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 7 **MONSANTO COMPANY**

8 UNITED STATES DISTRICT COURT
 9 NORTHERN DISTRICT OF CALIFORNIA

10 IN RE: ROUNDUP PRODUCTS
 LIABILITY LITIGATION

MDL No. 2741

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

11
 12 This document relates to:

13 *Marilyn Upshaw and James Upshaw v.*
Monsanto Co.,
 14 Case No. 3:18-cv-01805-VC

15 **MONSANTO COMPANY’S ANSWER TO PLAINTIFFS’ 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 plaintiffs Marilyn Upshaw and James Upshaw’s Complaint and Jury
 19 Demand (“the Complaint”), except as set forth below. As defined in the Complaint and as used
 20 in this Answer, Monsanto refers to Monsanto Company, a United States based company
 21 incorporated in Delaware, and not to other Monsanto-affiliated companies. Although many
 22 paragraphs in the Complaint allege exposure or use of Monsanto products by “Plaintiffs,”
 23 Monsanto nevertheless responds to the allegations in those paragraphs as if they refer to plaintiff
 24 Marilyn Upshaw. Silence as to any allegations shall constitute a denial.

25 1. Monsanto admits that plaintiffs purport to bring an action for damages allegedly
 26 related to exposure to Roundup[®]-branded products but denies any liability to plaintiffs.

27 Monsanto denies the remaining allegations in paragraph 1.

28 2. Monsanto denies the allegations in paragraph 2.

1 3. Monsanto denies the allegations in paragraph 3.

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

5 5. Monsanto admits the allegations in paragraph 5.

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

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

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

18 9. The allegations in paragraph 9 comprise attorney characterizations and are
19 accordingly denied. Monsanto states that the Roundup®-branded products identified by plaintiffs
20 have a variety of separate and distinct uses and formulations.

21 10. Monsanto admits the allegations in paragraph 10.

22 11. The allegations in paragraph 11 comprise attorney characterizations and are
23 accordingly denied.

24 12. In response to the allegations in paragraph 12, Monsanto admits that it sells
25 Roundup®-branded products in Missouri.

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

28

1 14. The allegations in paragraph 14 are vague and conclusory and comprise attorney
2 characterizations and are accordingly denied.

3 15. The allegations in paragraph 15 are vague and conclusory and comprise attorney
4 characterizations and are accordingly denied.

5 16. Monsanto admits the allegations in paragraph 16.

6 17. Monsanto admits that it is authorized to do business in Missouri. The remaining
7 allegations in paragraph 17 are vague and conclusory and comprise attorney characterizations
8 and are accordingly denied.

9 18. The allegations in paragraph 18 set forth conclusions of law for which no
10 response is required.

11 19. Monsanto denies the allegations in paragraph 19.

12 20. Monsanto admits that it has designed, researched, manufactured, tested,
13 advertised, promoted, marketed, sold, and distributed Roundup[®]-branded products. The
14 remaining allegations in paragraph 20 set forth conclusions of law for which no response is
15 required.

16 21. Monsanto admits that it is an agricultural biotechnology corporation with a
17 principal place of business in St. Louis County, Missouri. Monsanto admits that it and its
18 affiliated companies have operations and offices in countries around the world. Monsanto states
19 that the remaining allegations in paragraph 21 are vague and that it accordingly lacks information
20 or knowledge sufficient to form a belief as to the truth of the remaining allegations and therefore
21 denies those allegations.

22 22. Monsanto admits the allegations in paragraph 22.

23 23. Monsanto admits the allegations in paragraph 23.

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

1 25. Monsanto admits that glyphosate’s mode of action is targeting EPSP synthase.
2 The remaining allegations in paragraph 25 comprise attorney characterizations and are
3 accordingly denied.

4 26. Monsanto admits the allegations in paragraph 26.

5 27. Monsanto generally admits the allegations in paragraph 27, but denies the
6 allegations in paragraph 27 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 28. Monsanto lacks information or knowledge sufficient to form a belief as to the
10 truth of the allegations in paragraph 28 and therefore denies those allegations.

11 29. 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 29 and therefore denies those allegations. Monsanto denies the
16 remaining allegations in paragraph 29.

17 30. Monsanto admits the allegations in the first two sentences of paragraph 30. In
18 response to the allegations in the third sentence of paragraph 30, Monsanto admits that
19 Roundup[®]-branded products have been used by farmers for approximately 40 years. Monsanto
20 denies that Roundup[®]-branded products have carcinogenic properties and denies the remaining
21 allegations in paragraph 30.

22 31. The allegations in paragraph 31 set forth conclusions of law for which no
23 response is required. To the extent that a response is deemed required, Monsanto admits the
24 allegations in paragraph 31.

25 32. In response to the allegations in paragraph 32, Monsanto admits that EPA requires
26 registrants of herbicides to submit extensive data in support of the human health and
27 environmental safety of their products and further admits that EPA will not register or approve
28 the labeling of herbicides that do not satisfy the requirements set forth in the Federal Insecticide,

1 Fungicide, and Rodenticide Act (“FIFRA”). The remaining allegations in paragraph 32 set forth
2 conclusions of law for which no response is required.

