

## **CONSUMER ATTORNEYS**

December 15, 2023

## NOTICE OF VIOLATION OF CALIFORNIA HEALTH & SAFETY CODE SECTION 25249.5 *ET SEQ*. (PROPOSITION 65)

Dear Alleged Violators and the Appropriate Public Enforcement Agencies:

I represent CalSafe Research Center, Inc. ("CRC"), 4533 MacArthur Blvd., Ste. 165, Newport Beach, CA 92660; Tel. (949) 630-0413. CRC's Executive Director is Eric Fairon. CRC is a California non-profit corporation dedicated to, among other causes, helping safeguard the public from health hazards by bringing about a reduction in the use and misuse of hazardous and toxic chemicals, facilitating a safe environment for consumers and employees, and encouraging corporate responsibility.

CRC has identified violations of California's Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"), which is codified at California Health & Safety Code §25249.5 et seq., with respect to the products identified below. These violations have occurred and continue to occur because the alleged Violators identified below failed to provide required clear and reasonable warnings with these products. This letter serves as a notice of these violations to the alleged Violators and the appropriate public enforcement agencies. Pursuant to Health and Safety Code Section 25249.7(d), CRC intends to pursue a private enforcement action in the public interest 60 days after effective service of this notice unless the public enforcement agencies have commenced and are diligently prosecuting an action to rectify these violations.

<u>General Information about Proposition 65</u>. A copy of a summary of Proposition 65, prepared by the Office of Environmental Health Hazard Assessment, is enclosed with this letter served to the alleged Violators identified below.

<u>Alleged Violators</u>. The names of the person/company covered by this notice that violated Proposition 65 (hereinafter the "Violators") are:

- 1. Phoenix Medicaments Pvt., Ltd.
- 2. Amazon.com Services, LLC



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<u>Consumer Products and Listed Chemical</u>. The products that are the subject of this notice and the chemical in those products identified as exceeding allowable levels are:

#### MB Herbals, Ashwagandha Powder, UPC#X001M5ULKR

On February 27, 1987, the State of California officially listed lead as a chemical known to cause developmental toxicity, and male and female reproductive toxicity. On October 1, 1992, the State of California officially listed lead and lead compounds as chemicals known to cause cancer.

It should be noted that CRC may continue to investigate other products that may reveal further violations and result in subsequent notices of violations.

<u>Route of Exposure</u>. The consumer exposures that are the subject of this notice result from the recommended use of these products. Consequently, the route of exposure to this chemical has been and continues to be through ingestion.

Approximate Time Period of Violations. Ongoing violations have occurred every day since at least June 14, 2023, as well as every day since the products were introduced into the California marketplace and will continue every day until clear and reasonable warnings are provided to product purchasers and users or until this known toxic chemical is either removed from or reduced to allowable levels in the products. Proposition 65 requires that a clear and reasonable warning be provided prior to exposure to the identified chemical. The method of warning should be a warning that appears on the product label. The Violators violated Proposition 65 because they failed to provide persons ingesting these products with appropriate warnings that they are being exposed to this chemical.

Consistent with the public interest goals of Proposition 65 and a desire to have these ongoing violations of California law quickly rectified, CRC is interested in seeking a constructive resolution of this matter that includes an enforceable written agreement by the Violators to: (1) reformulate the identified products so as to eliminate further exposures to the identified chemical, or provide appropriate warnings on the labels of these products; (2) pay an appropriate civil penalty; and (3) provide clear and reasonable warnings compliant with Proposition 65 to all persons located in California who purchased the above products in the last three years. Such a resolution will prevent further unwarned consumer exposures to the identified chemical, as well as an expensive and time-consuming litigation.

CRC has retained me as legal counsel in connection with this matter. Please direct all communications regarding this Notice of Violation to my attention at the law office



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address and telephone number indicated on the letterhead or at P65@ManningLawOffice.com.

Sincerely,

Joseph R. Manning, Jr.

