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FILED BY FAX
ALAMEDA COUNTY
June 04, 2021
CLERK OF
THE SUPERIOR COURT
By Keisha Ghee, Deputy
CASE NUMBER:
RG21101129

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

ENVIRONMENTAL RESEARCH CENTER, INC., a California non-profit corporation, **Plaintiff,** **vs.** **BIOHM HEALTH LLC and DOES 1-100** **Defendants.**	**CASE NO.** **COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF AND CIVIL PENALTIES** [Miscellaneous Civil Complaint (42)] Proposition 65, Health & Safety Code Section 25249.5 et seq.]

Plaintiff Environmental Research Center, Inc. hereby alleges:

I

INTRODUCTION

1. Plaintiff Environmental Research Center, Inc. (hereinafter "Plaintiff" or "ERC") brings this action as a private attorney general enforcer and in the public interest pursuant to Health & Safety Code section 25249.7, subdivision (d). The Safe Drinking Water and Toxic Enforcement Act of 1986 (Health & Safety Code section 25249.5 *et seq.*) also known as "Proposition 65," mandates that businesses with ten or more employees must provide a "clear and reasonable warning" prior to exposing any individual to a chemical known to the state to cause cancer or reproductive toxicity. Lead is a chemical known to the State of California to cause cancer, birth defects, and other reproductive harm. This Complaint seeks injunctive and declaratory relief

and civil penalties to remedy the ongoing failure of Defendants BIOHM Health LLC ("BIOHM") and Does 1-100 (hereinafter individually referred to as "Defendant" or collectively as "Defendants"), to warn consumers that they have been exposed to lead from a number of BIOHM's nutritional health products as set forth in paragraph 3 at levels exceeding the applicable Maximum Allowable Dose Level ("MADL") and requiring a warning pursuant to Health & Safety Code section 25249.6.

II

PARTIES

2. Plaintiff ERC is a California non-profit corporation dedicated to, among other causes, helping safeguard the public from health hazards by reducing the use and misuse of hazardous and toxic chemicals, facilitating a safe environment for consumers and employees, and encouraging corporate responsibility.

3. Defendant BIOHM is a business that develops, manufactures, markets, distributes, and/or sells nutritional health products that have exposed users to lead in the State of California within the relevant statute of limitations period. These "SUBJECT PRODUCTS" (as identified in the Notice of Violation dated March 25, 2021 attached hereto as ***Exhibit A***) are: (1) Biohm Probiotic Supplement with Super Greens and (2) Biohm Super Greens Probiotic Energy Supplement Clean Energy Greens. Defendant BIOHM Health LLC is a company subject to Proposition 65 as it employs ten or more persons and has employed ten or more persons at all times relevant to this action.

4. Defendants Does 1-100, are named herein under fictitious names, as their true names and capacities are unknown to ERC. ERC is informed and believes, and thereon alleges, that each of said Does is responsible, in some actionable manner, for the events and happenings hereinafter referred to, either through said Does' conduct, or through the conduct of its agents, servants or employees, or in some other manner, causing the harms alleged by ERC in this Complaint. When said true names and capacities of Does are ascertained, ERC will seek leave to amend this Complaint to set forth the same.

///

III

JURISDICTION AND VENUE

5. This Court has jurisdiction pursuant to California Constitution Article VI, Section 10, which grants the Superior Court original jurisdiction in all causes except those given by statute to other trial courts. The statute under which this action is brought does not specify any other basis for jurisdiction.

6. This Court has jurisdiction over BIOHM because BIOHM has sufficient minimum contacts with California, and otherwise intentionally avails itself of the California market through the marketing, distribution, and/or sale of the SUBJECT PRODUCTS in the State of California so as to render the exercise of jurisdiction over it by the California courts consistent with traditional notions of fair play and substantial justice.

