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 13 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**
 14 **FOR THE COUNTY OF ALAMEDA**
 15

16 PILLIOD, et al.
 17 Plaintiffs,
 18 vs.
 19 MONSANTO COMPANY,
 20 Defendant.

Case No. RG17862702
 ASSIGNED FOR ALL PURPOSES TO
 JUDGE WINIFRED SMITH
 DEPARTMENT 21
 MONSANTO COMPANY'S BENCH BRIEF
 TO EXCLUDE THE NO SIGNIFICANT
 RISK LEVEL ("NSRL")
 Complaint Filed: June 2, 2018
 Trial Date: March 18, 2019

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1 **I. INTRODUCTION**

2 Monsanto Company (“Monsanto”) requests the Court deny Plaintiffs’ request for judicial
3 notice of California’s April 19, 2018 Final Statement of Reasons for the No Significant Risk Level
4 (“default NSRL”) of Glyphosate (“Final Statement”). The default NSRL post-dates Plaintiffs’ last
5 use of Roundup® products by well over a year, making it legally irrelevant to any notice issue in
6 this case.

7 Moreover, it is irrelevant to any causation issue because the purpose of the default NSRL
8 is simply to establish a conservative, default safe harbor¹ level as guidance for businesses as to
9 when a Proposition 65 warning categorically is not required. It does *not* establish a level above
10 which there is a recognized risk of injury. In the words of the Office of Environmental Health
11 Hazard Assessment (“OEHHA”), the establishment of a default safe harbor NSRL is “expressly
12 not a determination that any level above the NSRL poses a significant risk.” *Baxter Healthcare*
13 *Corp. v. Denton*, 120 Cal. App. 4th 333, 358 (2004). In litigation under Proposition 65, businesses
14 are entitled to prove that the actual NSRL is higher than the default NSRL promulgated by
15 OEHHA. Cal. Health & Safety Code § 25249.10(c).

16 The earliest effective date of any requirement to provide a Proposition 65 warning for
17 glyphosate was July 7, 2018, more than one year after either Plaintiff’s last use of a glyphosate-
18 based product. And a federal court has preliminarily enjoined the warning requirement as applied
19 to glyphosate, finding that a cancer warning on glyphosate would be “false and misleading.”
20 There therefore is not now, nor has there ever been, a requirement to place a Proposition 65 cancer
21 warning on glyphosate-based products. *See Nat’l Ass’n of Wheat Growers v. Zeise*, 309 F. Supp.
22 3d 842, 853 (E.D. Cal. 2018) (“*Wheat Growers*”). The default NSRL thus has no relevance here

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24 ¹ The commonly used term “safe harbor” is not related to the essential safety of the chemical, but
25 instead refers to the protection of businesses from litigation under Proposition 65. That is, it is a
26 legal safe harbor for warnings for Proposition 65 defendants. OEHHA explained, for example,
27 that its “regulatory proposal [to adopt a safe harbor NSRL for glyphosate] does not create
28 additional compliance requirements, but instead provides a ‘safe harbor’ value that aids businesses
in determining whether a warning is required for a given exposure.” Final Statement at 46
(Plaintiffs’ Request for Judicial Notice (“RJN”), Ex. 9); *see also* Black’s Law Dictionary (defining
“safe harbor” as “The provision in a law or agreement that will protect from any liability or
penalty as long as set conditions have been met.”).

1 when its purpose is simply to aid businesses in determining whether to warn, particularly when the
2 Plaintiffs' last exposure pre-dates both the issuance of the default NSRL and the effective date for
3 any warning requirement.

4 While the Court has indicated it will allow Proposition 65 into evidence, neither party
5 discussed the default NSRL—as distinct from the listing—in opening statements.² This is not a
6 lawsuit by private citizen enforcers over whether a Proposition 65 warning was required. Here,
7 the admission of the default NSRL will only confuse the jury to the prejudice of Monsanto, and
8 result in the undue consumption of time. Cal. Evid. Code § 350.

