicide, insecticide *etc.*)	Y	Doc M-IIIA1 Sec 1/01	Y		☐
1.7	Other/special studies	Y	Doc M-IIIA1 Sec 1/01	Y		☐
2	Physical, chemical and technical properties of the plant protection product					
2.1	Description of the physical state of the preparation (formulation) and its colour and odour	Y	KIIIA1 2.1/01	Y		☐
2.2	Explosivity and oxidizing properties					
2.2.1	Explosive properties of the preparation	Y	KIIIA1 2.2.1/01	Y		☐
2.2.2	Oxidizing properties of the preparation	Y	KIIIA1 2.2.2/01	Y		☐
2.3	Flash point and other indication of flammability or spontaneous ignition					
2.3.1	The flash point of the preparation	Y	KIIIA1 2.3.1/01	Y		☐
2.3.2	The flammability of the preparation	Not relevant				☐
2.3.3	The auto-flammability of the preparation	Y	KIIIA1 2.3.3/01	Y		☐
2.4	Acidity/alkalinity and if necessary pH value					
2.4.1	Acidity or alkalinity and pH value	Not relevant				☐
2.4.2	pH of a 1 % aqueous dilution, emulsion or dispersion	Y	KIIIA1 2.4.2/01	Y		☐
2.5	Viscosity and surface tension					
2.5.1	Kinematic viscosity of the preparation	Y	KIIIA1 2.5.1/01	Y		☐
2.5.2	Viscosity of the preparation and details of the test conditions	Y	KIIIA1 2.5.2/01	Y		☐
2.5.3	Surface tension of the preparation	Y	KIIIA1 2.5.3/01	Y		☐
2.6	Relative density and bulk density					
2.6.1	Relative density of the preparation	Y	KIIIA1 2.6.1/01	Y		☐
2.6.2	Bulk or tap density of the preparation	Not relevant				☐
2.7	Storage stability and shelf-life					
2.7.1	Stability after storage for 14 days at 54 °C	Y	KIIIA1 2.7.1/01	Y		☐
2.7.2	Stability after storage for other periods and/or temperatures	Y	Doc M-IIIA1 Sec 1/02	Y		☐
2.7.3	Minimum content after heat stability testing	Y	KIIIA1 2.7.3/01	Y		☐
2.7.4	Effect of low temperature on stability	Y	KIIIA1 2.7.4/01	Y		☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
2.7.5	Shelf life following storage at ambient temperature	Y	Doc M-IIIA1 Sec 1/02 (study on going)	Y		☐
2.7.6	Shelf life in months	Y	Doc M-IIIA1 Sec 1/02	Y		☐
2.8	Technical characteristics of the plant protection product					
2.8.1	Wettability	Not relevant				☐
2.8.2	Persistent foaming	Y	KIIIA1 2.8.2/01	Y		☐
(2.8.3)	Suspensibility and suspension stability	Not relevant				
2.8.3.1	Suspensibility	Not relevant				☐
2.8.3.2	Spontaneity of dispersion	Not relevant				☐
2.8.4	Dilution stability	Y	KIIIA1 2.8.4/01	Y		☐
(2.8.5)	Sieve test	Not relevant				
2.8.5.1	Dry sieve test	Not relevant				☐
2.8.5.2	Wet sieve test	Not relevant				☐
(2.8.6)	Particle size distribution	Not relevant				
2.8.6.1	Size distribution of particles	Not relevant				☐
2.8.6.2	Nominal size range of granules	Not relevant				☐
2.8.6.3	Dust content	Not relevant				☐
2.8.6.4	Particle size of dust	Not relevant				☐
2.8.6.5	Friability and attrition characteristics of granules	Not relevant				☐
(2.8.7)	Emulsion characteristics					
2.8.7.1	Emulsifiability	Not relevant				☐
2.8.7.2	Emulsion stability	Not relevant				☐
2.8.7.3	Re-emulsifiability	Not relevant				☐
2.8.7.4	Stability of dilute emulsions	Not relevant				☐
2.8.7.5	Stability of emulsions	Not relevant				☐
(2.8.8)	Flowability, pourability and dustability					
2.8.8.1	Flowability	Not relevant				☐
2.8.8.2	Pourability (including rinsed residue)	Not relevant				☐
2.8.8.3	Dustability following accelerated storage	Not relevant				☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
2.9	Physical and chemical compatibility with other products					
2.9.1	Physical compatibility of tank mixes	Not relevant				☐
2.9.2	Chemical compatibility of tank mixes	Not relevant				☐
2.10	Distribution and adherence to seeds					
2.10.1	Distribution (seed treatment)	Not relevant				☐
2.10.2	Adhesion (seed treatment)	Not relevant				☐
2.11	Miscibility	No EC data requirement				
2.12	Dielectric breakdown voltage	No EC data requirement				
2.13	Corrosion characteristics	No EC data requirement				
2.14	Container Material	No EC data requirement				
2.15	Other/special studies	Not relevant				☐
2.16	Summary and evaluation of points 2.1 to 2.15 according to the dRR, **see the Ctgb website**	Y	Doc M-IIIA1 Sec 1/02	Y		☐
3	Data on application					
3.1	Fields of use *e.g.* forestry	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.2	Nature of the effects on harmful organisms *e.g.* contact action	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.3	Details of intended uses **See format on the Ctgb website**					
3.3.1	Details of existing and intended uses (crops, groups of crops, plant or plant products treated or protected)	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.3.2	Details of harmful organisms against which protection is afforded	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.3.3	Effects achieved *e.g.* sprout suppression	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.4	Rate of application per unit treated (ha, m^2, m^3, tonne), in terms of g or kg of preparation and active substance	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.5	Concentration of active substance in material used (*e.g.* diluted spray, baits, treated seed) in g/l, g/kg, mg/kg or g/tonne	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.6	Description of the method of application, type of equipment used and type and volume of diluent per unit of area or volume	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.7	Number and timing of applications and duration of protection					
3.7.1	Maximum number of applications and their timing	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.7.2	For each application, growth stages of the crop or plants to be protected	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.7.3	For each application, development stages of the harmful organism concerned	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.7.4	Duration of protection afforded by each application	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.7.5	Duration of protection afforded by the maximum number of applications	Y	Doc M-IIIA1 Sec 1/03	Y		☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
3.8	Necessary waiting periods and other precautions to avoid phytotoxic effects on succeeding crops					
3.8.1	Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.8.2	Limitations on choice of succeeding crops	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.8.3	Description of damage to rotational crops	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.9	Proposed instructions for use as printed, or to be printed, on labels **See format on the Ctgb website**	Y	Doc M-IIIA1 Sec 1/03	Y		☐
3.10	Other/special studies	Y	Doc M-IIIA1 Sec 1/03	Y		☐
4	Further information on the plant protection product					
4.1	Packaging and compatibility with the preparation					
4.1.1	Description and specification of the packaging and materials used in packaging, size, capacity, size of openings, types of closure and seals	Y	KIIIA1 4.1/01	Y		☐
4.1.2	Suitability of the packaging and closures					
4.1.2a	* strength	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.1.2b	* leakproofness	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.1.2c	* resistance to normal transport and handling	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.1.3	Resistance of the packaging material to its contents	Y	Doc M-IIIA1 Sec 1/04 and KIIIA1 4.1.3 /01	Y		☐
4.2	Procedures for cleaning application equipment					
4.2.1	Procedures for cleaning application equipment and protective clothing	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.2.2	Effectiveness of the cleaning procedures	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.3	Re-entry periods, necesarry waiting periods or other precautions to protect man, livestock and the environment					
4.3.1	Pre-harvest interval (in days) for each relevant crop	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.3.2	Re-entry period (in days) for livestock, to areas to be grazed	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.3.3	Re-entry period (in hours or days) for man to crops, buildings or spaces treated	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.3.4	Withholding period (in days) for animal feedingstuffs	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.3.5	Waiting period (in days) between application and handling treated products	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.3.6	Waiting period (in days) between last application and sowing or planting succeeding crops	Y	Doc M-IIIA1 Sec 1/04	Y		☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
4.3.7	Information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.4	Statement of the risks arising and the recommended methods, precautions and handling procedures to minimize those risks, relating to					
4.4.1	Warehouse storage	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.4.2	User level storage	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.4.3	Transport	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.4.4	Fire	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.4.5	Protective clothing and equipment proposed for use in storage, transport or in the event of fire -Nature	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.4.6	Protective clothing and equipment proposed for use in storage, transport or in the event of fire -Characteristics	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.4.7	Sufficient data to evaluate the suitability and effectiveness of the protective clothing and equipment under realistic conditions of use	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.4.8	Procedures to minimize the generation of waste	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.4.9	Information on combustion products likely to be generated in the event of fire	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.5	Detailed procedures for use in the event of an accident during transport, storage or use					
4.5.1	Containment of spillages	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.5.2	Decontamination of areas, vehicles and buildings	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.5.3	Disposal of damaged packaging, adsorbents and other materials	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.5.4	Protection of emergency workers and bystanders	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.5.5	First aid measures	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.6	Neutralization procedures (*e.g.* reaction with alkali to form less toxic compounds) for use in the event of accidental spillages					
4.6.1	Details of proposed procedures for small quantities	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.6.2	Evaluation of products of neutralization (small quantities)	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.6.3	Procedures for disposal of neutralized waste (small quantities)	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.6.4	Details of proposed procedures for large quantities	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.6.5	Evaluation of products of neutralization (large quantities)	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.6.6	Procedures for disposal of neutralized waste (large quantities)	Y	Doc M-IIIA1 Sec 1/04	Y		☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
4.7	Pyrolytic behaviour of the active substance under controlled conditions at 800° C and the content of polyhalogenated dibenzo-p-dioxins in the products of pyrolysis	Y	KIIIA1 4.7/01	Y		☐
4.8	Disposal procedures for the plant protection product					
4.8.1	Detailed instructions for safe disposal of the plant protection product and its packaging	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.8.2	Methods other than controlled incineration for disposal					
4.8.2.a	* detailed description of such methods	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.8.2b	* data to establish their effectiveness and safety	Y	Doc M-IIIA1 Sec 1/04	Y		☐
4.9	Other/special studies	Y	Doc M-IIIA1 Sec 1/04	Y		☐
5	Methods of analysis					
5.1	Analytical standards and samples					
5.1.1	Samples of the preparation	Y	Doc M-IIIA1 Sec 2/01	Y		☐
5.1.2	Analytical standards for pure active substance	Y	Doc M-IIIA1 Sec 2/01	Y		☐
5.1.3	Samples of the active substance as manufactured	Y	Doc M-IIIA1 Sec 2/01	Y		☐
5.1.4	Analytical standards for relevant metabolites and all other components included in the residue definition	Y	Doc M-IIIA1 Sec 2/01	Y		☐
5.1.5	Samples of reference substances for relevant impurities	Not relevant				☐
5.2	Methods for the analysis of plant protection products					
5.2.1	Description of analytical methods for the determination of the active substance in plant protection products For each method submitted:	Y	KIIIA1 5.2.1/01-02	Y		☐
5.2.1a	* specificity	Y	See 5.2.1	Y		☐
5.2.1b	* extent of interference by other substances present in the preparation	Y	See 5.2.1	Y		☐
5.2.1c	* explanation of interferences which contribute more than ± 3 % of the total quantity determined	Y	See 5.2.1	Y		☐
5.2.1.d	Linearity over an appropriate range:					
5.2.1.e	* equation of the calibration line	Y	See 5.2.1	Y		☐
5.2.1.f	* correlation co-efficient	Y	See 5.2.1	Y		☐
5.2.1.g	* representative labelled documentation e.g. chromatograms	Y	See 5.2.1	Y		☐
5.2.1.h	Accuracy:					
5.2.1.i	* pure active substance	Y	See 5.2.1	Y		☐
5.2.1.j	* impurities					☐
5.2.1.k	Repeatability (at least 5 determinations):					
5.2.1.l	* % relative standard deviation (RSD)	Y	See 5.2.1	Y		☐
5.2.1.m	* indication as to whether outliers identified have been discarded	Y	See 5.2.1	Y		☐
5.2.1.n	* reasons for the occurrence of outliers	Y	See 5.2.1	Y		☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
5.2.2	For preparations containing more than one active substance, a description of a method capable of determining each in the presence of the other For each method submitted:	Y	Doc M-IIIA1 Sec 2/01	Y		☐
5.2.2a	* specificity	Y	See 5.2.2	Y		☐
5.2.2b	* extent of interference by other substances present in the preparation	Y	See 5.2.2	Y		☐
5.2.2c	* explanation of interferences which contribute more than ± 3 % of the total quantity determined	Y	See 5.2.2	Y		☐
5.2.2d	Linearity over an appropriate range:					
5.2.2.e	* equation of the calibration line	Y	See 5.2.2	Y		☐
5.2.2.f	* correlation co-efficient	Y	See 5.2.2	Y		☐
5.2.2.g	* representative labelled documentation e.g. chromatograms	Y	See 5.2.2	Y		☐
5.2.2.h	Accuracy:					
5.2.2.i	* pure active substance	Y	See 5.2.2	Y		☐
5.2.2.j	* impurities	Y	See 5.2.2	Y		☐
5.2.2.k	Repeatability (at least 5 determinations):					
5.2.2.l	* % relative standard deviation (RSD)	Y	See 5.2.2	Y		☐
5.2.2.m	* indication as to whether outliers identified have been discarded	Y	See 5.2.2	Y		☐
5.2.2.n	* reasons for the occurrence of outliers	Y	See 5.2.2	Y		☐
5.2.3	Applicability of existing CIPAC methods	Y	Doc M-IIIA1 Sec 2/01	Y		☐
5.2.4	Description of analytical methods for the determination of impurities (non-active components arising from the manufacturing process or from degradation during storage) which are of toxicological, ecotoxicological or environmental concern, in the preparation For each method submitted:	Y	Doc M-IIIA1 Sec 2/01	Y		☐
5.2.4a	* specificity	Y	See 5.2.4	Y		☐
5.2.4b	* extent of interference by other substances present in the preparation	Y	See 5.2.4	Y		☐
5.2.4c	* explanation of interferences which contribute more than ± 3 % of the total quantity determined	Y	See 5.2.4	Y		☐
5.2.4d	Linearity over an appropriate range:					
5.2.4.e	* equation of the calibration line	Y	See 5.2.4	Y		☐
5.2.4.f	* correlation co-efficient	Y	See 5.2.4	Y		☐
5.2.4.g	* representative labelled documentation e.g. chromatograms	Y	See 5.2.4	Y		☐
5.2.4.h	Accuracy:					
5.2.4.i	* pure active substance	Y	See 5.2.4	Y		☐
5.2.4.j	* impurities	Y	See 5.2.4	Y		☐
5.2.4.k	Repeatability (at least 5 determinations):					
5.2.4.l	* % relative standard deviation (RSD)	Y	See 5.2.4	Y		☐
5.2.4.m	* indication as to whether outliers identified have been discarded	Y	See 5.2.4	Y		☐
5.2.4.n	* reasons for the occurrence of outliers	Y	See 5.2.4	Y		☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
5.2.5	Description of analytical methods for the determination of formulants or constituents of formulants in the plant protection product For each method submitted:	Y	Doc M-IIIA1 Sec 2/01	Y		☐
5.2.5a	* specificity	Y	See 5.2.5	Y		☐
5.2.5b	* extent of interference by other substances present in the preparation	Y	See 5.2.5	Y		☐
5.2.5c	* explanation of interferences which contribute more than ± 3 % of the total quantity determined	Y	See 5.2.5	Y		☐
5.2.5.d	Linearity over an appropriate range:					
5.2.5.e	* equation of the calibration line	Y	See 5.2.5	Y		☐
5.2.5.f	* correlation co-efficient	Y	See 5.2.5	Y		☐
5.2.5.g	* representative labelled documentation e.g. chromatograms	Y	See 5.2.5	Y		☐
5.2.5.h	Accuracy:					
5.2.5.i	* pure active substance	Y	See 5.2.5	Y		☐
5.2.5.j	* impurities	Y	See 5.2.5	Y		☐
5.2.5.k	Repeatability (at least 5 determinations):					
5.2.5.l	* % relative standard deviation (RSD)	Y	See 5.2.5	Y		☐
5.2.5.m	* indication as to whether outliers identified have been discarded	Y	See 5.2.5	Y		☐
5.2.5.n	* reasons for the occurrence of outliers	Y	See 5.2.5	Y		☐
5.3	Description of analytical methods for the determination of residues (all components included in the residue definition proposed (see point IIIA 8) to enable compliance with MRLs to be determined or to determine dislodgeable residues)	Y	Refer to Annex II : KIIA 4.3 and KIIA 6.1.2	Y		☐
	For each method and representative matrix:	Y	See 5.3	Y		
5.3.a	* specificity (using a confirmatory method, if appropriate)	Y	See 5.3	Y		☐
5.3.b	* repeatability	Y	See 5.3	Y		☐
5.3.c	* validation - independent laboratory	Y	See 5.3	Y		☐
5.3.d	* limit of determination	Y	See 5.3	Y		☐
5.3.e	* individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level	Y	See 5.3	Y		☐
5.3.f	Storage stability of working solutions in analytical methodology	No EC data requirement				
5.4	Description of methods for analysis of soil for parent compound and metabolites of toxicological, ecotoxicological or environmental concern	Y	Refer to Annex II: KIIA 4.4	Y		☐
	For each method:	Y	See 5.4	Y		
5.4.a	* specificity (using a confirmatory method, if appropriate)	Y	See 5.4	Y		☐
5.4.b	* repeatability	Y	See 5.4	Y		☐
5.4.c	* limit of determination	Y	See 5.4	Y		☐
5.4.d	* individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level	Y	See 5.4	Y		☐
5.5	Description of methods for analysis of sediment	No EC data requirement – Refer to Annex II: KIIA 4.6				