3 33. The allegations in paragraph 33 set forth conclusions of law for which no
4 response is required.

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

8 35. In response to the allegations in paragraph 35, 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 35 is vague and
13 ambiguous, and Monsanto therefore denies the same. The remaining allegations in paragraph 35
14 set forth conclusions of law for which no answer is required.

15 36. Monsanto denies the allegations in paragraph 36 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 36 regarding such pesticide products generally and therefore
20 denies those allegations. The remaining allegations in paragraph 36 set forth conclusions of law
21 for which no response is required.

22 37. In response to the allegations in paragraph 37, 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 Monsanto lacks information or knowledge sufficient to form a belief as to the truth
8 of the remaining allegations in paragraph 37 and therefore denies those allegations.

9 38. In response to the allegations in paragraph 38, Monsanto admits that the New
10 York Attorney General filed a lawsuit against Monsanto in 1996 alleging false and misleading
11 advertising of Roundup[®]-branded products. This lawsuit was subsequently resolved without any
12 admission of wrongdoing by Monsanto. Monsanto states that none of the New York Attorney
13 General's allegations related in any way to a purported or alleged risk of cancer. To the extent
14 the subparts purport to quote a document, the document speaks for itself and thus does not
15 require any further answer. The remaining allegations in paragraph 38 are vague and conclusory
16 and comprise attorney characterizations and are accordingly denied.

17 39. In response to the allegations in paragraph 39, Monsanto admits it entered into an
18 assurance of discontinuance with the New York Attorney General. The assurance speaks for
19 itself and thus does not require any further answer. The remaining allegations in paragraph 39
20 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

21 _____
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/
24 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
25 anticipation of an EPA Scientific Advisory Panel meeting on glyphosate's carcinogenic
26 potential.

27 ² Cancer Assessment Review Committee, Health Effects Division, Office of Pesticide Programs,
28 U.S. 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"), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0014>.

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 40. Monsanto denies the allegations in paragraph 40.

2 41. In response to the allegations in paragraph 41, Monsanto admits that the French
3 court ruled that Monsanto had falsely advertised its herbicide Roundup[®] as “biodegradable” and
4 that it “left the soil clean,” but denies the allegations in paragraph 41 to the extent that they
5 suggest that this ruling was in any way related to plaintiffs’ claim here that glyphosate can cause
6 cancer. Monsanto denies the remaining allegations in paragraph 41.

7 42. Monsanto denies the allegations in paragraph 42.

8 43. In response to the allegations in paragraph 43, Monsanto states that the cited
9 document speaks for itself and does not require a response. To the extent that the allegations in
10 paragraph 43 go beyond a restatement of the cited document, Monsanto lacks information or
11 knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 43
12 and therefore denies those allegations.

13 44. Monsanto admits the allegations in paragraph 44.

14 45. In response to the allegations in paragraph 45, Monsanto states that the cited
15 document speaks for itself and does not require a response. To the extent that the allegations in
16 paragraph 45 go beyond a restatement of the cited document, Monsanto lacks information or
17 knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 45
18 and therefore denies those allegations.

19 46. Monsanto states that the term “toxic” as used in paragraph 46 is vague and
20 ambiguous to the extent it is intended to suggest any evidence of carcinogenicity. Monsanto
21 denies the allegations in paragraph 46.

22 47. Monsanto admits the allegations in paragraph 47.

23 48. In response to the allegations in paragraph 48, Monsanto states that the document
24 speaks for itself and does not require a response. To the extent that a response is deemed
25 required, Monsanto denies the allegations in paragraph 48.

26 49. In response to the allegations in paragraph 49, Monsanto admits that Julie Marc
27 published a study entitled “Glyphosate-based pesticides affect cell cycle regulation” in 2004. To
28

1 the extent that paragraph 49 characterizes the meaning of the cited study, Monsanto denies the
2 remaining allegations in paragraph 49.

3 50. In response to the allegations in paragraph 50, Monsanto states that these
4 documents speak for themselves and do not require a response. To the extent that a response is
5 deemed required, Monsanto denies the allegations in paragraph 50.

6 51. In response to the allegations in paragraph 51, Monsanto states that the cited
7 document speaks for itself and does not require a response. To the extent that paragraph 51
8 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in
9 paragraph 51.

10 52. Monsanto denies the allegations in paragraph 52.

11 53. In response to the allegations in paragraph 53, Monsanto states that the cited
12 document speaks for itself and does not require a response. To the extent that paragraph 53
13 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in
14 paragraph 53.

15 54. In response to the allegations in paragraph 54, Monsanto states that the cited
16 document speaks for itself and does not require a response. To the extent that paragraph 54
17 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in
18 paragraph 54.

19 55. Monsanto denies the allegation that the cited studies support the allegation that
20 glyphosate or Roundup[®]-branded products pose any risk to human health and denies the
21 remaining allegations in paragraph 55.

22 56. Monsanto denies the allegations in paragraph 56.

23 57. Monsanto denies the allegations in paragraph 57.

24 58. Monsanto denies the allegations in paragraph 58.

