15347 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 WEDERZIJDSE ERKENNING

Op 21 januari 2009 is van

Globachem N.V.
Lichtenberglaan 2019 Brustem Industriepark
B-3800 SINT-TRUIDEN
Belgium

een aanvraag ontvangen voor wederzijdse erkenning van het gewasbeschermingsmiddel

Quad-Glob 200 SL

op basis van de werkzame stof diquat.

HET COLLEGE BESLUIT tot toelating 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 wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in bijlage III.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.

2 WETTELIJKE GRONDSLAG

Besluit	Artikel 36, Wet gewasbeschermingsmiddelen en biociden, juncto artikel 80, lid 5 Verordening (EG) 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Rgb H2 en HTB 1.0

3 BEOORDELINGEN

Gezien de aard van de wederzijdse erkenning wordt ervan uitgegaan dat de beoordeling door het Verenigd Koninkrijk is uitgevoerd conform de Uniforme Beginselen (annex VI bij richtlijn 91/414/EEG). Voor de beoordeling van de aspecten fysische en chemische eigenschappen, analysemethoden, werkzaamheid en delen van de aspecten risico voor de mens en risico voor het milieu refereert het Ctgb aan het toelatingsbesluit in Verenigd Koninkrijk (MAPP 14758). Op een aantal voor de Nederlandse situatie specifieke punten, toetst het Ctgb zelf inhoudelijk.

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.

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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 mei 2017

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

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HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20090041 WERG
Type aanvraag:	Wederzijdse erkenning gewasbeschermingsmiddel
Middelnaam:	Quad-Glob 200 SL
Verzenddatum aanvraag:	20 januari 2009
Formele registratiedatum: *	29 januari 2009
Datum in behandeling name:	10 augustus 2011

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

2 Stofinformatie

Werkzame stof	Gehalte
Diquat	200 g/L

De stof is per 1 januari 2002 geplaatst op Annex I van Richtlijn 91/414/EEG en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van deze werkzame stof expireert op grond van Uitvoeringsverordening (EU) 2016/549 op 30 juni 2017.

3 Toelatingsinformatie

Toelatingsnummer:	15347 N
Expiratiedatum:	30 juni 2018
Afgeleide parallel of origineel:	n.v.t.
gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel

4 Verpakkingsinformatie

Aard van het preparaat: Met water mengbaar concentraat.

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BIJLAGE II Etikettering van het middel Quad-Glob 200 SL

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

Pictogram	GHS07 GHS08 GHS09
Signaalwoord	GEVAAR
Gevarenaanduidingen	H302 Schadelijk bij inslikken. H315 Veroorzaakt huidirritatie. H317 Kan een allergische huidreactie veroorzaken. H319 Veroorzaakt ernstige oogirritatie. 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. P280C Beschermende handschoenen en beschermende kleding dragen. P302 + P352 BIJ CONTACT MET DE HUID: Met veel water/... wassen. P304 + P340 NA INADEMING: de persoon in de frisse lucht brengen en ervoor zorgen dat deze gemakkelijk kan ademen. P314 Bij onwel voelen een 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.

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BIJLAGE III WG van het middel Quad-Glob 200 SL

Wettelijk Gebruiksvoorschrift
Toegestaan is uitsluitend het professionele gebruik als onkruidbestrijdingsmiddel of doodspuitmiddel door middel van een gewasbehandeling in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden.

Toepassings-gebied	Type behandeling	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus	Maximaal aantal liter middel per teeltcyclus	Minimum interval tussen de toepassingen in dagen
Aardappelen	voor opkomst	Eenjarige breedbladige onkruiden	2 L/ha	1	4 L/ha	-
	doodspuiten	Aardappelloof	2-4 L/ha	2		2
Bieten	voor opkomst	Eenjarige breedbladige onkruiden	2 L/ha	1	2 L/ha	-
Groenteteelt	voor opkomst	Eenjarige breedbladige onkruiden	2 L/ha	1	2 L/ha	-

Toepassingsvoorwaarden
Het middel toepassen in 200-500 liter water per ha.

Om niet tot de doelsoorten behorende terrestrische planten/geleedpotigen/insecten te beschermen is doodspuit toepassing in aardappel uitsluitend toegestaan wanneer gebruik wordt gemaakt van een lage spuitboomhoogte (maximaal 30 cm boven de top van het gewas), met venturidop en een kantdop in acht neming van een teeltvrije zone van 1,25 m (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens).

Om niet tot de doelsoorten behorende terrestrische planten/geleedpotigen/insecten te beschermen is toepassing voor opkomst in alle gewassen uitsluitend toegestaan wanneer gebruik wordt gemaakt van minimaal 75% drift reducerende spuitdoppen en een kant dop.

Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen 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.

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BIJLAGE IV

RISKMANAGEMENT

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1. Identity of the plant protection product

1.1 Applicant

Globachem nv
Lichtenberglaan 2019
3800 SINT-TRUIDEN
België

1.2 Identity of the active substance

Common name	Diquat (as diquat dibromide)
Name in Dutch	Diquat (as diquat dibromide)
Chemical name	9,10-dihydro-8a,10a-diazoniaphenanthrene [IUPAC, 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 January 1st, 2002.

The active substance is formulated as its variant diquat dibromide, which is included in the evaluation of the active substance diquat in Annex I of Directive 91/414/EEC.

1.3 Identity of the plant protection product

Name	Quad-Glob 200 SL
Formulation type	SL
Content active substance	200 g/L pure Diquat (374 g/L diquat dibromide)

The formulation was assessed in the United Kingdom according to the Uniform Principles of 91/414/EEC

1.4 Function

Herbicide.

1.5 Uses applied for

Crop and/or situation	Member State	Product name	F G or I	Pests or Group of pest controlled	Formulation		Application						Application rate per treatment						PHI days (days)	Remarks:
(a)			(b)	(c)	Type (d-f)	Conc. Of as g/kg (i)	method kind (f-h)	growth stage & season (j)	number (k)		interval between applications (days)	kg as/hl		water L/ha		kg as/ha		(l)	(m)
									min	max		min	max	min	max	min	max		
ware potatoes starch potatoes	NL	Di-QUAT	F	desiccation	SL	200	overall spray	BBCH >69 Aug.-Okt	-	2	2	0,08	0,40	200	500	0,4	0,8		max. 4 litre product (=0,8 kg as/ha) per year
seed potatoes	NL	Di-QUAT	F	desiccation	SL	200	overall spray	BBCH >50 July, Aug.	-	2	2	0,08	0,40	200	500	0,4	0,8		max. 4 litre product (=0,8 kg as/ha) per year
barley (animal feed)	NL	Di-QUAT	F	desiccation	SL	200	overall spray	BBCH 89	-	1	-	0,08	0,40	200	500	0,4	0,8	4	
oats (animal feed)	NL	Di-QUAT	F	desiccation	SL	200	overall spray	BBCH 89	-	1	-	0,08	0,40	200	500	0,4	0,8	4	
dry peas (animal feed)	NL	Di-QUAT	F	desiccation	SL	200	overall spray	June-aug	-	1	-	0,08	0,30	200	500	0,4	0,6	4	
field beans (animal feed)	NL	Di-QUAT	F	desiccation	SL	200	overall spray	July-Sept	-	1	-	0,12	0,30	200	500	0,6	0,6		
flax	NL	Di-QUAT	F	desiccation	SL	200	overall spray	June-July	-	1	-	0,12	0,20	300	500	0,6	0,6		
oilseed rape	NL	Di-QUAT	F	desiccation	SL	200	overall spray	July	-	1	-	0,12	0,24	250	500	0,6	0,6		
clover	NL	Di-QUAT	F	desiccation	SL	200	overall spray	sept-okt, mature crop	-	1	-	0,08	0,30	200	500	0,4	0,6		
arable farming	NL	Di-QUAT	F	Annual dicotyledonous	SL	200	overall spray	Mrt-April BBCH 0	-	1	-	0,08	0,20	200	500	0,4	0,4		
arable farming	NL	Di-QUAT	F	Annual dicotyledonous weeds	SL	200	inter-row treatment	Mrt-April BBCH 0-14	-	1	-	0,08	0,20	200	500	0,4	0,4*		* The amount is given per treated surface. For inter-row spraying the cropped surface is partially treated
vegetables	NL	Di-QUAT	F	Annual dicotyledonous weeds	SL	200	overall spray	Mrt-April BBCH 0	-	1	-	0,08	0,20	200	500	0,4	0,4		
vegetables	NL	Di-QUAT	F	Annual dicotyledonous weeds	SL	200	inter-row treatment	Mrt-April BBCH 0-14	-	1	-	0,08	0,20	200	500	0,4	0,4*		* The amount is given per treated surface. For inter-row spraying the cropped surface is partially treated
ornamentals	NL	Di-QUAT	F	Annual dicotyledonous weeds	SL	200	overall spray	Mrt-April BBCH 0	-	1	-	0,08	0,20	200	500	0,4	0,4		
ornamentals	NL	Di-QUAT	F	Annual dicotyledonous weeds	SL	200	inter-row treatment	Mrt-April BBCH 0-14	-	1	-	0,08	0,20	200	500	0,4	0,4*		* The amount is given per treated surface. For inter-row spraying the cropped surface is partially treated