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
	For each method:					
5.5.a	* specificity (using a confirmatory method, if appropriate)	No EC data requirement				
5.5.b	* repeatability	No EC data requirement				
5.5.c	* limit of determination	No EC data requirement				
5.5.d	* individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level	No EC data requirement				
5.6	Description of methods for analysis of water (drinking water, ground water and surface water) for parent compound and metabolites of toxicological, ecotoxicological or environmental concern	Y	Refer to Annex II: KIIA 4.5	Y		☐
	For each method:	Y	See 5.6	Y		
5.6.a	* specificity (using a confirmatory method, if appropriate)	Y	See 5.6	Y		☐
5.6.b	* repeatability	Y	See 5.6	Y		☐
5.6.c	* limit of determination	Y	See 5.6	Y		☐
5.6.d	* individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level	Y	See 5.6	Y		☐
5.7	Description of methods for analysis of air for active substance and metabolites, formed during or shortly after application, of toxicological concern	Y	Refer to Annex II: KIIA 4.7	Y		☐
	For each method:	Y	See 5.7	Y		☐
5.7.a	* specificity (using a confirmatory method, if appropriate)	Y	See 5.7	Y		☐
5.7.b	* repeatability	Y	See 5.7	Y		☐
5.7.c	* limit of determination	Y	See 5.7	Y		☐
5.7.d	* individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level	Y	See 5.7	Y		☐
5.8	Analytical methods for parent compound and toxicologically, ecotoxicologically or environmentally significant metabolites in body fluids and tissues	Y	Refer to Annex II: KIIA 4.8	Y		☐
	For each method:	Y	See 5.8	Y		☐
5.8.a	* specificity (using a confirmatory method, if necessary)	Y	See 5.8	Y		☐
5.8.b	* repeatability	Y	See 5.8	Y		☐
5.8.c	* limit of determination	Y	See 5.8	Y		☐
5.8.d	* individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level	Y	See 5.8	Y		☐
5.9	Other/special studies	Y	Refer to Annex II: KIIA 4.9	Y		☐
6	Efficacy data	Y	Doc M-IIIA1 Sec 7/01	Y		☐
7	Toxicological studies and exposure data and information					
7.1	Acute toxicity					
7.1.1	Acute oral toxicity	Y	KIIIA1 7.1.1/01	Y		☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
7.1.2	Acute percutaneous (dermal) toxicity	Y	KIIIA1 7.1.2/01	Y		☐
7.1.3	Acute inhalation toxicity to rats	Y	KIIIA1 7.1.3/01	Y		☐
7.1.4	Skin irritation	Y	KIIIA1 7.1.4/01	Y		☐
7.1.5	Eye irritation	Y	KIIIA1 7.1.5/01	Y		☐
7.1.6	Skin sensitization	Y	KIIIA1 7.1.6/01	Y		☐
7.1.7	Supplementary studies for combinations of plant protection products	Not relevant				☐
7.2	Short-term toxicity studies	No EC data requirement				
7.3	Operator exposure					
7.3.1	Estimation of operator exposure assuming personal protective equipment is not used	Y	KIIIA1 7.3.1/01 Doc M-IIIA1 Sec 3/01	Y		☐
7.3.2	Estimation of operator exposure assuming personal protective equipment is used	Y	See 7.3.1	Y		☐
7.3.3	Measurement of operator exposure – (Mixer/Loader/Applicator)	Y	Doc M-IIIA1 Sec 3/01	Y		☐
7.4	Bystander exposure					
7.4.1	Estimation of bystander exposure assuming personal protective equipment is not used	Y	Doc M-IIIA1 Sec 3/01	Y		☐
7.4.2	Measurement of bystander exposure	Y	Doc M-IIIA1 Sec 3/01	Y		☐
7.5	Worker exposure					
7.5.1	Estimation of worker exposure assuming personal protective equipment is not used	Y	Doc M-IIIA1 Sec 3/01	Y		☐
7.5.2	Estimation of worker exposure assuming personal protective equipment is used	Y	Doc M-IIIA1 Sec 3/01	Y		☐
7.5.3	Estimation of worker exposure assuming personal protective equipment is used and using data generated on dislodgeable residues under the proposed conditions of use	Not relevant				☐
7.5.4	Measurement of worker exposure	Not relevant				☐
7.6	Dermal absorption					
7.6.1	Dermal absorption, *in vivo* in the rat	Y	KIIIA1 7.6.1/01	Y		☐
7.6.2	Comparative dermal absorption, *in vitro* using rat and human skin	Y	KIIIA1 7.6.2/01	Y		☐
7.7	Dislogeable residues	No EC data requirement				
7.7.1	Dislogeable residues - foliar	No EC data requirement Y KIIIA1 7.7.1/01-03				
7.7.2	Dislogeable residues - soil	No EC data requirement				
7.7.3	Dislogeable residues indoor surface re-volatilization	No EC data requirement				
7.8	Epidemiology	No EC data requirement				
7.9	Data on formulants					
7.9.1	Material safety data sheet for each formulant	Y	Annex II Doc H	N		☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
7.9.2	Available toxicological data for each formulant	Y	Annex II Doc H	N		☐
7.10	Domestic animal/livestock safety	No EC data requirement				
7.11	Other/special studies	Not relevant				☐
8	Metabolism and residues data	**For Metabolism and Residue data See Annex II dossier – Section 4/01 (Section 4, Point 6)**				
8.1	Stability of residues					
8.1.1	Stability of residues during storage of samples					☐
8.1.2	Stability of residues in sample extracts					☐
8.2	Supplementary studies on metabolism, distribution and expression of residues in plants or livestock					☐
8.3	Supplementary residue trials (supervised field trials) for crops or plant products used as food or feed on which use is proposed – if it is not possible to extrapolate from the data provided in the context of point IIA 6.3, *e.g.* special formulations, different application methods, additional crops					
8.3.1	Pre-harvest use on major crops					☐
8.3.2	Pre-harvest use on minor crops					☐
8.3.3	Post-harvest uses					☐
8.3.4	Tobacco					☐
8.4	Supplementary livestock feeding studies - if it is not possible to extrapolate from the data provided in the context of point IIA 6.4, *e.g.* use on additional fodder crops is proposed, leading to an increased intake of residues by livestock					
8.4.1	Poultry					☐
8.4.2	Lactating ruminants (goat or cow)					☐
8.4.3	Pigs					☐
8.4.4	Nature of residue in fish	No EC data requirement				
8.5	Supplementary studies on the effects of industrial processing and/or household preparation on residue levels - if it is not possible to extrapolate from the data provided in the context of point IIA 6.5, *e.g.* additional crops					
8.5.1	Effects of industrial processing and/or household preparation (representative processing situations) on the nature of the residue					☐
8.5.2	Distribution of the residue in peel/pulp					☐
8.5.3	Balance studies on a core set of representative processes					☐
8.5.4	Follow-up studies to determine concentration or dilution factors					☐
8.5.4.a	Potable water	No EC data requirement				
8.5.4.b	Irrigated crops	No EC data requirement				

