No. 24-1068

IN THE
Supreme Court of the United States

MONSANTO COMPANY,
Petitioner,

v.

JOHN L. DURNELL,
Respondent.

On Petition for a Writ of Certiorari to the Missouri Court of Appeals

BRIEF IN OPPOSITION FOR RESPONDENT

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QUESTION PRESENTED

In *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), this Court held that the Federal Insecticide, Fungicide, and Rodenticide Act preempts only state-law labeling requirements that are broader than the statute's misbranding standard. State-law claims that target product marketing are not preempted because they do not "require[] that manufacturers label or package their products in any particular way." *Id.* at 444. And claims that target product labeling are preempted only if they impose "requirements that are '*in addition to or different from*' the labeling and packaging requirements under FIFRA." *Id.* at 447 (quoting 7 U.S.C. § 136v(b)) (emphasis in *Bates*).

Respondent John L. Durnell developed non-Hodgkin lymphoma after long exposure to petitioner Monsanto Company's weedkiller, Roundup. Durnell relied on Monsanto's off-label advertisements, which marketed Roundup as safe to spray without the need for personal protective equipment or other precautions. And he relied on Roundup's labeling, which contained no warning that the International Agency for Research on Cancer considers glyphosate, one of Roundup's ingredients, a probable human carcinogen. A jury found that Roundup caused Durnell's cancer and held Monsanto liable for failing to warn of the product's danger in off-label marketing or in its label.

The question presented is:

Whether this Court should issue an advisory opinion holding that the Missouri Court of Appeals correctly applied *Bates* in holding that Durnell's label-based failure-to-warn claim was not preempted when it was equivalent to FIFRA's misbranding standard.

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INTRODUCTION

Monsanto has known for decades that its popular weedkiller, Roundup, can cause cancer. But the company has refused to make its product safer or to inform consumers that they should exercise caution when using it. Instead, Monsanto has marketed Roundup as safe to spray in a t-shirt and shorts.

Respondent John L. Durnell is one of Monsanto's victims. Unaware of the dangers, he used Roundup to keep his St. Louis community free from weeds. From the 1990s until his cancer diagnosis in 2018, Durnell sprayed the weedkiller in parks near his home. The result was a deadly and incurable form of non-Hodgkin lymphoma, a blood cancer. The jury found that Roundup caused that cancer and that Monsanto was liable for Durnell's damages.

Monsanto now argues—as it has argued with little success for years—that it should be immune from claims like Durnell's, which it says are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y, or FIFRA. As the Solicitor General explained in a similar case, Monsanto is incorrect.

This case meets none of the traditional criteria for certiorari. To begin, this Court's review of Monsanto's preemption argument would be purely advisory. In *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), the leading case on FIFRA preemption, this Court held it was "perfectly clear" that FIFRA does not preempt claims that would not require manufacturers to "label or package their products in any particular way." *Id.* at 444. That describes Durnell's claim, which covered off-label conduct like Monsanto's failure to warn of Roundup's dangers in advertisements on which Durnell relied. Nothing in FIFRA prevented

those advertisements from warning consumers that Roundup may be carcinogenic or that they should wear protective gear when spraying it. This Court's review of the labeling issue would not affect this alternative basis for affirmance, which Monsanto ignores.

Even if this Court views the labeling issues as central, there is no split in authority and the decision below is correct. The only case Monsanto cites as favorable is *Schaffner v. Monsanto Corp.*, 113 F.4th 364 (3d Cir. 2024), where the Third Circuit "express[ed] no opinion as to whether" the theory of liability Durnell has advanced was preempted. *Id.* at 386 n.13. It is not: FIFRA preempts only state-law labeling requirements broader than federal requirements. Missouri failure-to-warn claims parallel FIFRA, so they are not preempted. As the Solicitor General has explained, FIFRA's preemption provision is "narrow" and does not cover claims like Durnell's.

Finally, Monsanto's implied-preemption argument —that federal law prohibits the cancer warning that Missouri law requires—lacks merit. Monsanto never has proposed a cancer warning for formulated Roundup, and the U.S. Environmental Protection Agency never has rejected one. Instead, EPA has confirmed that FIFRA permits Monsanto to warn that the science shows Roundup is carcinogenic.

Missouri has a right to protect its citizens from the detrimental health effects of dangerous pesticides. And Monsanto has exposed unwitting Missourians to deadly harm. The company has tried and failed to get Missouri's legislature to immunize it from liability for this misconduct. This Court should reject the company's attempt to get that same relief by judicial fiat.

STATEMENT

A. Statutory And Regulatory Background

1. FIFRA regulates "the use, as well as the sale and labeling, of pesticides." *Bates* 544 U.S. at 437. As relevant here, the statute proscribes marketing "any pesticide which is . . . misbranded." § 136j(a)(1)(E).[1] A pesticide is "misbranded" if its label contains a statement that is "false or misleading," § 136(q)(1)(A), or omits adequate instructions for use, necessary warnings, or cautionary statements, § 136(q)(1)(F), (G).

If EPA determines a pesticide is misbranded, it may cancel the pesticide's registration, § 136d(b); issue "stop sale, use, or removal" orders, § 136k(a); and seize misbranded products, § 136k(b). Manufacturers that sell misbranded products face civil and criminal penalties. § 136*l*.

2. FIFRA requires pesticide manufacturers to register their products. § 136a(a). EPA will register a pesticide if it determines—based on data the manufacturer submits—that (1) the product will not cause unreasonable harm to humans and the environment and (2) the product label is not "misbranded" under FIFRA. § 136a(c)(5)(B)-(D). EPA re-reviews a pesticide's registration, including its effects on human health, every 15 years. § 136a(g)(1)(A).

FIFRA confirms that obtaining registration does not relieve the registrant of liability if the pesticide is misbranded. "In no event shall registration of an article be construed as a defense for the commission of any offense under [FIFRA]." § 136a(f)(2). Instead, registration is merely "prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions." *Id.* "Because it is unlawful

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[1] Except where noted, U.S. Code citations are to Title 7.

under the statute to sell a pesticide that is registered but nevertheless misbranded, manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements." *Bates*, 544 U.S. at 438.

Monsanto has updated Roundup's labeling 44 times since 1991 but never has sought permission from EPA to warn of the product's cancer risks. As part of a proposed settlement of multidistrict litigation, the company agreed to seek permission from EPA to add on Roundup labels "links to relevant scientific evidence and materials related to whether exposure to Roundup Products causes [non-Hodgkin lymphoma]" going forward. Class Action Settlement Agreement at PDF p. 167, *In re Roundup Prods. Liab. Litig.*, No. 3:16-md-2741-VC, ECF #12509-2 (N.D. Cal. Feb. 3, 2021). The MDL court rejected the settlement on other grounds, and Monsanto never made that request of EPA.

3. FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Bates*, 544 U.S. at 450. Indeed, States may ban a federally registered pesticide, even if EPA does not consider it misbranded. *Id.* at 446. Section 136v(a) thus recognizes States' historic authority to regulate pesticides:

> **(a) In general**
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by [FIFRA].

§ 136v(a).

The only statutory limit on that traditional state authority is a "narrow" preemption provision, *Bates*, 544 U.S. at 452, which "prohibits only state-law labeling and packaging requirements that are '*in addition to*

or different from' the labeling and packaging requirements under FIFRA," *id.* at 447 (quoting § 136v(b)) (emphasis in *Bates*):

> **(b) Uniformity**
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under [FIFRA].

§ 136v(b).

Companies like Monsanto routinely obtain approval for state- and locality-specific warnings on the labels of their products. For example, Roundup Power Max's label discusses "requirements specific to your State or Tribe," App.30a,[2] and includes such state-specific requirements as restrictions on aerial spraying in California and Arkansas, App.35a-40a, or different application rates for sugarcane in Florida, Hawaii, Louisiana, and Texas, App.42a-43a.

B. Factual Background

Roundup is a weedkiller developed by Monsanto. It contains the active ingredient glyphosate, which kills plants at their roots. Court of Appeals Respondent's Appendix ("RA") 4 (¶ 12); 3 Tr. 1663:23-25.[3] What follows is the evidence relevant to preemption introduced at Durnell's trial, where the jury found Monsanto liable for failing to warn of Roundup's cancer risks. This Court "view[s] the evidence in the light most favorable" to the jury's verdict. *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 213 (1993).

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[2] Citations to "App.__a" are to the Appendix accompanying this brief, which reproduces certain trial exhibits.

[3] Citations to "Tr." are to the Transcript on Appeal in No. ED112410 (Mo. Ct. App. June 13, 2024).

1. Monsanto long has marketed Roundup as a general-purpose weedkiller. RA4 (¶ 13), RA45 (¶ 38). Roundup's labeling does not tell consumers to wear a mask, gloves, or other personal protective equipment when spraying the weedkiller. 4 Tr. 2509:9-21. And Monsanto has marketed Roundup as safe to use without such precautions, including in television advertisements with a man using Roundup "sort of like a sharp shooter" shooting "weeds in his driveway" while dressed in a "[s]hort-sleeve shirt, no gloves." 4 Tr. 2515:11-2516:11.

The company offers stronger warnings to more sophisticated users. Farmers, who typically buy Roundup in concentrated form, are warned to wear gloves when spraying the product and to wash their clothes afterward. 3 Tr. 2344:10-2347:21; App.30a.

2. Monsanto has had EPA's approval to sell glyphosate-based weedkillers since the mid-1970s. RA4 (¶ 12), RA8 (¶ 16). To obtain that approval, Monsanto submitted studies conducted by Industrial Bio-Test Laboratories, or IBT. RA39 (¶ 9).

IBT's studies were fraudulent, as the Food and Drug Administration (not EPA) later uncovered. RA68; 2 Tr. 1020:8-1022:24; *see Pilliod v. Monsanto Co.*, 282 Cal. Rptr. 3d 679, 710 (Ct. App. 2021) ("fraudulent data" from IBT). Three IBT executives were convicted of criminal fraud in 1983. RA39 (¶ 11). Dr. Paul Wright, a longtime Monsanto employee, was one of them. *Id.*; 2 Tr. 1021:14-16.

IBT's fraud surfaced in 1976. RA68. Yet Monsanto did not inform consumers about the fraud, remove Roundup from the market, or add warnings. *See Pilliod*, 282 Cal. Rptr. 3d at 712. A 1983 EPA report explained that, after IBT's fraud was exposed, some experts advocated "that all 212 pesticides tested in

whole or in part by IBT be removed from the market pending retesting." RA63. But "that option [wa]s not available under [then-]current law." *Id.*

Nearly a decade passed before a valid study assessed glyphosate. RA40 (¶ 13). In 1985, EPA reviewed studies showing that glyphosate could cause cancer in laboratory animals. *Id.* (¶ 15); App.18a. Based on that review, EPA classified glyphosate as a possible human carcinogen. RA40 (¶ 15); *see Hardeman v. Monsanto Co.*, 997 F.3d 941, 951 (9th Cir. 2021).

3. In the late 1990s, four studies concluded that glyphosate was possibly genotoxic. RA41 (¶ 22); *see* RA73. Genotoxic substances damage genetic information in cells, causing mutations that may lead to cancer. *See Pilliod*, 282 Cal. Rptr. 3d at 689 n.2. Monsanto hired Dr. James Parry to review the studies. App.1a; 3 Tr. 1702:21-1703:4. Dr. Parry concluded that glyphosate could be genotoxic and suggested a battery of tests that Monsanto could conduct to learn more. App.1a-8a.

After reading one of Dr. Parry's reports, Monsanto's Dr. William Heydens candidly wrote to colleagues:

> [L]et's step back and look at what we are really trying to achieve here. We want to find/develop someone who is comfortable with the genetox profile of glyphosate/Roundup and who can be influential with regulators and Scientific Outreach operations when genetox[] issues arise. My read is that Parry is not currently such a person, and it would take quite some time and $$$/studies to get him there. . . . Mark, do you think Parry can become a strong advocate without doing this work . . . ? If not, we should ***seriously*** start looking for one or more other individuals to work with. Even

> if we think we can eventually bring Parry around closer to where we need him, we should be currently looking for a second/back-up genetox[] supporter.

App.9a-10a. Dr. Heydens decreed that "We simply aren't going to do the studies Parry suggests." *Id.* And Monsanto never did conduct any of Dr. Parry's suggested tests. RA43 (¶ 28). Nor did Monsanto share Dr. Parry's report or suggestions with EPA. RA44 (¶ 30).[4]

Monsanto instead retained Dr. Gary Williams, a pathologist. RA45 (¶ 39). Dr. Williams published an article in 2000 concluding that Roundup does not pose a health risk to humans. *Id.* But Dr. Williams did not write that article; Monsanto's Dr. Heydens ghostwrote it. RA46 (¶ 40). EPA later relied on the Williams article when evaluating glyphosate's carcinogenic potential. *Id.* (¶ 42).