7. The Complaint is based on allegations contained in the Notice of Violation dated March 25, 2021, served on the California Attorney General, other public enforcers, and BIOHM. The Notice of Violation constitutes adequate notice to BIOHM because it provided adequate information to allow BIOHM to assess the nature of the alleged violations, consistent with Proposition 65 and its implementing regulations. A certificate of merit and a certificate of service accompanied each copy of the Notice of Violation, and both certificates comply with Proposition 65 and its implementing regulations. The Notice of Violation served on BIOHM also included a copy of "The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): A Summary." Service of the Notice of Violation and accompanying documents complied with Proposition 65 and its implementing regulations. Attached hereto as ***Exhibit A*** is a true and correct copy of the Notice of Violation and associated documents. More than 60 days have passed since ERC mailed the Notice of Violation and no public enforcement entity has filed a Complaint in this case.

8. This Court is the proper venue for the action because the causes of action have arisen in the County of Alameda where some of the violations of law have occurred, and will continue to occur, due to the ongoing sale of BIOHM's products. Furthermore, venue is proper in this Court under Code of Civil Procedure section 395.5 and Health & Safety Code section 25249.7.

IV

STATUTORY BACKGROUND

9. The Safe Drinking Water and Toxic Enforcement Act of 1986 is an initiative statute passed as "Proposition 65" by an overwhelming majority vote of the people in November of 1986.

10. The warning requirement of Proposition 65 is contained in Health & Safety Code section 25249.6, which provides:

> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

11. The Office of Environmental Health Hazard Assessment ("OEHHA"), a division of Cal EPA, is the lead agency in charge of the implementation of Proposition 65. OEHHA administers the Proposition 65 program and administers regulations that govern Proposition 65 in general, including warnings to comply with the statute. The warning regulations are found at Title 27 of the California Code of Regulations, Article 6. The regulations define expose as "to cause to ingest, inhale, contact via body surfaces or otherwise come into contact with a listed chemical. An individual may come into contact with a listed chemical through water, air, food, consumer products and any other environmental exposure as well as occupational exposures." (Cal. Code Regs., tit. 27, § 25102, subd. (i).)

12. In this case, the exposures are caused by consumer products. A consumer product is defined as "any article, or component part thereof, including food, that is produced, distributed, or sold for the personal use, consumption or enjoyment of a consumer." (Cal. Code Regs., tit. 27, § 25600.1, subd. (d).) Food "includes 'dietary supplements' as defined in California Code of Regulations, title 17, section 10200." (*Id.* at subd. (g).) A consumer product exposure is "an exposure that results from a person's acquisition, purchase, storage, consumption, or any reasonably foreseeable use of a consumer product, including consumption of a food." (*Id.* at subd. (e).)

13. On August 30, 2016, the Office of Administrative Law approved the adoption of OEHHA's amendments to Article 6, Clear and Reasonable Warnings of the California Code of Regulations. This action repealed virtually all of the regulatory provisions of Title 27 of the California Code of Regulations, Article 6 (sections 25601 *et seq*.) and replaced the repealed sections with new regulations set forth in two new Subarticles to Article 6 that became operative on August 30, 2018 (the "New Warning Regulations"). The New Warning Regulations provide, among other things, methods of transmission and content of warnings deemed to comply with Proposition 65. BIOHM is subject to the warning requirements set forth in the New Warning Regulations that became operative on August 30, 2018.

14. Health & Safety Code section 25249.6 provides that "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual . . . ." The New Warning Regulations apply when clear and reasonable warnings are required under Section 25249.6. Pursuant to the New Warning Regulations, consumer product warnings "must be prominently displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning likely to be seen, read, and understood by an ordinary individual under customary conditions of purchase or use." (*Id.* at § 25601, subd. (c).)

15. Proposition 65 establishes a procedure by which the State is to develop a list of chemicals "known to the State to cause cancer or reproductive toxicity." (Health & Safety Code, § 25249.8.) There is no duty to provide a clear and reasonable warning until 12-months after the chemical is published on the State list. (Health & Safety Code, § 25249.10, subd. (b).)

