

## STATEMENT OF EFSA

### Risks for public health due to the presence of chlormequat in table grapes from India<sup>1</sup>

European Food Safety Authority<sup>2, 3</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

On 21 April 2010 EFSA received an urgent request from the European Commission to provide a statement on the risks to public health related to the presence of chlormequat residues in table grapes originating from India which may be exceeding the current legal limit established at European level. The European Commission asked EFSA to calculate the threshold residue concentration that will not cause an exceedance of the toxicological threshold for acute exposure (Acute Reference Dose, ARfD) for any of the European Consumer groups in the EFSA PRIMo.

Chlormequat is an active substance used as plant growth regulator in plant protection products. Chlormequat was included in Annex I of Directive 91/414/EEC with the restriction to be used only on cereals and non-edible crops. The MRL for table grapes is therefore set at the limit of quantification (0.05 mg/kg).

In the peer review under Directive 91/414/EEC the toxicological profile of chlormequat chloride, the salt used in pesticide formulations, was investigated. The data were sufficient to derive an Acceptable Daily Intake value (ADI) of 0.04 mg/kg bw/d and an ARfD of 0.09 mg/kg. The recalculation of the toxicological reference values for chlormequat cation, taking into account the molecular weight correction factor, leads to an ADI of 0.031 mg/kg bw/d and ARfD of 0.07 mg/kg bw.

No information is currently available regarding the source of the chlormequat residues in grapes. In case the residues result from an agricultural use, the metabolism of chlormequat on grapes should be further investigated. In absence of appropriate metabolism studies, the presence of unknown metabolites can not be excluded. In the context of this statement, EFSA had to make the assumption that the residue of concern on grapes comprises only the parent compound chlormequat.

**The calculated acute threshold residue concentration for chlormequat on table grapes is 1.06 mg/kg.** Consequently, EFSA concludes that no acute consumer health risk is expected if table grapes with a mean chlormequat residue concentration of 1.06 mg/kg are consumed. The calculation is based on the most critical European consumer groups (German child, body weight 16.15 kg) eating in one eating occasion 211.5 g of table grapes (13.1 g grapes per kg body weight). The calculation also takes into account a possible inhomogeneous distribution of the residues within the lot of grapes analysed.

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1 On request from the European Commission, Question No EFSA-Q-2010-00790, issued on 22 April 2010.

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If this threshold concentration of 1.06 mg/kg is exceeded, a potential consumer health risk can not be excluded in case an extreme food consumption event (consumption of more than 13.1 g grapes per kg body weight) coincides with an inhomogeneous residue distribution within the lot from which the table grapes have been taken.

EFSA also performed a long-term consumer exposure assessment using the existing MRLs as input parameters in the calculation of the theoretical maximum daily intake (TMDI). For table grapes the MRL was replaced with the threshold residue derived in the iterative acute risk assessment. Regarding the long-term exposure, no potential consumer health risk was identified; the exposure accounted for maximum 77% of the ADI. The contribution of the residues in table grapes did not exceed 5% of the ADI. Assuming, there are no other non-authorised uses, it is concluded that the existing MRLs do not pose a long-term consumer health risk. There is a sufficient safety margin to exclude that a slightly higher exposure for a short period due to the consumption of table grapes with higher residues than the existing MRLs would lead to a critical intake situation.

The results of the risk assessment have to be taken as provisional and temporary, since a full data package as required for assessing the safety of residues on food resulting from the use of pesticides is not available to EFSA at this time. The following issues have to be clarified before a final risk assessment can be performed:

- Clarification of the source of the chlormequat residues on table grapes. If it is confirmed that the residues result from an agricultural use, the description of the Good Agricultural Practice (GAP) in the country of origin has to be provided.
- Studies investigating the nature and magnitude of chlormequat residues on grapes in accordance with the use pattern described in the GAP have to be provided.
- If metabolites are identified in fruit crops, their toxicological relevance has to be clarified, and if relevant, toxicological reference values have to be derived.
- The residue definition might need to be revised.

