



MEMORANDUM

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SUBJECT: Response to Comments by the US Environmental Protection Agency on DPR's Draft Human Exposure Assessment for Fipronil

Background

At the request of the Department of Pesticide Regulation (DPR), the Health Effects Division (HED) of US Environmental Protection Agency's (US EPA) Office of Pesticide Programs reviewed the January 2021 Draft Exposure Assessment Document (EAD) for Fipronil. HED was asked to comment on a series of charge questions covering the hazard identification, exposure assessment, risk characterization, and worker and bystander margins of exposure, and provided comments in a letter submitted to DPR on May 18, 2021.

Responses to specific comments received on the charge questions related to the exposure assessment are detailed below. Response to the remaining charge questions are detailed in a separate memorandum. DPR sincerely appreciates HED's review. We consider comments by other regulatory agencies to be helpful in the development of technically complex, science-based regulatory documents. When appropriate, HED's comments were incorporated into the final Fipronil EAD.

Note that references cited in the HED comments are not included in the reference section of this document; table references within DPR's responses correspond to tables in this memorandum and not those in the draft or final RCD unless otherwise specified.

Responses to Exposure Assessment Charge Questions

Exposure Charge Question 1. Due to a lack of fipronil monitoring data, handler exposures for structural liquid concentrate (LC), structural dust and turf granule products were assessed using surrogate data.

US EPA Comment: It is a standard practice for HED to use surrogate unit exposure data for assessment of handler exposure for which formulation and application type data are not available. The following table summarizes the exposure data used for the fipronil EAD as

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requested for review (i.e., structural LC, structural dust, and turf granular products) and those used by HED for its 2020 Fipronil Draft Risk Assessment (DRA) for Registration Review (A. Wray; D431560) for the same exposure scenarios. The notes present a summary of the comparisons for each study data source used. [Note: The US EPA comments included a summary table of four exposure scenarios.]

DPR Response: The scenarios with different unit exposure values used between Department of Pesticide Regulation (DPR) and US Environmental Protection Agency (US EPA) were summarized in the table below. For each scenario, DPR used two values for exposure assessment, i.e., the upper-bound estimate for short-term exposure, and the average for intermediate- and long-term exposures. US EPA only calculated short-term exposures, as “*the same endpoint and POD was selected for short- and intermediate-term durations*” (US EPA, 2020). DPR may also apply additional adjustment factors to account for the differences of personal protective equipment (PPE) requirements between fipronil products and the data source(s) where the unit exposure values were obtained. Detailed discussions for each scenario are provided below.

Table 1. Summary of unit exposure values used by DPR and US EPA for handler exposure assessment

Handler scenario	DPR (µg/lb)				US EPA ^b (µg/lb)	
	Short-term		Intermediate-/Long-term		Dermal	Inhalation
Exposure route	Dermal	Inhalation	Dermal	Inhalation		
Structural LC ^a product w/o overhead	5271	89	1895	32	100000	30
Structural LC product w/ overhead	12745	21	5092	11	29000	1100
Structural dust product	1254182	14152	200850	1996	166000	1690
Turf granular product	86100	266	30992	96	10000	62

a: liquid concentrate

b: Values were obtained from US EPA draft risk assessment for fipronil (USEPA, 2020).

Structural LC products w/o overhead: The unit exposures used in the DPR exposure assessment document (EAD) were retrieved from the DPR memorandum titled “Surrogate handler exposure estimates for use in assessments by the California Department of Pesticide Regulation” (Memo HS-1826), which was developed based on the Pesticide Handler Exposure Database (PHED; Beauvais et al., 2007). DPR also assumed the personal protective equipment (PPE) used by the handler is long sleeved shirt, long pants, gloves, shoes, socks and respirator, which is based on the requirements on the fipronil product labels. The unit exposures used in the US EPA assessment were retrieved from the Occupational Pesticide Handler Unit Exposure Surrogate Reference Table (US EPA, 2021).

For this particular scenario, the unit exposure values used by US EPA were also derived from the PHED database and assumed “single layer, no gloves” PPE.

Structural LC products w/ overhead: The unit exposure values in the Draft EAD were retrieved from a surrogate study that monitored handler exposures from carbaryl applications to citrus (around 8 ft tall) and ornamental (around 4 ft tall) trees using hand-held pump sprayer (Merricks, 1998). This study was used because 1) there were no data that monitored handler exposures for a structural overhead scenario, and 2) handlers in this study used low-pressure sprayers, which agrees to the requirements on the fipronil product labels. DPR also assumed the handler PPEs are long sleeved shirt, long pants, gloves, shoes, socks and respirator. This scenario was not assessed by US EPA. Instead, US EPA assessed handler exposures during “*applications in warehouse, residential living spaces, childcare center/schools/institutions, and structural components such as walls and framing*” (US EPA, 2020). The unit exposure values in the US EPA assessment were derived from PHED database and assumed “single layer, no glove” PPE (US EPA, 2021). DPR did not assess handler exposures in those settings as structural LC products are not allowed for indoor use except for applications into structural voids.

