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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS
LIABILITY LITIGATION

MDL No. 2741
Case No. 3:16-md-02741-VC

This document relates to:

Nicole Soltyka et al., v. Monsanto Co.,
Case No. 3:22-cv- 05734-VC

MONSANTO COMPANY’S ANSWER TO PLAINTIFF’S COMPLAINT

Pursuant to Rule 12 of the Federal Rules of Civil Procedure, Defendant Monsanto Company (“Monsanto”), by and through its counsel, respectfully responds by generally denying all allegations contained in plaintiff’s Complaint (“the Complaint”), except as set forth below. As defined in the Complaint and as used in this Answer, Monsanto refers to Monsanto Company, a United States based company incorporated in Delaware, and not to other Monsanto-affiliated companies. Silence as to any allegations shall constitute a denial.

In response to the allegations in the unnumbered paragraph under the section titled “INTRODUCTION,” Monsanto denies that any exposure to Roundup®-branded products can cause non-Hodgkin’s lymphoma (“NHL”). Monsanto admits that plaintiff purports to bring an action for damages allegedly related to exposure to Roundup®-branded products but denies any liability to plaintiff. Monsanto denies the remaining allegations in the section titled “INTRODUCTION.”

1 Environmental Protection Agency (“EPA”) has classified surfactants and adjuvants as inert. In
2 response to the final sentence of paragraph 9, Monsanto admits that certain scientific,
3 manufacturing, marketing, and sales decisions regarding Roundup®-branded products were made
4 in the State of Missouri, but states that the terms “important” and “business decisions” are vague
5 and ambiguous, and therefore Monsanto denies the same. Monsanto denies the remaining
6 allegations in the final sentence of paragraph 9.

7 10. Monsanto denies the allegations in paragraph 10.

8 11. The allegations in paragraph 11 set forth conclusions of law for which no response
9 is required.

10 12. The allegations in paragraph 12 set forth conclusions of law for which no response
11 is required. To the extent that a response is deemed required, Monsanto admits the allegations in
12 paragraph 12 based upon the allegations in plaintiff’s Complaint.

13 13. The allegations in paragraph 13 set forth conclusions of law for which no response
14 is required.

15 14. The allegations in paragraph 14 set forth conclusions of law for which no response
16 is required.

17 15. Monsanto admits the allegations in the first two sentences of paragraph 15. In
18 response to the third sentence of paragraph 15, Monsanto admits that certain Roundup®-branded
19 herbicides contain POEA and adjuvants and that EPA has classified surfactants and adjuvants as
20 inert. In response to the last sentence of paragraph 15, Monsanto admits that glyphosate was one
21 of the world’s most widely used herbicides in 2013, but notes that Monsanto has not been the
22 only manufacturer of glyphosate-based herbicides. Monsanto lacks information or knowledge
23 sufficient to form a belief as to the accuracy of the specific numbers and statistics cited in the
24 remaining sentences of paragraph 15 and therefore denies those allegations.

25 16. In response to the allegations in paragraph 16, Monsanto admits that its
26 headquarters are in St. Louis County, Missouri, and that it is incorporated in Delaware. Monsanto
27 admits that it and its affiliated companies have operations and offices in countries around the

1 world. Monsanto admits that it has been a producer of glyphosate-based herbicides but lacks
2 sufficient information regarding the business of other glyphosate producers to admit or deny the
3 allegation as written in the second sentence of paragraph 16. Monsanto admits that it has been
4 the leading producer of seeds that contain the Roundup Ready® trait and that use of crops with
5 the Roundup Ready® trait substantially improve a farmer's ability to control weeds. Monsanto
6 lacks information or knowledge sufficient to form a belief as to the accuracy of the specific
7 numbers and statistics provided in the remaining sentences of paragraph 16 and therefore denies
8 those allegations.

9 17. Monsanto admits the allegations in the first sentence of paragraph 17. Monsanto
10 admits that certain studies have reported that glyphosate is found at *de minimis* levels significantly
11 below regulatory safety limits in various locations and media. Monsanto otherwise denies the
12 remaining allegations in paragraph 17.

13 18. Monsanto admits the allegations in the first sentence of paragraph 18. Monsanto
14 denies the allegations in the second sentence of paragraph 18 to the extent they suggest that the
15 International Agency for Research on Cancer ("IARC") based its evaluation on a complete or
16 accurate assessment of the scientific research regarding glyphosate.

17 19. Monsanto admits the allegations in the first sentence of paragraph 19. Monsanto
18 denies the allegations in the second sentence of paragraph 19.

19 20. In response to the allegations in paragraph 20, Monsanto admits that the IARC
20 working group classified glyphosate under Group 2A. Monsanto denies the remaining allegations
21 in paragraph 20.

22 21. Monsanto denies the allegations in paragraph 21.

23 22. In response to paragraph 22, Monsanto admits that glyphosate repeatedly has been
24 found to be safe to humans and the environment by regulators in the United States and around
25 the world and further admits that it has labeled glyphosate products as approved by regulatory
26 bodies consistent with those findings. Monsanto also admits that the EPA repeatedly has
27 concluded pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") that

1 glyphosate-based herbicides create no unreasonable risk to human health or to the environment
2 when used in accordance with the label. To the extent that paragraph 22 alleges that Monsanto
3 has labeled glyphosate-based or Roundup®-branded herbicides in any manner different or in
4 addition to such regulatory approval, Monsanto denies such allegations.

5 23. In response to the allegations in paragraph 23, Monsanto admits that glyphosate is
6 an herbicide that is used to kill invasive plants and weeds. The remaining allegations in paragraph
7 23 are vague and ambiguous and Monsanto lacks information or knowledge sufficient to form a
8 belief as to the truth of the remaining allegations in paragraph 23 and therefore denies those
9 allegations.

