

## DELTAMETHRIN

First draft prepared by

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### ADDENDUM

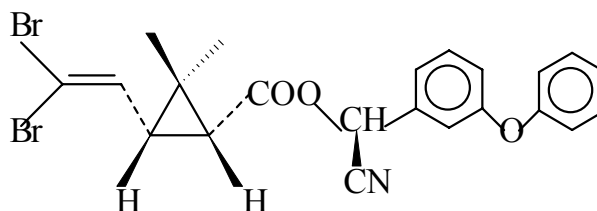
To the monograph prepared by the 52<sup>nd</sup> meeting of the Committee and published in the FAO Food and Nutrition Paper 41/12

### IDENTITY

**Chemical Name:** S-cyano-3-phenoxybenzyl-*cis*-(1R, 3R) -3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate

**Synonyms:** RU 22974, Decamethrin, Butox®

**Structural formula:**



**Molecular formula:** C<sub>22</sub>H<sub>19</sub> Br<sub>2</sub>NO<sub>3</sub>

**Molecular weight:** 505.2

### CONDITIONS OF USE

Deltamethrin is an insecticide belonging to the synthetic pyrethroid class and used particularly for control of Diptera and Mallophaga in veterinary use. It is a neurotoxic agent that is widely used for insect control as a pesticide. For veterinary use it is applied topically as a dip, spray or a pour-on preparation to cattle, sheep, pigs, poultry and salmon.

### BACKGROUND

Deltamethrin has been evaluated previously by the 52<sup>nd</sup> Committee for maximum residue limits (MRL) in food animals. The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) evaluated deltamethrin toxicologically in 1980, 1981, and 1982 (JMPR 1980, JMPR 1981, JMPR 1982). An Acceptable Daily Intake (ADI) of 0-10 µg/kg of body weight was established at the 1982 meeting. MRLs were recommended for veterinary use in 1990 and for use as a pesticide for plant protection purposes in 1982 by JMPR. MRLs in food animal tissues were recommended by the 52<sup>nd</sup> meeting of the Committee that affirmed the MRLs for liver, kidney and fat (FAO, 2000). The 52<sup>nd</sup> meeting of Committee noted that the concentrations of residues in muscle, milk and eggs were less than twice the limit of quantification of the analytical methods used and, therefore, recommended MRLs based on the limit of quantification of the methods in muscle in cattle, sheep, chickens and salmon and for cows' milk and chickens' eggs at 30 µg/kg, expressed as parent drug.

The thirteenth Session of the Codex Committee on Residues of Veterinary Drugs in Food (Codex Alimentarius Commission, 2001) commented with regard to information relevant to the intake of deltamethrin from use as a pesticide and veterinary drug. In particular, some concern was suggested regarding the JECFA MRLs and the possible consideration to amend the MRLs (for veterinary drug residues) to accommodate results of the information on intake, particularly with regard to dietary intake from pesticide use and veterinary use.

## NEW INFORMATION

The 2002 meeting of the JMPR evaluated the possible risk associated with the intake of ~~for~~ pesticide residues in food, including those from food animals, using procedures developed in 1999 (JMPR, 2002). Estimates of both, long-term and short term dietary intakes were carried out and expressed as international estimated daily intakes (IEDIs) and international estimate of short-term intake (IESTI). Dietary intakes were calculated by multiplying the concentrations of residue based on supervised trial median residue values (STMRs) with the average daily *per capita* consumption estimated for each commodity on the basis of the WHO Global Environmental Monitoring System (GEMS Food) diet. Long-term dietary intakes were expressed as a percentage of the ADI for a 60 kg person. For dietary intake calculations, JMPR considers that for mammalian animals, 20% of the cattle meat, for example, consumption value-large portion should be considered to contain residues at the concentration amount in fat and that 80% of the meat consumption –large portion would be considered to contain residues at the amount found in meat with trimmable fat removed. For poultry calculations, JMPR use percentages of 10% and 90%, respectively for fat and muscle tissue. This applies to both fat-soluble and non fat-soluble pesticides.. In circumstances when adequate data are not available for theoretical maximum daily intake calculations (for example) the dietary intake calculation would be based on the MRL for meat fat for fat soluble pesticides and the MRL for meat for non-fat soluble pesticides. For deltamethrin, with an ADI of 0-10 µg/kg of body weight, the estimated long-term intake expressed as a percentage of the ADI was ranged between 20-30 percent. The data used for the IEDI (long-term) determination is reprinted below in Table 1 (JMPR, 2002). The following concentration values were used for the estimation of dietary exposure (JMPR, 2002, pp 95ff): fat of cattle: 0.19 mg/kg as the high residue value and 0.16 mg/kg for the supervised trial median residue value; muscle of cattle: 0.027 mg/kg for the high residue level value and 0.01 mg/kg for the STMR. Corresponding residue values for poultry fat were 0.09 mg/kg for the high residue level 0.04 mg/kg for the STMR. The residue values for muscle of poultry were 0.02 mg/kg for both, the high residue level and the STMR. On this basis the percent ADI attributed to the IEDI for meat and poultry is 0-1% depending on the individual GEMS Food diet, while the residues from all sources is no more than 25 percent of the ADI for any of the five regional diets.