It is noted that therefore the calculated threshold residue should not be understood as an MRL recommendation, but it is the result of a safety assessment for a certain lot. This value is provided for use by risk managers to decide on risk management actions to be taken in order to protect European consumers with regard to the lots for which the urgent request was sent to EFSA.

**KEY WORDS:**

Chlormequat, grapes, threshold residue, quaternary ammonium plant growth regulator

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## BACKGROUND

The Commission has been informed by food business operators that table grapes originating from India may contain levels of chlormequat higher than 0.05 mg/kg (lowest limit of analytical determination, LOD fixed in Regulation (EC) No 396/2005). According to the preliminary information levels up to 0.5 mg/kg may be expected to be found affecting 95% of the samples taken so far from grapes that have been received by EU food traders.

The origin of the residues is most likely agricultural use, although other causes cannot be excluded as the Indian authorities have stated that no change of use has occurred since last year's seasonal supply of grapes by India.

Pending further investigation a temporary solution is needed as these grapes may soon arrive on the EU market.

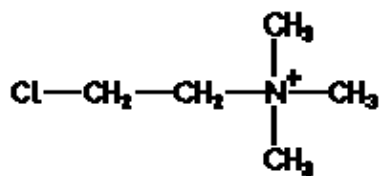
On 21 April 2010 the European Commission submitted an urgent request regarding the risks for public health due to the presence of chlormequat in table grapes from India to EFSA. The request was included in the EFSA Register of Question with the reference number EFSA-Q-2010-00790.

## TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Article 43 of Regulation (EC) No 396/2005, the European Commission asks the European Food Safety Authority to provide by 22 April 2010 a statement on the threshold for the acute risk to human health related to the presence of chlormequat in table grapes. By this threshold is meant the highest residue level that will not cause an exceedence of the ARfD for any of the European Consumer groups in the EFSA PRIMO model. The European Commission asked EFSA to derive the threshold residue level for chlormequat on table grapes based on the most sensitive consumer group.

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Chlormequat is the ISO common name for 2-chloroethyltrimethylammonium (IUPAC). It is also commonly known as CCC or chlorocholine chloride.



The molecular weight for chlormequat cation is 122.6; for chlormequat chloride it is 158.1.

Chlormequat belongs to the class of quaternary ammonium plant growth regulators. It is usually applied as a chloride salt. Chlormequat inhibits cell elongation, which results in a sturdier plant by shortening and strengthening the stem. It may also be used to increase the flowering and/or fruit setting. It mainly acts by inhibiting the gibberellin biosynthesis. Chlormequat is currently authorised in 23 EU Member States. However, the use on grapes is not allowed in the EU Member States.

Chlormequat was evaluated in the framework of Directive 91/414/EEC with the United Kingdom being the designated Rapporteur Member State (RMS). EFSA issued a conclusion on the peer review in September 2008 (EFSA, 2008). The peer review for this active substance resulted in a decision on inclusion of the active substance (chlormequat, CAS No 7003-89-6 and chlormequat chloride, CAS No 999-81-5) in Annex I of the Directive, which entered into force on 1 December 2009 (Directive 2009/37/EC). According to the restrictions defined in the Annex I inclusion, the use of chlormequat is now restricted to the use as plant growth regulator on cereals and non edible crops.

## ASSESSMENT

It is noted that this assessment is performed in reply to the urgent request of the European Commission aiming to provide the risk managers with supporting information on pesticide levels of chlormequat on table grapes that would be acceptable from a consumer safety point of view. Thus, the assessment is a safety assessment applicable for a certain lot.

The safety level for chlormequat derived in this assessment is not a recommendation to establish an MRL at this level. For the setting of MRLs, the procedures as described in Article 6 to 10 of Regulation (EC) No 396/2005 are applicable. In the case of import tolerances request, commercially interested parties such as manufacturers, growers, importers and producers of food commodities falling under the provisions of the MRL legislation, have to submit an application, including a dossier, substantiating the request. No application and no supporting dossier was submitted for the purpose of establishing an import tolerance of chlormequat on table grapes produced in India. Lacking a full dossier, EFSA had to make several assumptions which have an impact on the safety assessment performed in the context of this request and contribute to the uncertainty of the assessment.