10 24. Monsanto admits the allegations in the first sentence of paragraph 24. Monsanto
11 denies the allegations in the second sentence of paragraph 24 because the impact of glyphosate
12 on treated plants varies depending upon the amount of glyphosate applied and the type of plant.
13 Monsanto denies the allegations in the third sentence of paragraph 24 to the extent that it suggests
14 that glyphosate is present in any plants at anything other than *de minimis* amounts well within
15 regulatory safety levels, as determined by EPA.

16 25. In response to the allegations in paragraph 25, Monsanto admits that farmers have
17 safely used Roundup®-branded products since the 1970s. Monsanto denies the remaining
18 allegations in paragraph 25.

19 26. Monsanto admits the allegations in the first two sentences of paragraph 26 and
20 admits that it has marketed Roundup®-branded products in accord with EPA's regulatory
21 determinations under FIFRA. Monsanto otherwise denies the remaining allegations in paragraph
22 26.

23 27. In response to the allegations in paragraph 27, Monsanto admits that certain
24 Roundup®-branded herbicides contain POEA and adjuvants, that EPA has classified surfactants
25 and adjuvants as inert, and that the specific surfactants and adjuvants used in Roundup®-branded
26 herbicides – like those in other manufacturers' herbicide products – are protected by EPA as
27 “trade secrets.” Monsanto notes that EPA has determined that the surfactants used in Roundup®-

1 branded herbicides do not pose an unreasonable risk to human health. Monsanto denies the
2 remaining allegations in paragraph 27.

3 28. The allegations in paragraph 28 set forth conclusions of law for which no response
4 is required.

5 29. In response to the allegations in paragraph 29, Monsanto admits that EPA requires
6 registrants of herbicides to submit extensive data in support of the human health and
7 environmental safety of their products and further admits that EPA will not register or approve
8 the labeling of herbicides that do not satisfy the requirements set forth in FIFRA. The remaining
9 allegations in paragraph 29 set forth conclusions of law for which no response is required.

10 30. The allegations in paragraph 30 set forth conclusions of law for which no response
11 is required.

12 31. In response to the allegations in paragraph 31, Monsanto admits that Roundup®-
13 branded products are registered by EPA for manufacture, sale, and distribution in the United
14 States and are registered by the State of California for sale and distribution.

15 32. In response to the allegations in paragraph 32, Monsanto admits that EPA requires
16 registrants of herbicides to submit extensive data in support of the human health and
17 environmental safety of their products and further admits that EPA will not register or approve
18 the labeling of herbicides that do not satisfy the requirements set forth in FIFRA. Monsanto states
19 that the term “the product tests” in the last sentence of paragraph 32 is vague and ambiguous, and
20 Monsanto therefore denies the same. The remaining allegations in paragraph 32 set forth
21 conclusions of law for which no response is required.

22 33. Monsanto denies the allegations in paragraph 33 to the extent they suggest that EPA
23 only evaluates the safety of pesticide products on the date of their initial registration. Monsanto
24 admits that EPA is in the process of conducting regulatory review of various pesticide products,
25 but Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the
26 allegations in paragraph 33 regarding such pesticide products generally. The remaining
27 allegations in paragraph 33 set forth conclusions of law for which no response is required.

1 34. In response to the allegations in paragraph 34, Monsanto admits that EPA has
 2 undertaken a regulatory review of glyphosate and further admits that EPA has not released its
 3 findings. Monsanto states, however, that: (a) in September 2016, EPA’s Office of Pesticide
 4 Programs (“OPP”) issued a 227-page evaluation of glyphosate’s carcinogenic potential,
 5 concluding that “[t]he strongest support is for [the descriptor] ‘not likely to be carcinogenic to
 6 humans’ at doses relevant to human health risk assessment”¹; and (b) at the same time, EPA
 7 posted an October 2015 final report by its standing Cancer Assessment Review Committee
 8 (“CARC”), in which CARC endorsed EPA’s existing classification of glyphosate as “Not Likely
 9 to be Carcinogenic to Humans.”²

10 35. In response to the allegations in paragraph 35, Monsanto admits that an EPA review
 11 committee classified glyphosate as Class C in 1985 based on limited data and that EPA changed
 12 its classification of glyphosate to Group E based upon a full evaluation of the scientific evidence,
 13 including but not limited to three animal carcinogenicity studies. Monsanto admits that plaintiff
 14 has accurately quoted from one passage in an EPA document in 1991 with respect to the
 15 designation of an agent as Group E, but states that EPA repeatedly has concluded that glyphosate
 16 does not pose any cancer risk to humans. In addition to the conclusions in the two EPA OPP
 17 reports and the EPA CARC Final Report discussed above, other specific findings of safety
 18 include:

- 19 • “In June 1991, EPA classified glyphosate as a Group E [carcinogen]—one that shows
 20 evidence of non-carcinogenicity for humans—based on the lack of convincing
 21 evidence of carcinogenicity in adequate studies.” EPA, *Glyphosate: Reregistration
 Eligibility Decision (RED) Facts*, 2 (Sept. 1993),
 22 <http://archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf>.

23 ¹ EPA’s Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* at
 24 141 (Sept. 12, 2016) (“EPA OPP Report”), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0094>. The EPA OPP Report was prepared in anticipation of an EPA Scientific Advisory Panel
 meeting on glyphosate’s carcinogenic potential.

25 ² Cancer Assessment Review Committee, Health Effects Division, Office of Pesticide Programs, U.S.
 26 Environmental Protection Agency, *Cancer Assessment Document – Evaluation of the Carcinogenic
 Potential of Glyphosate* at 10, 77 (Final Report, Oct. 1, 2015) (“EPA CARC Final Report”),
 27 <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0014>.