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

As the United Kingdom withdrew the authorisation ofQuad-Glob 200 SL for the use in barley, the use in barley is no longer part of the application.

During the evaluation, the applicant changed the product name from DI-QUAD in Quad-Glob 200 SL.

1.6 Background to the application

It concerns an application for the mutual recognition of the ppp Quad-Glob 200SL.

1.7 Packaging details

Material:	HDPE
Capacity:	1, 5, 10, 20 and 25 L
Type of closure and size of opening:	Type of opening not specified, size of opening 42 mm (1 L), 55 mm (others).
Other information	UN approved.

No particular recommendations.

2. Physical and chemical properties

For applications for mutual recognition, the physical and chemical properties of the active substances and the formulation do not require re-evaluation. Please refer to the assessment by the United Kingdom.

3. Methods of analysis

For applications for mutual recognition, the analytical methods of the active substances and the formulation do not require re-evaluation. Please refer to the assessment by the 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 Quad-Glob 200 SL, we refer to the member state of the original authorisation (UK).

4.2 Dermal absorption (IIIA 7.3)

UK used a dermal absorption value of 0.3% for the formulation and 0.35% for the spray dilution in the risk assessment. Since this application is a request for mutual recognition these values are 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 UK.

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

Overview of the intended uses

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

Quad-Glob 200 SL is an SL formulation and contains 200 g/L diquat.

The formulation Quad-Glob 200 SL is applied by mechanical downward spraying in the culture of potatoes, diverse vegetables and ornamentals, flax, oilseed rape, and clover. The formulation is

applied 1-2 times per growing season with an interval of 2 days with a maximum dose of 4 L formulation / ha (per year). Therefore, a semi-chronic exposure duration is applicable for the operator (including contract workers).

4.4.1 Operator exposure/risk

Calculation of the EU-AOEL / Tolerable Limit Value (TLV)
For diquat no TLV has been set. The AOEL will be used for the risk assessment.
Since diquat is included in Annex I of 91/414/EEC, the semi-chronic EU-AOEL of 0.001 mg/kg bw/day (= 0.07 mg/day for a 70-kg operator), based on the 2 year study (90 day endpoint) in rat is used for the risk assessment. This AOEL has also been used in the risk assessment performed by UK.

Exposure/risk
Exposure to diquat during mixing and loading and application of Quad-Glob 200 SL is estimated with models. The exposure is estimated for the unprotected operator. In general, mixing and loading and application is performed by the same person. Therefore, for the total exposure, the respiratory and dermal exposure during mixing/loading and application have to be combined.
In the Table below the estimated internal exposure is compared with the systemic EU-AOEL.
According to the applicant, Quad-Glob 200 SL is applied with a standard tractor, and not manually. Therefore, only exposure during mechanical application is estimated.

Table T.1 Internal operator exposure to diquat and risk assessment for the use of Quad-Glob 200 SL

	Route	Estimated internal exposure [a] (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Mechanical downward spraying in the culture of potatoes, diverse vegetables, flax, oilseed rape, clover, arable farming and ornamentals (uncovered)				
Mixing/ Loading[c]	Respiratory	0.040	0.07	0.57
	Dermal	0.480	0.07	6.86
Application[c]	Respiratory	0.064	0.07	0.91
	Dermal	0.084	0.07	1.20
	Total	0.67	0.07	9.54

a Internal exposure was calculated with:
- biological availability via the dermal route: 0.3% (concentrate) and 0.35% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.
c External exposure is estimated with EUROPOEM.

Since the EU-AOEL is exceeded without the use of PPE, a tier 2 assessment has to be performed using the NL-AOEL.

<u>Tier 2</u>

Calculation of the NL-AOEL
The risk index calculated with the EU-AOEL is >1. Therefore, the Plant Protection Products and Biocides Regulations (NL: Rgb) prescribes the calculation of the risk with an AOEL based on allometric extrapolation (known as the NL-AOEL). This method takes into account the caloric demand of the species studied and results in a more specific value than the EU-AOEL for which a standard factor of 100 is applied.

The calculation of the systemic AOEL for semi-chronic exposure is based on the NOAEL of 1 mg/kg bw/day in the 2-year study with the rat (90 day end point) Calculations from other studies result in

higher AOELs.
Safety factors are used to compensate for the uncertainties, which arise, for example, from extrapolation from the tested species to humans and the differences between experimental circumstances, and to ensure that at the acceptable exposure level no adverse health effects will occur.

Used factors are:

- extrapolation rat → human on basis of caloric demand 4
- other interspecies differences: 3
- intraspecies differences: (professional use) 3
- biological availability via oral route: 10%*
- weight of professional operator/worker: 70 kg

* If the absorbed dose is significantly lower (<80%) than the administered dose, this is adjusted by a correction factor equal to the percentage absorption.

AOELsystemic: 1 x 0.1 x 70 / (4 x 3 x 3) = 0.19 mg/day

Exposure/risk

Table T.2 Internal operator exposure to diquat and risk assessment for the use of Quad-Glob 200 SL

	Route	Estimated internal exposure [a] (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Mechanical downward spraying in the culture of potatoes, diverse vegetables, flax, oilseed rape, clover, arable farming and ornamentals (uncovered)				
Mixing/ Loading[c]	Respiratory	0.040	0.19	0.21
	Dermal	0.480	0.19	2.53
Application[c]	Respiratory	0.064	0.19	0.32
	Dermal	0.084	0.19	0.42
	Total	0.67	0.19	3.53

a Internal exposure was calculated with:
- biological availability via the dermal route: 0.3% (concentrate) and 0.35% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.
c External exposure is estimated with EUROPOEM.

Since the NL-AOEL is exceeded without the use of PPE, a tier 3 assessment has to be performed.

Tier 3
Since the results of acceptable dermal absorption studies were already used in tier 1 and 2, a further refinement with additional dermal absorption data is not considered relevant and a tier 4 assessment will be performed.

