Miljøministeriet
Miljøstyrelsen

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Pesticider og Biocider
J.nr. 2024-3472
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Afslag på ansøgning om dispensation til anvendelse af Reglone til nedvisning af kartofler

Miljøstyrelsen har den 8. januar 2024 modtaget ansøgning om dispensation iht. art. 53 i plantebeskyttelsesmiddelforordningen[1] til brug af Reglone, med aktivstoffet diquat, til nedvisning af certificerede læggekartofler i 2024.

Reglone er et vandopløseligt koncentrat indeholdende 0,2 kg/L diquat, CAS-nr.: 2764-72-9. Diquat er blevet ikke-godkendt i EU i 2018, jf. Kommissionens gennemførelsesforordning (EU) 2018/1532 af 12. oktober 2018.

I forbindelse med behandling af ansøgningen har Miljøstyrelsen opdateret vurderingen af det tidligere indsendte studie angående dislodgeable foliar residue (DFR) og halveringstid for diquat på overfladen af kartoffelblade (DT_{50}) samt udført opdaterede eksponeringsberegninger for anvendelsen.

Miljøstyrelsen har genvurderet det tidligere indsendte studie vedr. DFR og DT_{50} for diquat i kartofler. Årsagen hertil er de nye krav for studier af denne type, som anført i EFSA's "Guidance on the assesment of exposure of operators, workers, resident and bystanders in risk assessment of plant protection products"[2] samt det nyeste Nordzone-guidance "Guidance document on work-sharing in the Northern zone version 11.1" fra September 2023[3]. Den opdaterede vurdering viser, at studiet ikke er acceptabelt iht. de nye vejledninger, og forfiningerne til eksponeringsberegningerne, der følger af studiet, ikke længere kan anvendes. Der skal derfor bruges standardværdier for DFR og DT_{50} i eksponeringsberegningerne for brug af Reglone i kartofler. De opdaterede beregninger viser uacceptabel risiko for børn og voksne der er bosat eller opholder sig nær sprøjtede marker.

Miljøstyrelsen vurderer, at den ansøgte dispensation ikke kan godkendes grundet uacceptabel risiko for børn og voksne, der er nabo til eller opholder sig tæt på sprøjtede marker. Den opdaterede sundhedsvurdering fremgår af bilag 1.

[1] Europa-Parlamentets og Rådets forordning (EF) Nr. 1107/2009 af 21. oktober 2009 om markedsføring af plantebeskyttelsesmidler og om ophævelse af Rådets direktiv 79/117/EØF og 91/414/EØF.
[2] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products, EFSA Journal 2022; 20(1):7032, 134 pp. https://doi.org/10.2903/j.efsa.2022.7032
[3] https://mst.dk/erhverv/sikker-kemi/pesticider/godkendelse-af-pesticider/samarbejde-om-godkendelse-i-nordzonen

Miljøstyrelsen har d. 7. juni 2024 sendt partshøring til ansøger vedr. den nye vurdering. Ansøger har d. 13. juni 2024 indsendt partshøringssvar, hvori en række landbrugsmæssige problemstillinger rejses. Ansøger oplyser dog i høringssvaret at de accepterer Miljøstyrelsens sundhedsmæssige vurdering.

Miljøstyrelsen vurderer på baggrund af ovenstående ikke, at der er grundlag for en dispensation til den ansøgte anvendelse af Reglone til nedvisning af certificerede læggekartofler, da der jf. sundhedsvurderingen er en uacceptabel risiko forbundet med den ansøgte anvendelse.

Regler
Dispensation til et ikke-godkendt plantebeskyttelsesmiddel kan gives efter plantebeskyttelsesmiddelforordningens[4] artikel 53 og kan alene gives i indtil 120 dage, under hensyntagen til en kontrolleret og begrænset anvendelse af midlet. Det er en betingelse for meddelelse af dispensation, at "det skønnes nødvendigt på grund af en fare, som ikke kan bekæmpes på nogen anden rimelig måde", jf. artikel 53 i plantebeskyttelsesmiddelforordningen[1]. Dette under forudsætning at anvendelsen ikke udgøre en uacceptabel risiko for grundvand, miljø og sundhed. Det er yderligere en betingelse for at give en gentagen dispensation til ikke-godkendte aktivstoffer, at de skærpede dokumentationskrav er opfyldt jf. EU-vejledning[5] vedr. dispensationer og administrativ praksis[6].

Miljøstyrelsens afgørelse
I medfør af artikel 53 i plantebeskyttelsesmiddelforordningen og gældende vejledninger meddeler Miljøstyrelsen Danske Kartofler afslag på dispensation til anvendelse af Reglone til nedvisning af certificerede læggekartofler, da anvendelsen vurderes at udgøre en uacceptabel risiko for sundhed.

Denne afgørelse kan ikke påklages til anden administrativ myndighed, jf. § 66 i bekendtgørelse nr. 961 af 26. juni 2023 om bekæmpelsesmidler. Afskæringen af klagemuligheden berører ikke retten til at anlægge civilt søgsmål efter retsplejelovens almindelige regler, men restsag skal være anlagt senest seks måneder efter at denne afgørelse er meddelt, jf. § 54 i lovbekendtgørelse nr. 6 af 4. januar 2023 med senere ændringer.

Med venlig hilsen

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Kopi til:
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[4] Europa-Parlamentets og Rådets forordning (EF) Nr. 1107/2009 af 21. oktober 2009 om markedsføring af plantebeskyttelsesmidler og om ophævelse af Rådets direktiv 79/117/EØF og 91/414/EØF.
[5] https://mst.dk/media/pithx5gg/eu-kommissionens-guidance-dokument.pdf
[6] https://mst.dk/kemi/pesticider/godkendelse-af-pesticider/ansoegningsformer-og-krav/andre-typer-af-godkendelser/

Pesticider og Biocider
Den 9. juni 2021
Rev. 6. juni 2022
Rev. 21. juni 2023
Rev. 07. juni 2024

Sundhedsvurdering af Reglone (200 g diquat/L) til nedvisning af kartofler.

Anvendelse:

SEGES har i 2021[1], 2022, ~~og~~ 2023 og 2024 ansøgt om dispensation til nedvisning af kartofler med Reglone med 2 x ~~180~~ 160 g as/ha (2 x ~~0,9~~ 0,8 L produkt/ha) med 7 dages interval i BBCH 48-89 udbragt med 90 L vand/ha.
Ansøgningen for 2022, 2023 og 2024 er identiske med den ansøgte anvendelse for 2021. Miljøstyrelsen er ikke bekendt med nye vurderinger eller materiale med betydning for denne vurdering. ~~Nedenstående er derfor uændret ift. den tidligere vurdering fra 2021. Dog er d~~Der i 2023 tilføjet en vurdering af hvorvidt produktet indeholder uacceptable co-formulanter iht. Annex III til forordning 1107/2009. I 2024 blev eksponeringsberegningerne for den ansøgte anvendelse opdateret grundet ibrugtagningen af den nye model "OPEX calculator" (EFSA 2022), som erstatter den tidligere anvendte model "EFSA Calculator". Yderligere er det indsendt studie på DFR og DT_{50} for diquat på overfladen af kartoffelblade blevet genvurderet ift. de opdaterede krav fundet i "Guidance Document on work-sharing in the Northern Zone", ver. 11.1 (September 2023), og EFSA's opdaterede "Guidance on the assessment of operators, workers, residents and bystanders in risk assessment of plant protection products" og implementeret i Nord Zonen pr. 1. november 2023 via Nordzone-guidance.

Tidligere vurderinger:

Reglone har været vurderet og godkendt i DK siden 2002. Sundhedsvurderingen fra 2002 opfylder ikke kravene i de nuværende vurderingsprincipper.

Reglone var det ene af to repræsentative produkter ved EU revurderingen af diquat (EFSA, 2015), hvor diquat ikke opnåede fornyet godkendelse i EU i 2018 (kommissionens gennemførelsesforordning (EU) 2018/1532 af 12. oktober 2018).

Klassificering af Reglone på sundhed er baseret på EU revurderingen (UK, 2015). Risikovurderingerne i EU vurderingen lever ikke op til de nuværende danske vurderingsprincipper.

Af EU vurderingen fra 2015 fremgår fsva. den sundhedsmæssige vurdering:
Klassificering:
Reglone blev under revurderingen af diquat i EU klassificeret (UK, 2015, B.6.11.9) og under EU vurderingen, blev der yderligere forslået en klassificering som "H361d Mistænkt for at skade det ufødte barn" for diquat (EFSA, 2015). Denne klassificering skal overføres til Reglone på grund af indholdet af diquat i produktet. Derudover har Reglone, en klassificering som "H290 Kan ætse metaller" og "H317 Kan udløse allergisk hudirritation".