- 1 • “No evidence of carcinogenicity.” Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,943 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180).
- 2 • “Glyphosate has no carcinogenic potential.” Glyphosate; Pesticide Tolerance, 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180).
- 3 • “There is [an] extensive database available on glyphosate, which indicate[s] that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant.” Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180).
- 4 • “EPA has concluded that glyphosate does not pose a cancer risk to humans.” 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180).
- 5 • “In 2014, EPA reviewed over 55 epidemiological studies conducted on the possible cancer and non-cancer effects of [g]lyphosate. Our review concluded that this body of research does not provide evidence to show that [g]lyphosate causes cancer and does not warrant any change in the EPA’s cancer classification for [g]lyphosate.” *Agriculture Biotechnology: A Look at Federal Regulation and Stakeholder Perspectives: Hearing Before the S. Comm. on Agr., Nutrition, & Forestry*, 114th Cong. (2015) (statement of Dr. William Jordan, Deputy Director of EPA’s Office of Pesticide Programs), <http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-0e55900753b4>, at time stamp 55:05 – 56:20.

13 Monsanto denies the remaining allegations in paragraph 35.

14 36. In response to the allegations in paragraph 36, Monsanto admits that it – along with
15 a large number of other companies and governmental agencies – was defrauded by two chemical
16 testing laboratories, and that Monsanto had hired both of these laboratories to conduct testing on
17 glyphosate. Monsanto states that only one of these laboratories was hired to conduct toxicity
18 tests of glyphosate. Monsanto denies that EPA’s registration of glyphosate or any glyphosate-
19 based herbicides is based upon any invalid Industrial Bio-Test (“IBT”) studies. To the extent that
20 the allegations in paragraph 36 are intended to suggest that Monsanto was anything other than a
21 victim of this fraud, such allegations are denied.

22 37. In response to the allegations in paragraph 37, Monsanto admits that IBT
23 Laboratories was hired to conduct toxicity studies in connection with the registration of a
24 Roundup®-branded product. Monsanto denies that EPA’s regulatory approval of such product is
25 based upon any fraudulent or false IBT studies.

26 38. Monsanto denies the allegations in paragraph 38 to the extent they suggest that EPA
27 performed an inspection of IBT Laboratories solely or specifically in connection with studies

1 conducted on glyphosate. Monsanto admits that EPA performed an audit of IBT Laboratories to
2 investigate that laboratory's fraudulent and/or improper testing procedures in connection with
3 services provided to a broad number of private and governmental entities and that this inspection
4 included a review of studies IBT conducted on glyphosate. Monsanto was one of several
5 pesticide manufacturers who had used IBT test results. The audit found some toxicology studies
6 conducted with the original Roundup® herbicide to be invalid. As a result, Monsanto repeated
7 all required studies in accordance with applicable EPA testing guidelines. Monsanto denies that
8 EPA's registration of glyphosate or any glyphosate-based herbicides is based upon any invalid
9 IBT studies. To the extent that the allegations in paragraph 38 are intended to suggest that
10 Monsanto was anything other than a victim of this fraud, such allegations also are denied.

11 39. In response to the allegations in paragraph 39, Monsanto admits that three IBT
12 employees were convicted of the charge of fraud, but Monsanto denies that any of the individuals
13 were convicted based upon studies conducted on glyphosate or glyphosate-based herbicides.

14 40. In response to the allegations in paragraph 40, Monsanto admits that it – along with
15 numerous other private companies – hired Craven Laboratories as an independent laboratory to
16 conduct residue studies for Monsanto agricultural products. Monsanto further admits that it was
17 defrauded by Craven Laboratories and that, as a result, Monsanto repeated the studies conducted
18 at Craven Laboratories at a substantial cost. To the extent that the allegations in paragraph 40 are
19 intended to suggest that Monsanto was anything other than a victim of this fraud, Monsanto
20 denies those allegations.

21 41. Monsanto denies the allegations in paragraph 41.

22 42. In response to the allegations in paragraph 42, Monsanto admits that Roundup®-
23 branded products are highly valued by customers because of their efficacy and safety. Monsanto
24 also admits that the patent for glyphosate expired in the United States in 2000. The remaining
25 allegations in paragraph 42 are vague and conclusory, comprise attorney characterizations, and
26 are accordingly denied.

1 48. In response the allegations in paragraph 48, Monsanto admits that the French court
2 ruled that Monsanto had falsely advertised its herbicide Roundup® as “biodegradable” and that it
3 “left the soil clean,” but denies the allegations to the extent they suggest that this ruling was in
4 any way related to plaintiff’s claims here that glyphosate can cause cancer. Monsanto denies the
5 remaining allegations in paragraph 48.

6 49. In response to the allegations in paragraph 49, Monsanto denies that IARC follows
7 stringent procedures for the evaluation of a chemical agent. Monsanto lacks information or
8 knowledge sufficient to form a belief as to the accuracy of the specific numbers cited in paragraph
9 49, which are not limited as of any specified date, and accordingly denies the same.

10 50. In response to the allegations in paragraph 50, Monsanto admits that IARC sets
11 forth in its Preamble the procedures that it claims to follow in its carcinogenicity evaluations.
12 Monsanto denies the remaining allegations in paragraph 50.

13 51. Monsanto denies any suggestion that IARC reviewed the full body of scientific
14 research in conducting its evaluation of glyphosate or that IARC reliably reviewed the studies
15 that it cited in its glyphosate monograph. Monsanto lacks information or knowledge sufficient to
16 form a belief as to the truth of the remaining allegations in paragraph 51 and therefore denies
17 those allegations.