In sum, "after its own hired expert, Dr. Parry, found that glyphosate—alone and when mixed with other chemicals in Roundup—had increased genotoxic risks, evidence was sufficient to infer that Monsanto largely failed to perform further studies. Instead, Monsanto helped author an article downplaying glyphosate's health and safety concerns." *Hardeman*, 997 F.3d at 971.

4. Monsanto has resisted testing formulated Roundup. Glyphosate is not the only ingredient in the weedkiller; it also contains a surfactant. In the United States, the surfactant is polyethoxylated tallow amine,

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[4] Monsanto's failure to share Dr. Parry's report with EPA violated FIFRA, which requires manufacturers to report "factual information regarding unreasonable adverse effects on the environment of [a] pesticide" to EPA on an ongoing basis, § 136d(a)(2); *see* 40 C.F.R. § 159.158(a).

or POEA. RA44 (¶ 33). Surfactants decrease surface tension, so POEA enables Roundup to penetrate the waxy surface of a leaf—or human skin. 3 Tr. 1664:3-6, 1665:4-8, 2008:12-16.

POEA makes Roundup more genotoxic. RA44 (¶ 34). POEA is banned in Europe, where Monsanto now sells Roundup with a less toxic surfactant. Monsanto's Dr. Heydens wrote in 2015 that he believed "the surfactant in the formulation . . . played a role" in a tumor promotion study. RA80; *see* RA45 (¶ 36).

Roundup contains other carcinogenic ingredients, too. App.20a-22a. As one of Durnell's experts testified, formulated Roundup contains "[s]everal" cancer-causing contaminants and impurities, including "Ethylene oxide and 1,4-Dioxane." 3 Tr. 2007:22-2008-2.

Monsanto never has tested whether Roundup as formulated causes cancer. App.45a. In a 2009 email, Dr. Farmer wrote that the company "cannot say that Roundup does not cause cancer . . . we have not done carcinogenicity studies with 'Roundup.'" App.11a (ellipsis in original).

5. In 2015, a working group at the International Agency for Research on Cancer, or IARC, concluded that glyphosate is probably carcinogenic to humans. RA48 (¶ 50). IARC is one "of the most well-respected and prestigious scientific bodies," whose assessments of the carcinogenicity of chemicals "are generally recognized as authoritative." Fed. Jud. Ctr., *Reference Manual on Scientific Evidence* 20, 564 n.46 (3d ed. 2011), https://perma.cc/V9UT-98DR. Soon after, other countries banned Roundup.

In 2017, based on IARC's finding, California categorized glyphosate as a chemical known to the State to cause cancer. *See* California Off. of Env't Health

Hazard Assessment, *Initial Statement of Reasons: Glyphosate Proposition 65 Safe Harbors* (Mar. 28, 2017), https://perma.cc/BL9Q-MPAY. California requires a warning label on glyphosate products. *See* OEHHA, *Glyphosate*, https://perma.cc/E6VM-MCAF.

6. EPA has made no formal findings about whether formulated Roundup causes cancer. In 2017, the agency determined that it could not reach "a conclusion regarding the association between glyphosate exposure and risk of [non-Hodgkin lymphoma]."[5] EPA explained that the data were uncertain, partly because "farmers and other applicators apply *formulations*, *not the active ingredient alone*."[6] Agency advisors had "conflicting views on how to interpret the overall results for [non-Hodgkin lymphoma]."[7] And EPA acknowledged the need for more research "to determine whether formulation components, such as surfactants, influence the toxicity of glyphosate formulations."[8]

In April 2019, EPA noted that "[m]any commenters expressed concerns that glyphosate formulations are more toxic than glyphosate alone and questioned the toxicity of inert ingredients and the lack of transparency for inert ingredients and other contaminants in pesticide products."[9] In response, EPA acknowledged

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[5] Off. of Pesticide Programs, EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 68 (Dec. 12, 2017), https://perma.cc/2WJM-MT7R.

[6] *Id.* at 137 (emphasis added).

[7] *Id.* at 67.

[8] *Id.* at 144.

[9] EPA, *Glyphosate: Proposed Interim Registration Review Decision*, No. 0178, at 10 (Apr. 2019), https://perma.cc/P84R-A93H.

that "few research projects" had tried to compare "technical grade glyphosate" to glyphosate-based formulations like Roundup.[10] EPA said if, "at any time, information becomes available that indicates adverse human health effects of concern for exposure to glyphosate or its formulations, the EPA intends to review it and determine the appropriate regulatory action."[11]

In August 2019, the Director of the Registration Division within EPA's Office of Pesticide Programs issued a letter to all glyphosate-based product registrants. Letter from EPA to Glyphosate Registrants (Aug. 7, 2019), https://perma.cc/6ZL4-JF8P ("August 2019 Letter"). The letter stated EPA would no longer approve labeling that warned consumers glyphosate was a chemical known to California to cause cancer, and that manufacturers must remove such a glyphosate-based cancer warning. *Id.* This letter was not the product of notice-and-comment rulemaking and took no position on whether Roundup causes cancer.

In April 2022, a higher-ranking EPA official, the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, wrote that "EPA could approve" California's newly proposed glyphosate-specific warning:

> CALIFORNIA PROPOSITION 65 WARNING: Using this product can expose you to glyphosate. [IARC] classified glyphosate as probably carcinogenic to humans. US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations. A wide variety of factors affect

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[10] *Id.* at 11.

[11] *Id.*

> your potential risk, including the level and duration of exposure to the chemical. For more information, including ways to reduce your exposure, go to www.P65Warnings.ca.gov/glyphosate.

RA57 ("April 2022 Letter"). The Assistant Administrator added that EPA "could" approve the warning "if pesticide registrants" like Monsanto "requested it for inclusion on glyphosate product labels." RA58. Because the warning "would not be considered false and misleading," products bearing it "would not be considered misbranded." *Id.*

7. EPA's conclusion that glyphosate is not likely to cause cancer has been vacated. FIFRA requires that "registrations of pesticides are to be periodically reviewed" by EPA every 15 years. § 136a(g)(1)(A). In 2009, EPA started its re-registration review of glyphosate. EPA "decided to conduct registration review on glyphosate, an active ingredient," rather than to "evaluate each pesticide product registration [such as Roundup] individually." *NRDC v. EPA*, 38 F.4th 34, 41 n.2 (9th Cir. 2022).

EPA's re-registration proceeding lasted 11 years. In January 2020, the agency "determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans." *Id.* at 43.

The Ninth Circuit vacated the agency's "not likely to be carcinogenic" conclusion, calling EPA's reasoning "the hallmark of arbitrary action." *Id.* at 51. The "not likely" determination was "in tension with parts of the agency's own analysis and with the guidelines it purports to follow," and thus not supported by "substantial evidence." *Id.* at 46, 51. For example, "most studies EPA examined indicated that human exposure to glyphosate is associated with an at least

somewhat increased risk of developing [non-Hodgkin lymphoma]." *Id.* at 46.

8. The United States has taken the position that EPA registration decisions do not preempt state-law claims. In May 2021, the Ninth Circuit in *Hardeman* affirmed a jury verdict that Roundup caused Edwin Hardeman's cancer. The court rejected Monsanto's preemption claim because "EPA actions that Monsanto alleges preempt Hardeman's claims"—registration of Roundup and the August 2019 Letter—"do not carry the force of law." *Hardeman*, 997 F.3d at 956.

Monsanto sought certiorari, and this Court called for the views of the Solicitor General. The United States opposed certiorari, explaining that *Hardeman* was correctly decided. *See* U.S. Amicus Brief, *Monsanto Co. v. Hardeman*, No. 21-241 (U.S. May 10, 2022) ("SG *Hardeman* Br."). The United States said, "EPA's approval of pesticide labeling without a chronic-risk warning is not naturally characterized as a FIFRA 'requirement' that no such warning appear," noting that a "'requirement is a rule of law that must be obeyed.'" *Id.* at 11-12 (quoting *Bates*, 544 U.S. at 445). The Court denied certiorari. *Monsanto Co. v. Hardeman*, 142 S. Ct. 2834 (2022); *see also Monsanto Co. v. Pilliod*, 142 S. Ct. 2870 (2022) (same).

9. For two years, Monsanto has been seeking a legislative fix in Missouri. It tried and failed to get a bill passed in 2024 granting it immunity from Missouri failure-to-warn liability. And it tried and failed to get similar legislation passed this year. *See* Jack Suntrup, *Nine Missouri Republicans declare Bayer legal shield 'dead on arrival' in Senate,* St. Louis Post-Dispatch (Feb. 24, 2025), *available at* https://www.stltoday.com/news/local/government-politics/article_4131afb6-f2c0-11ef-ae59-dfe1b4dfa17d.html.

C. Procedural History

1. Respondent John L. Durnell started using Roundup in 1996. 4 Tr. 2584:18-22. For more than two decades, Durnell sprayed the weedkiller at the parks around the historic Soulard neighborhood of St. Louis—he "was the spray guy" for a neighborhood association. 4 Tr. 2461:4-10, 2463:9-12, 2520:13-15. Spraying Roundup would take Durnell hours each week during the growing months. 4 Tr. 2537:10-23. He did not wear protective equipment—gloves, a face mask, or goggles—when spraying. 4 Tr. 2518:14-19.

Durnell thought safety precautions were unnecessary. Based on Roundup's marketing and labeling, he thought the weedkiller "was a safe product to use." 4 Tr. 2485:17-21. He trusted Monsanto to sell safe products—or at least to warn about any dangers or risks associated with its products. 4 Tr. 2514:12-22. Monsanto never included such a safety warning on its Roundup bottles or in its advertisements. 4 Tr. 2514:23-25, 2515:21-2516:4. Instead, the company marketed the weedkiller with Western-themed advertisements featuring a homeowner wearing short sleeves and "using the small Windex-size bottle of Roundup sort of like a sharp shooter." 4 Tr. 2515:15-20, 2516:7-11. Durnell would not have bought Roundup if Monsanto had disclosed that the weedkiller could cause cancer. 4 Tr. 2515:7-10, 2517:8-10.

Durnell was diagnosed with mantle cell lymphoma in 2018. Mantle cell lymphoma is both fatal and incurable—in other words, if Durnell does not die of other means, he will die of this cancer. 4 Tr. 2671:23-24, 2681:8-12. Durnell's first thought after receiving his diagnosis was "who's going to take care of Richard," his husband and partner of five decades. 4 Tr. 2564:3-8.

Durnell is in remission. 4 Tr. 2569:19; *see* App.49a. But multiple rounds of chemotherapy have left a lasting mark: Durnell lost 15 pounds, 4 Tr. 2567:14, endured excruciating pain, and has continuing issues with his legs, 4 Tr. 2568:10-12, 2568:19-2569:25. He is no longer able to work to beautify his neighborhood—in his words, "I'm not that physical any longer." 4 Tr. 2573:1-5.

2. Durnell sued Monsanto in January 2019. RA2 (¶ 1). He brought design-defect and failure-to-warn claims in strict liability and negligence.

At summary judgment, the trial court rejected Monsanto's express- and implied-preemption arguments. Court of Appeals Appellant's Appendix ("AA") 4. The court likewise found a triable issue of fact on Durnell's claim for punitive damages. *Id.*

At trial, Durnell presented expert testimony proving that Roundup causes non-Hodgkin lymphoma and that his own exposure to Roundup was a direct cause of his cancer. And the jury heard testimony about Monsanto's reprehensible conduct.

The jury awarded $1.25 million to Durnell in compensatory damages on his failure-to-warn claim. AA10. The jury found for Monsanto on Durnell's claims for design defect, negligence, and punitive damages. *Id.*

Monsanto moved for judgment notwithstanding the verdict. The trial court denied the motion. AA9.

3. Monsanto appealed on preemption grounds. App.4. The Missouri Court of Appeals, Eastern District, affirmed. App.2. The appellate court found Durnell's claim not preempted because "a strict liability failure to warn claim in Missouri does not impose a requirement 'in addition to or different from' the requirements of FIFRA." App.7.

Monsanto sought further review from the Supreme Court of Missouri, which denied the application. App.1.

REASONS FOR DENYING THE PETITION

Monsanto's petition does not challenge Durnell's off-label failure-to-warn claim. FIFRA does not reach that claim, which presents an alternative basis to affirm the Missouri Court of Appeals. That court also rightly decided that Durnell's label-based failure-to-warn claim against Monsanto was neither expressly nor impliedly preempted. There is no split on that issue, and no other criterion for certiorari is met. The petition therefore should be denied.