H290 Kan ætse metaller
H302 Farlig ved indtagelse (Cat 4)
H331 Giftig ved indånding (Cat 3)

[1] I 2021 er der oprindeligt ansøgt om godkendelse af 2 x 180 g as/ha (2 x 0,9 L produkt/ha)

H315 Forårsager Hudirritation (Cat 2)
H335 Kan forårsage irritation af luftvejene (Cat 3) STOT SE 3
H372 Forårsager skade på øjnene ved længerevarende eller gentagen eksponering STOT RE 1
H361d Mistænkt for at skade det ufødte barn (Cat 2)
H317 Kan udløse allergisk hudreaktion (Cat 1)

Vurdering af indhold af Annex III co-formulanter:
På baggrund af de tilgængelige oplysninger om produktets sammensætning er det Miljøstyrelsens vurdering, at produktet ikke indeholder uacceptable hjælpestoffer eller at eventuelle hjælpestoffer i produkterne ikke forefindes over grænseværdierne i Annex III.

Sundhedsmæssig risikovurdering:

Diquat fik ikke fornyet sin godkendelse i EU, da der blandt andet var høj risiko for arbejdstagere og beboere. Der kunne ikke påvises en sikker anvendelse af diquatholdige midler til de i EU vurderede repræsentative anvendelser (kartofler, løg, ærter, tomater, sukkerroe, gulerødder, bønner, solsikke, cikorie, vindruer og raps, frugttræer).

Der er derfor udført eksponeringsberegninger for nedvisning af kartofler.

Dermal absorption:
Et humant in vitro dermal absorptionsstudie er til rådighed for Reglone i RAR'en (UK, 2015). Dermal absorption er blevet korrigeret efter den nyeste guidance fra EFSA (2017), da en ældre guidance (EFSA, 2012) blev anvendt under EU vurderingen.

Ifølge EFSA guidance (2017) skal standardafvigelsen ganges med en faktor, der er afhængig af antallet af replikater. Da der er 5 replikater i denne undersøgelse, skal en faktor på 1,2 anvendes. Afrunding af betydende cifre er foretaget i henhold til EFSA, 2017.

Koncentrat:
Gennemsnit: 0.228%
SD: 0.26
Dermal absorption: 0.228 + (1.2*0.26) = 0.54%

1 til 100 fortynding:

Gennemsnit: 0.335%
SD: 0.19
Dermal absorption: 0.335 + (1.2*0.19) = 0.563 = 0.56%

1 til 200 dilution:
Mean: 0.854%
SD: 0.77
Dermal absorption: 0.854 + (1.2*0.77) = 1.778 = 1.8%

Input parametre i eksponeringsberegningen

AOEL er 0.0002 mg/kg bw/dag ifølge den seneste EU vurdering.
De ansøgte anvendelser kan ses i GAP i Appendix 1.

Eksponeringsberegningen blev i 2024 opdateret. De er således udført i den online OPEX calculator, der erstattede EFSA calculator i 2023 (EFSA 2022). Ved beregninger i OPEX calculator anvendes normalvis mængden af det tekniske aktivstof i et bekæmpelsesmiddel, hvor det ved tidligere beregninger i EFSA calculator har været kutyme at anvende mængden af rent aktivstof i et bekæmpelsesmiddel. Bemærk dog, at der for de nedenstående eksponeringsberegninger for Reglone er anvendt indholdet af rent diquat i produktet. Dette skyldes, at det tekniske aktivstof er et salt (diquat dibromid), og at EFSA som udgangspunkt ikke anser mod-ionen i aktivstoffer, som er salte, for værende en del af aktivstoffet. Således er AOEL-værdien for diquat fastsat på baggrund af mængden af diquat-ionen i det aktive stof (EFSA 2015). Det antages derfor, at der under beregningen af AOEL-værdien er taget højde for renheden af aktivstoffet anvendt i de toksikologiske forsøg, hvorfra AOEL-værdien er afledt, og at der ikke skal tages højde for renheden ved eksponeringsberegninger for bekæmpelsesmidler indeholdende diquat.

Begrænser man vandmængden til 90 l/ha og de ~~180~~ 160 g diquat/ha får man en koncentration på ~~2~~ 1.78 g/l i brugsblandingen. ~~Brugsblandingen er dermed samme koncentration som den målte dermale absorption ved 2 g/l (1:100 fortynding), på 0,56 % og denne værdi vil derfor være dækkende for denne anvendelse.~~ Brugsblandingen er dermed fortyndet 1:112,5. Jf. principperne i EFSA (2017) dækkes denne af dermal absorption for 1:200 opløsningen på 1,8 % fra studiet vedr. dermal absorption.

Oral absorption er 4 % og DFR og DT_{50} er default, da det indsendte studie ikke findes acceptabelt efter nuværende praksis jf. "Guidance document on work-sharing in the Northern Zone", ver. 11.1 (NZ 2023), ~~da der ikke findes specifikke målinger på spinat og purløg.~~ Der er anvendt damptrykket fra det nye indsendte damptryksstudie, som giver et bidrag til eksponeringen under 1 %. Derfor er der set bort fra bidrag fra fordampning i beregningen, men man kan i Appendix 2 se tallene for eksponering af naboer både med og uden bidrag fra fordampning.

Nedenfor beskrives yderligere tiltag for at forfine eksponeringsberegninger fordelt på berørte populationer:

Syngenta used several refinements of default values, which were included in the EFSA calculator which will be addressed under the sections concerning the exposure groups.

Operator:

For uses the intended uses with application rates of ~~0.180~~ 0.160 kg as/ha, exposure estimates are below the AOEL (~~72~~ 75 %) according to the EFSA calculator with the use of PPE (appendix 2).

Worker

Syngenta submitted a DFR (dislogeable foliar residue) study on potatoes (Kennedy, 2017) in order to refine DFR and DT_{50}. According to the report, the following guidelines were followed:

EU 1999: 1607/VI/97, OECD Test Guideline 504. SANCO/3029/99 rev. 4. SANCO/825/00 rev. 8.1. Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 544/2011 and 545/2011 implementing Regulation (EC) 1107/2009 (for residue studies).
OECD Series on Testing and Assessment No. 9 "Guidance document on the conduct of studies of occupational exposure to pesticides during agricultural application", Paris 1997. OCDE/GD(97)148.
The study was performed under GLP.

As EFSAs “Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products” (EFSA 2022, see appendices C, D and J) and NZ 2023 (see section 18.2.4.2 and appendix XI) sets out a comprehensive list of new requirements and recommendations for studies on DFR and foliar DT50, the study has been reassessed to reflect current practice.

Study summary

The report (Kennedy 2017) describes four studies of DFR and DT_{50} of diquat in Reglone at four study sites in Europe. The sites were located in the UK, Spain, Italy and Hungary. For all study sites, one undivided plot (i.e. the plot was not divided into subplots) covered with potato plants at either growth stage BBCH 45 or 89-92 was sprayed once with Reglone. The application rate was 0.8 kg diquat/ha in approximately 200 L water/ha.

For all four plots, treated plants were sampled in triplicate just before, immediately after and until 2-4 days after spraying. The leaf punches (40 punches totaling a one-sided surface area of 200 cm^2) were extracted with 200 ml 0.01 % Aerosol OT (a detergent) in water. Concurrently, fortified blank samples were made in a concentration of either 4,000 or 40,000 × LOQ. A concurrent negative control field was also sampled.

The extracts were analyzed using an independently validated analytical method. The method utilized HPLC-MS/MS for sample analysis.

Evaluation

Of the four study sites, only the site in the UK have climatic conditions representative of Denmark when assessed against EPPO climatic zones. Both Denmark and the UK are in the maritime climatic zone. The UK test site therefore adequately represents the climatic conditions found in Denmark. Hungary is in the South-East climatic zone, though bordering on the maritime climatic zone, and is therefore not representative of the climatic conditions of Denmark. Both Spain and Italy are in the Mediterranean climatic zone and are therefore not representative of the climatic conditions of Denmark. According to both EFSA 2022 and NZ 2023, the study sites should be placed in climatic zone which are representative to the geographical area in which a given product is to be used. In this regard, the studies from Hungary, Italy and Spain are not acceptable. This is further underpinned by the fact that the breakdown of diquat on leaf surfaces can be observed in the results of the mainland study sites to be highly affected by climatic conditions. Considering the mechanism of action of diquat (production of free radicals when exposed to light), exposure time to and intensity of sun light can be theorized to be a deciding factor for break down. Further, NZ 2023 requires studies on DFR and DT50 to be conducted in at least triplicate. In other words, three distinct sites should be studied in order to ensure production of valid data that properly reflects the climatic conditions of a given geographical area. In this regard, the study is not acceptable, as only a single study site in the UK is representative of Denmark.

According to NZ 2023, each site should be divided into at least three subplots. One replicate should be taken from each subplot. All sites of the report were undivided. Further, the sampling technique used to collect leaf samples was not adequately described. This is not acceptable. As leaf samples should not be taken from the edge of study sites, and since the UK study site was very small (10×3 m) and consisted only of four rows of potato plants, this is concluded to be a serious error in the methodology of the study.

OPEX 2022 recommends that data collection should continue until several half-lives have passed. This is not the case for the UK site. The Danish EPA acknowledges that the mechanism of action (dessication) of diquat is a serious challenge in this regard, however, when taken together with the limited data set, the robustness of the data is questionable.