### 1. Current MRLs and residue definition for chlormequat

EU MRLs for chlormequat are established in Annex II and IIIB of Regulation 396/2005 (Appendix B). The residue definition for enforcement is set as chlormequat (cation). Currently the MRL for table grapes is established at the LOQ of 0.05 mg/kg. In 2009 EFSA issued a reasoned opinion on the modification of the existing MRL for chlormequat in pears (EFSA, 2009). The recommendation of EFSA regarding the lowering of the MRL for pears was included in Regulation (EC) No 822/2009.

Codex Alimentarius has established CXLs for a range of crops, but not for grapes. In 1994 JMPR evaluated the use of chlormequat on grapes registered in Italy, Spain and several non-European countries for bloom induction (WHO/FAO, 1994). JMPR recommended to withdraw the CXL of 1 mg/kg valid in 1994 because the required number of supervised field trials was not available.

In the framework of the peer review under Directive 91/414/EEC, the metabolism of chlormequat chloride, which is the salt used in formulations, was investigated on wheat (EFSA, 2008). The major component in grain and straw at harvest was unmetabolised chlormequat. No information is available on the metabolic behaviour on fruit crops like grapes or other crop except cereals.

Based on the available metabolism studies the peer review concluded that the residue definition for risk assessment should be established as sum of chlormequat and its salts expressed as chlormequat chloride.

In absence of appropriate metabolism studies of chlormequat on grapes, the presence of unknown metabolites can not be excluded. In the context of the given request, EFSA had to make the assumption that the residue of concern on table grapes comprises only the parent compound chlormequat.

Since the current MRLs are expressed as chlormequat cation, EFSA decided that the risk assessment residue definition in the framework of this evaluation should be expressed as chlormequat cation to align it with the current enforcement residue definition. By this approach the risk assessment is simplified because the existing MRLs can be incorporated without a re-calculation by applying a molecular weight correction factor.

### 2. Mammalian toxicology

The toxicological properties of chlormequat have been evaluated under Directive 91/414/EEC (EFSA, 2008) and reference values have been derived for chlormequat chloride. Considering that the residue

definition for risk assessment is defined as chlormequat as discussed in the previous section, the reference values were recalculated to chlormequat based on the molecular weight of both compounds (ratio of 122.6 to 158.1 = 0.775). The reference values are summarized in the table below.

**Table 2-1.** Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Reference values <b>expressed as chlormequat chloride</b>					
ADI	EFSA	2008	0.04	1-year dog study	100
ARfD	EFSA	2008	0.09	4-week dog study	100
Reference values <b>expressed as chlormequat</b> , recalculated taking into account the molecular weight for chlormequat.					
ADI			0.031	1-year dog study	100
ARfD			0.070	4-week dog study	100

### 3. Consumer risk assessment

EFSA was requested to calculate the threshold residue for chlormequat on table grapes, i.e. the residue concentration that would not raise an acute consumer health risk. This threshold residue is the chlormequat concentration on table grapes that leads to an exhaustion of 100% of the ARfD.

EFSA calculated the threshold residue by means of the EFSA Pesticide Residue Intake Model (PRIMo, EFSA, 2007), which comprises representative food consumption data for European consumer groups (e.g. adults, children, vegetarians from different regions in the EU).

For table grapes the most critical European consumer was identified as the German child, with a reported 97.5<sup>th</sup> percentile consumption of 13.1 g/kg body weight. Taking into account the body weight of 16.15 kg for this consumer group, the resulting large portion (LP) is calculated to be 211.5 g/person. It is noted that for the adult population the intake situation is less critical, since generally lower table grape consumption figures were reported in food surveys (maximum food intake for adults: Netherlands, 6.35 g/kg body weight, for a consumer with 63 kg body weight).

