M E M O R A N D U M

TO: Minh Pham, Chief
Environmental Monitoring Branch

VIA: Shelley DuTeaux, PhD MPH, Chief
Human Health Assessment Branch

FROM: Chunbo Zhang, PhD, Staff Toxicologist
Pete Lohstroh, PhD, Senior Toxicologist
Toxicology and Dose Response Assessment Section

Svetlana Koshlukova, PhD, Senior Toxicologist
Risk Assessment Section

DATE: December 11, 2023

SUBJECT: HUMAN HEALTH REFERENCE LEVELS FOR BENTAZON IN GROUNDWATER

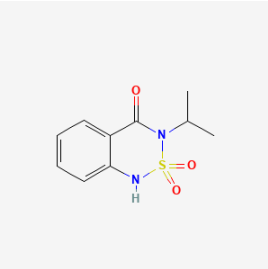
On August 22, 2023, the Department of Pesticide Regulation's (DPR) Human Health Assessment Branch (HHA) was requested by the Environmental Monitoring Branch (EMB) to provide Human Health Reference Levels (HHRLs) for bentazon to screen detections of its residue levels in groundwater (see request, Appendix 1). This memorandum is in response to the request.

Conclusions and Recommendations:

1. HHA calculated Human Health Reference Levels (HHRLs) to be used for detections of bentazon residue levels in groundwater 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. Based on the mode of action, bentazon and its degradates 6-hydroxybentazon, 8-hydroxybentazon, and anthranilic acid isopropylamide are considered to have equivalent toxicity and should be summed when they are detected in the same samples.
3. Maximum residue concentrations of bentazon equal to or less than the DPR HHRL of 1500 parts-per-billion (ppb) in drinking water are not expected to pose a risk to human health, including for sensitive subpopulations.

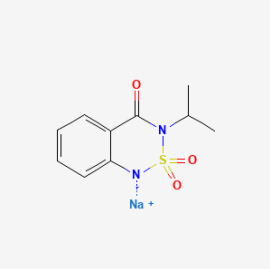
Background

Technical Name: Bentazon
Chemical Name: 2,2-dioxo-3-propan-2-yl-1*H*-2λ^6,1,3-benzothiadiazin-4-one
Chemical Abstracts Service Registry Number (CAS #): 25057-89-0
Molecular Weight: 240.28 g/mol (NIH, 2023a)
Chemical Structure:



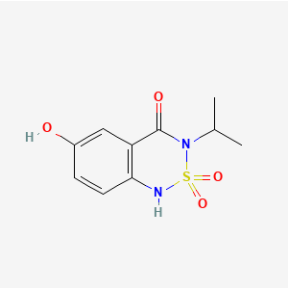
(NIH, 2023a)

Technical Name: Sodium bentazon
Chemical Name: sodium;2,2-dioxo-3-propan-2-yl-2λ^6,1,3-benzothiadiazin-1-id-4-one
Chemical Abstracts Service Registry Number (CAS #): 50723-80-3
Molecular Weight: 262.26 g/mol (NIH, 2023e)
Chemical Structure:



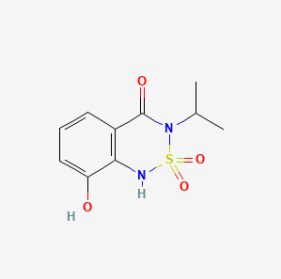
(NIH, 2023e)

Technical Name: 6-Hydroxybentazon
Chemical Name: 6-hydroxy-2,2-dioxo-3-propan-2-yl-1*H*-2λ^6,1,3-benzothiadiazin-4-one
Chemical Abstracts Service Registry Number (CAS #): 60374-42-7
Molecular Weight: 256.28 g/mol (NIH, 2023b)
Chemical Structure:



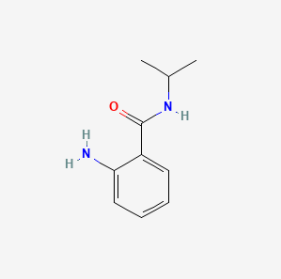
(NIH, 2023b)

Technical Name: 8-Hydroxybentazon
Chemical Name: 8-hydroxy-2,2-dioxo-3-propan-2-yl-1*H*-2λ^6,1,3-benzothiadiazin-4-one
Chemical Abstracts Service Registry Number (CAS #): 60374-43-8
Molecular Weight: 256.28 g/mol (NIH, 2023c)
Chemical Structure:



(NIH, 2023c)

Technical Name: Anthranilic acid isopropylamide (AIBA)
Chemical Name: 2-amino-*N*-propan-2-ylbenzamide
Chemical Abstracts Service Registry Number (CAS #): 30391-89-0
Molecular Weight: 178.23 g/mol (NIH, 2023d)
Chemical Structure:



(NIH, 2023d)

Bentazon is a selective early postemergence contact herbicide for controlling broadleaf weeds and sedges in agricultural field crops, including corn, soybeans, beans, rice, cereals, potatoes, and various fruit and nut crops (US EPA, 1995; US EPA, 2016b). Applied as a spray, it is also

registered for use to control weeds in residential and recreational lawns and around ornamental plants (US EPA, 2016b). Pesticide products using bentazon as an active ingredient were first registered by the United States Environmental Protection Agency (US EPA) in 1972, followed by registration of sodium bentazon in 1982 (US EPA, 2016b). Between 2009-2013, sodium bentazon was applied to approximately 1.9 million acres of cropland annually in the United States with maximum single application rates of 1 to 1.5 pounds of active ingredient per acre (US EPA, 2016a). Bentazon, as sodium bentazon, was first registered in California in 2005. As of September 2023, there are ten active registrations in California (DPR, 2023d). According to the most currently available data from the DPR's Pesticide Use Reporting (PUR) database, 7,120 pounds of sodium bentazon active ingredient were used in 552 California agricultural applications in 2021 (DPR, 2021).

Bentazon's degradates of concern include the benzene-ring hydroxylation products 6-hydroxybentazon and 8-hydroxybentazon, and anthranilic acid isopropylamide (AIBA) (US EPA, 2014e; eCFR, 2023). Bentazon, AIBA, 6-hydroxybentazon, and 8-hydroxybentazon are considered to be bentazon equivalents and should be summed if they are detected in the same samples (US EPA, 2014e; eCFR, 2023).

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)
US EPA	1994	Bentazon. List A Reregistration Case No. 0182, Chemical No. 103901. Product and Residue Chemistry Chapters for the Reregistration Eligibility Decision Document (RED). CBRS No. 11440; DP BARCODE D188712	US EPA, 1994
US EPA	1995	Reregistration Eligibility Decision (RED) Bentazon	US EPA, 1995
DPR	1999	Summary of Toxicology Data Bentazon/Bentazon Sodium	DPR, 1999
DPR	2009	Guidance for Dietary Exposure Assessment	DPR, 2009
US EPA	2010	Bentazon Summary Document Registration Review: Initial Docket	US EPA, 2010
US EPA	2011	Integrated Risk Information System (IRIS) Glossary.	US EPA, 2011
US EPA	2014	Bentazon. Occupational and Residential Exposure and Risk Assessment for Registration Review	US EPA, 2014a
US EPA	2014	Dietary Exposure Evaluation Model User's Guide	US EPA, 2014b

