European Food Safety Authority

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CONCLUSION ON PESTICIDE PEER REVIEW

Peer review of the pesticide risk assessment of the active substance incorrectly named didecyldimethylammonium chloride[1], (it is in fact a mixture of alkyl-quaternary ammonium salts with typical alkyl chain lengths of C8, C10 and C12, with more than 90% of C10)

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SUMMARY

Didecyldimethylammonium chloride is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[2], as amended by Regulation (EC) No 1095/2007[3]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within six months a conclusion on the risk assessment to the EU-Commission.

The Netherlands being the designated rapporteur Member State submitted the DAR on didecyldimethylammonium chloride in accordance with the provisions of Article 22(1) of the Regulation (EC) No 2229/2004, which was received by the EFSA on 28 November 2007. The peer review was initiated on 23 June 2008 by dispatching the DAR for consultation to the Member States and on 5 March 2008 to the sole notifier Lonza GmbH. Subsequently, the comments received on the DAR were examined and responded by the rapporteur Member State in the reporting table. This table was evaluated by the EFSA to identify the remaining issues. The identified issues as well as further information made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in October 2008.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in November-December 2008 leading to the conclusions as laid down in this report.

[1] For citation purposes: Conclusion on pesticide peer review regarding the risk assessment of the active substance didecyldimethylammonium chloride. *EFSA Scientific Report* (2008) 214, 1-54.
[2] OJ L379, 24.12.2004, p.13.
[3] OJ L246, 21.9.2007, p. 19.

The active substance called didecyldimethylammonium chloride is a mixture of compounds and has no ISO common name. However, to facilitate the peer review, the name didecyldimethylammonium chloride (DDAC) was used.

The conclusion was reached on the basis of the evaluation of the representative uses as bactericide, fungicide, herbicide and algicide, as proposed by the notifier, which comprise soaking or dipping applications for the disinfection of horticultural vessels and equipment, and watering applications for the disinfection of surfaces, controlling plant pathogenic bacteria, fungi, weed seeds and algae. Full details of the GAP can be found in the endpoints.

The representative formulated product for the evaluation was 'M&ENNO-TER forte', a soluble liquid (SL) containing 310 g/L didecyldimethylammonium chloride.

Data gaps were identified for adequate information on identity, production process, starting materials, purity and how to express it, specification, analytical methods and test materials used in toxicity testing.

Data gaps were identified for an analytical method for the determination of the active substance in the technical material and formulation, and also for monitoring of DDAC residues in surface water.

Sufficient methods and data relating to physical, chemical and technical properties, except for the active substance content, are available to ensure that quality control measurements of the plant protection product are possible.

Considering the proposed uses, residues in food of plant and animal origin, soil, ground water and air are not relevant, and therefore analytical methods for these matrices are not required.

With regard to its toxicological properties, DDAC was absorbed to a very limited extent after oral administration, without accumulation in the organism. Based on acute toxicity results, the proposed classification **Xn; R22 "Harmful if swallowed"** and **C; R34 "Causes burns"** was agreed for DDAC.

In repeated dose studies, even though the systemic effects were considered as secondary to the primary effect of corrosivity, they were taken into account for the setting of the NOAELs. Therefore, the agreed oral short-term NOAEL was 60.7 mg DDAC/kg bw/day in rats, and 10 mg DDAC/kg bw/day in dogs. Similarly, in the dermal study, only local effects in the skin were observed and lead to a dermal short term LOAEL of 2 mg/kg bw/day (lowest dose tested). DDAC did not show genotoxic or carcinogenic potential. The agreed long-term NOAEL was 32 mg DDAC/kg bw/day in rats based on decreased bodyweight gain and histopathology in the liver and lymph nodes, and 76.3 mg DDAC/kg bw/day in mice based on reduced bodyweight gain. In the reproductive toxicity studies, neither adverse effects on the reproductive parameters, nor any indication of teratogenic properties were observed. In the multigeneration study, the agreed parental and offspring NOAEL was 50 mg DDAC/kg bw/day. In the developmental studies, clinical signs indicative of primary local effects (attributed to the corrosive properties of DDAC) were taken into account for the derivation of an agreed maternal NOAEL of 1 mg DDAC/kg bw/day in rats and rabbits. Foetal effects (if any) were only observed in the presence of maternal toxicity.

With regard to the setting of the reference values, considering the restricted representative use in floriculture, the experts agreed that no dietary exposure of the consumers was expected, and therefore no acceptable daily intake (ADI) or acute reference dose (ARfD) were needed. The derivation of the acceptable operator exposure level (AOEL) was extensively discussed

by the experts, who agreed that, according to the toxicological profile of DDAC, an AOEL had not to be set. Concerning the operators, it was assumed that the exposure was safe with the use of personal protective equipment (due to the corrosive properties of DDAC). The exposure of bystanders was excluded due to the use indoors or in greenhouses. The worker exposure was expected to be negligible.

No data were submitted to study and assess the residue behaviour of didecyldimethylammonium chloride in plants and livestock animals in order to define the relevant residues for dietary consumer risk assessment. The representative use of didecyldimethylammonium chloride as a disinfectant of surfaces, plant pots and equipment only used for ornamental plant production is normally not expected to result in any dietary exposure to humans or livestock animals. Under conditions excluding any potential consumer exposure to didecyldimethylammonium chloride residues, there will be no dietary consumer risk related to the notified representative uses.

With regard to the applied for representative uses, the contamination of the soil compartment or the groundwater was deemed to be negligible. However, reliable soil batch adsorption data were available indicating that didecyldimethylammonium chloride is immobile.

No reliable natural water sediment study was available, however, a data gap was not considered necessary by the peer review, as the risk from the metabolites that may be formed was deemed to be covered by the risk assessment of the parent compound. As the FOCUS approach could not be applied to the representative uses of DDAC, the predicted environmental concentrations in surface water and sediment were estimated using USES 2.0 model, which can estimate the exposure via the sewage systems including a sewage treatment plant. For the calculations it was assumed that a user applies not more than 20 kg (for tier 1 calculation) or 5 kg (for tier 2 calculation) of DDAC on one occasion. Moreover, as an exposure refinement, it was assumed that a certain amount of DDAC is retained in the sewage system by adsorption to the organic matter. The values from these calculations are the basis for the risk assessment discussed in this conclusion, which might not cover a wide range of situations in all Member States.

DDCA was toxic to aquatic organisms (**N** "**Dangerous for the environment**", **R50/R53** "**very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment**"). A high risk was identified for invertebrates and algae, even considering the surface water exposure reduction, which can occur as a consequence of the adsorption of the active substance to the organic matter in the sewage system. Therefore, a data gap was identified to further address the risk to aquatic organisms. The risk was assessed as low for terrestrial vertebrates, bees, non-target arthropods, earthworms, soil macro and micro-organisms, other non-target organisms and biological methods for sewage treatment.

Key words: didecyldimethylammonium chloride, DDAC, peer review, risk assessment, pesticide, bactericide, fungicide, herbicide, algicide

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BACKGROUND

Commission Regulation (EC) No 2229/2004 laying down the detailed rules for the implementation of the fourth stage of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 1112/2002, as amended by Commission Regulation (EC) No 1095/2007, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Didecyldimethylammonium chloride is one of the 295 substances of the fourth stage, covered by the amended Regulation (EC) No 2229/2004 designating the Netherlands as rapporteur Member State.

In accordance with the provisions of Article 22(1) of the Regulation (EC) No 2229/2004, the Netherlands submitted the report of its initial evaluation of the dossier on didecyldimethylammonium chloride, hereafter referred to as the draft assessment report, received by the EFSA on 28 November 2007. Following an administrative evaluation, the draft assessment report was distributed for consultation in accordance with Article 24(2) of the Regulation (EC) 1095/2007 on 23 June 2008 to the Member States and on 5 March 2008 to the sole applicant Lonza GmbH, as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, the EFSA identified and agreed on lacking information to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the requested information received from the notifier, a scientific discussion took place in expert meetings in October 2008. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in November-December 2008 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Protection Products and their Residues (PPR).

In accordance with Article 24c(1) of the amended Regulation (EC) No 2229/2004, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant endpoints for the active substance as well as the formulation is provided in appendix A.

The documentation developed during the peer review was compiled as a peer review report comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received,
- the resulting reporting table (revision 1-1, 20 August 2008),

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation,
- the evaluation table (revision 2-1, 16 December 2008).

Given the importance of the draft assessment report including its addendum (compiled version of November 2008 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Didecyldimethylammonium chloride (DDAC) has no ISO common name and a unique IUPAC name cannot be given as the active substance is a mixture of several compounds.

