



## HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

### 1. WEDERZIJDSE ERKENNING

Op 27 juli 2016 is van

Certiplant N.V.  
Lichtenberglaan 2045  
B-3800 SINT-TRUIDEN  
Belgium

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

#### **Dragoon**

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

**HET COLLEGE BESLUIT** tot uitbreiding van de toelating van bovenstaand middel.

Alle bijlagen, waaronder registratierapport deel A en deel B, vormen een onlosmakelijk onderdeel van dit besluit.

#### **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 voorgescreven.

#### **1.3 Classificatie en etikettering**

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

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

**1.4 Aflever- en opgebruiktermijn (respijtperiode)**

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

**2. WETTELIJKE GRONDSLAG**

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

**3. BEOORDELINGEN****3.1 Fysische en chemische eigenschappen**

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

**3.2 Analysemethoden**

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

**3.3 Risico voor de mens**

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

**3.4 Risico voor het milieu**

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

**3.5 Werkzaamheid**

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

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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, 3 maart 2017

HET COLLEGE VOOR DE TOELATING VAN  
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw  
Voorzitter

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## BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

### 1 Aanvraaginformatie

*Aanvraagnummer:* 20161114 NLWERGU  
*Type aanvraag:* NLWERGU  
*Middelnaam:* Dragoon  
*Verzenddatum aanvraag:* 20 juli 2016  
*Formele registratiedatum: \** 26 augustus 2016  
*Datum in behandeling name:* 10 oktober 2016

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

### 2 Stofinformatie

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

De stof is per 1 januari 2002 geplaatst op Annex I van Richtlijn 91/414/EEG (01/21/EC d.d. 5 maart 2001) en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd. De expiratiedatum van de stof is verlengd tot 30 juni 2017 (Uitvoeringsverordening (EU) 2016/549 d.d. 8 april 2016).

### 3 Toelatingsinformatie

*Toelatingsnummer:* 13849 N  
*Expiratiedatum:* 30 juni 2018  
*Afgeleide parallel of origineel:* Origineel  
*Biocide, gewasbeschermingsmiddel of toevoegingsstof:* Gewasbeschermingsmiddel  
*Gebruikers:* Professioneel

### 4 W-coderingen en aflever- en opgebruiktermijnen

- *W-codering professioneel gebruik:* W2
- *Vorige w-codering professioneel gebruik:* W1
- *Aflevertermijn professioneel gebruik:* 6 maanden
- *Opgebruiktermijn professioneel gebruik:* 6 maanden

### 5 Verpakkingsinformatie

*Aard van het preparaat:*  
Met water mengbaar concentraat

**BIJLAGE II Etikettering van het middel Dragoon**

Professioneel gebruik

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

Pictogram	GHS05 GHS06 GHS08 GHS09
Signaalwoord	GEVAAR
Gevarenaanduidingen	H290 Kan bijtend zijn voor metalen. H302 Schadelijk bij inslikken. H315 Veroorzaakt huidirritatie. H317 Kan een allergische huidreactie veroorzaken. H319 Veroorzaakt ernstige oogirritatie. H331 Giftig bij inademing. H335 Kan irritatie van de luchtwegen veroorzaken. H372 Veroorzaakt schade aan organen <of alle betrokken organen vermelden indien bekend> bij langdurige of herhaalde blootstelling. H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P102 Buiten het bereik van kinderen houden. P261 Inademing van stof/rook/gas/nevel/damp/spuitnevel vermijden. P270 Niet eten, drinken of roken tijdens het gebruik van dit product. P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. P284 Adembescherming dragen. P301 + P310 NA INSLIKKEN: Onmiddellijk een ANTIGIFCENTRUM/arts/... raadplegen. 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. P391 Gelekte/gemorste stof opruimen. P501 Inhoud/verpakking afvoeren naar .... SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt. SPe 3 Om [in het water levende organismen/niet tot de doelsoorten behorende planten en dieren/niet tot de doelsoorten behorende geleedpotigen/ insecten] te beschermen mag u in een bufferzone van (geef de afstand aan) rond [niet-landbouwgrond/oppervlaktewater] niet spuiten. SPo 2 Was alle beschermende kleding na gebruik.
Aanvullende etiketelementen	EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

**Bijlage III. WG-format 2.0 WG professioneel gebruik****Wettelijk Gebruiksvoorschrift**

Het middel is uitsluitend toegelaten als onkruidbestrijdingsmiddel of doodspuitmiddel voor het professionele gebruik in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de hierna vermelde toepassingsvoorwaarden.

**Toepassingsvoorwaarden:**

Toepassings-Gebied	Type toepassing	Werkzaamheid getoetst op	Dosering* middel per toepassing	Maximale dosering middel per toepassing	Maximaal aantal toepassingen per teeltcyclus of per 12 maanden	Veiligheidstermijn in dagen
Aardappelen	voor opkomst	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per teeltcyclus	-
	doodspuiten	aardappelloof	4 l/ha	4 l/ha	1 per teeltcyclus	-
Bieten	voor opkomst	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per teeltcyclus	-
Cichorei	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5 l/ha**	1,5 l/ha	1 per teeltcyclus	-
Aardbei (onbedekt)	Na opkomst, tussen de rijen	Eenjarige breedbladige onkruiden	1,5 l/ha**	1,5 l/ha	1 per teeltcyclus	-
Bladgroenten (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per 12 maanden	-
Peulgroenten (onbedekt)	voor opkomst	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per teeltcyclus	-
Vruchtgroenten (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per teeltcyclus	-
Koolgewassen (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per 12 maanden	-
Wortel- en knolgewassen (onbedekt)	voor opkomst	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per 12 maanden	-

Toepassings- Gebied	Type toepassing	Werkzaamheid getoetst op	Dosering* middel per toepassing	Maximale dosering middel per toepassing	Maximaal aantal toepassingen per teeltcyclus of per 12 maanden	Veiligheidsstermijn in dagen
Ui-achtigen	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5 l/ha	1,5 l/ha	1 per 12 maanden	-
Stengelgroenten (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per 12 maanden	-
Sierteeltgewassen (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5 l/ha**	1,5 l/ha	1 per 12 maanden	-
Bloembol- en bloemknolgewassen (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per 12 maanden	-

\* Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken. Werkzaamheid is bij lagere dosering niet beoordeeld.

\*\*Dragoon dient altijd in combinatie met een uitvloeier op basis van alcoholethoxylaat te worden toegepast in de teelt van chicorei, aardbei en sierteeltgewassen.

### Overige toepassingsvoorwaarden

In ui-achtigen Dragoon toepassen in 500 liter water per ha. In de overige toepassingen Dragoon toepassen in 200-500 liter water per ha.

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

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

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

In de teelt van chicorei, aardbei, ui-achtigen en sierteeltgewassen kan de werking onvoldoende zijn.

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**Bijlage II**

**RISKMANAGEMENT**

## 1. Identity of the plant protection product

### 1.1 Applicant

Certiplant NV  
Lichtenberglaan 2045  
B-3800 Sint-Truiden  
Belgium

### 1.2 Identity of the active substance

Common name	Diquat
Name in Dutch	Diquat
Chemical name	9,10-dihydro-8a,10a-diazoniaphenanthrene ion (diquat) [IUPAC]
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 1 January 2002. From 14 June 2011 forward, according to Reg. (EU) No 540/2011 the substance is approved under Reg. (EC) No 1107/2009, repealing Directive 91/414/EEC. The expiration date of the active substance is extended until 30 June 2017.

### 1.3 Identity of the plant protection product

Name	Dragoon
Formulation type	SL, soluble concentrate
Content active substance	200 g/L pure diquat, equivalent to 374 g/L pure diquat dibromide)

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

### 1.4 Function

Herbicide

### 1.5 Uses applied for

See GAP (Appendix I).

### 1.6 Background to the application

Application for the extension of a mutual recognition with applications in chicory, strawberries and floriculture crops.

### 1.7 Packaging details

#### 1.7.1 Packaging description

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

#### 1.7.2 Detailed instructions for safe disposal

No particular recommendations.

## **2. Physical and chemical properties**

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

## **3. Methods of analysis**

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

## **4. Mammalian toxicology**

### **4.1 Toxicity of the formulated product (IIIA 7.1)**

For the evaluation of the toxicity of the formulated product Dragoon, we refer to the member state of the original authorisation (UK).

### **4.2 Dermal absorption (IIIA 7.3)**

UK used a value of 1% for diquat for dermal absorption in the risk assessment and since this application is a request for mutual recognition the value of 1% is also used in this risk assessment.

