HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 WEDERZIJDSE ERKENNING

Op 22 december 2014 is van

UPL Europe Ltd.
1st Floor, The Centre, Birchwood Park
WARRINGTON, Cheshire WA3 6YN
GROOT-BRITTANNIE

Een aanvraag tot uitbreiding van een toelating via wederzijdse erkenning ontvangen als bedoeld in artikel 33 Verordening (EG) 1107/2009 (verder te noemen: de Verordening) voor het gewasbeschermingsmiddel

Mission 200 SL

op basis van de werkzame stof diquatdibromide, uitgedrukt als diquat.

HET COLLEGE BESLUIT tot uitbreiding van bovenstaand middel.

Alle bijlagen vormen een onlosmakelijk onderdeel van dit besluit.

Voor nadere gegevens over deze toelating wordt verwezen naar de bijlagen:
- Bijlage I voor details van de aanvraag en toelating;
- Bijlage II voor de etikettering;
- Bijlage III voor wettelijk gebruik;
- Bijlage IV voor de onderbouwing.

1.1 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.2 Gebruik

Het middel mag slechts worden gebruikt met inachtneming van hetgeen in bijlage III bij dit besluit is voorgeschreven.

1.3 Classificatie en etikettering

Mede gelet op de onder “wettelijke grondslag” vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen op de verpakking te worden vermeld:

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder “verpakkingsinformatie” in bijlage I.
- Het toelatingsnummer met een cirkel met daarin de aanduiding van de w-coderingen zoals vermeld onder “toelatingsinformatie” in bijlage I.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in bijlage III.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Het nieuwe gebruiksvoorschrift en de nieuwe etikettering dienen bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. De te hanteren w-coderingen en aflever- en opgebruiktermijnen voor oude verpakkingen staan vermeld onder “toelatingsinformatie” in bijlage I.

2 WETTELIJKE GRONDSLAG

Besluit	artikel 40 van de Verordening (EG) 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Bgb en Rgb d.d. 16 december 2011 en Evaluation Manual Zonaal 2.0

3 BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

3.2 Analysemethoden

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

3.5 Werkzaamheid

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

Bezwaarmogelijkheid
Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 8030, 6710 AA, EDE. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Ede, 4 maart 2016

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

13848 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20150026 NLWERGU
Type aanvraag:	NLWERGU
Middelnaam:	Mission 200 SL
Verzenddatum aanvraag:	22 december 2014
Formele registratiedatum: *	26 januari 2015
Datum in behandeling name:	24 juni 2015

* Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

2 Stofinformatie

Werkzame stof	Gehalte
diquatdibromide	374 g/L
uitgedrukt als diquat	200 g/L

De stof is per 1 januari 2002 geplaatst op Annex I van richtlijn 91/414 (Richtlijn 2001/21/EG, 5 maart 2001), met expiratiedatum 31 december 2015 (Richtlijn 2010/77/EG d.d. 10 november 2010), en vervolgens goedgekeurd krachtens Verordening (EG) No 1107/2009 (Uitvoeringsverordening (EU) No 540/2011 d.d. 25 mei 2011).

3 Toelatingsinformatie

Toelatingsnummer:	13848 N
Expiratiedatum:	30 juni 2017
Afgeleide parallel of origineel:	Origineel
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	professioneel
W-codering professioneel gebruik:	W.1
Vorige w-codering professioneel gebruik:	-
Aflevertermijn professioneel gebruik:	niet van toepassing
Opgebruiktermijn professioneel gebruik:	niet van toepassing

4 Verpakkingsinformatie

Aard van het preparaat:
met water mengbaar concentraat (SL)

13848 N

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BIJLAGE II Etikettering van het middel Mission 200 SL

Professioneel gebruik
de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:
diquatdibromide, uitgedrukt als diquat

Pictogram	GHS06 GHS08 GHS09
Signaalwoord	GEVAAR
Gevarenaanduidingen	H302 Schadelijk bij inslikken. H315 Veroorzaakt huidirritatie. H317 Kan een allergische huidreactie veroorzaken. H319 Veroorzaakt ernstige oogirritatie. H330 Dodelijk bij inademing. H335 Kan irritatie van de luchtwegen veroorzaken. H372 Veroorzaakt schade aan organen <of alle betrokken organen vermelden indien bekend> bij langdurige of herhaalde blootstelling. H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P260 Stof/rook/gas/nevel/damp/spuitnevel niet inademen. P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. P284 Adembescherming dragen. P304 + P340 NA INADEMING: de persoon in de frisse lucht brengen en ervoor zorgen dat deze gemakkelijk kan ademen. P310 Onmiddellijk een ANTIGIFCENTRUM/arts/... raadplegen. P501 Inhoud/verpakking afvoeren naar .... SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
Aanvullende etiketelementen	EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

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BIJLAGE III WG van het middel

Wettelijk Gebruiksvoorschrift

Toegestaan is uitsluitend het professionele gebruik als onkruidbestrijdingsmiddel of doodspuitmiddel in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden:

Toepassingsgebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus of per 12 maanden	Maximaal aantal liter middel per ha per teeltcyclus of per 12 maanden	Minimum interval tussen toepassingen in dagen	Veiligheidstermijn in dagen
Aardappelen	voor opkomst	Eenjarige breedbladige onkruiden	1,5-2 l/ha	1 per teeltcyclus	2 l/ha	-	-
	doodspuiten	Aardappelloof	4 l/ha	1 per teeltcyclus	4 l/ha	-	-
Bieten	voor opkomst	Eenjarige breedbladige onkruiden	1,5-2 l/ha	1 per teeltcyclus	2 l/ha	-	-
Cichorei	voor opkomst of voor uitplanten	Vogelmuur[1]	1,5 l/ha	1 per 12 maanden	1,5 l/ha	-	-
Aardbei	tussen de rijen	Vogelmuur[1]	1,5 l/ha	1 per teeltcyclus	1,5 l/ha	-	-
Bladgroenten (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5-2 l/ha	1 per 12 maanden	2 l/ha	-	-
Peulgroenten (onbedekt)	voor opkomst	Eenjarige breedbladige onkruiden	1,5-2 l/ha	1 per teeltcyclus	2 l/ha	-	-

Toepassingsgebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus of per 12 maanden	Maximaal aantal liter middel per ha per teeltcyclus of per 12 maanden	Minimum interval tussen toepassingen in dagen	Veiligheidstermijn in dagen
Vruchtgroenten (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5-2 l/ha	1 per teeltcyclus	2 l/ha	-	-
Koolgewassen (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5-2 l/ha	1 per 12 maanden	2 l/ha	-	-
Wortel- en knolgewassen (onbedekt)	voor opkomst	Eenjarige breedbladige onkruiden	1,5-2 l/ha	1 per 12 maanden	2 l/ha	-	-
Uien	voor opkomst of voor uitplanten	Vogelmuur[1]	1,5 l/ha	1 per 12 maanden	1,5 l/ha	-	-
Stengelgroenten (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5-2 l/ha	1 per 12 maanden	2 l/ha	-	-
Sierteeltgewassen (onbedekt)	voor opkomst of voor uitplanten	Vogelmuur[1]	1,5 l/ha	1 per 12 maanden	1,5 l/ha	-	-

[1] Vogelmuur (*Stellaria media*)

Toepassingsvoorwaarden
Mission in een watervolume van 200-500 l/ha toepassen.

Dit product mag uitsluitend machinaal toegepast worden omdat gezondheidseffecten niet zijn uit te sluiten bij handmatige toepassing.

Om niet tot de doelsoorten behorende geleedpotigen / insecten en niet tot de doelsoorten behorende planten te beschermen is de toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met een kantdop en een teeltvrije zone van 1,5 m *(gemeten vanaf het midden van de laatste gewasrij tot aan de perceelgrens).*

Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels. Gebruik dit product niet wanneer bloeiende onkruiden aanwezig zijn.

In de teelt van cichorei, aardbei, uien en sierteeltgewassen kan de werking onvoldoende zijn.

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BIJLAGE IV

1. Identity of the plant protection product

1.1 Applicant

UPL Europe Ltd.
1st Floor, The Centre
Warrington
WA3 6YN
United Kingdom

1.2 Identity of the active substance

Common name	Diquat
Name in Dutch	Diquat
Chemical name	9,10-dihydro-8a,10a-diazoniaphenanthrene ion (diquat)
CAS no	2764-72-9 (diquat), 85-00-7 (diquat dibromide)
EC no	220-433-0 (diquat), 201-579-4 (diquat dibromide)

The active substance was included in Annex I of Directive 91/414/EEC on 5 March 2001
From 14 June 2011 forward, according to Reg. (EU) No 540/2011 the substance is approved under Reg. (EC) No 1107/2009, repealing Directive 91/414/EEC.

1.3 Identity of the plant protection product

Name	Mission 200 SL
Formulation type	SL, Soluble concentrate
Content active substance	374 g/l pure diquat-dibromide, equivalent to 200 g/l pure diquat

For the assessment of the formulation and its proposed use we refer to the member state of the original authorisation (United kingdom).

1.4 Function

Herbicide and desiccant.

1.5 Uses applied for

See GAP (Appendix I).

1.6 Background to the application

Mission 200 SL was authorised in 2012 by mutual recognition of the authorisation in the United Kingdom. The UK authorisation was extended with new uses. This application concerns a mutual recognition of the extension in the UK.

1.7 Packaging details

1.7.1 Packaging description

Material:	HDPE container
Capacity:	1, 5, or 10L
Type of closure and size of opening:	Screw cap with induction seal, resp. 45 mm, 63 mm, 63 mm
Other information	ADR/UN compliant

1.7.2 Detailed instructions for safe disposal

No particular recommendations

2. Physical and chemical properties

For the assessment of the physical and chemical properties of Mission 200 SL we refer to the member state of the original authorisation (United Kingdom).

3. Methods of analysis

For the assessment of the methods of analysis required for Mission 200 SL we refer to the member state of the original authorisation (United Kingdom).

4. Mammalian toxicology

4.1 Toxicity of the formulated product (IIIA 7.1)

For the evaluation of the toxicity of the formulated product Mission 200 SL, we refer to the member state of the original authorisation (United Kingdom).

4.2 Dermal absorption (IIIA 7.3)

The United Kingdom used a value of 1% for dermal absorption for both the concentrate and spray dilution in the risk assessment and since this application is a request for mutual recognition the value of 1% is also used in this risk assessment.

4.3 Available toxicological data relating to non-active substances (IIIA 7.4)

For toxicological data relating to non-active substances we refer to the registration report written by the United Kingdom.

4.4 Exposure/risk assessments *(Dutch specific aspect)*

Overview of the intended uses

An application (request for mutual recognition) has been submitted for the extension of the authorisation of the plant protection product Mission 200 SL, a herbicide based on the active substance diquat.

Mission 200 SL (soluble concentrate) formulation and contains 200 g/L diquat.

The formulation Mission 200 SL is applied up to two times during the period the cultivation period. Therefore, a semi-chronic exposure duration is applicable for the operator (including contract workers).

4.4.1 Operator exposure/risk

Mechanical downward spraying

It is referred to the UK assessment, the same GAP for the intended uses is authorised in the UK. Furthermore, the use extension is covered by the risk envelop of the current authorisation regarding Mission 200 SL in the Netherlands.

In conclusion, it is not expected that due to respiratory and dermal exposure to diquat as the result of the application of Mission 200 SL in the intended uses an unacceptable risk occurs for operators in case personal protective equipment (respiratory protective equipment and gloves during mixing/loading and respiratory protective equipment, gloves and coverall during application) is worn.

Manual downward spraying

The UK assessment and the previous Dutch assessment did not consider manual downward spraying. One of the uses of the use extension concerns application in strawberries. As in the Netherlands manual downward spraying cannot be excluded for strawberries the following restriction sentence is proposed:

"*Dit product mag uitsluitend machinaal toegepast worden omdat gezondheidseffecten niet zijn uit te sluiten bij handmatige toepassing.*"

4.4.2 Bystander exposure/risk

Regarding professional bystanders, it is referred to the UK assessment, the same GAP for the intended uses is authorised in the UK. Furthermore, the use extension is covered by the risk envelop of the current authorisation regarding Mission 200 SL in the Netherlands.
In conclusion, it is not expected that due to exposure to diquat as the result of the application of Mission 200 SL in the intended uses an unacceptable risk occurs for professional bystanders.

Non-professional bystanders and residents may be exposed via the dermal route to spray drift deposits or by inhalation of vapour drift within or directly adjacent to an application area (bystander), or in the vicinity of the application (resident). The internal bystander and resident exposure is calculated in addition to the internal bystander exposure and risk assessment calculated with EUROPOEM II above, which is intended to estimate the work-related bystander exposure. Two different methods are used: 1) the German model which calculates the total exposure for adults, and children, and considers for the latter also the oral exposure via hand-to-mouth or object-to-mouth transfer; and 2) the UK method which calculates the total bystander exposure for adults, and separately the respiratory and dermal/oral route for resident children. In the table below the estimated internal exposure values from these methods are compared with the systemic EU-AOEL.

Table T.4 Internal bystander and resident exposure to diquat and risk assessment for the application of Mission 200 SL

	Route	Estimated internal exposure [a] (mg/day)	Systemic AEL (mg/day) [b]	% AEL [c]
Bystander exposure during application in intended uses according to the German model				
Child	Total	<0.01	0.02	15
Adult	Total	0.01	0.06	19
Resident exposure during application in intended uses according to the German model				
Child	Total	0.01	0.02	57
Adult	Total	0.02	0.06	30
Bystander exposure during application in intended uses according to the UK method				
Adult	Total	<0.01	0.06	4
Resident exposure during application in intended uses according to the UK method				
Child	Respiratory	0.01	0.02	55
	Dermal + Oral	<0.01	0.02	4

a External exposure was estimated according to 1) the German guidance paper for exposure and risk assessment for bystanders and residents (Martin *et al.* 2008, *J. Verbr. Lebensm.* 3: 272-281), and 2) the UK method. Internal exposure was calculated with:
- biological availability via the respiratory route: 100% (worst case)
- biological availability via the dermal route: 1% (spray dilution)
- biological availability via the oral route: 10% (see List of Endpoints)

b From the systemic AEL of 0.001 mg/kg bw/day a specific AEL is derived assuming a body weight of 16.15 or 15 kg for children in the German model or UK method, respectively, and of 60 kg for adults.
c The % AEL is calculated by dividing the internal exposure by the systemic AEL and multiplying this by 100%.