DDAC belongs to the class of quaternary alkyl-ammonium compounds. It is a non-systemic broad-spectrum fungicide, bactericide and herbicide (algicide). DDAC inhibits the growth of and kills phytopathogenic fungi, phytopathogenic bacteria and algae in hydroponic systems, on hard surfaces, equipment, glasshouse walls and pavements, pots and knives. DDAC is used in horticulture, only inside glasshouses. It is not used on the plants themselves.

The representative formulated product for the evaluation was 'M&ENNO-TER forte', a soluble liquid (SL) containing 310 g/L (325 g/kg) didecyldimethylammonium chloride, registered under different trade names in some European countries.

The representative uses evaluated comprise:

- soaking of horticultural vessels after the last use to control plant pathogenic bacteria, plant pathogenic fungi and weed seeds (*Poa annua, Cardamine hirsuta, Senecio vulgaris, Veronica peregrina, Sagina procumbens)*, in all EU countries, single application at 0.31 kg a.s./hL as a bactericide or fungicide, and at maximum 1.55 kg a.s./hL respectively, as a herbicide;
- dipping of equipment (e.g. knives) before use to control plant pathogenic bacteria, in all EU countries, single application at 0.0775 kg a.s./hL, and
- watering applications on surfaces after the last use or before use, to control plant pathogenic bacteria, plant pathogenic fungi and algae, in all EU countries, single application at a maximum application rate per treatment of 62 kg a.s./ha.

The rapporteur Member State identified a data gap for clarification whether the use on sand beds should be included in the table of representative uses.

SPECIFIC CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The minimum purity of DDAC could not be concluded on. No FAO specification exists.

The identity and purity of technical DDAC has not been sufficiently established. The identity of the active substance is unclear, it is a mixture of alkyl-quaternary ammonium salts with typical alkyl chain lengths of C8, C10 and C12, with more than 90% of C10.

The rapporteur Member State identified data gaps concerning information on production process, starting materials, purity and how to express it, specification and relevant impurities, analytical methods, test materials used in toxicity testing. The data gaps identified in Volume 1 Level 4 and, for confidentiality reasons, listed in Volume 4 under C.1.5, were confirmed by PRAPeR 56 meeting of experts (October 2008).

Additional data gaps identified by the rapporteur Member State and confirmed by PRAPeR 56 meeting of experts are the following:

- five-batch analysis of the technical active substance (pure) or of a representative technical concentrate

- an unequivocal specification for the purified technical grade didecyldimethylammonium chloride based on dry matter content
- a specification for a representative technical concentrate, expressed on dry weight basis.

Since clarification is required with respect to the identity and composition of the active substance, no specification for the technical material exists for the moment.

Besides the identity and the specification, the assessment of the data package revealed no issues that need to be included as critical areas of concern with respect physical, chemical and technical properties of DDAC or the respective formulation. However, the PRAPeR 56 meeting of experts could not conclude on the acceptability of the physical, chemical and technical properties of the active substance until the identity of the material used for the tests is clarified.

Data gaps concerning physical, chemical and technical properties of DDAC or the respective formulation identified in Volume 1 level 4, confirmed by PRAPeR 56 meeting of experts, are as follows:

- to clarify by which analytical method the reported purity of 98.2% of the pure active substance used in a number of physico-chemical tests was determined.
- appearance (physical state, colour).
- relative density of “BARDAC 2270”
- interpretation of individual peaks in each spectrum in relation to the structure of DDAC for the confirmation of the identity of DDAC by IR and mass spectra
- statement on explosive properties evaluating all components present in the product (and also in the surfactant) individually
- statement on oxidising properties evaluating all components present in the product (and also in the surfactant) individually
- to provide evidence that during preparation of the in-use concentration and its use no unacceptable amounts of foam are formed that represent a hazard to operators
- to indicate whether sand beds should be included in the GAP or not
- to provide the content of the technical active substance and the pure active substance in the plant protection product

Standard ISO method (ISO 2871-2 part 2; determination of cationic-active matter content of low molecular mass (between 200 and 500) in surface active agents and detergents) is available for the determination of DDAC in the technical material, however it is not specific to DDAC. The rapporteur Member State identified a data gap, confirmed by PRAPeR 56 meeting of experts, to provide an acceptable justification why LC-MS method was not used to determine DDAC and impurities in the technical material, or to provide a specific method to determine DDAC and impurities. A new data gap was identified for an analytical method for the determination of the active substance in the formulation.

Sufficient test methods and data relating to physical, chemical and technical properties, except for the active substance content, are available to ensure that quality control measurements of the plant protection product are possible.

Considering the proposed uses, residues in food of plant and animal origin and soil are not relevant, therefore monitoring analytical methods in these matrices are not required.

Residue definition was set only for surface water, as parent DDAC.

An LC-MS method exists to determine DDAC in ground water, drinking water and surface water with an LOQ of 0.1 μg/L, however it is not sufficiently specific. For the acceptance of the LC-MS method justification was requested that further confirmation by additional ions (LC-MS/MS) is not feasible.

No method for determination of DDAC in air was submitted, however no residue definition for air was proposed.

As DDAC is not classified as toxic, no analytical methods for the determination of residues of DDAC in body fluids and/or tissues are needed.

2. Mammalian toxicity

Didecyldimethylammonium chloride was discussed by the PRAPeR 59 meeting of experts in mammalian toxicology (October 2008, round 12).

Since the active substance is not produced as a purified substance but as an alcoholic/aqueous solution of DDAC, the toxicological tests were performed with alcoholic/aqueous solutions containing 50 to 80% of DDAC. As far as possible, the doses were expressed in mg DDAC/kg bw/day.

The confirmation that the toxicological batches have the same composition as the technical material could not be given with analytical data. Therefore, the experts agreed on a data gap for a reasoned statement on the identity of all test materials used in the toxicological tests to prove that all test materials are identical to that which is the subject of the DAR. For the same reason, it was not possible to evaluate the toxicological relevance of unidentified impurities.

The evaluations of DDAC under the scope of the Biocide Directive[4] and by US-EPA were considered during the discussions. Based on an overview presented in the addendum to Volume 3 (September 2008), they were concluded not to present major differences.

2.1. Absorption, distribution, excretion and metabolism (toxicokinetics)

After oral administration, DDAC was absorbed to a very limited extent (1.2 to 2.5% based on urine excretion, tissues and residual carcass). Similarly, residues in individual tissues and organs were low, the highest values being observed in pancreas or adrenals. Limited data on the rat metabolism of DDAC did not allow a reliable identification of the metabolites, but this was not a concern for the experts since no relevant environmental metabolites were identified and no consumer exposure was expected according to the intended uses.

2.2. Acute toxicity

Based on the revised acute oral toxicity results in rats (LD_{50} 256 mg DDAC/kg bw), the classification **Xn, R22 "Harmful if swallowed"** was agreed by the experts. This is in accordance with the ECB classification (adopted in 1998, in the 24th ATP), as well as with the biocide evaluation and US EPA report. It was agreed during the meeting that an acute

[4] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market

inhalation study was not necessary, considering that the vapour pressure of DDAC is expected to be low (however PRAPeR 56 meeting of experts could not conclude on the acceptability of the physical, chemical and technical properties of the active substance until the identity of the material used for the tests is clarified), and the fact that the formulation will not be sprayed.

Even though the acute toxicity after dermal application was low (rabbit LD_{50} 3720 mg DDAC/kg bw), the compound was shown to be corrosive to skin (**C, R34 "Causes burns"**) and therefore, the eye irritation test was not required. The skin sensitisation study evaluated in the DAR was considered as non-acceptable, but further data were not required due to the corrosive properties of the active substance. Additionally, the meeting noted that two Buehler tests had been performed for the biocide and/or US EPA evaluations and were reported to have given negative results, and that ECB had not classified DDAC for skin sensitization properties (24th ATP, 1998).

2.3. Short-term toxicity

The short-term toxicity of DDAC was investigated in rats (13-week oral study and 13-week dermal study) and in dogs (12-month oral study).

In the 13-week oral study in rats, the agreed NOAEL was 60.7 mg DDAC/kg bw/day, based on mortality, reduced food consumption and bodyweight gain, clinical signs, haematology, clinical chemistry and histopathological findings. In this study, all the systemic effects were considered as secondary to the primary effect of corrosivity.

