



## OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

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### **Subject: EPA's response to AMVAC's proposed DCPA product label**

Dr. Turnbough:

This letter serves as EPA's response to AMVAC's April 9, 2024, submission of a newly proposed Dacthal Flowable Herbicide (EPA Reg. No. 5481-487) label to the Agency. A summary of prior correspondence between EPA and AMVAC is included below, as is an overview of EPA's analysis of AMVAC's proposed product label.

EPA thanks AMVAC for advising the Agency that it has voluntarily ceased the sale of Dacthal Flowable Herbicide and will not continue sales unless EPA approves an amended label. EPA further thanks AMVAC for voluntarily proposing to discontinue DCPA use on onions; voluntarily proposing to discontinue broadcast applications of DCPA to crops; and voluntarily proposing to restrict the use of DCPA to the states of Arizona and California.

While AMVAC's draft label proposes new restrictions, mitigations, and use deletions when compared to the existing label,<sup>1</sup> and the bystander risks previously identified by EPA have been resolved in this proposed label, some of the other risks identified by the Agency would remain of concern if this label were to be approved and implemented. As explained in our letter to AMVAC dated April 1, 2024, pregnant women could be exposed to DCPA without experiencing adverse health effects to their own body, while the fetus being carried could experience permanent and significant lifelong adverse effects. Given the risks of these adverse effects that remain after consideration of the changes made in AMVAC's proposed label for Dacthal Flowable Herbicide, EPA cannot make a determination that this product label satisfies the standard for registration as stated in FIFRA § 3(c)(5) and, accordingly, **cannot approve this product label.**

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<sup>1</sup> Dacthal Flowable Herbicide product label (accepted October 12, 2012), available at [https://www3.epa.gov/pesticides/chem\\_search/ppls/005481-00487-20121012.pdf](https://www3.epa.gov/pesticides/chem_search/ppls/005481-00487-20121012.pdf).

## Summary of Preceding Correspondence Related to Mitigation

After EPA published its Occupational and Residential Exposure (ORE) assessment on June 1, 2023, the Agency and AMVAC briefly met to discuss the document. AMVAC submitted its public comment on the ORE assessment on July 3, 2023, in which it outlined an initial mitigation strategy for DCPA. EPA sent AMVAC clarifying questions about its strategy on September 8, 2023; AMVAC responded on September 18, 2023, and the two parties met to discuss these responses on September 25, 2023. The Agency sent an analysis of AMVAC's initial mitigation strategy and clarifications on October 16, 2023. EPA sent AMVAC a summary of this analysis on November 2, 2023, and the two parties met on November 8, 2023 to discuss this analysis. EPA sent AMVAC further clarifying information on November 15, 2023, and AMVAC responded to EPA's analysis and supplemental materials on November 21, 2023. EPA commented on AMVAC's response to its analysis of the mitigation proposal on December 14, 2023. AMVAC responded with comments again on January 30, 2024. The two parties met again on February 13, 2024. AMVAC followed up with further commentary on its mitigation strategy. EPA sent its response on AMVAC's mitigation strategy on April 1, 2024, and stated its intent to pursue other regulatory options to resolve the remaining risks of concern associated with DCPA use.

## Summary of Remaining Risk Concerns

### *Post-application Risk*

AMVAC's proposed label retains uses on both direct-seeded and transplanted crops. The post-application risks from applications made over transplanted crops remain of concern. AMVAC submitted a proposed rationale for the Agency to use an early-season transfer coefficient (TC) in its re-entry calculations since the foliage on transplants is anticipated by AMVAC to be minimal. Upon further review by the Agency, the use of the early-season TC will not appreciably reduce the risk estimates.

The Agency has calculated margins of exposure (MOEs) based on AMVAC's proposed re-entry restrictions that range from 6.6 to 8.9 depending on the re-entry task. MOEs calculated using the current label's restricted entry interval of 12 hours range from 0.12 to 1.6 depending on the re-entry task. The level of concern (LOC) for these post-application scenarios is 100; MOEs greater than or equal to the LOC are not a risk of concern. EPA has previously stated in communications to AMVAC that, given the low dosage at which effects were identified in the thyroid study and the extended timeframe required for DCPA residues to dissipate on foliage after application, over the top applications of DCPA to the foliage of crops would result in risks of concern.<sup>2</sup> While AMVAC's proposed re-entry restrictions do incrementally decrease the risks posed by DCPA to post-application workers, the risks remain of concern.