The position of the control plot relative to the sprayed plot for the UK study site was not described. This is required to adequately assess if contamination of the control plot have been avoided. This is not acceptable. Further, data from the control plot indicates cross contamination between the control plot

and the sprayed plot as blank samples from the control plot had content of diquat >LOQ. Furthermore, the field recovery samples taken from the control plot at 48 hours after spraying showed significantly higher recovery after spraying. This indicates either a consistent error in fortification on either day 0 or day 2, or that the control plot was contaminated during spraying. Further details can be seen in appendix 4 and 5 where the study has been assessed against the acceptability criteria according to OPEX 2022 and NZ 2023.
The analytical method enclosed in Braid 2017 is fully validated according to SANCO/2020/12830, rev. 2. The analytical method contained in the study report was conducted according to Braid 2017. However, it could not be fully validated, but is deemed fit for purpose as it fulfills the minimum validations criteria of SANCO/2020/12830, rev. 2.

Conclusion.
The studies included in the study report are found to be inadequate according to current standards. Particularly when considering the limited data set representative of the climatic conditions in Denmark, the poorly described sampling technique when considering the size of the sprayed plot and limited amount of break down observed on the leaves of the UK site. As such, the study can no longer be accepted for refinement of DFR and DT_{50} of diquat in potatoes.

~~In the Northern zone Guidance Document (2019) it is stated that if data on the amount of dislodgeable foliar residues (DFR) under the proposed conditions of use are not available, default assumption (3 µg a.s./cm² of foliage/kg a.s. applied/ha;) shall be used. Furthermore, a default dissipation half-life of 30 days should be used for organic substances if no DT_{50} value or half-life data representative of the supported use(s) are reported.~~

~~According to the Norther zone Guidance Document (2019) all of the following requirements should be met for a DFR study;~~

~~The study covers all the intended uses (GAP). This includes the application rate, number of applications, application efficiency, equipment, environmental conditions (i.e. relevant time of year and geographic location), crop type, physical and chemical properties of the applied PPP.~~

~~The study submitted by Syngenta deviates from the requirements according to the current northern zone worksharing document (2019) on the following points:~~

- ~~Geographical location is not in the Northern zone and no justification to support similar environmental conditions was submitted. It is considered unlikely that calculating a mean from all locations (Spain, Hungary, Italy, UK) are representative of conditions in DK.~~
- ~~In the study submitted by Syngenta, only one application was used, this does not cover uses with more than one application (eg. potatoes, strawberries, roses/seed beds).~~
- ~~Crop type used in the study is potato, which does not cover other types of crops.~~

~~It is noted that leaf discs were only washed twice and not three times as is specified in the Californian guidance on determination of dislodgeable foliar residues. Samples was collected in glass containers (UK) or stored in glass containers (Spain) which may be problematic as diquat adsorbs to glass according to the method of analysis validation reports (Braid & Langridge; Langridge, 2017).~~

~~For the uses applied for in potatoes (2 x 180 g as/ha), the values for DFR and DT_{50} determined in the field study may be used as a refinement of the default values in the EFSA calculator. The DFR and DT_{50} proposed by the applicant was the highest mean DFR value observed at 6 hours after application of 0.61 µg/cm²/kg a.s./ha and a DT_{50} (geometric mean) of 0.84 days, respectively. However, an average of the DFR values or the geometric mean of the DT_{50} values is not considered adequate to cover a~~

~~worst case under Danish conditions. In accordance with EFSA procedures the maximum DFR values should be used in the risk assessment. According to the results in the study report the maximum DFR of 755,959 ng/cm² was measured in Spain and the application rate was 800 g as/ha, resulting in a DFR of 0.94 µg as/cm₂/kg as/ha.~~
~~For DT_{50} a representative value for Danish conditions must be used. Syngenta calculated the maximum DT_{50} from the 4 trials to be 3 days from the trial in UK. DEPA performed a kinetic analysis of the data from UK (trial 1) which was assumed to have been conducted under more comparable conditions to Denmark than the trials in Hungary, Spain and Italy. This kinetic analysis resulted in an acceptable SFO fit with a chi² value of 16.3% and a DT50 of 3.0 days (CAKE Kinetic Evaluation Report). 1 trial is not normally considered adequate for determining a DT_{50} in residues or in ecotox evaluations. Thus, the DT_{50} and the DFR value determined in this field study are considered uncertain. However, the value is consistent with findings in the ecotox assessment and is considered acceptable for potatoes.~~

~~A validation method for the analytical method was submitted by Syngenta on 25. June 2020. The method is in principle considered acceptable, however DEPA note that the measurements in Spain and UK have been performed with glassware, despite of the method stating that diquat adheres to glass (Braid & Langridge; Langridge, 2017). This introduces some uncertainty in the measurements.~~

In light of the above conclusion regarding the report on DFR and DT_{50}, default DFR and DTe5 values were used in the calculation of worker exposure. For the use in potatoes 2 x ~~180~~ 160 g as/ha in 90 l water/ha, the worker exposure is unacceptable unless a re-entry period of 6 days is observed (~~27~~ 333 % of AOEL on day 0) with the following risk mitigation measures:

- work wear

<u>Resident and bystander</u>

<u>Drift:</u>

Syngenta referred to results from a wind tunnel study with a dye tested on 3 different drift reduction nozzles. This study was used in support of increasing the drift reduction in the EFSA calculator from 50% to 90%. Syngenta also argued that preliminary results from a study on the active substance showed similar results.

More robust data should be available in order to demonstrate that using drift reducing nozzles reliably reduce the drift with more than 50% for the types of equipment used and under relevant conditions. Such technical data should be submitted to EFSA for evaluation and if acceptable used in the update of the EFSA calculator. The default of 50% is considered a realistic worst case choice based the lack of robust data in support of further reduction.

<u>Inhalation from vapour:</u>
Der er anvendt damptrykket fra et nyt indsendt damptryksstudie på diquat (O'Connor, 2017) til at forfine risikovurderingen. Studiet blev ikke evalueret ved EU vurderingen men DEPA har tidligere spurgt EFSA til deres vurdering af studiet og til det svarede EFSA den 1. juli 2020, at studiet er acceptabelt.

Eksponering via inhalation ved fordampning er relevant for naboer og forbipasserende. En metode til at forfine på eksponeringsbidraget fra inhalation kaldes "The saturated vapour concentration (SVC) approach" (HEEG opinion 13 (European Commission, 2011) og hertil kan man anvende det eksperimentelt bestemte damptryk fra studiet. Den metode er også anvendt af EFSA (EFSA, 2018) og er inkorporeret i OPEX calculator. Damptrykket blev i studiet bestemt til $1{,}6\times10^{-14}$ Pa ved 20°C.
~~Damptrykket, som blev bestemt i studiet, er 1.6 x 10^{-14} Pa ved 20 °C og Molekylvægten (mw) for diquat~~

er 184.2g/mol, T er temperaturen i Kelvin og R er gaskonstanten. Disse bruges til at beregne SVC ved nedenstående formel:

$$SVC = \frac{mw[\text{g/mol}] \cdot vp[\text{Pa}]}{R[\text{J mol}^{-1}\ \text{K}^{-1}] \cdot T[\text{K}]} = 0.41 \cdot mw \cdot vp \quad [\text{mg/m}^3]$$

SVC=184.2 g/mol x 1.6 x 10-14 J/m3/(8,31451 j/mol*k x 293K)*1000000= 1,2245 x 10^{-09} µg/m^3.

Denne værdi kan indsættes i følgende ligning for at beregne eksponeringen via inhalation for voksne og børn, som er naboer eller forbipasserende (EFSA,2014):

SERI = (DC × IR × IA)

hvor,

- SERI = systemic exposure of residents via the inhalation route (mg/kg bw per day)
- DC = damp koncentration (mg/m^3) – 1,2245 x 10-09 µg/m^3 bestemt ud fra studiet (O'Connor, 2017)
- IR = inhalations rate (m^3/day/kg) – 0.23 m^3/day/kg for voksne og 1.07 m^3/day/kg for børn
- IA = inhalations absorption (%) – 100 %

SERI (børn) = 1,2245E-09 µg/m^3 x 1.07 m^3/day/kg = 1,3E-12 mg/kg bw/day
Svarende til 6,5 x 10^{-7} % of AOEL

SERI (voksne) = 1,2245E-09 µg/m^3 x 0.23 m^3/day/kg = 2,8E-13 mg/kg bw/day
Svarende til 1,4 x 10^{-7} % of AOEL

Da det nye studie er acceptabelt (baseret på EFSA's respons) er bidraget fra fordampning forsvindende lille i sammenligning med AOEL. Derfor er der set bort fra bidrag fra fordampning i beregningen, men man kan i Appendix 2 3 se tallene for eksponering af naboer både med og uden bidrag fra inhalation, hvor eksponeringen fra inhalation er udregnet ud fra de værdier man bruger som default i EFSA calculator OPEX calculator uden forfining.

Transfer Coefficient:
Syngenta submitted a study on a terbuthylazine product used on maize crops at BBCH stage 14-18 in Germany (Aitken, 2017) to refine and reduce the TC used in the calculation of child resident and bystander exposure. Syngenta argues that the studies used in the EFSA calculator are less relevant because they were performed on higher crops (peas and sweet corn) and the workers had more intensive contact with the plants than is expected with the crops applied for.