18 52. Monsanto denies any suggestion that IARC reviewed the full body of scientific
19 research in conducting its evaluation of glyphosate or that IARC reliably reviewed the studies
20 that it cited in its glyphosate monograph. Monsanto lacks information or knowledge sufficient to
21 form a belief as to the truth of the remaining allegations in paragraph 52 and therefore denies
22 those allegations.

23 53. Monsanto denies the allegations in paragraph 53 to the extent that they suggest that
24 IARC had previously assessed glyphosate. Monsanto admits that IARC classified glyphosate as
25 a Group 2A agent in March 2015.

26 54. In response to the allegations in paragraph 54, Monsanto admits that IARC issued
27 its monograph for glyphosate, Monograph 112, on July 29, 2015, and that a draft of the

1 monograph was prepared by a “working group” of individuals selected by IARC who met over a
2 one week period in March 2015 to consider glyphosate along with a number of other substances.
3 Monsanto denies the allegation that all members of the working groups are “experts.” Monsanto
4 denies that the working group or anyone at IARC conducted a one-year review of the scientific
5 evidence related to glyphosate or that the working group’s findings reflected a comprehensive
6 review of the latest available scientific evidence. Monsanto also denies that the working group
7 considered all information available in the scientific literature and all data from government
8 reports that are publicly available. Monsanto denies the remaining allegations in paragraph 54.

9 55. In response to the allegations in paragraph 55, Monsanto denies that the IARC
10 working group considered all of the data in the numerous studies that have been conducted
11 looking at the safety of glyphosate and glyphosate-containing herbicides in human populations
12 or that it reliably considered the studies that it purports to have reviewed, which frequently reach
13 conclusions directly contrary to those espoused by the IARC working group. To the extent the
14 allegations purport to characterize statements made in the IARC monograph for glyphosate, the
15 statements in that document speak for themselves, but Monsanto lacks information or knowledge
16 sufficient to form a belief as to the accuracy of the source of said information and accordingly
17 denies the allegations.

18 56. The allegations in paragraph 56 are vague and conclusory. To the extent they
19 purport to characterize statements made in the IARC monograph for glyphosate, the statements
20 in that document speak for themselves, but Monsanto lacks information or knowledge sufficient
21 to form a belief as to the accuracy of the source of said information and accordingly denies the
22 allegations.

23 57. In response to the allegations in paragraph 57, to the extent the allegations purport
24 to characterize statements made in the IARC monograph for glyphosate, the statements in that
25 document speak for themselves, but to the extent that this paragraph means that more than *de*
26 *minimis* amounts of exposure are present, the allegations in paragraph 57 are denied.

1 repeatedly have concluded that glyphosate is not genotoxic. Monsanto denies the remaining
2 allegations in paragraph 63.

3 64. In response to the allegations in paragraph 64, Monsanto admits that the IARC
4 working group purported to find such effects, but denies that there is any reliable scientific basis
5 for such conclusion. Monsanto denies the remaining allegations in paragraph 64.

6 65. In response to the allegations in paragraph 65, Monsanto admits that the working
7 group reviewed the findings of an Agricultural Health Study (“AHS”) published in 2005, but
8 denies that the working group characterized that study as supporting an association between
9 glyphosate and the specified cancers. The AHS cohort study did not find a positive association
10 between glyphosate and any type of cancer. Monsanto denies all other allegations in paragraph
11 65.

12 66. In response to the allegations in paragraph 66, Monsanto admits that EPA has a
13 technical fact sheet, as part of its Drinking Water and Health, National Primary Drinking Water
14 Regulations, relating to glyphosate that predates the IARC March 20, 2015 evaluation, which
15 should be read in context of EPA’s precautionary regulatory mandate and EPA’s consistent
16 finding that glyphosate does not pose any cancer risk to humans.

17 67. In response to the allegations in paragraph 67, Monsanto admits that the Northwest
18 Coalition for Alternatives to Pesticides made the identified claims, but denies that the Coalition
19 provides any reliable basis for any conclusions regarding potential health risks from glyphosate.
20 Monsanto notes that a federal district court has characterized this same publication as an
21 “advocacy piece[] published in [a] non-peer-reviewed journal.” *See Arias v. DynCorp*, 928 F.
22 Supp. 2d 10, 24 (D.D.C. 2013).

23 68. Monsanto states that the term “toxic” as used in paragraph 68 is vague and
24 ambiguous to the extent it is intended to suggest any evidence of carcinogenicity. Monsanto
25 denies the allegations in paragraph 68.

26 69. In response to the allegations in paragraph 69, Monsanto admits that Julie Marc
27 published the cited study in 2002 and states that the document speaks for itself and does not

1 require a response. To the extent that a response is deemed required, Monsanto denies the
2 allegations in paragraph 69.

3 70. In response to the allegations in the first sentence of paragraph 70, Monsanto admits
4 that Julie Marc published a study titled “Glyphosate-based pesticides affect cell cycle regulation”
5 in 2004. To the extent that the first sentence of paragraph 70 characterizes the meaning of the
6 cited study, Monsanto denies the allegations in the first sentence of paragraph 70. In response to
7 the remaining allegations in paragraph 70, Monsanto states that the document speaks for itself
8 and does not require a response. To the extent that a response is deemed required, Monsanto
9 denies the remaining allegations in paragraph 70.

10 71. In response to the allegations in paragraph 71, Monsanto states that the cited
11 document speaks for itself and does not require a response. To the extent that paragraph 71
12 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in
13 paragraph 71.

14 72. In response to the allegations in paragraph 72, Monsanto states that the cited
15 document speaks for itself and does not require a response. To the extent that paragraph 72
16 characterizes the meaning of the cited study, Monsanto denies the allegation that the cited studies
17 support the allegation that glyphosate or Roundup®-branded products pose any risk to human
18 health and denies the remaining allegations in paragraph 72.