The calculation of the short-term exposure is performed according to the following equation which is in line with the recommended JMPR methodology (FAO, 2009):

$$\text{IESTI} = \frac{\text{LP} \times (\text{HR or HR-P}) \times v}{\text{bw}}$$

IESTI: international estimate short term intake

LP: Large portion, highest large portion reported (97.5<sup>th</sup> percentile of eaters), in kg food per day

HR: highest residue, in mg/kg

HR-P: highest residue in processed commodity, calculated by multiplying the HR by a processing factor. For chlormequat in table grapes no processing factors are applicable.

v: variability factor- the factor applied to the composite residue to estimate the residue level in a high-residue unit.



Deviating from the JMPR practice, it was agreed among Member States and the European Commission to use the variability factor of five in the acute risk assessment for food commodities like grapes where the unit of one food item (i.e. bunch of grapes) exceeds 250 g. This factor of five is derived from the assumption that a composite sample representative for a lot/consignment has to comprise at least five bunches of grapes (Directive 2002/63). Under the assumption of an extremely inhomogeneous distribution of the residues among the individual bunches, the measured residue might result from residues in one bunch only. Thus, the overall residue would be only 20% of the residue in the highly contaminated bunch. In order to protect the consumer of the highly contaminated bunch adequately, the factor five was introduced in the exposure calculation. It is noted that JMPR generally uses a lower variability factor of three.

The calculation spreadsheet of the PRIMo rev. 2 is attached in Appendix A.

EFSA performed an iteration, calculating the limit for the HR which would not lead to an exceedance of the ARfD value (less or equal to 100% of the ARfD).

**The calculated threshold residue concentration for chlormequat on table grapes is 1.06 mg/kg.**

In other words: No acute consumer health risk is expected if a lot containing mean residues of 1.06 mg/kg is consumed by European consumers. The calculation is based on the most critical European consumer group (German child, body weight 16.15 kg) eating in one eating occasion 211.5 g of table grapes (13.1 g table grapes per kg body weight). The calculation also takes into account a possible inhomogeneous distribution of the residues within the lot of table grapes analysed.

If this threshold concentration of 1.06 mg/kg is exceeded, a potential consumer health risk can not be excluded, in case extreme food consumption event (consumption of more than 13.1 g grapes per kg body weight) coincides with an inhomogeneous residue distribution within the lot of grapes.

EFSA also performed a long-term consumer exposure assessment using the existing MRLs as input parameters in the EFSA PRIMo. The methodology for the calculation is in accordance with the TMDI calculation methodology developed by JMPR (FAO, 2009). For table grapes the MRL was replaced with the threshold residue derived in the iterative acute risk assessment. Regarding the long-term exposure, no potential consumer health risk was identified; the exposure accounted for maximum 77% of the ADI. The contribution of the residues in table grapes did not exceed 5% the ADI. Assuming, there are no other non-authorised uses, it is concluded that the existing MRLs do not pose a long-term consumer health risk. There is a sufficient safety margin to exclude that a slightly higher exposure for a short period due to the consumption of table grapes with higher residues than the existing MRLs would lead to a critical intake situation.

The results of the risk assessment have to be taken as provisional and temporary, since a full data package as required for assessing the safety of residues on food resulting from the use of pesticides is not available to EFSA at this time. The following issues have to be clarified before a final risk assessment can be provided:

- Clarification of the source of the chlormequat residues on table grapes. If it is confirmed that the residues result from an agricultural use, the description of the Good Agricultural Practice in the country of origin has to be provided.
- Studies investigating the nature and magnitude of chlormequat residues on grapes in accordance with the use pattern described in the GAP have to be provided.
- If metabolites are identified in fruit crops, their toxicological relevance has to be clarified, and if relevant, toxicological reference values have to be derived.



- The residue definition might need to be revised.

