CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion regarding the peer review of the pesticide risk assessment of the active substance chlormequat (considered variant chlormequat chloride)

Issued on 29 September 2008

SUMMARY

Chlormequat is one of the 84 substances of the third stage Part B of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. 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 United Kingdom being the designated rapporteur Member State submitted the DAR on chlormequat in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 27 April 2007. The peer review was initiated on 4 October 2007 by dispatching the DAR for consultation of the Member States and the applicant task force, comprising BASF AG, CIBA Speciality Chemicals, NUFARM GmbH & Co KG and Taminco SA. 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 applicant upon request were evaluated in a series of scientific meetings with Member State experts in May – June 2008.

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

The conclusion was reached on the basis of the evaluation of the representative uses as plant growth regulator in cereals for stem stabilisation as proposed by the applicants. Full details of the GAP can be found in the attached endpoints.

[1] OJ No L 224, 21.08.2002, p. 25, as amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19)

The representative formulated product for the evaluation was 'Chlormequat-chloride 750 g/L', a soluble concentrate (SL) containing 750 g/l chlormequat chloride.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

Adequate analytical methods are available to monitor all compounds given in the respective residue definitions in food/feed of plant origin, soil and air.

There are no adequate methods available to monitor chlormequat in animal products and in water.

With regard to the evaluation of the toxicological properties, the studies were performed with chlormequat chloride. The active substance was extensively absorbed, barely metabolised and rapidly excreted mainly by urine. The acute toxicity results with rats (after oral administration) and rabbits (after dermal administration) triggered the classification **Xn**, **R21/22** "**Harmful in contact with skin and if swallowed**". In repeated dose studies, the dog appeared to be the most sensitive species, showing neuropharmacological effects, with an overall NOAEL of 4 mg/kg bw/day in the 1-year study. In mutagenicity and long-term tests, chlormequat chloride was not shown to have any genotoxic or carcinogenic properties. During the reproductive toxicity testing, fertility was affected at a maternal toxic dose level, leading to an overall parental NOAEL of 75 mg/kg bw/day and a reproductive NOAEL of 74 mg/kg bw/day. However, based on reduced body weight gain and focal muscular dystrophy, the offspring NOAEL was 41 mg/kg bw/day. No variations, retardations or malformations were observed in the developmental studies with rats and rabbits, and the maternal NOAEL was 75 mg/kg bw/day in rats and 20 mg/kg bw/day in rabbits. In mechanistic studies *in vitro* for neurotoxicity, chlormequat chloride showed a weak agonistic activity on muscarinic and nicotinic receptors.

With regard to the toxicological reference values, the agreed values reported as chlormequat chloride were **0.04 mg/kg bw/day for the Acceptable Daily Intake** (ADI), **0.04 mg/kg bw/day for the Acceptable Operator Exposure Level** (AOEL) and **0.09 mg/kg bw for the Acute Reference Dose** (ARfD). The dermal absorption values were 4% for the concentrate and the dilution, based on an *in vivo* test. The operator exposure estimates were below the AOEL according to the German model with the use of personal protective equipment, but above the AOEL according to the UK POEM even with the use of personal protective equipment. The different exposure estimates for the worker and the bystander led to values below the AOEL.

With regard to residues, the metabolism of chlormequat chloride was investigated in wheat. The major component in grain and straw at harvest was unmetabolised chlormequat. Rotational crops data

show that significant residues in succeeding and rotational crops are not expected to occur except in rotated cereals. However residues should not be higher than in cereals directly treated with chlormequat chloride according to the notified GAP. Currently, according to the conclusion of the expert meeting, only the use of chlormequat chloride on rye and triticale in Northern Europe would be supported by a sufficient number of residue trials to allow at least a provisional proposal of maximum residue levels (MRL) whereas uses have also been notified for wheat, barley and oats and also for use in Southern Europe. It is noted that the rapporteur Member State does not agree with this conclusion. Data gaps for further residue trials for all notified uses have been identified. On the basis of processing studies, processing factors have been calculated.

After evaluation of animal metabolism studies and animal transfer studies with ruminants and poultry, MRLs for animal products have been provisionally proposed pending the submission of residue trials on primary crops and the demonstration of the validity of the analytical method used in feeding studies.

If the use of chlormequat chloride on only rye and triticale is considered in a provisional calculation, then the consumer exposure is expected to be below the toxicological reference values. However it is noted that the risk assessment does not cover the intake of barley, oats and wheat and therefore it is only indicative and the final assessment is pending submission of additional data.

With regard to the environmental fate and behaviour data, no significant metabolites were identified in laboratory aerobic route and rate of degradation studies using [chloroethyl-U-^{14}C] labelled chlormequat chloride. However a minor unidentified non-transient metabolite was found above 5% at two consecutive occasions. The formation of unextractable residues accounted for 19-28% of the applied radioactivity (AR) after 112 days, while significant mineralisation was observed (28.3-61.1% after 112 days). Chlormequat chloride exhibited moderate persistency in soil, first-order DT_{50} values were in the range from 27 to 34 days. The peer review concluded that no reliable data were available regarding the mobility of chlormequat chloride.

In dark natural water sediment systems chlormequat chloride degraded exhibiting low persistence without forming major metabolites. Peak partitioning of chlormequat chloride to the sediment was measured 30 days after dosing at a maximum of 63.3% AR. Mineralisation was significant and by the termination of the study $^{14}CO_2$ represented 55.6-67.0% AR.

Based on the calculated photochemical oxidative degradation, air is not a likely route of environmental contamination by chlormequat chloride.

No reliable FOCUS calculations regarding the predicted environmental concentrations in surface water and sediment as well as for the leaching potential were available.

A potential high risk was indicated in the first-tier risk assessment for birds and mammals except for the long-term risk to insectivorous mammals. The refined risk assessment based on measured residues in plants resulted in TERs above the trigger for herbivorous birds. However the long-term risk assessment to insectivorous birds needs further refinement. The acute risk to insectivorous mammals and small herbivorous mammals and the long-term risk to herbivorous mammals were not sufficiently addressed and need further refinement. The log P_{ow} of chlormequat chloride was less than 3 and therefore no risk assessment is triggered for secondary poisoning of fish- and earthworm-eating birds and mammals. No major metabolites were found in plants and hence no risk assessment for the uptake of plant metabolites was conducted. *Daphnia magna* was the most sensitive aquatic species tested. The FOCUS step 1 calculations resulted in TERs above the trigger of 100 and 10 for fish, algae and higher aquatic plants but not for daphnids. The TERs for daphnids exceeded the Annex VI trigger values by a factor of 3.5 (acute) and 2.6 (chronic) with FOCUS step 2 PEC_{SW} values. However there is some uncertainty with regard to the reliability of the PEC_{SW} water values since the adsorption/desorption study was conducted at too low temperatures. If the new PEC_{SW} values would be increased by more than 2.6 times then further refinement of the aquatic risk assessment would be needed (e.g. FOCUS step 3 or step 4 calculations). A final conclusion on the risk to aquatic organisms can be drawn once reliable PEC_{SW} values are available.

The risk to bees, non-target arthropods, earthworms, non-target macro- and micro-organisms, non-target plants and biological methods of sewage treatment was assessed as low for all representative uses.

Key words: chlormequat, chlormequat chloride, peer review, risk assessment, pesticide, plant growth regulator

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BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000 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. Chlormequat is one of the 84 substances of the third stage, part B, covered by the Regulation (EC) No 1490/2002 designating the United Kingdom as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, the United Kingdom submitted the report of its initial evaluation of the dossier on chlormequat, hereafter referred to as the draft assessment report, received by the EFSA on 27 April 2007. Following an administrative evaluation, the draft assessment report was distributed for consultation in accordance with Article 11(2) of the Regulation (EC) No 1490/2002 on 15 October 2007 to the Member States and on 4 October 2007 to the applicant task force, comprising BASF AG, CIBA Speciality Chemicals, NUFARM GmbH & Co KG and Taminco SA 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 applicant, a scientific discussion took place in expert meetings in May – June 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 August 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 11c(1) of the amended Regulation (EC) No 1490/2002, 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 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising 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, 29 February 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 September 2008).

Given the importance of the draft assessment report including its addendum (compiled version of July 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

Chlormequat is the ISO common name for 2-chloroethyltrimethylammonium (IUPAC). However the data submitted in the dossier refer to the variant chlormequat chloride (2-chloroethyltrimethylammonium chloride).

Chlormequat is a quaternary ammonium plant growth regulator. Chlormequat acts as an inhibitor of the biosynthesis of gibberellins. It is absorbed and translocated throughout the plant. Chlormequat is a growth retardant used on cereals to reduce unwanted longitudinal shoot growth without lowering plant productivity.

The representative formulated product for the evaluation was 'Chlormequat-chloride 750 g/L', a soluble concentrate (SL) containing 750 g/l chlormequat chloride, registered in EU Member States under different trade names.

The representative uses evaluated comprise foliar spraying with conventional spraying devices on winter and spring wheat, winter and spring barley, triticale, durum wheat, spelt wheat, rye and oats from growth stage of BBCH 30 up to growth stage of BBCH 49, in all EU countries, at a single application at a maximum application rate of 1.5 kg a.s./ha (chlormequat chloride).

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

As the data submitted in the dossier refer to the variant of chlormequat, the specification is expressed on the basis of chlormequat chloride. Chlormequat chloride is very hygroscopic and therefore the dry technical material (TC) is not isolated during production, but is diluted with water to give an aqueous technical concentrate (TK). The experts at the PRAPeR Meeting 46 (May 2008) agreed that the specification should be for the TK.

The experts at PRAPeR meeting 49 (June 2008) agreed that 1,2-dichloroethane is a relevant impurity but acceptable at levels proposed in the FAO specification (0.01%). They also agreed that vinyl chloride[2] is a relevant impurity and the highest proposed level in the technical specification (0.0004 g/l in the technical concentrate, which corresponds to 0.0005 g/kg in the technical material) does not give raise to significant toxicological concern.

The minimum purity of chlormequat chloride could not be concluded on as the experts at the PRAPeR Meeting 46 did not accept the technical specifications for the active substance. The batch analysis data did not support the technical specifications for some impurities (CIBA, Nufarm, Taminco), and for all of the sources the batch analyses were not fully supported by validated methods. PRAPeR 46 meeting could not agree on the acceptability of the technical specification for the technical material of the sources mentioned in the DAR because the acceptability of the methods used for impurity determination could not be concluded on. The meeting identified new data gaps as detailed under point “List of studies to be generated” of this conclusion.

The meeting also requested the revision of the maximum value for the relevant impurities 1,2-dichloroethane (relevant for two sources) and vinyl chloride (relevant for one source). Data gaps were identified for the applicants to provide revised specifications. The BASF source was proposed as the reference source by the task force.

The minimum purity of chlormequat chloride in the FAO specification 143.302/TK (August 2005) is 725 g/l (636 g/kg), the maximum content is 775 g/l (680 g/kg), and the 1,2-dichloroethane content is maximum 0.1 g/kg of the dry chlormequat chloride content. Supporting data for the FAO specification were provided by BASF, Nufarm, Ciba Speciality Chemicals and Taminco.

[2] vinyl chloride: chloroethene

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of chlormequat chloride or the respective formulation, however the following data gaps were identified:
-a full explanation for the very high result obtained for the relevant impurity 1,2-dichloroethane in one of the batches analysed (relevant for one source);
-clarification concerning the batches analysed in the batch analysis and whether they have been blended or not (relevant for one source);
-information details about the purity and commercial availability of starting materials used in manufacture (relevant for two sources);
-a new study for the determination of the vapour pressure;
-a new calculation for Henry's law constant based on the vapour pressure.

The main data regarding the identity of chlormequat chloride and its physical and chemical properties are given in appendix 1.

Ion chromatographic methods (CIPAC 143/TK/M2/; 143/SL/M2/) are available for the determination of chlormequat chloride in the technical material and in the representative formulation. Adequate methods are available for the determination of the relevant impurities (GC-FID, ion chromatography) in the technical concentrate.

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

The residue definition for monitoring purposes was set as the sum of chlormequat and its salts expressed as chlormequat chloride for all commodities.

Adequate methods are available to monitor all compounds given in the respective residue definitions in food/feed of plant origin. A HPLC-MS/MS method is available to monitor residues with LOQ 0.05 mg/kg in wet, oily and acidic crops, and 0.5 mg/kg in dry crops.

There are no acceptable methods to determine residues in foodstuff of animal origin, as data gaps were set to demonstrate the extraction efficiency of the ion chromatographic method and for independent laboratory validation of the method for the determination of residues of chlormequat in animal products. It should be noted that the validation study has been submitted to the rapporteur Member State, however in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, the new studies could not be considered in the peer review.

Adequate methods are available (ion chromatography with suppressed conductivity detection) to monitor residues of chlormequat in soil with LOQ of 0.01 mg/kg and in air with an LOQ of 0.0014 mg/m^3.

There are no acceptable monitoring methods for the determination of chlormequat in water. It should be noted that the study has been submitted to the rapporteur Member State, however in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, the new studies could not be considered in the peer review.

Analytical methods for the determination of residues in body fluids and tissues are not required as chlormequat is not classified as toxic or highly toxic.

2. Mammalian toxicology

Chlormequat chloride was discussed by the experts in mammalian toxicology in June 2008 (PRAPeR meeting 49, round 10, subgroup 2).

According to the section on physico-chemical properties and identity, the active substance is chlormequat, and chlormequat chloride represents a variant. The toxicological studies were performed with chlormequat chloride and the doses and reference values are reported as chlormequat chloride.