Tier 4
The NL-AOEL is exceeded without the use of PPE and dermal absorption data have already been taken into account in the risk assessment. Therefore, in Tier 4 a risk assessment is performed with and without the use of PPE.

Table T.3 Internal operator exposure to diquat and risk assessment for the use of Quad-Glob 200 SL

	Route	Estimated internal exposure [a] (mg /day)	Systemic NL-AOEL	Risk-index [b]

		without PPE	with PPE	(mg/day)	without PPE	with PPE
Mechanical downward spraying in the culture of potatoes, diverse vegetables, flax, oilseed rape, clover, arable farming and ornamentals (uncovered)						
Mixing/ Loading[c]	Respiratory	0.04	(0.04)	0.19	0.21	(0.21)
	Dermal	0.48	0.05	0.19	2.53	0.25
Application[c]	Respiratory	0.06	(0.06)	0.19	0.32	(0.32)
	Dermal	0.08	0.01	0.19	0.42	0.04
	Total	0.67	0.16	0.19	3.53	0.63[d]

a Internal exposure was calculated with:
- biological availability via the dermal route: 0.3% (concentrate) and 0.35% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.
c External exposure is estimated with EUROPOEM.
d PPE: gloves and coverall during mixing/loading and application

4.4.2 Bystander exposure/risk

Tier 1

The exposure is estimated for the unprotected bystander. In Table T. 4 the estimated internal exposure is compared with the systemic EU-AOEL.

Table T. 4 Internal bystander exposure to diquat and risk assessment after application of Quad-Glob 200 SL

	Route	Estimated internal exposure [a] (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Bystander exposure during application in the culture of potatoes, diverse vegetables, flax, oilseed rape, clover, arable farming and ornamentals (uncovered)				
	Respiratory	0.15	0.07	2.14
	Dermal	<0.01	0.07	0.04
	Total	0.15	0.07	2.18

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:
- biological availability via the dermal route: 0.35% (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.

Since the EU-AOEL is exceeded without the use of PPE, a tier 2 assessment has to be performed using the NL-AOEL.

Tier 2

Table T. 5 Internal bystander exposure to diquat and risk assessment after application of Quad-Glob 200 SL

	Route	Estimated internal exposure [a] (mg /day)	Systemic NL-AOEL (mg/day)	Risk-index [b]
Bystander exposure during application in the culture of potatoes, diverse vegetables, flax, oilseed rape, clover, arable farming and ornamentals (uncovered)				
	Respiratory	0.15	0.19	0.79
	Dermal	<0.01	0.19	0.01
	Total	0.15	0.19	0.80

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:
- biological availability via the dermal route: 0.35% (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.

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 AEL.

Table T.6 Internal bystander and resident exposure to diquat and risk assessment for the application of Quad-Glob 200 SL

	Route	Estimated internal exposure [a] (mg /day)	Systemic AEL (mg/day)[b]	Risk-index [c]
Bystander exposure during application in representative uses according to the German model				
Child	Total	0.0018	0.02	0.11
Adult	Total	0.0080	0.06	0.13
Resident exposure during application in all representative uses according to the German model				
Child	Total	0.0099	0.02	0.61
Adult	Total	0.0010	0.06	0.02
Bystander exposure during application in representative uses according to the UK method				
Adult	Total	0.0254	0.06	0.42
Resident exposure during application in representative uses according to the UK method				
Child	Dermal+Oral	0.0043	0.02	0.29

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: 0.35% (see 4.2)
- biological availability via the oral route: 100% (see List of EndPoints)

b From the systemic AOEL 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 risk-index is calculated by dividing the internal exposure by the systemic AEL.

Based on the calculated risk indexes for diquat, the resident exposure of children and adults living next to a field treated with Quad-Glob 200 SL is considered to be safe.

4.4.3 Worker exposure/risk

In case of overall spray application, re-entry will not be necessary since Quad-Glob 200 SL is used for desiccation. Crop inspection to determine the efficacy of the treatment is unnecessary due to the quick and obvious effects to treatment. As the treated foliage will have died back by the time of harvest, even manual harvesting operations are unlikely to lead to significant levels of exposure to dislodgeable foliar residues.

In case of inter-row treatment of ornamentals, vegetables and arable farming, the crop should be protected during application of Quad-Glob 200 SL, preferable with special equipment. As a

consequence, little or no Quad-Glob 200 SL will be present on vegetables, ornamentals or arable corps and negligible worker exposure will occur during re-entry activities.
For these reasons, the level of worker exposure resulting from the proposed use of Quad-Glob 200 SL is expected to be negligible.

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
For the unprotected operator, adverse health effects after dermal exposure to diquat as a result of the application of Quad-Glob 200 SL in the culture of diverse vegetables, flax, oilseed rape, clover, arable farming and ornamentals cannot be excluded. Correct use of personal protective equipment will reduce the dermal exposure and results in a sufficient reduction of the exposure to diquat for the application of Quad-Glob 200 SL in seed, ware and starch potatoes.

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 Quad-Glob 200 SL in the culture of diverse vegetables, flax, oilseed rape, clover, arable farming and ornamentals.

Worker exposure
Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected worker after dermal and respiratory exposure during re-entry activities in in the culture of diverse vegetables, flax, oilseed rape, clover, arable farming and ornamentals due to exposure to diquat after application of Quad-Glob 200 SL.

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

See List of Endpoints.

4.6 Data requirements

Based on this evaluation, no additional data requirements are identified.

4.7 Combination toxicology

Quad-Glob 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 (United Kingdom). 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.

5.2.1 Data requirements

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No data requirements were identified.

6. Environmental fate and behaviour

The list of endpoints (LoEP) from the final review report is used. This version of the LoEP is dated 16th August 2000.

List of Endpoints

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)

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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}

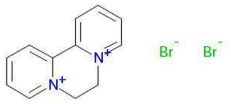
Photolytic degradation

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 pesticide Quad-Glob 200 SL with active substance diquat-dibromide.

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

Compound name	Code number(s)	IUPAC name	Structural formula	Structure	Molecular Weight [g/mol]
Diquat-dibromide		Dipyrido[1,2-a:2 ,1 -c] pyrazinediium, 6,7-dihydro-, dibromide	$C_{12}H_{12}Br_2N_2$		344.1
No relevant metabolites					

6.1 Fate and behaviour in soil

6.1.1 Persistence in soil

Preceding the harmonisation of the persistence assessment in The Netherlands with regulation 1107/EG (expected autumn 2011), the EU approach for persistence assessment is followed. In case of a mutual recognition this means that the assessment of the original member state is adopted.

The risk assessment of persistence in soil is not a Dutch national specific criterion. 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 national specific criterion. 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 2.9 of the *Plant Protection Products and Biocides Regulations* (RGB) describes the authorisation criterion leaching to groundwater.