16. Lead was listed as a chemical known to the State of California to cause developmental toxicity in the fetus and male and female reproductive toxicity on February 27, 1987. Lead was listed as a chemical known to the State of California to cause cancer on October 1, 1992. (State of California EPA OEHHA Safe Drinking Water and Toxic Enforcement Act of 1986 Chemicals Known to the State to Cause Cancer and Reproductive Toxicity.) The MADL for

lead as a chemical known to cause reproductive toxicity is 0.5 micrograms per day. (Cal. Code Regs., tit. 27, §25805, subd. (b).) The No Significant Risk Level for lead as a carcinogen is 15 micrograms per day. (Cal. Code Regs., tit. 27, §25705, subd. (b).)

17. Proposition 65 provides that any person "violating or threatening to violate" Proposition 65 may be enjoined in any court of competent jurisdiction. (Health & Safety Code, §25249.7, subd. (a).) To "threaten to violate" means "to create a condition in which there is a substantial probability that a violation will occur." (Health & Safety Code, § 25249.11, subd. (e).) Furthermore, violators are subject to a civil penalty of up to $2,500 per day for each violation. (Health & Safety Code, § 25249.7, subd. (b)(1).)

18. Proposition 65 may be enforced by any person in the public interest who provides notice sixty days before filing suit to both the violator and designated law enforcement officials. The failure of law enforcement officials to file a timely Complaint enables a citizen suit to be filed pursuant to Health & Safety Code section 25249.7, subdivisions (c) and (d).

V

STATEMENT OF FACTS

19. BIOHM has developed, manufactured, marketed, distributed, and/or sold the SUBJECT PRODUCTS containing lead into the State of California. Consumption of the SUBJECT PRODUCTS according to the directions and/or recommendations provided for said products cause consumers to be exposed to lead at levels exceeding the 0.5 micrograms per day MADL and requiring a warning. Consumers have been ingesting these products for many years, without any knowledge of their exposure to this very dangerous chemical.

20. For many years, BIOHM has knowingly and intentionally exposed numerous persons to lead without providing any type of Proposition 65 warning. Prior to ERC's Notice of Violation and this Complaint, BIOHM failed to provide a warning on the labels of the SUBJECT PRODUCTS or provide any other legally acceptable warning. BIOHM has, at all times relevant hereto, been aware that the SUBJECT PRODUCTS contained lead and that persons using these products have been exposed to this chemical. BIOHM has been aware of the presence of lead in the SUBJECT PRODUCTS and has failed to disclose the presence of this chemical to the

public, who undoubtedly believe they have been ingesting totally healthy and pure products pursuant to the company's statements.

21. Both prior and subsequent to ERC's Notice of Violation, BIOHM failed to provide consumers of the SUBJECT PRODUCTS with a clear and reasonable warning that they have been exposed to a chemical known to the State of California to cause cancer, birth defects and other reproductive harm. This failure to warn is ongoing.

FIRST CAUSE OF ACTION
(Violation of Section 25249.6 of the Health and Safety Code, Failure to Provide Clear and Reasonable Warning under Proposition 65)

22. ERC refers to paragraphs 1-21, inclusive, and incorporates them herein by this reference.

23. By committing the acts alleged above, BIOHM has, in the course of doing business, knowingly and intentionally exposed users of the SUBJECT PRODUCTS to lead, a chemical known to the State of California to cause cancer, birth defects, and other reproductive harm, without first giving clear and reasonable warning to such individuals within the meaning of Health & Safety Code section 25249.6. In doing so, BIOHM has violated Health & Safety Code section 25249.6 and continues to violate the statute with each successive sale of the SUBJECT PRODUCTS.

24. Said violations render BIOHM liable for civil penalties, up to $2,500 per day for each violation, and subject BIOHM to injunction.

SECOND CAUSE OF ACTION
(Declaratory Relief)

25. ERC refers to paragraphs 1-24, inclusive, and incorporates them herein by this reference.

26. There exists an actual controversy relating to the legal rights and duties of the Parties, within the meaning of Code of Civil Procedure section 1060, between ERC and BIOHM, concerning whether BIOHM has exposed individuals to a chemical known to the State of California to cause cancer, birth defects, and other reproductive harm without providing clear

and reasonable warning.

