

TEBUFENOZIDE

EXPLANATION

The insecticide tebufenozide was first evaluated by the 1996 JMPR when an ADI was allocated and MRLs were recommended for pome fruit, grapes, walnut and husked rice. Residue trials on kiwifruit in accordance with revised New Zealand GAP were reviewed by the 1997 JMPR and an MRL was recommended.

At the 31st (1999) Session of the CCPR the delegation of Germany stated that the German GAP for grapes and pome fruit was no longer pending (ALINORM 99/24A, para 103). Information on current GAP in Germany was submitted to allow re-evaluation of tebufenozide residues in grapes and pome fruit.

USE PATTERN

Registered German GAP allows application of tebufenozide to grapes and pome fruit to control moths 2-4 times at intervals of 14 days. Details are shown in Table 1.

Table 1. Registered uses of tebufenozide in Germany.

Crop	Form.	Application					PHI, days
		Method	Rate, kg ai/ha	Water, l/ha	Spray conc., kg ai/hl	No.	
Pome fruit	SC	Foliar spraying or atomizing spraying	0.18 ¹	1500 ¹	0.012 ¹	3	14
Wine grapes	SC	Foliar spraying or atomizing spraying	0.048 - 0.19	400 – 1600 ²	0.012 ²	2-4	28

¹Application rate for a standard tree of 3 m height (0.06 kg ai/ha, 500 l water/ha per m tree height)

² Standard application = 1600 l water/ha, 0.012 kg ai/ha. Higher concentration for low volume (atomizing) spraying

RESIDUES RESULTING FROM SUPERVISED TRIALS

Pome fruit. The 1996 JMPR evaluated eight German trials on apples according to Belgium GAP (3 x 0.12 kg ai/ha, 0.012 kg ai/hl, PHI 28 days) as the more severe German GAP was pending. The data are re-evaluated against German GAP in Table 2.

Table 2. Residues of tebufenozide from supervised trials on apples in Germany (1996 JMPR).

Reference, location, year	Form.	Application rate per treatment		No. of treatments	PHI, days	Residues, mg/kg
		kg ai/ha	kg ai/hl			
Raquet <i>et al</i> , 1993, Drage-Elbersdorf, 1992	SC	0.19	0.013	3	0	0.29
					7	0.24
					14	<u>0.24</u>
					28	0.16
Raquet <i>et al</i> , 1993, Bornheim, 1992	SC	0.16	0.013	3	0	0.05
					7	0.03
					14	<u>0.02</u>
					28	<0.02

Reference, location, year	Form.	Application rate per treatment		No. of treatments	PHI, days	Residues, mg/kg
		kg ai/ha	kg ai/hl			
Raquet <i>et al.</i> , 1993, Bodeneegg, 1992	SC	0.2	0.013	3	0	0.39
					7	0.28
					14	<u>0.35</u>
					28	0.2
Raquet <i>et al.</i> , 1993, Hoechst, 1992	SC	0.12	0.013	3	0	0.27
					7	0.2
					14	<u>0.11</u>
					28	0.08
Raquet <i>et al.</i> , 1993, Niederdorfelden, 1992	SC	0.12	0.013	1	0	0.13
		0.13		2	7	0.15
					14	0.06
					21	<u>0.11</u>
Brusche and Holzwarth, 1995, Drage-Elbersdorf, 1993	SC	0.18	0.012	3	12	0.15
					25	<u>0.16</u>
Brusche and Holzwarth, 1995, Drage-Elbersdorf, 1993	SC	0.18	0.012	3	13	<u>0.15</u>
					27	0.09
Brusche and Holzwarth, 1995, Kippenhausen, 1993	SC	0.18	0.012	3	12	0.21
					27	<u>0.23</u>

Grapes. Nine German trials were reported to the 1996 JMPR but could not be evaluated because German GAP was pending. The data are evaluated against German GAP in Table 3.

Table 3. Residues of tebufenozide from supervised trials on grapes in Germany (JMPR 1996).