The leaching potential of the active substance (and metabolites) is calculated in the first tier using Pearl 3.3.3 and the FOCUS Kremsmünster scenario. Input variables are the actual worst-case application rate [0.4 kg/ha], the crop [vegetables] and an interception value appropriate to the crop stage of [0.0]. Date of yearly application is May 25th. No metabolite 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-dibromide:
DT_{50} for degradation in soil (20°C): 3650 days
Arithmetic mean K_{om} (pH-independent): 1.267.256 L/kg (range 18.561 – 4.582.366 L/kg)
1/n: 0.9 (default in the absence of experimental data in the DAR)

Saturated vapour pressure: 1 x 10^{-5} Pa (25°C)
Solubility in water: 718.000 mg/L (20°C)
Molecular weight: 344.1 g/mol

Plant uptake factor: 0.0
Q10: 2.2

Other parameters: standard settings of PEARL 3.3.3

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

Table M.1 Leaching of active substance diquat-dibromide as predicted by PEARL 3.3.3

Use	Substance	Rate substance [kg/ha]	Frequency/ Interval [days]	Fraction Intercepted *	PEC groundwater [µg/L]
					spring
ware potatoes starch potatoes	diquat-dibr.	0.8	2 / 2 **	0.8	<0.001
seed potatoes	diquat-dibr.	0.8	2 / 2 **	0.8	<0.001
barley (animal feed)	diquat-dibr.	0.8	1	0.9	<0.001
oats (animal feed)	diquat-dibr.	0.8	1	0.9	<0.001
dry peas (animal feed)	diquat-dibr.	0.6	1	0.55	<0.001
field beans (animal feed)	diquat-dibr.	0.6	1	0.4	<0.001
flax	diquat-dibr.	0.6	1	0.4	<0.001
oilseed rape	diquat-dibr.	0.6	1	0.4	<0.001
clover	diquat-dibr.	0.6	1	0.4	<0.001
arable farming	diquat-dibr.	0.4	1	0.0	<0.001
arable farming	diquat-dibr.	0.4 ***	1	0.0	<0.001
vegetables	diquat-dibr.	0.4	1	0.0	<0.001
vegetables	diquat-dibr.	0.4 ***	1	0.0	<0.001
ornamentals	diquat-dibr.	0.4	1	0.0	<0.001
ornamentals	diquat-dibr.	0.4 ***	1	0.0	<0.001

* interception values derived from Table 1.6 in "generic guidance for FOCUS groundwater scenarios". For potatoes, barley (spring cereals), oats (spring cereals), dry beans, oilseed rape conservative interception fractions were taken for the Table 1.6. For flax and clover interception value of oilseed rape was used and for arable farming, vegetables and ornamentals worst case interception of 1 was applied.
** max. 4 litre product (=0,8 kg as/ha) per year
*** the amount is given per treated surface. For inter-row spraying the cropped surface is partially treated

Results of Pearl 3.3.3 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-dibromide is 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 active substance diquat-dibromide in groundwater.

Conclusions
The proposed application(s) of the product complies with the requirements laid down in the RGB concerning persistence in soil and leaching to groundwater.

6.2 Fate and behaviour in water

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

Since the Netherlands has its own national drift values, the exposure concentrations of the active substance 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.

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

TOXSWA:
Active substance diquat-dibromide:
Geometric mean DT_{50} for degradation in water at 20°C: 10.000 days*
DT_{50} for degradation in sediment at 20°C: 1.000 days (default).

Arithmetic mean K_{om} for suspended organic matter: 1.000.000 L/kg (maximum input value for TOXSWA)
Arithmetic mean K_{om} for sediment: 1.000.000 L/kg (maximum input value for TOXSWA)
1/n:0.9 (default in the absence of experimental data in the DAR)

Q10: 2.2

Saturated vapour pressure: 1 x 10^{-5} Pa (25°C)
Solubility in water: 718 g/L (20°C)
Molecular weight: 344.1 g/mol

* In the LoEP no system DT_{50} is reported, only a dissipation-DT_{50} from the water phase. The retention time in the system is however completely determined by the extremely strong adsorption van diquat-dibromide to sediment. The $DT_{50,system}$ is therefore set to 10.000 days

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.

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

Table M.2a Overview of surface water concentrations for active substance diquat-dibromide in the edge-of-field ditch following spring/autumn application

Use	Substance	Rate a.s. [kg/ha]	Freq. / Interval [days]	Drift [%]	PIEC [µg/L]* spring	PEC21 [µg/L]* spring	PEC28 [µg/L]* spring
ware potatoes starch potatoes	diquat-dibr.	0.8	2 / 2 **	1	0.415	0.337	0.311

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Use	Substance	Rate a.s. [kg/ha]	Freq. / Interval [days]	Drift [%]	PIEC [µg/L] *	PEC21 [µg/L] *	PEC28 [µg/L] *
					spring	spring	spring
seed potatoes	diquat-dibr.	0.8	2 / 2 **	1	0.415	0.337	0.311
barley (animal feed)	diquat-dibr.	0.8	1	1	0.415	0.337	0.311
oats (animal feed)	diquat-dibr.	0.8	1	1	0.415	0.337	0.311
dry peas (animal feed)	diquat-dibr.	0.6	1	1	0.302	0.247	0.228
field beans (animal feed)	diquat-dibr.	0.6	1	1	0.302	0.247	0.228
flax	diquat-dibr.	0.6	1	1	0.302	0.247	0.228
oilseed rape	diquat-dibr.	0.6	1	1	0.302	0.247	0.228
clover	diquat-dibr.	0.6	1	1	0.302	0.247	0.228
arable farming	diquat-dibr.	0.4	1	1	0.194	0.159	0.147
arable farming	diquat-dibr.	0.4***	1	1	0.194	0.159	0.147
vegetables	diquat-dibr.	0.4	1	1	0.194	0.159	0.147
vegetables	diquat-dibr.	0.4***	1	1	0.194	0.159	0.147
ornamentals	diquat-dibr.	0.4	1	1	0.194	0.159	0.147
ornamentals	diquat-dibr.	0.4***	1	1	0.194	0.159	0.147

* calculated according to TOXSWA

** max. 4 litre product (=0,8 kg as/ha) per year

*** the amount is given per treated surface. For inter-row spraying the cropped surface is partially treated

$PEC_{sediment}$

To address the risk to sediment organisms, a PEC sediment value is needed for active substance 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 day 33 after application. See Table M.2b for calculation of $PEC_{sediment}$.

Table M.2b Maximum sediment concentration for active substance [name] following spring application (worst-case)

Use	Substance	Rate a.s. [kg/ha]	drift [%]	PECsediment [g a.s./m^3 sediment] *	PECsediment [mg a.s./kg sediment dw] **
				spring	spring
ware potatoes starch potatoes	diquat-dibr.	0.8	1	0.0475	0.594
seed potatoes	diquat-dibr.	0.8	1	0.0475	0.594
barley (animal feed)	diquat-dibr.	0.8	1	0.0475	0.594
oats (animal feed)	diquat-dibr.	0.8	1	0.0475	0.594
dry peas (animal feed)	diquat-dibr.	0.6	1	0.0349	0.436
field beans (animal feed)	diquat-dibr.	0.6	1	0.0349	0.436
flax	diquat-dibr.	0.6	1	0.0349	0.436
oilseed rape	diquat-dibr.	0.6	1	0.0349	0.436
clover	diquat-dibr.	0.6	1	0.0349	0.436
arable farming	diquat-dibr.	0.4	1	0.0226	0.283
arable farming	diquat-dibr.	0.4	1	0.0226	0.283
vegetables	diquat-dibr.	0.4	1	0.0226	0.283
vegetables	diquat-dibr.	0.4	1	0.0226	0.283
ornamentals	diquat-dibr.	0.4	1	0.0226	0.283
ornamentals	diquat-dibr.	0.4	1	0.0226	0.283

* TOXSWA output

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

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

Monitoring data

The Pesticide Atlas on internet (www.pesticidesatlas.nl, www.bestrijdingsmiddelenatlas.nl) is used to evaluate measured concentrations of pesticides in Dutch surface water, and to assess whether the observed concentrations exceed threshold values. Dutch water boards have a well-established programme for monitoring pesticide contamination of surface waters. In the Pesticide Atlas, these monitoring data are processed into a graphic format accessible on-line and aiming to provide an insight into measured pesticide contamination of Dutch surface waters against environmental standards. Recently, the new version 2.0 was released. This new version of the Pesticide Atlas does not contain the land use correlation analysis needed to draw relevant conclusions for the authorisation procedure. Instead a link to the land use analysis performed in version 1.0 is made, in which the analysis is made on the basis of data aggregation based on grid cells of either 5 x 5 km or 1 x 1 km.

