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MEMORANDUM

TO: Minh Pham
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VIA: Shelley DuTeaux, PhD MPH, Chief
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DATE: June 7, 2024

SUBJECT: HUMAN HEALTH REFERENCE LEVEL REQUEST FOR HALOSULFURON-METHYL IN DRINKING WATER

On November 16, 2020, DPR’s Pesticide Registration Branch asked the Human Health Assessment (HHA) Branch to provide Human Health Reference Levels (HHRLs) for the DPR’s Surface Water Protection Program (SWPP) for halosulfuron-methyl for screening detected or model-estimated concentrations of its residues in drinking water. This request was in response to a request by the Sacramento River Source Water Protection Program (SRSWPP) to evaluate the impact of Butte Herbicide use in rice fields north (upstream) of the greater Sacramento area. The updated DPR HHRLs in this memo supersede the corresponding HHRL for halosulfuron-methyl established in 2021 (DPR, 2021a). Since the completion of the 2021 evaluation, HHA revised its approach and now establishes separate HHRLs for maximum and average residue levels for surface water.

Conclusions and Recommendations:

1. HHA calculated Human Health Reference Levels (HHRLs) to be used for detected or model-estimated residues of halosulfuron-methyl in surface water using (1) acute and chronic consumption rates for drinking water from the National Health and Nutrition Examination Survey (NHANES) 2005–2010 database; and (2) toxicological endpoints established by the United States Environmental Protection Agency (US EPA).
2. Halosulfuron-methyl does not have any degradates of concern in drinking water consumption requiring evaluation as chemical equivalents in risk assessment.

3. The DPR Acute Surface Water HHRL of 2,632 ppb for halosulfuron-methyl applies to the evaluation of **maximum** residue concentrations in drinking water from surface water sources. Halosulfuron-methyl maximum residue concentrations equal to or less than DPR Acute HHRL are not expected to pose a risk to human health, including for sensitive subpopulations. This DPR Acute Surface Water HHRL supersedes corresponding HHRL (1004 ppb) previously issued in 2021 (DPR, 2021a).
4. The DPR Chronic Surface Water HHRL of 200 ppb for halosulfuron-methyl applies to the evaluation of **average** residue concentrations in drinking water from surface water sources. Average residue concentrations of halosulfuron-methyl equal to or less than the DPR Chronic HHRL are not expected to pose a chronic risk to human health, including for sensitive subpopulations.

Background

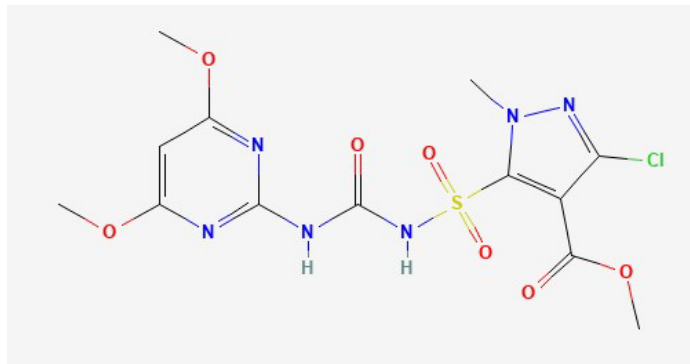
Technical Name: Halosulfuron-methyl

Chemical Name: Methyl 3-chloro-5-[(4,6-dimethoxypyrimidin-2-yl)carbamoylsulfamoyl]-1-methylpyrazole-4-carboxylate

Chemical Abstracts Service Registry Number (CAS #): 100784-20-1

Molecular Weight: 434.81 g/mol (NCBI, 2023)

Chemical Structure:



Halosulfuron-methyl is a selective herbicide belonging to the sulfonamide group of herbicides. It inhibits the plant specific enzyme of acetolactate synthase, which is involved in the synthesis of branched-chain amino acid. Halosulfuron-methyl is used for pre- and post-emergence control of annual broadleaf weeds and nut sedges on various agricultural crops, as well as on residential turf grass and ornamentals. Halosulfuron-methyl was first registered in the U.S. in 1994 (USEPA, 2017) and in California in 1996 (DPR, 2024b). As of June 2024, there were 21 active registrations in California (DPR, 2024c). According to the most recent available data from the DPR's Pesticide Use Reporting (PUR) database, 10,537 pounds of halosulfuron-methyl active ingredient were used in 2,374 California agricultural applications in 2021 (DPR, 2021b).