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

For toxicological data relating to non-active substances we refer to the registration report written by 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 Dragoon, a herbicide based on the active substance diquat.

Dragoon is a SL formulation and contains 200 g/L diquat.

The formulation Dragoon is applied once during the period February-August. 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 and approved under Regulation (EC) No 1107/2009, 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 in rat (90-day endpoint) is used for the risk assessment (see List of Endpoints).

This AOEL has also been used in the risk assessment performed by United Kingdom.

**Exposure/risk****Mechanical downward spraying**

Please, refer to the UK assessment, the same GAP for the intended uses is authorised in the UK. Furthermore, the use extension in the intended uses is covered by the risk envelope of the current authorisation regarding Dragoon in the Netherlands.

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

**Manual downward spraying**

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

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

**4.4.2 Bystander exposure/risk**

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

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

**Table T.4 Internal bystander and resident exposure to diquat and risk assessment for the application of Dragoon**

Route		Estimated internal exposure <sup>a</sup> (mg/day)	Systemic AEL (mg/day) <sup>b</sup>	% AEL <sup>c</sup>
<i>Bystander exposure during application in intended uses according to the German model</i>				
Child	Total	0.0018	0.02	11
Adult	Total	0.0084	0.06	14
<i>Resident exposure during application in intended uses according to the German model</i>				
Child	Total	0.0087	0.02	54
Adult	Total	0.0172	0.06	29

Route		Estimated internal exposure <sup>a</sup> (mg/day)	Systemic AEL (mg/day) <sup>b</sup>	% AEL <sup>c</sup>
<i>Bystander exposure during application in intended uses according to the UK method</i>				
Adult	Total	0.0105	0.06	18
<i>Resident exposure during application in intended uses according to the UK method</i>				
Child	Respiratory	0.0083	0.02	55
	Dermal+Oral	0.0002	0.02	2

a External exposure was estimated according to 1) the German guidance paper for exposure and risk assessment for bystanders and residents (Martin *et al.* 2008, *J. Verbr. Lebensm.* 3: 272-281), and 2) the UK method. Internal exposure was calculated with:

- biological availability via the respiratory route: 100% (worst case)
- biological availability via the dermal route: 1% (spray dilution)
- biological availability via the oral route: 10% (see List of Endpoints)

b From the systemic AEL of 0.001 mg/kg bw/day a specific AEL is derived assuming a body weight of 16.15 or 15 kg for children in the German model or UK method, respectively, and of 60 kg for adults.

c The % AEL is calculated by dividing the internal exposure by the systemic AEL and multiplying this by 100%.

#### 4.4.3 Worker exposure/risk

Please, refer to the UK assessment, the same GAP for the intended uses is authorised in the UK. Furthermore, the use extension in the intended uses is covered by the risk envelop of the current authorisation regarding Dragoon in the Netherlands.

In conclusion, it is not expected that due to respiratory and dermal exposure to diquat as the result of the application of Dragoon in the intended uses an unacceptable risk occurs for unprotected workers.

#### 4.4.4 Re-entry

See 4.4.3 Worker exposure/risk.

### Overall conclusion of the exposure/risk assessments of operator, bystander, and worker

The product complies with the Uniform Principles.

#### Operator exposure

For the unprotected operator, adverse health effects after dermal/respiratory exposure to diquat as a result of the application of Dragoon in chicory, strawberries and floriculture crops cannot be excluded. Correct use of personal protective equipment will reduce the dermal exposure and respiratory exposure and results in a sufficient reduction of the exposure to diquat for the application of Dragoon in chicory, strawberries and floriculture crops.

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

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

#### 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 Dragoon in chicory, strawberries and floriculture crops.

#### 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 chicory, strawberries and floriculture crops due to exposure to diquat after application of Dragoon.

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

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

See List of Endpoints.

#### **4.6 Data requirements**

None.

#### **4.7 Combination toxicology**

Dragoon 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.

### **6. Environmental fate and behaviour**

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

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

#### **List of Endpoints Fate/behaviour**

The LoEP is taken from the final registration report 2001/21/EC OJ L69; dd 10/03/2001.

**Fate and behaviour in soil****Route of degradation**

Aerobic:

Mineralization after 100 days:

Microbial degradation has been demonstrated only in isolation due to strong adsorption to soil.

Non-extractable residues after 100 days:

Not relevant. See comment above.

Relevant metabolites above 10 % of applied active substance: name and/or code  
% of applied rate (range and maximum)

Not relevant. See comment above.

Supplemental studies

Anaerobic:

Relatively stable, withstands degradation

Soil photolysis:

No significant degradation in 32 d

Remarks:

Standard requirements are not applicable due to strong adsorption to soil.

**Rate of degradation**

Laboratory studies

DT<sub>50lab</sub> (20 °C, aerobic):

No measurable degradation in soil under laboratory conditions after one year.

DT<sub>90lab</sub> (20 °C, aerobic):

Not relevant. See comment above.

DT<sub>50lab</sub> (10 °C, aerobic):

Not relevant. See comment above.

DT<sub>50lab</sub> (20 °C, anaerobic):

Not relevant. See comment above.

Field studies (country or region)

DT<sub>50f</sub> from soil dissipation studies:DT<sub>50</sub> = 10 - 20 y (UK), 1.2 - 3.6 y (US)DT<sub>90f</sub> from soil dissipation studies:DT<sub>90</sub> 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 <i>et al</i> , 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 bioassay (SAC-WB). Most soils have a large excess in adsorption capacity. For very sandy soil exceedance may be a possibility following repeated high application rates.

**Fate and behaviour in water****Abiotic degradation**

Hydrolytic degradation:

No sterile hydrolysis at environmental pHs.

Relevant metabolites:

None

Photolytic degradation:

 $DT_{50} < 7$  d (UK summer conditions)

Relevant metabolites:

None

**Biological degradation**

Ready biological degradability:

No, due to rapid adsorption by sediment or suspended solids.

Water/sediment study:

 $DT_{50} = 12 - 24$  hours.

DT<sub>50</sub> water:DT<sub>90</sub> water:DT<sub>50</sub> whole system:DT<sub>90</sub> 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<sup>-8</sup> kPa at 25 °C

Henry's law constant:

5 · 10<sup>-12</sup> Pa·m<sup>3</sup>·mol<sup>-1</sup>**Photolytic degradation**

Direct photolysis in air:

Not relevant, due to low vapour pressure.

Photochemical oxidative degradation in air

Not relevant, due to low vapour pressure.

DT<sub>50</sub>:

Volatilisation:

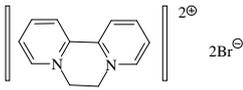
Not relevant, due to low vapour pressure.

Remarks:

None

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

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

Compound name	IUPAC name	Structural formula	Structure	Molecular Weight [g/mol]	Observed in study (% of occurrence/formation)
diquat (ion), diquat dibromide	9,10-dihydro-8a,10a-diazoniaphenanthrene ion (dibromide)	C <sub>12</sub> H <sub>12</sub> N <sub>2</sub> , C <sub>12</sub> H <sub>12</sub> Br <sub>2</sub> N <sub>2</sub>		184.2 (diquat)	Parent substance

## 6.1 Fate and behaviour in soil

### 6.1.1 Persistence in soil

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

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

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

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

The leaching potential of the active substance diquat (as diquat dibromide) is calculated in the first tier using Pearl 4.4.4 and the FOCUS Kremsmünster scenario. Input variables are the actual worst-case application rate of 0.3 kg a.s./ha, the crop (resp. winter cereals (chicory), strawberries (strawberries) and winter cereals (floriculture crops) and an interception value appropriate to the crop stage of 0.0 (pre-emergence and/or post planting application). Date of yearly application is May 25<sup>th</sup> (default).