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
8.6	Supplementary studies for residues in representative succeeding crops					☐
8.7	Proposed residue definition and maximum residue levels					☐
8.7.1	Proposed residue definition					☐
8.7.2	Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed, including details of statistical analyses used. If new MRLs are proposed, applicant also has send in 'Application form MRL'					☐
8.8	Proposed pre-harvest intervals, re-entry intervals or withholding periods to minimize residues in crops, plants, plant products, treated areas or spaces and a justification for each proposal					
8.8.1	Pre-harvest interval (in days) for each relevant crop					☐
8.8.2	Re-entry period (in days) for livestock, to areas to be grazed					☐
8.8.3	Re-entry period (in hours or days) for man to crops, buildings or spaces treated					☐
8.8.4	Withholding period (in days) for animal feeding stuffs					☐
8.8.5	Waiting period (in days) between last application and sowing or planting the crop to be protected					☐
8.8.6	Waiting period (in days) between application and handling treated products					☐
8.8.7	Waiting period (in days) between last application and sowing or planting succeeding crops					☐
8.9	Other/special studies					☐
8.10	Estimation of the potential and actual exposure through diet and other means					
8.10.1	TMDI calculations					☐
8.10.2	NEDI calculations					☐
8.10.3	NESTI calculations					☐
8.11	Summary and evaluation of residue behaviour according to the dRR, **see the Ctgb website**					☐
9	Fate and behaviour in the environment					
9.1	Rate of degradation in soil - if it is not possible to extrapolate from the data provided for the active substance and relevant metabolites, degradation and reaction products (*e.g.* slow release formulations)					
9.1.1	Aerobic degradation of the preparation in soil	Y	Doc M-IIIA1 Sec 5/01	Y		☐
9.1.2	Anaerobic degradation of the preparation in soil	Y	Doc M-IIIA1 Sec 5/01	Y		☐
9.2	Field studies					
9.2.1	Soil dissipation testing on a range of representative soils (for NL: minimum 4 types of soil)	Y	Doc M-IIIA1 Sec 5/01	Y		☐
9.2.2	Soil residue testing	Not relevant				☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
9.2.3	Soil accumulation testing	Y	Doc M-IIIA1 Sec 5/01	Y		☐
9.2.4	Aquatic (sediment) field dissipation	No EC data requirement				
9.2.5	Forestry field dissipation	No EC data requirement				
9.3	Mobility of the plant protection product in soil					
9.3.1	Column leaching	Not relevant				☐
9.3.2	Lysimeter studies	Not relevant				☐
9.3.3	Field leaching studies	Not relevant				☐
9.3.4	Volatility – laboratory study	Not relevant				☐
9.3.5	Volatility – field study	Not relevant				☐
9.4	Predicted environmental concentrations in soil (PEC_s) for the active substance at the highest rate of application proposed and relating to the maximum number and highest rates of application proposed, for each relevant soil tested					
9.4.1	Initial PEC_s value	Y	KIIIA1 9.4/01	Y		☐
9.4.2	Short-term PEC_s values – 24 hours, 2 days and 4 days after last application	Y	KIIIA1 9.4/01	Y		☐
9.4.3	Long-term PEC_s values - 7, 28, 50 and 100 days after last application	Y	KIIIA1 9.4/01	Y		☐
9.5	Predicted environmental concentrations in soil (PEC_s) for relevant metabolites, degradation and reaction products, at the highest rate of application proposed and relating to the maximum number and highest rates of application proposed, for each relevant soil tested	Y	KIIIA1 9.5/01	Y		☐
9.5.1	Initial PEC_s value	Y	KIIIA1 9.5/01	Y		☐
9.5.2	Short-term PEC_s values – 24 hours, 2 days and 4 days after last application	Y	KIIIA1 9.5/01	Y		☐
9.5.3	Long-term PEC_s values - 7, 28, 50 and 100 days after last application	Y	KIIIA1 9.5/01	Y		☐
9.6	Predicted environmental concentrations in ground water (PEC_{gw}) at the highest rate of application proposed and relating to the maximum number and highest rates of application proposed					
9.6.1	Active substance PEC_{gw} value	Y	KIIIA1 9.6.1/01-06	Y		☐
9.6.2	Relevant metabolites, degradation and reaction products PEC_{gw} values	Y	KIIIA1 9.6.2/01-06	Y		☐
9.6.3	Additional field testing	Not relevant				☐
9.6.4	Information on impact on water treatment procedures	Y	Doc M-IIIA1 Sec 5/01	Y		☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
9.7	Predicted environmental concentrations in surface water (PEC_{sw}) for the active substance at the highest rate of application proposed and relating to the maximum number and highest rates of application proposed, relevant to lakes, ponds, rivers, canals, streams, irrigation/drainage canals and drains					
9.7.1	Initial PEC_{sw} value for static water bodies	Y	KIIIA1 9.7/01	Y		n.a.
9.7.2	Initial PEC_{sw} value for slow moving water bodies	Y	KIIIA1 9.7/01	Y		n.a.
9.7.3	Short-term PEC_{sw} values for static water bodies - 24 hours, 2 days and 4 days after last application	Y	KIIIA1 9.7/01	Y		n.a.
9.7.4	Short-term PEC_{sw} values for slow moving water bodies - 24 hours, 2 days and 4 days after last application	Y	KIIIA1 9.7/01	Y		n.a.
9.7.5	Long-term PEC_{sw} values for static water bodies - 7, 14, 21, 28, 42 days after last application	Y	KIIIA1 9.7/01	Y		n.a.
9.7.6	Long-term PEC_{sw} values for slow moving water bodies - 7, 14, 21, 28, 42 days after last application	Y	KIIIA1 9.7/01	Y		n.a.
9.8	Predicted environmental concentrations in surface water (PEC_{sw}) for relevant metabolites, degradation and reaction products at the highest rate of application proposed and relating to the maximum number and highest rates of application proposed, relevant to lakes, ponds, rivers, canals, streams, irrigation/drainage canals and drains					
9.8.1	Initial PEC_{sw} value for static water bodies	Y	KIIIA1 9.8/01	Y		n.a.
9.8.2	Initial PEC_{sw} value for slow moving water bodies	Y	KIIIA1 9.8/01	Y		n.a.
9.8.3	Short-term PEC_{sw} values for static water bodies - 24 hours, 2 days and 4 days after last application	Y	KIIIA1 9.8/01	Y		n.a.
9.8.4	Short-term PEC_{sw} values for slow moving water bodies - 24 hours, 2 days and 4 days after last application	Y	KIIIA1 9.8/01	Y		n.a.
9.8.5	Long-term PEC_{sw} values for static water bodies - 7, 14, 21, 28, 42 days after last application	Y	KIIIA1 9.8/01	Y		n.a.
9.8.6	Long-term PEC_{sw} values for slow moving water bodies - 7, 14, 21, 28, 42 days after last application	Y	KIIIA1 9.8/01	Y		n.a.
9.8.7	Additional field testing	Y	KIIIA1 9.8/01	Y		☐
9.9	Fate and behaviour in air	Y	Doc M-IIIA1 Sec 5/01	Y		☐
9.9.1	Spray droplet size spectrum – laboratory studies	No EC data requirement				
9.9.2	Drift – field evaluation	No EC data requirement				