## CONCLUSIONS AND RECOMMENDATIONS

EFSA concludes that residue of chlormequat on table grapes are not likely to pose a consumer health risk if the measured concentration in lot does not exceed 1.06 mg/kg. If this threshold concentration of 1.06 mg/kg is exceeded, a potential consumer health risk can not be excluded in case an extreme food consumption event (consumption of more than 13.1 g grapes per kg body weight) coincides with an inhomogeneous residue distribution within the lot of from which the grapes were taken.

This threshold residue value for chlormequat should not be taken as a MRL recommendation since it is affected by uncertainties. It is the result of a safety assessment for a certain lot. This value is provided for use by risk managers to decide on adequate risk management actions to be taken in order to protect European consumers with regard to the lots for which the urgent request was sent to EFSA.

Since no information is available regarding the agricultural practices used in India, EFSA recommends to further investigate how chlormequat is used. This would also help to get an idea about the potential formation of metabolites. Chlormequat is known to have a potential to build up a residue plateau in pear trees (Maas, 2006). This residue behaviour leads to high residues in pears even several years after the use of chlormequat has been stopped. If a similar residue behaviour is observed in grapes, the use of chlormequat on grapes needs to be carefully considered.

## REFERENCES

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## APPENDIX A: RISK ASSESSMENT CALCULATION WITH EFSA PRIMO (PESTICIDE RESIDUE INTAKE MODEL)

Chlormequat			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0,05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,031	ARfD (mg/kg bw):	0,07
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2008	Year of evaluation:	2008

The toxicological reference values have been agreed with Member States and are published in EFSA conclusion, corrected for the molecular weight.

Chronic risk assessment - refined calculations															
			TMDI (range) in % of ADI minimum - maximum 7                      77												
			No of diets exceeding ADI:                      ---												
	Highest calculated TMDI values in % of ADI		Highest contributor to MS diet (in % of ADI)		Commodity / group of commodities		2nd contributor to MS diet (in % of ADI)		Commodity / group of commodities		3rd contributor to MS diet (in % of ADI)		Commodity / group of commodities		pTMRls at LOQ (in % of ADI)
		MS Diet													
	77,2	DK child	35,5	Wheat	28,5	Rye	6,4	Oats	4,5						
	66,4	WHO Cluster diet B	55,1	Wheat	1,8	Barley	1,2	Table grapes	5,0						
	55,7	WHO cluster diet E	25,4	Wheat	13,4	Rape seed	5,2	Barley	3,3						
	51,7	WHO cluster diet D	42,0	Wheat	2,6	Rye	1,4	Barley	3,0						
	50,2	NL child	30,6	Wheat	4,7	Milk and cream,	4,0	Cultivated fungi	9,4						
	49,9	DE child	26,5	Wheat	5,1	Rye	4,3	Table grapes	7,3						
	46,3	IT kids/toddler	42,9	Wheat	1,3	Cultivated fungi	0,4	Table grapes	1,5						
	45,9	WHO Cluster diet F	23,2	Wheat	7,0	Rape seed	4,9	Rye	2,8						
	44,1	IE adult	14,8	Wheat	8,0	Barley	7,6	Cultivated fungi	5,0						
	38,5	UK Toddler	25,3	Wheat	3,7	Sugar beet (root)	3,3	Milk and cream,	9,4						
	34,4	ES child	28,6	Wheat	2,0	Milk and cream,	0,7	Cultivated fungi	4,4						
	31,9	UK Infant	16,9	Wheat	6,2	Milk and cream,	4,1	Oats	10,4						
	31,1	WHO regional European diet	19,1	Wheat	2,7	Rape seed	2,2	Cultivated fungi	3,4						
	30,6	PT General population	25,3	Wheat	1,0	Table grapes	0,9	Rye	2,4						
	30,1	IT adult	26,7	Wheat	1,6	Cultivated fungi	0,4	Table grapes	1,2						
	27,9	FR toddler	16,9	Wheat	6,4	Milk and cream,	0,8	Potatoes	10,1						
	27,3	SE general population 90th percentile	20,7	Wheat	2,0	Milk and cream,	1,9	Rye	4,6						
	24,4	FR all population	21,2	Wheat	0,6	Wine grapes	0,4	Milk and cream,	2,2						
	23,5	NL general	13,4	Wheat	2,6	Cultivated fungi	2,4	Barley	3,1						
	23,4	ES adult	15,1	Wheat	3,2	Barley	2,1	Cultivated fungi	2,4						
	23,3	DK adult	13,0	Wheat	4,4	Rye	1,9	Oats	2,2						
	21,1	UK vegetarian	13,2	Wheat	4,1	Cultivated fungi	0,8	Oats	2,4						
	17,9	LT adult	6,9	Rye	6,8	Wheat	1,5	Oats	2,2						
	15,8	UK Adult	10,8	Wheat	2,0	Cultivated fungi	0,6	Sugar beet (root)	2,3						
	14,4	FI adult	6,3	Wheat	4,4	Rye	1,4	Oats	1,9						
	12,7	FR infant	5,4	Wheat	4,2	Milk and cream,	0,7	Potatoes	6,9						
	6,7	PL general population	4,1	Cultivated fungi	1,1	Table grapes	0,6	Potatoes	1,4						
<b>Conclusion:</b>															
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRls were below the ADI.															
A long-term intake of residues of Chlormequat is unlikely to present a public health concern.															