4.4.3 Worker exposure/risk

It is referred to the UK assessment, the same GAP for the intended uses is authorised in the UK. Furthermore, the use extension is covered by the risk envelop of the current authorisation regarding Mission 200 SL in the Netherlands.
In conclusion, it is not expected that due to respiratory and dermal exposure to diquat as the result of the application of Mission 200 SL in the intended uses an unacceptable risk occurs for unprotected workers.

4.4.4 Re-entry

See 4.4.3 Worker exposure/risk.

Overall conclusion of the exposure/risk assessments of operator, bystander, and worker
The product complies with the Uniform Principles.

Operator exposure
No adverse health effects are expected after respiratory and dermal exposure to diquat for the operator as a result of the application of Mission 200 SL in the intended uses in case personal protective equipment (respiratory protective equipment and gloves during mixing/loading and respiratory protective equipment, gloves and coverall during application) is worn.

Bystander exposure
Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected bystander, nor for nearby non-work related bystanders and residents, due to exposure to diquat during application of Mission 200 SL in the intended uses.

Worker exposure
Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected worker after respiratory and dermal exposure during re-entry activities in the intended uses due to exposure to diquat after application of Mission 200 SL.

The current classification and labelling of the formulation can be maintained.

4.5 Appropriate mammalian toxicology and operator exposure endpoints relating to the product and approved uses

See List of Endpoints.

4.6 Data requirements

None.

4.7 Combination toxicology

Mission 200 SL contains only one active substance and it is not described that it should be used in combination with other formulations.

5. Residues

For the aspect ‘Residues’ and risk for consumers we refer to the member state of the original authorisation (UK). The Guidelines for the generation of data concerning residue data

Appendix C 7524/VI/95 rev.2 require that the residue situation in rotational crops must always be considered if, after the treated crop has been harvested (or in the event of early ploughing), it is possible to sow or plant a crop which can be used as a foodstuff and/or feed. Since the product was assessed according to the Uniform Principles by the member state of the original authorisation, residues in succeeding crops need no further consideration.

6. Environmental fate and behaviour

Risk assessment is done in accordance with Chapter 4 of the BGB published in the Bulletin of Acts and Decrees (Staatsblad) 594 of November 30th 2011 and Chapter 2 of the Rgb published in the Government Gazette (Staatscourant) 22280 of December 2nd 2011.

The underlying risk assessment is based on the final list of endpoints for active substance diquat (as diquat dibromide) and on the UK authorization for Mission 200 SL. For the Dutch specific aspects data from previous assessment is used.

List of Endpoints Fate/behaviour
The LoEP is taken from the final registration report 2001/21/EC OJ L69; d.d. 10/03/2001.

Fate and behaviour in soil

Route of degradation

Aerobic:	
Mineralization after 100 days:	Microbial degradation has been demonstrated only in isolation due to strong adsorption to soil.
Non-extractable residues after 100 days:	Not relevant. See comment above.
Relevant metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	Not relevant. See comment above.
Supplemental studies	
Anaerobic:	Relatively stable, withstands degradation
Soil photolysis:	No significant degradation in 32 d
Remarks:	Standard requirements are not applicable due to strong adsorption to soil.

Rate of degradation

Laboratory studies	
DT_{50}lab (20 °C, aerobic):	No measurable degradation in soil under laboratory conditions after one year.
DT_{90}lab (20 °C, aerobic):	Not relevant. See comment above.
DT_{50}lab (10 °C, aerobic):	Not relevant. See comment above.
DT_{50}lab (20 °C, anaerobic):	Not relevant. See comment above.
Field studies (country or region)	
DT_{50f} from soil dissipation studies:	DT_{50} = 10 - 20 y (UK), 1.2 - 3.6 y (US)

DT_{90f} from soil dissipation studies:	DT_{90} values were never reached
Soil accumulation studies:	Performed as part of US soil dissipation study - refer to detailed results. (16% of diquat applied remained in the soil after 11 years of annual application to the soil at 1 kg diquat/ha/yr)
Soil residue studies:	< 0.05 - 2.3 mg/kg (Denmark 32 sites) 0.11 mg/kg (maximum), 0.03 mg/kg (average) for various Western European Countries

Remarks

e.g. effect of soil pH on degradation rate	The strong adsorption of diquat to soil precludes diquat degradation in soil being studied effectively by standard guideline methods. The strong adsorption also greatly reduces the rate of formation of degradation products to amounts that would not be detectable using standard methods. Soil microbial studies fulfil the scientific intent of demonstrating the intrinsic degradability of diquat.

Adsorption/desorption

	Following end points based on the results obtained from a soil residue study performed at 32 sites in Denmark. (Bewick *et al*, 1984)
K_f / K_{OC}	Koc values (32 soils in study) ranged from 32,000 to 7,900,000 (very strong adsorption in all the soils tested - with 31 of the soils having Koc values at least one order of magnitude greater than 5,000). Mean Koc value = 2,184,750 Median Koc value = 1,600,000
K_d	Kd values (32 soils in study) ranged from 1,200 to 92,000 (very strong adsorption in all the soils tested) Mean Kd value = 27,100 Median Kd value = 23,500
pH dependence	Not relevant

Mobility

Laboratory studies:

Column leaching:	Not relevant as all studies indicate that diquat is immobile.
Aged residue leaching:	Not relevant as all studies indicate that diquat is immobile.

Field studies:

Lysimeter/Field leaching studies:	Not relevant as all studies indicate that diquat is immobile.

Remarks:	Adsorption is correlated to clay content. Adsorption capacity is quantified by wheat

	bioasssay (SAC-WB). Most soils have a large excess in adsorption capacity. For very sandy soil exceedance may be a possibility following repeated high application rates.

Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	No sterile hydrolysis at environmental pHs.
Relevant metabolites:	None
Photolytic degradation:	DT_{50} < 7 d (UK summer conditions)
Relevant metabolites:	None

Biological degradation

Ready biological degradability:	No, due to rapid adsorption by sediment or suspended solids.
Water/sediment study:	DT_{50} = 12 - 24 hours.
DT_{50} water: DT_{90} water: DT_{50} whole system: DT_{90} whole system: Distribution in water / sediment systems (active substance) Distribution in water / sediment systems (metabolites)	Aquatic biodegradation studies, (two water/sediment studies performed in the laboratory under aerobic or anaerobic conditions, and a field study performed in natural ponds in the US) show similar results. The primary route of dissipation of diquat from natural water is through very rapid adsorption onto sediment, or by adsorption onto plant material and/or suspended particulate matter which ultimately settle to the bottom of the pond or water course. The field study in natural ponds shows that diquat dispersion within and dissipation from water are both extremely rapid with difficulties in measuring these accurately. Substantial dissipation occurs after a few hours, with estimates of the DT50 for the partition to sediment ranging from <8 to 34 hours, with a mean of 12 to 24 hours. Diquat was stable withstanding degradation under the conditions of the aerobic and anerobic studies conducted in pond water and sand sediment.
Accumulation in water and/or sediment:	Not relevant as diquat dissipates very rapidly by adsorption onto sediment; plant material and/or suspended particulate matter which settle to the bottom of the pond or water course. There is no evidence of desorption of diquat back into the water in the relevant studies.
Degradation in the saturated zone	See above remarks.
Remarks:	None

Fate and behaviour in air

Volatility

Vapour pressure:	< 10^{-8} kPa at 25 °C
Henry's law constant:	5 · 10^{-12} Pa·m^3·mol^{-1}

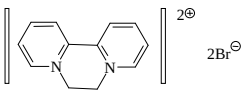
Photolytic degradation

Direct photolysis in air:	Not relevant, due to low vapour pressure.
Photochemical oxidative degradation in air DT_{50}:	Not relevant, due to low vapour pressure.
Volatilisation:	Not relevant, due to low vapour pressure.

Remarks:	None

Appendix A: Metabolite names, codes and other relevant information of the plant protection product Mission 200 SL with active substance diquat.

The compounds shown below were found in one or more studies involving the metabolism and/or environmental fate of active substance diquat. The parent compound structure of diquat is shown first in this list and followed by degradates or related compounds.

Compound name	IUPAC name	Structural formula	Structure	Molecular Weight [g/mol]	Observed in study (% of occurrence/ formation)
diquat (ion), diquat dibromide	9,10-dihydro-8a,10a-diazoniaphenanthrene ion (dibromide)	$C_{12}H_{12}N_2$, $C_{12}H_{12}Br_2N_2$		184.2 (diquat)	Parent substance

6.1 Fate and behaviour in soil

6.1.1 Persistence in soil

The risk assessment of persistence in soil is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorization (UK).

6.1.2 Leaching to shallow groundwater *(Dutch specific aspect)*

Leaching to shallow ground water is a Dutch specific aspect. For the current application for mutual recognition this means that the UK risk assessment for leaching to ground water cannot be used for mutual recognition and a national risk assessment has to be performed.

Article 8e of the Plant Protection Products and Biocides Decree (BGB) describes the authorization criterion for leaching to groundwater.

The leaching potential of the active substance diquat (as diquat dibromide) is calculated in the first tier using Pearl 4.4.4 and the FOCUS Kremsmünster scenario. Input variables are the actual worst-case application rate of 0.4 kg a.s./ha, the crop (resp. potatoes (potatoes), onions (onions), winter cereals (ornamentals and chicory) and strawberries (strawberries) and an interception value appropriate to the crop stage of 0.5 for potatoes, and 0 for the remaining 4 uses applied for (pre-emergence and/or post planting application. (First) date of yearly application is May 25th (default). For the use in potatoes, a pre-planting application (weed control) already has been authorised for use, in combination with the currently submitted application at growth stage BBCH 45-91. The

(already authorised) application pre planting, has been modelled as well, starting at May 25th. The two remaining applications from the currently submitted application are modelled at August 1st and August 3rd.
For metabolites all available data concerning substance properties are regarded. No metabolites occurred above > 10 % of AR, > 5 % of AR at two consecutive sample points or had an increasing tendency. The following input data are used for the calculation:

PEARL:

Active substance: diquat (as diquat dibromide)
DT_{50} for degradation in soil (20°C): 3650 days (UK soil dissipation study)
Median K_{om} (pH-independent): 928074 L/kg (n=32)
1/n: 0.9 (default)

Saturated vapour pressure: 1 x 10^{-5} Pa (25 ºC)
Solubility in water: 718 g/L (20 ºC)
Molecular weight: 184.2 g/mol

Q10: 2.2
Plant uptake factor: 0.0

Other parameters: standard settings of PEARL 4.4.4

The following concentrations are predicted for the active substance diquat (as diquat dibromide) following the realistic worst case GAP, see Table M.1.

Table M.1 Leaching of active substance diquat (as diquat dibromide) as predicted by PEARL 4.4.4.

Use	Substance	Rate substance [kg/ha]	Freq. / Int. [days]	Fraction intercepted	PEC groundwater [µg/L]
Potatoes	diquat (as diquat dibromide)	0.4	2 / 2 **	0.5	<0.001
Onions	diquat (as diquat dibromide)	0.4	1 / -	0	<0.001
Ornamentals (Flowers, flower bulbs, ornamental plant production)	diquat (as diquat dibromide)	0.4	1 / -	0	<0.001
Chicory	diquat (as diquat dibromide)	0.4	1 / -	0	<0.001
Strawberries	diquat (as diquat dibromide)	0.4	1 / -	0	<0.001

* interception values derived from Table 1.5 in Generic Guidance for Tier 1 FOCUS Ground Water Assessments. (FOCUS, 2011). A worst case interception of 0.5 is appropriate for potatoes at BBCH growth stage 45-91. An interception of 0 is appropriate for the remaining crops, as the application is pre-emergence/ pre-planting or post-planting.

** For potatoes, an additional application pre-planting has been modelled, corresponding with the already authorised use in potatoes.

Results of Pearl 4.4.4 using the Kremsmünster scenario are examined against the standard of 0.01 µg/L. This is the standard of 0.1 µg/L with an additional safety factor of 10 for vulnerable groundwater protection areas (NL-specific situation).

From Table M.1 it reads that the expected leaching based on the PEARL-model calculations for the active substance diquat (as diquat dibromide) smaller than 0.01 µg/L for all proposed applications. Hence, the applications meet the standards for leaching as laid down in the RGB.

Monitoring data
There are no data available regarding the presence of the substance diquat (as diquat dibromide) in groundwater.

Conclusions
The proposed applications of the product Mission 200 SL comply with the requirements laid down in the BGB concerning leaching to groundwater.

6.2 Fate and behaviour in water

6.2.1 Rate and route of degradation in surface water *(Dutch specific aspect)*

Article 8f of the *Plant Protection Products and Biocides Decree* (BGB) prescribes the use of Dutch specific drift percentages.

Since the Netherlands has its own national drift values, the exposure concentrations of the active substance diquat (as diquat dibromide) in surface water have been estimated for the various proposed uses using calculations of surface water concentrations (in a ditch of 30 cm depth), which originate from spray drift during application of the active substance. The spray drift percentage depends on the use. A default of 1% drift has been used for TOXSWA.

Concentrations in surface water are calculated using the model TOXSWA. The following input data are used for the calculation:

TOXSWA:
Active substance diquat (as diquat dibromide) :
DT_{50} for degradation in water at 20°C: 1000 days (no degradation in the total system)
DT_{50} for degradation in sediment at 20°C: 1000 days (default).