For the 1-year dog study, the clinical findings of emesis and salivation were discussed by the experts. In this gavage study, emesis was considered as the critical effect rather than salivation. The incidence at the dose of 10 mg/kg bw/day being the same as in the control group was not considered adverse. Therefore, the agreed NOAEL was 10 mg DDAC/kg bw/day based on emesis, decreased bodyweight gain and haematological changes in both sexes, decreased albumin and total protein in males, and increased liver weight in females.

In the 13-week dermal study with rats, the application of DDAC at 12 mg/kg bw/day resulted in excoriation, ulceration and fissuring of the skin without adverse effect of systemic toxicity. The agreed LOAEL was 2 mg/kg bw/day (the lowest dose tested) based on the histopathological finding of epidermitis at all doses.

Repeated exposure by inhalation was not considered necessary, considering that the vapour pressure of DDAC is probably low (even though the PRAPeR 56 meeting of experts could not conclude on the acceptability of the physical, chemical and technical properties of the active substance until the identity of the material used for the tests is clarified), and that the mode of application does not include spraying.

Several additional short-term studies provided under the US EPA review were mentioned during the commenting period (one 90-day dog study and one 21-day dermal rat study). Based on the review of the EPA report presented in the addendum to Volume 3 (September 2008), the experts agreed that the effects and NOAEL in the 90-day dog study were comparable with the 1-year dog study, and that the 21-day dermal rat study was not more critical than the 13-week dermal study.

2.4. Genotoxicity

DDAC did not induce point mutations in bacterial cells (Ames test), neither with nor without metabolic activation. Negative results were also obtained during the *in vitro* chromosome aberration and gene mutation tests with Chinese hamster cells. In addition, DDAC was negative in an *in vivo* cytogenetic assay in rats. Overall, even though the *in vitro* chromosome aberration study had some limitations, the experts concluded that DDAC has no genotoxic potential.

2.5. Long-term toxicity

The chronic toxicity and carcinogenicity of DDAC has been studied in rats (2-year study) and in mice (78-week study). In the 2-year rat study, the agreed NOAEL is 750 ppm (32 mg DDAC/kg bw/day) based on decreased bodyweight gain in females, and histological changes in bile ducts and mesenteric lymph nodes in both sexes. The relevance of testicular interstitial adenomas exceeding the historical control range at the mid-dose (32 mg DDAC/kg bw/day) was discussed by the experts. Taking into account the absence of dose-response, the low systemic bioavailability of DDAC and the absence of genotoxic potential, they agreed that these adenomas were not treatment-related.

In the 78-week mouse study, at 500 and 1000 ppm, reduced bodyweight gain was observed in both sexes. No other treatment-related findings were observed. The reduction at 500 ppm was considered as borderline and not adverse, leading to an agreed NOAEL of 76.3 mg DDAC/kg bw/day.

No oncogenic potential was observed in rats or mice.

2.6. Reproductive toxicity

Investigations of the reproductive toxicity of DDAC were performed in a rat multigeneration study, and in two teratogenicity studies (one with rats and the other with rabbits).

Several limitations were observed in the rat multigeneration study, but they were not considered to invalidate the negative results. With regard to the fertility parameters, no adverse effects were observed. The agreed parental and offspring NOAEL is 50 mg DDAC/kg bw/day based on decreased bodyweight gain (and food consumption for the parents), whereas the agreed reproductive NOAEL is 100 mg DDAC/kg bw/day (highest dose tested).

For both teratogenicity studies, more details were provided in the addendum to Volume 3 (September 2008). In the developmental rat study, the rapporteur Member State proposed a local and a systemic maternal NOAEL, whereas the experts agreed that only one overall NOAEL should be derived taking into account local effects (as being primary effects, and attributed to the corrosive properties of DDAC). Therefore, based on clinical signs (audible respiration) observed at 10 mg/kg bw/day, the agreed maternal NOAEL was 1 mg DDAC/kg bw/day. In the absence of any treatment-related findings in foetuses, the agreed developmental NOAEL was 20.0 mg DDAC/kg bw/day (highest dose tested).

In the rabbit developmental study, it was also proposed by the rapporteur Member State to derive a local and a systemic NOAEL for maternal toxicity. Again, the experts agreed to derive one overall NOAEL taking into account local adverse effects. Consequently, a maternal NOAEL of 1 mg DDAC/kg bw/day was agreed by the meeting, based on clinical signs (audible respiration) and decreased bodyweight gain. Based on reduced foetal weight

and increased incidence of dead foetuses at 10 mg DDAC/kg bw/day, the NOAEL for developmental toxicity was set at 3.0 mg DDAC/kg bw/day.

In both species, there was no indication of teratogenic properties up to the highest dose tested.

2.7. Neurotoxicity

No neurotoxicity studies were submitted. In the absence of clinical signs potentially indicative of neurotoxicity in any of the studies performed, it was considered that no specific neurotoxicity studies were needed.

2.8. Further studies

No mechanistic data and no toxicity studies with metabolites were submitted.

2.9. Medical data

In the initial DAR, the notifier was requested to provide data on medical surveillance in manufacturing plant personnel. These data were provided in the addendum to Volume 3 (September 2008) and revealed that no substance-specific effects had been noted in people working at the manufacturing site. Some clinical cases of poisoning incidents were reported, limited to reversible irritation of skin or mucous membranes.

2.10. Acceptable daily intake (ADI), acceptable operator exposure level (AOEL) and acute reference dose (ARfD)

Acceptable Daily Intake (**ADI**) and Acute Reference Dose (**ARfD**)

In the DAR, an ADI was proposed based on the 1-year dog study, whereas an ARfD was not considered necessary based on the acute toxicity profile of DDAC. In the addendum to Volume 3 (September 2008), further considerations were given about the need to derive an ADI and an ARfD.

During the PRAPeR 59 meeting of experts, it was noted that the only application of DDAC was in floriculture (not on edible crops). Therefore no exposure of the consumers is expected and no trigger values are needed to perform a risk assessment for the consumers. This was agreed by the meeting of experts, highlighting that the use should be restricted to floriculture.

Acceptable operator exposure level (**AOEL**)

When considering the oral repeated dose studies with DDAC, the critical effects are reduced bodyweight (gain) and reduced food consumption in all species, and emesis in dogs. These effects are however secondary to the corrosive properties of DDAC in the gastro-intestinal tract. Considering these properties, it is not possible to apply route-to-route extrapolation and derive an AOEL (for dermal exposure) based on an oral study.

In addition, no systemic effects are observed after dermal repeated exposure (in rats), because DDAC reacts locally (inducing corrosivity) and does not become systemically available (which is confirmed by a low oral absorption of 2.5%). The meeting of experts agreed, in line with the guidance document on AOEL, that local skin effects such as irritation and sensitisation are not appropriate for setting an AOEL. The dermal NOAEL used to derive an AOEL should be based on systemic effects.

It was therefore considered not relevant to derive a systemic AOEL (either from oral or dermal studies) for DDAC. In addition, for the operator risk assessment, local effects are not considered, since such effects will normally be addressed by classification and labelling and the use of appropriate personal protective equipment (see also 2.12).

2.11. Dermal absorption

In the DAR, since no systemic effects were anticipated after dermal exposure, it was concluded that setting of a dermal absorption value was not relevant for the occupational risk assessment.

The meeting of experts noted that based on the guidance document on dermal absorption (Sanco/222/2000 rev.7, 2004), a default value of 100% could be assumed (but was expected to be much lower in reality). It was also mentioned that a study had been provided for the biocide evaluation, but was not available for the pesticide peer-review. Nevertheless, it was agreed that no study was required.

2.12. Exposure to operators, workers and bystanders

The representative plant protection product "M&ENNO-TER forte" is a solution containing 310 g DDAC/L for the disinfection of surfaces (by watering with 1% solution), culture vessels (by soaking with 1 or 5% solution) and gardening equipment (by manual dipping with 0.25% solution) in horticulture (greenhouse or indoor applications).

Operator

It was clarified by the applicant in the evaluation table (point of clarification 2.4) that "M&ENNO-TER forte" was not used on a routine schedule but either in emergency cases or once per year (at the end or at the beginning of the season). According to the GAP, one application per culture is foreseen.

In the DAR, exposure estimates for the different scenarios were presented. During the manual pouring on surfaces, the exposure was considered to be equivalent to exposure during mixing and loading, as estimated by the UK-POEM and the German model. For manual dipping of equipment and mechanical dipping of culture vessels, the exposure during mixing and loading was estimated by the UK model for manual applications; and the exposure during application by the Dutch model for flower bulb dipping.