25 59. Monsanto denies the allegations in paragraph 59.

26 60. Monsanto admits that it has in the past promoted, and continues to promote,
27 Roundup[®]-branded herbicides as safe when used in accordance with the products' labeling.
28 Monsanto denies the remaining allegations in paragraph 60.

1 61. Monsanto admits that the International Agency for Research on Cancer (“IARC”)
2 is a subgroup of the World Health Organization (“WHO”) of the United Nations. Monsanto
3 lacks information or knowledge sufficient to form a belief as to the truth of the remaining
4 allegations in paragraph 61 and therefore denies those allegations.

5 62. Monsanto lacks information or knowledge sufficient to form a belief as to the
6 truth of the allegations in paragraph 62 and therefore denies those allegations. Monsanto denies
7 that glyphosate met the criteria necessary to be eligible for review.

8 63. Monsanto lacks information or knowledge sufficient to form a belief as to the
9 truth of the allegations in paragraph 63 and therefore denies those allegations. Monsanto denies
10 that glyphosate met the criteria necessary to be eligible for review.

11 64. Monsanto admits that in March 2015 IARC classified glyphosate as a class 2A
12 carcinogen. Monsanto specifically denies that IARC’s evaluation of human, animal or genotoxic
13 evidence was “cumulative.” The remaining allegations in paragraph 64 are vague and
14 conclusory and comprise attorney characterizations and are accordingly denied.

15 65. Monsanto admits that the full IARC Monograph regarding glyphosate was
16 published on July 29, 2015 and that the Monograph purported to classify glyphosate as a class
17 2A carcinogen. In response to the remaining allegations in paragraph 65, Monsanto states that
18 the document speaks for itself and does not require a response. To the extent that a response is
19 deemed required, the remaining allegations in paragraph 65 comprise attorney characterizations
20 and are accordingly denied.

21 66. In response to the allegations in paragraph 66, Monsanto states that the document
22 speaks for itself and does not require a response. To the extent that a response is deemed
23 required, the allegations in paragraph 66 comprise attorney characterizations and are accordingly
24 denied.

25 67. In response to the allegations in paragraph 67, Monsanto states that the document
26 speaks for itself and does not require a response. To the extent that a response is deemed
27 required, the allegations in paragraph 67 comprise attorney characterizations and are accordingly
28 denied.

1 68. Monsanto denies the allegations in paragraph 68.

2 69. The allegations in paragraph 69 comprise attorney characterizations and are
3 accordingly denied.

4 70. Monsanto admits the allegations in paragraph 70.

5 71. In response to the allegations in paragraph 71, Monsanto states that the cited
6 document speaks for itself and does not require a response. To the extent that paragraph 71
7 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in
8 paragraph 71.

9 72. In response to the allegations in paragraph 72, Monsanto admits that certain
10 studies have reported that glyphosate and glyphosate-based formulations induced oxidative stress
11 under artificial experimental conditions. Monsanto denies that these studies provide any reliable
12 evidence that glyphosate or glyphosate-based formulations induce oxidative stress in humans or
13 animals under real-world exposure conditions. Monsanto denies the remaining allegations in
14 paragraph 72.

15 73. The allegations in paragraph 73 are vague and ambiguous and are accordingly
16 denied.

17 74. In response to the allegations in paragraph 74, Monsanto states that the cited
18 document speaks for itself and does not require a response.

19 75. In response to the allegations in paragraph 75, Monsanto states that the cited
20 document speaks for itself and does not require a response. To the extent that paragraph 75
21 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in
22 paragraph 75.

23 76. Monsanto denies the allegations in paragraph 76.

24 77. In response to the allegations in paragraph 77, Monsanto states that the cited
25 document speaks for itself and does not require a response. Monsanto otherwise denies the
26 allegations in paragraph 77.

27 78. Monsanto admits that there is no reliable evidence that Roundup[®]-branded
28 products are genotoxic and that regulatory authorities and independent experts agree that

1 Roundup[®]-branded products are not genotoxic. Monsanto otherwise denies the allegations in
2 paragraph 78.

3 79. Monsanto denies the allegations in paragraph 79.

4 80. Monsanto denies the allegations in paragraph 80.

5 81. Monsanto denies the allegations in paragraph 81.

6 82. Monsanto admits that in 1985 EPA reviewed a regulatory study involving mice
7 exposed to glyphosate. Monsanto denies the remaining allegations in paragraph 82.

8 83. Monsanto denies the allegations in paragraph 83.

9 84. Monsanto denies the allegations in paragraph 84.

10 85. Monsanto admits the allegations in paragraph 85.

11 86. Monsanto denies the allegations in paragraph 86.

12 87. Monsanto admits the allegations in paragraph 87.

13 88. Monsanto denies the allegations in paragraph 88.

14 89. Monsanto denies the allegations in paragraph 89.

15 90. Monsanto denies the allegations in paragraph 90.

16 91. Monsanto denies the allegations in paragraph 91.

17 92. Monsanto denies the allegations in paragraph 92.

18 93. Monsanto denies the allegations in paragraph 93.

19 94. Monsanto denies the allegations in paragraph 94.