Children entering a field could be expected to behave differently than a worker and thereby may come into considerable contact with the plants. Because children are smaller than an adult worker it is also possible that they come into more contact with foliage on different parts of the plant than adults. Since there are considerable uncertainties regarding the actual exposure of resident children, the submitted study is not considered more relevant/representative than the data from the EFSA calculator. The TC input values from the EFSA guidance (2014) was used as a conservative approach and the study has not been included in the risk assessment and was not further evaluated.

Risikovurdering:

Beregningerne er lavet for 2 x ~~180~~ 160 g diquat/ha i 90 l vand/ha.

Sprøjteførere:

For sprøjteførere er der acceptabel risiko (~~72~~ 75 % af AOEL) for den ansøgte anvendelser med værnemidler (handsker, åndedrætsværn (P1, FP1 e. lign. og arbejdstøj) ved blanding og påfyldning. Ved udsprøjtning skal brugerne anvende handsker, arbejdstøj og sidde i lukket førerkabine med kulfilter (se Appendix 2 og 3).

Arbejdstagere:

Der kan vises acceptabel risiko, hvis en re-entry periode på 6 dage overholdes (~~27~~ 373 % af AOEL på dag 0) for arbejdstager ved brug af arbejdstøj (se Appendix 2 og 3).

Naboer og forbipasserende

Anvendes 2 x ~~180~~ 160 g diquat/ha udbragt i 90 l vand viser risikovurderingen, at der ~~ikke~~ er uacceptabel risiko for naboer og forbipasserende (se Appendix 2 og 3). AOEL overskrides ved eksponering for afdrift fra udbringningen samt ved ophold i marken efter sprøjtning. Eksponering for den 75. percentil er 123 % af AOEL for afdrift og 450 % af AOEL for ophold i marken for børn. Den samlede gennemsnitlige eksponering fra alle eksponeringsveje for børn er 431 % af AOEL. For voksne, der opholder sig marken, svarer eksponeringen til 250 % af AOEL. Den gennemsnitlige eksponering fra alle eksponeringsveje for voksne er 213 % af AOEL. Dette er på trods af, ~~under forudsætning af~~ at der anvendes min. 50% afdriftsreducerende dyser samt en 10 m bufferzone i beregningen.

Miljøstyrelsens samlede sundhedsvurdering:

Risikovurderingen for ovennævnte dosering og justerede vandmængde viser sikker anvendelse ift. brugere og arbejdere ~~og beboere og forbipasserende~~. Dog kan der ikke vises sikker anvendelse for beboere og forbipasserende. Der opstår dermed en uacceptabel risiko for disse populationer.

Vurderinger af de tidligere ansøgte doseringer viste, at sprøjtningen især kan udgøre en risiko for børn og voksne, som går ind i marken og rører ved sprøjtede planter, eller børn som opholder sig i nærheden af marken og bliver udsat for afdrift af diquat.

I de indsendte risikovurderinger foretaget af Agrolab foreslås en række forfininger af risikovurderingen baseret på studier indsendt af Syngenta ifm. den oprindelige ansøgning. Miljøstyrelsen finder efter yderligere vurderinger og svar fra EFSA, ~~at disse forfininger er acceptable (se nedenfor).~~ at studiet angående damptrykket for diquat dibromid findes at være acceptabelt, men at studiet angående DFR og DT_{50} for diquat på kartoffelblade lever ikke op til nuværende vurderingspraksis, og det kan derfor ikke accepteres.

I alle beregningerne er det forudsat, at der bruges de maksimale risikobegrænsninger foranstaltninger, som er mulige i ~~EFSA~~ OPEX calculator, på 10 m afstandskrav fra marken til beboelse, veje mm. og 50% afdriftsreduktion. Den detaljerede vurdering og resultater fra beregningerne fremgår af Appendix 1.

For anvendelsen af 2 x ~~180~~ 160 g as/ha udbragt med 90 l vand viser Miljøstyrelsens vurdering, at der ikke er sikker anvendelse for børn og voksne, der er naboer eller forbipasserende til sprøjtede marker.~~,~~

idet den samlede gennemsnitlige eksponering af børn udgør 55 % af AOEL, når bidraget fra fordampning udelades..

Miljøstyrelsen vurderer på baggrund af beregningerne, som viser eksponering af børn på ca. 50 % af AOEL (55 %), og det store antal forfininger, som er anvendt i vurderingen, at der er behov for yderligere risikobegrænsninger for at sikre børn mod eksponering. Derfor fastsættes følgende risikobegrænsende foranstaltninger for anvendelsen af 2 x 180 g diquat/ha udbragt med 90 L vand:

- **Må ikke anvendes nærmere end 20 meter fra veje, boliger, institutioner og offentlige arealer for at beskytte beboere og forbipasserende. Samtidig skal afdriftsreducerende udstyr med minimum 50 % afdriftsreduktion anvendes ved udbringning.**
- **Brugere skal anvende handsker, arbejdstøj og ansigtsbeskyttelse/visir ved blanding og påfyldning. Ved udsprøjtning skal brugerne anvende handsker, arbejdstøj og sidde i lukket førerkabine med kulfilter.**

- **Ved håndtering af behandlede planter efter sprøjtning skal der anvendes arbejdstøj.**

De accepterede forfininger omhandler følgende værdier:

- Værdier fra et feltstudie, hvor frigørelse fra kartoffelplanter (DFR studie af dislodgeable fraktion) og halveringstiden for nedbrydning i plantemateriale er undersøgt:

  Den væsentligste faktor er frigivelsen fra plantemateriale, som medfører eksponering, hvis børn eller voksne går ind i behandlede marker. Der er resultater fra test i 4 lande, og resultatet vurderes umiddelbart at være relativt robust. I Miljøstyrelsens forfinede vurdering er standardværdien på 3,0 nedsat til 0,94 µg/cm²/kg as/ha pba. feltstudiet.

  For halveringstiden er der kun et feltforsøg fra ét land, der ligner Danmark (UK). Derfor anses data for halveringstiden at være baseret på et spinkelt grundlag og er dermed behæftet med en vis usikkerhed. I Miljøstyrelsens forfinede vurdering er anvendt en halveringstid på 3 dage i stedet for standardværdien på 30 dage.

  Der har været yderligere usikkerheder omkring disse data, da der først efterfølgende er indsendt en validering af analysemetoden, som er anvendt i studiet. Miljøstyrelsen har vurderet analysemetoden, og finder den i princippet acceptabel.

- Resultater fra et nyt damptryksstudie, som er udført med et stof i en anden form end aktivstoffet:

  Miljøstyrelsen har spurgt EFSA, om det er acceptabelt at teste på den anden form af stoffet, og om det pågældende studie er acceptabelt. EFSA har svaret endeligt d. 1. juli 2020, at teststoffet og studiet er acceptabelt. I den forfinede vurdering er der lavet beregninger, hvor bidraget fra fordampning er helt udeladt, da det er minimalt når det nye damptryk anvendes i beregningen.

Fastsættelse af risikobegrænsende foranstaltninger:

Generelle sætninger:

Reglone må kun anvendes til nedvisning af kartofler, der må maksimalt anvendes 2 x 180 g diquat/ha udbragt med 90 l vand/ha.

~~Dette plantebeskyttelsesmiddel må kun købes af professionelle og anvendes erhvervsmæssigt og kræver gyldig autorisation.~~

~~Særlige sætninger ift. den sundhedsmæssige vurdering:~~

~~Må ikke anvendes nærmere end 20 meter fra veje, boliger, institutioner og offentlige arealer for at beskytte beboere og forbipasserende. Samtidig skal afdriftsreducerende udstyr med minimum 50 % afdriftsreduktion anvendes ved udbringning.~~

~~Brugere skal anvende handsker, arbejdstøj og ansigtsbeskyttelse/visir ved blanding og påfyldning. Ved udsprøjtning skal brugerne anvende handsker, arbejdstøj og sidde i lukket førerkabine med kulfilter.~~

~~Ved håndtering af behandlede planter efter sprøjtning skal der anvendes arbejdstøj.~~

Referencer:

Aitken, A. (2017). Terbuthylazine: Measurement of Worker Exposure following application to maize with A13726E (suspension concentrate containing 330 g/L terbuthylazine) during re-entry activities associated with scouting Maize. Report Number: 39661. Charles River Laboratories Edinburgh Ltd Elphinstone Research Centre. Tranent, East Lothian, EH32 2NE, UK.

Braid, S. and Langridge, G. 2017. Diquat Dibromide - Analytical Method GRM013.07A for the Determination of Dislodgeable Foliar Residues of Diquat Dibromide as Diquat Cation in Leaf Wash Solutions. Report No. GRM013.07A.

CAKE Kinetic Evaluation Report.2020.

EFSA (European Food Safety Authority), ~~2014~~ 2022. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal ~~2014;12(10):3874~~ 2022;20(1):7032, ~~55~~ 134 pp., https://doi.org/10.2903/j.efsa.2022.7032 ~~2014.3874~~.

EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance diquat. EFSA Journal 2015;13(11):4308, 127 pp. doi:10.2903/j.efsa.2015.4308.

EFSA (European Food Safety Authority), 2018. Statement on non-dietary exposure on diquat. EFSA Journal 2018;16(5):5260, 15 pp. https://doi.org/10.2903/j.efsa.2018.5260.

Guidance for determination of dislodgeable foliar residue, HS-1600 revised 2002, California EPA.

