

Julie Henderson Director

MEMORANDUM

Jared Blumenfeld Secretary for Environmental Protection

- TO: Minh Pham Environmental Program Manager II Environmental Monitoring Branch
 VIA: Shelley DuTeaux, PhD MPH, Chief Human Health Assessment Branch
- FROM: Chunbo Zhang, PhD, Associate Toxicologist Pete Lohstroh, PhD, Senior Toxicologist Toxicology and Dose Response Assessment Section

Svetlana Koshlukova, PhD, Senior Toxicologist Risk Assessment Section

DATE: May 16, 2022

SUBJECT: RISKS FROM HUMAN EXPOSURE TO METHOXYFENOZIDE RESIDUES IN GROUNDWATER

On January 12, 2022, the Department of Pesticide Regulation's (DPR) Human Health Assessment (HHA) Branch was notified by the Environmental Monitoring Branch (EMB) that the United States Geological Survey (USGS) reported detections of methoxyfenozide in California's groundwater at or above the method detection limit (MDL) of 0.002 parts per billion (ppb) in eight wells, with the highest reported detection being 0.286 ppb. DPR's Groundwater Protection Program (GWPP) conducted follow-up monitoring and detected methoxyfenozide in four wells that exceeded the MDL (0.006 ppb). The maximum detected concentration was 0.201 ppb. EM requested that HHA determine if there is a health concern for individuals using these wells as a source of drinking water (see the request, Appendix 1). This memorandum is in response to that request.

Conclusions and Recommendations:

 HHA evaluated the human health risk from exposure to methoxyfenozide in California well water using (1) acute and chronic dietary exposure estimates based on consumption rates for drinking water from the National Health and Nutrition Examination Survey (NHANES) 2005-2010 database and (2) toxicological endpoints established by United States Environmental Protection Agency (US EPA) for chronic exposure and by European Food Safety Authority (EFSA) for acute exposure.

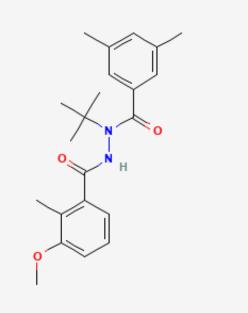
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- 2. The results indicate that the detected methoxyfenozide concentrations in California well water, including the highest residue (0.201 ppb) measured by DPR, do not pose either an acute or chronic health risk to humans.
- 3. HHA also calculated a human health reference level (HHRL) of 504 ppb to be used as a screening level for methoxyfenozide residues. Residues measured in groundwater exceeding this reference level should be sent to HHA for further evaluation.
- 4. Based on comparison to the DPR HHRL (504 ppb), the highest detected residue level of methoxyfenozide reported by USGS in California groundwater (0.286 ppb) does not pose either an acute or chronic health risk to humans.

Background

Technical Name: Methoxyfenozide

Chemical Name: N'-tert-butyl-N'-(3,5-dimethylbenzoyl)-3-methoxy-2-methylbenzohydrazide 3-methoxy-2-methylbenzoic acid 2-[3,5-dimethylbenzoyl]-2-[1,1-dimethylethyl] hydrazide Chemical Abstracts Service Registry Number (CAS): 161050-58-4 (NIH, 2022) Chemical Structure:



Methoxyfenozide is a bis-diacylhydrazine insecticide that acts as an insect growth regulator. It mimics the action of the insect molting hormone 20-hydroxyecdysone by inducing precocious incomplete molts in invertebrates, which ultimately results in their death (US EPA, 2007; US EPA, 2018). It is used for control of lepidopterous insects on a variety of agricultural crops (US EPA, 2015). Formulated products containing methoxyfenozide are registered federally and in

California. In 2018, 0.6 million pounds of methoxyfenozide were used in 40,000 California agricultural applications (DPR, 2018).

Methoxyfenozide is not included on the Proposition 65 (the California Safe Drinking Water and Toxic Enforcement Act of 1986) list of chemicals known to cause cancer, reproductive toxicity, or developmental toxicity (OEHHA, 2022).

Regulatory Document Review

A review of pertinent regulatory documents was performed to ensure that the most scientifically supportable toxicological data were used for this evaluation (summarized in Table 1, below). A comprehensive systematic review was beyond the scope of the request.