For metabolites all available data concerning substance properties are regarded. No metabolites occurred above > 10 % of AR, > 5 % of AR at two consecutive sample points or had an increasing tendency. The following input data are used for the calculation:

#### PEARL:

Active substance: diquat (as diquat dibromide)

DT<sub>50</sub> for degradation in soil (20°C): 3650 days (UK soil dissipation study)

Median K<sub>om</sub> (pH-independent): 928074 L/kg (n=32)

1/n: 0.9 (default)

Saturated vapour pressure: 1 x 10<sup>-5</sup> Pa (25 °C)

Solubility in water: 718 g/L (20 °C)

Molecular weight: 184.2 g/mol

Q10: 2.2

Plant uptake factor: 0.0

Other parameters: standard settings of PEARL 4.4.4

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

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

Use	Substance	Rate substance [kg/ha]	Freq. / Int. [days]	Fraction intercepted	PEC groundwater [µg/L]
Chicory	diquat (as diquat dibromide)	0.3	1 / -	0	<0.001
Strawberries	diquat (as diquat dibromide)	0.3	1 / -	0	<0.001
Floriculture crops	diquat (as diquat dibromide)	0.3	1 / -	0	<0.001

\* interception values derived from Table 1.5 in Generic Guidance for Tier 1 FOCUS Ground Water Assessments. (FOCUS, 2011). An interception of 0 is appropriate for the crops applied for, as the application is pre-emergence/ pre-planting or post-planting.

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

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

### Monitoring data

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

### Conclusions

The proposed applications of the product Dragoon comply with the requirements laid down in the Bgb concerning leaching to groundwater.

## 6.2 Fate and behaviour in water

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

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

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

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

**TOXSWA:**

Active substance diquat (as diquat dibromide) :

DT<sub>50</sub> for degradation in water at 20°C: 1000 days (no degradation in the total system)

DT<sub>50</sub> for degradation in sediment at 20°C: 1000 days (default).

Median K<sub>om</sub> for suspended organic matter: 928074 L/kg

Median K<sub>om</sub> for sediment: 928074 L/kg

1/n: 0.9 (default)

Saturated vapour pressure:  $1 \times 10^{-5}$  Pa (25 °C)

Solubility in water: 718 g/L (20 °C)

Molecular weight: 184.2 g/mol

Q10: 2.2

Other parameters: standard settings TOXSWA

When no separate degradation half-lives (DegT<sub>50</sub> values) are available for the water and sediment compartment (accepted level P-II values), the system degradation half-life (DegT<sub>50</sub>-system, level P-I) is used as input for the degrading compartment and a default value of 1000 days is to be used for the compartment in which no degradation is assumed. This is in line with the recommendations in the FOCUS Guidance Document on Degradation Kinetics.

For metabolites, the level M-I values are used (system DegT<sub>50</sub> value) only, since level M-II criteria have not been fully developed under FOCUS Degradation Kinetics.

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

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

Use	Substance	Rate a.s. [kg/ha]	Freq./ Inter- val [days]	Drift [%]	PIEC [µg/L] *	PEC21 [µg/L] *	PEC28 [µg/L] *
All uses	diquat (as diquat dibromide)	0.3	1 / -	1	0.152	0.124	0.114

\* calculated according to TOXSWA

#### *PEC<sub>sediment</sub>*

To address the risk to sediment organisms, a PEC<sub>sediment</sub> value is needed for active substance diquat (as diquat dibromide) . The PEC<sub>sediment</sub> values calculated with TOXSWA are expressed in g a.s./m<sup>3</sup> sediment. This PEC<sub>sediment</sub> 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<sup>3</sup>. The maximum PEC value in sediment in the top 1 cm of sediment is reached at day 34 after the first application. See Table M.2b for calculation of PEC<sub>sediment</sub>.

**Table M.2b Maximum sediment concentration for active substance diquat (as diquat dibromide) following spring application (worst-case)**

Use	Substance	Rate a.s. [kg/ha]	Drift [%]	PEC <sub>sediment</sub>	PEC <sub>sediment</sub>
				[g a.s./m <sup>3</sup> sediment] *	[mg a.s./kg sediment dw]**
				spring	Spring
All uses	diquat (as diquat dibromide)	0.3	1	0.0175	0.219

\* TOXSWA output

\*\* calculated as (PEC<sub>sed</sub> in g/m<sup>3</sup> / 80 kg/m<sup>3</sup>) x 1000 (conversion of g/kg to mg/kg)

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

### **Monitoring data**

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

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

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

### Active substance diquat (as diquat dibromide)

There are no data available in the Pesticide Atlas regarding the presence of the substance diquat in surface water.

### **Drinking water criterion**

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

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

It follows from the decision of the Court of Appeal on Trade and Industry of 19 August 2005 (Awb 04/37 (General Administrative Law Act)) that when considering an application, the Ctgb should, on the basis of the scientific and technical knowledge and taking into account the data submitted with the application, also judge the application according to the drinking water criterion 'surface water intended for drinking water production'.

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

The assessment methodology followed is developed by the WG implementation drinking water criterion and outlined in Alterra report 1635<sup>2</sup>.

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).
  - o If for an existing substance based on monitoring data no problems are expected by VEWIN, Ctgb follows this VEWIN assessment.
  - o If for an existing substance based on monitoring data a potential problem is identified by VEWIN, Ctgb assesses whether the 90<sup>th</sup> percentile of the monitoring data meet the drinking water criterion at each individual drinking water abstraction point.

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

### **6.3 Fate and behaviour in air**

#### **Route and rate of degradation in air**

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

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

#### **6.4 Appropriate fate and behaviour end-points relating to the product and approved uses**

See List of Endpoints.

#### **6.5 Data requirements**

None.

**The following restriction sentences were proposed by the applicant:**

-

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

-

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

## 6.6 Overall conclusions fate and behaviour

It can be concluded that:

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

## 7. Ecotoxicology

E.M. 2.0 Risk assessment is done in accordance with Chapter 2 of the RGB published in the Government Gazette (Staatscourant) 188 of 28 September 2007, including the updates of 20 October 2009 (which came into effect on 1 January 2010) and 18 April 2011 (which came into effect on 23 April 2011).

The underlying risk assessment is based on the final list of endpoints for diquat and on the UK authorisation of Dragoon.

### List of Endpoints Ecotoxicology

Diquat is placed on Annex I since 2002. For the risk assessment the LoEP from the final conclusion (03/2001) is used.

### Ecotoxicology

#### Terrestrial Vertebrates

Acute toxicity to mammals:

Short term oral toxicity to mammals:

Acute toxicity to birds:

Dietary toxicity to birds:

Reproductive toxicity to birds:

LD50 (diquat ion - rat)= 214 - 222 mg/kg bw
NOAEL 8.9mg /kg bw/d, 90 day rat (diquat ion) NOAEL 0.5 mg/kg bw/d, 1 y dog - (diquat ion)
LD <sub>50</sub> = 83 mg /kg bw (diquat ion) <i>Anas platyrhynchos</i>
LC <sub>50</sub> = 721 ppm, 5 d study (diquat ion) <i>Coturnix japonica</i> (162 mg a.s./kg bw/d, recalculated by applicant)
NOEC = 5 mg/kg (diquat ion) (= 0.6 mg a.s./kg bw/d based on FIR/bw 0.121 <sup>1</sup> )  28 d NOEC = 100 ppm = 21.7 mg a.s./kg bw/d (Mallard ducklings, 1 d old) <sup>2</sup>  9 w NOEC = 40 ppm = 6.6 mg a.s./kg bw/d (Mallard duck)  12 w NOEC = <80 ppm (Mallard duck), quick recovery – see discussion below <sup>2</sup>

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

<sup>2</sup> evaluated in RIVM-report 12465A00

### Relevant long-term toxicity value

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

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

### Long-term toxicity of diquat to birds

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

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

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

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

$$\text{Female feed consumption at plateau} = \text{Feed}_{\text{week1}} + 2 * (\text{Feed}_{\text{week5-9}} - \text{Feed}_{\text{week1}})$$

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

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

The Temple et al. study of 2009 was furthermore initiated to give an answer to the question whether outside the breeding period a NOEC of 21.7 mg/kg bw/d for adult birds could be used instead of a NOEC of 9.4 mg/kg bw/d which is the applicable NOEC for the reproductive phase of the birds. Clinical observations of adults did not show overt signs of toxicity and gross pathology did not show treatment related abnormalities. Feed consumption was significantly reduced during week 1 in the 80 mg diquat cation per kg food (~ 11.1 mg/kg bw/d) but not in the 5 following weeks of exposure. Feed consumption was significantly reduced during week 1, 3, 4, 5 and 6 in the 160 mg diquat cation per kg food (~ 19.7 mg/kg bw/d). Feed consumption after the exposure period was comparable to the control group.

No significant changes in body weight were noticed in any of the two exposure levels.