Data from the Pesticide Atlas are used to evaluate potential exceeding of the authorisation threshold and the MPC (*ad-hoc* or according to INS) threshold. 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-dibromide

The active substance diquat-dibromide was observed in the surface water (most recent data from 2009). In Table M.3 the number of observations in the surface water are presented.
In the Pesticide Atlas, surface water concentrations are compared to the authorisation threshold value of 0.84 µg/L (C-165.3.8 23/01/2006 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 x NOEC Lemna) and to the indicative Maximum Permissible Concentration (MPC) of 1.0 µg/L as presented in the Pesticide Atlas (data source for the MPC: *Zoeksysteem normen voor het waterbeheer, http://www.helpdeskwater.nl/normen_zoeksysteem/normen.php*).

Currently, this MPC value is not harmonised, which means that not all available ecotoxicological data for this substance are included in the threshold value. In the near future and in the framework of the Water Framework Directive, new quality criteria will be developed which will include both MPC data as well as authorisation data. The currently available MPC value is reported here for information purposes. Pending this policy development, however, no consequences can be drawn for the proposed applications.

Table M.3 Monitoring data in Dutch surface water (from www.pesticidesatlas.nl, version 2.0)

Total no of locations (2009)	***n* > authorisation threshold**	***n* > indicative/ad hoc MPC threshold**	***n* > MPC-INS threshold ***
14**	0	0	n.a.

* n.a.: no MPC-INS available. < : exceeding expected to be lower than with indicative/ad hoc MPC value; > : exceeding expected to be higher than with indicative MPC value

** the number of observations at each location varies between 1 and 3, total number of measurements is 56 in 2009.

As there are no exceedings of thresholds, the monitoring data have no consequences for the proposed uses of the product.

Drinking water criterion

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

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[1].

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.

Diquat-dibromide has been on the Dutch market for > 3 years (authorised since 20/03/1991). 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 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 RGB are met.

Conclusion drinking water criterion

The original registration in the UK was not assessed against the drinking water criterion. Conclusion risk assessment according to EM 1.0: all proposed applications of the product comply with the RGB.

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 national specific criterion. For the risk assessment we refer to the member state of the original authorization (Member State).

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

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

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No data requirements based on the environmental fate and behaviour risk assessment

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:
None.

6.6 Overall conclusions fate and behaviour

It can be concluded that:

1. the active substance diquat-dibromide meets the standards for persistence in soil as laid down in the RGB.
2. all proposed applications of the active substance diquat-dibromide meet the standards for leaching to the shallow groundwater as laid down in the RGB.
3. The proposed applications of the product comply with the RGB with regard to the standards for surface water destined for the production of drinking water.

7. Ecotoxicology

The underlying risk assessment is based on the final list of endpoints for diquat-dibromide and on the UK authorisation for Quad-Glob 200SL (former name: Quad). This UK authorisation is for the large part based on the authorisation of Reglone.

List of Endpoints Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD_{50} (diquat ion - rat)= 214 - 222 mg/kg bw
Short term oral toxicity to mammals:	NOAEL 8.9 mg /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/kg bw/d*
Reproductive toxicity to birds:	NOEC = 5 mg/kg (diquat ion) *= 0.6 mg/kg bw/d*

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)

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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 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 = *1000 g diquat/ha*) there was significant mortality of wasps in the treatment compared to the control. No adverse effects were noted on either fecundity or behaviour. *<u>Ctgb</u>: Further information taken from Addendum 1:Study on treated barley plants. Mean adult mortality: 58.0% + 8% moribund in treated group, compared with 4% mortality in the control and 100% mortality for the dimethoate toxic standard, no repellency to diquat was observed. Fecundity in the treated group was 11.6 aphid mummies/female compared with 10.8 in the control.*
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

Additional information (summarized and avaluated by Ctgb (02/2017)

Non-target arthropods

Form.	Species	Method	Dose [L/ha]	Dose [g a.s./ha]	Parameter	$L(E)R_{50}$ [g a.s./ha]
Diquat 200 g/L SL	*Typhlodromus pyri*	Ext.Lab.test bean leaves			Mortality Reproduction	14.87 17.35

Non target plants

Vegetative vigour

ER 50 and ER 10 values (ml product/ha) based on foliar fresh weight

with corresponding R-Sq values

Species	ER10 (ml product/ha)	ER50 (mL product/ha)	CI (mL product/ha)
Wheat	10.45	>4000	
Onion	n/a	>4000	
Carrot	255.6	830.8	670 - 995

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Soybean	20.0	372.3	254 – 494
Cabbage	258.6	>1600	
Lettuce	7.4	53.4	38.2 - 69

Additional test: ER 50 and ER 10 values (ml product/ha) based on foliar fresh weight with corresponding R-Sq values

Species	**ER10 (ml product/ha)**	**ER50 (mL product/ha)**	**CI (mL product/ha)**
Wheat	1857	6927	5439 – 8449
Onion	1540	17966	9766 – 26357
Cabbage	143.7	1242.8	321 – 2158

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, major issues have arisen when considering the risk to birds from other diquat products intended for various uses. These have never been resolved despite various attempts at refinement. The original dossier from the UK does not contain a risk assessment addressing these issues. To date, the only uses for which an acceptable risk for diquat has ever been established in the Netherlands are:
-dessication in potatoes
-pre-emergence application in beets, vegetable crops, flower bulb and flower tuber crops and ornamentals with a lower dose (1.5 L/ha) than applied for (2.0 L/ha).

For other uses no acceptable risk has been established and authorization cannot be granted without additional information.

The risk assessment for birds 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.

drinking water

The risk from exposure through drinking surface water is calculated for a small bird with body weight 10 g and a DWI (daily water intake) of 2.7 g/d. Surface water concentrations are calculated using TOXSWA (see paragraph 6.2.1). In the first instance, acute exposure is taken into account. The highest $PIEC_{water}$ is 0.415 µg/L. It follows that the risk of drinking water is (LD50 * bw) / (PIEC*DWI) = (83 * 0.010) / (0.000415 * 0.0027) = $>7x10^5$. Since the TER is >>10, the risk is acceptable.

7.1.2 Secondary poisoning

The risk as a result of secondary poisoning is assessed based on bioconcentration 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 birds

The application for mutual recognition of the product for the dessication use in potatoes, and pre-emergence uses in potatoes, beets and vegetables does comply with the RGB.

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.1.

Because the application for authorisation concerns a herbicide, also the effects on macrophytes (aquatic plants) should be evaluated. However, no endpoint for macrophytes is available in the EU-dossier (there was no data requirement set at the time of review). According to current guidance however, a test on macrophytes is required for herbicides. The UK said the following about the risk to aquatic plants in their risk assessment:

' No data requirement was set for aquatic plant testing at the time of Annex 1 listing, hence, as the aquatic PECs for the supported UK uses are within those considered for Annex 1 listing, it would not be appropriate to do so now. Although a new study has been presented it has not therefore been evaluated.' (Ctgb: It should be noted that the new study UK refers to is for the product Reglone, hence this is data to which the current applicant has no access to.)