Regulatory Agency	Year	Title	Reference(s)
DPR	2000	Summary of Toxicology Data; Methoxyfenozide	(DPR, 2000)
US EPA	2007	Ecological Risk Assessment for the Methoxyfenozide Section 3 New Uses (Variety of Uses)	(US EPA, 2007)
DPR	2009	Guidance for Dietary Exposure Assessment	(DPR, 2009)
US EPA	2014	Dietary Exposure Evaluation Model User's Guide	(US EPA, 2014a)
US EPA	2014	Methoxyfenozide. Revised Human Health Risk Assessment to Support Proposed New Section 3 Use on Pineapple	(US EPA, 2014b)
US EPA	2015	Methoxyfenozide. Human Health Draft Risk Assessment for Registration Review and New Use Risk Assessment to Support the Registration of Proposed Use on Chives, and Crop Group Expansions for Stone Fruit and Tree Nuts	(US EPA, 2015)
EFSA	2017	Peer Review of the Pesticide Risk Assessment of the Active Substance Methoxyfenozide	(EFSA, 2017)
DPR	2018	2018 Annual Statewide Pesticide Use Report Chemical Totals.	(DPR, 2018)
US EPA	2018	Methoxyfenozide. Human Health Risk Assessment to Support the Proposed Establishment of a Tolerance (without Section 3 Registration) on Imported Tea	(US EPA, 2018)
EFSA	2020	Focused Assessment of Certain Existing MRLs of Concern for Methoxyfenozide	(EFSA, 2020)
DPR	2022	California Code of Regulations (Title 3. Food and Agriculture) Division 6. Pesticides and Pest Control Operations	(DPR, 2022a)
DPR	2022	California Pesticide Illness Query (CalPIQ)	(DPR, 2022b)
OEHHA	2022	The Proposition 65 List	(OEHHA, 2022)
US EPA	2022	Human Health Benchmarks for Pesticides (HHBPs), Methoxyfenozide	(US EPA, 2022)

Table 1. A list of reviewed regulatory documents

Summary of Toxicology

Methoxyfenozide was placed in Toxicity Category IV for acute oral and inhalation toxicity¹ based on its median lethal oral and inhalation doses ($LD_{50} > 5000 \text{ mg/kg}$ and $LC_{50} > 4.3 \text{ mg/L}$, respectively) in rats and mice. It is a Category III dermal toxicant based on its median lethal dermal dose in rats ($LD_{50} > 2000 \text{ mg/kg}$) and a Category IV skin and eye irritant (US EPA, 2015). Methoxyfenozide is not a skin sensitizer. US EPA classified methoxyfenozide as "Not likely to be Carcinogenic to Humans" and concluded that "quantifications of acute dietary and human cancer risks are not required" (US EPA, 2018). In the available database, methoxyfenozide did not show reproductive, developmental, or neurotoxic effects in laboratory animals (US EPA, 2015).

Results from short-term toxicity studies in dogs and rats showed that the targets of toxicity were the liver and the haemopoietic system. In longer term studies in dogs, the target organs were the liver, thyroid gland, and the haemopoietic system (EFSA, 2017). Reports from the DPR's Pesticide Illness Surveillance Program (PISP) showed that there were 74 cases involving exposure to methoxyfenozide alone or in combination with other active ingredients from 1992 to 2018 (DPR, 2022b). Two cases reported exposure to only methoxyfenozide. One of them showed serious symptoms including coughing, tightness of nose and throat, difficulty breathing, and nausea. Two weeks following the exposure, wheezing throughout lungs was recorded. Twelve days later, red nose & throat with white discharge were noted.

Although HHA have evaluated all required toxicity data submitted as part of registration in California, HHA have not conducted a human health risk assessment for methoxyfenozide. For purposes of this evaluation, HHA adopted the critical acute point of departure (POD) established by EFSA (EFSA, 2017). The acute POD was a no observed adverse effect level (NOAEL) of 9.8 mg/kg/day based on hematological changes at the lowest observed adverse effect level (LOAEL) (106 mg/kg/day) in a 1-year dietary toxicity study in dogs (DPR, 2000; EFSA, 2017). The NOAEL was divided by a total uncertainty factor (UF_{TOTAL}) of 100 to calculate an acute reference dose (aRfD²) of 0.1 mg/kg/day (EFSA, 2017). The UF_{TOTAL} includes 10x for interspecies extrapolation (UF_A) and 10x for intraspecies variation (UF_H) (EFSA, 2017). HHA

