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 7 **MONSANTO COMPANY**

8 UNITED STATES DISTRICT COURT
 9 NORTHERN DISTRICT OF CALIFORNIA

10 IN RE: ROUNDUP PRODUCTS
 11 LIABILITY LITIGATION

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

12 This document relates to:

13 *Michael Klodzinski v. Monsanto Co.*,
 14 Case No. 3:18-cv-02941-VC

15 **MONSANTO COMPANY’S ANSWER TO PLAINTIFF’S COMPLAINT**

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

23 1. Monsanto admits that plaintiff purports to bring an action for damages allegedly
 24 related to exposure to Roundup®-branded products but denies any liability to plaintiff. Monsanto
 25 denies the remaining allegations in paragraph 1.

26 2. Monsanto denies the allegations in paragraph 2.

27 3. Monsanto denies the allegations in paragraph 3.

1 4. The allegations in paragraph 4 set forth conclusions of law for which no response
2 is required. To the extent that a response is deemed required, Monsanto admits the allegations in
3 paragraph 4 based upon the allegations in plaintiff's Complaint.

4 5. Monsanto admits the allegations in paragraph 5.

5 6. The allegations in paragraph 6 set forth conclusions of law for which no response
6 is required.

7 7. The allegations in the first sentence of paragraph 7 set forth conclusions of law for
8 which no response is required. In response to the second sentence of paragraph 7, Monsanto
9 admits that it sells Roundup®-branded products in New York. In response to the allegations in
10 the final sentence of paragraph 7, Monsanto denies certain events giving rise to plaintiff's claims
11 and Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the
12 allegations regarding where certain other events giving rise to plaintiff's claims occurred and
13 therefore denies those allegations.

14 8. Monsanto lacks information or knowledge sufficient to form a belief as to the
15 truth of the allegations in paragraph 8 and therefore denies those allegations.

16 9. Monsanto denies the allegations in paragraph 9.

17 10. The allegations in paragraph 10 comprise attorney characterizations and are
18 accordingly denied. Monsanto states that the Roundup®-branded products identified by plaintiff
19 have a variety of separate and distinct uses and formulations.

20 11. Monsanto admits the allegations in paragraph 11.

21 12. The allegations in paragraph 12 comprise attorney characterizations and are
22 accordingly denied.

23 13. In response to the allegations in paragraph 13, Monsanto admits that it sells
24 Roundup®-branded products in New York.

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

27 15. The allegations in paragraph 15 are vague and conclusory and comprise attorney
28 characterizations and are accordingly denied.

1 16. The allegations in paragraph 16 are vague and conclusory and comprise attorney
2 characterizations and are accordingly denied.

3 17. Monsanto admits the allegations in paragraph 17.

4 18. Monsanto admits that it is authorized to do business in New York. The remaining
5 allegations in paragraph 18 are vague and conclusory and comprise attorney characterizations
6 and are accordingly denied.

7 19. The allegations in paragraph 19 set forth conclusions of law for which no
8 response is required.

9 20. Monsanto denies the allegations in paragraph 20.

10 21. Monsanto admits that it has designed, researched, manufactured, tested,
11 advertised, promoted, marketed, sold, and distributed Roundup[®]-branded products. The
12 remaining allegations in paragraph 21 set forth conclusions of law for which no response is
13 required.

14 22. Monsanto admits that it is an agricultural biotechnology corporation with a
15 principal place of business in St. Louis County, Missouri. Monsanto admits that it and its
16 affiliated companies have operations and offices in countries around the world. Monsanto states
17 that the remaining allegations in paragraph 22 are vague and that it accordingly lacks information
18 or knowledge sufficient to form a belief as to the truth of the remaining allegations and therefore
19 denies those allegations.

20 23. Monsanto admits the allegations in paragraph 23.

21 24. Monsanto admits the allegations in paragraph 24.

22 25. In response to the allegations in paragraph 25, Monsanto admits that glyphosate is
23 an herbicide that is used to kill invasive plants and weeds. The remaining allegations in
24 paragraph 25 are vague and ambiguous and Monsanto lacks information or knowledge sufficient
25 to form a belief as to the truth of the remaining allegations in paragraph 25 and therefore denies
26 those allegations.

1 26. Monsanto admits that glyphosate’s mode of action is targeting EPSP synthase.
2 The remaining allegations in paragraph 26 comprise attorney characterizations and are
3 accordingly denied.

4 27. Monsanto admits the allegations in paragraph 27.

5 28. Monsanto generally admits the allegations in paragraph 28, but denies the
6 allegations in paragraph 28 to the extent that they suggest that glyphosate is present in any plants
7 at anything other than *de minimis* amounts well within regulatory safety levels, as determined by
8 the United States Environmental Protection Agency (“EPA”).

9 29. Monsanto lacks information or knowledge sufficient to form a belief as to the
10 truth of the allegations in paragraph 29 and therefore denies those allegations.