There was a marked reduction of number of eggs laid during the 6 weeks exposure period in both treatment groups. During the withdrawal phase the 80 mg diquat per kg food treatment group (11.1 mg/kg bw/d) recovered quickly. Egg production in the 160 mg diquat per kg food treatment group (19.7 mg/kg bw/d) remained depressed in the first week of the withdrawal phase, increased during the second week and was comparable to the control during the third and following weeks of the experiment. No other reproductive effects were noticed. If the application of Reglone is during the egg-laying season, the NOEL of 10 mg as/kg bw/d can be used for mallard. For quail a slightly lower NOEL of 9.4 mg as/kg bw/d is available. Therefore, the relevant endpoint during the egg-laying season is 9.4 mg as/kg bw/d.

From the Temple et al. study of 2009 it could be concluded that the use of diquat will not influence the breeding success in the following breeding period. It is evident that birds do not like diquat and probably will look for other types of food. No other effects have been noticed that are relevant for the survival of birds outside the breeding period. Therefore, if the application of Reglone is outside the egg-laying season, the NOEL for duckling development can be used, which is 21.7 mg/kg bw/d based on the Frey et al study from 1995.

### Aquatic Organisms

Acute toxicity fish:

LC<sub>50</sub> = 21 mg /l, 96 h static study (diquat ion)

*Oncorhynchus mykiss*

LC<sub>50</sub> = 6.1 mg /l, 96 h flow through study (diquat ion)

*Oncorhynchus mykiss*

Long term toxicity fish:	<i>Pimephales promelas</i> 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 <sub>50</sub> = 1.2 mg/l, 48 h study <i>Daphnia magna</i> (diquat ion)
Chronic toxicity invertebrate:	21-day LC50 was 0.16 mg/l based on nominal concentration <i>Daphnia magna</i> (diquat ion). 21-day NOEC = 0.125 mg/l based on nominal concentration.
Acute toxicity algae:	EC <sub>50</sub> = 0.011 - 1.0 mg/l, 96 h study (diquat ion) <i>Psuedokirchneriella subcapitata</i> (syn. <i>Rhaphidocellis subcapitata</i> and <i>Selenastrum capricornutum</i> )
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). <i>Psuedokirchneriella subcapitata</i> (syn. <i>Rhaphidocellis subcapitata</i> and <i>Selenastrum capricornutum</i> )
Chronic toxicity sediment dwelling organism:	NOEC > 100 mg diquat ion/kg <sup>-1</sup> sediment (diquat ion). <i>Chironomus riparius</i>
Acute toxicity aquatic plants:	No data requirement set at time of review.

### Honeybees

Acute oral toxicity:	LD <sub>50</sub> = 13 µg /bee (diquat ion)
Acute contact toxicity:	LD <sub>50</sub> = 60 µg /bee (diquat ion)

### Other arthropod species

Test species	% Effect
<i>Aphidius rhopalosiphi</i>	An extended laboratory study. At full field rate (i.e. 5 l/ha) there was significant mortality of wasps in the treatment compared to the control. No adverse effects were noted on either fecundity or behaviour.
<i>Coccinella septumpunctata</i> .	Extended laboratory study. Bean plants treated with 'Reglone' at 5 l/ha (1000 g /ha) - equivalent to the maximum field rate. Larvae of <i>Coccinella septumpunctata</i> exposed to residues of the test substance. Corrected pre-imaginal mortality of <i>Coccinella septumpunctata</i> was 58%, mortality for the positive control was 78.9%. The reproduction rate was: <ul style="list-style-type: none"> <li>• 640.9 eggs/female in the treatment</li> </ul>

	<ul style="list-style-type: none"> <li>• 255.3 eggs/female in the control.</li> </ul> <p>R value 151.0%. Results within the range of historical control variability. IOBC classification : slightly harmful</p>
<i>Trichogramma cacoeciae</i>	<p>Laboratory study: exposed to 'Reglone' at 1000 g diquat ion/ha - equivalent to maximum field rate. Parasitisation capacity reduced by 58 %. Exposed adults reduced by 98%.</p>
<i>Chrysoperla carnea</i>	<p>Laboratory study: exposed to 'Reglone' at 1600 g diquat ion/ha. 96% mortality recorded in exposed larvae.</p>
<i>Pterosticus melanarius</i>	<p>Exposed to 'Reglone' at 1600g diquat ion/ha on loamy sand. No lethal or sublethal effects.</p>
<i>Pardosa spp.</i>	<p>Exposed to 'Reglone' at 1600g diquat ion/ha on loamy sand. No lethal or sublethal effects.</p>

**Earthworms**

Acute toxicity:	<p>LC<sub>50</sub> = 130 mg as/kg soil 14 day (diquat ion) NOEC &gt; 18 mg as/kg soil 14 day (diquat ion)</p>
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**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

**Dragoon (200 g/L diquat)**

Additional studies were summarized and evaluated by EPP consultancy (report 120603, 06/2012). These studies were submitted for Dragoon 13849 N and are used as well for the current application.

**Aquatic Organisms**

Acute toxicity aquatic plants ( <i>Lemna minor</i> ):	<p>7-d E<sub>r</sub>C<sub>50</sub> 357 µg form*/L (62.5 µg a.s./L) 7-d E<sub>b</sub>C<sub>50</sub> 173µg form./L (30.2 µg a.s./L) 7-d NOE<sub>r,b</sub>C 33.7 µg form./L (5.9 µg a.s./L)</p>
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\* SL formulation containing 203.5 g diquat/L (174.9 g diquat/kg)

**Other arthropod species**

Test species	Organism stage/Type of test	Value/ Adverse effect
<i>Typhlodromus pyri</i>	Protonymphs 2-3 days old/Dried residues on sprayed sweet-pepper leaves	<p>Mortality: LR<sub>50</sub> 23.4 mL form*/ha (4.75 g a.s./ha) Reproduction: ER<sub>50</sub> &gt;64.0 mL form./ha (&gt;13.0 g a.s./ha)</p>

*Chrysoperla carnea* Larvae 2-4 days old/Dried residues on sprayed bean plants

Mortality: LR<sub>50</sub> 4.46 L form./ha (0.90 kg a.s./ha)  
 Reproduction (viable eggs/female/d):  
 2.0 L form./ha (0.41 kg a.s./ha) +16%\*\*  
 4.0 L form/ha (0.81 kg a.s./ha) 18%

\* SL formulation containing 202.9 g diquat/L

\*\* + means increase compared to control

### Earthworms

Reproduction toxicity (*Eisenia fetida*):

NOEC 248 mg form./kg dw (43.3 mg a.s./kg dw)

### Other soil non-target macro-organisms

Reproduction toxicity (*Folsomia candida*):

Mortality:  
 LR<sub>50</sub> 29.1 mg form./kg dw (5.08 mg a.s./kg dw)

Reproduction:  
 EC<sub>50</sub> 20.4 mg form./kg dw (3.56 mg a.s./kg dw)  
 NOEC 5.6 mg form./kg dw (0.98 mg a.s./kg dw)

### Effects on non-target plants

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

\* SL formulation containing 202.9 g diquat/L

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

The applicant has submitted a letter report on "Assessment of the effect of Diquat 200 g/L SL on the emergence of non-target terrestrial plants". This is a screening test performed with doses of 4-36 L formulation/ha in 9 plant species: *Allium cepa*, *Avena sativa*, *Brassica napus*, *Linum usitatissimum*, *Helianthus annuus*, *Lycopersicon esculentum*, *Pisum sp.*, *Daucus carota subsp. Sativus*, *Lactuca sativa*. In this letter it was concluded that at doses up to 36 L form/ha the emergence and plant weights are not affected. The report was not evaluated for reliability by Ctgb.

### Additional studies

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

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

Diet	n=	Initial residue value, 90 <sup>th</sup> ile or max, at 0.55 kg/ha (mg/kg fresh weight)	Initial residue value, 90 <sup>th</sup> ile or max, RUD for 1.0 kg/ha (mg/kg fresh weight)	Initial mean residue value at 0.55 kg/ha (mg/kg fresh weight)	Initial mean residue value, RUD at 1.0 kg/ha (mg/kg fresh weight)	DT <sub>50</sub> value (days)	21-day TWA residue (mg/kg)	f <sub>twa</sub>	r <sup>2</sup>	Ri <sup>c</sup>
Terrestrial vegetation	12	60.3 (90 <sup>th</sup> percentile) <sup>a</sup>	110	36.8	66.9	1.59	4.07	0.11	0.85	1
Terrestrial invertebrates (pitfall traps)	2	6.9 (maximum) <sup>a</sup>	12.5	4.80	8.73	1.23	0.40	0.084	0.76	1
Whole seeds	5	42 (maximum) <sup>a</sup>	76	22	40	13.4	14.2	0.61	0.15	3
Seeds without husk	5	64 (maximum) <sup>a</sup>	116	21	38	13.7	9.44	0.62	0.16	3
Crop seed	nd	nd <sup>b</sup>		0.521	nd <sup>b</sup>	4.62	0.155	0.31	0.24	3
Aquatic vegetation	nd	nd <sup>b</sup>		5.23	nd <sup>b</sup>	2.96	1.06	0.20	0.20	3
Aquatic invertebrates	nd	nd <sup>b</sup>		1.61	nd <sup>b</sup>	1.58	0.11	0.068	0.56	3
Aquatic tubers	nd	nd <sup>b</sup>		0.583	nd <sup>b</sup>	7.53	0.256	0.45	0.50	3
Aquatic seeds	nd	nd <sup>b</sup>		1.07	nd <sup>b</sup>	17.5	0.625	0.68	0.16	3

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

<sup>b</sup> Not given, because not relevant for the risk assessment.