For other registrations for mutual recognition, UK further stated that in the DAR (1996), data are available that indicate that aquatic plant species are not significantly more sensitive than algae.

Based on this and knowing that the risk to macrophytes was found to be acceptable for a comparable diquat use which was assessed in the Netherlands recently, Ctgb will not ask for a study on macrophytes. The risk assessment for algae below is considered to cover the risk for Lemna.

Table E.1 Overview toxicity endpoints for aquatic organisms

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

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 (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 table E.2 TER values for aquatic organisms are shown.

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Table E.2a TER values: acute

Use	Substance	PECsw [µg a.s./L]	TER_{st} (trigger 10) Algae spring	TER_{st} (trigger 100) Invertebrates spring	TER_{st} (trigger 100) Fish spring	TER_{st} (trigger 10) Macrophytes spring	
potatoes	Diquat	0.415	27	2892	14699	-	-

Table E.2b TER values: chronic

Use	Substance	PECsw [µg a.s./L]	TER_{lt} (trigger 10) Invertebrates spring	TER_{lt} (trigger 10) Fish spring
potatoes	Diquat	0.415	301	289

Taking the results in Table E.2a and b into account, it appears that the proposed uses meet the standards for aquatic organisms as laid down in the RGB.

7.2.2 Risk assessment for bioconcentration

Since the log Kow of diquat < 3 (-4.6), the potential for bioconcentration is considered low and no further assessment is deemed necessary.

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 0.594 mg/kg dw, the TER value is ≥ 168, which is above the trigger of 10. Therefore, the proposed uses meet the standards for sediment organisms as laid down in the RGB.

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).

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.

drinking water

The risk from exposure through drinking from surface water is calculated for a small mammal with body weight 10 g and a DWI (daily water intake) of 1.57 g/d. Surface water concentrations are calculated using TOXSWA (see paragraph 6.2.1). In the first instance, acute exposure is taken into account. The highest $PIEC_{water}$ is 0.415 µg/L. It follows that the risk of drinking water is (LD50 * bw) / (PIEC*DWI) = (214 * 0.010) / (0.000415 * 0.00157) = $>3x10^6$. Since the TER is >> 10, the risk is acceptable.

7.3.2 Secondary poisoning

The risk as a result of secondary poisoning is assessed based on bioconcentration 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 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 in principle refer to the member state of the original authorization (UK).

However, for a comparable product and use in the Netherlands, a restriction sentence was included as a precautionary measure. This was done because a risk cannot be excluded based on first tier calculations. This sentence should also be included for Quad-Glob 200 SL:

Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen 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 *Aphidius rhopalosiphi* and *Typhlodromus 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 arthopods is assessed by calculating Hazard Quotients. For this, Lethal Rate values (LR_{50}) are needed. Based on L/ER_{50}-values from an studies with the two standard species *Aphidius rhopalosiphi* (LR_{50} = < 1 kg a.s./ha; ER50 = > 1 kg a.s./ha; extended laboratory study on barley plants) and *Typhlodromus pyri* (LR_{50} = 14.87) 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 HTB (v 1.0). The Hazard Quotient for A. rhopalosiphi should be below the trigger value of 1 to meet the standards for extended laboratory tests. The resulting Hazard Quotients are presented in Table E.3.

Table E.3 HQ-values for *A. rhopalosiphi* and *T. pyri*

	Application rate (kg a.s./ha)	MAF[1]	Drift factor/ Vegetation factor[2]	Safety factor[2]	L/ER_{50} (kg a.s./ha)	HQ
Off-field						
A. rhopalosiphi	0.8		0.10/1	5	< 1 (LR_{50})	>**0.4**
					>1 (ER_{50})	<0.4
T. pyri	0.8		0.10/10	5	0.01487	**2.89**
	0.4		0.10/10	5	0.01487	**1.34**

[1]: Multiple Application Factor

[2]: off-field: drift factor = 10%, vegetation distribution factor = 1 for 3-D test systems, safety factor = 5 for extended lab (default values)

As the above table shows, the off-field HQ value is possibly above the trigger value of 1 for *A. rhopalosiphi*, when using the LR50. However, the LR50 < 1 kg a.s./ha was based on adult mortality of 58.0% + 8% moribund in treated group. Since this is not far above 50%, the HQ-value is not expected to be > 1. Thererfore, the risk to *A. rhopalosiphi* is considered acceptable.

For *T. pyri*. an off-field risk cannot be excluded.

In the UK registration document, no risk assessment for non-target arthropods is included. It is referred to the EU-dossier, stating that the proposed uses are covered by those in the monograph.

In the EU-dossier (Addendum 2), it was stated that since diquat is applied as a total herbicide either pre-emergence, post-emergence between the rows or as a desiccant, only ground-dwelling arthropods are considered relevant for risk assessment (dessicated crops being non-attractive due to growth stage and short time to harvest). However, this is not acceptable for the current risk assessment: diquat is a contact herbicide and is applied onto the weeds, not onto the soil, thus presence of foliar dwelling arthopods cannot be excluded. In addition, the line of reasoning in the Addendum is only applicable to the in-field situation, whilst for the off-field there are no reasons to exclude a risk assessment for foliar dwellers. Therefore this statement cannot be used and an adequate risk assessment is required for *T. pyri.*
The risk for the in potatoes will be acceptable for arthropods if the drift will be 3% or lower for dessication and 7% or lower for the pre-emegence uses .

The applicant proposes to include drift reducing nozzles: a low boom nozzle, end nozzle, venture nozzle and an additional crop fee zone of 1 m for pre-emergence uses and 1.5m for dessication uses. However these mitigation measures are too strict (the applicant assumed that the vegetation distribution factor could not be used, however the test was performed on leaves and is considered a 2D-test).
For the pre-emergence uses, the risk will be acceptable when prescribing at least 75% drift reducing nozzles and an end nozzle (5.5%drift). For the dessication uses, the risk will be acceptable with a low boom nozzle, end nozzle, and at least 75% drift reducing nozzles and an additional crop free zone of 25 cm. As the zone of evaluation is set on 1 m, the total crop free zone is 1.25 m (measured from the middle of the last rows till the edge off-field).

The Ctgb notes that the measured drift values for 90% drift-reducing nozzles are higher than those for 50 and 75% drift-reducing nozzles, which seems contradictory. It may be a result of the fact that fewer measurements were performed for 90% drift-reducing nozzles. That said, it may also be a result of the fact that the reduction percentiles are defined based on their reduction of drift into surface water, which is further from the use area (field). Thus, nozzles with a high reduction percentage for water bodies bordering a field may actually have higher drift in the non-crop vicinity closer to the edge of the field. If an end nozzle is used in conjunction with the drift-reducing nozzle, this situation can be improved (as end nozzles ensure that there is less spray drift off the field area). Since it would be difficult for the end-user and general public to understand why the use of a 50% drift-reducing nozzle is acceptable but a 90% drift-reducing nozzle is not acceptable, the instructions for use will contain only the lowest acceptable drift-reduction percentage and the words "at least", indicating that nozzles with a higher reduction percentage are also acceptable. The use of an end nozzle will be universally prescribed.

The restriction sentences are (in Dutch):

-Om niet tot de doelsoorten behorende geleedpotigen/insecten te beschermen is doodspuit toepassing in aardappel uitsluitend toegestaan wanneer gebruik wordt gemaakt van een lage spuitboomhoogte (maximaal 30 cm boven de top van het gewas), met minimaal 75% drift reducerende spuitdoppen en een kantdop met in acht neming van een teeltvrije zone van 1.25 m (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens).