Review of Regulatory Documents and Databases

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.

Table 1. Review of Regulatory Documents and Databases

Regulatory Agency	Year	Title	Reference(s)
DPR	1996	Halosulfuron: Summary of Toxicology Data	DPR (1996)
USEPA	1999	Halosulfuron; Pesticide Tolerance	USEPA (1999)
USEPA	2000	Halosulfuron-methyl; Pesticide Tolerance	USEPA (2000a)
USEPA	2001	Halosulfuron-methyl; Pesticide Tolerance	USEPA (2001)
USEPA	2002	Halosulfuron-methyl; Pesticide Tolerance	USEPA (2002)
USEPA	2006	Halosulfuron-methyl: Human Health Risk Assessment for Proposed Uses on Alfalfa.	USEPA (2006)
USEPA	2009	Halosulfuron-methyl Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration Action on Soybeans.	USEPA (2009a)
USEPA	2009	Halosulfuron-methyl: Human Health Risk Assessment for Proposed Uses on Soybean.	USEPA (2009b)
USEPA	2010	Halosulfuron-methyl: Human Health Risk Assessment for IR-4 Proposed Uses on Crop Group 6B Succulent Shelled Pea and Bean Subgroup, Crop Group 1C Tuberos and Corn Vegetables Subgroup, Crop Group 6C Dried Shelled Pea and Bean (Except Soybean), Subgroup 13-07B Bushberry, Okra, Apples, and Rhubarb.	USEPA (2010a)
USEPA	2010	Halosulfuron-methyl Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration Action on Pea and Bean, Succulent Shelled, Subgroup 6B; Vegetable, Tuberos and Corm, Subgroup 1C; Rhubarb; Bushberry Subgroup 13-07B; Apple; and Okra.	USEPA (2010b)
NRA	2011	Public Release Summary Halosulfuron-methyl	NRA (2011)
EFSA	2012	Conclusion on the peer review of the pesticide risk assessment of the active substance halosulfuron (evaluated variant halosulfuron-methyl)	EFSA (2012)
USEPA	2012	Halosulfuron-methyl: Human Health Risk Assessment for Proposed New Uses on Proso Millet and Crop Group 17 (Grass, Forage, Fodder, and Hay).	USEPA (2012a)
USEPA	2012	Halosulfuron-methyl Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration Action on Proso Millet and Crop Group 17 (Grass, Forage, Fodder, and Hay).	USEPA (2012b)
USEPA	2013	Halosulfuron-methyl: Human Health Risk Assessment for Proposed New Uses on Artichoke and Caneberry (Crop subgroup 13-07A)	USEPA (2013a)