Acute risk assessment /children - refined calculations							Acute risk assessment / adults / general population - refined calculations																				
The acute risk assessment is based on the ARfD. For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation. In the <b>IESTI 1</b> calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used. In the <b>IESTI 2</b> calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3. <b>Threshold MRL</b> is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.																											
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):						No of commodities for which ARfD/ADI is exceeded (IESTI 2):						No of commodities for which ARfD/ADI is exceeded (IESTI 1):						No of commodities for which ARfD/ADI is exceeded (IESTI 2):								
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	IESTI 1                   *)                   **)						IESTI 2                   *)                   **)						IESTI 1                   *)                   **)						IESTI 2                   *)                   **)								
	Highest % of ARfD/ADI			pTMRL/ threshold MRL (mg/kg)			Highest % of ARfD/ADI			pTMRL/ threshold MRL (mg/kg)			Highest % of ARfD/ADI			pTMRL/ threshold MRL (mg/kg)			Highest % of ARfD/ADI			pTMRL/ threshold MRL (mg/kg)					
	99,2           Table grapes			1,06 / -			99,2           Table grapes			1,06 / -			48,1           Table grapes			1,06 / -			48,1           Table grapes			1,06 / -					
No of critical MRLs (IESTI 1)														No of critical MRLs (IESTI 2)													
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Processed commodities	No of commodities for which ARfD/ADI is exceeded:						No of commodities for which ARfD/ADI is exceeded:						No of commodities for which ARfD/ADI is exceeded:						No of commodities for which ARfD/ADI is exceeded:								
	---						---						---						---								
	***)						***)						***)						***)								
	Highest % of ARfD/ADI			Processed commodities			pTMRL/ threshold MRL (mg/kg)			Highest % of ARfD/ADI			Processed commodities			pTMRL/ threshold MRL (mg/kg)			Highest % of ARfD/ADI			Processed commodities			pTMRL/ threshold MRL (mg/kg)		
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported. **) pTMRL: provisional temporary MRL ***) pTMRL: provisional temporary MRL for unprocessed commodity																											
<b>Conclusion:</b> For Chlormequat IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity.  For processed commodities, no exceedance of the ARfD/ADI was identified.																											