Median K_{om} for suspended organic matter: 928074 L/kg
Median K_{om} for sediment: 928074 L/kg
1/n: 0.9 (default)

Saturated vapour pressure: 1 x 10^{-5} Pa (25 ºC)
Solubility in water: 718 g/L (20 ºC)
Molecular weight: 184.2 g/mol
Q10: 2.2

Other parameters: standard settings TOXSWA

When no separate degradation half-lives ($DegT_{50}$ values) are available for the water and sediment compartment (accepted level P-II values), the system degradation half-life ($DegT_{50}$-system, level P-I)

is used as input for the degrading compartment and a default value of 1000 days is to be used for the compartment in which no degradation is assumed. This is in line with the recommendations in the FOCUS Guidance Document on Degradation Kinetics.

For metabolites, the level M-I values are used (system $DegT_{50}$ value) only, since level M-II criteria have not been fully developed under FOCUS Degradation Kinetics.

In Table M.2a., the drift percentages and calculated surface water concentrations for the active substance diquat (as diquat dibromide) for each intended use are presented.

Table M… Overview of surface water concentrations for active substance diquat (as diquat dibromide) in the edge-of-field ditch following spring/autumn application

Use	Substance	Rate a.s. [kg/ha]	Freq./ Inter-val [days]	Drift [%]	PIEC [µg/L] *	PEC21 [µg/L] *	PEC28 [µg/L] *
Potatoes	diquat (as diquat dibromide)	0.4	2 / 2	1	0.439	0.351	0.322
Onions, Ornamentals, Chicory, Strawberries	diquat (as diquat dibromide)	0.4	1 / -	1	0.208	0.168	0.156

* calculated according to TOXSWA

$PEC_{sediment}$

To address the risk to sediment organisms, a $PEC_{sediment}$ value is needed for active substance diquat (as diquat dibromide) . The $PEC_{sediment}$ values calculated with TOXSWA are expressed in g a.s./m^3 sediment. This $PEC_{sediment}$ has to be converted to mg a.s./kg sed dw by dividing it by the dry bulk density. It is assumed that the substance will be present mainly in the top 1 cm layer. This layer has a density of 80 kg/m^3. The maximum PEC value in sediment in the top 1 cm of sediment is reached at resp. day 94 and 34 after the first application. See Table M.3b for calculation of PECsediment.

Table M.3b Maximum sediment concentration for active substance diquat (as diquat dibromide) following spring application (worst-case)

Use	Substance	Rate a.s. [kg/ha]	Drift [%]	$PEC_{sediment}$ [g a.s./m^3 sediment] * spring	$PEC_{sediment}$ [mg a.s./kg sediment dw]** Spring
Potatoes	diquat (as diquat dibromide)	0.4	1	0.0711	0.889
Onions, Ornamentals, Chicory, Strawberries	diquat (as diquat dibromide)	0.4	1	0.0237	0.296

* TOXSWA output

** calculated as (PECsed in g/m3 / 80 kg/m3) x 1000 (conversion of g/kg to mg/kg)

The exposure concentrations in surface water and sediment are compared to the ecotoxicological threshold values in section 7.2.

Monitoring data

In 2014, version 3 of the Pesticide Atlas was launched, which includes a statistical correlation analysis between concentrations, threshold exceedance and land use, which may indicate probable relationships. In this version also the correlation analysis of land use with the environmental quality standards (EQS) of the Water Framework Directive (WFD) is included.

Data from the Pesticide Atlas are used to evaluate potential exceedances of the authorisation threshold and environmental quality standards (MKN in Dutch, data source http://www.rivm.nl/rvs/Normen). These environmental quality standards consist either of the harmonised WFD thresholds derived according to the Fraunhofer methodology[1] (AA-EQS and MAC-EQS) or of an MPC value (which is usually derived on the basis of outdated guidance). When EQS values according to the Water Framework Directive are available, the MPC value is not used further in the analysis of monitoring data for the purpose of the registration.

For examination against the drinking water criterion, another database (VEWIN) is used, since the drinking water criterion is only examined at drinking water abstraction points. For the assessment of the proposed applications regarding the drinking water criterion, see next section.

Active substance diquat (as diquat dibromide)

The active substance diquat (as diquat dibromide) was not observed in the surface water (most recent data from 2013). In Table M.3 the number of observations in the surface water from 2012 are presented. (Only measurements in Zeeland are reported in the Pesticide Atlas for 2012.)

The authorisation threshold equals 0.84 µg a.s./L (consisting of first or higher tier acute or chronic ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case 0.1*NOEC for Lemna). The relevant environmental quality standards (EQS) for this substance are not available.

Table M4 Monitoring data in Dutch surface water for diquat (from www.pesticidesatlas.nl, version 3.0)

Total no of locations (2012)	***n* > authorisation threshold**	***n* > EQS**		
		MAC-EQS	**AA-EQS**	**MPC (ad-hoc/indicative)**
21	2 (1 > authorisation threshold; 1 > 5 x authorisation threshold)	n.a.	n.a.	n.a.

[1] P.L.A. van Vlaardingen and E.M.J. Verbruggen, Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS). Revision 2007'. RIVM report 601782001.

* the number of observations at each location varies between 1 and 10, total number of measurements is 83 in 2012.
** n.a. not available

Two locations show an exceedance of the authorisation threshold.

Therefore it is assessed whether there is a correlation between the observed exceedances and land use types. The correlation analysis as included in the Pesticide Atlas uses a progressive three-year period to assess whether there is a relation. The last three available years, in this case 2011-2013 are used to establish the relation.

The observed exceedance of the water quality standard authorisation threshold is not significantly correlated to the proposed use.

Therefore, no consequences can be drawn from the observed exceedance.

Drinking water criterion
Assessment of the drinking water criterion is in principle not a Dutch specific aspect however the interpretation is done in a Dutch specific way.

Article 8g of the *Plant Protection Products and Biocides Decree* (BGB) describes the Assessment of the drinking water criterion.

It follows from the decision of the Court of Appeal on Trade and Industry of 19 August 2005 (Awb 04/37 (General Administrative Law Act)) that when considering an application, the Ctgb should, on the basis of the scientific and technical knowledge and taking into account the data submitted with the application, also judge the application according to the drinking water criterion 'surface water intended for drinking water production'.
The assessment methodology followed is developed by the WG implementation drinking water criterion and outlined in Alterra report 1635[2].

Substances are categorized as new substances on the Dutch market (less than 3 years authorisation) or existing substances on the Dutch market (authorised for more than 3 years).

- For new substances, a preregistration calculation is performed.
- For existing substances, the assessment is based on monitoring data of VEWIN (drinking water board).
    - If for an existing substance based on monitoring data no problems are expected by VEWIN, Ctgb follows this VEWIN assessment.
    - If for an existing substance based on monitoring data a potential problem is identified by VEWIN, Ctgb assesses whether the 90th percentile of the monitoring data meet the drinking water criterion at each individual drinking water abstraction point.

Active substance diquat (as diquat dibromide) has been on the Dutch market for > 3 years (authorised since (authorised since 30/09/1994)). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. The Ctgb does

[2] Adriaanse et al. (2008). Development of an assessment methodology to evaluate agricultural use of plant protection products for drinking water production from surface waters - A proposal for the registration procedure in the Netherlands. Alterra-Report 1635.

under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water as laid down in the BGB are met.

6.3 Fate and behaviour in air

Route and rate of degradation in air
Assessment of fate and behaviour in air is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorisation (UK).

At present there is no framework to assess fate and behaviour in air of plant protection products.

6.4 Appropriate fate and behaviour end-points relating to the product and approved uses
See List of End-points.

6.5 Data requirements
None.

The following restriction sentences were proposed by the applicant:
None.

Based on the current assessment, the following has to be stated in the GAP/legal instructions for use (WG):
None.

6.6 Overall conclusions fate and behaviour
It can be concluded that:

1. all proposed applications of the active substance diquat (an diquat dibromide) meet the standards for leaching to the shallow groundwater as laid down in the BGB.
2. all proposed applications of the active substance diquat (as diquat dibromide) meet the standards for surface water destined for the production of drinking water as laid down in the BGB.

7. Ecotoxicology

For the extension of the current application of mutual recognition of Mission 200 SL, risk assessment is done in accordance with the BGB and RGB d.d. 16 December 2011 and the Ctgb Evaluation Manual 1107, version 2.0 (2014).

The underlying risk assessment is based on the final list of endpoints for diquat (EU Review Report, 1688/VI/97-final, 2001/21/EC OJ L69, d.d. 22 March 2001) and on the UK authorisation for Mission. For the Dutch specific aspects data from the previous assessment of the product Dragoon (20140020 NL WERGU, d.d. April 29, 2015), containing diquat as active substance, is used.

List of Endpoints Ecotoxicology
Diquat is placed on Annex I since 2002. For the risk assessment the LoEP from the final registration report (d.d. 10/03/2001) is used, complemented with additional studies submitted during and after EU peer review of the active substance, as stated in the Dutch authorisation from 2012 (13849 N).

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 (diquat ion - rat)= 214 - 222 mg/kg bw

Short term oral toxicity to mammals:	NOAEL 8.9mg /kg bw/d, 90 day rat (diquat ion) NOAEL 0.5 mg/kg bw/d, 1 y dog - (diquat ion)
Acute toxicity to birds:	LD_{50} = 83 mg /kg bw (diquat ion) *Anas platyrhynchos*
Dietary toxicity to birds:	LC_{50} = 721 ppm, 5 d study (diquat ion) *Coturnix japonica (162 mg a.s./kg bw/d, recalculated by applicant)*
Reproductive toxicity to birds:	NOEC = 5 mg/kg (diquat ion) (= *0.6 mg a.s./kg bw/d based on FIR/bw 0.121* [1]*)* *28 d NOEC = 100 ppm = 21.7 mg a.s./kg bw/d (Mallard ducklings, 1 d old)* [2] *9 w NOEC = 40 ppm = 6.6 mg a.s./kg bw/d (Mallard duck)* *12 w NOEC = <80 ppm (Mallard duck), quick recovery – see discussion below*[2]

1 based on FIR/bw = (146/1205 =) 0.121 (data provided by notifier)

[2] *evaluated in RIVM-report 12465A00*

Relevant long-term toxicity value

(Statement provided by the notifier for their own product; and repeated by the applicant. The applicant has a LoA from the notifier for the essential studies)

The above risk assessment is based on the lowest reproduction NOEC given in the LoE. However, more reproduction studies were done. Below an overview is given of the available chronic bird studies with a.s. diquat.

Long-term toxicity of diquat to birds

Study type	Species	Endpoint	Value (expressed as diquat ion)	Reference
Studies submitted during EU Peer Review:				
Effects on reproduction (18 weeks exposure)	*Colinus virginianus* (Bobwhite quail)	NOEC (NOEL)	100 mg/kg diet (9.4 mg/kg bw/d)	**Beavers and Fink, 1982b**
Effects on reproduction (18 weeks exposure, including poor layers)	*Anas platyrhynchos* (Mallard duck)		5 mg/kg diet according to LoE (0.6 mg/ a.s.kg bw/d[1])	**Beavers and Fink, 1982c**
Effects on duckling growth (2 and 4 weeks exposure)	*Anas platyrhynchos* (Mallard duck)	NOEC (NOEL)	100 mg/kg diet (21.7 mg/kg bw/day)	**Frey et al., 1995**
New studies, submitted to Ctgb after EU Peer Review:				
Effect on reproduction (3 weeks pre-egg laying plus 6 weeks post-egg laying exposure, including poor layers) Only egg production and egg weight measured	*Anas platyrhynchos* (Mallard duck)	NOEC (NOEL)	40 mg/kg diet (6.6 mg/kg bw/day for males + females; 10.0 mg/kg bw/d for females only)	**Temple et al., 2004a PP901/1436**
Effect on reproduction (6 weeks post-egg laying exposure, normal layers) Only egg production and egg weight measured	*Anas platyrhynchos* (Mallard duck)		80 mg/kg diet (11.1 mg/kg bw/day)	**Temple et al., 2004b PP901/1437**
Effect on reproduction (6 weeks post-egg laying exposure, late layers) Only egg production and egg weight measured	*Anas platyrhynchos* (Mallard duck)		>20 mg/kg diet (2.7 mg/kg bw/day)	
Reproduction Study to Evaluate Reversibilty oin Effects (6 weeks exposure during egg laying, and 6 weeks recovery)	*Anas platyrhynchos* (Mallard duck)	LOEC = 80 mg/kg diet (11.1 mg/kg bw/day), but complete recovery seen after 1 week at this rate. Recovery seen after 2 weeks at 160 mg/kg diet (19.7 mg/kg bw/day)		**Temple et al., 2009 (PP901/10751)**

[1] based on FIR/bw = (146/1205 =) 0.121 (data provided by notifier)

Besides these studies in which the effects of diquat on birds were studied, the applicant also performed a feeding regime study without active substance (Temple, 2006). The purpose of this study was to investigate the differences in food consumption between male and female mallard ducks and to consider how this might affect the estimate of the LOEL and NOEL for sex specific endpoints. This study demonstrates that following the onset of egg-laying, female exposure may double through increased food consumption, while in the male it remains relatively constant. Thus the NOED based on the daily dose per bird for female specific endpoints tends to be underestimated when the calculation from the NOEL to the NOED is based on the mean feed consumption for both sexes.

Based on this study, female feed consumption can be calculated as follows:

Female feed consumption at plateau = $Feed_{week1} + 2 * (Feed_{week5-9} - Feed_{week1})$

This approach can be considered as a generic method for calculating female feed consumption and therefore be applied to mallard reproduction studies, unless food avoidance behaviour is noticed. Based on the above formula, the NOEC of 40 ppm from the Temple & Martin study of 2004a is recalculated to 10 mg a.s./kg bw/d for females only.