Langridge, G. 2017. Diquat – Validation of Analytical Method GRM013.07A for the Determination of Dislodgeable Foliar Residues of Diquat in Potato Leaf Wash Solutions by LC-MS/MS. Method Validation. Report Number: CEMR-7788-REG.

United Kingdom, 2015. Revised Renewal Assessment Report on Diquat, June 2015 (Diquat_RAR_08_Volume_3_B-6 (24 06 2015).pdf. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), Buist H, Craig P, Dewhurst I, Hougaard Bennekou S, Kneuer C, Machera K, Pieper C, Court Marques D, Guillot G, Ruffo F and Chiusolo A, 2017. Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp. Https://doi.org/10.2903/j.efsa.2017.4873.

~~EFSA Panel on Plant Protection Products and their Residues (PPR); Guidance on Dermal Absorption. EFSA Journal 2012;10(4):2665. [30 pp.] doi:10.2903/j.efsa.2012.2665.~~

EFSA (European Food Safety Authority), Buist H, Craig P, Dewhurst I, Hougaard Bennekou S, Kneuer C, Machera K, Pieper C, Court Marques D, Guillot G, Ruffo F and Chiusolo A, 2017. Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp. https://doi.org/10.2903/j.efsa.2017.4873.

European Commission, 2011. HEEG opinion on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance. HEEG opinion 13.

Framework for the Assessment of Plant Protection Products (2019). Department of Pesticides ~~and Biocides~~ Danish Environmental Protection Agency.

Kennedy, S. (2017). Diquat – Dislodgeable Foliar Residue Decline Study on Potato in United Kingdom, Hungary, Italy and Spain in 2016. Report Number: CEMR-7786. CEM Analytical Services Ltd (CEMAS), Imperial House, Oaklands Business Centre, Oaklands Park, Wokingham, Berkshire, RG41 2FD, United Kingdom.

Martin S, Westphal D, Erdtmann-Vourliotis M, Dechet F, Schulze-Rosario C, Stauber F, Wicke H and Chester G, 2008. Guidance for exposure and risk evaluation for bystanders and residents exposed to plant protection products during and after application. Journal fur Verbraucherschutz und Lebensmittelsicherheit, 3, 272–281. https://doi.org/10.1007/s00003-008-0361-5.

Northern Zone, ~~2019~~ 2023, Guidance document on work-sharing in the Northern zone in the authorization of plant protection products. Version ~~8, July 2019~~ 11.1, September 2023.

O'Connor, B (20187). Diquat Dibromide – Determination of Vapor Pressure by the Vapor Pressure Balance Method. Report Number: BF09DJ. GLP Testing Facility. Envigo Research Limited. Shardlow Business Park, Shardlow. Derbyshire, DE72 2GD, UK.

United Kingdom, 2015. Revised Renewal Assessment Report on diquat, June 2015 (Diquat_RAR_08a_Volume_3_B-6_Exposure_(24 06 2015).pdf. Available online: www.efsa.europa.eu

OECD (Organisation for Economic Co-operation and Development), 1997. OCDE/GD(97)148, Series on Testing and Assessment, No. 9, Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application.

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Rev. 6. juni 2022
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Rev. 07. juni 2024

Appendix 1 – GAP tabel for ansøgt anvendelse

GAP for potatoes:

1	2	3	4	5	6	7	8	9	10	11	12
Use-No. *	**Crop and/ or situation** (crop destination / purpose of crop)	**F***	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)
				Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	
1	Potato	F	Post emergence herbicide desiccation of potato crop	Spraying, tractor mounted	BBCH Stage 48	Max. 2 spray/season	7	a) ~~0,9~~ 0,8 L/ha b) ~~1,8~~ 1,6 L/ha	a) ~~180~~ 160 g a.s./ha b) ~~360~~ 320 g a.s./ha	90	7

Appendix 2 – Oversigtstabeller over eksponering

Overview tables of worker and resident/bystander

As no AAOEL was derived during the EU evaluation bystander is assumed to be covered by resident exposure assessment.
All results reported for resident/bystander are for calculations based on 50% drift reduction and 10 m bufferzone.

Operator:

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 50 %/75th percentile Crop density: Normal			
Diquat	Number of applications and application rate: 2 x 0.16 kg a.s./ha Dermal absorption (concentrate): 0.54 % Dermal absorption (in-use dilution): 1.8 %		
	M/L: Workwear + Protected hands + FP1, P1 and similar App: Workwear + Protected hands	0.0002	75.1

Worker:

~~Crop~~	~~Application rate (g a.s./ha) (water volume)~~	~~% of AOEL (work wear)~~
~~Potato#~~	~~2 x 180 (90 l water)~~	~~27 %~~

	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
				Inspection, irrigation (All) / Outdoor Work rate: 2 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 12500 cm²/h TC (workwear (arms, body and legs covered)): 1400 cm²/h TC (workwear (arms, body and legs covered) and gloves): 1250 cm²/h TC (gloves): NA cm²/h
	Diquat			Number of applications & application rate: 2 x 0.16 kg a.s./ha Dermal absorption: 1.8 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days
Potential		0.007	3330	16
Workwear		0.0007	373	6
Workwear and gloves		0.0007	333	6
Hands covered, no workwear				

Resident/bystander

Crop	Application rate (g a.s./ha)	Percentile	EFSA predicted mean exposure with DRT, 10m buffer (mg/kg bw/day) children	% of AOEL	EFSA predicted mean exposure with DRT, 10m buffer (mg/kg bw/day) adult	% of AOEL
Potato#	2 x 180 (90 L water)	Spray drift (75th percentile) mg/kg bw/day	0,0001	48 %	0,0000	8,6 %
		Vapour (75th percentile) mg/kg bw/day	0,0011	535 %	0,0002	115 %
		Surface deposits (75th percentile) mg/kg bw/day	0,0000	1,4 %	0,0000	0,5 %
		Entry into treated crops (75th percentile) mg/kg bw/day	0,0001	32 %	0,0000	18 %
		All pathways (mean) mg/kg bw/day	0,0012	590 %	0,0003	134 %
		All pathways (mean) mg/kg bw/day excluding vapour	0,00011*	55 %	0,0000386*	19 %

* Sum of each exposure pathway excluding vapour.
# calculation made with DFR: 0.94 µg/cm²/kg as/ha and DT50 of 3 days from the DFR study.

Exposure calculation without contribution from exposure to vapours:

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
			Season: Not relevant Buffer zone: 10 m Drift reduction technology: 50 % Interval between treatments: 7 days Minimum volume of water: 90 l
Diquat			Number of applications and application rate: 2 x 0.16 kg a.s./ha Dermal absorption: 1.8 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0002	123
	Vapour (75th perc.)		
	Deposits (75th perc.)	1e-05	5.1
	Re-entry (75th perc.)	0.0009	450
	Sum (mean)	0.0009	431
Resident adult Body weight: 60 kg	Drift (75th perc.)	5e-05	22.6
	Vapour (75th perc.)		
	Deposits (75th perc.)	4e-06	2.1
	Re-entry (75th perc.)	0.0005	250
	Sum (mean)	0.0004	213

Expoure calculation with contribution from exposure to vapours with a default vapour pressure of 0,001 Pa:

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
			Season: Not relevant Buffer zone: 10 m Drift reduction technology: 50 % Interval between treatments: 7 days Minimum volume of water: 90 l
Diquat (refined dfr & dt50)			Number of applications and application rate: 2 x 0.16 kg a.s./ha Dermal absorption: 1.8 % DFR: 0.94 µg/cm² foliage per kg a.s./ha DT50: 3 days
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0002	123
	Vapour (75th perc.)	0.0008	400
	Deposits (75th perc.)	7e-06	3.3
	Re-entry (75th perc.)	0.0002	91.4
	Sum (mean)	0.001	545
Resident adult Body weight: 60 kg	Drift (75th perc.)	5e-05	22.6
	Vapour (75th perc.)	0.0003	135
	Deposits (75th perc.)	3e-06	1.4
	Re-entry (75th perc.)	0.0001	50.8
	Sum (mean)	0.0004	189

Expoure calculation with contribution from exposure to vapours with the experimentally derived vapour pressure of 1.6 x 10^{-14} Pa:

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
			Season: Not relevant Buffer zone: 10 m Drift reduction technology: 50 % Interval between treatments: 7 days Minimum volume of water: 90 l
Diquat			Number of applications and application rate: 2 x 0.16 kg a.s./ha Dermal absorption: 1.8 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0002	123
	Vapour (75th perc.)	1e-12	5e-07
	Deposits (75th perc.)	1e-05	5.1
	Re-entry (75th perc.)	0.0009	450
	Sum (mean)	0.0009	431
Resident adult Body weight: 60 kg	Drift (75th perc.)	5e-05	22.6
	Vapour (75th perc.)	3e-13	2e-07
	Deposits (75th perc.)	4e-06	2.1
	Re-entry (75th perc.)	0.0005	250
	Sum (mean)	0.0004	213

Appendix 3 – Detaljerede eksponeringsberegninger

Exposure estimates, detailed calculations

Relevant input parameters are:

Dermal absorption
Concentrate: 0.54 %
Dilution 1:100: 0.56 %
Dilution 1:200: 1.8 %

~~Calculations of exposure estimates are based on the refined values from the DFR study for potatoes.~~
~~DFR suggested based on DFR field study: 0.94 µg/cm²/kg as/ha.~~
~~DT_{50}: 3 days.~~

Default values were used for DFR (3 µg/cm_2/kg a.s./ha) and DT50 (30 days).