I. This Case Implicates No Circuit Conflict

Monsanto's purported circuit split is (1) irrelevant and (2) illusory. It is irrelevant because the jury's verdict here did not turn exclusively on Roundup's labeling. The evidence at trial showed that Monsanto had marketed Roundup as safe in television advertisements that failed to warn Durnell that the weedkiller can cause cancer. Those advertisements are beyond FIFRA's reach; § 136v(b) addresses only pesticide labeling, not TV ads. So no federal requirement stopped Monsanto from warning Durnell about Roundup's cancer risks in advertising or elsewhere. Monsanto ignores this issue, but it provides an independent basis to deny review.

But even as to Monsanto's failure to warn of Roundup's risks in its labeling, there is no real split. In the company's lead case, the Third Circuit "express[ed] no opinion" on the core preemption question here: whether "FIFRA required Monsanto" to seek "EPA approval for a modified Roundup label that included" a cancer warning, thus imposing a federal duty that parallels Missouri law. *Schaffner*,

113 F.4th at 386 n.13. Monsanto's claimed split is an illusion, not a basis for certiorari.

A. Durnell's Failure-To-Warn Verdict Imposed No Labeling Requirements, So Monsanto's Preemption Arguments Are Irrelevant

When the government opposed certiorari in *Hardeman*, it noted that "[f]uture cases involving similar state-law claims may contemplate warnings through non-labeling mechanisms that would not require altering EPA-approved labeling." SG *Hardeman* Br. 20. This is such a case, which makes it unsuitable for further review: no appellate court has assessed whether a failure-to-warn claim involving Monsanto's marketing of Roundup is preempted under FIFRA. "[U]nless and until a conflict in authority emerges" *on that issue*, "[t]here is no sound reason for the Court to grant review." *Id.* at 19.

1. FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Bates*, 544 U.S. at 450. Indeed, States may ban a federally registered pesticide, even if EPA does not consider it misbranded. *Id.* at 446 (citing § 136v(a)).

State tort claims supplement federal pesticide regulation. Although FIFRA itself "does not provide a federal remedy to [those] who are injured as a result of a manufacturer's violation of FIFRA's labeling requirements, nothing in § 136v(b) precludes States from providing such a remedy." *Id.* at 448. There is a "long history of tort litigation against manufacturers of poisonous substances." *Id.* at 449-51. This Court thus observed that "[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder," FIFRA's functioning. *Id.* at 451.

The only statutory limit on state authority is a "narrow" preemption provision, *id.* at 452, which

"prohibits only state-law labeling and packaging requirements that are '*in addition to or different from*' the labeling and packaging requirements under FIFRA," *id.* at 447 (quoting § 136v(b)) (emphasis in *Bates*). This provision "calls for an examination of the elements of the common-law duty at issue." *Id.* at 445. For a state tort claim to be preempted, it must set forth (1) "a requirement '*for labeling or packaging*'" (2) "that is '*in addition to or different from*'" one of FIFRA's requirements. *Id.* at 443-44 (quoting § 136v(b)) (emphases in *Bates*).

The preemption inquiry thus proceeds in two steps: Courts first ask whether a state-law claim imposes any requirement for pesticide labeling or packaging. Claims that would not require manufacturers to "label or package their products in any particular way" are not preempted. *Id.* at 444; *see id.* ("petitioners' claims for defective design . . . are not pre-empted"). For example, *Bates* found it "perfectly clear" that common-law claims "that require manufacturers to design reasonably safe products" and "use due care in conducting appropriate testing of their products" are not preempted. *Id.*

Next, courts ask whether the state-law labeling requirement is "in addition to or different from those required under [FIFRA]." § 136v(b). Common-law duties are not preempted if they are "equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Bates*, 544 U.S. at 447; *see id.* at 454 ("[A] manufacturer should not be held liable under a state labeling requirement subject to § 136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA."). In other words, FIFRA does not preempt state-law claims that impose "parallel requirements" to those in FIFRA. *Id.* at 447.

2. Monsanto's argument fails at the first step, as Durnell's failure-to-warn claim imposed no labeling or packaging requirements. Monsanto ignores this issue, but it provides an independent basis to affirm the judgment and to deny the petition.

Durnell's failure-to-warn claim was not limited to Roundup's labeling. Under Missouri law, he just had to show that Monsanto failed to "give adequate warning of the danger." *Moore v. Ford Motor Co.*, 332 S.W.3d 749, 756 (Mo. 2011) (en banc); *see* 5 Tr. 3378:21-22 (instructing jury to consider whether Monsanto failed to "give an adequate warning of the danger" from Roundup). The jury thus heard evidence about the marketing and promotion of Roundup, where Monsanto failed to warn consumers like Durnell about the product's cancer risks. For example, Durnell described an advertisement depicting Roundup as a product that ordinary consumers safely could spray without needing any particular precautions or protective gear. And the jury heard evidence that Durnell saw an advertisement, relied on it, and sprayed the weedkiller around his neighborhood for two decades, all while thinking it was safe. The jury then concluded that "Roundup being sold without an adequate warning"—whether in advertising or elsewhere—"directly [caused] or directly contributed to cause damage to plaintiff John Durnell." 5 Tr. 3378:24-3379:2.

Durnell's failure-to-warn claim thus imposed no requirements for labeling or packaging. *First*, television advertising is not "labeling," which FIFRA defines as "all labels and all other written, printed, or graphic matter" that accompany a pesticide. § 136(p)(2). Like "a sales agent's *oral* representations," *Bates*, 544 U.S. at 444 n.17, a video advertisement does not meet this definition.

Second, Durnell's failure-to-warn claim did not require Monsanto to "label or package their products in any particular way." *Id.* at 444; *cf.* SG *Hardeman* Br. 20 ("It is far from clear . . . that California common law actually requires an on-label warning."). The company could have avoided liability by adding a warning to its television commercials, but chose not to.

Monsanto also could have avoided failure-to-warn liability by providing adequate warnings on Roundup's labeling. But that does not transform Durnell's claim into a labeling or packaging requirement subject to § 136v(b). Under *Bates*, "[a] requirement is a rule of law that *must be obeyed*." 544 U.S. at 445 (emphasis added). Monsanto did not have to obey any labeling or packaging rule—it could have kept Roundup's labeling and packaging the same yet avoided liability by adding a warning to its advertisements.

B. The Third Circuit's Decision In *Schaffner* Created No Split Relevant Here

Even as to Roundup's labeling, this case implicates no circuit conflict. The central feature of Monsanto's petition is an illusory split the company says was opened by *Schaffner*.[12] But that narrow decision provides no support for Monsanto's petition.

1. In *Schaffner*, the Third Circuit found that the plaintiff's Pennsylvania-law claim against Monsanto was preempted. The court explained that a pesticide manufacturer generally has two options to update its product labeling: (1) "'by notification,' a procedure under which the registrant must inform the EPA of

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[12] Counsel for Durnell represented Schaffner in petitioning for en banc review in the Third Circuit, which evidently disagreed that the panel had created a conflict warranting further review.

the modification but need not receive approval before selling or distributing the modified pesticide"; or (2) by applying for amended registration, which requires EPA approval. 113 F.4th at 382. *Schaffner* addressed only the first option, finding it unavailable. *Id.* at 385.

Schaffner did not address the second option because of a unique quirk of that case: The plaintiff there had not argued that "FIFRA required Monsanto" to seek "EPA approval for a modified Roundup label that included" a cancer warning." *Id.* at 386 n.13. So the court "express[ed] no opinion as to whether [that argument] could succeed." *Id.* That express limitation deprives *Schaffner* of any broader applicability.

In contrast to the plaintiff in *Schaffner*, Durnell has argued all along that FIFRA requires Monsanto to seek EPA approval for a modified Roundup label that includes a cancer warning. Indeed, that conclusion is compelled by *Bates*. There, the Court made clear that "manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements." 544 U.S. at 438. "[I]t is unlawful under the statute to sell a pesticide that is registered but nevertheless misbranded." *Id.* *Bates* thus requires a manufacturer of a registered-but-misbranded pesticide to fix the issue, "including by seeking EPA approval to amend a label that does not contain all 'necessary warnings or cautionary statements.'" SG *Hardeman* Br. 2 (quoting *Bates*, 544 U.S. at 438-39). FIFRA and its regulatory regime thus "contemplate[] that pesticide labels will evolve over time, as manufacturers gain more information." *Bates*, 544 U.S. at 451; *see* SG *Hardeman* Br. 12 n.3.[13]

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[13] Manufacturers have seized on that flexibility. "EPA has repeatedly permitted pesticide manufacturers . . . to add notices related to cancer to their products' labels." *Hardeman*, 997 F.3d at 959. For example, under 40 C.F.R. § 152.46(a), "Bayer

2. Because of the way it was argued, *Schaffner* rests on the assumption that Monsanto had no option to update Roundup's labeling. So to rely on *Schaffner* here, Monsanto echoes that assumption, asserting (at 20-21, 24) that Roundup's labeling is "lock[ed] . . . in place." But Monsanto's assumption is false and was disproved in this case.

Monsanto's own actions put the lie to its claim that Roundup's labeling cannot be changed: The company has updated Roundup's labeling 44 times. And when Monsanto thought it might rid itself of future liability through a settlement of federal multidistrict litigation, it proposed to seek EPA permission to add information about Roundup's cancer risks to its labeling. *Supra* p. 4. The company can add a cancer warning at any time; it has made the business decision not to.

Monsanto focuses (at 20, 29) on 40 C.F.R. § 152.44. But that regulation does not forbid the company from warning of Roundup's cancer risks; it just establishes procedures for manufacturers to update their labels. For example, § 152.44(a) provides that a manufacturer generally must submit proposed labeling changes for EPA approval, and § 152.44(b) gives EPA discretion to waive that requirement. So § 152.44 not only permits Monsanto to add a cancer warning to Roundup's labeling, but explains how to do so—indeed, the title of that regulation is "Application for amended registration."

CropScience notified EPA 'of a minor labeling amendment for LARVIN Technical,' informing EPA that 'as required by California Proposition 65, the following statement has been added to the label, "This product contains a chemical known to the state of California to cause cancer."'" 997 F.3d at 959 n.10 (cleaned up). Had Monsanto—now a Bayer subsidiary—taken the same approach here, it could have prevented Durnell's injuries.

The United States has explained that nothing in FIFRA or its implementing regulations prevents Monsanto from warning of Roundup's cancer risks. "In the FIFRA registration process," where EPA reviews and approves a manufacturer's proposed pesticide label, "EPA neither requires nor precludes any specific chronic-risk warnings, through regulation or otherwise." SG *Hardeman* Br. 19.

II. The Decision Below Is Correct

A. Durnell's Failure-To-Warn Claim Is Not Expressly Preempted

The court of appeals was correct: "Missouri's strict liability failure to warn cause of action is fully consistent" with FIFRA's requirements. App.6. Durnell's claim thus is "equivalent to, and fully consistent with, FIFRA's misbranding provisions," *Bates*, 544 U.S. at 447, not preempted.

First, Durnell had to prove at trial that Monsanto failed to "give an adequate warning of the danger" posed by Roundup. 5 Tr. 3378:21-22; App.6. That duty tracks § 136(q)(1)(G), which requires a warning "necessary" and "adequate to protect health."

Second, Durnell's claim requires warnings in narrower circumstances than FIFRA does. FIFRA requires adequate safety warnings no matter the consumer's knowledge. § 136(q)(1)(G). Missouri requires a warning only if the product is "unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics." 5 Tr. 3378:19-21; *see Moore*, 332 S.W.3d at 756; App.6-7. So Durnell's claim, if anything, imposes less of a duty on Monsanto than FIFRA does.

Because Durnell's failure-to-warn claim parallels FIFRA's misbranding provisions, it functionally enforces the statutory misbranding prohibition. "[A]

state cause of action that seeks to enforce" FIFRA's misbranding provisions "'does not impose a requirement that is "different from, or in addition to," requirements under federal law,'" and so is not preempted. *Bates*, 544 U.S. at 447-48 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 513 (1996) (O'Connor, J., concurring in part and dissenting in part)).

B. Monsanto's Express-Preemption Arguments Lack Merit

Monsanto's cornerstone argument is that EPA's decision to register a pesticide and approve its label imposes a preemptive "requirement" under FIFRA. That argument always has been "incorrect," SG *Hardeman* Br. 6-7; *see infra* pp. 25-27, but it is even less persuasive now that the Ninth Circuit has vacated the reasoning EPA used when registering glyphosate.