For the international estimate of short-term intake (IESTI) in the general population the data are compiled in Table 2. The acute dietary reference dose (RfD) value assigned by JMPR is 0.05 mg/kg body weight. The procedure for calculating the international estimate of short-term dietary intake was first developed by the Geneva Consultation in 1997 and first applied by JMPR in 1999. The calculation for animal commodities was first applied at the 2002 JMPR meeting. For deltamethrin, the IESTI attributed to meat and poultry tissues was 1-2% of the acute RfD. These data are for information only and are not used in estimating dietary exposure ~~of~~ to deltamethrin resulting from the use as a pesticide and a veterinary drug

Table 1. Long-term International Estimated Dietary Intake for Deltamethrin

Commodity	MRL	STMR	Diets: g/person/day. Intake = daily intake: µg/person									
			Mid-East		Far-East		African		Latin American		European	
	mg/kg	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
Apple		0.03	7.5	0.2	4.7	0.1	0.3	0.0	5.5	0.2	40	1.2
Apple juice		0.0027										
Carrot		0.01	2.8	0.0	2.5	0.0	0	0.0	6.3	0.1	22	0.2
Cattle kidney (2)	0.05		0.1	0.0	0	0.0	0.1	0.0	0.2	0.0	0.2	0.0
Cattle liver (2)	0.05		0.2	0.0	0	0.0	0.1	0.0	0.3	0.0	0.4	0.0
Cereal grain (1)		0.7	56.6	39.6	49.2	34.4	160	112.0	54	37.8	38.6	27.0
Citrus fruit		0.01	54.3	0.5	6.3	0.1	5.1	0.1	54.8	0.5	49	0.5
Eggs (2)		0.02	14.6	0.3	13.1	0.3	3.7	0.1	11.9	0.2	37.6	0.8
Flat bread		0.35										
Flowerhead brassicas		0.02	1.8	0.0	2.5	0.1	0	0.0	1.4	0.0	15.7	0.3
Fruiting vegetables. cucurbits		0.02	80.5	1.6	18.2	0.4	0	0.0	30.5	0.6	38.5	0.8
Grapes		0.04	15.8	0.6	1	0.0	0	0.0	1.3	0.1	13.8	0.6
Hazelnut		0.02	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.3	0.0
Leafy vegetables		0.125	7.8	1.0	9.7	1.2	0.0	0.0	16.5	2.1	51.3	6.4
Leek		0.07	0.5	0.0	0.0	0.0	0.0	0.0	0.3	0.0	2.0	0.1
Legume vegetables		0.01	9.5	0.1	1.5	0.0	0.0	0.0	4.3	0.0	26.0	0.3
Maize germ		0.224										
Maize oil		12.6	1.8	22.7	0	0.0	0.3	3.8	0.5	6.3	1.3	16.4
Meat (from mammals other than marine animals) (2)			37		32.8		23.8		47		155.5	
Meat×0.2 (fat)	0.5	0.16	7.4	3.7	6.56	3.3	4.76	2.4	9.4	4.7	31.1	15.6
Meat×0.8 (muscle)	0.03		29.6	0.9	26.24	0.8	19.04	0.6	37.6	1.1	124.4	3.7
Milks (2)	0.05		116.8	5.8	32	1.6	41.8	2.1	160	8.0	294	14.7
Mushrooms		0.02	0.3	0.0	0.5	0.0	0	0.0	0	0.0	4	0.1
Nectarine		0.02	1.25	0.0	0.25	0.0	0	0.0	0.4	0.0	6.25	0.1
Olive oil. crude		0.315	1.5	0.5	0	0.0	0	0.0	0	0.0	7.8	2.5
Olive oil. refined		0.336	1.5	0.5	0	0.0	0	0.0	0	0.0	7.8	2.6
Olives (used preserved)		0.21	1.3	0.3	0	0.0	0	0.0	0.3	0.1	2.8	0.6