The impurity profile of the toxicological batches was not available (neither in volume 4 of the DAR, nor in an addendum). Considering that the production process is well established for many years and that the purity of chlormequat chloride was varying slightly only by addition or removal of water, the experts agreed that the batches could be expected to have the same impurity profile. The proposed levels of the impurities in the technical specification (April 2008) were considered to be acceptable and the impurities 1,2-dichloroethane and vinyl chloride were considered to be toxicologically relevant.

2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics)

Almost completely absorbed from the gastro-intestinal tract (maximum concentration in plasma after 2 hours), chlormequat is rapidly excreted mostly via urine (75-85% within 24h) but also via faeces and bile (<5%). The highest amounts were found in the liver and the kidneys, but there was no evidence for bioaccumulation. Chlormequat chloride is barely metabolised and excreted essentially unchanged; choline chloride was the only metabolite identified (up to 3% in urine).

2.2. ACUTE TOXICITY

Several species were used to determine acute oral and percutaneous toxicity (rat, rabbit and mouse). After oral administration, the rabbit was the most sensitive, with a dermal LD_{50} <2000 mg/kg bw (Xn) and an oral LD_{50} of 115 mg/kg bw (T) whereas several rat and mouse studies showed a dermal LD_{50} >2000 mg/kg bw and an oral LD_{50} between 400 and 1000 mg/kg bw (Xn). Additionally, the rabbit oral study was quite old, had some drawbacks, and taking into account data with other species (i.e. monkey) reported in the JMPR report (1997) the experts agreed that the results of acute oral toxicity with rabbits were not the most relevant to humans. Therefore the proposed classification was **Xn, R21/22** "**Harmful in contact with skin and if swallowed**" in agreement with ECB (19th ATP, 1993).

In the inhalation studies rats only were used and did not show chlormequat chloride to be classifiable via the inhalation route (LC_{50} by inhalation >5 mg/L). Furthermore it was not irritating to the eyes or skin and did not induce skin sensitisation in guinea pigs (Buehler and maximisation tests).

2.3. SHORT TERM TOXICITY

The adverse effects of chlormequat chloride after short-term dietary exposure were studied in several species: rats (4-week, 59-day, 90-day), mice (4-week, 90-day) and dogs (4-week, 90-day and 12-month). In rats no specific organ was affected by chlormequat chloride and the main adverse effect was a decreased body weight gain (more pronounced in males) resulting in an overall NOAEL of 150 mg/kg bw/day. In mice the absence of toxicity at the highest doses tested led to a NOAEL of 1070 mg/kg bw/day. Dog appeared to be the most sensitive species, showing neuropharmacological effects attributed to chlormequat chloride (mainly increased salivation and diarrhea, see also 2.8) already during the first week of administration in the 4-week studies (NOAEL 9 mg/kg bw/day). The meeting agreed on an overall short-term NOAEL in dogs of 4 mg/kg bw/day (1-year study). In the 21-day dermal study in rabbits only possible signs of local irritation were observed but no systemic toxicity up to 150 mg/kg bw/day (highest dose).

2.4. GENOTOXICITY

Chlormequat chloride was negative in all mutagenicity tests performed covering all three endpoints (point mutation, chromosome aberration and DNA damage and repair). This was true for *in vitro* tests in bacterial and mammalian cells (mouse lymphoma cells, Chinese hamster cells, human lymphocytes, rat hepatocytes) as well as in studies *in vivo* using rats and mice. Chlormequat chloride was also negative in the sex linked recessive lethal test and dominant lethal test.

2.5. LONG TERM TOXICITY

Several studies were performed in rats (18-month, 24-month, 108-week) and mice (110-week, 18-month) and the effects were similar to those observed in the short-term studies. The agreed long-term

NOAEL in rats was 14 mg/kg bw/day based on reduced body weight in the 24-month study, and the overall NOAEL in mice was higher than 336 mg/kg bw/day (highest dose tested) in the absence of adverse effects in the 110-week study. Chlormequat chloride was not oncogenic in any of the studies up to the highest doses tested (i.e. 150 mg/kg bw/day in rats and 336 mg/kg bw/day in mice).

2.6. REPRODUCTIVE TOXICITY

The adverse effects of chlormequat chloride on the reproductive parameters were investigated in three rat multigeneration studies. The fertility was only affected at very high dose in one study (reduced conceptions per mating and mean number of pups by litter) leading to a reproductive NOAEL of 74 mg/kg bw/day (Hellwig, 1993). The primary effects in parents were reduced body weight gain and clinical signs, resulting in an overall parental NOAEL of 75 mg/kg bw/day (Suresh, 1995). Based on reduced body weight gain during lactation and focal muscular dystrophy in the third study (Gandalovicova, 1993), the offspring NOAEL was 41 mg/kg bw/day.

The teratogenicity studies were performed in rats (1 study) and rabbits (2 studies). The second rabbit study (Merkle, 1979) showed a higher sensitivity of the animals but presented also some deficiencies and uncertainties. Therefore the experts agreed that the clinical findings in one animal at the two high doses were not relevant in the absence of effects on pregnancy and foetuses, and only the clinical signs and the body weight loss observed in the first study (Becker, 1992) were taken into account to derive the maternal NOAEL of 20 mg/kg bw/day in rabbits (instead of 3 mg/kg bw/day initially proposed in the DAR). In rats, a maternal NOAEL of 75 mg/kg bw/day was driven by body weight changes and clinical signs. No variations, retardations or malformations were observed in both species at any dose level tested. As a result the developmental NOAEL in rats was 225 mg/kg bw/day based on the absence of effects on the reproductive parameters at the highest dose tested, whereas the developmental NOAEL in rabbits was 20 mg/kg bw/day (Becker, 1992) based on increased post implantation loss at the high dose (40 mg/kg bw/day).

2.7. NEUROTOXICITY

Chlormequat chloride did not exhibit delayed neurotoxicity in a delayed neurotoxicity study with hens. The potential neuropharmacological properties of the compound were investigated further. In *in vitro* studies, chlormequat chloride showed a weak agonistic activity on muscarinic receptors (with a potency about 5 orders of magnitude lower than for atropine), and it was shown to be at least a partial agonist of the nicotinic acetylcholine receptor (with a potency of about 1% of that of acetylcholine).

2.8. FURTHER STUDIES

No further data available.

2.9. MEDICAL DATA

Therapy studies were performed with rats but neither choline chloride nor atropine was indicated in the case of acute intoxication with chlormequat chloride.

In plant manufacturing personnel, no association has been observed between the exposure to chlormequat chloride and any specific medical effect. Few cases of poisoning (with unspecific symptoms) were observed during medical surveillance. No epidemiological studies are available.

2.10. ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARFD)

Acceptable daily intake (**ADI**)

In the DAR the proposed ADI was 0.03 mg/kg bw/day based on the developmental rabbit study (Merkle, 1979). Considering the previous discussions (see 2.6), the meeting agreed on an ADI of **0.04 mg/kg bw/day** based on the 1-year dog study, using a safety factor of 100 and expressed as chlormequat chloride.

Acceptable operator exposure level (**AOEL**)

In the DAR, the proposed AOEL was 0.03 mg/kg bw/day based on the developmental rabbit study (Merkle, 1979). Considering the previous discussions, the meeting agreed on an AOEL of **0.04 mg/kg bw/day** based on the 1-year dog study, using a safety factor of 100 and expressed as chlormequat chloride.

Acute reference dose (**ARfD**)

The agreed ARfD for chlormequat chloride was **0.09 mg/kg bw** based on the 4-week dog studies where the neurological effect was manifested from the first week of treatment, applying a safety factor of 100 and expressed as chlormequat chloride.

2.11. DERMAL ABSORPTION

Based on the results of an *in vivo* test with rats performed with the formulation BAS 062 03W (similar to the representative formulation since water is the only co-formulant), the agreed dermal absorption values were 4% for both the concentrate and the field dilution.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product 'Chlormequat-chloride 750 g/L' is an aqueous solution containing 750 g chlormequat chloride/L for use as a plant growth regulator in cereals, with maximum one application per crop using conventional field crop sprayers.

Operator exposure

Estimated operator exposures are presented in the table below as percentage of AOEL (0.04 mg/kg bw/day), according to calculations with the German and UK POEM models. The default for operator body weight is 70 kg in the German model and 60 kg in the UK-POEM model. The assumed work rate is 20 ha/day in the German model and 50 ha/day in the UK-POEM model.

Model	No PPE	With PPE[1]	With PPE[2]	With PPE[3]
German	192	90	74	-
UK POEM	1343	749	-	164

PPE[1] (personal protective equipment): gloves during mixing and loading, PPE[2]: gloves during mixing/loading and application, PPE[3]: gloves during mixing/loading and when handling contaminated surfaces.

The German model estimates of exposure indicate that levels of exposure for operators wearing suitable PPE will be within the systemic AOEL. Predicted exposures using UK POEM exceed the AOEL even when suitable PPE are worn.

Worker exposure

Re-entry exposure of workers during crop inspection has been estimated using an exposure model proposed by Hoernicke *et al*. (1998)[3] using agreed dislodgeable foliar residue and transfer coefficient values according to the EUROPOEM database. Using these agreed values and an appropriate work period of two hours/day for inspection activities in cereal crops resulted in an estimated worker exposure of 75% of the AOEL.

Bystander exposure

Using the data from Lloyd and Bell,[4] the estimated bystander exposure was 4% of the AOEL. Estimates were also provided of possible exposure to spray drift fallout from applications which may be deposited in gardens adjacent to treated areas. The estimates were refined in addendum 2 (July 2008), considering exposure to vapour post application where the highest value was 21% of the AOEL. Additionally, residential exposure from deposits in gardens was estimated to be 1% of the AOEL for a small child playing on a lawn.

[3] Hoenicke E, Nolting HG and Westphal D (1998), Hinweise in der Gebrauchsanleitung zum Schutz von Personen bei Nachfolgearbeiten in mit Pflanzenschutzmitteln behandelten Kulturen, Nachrichtenblatt des Deutschen Pflanzenschutzdienstes, Vol 50 (10), p 267.

[4] Lloyd and Bell (1983), Hydraulic nozzles: comparative spray drift study, UK Ministry of Agriculture Fisheries and Food.

3. Residues

The active substance chlormequat chloride was discussed at the PRAPeR experts' meeting for residues (PRAPeR 50, round 10) in June 2008.

It is noted that the chlormequat chloride, the chloride salt variant of chlormequat, is used in the residue studies. Thus the evaluated data belong to the variant chlormequat chloride and the reported residue levels are expressed as chlormequat chloride.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The nature of the residues in plants following the use of chlormequat chloride was studied in wheat. After a single application of 2-chloroethyl-[1,2-^{14}C]-triethylammonium chloride at a rate slightly below the critical GAP (0.9N) at GS71 (intended uses: GS 30-49 for different commodities and regions) samples were collected 0, 28 and 84 days after treatment and at maturity. Total radioactive residues (TRR) in forage samples decreased from 49.24 mg/kg at day 0 to 14.35 mg/kg at day 84 after application. TRR in straw and grain was 45.8 mg/kg and 1.3 mg/kg respectively. Whereas the radioactive residues in forage and straw samples were mostly extractable (85-90% TRR and 89% TRR respectively), only 52% TRR was extracted from grain samples. The unextracted residues in straw and grain samples were further investigated. In grain 0.2%, 35.6%, 1.2% and 15.8% TRR were found in the protein, lignin, cellulose and starch fraction respectively. In straw 5.1% and 0.1% TRR were found in the lignin and the cellulose fraction respectively. In extracts of forage sampled at day 0, 28 and 84 respectively, 40-42 mg/kg, 32-33 mg/kg and 9.7-10.5 mg/kg chlormequat were found. Concentrations of 36-37 mg/kg (78-81% of TRR) and 0.37-0.41 mg/kg (28-30% of TRR) chlormequat were detected in straw and grain. Betain[5] was the only other radioactive component identified (0.04-0.05 mg/kg or 3-5% of TRR in grain and at 0.06 mg/kg or 0.1% of TRR in straw).

The expert meeting discussed the reliability of the metabolism study. Main points of concern were a metabolite found at concentrations of 1.5% TRR (0.026 mg/kg) in grain and 3.8% (1.75 mg/kg) in straw which was not identified, and the fact that in this study identification was only tentatively carried out using TLC. Furthermore, it was noted that the design of the metabolism study did not precisely match the supported GAPs. The experts concluded that taking into account the fact that reference material for several possible metabolites were used for the identification and the polar nature of the active substance, the metabolism study could be considered as acceptable.

[5] Betain: (trimethylammonio)acetate

The metabolism study submitted showed that chlormequat is the main compound identified in straw and grain. Oxidation to form minor amounts of betain has been shown for straw and grain. Betain is found in biochemical pathways of the body and is of no toxicological concern. Furthermore incorporated residues mainly in the lignin fraction (for grain and straw) and the starch fraction (in grain) have been found.

The experts' meeting discussed the residue definition for food of plant and animal origin. It was concluded that the available analytical methods determine the chlormequat cation but not chlormequat chloride. Therefore, the experts concluded on the following residue definition for plants for monitoring and risk assessment: sum of chlormequat and its salts expressed as chlormequat chloride.

The meeting noted that the GAPs for the intended uses as listed in the DAR deviate from the notified critical GAPs for Southern Europe regarding the growth stage (GS) for different uses. The rapporteur Member State confirmed after the meeting that the Southern Europe GAPs included in the list of endpoints reflect the GAPs included in the dossier submitted by the applicant. The notified GS were as follows: Northern Europe: barley: GS 30; wheat: GS 31/32; triticale: GS 37; rye: GS 37; oats GS49; Southern Europe: wheat: GS 31/32; rye: GS37; oats: GS 49.