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
9.10	Other/special studies					
9.10.1	Other/special studies – laboratory studies	Not relevant				☐
9.10.2	Other/special studies – field studies	Not relevant				☐
10	Ecotoxicological studies on the plant protection product					
10.1	Effects on birds					
10.1.1	Acute toxicity exposure ratio (TER_A) for birds	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.1.2a	Short-term toxicity exposure ratio (TER_{ST}) for birds	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.1.2b	Long-term toxicity exposure ratio (TERlt)	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.1.3	In the case of baits, the concentration of active substance in the bait in mg/kg		Not relevant			
10.1.4	In the case of pellets, granules, prills or treated seed					
10.1.4.1	Amount of the active substance in or on each pellet, granule, prill or treated seed	Not relevant				☐
10.1.4.2	Proportion of the LD_{50} for the active substance in 100 particles and per gram of particles	Not relevant				☐
10.1.5	In the case of pellets, granules, and prills, their size and shape	Not relevant				☐
10.1.6	Acute oral toxicity of the preparation to the more sensitive of the species identified in tests with the active substance	Y	KIIIA1 10.1.6/01-02	Y		☐
10.1.7	Supervised cage or field trials	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.1.8	Acceptance of bait, granules or treated seeds by birds (palatability test)	Not relevant				☐
10.1.9	Effects of secondary poisoning	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2	Effects on aquatic organisms	Y	Doc M-IIIA1 Sec 6/01	Y		
10.2.1	Toxicity exposure ratios for aquatic species	Y	Doc M-IIIA1 Sec 6/01	Y		
10.2.1.1	* TER_A for fish	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.1.2	* TER_{LT} for fish	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.1.3	* TER_A for *Daphnia*	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.1.4	* TER_{LT} for *Daphnia*	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.1.5	* TER_A for an aquatic insect species	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.1.6	* TER_{LT} for an aquatic insect species	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.1.7	* TER_A for an aquatic crustacean species	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.1.8	* TER_{LT} for an aquatic crustacean species	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.1.9	* TER_A for an aquatic gastropod mollusc species	Y	Doc M-IIIA1 Sec 6/01	Y		☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
10.2.1.10	* TER_{LT} for an aquatic gastropod mollusc species	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.1.11	* TER_{LT} for algae	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.2	Acute toxicity (aquatic) of the preparation	Y	Doc M-IIIA1 Sec 6/01	Y		
10.2.2.1	Fish acute toxicity LC_{50}	Y	KIIIA1 10.2.2.1/ 01-02	Y		☐
10.2.2.2	Acute toxicity (24 & 48 h) for *Daphnia* preferably *Daphnia magna*	Y	KIIIA1 10.2.2.2/ 01	Y		☐
10.2.2.3	Effects on algal growth and growth rate	Y	KIIIA1 10.2.2.3/ 01	Y		☐
10.2.2.4	Marine or estuarine organisms acute toxicity LC_{50}/EC_{50}	No EC data requirement – Y Doc M-IIIA1 Sec 6/01				
10.2.2.5	Marine sediment invertebrates, acute toxicity LC_{50}/EC_{50}	No EC data requirement Y Doc M-IIIA1 Sec 6/01				
10.2.3	Microcosm or mesocosm study	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.4	Residue data in fish (long-term)	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.5	Chronic fish toxicity data					
10.2.5.1a	Chronic toxicity (28 day exposure) to juvenile fish	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.5.1b	Analytical data on concentrations in the test media	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.5.2a	Fish early life stage toxicity test	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.5.2b	Analytical data on concentrations in the test media	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.5.3a	Fish life cycle test	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.5.3b	Analytical data on concentrations in the test media	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.6	Chronic toxicity to aquatic invertebrates					
10.2.6.1a	Chronic toxicity in *Daphnia magna* (21-day)	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.6.1b	Analytical data on concentrations in the test media	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.6.2a	Chronic toxicity for a representative species of aquatic insects	Y	KIIIA1 10.2.6.2/ 01	Y		☐
10.2.6.2b	Analytical data on concentrations in the test media	Y	KIIIA1 10.2.6.2/ 01	Y		☐
10.2.6.3a	Chronic toxicity for a representative species of aquatic gastropod molluscs	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.6.3b	Analytical data on concentrations in the test media	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.2.7	Accumulation in aquatic non-target organisms	No EC data requirement – Y Doc M-IIIA1 Sec 6/01				
10.2.7.a	Accumulation in aquatic non-target organisms	No EC data requirement				
10.2.7.b	Analytical data on concentrations in the test media	No EC data requirement				