VI

PRAYER

WHEREFORE ERC prays for relief as follows:

1. On the First Cause of Action, for civil penalties for each and every violation according to proof;

2. On the First Cause of Action, and pursuant to Health & Safety Code section 25249.7, subdivision (a), for such temporary restraining orders, preliminary and permanent injunctive orders, or other orders as are necessary to prevent BIOHM from exposing persons to lead without providing clear and reasonable warning;

3. On the Second Cause of Action, for a declaratory judgment pursuant to Code of Civil Procedure section 1060 declaring that BIOHM has exposed individuals to lead without providing clear and reasonable warning; and

4. On all Causes of Action, for reasonable attorneys' fees pursuant to Code of Civil Procedure section 1021.5 or the substantial benefit theory;

5. For costs of suit herein; and

6. For such other relief as the Court may deem just and proper.

DATED: June 4, 2021

ENVIRONMENTAL RESEARCH CENTER, INC.

Charles W. Poss
In-House Counsel

EXHIBIT A

Environmental Research Center
3111 Camino Del Rio North, Suite 400
San Diego, CA 92108
619-500-3090

March 25, 2021

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

Dear Alleged Violator and the Appropriate Public Enforcement Agencies:

I am the Executive Director of Environmental Research Center, Inc. ("ERC"). ERC 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.

ERC 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 Violator 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 Violator and the appropriate public enforcement agencies. Pursuant to Section 25249.7(d) of the statute, ERC intends to file 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.

General Information about Proposition 65. A copy of a summary of Proposition 65, prepared by the Office of Environmental Health Hazard Assessment, is attached with the copy of this letter served to the alleged Violator identified below.

Alleged Violator. The name of the company covered by this notice that violated Proposition 65 (hereinafter the "Violator") is:

BIOHM Health LLC

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

1. **Biohm Probiotic Supplement with Super Greens - Lead**
2. **Biohm Super Greens Probiotic Energy Supplement Clean Energy Greens - Lead**

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 ERC may continue to investigate other products that may reveal further violations and result in subsequent notices of violations.

Route of Exposure. 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 March 25, 2018, 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 Violator violated Proposition 65 because it 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, ERC is interested in seeking a constructive resolution of this matter that includes an enforceable written agreement by the Violator 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.

Please direct all questions concerning this notice to ERC at the above listed address and telephone number.

Sincerely,

Chris Heptinstall
Executive Director
Environmental Research Center

Attachments

Certificate of Merit
Certificate of Service
OEHHA Summary (to BIOHM Health LLC and its Registered Agent for Service of Process only)
Additional Supporting Information for Certificate of Merit (to AG only)

CERTIFICATE OF MERIT

Re: Environmental Research Center, Inc.'s Notice of Proposition 65 Violations by BIOHM Health LLC

I, Chris Heptinstall, declare:

1. This Certificate of Merit accompanies the attached 60-day notice in which it is alleged the party identified in the notice violated California Health & Safety Code Section 25249.6 by failing to provide clear and reasonable warnings.

2. I am the Executive Director 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 consultants, 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 Violator 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: March 25, 2021

Chris Heptinstall

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 306 Joy Street, Fort Oglethorpe, Georgia 30742. I am a resident or employed in the county where the mailing occurred. The envelope or package was placed in the mail at Fort Oglethorpe, Georgia.

On March 25, 2021, between 8:00 a.m. and 5:00 p.m. Eastern Time, I served the following documents: **NOTICE OF VIOLATIONS 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 in a U.S. Postal Service Office with the postage fully prepaid for delivery by Certified Mail:

Current President or CEO
BIOHM Health LLC
737 Bolivar Rd, Ste 200
Cleveland, OH 44115

Mahmoud Ghannoum
(Registered Agent for BIOHM Health LLC)
737 Bolivar Rd, Ste 200
Cleveland, OH 44115