11 30. Monsanto admits that it is the leading producer of seeds that contain the Roundup
12 Ready[®] trait and that use of crops with the Roundup Ready[®] trait substantially improve a
13 farmer’s ability to control weeds. Monsanto lacks information or knowledge sufficient to form a
14 belief as to the accuracy of the specific numbers and statistics provided in the remaining
15 sentences of paragraph 30 and therefore denies those allegations. Monsanto denies the
16 remaining allegations in paragraph 30.

17 31. Monsanto admits the allegations in paragraph 31.

18 32. Monsanto admits that Roundup[®]-branded products have been used by farmers for
19 approximately 40 years. Monsanto denies that Roundup[®]-branded products have carcinogenic
20 properties and denies the remaining allegations in paragraph 32.

21 33. The allegations in paragraph 33 set forth conclusions of law for which no
22 response is required. To the extent that a response is deemed required, Monsanto admits the
23 allegations in paragraph 33.

24 34. In response to the allegations in paragraph 34, Monsanto admits that EPA requires
25 registrants of herbicides to submit extensive data in support of the human health and
26 environmental safety of their products and further admits that EPA will not register or approve
27 the labeling of herbicides that do not satisfy the requirements set forth in the Federal Insecticide,
28

1 Fungicide, and Rodenticide Act (“FIFRA”). The remaining allegations in paragraph 34 set forth
2 conclusions of law for which no response is required.

3 35. The allegations in paragraph 35 set forth conclusions of law for which no
4 response is required.

5 36. Monsanto admits that Roundup[®]-branded products are registered by EPA for
6 manufacture, sale and distribution and are registered by the State of New York for sale and
7 distribution.

8 37. In response to the allegations in paragraph 37, Monsanto admits that EPA requires
9 registrants of herbicides to submit extensive data in support of the human health and
10 environmental safety of their products and further admits that EPA will not register or approve
11 the labeling of herbicides that do not satisfy the requirements set forth in FIFRA. Monsanto
12 states that the term “the product tests” in the final sentence of paragraph 37 is vague and
13 ambiguous, and Monsanto therefore denies the same. The remaining allegations in paragraph 37
14 set forth conclusions of law for which no answer is required.

15 38. Monsanto denies the allegations in paragraph 38 to the extent that they suggest
16 that EPA only evaluates the safety of pesticide products on the date of their initial registration.
17 Monsanto admits that EPA is in the process of conducting regulatory review of various pesticide
18 products, but Monsanto lacks information or knowledge sufficient to form a belief as to the truth
19 of the allegations in paragraph 38 regarding such pesticide products generally and therefore
20 denies those allegations. The remaining allegations in paragraph 38 set forth conclusions of law
21 for which no response is required.

22 39. In response to the allegations in paragraph 39, Monsanto admits that EPA has
23 undertaken a regulatory review of glyphosate and further admits that EPA has not released its
24 findings. Monsanto states, however, that: (a) in September 2016, EPA’s Office of Pesticide
25 Programs (“OPP”) issued a 227-page evaluation of glyphosate’s carcinogenic potential,
26 concluding that “[t]he strongest support is for [the descriptor] ‘not likely to be carcinogenic to
27
28

1 humans’ at doses relevant to human health risk assessment”¹; and (b) at the same time, EPA
 2 posted an October 2015 final report by its standing Cancer Assessment Review Committee
 3 (“CARC”), in which CARC endorsed EPA’s existing classification of glyphosate as “Not Likely
 4 to be Carcinogenic to Humans.”² Monsanto further states that, in December 2017, EPA’s OPP
 5 issued a detailed, lengthy revised evaluation of glyphosate’s carcinogenic potential that reiterated
 6 the conclusion that “[t]he strongest support is for [the descriptor] ‘not likely to be carcinogenic to
 7 humans’.”³ In addition, other specific findings of safety include:

- 8 • “In June 1991, EPA classified glyphosate as a Group E [carcinogen]—one that
 9 shows evidence of non-carcinogenicity for humans—based on the lack of
 10 convincing evidence of carcinogenicity in adequate studies.” EPA, *Glyphosate:
 Reregistration Eligibility Decision (RED) Facts*, 2 (Sept. 1993),
<http://archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf>.
- 11 • “No evidence of carcinogenicity.” *Glyphosate; Pesticide Tolerances*, 67 Fed.
 12 Reg. 60,934, 60,943 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180).
- 13 • “Glyphosate has no carcinogenic potential.” *Glyphosate; Pesticide Tolerance*, 69
 14 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180).
- 15 • “There is [an] extensive database available on glyphosate, which indicate[s] that
 16 glyphosate is not mutagenic, not a carcinogen, and not a developmental or
 17 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).
- 18 • “EPA has concluded that glyphosate does not pose a cancer risk to humans.”
 19 *Glyphosate; Pesticide Tolerances*, 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to
 20 be codified at 40 C.F.R. pt. 180).
- 21 • “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 EPA’s cancer classification for
 [g]lyphosate.” *Agriculture Biotechnology: A Look at Federal Regulation and*

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

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

28 ³ EPA’s Office of Pesticide Programs, *Revised Glyphosate Issue Paper: Evaluation of*
Carcinogenic Potential at 143, 144 (Dec. 12, 2017), [https://www.regulations.gov/
 document?D=EPA-HQ-OPP-2016-0385-0528](https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0528).