9 **II. THE DEFAULT SAFE HARBOR NSRL IS IRRELEVANT HERE**

10 **A. The Very Purpose of the Default NSRL Renders it Irrelevant**

11 The April 19, 2018 default NSRL is not evidence of causation. OEHHA can—but is not
12 required to—adopt a “safe harbor” NSRL for listed chemicals, which is the level of exposure
13 “deemed to pose no significant risk within the meaning of Section 25249.10(c) of the Act.” Cal.
14 Code Regs. tit. 27 §25705(a). OEHHA calculated the safe harbor NSRL for glyphosate using the
15 single rodent carcinogenicity study that would generate the lowest NSRL. Final Statement at 1, 26
16 (Plaintiffs' RJN, Ex. 9). OEHHA did not rely upon the 15 other rodent carcinogenicity studies for
17 glyphosate, nor did it rely upon epidemiological evidence. *Id.* at. 4-5, 10. That is because the
18 default NSRL is—by design—a conservative regulatory threshold for establishing, as a legal safe
19 harbor and a benefit to businesses, when a Proposition 65 warning is *not* required.

20 Plaintiffs nevertheless inaccurately portray the default NSRL as OEHHA's establishment
21 of a level “for determining how much glyphosate is necessary to cause cancer.” *See* Plaintiffs'
22 RJN at 6-7.³ But default NSRL is *not* a determination of an exposure level above which a
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24 ² The listing and the adoption of the default NSRL were two separate administrative actions by
25 OEHHA. The listing was non-discretionary and compelled by statute. *Monsanto v. OEHHA*, 22
26 Cal. App. 5th 534, 542 (2018) (noting that the listing is “ministerial” and OEHHA “cannot
27 consider scientific arguments concerning the weight or quality of the evidence”). The default
28 NSRL was later adopted to “spare[] businesses the expense of calculating their own NSRL” and
“enable them to reduce or avoid litigation costs.” *See* OEHHA, Notice of Proposed Rulemaking
re: Glyphosate NSRL, April 7, 2017, at 3-4.

³ Plaintiffs also inaccurately state that OEHHA agreed with IARC in the Final Statement that

1 chemical is carcinogenic; to the contrary, it is a regulatory establishment of a safe harbor level,
2 i.e., a determination that an exposure to a listed chemical *below* that level is not a significant risk
3 such that a business is not required to provide a Proposition 65 warning. *See* Cal. Health & Safety
4 Code §25249.10(c). Indeed, the Court of Appeal has emphasized that the “regulatory
5 establishment of a NSRL is only a determination that an exposure below the level is not a
6 significant risk. In OEHHA’s own words, its establishment of a NSRL ‘*expressly is not a*
7 *determination that any level above the NSRL poses a significant risk.*’” *Baxter*, 120 Cal. App.
8 4th at 358 (emphasis added).

9 As the Final Statement makes clear, “NSRLs are intended to aid businesses in determining
10 if they must comply with the warning and discharge provisions of Proposition 65; NRSLs [sic] are
11 not intended to establish exposure or risk levels for other regulatory purposes.” *See* Final
12 Statement at 17 (Plaintiffs’ RJN, Ex. 9). The regulatory language confirms the narrow application
13 of a NSRL determination, stating that a safe harbor NSRL is established “solely for the purposes
14 of Section 25249.10(c) of the Act” (the provision establishing exceptions to Proposition 65’s
15 warning requirement), and that “[n]othing in this article shall be construed to establish exposure or
16 risk levels for other regulatory purposes.” *See* Cal. Code Regs. tit. 27 § 25701(d). As such, the
17 default NSRL is not relevant to causation.

18 **B. The Safe Harbor NSRL Post-Dates Plaintiffs’ Use of Roundup® Products**

19 Glyphosate was added to the Proposition 65 list on July 7, 2017. Under California law,
20 there is no warning requirement with regard to any “exposure that takes place less than twelve
21 months subsequent to the listing of the chemical in question on the list required to be published”
22 under Proposition 65. *See* Cal. Health & Safety Code § 25249.10(b). The earliest effective date
23 glyphosate is carcinogenic and genotoxic. *Id.* That is simply not true. In establishing the safe
24 harbor NSRL, OEHHA was not evaluating *whether* glyphosate is carcinogenic; that determination
25 was already made at the listing stage, in which OEHHA simply incorporated by reference IARC’s
26 classification decision. Moreover, the Proposition 65 regulations compel OEHHA to base the safe
27 harbor NSRL on ‘evidence and standards of comparable scientific validity to the evidence and
28 standard which form the scientific basis for listing the chemical.’ *See* Cal. Code Regs. tit. 27
§25703(a). Because OEHHA ministerially listed glyphosate pursuant to the Labor Code
mechanism based solely on IARC’s classification, OEHHA based its safe harbor NSRL on the
same IARC evidence and standards, i.e., the results of the most sensitive scientific study as
interpreted by IARC.’”

