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5 Attorney for Plaintiff Environmental Research Center, Inc.

FILED BY FAX
 ALAMEDA COUNTY
 September 30, 2019
 CLERK OF
 THE SUPERIOR COURT
 By Burt Moskaira, Deputy
 CASE NUMBER:
RG19037240

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 8 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**
 9 **COUNTY OF ALAMEDA**

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 11 **ENVIRONMENTAL RESEARCH CENTER,**
INC., a California non-profit corporation

12
 13 **Plaintiff,**

14 vs.

15 **SWISS NATURALS, INC., individually and**
dba BIOFORCE USA; and DOES 1-100

16
 17 **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.]

18
 19 Plaintiff Environmental Research Center, Inc. hereby alleges:

20 **I**

21 **INTRODUCTION**

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

1 defects, and other reproductive harm. This Complaint seeks injunctive and declaratory relief
2 and civil penalties to remedy the ongoing failure of Defendants Swiss Naturals, Inc.,
3 individually and dba Bioforce USA (“Bioforce USA”) and Does 1-100 (hereinafter individually
4 referred to as “Defendant” or collectively as “Defendants”), to warn consumers that they have
5 been exposed to lead from one of Bioforce USA’s nutritional health products as set forth in
6 paragraph 3 at a level exceeding the applicable Maximum Allowable Dose Level (“MADL”)
7 and requiring a warning pursuant to Health & Safety Code section 25249.6.

8 **II**
9 **PARTIES**

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

14 3. Defendant Swiss Naturals, Inc., individually and dba Bioforce USA, is a business that
15 develops, manufactures, markets, distributes, and/or sells a nutritional health product that has
16 exposed users to lead in the State of California within the relevant statute of limitations period.
17 This “SUBJECT PRODUCT” (as identified in the Notice of Violation dated May 30, 2019
18 attached hereto as **Exhibit A**) is: Sinupret Adult Strength Sinus + Immune Support. Bioforce
19 USA is a company subject to Proposition 65 as it employs ten or more persons and has
20 employed ten or more persons at all times relevant to this action.

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

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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 Bioforce USA because Bioforce USA 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 May 30, 2019, served on the California Attorney General, other public enforcers, and Bioforce USA. The Notice of Violation constitutes adequate notice to Bioforce USA because it provided adequate information to allow Bioforce USA 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 Bioforce USA 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 Bioforce USA’s product. Furthermore, venue is proper in this Court under Code of Civil Procedure section 395.5 and Health & Safety Code section 25249.7.

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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).)

1 13. On August 30, 2016, the Office of Administrative Law approved the adoption of
2 OEHHA's amendments to Article 6, Clear and Reasonable Warnings of the California Code of
3 Regulations. This action repealed virtually all the regulatory provisions of Title 27 of the
4 California Code of Regulations, Article 6 (sections 25601 et seq.) The action replaced the
5 repealed sections with a new regulation set forth in two new Subarticles to Article 6 that became
6 operative on August 30, 2018. The repealed and new regulations provide, among other things,
7 methods of transmission and content of warnings deemed to comply with Proposition 65.
8 Bioforce USA is subject to the warning regulations set forth both prior to and subsequent to
9 August 30, 2018.

10 14. Prior to the enactment of the new warning regulations, whenever a clear and reasonable
11 warning was required under Health & Safety Code section 25249.6, the "method employed to
12 transmit the warning must be reasonably calculated considering the alternative methods
13 available under the circumstances, to make the warning message available prior to exposure."
14 (Cal. Code Regs., tit. 27, §25601.) The warning requirement would be satisfied by a warning
15 that appeared on a product's label or other labeling, shelf labeling, signs, a system of signs,
16 public advertising identifying the system and toll-free information services, or any other system,
17 that provided clear and reasonable warnings. (Cal. Code Regs., tit. 27, §25603.1, subd. (a)-(d).)
18 Pursuant to the new warning regulations, consumer product warnings "must be prominently
19 displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as
20 compared with other words, statements, designs or devices on the label, labeling, or sign, as to
21 render the warning likely to be seen, read, and understood by an ordinary individual under
22 customary conditions of purchase or use." (*Id.* at § 25601, subd. (c).)

23 15. Proposition 65 establishes a procedure by which the State is to develop a list of
24 chemicals "known to the State to cause cancer or reproductive toxicity." (Health & Safety Code,
25 § 25249.8.) There is no duty to provide a clear and reasonable warning until 12-months after
26 the chemical is published on the State list. (Health & Safety Code, § 25249.10, subd. (b).)

27 16. Lead was listed as a chemical known to the State of California to cause developmental
28 toxicity in the fetus and male and female reproductive toxicity on February 27, 1987. Lead was

1 listed as a chemical known to the State of California to cause cancer on October 1, 1992. (State
2 of California EPA OEHHA Safe Drinking Water and Toxic Enforcement Act of 1986
3 Chemicals Known to the State to Cause Cancer and Reproductive Toxicity.) The MADL for
4 lead as a chemical known to cause reproductive toxicity is 0.5 micrograms per day. (Cal. Code
5 Regs., tit. 27, §25805, subd. (b).) The No Significant Risk Level for lead as a carcinogen is 15
6 micrograms per day. (Cal. Code Regs., tit. 27, §25705, subd. (b).)