1 *Stakeholder Perspectives: Hearing Before the S. Comm. on Agr., Nutrition, &*
2 *Forestry*, 114th Cong. (2015) (statement of Dr. William Jordan, Deputy Director
3 of EPA’s Office of Pesticide Programs),
4 [http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-](http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-0e55900753b4)
5 [0e55900753b4](http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-0e55900753b4), at time stamp 55:05-56:20 (“EPA 2015 Desk Statement”).

6 Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the
7 remaining allegations in paragraph 39 and therefore denies those allegations.

8 40. In response to the allegations in paragraph 40, Monsanto admits that the New
9 York Attorney General filed a lawsuit against Monsanto in 1996 alleging false and misleading
10 advertising of Roundup[®]-branded products. This lawsuit was subsequently resolved without any
11 admission of wrongdoing by Monsanto. Monsanto states that none of the New York Attorney
12 General’s allegations related in any way to a purported or alleged risk of cancer. To the extent
13 the subparts purport to quote a document, the document speaks for itself and thus does not
14 require any further answer. The remaining allegations in paragraph 40 are vague and conclusory
15 and comprise attorney characterizations and are accordingly denied.

16 41. In response to the allegations in paragraph 41, Monsanto admits it entered into an
17 assurance of discontinuance with the New York Attorney General. The assurance speaks for
18 itself and thus does not require any further answer. The remaining allegations in paragraph 41
19 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

20 42. Monsanto denies the allegations in paragraph 42.

21 43. In response to the allegations in paragraph 43, Monsanto admits that the French
22 court ruled that Monsanto had falsely advertised its herbicide Roundup[®] as “biodegradable” and
23 that it “left the soil clean,” but denies the allegations in paragraph 43 to the extent that they
24 suggest that this ruling was in any way related to plaintiff’s claim here that glyphosate can cause
25 cancer. Monsanto denies the remaining allegations in paragraph 43.

26 44. Monsanto denies the allegations in paragraph 44.

27 45. In response to the allegations in paragraph 45, Monsanto states that the cited
28 document speaks for itself and does not require a response. To the extent that the allegations in
29 paragraph 45 go beyond a restatement of the cited document, Monsanto lacks information or

1 knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 45
2 and therefore denies those allegations.

3 46. Monsanto admits the allegations in paragraph 46.

4 47. In response to the allegations in paragraph 47, Monsanto states that the cited
5 document speaks for itself and does not require a response. To the extent that the allegations in
6 paragraph 47 go beyond a restatement of the cited document, Monsanto lacks information or
7 knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 47
8 and therefore denies those allegations.

9 48. Monsanto states that the term “toxic” as used in paragraph 48 is vague and
10 ambiguous to the extent it is intended to suggest any evidence of carcinogenicity. Monsanto
11 denies the allegations in paragraph 48.

12 49. Monsanto admits the allegations in paragraph 49.

13 50. In response to the allegations in paragraph 50, Monsanto states that the document
14 speaks for itself and does not require a response. To the extent that a response is deemed
15 required, Monsanto denies the allegations in paragraph 50.

16 51. In response to the allegations in paragraph 51, Monsanto admits that Julie Marc
17 published a study entitled “Glyphosate-based pesticides affect cell cycle regulation” in 2004. To
18 the extent that paragraph 51 characterizes the meaning of the cited study, Monsanto denies the
19 remaining allegations in paragraph 51.

20 52. In response to the allegations in paragraph 52, Monsanto states that these
21 documents speak for themselves and do not require a response. To the extent that a response is
22 deemed required, Monsanto denies the allegations in paragraph 52.

23 53. In response to the allegations in paragraph 53, Monsanto states that the cited
24 document speaks for itself and does not require a response. To the extent that paragraph 53
25 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in
26 paragraph 53.

27 54. Monsanto denies the allegations in paragraph 54.

28

1 55. In response to the allegations in paragraph 55, Monsanto states that the cited
2 document speaks for itself and does not require a response. To the extent that paragraph 55
3 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in
4 paragraph 55.

5 56. In response to the allegations in paragraph 56, Monsanto states that the cited
6 document speaks for itself and does not require a response. To the extent that paragraph 56
7 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in
8 paragraph 56.

9 57. Monsanto denies the allegation that the cited studies support the allegation that
10 glyphosate or Roundup[®]-branded products pose any risk to human health and denies the
11 remaining allegations in paragraph 57.