Table 1. Review of Regulatory Documents and Databases

Regulatory Agency	Year	Title	Reference(s)
US EPA	2014	Drinking Water Assessment in support of the Registration Review Preliminary Risk Assessment and Clarification on the Degradates of Concern for the Sodium Salt of Bentazon	US EPA, 2014c
US EPA	2014	Registration Review Ecological Risk Assessment and Effects Determination for Sodium Bentazon	US EPA, 2014d
EFSA	2015	Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Bentazone	EFSA, 2015
US EPA	2015	Human Health Ambient Water Quality Criteria: 2015 Update.	US EPA, 2015a
US EPA	2015	Response to Public Comments on the EFED's Preliminary Risk Assessment on the Registration Review of Sodium Bentazon	US EPA, 2015b
US EPA	2016	Bentazon Usage Information (PC# 103901)	US EPA, 2016a
US EPA	2016	Bentazon. Interim Registration Review Decision Case Number 0182	US EPA, 2016b
US EPA	2018	2018 Edition of the Drinking Water Standards and Health Advisories Tables	US EPA, 2018a
US EPA	2018	Label Review Manual, Chapter 7: Precautionary Statements	US EPA, 2018b
USGS	2018	Health-Based Screening Levels for Evaluating Water-Quality Data	USGS, 2018
US EPA	2019	Environmental Protection Agency 40 CFR Part 180 [EPA–HQ–OPP–2017–0476; FRL–9991–75] Bentazon; Pesticide Tolerances	US EPA, 2019a
US EPA	2019	Interregional Research Project Number 4 (IR-4) Notice of Filing Pesticide Petition No. 7E8597 to Amend an Established Tolerance for the Combined Residues of the Herbicide Bentazon, Including its Metabolites and Degradates, in or on Food Commodities	US EPA, 2019b
DPR	2021	2021 Annual Statewide Pesticide Use Report Chemical Totals	DPR, 2021
EFSA	2021	Modification of the Existing Maximum Residue Levels for Bentazone in Beans and Peas with and without Pods	EFSA, 2021
US EPA	2021	2021 Human Health Benchmarks for Pesticides	US EPA, 2021a
US EPA	2021	Human Health Benchmarks for Pesticides: Updated 2021 Technical Document	US EPA, 2021b
DPR	2023	California Code of Regulations Title 3. Food and Agriculture Division 6. Pesticides and Pest Control Operations	DPR, 2023a
DPR	2023	California Pesticide Illness Query CalPIQ	DPR, 2023b
DPR	2023	Environmental Monitoring Programs and Projects	DPR, 2023c
DPR	2023	Search for Chemical Ingredient by Partial Name, Chemical Code or CAS Number	DPR, 2023d
eCFR	2023	Code of Federal Regulation. § 180.355 Bentazon; tolerances for residues	eCFR, 2023
OEHHA	2023	The Proposition 65 List.	OEHHA, 2023

Table 1. Review of Regulatory Documents and Databases

Regulatory Agency	Year	Title	Reference(s)
US EPA	2023	CompTox Chemicals Dashboard: 2-Amino-N-(1-methylethyl)benzamide	US EPA, 2023a
US EPA	2023	CompTox Chemicals Dashboard: Bentazon	US EPA, 2023b
US EPA	2023	Human Health Water Quality Criteria and Methods for Toxics	US EPA, 2023c
US EPA	2023	Incident Data System (IDS) - Incidents Submitted in Aggregate	US EPA, 2023d
DPR: Department of Pesticide Regulation; eCFR: online version of Code of Federal Regulation; EFSA: European Food Safety Authority; US EPA: United States Environmental Protection Agency; USGS: United States Geological Survey; OEHHA: Office of Environmental Health Hazard Assessment			

Summary of Toxicology

Bentazon has an acute Toxicity Category[1] value of III for oral and dermal toxicities and Toxicity Category IV for inhalation toxicity based on median lethal doses. It is a skin sensitizer, moderate eye irritant (Toxicity Category II), and a slight skin irritant (Toxicity Category IV) (US EPA, 2014e). US EPA classified bentazon as an "evidence of non-carcinogenicity for humans" (Group E) chemical based on lack of evidence of carcinogenicity in rats and mice (US EPA, 2014e).

Bentazon 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).

Increased incidences of abortions and embryo resorptions were observed in a rabbit developmental study, and increased incidence of resorptions, delayed skeletal ossification, and decreased fetal bodyweights were noted in rat developmental studies (DPR, 1999; US EPA, 2014e). In subchronic and chronic studies in rats and dogs, changes in hematological/coagulation parameters and lesions on the liver and kidneys were observed (US EPA, 2014e; EFSA, 2015; US EPA, 2019a).

DPR's Pesticide Illness Surveillance Program (PISP) maintains a database of pesticide-related illnesses and injuries reported in California from 1992 to 2018 (the most recent data available). There was one reported case involving exposure to bentazon and an adjuvant. The exposed worker had a pink scaly rash on both hands (DPR, 2023b).

[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. Available at https://www.epa.gov/sites/default/files/2018-04/documents/chap-07-mar-2018.pdf (US EPA, 2018b).