Overall, for Northern Europe 25 residue trials on wheat, 9 trials on barley, 11 trials on oat, 12 trials on rye and 4 trials on triticale were submitted, and for Southern France 6 trials on wheat were submitted.

The meeting of experts discussed the acceptability of the evaluation of the residue trials carried out in Northern Europe and presented in the DAR. According to draft guidance document SANCO 7525/VI/95-rev.8, it is possible to derive a data set from any combination of the specified cereals when the active substance is applied early in the growing season (last application before consumable parts of the crop have started to form). The guidance document does not specify special requirements for growth regulators. The meeting of experts concluded however that as chlormequat chloride is a plant growth regulator, it interferes with plant growth and plant metabolism and therefore the residue situation may differ from one cereal crop to the other and it was considered that growth stage at application is a very important factor. It is noted that also PRAPeR meeting 30, when discussing the growth regulator mepiquat, deviated from the recommendations of the guideline (see 'Conclusion regarding the peer review of the pesticide risk assessment of the active substance mepiquat').

It was noted that different GAPs were notified for chlormequat chloride for the different cereal crops. Therefore extrapolation from the database on wheat and barley to triticale, rye and oat respectively is not possible. Furthermore the experts concluded that the residue trials in wheat and barley accepted by the rapporteur Member State did not match the supported GAPs (GS30 and GS31/32) since they

were mainly performed at GS 37. The rapporteur Member State was asked to perform a complete re-evaluation of the residue trials on wheat and barley. Upon clarification of the notified GAP, the residue trials reported for oat, triticale and rye should also be evaluated according to the critical GAP.

The rapporteur Member State addressed this request in Addendum 2 of the DAR (July 2008). Based on four residue trials on wheat and three on barley, the setting of MRLs for wheat, barley, rye and triticale was proposed. The rapporteur Member State stressed that this evaluation was made in accordance with the guidance document. The provided evaluation was not peer-reviewed. EFSA notes that it does not follow the conclusion of the experts' meeting. Residue trials at GS 34 and GS 37 were regarded as representative for wheat (GS31/32) and barley (GS30).

In line with the conclusions of PRAPeR experts' meeting 50, EFSA proposes the provisional setting of MRLs for rye and triticale on the basis of three trials each on wheat and barley carried out with applications at GS37 which match the GAP defined for rye and triticale. In wheat grain residues of 0.20, 0.45 and 0.80 mg/kg and in wheat straw 13.4, 18.8 and 31.3 mg/kg were found. In barley grain residues were 0.49, 0.64 and 0.99 mg/kg, in barley straw 5.23, 7.27 and 9.12 mg/kg. Two of the trials on wheat have been carried out as replicates and the results can be regarded as supporting data. Additional trials on rye and triticale are required to achieve a complete data base of independent trials and also to confirm that extrapolation from wheat and barley to rye and triticale is justified for the application of chlormequat chloride. It is noted that PRAPeR meeting 30 has concluded that it is not acceptable to extrapolate between cereal crops for plant growth regulators. To support the uses on wheat, barley and oats complete data bases supporting the critical GAPs (GS 30, GS31/32 and GS 49 respectively) for these crops in Northern Europe are required.

Only six residue trials on wheat were submitted to support the intended uses in Southern Europe. The experts concluded that they did not match the notified GAPs and that complete data bases for wheat, barley, rye and oats are required to support the uses in Southern Europe.

One Member State stated that mushrooms grown on chlormequat containing straw show an uptake of residues. This practice may result in residues of chlormequat in edible crops other than directly treated crops. The meeting was not able to address a dietary risk assessment because respective residue trials were not available during the meeting. Furthermore, since this practice is relevant in some Member States only, it was not considered necessary to follow this issue further for Annex I inclusion. However, the meeting noted that the potential presence of residues of chlormequat chloride in mushrooms grown on treated straw should be taken into account in the assessment of consumer risk and MRLs during the registration procedures in Member States.

Effects of processing on the nature of the residues of chlormequat chloride were investigated in hydrolysis studies simulating beer brewing and bread making respectively. Under both hydrolytic

conditions a decline of the concentration of chlormequat chloride was observed and four minor degradation products were found. As these compounds were already present at the beginning of the studies and because of the low concentrations (up to 6.8%) no further characterisation was performed.

A balance study and three follow-up studies each were performed with wheat grain containing 0.1 mg chlormequat/kg, barley containing residues of 1.3 mg chlormequat/kg and oats containing 2.3 mg chlormequat/kg. The following transfer factors were derived: 3.1, 0.3, 1.0 and 0.5 for wheat bran, flour type 550, whole meal flour and whole grain bread; 0.9, 0.9 and 0.2 for pot barley, malt and beer and 1.0 for oat flakes.

Storage stability studies show that chlormequat chloride is stable in wheat grain and straw for at least 24 months and in processed fractions of cereals for at least 13 months when stored under deep frozen conditions.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

The metabolism and distribution in rotational crops was investigated in two studies. In the first study, soil was treated with 2-chloroethyl-[1-^{14}C]-triethylammonium chloride at a rate of 2 kg a.s./ha (1.3N). Lettuce, white radish and spring wheat were planted after 30, 120 and 365 days of aging. TRR was relatively low in lettuce and radish for all three plant-back intervals (max. 0.021 mg/kg, 0.046 mg/kg and 0.037 mg/kg in lettuce, radish leaves and radish roots respectively). Considerable concentrations of radioactive residues were found in wheat (max. 0.153 mg/kg, 0.336 mg/kg, 0.229 mg/kg and 0.197 mg/kg in forage, straw, chaff and grain respectively). Extractability of the TRR by methanol and water ranged from 46-68% in radish root to 12-20% in wheat grain. Further residues could be released by treatment with ammonia or enzymes. Extracts were analysed by HPLC. Besides chlormequat, further polar compounds were found but could not be identified. Radioactive residues in soil were 19.9-24.0 mg/kg, 0.29-0.51 mg/kg, 0.31 mg/kg and 0.26 mg/kg after 0, 30, 120 and 365 days of ageing respectively.

In a second rotational crop study, soil was treated with 2-chloroethyl-[1,2-^{14}C]-triethylammonium chloride at a rate equivalent to 1.5 kg a.s./ha (1N). After ageing of the soil for 30 days, spring wheat, carrot, lettuce and green beans were planted. Low concentrations of TRR were found in beans, carrot and lettuce (max. 0.01 mg/kg in crop parts for human consumption; TRR of 0.052 mg/kg, 0.041and 0.066 mg/kg were found in wheat grain, forage and straw respectively).

The experts' meeting discussed the poor identification of metabolites in lettuce, radish and wheat (mainly chlormequat at low levels and unidentified polar peaks) in the first study. However the meeting assumed that the metabolic pattern in the rotational crops would be similar to the metabolic pattern depicted in the wheat metabolism study with a considerable amount of radioactivity

incorporated into the matrix. The meeting noted that the second study showed considerably lower radioactive residues compared to the first study. The applicant was asked for clarification. In both studies, the total residues recovered in wheat were significant. The experts concluded that there were only concerns regarding chlormequat residues when cereals are planted as rotational crops. However, provided there is authorisation of use in all the cereal crops, residues in rotated cereals should not be higher than in cereals directly treated with chlormequat chloride according to the notified GAP.

It is not expected that rotational crops used for human consumption will contain residues above the LOQ of the analytical method for monitoring (0.05 mg/kg in wet, oily and acidic crops; 0.50 mg/kg in dry crops) when chlormequat chloride is used according to the critical GAP.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

The metabolism and distribution of residues in animals was investigated in goats and chickens, using ^{14}C-labelled chlormequat chloride.

In lactating goats dosed at 62.5 mg (28.9 mg/kg diet as received) for 7 consecutive days, the majority of the applied radioactivity was found in excreta (49% in urine, 30% in faeces and 0.6% in milk). Additional 8% were recovered in cage wash and 1.6% in the gastro-intestinal contents. Tissues accounted only for 0.13% of the applied dose (0.36 mg/kg TRR in liver, 1.45 mg/kg TRR in kidney, 0.23 mg/kg TRR in muscle and 0.030 mg/kg TRR in fat). Organic extraction recovered 67% of TRR in fat and 77-92% of TRR in other tissues, but only 17-20% of TRR in milk. Chlormequat accounted for 42%, 83%, 76% and 4% of TRR in the organic extracts of liver, kidney, muscle and milk respectively. No further metabolites were identified. Unextractable residues were further characterised using acid and enzyme treatment.

For laying hens dosed at 3.0 mg a.s. for 14 consecutive days the majority of the radioactivity was recovered in excreta (92.6%). Egg white and egg yolk contained 0.05% and 0.34% of the administered radioactivity, tissues only approximately 0.04%. In kidney, liver, muscle and abdominal fat TRR of 0.352 mg/kg, 0.36 mg/kg, 0.12 mg/kg and 0.06 mg/kg were found. Organic extraction recovered 65% of TRR in liver and kidney, 75% in muscle and 62-69% in egg yolk, but only 6% in egg white and 15% in fat. Unextractable residues were further characterised by various treatments. Only in one of the egg yolk samples a substantial amount of the radioactive residues (0.210 mg/kg, 21.6%) remained unextracted. Chlormequat was the only identified component of the residue. It was present at levels of 6.5% TRR (0.023 mg/kg) in kidney, 1.8% (0.007 mg/kg) TRR in liver and 48% TRR (0.47 mg/kg) in one egg yolk sample.

After oral administration of chlormequat chloride to goats or hens, residues are rapidly excreted. Only small amounts of residues are transferred to tissues, milk or eggs. Radioactivity was recovered as parent, extractable and incorporated residues.

Comparison of metabolism in ruminants and rats is not included in the DAR. EFSA notes that in goats and rats, residues of chlormequat are mainly excreted and no accumulation in tissues has been observed. The main component identified in excreta or tissues was chlormequat. In the rat study choline chloride was identified in faeces, which was not found in goats but is part of the metabolic pathway in mammals.

The experts' meeting concluded on the following residue definition for animal products for monitoring and risk assessment: sum of chlormequat and its salts expressed as chlormequat chloride. (See also discussion concerning the residue definition in section 3.1).

Calculations for livestock for intake of cereal grain, straw and bran on the basis of the highest residues found and taking into account a processing factor for bran show the following results: 8 mg/kg diet (DM)/day for dairy cattle, 19 mg/kg diet (DM)/day for beef cattle, 1 mg/kg diet (DM)/day for chicken and 2 mg/kg diet (DM)/day for pigs. EFSA states that these calculations have to be regarded as provisional (see discussion on acceptability of residue trials in section 3.1).

Animal transfer studies were carried out on dairy cattle dosed at three dose rates corresponding to 12, 36 and 120 mg/kg feed. Residues were detected in all types of samples with the exception of meat from the lowest dose group. In the lowest dose group, which is relevant to the GAP concerning dairy cattle, mean steady-state residues in milk, skimmed milk and cream were 0.03, 0.04 and 0.03 mg/kg with highest residues of 0.08, 0.10 and 0.03 mg/kg. Based on the residues in milk of the highest dose group, it was estimated that a residue plateau in milk was reached after 5 to 6 days. In the medium dose group, which is relevant to the GAP concerning beef cattle, mean residues in meat, liver, kidney and fat were 0.05, 0.08, 0.40 and <0.05 mg/kg respectively with highest residues of 0.11, 0.09, 0.46 and 0.05 mg/kg respectively.

Laying hens were dosed chlormequat chloride at 6, 18 and 60 mg/kg feed. Residues above the LOQ were only found in liver samples of all dose groups (0.05 mg/kg for the low dose group), in one egg of the middle dose group and most eggs of the highest dose group. Based on the data from the high dose group, a residue plateau is reached at 5 – 6 days. As residues were at or below the LOQ in tissues and eggs from the lowest dose group, it can be concluded that no detectable residues are expected in products of poultry fed with products from cereal plants treated with chlormequat chloride according to the GAP.

The PRAPeR meeting 46 concluded that the method submitted for monitoring of residues in food of animal origin was not acceptable as the extraction efficiency has not been demonstrated. This method was also used in the feeding studies. Therefore, EFSA notes that the feeding studies can only be regarded as valid, if the validity of the analytical method is proved.

Storage stability studies show that chlormequat chloride is stable in meat, milk and eggs for at least 12 months when stored under deep frozen conditions.

3.3. CONSUMER RISK ASSESSMENT

The PRAPeR 49 toxicology meeting changed the reference values for chlormequat (ADI: 0.04 mg/kg bw/day and ARfD: 0.09 mg/kg bw). A calculation for the intake on the basis of provisionally proposed MRLs for rye (2 mg/kg) and meat, liver, kidney, milk and eggs of all types of animals (0.05 mg/kg, 0.1 mg/kg, 0.3 mg/kg, 0.1 mg/kg and 0.05 mg/kg) with the EFSA PRAPeR model was carried out by EFSA. It showed that the Danish model for children (TMDI = 25.4% ADI) and the French model for toddlers (TMDI = 10.3% ADI) are the most critical models for the chronic intake. The acute exposure is not expected to exceed the ARfD. NESTIs for consumer/intake combinations are maximal 14% of the ARfD (for rye and milk/milk products respectively).

EFSA notes that the risk assessment was not peer-reviewed. It is based only on the intake of rye and food of animal origin. The final assessment is pending the submission of additional residue trials and the re-evaluation for all intended uses.

3.4. PROPOSED MRLS

EFSA provisionally proposes MRLs of 2.0 mg/kg for triticale and rye only. It is noted that the rapporteur Member State is of the opinion that the available residue trials are sufficient to propose also MRLs for wheat and barley (for further details on the acceptability of residue trials and possible extrapolation see section 3.1.1). The proposal was not peer reviewed and has to be re-evaluated when additional residue trials are available.