P65@ManningLawOffice.com

#### Attachments

Certificate of Merit Certificate of Service

OEHHA Summary (to Alleged Violators only)

Factual Information in Support of Certificate of Merit (to AG only)



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#### **CERTIFICATE OF MERIT**

Re: Calsafe Research Center, Inc.'s Notice of Proposition 65 Violations by Phoenix Medicaments Pvt., Ltd., and Amazon.com Services, LLC

### I, Joseph R. Manning, Jr., declare:

- 1. This Certificate of Merit accompanies the attached 60-day notice in which it is alleged that the parties identified in the notice violated California Health & Safety Code Section 25249.6 by failing to provide clear and reasonable warnings.
- 2. I am an attorney for the noticing party.
- 3. I have consulted with one or more persons with relevant and appropriate experience or expertise who have reviewed facts, studies, or other data regarding the exposure to the listed chemical that is the subject of the notice.
- 4. Based on the information obtained through those consultations, and on other information in my possession, I believe there is a reasonable and meritorious case for the private action. I understand that "reasonable and meritorious case for the private action" means that the information provides a credible basis that all elements of the plaintiff's case can be established, and that the information did not prove that the alleged Violators will be able to establish any of the affirmative defenses set forth in the statute.
- 5. Along with the copy of this Certificate of Merit served on the Attorney General is attached additional factual information sufficient to establish the basis for this certificate, including the information identified in California Health & Safety Code §25249.7(h)(2), i.e., (1) the identity of the persons consulted with and relied on by the certifier, and (2) the facts, studies, or other data reviewed by those persons.

Dated: December 15, 2023

Joseph R. Manning, Jr.

P65@ManningLawOffice.com



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### **CERTIFICATE OF SERVICE PURSUANT TO 27 CCR § 25903**

I, the undersigned, declare under penalty of perjury under the laws of the State of California that the following is true and correct:

I am a citizen of the United States and over the age of 18 years of age. My business address is 26100 Towne Centre Drive, Foothill Ranch, CA 92610. I am a resident or employed in the county where the mailing occurred. The envelope or package was placed in the mail at Foothill Ranch, California.

On December 15, 2023 between 8:00 a.m. and 5:00 p.m. Pacific Standard Time, I served the following documents: **NOTICE OF VIOLATION OF CALIFORNIA HEALTH & SAFETY CODE §25249.5** *ET SEQ.*; **CERTIFICATE OF MERIT**; "THE SAFE **DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (PROPOSITION 65): A SUMMARY**" on the following parties by placing a true and correct copy thereof in a sealed envelope, addressed to each of the parties listed below and depositing it at a U.S. Postal Service Office with the postage fully prepaid for delivery by Certified Mail:

Current CEO, President, or General	Amazon.com Services,	CEO Michael Deal or Current
Counsel	LLC	CEO, President, or General
Phoenix Medicaments Pvt., Ltd.	Agent CSC	Counsel
F-80 Tulsi Industrial Estate	2710 Gateway Oaks Drive	Amazon.com Services, LLC
Changodar, Ahmedabad 382213	Sacramento, CA 95833	410 Terry Avenue North
INDIA		Seattle, WA 98109

On December 15, 2023 between 8:00 a.m. and 5:00 p.m. Pacific Standard Time, I verified the following documents NOTICE OF VIOLATIONS, CALIFORNIA HEALTH & SAFETY CODE §25249.5 ET SEQ.; CERTIFICATE OF MERIT INCLUDING A SUMMARY OF CONFIDENTIAL FACTUAL INFORMATION; ADDITIONAL SUPPORTING INFORMATION FOR CERTIFICATE OF MERIT AS REQUIRED BY CALIFORNIA HEALTH & SAFETY CODE §25249.7(d)(1) were served on the following party when a true and correct copy thereof was uploaded on the California Attorney General's website, which can be accessed at https://oag.ca.gov/prop65/add-60-day-notice:

Office of the California Attorney General Prop 65 Enforcement Reporting 1515 Clay Street, Suite 2000 Oakland, CA 94612-0550