The lowest available NOEC is 5 mg/kg diet, which is equivalent to a NOEL of 0.6 mg/kg bw/d, based on effects on the number of viable embryo's, the number of live 3 weeks embryo's, the number of hatchlings and the number of 14 day old survivors (Fink & Beavers, 1982b). These parameters were also measured in the new study by Temple et al. of 2009 and they were found not to be affected at 80 and 160 ppm. The Temple study is considered more relevant in exposure duration (diquat is applied only once per season and availability for birds is expected to be much shorter than the 18 weeks exposure used in the old study) and furthermore of better quality (higher statistical power because more replicates were used). Therefore, it is considered that the EU-endpoint of 0.6 mg a.s./kg bw/d based on the Fink & Beavers study of 1982b can be superseded. The relevant endpoints for use in the egg-laying period are the NOEL of 10 mg a.s./kg bw/d for mallard duck and 9.4 mg as/kg bw/d for bobwhite quail (the underlying studies are based on exposure of parents (and eggs) in the egg-laying period). Thus, the NOEL to be used for risk assessment during the egg-laying season is 9.4 mg a.s./kg bw/d.

The Temple et al. study of 2009 was furthermore initiated to give an answer to the question whether outside the breeding period a NOEC of 21.7 mg/kg bw/d for adult birds could be used instead of a NOEC of 9.4 mg/kg bw/d which is the applicable NOEC for the reproductive phase of the birds.
Clinical observations of adults did not show overt signs of toxicity and gross pathology did not show treatment related abnormalities. Feed consumption was significantly reduced during week 1 in the 80 mg diquat cation per kg food (~ 11.1 mg/kg bw/d) but not in the 5 following weeks of exposure. Feed consumption was significantly reduced during week 1, 3, 4, 5 and 6 in the 160 mg diquat cation per kg food (~ 19.7 mg/kg bw/d). Feed consumption after the exposure period was comparable to the control group.
No significant changes in body weight were noticed in any of the two exposure levels.
There was a marked reduction of number of eggs laid during the 6 weeks exposure period in both treatment groups. During the withdrawal phase the 80 mg diquat per kg food treatment group (11.1 mg/kg bw/d) recovered quickly. Egg production in the 160 mg diquat per kg food treatment group (19.7 mg/kg bw/d) remained depressed in the first week of the withdrawal phase, increased during the second week and was comparable to the control during the third and following weeks of the experiment. No other reproductive effects were noticed. If the application of Reglone is during the egg-laying season, the NOEL of 10 mg as/kg bw/d can be used for mallard. For quail a slightly lower NOEL of 9.4 mg as/kg bw/d is available. Therefore, the relevant endpoint during the egg-laying season is 9.4 mg as/kg bw/d.
From the Temple et al. study of 2009 it could be concluded that the use of diquat will not influence the breeding success in the following breeding period. It is evident that birds do not like diquat and probably will look for other types of food. No other effects have been noticed that are relevant for the survival of birds outside the breeding period. Therefore, if the application of Reglone is outside the egg-laying season, the NOEL for duckling development can be used, which is 21.7 mg/kg bw/d based on the Frey et al study from 1995.

Aquatic Organisms

Acute toxicity fish:	LC_{50} = 21 mg /l, 96 h static study (diquat ion) *Oncorhynchus mykiss* LC_{50} = 6.1 mg /l, 96 h flow through study (diquat

	ion) *Oncorhynchus mykiss*
Long term toxicity fish:	*Pimephales promelas* 34 day study on embryos/larvae - NOEC (larval weight) considered to be 0.12 mg diquat/litre based on mean measured concentration
Bioaccumulation fish:	Low risk of bioaccumulation
Acute toxicity invertebrate:	EC_{50} = 1.2 mg/l, 48 h study *Daphnia magna* (diquat ion)
Chronic toxicity invertebrate:	21-day LC50 was 0.16 mg/l based on nominal concentration *Daphnia magna* (diquat ion). 21-day NOEC = 0.125 mg/l based on nominal concentration.
Acute toxicity algae:	EC_{50} = 0.011 - 1.0 mg/l, 96 h study (diquat ion) *Psuedokirchneriella subcapitata (syn. Rhapidocellis subcapitata and Selenastrum capricornutum)*
Acute toxicity algae - study in presence of sediment	NOEC biomass = 320 µg/l with EbC50 of >320 µg/l. 72 hours (diquat ion).. NOEC growth rate = 320 µg/l with ErC50 of >320 µg/l. 72 hours (diquat ion). *Psuedokirchneriella subcapitata (syn. Rhapidocellis subcapitata and Selenastrum capricornutum)*
Chronic toxicity sediment dwelling organism:	NOEC > 100 mg diquat ion/kg^{-1} sediment (diquat ion). *Chironomus riparius*
Acute toxicity aquatic plants:	No data requirement set at time of review.

Honeybees

Acute oral toxicity:	LD_{50} = 13 µg /bee (diquat ion)
Acute contact toxicity:	LD_{50} = 60 µg /bee (diquat ion)

Other arthropod species

Test species	% Effect
Aphidius rhopalosiphi	An extended laboratory study. At full field rate (i.e. 5 l/ha) there was significant mortality of wasps in the treatment compared to the control. No adverse effects were noted on either fecundity or behaviour.
Coccinella septumpunctata.	Extended laboratory study. Bean plants treated with 'Reglone' at 5 l/ha (1000 g /ha) - equivalent to the maximum field rate. Larvae of *Coccinella septumpunctata* exposed to residues of the test substance.

	Corrected pre-imaginal mortality of *Coccinella septumpunctata* was 58%, mortality for the positive control was 78.9%. The reproduction rate was: • 640.9 eggs/female in the treatment • 255.3 eggs/female in the control. R value 151.0%. Results within the range of historical control variability. IOBC classification : slightly harmful
Trichogramma cacocecie	Laboratory study: exposed to 'Reglone' at 1000 g diquat ion/ha - equivalent to maximum field rate. Parisitisation capacity reduced by 58 %. Exposed adults reduced by 98%.
Chrysoperla carnea	Laboratory study: exposed to 'Reglone' at 1600 g diquat ion/ha. 96% mortality recorded in exposed larvae.
Pterosticus melanarius	Exposed to 'Reglone' at 1600g diquat ion/ha on loamy sand. No lethal or sublethal effects.
Pardosa spp.	Exposed to 'Reglone' at 1600g diquat ion/ha on loamy sand. No lethal or sublethal effects.

Earthworms

Acute toxicity:	LC_{50} = 130 mg as/kg soil 14 day (diquat ion) NOEC > 18 mg as/kg soil 14 day (diquat ion)

Soil micro-organisms

Nitrogen mineralization:	No significant effects up to 50.0 kg diquat/ha
Carbon mineralization:	No significant effects up to 720 kg as/ha

Mission (200 g/L diquat)

Additional studies were summarized and evaluated by EPP consultancy (report 120603, 06/2012)

Aquatic Organisms

Acute toxicity aquatic plants (*Lemna minor*):	7-d E_rC_{50} 357 µg form*./L (62.5 µg a.s./L) 7-d E_bC_{50} 173µg form./L (30.2 µg a.s./L) 7-d $NOE_{r,b}C$ 33.7 µg form./L (5.9 µg a.s./L)

* SL formulation containing 203.5 g diquat/L (174.9 g diquat/kg)

Other arthropod species

Test species	Organism stage/Type of test	Value/ Adverse effect

Typhlodromus pyri	Protonymphs 2-3 days old/Dried residues on sprayed sweet-pepper leaves	Mortality: LR_{50} 23.4 mL form*./ha (4.75 g a.s./ha) Reproduction: ER_{50} >64.0 mL form./ha (>13.0 g a.s./ha)
Chrysoperla carnea	Larvae 2-4 days old/Dried residues on sprayed bean plants	Mortality: LR_{50} 4.46 L form./ha (0.90 kg a.s./ha) Reproduction (viable eggs/female/d): 2.0 L form./ha (0.41 kg a.s./ha) +16%** 4.0 L form/ha (0.81 kg a.s./ha) 18%

* SL formulation containing 202.9 g diquat/L

** + means increase compared to control

Earthworms

Reproduction toxicity (*Eisenia fetida*):	NOEC 248 mg form./kg dw (43.3 mg a.s./kg dw)

Other soil non-target macro-organisms

Reproduction toxicity (*Folsomia candida*):	Mortality: LR_{50} 29.1 mg form./kg dw (5.08 mg a.s./kg dw) Reproduction: EC_{50} 20.4 mg form./kg dw (3.56 mg a.s./kg dw) NOEC 5.6 mg form./kg dw (0.98 mg a.s./kg dw)

Effects on non-target plants

Test substance	Test type	Species	Endpoint	Value
Diquat 200 g/L SL*	Vegetative vigour	*Zea mays*	21-d NOER 21-d ER_{50}	<0.0512 L form./ha 1.16 L form./ha
		Allium cepa	21-d NOER 21-d ER_{50}	0.32 L form./ha 1.94 L form./ha
		Beta vulgaris	21-d NOER 21-d ER_{50}	0.0102 L form./ha 0.153 L form./ha
		Brassica napus	21-d NOER 21-d ER_{50}	<0.0512 L form./ha 0.242 L form./ha
		Daucus carota	21-d NOER 21-d ER_{50}	0.0512 L form./ha 0.240 L form./ha
		Glycine max	21-d NOER 21-d ER_{50}	0.128 L form./ha 0.512 L form./ha

* SL formulation containing 202.9 g diquat/L

Based on the results of the vegetative vigour, the applicant has submitted a resulted HC5 of 0.081154 L form/ha calculated using ETX 2.0.

The applicant has submitted a letter report on " Assessment of the effect of Diquat 200 g/L SL on the emergence of non-target terrestrial plants" . This is a screening test performed with doses of 4-36 L formulation/ha in 9 plant species: *Allium cepa, Avena sativa, Brassica napus, Linum usitatissium, Helianthus annuus, Lycopersicon esculentum, Pisum sp., Daucus carota subsp. Sativus, Lactuca sativa.* In

this letter it was concluded that at doses up to 36 L form/ha the emergence and plant weights are not affected. The report was not evaluated for reliability by Ctgb.

Additional studies

Measured residues of diquat in a Canadian field study (for bird and mammal risk assessment)
(evaluated in RIVM-report 11162A00, also available in EU-monograph (Edwards et al. 1991))

A study has been conducted in Canada to assess the potential effect of accidental overspray application on plant cover (bird nesting habitat) and on exposure to residues on their food. Six sites, each comprising a field, slough (prairie pond) and upland, were deliberately sprayed with diquat both on- and off-crop from the air at a rate of 550 g diquat/ha in July and August. Resulting residue values and residue degradation are shown in the Table below.

Diet	**n=**	**Initial residue value, 90thile or max, at 0.55 kg/ha (mg/kg fresh weight)**	**Initial residue value, 90thile or max, RUD for 1.0 kg/ha (mg/kg fresh weight)**	**Initial mean residue value at 0.55 kg/ha (mg/kg fresh weight)**	**Initial mean residue value, RUD at 1.0 kg/ha (mg/kg fresh weight)**	**DT_{50} value (days)**	**21-day TWA residue (mg/kg)**	**f_{twa}**	**r^2**	**Ri[c]**
Terrestrial vegetation	12	60.3 (90th percentile)[a]	110	36.8	66.9	1.59	4.07	0.11	0.85	1
Terrestrial invertebrates (pitfall traps)	2	6.9 (maximum) [a]	12.5	4.80	8.93	1.23	0.40	0.084	0.76	1
Whole seeds	5	42 (maximum) [a]	76	22	40	13.4	14.2	0.61	0.15	3
Seeds without husk	5	64 (maximum) [a]	116	21	38	13.7	9.44	0.62	0.16	3
Crop seed	nd	nd[b]		0.521	nd[b]	4.62	0.155	0.31	0.24	3
Aquatic vegetation	nd	nd[b]		5.23	nd[b]	2.96	1.06	0.20	0.20	3
Aquatic invertebrates	nd	nd[b]		1.61	nd[b]	1.58	0.11	0.068	0.56	3
Aquatic tubers	nd	nd[b]		0.583	nd[b]	7.53	0.256	0.45	0.50	3
Aquatic seeds	nd	nd[b]		1.07	nd[b]	17.5	0.625	0.68	0.16	3

[a] According to SANCO/4145/2000, 90th percentile residue values can be used for acute risk assessment. However, this is only acceptable when the sample size is sufficiently large. In this case, maximum values are given when n<10 and 90th percentile values when n≥10.

[b] Not given, because not relevant for the risk assessment.

[c] Ri = Risk index. Ri 1: acceptable; Ri 3: not acceptable. Ri values refer only to degradation, not to initial values.

Remarks:
The study is considered relevant for spray application of diquat in the Netherlands.
All initial residue values can be used for risk assessment. The recalculated DT_{50} values, 21-day TWA residues and f_{twa} for terrestrial vegetation and invertebrates can also be used for long-term risk assessment. For the other feed substances the fit was not good enough resulting in unreliable DT_{50} values, 21-day TWA and f_{twa} (Ri = 3).

The residue data from the Canadian field study are based on invertebrates sampled with pitfall traps. Thus, foliar dwelling invertebrates are not included, whilst it cannot be excluded that these will be exposed as well, and may be exposed to a higher degree because no crop interception takes place. However, two field studies with paraquat in which residues on invertebrates were measured after

application of 1.1 kg paraquat/ha in an apple orchard and melon field in Spain (Bakker (2004 and 2005), evaluated in RIVM-report 10994A01), show a mean (over different invertebrate groups) maximum (in time) residue value of 6.43 mg a/s/kg for foliar dwelling/flying invertebrates. Considering the similarities in physico-chemical and fate/behaviour properties of paraquat and diquat, which makes a comparison of residue data acceptable, it can be concluded that the RUD value of 8.93 mg a.s./kg for diquat based on pitfall samples only, is not likely to result in an underestimation of exposure, and is therefore acceptable.