<sup>c</sup> Ri = Risk index. Ri 1: acceptable; Ri 3: not acceptable. Ri values refer only to degradation, not to initial values.

#### Remarks:

The study is considered relevant for spray application of diquat in the Netherlands.

All initial residue values can be used for risk assessment. The recalculated DT<sub>50</sub> values, 21-day TWA residues and f<sub>twa</sub> for terrestrial vegetation and invertebrates can also be used for long-term risk assessment. For the other feed substances the fit was not good enough resulting in unreliable DT<sub>50</sub> values, 21-day TWA and f<sub>twa</sub> (Ri = 3).

The residue data from the Canadian field study are based on invertebrates sampled with pitfall traps. Thus, foliar dwelling invertebrates are not included, whilst it cannot be excluded that these will be exposed as well, and may be exposed to a higher degree because no crop interception takes place. However, two field studies with paraquat in which residues on invertebrates were measured after application of 1.1 kg paraquat/ha in an apple orchard and melon field in Spain (Bakker (2004 and 2005), evaluated in RIVM-report 10994A01), show a mean (over different invertebrate groups) maximum (in time) residue value of 6.43 mg a.s./kg for foliar dwelling/flying invertebrates. Considering the similarities in physico-chemical and fate/behaviour properties of paraquat and diquat, which makes a comparison of residue data acceptable, it can be concluded that the RUD value of 8.73 mg a.s./kg for diquat based on pitfall samples only, is not likely to result in an underestimation of exposure, and is therefore acceptable.

### Metabolites of diquat

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

### 7.1 Effects on birds

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

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

Table E.1 presents an overview of toxicity data.

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

	Endpoint	Value
Acute toxicity to birds:	LD <sub>50</sub>	83 mg a.s./kg bw
Reproductive toxicity to birds:	NOEL	5 ppm mg a.s./kg bw/d = 0.6 mg/kg bw/d

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

In addition to the acute toxicity value in the LoEP from the review report, another acute toxicity study with diquat was presented in the DAR (March 1996):

- test species: Partridge
- endpoint: LD<sub>50</sub> = 158 mg a.s./kg bw.

Also, another reproductive toxicity study with diquat was presented in the DAR (March 1996):

- test species: Bobwhite quail
- endpoint: NOEL = 9.4 mg a.s./kg bw/d.

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

### 7.1.1 Natural food and drinking water

#### **Sprayed products**

The risk assessment for birds is carried out following the latest guidance document by EFSA (*Anonymous 2009: Guidance Document on risk assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. European Food Safety Authority*), hereafter cited as GD (EFSA 2009). . These correspond with the bare soil, and strawberries scenarios. For the applications in strawberries (post-planting) the indicator species is a small omnivorous bird. For the application in bare soils and strawberries (pre-planting) the indicator species is a small granivorous bird. For uses with a frequency > 1, a MAF (Multiple Application Factor) may be applicable.

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

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

Crop group	Substance	Indicator species	LD <sub>50</sub> [mg a.s./ kg bw]	DDD			DDD <sub>m</sub> [mg a.s./ kg bw/d]	TER <sub>A</sub>	Trigger = 10
				Appl. rate [kg a.s./ha]	SV <sub>90</sub>	MAF <sub>90</sub>			
Strawberries	diquat	Small omnivorous bird	115	0.3	158.8	1	47.6	2.41	
Bare soils		Small granivorous bird			24.7	1	7.41	15.5	

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

Crop group	Substance	Indicator species	NOEL [mg a.s./kg bw]	DDD				DDD <sub>m</sub> [mg a.s./ kg bw/d]	TER <sub>LT</sub>	Trigger = 5
				Appl. rate [kg a.s./ha]	SV <sub>m</sub>	TWA	MAF <sub>m</sub>			
Strawberries	Diquat	Small omnivorous bird	0.6	0.3	64.8	0.53	1	10.3	0.06	
Bare soils	Diquat	Small granivorous bird	0.6	0.3	11.4	0.53	1	1.81	0.33	

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

#### Tier 1 assessment

For the applications in strawberries (post-planting), generic focal species are the small omnivorous bird "lark" and the small insectivorous bird "wagtail". For the application in bare soils the screening

assessment indicates a low acute risk. Thus, Tier 1 acute risk assessment is performed only for the application in strawberries (post-planting). For the long-term risk, a Tier 1 assessment is conducted for all proposed applications, as a risk was indicated in the screening level long-term assessment for all proposed uses.

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

Crop group	Substance	Indicator species	LD <sub>50</sub> [mg a.s./ kg bw]	DDD			DDD <sub>m</sub> [mg a.s./ kg bw/d]	TER <sub>A</sub>	Trigger
				Appl. rate [kg a.s./ha]	SV <sub>90</sub>	MAF <sub>90</sub>			
Strawberries (BBCH 10-39)	Diquat	Small omnivorous bird "lark" (BBCH 10-39)	115	0.3	24	1	7.2	16.0	
		Small insectivorous bird "wagtail" (BBCH 10-19)		0.3	26.8	1	8.04	14.3	
		Small insectivorous bird "wagtail" (BBCH ≥ 20)		0.3	25.2	1	7.56	15.2	

\*Calculated by the Ctgb assessor based on a default DT<sub>50</sub> of 10 days.

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

Crop group	Substance	Generic focal species	NOEL [mg a.s./kg bw]	DDD				DDD <sub>m</sub> [mg a.s./ kg bw/d]	TER <sub>LT</sub>	Trigger
				Appl. rate [kg a.s./ha]	SV <sub>m</sub>	TWA	MAF <sub>m</sub>			
Strawberries (BBCH 10-39)	diquat	Small omnivorous bird "lark" (BBCH 10-39)	0.6	0.3	10.9	0.53	1	1.73	<b>0.35</b>	5
		Small insectivorous bird "wagtail" (BBCH 10-19)			11.3	0.53	1	1.80	<b>0.33</b>	
		Small insectivorous bird "wagtail" (BBCH ≥ 20)			9.7	0.53	1	1.54	<b>0.39</b>	
Bare soils (00- 09)	diquat	Small granivorous bird "finch" (BBCH < 10)	0.6	0.3	11.4	0.53	1	1.81	<b>0.33</b>	5
		Small omnivorous bird "lark" (BBCH < 10)			8.2	0.53	1	1.30	<b>0.46</b>	
		Small insectivorous bird "wagtail" (BBCH < 10)			5.9	0.53	1	0.94	<b>0.64</b>	

Acute Tier 1 risk assessment (Table E.3a) indicates an acceptable risk as the TER value for all generic focal species is above the trigger of 10. However, a long-term risk to birds is expected as all TER values (Table E3.b) are below the trigger of 5. Further refinement of the risk is given below.

### Refined risk assessment

#### Relevant endpoints

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

**Table E.4 Refined risk for birds**

Crop group	Substance	Generic focal species	LD <sub>50</sub> or NOEL [mg a.s./kg bw (d)]	DDD			DDD <sub>m</sub> [mg a.s./kg bw/d]	TER <sub>A/LT</sub>	Trigger	
				Appl. rate [kg a.s./ha]	SV <sub>90/m</sub>	TWA				MAF <sub>90/m</sub>
Strawberries (BBCH 10-39)	Diquat	Small omnivorous bird "lark" (BBCH 10-39) (covering for BBCH ≥ 40)	9.4	0.3	0.4	0.53	1	1.73	5.42	5
		Small insectivorous bird "wagtail" (BBCH 10-19)			11.3	0.53	1	1.80	5.23	
		Small insectivorous bird "wagtail" (BBCH ≥ 20)			9.7	0.53	1	1.54	6.09	
Bare soils (BBCH 00-09)		Small granivorous bird "finch" (BBCH < 10)			11.4	0.53	1	1.81	5.19	
		Small omnivorous bird "lark" (BBCH < 10)			8.2	0.53	1	1.30	7.21	
		Small insectivorous bird "wagtail" (BBCH < 10)			5.9	0.53	1	0.94	10.02	

The results shown in Table E.4 indicate acceptable long-term risk to birds for all proposed applications of diquat.