7 17. Proposition 65 provides that any person “violating or threatening to violate” Proposition
8 65 may be enjoined in any court of competent jurisdiction. (Health & Safety Code, §25249.7,
9 subd. (a).) To “threaten to violate” means “to create a condition in which there is a substantial
10 probability that a violation will occur.” (Health & Safety Code, § 25249.11, subd. (e).)
11 Furthermore, violators are subject to a civil penalty of up to \$2,500 per day for each violation.
12 (Health & Safety Code, § 25249.7, subd. (b)(1).)

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

17 V

18 STATEMENT OF FACTS

19 19. Bioforce USA has developed, manufactured, marketed, distributed, and/or sold the
20 SUBJECT PRODUCT containing lead into the State of California. Consumption of the
21 SUBJECT PRODUCT according to the directions and/or recommendations provided for said
22 product causes consumers to be exposed to lead at levels exceeding the 0.5 micrograms per day
23 MADL and requiring a warning. Consumers have been ingesting this product for many years,
24 without any knowledge of their exposure to this very dangerous chemical.

25 20. For many years, Bioforce USA has knowingly and intentionally exposed numerous
26 persons to lead without providing any type of Proposition 65 warning. Prior to ERC’s Notice of
27 Violation and this Complaint, Bioforce USA failed to provide a warning on the labels of the
28 SUBJECT PRODUCT or provide any other legally acceptable warning. Bioforce USA has, at

1 all times relevant hereto, been aware that the SUBJECT PRODUCT contained lead and that
2 persons using this product have been exposed to this chemical. Bioforce USA has been aware
3 of the presence of lead in the SUBJECT PRODUCT and has failed to disclose the presence of
4 this chemical to the public, who undoubtedly believe they have been ingesting a totally healthy
5 and pure product pursuant to the company's statements.

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

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

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

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

22 24. Said violations render Bioforce USA liable for civil penalties, up to \$2,500 per day for
23 each violation, and subject Bioforce USA to injunction.

24 **SECOND CAUSE OF ACTION**
25 **(Declaratory Relief)**

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

28 ///

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

6 **VI**

7 **PRAYER**

8 WHEREFORE ERC prays for relief as follows:

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

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

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


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

20 5. For costs of suit herein; and

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

22
23 DATED: 9/27/19

MICHAEL FREUND & ASSOCIATES

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26 _____
27 Michael Freund
28 Attorney for Plaintiff
Environmental Research Center, Inc.

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EXHIBIT A

Michael Freund & Associates

1919 Addison Street, Suite 105
Berkeley, CA 94704
Voice: 510.540.1992 • Fax: 510.371.0885

Michael Freund, Esq.

May 30, 2019

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

Dear Alleged Violator and the Appropriate Public Enforcement Agencies:

I represent Environmental Research Center, Inc. ("ERC"), 3111 Camino Del Rio North, Suite 400, San Diego, CA 92108; Tel. (619) 500-3090. ERC's Executive Director is Chris Heptinstall. 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 product 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 this product. This letter serves as a notice of these violations to the alleged Violator and the appropriate public enforcement agencies. Pursuant to Health and Safety Code Section 25249.7(d), 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 enclosed with 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:

Swiss Naturals, Inc., individually and dba Bioforce USA

Consumer Product and Listed Chemical. The product that is the subject of this notice and the chemical in that product identified as exceeding allowable levels are:

Sinupret Adult Strength Sinus + Immune Support - 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.

May 30, 2019

Page 2

Route of Exposure. The consumer exposures that are the subject of this notice result from the recommended use of this product. 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 May 30, 2016, as well as every day since the product was 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 product. 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 this product 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 product so as to eliminate further exposures to the identified chemical, or provide appropriate warnings on the labels of this product; (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 product 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.

ERC 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 address and telephone number indicated on the letterhead or at freund1@aol.com.**

Sincerely,



Michael Freund

Attachments

Certificate of Merit

Certificate of Service

OEHHA Summary (to Swiss Naturals, Inc., individually and dba Bioforce USA)

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 Swiss Naturals, Inc., individually and dba Bioforce USA

I, Michael Freund, declare:

1. This Certificate of Merit accompanies the attached 60-day notice in which it is alleged that 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 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 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: May 30, 2019

Michael Freund

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 May 30, 2019, between 8:00 a.m. and 5:00 p.m. Eastern 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 President or CEO
Swiss Naturals, Inc., individually
and dba Bioforce USA
6 Grandinetti Dr
Ghent, NY 12075

On May 30, 2019, 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
Oakland, CA 94612-0550

On May 30, 2019, 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** 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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Notice of Violation of California Health & Safety Code §25249.5 *et seq.*

May 30, 2019

Page 5

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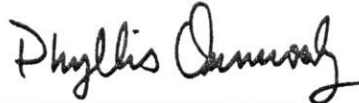
Gregory D. Totten, District Attorney
Ventura County
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daspecialops@ventura.org

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

Notice of Violation of California Health & Safety Code §25249.5 *et seq.*
May 30, 2019
Page 6

On May 30, 2019, between 8:00 a.m. and 5:00 p.m. Eastern Time, I served the following documents: **NOTICE OF VIOLATION, 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 at a U.S. Postal Service Office with the postage fully prepaid for delivery by First Class Mail.

Executed on May 30, 2019, 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
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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
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Placerville, CA 95667

District Attorney, Fresno
County
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Fresno, CA 93721

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

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

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Bakersfield, CA 93301

District Attorney, Kings
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District Attorney, Los Angeles
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Hall of Justice
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Los Angeles, CA 90012

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Madera, CA 93637

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San Rafael, CA 94903

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District Attorney, Mendocino
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District Attorney, Placer
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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 contaminant² 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.

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.

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.