The refinement of TC for resident children was not considered justified.
For resident the contribution from vapour has been removed.

Calculations for resident/bystander are based on 50% drift reduction and 10 m bufferzone.

~~Calculations for potatoes excluding vapour exposure for resident child, recalculated means for all pathways.~~

Please see use 4 for operator, worker and resident in the following document for detailed information on calculations:

Reglone, kartofler, eksp beregninger, OP

Potatoes: 2 x 0,180 0,160 kg as/ha, 90 l/ha, refined DFR and DT50.

Substance name	diquat	-
Product name	Reglone	-
-	-	-
Reference value non acutely toxic active substance (RVNAS)	0,0002	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	-	mg/kg bw/day
-	-	-
Crop type	Root and tuber vegetables	-
-	-	-
Substance properties	-	-
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	-
Miniumum volume water for application (liquids)	90	L/ha
Maximum application rate of active substance	0,18	kg a.s. /ha
50% Dissipation Time DT50	3	days
Initial Dislodgeable Foliar Residue	0,94	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	0,54%	-
Dermal absorption of in-use dilution	0,56%	-
Oral absorption of active substance	4,00%	-
Inhalation absorption of active substance	100,00%	-
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	-
-	-	-
Scenario	-	-
Indoor or Outdoor application	Outdoor	-
Application method	Downward spraying	-
Application equipment	Vehicle-mounted-Drift Reduction	-
Buffer strip	10	m
Number of applications	2	-

Interval between multiple applications	7	days	-
Season (upward spraying orchards only)	not relevant	-	-

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0042	% of RVNAS	2076,28%
	Acute systemic exposure mg/kg bw/day		0,0222	% of RVAAS	-
Mixing and Loading		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = FP1, P1 and similar	Soluble bags = No
Application		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = Yes
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day		0,0001	% of RVNAS	72,08%
	Acute systemic exposure mg/kg bw/day		0,0007	% of RVAAS	-
-	-	-	-	-	-

Worker - Inspection, irrigation	Potential exposure mg/kg bw/day	0,0005	% of RVNAS	236,57%
	Working clothing mg/kg bw/day	0,0001	% of RVNAS	26,50%
	Working clothing and gloves mg/kg bw/day	-	% of RVNAS	-
-	-	-	-	-

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0,0001	% of RVNAS	47,75%
	Vapour (75th percentile) mg/kg bw/day	0,0011	% of RVNAS	535,00%
	Surface deposits (75th percentile) mg/kg bw/day	0,0000	% of RVNAS	1,43%
	Entry into treated crops (75th percentile) mg/kg bw/day	0,0001	% of RVNAS	31,94%

	All pathways (mean) mg/kg bw/day	0,0012	% of RVNAS	590,02%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0,0000	% of RVNAS	8,55%
	Vapour (75th percentile) mg/kg bw/day	0,0002	% of RVNAS	115,00%
	Surface deposits (75th percentile) mg/kg bw/day	0,0000	% of RVNAS	0,48%
	Entry into treated crops (75th percentile) mg/kg bw/day	0,0000	% of RVNAS	17,74%
	All pathways (mean) mg/kg bw/day	0,0003	% of RVNAS	134,30%

3. Summing of exposure pathways mean

-	**Systemic exposure [mg a.s./day]**	**Systemic exposure [mg a.s./kg bw/day]**
1-3 year old child	-	-
Spray drift	**0,0005692**	**0,0000569**
Vapour	**0,0107000**	**0,0010700**
Surface deposits	-	-
Dermal	**0,0000157**	**0,0000016**
Hand to mouth	**0,0000041**	**0,0000004**
Object to mouth	**0,0000022**	**0,0000002**
Entry into treated crops	-	-
Dermal	**0,0005093**	**0,0000509**

Hand to mouth	-	-
Object to mouth	-	-
Adult	-	-
Spray drift	**0,0005739**	**0,0000096**
Vapour	**0,0138000**	**0,0002300**
Surface deposits (dermal)	**0,0000441**	**0,0000007**
Entry into treated crops (dermal)	**0,0016976**	**0,0000283**

2 x 180 g as/ha (90 L water)	With vapour		Without vapour	
Exposure	Child	Adult	Child	Adult
Spray drift	0,0000569	0,0000096	0,0000569	0,0000096
Vapour	0,00107	0,00023	-	
Surface deposit	0,0000016	0,0000007	0,0000016	0,0000007
Hand to mouth	0,0000004		0,0000004	
Object to mouth	0,0000002		0,0000002	
Entry treated fields	0,0000509	0,0000283	0,0000509	0,0000283
Means sum	0,00118	0,0002686	0,00011	0,0000386
% AOEL	**590**	**134**	55	19

Appendix 4 – Overview of requirements for DFR/DT_{50} studies according to OPEX 2022

General considerations/Quality		
Requirement	Relevant to	Comments
A GLP compliance certificate.	DFR	Acceptable. A GLP certificate is attached to the report.
A GLP compliance statement. When the field phase and analytical phase are conducted by separate facilities, the appropriate documentation for the laboratory sub-contracted to perform the analytical work is expected.	DFR	Acceptable. A GLP compliance statement is attached to the report.
QA statement This should provide inspection dates for the key elements of the study (field and laboratory phases).	DFR	Acceptable. A QA statement is attached to the report.
Study design		
The study includes a review which shows that the study design used is representative of the scenario to be considered (e.g. currently typical cultivation and application methods in Europe, including demonstration of representative	DFR	Unacceptable. No justification for how the study sites are representative to the climatic conditions of Denmark is found in the report or separately by the applicant. No comments on typical cultivation and application methods are contained in the report.

climatic conditions, e.g. with Köppen-Geiger criteria).		
Representative application methods and application techniques, according to the current agricultural application practices in Europe. Application equipment, tank volume, water volume, pressure, forward speed etc. should be described and reported.	DFR	Acceptable with provisions. Sprayer type, number of nozzle, nozzle type (flat fan), volume of spray and volume of product is described. Pressure, forward speed, tank volume is not described.
Representative crop activities should be tested, reflecting current agricultural practices in Europe. Activities carried out by workers should be described in detail.	DFR	Unacceptable. This is poorly described in the report.
The test site is clearly defined, including location and positioning of the sampling points/person being exposed.	DFR	Unacceptable. Sampling points are not well described. Neither is the sampling technique. Coordinates of test site is included.
At least three test sites in different locations to capture variation in working/agronomic practices and environmental conditions would be desirable. A justification for the selection of the locations and the working/agronomic practices used in the study shall be provided.	DFR	Unacceptable. Only a single test site can be considered representative of the climatic conditions of Denmark.
The meteorological conditions must be fully reported. As a minimum, this must include temperature, humidity and rainfall (for worker exposure and DFR studies, information about	DFR	Acceptable with provisions. Temperature, humidity and amount of precipitation is described for the test site on the test days.

date, duration and amount of rainfall is necessary).		
Key experimental data must be reported. As a minimum this should be identification of the plant protection substance, formulation, application rate and crop (BBCH, age of the crop). Sprayer description should also be included.	DFR	Acceptable with provisions. The substance, formulation, application rate and crop including age is well described in the report. Sprayer type is not well-described but can be accepted.
It is recommended to consider the worst-case intended use for each crop investigated (e.g. maximum application rates; multiple applications using the minimum treatment interval; late growth stage).	DFR	Acceptable with provisions. The report describes a single application with an application rate 0.80 kg diquat/ha. The applied for use is two applications of 0.16 kg diquat/ha. Therefore, the study does not take into consideration built up of residue between applications. However, the application rate is considerably higher than the one described in the GAP in appendix 1. It is therefore deemed to be acceptable in this particular case.
The timing of the applications should bracket the time frames when re-entry activities are anticipated to occur, with a focus on the timeframes where higher exposure activities occur. Likewise, the transferable residue (e.g. DFR/TTR) samples should be collected accordingly.	DFR	Acceptable. The growth stage of the plants of the study is representative of the actual use (i.e. BBCH stage 89-92).
Agricultural spray adjuvants should not be used unless they are recommended for the respective product (e.g. in cases where the use of adjuvants is mandatory).	DFR	Acceptable. No adjuvants where used in the study. No adjuvants are recommended when applying Reglone.