Table 1. Review of Regulatory Documents and Databases

Regulatory Agency	Year	Title	Reference(s)
USEPA	2013	Halosulfuron-methyl. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration Action on Artichoke and Caneberry Subgroup 13-07A.	USEPA (2013b)
USEPA	2015	Halosulfuron-methyl. Human Health Risk Assessment for a Proposed Use on Pome Fruit Crop Group I 1-1 0 and Small Fruit Vine Climbing Subgroup, Except Fuzzy Kiwifruit, Subgroup I 3-07F.	USEPA (2015a)
USEPA	2015	Halosulfuron-methyl. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration Action on Pome Fruit Group 11 - 10 and Fruit, Small Vine Climbing Subgroup 13-07F.	USEPA (2015b)
USEPA	2015	Halosulfuron-methyl. Human Health Draft Risk Assessment for Registration Review.	USEPA (2015c)
USEPA	2017	Interim Registration Review Decision for 22 Sulfonylurea (SU) Herbicides.	USEPA (2017)
USEPA	2018	2018 Edition of the Drinking Water Standards and Health Advisories Tables.	USEPA (2018a)
USGS	2018	Health-Based Screening Levels for evaluating water-quality data (2d ed.)	USGS (2018)
USEPA	2021	Human Health Benchmarks for Pesticides.	USEPA (2021)
EFSA: European Food Safety Authority; NRA: National Registration Authority for Agricultural and Veterinary Chemicals in Australia; USEPA: United States Environmental Protection Agency; USGS: U.S. Geological Survey.			

Summary of Toxicology

Halosulfuron-methyl was placed in Toxicity Category^a value of IV for oral and inhalation, and III for dermal hazards based on median lethal doses. It is not a skin sensitizer or a skin or eye irritant (Toxicity Category IV) (USEPA, 2015c). US EPA classified halosulfuron-methyl as "not likely to be carcinogenic to humans" based on carcinogenicity studies in rats and mice (USEPA, 2015c).

Halosulfuron-methyl is not included on the Proposition 65 (the California Safe Drinking Water and Toxic Enforcement Act of 1986) list for chemicals known to cause cancer, reproductive toxicity, or developmental toxicity (OEHHA, 2023).

^a 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. Available at <https://www.epa.gov/sites/default/files/2018-04/documents/chap-07-mar-2018.pdf> USEPA. 2018b. Label Review Manual, Chapter 7: Precautionary Statements. <https://www.epa.gov/sites/production/files/2018-04/documents/chap-07-mar-2018.pdf>.

Fetal effects such as increases in resorptions, soft tissue and skeletal variations, decreases in body weights, post-implantation losses and decreases in mean litter size were found in prenatal developmental toxicity studies in rats and rabbits at doses that also caused maternal toxicity (USEPA, 2015c). No specific target organ or tissue were identified following repeated exposures, but decreases in body weight were seen in dogs and rats. No reproductive/offspring effects or neurotoxicity were observed in the reproductive and acute/subchronic neurotoxicity studies in rats (USEPA, 2015c).

DPR's Pesticide Illness Surveillance Program (PISP) maintains a database of pesticide-related illnesses and injuries reported in California from 1992 to 2019 (the most recent data available). There were six reported cases involving exposure to halosulfuron-methyl in combination with other active ingredients and three cases for halosulfuron-methyl alone. In these three cases, one individual experienced dizziness and nausea, one individual experienced sore throat, headache, and a bitter taste in the mouth after a possible oral exposure. Another individual experienced red, itchy, burning and peeling skin on the back after dermal exposure (DPR, 2024a).

HHA has evaluated all required toxicity data submitted for halosulfuron-methyl as part of registration in California but has not conducted a human health risk assessment (DPR, 1996). For purposes of this evaluation, HHA reviewed relevant regulatory documents (Table 1) and adopted toxicological endpoints and points of departure (PODs) established by US EPA for halosulfuron-methyl.

US EPA's acute POD was a no-observed-adverse-effect-level (NOAEL) of 50 mg/kg/day based on increases in resorptions and post implantation loss observed at the lowest-observed-adverse-effect-level (LOAEL) of 150 mg/kg/day in a rabbit developmental study (USEPA, 2015c). This NOAEL was divided by a total uncertainty factor (UF_{TOTAL}) of 100 to calculate an acute reference dose (aRfD^b) of 0.50 mg/kg/day. The UF_{TOTAL} included a 10x for interspecies extrapolation (UF_A) and 10x for intraspecies variability (UF_H) (USEPA, 2015c). The chronic POD was a NOAEL of 10 mg/kg/day based on decreased body weight at the LOAEL of 40 mg/kg/day in a chronic toxicity study in dogs (USEPA, 2015c). The chronic RfD (cRfD) of 0.10 mg/kg/day was calculated by dividing the NOAEL by the UF_{TOTAL} of 100 as described above.