¹ Acute Toxicity Categories. US EPA Label Review Manual Chapter 7: Precautionary Statements. US Environmental Protection Agency, Office of Pesticide Programs, Registration Division. Revised March 2018. https://www.epa.gov/sites/production/files/2018-04/documents/chap-07-mar-2018.pdf

² An RfD is an estimate of a daily oral exposure for specific duration (acute or chronic) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime (US EPA, 2011).

also uses the EFSA aRfD for methoxyfenozide for evaluating risk from illegal residues on fresh produce for the California Pesticide Residue Monitoring Program.

The chronic POD was a NOAEL of 10.2 mg/kg/day based on observed hematological effects at the LOAEL in a 24-month chronic toxicity/carcinogenicity study in rats (411 mg/kg/day) (DPR, 2000; US EPA, 2018). The chronic POD was considered to be co-critical with a NOAEL of 9.8 mg/kg/day based on hematological and clinical chemistry effects at the LOAEL of 106.1 mg/kg/day in a 1-year chronic toxicity study in dogs (US EPA, 2018). The chronic RfD (cRfD) of 0.1 mg/kg/day (all populations) was calculated by dividing the NOAEL by the UF_{TOTAL} of 100 (10x each for interspecies and intraspecies extrapolation). US EPA assigned a Food Quality Protection Act (FQPA) Safety Factor of 1 based on completeness of database, lack of evidence for increased susceptibility of developing fetus or offspring, lack of neurotoxicity, and the conservative nature of the exposure assessment (US EPA, 2015).

Risk Evaluation of Methoxyfenozide Residues in Well Water

Groundwater Exposure Analysis

HHA estimated the acute and chronic exposures to methoxyfenozide in drinking water using the Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID, version 4.02, 05-10-c) and the What We Eat in America (WWEIA) database (see DEEM-FCID outputs, Appendices 2 and 3). WWEIA is the dietary intake interview component of the National Health and Nutrition Examination Survey (NHANES). It is a collection of two-day dietary survey data (including drinking water consumption) from 2005 to 2010 for the US population and select subgroups (US EPA, 2014a). HHA use the 95th percentile of the exposure levels for each population subgroup as the default upper bound for acute exposures, while two-day nonconsecutive food intake is used as a surrogate for chronic consumption patterns (DPR, 2009). The maximum detected level of methoxyfenozide in well water (0.201 ppb) was used for both the acute and chronic analyses.

The acute POD of 9.8 mg/kg/day, based on a 1-year dietary toxicity study in dogs, was used to calculate the acute risk (DPR, 2000; EFSA, 2017). The exposure estimates were calculated for general US population and for sensitive subpopulations including infants, children aged 1 - 2, and women of childbearing age (13 – 49 years old). The chronic POD of 10.2 mg/kg/day from a combined chronic toxicity/carcinogenicity study in rats was used to evaluate chronic risk in the same manner (DPR, 2000; US EPA, 2018).

The margin of exposure (MOE) is a quantitative tool used by HHA to determine the potential risk arising from exposure to a pesticide. An MOE is defined as the ratio of the POD to the anticipated human exposure. The resulting value is compared to target MOE. Values at or above

the target MOE are generally considered as having no health concern. The target MOE for both acute and chronic risk was equivalent to the UF_{TOTAL} of 100. A calculated MOE lower than the target (100) would indicate a potential health concern.

- <u>Acute Exposure:</u> At the 95th exposure percentile, the estimated acute exposures to methoxyfenozide ranged from 0.009 µg/kg/day for several populations, to 0.039 µg/kg/day for non-nursing infants.
- <u>Chronic Exposure</u>: Estimates for chronic exposure to methoxyfenozide residues in drinking water ranged from 0.003 µg/kg/day for several populations to 0.020 µg/kg/day for non-nursing infants.
- <u>Acute Risk:</u> Acute MOEs at the 95th percentile exposure were greater than 250,000 for all population subgroups, thereby exceeding the target MOE of 100 and indicating no risk.
- <u>Chronic Risk:</u> Chronic MOEs were greater than 500,000 for all population subgroups, thereby exceeding the target MOE of 100 and indicating no risk.