The meeting of experts concurred that there is no valid model, no AOEL is proposed, and therefore, given this specific situation, operator exposure did not need to be calculated, but has to be managed by the use of appropriate personal protective equipment (to be specified at Member State level).

Bystander

Exposure of bystanders can be excluded, since "M&ENNO-TER forte" is used indoor or in greenhouses.

Worker

Further details on re-entry activities were given in the evaluation table (point of clarifications 2.3 and 2.5) by the applicant. The exposure of workers during these activities (handling of dried equipment/vessels/surfaces and automatic filling of pots/trays) was expected to be negligible. As the level of automation may vary in the different Member States, the use of PPE will have to be considered at Member State level for the re-entry activities.

3. Residues

No data were submitted to study and assess the residue behaviour of didecyldimethylammonium chloride in plants and livestock animals in order to define the relevant residues for dietary consumer risk assessment. The representative use of didecyldimethylammonium chloride as a disinfectant of surfaces, plant pots and equipment only used for ornamental plant production is normally not expected to result in any dietary exposure to humans or livestock animals. Under conditions excluding any potential consumer exposure to didecyldimethylammonium chloride residues, there will be no dietary consumer risk related to the notified representative uses.

4. Environmental fate and behaviour

Didecyldimethylammonium chloride was discussed at the PRAPeR 57 meeting of experts for environmental fate and behaviour (October 2008) on basis of the DAR (November 2007) and the addendum to Volume 3 (B.8) (September 2008).

4.1. Fate and behaviour in soil

4.1.1. Route of degradation in soil

No aerobic or anaerobic degradation data were available for didecyldimethylammonium chloride, nor photolysis in soil was studied. These data were not considered necessary, taking into consideration that for the applied for uses the contamination of soil was deemed to be negligible.

4.1.2. Persistence of the active substance and their metabolites, degradation or reaction products

The degradation rate of didecyldimethylammonium chloride was not investigated, and no reliable field dissipation studies were available. These data were not required as the contamination of soil was deemed to be negligible.

As for the applied for uses of didecyldimethylammonium chloride no contamination of the soil is expected, the predicted environmental concentration in soil was not calculated.

4.1.3. Mobility in soil of the active substance and their metabolites, degradation or reaction products

The adsorption/desorption of didecyldimethylammonium chloride was investigated in four soils (pH 6.3-7.9, OC 0.25-2.1%, clay 4-32%) in satisfactory batch adsorption experiments, however, the resulted K_{foc} value of one of the four soils was not accepted due to the low organic carbon content of this soil. The calculated K_{foc} values of the three soils varied from 908757 to 1599564 mL/g (mean 1325801 mL/g) (1/n 0.96 – 1.03, mean 1.0). Adsorption to soil showed a positive correlation with organic carbon content and also with clay content, but there was no evidence of any correlation with pH.

4.2. Fate and behaviour in water

4.2.1. Surface water and sediment

Didecyldimethylammonium chloride was essentially stable to hydrolysis at 25°C at pH 5, 7 and 9. No reliable photolytic degradation study in water was available, however further information was not required as DDAC was assumed to be stable to photolysis, based on that the molar extinction coefficient of DDAC is expected to be low. However, the PRAPeR 56 meeting of experts on physical-chemical properties could not conclude on the acceptability of the physical, chemical and technical properties of the active substance until the identity of the material used is clarified.

A non-standard ready biodegradability test, in which the applied method deviated from the requirements of the relevant OECD guidelines (the used guideline was EPA 40 CFR § 796.3100 instead of OECD 301 or 302), indicated that didecyldimethylammonium chloride cannot be classified as 'readily biodegradable', but can be classified as 'inherently biodegradable'.

The degradation of didecyldimethylammonium chloride under aerobic aquatic conditions was investigated in two different natural systems of water and sediment, but the methodology of the study had several significant shortcomings. Consequently, the results were considered as not reliable. The PRAPeR 57 meeting of experts discussed the requirement for a new water-sediment study proposed in the original DAR, in particular the issue of the identification of metabolites that may be formed. The applicant presented a case in the addendum to Volume 3 (B.8) (September 2008) that the risk from the possible major metabolites might be covered by the risk assessment of the parent compound, as it is unlikely that the metabolites, which have the potential to be formed, are more toxic than the parent compound, taking into account the structure of the molecule and the most likely degradation pathway, which starts with the breakdown of the alkyl chains into smaller fractions. The PRAPeR 58 meeting of experts on ecotoxicology confirmed that this case was appropriate. Therefore, based on the conclusions of the PRAPeR 57 and PRAPeR 58 meetings, there is no requirement for a new water-sediment study.

Since the applied for representative uses and the special conditions of the applications of DDAC cannot be compared with any type of field application or a spray application in glasshouse, the FOCUS approach (scenarios for edge of field water body situations) was not followed, and no FOCUS modelling for PECsw or PECsed was performed. However, an assessment of surface water exposure is necessary, and an assessment of exposure via the sewage systems was provided in the addendum. The predicted environmental concentrations in surface water and sediment for didecyldimethylammonium chloride were estimated using USES 2.0 model, which is designed for regulatory assessments for biocides and other general chemicals. The model can estimate the concentrations in natural water and sediment, following exposure via the sewage systems including purgation (e.g. biodegradation) in a sewage treatment plant (STP). The PRAPeR 57 meeting of Member State experts agreed that the use of 20 kg (at once) or 5 kg (as tier 2 calculation, assuming that the 20 kg used by a grower a year is applied 4 times) of DDAC discharge into the sewage system a day is appropriate to use as the input parameter for the model. Moreover, it was discussed and agreed by the meeting of experts that as an exposure refinement, it is reasonable to assume that a significant part of the active substance in the sewage system is retained by the organic matter present in the sewage system, before the contaminated sewage enters into the sewage treatment plant (since DDAC has a strong adsorption potential). It was agreed by the meeting

of experts that for the distribution of DDAC in the pre-STP (adsorption by the organic matter), the use of the same ratio, as calculated by the program for elimination by the sewage treatment plant, is acceptable. This means that the assessment indicates that 91.5% of DDAC is retained in the pre-STP system and 8.5% of the total load emitted at the site of application actually reaches the sewage treatment plant at the day of the discharge.

The results of these calculations are considered as the agreed endpoints and are included in the Appendix A of this conclusion. For more details about the calculation see addendum to Volume 3 (B.8) (September 2008). As some physical-chemical properties (e.g. water solubility, vapour pressure) are used by the model program, it is noted, that the PRAPeR 56 meeting of experts on physical-chemical properties could not conclude on the acceptability of the physical, chemical and technical properties of the active substance until the identity of the material used is clarified.

4.2.2. Potential for ground water contamination of the active substance, their metabolites, degradation or reaction products

As for the applied for uses of didecyldimethylammonium chloride no contamination of the soil is expected, the predicted environmental concentration in groundwater was not calculated.

4.3. Fate and behaviour in air

The vapour pressure of didecyldimethylammonium chloride is expected to be low, however, the PRAPeR 56 meeting of experts on physical-chemical properties could not conclude on the acceptability of the physical, chemical and technical properties of the active substance until the identity of the material used is clarified. Calculations using the method of Atkinson (using the software AOPWIN) for indirect photo-oxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half-life estimated at 2.77 hours (assuming an atmospheric hydroxyl radical concentration of $1.5x10^6$ radicals cm^{-3}). This half-life indicates that the proportion of didecyldimethylammonium chloride, which is volatilised, is unlikely to be subject to long-range atmospheric transport.

5. Ecotoxicology

Didecyldimethylammonium chloride was discussed at the PRAPeR 58 meeting of experts for ecotoxicology (October 2008) on the basis of the draft assessment report and the addendum from September 2008.

The representative use evaluated was as bactericide/fungicide/herbicide/algaecide in horticulture for disinfection (greenhouse and indoor use).

No data were presented for the pure active substance DDAC. Data related to the synthesis products “BARDAC 22” (50% DDAC) and “BARDAC 2270” (70% DDAC), which are alcoholic/aqueous solutions of DDAC. The proposed formulation product was “M&ENNO-TER forte” containing 310 g /L.

5.1. Risk to terrestrial vertebrates

No toxicity data were submitted for birds. On the basis of the mammalian toxicity data, the lowest LD_{50} in rat for “M&ENNO-TER forte” was 25-200 mg product/kg bw, equivalent to

8.1 - 65 mg DDAC /kg bw; the NOAEL (for development) was 3 mg/kg bw/day (teratogenicity study on rabbit).