Calculation of Human Health Reference Levels

An HHRL is the threshold pesticide residue for a maximum water intake that results in the maximum safe oral exposure. HHRLs for halosulfuron-methyl were calculated using their

^b 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. Available at <https://www.epa.gov/iris/iris-glossary>

respective acute and chronic RfDs as the maximum safe exposure and the acute (95th percentile) and chronic (mean) drinking water intake rates for non-nursing infants as the maximum water intake. Non-nursing infants are the population identified as having the highest consumption of drinking water per kilogram of bodyweight among the standard populations that HHA evaluates, including the general US population and other sensitive subpopulations such as children 1–2 years of age and women of childbearing age (13–49 years). The water consumption rates were extracted from 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. 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 (USEPA, 2014). HHA uses 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).

Formulas Used to Calculate Acute and Chronic Surface Water HHRLs

$$\text{Acute Surface Water HHRL (ppb)} = \frac{\text{aRfD}}{\text{acute DWI}} \times 1000$$

$$\text{Chronic Surface Water HHRL (ppb)} = \frac{\text{cRfD}}{\text{Chronic DWI}} \times 1000 \times \text{RSC}$$

Drinking Water Intake (DWI) is 95th percentile (acute) or mean (chronic) water consumption rates for non-nursing infants. Acute and chronic water consumption data were extracted using the DEEM-FCID (version 4.02, 05-10-c). A residue concentration of 1 ppm consumption defaults to the consumption rates by dimensional analysis (acute = 0.194566 L water/kg BW and chronic = 0.099559 L water/kg BW). The values were then rounded to two decimal points for the calculation of corresponding HHRLs (0.19 and 0.10 L water/kg BW).

DPR Chronic Surface Water HHRLs incorporate a relative source contribution (RSC) factor of 0.2. The RSC factor accounts for the possibility that exposure to a pesticide residue may come from sources other than drinking water (*i.e.*, food and air). A default RSC of 0.2 assumes that the exposure from water sources will be 20% of the total exposure while other intakes will make up the remainder (80%). This RSC factor is routinely used by regulatory agencies for deriving chronic screening levels of drinking water (USEPA, 2000b; USEPA, 2015d).

DPR Acute Surface Water HHRL for Halosulfuron-methyl

DPR Acute Surface Water HHRLs are for screening maximum pesticide residue concentrations in drinking water from surface water sources. Maximum residue concentrations of halosulfuron-

methyl in drinking water equal to or less than DPR Acute Surface Water HHRL (**2,632 ppb**, Table 2) are not expected to pose a risk to human health including for sensitive subpopulations.

DPR Chronic Surface Water HHRL for Halosulfuron-methyl

DPR Chronic Surface Water HHRLs are for screening average pesticide residue concentrations in drinking water from a surface water body. Average residue concentrations of halosulfuron-methyl in drinking water equal to or less than DPR Chronic Surface Water HHRL (**200 ppb**, Table 2) are not expected to pose a risk to human health including for sensitive subpopulations. DPR Chronic Surface Water HHRLs that incorporate RSCs are only appropriate for the evaluation of averaged (*i.e.*, mean) residue concentrations in surface water.

Other Reference or Regulatory Levels for Halosulfuron-methyl in Drinking Water

DPR considers other reference and regulatory levels for drinking water in the developmental of HHRLs, especially with regards to best practices in dietary and drinking water exposure assessments. Common federal regulatory levels for drinking water include US EPA enforceable Maximum Contaminant Levels (MCLs^c), non-legally enforceable Health Advisories (HAs^d), and Human Health Benchmark for Pesticides (HHBP^e), and United States Geological Survey (USGS) Health-Based Screening Levels (HBSLs^f) (USEPA, 2018a; USEPA, 2021; USGS, 2018). For halosulfuron-methyl, US EPA issued an acute HHBP of 10,000 ppb for females 13-49 years and a chronic HHBP of 600 ppb for general population (USEPA, 2021). Although US EPA chronic HHBP and DPR chronic HHRL for halosulfuron-methyl are both based on the same chronic PODs, these two values differ because they were calculated using different water consumption rates.