Commodity	MRL	STMR	Diets: g/person/day. Intake = daily intake: µg/person									
			Mid-East		Far-East		African		Latin American		European	
	mg/kg	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
Onion. bulb		0.02	23	0.5	11.5	0.2	7.3	0.1	13.8	0.3	27.8	0.6
Peach		0.02	1.25	0.0	0.25	0.0	0	0.0	0.4	0.0	6.25	0.1
Plum (includes prune)		0.05	1.8	0.1	0.5	0.0	0	0.0	0	0.0	4.3	0.2
Potato		0.01	59	0.6	19.2	0.2	20.6	0.2	40.8	0.4	240.8	2.4
Poultry meat (2)			31		13.2		5.5		25.3		53	
Poultry fat (meat×0.1)	0.5	0.04	3.1	1.6	1.32	0.7	0.55	0.3	2.53	1.3	5.3	2.7
Poultry muscle (meat×0.9)	0.03		27.9	0.8	11.88	0.4	4.95	0.1	22.77	0.7	47.7	1.4
Poultry. edible offal (2)	0.05		0.1	0.0	0.1	0.0	0.1	0.0	0.4	0.0	0.4	0.0
Pulses		0.5	24.6	12.3	19.8	9.9	17.8	8.9	23.1	11.6	12.1	6.1
Radish		0.01	0.5	0.0	0	0.0	0	0.0	0.3	0.0	2	0.0
Rice. bran (unprocessed)		1.05										
Rice. husked (brown)		0.105	0	0.0	1.8	0.2	34.7	3.6	21	2.2	2.5	0.3
Rice. polished		0.042	48.8	2.0	277.5	11.7	68.8	2.9	65.5	2.8	9.3	0.4
Salmon (2)	0.03		1.3	0.0	5.3	0.2	4.7	0.1	1.3	0.0	1.5	0.0
Sorghum flour		0.231	2	0.5	9.7	2.2	26.6	6.1	0	0.0	0	0.0
Sorghum starch		0.028										
Steamed bread (Dumplings etc)		0.098										
Strawberry		0.02	0	0.0	0	0.0	0	0.0	0	0.0	5.3	0.1
Sunflower seed		0.05	1	0.1	0	0.0	0.6	0.0	0	0.0	0	0.0
Sweet corn (corn-on-the-cob)		0.02	0	0.0	0	0.0	4.4	0.1	0	0.0	8.3	0.2
Tea. green. black (3)		0.0044	2.3	0.0	1.2	0.0	0.5	0.0	0.5	0.0	2.3	0.0
Tomato		0.02	44.4	0.9	5.72	0.1	14.58	0.3	25.5	0.5	40.4	0.8
Tomato paste		0.002	5.8	0.0	0.2	0.0	0.3	0.0	0	0.0	4	0.0
Tomato puree		0.002										
Walnuts		0.02	0	0.0	0	0.0	0	0.0	0	0.0	0.5	0.0
Wheat bran. unprocessed		2.31										
Wheat flour		0.217										
Wheat germ		0.84	0.1	0.1	0.1	0.1	0	0.0	0.1	0.1	0.1	0.1
Wheat wholemeal		0.637	0.3	0.2	0	0.0	0	0.0	0	0.0	0	0.0

Commodity	MRL	STMR	Diets: g/person/day. Intake = daily intake: µg/person									
			Mid-East		Far-East		African		Latin American		European	
	mg/kg	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
White bread		0.098	215.3	21.1	76	7.4	18.9	1.9	37.3	3.7	117.2	11.5
White noodles		0.091										
Wholemeal bread		0.294	107.7	31.7	38	11.2	9.4	2.8	74.7	22.0	58.6	17.2
Yellow alkaline noodles		0.119										
Total=				151		87		148		107		138
%ADI				25%		16%		25%		18%		23%
Rounded				30%		20%		30%		20%		20%

1. Where residue information were available the consumption of the processed commodities were subtracted for the cereal grain.