12 58. Monsanto denies the allegations in paragraph 58.

13 59. Monsanto denies the allegations in paragraph 59.

14 60. Monsanto denies the allegations in paragraph 60.

15 61. Monsanto denies the allegations in paragraph 61.

16 62. Monsanto admits that it has in the past promoted, and continues to promote,
17 Roundup[®]-branded herbicides as safe when used in accordance with the products' labeling.
18 Monsanto denies the remaining allegations in paragraph 62.

19 63. Monsanto admits that the International Agency for Research on Cancer ("IARC")
20 is a subgroup of the World Health Organization ("WHO") of the United Nations. Monsanto
21 lacks information or knowledge sufficient to form a belief as to the truth of the remaining
22 allegations in paragraph 63 and therefore denies those allegations.

23 64. Monsanto lacks information or knowledge sufficient to form a belief as to the
24 truth of the allegations in paragraph 64 and therefore denies those allegations. Monsanto denies
25 that glyphosate met the criteria necessary to be eligible for review.

26 65. Monsanto lacks information or knowledge sufficient to form a belief as to the
27 truth of the allegations in paragraph 65 and therefore denies those allegations. Monsanto denies
28 that glyphosate met the criteria necessary to be eligible for review.

1 66. Monsanto admits that in March 2015 IARC classified glyphosate as a class 2A
2 carcinogen. Monsanto specifically denies that IARC’s evaluation of human, animal or genotoxic
3 evidence was “cumulative.” The remaining allegations in paragraph 66 are vague and
4 conclusory and comprise attorney characterizations and are accordingly denied.

5 67. Monsanto admits that the full IARC Monograph regarding glyphosate was
6 published on July 29, 2015 and that the Monograph purported to classify glyphosate as a class
7 2A carcinogen. In response to the remaining allegations in paragraph 67, Monsanto states that
8 the document speaks for itself and does not require a response. To the extent that a response is
9 deemed required, the remaining allegations in paragraph 67 comprise attorney characterizations
10 and are accordingly denied.

11 68. In response to the allegations in paragraph 68, Monsanto states that the document
12 speaks for itself and does not require a response. To the extent that a response is deemed
13 required, the allegations in paragraph 68 comprise attorney characterizations and are accordingly
14 denied.

15 69. In response to the allegations in paragraph 69, Monsanto states that the document
16 speaks for itself and does not require a response. To the extent that a response is deemed
17 required, the allegations in paragraph 69 comprise attorney characterizations and are accordingly
18 denied.

19 70. Monsanto denies the allegations in paragraph 70.

20 71. The allegations in paragraph 71 comprise attorney characterizations and are
21 accordingly denied.

22 72. Monsanto admits the allegations in paragraph 72.

23 73. In response to the allegations in paragraph 73, Monsanto states that the cited
24 document speaks for itself and does not require a response. To the extent that paragraph 73
25 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in
26 paragraph 73.

27 74. In response to the allegations in paragraph 74, Monsanto admits that certain
28 studies have reported that glyphosate and glyphosate-based formulations induced oxidative stress

1 under artificial experimental conditions. Monsanto denies that these studies provide any reliable
2 evidence that glyphosate or glyphosate-based formulations induce oxidative stress in humans or
3 animals under real-world exposure conditions. Monsanto denies the remaining allegations in
4 paragraph 74.

5 75. The allegations in paragraph 75 are vague and ambiguous and are accordingly
6 denied.

7 76. In response to the allegations in paragraph 76, Monsanto states that the cited
8 document speaks for itself and does not require a response.

9 77. In response to the allegations in paragraph 77, Monsanto states that the cited
10 document speaks for itself and does not require a response. To the extent that paragraph 77
11 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in
12 paragraph 77.

13 78. Monsanto denies the allegations in paragraph 78.

14 79. In response to the allegations in paragraph 79, Monsanto states that the cited
15 document speaks for itself and does not require a response. Monsanto otherwise denies the
16 allegations in paragraph 79.

17 80. Monsanto admits that there is no reliable evidence that Roundup[®]-branded
18 products are genotoxic, and that regulatory authorities and independent experts agree that
19 Roundup[®]-branded products are not genotoxic. Monsanto otherwise denies the allegations in
20 paragraph 80.

21 81. Monsanto denies the allegations in paragraph 81.

22 82. Monsanto denies the allegations in paragraph 82.

23 83. Monsanto denies the allegations in paragraph 83.

24 84. Monsanto admits that in 1985 EPA reviewed a regulatory study involving mice
25 exposed to glyphosate. Monsanto denies the remaining allegations in paragraph 84.

26 85. Monsanto denies the allegations in paragraph 85.

27 86. Monsanto denies the allegations in paragraph 86.

28 87. Monsanto admits the allegations in paragraph 87.

1 88. Monsanto denies the allegations in paragraph 88.