On March 25, 2021, between 8:00 a.m. and 5:00 p.m. Eastern Time, I verified the following documents **NOTICE OF VIOLATIONS, CALIFORNIA HEALTH & SAFETY CODE §25249.5 *ET SEQ.*; CERTIFICATE OF MERIT; 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
Post Office Box 70550
Oakland, CA 94612-0550

On March 25, 2021, between 8:00 a.m. and 5:00 p.m. Eastern Time, 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:

Nancy O'Malley, District Attorney
Alameda County
7677 Oakport Street, Suite 650
Oakland, CA 94621
CEPDProp65@acgov.org

Stacey Grassini, Deputy District Attorney
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Barbara Yook, District Attorney
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600 Administration Dr
Sonoma, CA 95403
jbarnes@sonoma-county.org

Jeff W. Reisig, District Attorney
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301 Second Street
Woodland, CA 95695
cfepd@yolocounty.org

On March 25, 2021, between 8:00 a.m. and 5:00 p.m. Eastern Time, I served the following documents: **NOTICE OF VIOLATIONS, CALIFORNIA HEALTH & SAFETY CODE §25249.5 *ET SEQ.*; CERTIFICATE OF MERIT** on each of the 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 with the U.S. Postal Service with the postage fully prepaid for delivery by First Class Mail.

Executed on March 25, 2021, in Fort Oglethorpe, Georgia.

Phyllis Dunwoody

Service List

District Attorney, Alpine County
P.O. Box 248
Markleeville, CA 96120

District Attorney, Amador County
708 Court Street, Suite 202
Jackson, CA 95642

District Attorney, Butte County
25 County Center Drive, Suite 245
Oroville, CA 95965

District Attorney, Colusa County
346 Fifth Street Suite 101
Colusa, CA 95932

District Attorney, Del Norte County
450 H Street, Room 171
Crescent City, CA 95531

District Attorney, El Dorado County
778 Pacific St.
Placerville, CA 95667

District Attorney, Fresno County
2220 Tulare Street, Suite 1000
Fresno, CA 93721

District Attorney, Glenn County
Post Office Box 430
Willows, CA 95988

District Attorney, Humboldt County
825 5th Street 4th Floor
Eureka, CA 95501

District Attorney, Imperial County
940 West Main Street, Ste 102
El Centro, CA 92243

District Attorney, Kern County
1215 Truxtun Avenue
Bakersfield, CA 93301

District Attorney, Kings County
1400 West Lacey Boulevard
Hanford, CA 93230

District Attorney, Lake County
255 N. Forbes Street
Lakeport, CA 95453

District Attorney, Los Angeles County
Hall of Justice
211 West Temple St., Ste 1200
Los Angeles, CA 90012

District Attorney, Madera County
209 West Yosemite Avenue
Madera, CA 93637

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San Rafael, CA 94903

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Ukiah, CA 95482

District Attorney, Modoc County
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Alturas, CA 96101-4020

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Santa Ana, CA 92703

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Hollister, CA 95023

District Attorney,San Bernardino County
303 West Third Street
San Bernadino, CA 92415

District Attorney, San Mateo County
400 County Ctr., 3rd Floor
Redwood City, CA 94063

District Attorney, Shasta County
1355 West Street
Redding, CA 96001

District Attorney, Sierra County
100 Courthouse Square, 2nd Floor
Downieville, CA 95936

District Attorney, Siskiyou County
Post Office Box 986
Yreka, CA 96097

District Attorney, Solano County
675 Texas Street, Ste 4500
Fairfield, CA 94533

District Attorney, Stanislaus County
832 12th Street, Ste 300
Modesto, CA 95354

District Attorney, Sutter County
463 2nd Street
Yuba City, CA 95991

District Attorney, Tehama County
Post Office Box 519
Red Bluff, CA 96080

District Attorney, Trinity County
Post Office Box 310
Weaverville, CA 96093

District Attorney, Tuolumne County
423 N. Washington Street
Sonora, CA 95370

District Attorney, Yuba County
215 Fifth Street, Suite 152
Marysville, CA 95901

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

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

[1] 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: http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html.

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[2] 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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[2] 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.

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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.