The risk to birds and mammals via contaminated drinking water uptake was considered. TER_a value was calculated only for mammals and it was low. The TER_a value for birds was not calculated, since toxicity data were not available. However, due to the low estimated exposure, and on the basis of the available information on mammals, it was considered unlikely that the TER_a value for birds would exceed the Annex VI trigger of 10.

No risk to fish-eating birds and mammals was expected, since the experimental BCF in fish was less than 100.

5.2. Risk to aquatic organisms

Acute and chronic data were provided for fish (*Oncorhynchus kisutch, Oncorhynchus mykiss, Lepomis macrochirus, Brachydanio rerio*), invertebrates (*Daphnia magna*) and algae (*Scenedesmus subspicatus, Selenastrum capricornutum*). On the basis of these studies DDAC was highly toxic to aquatic organisms. The proposed classification was **N** "**Dangerous for the environment**", **R50/R53** "**Very toxic to aquatic organisms; May cause long-term adverse effects in the aquatic environment**".

The lowest acute endpoint for fish was observed in the study with the active substance and *L. macrochirus* (96h-LC_{50} = 0.32 mg a.s./L, "BARDAC 22"). The lowest endpoint for invertebrates was EC_{50} = 17 µg a.s./L ("M&ENNO-TER forte") and for algae E_bC_{50} = 7 µg a.s./L ("M&ENNO-TER forte").

Out of the two available chronic studies on fish, only the study with *B. rerio* was accepted (NOEC 32 µg/L). The study on *O.mykiss* was not accepted by the rapporteur Member State, because the validity criterion on the weight increase was not met and the study was not transparently documented.

The NOEC from a chronic study on *Daphnia* was 10 µg/L ("BARDAC 22").

A bioaccumulation study was submitted and the BCF whole fish was 66 L/kg w/w.

Acute and long-term TER values were calculated on the basis of local $PEC_{surface\ water}$ values, which were agreed by the PRAPeR 57 meeting of fate experts. Among the different potential emission-scenarios from the sewage treatment plant, the fate experts considered the emission of 5 kg DDAC (4 discharges per year) as a realistic worst-case. All the TER values calculated on the related PEC value of 10.7 µg/L were below the Annex VI trigger values.

The fate experts agreed that the pre-sewage treatment plant dilution, which occurs as a consequence of the adsorption of the active substance to the organic matter in the sewage system, can reduce the exposure of surface water. Therefore, the emission of 5 kg DDAC (4 discharges per year) can be reduced to 0.425 kg DDAC (see section 4.2.1). TER values calculated on the related PEC value of 0.91 µg/L were above the Annex VI triggers, except for invertebrates (acute, TER=18.7) and for algae (TER=7.69).

Overall, a high risk to aquatic organisms was identified, and therefore, a data gap was agreed by the PRAPeR 58 meeting of experts to provide a refined risk assessment.

5.3. Risk to bees

No data were submitted. According to the notified representative uses of DDAC the exposure of bees was not expected.

5.4. Risk to other arthropod species

No data were submitted. According to the notified representative uses of DDAC the exposure of non-target arthropods was not expected.

5.5. Risk to earthworms

The acute toxicity to earthworms was tested with "BARDAC 22". The 14-day LC_{50} was >1000 mg a.s./kg soil. Chronic testing was considered not necessary.

According to the notified representative uses of DDAC the exposure of earthworms was not expected. The risk can be considered low.

5.6. Risk to other soil non-target macro-organisms

No data were submitted. According to the notified representative uses of DDAC the exposure of soil non-target organisms was not expected.

5.7. Risk to soil non-target micro-organisms

No valid study was available on respiration and nitrification effects (The rapporteur Member State did not accept the study provided with "BARDAC 22" due to important guideline deviation and not reliable results).

Since exposure was not expected, the risk was considered low.

5.8. Risk to other non-target-organisms (flora and fauna)

No data were submitted. Since exposure was not expected, the risk was considered low.

5.9. Risk to biological methods of sewage treatment

The effects of "BARDAC 22" on the rate of respiration of activated sewage sludge were addressed and the 3 hour-EC_{50} was 22 mg product/L, equivalent to 11 mg a.s./L.

Exposure was expected following discharge of solutions into the sewage system.

A TER value of 608 was calculated on the basis of PEC_{STP} value of 18.1 µg a.s./L, which was estimated for the 5 kg scenario for pre-STP dilution. Although a trigger value is not available, the PRAPeR 58 meeting of experts considered the risk to be low (the technical guidance document for biocides suggests a trigger of 100).

6. Residue definitions

6.1. Soil

Definition for risk assessment: None

Definition for monitoring: None

6.2. Water

6.2.1. Ground water

Definition for exposure assessment: None

Definition for monitoring: None

6.2.2. Surface water

Definition for risk assessment

in surface water: didecyldimethylammonium chloride

in sediment: didecyldimethylammonium chloride

Definition for monitoring: didecyldimethylammonium chloride

6.3. Air

Definition for risk assessment: None

Definition for monitoring: None

6.4. Food of plant origin

Definition for risk assessment: None

Definition for monitoring: None

6.5. Food of animal origin

Definition for risk assessment: None

Definition for monitoring: None

6.6. Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

6.6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
None	Information is not necessary	-

6.6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
None	Information is not necessary	Information is not necessary	-	-	-

6.6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
didecyldimethylammonium chloride	High toxicity to aquatic organisms and high risk identified.

6.6.4. Air

Compound (name and/or code)	Toxicology
None	Information is not necessary

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- Data concerning information on production process, starting materials, purity and its expression, specification and relevant impurities, analytical methods, test materials used in toxicity testing (relevant for all representative uses evaluated, data gaps identified by the rapporteur Member State, for confidentiality reasons listed in Volume 4 under C.1.5, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- Five-batch analysis of the technical active substance (pure) or of a representative technical concentrate (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- An unequivocal specification for the purified technical grade didecyldimethylammonium chloride based on dry matter content (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- Specification for a representative technical concentrate, expressed on dry weight basis (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- Clarification, by which analytical method the reported purity of 98.2% of the pure active substance used in a number of physico-chemical tests was determined (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- Appearance (physical state, colour) (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- Relative density of BARDAC 2270 (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- Interpretation of individual peaks in each spectrum in relation to the structure of DDAC, for the confirmation of the identity of DDAC by IR and mass spectra (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- Statement on explosive properties evaluating all components present in the product (and also in the surfactant) individually (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- Statement on oxidising properties evaluating all components present in the product (and also in the surfactant) individually (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)

- To provide evidence that during preparation of the in-use concentration and its use no unacceptable amounts of foam are formed that represent a hazard to operators (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- To indicate whether sand beds should be included in the GAP table or not (relevant for uses in sand beds, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- The content of the technical active substance and the pure active substance in the plant protection product (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- To provide an acceptable justification as to why LC-MS method was not used to determine DDAC and impurities in the technical material, or to provide a specific method to determine DDAC and impurities in the technical material (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- Analytical method for the determination of the active substance in the formulation (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- Justification that in the method for the determination of DDAC residues in surface water further confirmation by additional ions (LC-MS/MS) is not feasible (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State, confirmed by PRAPeR 56 meeting of experts (October 2008), date of submission unknown; refer to chapter 1)
- Equivalence of toxicological batches with declared technical specification needs to be confirmed (relevant for the representative uses evaluated; no submission data proposed by the notifier; see section 2)
- Pending on the identification and quantification of the impurities, their toxicological relevance in the technical material will have to be assessed (relevant for the representative uses evaluated; no submission data proposed by the notifier; see section 2)
- To provide a refined risk assessment for aquatic organisms (relevant for the representative uses evaluated; no submission data proposed by the notifier; see section 5)

CONCLUSIONS AND RECOMMENDATIONS

OVERALL CONCLUSIONS

The conclusion was reached on the basis of the evaluation of the representative uses as bactericide, fungicide, herbicide and algicide, as proposed by the notifier, which comprise soaking or dipping applications for the disinfection of horticultural vessels and equipment, and watering applications for the disinfection of surfaces, controlling plant pathogenic bacteria, plant pathogenic fungi, weed seeds and algae.

The representative formulated product for the evaluation was 'M&ENNO-TER forte', a soluble liquid (SL) containing 310 g/L didecyldimethylammonium chloride, registered under different trade names in some European countries.

Data gaps were identified for adequate information on identity, production process, starting materials, purity and how to express it, specification, analytical methods, and test materials used in toxicity testing.

Data gaps were identified for an analytical method for the determination of the active substance in the technical material and formulation, and also for monitoring of DDAC residues in surface water.

Sufficient methods and data relating to physical, chemical and technical properties, except for the active substance content, are available to ensure that quality control measurements of the plant protection product are possible.