2 89. Monsanto admits the allegations in paragraph 89.

3 90. Monsanto denies the allegations in paragraph 90.

4 91. Monsanto denies the allegations in paragraph 91.

5 92. Monsanto denies the allegations in paragraph 92.

6 93. Monsanto denies the allegations in paragraph 93.

7 94. Monsanto denies the allegations in paragraph 94.

8 95. Monsanto denies the allegations in paragraph 95.

9 96. Monsanto denies the allegations in paragraph 96.

10 97. In response to the allegations in paragraph 97, Monsanto admits that independent
11 experts and regulatory agencies agree that there is no evidence of carcinogenicity or genotoxicity
12 in glyphosate and Roundup[®]-branded products and admits that it has made statements reflecting
13 this fact. Monsanto denies the remaining allegations in paragraph 97.

14 98. In response to the allegations in paragraph 98, Monsanto admits that Roundup[®]-
15 branded products are safe, non-carcinogenic and non-genotoxic when used in accordance with
16 the product's EPA approved labeling. Monsanto otherwise denies the allegations in paragraph
17 98.

18 99. In response to the allegations in paragraph 99, Monsanto admits that it has stated
19 and continues to state that Roundup[®]-branded products are safe when used as labeled and that
20 they are non-carcinogenic and non-genotoxic.

21 100. In response to the allegations in paragraph 100, Monsanto admits that a 1986 joint
22 report of the World Health Organization and Food and Agriculture Organization of the United
23 Nations is cited in support of the safety of glyphosate and Roundup[®]-branded products.
24 Monsanto denies that this report is the "primary" cite in support of the safety of glyphosate and
25 Roundup[®]-branded products, and denies that WHO considers glyphosate to be a probable
26 carcinogen. Monsanto denies the remaining allegations in paragraph 100.

27 101. Monsanto denies the allegations in paragraph 101.

28 102. Monsanto denies the allegations in paragraph 102.

1 103. Monsanto denies the allegations in paragraph 103.

2 104. Monsanto denies the allegations in paragraph 104.

3 105. Monsanto denies the allegations in paragraph 105.

4 106. Monsanto denies the allegations in paragraph 106.

5 107. Monsanto denies the allegations in paragraph 107.

6 108. Monsanto denies the allegations in paragraph 108.

7 109. Monsanto denies the allegations in paragraph 109.

8 110. Monsanto denies the allegations in paragraph 110.

9 111. Monsanto denies the allegations in paragraph 111.

10 112. Monsanto incorporates by reference its responses to paragraphs 1 through 111 in
11 response to paragraph 112 of plaintiff's Complaint.

12 113. Monsanto lacks information or knowledge sufficient to form a belief as to the
13 truth of the allegations in paragraph 113 and therefore denies those allegations.

14 114. Monsanto lacks information or knowledge sufficient to form a belief as to the
15 truth of the allegations paragraph 114 and therefore denies those allegations.

16 115. Monsanto denies the allegations in paragraph 115.

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

19 117. In response to the allegations in paragraph 117, Monsanto denies that it has
20 concealed the alleged "true risks associated with Roundup and glyphosate." The remaining
21 allegations in paragraph 117 set forth conclusions of law for which no response is required.

22 118. In response to the allegations in paragraph 118, Monsanto admits that it has stated
23 and continues to state that Roundup[®]-branded products are safe when used as labeled and that
24 they are non-toxic and non-carcinogenic.

25 119. In response to the allegations in paragraph 119, Monsanto states that the cited
26 document speaks for itself and does not require a response.

27 120. Monsanto denies that exposure to Roundup[®]-branded products and glyphosate
28 exposed plaintiff to risk of his alleged cancer and denies the remaining allegations in paragraph

1 120. Monsanto states, however, that the scientific studies upon which IARC purported to base
2 its classification were all publicly available before March 2015.

3 121. Monsanto denies that it concealed “the true character, quality and nature of
4 Roundup.” The remaining allegations of paragraph 121 set forth conclusions of law for which
5 no response is required. To the extent that a response is deemed required, Monsanto denies all of
6 plaintiff’s allegations in paragraph 121. Monsanto states, however, that the scientific studies
7 upon which IARC purported to base its classification were all publicly available before March
8 2015.

9 122. Monsanto denies that it engaged in the “wrongdoing” alleged in the Complaint
10 and denies that there is any reliable scientific evidence that exposure to glyphosate or Roundup[®] -
11 branded products can cause cancer. Monsanto states, however, that the scientific studies upon
12 which IARC purported to base its classification were all publicly available before March 2015.
13 The remaining allegations in paragraph 122 set forth conclusions of law for which no response is
14 required, consist of attorney characterizations and are accordingly denied, or comprise
15 allegations for which Monsanto lacks information or knowledge sufficient to form a belief as to
16 the truth of the allegations asserted and therefore denies those allegations.