1. After an 11-year re-registration process that began in 2009, EPA failed to sustain its initial view that glyphosate was not likely to cause cancer. The Ninth Circuit held that EPA lacked substantial evidence for that position and that its reasoning was "the hallmark of arbitrary action." *NRDC*, 38 F.4th at 51.

Though glyphosate remains registered, whatever preemptive effect registration might have had has been nullified. An agency decision that has been vacated has no legal effect. "In essence, a vacatur order takes the unlawful agency action off the books, which is an entirely appropriate response when a plaintiff successfully establishes that the agency's conduct violates the law." *Kiakombua v. Wolf*, 498 F. Supp. 3d 1, 50 (D.D.C. 2020) (Jackson, J.) (cleaned up). The D.C. Circuit therefore has vacated an agency order because it "relied not only on [an already vacated order] but also on its defective reasoning." *WorldCom, Inc. v. FCC*, 246 F.3d 690, 696 (D.C. Cir. 2001).

EPA's now-vacated conclusion that glyphosate is not carcinogenic thus cannot support preemption. Even so, Monsanto cites (at 11) EPA's statement that its "underlying scientific findings regarding glyphosate, including its finding that glyphosate is not likely to be carcinogenic in humans, remain the same." EPA, *EPA Withdraws Glyphosate Interim Decision* (Sept. 23, 2022), https://perma.cc/EU77-LMGN. That bare (and incorrect) statement has no legal effect, much less a preemptive one. As the United States itself has explained, "EPA's repeated statements that glyphosate is unlikely to be carcinogenic to humans" "do[] not alone preempt enforcement of state tort law." SG *Hardeman* Br. 12-13.

2. Even setting vacatur aside, EPA's decision to register glyphosate cannot immunize Monsanto from tort liability. Registration is not even the last word on whether the pesticide's labeling is misbranded. The agency determines whether a pesticide's warnings are "necessary" and "adequate to protect [public] health" based on material the manufacturer submits. § 136(q)(1)(G); *see* § 136a(c)(2), (c)(5)(B)-(D). If other information, like an "incident[] involving a pesticide's toxic effects," shows the labeling to be misbranded, *Bates*, 544 U.S. at 439, EPA's prior registration decision offers a manufacturer no safe harbor: "EPA may institute cancellation proceedings and take other enforcement action if it determines that a registered pesticide is misbranded." *Id.* (citation omitted).

A manufacturer cannot use EPA's registration of its pesticide "as a defense for the commission of any offense under [FIFRA]," including the misbranding offense. § 136a(f)(2). Rather, registration is only "prima facie evidence" that the pesticide is not misbranded.

Id.[14] As a result, even if EPA approved a label, "a judge or jury" could "find that [the] same label violates FIFRA." *Hardeman*, 997 F.3d at 956.

That is why *Bates* recognized that a pesticide can be "registered but nevertheless misbranded." 544 U.S. at 438. "Against that backdrop," the United States has explained, "EPA's approval of pesticide labeling without a chronic-risk warning is not naturally characterized as a FIFRA 'requirement' that no such warning appear." SG *Hardeman* Br. 11-12. And for good reason: EPA's registration decisions are "based in significant part on proposed labeling and scientific studies submitted by the manufacturer." *Id.* at 12 n.3. Those submissions may be inaccurate, incomplete, or proven inadequate based on later research.

If a pesticide is "registered but nevertheless misbranded," the manufacturer has a duty to update its label. *Id.* at 2. FIFRA does not authorize, much less require, a manufacturer to retain the label of a misbranded pesticide just because EPA registered the pesticide. Indeed, retaining a registered but misbranded label is not a "requirement" of FIFRA—it is a violation. And registration does not establish any relevant "requirement" that might supersede a duty under state law. For this reason, EPA's registration of glyphosate does not preempt Durnell's claims. *See Hardeman*, 997 F.3d at 956 ("[B]ecause EPA's labeling

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[14] Section 136a(f)(2) provides in full:

(2) Registration not a defense

In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

determinations are not dispositive of FIFRA compliance, they similarly are not conclusive as to which common law requirements are 'in addition to or different from' the requirements imposed by FIFRA."); *Indian Brand Farms, Inc. v. Novartis Crop Prot. Inc.*, 617 F.3d 207, 222 (3d Cir. 2010) (similar).

3. Monsanto's counterarguments lack merit. *First*, the company contends that § 136a(f)(2) "has 'no bearing on'" preemption. Pet. 28 (quoting *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994)). "But the fact that 'EPA's labeling determinations are not dispositive of FIFRA compliance' supports the . . . conclusion that, for purposes of preemption . . . , those determinations 'similarly are not conclusive as to which common law requirements are "in addition to or different from" the requirements imposed by FIFRA.'" SG *Hardeman* Br. 8-9 (quoting *Hardeman*, 997 F.3d at 956). Just as a manufacturer with a registered pesticide still may be liable for misbranding under FIFRA, a manufacturer with a registered pesticide still may be liable under state law. *See Bates*, 544 U.S. at 451 (discussing "[p]rivate remedies that enforce federal misbranding requirements").

Monsanto relies (at 28) on *MacDonald*, in which a pre-*Bates* panel of the Fifth Circuit adopted its view of § 136a(f)(2). But *MacDonald*, decided 11 years before *Bates*, is no longer good law. *See Indian Brand Farms*, 617 F.3d at 221-22 ("*Bates* introduced a different analysis of FIFRA preemption, one that compels us to depart from this pre-*Bates* precedent.").

Second, § 136a(f)(2) also shows why Monsanto cannot rely (at 25-26) on *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). In *Riegel*, the Court held that FDA's premarket medical-device approval imposes "requirements" under the preemption clause of a

Medical Device statute and preempts state failure-to-warn claims based on inconsistent duties. *Id.* at 322-23, 327-30. FDA's premarket approval of the riskiest medical devices serves as conclusive evidence that "the approved form [of the devices] provides a reasonable assurance of safety and effectiveness." *Id.* at 323.

In contrast, FIFRA provides that registration is only "prima facie evidence" of compliance, § 136a(f)(2), not proof the labeling is "adequate to protect health," § 136(q)(1)(F), (G). And because a manufacturer with a registered product still could be liable for misbranding, it could be liable for state-law claims (like Durnell's) "that are fully consistent with federal requirements." *Bates*, 544 U.S. at 452.

More generally, the statutory schemes in *Riegel* and here are meaningfully different. The Medical Device Amendments "swept back some state obligations and imposed a regime of detailed federal oversight," *Riegel*, 552 U.S. at 316, while FIFRA "authorizes a relatively decentralized scheme" that leaves States with broad power to regulate pesticide products—including the power to ban the sale of unsafe, but registered, pesticides, *Bates*, 544 U.S. at 450 (citing § 136v(a)). Thus, "different federal statutes and regulations may . . . lead to different pre-emption results." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 626 (2011).

For medical devices, "premarket approval is specific to individual devices," requiring FDA to determine the device "offers a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 322-23. By contrast, FIFRA's misbranding provisions impose only "general standards." *Bates*, 544 U.S. at 453 n.27; *see Lohr*, 518 U.S. at 501 (no preemption when federal requirements "reflect[ed] important but entirely generic concerns about device regulation generally"). And EPA has

acknowledged that it has not specifically evaluated glyphosate "formulations" like Roundup. *See supra* pp. 10-11; *Hardeman*, 997 F.3d at 952 ("EPA explained that there are few research projects that have attempted to directly compare technical grade glyphosate to the formulations under the same experimental design, but if at any time, information becomes available that indicates adverse human health effects of concern for exposure to glyphosate or its formulations, EPA intends to review it and determine the appropriate regulatory action.") (cleaned up).

Third, the company argues (at 33) that permitting States to require cancer warnings would undermine Congress's goal of national "uniformity" in pesticide labeling. But *Bates* cautioned against "overstat[ing] the degree of uniformity and centralization that characterizes FIFRA," noting that "[FIFRA] authorizes a relatively decentralized scheme that preserves a broad role for state regulation." 544 U.S. at 450. So to *Bates*, "it seem[ed] unlikely that Congress considered a relatively obscure provision like § 136v(b) to give pesticide manufacturers virtual immunity from certain forms of tort liability." *Id.*

To be sure, FIFRA's preemption provision plays "a narrow, but still important, role": it bars state-law labeling requirements that conflict with federal ones. *Id.* at 452. "For example, a failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would be pre-empted because it is inconsistent with 40 CFR § 156.64 (2004), which specifically assigns these warnings to particular classes of pesticides based on their toxicity." *Id.* at 453.

No such federal regulation exists for chronic-risk warnings about glyphosate. EPA could have, through a

"notice-and-comment process," issued "binding requirements or prohibitions governing chronic-hazard warnings for glyphosate." SG *Hardeman* Br. 13 n.4. But "it did not." *Id.* So FIFRA's "narrow, but still important," preemption provision does not apply.

The existing regulatory structure confirms that FIFRA already accommodates meaningful variation. For example, Roundup Power Max's label discusses "requirements specific to your State or Tribe," instructing users to "consult the agency responsible for pesticide regulation." App.30a. That label also includes state-specific deviations—for example, special restrictions on aerial spraying in California and Arkansas, App.35a-40a, or different application rates for sugarcane in Florida, Hawaii, Louisiana, and Texas, App.42a-43a. Monsanto complains (at 34) about the problem of 50 different state labeling regimes, but never explains why it can offer state-specific advice for sugarcane but not cancer.

C. Durnell's Failure-To-Warn Claim Is Not Impliedly Preempted

The court of appeals also was right that Monsanto cannot show implied preemption. As the court noted, the company did not even try to carry its heavy burden: "The record contains no evidence that Monsanto either informed the EPA of the justifications for a change to its warning label or that the EPA has informed Monsanto it would not approve such a warning." App.9.

Monsanto draws its implied-preemption arguments from prescription-drug cases under the Federal Food, Drug, and Cosmetic Act. This Court conducts an implied-preemption analysis in such cases because Congress has "declined to enact [an express-preemption] provision for prescription drugs." *Wyeth v. Levine*, 555

U.S. 555, 567 (2009). Those cases have little relevance here because FIFRA has an express-preemption provision, and implied preemption likely does not apply. *See Bates*, 544 U.S. at 459 (Thomas, J., concurring in judgment in part and dissenting in part) (favorably noting "this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption"). But even setting that threshold issue aside, Monsanto's implied-preemption arguments lack merit.

1. Monsanto's first implied-preemption theory (at 28-30) is that it could not add a warning to Roundup's labels without EPA's approval. But the company misunderstands the case from which it derives this supposed rule: In *PLIVA*, the Court addressed implied preemption in the generic-drug context. Under the FDCA, FDA imposes a "duty of sameness" on generic-drug labels, which must always match the label of the brand-name equivalent drug. 564 U.S. at 616. If a generic-drug manufacturer wants to update a label, it must "ask the agency to work toward strengthening the label that applies to both the generic and brand-name equivalent drug." *Id.* The manufacturer has no right to update the label on its own, so when a state-law claim imposes a duty to change the label, it is impliedly preempted.

Unlike generic-drug manufacturers, which have a "federal-law duty to keep the label the same," *id.* at 618, pesticide manufacturers "have a continuing obligation to adhere to FIFRA's labeling requirements," *Bates*, 544 U.S. at 438. The statute "contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings." *Id.* at 451. When an updated label is necessary, a manufacturer generally

must submit the revisions to EPA. *See* § 136a(f)(1); 40 C.F.R. § 152.50(e). And when a manufacturer's proposed label is not misbranded, FIFRA provides that EPA "shall" approve it. § 136a(f)(1).

EPA has made clear it would approve a label warning of Roundup's cancer risks. In its April 2022 Letter, the agency said that, if a company like Monsanto asked to include a warning that IARC "classified glyphosate as probably carcinogenic to humans," "this revised language could be approved by EPA" because it would not be misbranded. RA57-58; *see* SG *Hardeman* Br. 14. As a result, federal law imposes no competing "duty to keep the label the same," *PLIVA*, 564 U.S. at 618, and Monsanto's argument lacks merit.

2. Monsanto's second theory (at 30-32) is that it cannot add a cancer warning to Roundup labels because EPA would not accept it. Again under the FDCA, failure-to-warn claims are preempted when there is "clear evidence" that FDA would not have approved the warning that state law requires. *Wyeth*, 555 U.S. at 571. The only sources of "clear evidence" of what an agency would do in such a hypothetical situation "are agency actions taken pursuant to the FDA's congressionally delegated authority": "notice-and-comment rulemaking," an order "formally rejecting a warning label," or "other agency action carrying the force of law." *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 315-16 (2019).