Only necessary maintenance products (plant protection products and fertilisers) should be used. These products must not interfere with the chemical analysis.	DFR	Acceptable. A description of maintenance products (i.e. other plant protection products necessary for a successful crop) is included in the study. No other products containing diquat were used.
For studies designed to provide estimate of TC values, the exposure measurements and DFR determinations should be done concurrently in the same crop and at the same sites.	DFR	Not relevant.
At the test site one or several field plot(s) and one control plot should be established. In order to obtain representative samples from a field plot, it must be divided into at least 3 subplots. Replicate sample should be taken from the different subplots of a field plot.	DFR	Unacceptable. The test sites were not divided into subplots. Further, the sampling technique was not described. Coupled with the fact that the test sites was very small (3×10 meters), it cannot be ensured that the sampling is representative of standard field spraying. E.g. plants on the border of plots are usually not sampled.
The control plot will be positioned upslope (if applicable) and upwind (at application) of the field plots to reduce the potential for contamination due to drift. The separation distance between control and field plots should be sufficient to avoid contamination of the control plot while ensuring that the crop, soil and environmental conditions are the same in field and control plots.	DFR	Unacceptable. No description of the placement of the control plot is included in the report. This is problematic in itself and due to signs of contamination of the control field noted elsewhere.
Since climatic conditions and growing conditions can influence the dissipation rate, studies should be performed at sites representative of the climatic and growing conditions representative	DFR/DT50	Unacceptable. Three out of four test sites were not representative of the climatic conditions of Denmark. As such they cannot be used to derive neither DFR nor DT_{50} for Danish conditions.

of the intended use areas. The Köppen–Geiger criteria may be useful when considering climatic equivalence. (Note: If the intended use is relevant for the entire EU then representativeness of climatic conditions should be covered by multiple field studies, unless comparability of climatic conditions or 'worst-case' conditions for the relevant crop can be justified, based on the residue guidelines (e.g. SANTE/2019/12752) a differentiation for northern and southern studies for outdoor crops should normally be sufficient).		
Individual studies should be conducted in areas where the slowest dissipation of residue is assumed, i.e. representing 'worst-case' conditions. There should be no rainfall for 24 h before and after applying the product. If the precipitation during the sampling period is higher than the typical precipitation at the field location, the study may not be acceptable for the estimation of half-lives (DT50). However, this should be decided on the basis of the resulting dissipation kinetics.	DFR	Acceptable. No precipitation was registered for the entire duration of the study.
Sampling parameters		
The sampling approach should be clearly described and be justifiable, representative and appropriate, allowing for a consistent sample collection. It should include sampling time,	DFR	Unacceptable. No description of the sampling technique is contained in the study report. As such, consistent, representative sampling cannot be ensured.

sampling interval, distance from application to sampling point, sampling height, foliage type, etc.		
To verify the application rate, and the amount of active substance loaded and applied per tank, tank mix samples should be taken and analysed. Various sampling techniques can be used, e.g. samples can be taken directly from the spray nozzles; from a tap attached to the tank or directly from the tank. It is recommended to take at least three samples (e.g. at the beginning in the middle and at the end of each treatment). The nozzles must be calibrated at the beginning of each treatment. Other sampling techniques can also be used if these methods are appropriate for analysing the concentration of the spray solution.	DFR	Unacceptable. No samples from the sprayer tank were described. Only volume of water and product was described. As such, uniformity of the spray solution cannot be guaranteed. Together with the lacking description of sampling technique, the validity of the study cannot be guaranteed.
The active substance, or any degradation products relevant to the risk assessment, should be sufficiently stable under field conditions to permit reliable estimation of exposure and other values.	DFR	Acceptable with provisions. No description of stability of diquat under field conditions is contained in the study. However, the leaf punches were extracted on the day of sampling. Stability can therefore be assumed to be of lesser importance.
It is recommended that the formulation used in the study should be used for fortification experiments when analytics is assumed to be	DFR	Acceptable. Reglone was used in the fortification experiments.

influenced by co-formulants (e.g. lower extraction efficiency).		
A minimum of three replicate samples should be taken in each field plot and at each sampling interval. However, more are recommended (e.g. four to six) to provide more robust data and a better estimate of the DFR value (see also Criteria below). Where only the minimum are provided, the representative DFR value is likely to be set at the maximum value observed.	DFR	Unacceptable. Three replicates were taken per site, however, the sites were not divided into subplots. The former is a requirement according to NZ 2023 and suggested in OPEX 2022.
Replicate samples are to be taken from the areas of the plant where contact with workers is expected. Different approaches are available e.g. non-directed sampling where field technicians enter a treated area and sample at their own discretion; the Iwata approach (Iwata et al., 1977) for tree crops where samples are collected at 45 degree intervals around the circumference of each sampled tree and at varying heights in the tree; the planned approach for row crops where investigators develop a scheme that predetermines sample collection locations.	DFR	Unacceptable. No description of sampling technique is enclosed in the study report.
To characterise dissipation rates of dislodgeable residue (DT50), data should be sufficient to cover several half-lives (e.g. three half-lives). Typical sampling intervals are 4 h, 12 h, 1, 3, 7, 14, 21, 28, 35 days after treatment (DAT). If the	DFR	Acceptable with provisions. For the UK site, samples are only taken until 48 hours after spraying. This is not ideal. However, as the product is used for desiccation, a limited study time is to be expected.

study involves multiple applications, samples should be taken prior to and after each application on the day of application. It is also suggested that samples are taken in the intervals between the application events at least every 7 days after each application.		As is apparent from the data from the UK site, several half-lives have not been covered. This cast doubt on the validity of the derived DT_{50}.
Sampling techniques		
Samples should be collected and prepared in the field, if necessary, transported and stored according to OECD 1997 (see also EC Guidance 7029/VI/95 rev. 5).	DFR	Acceptable. The leaf punches were extracted shortly after they were collected and transported and stored in line with OECD 1997.
For sampling and extracting of leaves, the protocol by Iwata et al. (1977) should be followed. In short, leaf samples should be gathered with a mechanical leaf punch device (equal to ~ 200 cm2 single side, or 400 cm2 double-sided). Some crops do not lend themselves to the use of a leaf punch (e.g. some ornamentals and conifers). Determinations of leaf sample surface areas should be addressed on a case-by-case basis. Ideally within 4 h and always within 24 h leaves, samples should be extracted by washing the surface of the leaf with a water/surfactant solution (e.g. a 0.01% dioctyl sulfosuccinate, sodium salt solution). The use of organic solvents should be avoided as they may carry	DFR	Acceptable with provisions. The size of leaf punches is not directly described in the protocol of the UK test site, however, the Spanish, Italian and Hungarian protocols all describe surface area of the mechanical punch as well as the total collected leaf punch samples. As such, it can be assumed that the UK site used a similar mechanical punch.

surface residue into the leaf tissues or extract penetrated residue. Non-extracted samples should not be stored freeze or with dry ice.		
Sample storage		
Samples should be stored in a manner that will minimise deterioration and loss of analyte(s) between collection and analysis. Sample storage time should be recorded. The study investigator is responsible for demonstrating the stability of the samples under the storage duration and conditions used (for further details see 'quality assurance/quality control' below).	DFR	Acceptable with provisions. Storage stability of diquat on leaf surfaces have not been assessed. However, the leaf punch samples were only stored for a few hours before being extracted. The storage stability of the extracts were assessed in the validation of the analytical method (Braid 2017). Here, it was shown that the extracts are stable for up to 76 days when stored frozen. The samples of the DFR study were stored frozen for approximately 3 weeks. This is acceptable.
Quality assurance/quality control (pre-field laboratory considerations)		
SANTE/2020/12830, Rev.1, 24. February 2021 should be used when generating and reporting methods of analysis. Any analytical method used to analyse samples from field studies needs to be sufficiently validated regarding all parameters in accordance with the available guidance in force.	DFR	The analytical method (Braid 2017) was fully validated according to SANCO/2020/12830, rev. 2, with minor deviations. The method described in the DFR study (Kennedy 2017) was based on the one described in Braid (2017), however, it was identical and was not fully validated according to SANCO/2020/12830, rev. 2. In spite of this, it was found to live up to the minimum validation criteria described in SANCO/2020/12830, rev. 2., and was therefore found to be fit for purpose.
Quality assurance/quality control (in field considerations)		

Valid field recovery data (and thus, the ability to accurately fortify field recovery samples with a known amount of mass ingredient) is essential to the study, to allow the experimental data to be corrected for losses that occur during all phases of sample collection and analysis.	DFR	Acceptable with provisions, see next point. Acceptable field recovery data is presented.
Ideally, a complete set of field recovery samples should be collected at each site and on each day of sampling. If it can be shown that the field recovery does not change over the sampling period, then in the case of DFR studies, a complete set of field recovery may not be required for each sampling day. It may be acceptable to collect a single set of field recovery samples if the environmental conditions are similar on each day and/or at each site.	DFR	Acceptable with provisions. Control samples for fortification were taken from the control plot at 0 and 48 hours after spraying. The recovery is considerably higher at 48 hours (mean recovery of 86-88 % at 0 hours and 102-110 % after 48 hours). This could indicate that the control plot may have been contaminated during spraying of the test plot.
A complete set of field recovery samples should include 3 (or more) samples, each blank control samples, low level fortification and high level fortification. The high and low fortification should cover the range of the anticipated level of chemical on the respective matrices. If the highest expected level is more than 100X the lowest spiking level, it is	DFR	Unacceptable. The study report only presents data on unfortified control samples at 0 hours after spraying. Samples were collected from the control field at 48 hours after spraying, however, the data is not presented in the report. The fortified field samples are spiked to a very high concentration (4000 and 40000 x LOQ). This is rather unorthodox as fortification at the LOQ is usually expected. However, as the concurrent laboratory

recommended that a midlevel of fortification is included.		fortified samples were spiked at the LOQ as well as 4,000 and 40,000x LOQ this was deemed acceptable.
Field recovery samples should be handled using the same procedures as the actual field samples. They should be collected, handled, transported and stored concurrently with actual field samples. Additionally, field recovery samples should be analysed concurrently with actual field samples to account for residue losses during sample extraction and analysis.	DFR	Acceptable. Field recovery samples were collected, stored and extracted in parallel with the actual field samples.
Field recovery results less than 95% should be used to correct the results of field samples. However, if field recoveries are below 70% they must be technically justified. Recovery results greater than 95–100% should be noted but not used to correct the data. Actual field samples should be corrected with the closest spiking level obtained from the fortified samples.	DFR	Acceptable. The samples were corrected adequately corrected.
Blank control field samples indicate whether contamination of the field recovery samples has occurred.	DFR	Acceptable with provisions. The blank samples contain diquat in a concentration >LOQ. As no product containing diquat was used prior to the study, this indicates cross contamination of the control samples. However, as the concentration is below 30 % of the LOQ, it is deemed acceptable.