AMVAC's proposed label restricts DCPA use to Arizona and California. "In Arizona and California apparently the majority of broccoli is directly seeded while the majority of cauliflower is

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<sup>2</sup> EPA mitigation analysis dated October 16, 2023; EPA mitigation analysis summary sent November 02, 2023; clarifying materials sent November 15, 2023; and EPA commentary on AMVAC's mitigation analysis responses dated December 14, 2023. See also EPA's April 01, 2024 letter to AMVAC, available at <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0374-0112>.

transplanted.”<sup>3</sup> Growers of cole crops that have been transplanted “typically need [workers] to re-enter those fields within the first week after transplanting for scouting (transplants are very sensitive to pest damage) or irrigation.”<sup>4</sup> EPA has calculated the re-entry restrictions necessary to eliminate risks of concern for these workers based on the parameters specified in AMVAC’s proposed label (Table 1). Depending on the post-application task being performed, these re-entry restrictions range from 28 days to over 30 days. EPA acknowledges that post-application exposure immediately after transplanting and treatment is likely to be minimal considering the size of the transplants. However, the fact that post-application exposures/risks are still of concern up to 28 days or more after treatment indicates that there is the potential for risk concerns for workers who need to enter the field to conduct various activities later in the season from exposure to treated transplants that have grown in size and still have residues present on the foliage. It should be noted that the dislodgeable foliar residue data available for DCPA indicates that residues are still detected out to 57 days (0.003 ug/cm<sup>2</sup>) which was the length of the study. Residues as low as 0.03 ug/cm<sup>2</sup> (estimated around day 40 based on the available data) result in risk estimates of concern for certain activities. For example, scouting in mature broccoli or cauliflower fields on day 40 would result in a MOE of 53 (level of concern is 100). Therefore, post-application worker risks are unlikely to be mitigated by re-entry restrictions alone, and the only way to mitigate post-application risks of concern is to prohibit any applications of DCPA over the top of the crop (only permit pre-plant applications).<sup>5</sup>

Table 1. Post-application risk estimates for DCPA.

Crop	Activity	TC (cm <sup>2</sup> /hr)	App rate (lb ai/A)	MOE on Day 0 (12 hours after application – current REI) (LOC = 100)	Day at which MOE ≥ LOC of 100 (MOE) (LOC = 100)	Amvac’s Proposed Post-App Mitigation (LOC = 100)
Broccoli, Brussels sprouts, Chinese cabbage (bok choy), Chinese cabbage (napa), cauliflower	Scouting	330	6.75	1.6	28 (110)	4/9/24 draft label: proposed 10 day REI (MOE: 7.2)
	Hand weeding	1400		0.37	>30 (35 on Day 30)	4/9/24 draft label: proposed 21 day hand-weeding restriction (MOE = 8.9)
	Hand set irrigation	1900		0.28	>30 (26 on Day 30)	4/9/24 draft label: proposed 21 day hand-set irrigation restriction (MOE = 6.6)
	Scouting, Hand harvesting, Hand weeding	4200		0.12	>30 (12 on Day 30)	AMVAC proposal is that high TC representing max foliage/full height is not applicable based on leaf size data and modeling they did with respect to leaf size/area and days after transplant <sup>1</sup>

1. According to AMVAC’s submission, early season transfer coefficients “based on crop character of low height and minimal foliage are appropriate for transplanted cole crops until at least day 37 post-transplant.”

<sup>3</sup> EPA/OPP Information & Inquiry Dacthal (DCPA) Use on Brassica and Cole Crops (USDA, March 8, 2024), available at <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0374-0114>.

<sup>4</sup> EPA/OPP Information & Inquiry Dacthal (DCPA) Use on Brassica and Cole Crops (USDA, March 8, 2024), available at <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0374-0114>.