The experts' meeting proposed the following MRLs for food of animal origin: milk: 0.1 mg/kg; meat: 0.05 mg/kg, liver: 0.1 mg/kg, kidney 0.3 mg/kg and eggs: 0.05 mg/kg. The experts concluded that the proposals are pending conformation of the LOQ by demonstration of the extraction efficiency of the method of analysis used for the feeding studies. EFSA notes that the validity of feeding studies and the data base used for the intake calculation of livestock are also under discussion.

4. Environmental fate and behaviour

Chlormequat chloride was discussed at the PRAPeR experts' meeting for environmental fate and behaviour PRAPeR 47 in May 2008 on basis of the DAR (April 2007) and the addendum (April 2008).

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

Degradation of chlormequat chloride under aerobic dark conditions (20ºC and 40% MWHC) was investigated in four soils. The formation of residues not extracted by methanol:water and water:hydrochloric acid were a sink for the applied ^{14}C-labelled chlormequat chloride (19.0-27.8% of the applied radioactivity (AR) after 112 days). Mineralisation to carbon dioxide was significant in each soil and accounted for 28.3-61.1% AR after 112 days.

In a single soil (Speyer 2.2, loamy sand), in which an extensive characterisation of the extractable soil residues were carried out, no major metabolites were identified (> 10% AR), but a minor unidentified metabolite was found above 5% at two consecutive occasions (5.4 and 7.2% AR at days 56 and 84). As this metabolite was not characterised further, in line with the opinion of the experts at the meeting, a data gap was identified for the identification of this non transient minor metabolite. A new metabolism study had been submitted to the rapporteur Member State, however in view of the restrictions concerning the acceptance of new (including newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, the new studies could not be considered in the peer review.

There were also concerns about the potential effect of the clay content of the soil on the degradation of chlormequat chloride since the soils used in the experiments had less clay content (4.3-7.0%) than is prescribed by the relevant guideline. The applicant submitted the above mentioned additional study for further addressing this issue but it could not be considered in the peer review. However, based on some additional information provided by the rapporteur Member State, the meeting of experts agreed that a reliable conclusion on the degradation of the parent compound could be drawn with the available information.

The degradation of chlormequat chloride under anaerobic conditions or photolysis in soil was not studied. These data were not considered necessary, taking into consideration the general conditions of the applied for uses (application during or after stem elongation in winter or spring sown cereals), the available data on soil degradation, the chemical structure of the parent molecule, UV absorbance and the photodegradation in water.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The degradation rate of chlormequat chloride was investigated in the same four soils described in chapter 4.1.1 above. Single first-order DT_{50} values were estimated to be 26.8-33.9 days. After normalisation to FOCUS reference conditions[6] (20°C and pF 2 soil moisture content) this range of single first-order DT_{50} became 17.0-31.6 days.

Field dissipation studies were not submitted and not required for chlormequat chloride since aerobic degradation in the laboratory resulted in half-lives below the trigger of 60 days.

The predicted environmental concentration in soil was calculated using the maximum proposed application rate (1500 g a.s./ha), the longest normalized laboratory DT_{50} value of 31.6 days and 70% crop interception value (stem elongation).

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The adsorption/desorption of chlormequat chloride was investigated in two studies on a total of seven soils in batch adsorption experiments ($K_f$oc values varied from 55 to 912 mL/g). All the experiments were carried out at 10ºC, instead of room temperature as required by the relevant guidelines. The experts from the Member States discussed the validity of these studies in a meeting. Since temperature affects the adsorption/desorption processes in soil, the experts agreed that the results of these experiments were not to be relied on. The applicant suggested to use worst case K_{oc} values calculated by extrapolation from 10ºC to 23ºC based on literature data (measurements at different temperatures on linuron and atrazine). As this calculation was submitted after the meeting of experts (further information could be found in addendum 2 to the DAR dated July 2008) the reliability of the possible extrapolation was not discussed and no reliable endpoints on adsorption/desorption were available. Moreover, in view of the restrictions concerning the acceptance of new (including newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, the new studies could not be considered in the peer review. Consequently, a data gap was identified to provide adsorption/desorption experiments on at least four different soils conducted at 20ºC.

A laboratory aged column leaching study was performed with aged (15 days at 20ºC) residues of chlormequat chloride in one soil (Speyer 2.1 loamy sand soil, organic carbon 0.75%). During the 15-day aging period a small amount (< 10%) of unidentified metabolites was formed. The total radioactivity found in the percolates of each experiment did not exceed 0.5% of the radioactivity applied to the column.

[6] Using section 2.4.2 of the generic guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Chlormequat chloride was essentially stable under sterile conditions at pH 4, 7 and 9 (50ºC). The quantum yield of direct photolysis of chlormequat chloride in aqueous solution was determined in a laboratory study. The results demonstrated that chlormequat chloride did not photodegrade in aqueous solution (quantum yield 4.74×10^{-7} mol Einstein^{-1} with half-life about 200 days).

Two ready biodegradability tests indicated that chlormequat chloride is 'readily biodegradable' using the criteria defined by the test (OECD 301B and 79/831 EEC).

The degradation of chlormequat chloride under aerobic aquatic conditions was investigated in two different natural systems of water and sediment (water pH 8.5 and 8.0, sediment pH 7.3 and 6.9) at 20ºC in the dark. The results showed that chlormequat chloride dissipated quickly from the water phase (square root first-order DT_{50} 0.5 day in both systems) and also quick degradations were observed from the whole systems resulting in square root first-order DT_{50} of 0.9 day (river system) and first-order DT_{50} of 6.6 days (pond system). Peak partitioning of chlormequat chloride to the sediment was measured at a maximum of 63.3% AR 30 days after the dosing (pond system). Mineralisation was significant and by the termination of the study carbon dioxide amounted to 55.6-67.0% AR. The maximum unextractable residues in the sediment accounted for 43.3-52.9% (AR) after 30 days. No major metabolites were detected; the only minor metabolite found in the sediment of the river system exceeded 5% AR at only one time point (8.3% on day 14 after the study initiation).

Predicted environmental concentrations in surface water and sediment for chlormequat chloride were calculated following the tiered approach recommended by the FOCUS working group. However, in line with the opinion of the meeting of experts, the results of these calculations were not relied on as appropriate soil adsorption/desorption data were not available at 20°C. A data gap was therefore identified for calculation of predicted environmental concentrations in surface water and sediment.

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The available calculations for the leaching potential of parent chlormequat chloride, showing there is no leaching potential, as well as the estimation of leaching potential of the non transient minor metabolite were not relied on as the meeting of experts considered that no reliable adsorption/desorption data were available (see point 4.1.3 above). A data gap was therefore identified by the experts at PRAPeR 47 meeting for new PEC_{GW} calculations.

4.3. FATE AND BEHAVIOUR IN AIR

The vapour pressure data and Henry's law constant were not reliable for chlormequat chloride. Calculations using the method of Atkinson (using the software APOWIN v.1.90) for indirect photo oxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half-life estimated at 1.45 hours (assuming an atmospheric hydroxyl radical concentration of $1.5x10^6$ radicals cm^{-3}). This half-life indicates that the proportion of chlormequat chloride which is volatilised is unlikely to be subject to long-range atmospheric transport.

5. Ecotoxicology

Chlormequat chloride was discussed at the PRAPeR experts' meeting for ecotoxicology (PRAPeR 48) in May 2008 on the basis of the information evaluated in the DAR and in the addendum of April 2008. The representative uses evaluated are as a plant growth regulator in cereals at an application rate of 1x1.5 kg a.s./ha.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The acute and short-term LD_{50} values for birds are 441 and >310 mg chlormequat chloride/kg bw. The long-term (reproductive) NOEC was 54.8 mg/kg bw/day. The acute, short-term and long-term TERs for herbivorous and insectivorous birds in the first tier risk assessment were below the Annex VI triggers of 10 and 5.

The refined risk assessment for herbivorous birds was based on measured residues on day 0. The suggested mean and 90th percentile values were questioned during the peer-review. The rapporteur Member State presented a re-evaluation of the residue trials and new mean and 90th percentile residue values of 27.9 and 51.8 mg a.s./kg in the addendum of April 2008. The new assessment was accepted by the experts. The acute, short-term and long-term TERs for herbivorous birds were above the Annex VI triggers.

The refined risk assessment for insectivorous birds was based on yellow wagtail (*Motacilla flava*) assuming that it feeds almost exclusively (proportion of different food types (PD) = 0.93) on ground dwelling insects for which a FOCUS interception factor of 70% was taken into account. However the long-term TER would still be below 5. The PD refinement was not agreed by the rapporteur Member State since the data were based on insects around dung-pats, and the size of insects taken in the cereal fields may be different from those in meadows with dung pats. The rapporteur Member State identified a data requirement for refinement of the long-term risk assessment for insectivorous birds. Further information on the choice of yellow wagtail as a focal species and the proportion of large and small insects taken up as food items was presented in the addendum of April 2008. However, it was not clear whether the risk assessment for yellow wagtail is indeed representative of a worst-case

scenario. It was questioned whether skylark (*Alauda arvensis*) and yellowhammer (*Emberiza citrinella*) would also be covered by the risk assessment for yellow wagtail. The experts agreed to a PD refinement of 0.8 small insects and 0.2 large insects in combination with standard residue per unit dose (RUD) values. The experts suggested a data gap for further refinement of the risk assessment for insectivorous birds considering all three suggested focal species.

The lowest acute endpoint for mammals was observed in a test with rabbits (LD_{50} = 115 mg a.s./kg bw). The first-tier acute and long-term TERs for herbivorous mammals were below the Annex VI trigger values of 10 and 5. The acute TER for insectivorous mammals was also below the trigger of 10 but not the long-term TER. The refinement of the residues on insects, taking into account interception, was rejected by the experts since the RUD values for insects already include interception. A data gap was identified to refine the acute risk assessment for insectivorous mammals.

A refined risk assessment for three herbivorous mammals (hare, *Lepus europaeus*; rabbit, *Oryctolagus cuniculus*; and wood mouse, *Apodemus sylvaticus*) was presented in the addendum of April 2008. The experts accepted the refinement of residues in the food. It was further suggested to use the acute endpoint derived from a study with rabbits only for lagomorph species. However the resulting refined acute TERs were still below the trigger of 10. It was considered as unlikely that the mammals would be able to consume enough food in a time-span short enough to obtain the LD_{50} before some of the active substance is metabolised. It was proposed by the applicant to refine the risk by using endpoints from dietary studies. The TERs for the dietary exposure were greater than 10. However the dietary endpoints are likely to underestimate the risk since the tested rats were not starved and therefore were not under pressure to eat as quickly as possible (as can happen under natural conditions in the field). The majority of the experts were of the opinion that the lowest observed endpoint from the mammalian studies should be used in the risk assessment (observed in studies with rabbits). The experts agreed that the refinement of the acute risk based on short-term toxicity endpoints is sufficiently robust to address the risk to medium sized herbivorous mammals but not for small herbivorous mammals. Further information is needed e.g. on the feeding pattern of small herbivorous mammals. A data gap was identified in the meeting for further refinement of the acute risk to herbivorous mammals.

The long-term endpoint for the mammal risk assessment was discussed. The experts suggested using the NOAEL of 75 mg/kg bw/d based on significant parental effects instead of the initially proposed NOAEL of 211 mg a.s./kg bw/d. It was further noted that significantly reduced pup weight was observed in the study of Hellwig (1993). The experts on toxicology confirmed that the relevant reproductive NOAEL from this study was 74 mg/kg bw/d, and based on effects on the offspring, it was 41 mg/kg bw/d. The rapporteur Member State provided a recalculation of the long-term TERs in addendum 2 from July 2008 (not peer-reviewed). The TERs were below the trigger of 5 for early applications (herbivorous mammals) based on measured residue values. Further refinement of the

long-term risk to mammals is needed. A data gap was identified for a refined long-term risk assessment for mammals.

The log P_{ow} of chlormequat chloride was less than 3 and therefore no risk assessment is triggered for secondary poisoning of fish- and earthworm-eating birds and mammals.

No major metabolites were found in plants and hence no risk assessment for the uptake of metabolites was conducted.

5.2. RISK TO AQUATIC ORGANISMS

The lowest endpoints were observed for aquatic invertebrates (48h EC_{50} = 31.7 mg a.s./L and a 21d NOEC = 2.4 mg a.s./L). The acute studies with fish (Thum, S. (1993a); Wüthrich, V. (1990a); Bogers, M. (1990)) were considered not valid by the experts since only 5 fish were tested per replicate instead of 7. The rapporteur Member State noted that 2 replicates per 5 fish (10 fish) were tested at each concentration. Therefore the studies can be considered valid and no new studies need to be generated. In addition, other sufficiently valid studies with fish were also made available.

The FOCUS step 1 calculations resulted in TERs above the trigger values of 100 and 10 for fish, algae and higher aquatic plants but not for daphnids. The trigger values were exceeded also for daphnids with FOCUS step 2 PEC_{SW} values. However there is some uncertainty with regard to the reliability of the PEC_{SW} water values since the adsorption/desorption study was conducted at temperatures which were too low (see point 4.2.1. in the section on fate and behaviour). The TERs were about 3.5 and 2.6 times above the trigger values of 100 and 10. If the new PEC_{SW} values would increase by more than 2.6 times then further refinement of the aquatic risk assessment would be needed (e.g. FOCUS step 3 or step 4 calculations). A final conclusion on the risk to aquatic organisms can be drawn once reliable PEC_{SW} values are available.