2. The 52<sup>nd</sup> JECFA recommended MRLs for cattle, sheep and chickens in fat at 0.5 mg/kg, liver and kidney at 0.05 mg/kg and 0.05 mg/kg for muscle, eggs and milk at 0.03 mg/kg. An MRL was also recommended for salmon at 0.03 mg/kg. As the JECFA recommendations were the same or higher than the JMPR recommended values and they comprised the major commodities consumed in the commodity group meat mammalian, kidney and liver of cattle, goats, pigs and sheep and for poultry for which JMPR recommendations were made, JMPR decided to utilize the recommendations of the 52<sup>nd</sup> JECFA for the purposes of estimating dietary intake.

3. The tea STMR was multiplied by the highest processing factor for tea water (brewed tea) = 2.2×0.002

**Table 2. Deltamethrin International estimate of short-term intake (IESTI) in the general population**

Commodity	STMR or STMR-P, mg/kg	HR, mg/kg	Large portion diet			Unit weight g			Var factor	Case	IESTI, ug/kg bw/day	% acute RfD
			Country	Body weight, kg	Large portion, g	Unit weight g	Country	Edible portion, g				
Apple		0.08	USA	65	1348	138	USA	127	7	2a	2.6	5
Apple juice	0.0027											
Barley	0.7		NLD	63	378					3	4.2	8
Carrot		0.02	NLD	63	336	100	FRA	89	7	2a	0.3	1
Cauliflower		0.04	UK	70.1	579	1733	UK	780	5	2b	1.7	3
Cereal grain (1)												
Chinese cabbage		1.00	USA	65	377	840	USA	798	5	2b	29.0	58
Citrus fruit (2)												
Common beans (pods and or immature seeds)		0.14	NLD	63	431					1	1.0	2
Cucumber		0.02	NLD	65	313	301	USA	286	5	2a	0.4	1
Eggs		0.03	FRA	62,3	219					1	0.1	0

Commodity	STMR or STMR-P, mg/kg	HR, mg/kg	Large portion diet			Unit weight g			Var factor	Case	IESTI, ug/kg bw/day	% acute RfD
			Country	Body weight, kg	Large portion, g	Unit weight g	Country	Edible portion, g				
Flat bread	0.35											
Flowerhead brassicas (3)												
Fruiting vegetables, cucurbits (4)												
Grapes (includes wine)		0.09	AUS	67	1004	125	FRA	118	7	2a	2.3	5
Hazelnut		0.02	AUS	67	70					1	0	0
Kidney of cattle, goats, pigs and sheep (5)		0.05	USA	65	788					1	0.6	1
Leafy vegetables (6)												
Leek		0.1	FRA	62.3	374	100	FRA	50	7	2a	1.4	3
Legume vegetables (7)												
Liver of cattle, goats, pigs and sheep (5)		0.05	USA	65	380					1	0.3	1
Maize germ	0.224											
Maize oil	12.6		NLD	63	43					3	8.6	17
Meat (mammalian) (5)			AUS	67	521							2
meat×0.2 (fat)		0.50	AUS	67	104					1	0.8	
meat×0.8 (muscle)		0.03	AUS	67	417					1	0.2	
Milks (5)	0.03		NLD	63	2515					3	1.2	2
Mushrooms		0.03	FRA	62.3	219					1	0.1	0
Nectarine		0.05	USA	65	590	136	USA	125	7	2a	1.0	2
Olive oil, crude	0.32		FRA	62.3	57					3	0.3	1
Olive oil, refined	0.34											
Olives (used preserved)		0.31	NLD	63	63					1	0.3	1
Onion, bulb		0.03	FRA	62,3	306	140	FRA	126	7	2a	0.5	1
Oranges, sweet		0.01	USA	65	564	131	USA	96	7	2a	0.2	0
Peach		0.05	JAP	52.6	626	122	UK	110	7	2a	1.2	2
Peas, dry												
Plum (includes prune)		0.05	USA	65	413	66	USA	62	7	2a	0.6	1
Potato		0.01	NLD	63	687	122	UK	99	7	2a	0.2	0
Poultry meat (5)			AUS	67	431							1
Poultry fat (meat×0.1)		0.50	AUS	67	43					1	0.3	