20 95. Monsanto admits that independent experts and regulatory agencies agree that
21 there is no evidence of carcinogenicity or genotoxicity in glyphosate and Roundup[®]-branded
22 products and admits that it has made statements reflecting this fact. Monsanto denies the
23 remaining allegations in paragraph 95.

24 96. In response to the allegations in paragraph 96, Monsanto admits that Roundup[®]-
25 branded products are safe, non-carcinogenic and non-genotoxic when used in accordance with
26 the product's EPA approved labeling. Monsanto otherwise denies the allegations in paragraph
27 96.

28

1 97. In response to the allegations in paragraph 97, Monsanto admits that an EPA
2 review committee classified glyphosate as Class C in 1985 based on limited data. Monsanto
3 denies the remaining allegations in paragraph 97.

4 98. In response to the allegations in paragraph 98, Monsanto admits that EPA
5 changed its classification of glyphosate to Group E based upon a full evaluation of the scientific
6 evidence, including but not limited to three animal carcinogenicity studies. Monsanto otherwise
7 denies the remaining allegations in paragraph 98.

8 99. In response to the allegations in paragraph 99, Monsanto admits that plaintiffs
9 have accurately quoted from one passage in an EPA document in 1991 with respect to the
10 designation of an agent as Group E, but states that EPA repeatedly has concluded that glyphosate
11 does not pose any cancer risk to humans. In addition to the conclusions in the two EPA OPP
12 reports and the EPA CARC Final Report discussed above, other specific findings of safety
13 include:

- 14 • “In June 1991, EPA classified glyphosate as a Group E [carcinogen]—one that shows
15 evidence of non-carcinogenicity for humans—based on the lack of convincing
16 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>.
- 17 • “No evidence of carcinogenicity.” *Glyphosate; Pesticide Tolerances*, 67 Fed. Reg.
18 60,934, 60,943 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180).
- 19 • “Glyphosate has no carcinogenic potential.” *Glyphosate; Pesticide Tolerance*, 69
20 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180).
- 21 • “There is [an] extensive database available on glyphosate, which indicate[s] that
22 glyphosate is not mutagenic, not a carcinogen, and not a developmental or
23 reproductive toxicant.” *Glyphosate; Pesticide Tolerances*, 73 Fed. Reg. 73,586,
24 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180).
- 25 • “EPA has concluded that glyphosate does not pose a cancer risk to humans.”
26 *Glyphosate; Pesticide Tolerances*, 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be
27 codified at 40 C.F.R. pt. 180).
- 28 • “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 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->

1 [5056-a055-64af-0e55900753b4](#), at time stamp 55:05 – 56:20 (“EPA 2015 Desk
2 Statement”).

3 Monsanto denies the remaining allegations in paragraph 99.

4 100. In response to the allegations in paragraph 100, Monsanto admits that it – along
5 with a large number of other companies and governmental agencies – was defrauded by two
6 chemical testing laboratories, and that Monsanto had hired both of these laboratories to conduct
7 testing on glyphosate. Monsanto states that only one of these laboratories was hired to conduct
8 toxicity tests of glyphosate. Monsanto denies that EPA’s registration of glyphosate or any
9 glyphosate-based herbicides is based upon any invalid Industrial Bio-Test (“IBT”) Laboratories
10 studies. To the extent that the allegations in paragraph 100 are intended to suggest that
11 Monsanto was anything other than a victim of this fraud, such allegations are denied.

12 101. In response to the allegations in paragraph 101, Monsanto admits that IBT
13 Laboratories was hired to conduct toxicity studies in connection with the registration of a
14 Roundup[®]-branded product. Monsanto denies that EPA’s regulatory approval of such product is
15 based upon any fraudulent or false IBT studies.

16 102. Monsanto denies the allegations in paragraph 102 to the extent they suggest that
17 EPA performed an inspection of IBT Laboratories solely or specifically in connection with
18 studies conducted on glyphosate. Monsanto admits that EPA performed an audit of IBT
19 Laboratories to investigate that laboratory’s fraudulent and/or improper testing procedures in
20 connection with services provided to a broad number of private and governmental entities and
21 that this inspection included a review of studies IBT conducted on glyphosate. Monsanto was
22 one of several pesticide manufacturers who had used IBT test results. The audit found some
23 toxicology studies conducted with the original Roundup[®] herbicide to be invalid. As a result,
24 Monsanto repeated all required studies in accordance with applicable EPA testing guidelines.
25 Monsanto denies that EPA’s registration of glyphosate or any glyphosate-based herbicides is
26 based upon any invalid IBT studies. To the extent that the allegations in paragraph 102 are
27 intended to suggest that Monsanto was anything other than a victim of this fraud, Monsanto
28 denies those allegations.

1 103. In response to the allegations in paragraph 103, Monsanto admits that three IBT
2 employees were convicted of the charge of fraud, but Monsanto denies that any of the
3 individuals were convicted based upon studies conducted on glyphosate or glyphosate-based
4 herbicides.

5 104. In response to the allegations in paragraph 104, Monsanto admits that it – along
6 with numerous other private companies – hired Craven Laboratories as an independent
7 laboratory to conduct residue studies for Monsanto agricultural products. Monsanto otherwise
8 denies the remaining allegations in paragraph 104.