5.3. RISK TO BEES

No treatment related mortality of bees was observed in the acute oral and contact toxicity studies up to the highest tested doses of 80.2 and 65.2 µg a.s./bee. The HQ values were below the Annex VI trigger of 50 indicating a low risk to bees from the representative uses.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Standard laboratory tests were conducted with the indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri*. No significant mortality was observed in the test with *T. pyri* at an application rate of 2.2 kg a.s./ha. However 30% mortality was observed in the test with *A. rhopalosiphi* at a rate of 2.229 kg a.s./ha. The tested rates were higher than the rate of 1.5 kg a.s./ha suggested in the GAP. The rapporteur Member State used an LR_{50} of >2.2 and 2.229 kg a.s./ha to calculate HQ values. The

in-field and off-field HQ values were below the trigger of 2. Additional studies with *Aleochara bilineata*, *Poecilus cupreus* and *Chrysoperla carnea* were submitted. No significant adverse effects were observed in the tests at application rates of 1.4 kg a.s./ha (*A. bilineata*; *P. cupreus*) and 2.23 kg a.s./ha (*C. carnea*). Overall it was concluded that the risk to non-target arthropods is low for the representative uses evaluated.

5.5. RISK TO EARTHWORMS

The acute and chronic toxicity of chlormequat chloride to earthworms is low (14 d LC_{50} = 320 mg a.s./kg soil and 56 d NOEC = 681 mg a.s./kg soil). The acute and long-term TERs were well above the Annex VI trigger values of 10 and 5 indicating a low risk to earthworms for the representative uses evaluated.

5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

The field DT_{90} of chlormequat chloride is >100 but the chronic risk to earthworms was assessed as low and the effects on soil micro-organisms is <25% at concentrations exceeding the calculated maximum PEC_{soil}. The in-field risk to non-target arthropods was assessed as low (HQ values <2). Hence no further studies are required to address the risk to other soil non-target macro-organisms.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

No effects of >25% on soil respiration and nitrification were observed in tests with formulated chlormequat chloride up to concentration of 18.6 mg a.s./kg soil dw. Since no effects were observed at a concentration significantly above the calculated maximum PEC_{soil} it is concluded that the risk to soil non-target micro-organisms is low for the representative uses evaluated.

5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

Herbicidal effects of the formulation on vegetative vigour and emergence were investigated in tests with three dicotyl plant species and two monocotyl plant species. The ER_{50} values were determined as >2.1 kg a.s./ha and >3.75 kg a.s./ha for emergence and vegetative growth. The TERs were well above the trigger of 5 based on PEC values from spray drift at 1m distance. Some growth effects (stunting) were observed in carrots and sunflower at low levels of exposure. However no biologically significant adverse effects are envisaged off-crop on non-target plants.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

Formulated chlormequat chloride was tested with activated sewage sludge and in a *Pseudomonas putida* growth inhibition test. No adverse effects were observed in the growth inhibition test with *P. putida* at the highest tested concentrations of 1522 mg a.s./L and only a slight inhibitory effect (4.7%) was observed in the test with sewage sludge at a concentration of 43 mg/L. It is not expected that the concentrations of chlormequat chloride in biological sewage treatment plants would reach a

concentration of more than 43 mg a.s./L if the product is applied according to the GAP and therefore the risk to biological methods of sewage treatment is considered to be low.

6. Residue definitions

Soil

Definition for risk assessment: chlormequat chloride (provisional pending the results of the new soil metabolism study)

Definition for monitoring: sum of chlormequat and its salts expressed as chlormequat chloride (provisional pending the results of the new soil metabolism study)

Water

Ground water

Definition for exposure assessment: chlormequat chloride (provisional pending the results of the new soil metabolism study)

Definition for monitoring: sum of chlormequat and its salts expressed as chlormequat chloride (provisional pending the results of the new soil metabolism study)

Surface water

Definition for risk assessment: chlormequat chloride (provisional pending the results of the new soil metabolism study)

Definition for monitoring: sum of chlormequat and its salts expressed as chlormequat chloride (provisional pending the results of the new soil metabolism study)

Air

Definition for risk assessment: chlormequat chloride

Definitions for monitoring: sum of chlormequat and its salts expressed as chlormequat chloride

Food of plant origin

Definition for risk assessment: sum of chlormequat and its salts expressed as chlormequat chloride

Definition for monitoring: sum of chlormequat and its salts expressed as chlormequat chloride

Food of animal origin

Definition for risk assessment: sum of chlormequat and its salts expressed as chlormequat chloride

Definition for monitoring: sum of chlormequat and its salts expressed as chlormequat chloride

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

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Chlormequat chloride	Moderate persistence Single first-order DT_{50} 17.0-31.6 days (20°C, pF 2 soil moisture)	Low risk to earthworms and soil micro-organisms

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
Chlormequat chloride	Data gap - available information is non reliable.	Data gap - available information is non reliable.	Yes	Yes	Yes
Uncharacterised minor non-transient metabolite	Data gap	Data gap - available information are non reliable	No data submitted. Assessment may be required.	No data available. Assessment may be required.	No data submitted. Assessment may be required.

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Chlormequat chloride (water and sediment)	Lowest endpoints observed for Daphnia magna (acute EC_{50} = 31.7 mg a.s./L, chronic NOEC = 2.4 mg a.s./L). Aquatic risk assessment not finalised.

Air

Compound (name and/or code)	Toxicology
Chlormequat chloride	Low toxicity by inhalation (LC_{50} >5 mg/L)

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

- Clarification with respect to the very high result obtained for the relevant impurity 1,2-dichloroethane in one of the batches analysed (relevant for one source, date of submission unknown, data gap identified by experts of PRAPeR 46 meeting, May 2008; refer to chapter 1).
- Clarification concerning the batches analysed in the batch analysis and whether or not they had been blended (relevant for one source, date of submission unknown, data gap identified by experts of PRAPeR 46 meeting, May 2008; refer to chapter 1).
- Information about the purity and commercial availability of starting materials used in manufacture (relevant for two sources, date of submission unknown, data gap identified by experts of PRAPeR 46 meeting, May 2008; refer to chapter 1).
- A GLP study for the determination of the vapour pressure (relevant for all sources and all representative uses evaluated, date of submission unknown, data gap identified by experts of PRAPeR 46 meeting, May 2008; refer to chapter 1).
- A new calculation for Henry's law constant based on the GLP vapour pressure study (relevant for all representative uses evaluated, date of submission unknown, data gap identified by experts of PRAPeR 46 meeting, May 2008; refer to chapter 1).
- Further data to ensure that the method for the determination of the impurities in line 3 and 5 of table C.1.2 of the DAR volume 4 (relevant for two sources) is validated for the levels determined in the 5 batch analysis (relevant for two sources, for all representative uses evaluated, date of submission unknown, data gap identified by experts of PRAPeR 46 meeting, May 2008; refer to chapter 1).
- Re-quantification of impurity in line 4 of table C.1.2 in DAR volume 4 (relevant for three sources) in representative batches is required with a method with chromatographic performance at least equivalent to that seen during the validation of the method M91/48e (relevant for three sources, for all representative uses evaluated, date of submission unknown, data gap identified by experts of PRAPeR 46 meeting, May 2008; refer to chapter 1).
- Further data to ensure that the method for the determination of 1,2-dichlorethane is validated for the levels determined in the 5 batch analysis (relevant for three sources, for all representative uses evaluated, date of submission unknown, data gap identified by experts of PRAPeR 46 meeting, May 2008; refer to chapter 1).
- Precision data to ensure that the method for the determination of vinyl chloride is validated for the levels determined in the 5 batch analysis (relevant for all sources for all representative uses evaluated, date of submission unknown, data gap identified by experts of PRAPeR 46 meeting, May 2008; refer to chapter 1).
- Further data to ensure that the method for the determination of the impurities in line 2, 3 and 5 of table C.1.2 of the DAR volume 4 (relevant for two sources) is validated for the levels determined in the 5 batch analysis (relevant for two sources, for all representative uses

evaluated, date of submission unknown, data gap identified by experts of PRAPeR 46 meeting, May 2008; refer to chapter 1).

- Demonstration of the extraction efficiency and an independent laboratory validation of method 397/0 for the determination of residues of chlormequat chloride in animal products (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State in volume 1 level 4, and confirmed by experts of PRAPeR 46 meeting, May 2008, date of submission: the validation study has been submitted to the rapporteur Member State on 11 September 2007, however in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, the new studies could not be considered in the peer review; refer to chapter 1).
- A validated method for the determination of chlormequat chloride in tap and surface water (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State in volume 1 level 4, and confirmed by experts of PRAPeR 46 meeting, May 2008; date of submission: the validation study has been submitted to the rapporteur Member State on 11 September 2007, however in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, the new studies could not be considered in the peer review; refer to chapter 1).
- Additional trials on rye and triticale carried out in Northern Europe to achieve a complete data base of independent trials and also to confirm that extrapolation from wheat and barley to rye and triticale is justified for application of chlormequat chloride (relevant for uses on rye and triticale, identified by EFSA, data of submission unknown; refer to chapter 3.1.1).
- Complete residue trials data base for uses on wheat in Northern Europe supporting the notified GAP GS30 (relevant for use on wheat identified by EFSA, data of submission unknown; refer to chapter 3.1.1).
- Complete residue trials data base for uses on barley in Northern Europe supporting the notified GAP GS31/32 respectively (relevant for use on barley identified by EFSA, data of submission unknown; refer to chapter 3.1.1).
- Complete residue trials data base for uses on oats in Northern Europe supporting the notified GAP GS 49 respectively (relevant for use on oats identified by EFSA, data of submission unknown; refer to chapter 3.1.1).
- Complete residue trial data base to support use of wheat in Southern Europe (relevant for use on wheat, data gap identified by PRAPeR 50 meeting June 2008, data of submission unknown; refer to chapter 3.1.1).
- Complete residue trial data base to support use of barley in Southern Europe (relevant for use on barley, data gap identified by PRAPeR 50 meeting June 2008, data of submission unknown; refer to chapter 3.1.1).

- Complete residue trial data base to support use of oats in Southern Europe (relevant for uses on oats, data gap identified by PRAPeR 50 meeting June 2008, data of submission unknown; refer to chapter 3.1.1).
- Complete residue trial data base to support use of rye in Southern Europe (relevant for uses on rye, data gap identified by PRAPeR 50 meeting June 2008, data of submission unknown; refer to chapter 3.1.1).
- Metabolism study on rotational crops: clarification of the presence of considerably lower radioactive residues in the study by Hoffmann (1992) compared to the study by Veit (2003) (relevant for all notified uses, data gap identified by PRAPeR 50 meeting June 2008, data of submission unknown; refer to chapter 3.1.2).
- Identification of unknown minor non-transient soil metabolite (relevant for all uses evaluated, data gap identified by PRAPeR meeting of experts May 2008, new soil metabolism study submitted to the rapporteur Member State, not evaluated nor peer reviewed; refer to chapter 4.1.1).
- A new study on adsorption/desorption in at least four different soils at 20ºC (relevant for all uses evaluated, data gap identified by PRAPeR meeting of experts May 2008, date of submission unknown; refer to chapter 4.1.3).
- A new FOCUS PEC_{SW} and PEC_{sed} calculation with the new adsorption/desorption data (relevant for all uses evaluated, data gap identified by PRAPeR meeting of experts May 2008, date of submission unknown; refer to chapter 4.2.1).
- A new FOCUS PEC_{GW} calculation with the new adsorption/desorption data (relevant for all uses evaluated, data gap identified by PRAPeR meeting of experts May 2008, date of submission unknown; refer to chapter 4.2.2).
- An assessment of the toxicological and ecotoxicological relevance and pesticidal activity of the unknown minor non-transient soil metabolite.
- The long-term risk assessment for insectivorous birds needs further refinement regarding all three suggested focal species (relevant for all representative uses; data gap identified by the rapporteur Member State and confirmed in the meeting of experts, PRAPeR 48 in May 2008; no submission date proposed; refer to chapter 5.1.).
- The acute risk assessment for insectivorous mammals and small herbivorous mammals needs further refinement (relevant for all representative uses; data gap identified in the meeting of experts, PRAPeR 48 in May 2008; no submission date proposed; refer to chapter 5.1.).
- The long-term risk to herbivorous mammals needs further refinement (relevant for all representative uses; data gap identified in the meeting of experts, PRAPeR 48 in May 2008; no submission date proposed; refer to chapter 5.1.).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as proposed by the applicants which comprise foliar spraying with conventional spraying devices for stem stabilisation on winter and spring wheat, winter and spring barley, triticale, durum wheat, spelt wheat, rye and oats from growth stage of BBCH 30 up to growth stage of BBCH 49, in all EU countries, at a single application at a maximum application rate of 1.5 kg a.s./ha (chlormequat chloride).

The representative formulated product for the evaluation was 'Chlormequat-chloride 750 g/L', a soluble concentrate (SL) containing 750 g/l chlormequat chloride, registered in EU Member States under different trade names.

Adequate analytical methods are available to monitor all compounds given in the respective residue definitions in food/feed of plant origin, soil and air.