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
10.3	Effects on terrestrial vertebrates other than birds					
10.3.1	Toxicity exposure ratios for terrestrial vertebrates other than birds					
10.3.1.1	Acute toxicity exposure ratio (TER_A)	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.3.1.2	Short-term toxicity exposure ratio (TER_{ST})	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.3.1.3	Long-term toxicity exposure ratio (TER_{LT})	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.3.2	Effects to terrestrial vertebrates other than birds, where the required information is not provided by testing in accordance with points 5 and IIIA 7, and where exposure is likely	Y	Doc M-IIIA1 Sec 6/01	Y		
10.3.2.1	Acute oral toxicity of the preparation	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.3.2.2	Acceptance of bait, granules or treated seeds by terrestrial vertebrates (palatability test)	Not relevant				☐
10.3.2.3	Effects of secondary poisoning	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.3.3	Supervised cage or field trials or other appropriate studies	Y	KIIIA1 10.3.3/01-04	Y		☐
10.4	Effects on bees	Y	Doc M-IIIA1 Sec 6/01	Y		
10.4.1	Hazard Quotients for bees	Y	Doc M-IIIA1 Sec 6/01	Y		
10.4.1.1	Oral exposure Q_{HO}	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.4.1.2	Contact exposure Q_{HC}	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.4.2	Acute toxicity of the preparation to bees	Y	Doc M-IIIA1 Sec 6/01	Y		
10.4.2.1	Acute oral toxicity	Y	KIIIA1 10.4.2.1/ 01	Y		☐
10.4.2.2	Acute contact toxicity	Y	See 10.4.2.1/ 01	Y		☐
10.4.3	Effects on bees of residues on crops	Y	KIIIA1 10.4.3/ 01	Y		☐
10.4.4	Cage tests	Y	See point 10.4.7	Y		☐
10.4.5	Field tests	Not relevant				☐
10.4.6	Investigation of special effects	Y	Doc M-IIIA1 Sec 6/01	Y		
10.4.6.1	Larval toxicity	Y	KIIIA1 10.4.6.1/ 01	Y		☐
10.4.6.2	Long residual effects	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.4.6.3	Disorienting effects on bees	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.4.7	Tunnel testing to investigate effects of feeding on contaminated honey dew or flowers	Y	KIIIA1 10.4.7/ 01-06	Y		☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
10.5	Effects on arthropods other than bees	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.5.1.	Effects on sensitive species already tested, using artificial substrates (effects on non-target terrestrial arthropods in laboratory tests)	Y	KIIIA1 10.5.1/01-02	Y		☐
10.5.2	Effects on non-target terrestrial arthropods in extended laboratory tests	Y	KIIIA1 10.5.2/01-04	Y		☐
10.5.3	Effects on non-target terrestrial arthropods in semi-field tests	Y	KIIIA1 10.5.3/01-02	Y		☐
10.5.4	Field tests on arthropod species	Y	KIIIA1 10.5.4/01-02	Y		☐
10.6	Effects on earthworms and other soil macro-organisms					
10.6.1	Toxicity exposure ratios for earthworms, TER_A and TER_{LT}	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.6.2	Acute toxicity to earthworms	Y	KIIIA1 10.6.2/01	Y		☐
10.6.3	Sublethal effects on earthworms	Y	KIIIA1 10.6.3/01	Y		☐
10.6.4	Field tests (effects on earthworms)	Y	KIIIA1 10.6.4/01	Y		☐
10.6.5	Residue content of earthworms	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.6.6	Effects on other soil non-target macro-organisms	Y	KIIIA1 10.6.6/01-02	Y		☐
10.6.7	Effect on organic matter breakdown	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.7	Effects on soil microbial activity					
10.7.1	Laboratory test to investigate impact on soil microbial activity	Y	KIIIA1 10.7.1/01-02	Y		☐
10.7.2	Further laboratory, glasshouse of field testing to investigate impact on soil microbial activity	Not relevant				☐
10.8	Effects on non-target plants					
10.8.1	Effects on non-target terrestrial plants					
10.8.1.1	Seed germination	Y	See 10.8.1.3/01	Y		☐
10.8.1.2	Vegetative vigour	Y	KIIIA1 10.8.1.2/01	Y		☐
10.8.1.3	Seedling emergence	Y	KIIIA1 10.8.1.3/01	Y		☐
10.8.1.4	Terrestrial field testing	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.8.2	Effects on non-target aquatic plants	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.8.2.1	Aquatic plant growth – *Lemna*	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.8.2.2	Aquatic field testing	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.9	Available preliminary data					
10.9.1	Summary of available data from preliminary tests used to assess biological activity and dose range finding, which may provide information on other non-target species (flora and fauna)	Y	Doc M-IIIA1 Sec 6/01	Y		☐