Metabolites of diquat

Diquat is considered immobile in the environment due to its strong binding affinity to soil and sediment. Hydrolytic degradation in water has not been reported to occur at environmentally relevant pH. Photolytic degradation DT50 was <7 d (UK summer conditions) but no relevant metabolites were identified. In general, no relevant metabolites above 10% have been identified in water, soil or sediment. Therefore metabolites will not be considered in this risk assessment.

7.1 Effects on birds (*Dutch specific aspect)*

The risk assessment for birds from exposure via sprayed natural food and secondary poisoning via earthworms is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorisation (UK).

However, it is known that diquat can be toxic to birds (evaluation of Reglone, C164.3.8, 01/2006). A refined risk assessment was required in this case.

Later, based upon protected studies in birds, it was shown that diquat can be toxic during the egg-laying period of reproduction (evaluation of Reglone, C187.3.14, 11/2007), which led to a discussion in the EU about the egg-laying period for birds. Finally, for the use of Reglone as desiccant in potatoes, the following was concluded:

… the standards for birds are met for the desiccation use of Reglone in potatoes, under the condition that the application takes place after the 15th of July and that within 2 years the applicant has to demonstrate that no unacceptable effects for birds will result from this application after 15 July.'

This statement was based upon a risk assessment performed according to the old birds and mammals Guidance (SANCO, 2000), and taking into account the reproductive (egg-laying period) for birds. The use of this refinement is no longer acceptable in the Central Zone, as the egg-laying period of representative species may be different from all of the species they are intended to cover in the risk assessment. In addition, an assessment via the current Guidance may result in other areas of concern. Therefore, a risk assessment for birds is presented below, according to the newer EFSA Guidance for Birds and Mammals Risk Assessment (2009):

Birds can be exposed to the active substance diquat via natural food (sprayed insects, seeds, leaves), drinking water and as a result of secondary poisoning.

The threshold value for birds is based on the trigger from the RGB. This means that Toxicity-Exposure Ratio's (TERs) for acute and short-term exposure should be ≥ 10 and TER for chronic exposure should be ≥ 5.

Table E.1 presents an overview of toxicity data.

Table E.1 Overview of toxicity data for birds for substance Diquat

	Endpoint	Value
Acute toxicity to birds:	LD_{50}	83 mg a.s./kg bw
Reproductive toxicity to birds:	NOEL	5 ppm mg a.s./kg bw/d = 0.6 mg/kg bw/d

The toxicity endpoints in Table E.1 are both derived from tests in Mallard duck.

In addition to the acute toxicity value in the LoEP from the review report, another acute toxicity study with diquat was presented in the DAR (March 1996):
- test species: Partridge
- endpoint: LD_{50} = 158 mg a.s./kg bw.

Also, another reproductive toxicity study with diquat was presented in the DAR (March 1996):
- test species: Bobwhite quail
- endpoint: NOEL = 9.4 mg a.s./kg bw/d.

7.1.1 Natural food and drinking water

Sprayed products
The risk assessment for birds is carried out following the latest guidance document by EFSA (*Anonymous 2009: Guidance Document on risk assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. European Food Safety Authority*), hereafter cited as GD (EFSA 2009).

Acute and long-term screening assessments
According to the GD (EFSA 2009) calculation of a geometric mean is recommended if acute toxicity studies from more than one species are available. The geometric mean from the available studies for diquat is 115 mg a.s./kg, which will be used for the acute risk assessment.

The proposed use of the product is for desiccation in potatoes before harvest (BBCH 45-91) and as weed control in onions, ornamentals (flowers, flower bulbs, ornamental plant production), chicory (all at BBCH 00-07 – pre-emergence), potatoes (pre-planting), and strawberries (pre- or post-planting). These correspond with the potato, bare soil, and strawberries scenarios. For the applications in potatoes (BBCH 45-91) and strawberries (post-planting) the indicator species is a small omnivorous bird. For the application in bare soils (and hop), potatoes and strawberries (both pre-planting) the indicator species is a small granivorous bird. For uses with a frequency > 1, a MAF (Multiple Application Factor) may be applicable.

The DDD_m values for the acute risk assessment are calculated as application rate * shortcut value * MAF_{90}. The DDD_m values for the long-term risk assessment are calculated as application rate * shortcut value * MAF_m * TWA. The values of DDD_m are compared to the relevant toxicity figure. TERs should be above the trigger for an acceptable risk (10 or 5 for acute or long-term risk assessment, respectively). The screening assessment is shown in Tables E.2a-b.

Table E.2a Acute risk for birds (screening assessment)

Crop group	Substance	Indicator species	LD_{50} [mg a.s./ kg bw]	DDD			DDD_m [mg a.s./ kg bw/d]	TER_A	Trigger
				Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}			
Potatoes	Diquat	Small	115	0.4	158.8	1.4	88.9	**1.29**	10

Crop group	Substance	Indicator species	LD_{50} [mg a.s./ kg bw]	DDD			DDD_m [mg a.s./ kg bw/d]	TER_A	Trigger
				Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}			
		omnivorous bird							
Strawberries		Small omnivorous bird			158.8	1	63.5	**1.81**	
Bare soils		Small granivorous bird			24.7	1	9.88	11.6	

Table E.2b Long-term risk for birds (screening assessment)

Crop group	Substance	Indicator species	NOEL [mg a.s./kg bw]	DDD				DDD_m [mg a.s./ kg bw/d]	TER_{LT}	Trigger
				Appl. rate [kg a.s./ha]	SVm	TWA	MAF_m			
Potatoes	Diquat	Small omnivorous bird	0.6	0.4	64.8	0.53	1.6	22	**0.03**	5
Strawberries		Small omnivorous bird			64.8	0.53	1	13.7	**0.04**	
Bare soils		Small granivorous bird			11.4	0.53	1	2.42	**0.25**	

The results presented in Table E.2a show that the acute screening assessment TER values for the application in potatoes (desiccation) and strawberries (post-planting) are below the required trigger of 10. Furthermore, the results shown in Table E.2b demonstrate that the long-term screening assessment TER values for the application in all proposed crop types are below the required trigger of 5. Therefore, all the proposed uses, do not meet the standards laid down in the RGB and a Tier 1 assessment is required.

Tier 1 assessment

For the applications in strawberries (post-planting), generic focal species are the small omnivorous bird “lark” and the small insectivorous bird “wagtail”. For the application in bare soils the screening assessment indicates a low acute risk. Thus, Tier 1 acute risk assessment is performed only for the application in strawberries (post-planting) and potatoes (desiccation). For the long-term risk, a Tier 1 assessment is conducted for all proposed applications, as a risk was indicated in the screening level long-term assessment for all proposed uses.

Table E.3a Acute risk for birds (Tier 1 assessment)

Crop group	Substance	Indicator species	LD_{50} [mg a.s./kg bw]	DDD			DDD_m [mg a.s./kg bw/d]	TER_A	Trigger
				Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}			
Potatoes (BBCH 45-91)	Diquat	Small omnivorous bird "lark" (BBCH ≥ 40)	115	0.4	7.2	1.6*	4.61	25	10
		Small insectivorous bird "wagtail" (BBCH ≥ 20)			25.2		16.1	**7.10**	
Strawberries (BBCH 10-39)		Small omnivorous bird "lark" (BBCH 10-39)			24	1	9.6	12	
		Small insectivorous bird "wagtail" (BBCH 10-19)			26.8	1	10.7	10.7	
		Small insectivorous bird "wagtail" (BBCH ≥ 20)			25.2	1	10.08	11.4	

*Calculated by the Ctgb assessor based on a default DT_{50} of 10 days.

Table E.3b Long-term risk for birds (Tier 1 assessment)

Crop group	Substance	Generic focal species	NOEL [mg a.s./kg bw]	DDD				DDD_m [mg a.s./kg bw/d]	TER_{LT}	Trigger
				Appl. rate [kg a.s./ha]	SVm	TWA	MAF_m			
Potatoes (BBCH 45-91)	Diquat	Small omnivorous bird "lark" (BBCH ≥ 40)	0.6	0.4	3.3	0.53	1.9*	1.32	**0.45**	5
		Small insectivorous bird "wagtail" (BBCH ≥ 20)			9.7			3.91	**0.15**	
Strawberries (BBCH 10-39)		Small omnivorous bird "lark" (BBCH 10-39)			10.9	0.53	1	2.31	**0.26**	
		Small insectivorous bird "wagtail" (BBCH 10-19)			11.3	0.53	1	2.40	**0.25**	
		Small insectivorous bird "wagtail" (BBCH ≥ 20)			9.7	0.53	1	2.06	**0.29**	
Bare soils (00-09)		Small granivorous bird "finch"(BBCH			11.4	0.53	1	2.42	**0.25**	

Crop group	Substance	Generic focal species	NOEL [mg a.s./kg bw]	DDD				DDD_m [mg a.s./ kg bw/d]	TER_{LT}	Trigger
				Appl. rate [kg a.s./ha]	SVm	TWA	MAF_m			
Potatoes (BBCH 45-91)		Small omnivorous bird "lark" (BBCH ≥ 40)	0.6	0.4	3.3	0.53	1.9*	1.32	**0.45**	5
		Small insectivorous bird "wagtail" (BBCH ≥ 20)			9.7			3.91	**0.15**	
		< 10)								
		Small omnivorous bird "lark" (BBCH < 10)			8.2	0.53	1	1.74	**0.35**	
		Small insectivorous bird "wagtail" (BBCH < 10)			5.9	0.53	1	1.25	**0.48**	

* Calculated by the Ctgb assessor based on a default DT_{50} of 10 days.

Acute Tier 1 risk assessment (Table E.3a) indicates an acute risk for a small insectivorous bird "wagtail" as the TER value for this generic focal species is below the trigger of 10. Furthermore, a long-term risk to birds is expected as all TER values (Table E3.b) are below the trigger of 5. Further refinement of the risk is given below.

Refined risk assessment

Relevant endpoints

In order to refine the exposure for acute risk, a geometric mean can be used (EFSA 2009). Considering data from additional studies presented in the DAR (UK, September 2014), a geometric mean LD_{50} value of 121 mg a.s./kg bw has been calculated. Therefore, this LD_{50} was further considered as a refined endpoint in the acute risk assessment for birds

For a long-term risk, the applicant has a LoA for the additional studies from Syngenta. The applicant proposes to use the NOEC of 9.4 kg/kg bw/d based on the new studies, also for the risk outside the breeding season, for which a NOEC of 21.7 mg a.s./kg /d was previously accepted. According to EFSA 2009, the risk assessment should be performed either with the lowest from the relevant chronic endpoints or the LC50/10, which is 11.5 mg/kg bw/d. Since the lowest NOEC for the reproduction studies is below this value, namely 9.4 mg/kg bw/d, this value will be used in risk assessment (Table E.4).

Table E.4 Refined risk for birds

Crop group	Substance	Generic focal species	LD_{50} or NOEL [mg a.s./kg bw (d)]	DDD				DDD_m [mg a.s./ kg bw/d]	$TER_{A/LT}$	Trigger
				Appl. rate [kg a.s./ha]	$SV_{90/m}$	TWA	$MAF_{90/m}$			
Refined acute risk assessment										
Potatoes (BBCH 45-91)	Diquat	Small omnivorous bird "lark" (BBCH ≥ 40)	121	0.4	7.2	-	1.6	4.61	26.3	10
		Small insectivorous bird "wagtail" (BBCH ≥ 20)			25.2	-	1.6	4.61	**7.5**	
Refined long-term risk assessment										
Potatoes (BBCH 45-91)	Diquat	Small omnivorous bird "lark" (BBCH ≥ 40)	9.4	0.4	3.3	0.53	1.9	1.33	7.7	
		Small insectivorous bird "wagtail" (BBCH ≥ 20)			9.7	0.53	1.9	3.91	**2.4**	
Strawberries (BBCH 10-39)		Small omnivorous bird "lark" (BBCH 10-39)			10.9	0.53	1	2.31	**4.07**	5
		Small insectivorous bird "wagtail" (BBCH 10-19)			11.3	0.53	1	2.40	**3.92**	
		Small insectivorous bird "wagtail" (BBCH ≥ 20)			9.7	0.53	1	2.06	**4.57**	
Bare soils (BBCH 00-09)		Small granivorous bird "finch"(BBCH < 10)			11.4	0.53	1	2.42	**3.89**	
		Small omnivorous bird "lark" (BBCH < 10)			8.2	0.53	1	1.74	5.41	
		Small insectivorous bird "wagtail" (BBCH < 10)			5.9	0.53	1	1.25	7.52	

The results shown in Table E.4 indicate an acute risk to insectivorous birds from use in potatoes and a long-term risk to birds for all proposed applications of diquat. Therefore, further refinements of the risk are given below.

Refinement of the risk for omnivorous birds

In a Canadian field study residues and dissipation on insects and vegetation were measured. The mean RUD of 8.93 mg/kg as well as the DT_{50} of 1.23 days was accepted before for the refinement of the insectivorous component and the mean RUD of 66.9 mg/kg as well as the DT_{50} of 1.59 days was accepted before for the refinement of the herbivorous component. For seeds, the mean RUD was 40 or 38 mg a.s./kg (either seeds with or without husk). These values are similar to those reported in the guidance document (40.2). The reported DT_{50} of 14.2 days was not considered reliable because of the bad fit (r^2 = 0.15). It could be used as a worst-case, since higher values than the default are reported. However the default value can be used. The generic focal species, Fir/bw and diet are the same as the standard first tier assessment. The refined risk assessment is given below:

Table E.5 Refined long-term risk assessment for the woodlark

Crop group	Dose kg a.s./ha	MAF	Fir/bw	Food type and PD	DF	RUD	F_{twa}	DDD	TER
Strawberries (BBCH 10-39)	0.4	1	0.52	0.25 crop leaves		66.9	0.11	0.383	
				0.25 weed seeds		40	0.63	1.310	
				0.50 arthropods		8.93	0.085	0.079	
Total								1.772	5.31

Based on the risk assessment presented above, an acceptable risk is expected for omnivorous birds for uses in strawberries.