# **CONSUMER ATTORNEYS**

On December 15, 2023 between 8:00 a.m. and 5:00 p.m. Pacific Standard Time, I verified the following documents **NOTICE OF VIOLATIONS, CALIFORNIA HEALTH & SAFETY CODE §25249.5** *ET SEQ.*; **CERTIFICATE OF MERIT** were served on the following parties when a true and correct copy thereof was sent via electronic mail to each of the parties listed below:

Barbara Yook, District Attorney	a a
Calaveras County 891 Mountain Ranch Road San Andreas, CA 95249 Prop65Env@co.calaveras.ca.us	Stacey Grassini, Deputy District Attorney Contra Costa County 900 Ward Street Martinez, CA 94553 sgrassini@contracostada.org
Michelle Latimer, Program Coordinator Lassen County 220 S. Lassen Street Susanville, CA 96130 mlatimer@co.lassen.ca.us	Dije Ndreu, Deputy District Attorney Monterey County 1200 Aguajito Road Monterey, CA 93940 Prop65DA@co.monterey.ca.us
Michael Hestrin, District Attorney Riverside County 3072 Orange Street Riverside, CA 92501 Prop65@rivcoda.org	Anne Marie Schubert, District Attorney Sacramento County 901 G Street Sacramento, CA 95814 Prop65@sacda.org
Mark Ankcorn, Deputy City Attorney San Diego City Attorney 1200 Third Avenue San Diego, CA 92101 CityAttyProp65@sandiego.gov	Valerie Lopez, Deputy City Attorney San Francisco City Attorney 1390 Market Street, 7th Floor San Francisco, CA 94102 Valerie.Lopez@sfcityatty.org
Eric J. Dobroth, Deputy District Attorney San Luis Obispo County County Government Center Annex, 4th Floor San Luis Obispo, CA 93408 edobroth@co.slo.ca.us	Christopher Dalbey, Deputy District Attorney Santa Barbara County 1112 Santa Barbara Street Santa Barbara, CA 93101 DAProp65@co.santa-barbara.ca.us
Bud Porter, Supervising Deputy District Attorney Santa Clara County 70 W Hedding St San Jose, CA 95110 EPU@da.sccgov.org	Phillip J. Cline, District Attorney Tulare County 221 S Mooney Blvd Visalia, CA 95370 Prop65@co.tulare.ca.us  Lori E. Frugoli, District Attorney
	891 Mountain Ranch Road San Andreas, CA 95249 Prop65Env@co.calaveras.ca.us  Michelle Latimer, Program Coordinator Lassen County 220 S. Lassen Street Susanville, CA 96130 mlatimer@co.lassen.ca.us  Michael Hestrin, District Attorney Riverside County 3072 Orange Street Riverside, CA 92501 Prop65@rivcoda.org  Mark Ankcorn, Deputy City Attorney San Diego City Attorney 1200 Third Avenue San Diego, CA 92101 CityAttyProp65@sandiego.gov  Eric J. Dobroth, Deputy District Attorney San Luis Obispo County County Government Center Annex, 4th Floor San Luis Obispo, CA 93408 edobroth@co.slo.ca.us  Bud Porter, Supervising Deputy District Attorney Santa Clara County 70 W Hedding St San Jose, CA 95110



## **CONSUMER ATTORNEYS**

Ventura County 800 S Victoria Ave Ventura, CA 93009 daspecialops@ventura.org Yolo County 301 Second Street Woodland, CA 95695 cfepd@yolocounty.org

Marin County 3501 Civic Center Drive, Room 130 San Rafael, CA 94903 consumer@marincountyda.org

On December 15, 2023 between 8:00 a.m. and 5:00 p.m. Pacific Standard Time, I served the following documents: NOTICE OF VIOLATION, CALIFORNIA HEALTH & SAFETY CODE §25249.5 ET SEQ.; CERTIFICATE OF MERIT on each parties on the Service List attached hereto by placing a true and correct copy thereof in a sealed envelope, addressed to each of the parties on the Service List attached hereto, and depositing it at a U.S. Postal Service Office with the postage fully prepaid for delivery by First Class Mail.

Executed on December 15, 2023, in Foothill Ranch, California.