<sup>5</sup> EPA mitigation analysis dated October 16, 2023; EPA mitigation analysis summary sent November 02, 2023; clarifying materials sent November 15, 2023; and EPA commentary on AMVAC’s mitigation analysis responses dated December 14, 2023. See also EPA’s April 01, 2024 letter to AMVAC, available at <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0374-0112>.

## Handler Risk

AMVAC's proposed label specifies that this product can only be applied by banded ground applications not to exceed 50% of crop bed width. AMVAC has furthermore proposed daily limits on the amounts of DCPA that can be handled by pesticide mixers/loaders and applicators as part of its plan to address risk concerns:

- For pesticide mixers/loaders, AMVAC has proposed a daily limit of 19.2 gallons product/day (equal to 115.2 lb of active ingredient (a. i.) per day). If applications are made to the entire crop area, this equates to an acreage limit for pesticide mixers/loaders of 17 A/day at the maximum rate. If a 50% banded application pattern is used, this equates to an acreage limit for pesticide mixers/loaders of 34 A/day at the maximum rate.
- For pesticide applicators, AMVAC has proposed a daily limit of 15 gallons product/day (equal to 90 lb a. i./day). If applications are made to the entire crop area, this equates to an acreage limit for pesticide applicators of 13 A/day at the maximum rate. If a 50% banded application pattern is used, this equates to an acreage limit for pesticide applicators of 26 A/day at the maximum rate.

AMVAC has proposed the use of engineering controls, in addition to a double layer of clothing (i.e., coveralls over long sleeve shirt, long pants, shoes, socks) and gloves as another part of its pesticide handler risk mitigation strategy. EPA can assume that the PPE proposed by AMVAC will provide greater protection for pesticide handlers than the PPE specified by the current product label. However, EPA currently has no means to quantify the extra amount of protection provided by this level of PPE with the use of engineering controls. Additionally, the Agency estimated risks assuming workers are using engineering controls along with a single layer of clothing (long sleeve shirt, long pants, shoes, socks) and gloves in its calculations for current product labels.

EPA has recalculated pesticide handler MOEs in light of AMVAC's proposed label. Considering AMVAC's proposed application rate, banded application specification, and limitations on amounts handled, the combined MOEs (dermal plus inhalation) for both mixers/loaders and applicators is 98 (LOC = 100).

EPA evaluated usage data obtained from the California Pesticide Use Reporting (CalPUR) database for the years 2017-2021. More than 95% of the individually-reported DCPA applications to broccoli, Brussels sprouts, cabbage, and cauliflower were less than 30 A total. A daily acreage application limitation of 30 A for *Brassica* crops would likely have the biggest impact on the largest farming operations, which represent a small proportion of growers of these crops. The CalPUR data further indicate that daily applications to crop areas less than the 13 A and 17 A proposed by AMVAC as limitations for pesticide handlers accounted for between 50-80% of the applications reported for these crops. EPA does not have similar usage data available for Arizona. While AMVAC's proposal may be feasible based on EPA's analysis of available usage data for some crops grown in California, uncertainty remains for crops grown in Arizona, there is no recordkeeping requirement to track each handler involved in each application, and no enforcement mechanism in place to ensure these limits are followed. Therefore, EPA cannot accept this level of uncertainty based on its current analysis.

EPA understands AMVAC submitted this draft label "in good faith based on strong scientific rationale," as stated in its email dated April 9, 2024. Unfortunately, given the risks of concern that remain after

consideration of the changes made in AMVAC's proposed label for Dacthal Flowable Herbicide (EPA Reg. No. 5481-487), EPA cannot make a determination that this proposed product label satisfies the standard for registration as stated in FIFRA § 3(c)(5). Therefore, EPA cannot approve this product label. Given the significant health risks to pregnant individuals and their developing babies exposed to DCPA, EPA is working to develop a regulatory response pursuant to FIFRA § 6. Due to the serious potential risks posed by DCPA use, EPA will be pursuing these regulatory options as soon as practical.

Sincerely,



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