## **Conclusion**

An acceptable risk is expected for the all proposed applications.

### Risk for birds through drinking water

#### *Leaf scenario*

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

#### *Puddle scenario*

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

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

According to EFSA Guidance Document for Birds and Mammals (2009), no specific calculations are necessary when the ratio of effective application rate (in g a.s./ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ( $K_{oc} < 500$  L/kg) or 3000 in the case of more sorptive substances ( $K_{oc} \geq 500$  L/kg). The mean  $K_{oc}$  of diquat is 2,184,750 L/kg. The ratio of effective application rate to acute endpoint is  $300 \text{ g a.s./ha} / 83 \text{ mg a.s./kg bw} = 3.6$ , and the ratio of application rate to chronic endpoint is  $300 \text{ g a.s./ha} / 0.6 \text{ mg a.s./kg bw/d} = 500$ . Neither ratio exceeds the trigger of 3000. The risk due to exposure to drinking water from puddles is concluded to be acceptable.

### **7.1.2 Secondary poisoning**

The risk as a result of secondary poisoning is assessed based on bio concentration in fish.

Since the  $\log K_{ow}$  of diquat  $< 3$  (-4.6), the potential for bioaccumulation is considered low and no further assessment is deemed necessary.

## **Conclusions birds**

The application for extension of the product complies with the RGB for all proposed applications.

## **7.2 Effects on aquatic organisms**

### **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 PEC<sub>sw</sub> 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.5. Because the application for authorisation concerns a herbicide, also the effects on macrophytes (aquatic plants) are evaluated.

**Table E. 5 overview toxicity endpoints for aquatic organisms**

Substance	Organism	Lowest		Toxicity value [µg/L]
		L(E)C <sub>50</sub> [mg/L]	NOEC [mg/L]	
	<i>Acute</i>			
	Algae	0.011		11
	Invertebrates	1.2		1200
	Fish	6.1		6100
Diquat	Macrophytes	0.0302*		30.2
	<i>Chronic</i>			
	Invertebrates		0.125	125
	Fish		0.12	120

\*no information in the DAR. Endpoint derived from a study with the formulated product, submitted by applicant for the current application.

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<sub>50</sub>-value) and 10 for algae and macrophytes (0.1 times the lowest EC<sub>50</sub>-value). Trigger values for chronic exposure are 10 for invertebrates and fish (0.1 times the lowest NOEC-values).

For acute and chronic risk, the initial concentration is used (PIEC).  
In tables E.6a and E.6b TER values for aquatic organisms are shown.

**Table E.6a TER values: acute**

Use	Substance	PIEC <sub>sw</sub> [µg a.s./L]	TER <sub>st</sub>	TER <sub>st</sub>	TER <sub>st</sub>	TER <sub>st</sub>
			(trigger 10) Algae	(trigger 100) Invertebrates	(trigger 100) Fish	(trigger 10) Macrophytes
All uses	Diquat	0.152	72	>1000	>1000	99

**Table E.6b TER values: chronic**

Use	Substance	PIEC <sub>sw</sub> [µg a.s./L]	TER <sub>lt</sub>	TER <sub>lt</sub>
			(trigger 10) Invertebrates	(trigger 10) Fish
All uses	Diquat	0.152	822	789

Taking the results in Table E.6a and E.6b into account, the acute TERs for fish and invertebrates are above the relevant Annex VI triggers of 100 and the acute TERs for algae and *Lemna* are above the relevant Annex VI triggers of 10. The chronic TERs for fish and invertebrates are above the relevant Annex VI triggers of 10. Thus, it appears that the proposed uses meet the standards for aquatic organisms as laid down in the RGB and BGB.

### 7.2.2 Risk assessment for bio concentration

Since logK<sub>ow</sub> of diquat is < 3 (-4.6), experimental data are not required. Considering the low log K<sub>ow</sub>, the risk for bio concentration is small. Therefore the active substance diquat meets the standards for bio concentration as laid down in the RGB and BGB.

### 7.2.3 Risk assessment for sediment organisms

The water–sediment study indicates that over 10% of diquat is found in the sediment after 14 days,

however the NOEC for daphnids is above 0.1 mg/L, therefore a low risk is expected for sediment organisms. This is confirmed by toxicity data on *Chironomus*.

The NOEC value for *Chironomus* is  $\geq 100$  mg/kg sediment. When this value is examined against the highest PIEC in sediment of 0.219 mg a.s./kg sediment dw, the TER value is 457, which is above the trigger of 10. Therefore, the active substance diquat meets the standards for sediment organisms as laid down in the RGB and BGB.

### Conclusions aquatic organisms

The proposed applications meet the standards for aquatic organisms.

### 7.3 Effects on terrestrial vertebrates other than birds

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

Table E.7 presents an overview of toxicity data.

**Table E.7 Overview of toxicity data for mammals for substance Diquat**

	Endpoint	Value
Acute toxicity to mammals:	LD <sub>50</sub>	214 mg a.s./kg bw
Reproductive toxicity to mammals:	NOEL	8.9 mg a.s./kg bw/d*

\* The EU final list of endpoints for diquat contains two long term endpoints for 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)

The notifier considers the 90 day rat toxicity value of 8.9 mg/kg bw/d as the most relevant value for long term risk assessment. The first argument is that a 1 year study is an unrealistically long exposure compared to the exposure in the field. The second argument is that mammalian carnivores are likely to be less exposed to diquat than rodents. Therefore, they propose to use the rat study instead of the dog study.

Ctgb does not agree with the second argument, because there will be small carnivorous animals living in the treated area (e.g. shrews). Shrews are not standardly tested and therefore all the available toxicity information should be used as a surrogate in the mammalian risk assessment.

However, Ctgb does agree with the first argument considering the exposure duration in the study as compared to the expected exposure duration in the field. After the use of diquat, treated vegetation will desiccate within 2-4 days, thus a continuous exposure of 1 year (as in the dog study) to diquat via either exposed vegetation or insects is a strong overestimation (insects: destruction of habitat), even taking into account that mammals can forage in different fields treated at different times. These arguments alone are not sufficient, because in principle, it cannot be excluded that long term effects are induced by short term exposure. However, there are indications that the effects seen in the studies are the result from long term exposure. Both the 90 d rat NOEL and the 1 year dog NOEL are based on cataract effects (eye lesions). In the monograph also a rat multi generation study (16-18 w exposure for F0 adults) is available, with a NOEL of 1.4 mg a.s./kg bw/d, also based on cataract effects. The cataract effects in all three studies were observed after several weeks of exposure (8-16 w). Based on these observations and with NOEL's decreasing with increasing study duration, there seems to be an indication that cataract effects are caused by long term rather than short term exposure. Further, in the DAR the mammalian long term risk assessment is based on the 90 d rat endpoint, and no discussion about this issue took place during the EU-peer review. It is unclear from the EU-dossier why the 1-year dog study was included in the ecotox section of the final list of endpoints.

*Conclusion:* The 90 d NOAEL of 8.9 mg /kg bw/d will be used for risk assessment.

#### 7.3.1 Natural food and drinking water

##### **Sprayed products**

The risk assessment for mammals is carried out following the guidance document by EFSA

(Anonymous 2009: Guidance Document on risk assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. European Food Safety Authority), hereafter cited as GD (EFSA 2009).

#### Acute and long-term screening assessments

The proposed use of the product is for bare soil application in chicory and floricultural crops and in strawberries (pre- or immediately post-planting). These correspond with the bare soil, and strawberries scenarios. For the applications in strawberries (post-planting) the indicator species is a small herbivorous mammal. For the application in bare soils the indicator species is a small granivorous mammal. For uses with a frequency > 1, a MAF (Multiple Application Factor) may be applicable.