There is no "clear evidence" showing Durnell's failure-to-warn claim is preempted. EPA has promulgated no regulation requiring certain warnings on glyphosate-based product labels and barring others. Nor has the agency taken other formal action rejecting a warning about the cancer risks of Roundup. Instead,

the agency said in its April 2022 Letter that, if a company like Monsanto asked to include a warning that IARC "classified glyphosate as probably carcinogenic to humans," "this revised language could be approved by EPA." RA57-58. That is the opposite of "clear evidence" showing that Durnell's claim regarding formulated Roundup is preempted.

Monsanto's argument also is incorrect on its face. Although the company suggests (at 30 n.7) that Durnell never requested the specific warning in the April 2022 Letter, Durnell's claims, like any common-law claim, did not turn on any specific warning. *See Moore*, 332 S.W.3d at 759 (Missouri failure-to-warn plaintiff does not bear burden "to propose the wording of an adequate warning to make a submissible case"). Monsanto needed only to provide an adequate warning of Roundup's health risks. It refused even that.

III. The Petition Meets No Other Traditional Reason For Certiorari

The petition presents one company's attempt to avoid further tort claims. And no company is less deserving of such sweeping immunity than Monsanto.

1. As Monsanto itself acknowledges (at 33), this case involves "a single product line." The company tries to infuse this case with broader legal import by drawing on other statutes with preemption provisions that prohibit state requirements "in addition to or different from" federal ones. But what matters is not the wording, but how the provision functions within each statutory scheme.

For example, Monsanto relies (at 35-36) on cases decided under the Federal Meat Inspection Act. That Act "establishes an elaborate system of inspecting live animals and carcasses," and "[o]ver the years, the [Department of Agriculture's Food Safety and

Inspection Service] has issued extensive regulations" fleshing out that system. *National Meat Ass'n v. Harris*, 565 U.S. 452, 455-56 (2012) (cleaned up). Because that Act and its regulations impose many requirements, its preemption provision necessarily "sweeps widely" when blocking applications of additional or different state requirements. *Id.* at 459-60. Here, by contrast, EPA has promulgated "relatively few regulations," so FIFRA's preemption provision is "narrow." *Bates*, 544 U.S. at 452, 453 n.28.

2. Monsanto's 50-year history of failing to test whether long-term use of formulated Roundup causes cancer further counsels against review. The company's position would bar essentially all failure-to-warn claims based on a pesticide's "labeling." But as *Bates* observed, "it seems unlikely that Congress considered a relatively obscure provision like § 136v(b) to give pesticide manufacturers virtual immunity from certain forms of tort liability." 544 U.S. at 450.

That immunity also would hinder the functioning of FIFRA: state-tort actions "may aid in the exposure of new dangers associated with pesticides," giving manufacturers "added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement." *Id.* at 451. Just so with Durnell, who used Roundup products for two decades around his community. His extended exposure, and that of thousands of others, can help inform EPA about the long-term effects of glyphosate-based products like Roundup and aid the agency in carrying out "its task of assessing the environmental and health dangers posed by pesticides." *Id.* at 440.

That task is exceptionally important in a case like this. Rather than test formulated Roundup for

long-term cancer risks or provide warnings, Monsanto instead has waged a decades-long campaign to mislead the scientific community and the public about the weedkiller's cancer risks. At the same time, the company has sought to avoid financial responsibility for the harms to human health that its product has caused and that warnings might have avoided. Based on such evidence, five appellate courts (*Johnson*,[15] *Hardeman*,[16] *Pilliod*,[17] *Anderson*,[18] and *Caranci*[19]) have upheld jury verdicts assessing significant punitive damages against Monsanto for its callous conduct.

CONCLUSION

The petition for a writ of certiorari should be denied.

---

[15] $250 million in punitive damages reduced to just over $10 million. *Johnson v. Monsanto Co.*, 266 Cal. Rptr. 3d 111, 120, 129, 136 (Ct. App. 2020).

[16] $75 million in punitive damages reduced to $20 million. *Hardeman*, 997 F.3d at 970.

[17] $2 billion in punitive damages to two plaintiffs reduced to approximately $70 million. *Pilliod*, 282 Cal. Rptr. 3d at 697-98, 720.

[18] $1.5 billion in punitive damages to three plaintiffs remitted to $549.9 million and affirmed in full. *Anderson v. Monsanto Co.*, 2025 WL 1497539, at *2-3, *31 (Mo. Ct. App. May 27, 2025).

[19] $150 million in punitive damages affirmed in full. *Caranci v. Monsanto Co.*, --- A.3d ---, 2025 WL 1340970, at *14-15 (Pa. Super. Ct. May 8, 2025).

Respectfully submitted,

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June 9, 2025

APPENDIX

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[Plaintiff's Trial Exhibit P-0151]

Message

From: MARK A MARTENS

Sent: 4/19/1999 8:49:08 AM

To: LARRY D KIER; WILLIAM F HEYDENS; ALAN G E WILSON; DONNA R FARMER

CC: STEPHEN J WRATTEN; CAM S VERDIN; WILLIAM GRAHAM; RICHARD P GARNETT

Subject: Re: Meeting Minutes 2/25

Donna,

Thanks for this, it accurately reflects the situation. Please take note of the following update:

I received from prof. Parry the signed secrecy agreement.

As a response I sent him a letter of authorisation and all relevant reports and publications re mutagenicity of glyphosate, its formulations and the surfactants for which we have mutagenicity testing data.

The list was based on the foulder that was composed for Gabriele and the German monograph on Glyphosate:

Glyphosate formulations Roundup:

– Ames test, Monsanto report ML-91-440

– Mouse micronucleus test, Monsanto report ML-91-434/437

– Comet test on Rana tadpoles, Clements et al., Environmental and Molecular Mutagenesis, 29, 277(1997)

– Drosophila SLRL, Kale et al., Environmental and Molecular Mutagenesis, 25, 148(1995)

– SCE, Vigfusson and Vyse, Mutation Research, 79, 53(1980)

Direct:

– Ames test, Monsanto report ML-91-442

– Mouse micronucleus test. Monsanto report ML-91-436/439

Rodeo:

– Ames test, Monsanto report ML-91-441

– Mouse micronucleus test, Monsanto report ML-91-435/438

Glifos:

– Ames test, BioAgri report G1.1-050/96

– Mouse micronucleus test, BioAgri report G1.2-060/96

Active ingredient (glyphosate):

– Ames test, rec-assay, HGPRT test, UDS test, in-vivo cytogenetics. Li and Long, Fundamental and Applied Toxicology, 10, 537(1988)

– In vitro cytogenetics in human lymphocytes. NOTOX report 141918

– Ames test, Jensen, Scantox report 12323 (1991)

– Mouse lymphoma test, Jensen, Scantox report 12325 (1991)

– Mouse micronucleus test, Jensen, Scantox report 12324 (1991)

– Mouse dominant lethal test, Monsanto report IR-79-014

Surfactants:

Polyethoxylated tallowamine (MON 0818):

– Ames test, Monsanto report ML-89-461

– Mouse micronucleus test, Monsanto report ML-89-463

C8-C10 alkyl sulphate IPA salt (MON 8080):

– Ames test, Monsanto report ML-80-294

Dodigen 4022:

– Ames test, Hoechst report 92.0336

– In-vitro cytogenetics, Hoechst report 92.0337

Tween 20:

– Mouse lymphoma test, Abstract P46, Environmental and Molecular Mutagenesis, 3(3), 320(1981)

Tween 80:

– Mouse micronucleus test, Jenssen and Ramel, Mutation Research, 75,191(1980)

Via separate mail I sent him the composition of all the formulations tested and data on the chemistry of the surfactants (not too detailed).

So, in principle he will start his review this week.

Once the review is ready it will be a good idea to have Larry visit Jim Parry for an overall discussion.

Regards, Mark.

----------Reply Separator----------

Subject: Meeting Minutes 2/25

Author: DONNA R FARMER at MONSL125

Date: 4/17/99 7:25 AM

Please find the meeting minutes and actions from our 2/25 meeting below.

We need to discuss where we are on each of these topics as well as well as finalize a letter of comment to the German Addendum. Steve has provided some valuable comments in a recent message. I will draft a letter and provide for discussion.

Bill – what is the drop dead date you need these comments?

Cam where are we in getting this meeting set up?

Donna

1) Update on the German Addendum

Steve Wratten joined us for this discussion. We understand that the Germans current position on the effects observed in the various studies with the formulatons as described in the open literature do not indicate a mutagenic response but rather a cytotoxic response associated with the surfactant(s). Glyphosate, it's salts, the G3 and G4 formulations (with the Dodigen surfactant) and Rodeo are free and clear.

For those formulations/surfactants that can be tested up to the limit levels per OECD guidelines and produce no toxicity such as the Dodigen (the major surfactant in MON 52276) they would be viewed favorably.

Roundup (with MON 0818), Roundup Ultra, the etheramine-based formulations and other formu-lations either do not meet this standard or the possiblity that they will is low.

It will be up to each country to decide which formulations it does and doesn't want and they could use this for that purpose.

It was felt that this position should not be a regulatory endpoint, it is not defensible and that once the German Addendum is made public comments and a response should be prepared for the ECCO Meetings preferably before 17th May (Mammalian Tox Meeting). Note that the Conclusion meetings are not until the 18th October – Donna will coordinate this response when a copy of the German Addendum is received.

2) Testing program – what do we test? formulations. .surfactants? When is data needed? Discussion is dependant upon info from agenda item # 1

No further mutagenicity testing is needed for MON 52276.

Steps have been taken to acquire the cocoamine surfactant used in MON 35012/Roundup 2000 sold in Denmark for testing in the microames and micromicronucleus assays. In addition based on the concern for cytotoxicity it was recommended to also to run this surfactant thru the NRU assay (this assay addresses cytotoxicity and has a good correlation with the oral LD50). – Donna will coordinate and monitor these tests

Management supports the investigation of MON 35050 toxicity to the liver and kidneys to address the findings in the Peluso study. Therfore it was recommended to move forward with a study . . . evaluating liver and kidney histology, serum enzymes as well as glutathionine levels following high-dose, i.p. exposures of the test material. – Alan will draft and circulate a protocol

Donna will followup with Bill Graham to get the details/and clarification behind his statement below (in green) as to what is expected, on what materials and by when. "We will need to demonstrate clearly negative Mutagenic (and cytogenic?) results for all the formulations we sell in Europe. These will certainly be required by end 2000 but public pressure may require us to do them earlier."

3) "Detergent-like molecule" testing program? Is this still something we need to do? When do we start? Discussion is dependent info from agenda item #1

In light of the position taken by the German government this investigation maybe even more important than before and could possibly be conducted by Dr. Parry?

Dr. Williams?

Donna will arrange for further meetings to discuss/ design this program

4) Global experts

Review Dr. Parry's analyis – what is our next step? Dr. Parry concluded on his evaluation of the four articles that glyphosate is capable of producing genotoxicity both in vivo and in vitro

by a mechanism based upon the production of oxidative damage.

The data that Dr. Parry evaluated is limited and is not consistant with other better conducted studies. In order to move Dr. Parry from his position we will need to provide him with the additional information as well as asking him to critically evalute the quality of all the data including the open literature studies.

As a followup Mark will contact Dr. Parry, discuss with him the existance of additional data and ask him to evaluate the full package. Mark will also explore his interest (if we can turn his opinion around) in being a spokes-person for us for these type of issues.

Larry as well as others will be available to discuss the data with Parry as needed by e-mail, phone or in person or all the above.

Dr. Williams – discuss the outcome of the Cantox meeting

The panel concluded that glyphosate and Roundup were not mutagenic. That in the evaluation of these types of studies criteria should be set. . . up front in the evaluation process as to what makes an acceptable study and what does not – this is to be included in t he manuscript as well as a weight of evidence approach.

5) Lioi followup

An analysis of what was tested in the Lioi studies was deemed important. Therefore it was recommended that Monsanto EU or Italy contact Lioi and try to get a sample of what they used in their study as well as getting a sample from the company that Lioi did. Donna will contact Gabrielle to ask him to make the requests.

[Plaintiff's Trial Exhibit P-0156]

Message

From: HEYDENS, WILLIAM F [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]

Sent: 9/16/1999 6:18:36 PM

To: MARTENS, MARK A [FND/5045] [/0=MONSANTO/OU=EA-5040-01/CN=RECIPIENTS/CN=21606]; 'KIER, LARRY D [NCP/1000]' [/O=MONSANTO/OU=GLB-STL/CN=LEGACY ADDRESSES/CN=33322]; 'FARMER, DONNA R [FND/1000]' [/O=MONSANTO/OU=GLB-STL/CN=LEGACY ADDRESSES/CN=180070]

CC: 'HEYDENS, WILLIAM F [FND/1000]' [/O=MONSANTO/OU=GLB-STL/CN=LEGACY ADDRESSES/CN=230737]

Subject: RE: Parry report

Mark, All,

I have read the report and agree with the comments – there are various things that can be done to improve the report.