19 73. In response to the allegations in paragraph 73, Monsanto states that the terms “at
20 all times” and these studies are vague and ambiguous, and therefore Monsanto denies the
21 allegations in paragraph 73.

22 74. In response to the allegations in paragraph 74, Monsanto denies that glyphosate or
23 Roundup®-branded products cause cancer. The allegations in paragraph 74 take statements out
24 of context; are vague, misleading, incomplete, and conclusory; and/or comprise attorney
25 characterizations – and are accordingly denied.

26 75. In response to the allegations in paragraph 75, Monsanto admits that the IARC
27 working group’s classification of glyphosate as a Class 2A carcinogen has resulted in ongoing

1 discussions and/or restrictions in certain countries, including The Netherlands, regarding the sale
2 and/or use of glyphosate-based herbicides, but denies that there is any scientific basis for the
3 concerns raised by the improper IARC classification. The allegations in paragraph 75 constitute
4 conclusions of law for which no response is required or are otherwise vague, misleading,
5 incomplete, and conclusory and/or comprise attorney characterizations – and are accordingly
6 denied.

7 76. In response to the allegations in paragraph 76, Monsanto admits that the IARC
8 working group classification led an individual government attorney in Brazil to write a letter to
9 the Brazilian regulatory authorities requesting a reevaluation of glyphosate. Monsanto denies the
10 remaining allegations in paragraph 76.

11 77. Monsanto admits that, in France, the sale to and use by amateurs (i.e., non-
12 professionals) of all pesticides (with certain exceptions for biocontrol pesticides) are prohibited
13 as of January 1, 2019, with certain exceptions. Monsanto denies the remaining allegations in
14 paragraph 77.

15 78. In response to the allegations in paragraph 78, Monsanto admits that some
16 employees of Bermuda's government announced an intention to suspend the importation of
17 glyphosate-based herbicides, but Monsanto lacks information sufficient to form a belief as to the
18 truth of the allegations about whether this suspension took effect and accordingly denies the same.
19 Monsanto denies the remaining allegations in paragraph 78.

20 79. In response to the allegations in paragraph 79, Monsanto admits that the IARC
21 monograph appears to be the alleged basis for the Sri Lankan government's actions, including
22 the allegation that glyphosate can cause kidney disease. Monsanto further states that the
23 allegations regarding kidney disease found in Sri Lanka are unrelated to plaintiffs' allegations
24 regarding claimed carcinogenicity. Monsanto denies the remaining allegations in paragraph 79.

25 80. In response to the allegations in paragraph 80, Monsanto denies the alleged basis
26 for Colombia's suspension of aerial spraying of glyphosate. Colombia's attorney general has
27 explained that the ban on aerial spraying of illicit coca plantations was a concession to the FARC

1 (“Fuerzas Armadas Revolucionarias de Colombia”), and had nothing to do with alleged safety
2 concerns. As of April 2016, the government of Colombia has resumed manual application of
3 glyphosate on illicit coca crops. A federal district court in the United States excluded plaintiffs’
4 expert testimony purporting to link these same aerial eradication operations with cancer as
5 scientifically unreliable. *See Arias v. DynCorp*, 928 F. Supp. 2d 10 (D.D.C. 2013). Monsanto
6 denies the remaining allegations in paragraph 80.

7 81. In response to the allegations in paragraph 81, Monsanto admits that, on November
8 12, 2015, the European Food Safety Authority issued its Renewal Assessment Report (RAR) on
9 glyphosate, in which it concluded that “glyphosate is unlikely to pose a carcinogenic hazard to
10 humans.”³ Monsanto further admits that this conclusion affirmed a similar finding by the German
11 Federal Institute for Risk Management (BfR). Monsanto admits that the European scientists who
12 reached these determinations were acting independently of Monsanto and were acting to protect
13 the public.

14 82. In response to the allegations in paragraph 82, Monsanto denies that “industry
15 groups” were afforded any ability to review the RAR beyond that afforded to the public generally.
16 Monsanto otherwise admits the allegations in paragraph 82.

17 83. Monsanto admits the allegations in paragraph 83.

18 84. In response to the allegations in paragraph 84, Monsanto states that the cited
19 document speaks for itself and does not require a response. Monsanto denies the allegations in
20 paragraph 84 to the extent that they purport to set forth all of the distinctions identified by EFSA
21 between its evaluation and the evaluation of the IARC working group. Monsanto states that in
22 the same document cited by plaintiff, EFSA states that, in contrast to IARC, “the EU peer review
23 concluded that no significant increase in tumour incidence could be observed in any of the treated
24 groups of animals in the nine long term rat studies considered” and explains that “[a]s well as
25 reviewing a larger number of studies [than IARC], EFSA for example considered that

26 ³ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.
27

1 carcinogenic effects observed at high doses were unreliable as they could be related to general
2 toxicity.”⁴ To the extent that paragraph 84 characterizes the meaning of the cited studies,
3 Monsanto denies the remaining allegations in paragraph 84.

4 85. In response to the allegations in paragraph 85, Monsanto states that the cited
5 document speaks for itself and does not require a response.

6 86. In response to the allegations in paragraph 86, Monsanto admits that EFSA set
7 acceptable exposure thresholds for glyphosate that are orders of magnitude higher than those
8 which occur in the ordinary use of glyphosate-based herbicides. Monsanto denies that these
9 exposure thresholds are based upon any alleged risk of carcinogenicity.