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
10.9.2	A critical assessment as to the relevance of the preliminary test data to potential impact on non-target species	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.10	Other/special studies (for instance for deriving a MPC-soil)					
10.10.1	Other/special studies – laboratory studies	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.10.2	Other/special studies – field studies	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.11	Summary and evaluation of points IIIA 9 and IIIA 10.1 to 10.10, together with a detailed and critical assessment of the data, according to the dRR, **see the Ctgb website**	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.11.1	Predicted distribution and fate in the environment and the time courses involved	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.11.2	Non-target species at risk and extent of potential exposure	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.11.3	Short and long term risks for non-target species, populations, communities and processes	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.11.4	Risk of fish kills and fatalities in large vertebrates or terrestrial predators	Y	Doc M-IIIA1 Sec 6/01	Y		☐
10.11.5	Precautions necessary to avoid or minimize contamination of the environment and for the protection of non-target species	Y	Doc M-IIIA1 Sec 6/01	Y		☐
(11)	Further information					
(11.1)	Information on authorisations in other countries (see Initial Evaluation Form 1 - document D-2)	Y	Doc M-IIIA1 Sec 1/05	Y		☐
(11.2)	Information on established MRLs in other countries (see Initial Evaluation Form 1 - documents E-1 and E-2)	Y	Doc M-IIIA1 Sec 1/05	Y		☐
(11.3)	Justified proposals for the classification and labelling of the preparation according to Directive 67/548/EEC and Directive 1999/45/EC	Y	Doc M-IIIA1 Sec 1/05 and KIIIA1 10.3/01	Y		
(11.3.a)	Hazard symbol(s)	Y	See 11.3	Y		☐
(11.3.b)	Indications of danger	Y	See 11.3	Y		☐
(11.3.c)	Risk phrases	Y	See 11.3	Y		☐
(11.3.d)	Safety phrases	Y	See 11.3	Y		☐
(11.4)	Proposals for risk and safety phrases in accordance with Article 15 (1), (g) and (h)	Y	KIIIA1 11.4/01	Y		☐
(11.5)	Proposed label (see Initial Evaluation Form 1 - document C)	Y	Doc M-IIIA1 Sec 1/05	Y		☐
(11.6)	Specimens of proposed packaging	Y	Doc M-IIIA1 Sec 1/05	Y		☐