There are no adequate methods available to monitor chlormequat in animal products and in water.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

With regard to its toxicological properties, chlormequat was extensively absorbed, barely metabolised and rapidly excreted mainly by urine. The acute toxicity results with rats (after oral administration) and rabbits (after dermal administration) triggered the classification **Xn**, **R21/22** "**Harmful in contact with skin and if swallowed**". In repeated dose studies, the dog appeared to be the most sensitive species, showing neuropharmacological effects, with an overall NOAEL of 4 mg/kg bw/day in the 1-year study. In mutagenicity and long-term tests, chlormequat chloride was not shown to have any genotoxic or carcinogenic properties. During the reproductive toxicity testing, fertility was affected at a maternal toxic dose level, leading to an overall parental NOAEL of 75 mg/kg bw/day and a reproductive NOAEL of 74 mg/kg bw/day. However, based on reduced body weight gain and focal muscular dystrophy, the offspring NOAEL was 41 mg/kg bw/day. No variations, retardations or malformations were observed in the developmental studies with rats and rabbits, and the maternal NOAEL was 75 mg/kg bw/day in rats and 20 mg/kg bw/day in rabbits. In mechanistic studies *in vitro* for neurotoxicity, chlormequat chloride showed a weak agonistic activity on muscarinic and nicotinic receptors.

With regard to the toxicological reference values, the agreed values reported as chlormequat chloride were **0.04 mg/kg bw/day for the Acceptable Daily Intake** (ADI), **0.04 mg/kg bw/day for the**

Acceptable Operator Exposure Level (AOEL) and **0.09 mg/kg bw for the Acute Reference Dose** (ARfD) . The dermal absorption values were 4% for the concentrate and the dilution, based on an *in vivo* test. The operator exposure estimates were below the AOEL according to the German model with the use of personal protective equipment, but above the AOEL according to the UK POEM even with the use of personal protective equipment. The different exposure estimates for the worker and the bystander led to values below the AOEL.

With regard to residues, the metabolism of chlormequat chloride was investigated in wheat. The major component in grain and straw at harvest was unmetabolised chlormequat. Rotational crop data show that significant residues in succeeding and rotational crops are not expected to occur except in rotated cereals. However residues should not be higher than in cereals directly treated with chlormequat chloride according to the notified GAP. Currently, according to the conclusion of the expert meeting, only the use of chlormequat chloride on rye and triticale in Northern Europe would be supported by a sufficient number of residue trials to allow at least a provisional proposal of MRLs, while uses have been notified also for wheat, barley and oats and also for Southern Europe. It is noted that the rapporteur Member State does not agree with this conclusion. Data gaps for further residue trials for all notified uses have been identified. On the basis of processing studies processing factors have been calculated.

After evaluation of animal metabolism studies and animal transfer studies with ruminants and poultry, MRLs for animal products have been provisionally proposed pending the submission of further residue trials on primary crops and the demonstration of the validity of the analytical method used in feeding studies.

If the use of chlormequat chloride on only rye and triticale is considered in a provisional calculation, then the consumer exposure is expected to be below the toxicological reference values. However it is noted that the risk assessment does not cover the intake of barley, oats and wheat and therefore it is only indicative and the final assessment is pending submission of additional data.

The information available on the fate and behaviour in the environment is not sufficient to carry out an appropriate environmental exposure assessment for chlormequat chloride at EU level. Identification of the unknown minor non-transient soil metabolite is needed. Further investigation is needed to determine the adequate adsorption/desorption properties of chlormequat chloride at 20°C. New FOCUS calculations for PEC_{SW}, PEC_{sed} and PEC_{GW} should be conducted using the new adsorption/desorption data for the parent chlormequat chloride and eventually to address the minor non-transient soil metabolite.

The long-term risk assessment to insectivorous birds needs further refinement. The acute risk to insectivorous mammals, small herbivorous mammals and the long-term risk to herbivorous mammals

are not sufficiently addressed and need further refinement. *Daphnia magna* was the most sensitive aquatic species tested. The FOCUS step 1 calculations resulted in TERs above the trigger of 100 and 10 for fish, algae and higher aquatic plants but not for daphnids. The TERs for daphnids exceeded the Annex VI trigger values by a factor of 3.5 (acute) 2.6 (chronic) with FOCUS step 2 PEC_{SW} values. However there is some uncertainty with regard to the reliability of the PEC_{SW} water values since the adsorption/desorption study was conducted at temperatures which were too low. If the new PEC_{SW} values would be increased by more than 2.6 times then further refinement of the aquatic risk assessment would be needed (e.g. FOCUS step 3 or step 4 calculations). A final conclusion on the risk to aquatic organisms can be drawn once reliable PEC_{SW} values are available.

The risk to bees, non-target arthropods, earthworms, non-target macro- and micro-organisms, non-target plants and biological methods of sewage treatment was assessed as low for all representative uses.

Particular conditions proposed to be taken into account to manage the risk(s) identified

- Use of personal protective equipment (gloves) by the operator is needed during mixing/loading in order to have an estimated exposure below the AOEL (refer to 2.12).

Critical areas of concern

- Risk assessment for the consumer could not be finalised and agreed on because of data gaps in different parts of the residue section.
- There are no acceptable monitoring methods for the determination of chlormequat in animal products and in water.
- Assessment of the potential for groundwater contamination can not be finalised
- Long-term risk to insectivorous birds.
- Acute risk to insectivorous and small herbivorous mammals and long-term risk to herbivorous mammals.
- Reliable PEC_{SW} values need to be established to finalise the aquatic risk assessment.

Appendix 1 –List of endpoints

APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

(Abbreviations used in this list are explained in appendix 2)

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

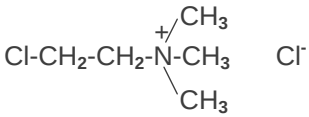
Active substance (ISO Common Name) ‡	Chlormequat (unless otherwise stated, the following data refer to the variant chlormequat chloride)
Function (*e.g.* fungicide)	Growth regulator
Rapporteur Member State	UK

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	2-chloroethyltrimethylammonium (chlormequat) 2-chloroethyltrimethylammonium chloride (chlormequat chloride)
Chemical name (CA) ‡	2-chloro-*N*,*N*,*N*-trimethylethanaminium chloride
CIPAC No ‡	143 (chlormequat) 143.302 (chlormequat chloride)
CAS No ‡	7003-89-6 (chlormequat) 999-81-5 (chlormequat chloride)
EC No (EINECS or ELINCS) ‡	213-666-4
FAO Specification (including year of publication) ‡	143.302/TK (August 2005) Purity 725-775 g/l (636-680 g/kg) 1,2-dichloroethane content: maximum 0.1 g/kg of the dry chlormequat chloride content
Minimum purity of the active substance as manufactured ‡	Open
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	1,2-dichloroethane, max. 0.1 g/kg of the dry chlormequat chloride content chloroethene: max 0.0004 g/l
Molecular formula ‡	$C_5H_{13}Cl_2$ N
Molecular mass ‡	158.1 g/mol

Appendix 1 –List of endpoints

Structural formula ‡



Appendix 1 –List of endpoints

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	225 °C (96.6%) 236 °C (99.5%)
Boiling point (state purity) ‡	Not determined as material decomposes immediately after melting.
Temperature of decomposition (state purity)	240 °C (99.5%)
Appearance (state purity) ‡	White crystalline solid (96.6%) Colourless crystalline solid (99.5%) Light yellow liquid (755 g/l TK)
Vapour pressure (state temperature, state purity) ‡	Open
Henry's law constant ‡	Open
Solubility in water (state temperature, state purity and pH) ‡	> 886 g/l at room temperature and unspecified pH (97.2%)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20°C in g/L (99.9%) Acetone: 0.13 g/l Acetonitrile: 3.0 g/l Dichloromethane: 0.07 g/l Ethylacetate: <0.01 g/l n-Heptane: <0.01 g/l 1-Octanol: 9.7 g/l Toluene: <0.01 g/l Methanol: 365 g/l
Surface tension ‡ (state concentration and temperature, state purity)	72.3 mN/m at 20.6 °C (90 % saturated solution)(97.2%) 72.0 mN/m at 20.7 °C (90 % saturated solution)(68.1% TK)
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{O/W}$ = -3.08 at 20 °C (pH 4) (99.5%) -3.47 at 20 °C (pH 7) (99.5%) -3.07 at 20 °C (pH 10) (99.5%)

Appendix 1 –List of endpoints

Dissociation constant (state purity) ‡	Chlormequat chloride completely dissociates in aqueous solution and therefore has no dissociation constant.
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	No significant absorption from 200 to 750 nm
Flammability ‡ (state purity)	Not classified as highly flammable (case)
Explosive properties ‡ (state purity)	Not classified as explosive (case)
Oxidising properties ‡ (state purity)	Not classified as oxidising (case)

Appendix 1 –List of endpoints

Summary of representative uses evaluated (chlormequat 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			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 (l)		
Winter Wheat (TRZAW)	see footnote 1)	Chlormequat chloride 750 g/L	F	plant growth regulator	SL	750 g/L	spraying	32[2)]	1	n.a.	0.33-1.0	150 – 450	1.5	see footnote 3	[1] [2]
Spring Wheat (TRZAS)	see footnote 1)	Chlormequat chloride 750 g/L	F	plant growth regulator	SL	750 g/L	spraying	31[2)]	1	n.a.	0.33-1.0	150 – 450	1.5	see footnote 3	[1] [2]
Triticale (TTLXX)	see footnote 1)	Chlormequat chloride 750 g/L	F	plant growth regulator	SL	750 g/L	spraying	37	1	n.a.	0.33-1.0	150 – 450	1.5	see footnote 3	[1] [3]
Durum Wheat (TRZDU)	see footnote 1)	Chlormequat chloride 750 g/L	F	plant growth regulator	SL	750 g/L	spraying	31	1	n.a.	0.33-1.0	150 – 450	1.5	see footnote 3	[1] [2]
Spelt Wheat (TRZSP)	see footnote 1)	Chlormequat chloride 750 g/L	F	plant growth regulator	SL	750 g/L	spraying	32	1	n.a.	.33-1.0	150 – 450	1.5	see footnote 3	[1] [2]
Rye (SECCE)	see footnote 1)	Chlormequat chloride 750 g/L	F	plant growth regulator	SL	750 g/L	spraying	37[2)]	1	n.a.	0.33-1.0	150 – 450	1.5	see footnote 3	[1] [3]
Oats (AVESA)	see footnote 1)	Chlormequat chloride 750 g/L	F	plant growth regulator	SL	750 g/L	spraying	49	1	n.a.	0.33-1.0	150 – 450	1.5	see footnote 3	[1] [2]
Winter Barley (HORVW)	see footnote 1)	Chlormequat chloride 750 g/L	F	plant growth regulator	SL	750 g/L	spraying	30[2)]	1	n.a.	0.33-1.0	150 – 450	1.5	see footnote 3	[1] [2]

Appendix 1 –List of endpoints

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			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 (l)		
Spring Barley (HORVS)	see footnote 1)	Chlormequat chloride 750 g/L	F	plant growth regulator	SL	750 g/L	spraying	30[2)]	1	n.a.	0.33-1.0	150 – 450	1.5	see footnote 3	[1] [2]
Winter Wheat (TRZAW)	France (North and South)	Chlormequat chloride 750 g/L	F	plant growth regulator	SL	750 g/L	spraying	32[2)]	1	n.a.	0.22 – 0.67	150 – 450	1.0	see footnote 3	[1] [2]
Spring Wheat (TRZAS)	France (North and South)	Chlormequat chloride 750 g/L	F	plant growth regulator	SL	750 g/L	spraying	31[2)]	1	n.a.	0.22 – 0.67	150 – 450	1.0	see footnote 3	[1] [2]
Durum Wheat (TRZDU)	France (North and South)	Chlormequat chloride 750 g/L	F	plant growth regulator	SL	750 g/L	spraying	31	1	n.a.	0.33-1.0	150 – 450	1.5	see footnote 3	[1] [2]
Rye (SECCE)	France (North and South)	Chlormequat chloride 750 g/L	F	plant growth regulator	SL	750 g/L	spraying	37[2)]	1	n.a.	0.27 – 0.80	150 – 450	1.2	see footnote 3	[1] [3]
Oats (AVESA)	France (North and South)	Chlormequat chloride 750 g/L	F	plant growth regulator	SL	750 g/L	spraying	49	1	n.a.	0.31 – 0.93	150 – 450	1.4	see footnote 3	[1] [2]

[1] Data gaps were identified in section 5 (ecotoxicology)
[2] Data gaps were identified in section 3 (residues)
[3] MRLs only provisionally proposed and the risk assessment provisionally carried out due to data gaps identified in section 3 (residues)

SL soluble concentrate
n.a. not applicable
1) Austria, Belgium, Denmark, Finland, Germany, Ireland, Luxembourg, The Netherlands, Sweden, United Kingdom, Poland, Czech Republic, Hungary, Slovenia, Slovakia, Estonia, Lituania and Latvia
2) co-formulations of Chlormequat chloride with other a.i.'s, where Chlormequat chloride is applied at reduced rates, are to be applied up to GS 49
3) fixed by approved use

Appendix 1 –List of endpoints

(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)	(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).**
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)	(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
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds	(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(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
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989	(m) PHI - minimum pre-harvest interval
(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	

Appendix 1 –List of endpoints

Methods of Analysis

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

Technical as (analytical technique)	CIPAC method 143/TK/M2-
Impurities in technical as (analytical technique)	IC, GC-FID
Plant protection product (analytical technique)	CIPAC method 143/SL/M2-

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Sum of chlormequat and its salts expressed as chlormequat chloride
Food of animal origin		Sum of chlormequat and its salts expressed as chlormequat chloride
Soil		Sum of chlormequat and its salts expressed as chlormequat chloride
Water	surface	Sum of chlormequat and its salts expressed as chlormequat chloride
	drinking/ground	Sum of chlormequat and its salts expressed as chlormequat chloride
Air		Sum of chlormequat and its salts expressed as chlormequat chloride

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Extraction into acidic aqueous methanol, clean up on an alumina column and analysis by LC-MS/MS monitoring for ion transitions 122 → 63 and 122 → 58. residues quantified using fragment ion m/z 58. LOQ 0.05 mg/kg in wet, oily and acidic crops, 0.50 mg/kg in dry crops.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Data requirement

Appendix 1 –List of endpoints

Soil (analytical technique and LOQ)	Extraction into sodium tetraphenyl borate and dichloromethane then back extraction in to hydrochloric acid and cleaned up on an alumina column. Residues determined by ion chromatography with suppressed conductivity detection. LOQ 0.01 mg/kg.
Water (analytical technique and LOQ)	None of the submitted methods are acceptable for use as monitoring methods; Method 370 is not reproducible, Method DrK086 is not specific and Method DrK119 uses hazardous reagents. Data requirement
Air (analytical technique and LOQ)	Extraction of adsorbed chlormequat chloride with water followed by concentration of the extracts and analysis by ion chromatography with suppressed conductivity detection. LOQ 0.0014 mg/m^3
Body fluids and tissues (analytical technique and LOQ)	No method required

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

	RMS/peer review proposal
Active substance	Not classified

Appendix 1 –List of endpoints

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapid (C_{max} 2 hours) and almost complete (>80% within 48h based on urinary excretion)
Distribution ‡	Widely distributed. Highest amounts in the excretory organs (gastro-intestinal tract, liver and kidneys).
Potential for accumulation ‡	No evidence for accumulation in any compartment.
Rate and extent of excretion ‡	Excretion rapid and >90% via urine. Elimination in faeces and bile <5%.
Metabolism in animals ‡	Barely metabolised, excreted essentially unchanged (> 90% as parent, up to 3% as choline chloride).
Toxicologically relevant compounds ‡ (animals and plants)	Parent compound.
Toxicologically relevant compounds ‡ (environment)	Parent compound.