Calculation of DPR Human Health Reference Levels for Methoxyfenozide

HHA calculated acute and chronic screening levels (human health reference levels or HHRLs) and selected the lower of the two values (the acute HHRL of 504 ppb) to be used by EM as a guide when methoxyfenozide residues are detected in groundwater. This HHRL should be used for screening maximum detected residue levels in groundwater.

An HHRL is the threshold pesticide residue for a maximum water intake that results in the maximum safe oral exposure. The reference levels were calculated using the acute and chronic RfDs for methoxyfenozide as the maximum safe exposure and the acute (95^{th} percentile) and chronic (mean) drinking water intake rates for non-nursing infants as the maximum water intake (see Appendices 2 and 3). Non-nursing infants are the population identified as having the highest consumption of drinking water among the standard populations that HHA evaluate, including the general US population and sensitive subpopulations such as infants, children aged 1-2, and women of childbearing age (13 - 49 years old). The water consumption rates were from the NHANES/WWEIA dietary survey as mentioned above.

The HHRLs for methoxyfenozide in drinking water are summarized below (Table 2). The lowest reference value (the acute level at 504 ppb) was selected as the HHRL for methoxyfenozide residues in groundwater (Table 2). For comparison, US EPA issued a chronic Human Health

Benchmarks for Pesticides (HHBP) for methoxyfenozide at 600 ppb for the general population (US EPA, 2022).

Duration	Residue Level (ppb)	Subpopulation with Highest Water Intake per Bodyweight	Exposure Estimate	Calculated MOEª	Target MOE ^b	DPR HHRL° (ppb)
Acute	0.201	Non-Nursing Infants	95 th Percentile	250,589	100	504
Chronic	0.201	Non-Nursing Infants	Average	509,713	100	1025

Table 2. Acute and o	chronic reference	e levels for methox	vfenozide in	drinking water
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a) MOE (Margin of Exposure) for non-nursing infants.

b) Target MOE is equal to the total uncertainty factors (UF_{TOTAL}) of 100 that accounts for interspecies sensitivity (10x) and intraspecies variability (10x).

c) The Human Health Reference Level (HHRL) is the Residue Level (pesticide concentration) that will result in an MOE at the Target MOE; HHRL (ppb) = (DEEM MOE/Target MOE) x (Residue Level at DEEM MOE (ppb). The HHRL recommended for evaluating corresponding residues in drinking water is bolded.

Conclusions

- 1. The detected methoxyfenozide residues in California well water ranging from 0.006 to 0.201 ppb should not be considered an acute or chronic health concern to residents that use the well for drinking water.
- 2. We recommend that methoxyfenozide detections in California wells be compared to a reference level of 504 ppb. Detected residues higher than this level should be sent to HHA for further evaluation.
- 3. Based on comparison to the DPR HHRL (504 ppb), the highest detected residue level of methoxyfenozide reported by USGS in California groundwater (0.286 ppb) does not pose an acute or chronic health risk to humans.

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- US EPA 2018. Methoxyfenozide. Human Health Risk Assessment to Support the Proposed Establishment of a Tolerance (without Section 3 Registration) on Imported Tea. ttps://www.regulations.gov/search?filter=EPA-HQ-OPP-2017-0494-0007.
- US EPA 2022. Human Health Benchmarks for Pesticides (HHBPs), Methoxyfenozide. Retrived Februrary 11, 2022 from <u>https://ordspub.epa.gov/ords/pesticides/f?p=HHBP:home</u>.

Appendices

Appendix 1. DPR Memo: Potential Health Effects of Methoxyfenozide in Groundwater 12 January 2022 (1 page)

STIL SUDIE	Department of Pes	Gavin Newsom Governor				
Julie Henderson Director						
TO:	Shelley DuTeaux Environmental Program Manager II Human Health Assessment Branch					
VIA:	Minh Pham Environmental Program Manager II Environmental Monitoring Branch	Original Signed by 1/12/22				
FROM:	Joy Dias Environmental Program Manager I Environmental Monitoring Branch	Original Signed by 1/12/22				
DATE:	January 12, 2022					

SUBJECT: POTENTIAL HEALTH EFFECTS OF METHOXYFENOZIDE IN GROUNDWATER

The Environmental Monitoring Branch (EMB) monitors the environment to determine the fate of pesticides, protecting the public and the environment from pesticide contamination through analyzing hazards and developing pollution prevention strategies. The Groundwater Protection Program (GWPP) gathers data from all public agencies that report groundwater monitoring data of pesticides and compiles the data into the Well Inventory Database (WIDB).