9 105. In response to the allegations in paragraph 105, Monsanto admits that EPA
10 investigated Craven Laboratories in March 1991 for fraud. To the extent that the allegations in
11 paragraph 105 are intended to suggest that Monsanto was anything other than a victim of this
12 fraud, Monsanto denies those allegations.

13 106. In response to the allegations in paragraph 106, Monsanto admits that it was
14 defrauded by Craven Laboratories and that, as a result, Monsanto repeated the studies conducted
15 at Craven Laboratories at a substantial cost. To the extent that the allegations in paragraph 106
16 are intended to suggest that Monsanto was anything other than a victim of this fraud, Monsanto
17 denies those allegations.

18 107. In response to the allegations in paragraph 107, 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.

21 108. In response to the allegations in paragraph 108, 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 108.

27 109. Monsanto denies the allegations in paragraph 109.

28 110. Monsanto denies the allegations in paragraph 110.

1 111. Monsanto denies the allegations in paragraph 111.

2 112. Monsanto denies the allegations in paragraph 112.

3 113. Monsanto denies the allegations in paragraph 113.

4 114. Monsanto denies the allegations in paragraph 114.

5 115. Monsanto denies the allegations in paragraph 115.

6 116. Monsanto denies the allegations in paragraph 116.

7 117. Monsanto denies the allegations in paragraph 117.

8 118. Monsanto denies the allegations in paragraph 118.

9 119. Monsanto denies the allegations in paragraph 119.

10 120. Monsanto incorporates by reference its responses to paragraphs 1 through 119 in
11 response to paragraph 120 of plaintiffs' Complaint.

12 121. In response to the allegations in paragraph 121, Monsanto denies that it has
13 concealed the alleged "true risks associated with Roundup and glyphosate." The remaining
14 allegations in paragraph 121 set forth conclusions of law for which no response is required.

15 122. In response to the allegations in paragraph 122, Monsanto admits that it has stated
16 and continues to state that Roundup[®]-branded products are safe when used as labeled and that
17 they are non-toxic and non-carcinogenic.

18 123. In response to the allegations in paragraph 123, Monsanto states that the cited
19 document speaks for itself and does not require a response.

20 124. Monsanto denies that exposure to Roundup[®]-branded products and glyphosate
21 exposed plaintiff to risk of her alleged cancer and denies the remaining allegations in paragraph
22 124. Monsanto states, however, that the scientific studies upon which IARC purported to base
23 its classification were all publicly available before March 2015.

24 125. Monsanto denies that it concealed "the true character, quality and nature of
25 Roundup." The remaining allegations of paragraph 125 set forth conclusions of law for which
26 no response is required. To the extent that a response is deemed required, Monsanto denies all of
27 plaintiffs' allegations in paragraph 125. Monsanto states, however, that the scientific studies
28

1 upon which IARC purported to base its classification were all publicly available before March
2 2015.

3 126. Monsanto denies that it engaged in the “wrongdoing” alleged in the Complaint
4 and denies that there is any reliable scientific evidence that exposure to glyphosate or Roundup[®]-
5 branded products can cause cancer. Monsanto states, however, that the scientific studies upon
6 which IARC purported to base its classification were all publicly available before March 2015.
7 The remaining allegations in paragraph 126 set forth conclusions of law for which no response is
8 required, consist of attorney characterizations and are accordingly denied, or comprise
9 allegations for which Monsanto lacks information or knowledge sufficient to form a belief as to
10 the truth of the allegations asserted and therefore denies those allegations.

11 127. Monsanto incorporates by reference its responses to paragraphs 1 through 126 in
12 response to paragraph 127 of plaintiffs’ Complaint.

13 128. In response to the allegations in paragraph 128, Monsanto admits that plaintiffs
14 purport to bring a claim for strict liability design defect, but denies any liability as to that claim.

15 129. In response to the allegations in paragraph 129, Monsanto lacks information or
16 knowledge sufficient to form a belief as to the truth of the allegation that plaintiff used
17 Roundup[®]-branded products and therefore denies that allegation. Monsanto denies the
18 remaining allegations in paragraph 129.

19 130. Monsanto denies the allegations in paragraph 130.

20 131. Monsanto lacks information or knowledge sufficient to form a belief as to the
21 truth of the allegations in paragraph 131 concerning the condition of any Roundup[®]-branded
22 product allegedly used by plaintiff or about plaintiff’s alleged uses of such product and therefore
23 denies those allegations. The remaining allegations in paragraph 131 set forth conclusions of
24 law for which no response is required.

25 132. Monsanto denies the allegations in plaintiffs’ first-numbered paragraph 132.

26 132. Monsanto denies the allegations in plaintiffs’ second-numbered paragraph 132.

27 133. Monsanto denies the allegations in paragraph 133.

28 134. Monsanto denies the allegations in paragraph 134 and each of its subparts.