Acute toxicity (Annex IIA, point 5.2)

Rabbit LD_{50} oral ‡	115 mg/kg bw	
Rat LD_{50} oral ‡	520 mg/kg bw	R22
Mouse LD_{50} oral ‡	544 mg/kg bw	
Rabbit LD_{50} dermal ‡	964 mg/kg bw	R21
Rat LD_{50} dermal ‡	> 4000 mg/kg bw	
Rat LC_{50} inhalation ‡	>5.2 mg/l (4h, aerosol, head/nose exposure)	
Skin irritation ‡	Not irritant	
Eye irritation ‡	Not irritant	
Skin sensitisation ‡	Not sensitising (M&K, Buehler)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Neurological effects (salivation and diarrhoea) in dogs. Reduced bw in mice and rats.

Appendix 1 –List of endpoints

Relevant oral NOAEL ‡	4 mg/kg bw/day (dog, 12-month) 150 mg/kg bw/day (rat, 90-day) 1070 mg/kg bw/day (mouse, 90-day)
Relevant dermal NOAEL ‡	>150 mg/kg bw/day (rabbit, 21-day, 15 exposures)
Relevant inhalation NOAEL ‡	No data, 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 bw gain	
Relevant NOAEL ‡	14 mg/kg bw/day (rat, 24-month) 336 mg/kg bw/day (mouse, 110-week)	
Carcinogenicity ‡	No carcinogenic potential	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parent: clinical signs and reduced bwg Fertility: reduced conceptions per mating and mean pups per litter Offspring: reduced body weight and muscular dystrophy	
Relevant parental NOAEL ‡	75mg/kg bw/day	
Relevant reproductive NOAEL ‡	74 mg/kg bw/day	
Relevant offspring NOAEL ‡	41mg/kg bw/day	

Developmental toxicity

Developmental target / critical effect ‡	No indications of an embryotoxic, fetotoxic or teratogenic effect. Maternal clinical signs and bw loss.	
Relevant maternal NOAEL ‡	20 mg/kg bw/day (rabbit) 75 mg/kg bw/day (rat)	
Relevant developmental NOAEL ‡	20 mg/kg bw/day (rabbit) 225 mg/kg bw/day (rat)	

Appendix 1 –List of endpoints

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No specific standard guideline compliant neurotoxicity studies with chlormequat chloride have been performed. See mechanistic studies below.	
Repeated neurotoxicity ‡		
Delayed neurotoxicity ‡	Does not produce delayed neurotoxicity	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	In mechanistic studies *in vitro*, chlormequat chloride showed weak agonist activity on muscarinic receptors (ca. 10^5 times lower potency than atropine), and was at least a partial agonist of the nicotinic acetylcholine receptor (ca. 100 times lower potency than acetylcholine).
Studies performed on metabolites or impurities ‡	None

Medical data ‡ (Annex IIA, point 5.9)

During medical surveillance programme of plant manufacturing personnel there a few cases of reported poisoning (oral and inhalation exposure). Signs amongst others were nausea, emesis, diarrhoea, salivation, seizures, cardiac dysrhythmia, coma. After dermal exposure, irritative or allergic skin reactions have been described in a few cases.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡ (expressed as chlormequat chloride)	0.04 mg/kg bw/d	1-year dog	100
AOEL ‡ (expressed as chlormequat chloride)	0.04 mg/kg bw/d	1-year dog	100
ARfD ‡ (expressed as chlormequat chloride)	0.09 mg/kg bw	4-week dog	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (BAS 062 03 W)	4 % for both the water-based formulation concentrate and for the field spray dilution.

Appendix 1 –List of endpoints

Exposure scenarios (Annex IIIA, point 7.2)

Operator (% AOEL)	Model	No PPE	PPE[1]	PPE[2]	PPE[3]
	German BBA	192	90	74	-
	UK POEM	1343	749	-	164
	PPE[1] : gloves during mixing and loading PPE[2] : gloves during mixing/loading and application PPE[3] : gloves during mixing/loading and when handling contaminated surfaces				
Workers	Exposure estimate during crop inspection is 52% of the AOEL (Hoernicke, 1998) With revised values of dislodgeable foliar residue and transfer coefficient: 75% of the AOEL (EUROPOEM data, 2002)				
Bystanders	Exposure estimate is 4% of the AOEL (Lloyd and Bell, 1983).				

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

	RMS/peer review proposal
Substance classified (chlormequat chloride)	Chlormequat chloride should be classified as Harmful, and labelled **Xn, R21/22** : Harmful in contact with skin and if swallowed.

Appendix 1 –List of endpoints

Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Cereals (Wheat)
Rotational crops	Leafy crop (lettuce), root crop (radish), cereals (wheat)
Plant residue definition for monitoring	Sum of Chlormequat and its salts expressed as Chlormequat chloride.
Plant residue definition for risk assessment	Sum of Chlormequat and its salts expressed as Chlormequat chloride.
Conversion factor (monitoring to risk assessment)	-

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Ruminant (goat); poultry (hens)
Animal residue definition for monitoring	Sum of Chlormequat and its salts expressed as Chlormequat chloride.
Animal residue definition for risk assessment	Sum of Chlormequat and its salts expressed as Chlormequat chloride.
Conversion factor (monitoring to risk assessment)	-
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Two confined rotational crop studies were submitted (Veit, 2003 and Hoffman, 1992). **Study Hoffmann, 1992 shows considerably lower radioactive residues compared to study Veit, 2003. The notifier has been asked for clarification.** It is not expected that parts of rotational crops used for human consumption contain residues above the LOQ of the analytical method for monitoring (0.05 mg/kg in wet, oily and acidic crops, 0.5 mg/kg in dry crops).

Appendix 1 –List of endpoints

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

Storage stability studies indicated that residues were stable in frozen samples of wheat and barley (grain and straw) for periods up to 24 months, processed products (bran, wholegrain bread, malt and beer) for periods up to 13 months and animal products (milk, meat and eggs) for periods up to 12 months.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3) *

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant:** Yes Dairy: 8.0 (DM) Beef: 19.2 (DM) Sheep: 18.8 (DM)	Poultry:** Yes Chicken: 1.3 (DM)	Pig:** Yes 1.6 (DM)
Muscle	mean = 0.05 mg/kg (max. =- 0.11 mg/kg, (1.8N based on beef cattle intake)	<0.05 mg/kg (4.5 N rate)	-
Liver	mean = 0.08 mg/kg, (max. = 0.09 mg/kg) (1.8N based on beef cattle intake)	0.05 mg/kg (4.5 N rate)	-
Kidney	mean = 0.40 mg/kg (max. = 0.46 mg/kg) (1.8N based on beef cattle intake)	-	-
Fat	mean = <0.05 mg/kg (max. = 0.05 mg/kg) (1.8N based on beef cattle intake)	<0.05 mg/kg (4.5 N rate)	-
Milk	Steady state: mean 0.03 mg/kg (max. = 0.08 mg/kg) (1.5N rate based on dairy cattle intake)	-	-
Eggs	-	All <0.05 mg/kg (4.5 N rate)	-

* Results of feeding studies can only be regarded as valid, if the validity of the analytical method used is proved. Data gap identified.

** Intake calculations are only provisional. Pending availability of additional residue trials.

Appendix 1 –List of endpoints

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Not peer reviewed. For further information see conclusion.

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (mg/kg) (a)	Recommendation/comments	MRL (mg/kg)	STMR (b)
Wheat			**Evaluation for use in Northern Europe not peer reviewed. For further information see conclusion.** **Data gap for uses in Southern Europe.**		
Triticale					
Rye					
Barley					
Oats					

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP
(c) Proposed provisionally

Appendix 1 –List of endpoints

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

The risk assessment was not peer reviewed. For further information see conclusion.

ADI	
TMDI (European Diet) (% ADI)	
NEDI (% ADI)	
Factors included in NEDI	
ARfD	
Acute exposure (% ARfD)	

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Residues transfer of chlormequat chloride in wheat/rye over processing	4 (wheat)	Bran: 3.1 Flour type 550: 0.3 Wholemeal flour: 1.0 Wholegrain bread: 0.5	
Residues transfer of chlormequat chloride in barley over processing	4 (barley)	Pot barley: 0.9 Malt: 0.9 Beer: 0.2	
Residues transfer of chlormequat chloride in oats over processing	4 (oats)	Oat flakes: 0.9	

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies

Appendix 1 –List of endpoints

Proposed MRLs* (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Wheat Triticale Rye Barley Oats	**Evaluation for use in Northern Europe not peer reviewed. For further information see conclusion.** **Data gap for uses in Southern Europe.**
Kidney	0.3
Liver	0.1
Meat	0.05**
Eggs	0.05**
Milk	0.10

* Provisionally proposed: Pending submission of additional residue trials and prove of the validity of the feeding studies.

** LOQ: Pending conformation of the LOQ by demonstration of the extraction efficiency of the method of analysis used for the feeding studies.

Appendix 1 –List of endpoints

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

Mineralization after 100 days ‡	28.3 – 61.1% after 112 d, ([chloroethyl-U-^{14}C] labelled)-radiochemical (n= 4)
Non-extractable residues after 100 days ‡	19.0 – 27.8% after 112 d, ([chloroethyl-U-^{14}C] labelled)-radiochemical (n = 4)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	A single unidentified metabolite occurring at >5% AR at two consecutive time points (5.4% at 56 d and 7.2% at 84 d).

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

Anaerobic degradation ‡	
Mineralization after 100 days	No study submitted and none considered necessary regarding the representative uses at EU level.
Non-extractable residues after 100 days	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No study submitted and none considered necessary regarding the representative uses at EU level.

Appendix 1 –List of endpoints

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	X[7]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Loamy sand		5.8	20 / 40	31.6/ 105.1[1]	31.6	0.991	SFO
Silt loam		7.4	20 / 40	30.6 / 101.8	19.8	0.949	SFO
Loamy sand		7.5	20 / 40	33.9 / 112.5	24.4	0.992	SFO
Silt loam		7.7	20 / 40	26.8 / 88.9	17.0	0.990	SFO
Geometric mean/median							

[1]: calculated based on data over 0 to 112 d only.

Laboratory studies ‡

No studies submitted or considered nesseccary by the rapporteur.

Parent	Anaerobic conditions						
Soil type	X[8]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Geometric mean/median							

Field studies ‡

No study submitted because the DT_{50} for degradation in laboratory soil degradation studies is <60 days.

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

Appendix 1 –List of endpoints

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n

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

Column leaching ‡	No column leaching study was submitted because there is sufficient data on the adsorption of Chlormequat chloride to soil available.
Aged residues leaching ‡	Aged for (d): 15 d Time period (d): 15 d Elution (ml): 393 ml
	Analysis of soil residues post ageing (soil residues pre-leaching): 48% soil extractable residue; 20% bound residue; <10% unidentified metabolite; 33% mineralized to $^{14}CO_2$
	Leachate: 0.29-0.49% of AR for a loamy sand in leachate.
Lysimeter/ field leaching studies ‡	No study submitted or considered necessary by the rapporteur.

Appendix 1 –List of endpoints

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 31.6 days Kinetics: single first order Longest laboratory DT_{50} corrected to 20°C and field capacity.
Application data	Crop: spring cereals Depth of soil layer: 5 cm % plant interception: 70% interception Number of applications: 1 Application rate(s): 1500 g as/ha

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average
Initial		0.600[1]	
Short term	24h	0.587	0.593
	2d	0.574	0.587
	4d	0.550	0.574
Long term	7d	0.515	0.556
	28d	0.325	0.448
	50d	0.200	0.364
	100d	0.067	0.243
Plateau concentration		n.a.	