However, let's step back and look at what we are really trying to achieve here. We want to find/develop someone who is comfortable with the genetox profile of glyphosate/Roundup and who can be influential with regulators and Scientific Outreach operations when genetox. issues arise. My read is that Parry is not currently such a person, and it would take quite

some time and $$$/studies to get him there. We simply aren't going to do the studies Parry suggests. Mark, do you think Parry can become a strong advocate without doing this work Parry? If not, we should ***seriously*** start looking for one or more other individuals to work with. Even if we think we can eventually bring Parry around closer to where we need him, we should be currently looking for a second/back-up genetox. supporter. We have not made much progress and are currently very vulnerable in this area. We have time to fix that, but only if we make this a high priority now.

Bill

------Original Message------

From: MARTENS, MARK A [FND/5045]
Sent: Thursday, September 16, 1999 2:02 AM
To: KIER, LARRY D [NCP/1000]; FARMER, DONNA R [FND/1000]
Cc: HEYDENS, WILLIAM F [FND/1000]
Subject: Parry report
Importance: High

Larry and Donna,

I would like to get some feedback to Jim Parry on his report. I sent you my comments but didn't get a reaction. Can I get your opinions and then have a discussion on the action to take?

Regards, Mark

[Plaintiff's Trial Exhibit P-0226]

Message

From: FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]

Sent: 9/21/2009 5:12:07 PM

To: COMBEST, JOHN C [AG/1000] [john.c.combest@Monsanto.com]

Subject: RE: Roundup article in Fremantle Herald

I didn't find anything on the Australian site either . . .however take this question 5. It is not Roundup that is taken up it is glyphosate. It stops the synthesis of 3 amino acids (they are used to make proteins) and this "process" is also found in microbes and fungi.

5. How does Roundup work?

Roundup is taken up through the leaves and moves in the sap flow throughout the plant. It stops the production of proteins so that the plant starves. This process is found only in plants; Roundup has extremely low toxicity to humans and wildlife.

Or this – you cannot say that Roundup does not cause cancer . . . we have not done carcinogenicity studies with "Roundup".

2. Will Roundup harm my family or me?

Based on the results of short term and long term testing, it can be concluded that Roundup poses no danger to human health when used according to label

directions. In long term exposure studies of animals, Roundup did not cause cancer, birth defects or adverse reproductive changes at dose levels far in excess of likely exposure.

I will follow up with the Monsanto folks who interface with Scotts . . . they are aware that Scotts does these things.

Donna

------Original Message------

From: COMBEST, JOHN C [AG/1000]

Sent: Monday, September 21, 2009 11:07 AM

To: FARMER, DONNA R [AG/1000]

Subject: RE: Roundup article in Fremantle Herald

I did not find any reference on their main (US) page to "biodegradable."

------Original Message------

From: FARMER, DONNA R [AG/1000]

Sent: Monday, September 21, 2009 11:06 AM

To: COMBEST, JOHN C [AG/1000]

Subject: RE: Roundup article in Fremantle Herald

Did you find the link?

This is to their Q&A and I can tell you they have a number of things that a not acceptable. http://www.scottsaustralia.com.au/FAQs/Roundup

------Original Message------

From: COMBEST, JOHN C [AG/1000]

Sent: Monday, September 21, 2009 8:11 AM

To: PERSON, JANICE L [AG/1030]; FARMER, DONNA R [AG/1000]; HELSCHER, THOMAS M [AG/1000]

Subject: Fw: Roundup article in Fremantle Herald

Janice and Donna,

Here's the Australian thread, to the latest message. John

------Original Message------

From: LEADER, MICHAEL [AG/5020]

To: ANDERSON, NEIL J [AG/5020]; MCNAUGHTON, HONI JANINE [AG/5020]; MCGREGOR, JOHN [AG/5020]; HELSCHER, THOMAS M [AG/1000]

Cc: MCLEAN, KERYN [AG/5020]; TAYLOR, IAN N [AG/5020]; ARMSTRONG, JANICE M [AG/5340]; COMBEST, JOHN C [AG/1000]

Sent: Mon Sep 21 00:08:56 2009

Subject: RE: Roundup article in Fremantle Herald

Thanks Neil. Honi has already have pointed out the flaws in the studies, but there can't be any harm in doing so again. Studies on the safety of Roundup is a good approach, but I believe there are also some on glyphosate's benefits for the environment (even if the

surfactant is not biodegradable). It's a shame the Scott's guy is blaming us too!!

Cheers

Michael

Michael Leader

Corporate and Regulatory Affairs Lead, Australia/ New Zealand

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<http://www.monsanto.com.au/>

From: ANDERSON, NEIL 3 [AG/5020]
Sent: Monday, September 21, 2009 12:39 PM
To: MCNAUGHTON, HONI JANINE [AG/5020]; MCGREGOR, JOHN [AG/5020]; HELSCHER, THOMAS M [AG/1000]
Cc: LEADER, MICHAEL [AG/5020]; MCLEAN, KERYN [AG/5020]; TAYLOR, IAN N [AG/5020]; ARMSTRONG, JANICE M [AG/5340]; COMBEST, JOHN C [AG/1000]
Subject: RE: Roundup article in Fremantle Herald

Hi Honi

The reporter has printed the correct information that "Glyphosate is biodegradable but the surfactant is not". However, then she goes into a sensationalism

mode quoting "studies" that suggest Roundup is not safe, which is probably derived from her interview of the Fremantle activist. I feel the response to FH needs to reiterate that her statement on biodegradability is correct, reiterate that Roundup is safe (and provide references), and if there are flaws in any of the studies quoted, point out these flaws.

Neil Anderson

QA & Formulations Lead, Asia Pacific

Monsanto Australia Ltd

Mobile phone: International 61409 382905; Australia 0409 382905

From: MCNAUGHTON, HONI JANINE [AG/5020]

Sent: Monday, September 21, 2009 10:56 AM

To: MCGREGOR, JOHN [AG/5020]; ANDERSON, NEIL J [AG/5020]; HELSCHER, THOMAS M [AG/1000]

Cc: LEADER, MICHAEL [AG/5020]; MCLEAN, KERYN [AG/5020]; TAYLOR, IAN N [AG/5020]; ARMSTRONG, JANICE M [AG/5340]; COMBEST, JOHN C [AG/1000]

Subject: Roundup article in Fremantle Herald

Importance: High

Hi John and Neil

The article in question has appeared in the Fremantle Herald as expected.

We need to think about our response. Possible suggestions:

Letter from Scott's to the FH reiterating the correct information

Letter from Monsanto to FH reiterating the safety of Roundup, etc

We may also need to compose a letter to all of Scott's Roundup customers (in WA) dismissing the allegations in the article. FH has a circulation of 20,000. However, the FTO concern is here in WA during this critical time.

Keryn: You may want to contact DAFWA and other stakeholders as well as growers to explain what we plan to do.

Ian: GSWG letter reiterating the safety of glyphosate from Steve Powles

Any actions and responses will need to be cleared with the US.

We will need to have a phone call about this including Scotts.

Please let me know your thoughts. I think you'll agree we need to jump on this.

Honi

Honi McNaughton
Public Affairs Manager

Monsanto Australia
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Monsanto's Blog: Monsanto According to Monsanto <http://www.monsantoblog.com>

Monsanto For the Record: http://www.monsanto.com/monsanto_today/for_the_record/default.asp <http://www.monsanto.com/monsanto_today/for_the_record/default.asp>

[Plaintiff's Trial Exhibit P-0318]

Monsanto

FROM
(NAME—LOCATION—PHONE) G.J. Levinskas, G2WF 4-8809
Dept. of Medicine & Environmental Health

DATE : April 3, 1985 CC: G. Roush, Jr., M.D.
SUBJECT :
REFERENCE :
TO : T. F. Evans

The following item of information is in addition to those included in the current monthly report.

Senior management at EPA is reviewing a proposal to classify glyphosate a a class C "possible human carcinogen" because of kidney adenomas in male mice. Dr. Marvin Kuschner will review kidney sections and present his evaluation of them to EPA in an effort to persuade the agency that the observed tumors are not elated to glyphosate.

/s/ George J. Levinskas
George J. Levinskas

GJL/sfd

[Plaintiff's Trial Exhibit P-0771]

Message

From: PERSON, JANICE L [AG/1030] [/0=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=JLPERS]

Sent: 12/24/2009 4:47:14 PM

To: GRAHAM, JEFF A CROP [AG/1000] [jeff.a.crop.graham@monsanto.com]; MURDOCK, SHEA W [AG/1000] [shea.w.murdock@monsanto.com]

CC: ADAMS, STEPHEN A [AG/1000] [stephen.a.adams@monsanto.com]; WATSON, GREGORY R [AG/1000] [gregory.r.watson@monsanto.com]; FARMER, DONNA R [AG/1000] [donna.r.farmer@monsanto.com]; HEYDENS, WILLIAM F [AG/1000] [william.f.heydens@monsanto.com]; COMBEST, JOHN C [AG/1000] [john.c.combest@monsanto.com]

Subject: Re: MEDIA REQUEST: EPA labeling of inert ingredients

Thanks. We have a couple of strings going here. I'm trying to delay & get more info on the announcement. Glenn & Donna have both suggested we need to get a few folks together on this.

Jp

Janice Person
Monsanto Public Affairs
PO 11425
Memphis, TN 38111
901-320-5760

------Original Message------

From: GRAHAM, JEFF A CROP [AG/1000]

To: MURDOCK, SHEA W [AG/1000]; PERSON, JANICE L [AG/1030]

Cc: ADAMS, STEPHEN A [AG/1000]; WATSON, GREGORY R [AG/1000]; FARMER, DONNA R [AG/1000]; HEYDENS, WILLIAM F [AG/1000]

Sent: Thu Dec 24 10:44:57 2009

Subject: RE: MEDIA REQUEST: EPA labeling of inert ingredients

Janice – the issue or topic is related to allegations that have been going on for some time, that the pesticide industry puts "bad" chemicals in their products that currently do not have to be disclosed because they are not the "active pesticidal ingredients".

Roundup products have been particularly targeted due to the fact that glyphosate is such a benign "pesticide" (yes – it is a pesticide as it controls pests, i.e. weeds) and so a number of academics and agenda driven researchers worldwide have claimed the inert materials in Roundup products are more toxic/ eco-toxic than glyphosate. Specifically they have been talking about the surfactant family in our Roundup

products, ethoxylated alkylamines, (most specifically ethoxylated tallow-derived amines).

I believe we need to discuss internally what the policy implications would be of listing all the chemicals in glyphosate products that are not glyphosate. Moreover we need to understand just how far reaching the proposed policy might be. For example, is there a cutoff level beyond what we do not have to report? It is somewhat confusing to the lay public just what all the components would mean.

For example for a basic Roundup formulation, i.e. Roundup Original, the ingredients (in order of level or concentration) are

Water
Glyphosate
15E0tallowamine ethoxylate
Isopropylamine
Polyethylene glycol
Ethylene glycol
Silicone Antifoam

Some trace level components PPM levels (if they were required to be listed) are:

Some 10+ byproducts of the glyphosate manufacturing process

1,4-dioxane

N-nitroso-glyphosate

Formal dehyde

This is not exhaustive, and it may even be incorrect (I just pulled it out of my head), but I think it makes the point that depending on how far reaching the rule or policy would be, we could end up with product labels

with a whole list of chemicals, which in turn may confuse and even scare the public. In market research done for Lawn & Garden, only about 25% of consumers identified glyphosate as the active ingredient in Roundup L&G products and most were unable to say if how long it controlled weeds; some said a year after application and in fact it is probably less than a day when incidentally applied to soil at recommended rates.

It is also likely the lists would be used by activists (NGO and government) to attack Roundup products and the Roundup Ready franchise as well.

That's it in a nutshell. If you like more information then the people cc'd on this email are the group to pull together.

Jeff Graham
Chemistry – Product and Process Technology
0291 / 02G
Office: 314.694.6310
Mobile: 314.422.4088
Fax: 314.694.9058

------Original Message------

From: MURDOCK, SHEA W [AG/1000]

Sent: Thursday, December 24, 2009 10:12 AM

To: PERSON, JANICE L [AG/1030]; ADAMS, STEPHEN A [AG/1000]; GRAHAM, JEFF A CROP [AG/1000]; WATSON, GREGORY R [AG/1000]

Subject: Re: MEDIA REQUEST: EPA labeling of inert ingredients

Janice.