1 135. Monsanto lacks information or knowledge sufficient to form a belief as to the
2 truth of the allegations in paragraph 135 concerning plaintiff’s claimed use of Roundup[®]-branded
3 products and therefore denies those allegations. Monsanto denies the remaining allegations in
4 135, including that Roundup[®]-branded products have “dangerous characteristics.”

5 136. Monsanto lacks information or knowledge sufficient to form a belief as to the
6 truth of the allegations in paragraph 136 concerning plaintiff’s claimed use of Roundup[®]-branded
7 products and therefore denies those allegations. Monsanto denies the remaining allegations in
8 paragraph 136, including that Roundup[®]-branded products have “dangerous characteristics.”

9 137. Monsanto denies the allegations in paragraph 137.

10 138. Monsanto denies the allegations in paragraph 138.

11 139. Monsanto denies the allegations in paragraph 139.

12 140. Monsanto denies the allegations in paragraph 140.

13 141. Monsanto denies the allegations in paragraph 141.

14 142. Monsanto denies the allegations in paragraph 142.

15 143. Monsanto denies the allegations in paragraph 143.

16 144. Monsanto denies the allegations in paragraph 144.

17 In response to the “WHEREFORE” paragraph following paragraph 144, Monsanto
18 demands that judgment be entered in its favor and against plaintiffs; that plaintiffs’ Complaint be
19 dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney’s
20 fees as allowed by law and such further and additional relief as this Court may deem just and
21 proper.

22 145. Monsanto incorporates by reference its responses to paragraphs 1 through 144 in
23 response to paragraph 145 of plaintiffs’ Complaint.

24 146. In response to the allegations in paragraph 146, Monsanto admits that plaintiffs
25 purport to bring a claim for strict liability failure to warn, but denies any liability as to that claim.

26 147. Monsanto denies the allegations in paragraph 147.

27 148. In response to the allegations in paragraph 148, Monsanto lacks information or
28 knowledge sufficient to form a belief as to the truth of the allegation that plaintiff or other

1 entities identified purchased or used Roundup[®]-branded products and therefore denies that
2 allegation. The allegations in paragraph 148 also set forth conclusions of law for which no
3 response is required. Monsanto denies the remaining allegations in paragraph 148.

4 149. The allegations in paragraph 149 set forth conclusions of law for which no
5 response is required.

6 150. Monsanto denies the allegations in paragraph 150. All labeling of Roundup[®]-
7 branded products has been and remains EPA-approved and in compliance with all federal
8 requirements under FIFRA.

9 151. Monsanto denies the allegations in paragraph 151.

10 152. Monsanto denies the allegations in paragraph 152.

11 153. Monsanto denies the allegations in paragraph 153.

12 154. Monsanto lacks information or knowledge sufficient to form a belief as to the
13 truth of the allegations in paragraph 154 and therefore denies those allegations.

14 155. Monsanto lacks information or knowledge sufficient to form a belief as to the
15 truth of the allegations in paragraph 155 concerning plaintiff's alleged use of Roundup[®]-branded
16 products and therefore denies those allegations. Monsanto denies the remaining allegations in
17 paragraph 155, including that Roundup[®]-branded products have "dangerous characteristics."

18 156. Monsanto lacks information or knowledge sufficient to form a belief as to the
19 truth of the allegations in paragraph 156 concerning plaintiff's alleged use and exposure to
20 Roundup[®]-branded products and therefore denies those allegations. Monsanto denies the
21 remaining allegations in paragraph 156, including that Roundup[®]-branded products have
22 "dangerous characteristics."

23 157. Monsanto denies the allegations in the first sentence of paragraph 157. Monsanto
24 lacks information or knowledge sufficient to form a belief as to the truth of the allegations in the
25 second sentence of paragraph 157 and therefore denies those allegations.

26 158. Monsanto denies the allegations in paragraph 158.

27 159. Monsanto denies the allegations in paragraph 159.

28 160. Monsanto denies the allegations in paragraph 160.

1 161. Monsanto denies the allegations in paragraph 161.

2 162. Monsanto denies the allegations in paragraph 162.

3 163. Monsanto denies the allegations in paragraph 163.

4 164. Monsanto denies the allegations in paragraph 164.

5 165. Monsanto denies the allegations in paragraph 165.

6 In response to the “WHEREFORE” paragraph following paragraph 165, Monsanto
7 demands that judgment be entered in its favor and against plaintiffs; that plaintiffs’ Complaint be
8 dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney’s
9 fees as allowed by law and such further and additional relief as this Court may deem just and
10 proper.

11 166. Monsanto incorporates by reference its responses to paragraphs 1 through 165 in
12 response to paragraph 166 of plaintiffs’ Complaint.

13 167. Monsanto lacks information or knowledge sufficient to form a belief as to the
14 truth of the allegations in paragraph 167 regarding the specific products allegedly used by
15 plaintiff or any advertising or marketing allegedly seen or considered by plaintiff and therefore
16 denies the allegations in paragraph 167.

17 168. The allegations in paragraph 168 set forth conclusions of law for which no
18 response is required.

19 169. The allegations in paragraph 169 set forth conclusions of law for which no
20 response is required.

21 170. Monsanto denies the allegations in paragraph 170.