17 123. Monsanto incorporates by reference its responses to paragraphs 1 through 122 in
18 response to paragraph 123 of plaintiff’s Complaint.

19 124. The allegations in paragraph 124 set forth conclusions of law for which no
20 response is required.

21 125. Monsanto denies the allegations in paragraph 125.

22 126. Monsanto denies the allegations in paragraph 126, including each of its subparts.

23 127. Monsanto denies the allegations in paragraph 127.

24 128. Monsanto denies the allegations in paragraph 128.

25 129. Monsanto denies the allegations in paragraph 129, including each of its subparts.

26 130. Monsanto denies the allegations in paragraph 130.

27 131. Monsanto denies the allegations in paragraph 131.

28 132. Monsanto denies the allegations in paragraph 132.

1 133. Monsanto denies the allegations in paragraph 133.

2 134. In response to paragraph 134, Monsanto demands that judgment be entered in its
3 favor and against plaintiff; that plaintiff's Complaint be dismissed, with prejudice; and that
4 Monsanto be awarded costs of suit and reasonable attorney's fees as allowed by law and such
5 further and additional relief as this Court may deem just and proper.

6 135. Monsanto incorporates by reference its responses to paragraphs 1 through 134 in
7 response to paragraph 135 of plaintiff's Complaint.

8 136. In response to the allegations in paragraph 136, Monsanto lacks information or
9 knowledge sufficient to form a belief as to the truth of the allegations that plaintiff used or was
10 exposed to Roundup[®]-branded products and therefore denies those allegations. Monsanto denies
11 the remaining allegations in paragraph 136.

12 137. Monsanto lacks information or knowledge sufficient to form a belief as to the
13 truth of the allegations in paragraph 137 and therefore denies those allegations.

14 138. Monsanto denies the allegations in paragraph 138.

15 139. Monsanto denies the allegations in paragraph 139.

16 140. Monsanto denies the allegations in paragraph 140.

17 141. Monsanto denies the allegations in paragraph 141, including each of its subparts.

18 142. Monsanto denies the allegations in paragraph 142.

19 143. Monsanto denies that Roundup[®]-branded products have "dangerous
20 characteristics." Monsanto lacks information or knowledge sufficient to form a belief as to the
21 truth of the remaining allegations in paragraph 143 and therefore denies those allegations.

22 144. Monsanto lacks information or knowledge sufficient to form a belief as to the
23 truth of the allegations in paragraph 144 and therefore denies those allegations.

24 145. Monsanto denies the allegations in paragraph 145.

25 146. The allegations in paragraph 146 set forth conclusions of law for which no
26 response is required.

27 147. Monsanto denies the allegations in paragraph 147.

28 148. Monsanto denies the allegations in paragraph 148.

1 149. Monsanto denies the allegations in paragraph 149.

2 150. Monsanto denies the allegations in paragraph 150.

3 151. Monsanto denies the allegations in paragraph 151.

4 152. Monsanto denies the allegations in paragraph 152.

5 153. Monsanto denies the allegations in paragraph 153.

6 154. Monsanto denies the allegations in paragraph 154.

7 155. Monsanto denies the allegations in paragraph 155.

8 156. Monsanto denies the allegations in paragraph 156.

9 157. In response to paragraph 157, Monsanto demands that judgment be entered in its
10 favor and against plaintiff; that plaintiff's Complaint be dismissed, with prejudice; and that
11 Monsanto be awarded costs of suit and reasonable attorney's fees as allowed by law and such
12 further and additional relief as this Court may deem just and proper.

13 158. Monsanto incorporates by reference its responses to paragraphs 1 through 157 in
14 response to paragraph 158 of plaintiff's Complaint.

15 159. The allegations in paragraph 159 set forth conclusions of law for which no
16 response is required.

17 160. Monsanto lacks information or knowledge sufficient to form a belief as to the
18 truth of the allegations in paragraph 160 and therefore denies those allegations.

19 161. Monsanto denies the allegations in paragraph 161. All labeling of Roundup[®]-
20 branded products has been and remains EPA-approved and in compliance with all federal
21 requirements under FIFRA.

22 162. Monsanto denies the allegations in paragraph 162.

23 163. Monsanto denies the allegations in paragraph 163. All labeling of Roundup[®]-
24 branded products has been and remains EPA-approved and in compliance with all federal
25 requirements under FIFRA.

26 164. Monsanto denies the allegations in paragraph 164. All labeling of Roundup[®]-
27 branded products has been and remains EPA-approved and in compliance with all federal
28 requirements under FIFRA.

1 165. Monsanto denies the allegations in paragraph 165.

2 166. Monsanto lacks information or knowledge sufficient to form a belief as to the
3 truth of the allegations regarding plaintiff's use history in paragraph 166 and therefore denies
4 those allegations. Monsanto denies the remaining allegations in paragraph 166.

5 167. The allegations in paragraph 167 set forth conclusions of law for which no
6 response is required.

