

Example of a Codex-based Import MRL Request - FENHEXAMID

This hydroxylanilide fungicide is approved for use against Botrytis (bunch rot) in grapes in a number of exporting economies in Asia, Europe, North America and the Pacific.

To facilitate trade in fresh grapes, dried grapes, grape juice and wine within the APEC community, an Import MRL is being requested for grapes. In addition, in economies where residues in dried commodities are not covered by the MRLs for the RAC (e.g. by correction for moisture loss), an Import MRL for dried grapes is also requested. The requested MRLs (higher than currently adopted in several economies) are at the same level as the Codex MRLs and references to the relevant JMPR evaluation reports are provided as supporting information.

Pesticide name (ISO)	Fenhexamid	
<i>IUPAC</i>	<i>2',3'-dichloro-4'-hydroxy-1-methylcyclohexanecarboxanilide</i>	
<i>CAS No.</i>	126833-17-8	
<i>Residue definitions</i>		<i>Source</i>
<i>For compliance with MRLs</i>	<i>Fenhexamid</i>	<i>JMPR 2005</i>
<i>For estimation of dietary intake</i>	<i>Fenhexamid</i>	<i>JMPR 2005</i>
Health based guidance values		
ADI	0-0.02 mg/kg bw	JMPR 2005
ARfD	Not necessary	JMPR 2005

Authorised GAP	Foliar sprays: max 2 × 0.05 kg ai/hL (high volume) or 0.25 kg ai/hL (low volume) Pre Harvest Interval: 21 days		
Name of the requested commodity or group	Grapes Dried grapes (if not covered by the RAC MRL)		
Commodity to be imported, including any processed commodities	FB 1235	Table grapes	
	FB 1263	Wine grapes (wine)	
	DF 269	Dried grapes	
	JF 269	Grape juice	
Requested MRLs	FB 269	Grapes	15 mg/kg
	DF 269	Dried grapes	25 mg/kg
Origin/source of the requested MRL	Codex (CAC 2006)		
<i>Residue Summary</i>			
<i>Supervised Trial Median Residue (STMR)</i>	<i>Grapes</i>	<i>4.3 mg/kg</i>	
	<i>Wine</i>	<i>1.2 mg/kg (processing factor of 0.28)</i>	
	<i>Dried grapes</i>	<i>8.0 mg/kg (processing factor of 1.86)</i>	
	<i>Grape juice</i>	<i>2.2 mg/kg ((processing factor of 0.51)</i>	
<i>Highest Residue (HR)</i>	<i>Grapes</i>	<i>11 mg/kg</i>	
	<i>Dried grapes</i>	<i>20 mg/kg (processing factor of 1.86)</i>	

Pesticide name (ISO)	Fenhexamid		
<i>Link to the source of the HR, STMR data</i>	http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Evaluation05/2005_Fenhexamid1.pdf		
<i>Reference link/s to published MRL in Codex or by alternative source other than Codex (if available)</i>	http://www.fao.org/fao-who-codexalimentarius/standards/pestres/search/en/		
<i>Current status for this MRL in other jurisdictions</i>	Australia	Grapes	10.0 mg/kg
		Dried grapes	20.0 mg/kg
	Canada	Grapes	4.0 mg/kg
	EU	Grapes	15.0 mg/kg
	Japan	Grapes	20.0 mg/kg
	Korea (Republic)	Grapes	3.0 mg/kg
	USA	Grapes	4.0 mg/kg
		Dried grapes	6.0 mg/kg

Dietary Exposure Assessments

Based on the information outlined above the following estimates of long-term dietary exposure have been calculated. Short-term exposure estimates have not been calculated as an Acute RfD is not considered necessary.

Commodities included in these estimates are table grapes, dried grapes, grape juice and wine. These have been calculated using the GEMS/Food Cluster Diets (2012) and the chronic exposure evaluation template published on the WHO website: http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/

Long-term dietary exposure assessment

FENHEXAMID		International Estimated Daily Intake (IEDI)				ADI = 0-0.02 mg/kg bw	
Commodity description	Expr as	STMR mg/kg	G09 diet	G09 intake	G10 diet	G10 intake	
Grape, raw	RAC	4.3	5.21	22.40	9.38	40.33	
Grape, dried (= currants, raisins and sultanas)	PP	8	0.10	0.80	1.38	11.04	
Grape juice	RAC	2.2	0.10	0.22	2.24	4.93	
Grape wine (incl vermouths)	RAC	1.2	1.84	2.21	25.07	30.08	
Total intake (µg/person)=			125.6		86.4		

Attachment 2

FENHEXAMID		International Estimated Daily Intake (IEDI)				ADI = 0-0.02 mg/kg bw	
Commodity description	Expr as	STM mg/kg	G09 diet	G09 intake	G10 diet	G10 intake	
Bodyweight per region (kg bw) =				55		60	
ADI (µg/person)=				11000		12000	
%ADI=				0.2%		0.7%	
Rounded %ADI=				0%		1%	
Group 9:	Bangladesh, Cambodia, China, DPR Korea, Guinea Bissau, Indonesia, Loa, Myanmar, Nepal, Philippines, Sierra Leone, Thailand, Timor Leste, Viet Nam.						
Group 10	Belarus, Bulgaria, Canada, Croatia, Cyprus, Estonia, Italy, Japan, Latvia, Malta, New Zealand, Republic of Korea, Russian Federation, USA						

Based on the above cluster diets and the IEDI for fenhexamid, the added dietary contribution of residues for grape commodities (table grapes, dried grapes, grape juice and wine) is not more than 1% of the acceptable daily intake.