-Om niet tot de doelsoorten behorende geleedpotigen/insecten te beschermen is toepassing voor opkomst in alle gewassen uitsluitend toegestaan wanneer gebruik wordt gemaakt van minimaal 75% drift reducerende spuitdoppen en een kant dop.

Additional species:
An extended laboratory test with *Coccinella septempunctata* shows that at 1 kg a.s./ha, mortality was 58%, but reproduction was not reduced (but increased). Since the proposed dose rate is 0.8 kg a.s./ha, this is a borderline case for acceptable risk.

A laboratory study with *Trichogramma cacocecie* showed adverse effects >50% at 1 kg a.s./ha and a laboratory study with *Chrysoperla carnea* showed adverse effects >50% at 1.6 kg a.s./ha. Thus a risk for these species cannot be excluded.

Adverse effects were <50% at 1.6 kg a.s./ha for the ground dwelling species *Pterosticus melanarius* and *Pardosa spp..*, showing that the risk for these species is acceptable.

In the EU Addendum (2), the following is reported:
Following ECCO and Evaluation Working Group discussions it was decided that higher tier data on the standard sensitive species, *Aphidius rhopalosiphi*, would be more applicable to the use pattern for diquat than data on *Trichogramma*. An extended laboratory study on *Coccinella septempunctata* was also accepted instead of further information on *Chrysopa*.

Based on the above, no further data are required for *Trichogramma cacocecie* and *Chrysoperla carnea.*

Hence, the standards for non-target arthropods as laid down in the RGB are met, provided that drift reducing measures are prescribed.

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 authorization (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 authorization (UK).

7.5.4 Effects on activated sludge (*Dutch specific aspect)*
The risk assessment for activated sludge is a Dutch specific aspect. However, for the proposed uses no exposure of activated sludge is expected. Therefore, the proposed applications comply with the standards for activated sludge as laid down in the RGB.

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.

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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.
A TER has to be calculated with the lowest EC_{50} value from a laboratory test with higher plants and the exposure concentration.

The list of endpoints for diquat does not contain any endpoints for terrestrial plants, and in the UK registration document no risk assessment for non-target plants is included. It is referred to the EU-dossier, stating that the proposed uses are covered by those in the monograph. In the EU-monograph no ER50 is available, but screening data showed that no serious phytotoxic effects were recorded at the minimum screen rates of 5 and 6 g a.s./ha (applied post-mergence to young seedlings). The applicant has submitted a new study on the vegetative vigour of diquat on plants. As the product is a contact herbicide, this is acceptable; it is expected that this will cover the risk for seedling emergence as well. The lowest endpoint is 53.4 mL product/ha for Lettuce.

Table E.4a Overview of exposure concentrations and indicative TERs for non target plants

Use	Substance	Dose [L /ha]	MAF	Drift% (off-field exposure)	Exposure (L/ha)	ER [L/ha]	TER	Trigger value
Potatoes	diquat	4	1	4.7%	0.188	0.0534	**0.28**	5

The ratio between the ER and the exposure concentration is < 5. Therefore, a risk for non-target plants cannot be excluded and a refined risk assessment is required.

The applicant submitted a refined risk assessment using SSD. This has been recalculated by Ctgb.

Species	ER50 (L product/ha)
Wheat	6.927
Onion	17.966
Carrot	0.831
Soybean	0.372
Cabbage	1.243
Lettuce	0.0534
HC5	**0.0308**

The test for normality was accepted on all levels. The HC5 will be used in the risk assessment with an safety factor of 1.

Table E.5 Overview of exposure concentrations and indicative TERs for non target plants

Use	Substance	Dose [L /ha]	MAF	Drift% (off-field exposure)	Exposure (L/ha)	HC5 [L/ha]	TER	Trigger value
Potatoes	diquat	4	1	4.7%	0.188	0.0308	**0.16**	1
Pre-emergence		2	1	4.7%	0.094	0.0308	**0.32**	

Based on these calculations, a further refinement is required. The risk for non-target plants will be acceptable when drift is reduced to 0.77 and 1.0% drift.

The applicant also proposes to include drift reducing nozzles: a low boom nozzle, end nozzle, venturi nozzle and an additional crop fee zone of 1 m for pre-emergence uses and 1.5m for dessication uses.

The risk for non-target plants will be acceptable when drift is reduced to 0.75 and 1.5% drift.
When prescribing a low boom nozzle, end nozzle, venture nozzle, the expected drift in the zone of evaluation is 0.3%. Therefore the risk for non-target plants will be acceptable with these mitigation

measures. An additional crop –free zone is not necessary. For the pre-emergence uses, the risk is acceptable with at least 75% drift reducing nozzles and an end nozzle.

The Ctgb notes that the measured drift values for 90% drift-reducing nozzles are higher than those for 75% drift-reducing nozzles, which seems contradictory. It may be a result of the fact that fewer measurements were performed for 90% drift-reducing nozzles. That said, it may also be a result of the fact that the reduction percentiles are defined based on their reduction of drift into surface water, which is further from the use area (field). Thus, nozzles with a high reduction percentage for water bodies bordering a field may actually have higher drift in the non-crop vicinity closer to the edge of the field. If an end nozzle is used in conjunction with the drift-reducing nozzle, this situation can be improved (as end nozzles ensure that there is less spray drift off the field area).
Since it would be difficult for the end-user and general public to understand why the use of a 75% drift-reducing nozzle is acceptable but a 90% drift-reducing nozzle is not acceptable, the instructions for use will contain only the lowest acceptable drift-reduction percentage and the words "at least", indicating that nozzles with a higher reduction percentage are also acceptable. The use of an end nozzle will be universally prescribed.

Therefore the following restriction sentence has to be included on the label:
Om niet tot de doelsoorten behorende terrestrische planten te beschermen is doodspuit toepassing in aardappel uitsluitend toegestaan wanneer gebruik wordt gemaakt van een lage spuitboomhoogte (30 cm boven de top van het gewas), met een venturi dop en een kantdop.

Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing voor opkomst in alle gewassen uitsluitend toegestaan wanneer gebruik wordt gemaakt van minimaal 75% drift reducerende spuitdoppen en een kant dop.

Conclusions any other organisms
The proposed applications of the product comply with the RGB for the aspect activated sludge.
The proposed applications of the product comply with the RGB for the aspects non-target arthropods (off-field) and terrestrial non-target plants, provided that drift reducing measures are prescribed.

7.6 Appropriate ecotoxicological end-points relating to the product and approved uses
See List of Endpoints.

7.7 Data requirements
None.

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 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.

Combined restriction sentence for non-target arthropods and non-target plants:
Om niet tot de doelsoorten behorende terrestrische planten/geleedpotigen/insecten te beschermen is doodspuit toepassing in aardappel uitsluitend toegestaan wanneer gebruik wordt gemaakt van een lage spuitboomhoogte (maximaal 30 cm boven de top van het gewas), met venturidop en een kantdop in acht neming van een teeltvrije zone van 1.25 m (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens).

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Om niet tot de doelsoorten behorende terrestrische planten/geleedpotigen/insecten te beschermen is toepassing voor opkomst in alle gewassen uitsluitend toegestaan wanneer gebruik wordt gemaakt van minimaal 75% drift reducerende spuitdoppen en een kant dop.