^c Maximum Contaminant Levels (MCLs) are used for the protection of public drinking water systems and do not apply to privately owned wells or any other individual water system. Available at <https://www.epa.gov/system/files/documents/2022-01/dwtable2018.pdf>

^d Health Advisories (HAs) are estimated acceptable drinking water levels for chemicals based on information of adverse health effects and are not legally enforceable Federal standards, but rather serve as technical references to be used by federal, state, and local officials. Available at <https://www.epa.gov/system/files/documents/2022-01/dwtable2018.pdf>

^e The 2021 US EPA Human Health Benchmark for Pesticides (HHBPs) contain 430 pesticides that currently have no federal drinking water standards. HHBPs are not legally enforceable, but rather are provided by US EPA for pesticides that have no drinking water standards or health advisory (HA). Available at <https://www.epa.gov/system/files/documents/2021-07/hh-benchmarks-technical-document-2021.pdf>

^f USGS Health-Based Screening Levels (HBSLs) are “non-enforceable water-quality benchmarks” that were developed using (1) the latest US EPA Office of Water methods for establishing drinking-water guidelines and (2) the most recent US EPA peer-reviewed publicly available toxicity information. Available at <https://water.usgs.gov/water-resources/hbsl/>

Table 2. DPR Acute and Chronic Surface Water HHRLs for Halosulfuron-methyl

Residue	Acute or Chronic	Water Consumption Rates for Non-Nursing Infants (L water/kg BW)	RfD ^a (mg/kg/day)	HHRL (ppb)	US EPA HHBP ^b (ppb)
Halosulfuron-methyl	Acute (Maximum Residues)	0.19	0.50	2,632	10,000 (Females 13-49 years)
	Chronic (Average Residues)	0.10	0.10	200	600 (General Population)

BW: bodyweight; DPR: Department of Pesticide Regulation; HHBP: Human Health Benchmark for Pesticides; HHRL: Human Health Reference Level; L: liter; RfD: reference dose; ppb: parts-per-billion.

^a Acute and chronic RfDs for halosulfuron-methyl were based on toxicological endpoints established by US EPA as described in text (USEPA, 2015c)

^b In 2021, US EPA provided Human Health Benchmark for Pesticides (HHBPs) containing 430 pesticides that currently have no federal drinking water standards. HHBPs are not legally enforceable, but rather are provided by US EPA for pesticides that have no drinking water standards or health advisories (USEPA, 2021). An Acute HHBP for Females 13-49 years (ppb) = [acute RfD (mg/kg/day) x 1000 (µg/mg)] / [0.0354 (L/kg/day) DWI-BW ratio]; A Chronic HHBP for General Population (ppb) = [chronic RfD (mg/kg/day) x 1000 x 0.2 RSC] / 0.0338 (L/kg/day) DWI-BW ratio. DWI: drinking water intakes.

Conclusions

HHA calculated Human Health Reference Levels (HHRLs) to be used for halosulfuron-methyl in drinking water. Maximum residue concentrations of halosulfuron-methyl equal to or less than the DPR Acute Surface Water HHRL of 2632 ppb in drinking water or average residue concentrations in surface water equal to or less than the DPR Chronic Surface Water HHRL of 200 ppb are not expected to pose a risk to human health, including for sensitive subpopulations, respectively. The DPR Acute HHRL supersedes corresponding HHRL (1004 ppb) previously issued in 2021 (DPR, 2021a)

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