## APPENDIX B – EXISTING EC MRLs

Pesticides - Web Version - EU MRLs (File created on 21/04/2010 10:27)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*
110030	Lemons (Citron, lemon )	0,05*
110040	Limes	0,05*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,05*
110990	Others	0,05*
120000	(ii) Tree nuts (shelled or unshelled)	0,1*
120010	Almonds	0,1*
120020	Brazil nuts	0,1*
120030	Cashew nuts	0,1*
120040	Chestnuts	0,1*
120050	Coconuts	0,1*
120060	Hazelnuts (Filbert)	0,1*
120070	Macadamia	0,1*
120080	Pecans	0,1*
120090	Pine nuts	0,1*
120100	Pistachios	0,1*
120110	Walnuts	0,1*
120990	Others	0,1*
130000	(iii) Pome fruit	
130010	Apples (Crab apple)	0,05*
130020	Pears (Oriental pear)	0,1
130030	Quinces	0,05*
130040	Medlar	0,05*
130050	Loquat	0,05*
130990	Others	0,05*
140000	(iv) Stone fruit	0,05*
140010	Apricots	0,05*
140020	Cherries (sweet cherries, sour cherries)	0,05*
140030	Peaches (Nectarines and similar hybrids)	0,05*
140040	Plums (Damson, greengage,	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
	mirabelle)	
140990	Others	0,05*
150000	(v) Berries & small fruit	0,05*
151000	(a) Table and wine grapes	0,05*
151010	Table grapes	0,05*
151020	Wine grapes	0,05*
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*
153030	Raspberries (Wineberries )	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*
154020	Cranberries	0,05*
154030	Currants (red, black and white)	0,05*
154040	Gooseberries (Including hybrids with other ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (arbutus berry)	0,05*
154070	Azarole (mediterranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,1*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomeac,	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
	rose apple, Brazilian cherry (grumichama), Surinam cherry)	
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammetomatoes sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	0,05*
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,05*
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,05*
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddloe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*
213010	Beetroot	0,05*
213020	Carrots	0,05*
213030	Celeriac	0,05*
213040	Horseradish	0,05*
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,05*
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,05*
213100	Swedes	0,05*
213110	Tumips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	0,05*
231000	(a) Solanacea	0,05*
231010	Tomatoes (Cherry tomatoes, )	0,05*
231020	Peppers (Chilli peppers)	0,05*
231030	Aubergines (egg plants) (Pepino)	0,05*
231040	Okra, lady's fingers	0,05*
231990	Others	0,05*
232000	(b) Cucurbits - edible peel	0,05*
232010	Cucumbers	0,05*
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson))	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb's lettuce (Italian comsalad)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	0,05*
251040	Cress	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,05*
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme ( marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	0,05*
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	10
280020	Wild (Chanterelle, Truffle, Morel,)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	7
401020	Peanuts	0,1*
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rape seed (Bird rapeseed, turnip rape)	7
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	0,1*
401100	Pumpkin seeds	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
401110	Safflower	0,1*
401120	Borage	0,1*
401130	Gold of pleasure	0,1*
401140	Hempseed	0,1*
401150	Castor bean	0,1*
401990	Others	0,1*
402000	(ii) Oilfruits	0,1*
402010	Olives for oil production	0,1*
402020	Palm nuts (palmoil kernels)	0,1*
402030	Palmfruit	0,1*
402040	Kapok	0,1*
402990	Others	0,1*
500000	5. CEREALS	
500010	Barley	2
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	5
500060	Rice	0,05*
500070	Rye	2
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	2
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
633010	Valerian root	0,1 *
633020	Ginseng root	0,1 *
633990	Others	0,1 *
639000	(d) Other herbal infusions	0,1 *
640000	(iv) Cocoa (fermented beans)	0,1 *
650000	(v) Carob (st johns bread)	0,1 *
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,1 *
800000	8. SPICES	0,1 *
810000	(i) Seeds	0,1 *
810010	Anise	0,1 *
810020	Black caraway	0,1 *
810030	Celery seed (Lovage seed)	0,1 *
810040	Coriander seed	0,1 *
810050	Cumin seed	0,1 *
810060	Dill seed	0,1 *
810070	Fennel seed	0,1 *
810080	Fenugreek	0,1 *
810090	Nutmeg	0,1 *
810990	Others	0,1 *
820000	(ii) Fruits and berries	0,1 *
820010	Allspice	0,1 *
820020	Anise pepper (Japan pepper)	0,1 *
820030	Caraway	0,1 *
820040	Cardamom	0,1 *
820050	Juniper berries	0,1 *
820060	Pepper, black and white (Long pepper, pink pepper)	0,1 *
820070	Vanilla pods	0,1 *
820080	Tamarind	0,1 *
820990	Others	0,1 *
830000	(iii) Bark	0,1 *
830010	Cinnamon (Cassia )	0,1 *
830990	Others	0,1 *
840000	(iv) Roots or rhizome	0,1 *
840010	Liquorice	0,1 *
840020	Ginger	0,1 *
840030	Turmeric (Curcuma)	0,1 *
840040	Horseradish	0,1 *
840990	Others	0,1 *
850000	(v) Buds	0,1 *
850010	Cloves	0,1 *