The  $DDD_m$  values for the acute risk assessment are calculated as application rate \* shortcut value \*  $MAF_{90}$ . The  $DDD_m$  values for the long-term risk assessment are calculated as application rate \* shortcut value \*  $MAF_m$  \* TWA. The values of  $DDD_m$  are compared to the relevant toxicity figure. TERs should be above the trigger for an acceptable risk (10 or 5 for acute or long-term risk assessment, respectively). The screening assessment is shown in Tables E.8a,b.

**Table E.8a Acute risk for mammals (screening assessment)**

Crop group	Substance	Indicator species	LD <sub>50</sub> [mg a.s./ kg bw]	DDD			DDD <sub>m</sub> [mg a.s./ kg bw/d]	TER <sub>A</sub>	Trigger
				Appl. rate [kg a.s./ha]	SV <sub>90</sub>	MAF <sub>90</sub>			
Strawberries	Diquat	Small herbivorous mammal	214	0.3	118.8	1	35.6	<b>6.00</b>	10
Bare soils		Small granivorous mammal			14.4	1	4.32		

**Table E.8b Long-term risk for mammals (screening assessment)**

Crop group	Substance	Indicator species	NOEL [mg a.s./kg bw]	DDD				DDD <sub>m</sub> [mg a.s./ kg bw/d]	TER <sub>LT</sub>	Trigger
				Appl. rate [kg a.s./ha]	SV <sub>m</sub>	TWA	MAF <sub>m</sub>			
Strawberries	Diquat	Small herbivorous mammal	8.9	0.3	48.3	0.53	1	7.68	<b>1.16</b>	5
Bare soils		Small granivorous mammal			6.6	0.53	1	1.05		

The results presented in Tables E.8a,b show that the acute and long-term screening assessment values of TER for the application in strawberries (post-planting) are below the required trigger of 10 and 5, respectively. Therefore, the use of the product post-emergence in strawberries does not meet the standards laid down in the RGB and a Tier 1 assessment is required. For the proposed use in bare soils, the acute and long-term screening assessments indicate a low risk, which complies with the standards laid down in the RGB.

#### Tier 1 assessment

A Tier 1 risk assessment is performed and the results are shown in Tables E.9a,b. Note that the product is applied for at BBCH 00-40 however, according to the BBCH scale, 'BBCH 40' does not exist in strawberry. The BBCH scale jumps from 19 to 41. At 41 is when stolons are growing. Application is not intended at that stage so the BBCH in terms of the B&M risk assessment is restricted to < 40, and thus the vole (relevant at from BBCH 40 onwards) is not relevant.

**Table E.9a Acute risk for mammals (Tier 1 assessment)**

Crop group	Substance	Generic focal species	LD <sub>50</sub> [mg a.s./ kg bw]	DDD			DDD <sub>m</sub> [mg a.s./ kg bw/d]	TER <sub>A</sub>	Trigger
				Appl. rate [kg a.s./ha]	SV <sub>90</sub>	MAF <sub>90</sub>			
Strawberries (BBCH 10-39)	Diquat	Small insectivorous mammal "shrew" (BBCH 10-19) (covering for BBCH ≥ 20)	214	0.3	7.6	1	2.28	94.9	10
		Small omnivorous mammal "mouse" (BBCH 10-39)			17.2	1	5.16	41.5	
		Large herbivorous mammal "lagomorph" (BBCH 10-39)			35.1	1	10.5	20.3	

**Table E.9b Long-term risk for mammals (Tier 1 assessment)**

Crop group	Substance	Generic focal species	NOEL [mg a.s./kg bw]	DDD				DDD <sub>m</sub> [mg a.s./ kg bw/d]	TER <sub>LT</sub>	Trigger
				Appl. rate [kg a.s./ha]	SV <sub>m</sub>	TWA	MAF <sub>m</sub>			
Strawberries (BBCH 10-39)	diquat	Small insectivorous mammal "shrew" (BBCH 10-19)	8.9	0.3	4.2	0.53	1	0.67	13.3	5
		Small omnivorous mammal "mouse" (BBCH 10-39)			7.8	0.53	1	1.24	7.18	
		Large herbivorous mammal "lagomorph" (BBCH 10-39)			14.3	0.53	1	2.27	<b>3.91</b>	

The acute Tier 1 risk assessment (Table E.9a) indicates an acceptable risk for the application in strawberry. However, a long-term risk to mammals cannot be excluded for a large herbivorous mammal "lagomorph" for the application in strawberries. For all other the scenarios a risk can be excluded. Refinement of the risks is needed.

Refinement of the risk for herbivorous mammals ("lagomorph")

For a refinement of the risk to the large herbivorous mammal "lagomorph" the RUD and DT<sub>50</sub> values

(n. B values from the terrestrial vegetation) from the Canadian study can be used as well. The refined risk assessment is given below:

**Table E.10 Refined long-term risk assessment for a “lagomorph”**

Crop group	Dose kg a.s./ha	MAF	Fir/bw	Food type and PD	RUD	F <sub>twa</sub>	DDD	TER
Strawberries (BBCH 10-39)	0.3	1	0.50	100% non- grass herbs	66.9	0.11	1.10	8.06

The TER value shown in Table E.10 is above the trigger of 5, which indicates a low risk to the large herbivorous mammal “lagomorph”.

### Conclusion

An acceptable risk is expected for the all proposed applications

An uncertainty analysis concerning the refinements can be found below, in Table E.11.

**Table E.11: Uncertainty analysis for refined risk assessment(s), mammals**

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

			substance, the RMS considers them to be only slightly less certain.
Use of refined DT <sub>50</sub> from Canadian field studies	-	-	The refined DT50s are less conservative than the default DT <sub>50</sub> s. However, the RMS considers them to be more relevant for use in risk assessment since they concern a realistic application pattern and a wide variety of plant/insect types. They are considered to be slightly more uncertain than the default values due to the fact that they were derived from a study in Canada (though the climatological data suggest relevance to the Netherlands) and a smaller data set was used than for the default values.
Overall assessment	<p>The refined risk assessment contains significant uncertainties. The largest uncertainties lie in the use of the refined RUD values and the extrapolation between plant types.</p> <p>The PT of 1 for the lagomorph are considered relatively conservative considering that there are likely anti-rabbit measures in place in strawberry fields, and considering that only the inter-row areas are sprayed, as opposed to the crop itself.</p> <p>The PD is not considered to be very conservative, as it excludes grass component of the leaves. However, the refined RUD is a mixture of terrestrial plants and will probably also include some monocots.</p> <p>Taking this into consideration, the RMS concludes that the uncertainty introduced into the risk assessment via the use of the refined RUDs and the extrapolation to crop plants from "terrestrial vegetation" is offset by the conservativeness of the PT assumptions and the use of mixed RUD (monocot/dicot).</p>		

### **Drinking water**

#### *Puddle scenario*

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

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

According to EFSA Guidance Document for Birds and Mammals (2009), no specific calculations are necessary when the ratio of effective application rate (in g a.s./ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg). The mean Koc of diquat is 2184750 L/kg. The ratio of application rate to acute endpoint is

300 g a.s./ha / 214 mg a.s./kg bw = 1.4, and the ratio of application rate to chronic endpoint is 300 g a.s./ha / 8.9 mg a.s./kg bw/d = 33.7. Neither ratio exceeds the trigger of 3000. The risk due to exposure to drinking water from puddles is concluded to be acceptable.

### 7.3.2 Secondary poisoning

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

### Conclusions mammals

The application extension of the product complies with the Rgb for all proposed applications,

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

### 7.4 Effects on bees

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

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

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

### Conclusions bees

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

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

### Conclusions bees

The product complies with the Rgb.

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

### 7.5.1 Effects on non-target arthropods

#### In-field

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

#### Off-field (Dutch specific aspect)

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

The risk for non-target arthropods is assessed by calculating Hazard Quotients. For this, Lethal Rate values (LR<sub>50</sub>) are needed. Based on LR<sub>50</sub>-values from studies with the two standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri* an off-field Hazard Quotient (HQ) can be calculated according to the assessment method established in the SETAC/ESCORT 2 workshop and described in the HTB (v 1.0). Hazard Quotients should be below the trigger value of 2 to meet the standards.

However, no Tier 1 data for *T. pyri* or other mites are available. For *A. rhopalosiphi* an extended laboratory test showed 58% effect on mortality at 1 kg a.s./ha, no effects on reproduction were found. Although the effects are > 50 % at the lowest rate tested, it can be assumed that the effects will be < 50% at the maximum rate of 0.30 kg a.s./ha (see also table E.12).