HHA has evaluated all required toxicity data submitted for bentazon as part of registration in California but has not conducted a human health risk assessment (DPR, 1999). For this evaluation, HHA considered toxicological endpoints and points of departure (PODs) established by US EPA for bentazon (US EPA, 2014e; US EPA, 2019a). US EPA's acute POD was a no observed adverse effect level (NOAEL) of 50 mg/kg/day based on decreased motor activity in males following a single dose of bentazon at the lowest observed adverse effect level (LOAEL) of 150 mg/kg/day in an acute neurotoxicity study in rats (US EPA, 2014e; US EPA, 2019a). The NOAEL was divided by a total uncertainty factor (UF_{TOTAL}) of 100 to calculate an acute reference dose (aRfD[2]) of 0.50 mg/kg/day. The UF_{TOTAL} included 10x for interspecies extrapolation (UF_A) and 10x for intraspecies variation (UF_H) (US EPA, 2014e). The chronic POD was a NOAEL of 15 mg/kg/day based on reduced offspring bodyweights during lactation at the LOAEL of 62 mg/kg/day in a reproductive toxicity study in rats (US EPA, 2014e). The cRfD of 0.15 mg/kg/day was derived by dividing the chronic POD by UF_{TOTAL} of 100 (10x each for interspecies and intraspecies extrapolation) (US EPA, 2014e).

Calculation of Human Health Reference Levels for Bentazon

An HHRL is the threshold pesticide residue for a maximum water intake that results in the maximum safe oral exposure. HHRLs were calculated using the acute and chronic RfDs for bentazon as the maximum safe exposure, and the 95th percentile of acute 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 (US EPA, 2014b). 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).

HHA calculated acute and chronic HHRLs for bentazon in groundwater or drinking water. The results were summarized in Table 2. The lower reference value, the chronic HHRL level of **1500**

[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. Available at https://www.epa.gov/iris/iris-glossary (US EPA, 2011).

ppb, was selected as the HHRL for residues of bentazon and its degradates in drinking water. Maximum residue concentrations of bentazon and its degradates in drinking water equal to or less than the DPR HHRL of 1500 ppb are not expected to pose a risk to human health, including for sensitive subpopulations.

Other Reference or Regulatory Levels for Bentazon in Drinking Water

Common federal reference levels for drinking water include US EPA enforceable Maximum Contaminant Levels (MCLs[3]), non-legally enforceable Health Advisories (HAs[4]), and Human Health Benchmark for Pesticides (HHBP[5]), and United States Geological Survey (USGS) Health-Based Screening Levels (HBSLs[6]). US EPA has not issued either an MCL or an HHBP for bentazon. One- and ten-day HAs of 300 ppb are expected to be protective for a 10-kg child consuming 1 liter of water per day. Other HAs include a Drinking Water Equivalent Level (DWEL) of 1000 ppb and a non-carcinogenic lifetime HA (NCHA) exposure level of 200 ppb for lifetime exposure (US EPA, 2018a). DWELs apply to situations where 100% of the residue intake are assumed to be from water sources while NCHA exposure levels incorporate a relative source contribution (RSC) factor of 0.2, assuming 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 for drinking water (US EPA, 2015a; US EPA, 2023c). USGS's non-cancer HBSL for bentazon was 1000 ppb (USGS, 2018). DPR's HHRL for bentazon differed from US EPA's HAs and USGS's HBSL because they were calculated using different parameters/assumptions such as water consumption rates, RfDs, and RSC factors. The DPR HHRL of 1500 ppb is the only reference level that is specifically intended to be used for screening maximum detected residue levels of bentazon in groundwater.

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[3] 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 (US EPA, 2018a).

[4] 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 (US EPA, 2018a).

[5] 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 (US EPA, 2021b).

[6] 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/ (USGS, 2018).

Table 2. DPR HHRLs[a] for Bentazon[b]

Residue	Acute or Chronic	Consumption Rates for Non-Nursing Infants[c] (L water/kg BW)	RfD[d] (mg/kg/day)	HHRL (ppb)	US EPA Health Advisories[e]		
					1-Day/10-Day[e] (10-kg Child) (ppb)	DWEL[e] (ppb)	NCHA[e] (ppb)
Bentazon	Acute	0.19	0.50	2632	300	1000	200
	Chronic	0.10	0.15	**1500**			
BW: bodyweight; DWEL: Drinking Water Equivalent Level; HHRL: Human Health Reference Level; L: liter; NCHA: non-carcinogenic lifetime health advisory; RfD: reference dose; ppb: parts-per-billion.							