Considering the proposed uses, residues in food of plant and animal origin, soil, ground water and air are not relevant, and therefore analytical methods for these matrices are not required.

With regard to its toxicological properties, DDAC was absorbed to a very limited extent after oral administration, without accumulation in the organism. Based on acute toxicity results, the proposed classification **Xn; R22 "Harmful if swallowed"** and **C; R34 "Causes burns"** was agreed for DDAC.

In repeated dose studies, even though the systemic effects were considered as secondary to the primary effect of corrosivity, they were taken into account for the setting of the NOAELs. Therefore, the agreed oral short-term NOAEL was 60.7 mg DDAC/kg bw/day in rats, and 10 mg DDAC/kg bw/day in dogs. Similarly, in the dermal study, only local effects in the skin were observed and lead to a dermal short-term LOAEL of 2 mg/kg bw/day (lowest dose tested). DDAC did not show genotoxic or carcinogenic potential. The agreed long-term NOAEL was 32 mg DDAC/kg bw/day in rats based on decreased bodyweight gain and histopathology in the liver and lymph nodes, and 76.3 mg DDAC/kg bw/day in mice based on reduced bodyweight gain. In the reproductive toxicity studies, neither adverse effects on the reproductive parameters were observed, nor any indication of teratogenic properties. In the multigeneration study, the agreed parental and offspring NOAEL was 50 mg DDAC/kg bw/day. In the developmental studies, clinical signs indicative of primary local effects (attributed to the corrosive properties of DDAC) were taken into account for the derivation of an agreed maternal NOAEL of 1 mg DDAC/kg bw/day in rats and rabbits. Foetal effects (if any) were only observed in the presence of maternal toxicity.

With regard to the setting of the reference values, considering the restricted representative use in floriculture, the experts agreed that no dietary exposure of the consumers was expected and therefore no ADI or ARfD were needed. The derivation of the AOEL was extensively discussed by the experts, who agreed that, according to the toxicological profile of DDAC, an AOEL had not to be set. Concerning the operators, it was assumed that the exposure was safe with the use of personal protective equipment (due to the corrosive properties of DDAC). The exposure of bystanders was excluded due to the use indoors or in greenhouses. The worker exposure was expected to be negligible.

No data were submitted to study and assess the residue behaviour of didecyldimethylammonium chloride in plants and livestock animals in order to define the relevant residues for dietary

consumer risk assessment. The representative use of didecyldimethylammonium chloride as a disinfectant of surfaces, plant pots and equipment only used for ornamental plant production is normally not expected to result in any dietary exposure to humans or livestock animals. Under conditions excluding any potential consumer exposure to didecyldimethylammonium chloride residues, there will be no dietary consumer risk related to the notified representative uses.

The information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment for didecyldimethylammonium chloride at EU level, where discharges are to sewage treatment facilities.

Reliable assessment for the soil or groundwater compartment was not performed as the contamination of these compartments was deemed to be negligible.

Regarding the particularity of the applied for representative uses, the assessment of the exposure of surface water and sediment could not follow the FOCUS approach, and the parameterization of the USES 2.0 model used contained some expert judgements. Therefore, the exposure assessment in this conclusion is applicable only for the applied for representative uses at EU level, where runoff or discharge from greenhouses occurs to a sewage system with the properties assumed in the model used. These assumptions will not cover the wide range of situations in all Member States.

DDAC was toxic to aquatic organisms (**N "Dangerous for the environment", R50/R53 "Very toxic to aquatic organisms; May cause long-term adverse effects in the aquatic environment"**). A high risk was identified for invertebrates and algae, even considering the surface water exposure reduction, which can occur as a consequence of the adsorption of the active substance to the organic matter in the sewage system. Therefore, a data gap was identified to further address the risk to aquatic organisms. The risk was assessed as low for terrestrial vertebrates, bees, non-target arthropods, earthworms, soil macro and micro-organisms, other non-target organisms and biological methods for sewage treatment.

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- Use of appropriate personal protective equipment by the operators is a specific requirement for the restricted indoor use of DDAC in floriculture. Protection of workers has to be considered at Member State level according to the re-entry activities (refer to 2.12).

CRITICAL AREAS OF CONCERN

- Identity and specification of the active substance.
- Potential risk for aquatic organisms via STP.

APPENDICES

APPENDIX A – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name)	None
Function (*e.g.* fungicide)	Fungicide, bactericide and herbicide (algaecide)
Rapporteur Member State	The Netherlands

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	Open A unique IUPAC name cannot be given as the active substance is a mixture of quaternary alkyl-ammonium salts with typical alkyl chain lengths of C8, C10 and C12
Chemical name (CA)	Open A unique CA name cannot be given as the active substance is a mixture of quaternary alkyl-ammonium salts with typical alkyl chain lengths of C8, C10 and C12
CIPAC No	Not allocated
CAS No	Open
EEC No (EINECS or ELINCS)	Not available
FAO Specification (including year of publication)	Not available
Minimum purity of the active substance as manufactured (g/kg)	Open

Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	Open
Molecular formula	Open The active substance is a mixture of quaternary alkyl-ammonium salts with typical alkyl chain lengths of C8, C10 and C12
Molecular mass	Open The active substance is a mixture of quaternary alkyl-ammonium salts with typical alkyl chain lengths of C8, C10 and C12
Structural formula	Open The active substance is a mixture of quaternary alkyl-ammonium salts with typical alkyl chain lengths of C8, C10 and C12

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	Open
Boiling point (state purity)	Open
Temperature of decomposition (state purity)	Open
Appearance (state purity)	Open
Vapour pressure (state temperature, state purity)	Open
Henry's law constant	Open
Solubility in water (state temperature, state purity and pH)	Open
Solubility in organic solvents (state temperature, state purity)	Open
Surface tension (state concentration and temperature, state purity)	Open
Partition co-efficient (state temperature, pH and purity)	Open
Dissociation constant (state purity)	Open
UV/VIS absorption (max.) incl. ε (state purity, pH)	Open
Flammability (state purity)	Open
Explosive properties (state purity)	Open
Oxidising properties (state purity)	Open

Summary of representative uses evaluated (didecyldimethylammonium chloride)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hL min – max (l)	water L/ha min – max	kg as/ha min – max (l)		
Disinfection of horticulture vessels	EU	M&ENNO-TER forte	G + I	Plant pathogenic bacteria	SL	325 g/kg (310 g/l)	soaking	after the last use	1	n.a.	0.31 (1 % solution)	n.a.	n.a.	n.a.	12 h The product is intended for use on materials used only for ornamental plants
Disinfection of Equipment (e.g. knives)	EU	M&ENNO-TER forte	G + I	Plant pathogenic bacteria	SL	325 g/kg (310 g/l)	dipping	before the use	1	n.a.	0.0775 (0.25 % solution)	n.a.	n.a.	n.a.	dipping (3 minutes) The product is intended for use on materials used only for ornamental plants
Disinfection of Surfaces	EU	M&ENNO-TER forte	G + I	Plant pathogenic bacteria	SL	325 g/kg (310 g/l)	watering	after the last use or before use	1	n.a.	0.31 (1 % solution)	2000-20000	6.2-62 only on hard surfaces	n.a.	12 h The product is intended for use on materials used only for ornamental plants
Disinfection of horticulture vessels	EU	M&ENNO-TER forte	G + I	Plant pathogenic fungi	SL	325 g/kg (310 g/l)	soaking	after the last use	1	n.a.	0.31 (1 % solution)	n.a.	n.a.	n.a.	12 h The product is intended for use on materials used only for ornamental plants
Disinfection of Surfaces	EU	M&ENNO-TER forte	G + I	Plant pathogenic fungi	SL	325 g/kg (310 g/l)	watering	after the last use or before use	1	n.a.	0.31 (1 % solution)	2000-20000	6.2-62 only on hard surfaces	n.a.	12 h The product is intended for use on materials used only for ornamental plants

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hL min – max (l)	water L/ha min – max	kg as/ha min – max (l)		
Disinfection of Surfaces	EU	M&ENNO-TER forte	G + I	Algae	SL	325 g/kg (310 g/l)	watering	after the last use or before use	1	n.a.	0.31 (1 % solution)	2000-20000	6.2-62 only on hard surfaces	n.a.	12 h The product is intended for use on materials used only for ornamental plants
Disinfection of horticulture vessels	EU	M&ENNO-TER forte	G + I	Weed seeds: Poa annua Cardamine hirsuta Senecio vulgaris	SL	325 g/kg (310 g/l)	soaking	after the last use	1	n.a.	0.31 (1 % solution)	n.a.	n.a.	n.a.	16 h The product is intended for use on materials used only for ornamental plants
Disinfection of horticulture vessels	EU	M&ENNO-TER forte	G + I	Weed seeds Veronica peregrina	SL	325 g/kg (310 g/l)	soaking	after the last use	1	n.a.	1.55 (5 % solution)	n.a.	n.a.	n.a.	16 h The product is intended for use on materials used only for ornamental plants
Disinfection of horticulture vessels	EU	M&ENNO-TER forte	G + I	Weed seeds Sagina procumbens	SL	325 g/kg (310 g/l)	soaking	after the last use	1	n.a.	1.55 (5 % solution)	n.a.	n.a.	n.a.	48 h The product is intended for use on materials used only for ornamental plants

n.a.: not applicable

Reasons for greying out:

- the active substance is not properly identified;

- exceeding of threshold values for aquatic organisms.