Refinement of the risk for insectivorous birds

In the Canadian field study residues and dissipation on insects were measured. The 90th percentile and the mean RUDs of 12.5 and 8.93 mg/kg, respectively, and the DT50 of 1.23 days was accepted before for the refinement for wagtails. The refined risk assessment is given below

Table E.6a Refined acute and long-term risk assessment for the wagtail

Crop group	Dose kg a.s./ha	$MAF_{90/m}$	Fir/bw	RUD	F_{twa}	DDD	TER
Acute – Potatoes (BBCH ≥ 20)							
	0.4	1.6	0.79	12.5	-	6.32	18.2
Long-term							
Strawberries (BBCH 10-19 and ≥ 20)							
	0.4	1	0.79	8.93	0.085	0.23	40.9
Potatoes (BBCH ≥ 20)							
	0.4	1.9	0.79	8.93	0.085	0.45	20.9

Based on the calculations presented above, an acceptable risk is expected for insectivorous birds.

Refinement of the risk for granivorous birds

The applicant refines the risk for granivorous birds by including dehusking in the risk assessment:

Granivorous birds are known to de-husk seeds prior to consumption. When this occurs, the actual intake of an active substance resulting from feeding on treated seeds is considerably less than expected. Numerous families of the by far species-richest Order in birds, the Passeriformes (i.e. songbirds) feed infrequently on seeds and/or limited to certain periods in the year, and these species are classified generally as omnivorous (e.g. larks, tits or crows). However, in some other Families of

this Order including Passeridae, Fringillidae and Emberizidae seeds are either periodically or even during the whole year a major diet component. Specialisation on seeds as major food items has resulted in a number of different functional and anatomic adaptations in such granivorous species. One such adaptation is an evolved beak structure that allows the bird to crack seeds and discard the husk (de-husking). De-husking is a strongly fixed component of the foraging behaviour of granivorous species (Ziswiler 1965). This behavioural adaptation is so strongly developed that some species e.g. chaffinches (Fringilla coelebs) are unwilling to take seeds that have already been de-husked (Glutz von Blotzheim and Bauer 1997). Finches and 'finch-like' granivorous birds, exhibiting a modified beak structure for de-husking seeds, generally de-husk seeds before swallowing the kernel (Ziswiler 1965). No data for de-husking behaviour in the linnet is currently available, but linnets do show as member of the Fringillidae the same beak structure. Prosser and Hart (2005) reported that a close relative of the linnet, the greenfinch (Carduelis chloris; same Genus as linnet, Carduelis cannabina), de-husks 96-100% of seeds it consumes. Based on these findings, it is assumed that under natural conditions, linnets will de-husk as well 96% of the seeds they consume. A conservative assumption is therefore that linnets will consume up to 20% of their total diet without de-husking the seeds.

How much de-husking seeds prior to ingestion reduces the residues to which granivorous birds are exposed to seed treatments was estimated by Edwards et al. (1998), who found that de-husking treated seeds can lead to an average reduction in pesticide intake of 87% (range 80 – 95%). Furthermore, Avery et al. (1997) studied the seed-handling behaviour of granivorous bird species feeding on millet, rice, sunflower and sorghum treated with imidacloprid. House finches (Carpodacus mexicanus), a species of the Fringillidae, i.e. finch family as well, feeding on imidacloprid-treated seeds discarded between 62% and 84% of the chemical that is on the seed. The overall findings led the authors to conclude that the seed-handling behaviour in granivorous birds results in a 60-85% reduction of their exposure to chemicals on treated seeds.

In view of the findings detailed above, a conservative assumption would be that de-husking behaviour in linnets results in a minimum of 60% less uptake of chemical residues from treated seeds. Accordingly, 40% of the residues are assumed to be ingested. Therefore a De-husking factor ***DH = 0.4*** *is considered as conservative in the higher tier risk assessment.*

<u>Reaction Ctgb</u>

Dehusking was taken into account in the new guidance document on birds and mammals. It is considered that dehusking can play an important role in minimizing the risk however:

'…., incorporation of dehusking as a mitigating factor in the DDD equation requires careful consideration of various parameters….
… it is important to note that dehusking is not all-or-nothing: not all small species dehusk, and some species dehusked some but not all of particular seed types. In the wild, the actual amount of seeds dehusked may be dependent on stressors such as feeding pressure, predation or competition (Prosser, 1999).

It is therefore recommended that:
••If dehusking is to be considered in a higher-tier assessment, case-specific evidence must be provided that it may actually play a role under field conditions for the relevant focal species;
•• Available information on actual extent of dehusking and on relevant environmental conditions for such behaviour should be thoroughly discussed;
•• Studies with the relevant focal species, the relevant seed type and the relevant product should be considered in preference to other studies requiring extrapolation;

•• *Particularly for birds, a risk assessment for a dehusking species should always be accompanied by an assessment for a second species that does not dehusk, in order to conclude on the actual species of concern.*

In this case, only the linnet was proposed, because it is the proposed focal species from the guidance document, not because field studies showed that this species is really is the most relevant. Studies have not been provided to suggest that the linnet dehusks significantly. Furthermore, it is unknown how much the exposure is reduced by dehusking as properties of the a.s. may affect how much a bird is exposed during dehusking. Certainly dehusking can be taken into account, but in this case only in a weight of evidence approach and not with a fixed dehusking value for both dehusking and residues ingested. The TER value for the granivorous bird is 3.89. Further refinement is necessary to conclude an acceptable long-term risk for the granivorous bird.

In consultation with the applicant, it was decided to reduce the exposure rate to 0.3 kg a.s./ha in order to address the reproductive risk to the small granivorous bird "finch". After the refinement, a new DDD is calculated to be 1.81 mg a.s./kg bw/d resulting in TERlt of 5.19. Therefore, reproductive risk to granivorous birds can be considered low.

Conclusion
An acceptable risk is expected for the all proposed applications provided that the application rate is reduced to 0.3 kg a.s./ha.
An uncertainty analysis concerning the refinements can be found below, in Table E.6b.

Table E.6b: Uncertainty analysis for refined risk assessment(s), birds

SOURCE OF UNCERTAINTY	CONSERVATIVENESS ADJUSTMENT	UNCERTAINTY ADJUSTMENT	EXPLANATION
Refined NOEL considering Syngenta studies	-	++	The new endpoint is higher than the original endpoint, and is thus less conservative. However, it is considered a more appropriate reproductive endpoint, since it considers more data available for reproductive toxicity, as well as the relevant endpoints.
Refined acute LD_{50}	-	++	The new endpoint is higher than the original endpoint, and is thus less conservative. However, it is considered a more appropriate acute endpoint (geomean of available endpoints) for use in risk assessment. (i.e. it is less conservative, but more certain).
Extrapolation from all	-	-	The extrapolation from

"terrestrial plants"to "crop leaves" only diet			the DT_{50}/RUD values for all terrestrial vegetation to only the crop leaves (as per the diet for the omnivorous bird) introduces a certain level of uncertainty in to the risk assessment.
Use of RUDs from Canadian field studies	-	--	EFSA (2009) suggests that refined RUD values should only be used if there is adequate evidence that the data supporting them are better than the data used by EFSA to create the default RUDs in the Guidance. This appears to be specifically referring to the large data set for plants that was used to derive the default RUDs. However, considering the fact that the RUDs in this study were derived from a large variety of plant matter and were specific to the substance, the RMS considers them to be only slightly less certain. The insect RUDs are considered to be similarly certain, as the data set used for the default RUD values for insects in the Guidance was not as large as that used for plants.
Use of refined DT_{50} from Canadian field studies	-	-	The refined DT50s are less conservative than the default DT_{50}s. However, the RMS considers them to be more relevant for use in risk assessment since they concern a realistic application pattern and a wide variety of plant/insect types. They are considered to be slightly more uncertain than the default values due to the fact that they were derived from a

			study in Canada (thought the climatological data suggest relevance to the Netherlands) and a smaller data set was used than for the default values.
Overall assessment	The refined risk assessment contains significant uncertainties. The largest uncertainties lie in the use of the refined RUD values. However, considering that for birds in particular a PT of 1 is highly conservative, the RMS considers this level of conservativeness still acceptable. The endpoint uncertainty inherent to the risk assessment is somewhat ameliorated by the availability of more data, which lowers the uncertainty in this area. The safety factors of 10 and 5 are intended to cover some of the uncertainty in the RA, particularly endpoint uncertainty, thus the RMS considers that in this case the total uncertainty introduced by the use of new RUDs and DT_{50}s is offset by the increased endpoint certainty, resulting in an overall no effect on the uncertainty of the risk assessment compared to the Tier 1 assessment.		

Risk for birds through drinking water

Leaf scenario

The leaf scenario is not relevant for any of the proposed applications, and is therefore not assessed.

Puddle scenario

The exposure of birds to drinking water from puddles formed on the field after rainfall is relevant for the proposed field uses of diquat.

According to EFSA/2009/1438, the puddle scenario is relevant for the acute and reproduction scenarios. The generic focal species is a small granivorous bird (body weight 15.3 g) with a DWR (daily drinking water rate) of 0.46 L/kg bw/d.

According to EFSA Guidance Document for Birds and Mammals (2009), no specific calculations are necessary when the ratio of effective application rate (in g a.s./ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc <500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥500 L/kg). The mean Koc of diquat is 2,184,750 L/kg. The ratio of effective application rate to acute endpoint is 560 g a.s./ha / 83 mg a.s./kg bw = 6.7, and the ratio of application rate to chronic endpoint is 640 g a.s./ha / 0.6 mg a.s./kg bw/d = 1067. Neither ratio exceeds the trigger of 3000. The risk due to exposure to drinking water from puddles is concluded to be acceptable.

7.1.2 Secondary poisoning

The risk as a result of secondary poisoning is assessed based on bioconcentration in fish.
Since the log K_{ow} of diquat < 3 (-4.6), the potential for bioaccumulation is considered low and no further assessment is deemed necessary.

Conclusions birds

The application for mutual recognition of the product complies with the RGB for all proposed applications, provided that the application rate is reduced to 0.3 kg a.s./ha.

7.2 Effects on aquatic organisms *(Dutch specific aspect)*

7.2.1 Aquatic organisms

Since the Netherlands have their own national drift values, the exposure concentrations in surface water have been estimated based on these drift values (see PECsw in section 6.2).

The risk for aquatic organisms is assessed by comparing toxicity values with surface water exposure concentrations from section 6.2. Risk assessment is based on toxicity-exposure ratio's (TERs). Toxicity data for aquatic organisms are presented in Table E.7. Because the application for authorisation concerns a herbicide, also the effects on macrophytes (aquatic plants) are evaluated.

Table E.7 Overview toxicity endpoints for aquatic organisms

Substance	**Organism**	**Lowest**		**Toxicity value**
		L(E)C_{50} [mg/L]	**NOEC [mg/L]**	**[µg/L]**
	Acute			
	Algae	0.011		11
	Invertebrates	1.2		1200
	Fish	6.1		6100
Diquat	Macrophytes	0.032*		30.2
	Chronic			
	Invertebrates		0.125	125
	Fish		0.12	120

*no information in the DAR. Endpoint derived from a study with the formulated product, submitted by UPL EU for the previous Mission WERG.

These toxicity values are compared to the surface water concentrations calculated in section 6.2. Trigger values for acute exposure are 100 for invertebrates and fish (0.01 times the lowest L(E)C_{50}-value) and 10 for algae and macrophytes (0.1 times the lowest EC_{50}-value). Trigger values for chronic exposure are 10 for invertebrates and fish (0.1 times the lowest NOEC-values).

For acute and chronic risk, the initial concentration is used (PIEC).
In tables E.8a and E.8b TER values for aquatic organisms are shown.

Table E.8a TER values: acute

Use	Substance	PIECsw [µg a.s./L]	TER_{st} (trigger 10) Algae	TER_{st} (trigger 100) Invertebrates	TER_{st} (trigger 100) Fish	TER_{st} (trigger 10) Macrophytes
Potatoes (desiccation)	Diquat	0.439	25	2733	13895	68.8
Onions, ornamentals, chicory, strawberries and potatoes (both pre-planting)	Diquat	0.208	52.9	5769	29327	145

Table E.8b TER values: chronic

Use	Substance	PIECsw [µg a.s./L]	TER_{lt} (trigger 10) Invertebrates	TER_{lt} (trigger 10) Fish
Potatoes (desiccation)	Diquat	0.439	285	273
Onions, ornamentals, chicory, strawberries and potatoes (both pre-planting)	Diquat	0.208	601	577

Taking the results in Table E.8a and E.8b into account, the acute TERs for fish and invertebrates are above the relevant Annex VI triggers of 100 and the acute TERs for algae and *Lemna* are above the relevant Annex VI triggers of 10. The chronic TERs for fish and invertebrates are above the relevant Annex VI triggers of 10. Thus, it appears that the proposed uses meet the standards for aquatic organisms as laid down in the RGB and BGB.

7.2.2 Risk assessment for bio concentration

Since logKow of diquat is < 3 (-4.6), experimental data are not required. Considering the low log Kow, the risk for bioconcentration is small. Therefore the active substance diquat meets the standards for bioconcentration as laid down in the RGB and BGB.

7.2.3 Risk assessment for sediment organisms

The water–sediment study indicates that over 10% of diquat is found in the sediment after 14 days, however the NOEC for daphnids is above 0.1 mg/L, therefore a low risk is expected for sediment organisms. This is confirmed by toxicity data on *Chironomus.*

The NOEC value for *Chironomus* is ≥ 100 mg/kg sediment. When this value is examined against the highest PIEC in sediment of 0.889, the TER value is >112, which is above the trigger of 10. Therefore, the active substance diquat meets the standards for sediment organisms as laid down in the RGB and BGB.

Conclusions aquatic organisms
The proposed applications meet the standards for aquatic organisms.