10 87. In response to the allegations in paragraph 87, Monsanto admits that certain
11 individuals, including Dr. Christopher Portier, sent the letter identified in paragraph 87
12 (hereinafter, “the Portier letter”). Monsanto denies that Dr. Portier or the other signatories to his
13 letter are “independent” and “renowned international experts in the field.” Monsanto states that
14 Dr. Portier has been disclosed as an expert witness retained by plaintiffs’ counsel in the
15 glyphosate cancer litigation against Monsanto and that Monsanto lacks information or knowledge
16 sufficient to form a belief as to whether the other signatories were aware, before they signed the
17 Portier letter, that Dr. Portier was working as a retained expert plaintiffs’ counsel. Monsanto
18 otherwise admits that this letter urged the EU Health Commissioner to disregard the scientific
19 findings reached by EFSA and by the BfR.

20 88. In response to the allegations in paragraph 88, Monsanto admits that Dr. Portier
21 sent the letter identified in paragraph 88. Monsanto denies that Dr. Portier or the other signatories
22 to his letter are “renowned international experts in the field.” Monsanto admits that certain
23 members of the IARC working group assigned to glyphosate signed on to the Portier letter, but
24 states that Monsanto lacks information or knowledge sufficient to form a belief as to whether
25

26 ⁴ EFSA, *EFSA Explains Risk Assessment Glyphosate*, [http://www.efsa.europa.eu/sites/default](http://www.efsa.europa.eu/sites/default/files/comorate_publications/files/efsaexplainsglyphosate151112en.pdf)
27 [files/comorate_publications/files/efsaexplainsglyphosate151112en.pdf](http://www.efsa.europa.eu/sites/default/files/comorate_publications/files/efsaexplainsglyphosate151112en.pdf).

1 those individuals or the other signatories were aware at the time that Dr. Portier was working as
2 a retained expert for plaintiffs' counsel.

3 89. In response to the allegations in paragraph 89, Monsanto states that the cited Portier
4 letter speaks for itself and does not require a response. Monsanto further admits that Dr. Portier
5 — who has been disclosed as an expert witness retained by plaintiffs' counsel in the glyphosate
6 cancer litigation against Monsanto — seeks in his letter to challenge the scientific conclusions
7 reached by EFSA in support of its finding that “glyphosate is unlikely to pose a carcinogenic
8 hazard to humans.”⁵ To the extent that paragraph 89 characterizes the meaning of the cited
9 document or of EFSA's evaluation of glyphosate, Monsanto denies the remaining allegations in
10 paragraph 89.

11 90. In response to the allegations in paragraph 90, Monsanto admits that IARC
12 concluded that the human epidemiologic data provides only “limited evidence of
13 carcinogenicity,” which IARC defines as meaning that “chance, bias, or confounding could not
14 be ruled out with reasonable confidence.”⁶ Monsanto further admits that Dr. Portier — who has
15 been disclosed as an expert witness retained by plaintiffs' counsel in the glyphosate cancer
16 litigation against Monsanto — seeks in his letter to challenge the scientific conclusions reached
17 by EFSA in support of its finding that “glyphosate is unlikely to pose a carcinogenic hazard to
18 humans.”⁷ In response to the remaining allegations in paragraph 90, Monsanto states that the cited
19 Portier letter speaks for itself and does not require a response. To the extent that paragraph 90
20 characterizes the meaning of the cited document or of EFSA's evaluation of glyphosate,
21 Monsanto denies the remaining allegations in paragraph 90.

22
23
24 ⁵ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

25 ⁶ <http://publications.iarc.ferc.org/publications/media/download/4566/1f986e57ea2ddd9830fec223aebc740d0bb2eca.pdf>

26 ⁷ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

1 91. In response to the allegations in paragraph 91, Monsanto states that the cited Portier
2 letter speaks for itself and does not require a response. Monsanto further admits that Dr. Portier
3 — who has been disclosed as an expert witness retained by plaintiffs’ counsel in the glyphosate
4 cancer litigation against Monsanto — seeks in his letter to challenge the scientific conclusions
5 reached by EFSA in support of its finding that “glyphosate is unlikely to pose a carcinogenic
6 hazard to humans.”⁸ To the extent that paragraph 91 characterizes the meaning of the cited
7 document or of EFSA’s and BfR’s evaluation of glyphosate, Monsanto denies the remaining
8 allegations in paragraph 91.

9 92. In response to the allegations in paragraph 92, Monsanto states that the cited Portier
10 letter speaks for itself and does not require a response. Monsanto further admits that Dr. Portier
11 — who has been disclosed as an expert witness retained by plaintiffs’ counsel in the glyphosate
12 cancer litigation against Monsanto — seeks in his letter to challenge the scientific conclusions
13 reached by EFSA in support of its finding that “glyphosate is unlikely to pose a carcinogenic
14 hazard to humans.”⁹ To the extent that paragraph 92 characterizes the meaning of the cited
15 document or of EFSA’s and BfR’s evaluation of glyphosate, Monsanto denies the remaining
16 allegations in paragraph 92.

17 93. Monsanto admit the allegations in paragraph 93.

18 94. In response to the allegations in paragraph 94, Monsanto states that the cited
19 document speaks for itself and does not require a response. Monsanto denies that the self-labeled
20 “consensus statement” represents the view of any consensus of scientific opinion. To the extent
21 that paragraph 94 characterizes the scientific evidence regarding the safety of glyphosate-based
22 herbicides, Monsanto denies the remaining allegations in paragraph 94.

25 ⁸ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

26 ⁹ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

1 “consensus statement” represents the view of any consensus of scientific opinion. To the extent
2 that paragraph 100 characterizes the scientific evidence regarding the safety of glyphosate-based
3 herbicides, Monsanto denies the remaining allegations in paragraph 100.