Naam middel: Sivanto (Flupyradifurone) SL 200

DOCUMENT Ctgb - Part 1

Efficacy data preparation

Explaining notes	
Information test or study provided	Three answers (yes, no, not relevant) are possible. In case "no" is filled in, the application is incomplete and will not be managed
Not relevant	This means - that data and information is not necessary owing to the nature of the substance, product or its supported uses; or - the data is not scientifically necessary or technically possible to supply information and/or data
Justification provided	If Y (yes) the location in the dossier has to be mentioned
Summary provided	If a summary is submitted, fill in Y (= yes). Otherwise fill in N (= no)
Reference list	The data that was submitted or has been provided for in an earlier application and which must be available at the Ctgb must be indicated. The location on the reference list must be given by filling in the Annex-Point.
Data gap	This column is for Ctgb-use only. Do not fill in.
OECD Annex point in brackets	Proposed new OECD point. Until further notice this item needs not to be submitted.
No EC data requirement	The OECD point concerned is no data requirement according to Council Directive 91/414/EEC. The data is therefor not required in the Netherlands.

Part Ctgb-1 **Evaluation Form Ctgb-1 -**
for checking that all test and study reports required in accordance with Annex IIIA 6 have been provided, for applications for approval of active substances

Active Substance: Flupyradifurone Preparation: Sivanto SL 200
Applicant: Bayer CropScience Date: April 2012