The United States Geological Survey (USGS) has reported detections of methoxyfenozide in California's groundwater at or above the method detection limit (MDL) of 0.002 parts per billion (ppb) in eight wells. The highest reported detection was 0.286 ppb. Consistent with EMB's mission, the GWPP requested method development of and conducted follow-up monitoring for methoxyfenozide due to the reported detections. To date, the GWPP has detected methoxyfenozide in four wells above the MDL of 0.00628 ppb. The highest concentration detected by GWPP was 0.201 ppb.

EMB requests the assistance of the Human Health Assessment Branch in determining whether these detections pose a significant risk to human health.

cc: Carissa Ganapathy, Senior Environmental Scientist (Supervisory)

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Appendix 2. Acute Drinking Water Exposure Analysis (Users Only) (2 pages)

Ver. 4.02, 05-10-cDEEM-FCID ACUTE Analysis for METHOXYFENOZIDENHANES 2005-2010 2-DayResidue file: methoxy201.R10Adjustment factor #2 NOT used.Analysis Date: 02-02-2022/21:16:46Residue file dated: 02-02-2022/20:56:21NOEL (Acute) =9.800000 mg/kg body-wt/dayRAC/FF intake summed over 24 hoursRun Comment: ""

Summary calculations--users:

95th Per Exposure % a	aRfD	MOE	99th Exposure	Percenti % aRfD	le MOE	99.9th Exposure	n Percent. % aRfD	ile MOE
Total US Popul	lation							
0.000011	0.01	901059	0.000019	0.02	509136	0.000037	0.04	267262
Hispanic:	0.01	502005	0.000010	0.01	009200	0.000007	0.01	20,202
0.000011	0.01	857174	0.000024	0.02	416845	0.000041	0.04	239066
Non-Hisp-White								
0.000011	0.01	905988	0.000018	0.02	536843	0.000034	0.03	288276
Non-Hisp-Black	<:							
0.000009	0.01>	1000000	0.000020	0.02	485785	0.000045	0.05	215960
Non-Hisp-Other	:							
-	0.01	776901	0.000021	0.02	473240	0.000035	0.04	278685
Nursing Infant	ts:							
0.000024	0.02	406105	0.000042	0.04	231582	0.000073	0.07	134747
Non-Nursing I	nfants	:						
0.000039	0.04	250589	0.000052	0.05	189903	0.000068	0.07	143331
Female 13+ PR	EG:							
0.00010	0.01	952583	0.000013	0.01	761560	0.000018	0.02	534326
Children 1-6:								
0.00013	0.01	732083	0.000021	0.02	461928	0.000036	0.04	272631
Children 7-12	:							
0.00009	0.01>	>1000000	0.000016	0.02	629977	0.000024	0.02	408240
Male 13-19:								
0.000009	0.01>	1000000	0.000014	0.01	712620	0.000031	0.03	312240
Female 13-19/1	NP:							
0.000010	0.01>	1000000	0.000014	0.01	682006	0.000021	0.02	462798
Male 20+:								
0.000009	0.01>	1000000	0.000015	0.02	648690	0.000022	0.02	448616
Female 20+/NP:	:							
0.000010	0.01	937233	0.000016	0.02	628465	0.000023	0.02	417540
Seniors 55+:								
0.000009	0.01>	1000000	0.000014	0.01	718198	0.000021	0.02	472585
All Infants:								
0.00038	0.04	258758	0.000051	0.05	192618	0.000069	0.07	142958
Female 13-50:								
0.000011	0.01	918488	0.000016	0.02	630116	0.000023	0.02	424188
Children 1-2:								
0.000016	0.02	624728	0.000023	0.02	418774	0.000061	0.06	161861
Children 3-5:								
0.000012	0.01	784671	0.000019	0.02	505895	0.000033	0.03	292650
Children 6-12:	:							
0.000010	0.01	999539	0.000016	0.02	614417	0.000026	0.03	372231
Youth 13-19:								
0.000009	0.01>	1000000	0.000014	0.01	686288	0.000021	0.02	462429
Adults 20-49:								
0.000011	0.01	922192	0.000016	0.02	614988	0.000022	0.02	439543
Adults 50-99:								
0.00009	0.01>	1000000	0.000014	0.01	677091	0.000023	0.02	430212
Female 13-49:								
0.000011	0.01	916992	0.000016	0.02	631959	0.000023	0.02	421544

