

Fluazinam (dietary risk profile) LRH 5-16-16 (updated)

The proposed 24c for Omega 500 is for an in-furrow use of fluazinam for potatoes to control Powdery Scab. The review of this 24c request resulted in a concern regarding residues. This concern relates to the fact that the residue study discussed by ISK Biosciences was for foliar application of Omega 500 rather than an in-furrow use. The only soil incorporation use on the section 3 label is for brassicas and the only tuber commodity included there is for turnip greens (Brassica (Cole) Leafy Vegetables (Crop Group 5), plus Turnip Greens (in Crop Group 2). There is a prohibition for use of turnip roots: “Turnip roots from turnip plants treated with Omega 500F must not be used for human or livestock consumption” (Syngenta 2013a)

Dietary Risk Assessment for Fluazinam (EPA 2016a)						
Subpopulation	mg/kg/day			LOC		% PAD ⁽⁶⁾
	NOAEL ⁽¹⁾	RfD ⁽²⁾	PAD ⁽³⁾	FQPA SF ⁽⁴⁾	UF ⁽⁵⁾	
Acute						
General population	50	0.5	0.5	1X	100	22
Females 13 to 49 (4)	7	0.07	0.07	1X	100	32
Chronic						
Infants	1.1	0.011	0.011	1X	100	92
General population	1.1	0.011	0.011	1X	100	41

- 1) NOAEL = No Observable Adverse Effect Level
- 2) RfD = reference dose = the NOAEL/UF
- 3) PAD = population adjusted dose= RfD/FQPA SF
- 4) FQPA SF = Food Quality Protection Act Safety Factor, used when there is an increase in sensitivity in the developing fetus and the study used for risk assessment for females of childbearing age is not a reproductive study, the current study used for the risk assessment for females of childbearing age is a developmental study.
- 5) UF = Uncertainty Factors, factor of 10 for extrapolating from rats to humans, factor of 10 for variability in the human population
- 6) % PAD is the percentage of the population adjusted dose used by current Section 3 labeled uses

“Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential” (EPA 2001b, EPA 2014e)

- Increase in thyroid follicular cell tumors in male rats (EPA 2001b)
- Increase in hepatocellular tumors in male mice (EPA 2001b)

“It is a non-systemic, preventive, contact fungicide with a multi-site mode of action. When applied to plants, it remains primarily on the plant surface, it is not taken up to any extent by the plant, and it is not translocated within the plant. Fluazinam operates by disrupting the production of energy at several metabolic sites within the fungal cell.” (EPA 2015ac)

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Disappearance time 50% (DT50) is \leq 30 days in sandy loam soil (EPA 2009ab), the calculated half-life 114 to 132 days.

30 day plant-back restriction for commodities not on the current label (Syngenta 2013a).

Cited as	References
EPA 2008y	EPA 2008y, Fluazinam. Human Health Risk Assessment to Address Requests for Label Amendments Adding Aerial Application of the Fungicide on Potatoes, and Reducing the Plant-Back Interval (PBI) for All Non-Label Crops from 70 to 30 Days Following Use of the Fungicide
EPA 2009ab	EPA 2009ab, Problem Formulation, for Ecological Risk Assessment, for Fluazinam
EPA 2014e	EPA 2014e, Chemicals Evaluated for Carcinogenic Potential, Office of Pesticides Programs 2014
EPA 2016a	EPA 2016a, Fluazinam. Human Health Risk Assessment to Support Section 3 Registration for New Uses on Tuberous and Corm, Subgroup IC, Mayhaw, Squash/Cucumber Subgroup 9B; Amended Uses on Cabbage.
EPA 2015bc	EPA 2015bc, Fluazinam. Petition for the Establishment of Permanent Tolerances and Registration for New Uses on Tuberous and Corm, Subgroup 1 C, Mayhaw, Squash/Cucumber Subgroup 9B; Amended Uses on Cabbage; and Removal of Cabbage from Vegetable, <i>Brassica</i> leafy, group 5. Summary of Analytical Chemistry and Residue Data
Syngenta 2013a	Syngenta 2013a, Omega 500 F, EPA# 71512-1-100 containing 40% Fluazinam (4.19 lbs ai/gal), specimen label