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s). (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I) (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989 (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).** (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application (k) Indicate the minimum and maximum number of application possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	Open
Impurities in technical as (analytical technique)	Open
Plant protection product (analytical technique)	Open

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		No residue definition required
Food of animal origin		No residue definition required
Soil		No residue definition required
Water	surface	Parent DDAC
	drinking/ground	No residue definition required
Air		No residue definition required

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	No method submitted (not required)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No method submitted (not required)
Soil (analytical technique and LOQ)	No acceptable method submitted (not required)
Water (analytical technique and LOQ)	Surface water: LC-MS, LOQ 0.1 µg/L Open Ground water: No method required
Air (analytical technique and LOQ)	No method submitted (not required)
Body fluids and tissues (analytical technique and LOQ)	Not required

Classification and proposed labelling (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	No classification and labelling is needed based on the physical and chemical properties of pure dried DDAC. Bardac 2270 is expected to have a flash point between 21°C and 55°C (R10 Flammable).

Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption	Low absorption (1.2-2.5% based on radiolabel recovered from urine, tissues and residual carcass within 168 h)
Distribution	Widely distributed, highest residues in pancreas and adrenals at 168 h.
Potential for accumulation	No evidence for accumulation
Rate and extent of excretion	Extensive within 168 h: mainly via faeces (89-99%), 1.2-2.3% via urine
Metabolism in animals	Partly metabolised, parent and 4 oxidation products (tentatively identified in faeces)
Toxicologically relevant compounds (animals and plants)	DDAC
Toxicologically relevant compounds (environment)	DDAC

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	256 mg DDAC/kg bw	**R22**
Rat LD50 dermal	> 4000 and < 6400 mg DDAC/kg bw	
Rat LC_{50} inhalation	No data available – not required	
Skin irritation	Corrosive	**R34**
Eye irritation	No data available – not required	
Skin sensitisation	No data available – not required	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Reduced bodyweight gain, clinical signs (oral) Local epidermitis (dermal)	
Relevant oral NOAEL	13-week, rat: 60.7 mg DDAC/kg bw/day 1-year, dog: 10 mg DDAC/kg bw/day	
Relevant dermal NOAEL	13-week, rat: < 2 mg DDAC/kg bw/day	
Relevant inhalation NOAEL	No data available – not required	

Genotoxicity (Annex IIA, point 5.4)

No genotoxic potential	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect	Reduced bodyweight gain (rat, mouse) Histopathology liver + lymph nodes (rat)	
Relevant NOAEL	2-year, rat: 32 mg DDAC/kg bw/day 78-week, mouse: 76.3 mg DDAC/kg bw/day	
Carcinogenicity	No carcinogenic potential	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	Parental: decreased bodyweight and food consumption Reproductive: no reproductive effects. Offspring: decreased bodyweight and bodyweight gain	
Relevant parental NOAEL	50 mg DDAC/kg bw/day	
Relevant reproductive NOAEL	100 mg DDAC/kg bw/day	
Relevant offspring NOAEL	50 mg DDAC/kg bw/day	

Developmental toxicity

Developmental target / critical effect	Maternal: mortality (rabbit), clinical signs (rat and rabbit) Developmental rat: no effect Developmental rabbit: increased number of dead foetuses and reduced foetal weight	
Relevant maternal NOAEL	Rat: 1.0 mg DDAC/kg bw/day Rabbit: 1.0 mg DDAC/kg bw/day	
Relevant developmental NOAEL	Rat: 20 mg DDAC/kg bw/day Rabbit: 3.0 mg DDAC/kg bw/day	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity	No data available – not required	
Repeated neurotoxicity	No data available – not required	
Delayed neurotoxicity	No data available – not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies	No data available – not required
Studies performed on metabolites or impurities	No data available – not required

Medical data (Annex IIA, point 5.9)

No adverse health effects from manufacturing. Case reports indicate reversible irritation of skin or mucous membranes.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI	not allocated – not necessary due to the indoor use in floriculture		
AOEL	not allocated – not necessary due to the primary corrosive effect and low systemic availability.		
ARfD	not allocated – not necessary due to the indoor use in floriculture		

Dermal absorption (Annex IIIA, point 7.3)

Formulation (M&ENNO-TER forte)	No data available - Not relevant (100% default).

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Use of appropriate personal protective equipment based on the corrosive nature of the test substance and the local effects observed.
Workers	Use of appropriate personal protective equipment should be considered at MS level based on re-entry activities.
Bystanders	Bystanders should not be allowed during the disinfection process in greenhouses.

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

ECB (24th ATP, 1998)	RMS/peer review proposal
Xn; **R22** Harmful if swallowed	**Xn** "Harmful"; **R22** "Harmful if swallowed"
C; **R34** Causes burns	**C** "Corrosive"; **R34** "Causes burns"

Chapter 2.4 – Residues

The use is only on ornamentals; there will be no consumer exposure. A consumer exposure assessment has not been conducted for this active substance.

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	No data
Non-extractable residues after 100 days ‡	No data
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No data

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡

Mineralization after 100 days	No data
Non-extractable residues after 100 days	No data
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡

Parent	Aerobic conditions - **persistence endpoints**						
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20°C	St. (r^2)	Method of calculation
no data							
Geometric mean/median/mean							

[1] X This column is reserved for any other property that is considered to have a particular impact on the degradation

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
no data									
Geometric mean/median/mean									

[1] X This column is reserved for any other property that is considered to have a particular impact on the degradation

pH dependence ‡ (yes / no) (if yes type of dependence)	No data
Soil accumulation and plateau concentration ‡	No data

Laboratory studies ‡

Parent	Anaerobic conditions - no data

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH (water)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam	0.90	6.3			8179	908757	1.03
Silty clay loam	2.05	7.9			32791	1599564	0.96
Silt loam	2.1	7.4			30851	1469081	1.02
Arithmetic mean / median					23940/ 30851	1325801/ 1469081	1.00/ 1.02
pH dependence, Yes or No	No						

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	No data
Aged residues leaching ‡	No data
Lysimeter/ field leaching studies ‡	No data

PEC (soil) (Annex IIIA, point 9.1.3)

Parent	Not calculated (no exposure of soil)
Method of calculation	
Application data	No calculation

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	Hydrolytically stable at pH 5, pH 7 and pH 9 and 25° C.
Photolytic degradation of active substance and metabolites above 10 % ‡	Not required (assumed to be stable to photolysis, ε assumed to be less than 10 L/mole/cm)
Quantum yield of direct phototransformation in water at Σ > 290 nm	no data
Readily biodegradable ‡ (yes/no)	inherently biodegradable in an aerobic test with 14-days adaptation of inoculum to DDAC, with incremental addition of DDAC (2 mg on day 0 with addition of 4 mg on day 7 and day 11 of the adaptation period)

Degradation in water / sediment

Parent	**Persistence endpoints** Distribution: no reliable data									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water[1]	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
no reliable data										
Geometric mean										
Median										
Mean										

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. Max x % after n d	Non-extractable residues in sed. Max x % after n d (end of the study)
no reliable data					

Metabolites >10% in water or sediment					
Water / sediment system	pH water phase	pH sed	Metabolite	Maximum in water. Max x % after n d	Maximum in sediment. Max x % after n d
no reliable data					

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Parent	Calculated for DDAC using USES 2.0 for discharge of use solution via STP. Assumptions:
Parameters used	Based on discharge figure of 20 kg DDAC per grower per year; Based on a use pattern of one application per year (i.e. 20 kg at once) and 4 applications per year (5 kg at once) and assuming one grower per STP. Pre-STP dilution due to sorption to organic matter present in the sewage system taken into account as refinement Rate constants for biodegradation: 0 h^{-1} K_{om} 768965 L/kg. Water solubility 100000 mg/L (max. possible input). Note: the physical-chemical properties are open Molecular mass 362 g/mole. All other parameters set to default values of USES 2.0.