4 101. In response to the allegations in paragraph 101, Monsanto admits that the United
5 States Food and Drug Administration (“FDA”) has authority to enforce pesticide residues and
6 that the FDA announced it would begin testing certain foods for glyphosate residues. In response
7 to the remaining allegations in paragraph 101, Monsanto states that the cited documents speak
8 for themselves and do not require a response.

9 102. In response to the allegations in paragraph 102, Monsanto admits that the U.S.
10 Government Accountability Office (“GAO”) issued the cited report regarding pesticide residue
11 monitoring programs, but Monsanto denies that the GAO report was limited to glyphosate. In
12 response to the remaining allegations in paragraph 102, Monsanto states that the cited documents
13 speak for themselves and do not require a response. To the extent, that paragraph 102
14 characterizes the meaning of the cited documents; Monsanto denies the remaining allegations in
15 paragraph 102.

16 103. In response to the allegations in paragraph 103, Monsanto admits that the FDA has
17 authority to enforce pesticide residues and that the FDA announced it would begin testing
18 certain foods for glyphosate residues. In response to the remaining allegations in paragraph
19 103, Monsanto states that the cited documents speak for themselves and do not require a response.
20 To the extent that paragraph 103 characterizes the meaning of the cited documents, Monsanto
21 denies the remaining allegations in paragraph 103.

22 104. In response to the allegations in paragraph 104, Monsanto admits that the FDA has
23 authority to enforce pesticide residues and that the FDA announced it would begin testing certain
24 foods for glyphosate residues. In response to the remaining allegations in paragraph 104,
25 Monsanto states that the cited documents speak for themselves and do not require a response. To
26 the extent, that paragraph 104 characterizes the meaning of the cited documents; Monsanto denies
27 the remaining allegations in paragraph 104.

1 112. Monsanto admits the allegations in paragraph 112.

2 113. In response to the allegations in paragraph 113, Monsanto admits that the EU voted
3 to extend the glyphosate license for five more years. In response to the remaining allegations in
4 paragraph 113, Monsanto states that the cited document speaks for itself and does not require a
5 response.

6 114. In response to the allegations in paragraph 114, Monsanto admits that plaintiff
7 purports to bring the described action for damages allegedly related to exposure to Roundup®-
8 branded products but denies any liability to plaintiff.

9 115. In response to the allegations in paragraph 115, Monsanto admits that plaintiff
10 purports to seek damages as described but denies any liability to plaintiff.

11 116. Monsanto incorporates by reference its responses to paragraphs 1 through 115 in
12 response to paragraph 116 of plaintiff's Complaint.

13 117. In response to the allegations in paragraph 117, Monsanto admits that plaintiff
14 purports to bring claims for strict liability but denies any liability to plaintiff.

15 118. Monsanto denies the allegations in paragraph 118.

16 119. Monsanto lacks information or knowledge sufficient to form a belief as to the truth
17 of the allegations in paragraph 119 and therefore denies those allegations.

18 120. Monsanto denies the allegations in paragraph 120.

19 121. Monsanto lacks information or knowledge sufficient to form a belief as to the truth
20 of the allegations in paragraph 121 and therefore denies those allegations.

21 122. Monsanto denies the allegations in paragraph 122.

22 123. Monsanto denies the allegations in paragraph 123.

23 124. Monsanto denies the allegations in paragraph 124.

24 125. Monsanto denies the allegations in paragraph 125, including each of its subparts.

25 126. Monsanto lacks information or knowledge sufficient to form a belief as to the truth
26 of the allegations in paragraph 126 regarding decedent's claimed use of and/or exposure to
27 Roundup®-branded products and therefore denies those allegations. Monsanto denies the

1 remaining allegations in paragraph 126, including that Roundup®-branded products have
2 “dangerous characteristics.”

3 127. Monsanto denies the allegations in paragraph 127.

4 128. Monsanto denies the allegations in paragraph 128.

5 129. Monsanto denies the allegations in paragraph 129.

6 130. Monsanto denies the allegations in paragraph 130.

7 131. Monsanto denies the allegations in paragraph 131.

8 132. Monsanto denies the allegations in paragraph 132.

9 133. Monsanto denies the allegations in paragraph 133.

10 134. Monsanto denies the allegations in paragraph 134.

11 135. Monsanto denies the allegations in paragraph 135.

12 136. Monsanto denies the allegations in paragraph 136.

13 137. Monsanto incorporates by reference its responses to paragraphs 1 through 136 in
14 response to paragraph 137 of plaintiff’s Complaint.

15 138. In response to the allegations in paragraph 138, Monsanto admits that plaintiff
16 purports to bring claims for strict liability but denies any liability to plaintiff.

17 139. Monsanto denies the allegations in paragraph 139.

18 140. In response to the allegations in paragraph 140, Monsanto lacks information or
19 knowledge sufficient to form a belief as to the truth of the allegations that plaintiff or other
20 persons or entities purchased Roundup®-branded products and therefore denies those allegations.
21 The allegations in paragraph 140 also set forth conclusions of law for which no response is
22 required. Monsanto denies the remaining allegations in paragraph 140.

23 141. The allegations in paragraph 141 set forth conclusions of law for which no response
24 is required.

25 142. Monsanto denies the allegations in paragraph 142. All labeling of Roundup®-
26 branded products has been and remains EPA-approved and in compliance with all federal
27 requirements under FIFRA.

1 143. Monsanto denies the allegations in paragraph 143.

2 144. Monsanto denies the allegations in paragraph 144.

3 145. Monsanto denies the allegations in paragraph 145.

4 146. Monsanto lacks information or knowledge sufficient to form a belief as to the truth
5 of the allegations in paragraph 146 and therefore denies those allegations.