22 171. Monsanto denies the allegations in paragraph 171.

23 172. Monsanto denies the allegations in paragraph 172. All labeling of Roundup[®]-
24 branded products has been and remains EPA-approved and in compliance with all federal
25 requirements under FIFRA.

26 173. Monsanto denies the allegations in paragraph 173.

27 174. Monsanto denies the allegations in paragraph 174.

28 175. Monsanto denies the allegations in paragraph 175, including each of its subparts.

1 176. Monsanto denies the allegations in paragraph 176.

2 177. Monsanto lacks information or knowledge sufficient to form a belief as to the
3 truth of the allegations in paragraph 177 regarding plaintiff's knowledge and therefore Monsanto
4 denies those allegations. Monsanto denies the remaining allegations in paragraph 177, including
5 that intended use and/or exposure to Roundup[®]-branded products causes any injuries.

6 178. Monsanto denies the allegations in paragraph 178.

7 179. Monsanto denies the allegations in paragraph 179.

8 180. Monsanto denies the allegations in paragraph 180. All labeling of Roundup[®]-
9 branded products has been and remains EPA-approved and in compliance with all federal
10 requirements under FIFRA.

11 In response to the "WHEREFORE" paragraph following paragraph 180, Monsanto
12 demands that judgment be entered in its favor and against plaintiffs; that plaintiffs' Complaint be
13 dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's
14 fees as allowed by law and such further and additional relief as this Court may deem just and
15 proper.

16 181. In response to the allegations in paragraph 181, Monsanto denies that plaintiffs
17 have alleged fraud, let alone fraud with specificity. Monsanto incorporates by reference its
18 responses to paragraphs 1 through 180 in response to paragraph 181 of plaintiffs' Complaint.

19 182. Monsanto denies the allegations in paragraph 182.

20 183. Monsanto denies the allegations in paragraph 183.

21 184. Monsanto denies the allegations in paragraph 184.

22 185. Monsanto denies the allegations in paragraph 185.

23 186. Monsanto denies the allegations in paragraph 186.

24 187. Monsanto denies the allegations in paragraph 187.

25 188. Monsanto denies the allegations in paragraph 188.

26 189. Monsanto denies the allegations in paragraph 189.

27 190. Monsanto denies the allegations in paragraph 190.

28 191. Monsanto denies the allegations in paragraph 191.

1 In response to the “WHEREFORE” paragraph following paragraph 191 Monsanto
2 demands that judgment be entered in its favor and against plaintiffs; that plaintiffs’ Complaint be
3 dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney’s
4 fees as allowed by law and such further and additional relief as this Court may deem just and
5 proper.

6 192. In response to the allegations in paragraph 192, Monsanto denies that plaintiffs
7 have alleged fraud, let alone fraud with specificity. Monsanto incorporates by reference its
8 responses to paragraphs 1 through 191 in response to paragraph 192 of plaintiffs’ Complaint.

9 193. Monsanto admits that plaintiffs purport to bring a cause of action pursuant to
10 California Business and Professions Code Sec. 17500, California Civil Code § 1750 et seq., and
11 Texas Deceptive Trade Practices-Consumer Protection Act, § 17.41, et seq., but denies any
12 liability as to that claim.

13 194. Monsanto denies the allegations in paragraph 194.

14 195. Monsanto denies the allegations in paragraph 195.

15 196. Monsanto denies the allegations in paragraph 196.

16 197. Monsanto denies the allegations in paragraph 197.

17 198. Monsanto denies the allegations in paragraph 198.

18 199. Monsanto denies the allegations in paragraph 199.

19 200. Monsanto denies the allegations in paragraph 200.

20 201. Monsanto lacks information or knowledge sufficient to form a belief as to the
21 truth of the allegations in paragraph 201 regarding plaintiff’s actions, and therefore Monsanto
22 denies those allegations. Monsanto denies the remaining allegations in paragraph 201.

23 202. Monsanto denies the allegations in paragraph 202.

24 203. Monsanto denies the allegations in paragraph 203. All labeling of Roundup[®]-
25 branded products has been and remains EPA-approved and in compliance with all federal
26 requirements under FIFRA.

27 204. Monsanto denies the allegations in paragraph 204.

28

1 In response to the “WHEREFORE ” paragraph following paragraph 204 Monsanto
2 demands that judgment be entered in its favor and against plaintiffs; that plaintiffs’ Complaint be
3 dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney’s
4 fees as allowed by law and such further and additional relief as this Court may deem just and
5 proper.

6 205. Monsanto incorporates by reference its responses to paragraphs 1 through 204 in
7 response to the first sentence of paragraph 205 of the plaintiffs’ Complaint.

8 206. The allegations of paragraph 206 set forth conclusions of law for which no
9 response is required.

10 207. Monsanto denies the allegations in paragraph 207.

11 In response to the “WHEREFORE” paragraphs following paragraph 207, Monsanto
12 demands that judgment be entered in its favor and against plaintiffs; that plaintiffs’ Complaint be
13 dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney’s
14 fees as allowed by law and such further and additional relief as this Court may deem just and
15 proper.