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
850020	Capers	0,1 *
850990	Others	0,1 *
860000	(vi) Flower stigma	0,1 *
860010	Saffron	0,1 *
860990	Others	0,1 *
870000	(vii) Aril	0,1 *
870010	Mace	0,1 *
870990	Others	0,1 *
900000	9. SUGAR PLANTS	0,05 *
900010	Sugar beet (root)	0,05 *
900020	Sugar cane	0,05 *
900030	Chicory roots	0,05 *
900990	Others	0,05 *
100000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
101000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
101100	(a) Swine	0,05 *
101101	Meat	0,05 *
101102	Fat free of lean meat	0,05 *
101103	Liver	0,05 *
101104	Kidney	0,05 *
101105	Edible offal	0,05 *
101199	Others	0,05 *
101200	(b) Bovine	
101201	Meat	0,05 *
101202	Fat	0,05 *
101203	Liver	0,1 *
101204	Kidney	0,2 *

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
101205	Edible offal	0,05 *
101299	Others	0,05 *
101300	(c) Sheep	0,05 *
101301	Meat	0,05 *
101302	Fat	0,05 *
101303	Liver	0,05 *
101304	Kidney	0,05 *
101305	Edible offal	0,05 *
101399	Others	0,05 *
101400	(d) Goat	0,05 *
101401	Meat	0,05 *
101402	Fat	0,05 *
101403	Liver	0,05 *
101404	Kidney	0,05 *
101405	Edible offal	0,05 *
101499	Others	0,05 *
101500	(e) Horses, asses, mules or hinnies	0,05 *
101501	Meat	0,05 *
101502	Fat	0,05 *
101503	Liver	0,05 *
101504	Kidney	0,05 *
101505	Edible offal	0,05 *
101599	Others	0,05 *
101600	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05 *
101601	Meat	0,05 *

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
0		
101602	Fat	0,05 *
101603	Liver	0,05 *
101604	Kidney	0,05 *
101605	Edible offal	0,05 *
101699	Others	0,05 *
101700	(g) Other farm animals (Rabbit, Kangaroo)	0,05 *
101701	Meat	0,05 *
101702	Fat	0,05 *
101703	Liver	0,05 *
101704	Kidney	0,05 *
101705	Edible offal	0,05 *
101799	Others	0,05 *
102000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05 *
102001	Cattle	0,05 *
102002	Sheep	0,05 *
102003	Goat	0,05 *
102004	Horse	0,05 *
102099	Others	0,05 *
103000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05 *
103001	Chicken	0,05 *

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
0		
1030020	Duck	0,05*
1030030	Goose	0,05*
103004	Quail	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
0		
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	0,05*
105000	(v) Amphibians and reptiles	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlormequat
0	(Frog legs, crocodiles)	
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products	0,05*

(\*) Indicates lower limit of analytical determination



## ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CCC	chlormequat
CXL	Codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/EEC)
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
HR	highest residue
IESTI	International estimate of short-term intake
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LOD	Limit of analytical determination
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
PRAPeR	Pesticide Risk Assessment Peer Review
PF	processing factor
PRIMo	Pesticide Residues Intake Model (EFSA, 2007)
RMS	rapporteur Member State
STMR	supervised trials median residue
TMDI	Theoretical maximum daily intake
WHO	World Health Organisation