7.3 Effects on terrestrial vertebrates other than birds (*Dutch specific aspect)*

The risk assessment for mammals via natural food and secondary poisoning via earthworms is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorisation (UK).

However, it is known that diquat can be toxic to mammals (evaluation of Reglone, C164.3.8, 01/2006). A refined risk assessment is required. To indicate the risk to mammals from the proposed use of Mission as weed control, a risk assessment according to the EFSA Guidance Document for Birds and Mammals (2009) has been performed and is shown below.

The risk assessment for mammals via surface water (drinking water and secondary poisoning via fish) is a Dutch specific aspect, since surface water concentrations are calculated based on national drift values.

The threshold value for mammals is based on the trigger from the RGB. This means that the Toxicity-Exposure Ratio (TER) for acute exposure should be ≥ 10 and TER for chronic exposure should be ≥ 5. Dietary toxicity is not taken into account for mammals.

Table E.9 presents an overview of toxicity data.

Table E.9 Overview of toxicity data for mammals for substance Diquat

	Endpoint	Value
Acute toxicity to mammals:	LD_{50}	214 mg a.s./kg bw
Reproductive toxicity to mammals:	NOEL	8.9 mg a.s./kg bw/d

7.3.1 Natural food and drinking water

sprayed products
The risk assessment for mammals is carried out following the guidance document by EFSA (*Anonymous 2009: Guidance Document on risk assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. European Food Safety Authority*), hereafter cited as GD (EFSA 2009).

Acute and long-term screening assessments
The proposed use of the product is for desiccation in potatoes before harvest (BBCH 45-91) and as weed control in onions, ornamentals (flowers, flower bulbs, ornamental plant production), chicory, potatoes (pre-planting), and strawberries (pre- or immediately post-planting). These correspond with the potato (late application), bare soil, and strawberries scenarios. For the applications in strawberries (post-planting) the indicator species is a small herbivorous mammal. For the application in bare soils the indicator species is a small granivorous mammal. For uses with a frequency > 1, a MAF (Multiple Application Factor) may be applicable.

The DDD_m values for the acute risk assessment are calculated as application rate * shortcut value * MAF_{90}. The DDD_m values for the long-term risk assessment are calculated as application rate * shortcut value * MAF_m * TWA. The values of DDD_m are compared to the relevant toxicity figure. TERs should be above the trigger for an acceptable risk (10 or 5 for acute or long-term risk assessment, respectively). The screening assessment is shown in Tables E.10a,b.

Table E.10a Acute risk for mammals (screening assessment)

Crop group	Substance	Indicator species	LD_{50} [mg a.s./ kg bw]	DDD			DDD_m [mg a.s./ kg bw/d]	TER_A	Trigger
				Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}			
Potatoes	Diquat	Small herbivorous mammal	214	0.4	118.8	1.6	75.8	**2.82**	10
Strawberries						1	47,4	**4,52**	
Bare soils		Small granivorous mammal			14.4	1	5,76	37.2	

Table E.10b Long-term risk for mammals (screening assessment)

Crop group	Substance	Indicator species	NOEL [mg a.s./kg bw]	DDD				DDD_m [mg a.s./ kg bw/d]	TER_{LT}	Trigger
				Appl. rate [kg a.s./ha]	SV_m	TWA	MAF_m			
Potatoes	Diquat	Small herbivorous mammal	8.9	0.4	48.3	0.53	1.9	19.5	**0.46**	5
Strawberries							1	10.2	**0.87**	
Bare soils		Small granivorous mammal			6.6	0.53	1	1.40	6.36	

The results presented in Tables E.10a,b show that the acute and long-term screening assessment values of TER for the application in strawberries (post-planting) and potatoes (desiccation) are below the required trigger of 10 and 5, respectively. Therefore, the use of the product post-emergence in strawberries and potatoes do not meet the standards laid down in the RGB and a Tier 1 assessment is required. For the proposed use in bare soils, the acute and long-term screening assessments indicate a low risk, which complies with the standards laid down in the RGB.

Tier 1 assessment

A Tier 1 risk assessment is performed and the results are shown in Tables E.11a,b.

Table E.11a Acute risk for mammals (Tier 1 assessment)

Crop group	Substance	Generic focal species	LD_{50} [mg a.s./ kg bw]	DDD			DDD_m [mg a.s./ kg bw/d]	TER_A	Trigger
				Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}			
Potatoes (BBCH 45-91)	Diquat	Small herbivorous mammal "vole" (BBCH ≥ 40)	214	0.4	40.9	1.6	26.2	**8.2**	10
		Small omnivorous mammal "mouse" (BBCH ≥ 40)			5.2		3.33	64.3	

		Large herbivorous mammal “lagomorph” (BBCH ≥ 40)			10.5		6.72	31.9	
Strawberries (BBCH 10-39)		Small insectivorous mammal “shrew” (BBCH 10-19)			7.6	1	3.04	70.4	
		Small omnivorous mammal “mouse” (BBCH 10-39)			17.2	1	6.88	31.1	
		Large herbivorous mammal “lagomorph” (BBCH 10-39)			35.1	1	14	15.2	

Table E.11b Long-term risk for mammals (Tier 1 assessment)

Crop group	Substance	Generic focal species	NOEL [mg a.s./kg bw]	DDD				DDD_m [mg a.s./ kg bw/d]	TER_{LT}	Trigger
				Appl. rate [kg a.s./ha]	SVm	TWA	MAF_m			
Potatoes (BBCH 45-91)	Diquat	Small herbivorous mammal “vole” (BBCH ≥ 40)	8.9	0.4	21.7	0.53	1.9	8.74	**1.02**	5
		Small omnivorous mammal “mouse” (BBCH ≥ 40)			2.3	0.53	1.9	0.93	9.57	
		Large herbivorous mammal “lagomorph” (BBCH ≥ 40)			4.3	0.53	1.9	1.73	5.14	
Strawberries (BBCH 10-39)		Small insectivorous mammal “shrew” (BBCH 10-19)			4.2	0.53	1	0.89	5.38	
		Small omnivorous mammal “mouse” (BBCH 10-39)			7.8	0.53	1	1.65	10	
		Large herbivorous mammal “lagomorph” (BBCH 10-39)			14.3	0.53	1	3.03	**2.94**	

The acute Tier 1 risk assessment (Table E.11a) indicates that a risk cannot be excluded for a small herbivorous mammal “vole” for the application in potatoes. In all other scenarios an acute risk can be excluded. Furthermore, a long-term risk to mammals (Table E3.b) cannot be excluded for a large

herbivorous mammal “lagomorph” for the application in strawberries and a small herbivorous mammals “vole” for the application in potatoes. For all other the scenarios a risk can be excluded. Refinement of the risks is needed.

Refinement of the risk for herbivorous mammals (“vole” and “lagomorph”)
For desiccation in potatoes it can be assumed that leaves are unpalatable to the vole and are unlikely to be consumed. However, the vole may still be exposed by eating vegetation under the potato cover. In the Canadian field study, the RUD and DT_{50} values for terrestrial vegetation have been reported. The risk assessment with the refined RUD and DT_{50} values is shown in tables E.12a,b. Note that extrapolating RUD and DT_{50} values from terrestrial plants (mixture of leaves from mono- and dicotyledones) to grasses (monocotyledons, 100% diet of the vole) introduces a level of uncertainty.

Table E.12a Refined acute risk assessment for the “vole”

Crop group	Dose kg a.s./ha	MAF	DF	FIR/bw	Food type and PD	RUD_{90}	F_{twa}	DDD	TER
Potatoes (BBCH ≥ 40)	0.4	1.6	0.3	1.33	100% grass	110	-	28.1	**7.62**

Table E.12b Refined long-term risk assessment for the “vole”

Crop group	Dose kg a.s./ha	MAF	DF	FIR/bw	Food type and PD	RUD_m	F_{twa}	DDD	TER
Potatoes (BBCH ≥ 40)	0.4	1.9	0.3	1.33	100% grass	66.9	0.11	2.23	**3.99**

The results presented in the tables above indicate high acute and long-term risks to the small herbivorous mammal “vole”. Therefore, refined acute and long-term risk assessments are required in order to demonstrate a low risk to the small herbivorous mammal “vole” from applications in desiccation of potatoes.

After consultations with the applicant, it was decided to reduce the exposure rate to 0.3 kg a.s./ha in order to address the acute and reproductive risk to the small herbivorous mammal “vole”. After the refinement, a new acute and long-term DDD is calculated to be 21.07 and 1.67 mg a.s./kg bw/d, respectively, resulting in TERa and TERlt of 10.2 and 5.32, respectively. Therefore, acute and reproductive risk to the small herbivorous mammal “vole” can be considered low.

For a refinement of the risk to the large herbivorous mammal “lagomorph” the RUD and DT_{50} values from the Canadian study can be used as well. In addition, the RMS notes that the uses in strawberries are intended for inter-row spraying, which would mean much less exposure to the strawberry leaves than what is assumed in the risk assessment (direct spraying of the crop leaves that form the diet of the lagomorph). The refined risk assessment is given below:

Table E.12c Refined long-term risk assessment for a “lagomorph”

Crop group	Dose kg a.s./ha	MAF	Fir/bw	Food type and PD	RUD	F_{twa}	DDD	TER

Strawberries (BBCH 10-39)	0.4	1	0.50	100% non-grass herbs	66.9	0.11	1.47	6.04

The TER value shown in Table E.12c is above the trigger of 5, which indicates a low risk to the large herbivorous mammal “lagomorph”.

Conclusion
An acceptable risk is expected for the all proposed applications provided that the application rate is reduced to 0.3 kg a.s./ha.

An uncertainty analysis concerning the refinements can be found below, in Table E.12d.

Table E.12d: Uncertainty analysis for refined risk assessment(s), mammals

SOURCE OF UNCERTAINTY	CONSERVATIVENESS ADJUSTMENT	UNCERTAINTY ADJUSTMENT	EXPLANATION
Extrapolation from all “terrestrial plants” to “crop leaves” only diet	-	-	The extrapolation from the DT_{50}/RUD values for all terrestrial vegetation to only the crop leaves (as per the diet for the lagomorph) or only monocots (as per the diet for the vole) introduces a certain level of uncertainty in to the risk assessment.
Use of RUDs from Canadian field studies	-	-	EFSA (2009) suggests that refined RUD values should only be used if there is adequate evidence that the data supporting them are better than the data used by EFSA to create the default RUDs in the Guidance. This appears to be specifically referring to the large data set for plants that was used to derive the default RUDs. However, considering the fact that the RUDs in this study were derived from a large variety of plant matter and were specific to the substance, the RMS considers them to be only slightly less certain. The insect RUDs are considered to be

			similarly certain, as the data set used for the default RUD values for insects in the Guidance was not as large as that used for plants.
Use of refined DT_{50} from Canadian field studies	-	-	The refined DT50s are less conservative than the default DT_{50}s. However, the RMS considers them to be more relevant for use in risk assessment since they concern a realistic application pattern and a wide variety of plant/insect types. They are considered to be slightly more uncertain than the default values due to the fact that they were derived from a study in Canada (thought the climatological data suggest relevance to the Netherlands) and a smaller data set was used than for the default values.
Overall assessment	The refined risk assessment contains significant uncertainties. The largest uncertainties lie in the use of the refined RUD values and the extrapolation between plant types. The PT and PD of 1 for voles is not overly conservative considering the relatively small home range of the vole. Considering these uncertainties, the use of the refinements contributes an unacceptable level of uncertainty to the risk assessment for voles. The PT and PD of 1 for the lagomorph are considered relatively conservative considering that there are likely anti-rabbit measures in place in strawberry fields, and considering that only the inter-row areas are sprayed, as opposed to the crop itself. Taking this into consideration, the RMS concludes that the uncertainty introduced into the risk assessment via the use of the refined RUDs and the extrapolation to crop plants from “terrestrial vegetation” is offset by the conservativeness of the PT and PD assumptions.		

Drinking water

Puddle scenario

The exposure of mammals to drinking water from puddles formed on the field after rainfall is relevant for the proposed field uses of diquat.

According to EFSA/2009/1438 the puddle scenario is relevant for the acute and reproduction scenario. Generic focal species is a small granivorous mammals (body weight 21.7 g) with a DWR (daily drinking water rate) of 0.24 L/kg bw/d.

According to EFSA Guidance Document for Birds and Mammals (2009), no specific calculations are necessary when the ratio of effective application rate (in g a.s./ha) to relevant endpoint (in mg/kg

bw/d) does not exceed 50 in the case of less sorptive substances (Koc <500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥500 L/kg). The mean Koc of diquat is 2184750 L/kg. The ratio of application rate to acute endpoint is 400 g a.s./ha / 214 mg a.s./kg bw = 1.9, and the ratio of application rate to chronic endpoint is 400 g a.s./ha / 8.9 mg a.s./kg bw/d = 44.9. Neither ratio exceeds the trigger of 3000. The risk due to exposure to drinking water from puddles is concluded to be acceptable.

7.3.2 Secondary poisoning

The risk as a result of secondary poisoning is assessed based on bio concentration in fish.
Since the log Kow of diquat < 3 (-4.6), the potential for bioaccumulation is considered low and no further assessment is deemed necessary.

Conclusions mammals

The application for mutual recognition of the product complies with the RGB for all proposed applications, provided that the application rate is reduced to 0.3 kg a.s./ha.

The application for mutual recognition of the product complies with the RGB for exposure of mammals via surface water and secondary poisoning.

7.4 Effects on bees

The risk assessment for bees is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorization (Member State).

However, a bee incident was reported in potatoes after use of Reglone. Therefore it was concluded that for the product Reglone, the following restriction sentence should be placed on the label:

Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels. Gebruik dit product niet wanneer bloeiende onkruiden aanwezig zijn.

For this application for Mission 200 SL, the applicant has proposed that this restriction sentence be present on the label. Therefore, it will remain on the label for the protection of pollinators.