16 In response to the allegations in the section entitled “PRAYER FOR RELIEF,” Monsanto
17 denies that plaintiffs are entitled to the relief sought therein, including any judgment for any
18 damages, interest, costs, or any other relief whatsoever.

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

21 **SEPARATE AND AFFIRMATIVE DEFENSES**

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

24 2. Venue in the Eastern District of Missouri may be inconvenient.

25 3. Plaintiffs’ claims are barred because plaintiffs cannot proffer any scientifically
26 reliable evidence that the products at issue were defective or unreasonably dangerous.

27
28

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

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

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

11 7. Plaintiffs' claims are barred, in whole or in part, by application of Tex. Civ. Prac.
12 & Rem. Code Ann. § 82.008.

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

17 9. Plaintiffs' claims are preempted, in whole or in part, by applicable federal law
18 relating to the design, testing, producing, manufacturing, labeling, distributing, modeling,
19 processing, and supply of Roundup[®]-branded products and/or glyphosate-containing products.

20 10. Plaintiffs' claims are preempted, in whole or in part, because of U.S. EPA
21 findings that glyphosate does not cause cancer in humans and/or because of U.S. EPA-approved
22 product labeling.

23 11. Plaintiffs' claims are barred, in whole or in part, by the doctrine of primary
24 jurisdiction, including by the authority delegated by Congress to the U.S. EPA.

25 12. Plaintiffs' claims are barred, in whole or in part, because plaintiffs' injuries, if
26 any, were the result of conduct of plaintiffs, independent third parties, and/or events that were
27 extraordinary under the circumstances, not foreseeable in the normal course of events, and/or
28

1 independent, intervening and superseding causes of the alleged injuries, including but not limited
2 to plaintiffs' pre-existing medical conditions.

3 13. The doctrines contained in Restatement (Second) of Torts § 402A, comments j
4 and k, bar plaintiffs' claims against Monsanto in whole or in part.

5 14. Applicable statutes of limitations and/or repose bar plaintiffs' claims in whole or
6 in part.

7 15. Plaintiff's misuse or abnormal use of the product or failure to follow instructions
8 bar plaintiffs' claims in whole or in part.

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

16 17. Monsanto had no legal relationship or privity with plaintiffs and owed no duty to
17 them by which liability could be attributed to it.

18 18. Plaintiffs' claims are preempted in whole or part by the Freedom of Speech
19 Clause of the First Amendment of the U.S. Constitution.

20 19. Plaintiffs' claims for punitive, exemplary, aggravated, and/or treble damages are
21 barred because such an award would violate Monsanto's due process, equal protection and other
22 rights under the United States Constitution, the California Constitution, the Texas Constitution,
23 and the Missouri Constitution, and/or other applicable state constitutions.

24 20. Plaintiffs' claims for punitive, exemplary, aggravated, and/or treble damages are
25 barred because plaintiffs have failed to allege conduct warranting imposition of such damages
26 under California law, Texas Law, Missouri law, and/or other applicable state laws.

1 21. Plaintiffs' claims for punitive, exemplary, aggravated, and/or treble damages are
2 barred and/or limited by operation of state and/or federal law, including Missouri Revised Statute
3 § 510.265.1 and Tex. Civ. Prac. & Rem. Code Ann. §§ 41.004(a), 41.008(b).

4 22. Monsanto's conduct and/or acts were not willful, wanton, malicious, reckless,
5 fraudulent or done with a conscious disregard for the rights of plaintiffs and/or the safety of the
6 public. Nor do any of Monsanto's conduct and/or acts demonstrate that Monsanto acted with a
7 high degree of moral culpability. In fact, Monsanto exercised reasonable care at all times alleged
8 in the Complaint, and plaintiffs have failed to clearly establish any entitlement to punitive,
9 exemplary, aggravated, and/or treble damages based on their allegations.

10 23. Plaintiffs' claims are barred in whole or in part by plaintiffs' own
11 contributory/comparative negligence.

12 24. Plaintiffs' claims are barred in whole or in part by plaintiffs' own failure to
13 mitigate damages.

14 25. Plaintiffs' claims are barred in whole or in part by the sophisticated user doctrine.

15 26. To the extent that plaintiffs recovered payments for plaintiffs' alleged injuries
16 from any collateral source(s) or other source(s), plaintiffs' recovery in this lawsuit, if any, shall
17 be reduced to the extent allowed by applicable law, including as allowed for under Missouri
18 Revised Statute § 490.715.

19 27. If plaintiffs have been injured or damaged, no injury or damages being admitted,
20 such injuries were not caused by a Monsanto product.

21 28. Plaintiffs have failed to allege fraud with sufficient particularity.

22 29. Plaintiffs' claims are barred or limited to the extent that plaintiffs assert claims
23 that are governed by the laws of a state that does not recognize or limit such claims.

24 30. Plaintiffs' claims are barred to the extent that plaintiffs seek relief under the laws
25 of states that do not govern plaintiffs' claims.

26 31. Monsanto hereby gives notice that it intends to rely upon such other defenses as
27 may become available or apparent during the course of discovery and thus reserves its right to
28 amend this Answer to assert such defenses.