OECD Annex AIIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary porvided	Reference list	*Data gap*
6	Efficacy data					
6.1	Efficacy data					
6.1.1	Preliminary range-finding tests	Y	KIIIA1 6.1.1/01-12	Y		☐
6.1.2	Minimum effective dose tests	Y	KIIIA1 6.1.2/01-02	Y		☐
6.1.3	Efficacy tests	Y	Doc M-IIIA1 Sec 7/01	Y		☐
6.1.4	Effects on yield and quality					
6.1.4.1	Impact on the quality of plants and plant products	Y	Doc M-IIIA1 Sec 7/01	Y		☐
6.1.4.2	Effects on the processing procedure	Y	Doc M-IIIA1 Sec 7/01	Y		☐
6.1.4.3	Effects on the yield of treated plants and plant products	Y	Doc M-IIIA1 Sec 7/01	Y		☐
6.2	Adverse effects					
6.2.1	Phytotoxicity to host crop	Y	Doc M-IIIA1 Sec 7/01	Y		☐
6.2.2	Adverse effect on site on health of host animals	No EC data requirement				
6.2.3	Adverse effects on site of application (discoloration, corrosion etc.)	No EC data requirement				
6.2.4	Adverse effects on beneficial organisms	Y	Doc M-IIIA1 Sec 7/01	Y		☐
6.2.5	Adverse effects on parts of plants used for propagating purposes (e.g. seeds, cuttings, runners)	Y	Doc M-IIIA1 Sec 7/01	Y		☐
6.2.6	Impact on succeeding crops	Y	Doc M-IIIA1 Sec 7/01	Y		☐
6.2.7	Impact on other plants including adjacent crops	Y	Doc M-IIIA1 Sec 7/01	Y		☐
6.2.8	Information on the possible occurrence of the development of resistance or crop-resistance	Y	Doc M-IIIA1 Sec 7/01	Y		☐
6.3	Economics	No EC data requirement				
6.4	Benefits	No EC data requirement				
6.4.1	Survey of alternative pest control measures (chemical and non chemical)	No EC data requirement				

OECD Annex AIIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary porvided	Reference list	*Data gap*
6.4.2	Compability with current management practices including IPM	No EC data requirement				
6.4.3	Contribution to risk reduction	No EC data requirement				
6.5	Other/special studies	Not relevant				☐
6.6	Summary and assessment of data according to points 6.1 to 6.5, according to the dRR, **see the Ctgb website**	Y	Doc M-IIIA1 Sec 7/01	Y		☐
6.7	List of test facilities including the corresponding certificates	Y	Doc M-IIIA1 Sec 7/01	Y		☐

Naam middel:Sivanto (Flupyradifurone) SL 200

DOCUMENT Ctgb - Part 2

Data preparation for Dutch addendum

Explaining notes	
Information test or study provided	Three answers (yes, no, not relevant) are possible. In case "no" is filled in, the application is incomplete and will not be managed
Not relevant	This means - that data and information is not necessary owing to the nature of the substance, product or its supported uses; or - the data is not scientifically necessary or technically possible to supply information and/or data
Justification provided	If Y (yes) the location in the dossier has to be mentioned
Summary provided	If a summary is submitted, fill in Y (= yes). Otherwise fill in N (= no)
Reference list	The data that was submitted or has been provided for in an earlier application and which must be available at the Ctgb must be indicated. The location on the reference list must be given by filling in the Annex-Point.
Data gap	This column is for Ctgb-use only. Do not fill in.
OECD Annex point in brackets	Proposed new OECD point. Until further notice this item needs not to be submitted.
No EC data requirement	The OECD point concerned is no data requirement according to Council Directive 91/414/EEC. The data is therefor not required in the Netherlands.

Part Ctgb-2 **Evaluation Form Ctgb-2 -**
for checking that all test and study reports required for evaluation of the Dutch specific aspects in the national addendum have been provided

Active Substance: Flupyradifurone Preparation: Sivanto SL 200
Applicant: Bayer CropScience Date: April 2012

This is an application for a new active substance. Therefore this form is not applicable and has been left blank.

8. Metabolism and residues data *

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
8.6	Supplementary studies for residues in representative succeeding crops					
8.11	Summary and evaluation of residue behaviour					

*Only relevant when residues in succeeding crops are not taken into account in MRL setting, see explanation.

9. Fate and behaviour

OECD Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
9.3.2	Lysimeter studies with standardisation to Dutch specific circumstances					☐
9.3.3	Field leaching studies with standardisation to Dutch specific circumstances					☐

Groundwater

9.6	Predicted environmental concentrations in ground water (PEC_{gw}) at the highest rate of application proposed and relating to the maximum number and highest rates of application proposed

Sediment/surface water

9.7	Predicted environmental concentrations in surface/sediment water ($PEC_{SW/SED\ Edge\ of\ field}$ and $PEC_{SW/Drinking\ water\ abstraction\ points}$) for the active substance at the highest rate of application proposed and relating to the maximum number and highest rates of application proposed

9.8	Predicted environmental concentrations in surface/sediment water ($PEC_{SW/SED\ Edge\ of\ field}$ and $PEC_{SW/Drinking\ water\ abstraction\ points}$) for relevant metabolites, degradation and reaction products at the highest rate of application proposed and relating to the maximum number and highest rates of application proposed
9.10	Other/special studies

10. Ecotoxicology

OECD Annex IIIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Summary provided	Reference list	*Data gap*
10.1	Effects on birds					
10.1.1	Acute toxicity exposure ratio (TER_A) for birds, via exposure of surface water					☐
10.1.9	Effects of secondary poisoning, via exposure of surface water					☐
10.2	Effects on aquatic organisms					☐
10.2.1	Toxicity exposure ratios for aquatic species					☐
10.2.1.1	* TER_A for fish					☐
10.2.1.2	* TER_{LT} for fish					☐
10.2.1.3	* TER_A for *Daphnia*					☐
10.2.1.4	* TER_{LT} for *Daphnia*					☐
10.2.1.5	* TER_A for an aquatic insect species					☐
10.2.1.6	* TER_{LT} for an aquatic insect species					☐
10.2.1.7	* TER_A for an aquatic crustacean species					☐
10.2.1.8	* TER_{LT} for an aquatic crustacean species					☐
10.2.1.9	* TER_A for an aquatic gastropod mollusc species					☐
10.2.1.10	* TER_{LT} for an aquatic gastropod mollusc species					☐
10.2.1.11	* TER_{LT} for algae					☐
10.3	Effects on terrestrial vertebrates other than birds					
10.3.1.1	Acute toxicity exposure ratio (TER_A), via exposure of surface water					☐
10.3.2.3	Effects of secondary poisoning, via exposure of surface water					☐
10.5	Effects on arthropods other than bees					
10.5.1	Effects on sensitive species already tested, using artificial substrates (effects on non-target terrestrial arthropods in laboratory tests)					☐
10.8	Effects on non-target plants					
10.8.1	Effects on non-target terrestrial plants					☐

10.9.2	A critical assessment as to the relevance of the preliminary test data to potential impact on non-target species, including: • off-field risk assessment to non-target terrestrial arthropods, • if relevant, risk assessment to non-target terrestrial arthropods in integrated pest management (IPM) in for example fruit crops and protected crops (e.g. greenhouses) • off-field risk assessment to non-target terrestrial plants	☐
10.10	Other/special studies	
10.11	Summary/evaluation of all studies submitted in support of the application including the studies submitted for the original authorisation (not part of the EU-dossier)	☐