Reference, year	Form.	Application rate per treatment			No. of treatments	PHI, days	Residues, mg/kg
		kg ai/ha	Water, l/ha	kg ai/hl			
Ulrich <i>et al.</i> , 1994	SC	0.077	615	0.013	1	0	0.59
		0.077	615	0.013	1	7	0.48
		0.2	541	0.037	1	14	1.1
		0.2	529	0.038	1	28	<u>0.28</u>
			(1600) ¹	(0.013) ¹			
Ulrich <i>et al.</i> , 1994	SC	0.074	580	0.013	1	0	0.37
		0.079	612	0.013	1	7	0.2
		0.185	483	0.038	1	14	0.44
		0.2	516	0.038	1	28	<u>0.5</u>
			(1600) ¹	(0.012) ¹			
Ulrich <i>et al.</i> , 1994	SC	0.074	585	0.013	1	0	0.5
		0.077	602	0.013	1	7	0.28
		0.19	499	0.038	1	14	0.79
		0.21	550	0.038	1	28	<u>0.24</u>
			(1600) ¹	(0.013) ¹			
Ulrich <i>et al.</i> , 1994	SC	0.074	591	0.013	1	0	0.33
		0.077	606	0.013	1	7	0.53
		0.2	535	0.038	1	14	0.47
		0.2	525	0.038	1	28	<u>0.27</u>
			(1600) ¹	(0.012) ¹			
Ulrich <i>et al.</i> , 1994	SC	0.074	587	0.013	1	0	0.54
		0.077	599	0.013	1	7	0.57
		0.21	542	0.038	1	14	0.4
		0.2	519	0.038	1	28	<u>0.4</u>
			(1600) ¹	(0.012) ¹			

Reference, year	Form.	Application rate per treatment			No. of treatments	PHI, days	Residues, mg/kg
		kg ai/ha	Water, l/ha	kg ai/hl			
Kaiser, 1994	SC	0.073	575	0.013	1	0	0.52
		0.079	625	0.013	1	7	0.95
		0.19	500	0.038	1	14	0.16
		0.21	550 (1600) ¹	0.038 (0.013) ¹	1	28	<u>0.21</u>
Kaiser, 1994	SC	0.079	625	0.013	1	0	0.33
		0.073	604	0.012	1	7	0.5
		0.2	541	0.037	1	14	0.15
		0.2	541 (1600) ¹	0.037 (0.125) ¹	1	28	<u>0.26</u>
Kaiser, 1994	SC	0.075	586	0.013	1	0	0.46
		0.074	579	0.013	1	7	0.42
		0.2	531	0.038	1	14	0.64
		0.2	510 (1600) ¹	0.038 (0.012) ¹	1	28	<u>0.22</u>
Kaiser, 1994	SC	0.079	621	0.013	1	0	0.46
		0.076	596	0.013	1	7	0.32
		0.21	540	0.038	1	14	0.28
		0.2	527 (1600) ¹	0.038 (0.0125) ¹	1	28	<u>0.42</u>

¹ Concentration (kg ai/hl) of last treatment calculated according to the standard water volume of 1600 l/ha

APPRAISAL

The insecticide tebufenozide was first evaluated by the 1996 JMPR when an ADI was allocated and MRLs for pome fruits, grapes, walnut and husked rice were recommended. German data on supervised residue trials on apples and grapes were provided to the 1996 Meeting, but could not be evaluated against German GAP because it was only pending. The present Meeting received information on currently registered GAP in Germany for re-evaluation of tebufenozide residues in grapes and pome fruit.

Pome fruit. The residues in the German trials on apples evaluated according to the new German GAP were 0.02, 0.11, 0.11, 0.15, 0.16, 0.23, 0.24 and 0.35 mg/kg. The German GAP has a PHI of 14 days and would be expected to produce higher residues than the Belgian GAP (PHI 28 days) which was used by the 1996 JMPR for the evaluation of the German trials (giving residues of <0.02, 0.08, 0.09, 0.11, 0.16, 0.16, 0.2 and 0.23 mg/kg). The Meeting agreed to replace the 28-day residues of the 1996 evaluation by the corresponding residues at 14 days, giving residues in pome fruit in rank order of 0.01, 0.02, 0.02, 0.05, 0.07, 0.077, 0.08, 0.09, 0.1, 0.1, 0.11, 0.11, 0.11, 0.12, 0.14, 0.14, 0.15, 0.16, 0.16, 0.18, 0.19, 0.23, 0.23, 0.24, 0.26, 0.27, 0.28, 0.32, 0.35, 0.37, 0.37, 0.43, 0.52, 0.52, 0.55, 0.75, 0.84 and 1.1 mg/kg.