[1]: For the proposed applications from BBCH 31 a crop interception value of 70% is applicable. In the risk assessment to soil organism 50% crop interception value was used as worst case. This would equate to a maximum initial PECsoil of 1.0 mg/kg

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4, 7 and 9; 5 days at 50 °C. <3% degradation after 5 days therefore compound is considered to be hydrolytically stable under the test conditions.
Photolytic degradation of active substance and metabolites above 10 % ‡	Laboratory study using artificial light at 20°C. DT_{50} : 4845 hours
Quantum yield of direct phototransformation in water at Σ > 290 nm	$4.74*10^{-7}$ mol · Einstein $^{-1}$

Appendix 1 –List of endpoints

Readily biodegradable ‡ (yes/no)	Yes

Degradation in water / sediment

Chlormequat chloride	Distribution in river system, max. in aqueous phase 105.5% at day 0, max. in sediment phase 62.2% at day 7. Distribution in pond system, max. in aqueous phase 107.1% at day 0, max. in sediment phase 63.3% at day 30.								
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	Method of calculation
RIVER	8.47	7.27	20	0.9 / 10.4	0.98	0.5 / 5.4	0.94	n.d.	First order SQRT
POND	7.97	6.89	20	6.6 / 21.9	0.98	0.5 / 5.3	0.91	n.d.	First order SQRT (water) / first order (whole system)
Arithmetic mean				3.75 / 16.2		0.5 / 5.35		n.d.	

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed[1]	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)
RIVER	8.47	7.27	67.0 (105 d)	43.3 (30 d)	26.9 (105 d)
POND	7.97	6.89	55.6 (105 d)	52.9 (30 d)	30.0 (105 d)

[1]PH in KCl
n.d. not determined

Appendix 1 –List of endpoints

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

Chlormequat chloride Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 158.1 Water solubility (mg/L): 500000 Kfoc (L/kg): DT50 soil (d): 31.60 days (Maximum lab determined, In accordance with FOCUS SFO) DT50 water/sediment system (d): 6.60 days (representative worst case from sediment water studies) DT50 water (d): 6.60 days DT50 sediment (d): 6.60 days Crop interception (%): 50 (intermediate)
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: Vapour pressure: Kom/Koc: 1/n: (Freundlich exponent general or for soil, susp. solids or sediment respectively)
Application rate	Crop: winter and spring cereals Crop interception: 50% Number of applications: 1 Application rate(s): 1500.00 g as/ha Depth of water body: 30 cm Application window: March-May
Main routes of entry	2.75% drift from 1.00 metres 10% drift (at FOCUS Step 1) 4.00% runoff/drainage (at FOCUSsw Step 2)

FOCUS STEP 1	Maximum PECsw (µg/l)	Maximum PECsed (µg/kg)
Spring cereals		

Appendix 1 –List of endpoints

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern Southern EU Winter and Spring cereals	0 h		---		---
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				
	21 d				
	28 d				
	42 d				

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUS gw scenarios, according to FOCUS guidance. Model(s) used: FOCUS-PEARL Scenarios (list of names): All nine FOCUS scenarios Crop: winter and spring cereals Interception: 50% as a worst case. For applications from BBCH 31 a crop interception factor of 70% could have been selected. Longest parent DT_{50lab} 31.60 d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.2). K_{fom}:
Application rate	Application rate: 1500.00 g/ha. No. of applications: 1 Time of application (month or season): 1st May

Appendix 1 –List of endpoints

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	Parent (µg/L)
PEARL spring and winter cereals	Chateaudun	
	Hamburg	
	Jokioinen	
	Kremsmunster	
	Okehampton	
	Piacenza	
	Porto	
	Sevilla	
	Thiva	

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
Photochemical oxidative degradation in air ‡	DT_{50} value of 1.45 days, assuming 12 hours of light per day, derived by the Atkinson method of calculation
Volatilisation ‡	No data submitted, none required
Metabolites	None determined

PEC (air)

Method of calculation	Not applicable

$PEC_{(a)}$

Maximum concentration	No data submitted

Appendix 1 –List of endpoints

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: chlormequat chloride (provisional pending on the results of the new soil metabolism study) Surface water: chlormequat chloride (provisional pending on the results of the new soil metabolism study) Ground water: chlormequat chloride (provisional pending on the results of the new soil metabolism study) Air: chlormequat chloride

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

Readily biodegradable

Appendix 1 –List of endpoints

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

Species	Test substance	Time scale	Endpoint (mg/kg bw/day)	Endpoint (mg/kg feed)
Birds				
Japanese Quail *Coturnix coturnix japonica*	chlormequat chloride	Acute	441	
Japanese Quail *Coturnix coturnix japonica*	chlormequat chloride	Short-term	>310	>5000
Japanese Quail *Coturnix coturnix japonica*	chlormequat chloride	Long-term	54.8	400
Mammals				
Rabbit	chlormequat chloride	Acute	115	
Rat multigeneration study	chlormequat chloride	Long-term	74 (reproduction) 41 (offspring)	

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

Cereals (early and late) at 1.5 kg a.s./ha

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Large herbivorous bird	Acute	93.72	4.71	10
Insectivorous bird	Acute	81.12	5.44	10
Large herbivorous bird	Short-term	50.16	6.18	10
Insectivorous bird	Short-term	45.24	6.85	10
Large herbivorous bird	Long-term	26.58	2.06	5
Insectivorous bird	Long-term	45.24	1.21	5

Appendix 1 –List of endpoints

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Higher tier refinement (Birds) [1]				
Large herbivorous bird	Acute	34.16	12.91	10
Yellow Wagtail	Acute	24.01	18.37	10
Large herbivorous bird	Short-term	18.40	>16.85	10
Yellow Wagtail	Short-term	13.07	23.72	10
Large herbivorous bird	Long-term	9.75	5.62	5
Yellow Wagtail	Long-term	13.07	4.19	5
Tier 1 (Mammals)				
Small herbivorous mammal	Acute	296.1	0.39	10
Insectivorous mammal	Acute	13.23	8.69	10
Small herbivorous mammal	Long-term	83.98	0.88	5
Insectivorous mammal	Long-term	4.82	15.4	5
Higher tier refinement (Mammals)[2]				
Wood mouse	Acute	73.82	6.10	10
Brown Hare	Acute	15.84	7.26	10
Rabbit	Acute	20.03	5.74	10
Small herbivorous mammal	Long-term	20.54	2.00	5

[1] Herbivorous bird refined using residue values. Insectivorous bird refined using the proportion ground and foliar dwelling insects in the diet of the Yellow Wagtail (acute) and the proportion of large and small insects in the diet of the Yellow Wagtail (short and long term).
[2] Herbivorous mammal refined using residue values. Acute further refined by considering wood mouse, brown hare and rabbit separately using the most appropriate toxicity value (rabbit or rat). Insectivorous mammal refined by considering crop interception reducing the residue on ground dwelling insects.

Appendix 1 –List of endpoints

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)	Endpoint	Toxicity[1] (mg a.s./L)
Laboratory tests				
Fish				
Oncorhynchus mykiss	chlormequat chloride	96 hr (flow-through)	Mortality, LC_{50}	>100 ($_{nom}$)
Oncorhynchus mykiss	chlormequat chloride	21 d (semi-static)	Growth NOEC	43.1 ($_{nom}$)
Aquatic invertebrate				
Daphnia magna	chlormequat chloride	48 h (static)	Mortality, EC_{50}	31.7 ($_{nom}$)
Daphnia magna	chlormequat chloride	21 d (semi-static)	Reproduction, NOEC	2.4 ($_{nom}$)
Sediment dwelling organisms: No studies submitted.				
Algae				
Pseudokirchneriella subcapitata	chlormequat chloride	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>100 ($_{nom}$) >100 ($_{nom}$)
Higher plant				
Lemna gibba	chlormequat chloride	7 d (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	5.3 ($_{nom}$) 28.0 ($_{nom}$)
Microcosm or mesocosm tests: No studies submitted.				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations endpoints are presented as units of a.s.

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

FOCUS Step1

Crop and application rate
No fully reliable PECsw values were available and therefore not reported.

Bioconcentration	
	chlormequat chloride
$logP_{O/W}$	-3.39

[1] log $P_{O/W}$ <3 for the active so no assessment is required.

Appendix 1 –List of endpoints

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

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
chlormequat chloride	>80.2	>65.2
Field or semi-field tests: No study submitted.		

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

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
chlormequat chloride	Contact	<23.0	50
chlormequat chloride	oral	<18.7	50

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	Endpoint	Effect (LR_{50} g a.s./ha^{1})
Typhlodromus pyri	chlormequat chloride	Mortality	>2250
Aphidius rhopalosiphi	chlormequat chloride	Mortality	>2200

Crop and application rate

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field (drift at 1 m)	Trigger
chlormequat chloride	*Typhlodromus pyri*	>2200	<0.683	<0.018	2
chlormequat chloride	*Aphidius rhopalosiphi*	>2229	<0.673	<0.019	2

Appendix 1 –List of endpoints

Further laboratory and extended laboratory studies

Species	Life stage	Test substance, substrate and duration	Dose (g a.s./ha)	Endpoint	% effect (-ve values show effects)	Trigger value
Poecilus cupreus (carabid beetle)	Adults	'STE 24371 W' (chlormequat chloride 720 g/l) Silica sand 14 day	1512	Mortality Behaviour Feeding	0 % None -40 %	50 %
Poecilus cupreus (carabid beetle)	Adults	'Stabilan' (chlormequat chloride 465 g/l) Quartz sand 14 day	1395	Mortality Feeding	0 % -1.3 %	50 %
Poecilus cupreus (carabid beetle)	Adults	'Stabilan' (chlormequat chloride 465 g/l) Quartz sand 14 day	1395	Mortality Feeding	0 % -15 %	50 %
Rove beetle (*Aleochara bilineata*)	Adults	'Stabilan' (chlormequat chloride 465 g/l) Sand 5 day survival 10 day hatching	1395	Mortality Reproduction	0 % No significant difference	50 %
Rove beetle (*Aleochara bilineata*)	Young beetles	'Stabilan' (chlormequat chloride 465 g/l) Moist sand 55 days	1395	'parasitic capacity'	+4.3 %	50 %
Rove beetle (*Aleochara bilineata*)	Adults	'Stabilan' (chlormequat chloride 465 g/l) Moist quartz sand 4 weeks	1395	Parasitisation	+26 %	50 %

Appendix 1 –List of endpoints

Species	Life stage	Test substance, substrate and duration	Dose (g a.s./ha)	Endpoint	% effect (-ve values show effects)	Trigger value
Green Lacewing (*Chrysoperia carnea*)	Larvae 2-3 days old	'BAS 062 03 W' (chlormequat chloride 765.8 g/l) Glass plates 4-5 days after pupation 7 day hatching	2297.4	Mortality Reproduction	Slight reduction No effects	50 %

Field or semi-field tests
Not required as HQ below the trigger value for in field and off field for both *Typhlodromus pyri* and *Aphidius rhopalosiphi*

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	Endpoint
Earthworms			
Eisenia fetida	chlormequat chloride	Acute 14 days	LC_{50} 320 mg a.s./kg d.w.soil (240,000 g a.s/ha)
Eisenia fetida	chlormequat chloride	Chronic 8 weeks	NOEC 681 mg a.s./kg d.w.soil (510,750 g a.s/ha)
Other soil macro-organisms: Not required as DT90 is 105.1 days and NTA HQ, earthworm TER and effect on soil micro-organisms all below triggers.			
Soil micro-organisms			
Nitrogen mineralisation	chlormequat chloride	28 days	No effect at day 28 at 18.6 mg a.s./kg d.w.soil (mg a.s/ha)
Carbon mineralisation	chlormequat chloride	28 days	No effect at day 28 at 18.6 mg a.s./kg d.w.soil (mg a.s/ha)
Field studies			
Not required as first tier trigger values are not exceeded.			

Appendix 1 –List of endpoints

Toxicity/exposure ratios for soil organisms

Crop and application rate

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia fetida	chlormequat chloride	Acute	1.00	320	10
Eisenia fetida	chlormequat chloride	Chronic	1.00	681	5
Other soil macro-organisms: No data submitted					

[1] Maximum initial PEC

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

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (ga.s./ha) vegetative vigour	ER_{50} (g a.s./ha) emergence	Exposure[1] (g/ha)	TER	Trigger
carrot and sunflower (4 other species also tested)	chlormequat chloride	>3750		41.55	90.3	5
oat (*Avena sativa*), onion (*Allium cepa*), sugar beet (*Beta vulgaris*), rape (*Brassica napus*), carrot (*Daucus carota*) and soybean (*Glycine max*))	chlormequat chloride	>2100	>2100	41.55	50.5	5

[1] Exposure based on Ganzelmeier drift data – 2.77% drift at 1m with an application rate of 1.5 g a.s./ha

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

No data submitted.

Appendix 1 –List of endpoints

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

Test type/organism	Endpoint
Activated sludge	IC50 > 43 mg a.s. /l
Pseudomonas sp	NOEC = 1522 mg a.s./l.

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

Compartment	
soil	Parent (chlormequat chloride), Metabolite 1 (Unknown 1)
water	Parent (chlormequat chloride)
sediment	
groundwater	Parent (chlormequat chloride)

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	No environmental labelling required.

	RMS/peer review proposal
Preparation	No environmental labelling required.

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
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
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre

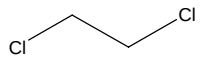
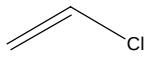
Appendix 2 – abbreviations used in the list of endpoints

LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_{soil}	predicted environmental concentration in soil
PEC_{sed}	predicted environmental concentration in sediment
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation

Appendix 2 – abbreviations used in the list of endpoints

WG	water dispersible granule
yr	year

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
1,2-dichloroethane	1,2-dichloroethane	
vinyl chloride	chloroethene	
betain	(trimethylammonio)acetate