USES 2.0 Application	Concentration in untreated wastewater (mg as/L)	PECSTP effluent (µg as/L)	local PECsurface water (µg as/L) (initial)	local PECsediment (mg as/kg wet weight) (initial)
20 kg at once	10	850	42.6	614
5 kg (assuming 4 discharges per year)	2.5	213	10.7	154
20 kg accounting for pre-STP dilution: 1.7 kg	0.85	72.3	3.62	52.2
5 kg accounting for pre-STP dilution: 0.425 kg	0.212	18.1	0.91	13.1

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Not calculated (no exposure of soil)
Application rate	No calculation

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	Not studied - no data requested
Photochemical oxidative degradation in air ‡	DT_{50} of 2.77 hours derived by the Atkinson model. OH concentration (for 12-hour day length) assumed = $1.5x10^6$ OH/cm^3
Volatilisation ‡	No data.
Metabolites	No data.

PEC (air)

Method of calculation	Expert judgement; based on vapour pressure, dimensionless Henry's Law Constant and Atkinson calculation Note: the physical-chemical properties are open

PEC(a)

Maximum concentration	Open, pending on physical-chemical data gaps for vapour pressure and water solubility

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: none Surface Water: DDAC Sediment: DDAC Ground water: none Air: none

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	No data provided - none requested
Surface water (indicate location and type of study)	No data provided - none requested
Ground water (indicate location and type of study)	No data provided - none requested
Air (indicate location and type of study)	No data provided - none requested

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Not readily biodegradable

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds				
no data				
Mammals				
Rat	M&ENNO-TER Forte	Acute	LD50: 8.1-65	-
Rat	a.s.	Long-term	NOEL: 3.0	-
Additional higher tier studies ‡				
No data available – not required				

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds): The TERa value would only exceed the annex VI trigger of 10 in case the LD_{50} is 0.12 mg/kg bw or lower. This is considered to be unlikely.				
Tier 1 (Mammals)				
Route: water	Acute	0.00654	1237	10

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity (µg DDAC/L)[(A)]
Laboratory tests				
Fish				
Oncorhynchus kisutch	BARDAC 22	96 hr (static)	Mortality, LC_{50}	1000_{mm}
Lepomis macrochirus	BARDAC 22	96 hr (static)	Mortality, LC_{50}	320_{mm}
Oncorhynchus mykiss	M&ENNO-TER forte	96 hr (static)	Mortality, LC_{50}	1160_{nom}
Brachydanio rerio	BARDAC 22	34-d (flow-through)	Reproduction, NOEC	32_{nom}

Group	Test substance	Time-scale (Test type)	End point	Toxicity (µg DDAC/L)(A)
Aquatic invertebrate				
Daphnia magna	BARDAC 22	48 h (static)	Mortality, EC_{50}	94_{mm}
Daphnia magna	M&ENNO-TER forte	48 h (static)	Mortality, EC_{50}	17_{nom}
Daphnia magna	BARDAC 22	21 d (flow-through)	Reproduction, NOEC	10_{nom}
Sediment dwelling organisms				
no data				
Algae				
Scenedesmus subspicatus	BARDAC 22	96 h (static)	Biomass: 72-h E_bC_{50} Growth rate: 72-h E_rC_{50}	250_{nom} 330_{nom}
Selenastrum capricornutum	M&ENNO-TER forte	72 h (static)	Biomass: 72-h E_bC_{50} Growth rate: 72-h E_rC_{50}	7_{nom} 10_{nom}
Higher plant – no data				
Microcosm or mesocosm tests – no data				

(A) Indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Emission of 5 kg (assuming 4 discharges per year), into sewage system

Test substance	Organism	Toxicity endpoint (µg/L)	Time scale	PECsw (initial) (µg/L)	TER	Annex VI Trigger[1]
a.s.	Fish	320	Acute	10.7	**29.9**	100
a.s.	Fish	32	Chronic	10.7	**2.99**	10
a.s.	Aquatic invertebrates	17	Acute	10.7	**1.59**	100
a.s.	Aquatic invertebrates	10	Chronic	10.7	**0.93**	10
a.s.	Algae	7	Chronic	10.7	**0.65**	10

Emission of 5 kg accounting for pre-STP dilution: 0.425 kg into sewage system

Test substance	Organism	Toxicity endpoint (µg/L)	Time scale	PECsw (initial) (µg/L)	TER	Annex VI Trigger[1]
a.s.	Fish	320	Acute	0.91	352	100
a.s.	Fish	32	Chronic	0.91	35.2	10
a.s.	Aquatic invertebrates	17	Acute	0.91	**18.7**	100
a.s.	Aquatic invertebrates	10	Chronic	0.91	11.0	10
a.s.	Algae	7	Chronic	0.91	**7.69**	10

Bioconcentration				
	Active substance			
$logP_{OW}$	<1			
Bioconcentration factor (BCF)(A)	66(B)			
Annex VI Trigger for the bioconcentration factor	100			
Clearance time (days) (CT_{50})	<14			
(CT_{90})	>18			
Level and nature of residues (%) in organisms after the 14 day depuration phase	no data			

(A) Only required if log $P_{O/W}$ >3.
(B) Determined for radioactivity.

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s.	no data	no data
Preparation	no data	no data
Tunnel tests		
no data		
Bee brood study		
no data		
Field or semi-field tests		
no data		

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Not relevant (no exposure)

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g a.s./ha)
Typhlodromus pyri	no data		
Aphidius rhopalosiphi	no data		

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field	Trigger
	Typhlodromus pyri		no exposure	no exposure	2
	Aphidius rhopalosiphi		no exposure	no exposure	2

Further laboratory and extended laboratory studies

Species	Life stage	Test type, substrate and duration	Dose (g a.s./ha)	Endpoint	% effect (positive effect is adverse) and LR_{50} and ER_{50} values	Trigger value
no data						

Field or semi-field tests
no data

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point
Earthworms			
Eisenia fetida	BARDAC 22	Acute 14 days	>1000 mg DDAC/kg at 5.8% oc
	Preparation	Acute 14 days	no data
Field tests			
no data			
Other soil macro-organisms			
Soil mite			
Collembola	no data		

Test organism	Test substance	Time scale	End point
Soil micro-organisms			
Nitrogen mineralisation	a.s.	Chronic 28 days	no data
	Preparation	Chronic 28 days	no acceptable data
Carbon mineralisation	a.s.	Chronic 28 days	no data
	Preparation	Chronic 28 days	no acceptable data
Field studies			
no data			

Toxicity/exposure ratios for soil organisms

Not relevant (no exposure)

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

no data

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha) vegetative vigour	ER_{50} (g/ha) emergence	Exposure (g/ha)	TER	Trigger
no data						

Additional studies (e.g. semi-field or field studies)

no data

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge	3-hour EC_{50} 11 mg a.s./L
Pseudomonas sp	no data

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	none
water	DDAC
sediment	DDAC
groundwater	none

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	BARDAC 22: N, R50 & R53

APPENDIX B – LIST OF ABBREVIATIONS

ε	decadic molar extinction coefficient
µg	microgram
µm	micrometer (micron)
a.s.	active substance
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
AV	avoidance factor
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstract Service
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
E_bC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECB	European Chemicals Bureau
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EPA	Environmental Protection Agency
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
G	glasshouse
GAP	good agricultural practice
GS	growth stage
h	hour(s)
ha	hectare

hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
IR	infrared
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{oc}	organic carbon adsorption coefficient
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OC	organic carbon content
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_{GW}	predicted environmental concentration in ground water
$PEC_{Sed.}$	predicted environmental concentration in sediment
PEC_{Soil}	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{STP}	predicted environmental concentration in sewage treatment plant
pH	pH-value
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between n-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
r^2	coefficient of determination
RMS	rapporteur member state

SL	soluble liquid
SD	standard deviation
SFO	single first order
SSD	species sensitivity distribution
STP	sewage treatment plant
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TWA	time weighted average
USES	The Uniform System for the Evaluation of Substances
UV	ultraviolet
W/S	water/sediment
w/w	weight per weight
WHO	World Health Organisation
yr	year

APPENDIX C – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
DDAC	*N*-decyl-*N*,*N*-dimethyldecan-1-aminium chloride