The Meeting agreed to recommend retention of the current CXL of 1 mg/kg for pome fruits and estimated an STMR of 0.17 mg/kg (previous STMR 0.16 mg/kg).

Processing factors of 2.5, 0.25 and 0.125 for apple pomace (wet), purée and juice respectively were reported by the 1996 JMPR. On the basis of the new STMR for pome fruits the Meeting estimated STMRs of 0.425 mg/kg for wet apple pomace, 0.0425 mg/kg for apple purée and 0.021 mg/kg for apple juice.

Grapes. The German residue data from 1996 evaluated according to current German GAP in rank order were 0.21, 0.22, 0.24, 0.26, 0.27, 0.28, 0.4, 0.42 and 0.5 mg/kg.

The nine trials in France in 1996 complied with GAP (3 applications at 0.144 kg ai/ha, 21 days PHI) and showed the residues 0.05, 0.06, 0.07, 0.08, 0.12, 0.18, 0.26, 0.28 and 0.28 mg/kg.

The rank order of the combined German and French trials was 0.05, 0.06, 0.07, 0.08, 0.12, 0.18, 0.21, 0.22, 0.24, 0.26, 0.26, 0.27, 0.28, 0.28, 0.28, 0.4, 0.42 and 0.5 mg/kg.

On the basis of the German and French trials, the Meeting estimated a maximum residue level of 1 mg/kg for grapes to replace current draft MRL (0.5 mg/kg) and an STMR of 0.25 mg/kg.

Processing factors of 0.25 and 2.7 for wine and grape pomace (wet) respectively, were reported by the 1996 JMPR. The Meeting estimated STMRs of 0.0625 mg/kg for wine and 0.675 mg/kg for wet grape pomace from the STMR of 0.25 mg/kg for grapes.

RECOMMENDATIONS

The Meeting estimated the following maximum residue levels which are recommended for use as MRLs.

Definition of residue for compliance with MRLs and for the estimation of dietary intake: tebufenozide.

The compound is fat-soluble.

Commodity		MRL, mg/kg		STMR, mg/kg
CCN	Name	New	Previous	
FP 0009	Pome fruits	1	1	0.17
	Apple pomace, wet			0.43
JF 0226	Apple juice			0.021
	Apple purée			0.043
FB 0269	Grapes	1	0.5	0.25
	Grape pomace, wet			0.68
	Wine			0.063

DIETARY RISK ASSESSMENT

Chronic intake

STMRs were estimated for 4 commodities (1999: pome fruits, grapes; 1996: walnuts, rice).

International Estimated Daily Intakes for the 5 GEMS/Food regional diets, based on estimated STMRs, were in the range of 0–1% of the ADI. The Meeting concluded that intake of residues of tebufenozide resulting from its uses that have been considered by the JMPR is unlikely to present a public health concern.

Acute intake

The international estimate of short-term intake (IESTI) for tebufenozide was calculated for the commodities for which MRLs and STMRs were established and for which consumption data (large portion consumption and unit weight) were available. The results are shown in Annex IV. The IESTI varied from 0.001 to 0.015 mg/kg bw for the general population and from 0 to 0.058 mg/kg bw for children. As no acute reference dose has been established, the acute risk assessment for tebufenozide was not finalized.

REFERENCES

Brusche, R. and Holzwarth, U. 1995. Tebufenozide Suspension Concentrate. Determination of Residues of Hoe 105540 to establish a Maximum Residue Level following Three Applications in Apples (1993, Germany). Rohm and Haas Report No. 34-95-153. Unpublished.

Kaiser, K. 1994. Tebufenozide. Investigation of Residues in Processed and Non-processed Grapes Following Four Applications of Hoe 105540 2SC (240 g/l) (1993, Germany). Rohm and Haas Report No. 34-94-112. Unpublished.

Raquet, H., Schuld, G. and Holzwarth, U. 1993. Tebufenozide (240 g/l) – Water Miscible Suspension Concentrate. Investigation of Residues of Hoe 105540 in Non-Processed and Processed Apples After Three Applications (1992, Germany). Rohm and Haas Report No. 34-94-72. Unpublished.

Ulrich, C., Schuld, G. and Holzwarth, U. 1994. Tebufenozide. Investigation of Residues in Processed and Non-processed Grapes Following Four Applications of Hoe 105540 2SC (240 g/l) (1992, Germany). Rohm and Haas Report No. 34-94-93. Unpublished.