7 168. Monsanto denies the allegations in paragraph 168.

8 169. Monsanto denies the allegations in paragraph 169.

9 170. Monsanto denies the allegations in paragraph 170.

10 171. Monsanto denies the allegations that Roundup[®]-branded products are defective
11 and accordingly denies the allegations in paragraph 171.

12 172. The allegations in paragraph 172 set forth conclusions of law for which no
13 response is required.

14 173. Monsanto lacks information or knowledge sufficient to form a belief as to the
15 truth of the allegations in paragraph 173 and therefore denies those allegations.

16 174. Monsanto denies the allegations in paragraph 174.

17 175. Monsanto denies the allegations in paragraph 175.

18 176. Monsanto denies the allegations in paragraph 176.

19 177. Monsanto denies the allegations in paragraph 177.

20 178. Monsanto denies the allegations in paragraph 178.

21 179. In response to paragraph 179, Monsanto demands that judgment be entered in its
22 favor and against plaintiff; that plaintiff's Complaint be dismissed, with prejudice; and that
23 Monsanto be awarded costs of suit and reasonable attorney's fees as allowed by law and such
24 further and additional relief as this Court may deem just and proper.

25 180. Monsanto incorporates by reference its responses to paragraphs 1 through 179 in
26 response to paragraph 180 of plaintiff's Complaint.

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1 181. Monsanto denies the allegations in paragraph 181. Additionally, the allegations
2 in the last sentence in paragraph 181 set forth conclusions of law for which no response is
3 required.

4 182. Monsanto lacks information or knowledge sufficient to form a belief as to the
5 truth of the allegations in paragraph 182 concerning the plaintiff's claimed use of Roundup[®]-
6 branded products and therefore denies those allegations. The remaining allegations in paragraph
7 182 set forth conclusions of law for which no response is required.

8 183. The allegations in paragraph 183 set forth conclusions of law for which no
9 response is required.

10 184. Monsanto denies the allegations in paragraph 184.

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

13 186. Monsanto lacks information or knowledge sufficient to form a belief as to the
14 truth of the allegations in paragraph 186 concerning the condition of any Roundup[®]-branded
15 product allegedly used by plaintiff or about plaintiff's alleged uses of such product and therefore
16 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. In response to the allegations in paragraph 190, Monsanto demands that judgment
21 be entered in its favor and against plaintiff; that plaintiff's Complaint be dismissed, with
22 prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's fees as allowed
23 by law and such further and additional relief as this Court may deem just and proper.

24 191. In response to the allegations in paragraph 191, Monsanto denies that plaintiff has
25 alleged fraud, let alone fraud with specificity. Monsanto incorporates by reference its responses
26 to paragraphs 1 through 190 in response to paragraph 191 of plaintiff's Complaint.
27
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1 192. Monsanto admits that plaintiff purports to bring a cause of action pursuant to
2 N.Y. Gen. Bus. Law §§ 349 & 350; N.Y. Exec. Law § 63(12); California Business and
3 Professions Code § 17500; and California Civil Code § 1750 et seq., but denies any liability as to
4 that claim.

5 193. Monsanto denies the allegations in paragraph 193.

6 194. Monsanto denies the allegations in paragraph 194.

7 195. Monsanto denies the allegations in paragraph 195.

8 196. Monsanto denies the allegations in paragraph 196.

9 197. Monsanto denies the allegations in paragraph 197.

10 198. Monsanto denies the allegations in paragraph 198.

11 199. Monsanto denies the allegations in paragraph 199.

12 200. Monsanto lacks information or knowledge sufficient to form a belief as to the
13 truth of the allegations in paragraph 200 regarding plaintiff's actions, and therefore Monsanto
14 denies those allegations. Monsanto denies the remaining allegations in paragraph 200.

15 201. Monsanto denies the allegations in paragraph 201.

16 202. Monsanto denies the allegations in paragraph 202. All labeling of Roundup[®]-
17 branded products has been and remains EPA-approved and in compliance with all federal
18 requirements under FIFRA.

19 203. Monsanto denies the allegations in paragraph 203.

20 204. In response to paragraph 204, Monsanto demands that judgment be entered in its
21 favor and against plaintiff; that plaintiff's Complaint be dismissed, with prejudice; and that
22 Monsanto be awarded costs of suit and reasonable attorney's fees as allowed by law and such
23 further and additional relief as this Court may deem just and proper.

24 In response to the allegations in the section entitled "PRAYER FOR RELIEF," Monsanto
25 denies that plaintiff is entitled to the relief sought therein, including any judgment for any
26 damages, interest, costs, or any other relief whatsoever.

27 Every allegation in the Complaint that is not specifically and expressly admitted in this
28 Answer is hereby specifically and expressly denied.

SEPARATE AND AFFIRMATIVE DEFENSES

1
2 1. The Complaint, in whole or part, fails to state a claim or cause of action against
3 Monsanto upon which relief can be granted.

