

Example of a Codex-based Import MRL Request - SULFOXAFLO

This sulfoximine insecticide is approved for use against a number of sap-feeding insect pests in grapes in a number of exporting economies, including Australia, Canada and USA.

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 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)		Sulfoxaflor	
IUPAC	<i>[methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ6-sulfanylidene]cyanamide</i>		
CAS No.	946578-00-3		
Residue definitions		Source	
For compliance with MRLs	Sulfoxaflor	JMPR 2011	
For estimation of dietary intake	Sulfoxaflor	JMPR 2011	
Health based guidance values			
ADI	0-0.05 mg/kg bw	JMPR 2011	
ARfD	0.3 mg/kg bw	JMPR 2011	

Authorised GAP	Foliar sprays: Max 4 × 0.1 kg ai/ha Pre Harvest Interval: 7 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	2.0 mg/kg
	DF 269	Dried grapes	6.0 mg/kg
Origin/source of the requested MRL	Codex (CAC 2013)		
<i>Residue Summary</i>			
<i>Supervised Trial Median Residue (STMR)</i>	<i>Grapes</i>	<i>0.14 mg/kg</i>	
	<i>Wine</i>	<i>0.098 mg/kg (processing factor of 0.7)</i>	
	<i>Dried grapes</i>	<i>0.49 mg/kg (processing factor of 3.5)</i>	
	<i>Grape juice</i>	<i>0.098 mg/kg ((processing factor of 0.7)</i>	

Pesticide name (ISO)	Sulfoxaflor		
Highest Residue (HR)	Grapes		1.6 mg/kg
	Dried grapes		5.6 mg/kg (processing factor of 3.5)
Link to the source of the HR, STMR data	http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Report11/Sulfoxaflor.pdf		
Reference link/s to published MRL in Codex or by alternative source other than Codex (if available)	http://www.fao.org/fao-who-codexalimentarius/standards/pestres/search/en/		
Current status for this MRL in other jurisdictions	Australia	Table grapes	3.0 mg/kg
		Dried grapes	10.0 mg/kg
	Canada	Grapes	2.0 mg/kg
	EU	Table grapes	2.0 mg/kg
	Korea (Republic)	Grapes	1.0 mg/kg
	USA	Grapes	2.0 mg/kg
		Dried grapes	6.0 mg/kg

Dietary Exposure Assessments

Based on the information outlined above the following estimates of dietary exposure have been calculated. 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 acute and chronic exposure evaluation templates published on the WHO website:

http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/

Short-term dietary exposure assessment

SULFOXAFLOR (252)							IESTI ^(b)				
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)							Maximum %ARfD:				
							40% all	20% gen pop	40% child		
Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Group	n	Large portion g/person	Unit weight g edible portion	IESTI µg/kg bw/day	% acute RfD	% acute RfD	% acute RfD
Grapes ^(a)	0.098 - 0.49	1.6 - 5.6	China	Child 1-6 yrs	232	366.72	636.6	1.89 - 109.09	1% - 40%	1% - 20%	0% - 40%

(a) All commodities

(b) Variability factor of 3 and case 3 calculation type for wine and juice

The NESTI for all grape commodities (table grapes, dried grapes, grape juice and wine) is less than 40% of the acute reference dose in the most sensitive population (1-6 year old children, from the consumption of fresh grapes).

Attachment 1

Long-term dietary exposure assessment

SULFOXAFLO		International Estimated Daily Intake (IEDI)			ADI = 0-0.05 mg/kg bw		
Commodity description	Expr as	STMR mg/kg	G09 diet	G09 intake	G10 diet	G10 intake	
Grape, raw	RAC	0.14	5.21	0.73	9.38	1.31	
Grape, dried (= currants, raisins and sultanas)	PP	0.49	0.10	0.05	1.38	0.68	
Grape juice	RAC	0.098	0.10	0.01	2.24	0.22	
Grape wine (incl vermouths)	RAC	0.098	1.84	0.18	25.07	2.46	

Total intake (µg/person)= 1.0 4.7

Bodyweight per region (kg bw) = 55 60

ADI (µg/person)= 2750 3000

%ADI= 0.0% 0.2%

Rounded %ADI= 0% 0%

- 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 sulfoxaflor, the added dietary contribution of residues for grape commodities (table grapes, dried grapes, grape juice and wine) is not more than 0.2% of the acceptable daily intake.