6 147. Monsanto lacks information or knowledge sufficient to form a belief as to the truth
7 of the allegations in paragraph 147 regarding plaintiff's claimed use of and/or exposure to
8 Roundup®-branded products and therefore denies those allegations. Monsanto denies the
9 remaining allegations in paragraph 147, including that Roundup®-branded products have
10 "dangerous characteristics."

11 148. In response to the allegations in paragraph 148, Monsanto denies that Roundup®-
12 branded products are associated with risks of NHL or other serious illness or that Roundup®-
13 branded products have "defects." Monsanto lacks information or knowledge sufficient to form a
14 belief as to the truth of the allegations in the last sentence of paragraph 148 and therefore denies
15 those allegations. Monsanto denies the remaining allegations in paragraph 148.

16 149. Monsanto denies the allegations in paragraph 149.

17 150. Monsanto denies the allegations in paragraph 150.

18 151. Monsanto denies the allegations in paragraph 151.

19 152. Monsanto denies the allegations in paragraph 152.

20 153. Monsanto denies the allegations in paragraph 153.

21 154. Monsanto denies the allegations in paragraph 154.

22 155. Monsanto denies the allegations in paragraph 155.

23 156. Monsanto denies the allegations in paragraph 156.

24 157. Monsanto denies the allegations in paragraph 157.

25 158. Monsanto denies the allegations in paragraph 158.

26 159. Monsanto denies the allegations in paragraph 159.

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1 178. Monsanto denies the allegations in paragraph 178.

2 179. Monsanto denies the allegations in paragraph 179.

3 180. Monsanto incorporates by references its responses to paragraphs 1 through 179 in
4 response to paragraph 180 of plaintiff's Complaint.

5 181. Monsanto denies the allegations in paragraph 181.

6 182. Monsanto lacks information or knowledge sufficient to form a belief as to the truth
7 of the allegations in paragraph 182 regarding decedent's claimed use of and/or exposure to
8 Roundup®-branded products and therefore denies those allegations. The remaining allegations
9 in paragraph 182 set forth conclusions of law for which no response is required.

10 183. Monsanto denies the allegations in paragraph 183. All labeling of Roundup®-
11 branded products has been and remains EPA-approved and in compliance with all federal
12 requirements under FIFRA.

13 184. Monsanto denies the allegations in paragraph 184.

14 185. Monsanto lacks information or knowledge sufficient to form a belief as to the
15 truth of the allegations in paragraph 185 and therefore denies those allegations.

16 186. Monsanto denies the allegations in paragraph 186.

17 187. Monsanto denies the allegations in paragraph 187.

18 188. Monsanto denies the allegations in paragraph 188.

19 189. Monsanto denies the allegations in paragraph 189.

20 190. Monsanto denies the allegations in paragraph 190.

21 191. Monsanto denies the allegations in paragraph 191.

22 192. Monsanto denies the allegations in paragraph 192.

23 193. Monsanto denies the allegations in paragraph 193.

24 194. Monsanto denies the allegations in paragraph 194.

25 195. Monsanto incorporates by references its responses to paragraphs 1 through 194 in
26 response to paragraph 195 of plaintiff's Complaint.

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1 3. Any alleged negligent or culpable conduct of Monsanto, none being admitted, was
2 so insubstantial as to be insufficient to be a proximate or substantial contributing cause of
3 plaintiff's and/or decedent's alleged injuries.

4 4. Plaintiff's claims are barred, in whole or in part, because the products at issue were
5 designed, manufactured, marketed and labeled with proper warnings, information, cautions and
6 instructions, in accordance with the state of the art and the state of scientific and technological
7 knowledge.

8 5. Plaintiff's claims are barred, in whole or in part, because the products at issue were
9 not defective or unreasonably dangerous in that they complied with, at all relevant times, all
10 applicable government safety standards.

11 6. Any claims based on allegations that Monsanto misled, defrauded, made
12 misrepresentations to, or withheld information from U.S. EPA are preempted by federal law. *See,*
13 *e.g., Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341 (2001); *Nathan Kimmel, Inc. v.*
14 *Dowelanco,* 275 F.3d 1199 (9th Cir. 2002).

15 7. Plaintiff's claims are preempted, in whole or in part, by applicable federal law
16 relating to the design, testing, producing, manufacturing, labeling, distributing, modeling,
17 processing, and supply of Roundup®-branded products and/or glyphosate-containing products.

18 8. Plaintiff's claims are preempted, in whole or in part, because of U.S. EPA findings
19 that glyphosate does not cause cancer in humans and/or because of U.S. EPA-approved product
20 labeling.

21 9. Plaintiff's claims are barred, in whole or in part, by the doctrine of primary
22 jurisdiction, including by the authority delegated by Congress to the U.S. EPA.

23 10. Plaintiff's claims are barred, in whole or in part, because plaintiff's and/or
24 decedent's injuries, if any, were the result of conduct of plaintiff, independent third parties, and/or
25 events that were extraordinary under the circumstances, not foreseeable in the normal course of
26 events, and/or independent, intervening and superseding causes of the alleged injuries, including
27 but not limited to plaintiff's and/or decedent's pre-existing medical conditions.

1 DATED: October 31, 2022

Respectfully submitted,

2 SHOOK, HARDY & BACON L.L.P.

3 BY: /s/Jennise W. Stubbs

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Attorneys for Defendant

MONSANTO COMPANY

CERTIFICATE OF SERVICE

I certify that on the 31st day of October, 2022, I electronically transmitted the foregoing **MONSANTO COMPANY’S ANSWER TO PLAINTIFF’S COMPLAINT** to the Clerk of the court using the ECF system for filing and transmittal of a true and correct copy of the foregoing document was served electronically or by another manner as authorized by FED. R. CIV. P. 5.

/s/Jennise W. Stubbs

Jennise W. Stubbs