7.9 Overall conclusions regarding the environment

It can be concluded that:

1. Due to the known risks to birds (exposure via food), only crops for which an authorisation in the Netherlands have been granted (dessication in potatoes, pre-emergence use in potatoes, beets and vegetables) are considered to be acceptable..
2. all proposed applications of the active substance diquat-dibromide meet the standards for birds (exposure via surface water; secondary poisoning via fish) as laid down in the RGB.
3. all proposed applications of the active substance diquat-dibromide meet the standards for aquatic organisms as laid down in the RGB.
4. the active substance diquat-dibromide meets the standards for bioconcentration as laid down in the RGB.
5. for the risk assessment for mammals via natural food and secondary poisoning via earthworms, Ctgb refers to the member state of the original authorisation (UK)
6. all proposed applications of the active substance diquat-dibromide meet the standards for mammals (exposure via surface water; secondary poisoning via fish) as laid down in the RGB.
7. for the risk assessment for bees, Ctgb refers to the member state of the original authorisation (UK).
8. for the risk assessment for non-target arthropods in-field, Ctgb refers to the member state of the original authorisation (UK).
9. all proposed applications of the active substance diquat-dibromide meet the standards for non-target arthropods (off-field) as laid down in the RGB, provided that drift reducing measures are prescribed.
10. for the risk assessment for earthworms, Ctgb refers to the member state of the original authorisation (UK).
11. for the risk assessment for soil micro-organisms, Ctgb refers to the member state of the original authorisation (UK)
12. all proposed applications of the active substance diquat-dibromide meet the standards for activated sludge as laid down in the RGB.
13. all proposed applications of the active substance diquat-dibromide meet the standards for non-target plants as laid down in the RGB, provided that drift reducing measures are prescribed.

8. Efficacy

The product is authorised in the UK for the use in agricultural crops as a herbicide or for the use of desiccation. Climatological and environmental circumstances relevant for the aspect efficacy in the claimed uses in The Netherlands are comparable to those in the UK. The cultivation method in claimed uses is similar in both countries and there are no country-specific situations for the use of Quad-Glob 200 SL as a herbicide and for desiccation in the claimed uses.

Efficacy evaluation

For the evaluation of the aspect ‘Efficacy’ we refer to the evaluation of the member state of the original authorisation (the UK).

Harmful effects

For the evaluation of the aspect ‘Harmful effects’ we refer to the evaluation of the member state of the original authorisation (the UK).

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Resistance
For the evaluation of the aspect 'Resistance' we refer to the evaluation of the member state of the original authorisation (the UK).

For vertebrate control agents: impact on target vertebrates
Because no vertebrates are controlled, this point is not relevant.

Any other relevant data / information
None.

9. Conclusion

The product does not comply with the Uniform Principles for the use in oats (animal feed), dry peas (animal feed), field beans (animal feed), flax, oilseed rape, clover, ornamentals and arable farming (with the exception of potatoes and beets).

The product complies with the Uniform Principles for the dessication use in potatoes, and pre-emergence uses in potatoes, beets and vegetables.

The evaluation is 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.

10. Classification and labelling

Proposal for the classification and labelling of the formulation
Based on the profile of the substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessment for the operator, as mentioned above, the following labeling of the preparation is proposed:

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
Diquat			
Pictogram:	GHS07 GHS08 GHS09	Signal word:	Danger
H-statements:	H302	Harmful if swallowed.	
	H315	Causes skin irritation.	
	H317	May cause an allergic skin reaction.	
	H319	Causes serious eye irritation.	
	H335	May cause respiratory irritation.	
	H372	Causes damage to organs <or state all organs affected, if known> through prolonged or repeated exposure.	
	H410	Very toxic to aquatic life with long lasting effects.	
P-statements:	P260	Do not breathe dust/fume/gas/mist/vapours/spray.	
	P280c	Wear protective gloves and protective clothing.	
	P302+P352	IF ON SKIN: Wash with plenty of water/...	
	P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.	

	P314	Get medical advice/attention if you feel unwell.
	P501	Dispose of contents/container to ....
Supplemental Hazard information:	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.
	SP1	Do not contaminate water with the product or its container.
Child-resistant fastening obligatory?		not applicable
Tactile warning of danger obligatory?		not applicable

Explanation:	
Pictogram:	-
H-statements:	-
P-statements:	P280c is required based on the risk assessment. The other P-statements were proposed by the applicant and are accepted
Other:	-

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

The following sentences have to be included in the Legal Instructions:
Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen 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 terrestrische planten/geleedpotigen/insecten te beschermen is doodspuit toepassing in aardappel uitsluitend toegestaan wanneer gebruik wordt gemaakt van een lage spuitboomhoogte (maximaal 30 cm boven de top van het gewas), met venturidop en een kantdop in acht neming van een teeltvrije zone van 1.25 m (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens).

Om niet tot de doelsoorten behorende terrestrische planten/geleedpotigen/insecten te beschermen is toepassing voor opkomst in alle gewassen uitsluitend toegestaan wanneer gebruik wordt gemaakt minimaal 75% drift reducerende spuitdoppen en een kant dop.

Appendix 1 Table of authorised uses

Crop and/or situation	Member State or Country	Product name	F G or I	Pests or Group of pest controlled	Formulation		Application					Application rate per treatment						PHI days (days)	Remarks:
(a)			(b)	(c)	Type (d-f)	Conc. Of as g/kg (i)	method kind (f-h)	growth stage & season (j)	number (k)		interval between applications (days)	kg as/hl		water L/ha		kg as/ha		(l)	(m)
									min	max		min	max	min	max	min	max		
ware potatoes starch potatoes	NL	Quad-Glob 200 SL	F	desiccation	SL	200	overall spray	BBCH >69 Aug.-Okt	-	2	2	0,08	0,40	200	500	0,4	0,8		max. 4 litre product (=0,8 kg as/ha) per year
seed potatoes	NL	Quad-Glob 200 SL	F	desiccation	SL	200	overall spray	BBCH >50 July, Aug.	-	2	2	0,08	0,40	200	500	0,4	0,8		max. 4 litre product (=0,8 kg as/ha) per year
potatoes	NL	Quad-Glob 200 SL	F	Annual dicotyledonous weeds	SL	200	overall spray	March-April BBCH 0	-	1	-	0,08	0,20	200	500	0,4	0,4	-	max. 4 litre product (=0,8 kg as/ha) per year
beets	NL	Quad-Glob 200 SL	F	Annual dicotyledonous weeds	SL	200	overall spray	March-April BBCH 0	-	1	-	0,08	0,20	200	500	0,4	0,4		
vegetable crops	NL	Quad-Glob 200 SL	F	Annual dicotyledonous weeds	SL	200	overall spray	March-April BBCH 0	-	1	-	0,08	0,20	200	500	0,4	0,4		

Appendix 2 Reference list

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Data protection granted? Y/N
IIIA 10.5.2	2012	Effects of Diquat 200 g/L SL on the predatory mite Typhlodromus pyri SCHEUTEN under extended laboratory conditions - Rate-response-test (LR50) – BioChem agrar Report No.: 12 10 48 002 A GLP, not published	Y	Globa-chem NV	Y
IIIA 10.8.1.2-01	2012	Evaluation of the Phytotoxicity of Diquat 200 SL GLP Vegetative Vigour Test Terrestrial Non Target Plants (Based on OECD Guideline 227) – 2012 Stockbridge Technology Centre Ltd Study No.: STC/12/E686 GLP, not published	Y	Globa-chem NV	Y
IIIA 10.8.1.2-02	2012	Evaluation of the Phytotoxicity of Diquat 200 SL GLP Vegetative Vigour Test Terrestrial Non Target Plants (Wheat, Onion and Cabbage) (Based on OECD Guideline 227) – 2012 Stockbridge Technology Centre Ltd Study No.: STC/12/E713 GLP, not published	Y	Globa-chem NV	Y

* in case of an earlier submission (for an earlier application)

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.