Conclusions bees

The application for mutual recognition of the product complies with the RGB and BGB if the following warning sentence is place on the label:

Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels. Gebruik dit product niet wanneer bloeiende onkruiden aanwezig zijn.)

7.5 Effects on any other organisms (see annex IIIA 10.5-10.8)

7.5.1 Effects on non-target arthropods (*Dutch specific aspect)*

In-field

The in-field risk assessment for non-target arthropods in accordance with ESCORT2 is not based on drift values and is therefore not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorisation (UK).

Off-field *(Dutch specific aspect)*
For the off-field risk assessment on non-target arthropods in accordance with ESCORT2, drift values are used to estimate the off-crop risk for the two standard species *A. rhopalosiphi* and *T. pyri.* Since the Netherlands have their own national drift values, the off-field risk assessment is a national specific aspect.

The risk for non-target arthropods is assessed by calculating Hazard Quotients. For this, Lethal Rate values (LR_{50}) are needed. Based on LR_{50}-values from studies with the two standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri* an off-field Hazard Quotient (HQ) can be calculated according to the assessment method established in the SETAC/ESCORT 2 workshop and described in the Evaluation Manual. Hazard Quotients should be below the trigger value of 2 to meet the standards.

However, no Tier 1 data for *T. pyri* or other mites are available. For *A. rhopalosiphi* an extended laboratory test showed 58% effect on mortality at 1 kg a.s./ha, no effects on reproduction were found. Although the effects are > 50 % at the lowest rate tested, it can be assumed that the effects will be < 50% at the maximum rate of 0.68 kg a.s./ha (after two applications, see also table E.13).

The applicant submitted two extended lab studies conducted with the formulation Diquat 200 g/L SL with *T. pyri* and *C. carnea*. The results of these studies are discussed below.

Table E.13 HQ-values for *A. rhopalosiphi* and *T. pyri*

	Application rate (kg a.s./ha)	**MAF[1]**	**Drift fraction / Vegetation factor[2]**	**Safety factor[2]**	**LR_{50} (kg a.s./ha)**	**HQ**
Off-field						
A. rhopalosiphi	0.4	1.7	0.1	5	< 1	> 0.34
T. pyri		1.7	0.1/10	5	0.00475 (lethal)	**7.2**
					> 0.013 (sub-lethal)	< **2.6**

[1] Multiple Application Factor

[2] Off-field: default drift = 10%, thus drift factor =10/100, vegetation dilution factor = 10 (not applicable for *A. rhopalosipohi* since whole plants were sprayed), safety factor = 5 (default value for second tier assessment)

The results presented in Table E.13 show that the off-field risk to *A.rhopalosiphi* can be considered acceptable. In the case of *T.pyri*, however, there is an off-field risk from diquat.

Some additional species were also tested: For *Coccinella septempunctata,* at concentrations of 1 kg diquat ion/ha, corrected pre-imaginal mortality was 58%. The reproduction rate was 640.9 eggs/female. In the case of *Pterostichus melanarius* and *Pardosa* spp., no lethal or sub-lethal effects were measured at 1.6 kg diquat ion/ha. For *Trichogramma cacocecie* a risk could be expected based on a standard laboratory study, however in the DAR it was concluded (and accepted) that the data for *A. rhopalosiphi* was more applicable and it was more appropriate to use this species.

For *Crysoperla carnea,* 96% mortality occurred at 1.6 kg a.s./ha. In the extended lab study submitted by the applicant, the LR_{50} is 0.9 kg a.s./ha and at 0.81 kg a.s./ha the resulting effect was 18% reduction of viable eggs/female/day. Since the effects are below 50% at relevant application rates, it can be concluded that the risk to *Crysoperla carnea* are low.

Overall the results show that *T.pyri* is the most sensitive species. Therefore, drift reducing measures are required in order to demonstrate a low off-field risk to *T. pyri*.

The applicant proposes 75% drift reducing measures to protect non-target arthropods:

Om niet tot de doelsoorten behorende geleedpotigen / insecten (en niet tot de doelsoorten behorende planten) te beschermen is de toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met een kantdop en een teeltvrije zone van 1,5 m.

With this sentence, the drift will be lowered by more than a factor of 5, meaning that the off-field HQs will be below 2. Thus, this restriction sentences is adequately protective.

However, for reasons of clarity, the restriction sentence should be updated:

Om niet tot de doelsoorten behorende geleedpotigen / insecten en niet tot de doelsoorten behorende planten te beschermen is de toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met een kantdop en een teeltvrije zone van 1.5 m (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelgrens).

Hence, the standards for non-target arthropods as laid down in the RGB are met provided that this restriction sentence is placed on the label.

7.5.2 Earthworms

The risk assessment for earthworms is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorisation (UK).

7.5.3 Effects on soil micro-organisms

The risk assessment for soil micro-organisms is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorisation (UK).

7.5.4 Effects on activated sludge

The risk assessment for activated sludge is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorisation (UK).

7.5.5 Effects on non-target-plants *(Dutch specific aspect)*

According to the Terrestrial guidance document (Sanco/10329/2002) spray drift is considered to be the key exposure route for non-target plants in the off-field area. Since the Netherlands have their own national drift values, the risk assessment for non-target plants is a national specific aspect. The risk assessment for non-target plants is performed below.

The risk assessment for non-target plants is based on an off-crop situation with a drift percentage of 4.7% The exposure thus equals [0.047] * the application rate * MAF (in case of multiple application). MAF-values are taken from ESCORT 2.

The applicant submitted a vegetative vigour test and a statement for effects on seedling emergence. The lowest EC_{50} of 0.031 kg a.s./ha from the vegetative vigour test was recorded for sugar beet. Based on the results of the vegetative vigour, the applicant submitted a resulted HC_5 of 0.081154 L form/ha (0.0162 kg a.s./ha) calculated using ETX 2.0. From the seedling emergence statement it was concluded by the applicant that no effects were seen up to the maximum test dose of 36 L form/ha (7.2 kg a.s./ha).

A TER is calculated with the lowest EC_{50} value from a laboratory test with higher plants and the exposure concentration. See table E.14 for TER calculation.

Table E.14 Overview of exposure concentrations and TERs for non-target plants

Use	Substance	Dose [kg a.s. /ha]	MAF	Drift% (off-field exposure)*	Exposure (kg a.s./ha)	EC_{50} [kg a.s./ha]	TER	Trigger value
Potatoes (desiccation)	Diquat	0.4	1.7	4.7	0.032	0.031	**0.97**	5

* For the Netherlands, the amount of drift for field crops is currently set at 4.7%. This is based by taking into account a total distance of the evaluation zone of 1.5-2.5 m from the centre of the last crop row. The standard position of the last spraying nozzle is assumed to be above the centre of the last crop row.

As it can be seen from the Table E.14 the TER is below the trigger of 5. Next, a probabilistic approach will be employed. Therefore, the risk can be determined by using the HC5 data. As this is considered Tier II assessment, the trigger value is set to 1.

Table E.15 Overview of exposure concentrations and TERs for non-target plants

Use	Substance	Dose [kg a.s. /ha]	MAF	Drift% (off-field exposure)*	Exposure (kg a.s./ha)	HC_5 [kg a.s./ha]	TER	Trigger value
Potatoes (desiccation)	Diquat	0.4	1.7	4.7	0.032	0.0162	**0.51**	1

The result presented in Table. E15 shows that the TER is below the trigger of 1, thus a risk to non-target plants from the proposed use as weed control in the onion family cannot be excluded.

The applicant proposed the following restriction sentence:

Om niet tot de doelsoorten behorende geleedpotigen / insecten en niet tot de doelsoorten behorende planten te beschermen is de toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met een kantdop en een teeltvrije zone van 1,5 m (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelgrens).

The drift will then be reduced to 0.9%, resulting in a worst-case TER of 2.6 (Trigger is 1). Therefore, the product complies with the RGB when this restriction sentence appears on the label.

Conclusions any other organisms
The application for mutual recognition of the product complies with the RGB and BGB for the aspects earthworms, soil micro-organisms and activated sludge.

The proposed application of the product complies with the RGB and BGB for the aspects non-target arthropods (off-field) and terrestrial non-target plants provided that a restriction sentence is placed on the label.

7.6 Appropriate ecotoxicological endpoints relating to the product and approved uses
See List of Endpoints.

7.7 Data requirements
None.

7.8 Restriction sentences
The following restriction sentences were proposed by the applicant:

Om niet tot de doelsoorten behorende geleedpotigen / insecten en niet tot de doelsoorten behorende planten te beschermen is de toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met een kantdop en een teeltvrije zone van 1,5 m.

Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels. Gebruik dit product niet wanneer bloeiende onkruiden aanwezig zijn.

Based on the current assessment, the following has to be stated in the GAP/legal instructions for use:

In the WG (legal instructions):

Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels. Gebruik dit product niet wanneer bloeiende onkruiden aanwezig zijn.

Om niet tot de doelsoorten behorende geleedpotigen / insecten en niet tot de doelsoorten behorende planten te beschermen is de toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met een kantdop en een teeltvrije zone van 1.5 m (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelgrens).

7.9 Overall conclusions regarding the environment

It can be concluded that:

1. all proposed applications of the active substance diquat meet the standards for birds as laid down in the RGB;
2. all proposed applications of the active substance diquat meet the standards for aquatic organisms as laid down in the RGB;
3. the active substance diquat meets the standards for bio concentration as laid down in the RGB;
4. all proposed applications of the active substance diquat meet the standards for mammals as laid down in the RGB;
5. all proposed applications of the active substance diquat meet the standards for bees as laid down in the RGB if a restriction sentence is placed on the label;
6. for the risk assessment for non-target arthropods in-field, Ctgb refers to the member state of the original authorisation (UK);
7. all proposed applications of the active substance diquat meet the standards for non-target arthropods off-field as laid down in the RGB if a restriction sentence is placed on the label;
8. for the risk assessment for earthworms, Ctgb refers to the member state of the original authorisation (UK);
9. for the risk assessment for soil micro-organisms, Ctgb refers to the member state of the original authorisation (UK);
10. for the risk assessment for activated sludge, Ctgb refers to the member state of the original authorisation (UK);
11. all proposed applications of the active substance diquat meet the standards for non-target plants as laid down in the RGB, provided that a restriction sentence is placed on the label.

8. Efficacy

8.1 Efficacy evaluation

For the evaluation of the aspect 'Efficacy' we refer to the evaluation of the member state of the original authorisation (United Kingdom).

As it concerns a mutual recognition, efficacy is not evaluated for the Netherlands, the authorised label of the UK or less can be approved for efficacy.

For other reasons than the efficacy evaluation the dose rate for the new uses for weed control has to be reduced to 1,5 L/ha. As 2 L/ha was evaluated as the effective dose rate for a good and consistent common chickweed control in different situations, applied at 1,5 L/ha it is expected that weed control is not sufficient in all situations. Therefore a warning sentence is placed on the label:

In de teelt van cichorei, aardbei, uien en sierteeltgewassen kan de werking onvoldoende zijn.

A split application at 2 * 2 L/ha cannot be supported by ecotoxicology. For the use in potatoes as a desiccant a decrease in dose rate to two applications at 1.5 L/ha however is not possible as only a split application at 2*2 L/ha is supported by the UK authorisation. The split application in potatoes can therefore not be authorised. The current application at 1*4 L/ha is not evaluated as part of this dossier.

The split application in potatoes was withdrawn by the applicant.

8.2 Harmful effects

For the evaluation of the aspect 'Harmful effects' we refer to the evaluation of the member state of the original authorisation (United Kingdom).

8.3 Resistance

Mission 200 SL is an herbicide with little potential for the development of resistance . A resistance management sentence is not necessary.

8.4 For vertebrate control agents: impact on target vertebrates

Because no vertebrates are controlled, this point is not relevant.

8.5 Any other relevant data / information

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9. Conclusion

The Ctgb evaluation has been performed in accordance with the Uniform Principles laid down in appendix VI of Directive 91/414/EEC. The evaluation has been carried out on basis of a dossier that meets the criteria of appendix III of the Directive.

The product is considered to comply with the Uniform Principles.

10. Classification and labelling

Classification and labelling remain unchanged.

Appendix 1 Table of new uses

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
2	UK, NL	Onions	F	Common chickweed (Stellaria media)	Overall spray	Pre-emergence, spring, summer BBCH 00-07	a) 1 b) 1	a) 1,5 L/ha b) 1,5 L/ha	a) 300 b) 300	200 500	NA	PHI covered by vegetation period
3	UK, NL	Ornamentals (Flowers, flower bulbs, ornamental plant production)	F	Common chickweed (Stellaria media)	Overall spray	Pre-emergence/ pre-transplanting, spring, summer BBCH 00-07	a) 1 b) 1	a) 1,5 L/ha b) 1,5 L/ha	a) 300 b) 300	200 500	NA	PHI covered by vegetation period
4	UK, NL	Chicory	F	Common chickweed (Stellaria media)	Overall spray	Pre-emergence, spring, summer BBCH 00-07	*a)* 1 *b)* 1	*a)* 1,5 L/ha *b)* 1,5 L/ha	*a)* 300 *b)* 300	200 500	NA	PHI covered by vegetation period
5	UK, NL	Strawberries	F	Common chickweed (Stellaria media)	Interrow	Pre- or post planting, spring, summer	a) 1 b) 1	a) 1,5 L/ha b) 1,5 L/ha	a) 300 b) 300	200 500	NA	PHI covered by vegetation period

Appendix 2 Reference list

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This appendix serves only to give an indication of which data have been used for decision making for the first time; as a result of concurring applications for authorisations, the data mentioned here may have been used for an earlier decisions as well. Therefore, no rights can be derived from this overview.

Deze appendix geeft een indicatief overzicht van de gegevens die voor het eerst gebruikt zijn ten behoeve van een besluit; het kan echter voorkomen dat (onder andere) door een samenloop van aanvragen, de hier opgenomen gegevens al eens eerder gebruikt zijn. Aan dit overzicht kunnen dan ook geen rechten ontleend worden.