Krystal Garzon



# **CONSUMER ATTORNEYS**

## **Service List**

District Attorney, Alpine County	District Attorney, Madera County	District Attorney, Shasta County
P.O. Box 248	209 West Yosemite Avenue	1355 West Street
Markleeville, CA 96120	Madera, CA 93637	Redding, CA 96001
District Attorney, Amador County	District Attorney, Mariposa County	District Attorney, Sierra County
708 Court Street, Suite 202	Post Office Box 730	100 Courthouse Square, 2nd Floor
Jackson, CA 95642	Mariposa, CA 95338	Downieville, CA 95936
District Attorney, Butte County	District Attorney, Mendocino County	District Attorney, Siskiyou County
25 County Center Drive, Suite 245	Post Office Box 1000	Post Office Box 986
Oroville, CA 95965	Ukiah, CA 95482	Yreka, CA 96097
District Attorney, Colusa County	District Attorney, Merced County	District Attorney, Solano County
310 6 <sup>th</sup> Street	550 W. Main Street	675 Texas Street, Ste 4500
Colusa, CA 95932	Merced, CA 95340	Fairfield, CA 94533
District Attorney, Del Norte County	District Attorney, Modoc County	District Attorney, Stanislaus County
450 H Street, Room 171	204 S Court Street, Room 202	832 12th Street, Ste 300
Crescent City, CA 95531	Alturas, CA 96101-4020	Modesto, CA 95354
District Attorney, El Dorado County	District Attorney, Mono County	District Attorney, Sutter County
778 Pacific St	Post Office Box 617	463 2nd Street
Placerville, CA 95667	Bridgeport, CA 93517	Yuba City, CA 95991
District Attorney, Fresno County	District Attorney, Nevada County	District Attorney, Tehama County
2100 Tulare St.,	201 Commercial Street	Post Office Box 519
Fresno, CA 93721	Nevada City, CA 95959	Red Bluff, CA 96080
District Attorney, Glenn County	District Attorney, Placer County	District Attorney, Trinity County
Post Office Box 430	10810 Justice Center Drive, Ste 240	Post Office Box 310
Willows, CA 95988	Roseville, CA 95678	Weaverville, CA 96093
District Attorney, Humboldt County	District Attorney, Plumas County	District Attorney, Tuolumne County
825 5th Street 4th Floor	520 Main Street, Room 404	423 N. Washington Street
Eureka, CA 95501	Quincy, CA 95971	Sonora, CA 95370
District Attorney, Imperial County	District Attorney, San Benito County	District Attorney, Yuba County
940 West Main Street, Ste 102	419 Fourth Street, 2nd Floor	215 Fifth Street, Suite 152
El Centro, CA 92243	Hollister, CA 95023	Marysville, CA 95901
District Attorney, Kern County 1215 Truxtun Avenue Bakersfield, CA 93301	Los Angeles City Attorney's Office City Hall East 200 N. Main Street, Suite 800 Los Angeles, CA 90012	San Jose City Attorney's Office 200 East Santa Clara Street, 16th Floor San Jose, CA 95113
District Attorney, Kings County 1400 West Lacey Boulevard Hanford, CA 93230	District Attorney, San Diego County 330 West Broadway, Suite 1300 San Diego, CA 92101	District Attorney, Los Angeles County Hall of Justice 211 West Temple St., Ste 1200 Los Angeles, CA 90012
District Attorney, Lake County 255 N. Forbes Street Lakeport, CA 95453	District Attorney, San Mateo County 400 County Ctr., 3rd Floor Redwood City, CA 94063	

#### APPENDIX A

# OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

# THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (PROPOSITION 65): A SUMMARY

The following summary has been prepared by the California Office of Environmental Health Hazard Assessment (OEHHA), the lead agency for the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly known as "Proposition 65"). A copy of this summary must be included as an attachment to any notice of violation served upon an alleged violator of the Act. The summary provides basic information about the provisions of the law, and is intended to serve only as a convenient source of general information. It is not intended to provide authoritative guidance on the meaning or application of the law. The reader is directed to the statute and OEHHA implementing regulations (see citations below) for further information.