The report should provide a valid explanation for the occurrence of residue in control samples when results are higher than 30% of LOQ.		
Travel recovery samples should be shipped and stored with the field recovery and actual field samples. Travel recovery samples are optional and reflect losses which may occur during shipment and possibly storage. These samples are not used to correct actual field samples but may be useful to determine where losses have occurred.	DFR	Acceptable. No travel recovery samples were made during the study, however, these are optional and the field recovery samples demonstrate acceptable recovery.
Quality assurance/quality control (post-field laboratory considerations)		
Laboratory recovery samples are analysed in the analytical laboratory concurrently with the actual field samples to determine the recovery efficiency of the analyte(s) from the respective matrices. It is recommended that the field recovery samples are used as concurrent laboratory samples whenever possible. When used in this manner, field recovery samples can be used to correct actual field samples for losses that occur both in the field and in the laboratory.	DFR	Acceptable. Laboratory recovery samples were analyzed concurrently to field samples. Field recovery samples were also analyzed in parallel to the laboratory recovery samples in the validation report for the analytical method (Braid 2017).

Presenting and analysing results		
Raw data must be provided as well as detailed observations on operators and workers (former only relevant for studies on exposure of operators and workers).	DFR	Unacceptable. Raw data for control samples taken 48 hours after spraying in the UK study is not presented.
Results should be reported as absolute values (µg or mg active ingredient per sample) as well as mg or µg active ingredient per kg active ingredient applied.	DFR	Acceptable with provisions. Results are presented as mass per volume of extraction fluid (µg/L) and mass per area of leaf (ng/cm^2). In principle, this is enough to calculate values in the required format and it is therefore accepted.
If residues are below the limit of quantification (LOQ) and above the limit of detection (LOD), they should be reported as below LOQ (e.g. < LOQ), but they should be considered as LOQ.	DFR	Not relevant. No results below the LOQ was found for the UK site.
If residue are below the limit of detection (LOD), they should be reported below LOD (e.g. < LOD), but they should be considered as LOD.	DFR	Not relevant. No results below the LOD was found for the UK site.
A justification for excluding outliers should be clearly stated in the study report and summary text. Although outliers may be excluded from the analysis if well justified, for technical or procedural reasons e.g. part of the sample extract was lost (note a statistical test alone is not sufficient justification), the data must nevertheless be presented. It should be noted that results treated as outliers should include spuriously low values as well as high values. Expert judgement might ultimately be applied	DFR	Not relevant. No outliers were noted.

on a case-by-case basis to increase values compensating for deficiencies in the quality of the study. Justification for choosing a certain increased value should be provided and fully documented in such cases.		
Statistical analysis is appropriate and must be provided addressing the variability of the study results.	DFR	Unacceptable. No statistical analysis were reported for any of the study results.
Correction for background concentration should not be performed. If the worst-case intended use for each crop investigated is considered, no correction is needed even in the case of multiple applications. If residue are found before the first application, then consideration should be given to use determined DFR/TTR value without correction or rejecting the study entirely.	DFR	Unacceptable. Results are noted to be corrected for background diquat. Furthermore, it is noted that no products containing diquat has been used before initiation of the study. This indicates cross contamination of samples. The cross contamination is limited as the found concentration of diquat in control samples is low.
The highest DFR/TTR value should be used if only 3 replicate samples were taken from a field plot per sampling interval. When ≥ 4 replicate samples are available per field plot and per sampling interval, the use of a mean might be justified. However, if there is significant variation between these replicate samples (i.e. the standard deviation is equal to or larger than 25% of the mean) the standard deviation should be added to the mean value.	DFR	Unacceptable. Three replicates were taken from the UK site, however, the study site was not divided into subplots and sampling technique was not adequately described. Therefore, representative sampling cannot be ensured. Further, no statistical analysis of results was performed and variation between samples cannot be assessed.

DT50 values can only be derived from acceptable DFR studies, therefore all validity criteria for DFR studies must be taken into account. For estimation of DT50 the standard procedures recommended by FOCUS (2014) should be followed, including e.g. the general procedure and the assessment of the goodness-of-fit. Since calculated DT50 values are used in models for exposure assessments (e.g. determination of the MAF), single first-order kinetics should generally be used (EFSA, 2014c). More recommendations on the fitting of DT50 data and the statistical validation of the fit can also be found in the EFSA Technical Report (2019).	DFR/DT50	Unacceptable. The DFR study is not deemed to be acceptable. Therefore, a DT_{50} cannot be derived.
In case of multiple applications, when a field study is available, but not considered sufficient for the specific DFR estimation, the following should be considered for the DT50 derivation: a) If appropriate data (adequate sampling points) in between the different applications are available then: – each application (and the following points until the next application) can be considered as a standalone trial	DT50	Not relevant. Crops were only sprayed once.

– a DT50 is calculated for each application and then the geomean (GM) of the calculated DT50 values, – depending on the amount and variability of the data, use either the GM or the highest DT50 value calculated as a worst case. b) If the sampling points for the in between applications are not adequate for the calculation of single DT50 values, the data set after the last application is to be used.		

Appendix 5 – Overview of requirements for DFR/DT_{50} studies according to NZ 2023

Number of studies/sites	< 3 sites[1] : use of default value 3-9 sites: use of maximal value[2] ≥ 10 sites: geometric mean[2] Test sites should have different locations to cover variation in environment and agronomic practices. The data shall include all outliers in the data set as they represent realistic use.	Only a single site can be considered relevant to Danish climatic conditions.
No. of replicates (within a study)	3 replicates[3] per field plot[4]: use of maximal DFR value ≥ 4 replicates per field plot: use of mean DFR value If SD ≥ 25 %: mean DFR + SD For the determination of DT_{50}, a minimum of 3 replicates per time point is required. In order to obtain representative samples from a field plot, it must be divided into at least 3 subplots.[5] Replicate samples should be taken from the different subplots of a field plot to ensure representative sampling. Relevant field plot size variates from crop to crop and should be large enough to allow application of the plant protection product in a manner which reflects routine use and such that sufficient representative sample(s) can be obtained without bias.[6]	Three replicates have been collected for the UK site but the site was not divided into subplots, and the sampling technique is poorly described. Therefore, the quality of data is questionable and not fit for deriving DFR or DT_{50} values.
Climatic conditions	Study sites are considered relevant if study conditions are comparable to conditions in Northern Zone (EPPO zones: Maritime and North-East). Another option is to apply Köppen–Geiger criteria to demonstrate representativeness in relation to NZ climatic conditions. Relevance will be assessed case-by-case.	Three out of four study sites are not in the same EPPO zone as Denmark, and they are not considered relevant to Danish conditions. This is also obvious from the study data where degradation is considerably faster for the Italian, Hungarian and Spanish test sites compared to the UK test site.
Fitting of data	In general, single first-order fitting) with assessment of goodness-of-fit.[11]	Fitting of data was not evaluated due to questions around validity of the presented data.
Analytical methods	Analytical methods should be validated in accordance with requirements in the respective reference documents listed in OPEX GD, table J.1.	The analytical methods are fully validated or deemed fit for purpose.

[1] A test site is the geographical location of the field study defined by unique geo-climatic conditions and agronomic practices under which the plant protection product will be used.
[2] Maximum or geometric mean of all DFR, DT50, TTR or human exposure values derived from each study.
[3] A replicate sample corresponds to total leaf punches with a surface area of 400 cm2 (double-sided)
[4] A field plot is the experimental unit/field at the defined site from which samples are taken. One or several field plots and one control plot should be established at the site.
[5] A subplot is a sub-division of a field plot.
[6] See further description in OECD test guideline No. 509
[7] See further description in Appendix XI.
[8] Extrapolation to crops within the same crop group or with high similarity to the crop in the specific use may be accepted case-by-case. See further description in Appendix XI.
[9] If conducted with another active substance, then the active substances should have similar relevant physical chemical parameters such as vapour pressure.
[10] Measurements should be conducted under conditions as similar as can be reasonably expected from the NZ GAP.
[11] Criteria are listed in FOCUS 2014 (FOCUS Work Group on Degradation Kinetics, Version 1.1., 18 December 2014) and EFSA 2019 (EFSA supporting publication 2019; EN-1673, 117 pp) and summed up in Appendix XI.