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

**Table E.12 HQ-values for *A. rhopalosiphi* and *T. pyri***

	Application rate (kg a.s./ha)	MAF <sup>1</sup>	Drift factor/ Vegetation factor <sup>2</sup>	Safety factor <sup>2</sup>	LR <sub>50</sub> (kg a.s./ha)	HQ
<b>Off-field</b>						
<i>A. rhopalosiphi</i>	0.3	1	0.1	5	<1.0	>0.2
<i>T.pyri</i>	0.3	1	0.1/10	5	0.00475 (lethal) > 0.013 (sub- lethal)	<b>3.16</b>  <b>&lt;1.2</b>

<sup>1</sup>: Multiple Application Factor

<sup>2</sup>: off-field: drift factor = 10%, vegetation dilution factor = 10 (not applicable for *A. rhopalosiphi* since whole plants were sprayed), safety factor = 5 (default value for second tier assessment)

The results presented in Table E.12 show that the off-field risk to *A.rhopalosiphi* can be considered acceptable. In the case of *T.pyri*, however, there is an off-field risk from diquat.

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

For *Crysoperla carnea* 96% mortality occurred at 1.6 kg a.s./ha. In the extended lab study submitted by the applicant, the LR50 is 0.9 kg a.s./ha and at 0.81 kg a.s./ha the resulting effect was 18% reduction of viable eggs/female/day. Since the effects are below 50% at relevant application rates, it can be concluded that the risk to *Crysoperla carnea* are low.

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

On the label, the following restriction sentence is reported:

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

However a buffer zone cannot be used in restriction sentences, (as also indicated in the earlier extension). With 75% drift reducing nozzles and end nozzle, the drift is 5.5% and the risk is not acceptable.

In order to lower the exposure to acceptable levels, an additional crop free zone of 0.5 m is prescribed. In this way the drift will be reduced to 2.6% and the risk to off-field non-target arthropods is acceptable.

Therefore the following restriction sentence should be included on the label:

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

The product does comply with Rgb provided that a restriction sentence is placed on the label.

#### **7.5.2 Earthworms**

The risk assessment for earthworms is not a Dutch specific criterion. For the current application for mutual recognition this means that the UK risk assessment should be used.

#### **7.5.3 Effects on soil micro-organisms**

The risk assessment for soil micro-organisms is not a Dutch specific criterion. For the current application for mutual recognition this means that the UK risk assessment should be used.

#### **7.5.4 Effects on activated sludge**

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**

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-crop area. Since the Netherlands have their own national drift values, the risk assessment for non-target plants is a Dutch specific criterion. The risk assessment for non-target plants is performed below.

The risk assessment for non-target plants is based on an off-crop situation with a drift percentage of 4.7%. The exposure thus equals  $0.047 \cdot$  the application rate.

For Dragoon 13849 N, the applicant has submitted a vegetative vigour test and a statement for the effects on seedling emergence. The lowest EC<sub>50</sub> of 0.031 kg a.s./ha from the vegetative vigour test was recorded for sugar beet. Based on the results of the vegetative vigour, the applicant has submitted a resulted HC5 of 0.081154 L form/ha (0.0162 kg a.s./ha) calculated using ETX 2.0. From the seedling emergence statement it was concluded by the applicant that no effects were seen up to the maximum test dose of 36 L form/ha (7.2 kg a.s./ha). The study was not evaluated by Ctgb, however it indicates that the vegetative vigour is the more sensitive test.

A TER is calculated with the lowest EC<sub>50</sub> value from a laboratory test with higher plants and the exposure concentration. See table E.13a. for TER calculation.

**Table E.13a: Overview of exposure concentrations and TERs for non-target plants**

Use	Substance	Dose [kg a.s. /ha]	MAF.	Drift% (off-field exposure)*	Exposure (kg a.s./ha)	EC <sub>50</sub> [kg a.s./ha]	TER	Trigger value
All uses	diquat	0.3	-	4.7	0.014	0.031	<b>2.20</b>	5

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

As it can be seen from the Table E.13 the TERs are below the trigger of 5. Next, a probabilistic approach will be employed. Therefore, the risk can be determined by using the HC5 data. As this is considered Tier II assessment, the trigger value is set to 1.

**Table E.13b: Overview of exposure concentrations and TERs for non-target plants**

Use	Substance	Dose [kg a.s. /ha]	MAF.	Drift% (off-field exposure)*	Exposure (kg a.s./ha)	HC <sub>5</sub> [kg a.s./ha]	TER	Trigger value
All uses	diquat	0.30	-	4.7	0.014	0.0162	1.1	1

The results presented in Table. E5a show that the TER is above the trigger of 1.

The product does comply with Rgb.

## 7.6 Appropriate ecotoxicological end-points relating to the product and approved uses

See List of Endpoints.

## 7.7 Data requirements

None.

## 7.8 Restriction sentences

The following restriction sentences are currently on the label:

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

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

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

In the WG (legal instructions):

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

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

## **7.9 Overall conclusions regarding ecotoxicology**

It can be concluded that:

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

## **8. Efficacy**

The applicant has claimed a label extension; an application in strawberries inter row against annual broadleaved weeds at 1,5 l/ha and an application in chicory and ornamental plants before crop emergence or transplanting against annual broadleaved weeds at 1,5 l/ha.

Dragoon is authorized for the professional use in United Kingdom for the use chicory, strawberries and floriculture crops at a dose rate of 1.5-2 l/ha. Climatological and environmental circumstances relevant for the aspect efficacy in the claimed uses in The Netherlands are comparable to those in the United Kingdom. The cultivation method in chicory, strawberry and floriculture crops is similar in both countries and there are no country-specific situations for the use of Dragoon as a herbicide in the claimed uses.

According to the UK label application is only allowed in combination with an alcohol ethoxylate adjuvant. Therefore the following sentence is added directly below the table:

Dragoon dient altijd in combinatie met alcohol ethoxylaar (bijvoorbeeld Trend 90) te worden toegepast in de teelt van chicorei, aardbei en sierteeltgewassen.

### **8.1 Efficacy evaluation**

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

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

For other reasons than the efficacy evaluation, the dose rate for the new uses for weed control has to be reduced to 1.5 l/ha. As 2 l/ha was evaluated as the effective dose rate for a good and consistent control in different situations, applied at 1.5 l/ha it is expected that weed control is not sufficient in all situations. Therefore chicory, strawberry and ornamental crops are added to the restriction sentence for bulb vegetables on the current WG/label that efficacy can be insufficient.

In de teelt van chicorei, aardbei, ui-achtigen en sierteeltgewassen kan de werking onvoldoende zijn.

### **8.2 Harmful effects**

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

### **8.3 Resistance**

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

### **8.4 For vertebrate control agents: impact on target vertebrates**

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

### **8.5 Any other relevant data / information**

None.

## **9. Conclusion**

The product complies with the Uniform Principles.

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**

The current label can be maintained.

**The following restriction sentences have to be included in the legal instructions:**

In ui-achtigen Dragoon toepassen in 500 liter water per ha. In de overige toepassingen Dragoon toepassen in 200-500 liter water per ha.

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

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

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

In de teelt van cichorei, aardbei, ui-achtigen en sierteeltgewassen kan de werking onvoldoende zijn.

## Appendix 1 Table of new authorised uses

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation	F G or I	Pests or Group of pests controlled	Application			Application rate per treatment			PHI (days)	Remarks: a) max. no. of applications per crop and season b) Maximum product rate per season c) additional remarks
					Method / Kind	Timing / Growth stage of crop & season	Number / (min. Interval between applications)	L product / ha	g as/ha	Water L/ha min / max		
Only new uses are included in the GAP, existing / unchanged uses are not included												
1	NL	Chicory	F	annual broadleaved weeds	Overall spraying	Pre-emergence, pre-transplanting Spring, summer February - June BBCH 00-07	1	1.5	300	200-500	NA	PHI covered by vegetation period  Ad an alcohol ethoxylate adjuvant.
2	NL	Strawberries	F	annual broadleaved weeds	Interrow	Post planting, Spring, summer February - August BBCH 00-40	1	1.5	300	200-500	NA	PHI covered by vegetation period Ad an alcohol ethoxylate adjuvant
3	NL	Floriculture crops	F	annual broadleaved weeds	Overall spraying	Pre-emergence/ Pre-transplanting, Spring, summer February-August BBCH 00-07	1	1.5	300	200-500	NA	PHI covered by vegetation period Ad an alcohol ethoxylate adjuvant

## **Appendix 2 Reference list**

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

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