Structural dust products: The unit exposure values in the Draft EAD were retrieved from a surrogate study that monitored handlers exposures from injecting dust/powder formulations into structural voids using plunger duster (Merricks, 1997). The same study was also used in the US EPA Standard Operating Procedures for Residential Pesticide Exposure Assessment (US EPA SOP) to develop unit exposure values for plunger duster handler (US EPA, 2012). The fipronil structural dust product labels do not have PPE requirements, so the assessment assumed a handler might wear a short-sleeve shirt and long pants. The unit exposure values used in the US EPA assessment were retrieved from the Occupational Pesticide Handler Unit Exposure Surrogate Reference Table, and for this particular scenario, these values were derived from the PHED database and assumed “single layer, no gloves” PPE (US EPA, 2021).

Turf granular products: The unit exposure values used in the DPR EAD was retrieved from DPR Memo HS-1826 which was developed based on PHED database (Beauvais et al., 2007). DPR also assumed handler PPEs are long sleeved shirt, long pants, gloves, shoes and socks, as the fipronil turf granular product labels require the use of gloves. The unit exposure values used in the US EPA assessment were retrieved from the Occupational Pesticide Handler Unit Exposure Surrogate Reference Table, and for this particular scenario, these values were also derived from the PHED database and assumed “single layer, no gloves” PPE (US EPA, 2021).

Exposure Charge Question 2: Due to a lack of post-application monitoring data, environmental sampling data at residential homes were used to assess post-application dermal and oral exposures for structural LC products.

US EPA Comment: Per the 2012 Standard Operating Procedures for Residential Pesticide Exposure Assessment (Residential SOPs) Indoor Environments SOP, post-application exposures can result from contact with indoor surfaces following a pesticide application. Post-application inhalation exposures are not expected from indoor crack and crevice applications and, therefore, this route of exposure was not assessed for the 2020 fipronil DRA. HED does not support the assessment of post-application inhalation presented in the RCD.

DPR Response: For fipronil bait gel products used for crack and crevice applications, DPR did not assess post-application inhalation exposures. For post-application dermal and incidental oral exposures, DPR did not use the 0.3 $\mu\text{g}/\text{cm}^2$ default surface deposition rate as recommended by the US EPA SOP, because this value is based on the assumption that 10% of total areas are treated (US EPA, 2012). However, the fipronil product labels instruct spot treatments (round spots or thin beads) at corners, cracks and crevices. Therefore, DPR determined the percentage of treated area for fipronil products should be much less than 10%, thus using the default 0.3 $\mu\text{g}/\text{cm}^2$ may cause overestimation of post-application exposures.

US EPA Comment, *continued*: In the RCD document, DPR describes that the post-application dermal and incidental oral exposure and risk assessment relies upon a study conducted by the US Geological Survey (USGS) in Austin, TX... HED has not conducted a formal review of the cited USGS study. However, it is the preference of HED that exposure study data: 1) are representative of the application equipment type for which the exposures are being assessed; 2) are applied at a known application rate specific to the registered use pattern; 3) are collected using an established residue collection method (e.g., handpress, drag sled, PUF roller, cloth roller, or California roller); and 4) are collected following an application event for which the day/time and application rate are known and residues are collected at known, repeated time points following the application event (to include the day of product application). Based on HED's informal review, it appears that the USGS survey would not meet HED's exposure study data criteria.

DPR Response: The rationale of using this Mahler et al. study (2009) from US Geological Survey have been discussed in details in the sections "IV. EXPOSURE ASSESSMENT" and "V. EXPOSURE APPRAISAL" of the EAD. This is the only study DPR found that measured fipronil levels on residential indoor surfaces. The measured fipronil levels may come from applications of multiple products (including both structural and pet products), and correspondingly represent aggregate exposures for both adult and child residents.

Exposure Charge Question 3. The drinking water assessment only relied on a subset of measured water samples.

US EPA Comment: [The Environmental Fate and Effects Division] agrees with CDPR's approach to exclude monitoring data from slough and storm drains for drinking water exposure

assessment since they do not represent drinking water intake sites. Since there are no agricultural uses of fipronil in California, and due to the lack of spatial use data for structural uses of fipronil, EFED also concurs with CDPR that exposure modeling refinements are ineffective.

DPR Response: Comment on this question is noted.

References:

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- Merricks, D. 1997. 2,4-D: carbaryl mixer/loader/applicator exposure study during application of RP-2 liquid (21%), Seven ready to use insect spray or Seven 10 dust to home garden vegetables. Research Triangle Park, NC: Rhone-Poulenc Ag Company. MRID 44459801. (DPR Vol. No. 142-0215, Record No. 175244).
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- US EPA. 2012. Standard operating procedures for residential pesticide exposure assessment. (October, 2012). https://www.epa.gov/sites/production/files/2015-08/documents/usepa-opp-hed_residential_sops_oct2012.pdf.
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