Ver. 4.02, 05-10-c

DEEM-FCID Acute analysis for METHOXYFENOZIDE Residue file name: C:\Users\czhang\OneDrive - California Department of Pesticide Regulation\Documents\DEEM\Food Consumption File\methoxy201.R10 Analysis Date 02-02-2022 Residue file dated: 02-02-2022/20:56:21 Reference dose: aRfD = 0.1 mg/kg bw/day NOEL = 9.8 mg/kg bw/day

EPA Code	Crop Grp	Food	Name	Def Res (ppm)	Adj.Fa #1	ctors #2	Comment
		,	direct, all sources indirect, all sources	0.000201 0.000201			

Appendix 3. Chronic Drinking Water Exposure Analysis (2 pages)

 Evaluation Copy
 Ver. 4.02, 05-10-c

 DEEM-FCID Chronic analysis for METHOXYFENOZIDE
 NHANES 2005-2010 2-day

 Residue file name: C:\Users\czhang\OneDrive - California Department of Pesticide

 Regulation\Documents\DEEM\Food Consumption File\methoxy201.R10

 Adjustment factor #2 NOT used.

 Analysis Date 02-02-2022/21:03:14
 Residue file dated: 02-02-2022/20:56:21

 NOEL (Chronic) = 10.2 mg/kg bw/day

 Total exposure by population subgroup

	Total Exposure			
Population Subgroup	mg/kg body wt/day	Percent of NOEL	Margin of Exposure	
Total US Population	0.00004	0.00%	>1,000,000)	
Hispanic	0.00004	0.00%	>1,000,000)	
Non-Hisp-White	0.000004	0.00%	>1,000,000)	
Non-Hisp-Black	0.00003	0.00%	>1,000,000)	
Non-Hisp-Other	0.00005	0.00%	>1,000,000)	
Nursing Infants	0.000005	0.00%	>1,000,000)	
Non-Nursing Infants	0.000020	0.00%	509,713	
Female 13+ PREG	0.00004	0.00%	>1,000,000)	
Children 1-6	0.000005	0.00%	>1,000,000)	
Children 7-12	0.00003	0.00%	>1,000,000)	
Male 13-19	0.00003	0.00%	>1,000,000)	
Female 13-19/NP	0.00003	0.00%	>1,000,000)	
Male 20+	0.00004	0.00%	>1,000,000)	
Female 20+/NP	0.00004	0.00%	>1,000,000)	
Seniors 55+	0.00004	0.00%	>1,000,000)	
All Infants	0.000015	0.00%	672 , 386	
Female 13-50	0.00004	0.00%	>1,000,000)	
Children 1-2	0.00006	0.00%	>1,000,000)	
Children 3-5	0.00005	0.00%	>1,000,000)	
Children 6-12	0.00003	0.00%	>1,000,000)	
Youth 13-19	0.00003	0.00%	>1,000,000)	
Adults 20-49	0.00004	0.00%	>1,000,000)	
Adults 50-99	0.00004	0.00%	>1,000,000)	
Female 13-49	0.00004	0.00%	>1,000,000)	

Evaluation Copy Ver. 4.02, 05-10-c DEEM-FCID Chronic analysis for METHOXYFENOZIDE Residue file: C:\Users\czhang\OneDrive - California Department of Pesticide Regulation\Documents\DEEM\Food Consumption File\methoxy201.R10 Adjust. #2 NOT used Analysis Date 02-02-2022 Residue file dated: 02-02-2022/20:56:21 Reference dose (NOEL) = 10.2 mg/kg bw/day

Food	Crop		Residue	Adj.Fa	actors
EPA Code	Grp	Food Name	(ppm)	#1	#2
		Water, direct, all sources Water, indirect, all sources	0.000201 0.000201	1.000 1.000	1.000 1.000