I don't have enough information to speak about what the potential policy is or what the impacts will be to our labeling.

I have included a few others that might have more knowledge than I.

Shea

Shea

------Original Message------

From: PERSON, JANICE L [AG/1030]

To: STITH, GLENN A [AG/1000]; KIRK, ANNETTE M [AG/1000]; ADAMS, TOM H [AG/1000]; HELMS, MATTHEW J [AG/1000]; MURDOCK, SHEA W [AG/1000]; FARMER, DONNA R [AG/1000]; HEYDENS, WILLIAM F [AG/1000]; STATER, STACEY L [AG/1000]

Cc: COMBEST, JOHN C [AG/1000]; KASPER, GARRETT D [AG/1000]

Sent: Wed Dec 23 23:27:11 2009

Subject: MEDIA REQUEST: EPA labeling of inert ingredients

Hey everyone,

Hate bothering you on the holiday, but we got the email below today and it's on something I'm not familiar with – a pending EPA announcement on labeling of inert ingredients. We are asking about his

timeline. . hope it can be deferred til Monday. But in the event someone is waiting for a while family runs a quick errand and can give me a bit of input, I'd appreciate it.

Happy holidays and I hope none of us have to deal with too many of these interruptions.

jp

New phone number included below

Janice Person
Monsanto Public Affairs

Phone 901-320-5760

http://twitter.com/JPlovesCOTTON

From: RICKETTS, MIMI [AG/1000]
Sent: Wednesday, December 23, 2009 6:12 PM
To: Greg Horstmeier; PERSON, JANICE L [AG/1030]
Subject: RE: Need Commentary

Greg,

I am looping in my colleague Janice Person; she handles media relations for our chemistry business. What is your deadline? Sounds like it is quick.

Mimi

From: Greg Horstmeier [mailto:Greg.Horstmeier@dtn.com]
Sent: Wednesday, December 23, 2009 10:32 AM
To: RICKETTS, MIMI [AG/1000]
Subject: Need Commentary
Importance: High

Mimi:

Hate to drop this on you, but I would like to get commentary on the announcement that EPA is planning to require companies to display "inert" ingredients on pesticide labels.

I know this has been a big issue with Monsanto over the years, particularly as it relates to the various Roundup formulations and the surfactants etc. in each. I'm sure someone can discuss the issue of trade secrets?

I am asking others as well, of course, but would especially like to include you all.

THANKS!

Greg

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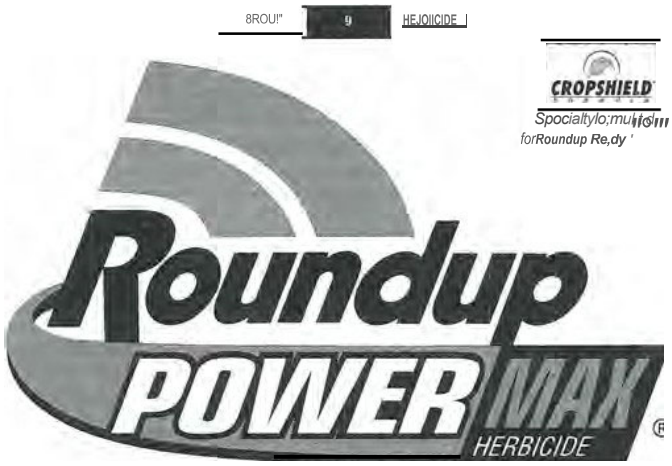
Omaha, NE 68114
www.dtnprogressivefarmer.com

[Plaintiff's Trial Exhibit P-1340]

ATTENTION:

This specimen label is provided for general information only.

- This pesticide product may not yet be available or approved for sale or use in your area.
- It is your responsibility to follow all Federal, state and local laws and regulations regarding the use of pesticides.
- Before using any pesticide, be sure the intended use is approved in your state or locality.
- Your state or locality may require additional precautions and instructions for use of this product that are not included here.
- Monsanto does not guarantee the completeness or accuracy of this specimen label. The information found in this label may differ from the information found on the product label. You must have the EPA approved labeling with you at the time of use and must read and follow all label directions.
- You should not base any use of a similar product on the precautions, instructions for use or other information you find here.
- Always follow the precautions and instructions for use on the label of the pesticide you are using.



Complete Directions for Use

Herbicide for Roundup Ready® Crops

Selective broad-spectrum weed control
in Roundup Ready® crops

Non-selective, broad-spectrum weed control for many agricultural systems and farmsteads

Read the entire label before using this product. Use only according to label directions.

AVOID CONTACT OF THIS HERBICIDE WITH FOLIAGE, GREEN STEMS, EXPOSED NON-WOODY ROOTS OR FRUIT OF CROPS, DESIRABLE PLANTS AND TREES, EXCEPT AS DIRECTED FOR USE ON ROUNDUP READY® CROPS, AS SEVERE PLANT INJURY OR DESTRUCTION COULD RESULT.

THIS IS AN END-USE PRODUCT. MONSANTO COMPANY DOES NOT INTEND AND HAS NOT REGISTERED IT FOR REFORMULATION. SEE INDIVIDUAL CONTAINER LABEL FOR REPACKAGING LIMITATIONS.

Read the "LIMIT OF WARRANTY AND LIABILITY" statement at the end of the label before buying or using. If terms are not acceptable, return at once unopened.

Not all products listed on this label are registered for use in California. Check the registration status of each product in California before using.

* * *

3.0 PRECAUTIONARY STATEMENTS

* * *

3.3 Physical or Chemical Hazards

Spray solutions of this product may be mixed, stored and applied using stainless steel, fiberglass, plastic or plastic-lined steel containers.

DO NOT MIX, STORE OR APPLY THIS PRODUCT OR SPRAY SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS. This product or spray solutions of this product react with such containers and tanks to produce hydrogen gas, which can form a highly combustible gas mixture. This gas mixture could flash or explode if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source and cause serious personal injury.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product may only be used in accordance with the Directions for Use on this label or in separately published supplemental labeling. Supplemental labeling for this product can be obtained from your Authorized

Monsanto Retailer or Monsanto Company Representative.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours. PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wean coveralls, shoes plus socks and chemical-resistant gloves made of any waterproof material.

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker

Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep people and pets off treated areas until spray solution has dried.

* * *

8.2 Aerial Application Equipment

Unless otherwise prohibited, all applications of this product described on this label may be made using aerial application equipment where appropriate, provided that the applicator complies with the precautions and restrictions specified on this label or on separate supplemental labeling published for this product.

DO NOT APPLY THIS PRODUCT USING AERIAL APPLICATION EQUIPMENT EXCEPT UNDER CONDITIONS SPECIFIED ON THIS LABEL OR ON SEPARATELY PUBLISHED SUPPLEMENTAL LABELING FOR THIS PRODUCT.

FOR SPECIFIC USE INSTRUCTIONS, RESTRICTIONS AND REQUIREMENTS RELATED TO THE AERIAL APPLICATION OF THIS PRODUCT IN ARKANSAS AND CALIFORNIA, OR SPECIFIC COUNTIES THEREIN, REFER TO THE LIMITATIONS ON AERIAL APPLICATION IN THAT STATE OR COUNTY PRESENTED IN THIS SECTION.

Unless otherwise directed, the maximum single application rate of this product is 44 fluid ounces per acre when using aerial application equipment. Apply this product at the appropriate rate in 3 to 15 gallons of water per acre unless otherwise directed on this label or on separate supplemental labeling for this product.

Refer to the individual use sections of this label for application rates, spray volumes and additional directions for use.

Drift control reduction additives may be used.

Ensure uniform application. To avoid streaked, uneven or overlapped application, use appropriate marking devices.

Aircraft Maintenance

Thoroughly wash aircraft, especially landing gear, after each day of spraying to remove residues of this product accumulated during spraying or from spills. PROLONGED EXPOSURE OF THIS PRODUCT TO UNCOATED STEEL SURFACES COULD RESULT IN CORROSION AND POSSIBLE FAILURE OF THE PART. LANDING GEAR IS MOST SUSCEPTIBLE. The maintenance of an organic coating (paint) that meets aerospace specification MIL-C-38413 can help prevent corrosion.

AERIAL SPRAY DRIFT MANAGEMENT

The following drift management requirements must be followed to minimize off-target drift movement during aerial application.

1. The distance of the outermost nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.

2. Nozzles must always point backward, parallel with the air stream and never be pointed downwards more than 45 degrees. Where states have more stringent regulations, they must be followed.

Importance of Droplet Size

The most effective way to reduce drift potential is to apply large droplets. The best drift management

strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if the application is made improperly, or under unfavorable environmental conditions, such as in windy, high temperature with law humidity, and/or inversion conditions as described below.

Controlling Droplet Size

- Volume: Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with the higher rated flows produce larger droplets.
- Pressure: Operate at a sprayer pressure towards the lower end of the range listed for the nozzle. Higher pressure reduces droplet size and does not improve canopy penetration. When higher flow rates are needed, use higher flow rate nozzles instead of increasing the pressure.
- Number of nozzles: Use the minimum number of nozzles that provide uniform coverage.
- Nozzle orientation: Orienting nozzles so that the spray is released backwards, parallel to the air stream, will produce larger droplets than other orientations. Significant deflection from the horizontal will reduce droplet size and increase drift potential.
- Nozzle type: Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce larger droplets than other nozzle types.
- Boom length: For some use patterns, reducing the effective boom length to less than 3/4 of the

wingspan or rotor length could further reduce drift without reducing swath width.

- Application height: Application must be made at a height of 10 feet or less above the top of the largest plants unless a greater height is required for aircraft safety. Making the application at the lowest height that is safe reduces the exposure of the droplets to evaporation and wind.

Swath Adjustment

When an application is made with a crosswind present, the swath will be displaced downwind. Therefore, on the upwind and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Increase the swath adjustment distance with increasing drift potential (higher wind, smaller droplets, etc.).

Wind

Drift potential is lowest at wind speeds of between 2 and 10 miles per hour. However, many factors, including droplet size and equipment type, determine drift potential at any given wind speed. Avoid application when wind speeds are below 2 miles per hour due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator must be familiar with local wind patterns and how they affect drift.

Temperature and Humidity

When making an application in low relative humidity, set application equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

Temperature Inversion

Do not apply this product during a temperature inversion as drift potential is high under these conditions. Temperature inversions restrict vertical air mixing, which causes small droplets to remain suspended in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

Sensitive Areas

Apply this product only when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g., when wind is blowing away from the sensitive areas).

Avoid direct application to any body of water.

State Specific Limitations on Aerial Application

LIMITATIONS ON AERIAL APPLICATION IN CALIFORNIA ONLY

DO NOT apply this product using aerial application equipment in residential areas.

AVOID DRIFT — DO NOT APPLY WHEN WINDS ARE GUSTY OR UNDER ANY OTHER CONDITION THAT FAVORS DRIFT. DRIFT OF THIS PRODUCT ONTO ANY VEGETATION TO WHICH APPLICATION WAS NOT INTENDED CAN CAUSE DAMAGE. TO PREVENT INJURY TO ADJACENT DESIRABLE VEGETATION, USE PROPER AERIAL APPLICATION EQUIPMENT FITTED WITH APPROPRIATE NOZZLES AND MAINTAIN ADEQUATE BUFFERS. Follow the directions below when making an aerial application near non-target crops, desirable annual vegetation, or desirable perennial vegetation after bud break and before total leaf drop.

1. Do not apply this product within 100 feet of all desirable vegetation or non-target crops.

2. If winds are blowing up to 5 miles per hour TOWARD desirable vegetation or non-target crops, do not apply this product within 500 feet of the desirable vegetation or crops.

3. If winds are blowing between 5 and 10 miles per hour TOWARD desirable vegetation or non-target crops, a buffer zone greater than 500 feet might be needed to protect the desirable vegetation or crops.

4. Do not apply this product using aerial application equipment when winds are blowing in excess of 10 miles per hour.

5. Do not apply this product using aerial application equipment when inversion conditions exist. When tank-mixing this product with 2,4-D, only 2,4-D amine formulations may be applied in California using aerial application equipment. Tank mixtures of this product with 2,4-D amine formulations may be applied by air in California in fallow fields and in reduced tillage

systems, and for alfalfa and pasture renovation applications only.

This product, when tank-mixed with dicamba, may not be applied by air in California.

ADDITIONAL LIMITATIONS FOR AERIAL APPLICATION IN FRESNO COUNTY, CALIFORNIA ONLY

Always read and follow the label directions and precautionary statements for all products used in the aerial application.