[illegible]

Commodity	STMR or STMR-P, mg/kg	HR, mg/kg	Large portion diet			Unit weight g			Var factor	Case	IESTI, ug/kg bw/day	% acute RfD
			Country	Body weight, kg	Large portion, g	Unit weight g	Country	Edible portion, g				
											IESTI =	

1. The cereal grain commodity with the highest consumption listed was for barley.
2. Calculations were conducted for both the commodity with the highest consumption (oranges) and the commodity with the highest unit weight (grapefruit).
3. See cauliflower
4. Calculations were conducted for both the commodity with the highest consumption (cucumber) and the commodity with the highest unit weight (pumpkin and watermelon).
5. The 52<sup>nd</sup> JECFA recommended MRLs for cattle, sheep and chickens in fat at 0.5 mg/kg, liver and kidney at 0.05 mg/kg and muscle, eggs and milk at 0.03 mg/kg. An MRL was also recommended for salmon at 0.03 mg/kg. As the JECFA recommendations were the same or higher than those of JMPR, and they comprised the major commodities consumed in the commodity groups, meat mammalian, kidney and liver of cattle, goats, pigs and sheep and for poultry for which recommendations were made, the JMPR decided to utilize recommendations of the 52<sup>nd</sup> JECFA for the purposes of estimating dietary intake.
6. Calculations were conducted for both the commodity with the highest consumption (spinach) and the commodity with the highest unit weight (Chinese cabbage).
7. The legume vegetable commodity with the highest consumption listed was Common beans.
8. The pulse commodity with the highest consumption was dry peas.
9. The tea STMR was multiplied by the highest processing factor for tea water (brewed tea) =  $2.2 \times 0.002$ .



## APPRAISAL

The ADI for deltamethrin is 0-10 µg per kg of body weight, equivalent to 600 µg for a 60 kg person. The data in Table 1 indicate that long term exposure of deltamethrin, using the current approach for estimating pesticide exposure by JMPR (i.e., using supervised trial median residue values) and using the five regional GEMS Food data base food consumption values, residue exposure does not exceed 25 percent of the ADI (ca. 150 µg). While not a component of the estimated dietary exposure of deltamethrin, the exposure of deltamethrin in acute, short term exposure (Table 2) accounts cumulatively to about seven percent of the ADI (ca. 42 µg) from all animal sources of deltamethrin residues (including milk which accounted for about 2%).

The 52<sup>nd</sup> Meeting of this Committee took account of the previous evaluations of deltamethrin by JMPR and, based on 1) the Committee theoretical daily intake values of 300g of muscle, 100g of liver, 50g of kidney and fat, 1.5 kg of milk and 100g of eggs, and 2) that the marker residue accounted for 4% of the total residues in liver, 3% of the total residues in kidney and 60 percent of the total residues in fat, the most conservative estimate of theoretical maximum daily intake of residues from veterinary drug use would be 250 µg as deltamethrin equivalents. The 250 µg value does not include the recommended guidance MRLs from the 52<sup>nd</sup> meeting of the Committee for muscle, milk and eggs. Using the guidance MRLs for muscle tissue and milk would add 108 µg of theoretical residues of deltamethrin. There is no information on eggs because residues are well below the limit of quantitation of the method.

The theoretical maximum intake from veterinary use from all food producing animals and animal products has an upper limit of 250 µg (including the guidance MRL this value would be 358 µg). The sum of theoretical deltamethrin residues from veterinary use and from secondary exposure is no more than 400 µg. This is equivalent to approximately 67 percent of the ADI (under the more conservative scenario which includes the guidance MRL it would be 85 percent of the ADI).

On this basis the committee affirmed the recommended MRLs from the 52<sup>nd</sup> meeting of the Committee for deltamethrin MRLs in food producing animals and that CCRVDF should be advised accordingly.

## REFERENCES

**Codex Alimentarius Commission** (2001). 13<sup>th</sup> Report of the Codex Committee on Residues of Veterinary Drugs in Food, ALINORM 03/31, Rome

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