FOR INFORMATION CONCERNING THE BASIS FOR THE ALLEGATIONS IN THE NOTICE RELATED TO YOUR BUSINESS, CONTACT THE PERSON IDENTIFIED ON THE NOTICE.

The text of Proposition 65 (Health and Safety Code Sections 25249.5 through 25249.13) is available online at: http://oehha.ca.gov/prop65/law/P65law72003.html. Regulations that provide more specific guidance on compliance, and that specify procedures to be followed by the State in carrying out certain aspects of the law, are found in Title 27 of the California Code of Regulations, sections 25102 through 27001.¹ These implementing regulations are available online at: http://oehha.ca.gov/prop65/law/P65Regs.html.

#### WHAT DOES PROPOSITION 65 REQUIRE?

The "Proposition 65 List." Under Proposition 65, the lead agency (OEHHA) publishes a list of chemicals that are known to the State of California to cause cancer and/or reproductive toxicity. Chemicals are placed on the Proposition 65 list if they are known to cause cancer and/or birth defects or other reproductive harm, such as damage to

<sup>&</sup>lt;sup>1</sup> All further regulatory references are to sections of Title 27 of the California Code of Regulations unless otherwise indicated. The statute, regulations and relevant case law are available on the OEHHA website at: http://www.oehha.ca.gov/prop65/law/index.html.

female or male reproductive systems or to the developing fetus. This list must be updated at least once a year. The current Proposition 65 list of chemicals is available on the OEHHA website at: <a href="http://www.oehha.ca.gov/prop65/prop65\_list/Newlist.html">http://www.oehha.ca.gov/prop65/prop65\_list/Newlist.html</a>.

Only those chemicals that are on the list are regulated under Proposition 65. Businesses that produce, use, release or otherwise engage in activities involving listed chemicals must comply with the following:

Clear and reasonable warnings. A business is required to warn a person before "knowingly and intentionally" exposing that person to a listed chemical unless an exemption applies. The warning given must be "clear and reasonable." This means that the warning must: (1) clearly make known that the chemical involved is known to cause cancer, or birth defects or other reproductive harm; and (2) be given in such a way that it will effectively reach the person before he or she is exposed to that chemical. Some exposures are exempt from the warning requirement under certain circumstances discussed below.

**Prohibition from discharges into drinking water.** A business must not knowingly discharge or release a listed chemical into water or onto land where it passes or probably will pass into a source of drinking water. Some discharges are exempt from this requirement under certain circumstances discussed below.

#### DOES PROPOSITION 65 PROVIDE ANY EXEMPTIONS?

Yes. You should consult the current version of the statute and regulations (http://www.oehha.ca.gov/prop65/law/index.html) to determine all applicable exemptions, the most common of which are the following:

**Grace Period.** Proposition 65 warning requirements do not apply until 12 months after the chemical has been listed. The Proposition 65 discharge prohibition does not apply to a discharge or release of a chemical that takes place less than 20 months after the listing of the chemical.

**Governmental agencies and public water utilities.** All agencies of the federal, state or local government, as well as entities operating public water systems, are exempt.

**Businesses with nine or fewer employees.** Neither the warning requirement nor the discharge prohibition applies to a business that employs a total of nine or fewer employees. This includes all employees, not just those present in California.

Exposures that pose no significant risk of cancer. For chemicals that are listed under Proposition 65 as known to the State to cause cancer, a warning is not required if the business causing the exposure can demonstrate that the exposure occurs at a level that poses "no significant risk." This means that the exposure is calculated to result in not more than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime. The Proposition 65 regulations identify specific "No Significant Risk Levels" (NSRLs) for many listed carcinogens. Exposures below these levels are exempt from the warning requirement. See OEHHA's website at:

http://www.oehha.ca.gov/prop65/getNSRLs.html for a list of NSRLs, and Section 25701 *et seq.* of the regulations for information concerning how these levels are calculated.