4 2. Venue in the Western District of New York may be inconvenient.

5 3. Plaintiff's claims are barred because plaintiff cannot proffer any scientifically
6 reliable evidence that the products at issue were defective or unreasonably dangerous.

7 4. Any alleged negligent or culpable conduct of Monsanto, none being admitted,
8 was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of
9 plaintiff's alleged injuries.

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

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

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

21 8. Plaintiff's claims are preempted, in whole or in part, by applicable federal law
22 relating to the design, testing, producing, manufacturing, labeling, distributing, modeling,
23 processing, and supply of Roundup[®]-branded products and/or glyphosate-containing products.

24 9. Plaintiff's claims are preempted, in whole or in part, because of U.S. EPA
25 findings that glyphosate does not cause cancer in humans and/or because of U.S. EPA-approved
26 product labeling.

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

1 11. Plaintiff's claims are barred, in whole or in part, because plaintiff's injuries, if
2 any, were the result of conduct of plaintiff, independent third parties, and/or events that were
3 extraordinary under the circumstances, not foreseeable in the normal course of events, and/or
4 independent, intervening and superseding causes of the alleged injuries, including but not limited
5 to plaintiff's pre-existing medical conditions.

6 12. The doctrines contained in Restatement (Second) of Torts § 402A, comments j
7 and k, bar plaintiff's claims against Monsanto in whole or in part.

8 13. Applicable statutes of limitations and/or repose bar plaintiff's claims in whole or
9 in part.

10 14. Plaintiff's misuse or abnormal use of the product or failure to follow instructions
11 bar plaintiff's claims in whole or in part.

12 15. If plaintiff suffered injury or damages as alleged, which is denied, such injury or
13 damage resulted from: (a) acts or omissions of persons or entities for which Monsanto is neither
14 liable nor responsible or, in the alternative, Monsanto is entitled to an assessment of the relative
15 degree of fault of all such persons and entities; or (b) resulted from diseases and/or causes that
16 are not related or connected with any product sold, distributed, or manufactured by Monsanto.
17 Such acts or omissions on the part of others or diseases or causes constitute an independent,
18 intervening and sole proximate cause of plaintiff's alleged injury or damages.

19 16. Monsanto had no legal relationship or privity with plaintiff and owed no duty to
20 plaintiff by which liability could be attributed to it.

21 17. Monsanto made no warranties of any kind or any representations of any nature
22 whatsoever to plaintiff. If any such warranties were made, which Monsanto specifically denies,
23 then plaintiff failed to give notice of any breach thereof.

24 18. Plaintiff's claims are preempted in whole or part by the Freedom of Speech
25 Clause of the First Amendment of the U.S. Constitution.

26 19. Plaintiff's claims for punitive and/or exemplary damages are barred because such
27 an award would violate Monsanto's due process, equal protection and other rights under the
28

1 United States Constitution, the California Constitution, the New York Constitution, and/or other
2 applicable state constitutions.

3 20. Plaintiff's claims for punitive and/or exemplary damages are barred because
4 plaintiff has failed to allege conduct warranting imposition of punitive damages under California
5 law, New York law, and/or other applicable state laws.

6 21. Plaintiff's claims for punitive and/or exemplary damages are barred and/or limited
7 by operation of state and/or federal law.

8 22. Monsanto's conduct and/or acts were not willful, wanton, malicious, reckless,
9 fraudulent or done with a conscious disregard for the rights of plaintiff and/or the safety of the
10 public. Nor do any of Monsanto's conduct and/or acts demonstrate that Monsanto acted with a
11 high degree of moral culpability. In fact, Monsanto exercised reasonable care at all times alleged
12 in the Complaint, and plaintiff has failed to clearly establish any entitlement to punitive damages
13 based on his allegations.

14 23. Plaintiff's claims are barred in whole or in part by plaintiff's own
15 contributory/comparative negligence.

16 24. Plaintiff's claims are barred in whole or in part by plaintiff's own failure to
17 mitigate damages.

18 25. Plaintiff's claims are barred in whole or in part by the sophisticated user doctrine.

19 26. Plaintiff has failed to allege fraud with sufficient particularity.

20 27. If plaintiff has been injured or damaged, no injury or damages being admitted,
21 such injuries were not caused by a Monsanto product.

22 28. Plaintiff's claims are barred to the extent that plaintiff seeks relief under the laws
23 of states that do not govern plaintiff's claims.

24 29. Plaintiff's claims are barred or limited to the extent that plaintiff asserts claims
25 that are governed by the laws of a state that does not recognize or limit such claims.

26 30. To the extent that plaintiff recovered payments for his alleged injuries from any
27 collateral source(s) or other source(s), plaintiff's recovery in this lawsuit, if any, shall be reduced
28 to the extent allowed by applicable law, including as allowed for under NY CPLR § 4545.