The following information applies only from February 15 through March 31 within the following boundaries of Fresno County, California:

North: Fresno County line
South: Fresno County line
East: State Highway 99
West: Fresno County line

Observe the following directions to minimize off-site movement during aerial application of this product. - Minimization of off-site movement is the responsibility of the grower, Pest Control Advisor and aerial applicator.

Written Directions

Written directions MUST be submitted by or on behalf of the applicator to the Fresno County Agricultural Commissioner 24 hours prior to the application. These written directions MUST state the proximity of surrounding crops and that conditions of each manufacturer's product label and this label have been satisfied.

Aerial Applicator Training and Equipment

Aerial application of this product is limited to pilots who have successfully completed a Fresno County Agricultural Commissioner and California Department of Pesticide Regulation approved training program for aerial application of herbicides. All aircraft must be inspected, critiqued in flight and certified at a Fresno County Agricultural Commissioner approved fly-in. Test and calibrate spray equipment at intervals sufficient to insure that proper rates of herbicides and adjuvants are being applied during commercial use. Applicator must document such calibrations and testing. Demonstration of performance at Fresno County Agricultural Commissioner approved fly-ins constitutes such documentation, or other written records showing calculations and measurements of tight and spray parameters acceptable to the Fresno County Agricultural Commissioner.

Application at Night — Do not apply this product by air earlier than 30 minutes prior to sunrise and/or later than 30 minutes after sunset without prior permission from the Fresno County Agricultural Commissioner.

To report known or suspected misuse of this product, call 1-800-332-3111.

For additional information on the proper aerial application of this product in Fresno County, call 1-800-332-3111.

LIMITATIONS ON AERIAL APPLICATION IN ARKANSAS ONLY

AVOID DRIFT. DO NOT APPLY INTO STILL AIR WHERE THERE IS A TEMPERATURE INVERSION

LAYER LOW ENOUGH FOR FINE SPRAY PARTICLES TO BECOME SUSPENDED AND MOVE OUTSIDE THE TARGET AREA WHEN THE INVERSION LAYER MOVES. DO NOT APPLY WHEN WINDS ARE GUSTY OR UNDER ANY OTHER CONDITION THAT FAVORS DRIFT. DRIFT IS LIKELY TO CAUSE DAMAGE TO ANY VEGETATION CONTACTED. TO PREVENT INJURY TO ADJACENT DESIRABLE VEGETATION, APPROPRIATE BUFFER ZONES MUST BE MAINTAINED.

Apply this product at the appropriate rate in 3 to 15 gallons of water per acre.

Use sufficient carrier volume and appropriate equipment set-up to form droplets large enough to avoid drift potential. Coarse droplets in the 300 to 500 (VMD) micron range have a lower drift potential.

Applications are typically to be made with the nozzle release point at 8 to 15 feet above the top of the target plants unless a greater height is required for aircraft safety.

The distance of the outermost nozzles on the boom must not exceed 75 percent of the length of the wingspan or rotor. In many cases, reducing this distance to 65 percent of the length of the wingspan or rotor will improve drift control without affecting the swath width.

Nozzles must always discharge backward parallel with the air stream and never discharge downwards more than 45 degrees on fixed wing aircraft or forward of the prevailing airflow on rotary winged aircraft. Avoid the use of nozzles with wide-angle discharge.

Do not apply this product when winds are in excess of 10 miles per hour.

Do not apply when there is a low-level inversion where fine spray particles could be suspended in still air and move outside the target area when the inversion layer moves. These conditions can occur when wind speeds are less than 2 miles per hour.

Follow the directions below when an aerial application is made near non-target crops or other desirable vegetation:

1. Do not apply this product within 100 feet of non-target crops or any desirable vegetation.

2. If winds are blowing up to 5 miles per hour TOWARD non-target crops or desirable vegetation, do not apply this product within 500 feet upwind of the desirable vegetation or crop.

3. If winds are blowing between 5 and 10 miles per hour TOWARD non-target crops or desirable vegetation, a buffer zone greater than 500 feet might be needed to protect the crop or desirable vegetation.

* * *

9.9 Sugarcane

TYPES OF APPLICATION: Those listed in Section 9.0, plus Spot Treatment

Preplant, At-Planting, Preemergence

USE INSTRUCTIONS: This product may be applied in or around sugarcane fields, or in fields prior to the emergence of plant cane.

RESTRICTIONS: Do not apply to vegetation in or around ditches, canals or ponds containing water to be used for irrigation.

Spot Treatment

USE INSTRUCTIONS: This product may be applied as a spot treatment in sugarcane. For control of

volunteer or diseased sugarcane, apply a 1-percent solution of this product in water using a handheld sprayer and a spray-to-wet technique. Enhanced results can be obtained on volunteer or diseased sugarcane when application is made when there are at least 7 new leaves. Avoid contact of this herbicide with healthy sugarcane plants as severe damage or destruction could result.

RESTRICTIONS: Do not feed or graze sugarcane foliage within the application area.

Hooded Sprayer

USE INSTRUCTIONS: This product may be applied using a hooded sprayer for weed control in between rows of sugarcane. See additional instructions on the use of hooded sprayers in the "APPLICATION EQUIPMENT AND TECHNIQUES" section of this label.

PRECAUTIONS: Do not allow weeds within the application area to come into contact with the crop.

Fallow Treatment

USE INSTRUCTIONS: This product may be used as a replacement for tillage in fields that are lying fallow between sugarcane crops. This product may also be used to remove the last stubble of ratoon cane by applying 2.5 to 3.3 quarts of this product in 10 to 40 gallons of water per acre to new growth having at least 7 new leaves. Allow a minimum of 7 days after application before tillage. Aerial application of up to 64 fluid ounces per acre may be made onto fallow sites where there is sufficient buffer to prevent drift onto adjacent crops. Tank mixtures with 2,4-D or dicamba may be used. Ensure that the product used is labeled for this application in sugarcane. Read and follow label directions for all products in the tank mixture.

9.9.1 Sugarcane Ripening

USE INSTRUCTIONS: This product may be used as a foliar-applied plant growth regulator to hasten ripening and extend the period of high sucrose level in both low- and high-tonnage sugarcane. Most of the sucrose increase is concentrated in the top nodes of the cane stalk. To maximize sugar recovery where topping is practiced at harvest, top at the base of the fourth leaf. Consult your state sugarcane authority or local Monsanto Company representative regarding the degree of sucrose response that can be anticipated prior to application of this product.

As a result of leaf desiccation, improved trash burn can be expected.

Apply this product at the following rates and timing according to the State in which the sugarcane is grown. Use the higher application rate within the given range when applying to sugarcane under adverse ripening conditions or to less responsive varieties.

FLORIDA — Apply 5 to 12 fluid ounces of this product per acre 3 to 5 weeks before harvest of LAST RATOON CANE ONLY.

HAWAII — Apply 9 to 21 fluid ounces of this product per acre 4 to 10 weeks before harvest.

LOUISIANA — Apply 4 to 12 fluid ounces of this product per acre 3 to 7 weeks before harvest of RATOON CANE ONLY.

PUERTO RICO — Apply 5 fluid ounces of this product per acre 3 to 5 weeks before harvest of RATOON CANE ONLY.

TEXAS — Apply 5 to 12 fluid ounces of this product per acre 3 to 5 weeks before harvest of RATOON CANE ONLY.

PRECAUTIONS: Application of this product could initiate development of shooting eyes. This product might not increase the sucrose content of sugarcane under conditions of good natural ripening. Within 2 to 3 weeks after application, this product could produce a slight yellowing to a pronounced browning and drying of leaves and a shortening of upper internodes. Spindle death could occur.

Rainfall within 6 hours after application could reduce the effectiveness of this product.

Application to sugarcane grown for seed could result in a reduction in germination or vigor. To the extent consistent with applicable law, buyer and all users are responsible for any and all loss or damage in connection with the preharvest use of this product on sugarcane grown for seed.

RESTRICTIONS: On not feed or graze sugarcane forage following application. Do not plant subsequent crops within 30 days after application of this product other than the following: alfalfa or other forage legumes, beans (all types), corn (all types), cotton, melons (all types), pasture grasses, peanuts, potatoes (Irish or sweet), sorghum (milo), soybeans, squash (all types) or wheat.

Do not apply for enhanced ripening to any crops other than sugarcane. Use of this product in any manner not consistent with this label could result in injury to persons, animals or crops, or have other unintended consequences.

* * *

[Plaintiff's Trial Exhibit P-2582]

Message

From: ADAMS, STEPHEN A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=113797]

Sent: 12/14/2010 6:07:35 PM

To: KLOPF, GARY J [AG/1000] [/O=MONSANTO/ OU=NA-1000-01/CN=RECIPIENTS/ CN=162545]

CC: HEMMINGHAUS, JOHN W [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=521714]; DYSZLEWSKI, ANDREW D [AG/1000] [/0=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=102676]; LASARTE, MARTIN A [AG/5001] [/0=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=22015]; KAVANAS, DIEGO [AG/5001] [/O=MONSANTO/OU=LA-5001-01/CN=RECIPIENTS/CN=191954]; GUIBERT, MELISA [AG/5000] [/O=MONSANTO/OU=LA-5000-01/CN=RECIPIENTS/CN=661675]; WATSON, GREGORY R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=GRWATS]; HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]; FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/

CN=180070]; SALTMIRAS, DAVID A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=DASALT]; MORRISON, BRINNON L [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=BLMORR1]

Subject: Re: Response Need – Re: Glyphosate Questions (Argentina); FW: publicaciones CASAFE en la pagina

All:

We have information and data to address most all of this. There are basically 2 parts that I see – 1) the chronic toxicity of glyphosate and its impurities and metabolites, and 2) the toxicity of the POEA surfactants.

With regards to the carcinogenicity of our formulations we don't have such testing on them directly but we do have such testing on the glyphosate component and some extensive tox testing on the surfactant. Since the glyphosate formulations are simply a blend of these components, I think we can address these questions in a confident manner. The biggest factor is time. With the approaching holiday season it may be several weeks before we can have the detailed response which this deserves prepared.

I have copied in the Tech Center people who would need to be involved in preparing the response and invite there comment. I will also follow-up with them.

Steve

From: KLOPF, GARY J [AG/1000]
To: ADAMS, STEPHEN A [AG/1000]
Cc: HEMMINGHAUS, JOHN W [AG/1000]; DYSZLEWSKI, ANDREW D [AG/1000]; LASARTE, MARTIN A [AG/5001]; KAVANAS, DIEGO [AG/5001]; GUIBERT, MELISA [AG/5000]
Sent: Tue Dec 14 08:28:57 2010
Subject: Response Need – Re: Glyphosate Questions (Argentina); FW: publicaciones CASAFE en la pagina

Steve,

Could you and/or someone else in the Regulatory group respond to the questions Martin has raised?

Thanks,

Gary

From: HEMMINGHAUS, JOHN W [AG/1000]
Sent: Monday December 13, 2010 4:58 PM
To: KLOPF, GARY J [AG/1000]
Cc: DYSZLEWSKI, ANDREW D [AG/1000]
Subject: FW: publicaciones CASAFE en la pagina

From: LASARTE, MARTIN A [AG/5001]
Sent: Monday December 13, 2010 3:37 PM
To: HEMMINGHAUS, JOHN W [AG/1000]; DYSZLEWSKI, ANDREW D [AG/1000]
Cc: KAVANAS, DIEGO [AG/5001]; GUIBERT, MELISA [AG/5000]
Subject: FW: publicaciones CASAFE en la pagina

John, Andy:

Please can you contact me with the right person to answer the bellow question regarding glysophate formulations metabolites and potential carcinogenic properties? We also would need some comprehensive information about POEAs surfactants.

The request is to assist us regarding some discussions talking place with some Universities and we don't have that kind of knowledge within the region.

Specifically we would need to understand:

1) Why Roundup formulations are not carcinogenic? What are their most relevant metabolites and what study showed they are not?

2) NNG and formaldehyde are the 2 impurities with known carcinogenic properties that we follow very closely with FAQ standards. Are they also present on the metabolites?

3) I know from the process stand point that the AMPA is also a impurity we have under control. Is AMPA also a metabolite? Is it carcinogenic?

4) POEAs surfacant definition and classification. Why are they questioned?

It would be very comprehensive if there is a table showing the metabolites, their concentration on a regular basis, they carcinogenic properties and the limits

Thank you! Martin

* * *


DURNELL_000001
PENGAD-Bayonne, N. J.
DEFENDANT'S DEPOSITION
EXHIBIT
3
FAITH
HOPE
Believe