[a] The DPR HHRLs (ppb) for screening maximum pesticide residue levels were calculated as [RfD (mg/kg/day) x 1000] / [Daily water intake (L/kg/day)]. Daily water intake is 95th percentile for acute or chronic (mean) water consumption rates for non-nursing infants (see Note c).

[b] Bentazon's degradates of concern, 6-hydroxybentazon, 8-hydroxybentazon and anthranilic acid isopropylamide, are considered equivalent to bentazon (US EPA, 2014e; eCFR, 2023).

[c] 95th percentile water consumption rates for non-nursing infants from NHANES database (2005–2010). Acute and chronic water consumption data were extracted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID, version 4.02, 05-10-c). A residue level 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 rounded to two decimal points for the calculation of HHRLs.

[d] Acute and chronic RfDs (mg/kg/day) were established by US EPA (US EPA, 2014e) as described in the text.

[e] US EPA Health Advisories (HAs) are not legally enforceable Federal standards. HAs serve as a technical guidance to assist Federal, State, and local officials (US EPA, 2018a). 1-Day and 10-day parameters are concentrations intended to protect a 10-kg child consuming 1 liter of water per day for up to one day (1-day) and 10 days (10-day) exposure, respectively. A DWEL is a drinking water lifetime maximum noncarcinogenic safe exposure level assuming 100% exposure from that medium. A noncancer lifetime health advisory (NCHA) incorporates a relative source contribution (RSC) factor above DWEL, assuming that the exposure from water sources will be 20% of the total exposure while other intakes will make up the remainder (80%).

The recommended HHRL for screening residue concentrations of bentazon and its degradates of concern in drinking water is **bolded**.

Conclusions

HHA calculated Human Health Reference Levels (HHRLs) to be used when bentazon and its degradates of concern (6-hydroxybentazon, 8-hydroxybentazon, and anthranilic acid isopropylamide) are detected in drinking water. Maximum concentrations of these residues, individually or in summation if detected in the same samples, equal to or less than the DPR HHRL of **1500** ppb are not expected to pose a risk to human health, including for sensitive subpopulations.

Chunbo Zhang

Chunbo Zhang, PhD
Staff Toxicologist, Toxicology and Dose Response Assessment Section

Svetlana Koshlukova

Svetlana Koshlukova, PhD
Senior Toxicologist, Risk Assessment Section

Peter Lohstroh

Peter N. Lohstroh, PhD
Senior Toxicologist, Toxicology and Dose Response Assessment Section

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Appendix 1: DPR Memo: Human Health Reference Level Request for Bentazon in Groundwater 22 August 2023 (1 page)

Department of Pesticide Regulation

Julie Henderson
Director

Gavin Newsom
Governor

Yana Garcia
Secretary for Environmental Protection

MEMORANDUM

TO: Shelley DuTeaux
Environmental Program Manager II
Human Health Assessment Branch

VIA: Minh Pham *Original Signed by 8/22/23*
Environmental Program Manager II
Environmental Monitoring Branch

FROM: Joy Dias *Original Signed by 8/22/23*
Environmental Program Manager I
Environmental Monitoring Branch

DATE: August 22, 2023

SUBJECT: HUMAN HEALTH REFERENCE LEVEL REQUEST FOR BENTAZON IN GROUNDWATER

The Environmental Monitoring Branch (EMB) monitors the environment to determine the fate of pesticides and protects the public and the environment from pesticide contamination by analyzing hazards and developing pollution prevention strategies. Consistent with EMB's mission, the Groundwater Protection Program (GWPP) routinely monitors for bentazon due to its occurrence in groundwater and status as a 3CCR 6800(a) pesticide. The GWPP also gathers data from all public agencies that report groundwater monitoring data of pesticides and their degradates and enters the data into the Well Inventory Database (WIDB).

To determine whether detections of bentazon pose a significant risk to human health, EMB requests that the Human Health Assessment Branch provide a human health reference level to use for screening detections in groundwater.

Table 1. Summary bentazon and degradates from the Well Inventory Database.

Chemical	**DPR Chemical Code**	**CAS Number**
Bentazon (applied as bentazon, sodium salt)	2999 (1944)	25057-89-0 (50723-80-3)

cc: Carissa Ganapathy, Senior Environmental Scientist (Supervisory)