**Exposures that will produce no observable reproductive effect at 1,000 times the level in question.** For chemicals known to the State to cause reproductive toxicity, a warning is not required if the business causing the exposure can demonstrate that the exposure will produce no observable effect, even at 1,000 times the level in question. In other words, the level of exposure must be below the "no observable effect level" divided by 1,000. This number is known as the Maximum Allowable Dose Level (MADL). See OEHHA's website at: http://www.oehha.ca.gov/prop65/getNSRLs.html for a list of MADLs, and Section 25801 *et seq.* of the regulations for information concerning how these levels are calculated.

**Exposures to Naturally Occurring Chemicals in Food.** Certain exposures to chemicals that naturally occur in foods (i.e., that do not result from any known human activity, including activity by someone other than the person causing the exposure) are exempt from the warning requirements of the law. If the chemical is a contaminant<sup>2</sup> it must be reduced to the lowest level feasible. Regulations explaining this exemption can be found in Section 25501.

Discharges that do not result in a "significant amount" of the listed chemical entering any source of drinking water. The prohibition from discharges into drinking water does not apply if the discharger is able to demonstrate that a "significant amount" of the listed chemical has not, does not, or will not pass into or probably pass into a source of drinking water, and that the discharge complies with all other applicable laws, regulations, permits, requirements, or orders. A "significant amount" means any detectable amount, except an amount that would meet the "no significant risk" level for chemicals that cause cancer or that is 1,000 times below the "no observable effect" level for chemicals that cause reproductive toxicity, if an individual were exposed to that amount in drinking water.

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<sup>&</sup>lt;sup>2</sup> See Section 25501(a)(4).

#### **HOW IS PROPOSITION 65 ENFORCED?**

Enforcement is carried out through civil lawsuits. These lawsuits may be brought by the Attorney General, any district attorney, or certain city attorneys. Lawsuits may also be brought by private parties acting in the public interest, but only after providing notice of the alleged violation to the Attorney General, the appropriate district attorney and city attorney, and the business accused of the violation. The notice must provide adequate information to allow the recipient to assess the nature of the alleged violation. The notice must comply with the information and procedural requirements specified in Section 25903 of Title 27 and sections 3100-3103 of Title 11. A private party may not pursue an independent enforcement action under Proposition 65 if one of the governmental officials noted above initiates an enforcement action within sixty days of the notice.

A business found to be in violation of Proposition 65 is subject to civil penalties of up to \$2,500 per day for each violation. In addition, the business may be ordered by a court to stop committing the violation.

A private party may not file an enforcement action based on certain exposures if the alleged violator meets specific conditions. For the following types of exposures, the Act provides an opportunity for the business to correct the alleged violation:

- An exposure to alcoholic beverages that are consumed on the alleged violator's premises to the extent onsite consumption is permitted by law;
- An exposure to a Proposition 65 listed chemical in a food or beverage prepared and sold on the alleged violator's premises that is primarily intended for immediate consumption on- or off-premises. This only applies if the chemical was not intentionally added to the food, and was formed by cooking or similar preparation of food or beverage components necessary to render the food or beverage palatable or to avoid microbiological contamination;
- An exposure to environmental tobacco smoke caused by entry of persons (other than employees) on premises owned or operated by the alleged violator where smoking is permitted at any location on the premises;
- An exposure to listed chemicals in engine exhaust, to the extent the exposure occurs inside a facility owned or operated by the alleged violator and primarily intended for parking non-commercial vehicles.

If a private party alleges that a violation occurred based on one of the exposures described above, the private party must first provide the alleged violator a notice of special compliance procedure and proof of compliance form.

A copy of the notice of special compliance procedure and proof of compliance form is included in Appendix B and can be downloaded from OEHHA's website at: http://oehha.ca.gov/prop65/law/p65law72003.html.

#### FOR FURTHER INFORMATION ABOUT THE LAW OR REGULATIONS...

Contact the Office of Environmental Health Hazard Assessment's Proposition 65 Implementation Office at (916) 445-6900 or via e-mail at P65Public.Comments@oehha.ca.gov.

Revised: May 2017

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5, 25249.6, 25249.7, 25249.9, 25249.10 and 25249.11, Health and Safety Code.