1 of any requirement to provide warnings under Proposition 65—a warning that is enjoined—was
2 July 7, 2018, one year after OEHHA’s listing of glyphosate in July 2017. *See* Final Statement at 1
3 (Plaintiffs’ RJN, Ex. 9). That effective date is *more than one year* after either Plaintiff stopped
4 using any Monsanto glyphosate-based herbicide. *See* Declaration of Eugene Brown (“Brown
5 Decl.”), ¶ 2, Ex. 1 (Alva Pilliod First Amended Plaintiff’s Fact Sheet at 8, Section VII.A.3.); ¶3,
6 Ex. 2 (Alberta Pilliod First Amended Plaintiff’s Fact Sheet at 8, Section VII.A.3). Similarly, the
7 Final Statement was not issued until April 2018, again more than one year after either Plaintiff’s
8 last use of any Roundup® products.

9 Moreover, there is no requirement today that glyphosate-based products contain a
10 Proposition 65 warning. *See Wheat Growers*, 309 F. Supp. 3d at 854. As this Court knows, a
11 California federal court has preliminarily enjoined the Proposition 65 warning requirement as
12 applied to glyphosate because a warning would *be misleading to consumers*. The court reasoned
13 that the warning “does not appear to be factually accurate and uncontroversial because it conveys
14 the message that glyphosate’s carcinogenicity is an undisputed fact, when almost all other
15 regulators have concluded that there is insufficient evidence that glyphosate causes cancer.” *Id.* at
16 852. The court stated “it is inherently misleading” to require a Proposition 65 warning “based on
17 the finding of one organization [IARC] (which as noted above, only found that substance is
18 probably carcinogenic), when apparently all other regulatory and governmental bodies have found
19 the opposite, including the EPA, which is one of the bodies California law expressly relies on in
20 determining whether a chemical causes cancer.” *Id.* at 852-53. Ultimately, the court issued the
21 preliminary injunction because “the heavy weight of evidence in the record” shows that
22 “glyphosate is not in fact known to cause cancer[.]” *Id.* at 853.

23 On June 12, 2018, the federal court affirmed its decision over OEHHA’s challenge, which
24 was based on (1) the NSRL and Final Statement of Reasons, (2) the decision upholding the Labor
25 Code listing mechanism (*Monsanto Co. v. OEHHA*, 22 Cal. App. 5th 534 (2018)), and (3)
26 additional information posted on OEHHA’s website. Despite OEHHA’s effort, this information
27 did “not change the court’s conclusion that the required Proposition 65 warning for glyphosate is
28 not purely factual and uncontroversial” and thus, violative of the First Amendment. *See Brown*

1 Decl.. ¶4, Ex. 3 (*Wheat Growers*, Memorandum and Order Re: Motion to Alter or Amend
2 Preliminary Injunction Order at 4 (ECF No. 97) (June 12, 2018)). While OEHHA has taken the
3 administrative step of establishing a safe harbor NSRL for glyphosate, that action is irrelevant
4 when the Proposition 65 warning requirement cannot be enforced.

5 **III. CONCLUSION**

6 The safe harbor NSRL for glyphosate merely sets a level of exposure below which a
7 business is *not* required to provide a Proposition 65 warning; it expressly is not a determination
8 that exposures above the threshold pose a significant risk of cancer. It thus has no relevance to the
9 causation issues in this case. In addition, Plaintiffs' last use of Roundup® products pre-dates the
10 issuance of that default NSRL, and also pre-dates the earliest effective date of any requirement to
11 provide a Proposition 65 warning on glyphosate-based products—a requirement that, in any event,
12 is enjoined. This is not a lawsuit brought by private citizen enforcers over whether a Proposition
13 65 warning was required. The default NSRL is of no relevance to the Plaintiffs' claims here, and
14 its introduction opens the door to a mini-trial on the Proposition 65 framework, the purpose of the
15 safe harbor NSRL, and the federal court's preliminary injunction of the Proposition 65 warning
16 requirement for glyphosate, all of which would unnecessarily consume time and potentially
17 confuse the jury. For these reasons, Monsanto requests that the Court exclude any evidence of the
18 default NSRL and deny Plaintiffs' Request for Judicial Notice of the Final Statement.

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1 Dated: April 2, 2019

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