



4-29-93

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 93NC0003. Section 18 Exemption for Use of Iprodione on Apples. DRES Dietary Exposure/Risk Estimates.

FROM: Richard Griffin *Richard Griffin* 4/29/93
Chemistry Branch I / Tolerance Support
Health Effects Division (H7509C)

THROUGH: Debra Edwards, Chief *Debra Edwards*
CBTS, Health Effects Division 4/29/93

TO: Susan Stanton, PM 41
Emergency Use and Minor Uses Section
Registration Support Branch

Toxicological endpoints for chronic risk assessment:

- o RfD: The Iprodione reference dose is 0.04 mg/kg/day based on the NOEL of a one-year dog study and an uncertainty factor of 100.
- o Carcinogenicity: Preliminary results submitted under 6(a)2 of FIFRA indicate a dose-related incidence of malignant tumors in mice and rats following dietary administration of Iprodione. Review of the studies has been given a high priority and will be followed by a meeting of the HED cancer Peer Review Committee. A preliminary upper-bound potency factor (Q_1^*) of 0.11 (mg/kg/day), based on the rat data, is used for this assessment.

Residue:

Tolerance level residues of 40 CFR 180.399 and 40 CFR 185.3750 are used to assess most commodities except anticipated residues, based on field trial data, have been estimated for grapes, strawberries, stonefruits, and milk (J. Smith memo, 5/24/89).

CBTS (Donna S. Davis memo, 4/26/93) has recommended an enforcement level of 2.0 ppm for apples.

Based on the grape processing study, DRES default concentration factors for apple, grape, and cherry juice are turned off.



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Percent use:

Exposure estimates are factored by percent use estimates for grapes, stonefruits, lettuce, and carrots (J. Ferrante memo, 3/15/89). All other commodities, including apples, are evaluated at 100 percent.

Exposure/risk estimates:

Published uses: Tolerance x 100 percent use: (TMRC)

mg/kg/day

Overall U.S. population:	0.046097	(115% RfD)
Non-nursing infants:	0.141870	(355% RfD)
Children (1-6):	0.106572	(266% RfD)

Published uses: with limited anticipated residue and percent use estimates: (ARC)

Overall U.S. population:	0.013281	(33% RfD)	(1.5E-3 C risk)
Non-nursing infants:	0.044402	(111% RfD)	
Children (1-6):	0.026858	(67% RfD)	8.0E4

Apples: 2.0ppm x 100% (TMRC)

Overall U.S. population:	0.001360	(3% RfD)	(1.5E-4 C risk)
Non-nursing infants:	0.012636	(32% RfD)	
Children (1-6):	0.004448	(11% RfD)	8.2E5

cc: 18 file, RF, R. Griffin file