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ENDORSED
FILED
ALAMEDA COUNTY

AUG 26 2014

CLERK OF THE SUPERIOR COURT

By Blanca Baker Deputy

6 Attorneys for Plaintiff Environmental Research Center

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

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

12 **Plaintiff,**

13 **vs.**

14 **TRANSFORMATION ENZYME**
15 **CORPORATION and DOES 1-100**

16 **Defendants.**

CASE NO.

RG14738322

**COMPLAINT FOR INJUNCTIVE
AND DECLARATORY RELIEF AND
CIVIL PENALTIES**

[Miscellaneous Civil Complaint (42)]
Proposition 65, Health & Safety Code
Section 25249.5 et seq.]

17
18 Plaintiff Environmental Research Center hereby alleges:

19 **I**

20 **INTRODUCTION**

21 1. Plaintiff Environmental Research Center (hereinafter "Plaintiff" or "ERC") brings this
22 action as a private attorney general enforcer and in the public interest pursuant to Health & Safety
23 Code section 25249.7, subdivision (d). This complaint seeks injunctive and declaratory relief and
24 civil penalties to remedy Defendant Transformation Enzyme Corporation and Does 1-100
25 (hereinafter "Transformation Enzyme") failure to warn consumers that they have been exposed to
26 lead from several of Transformation Enzyme's nutritional health products. Lead is a chemical
27 known to the State of California to cause cancer, birth defects and other reproductive harm. Based
28 on the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health & Safety Code section

1 25249.5 *et seq.*) also known as “Proposition 65,” businesses with ten or more employees must
2 provide a “clear and reasonable warning” prior to exposing people to this chemical.

3
4 **II**

5 **PARTIES**

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

10 3. Defendant Transformation Enzyme is a business that develops, manufactures, distributes
11 and/or sells nutritional health products that have exposed users to lead in the State of California
12 within the relevant statute of limitations period. These “Covered Products” are Transformation
13 Enzyme Corp. ExcellZyme, Transformation Enzyme Corp. Gastro, Transformation Enzyme Corp.
14 MasterZyme, Transformation Enzyme Corp. ReleaseZyme, Transformation Enzyme Corp.
15 BalanceZyme Plus, Transformation Enzyme Corp. GastroZyme, and Transformation Enzyme Corp.
16 Super CellZyme. Transformation Enzyme is a company subject to Proposition 65 as it employs ten
17 or more persons, and has employed ten or more persons at all times relevant to this action.

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

25 **III**

26 **JURISDICTION AND VENUE**

27 5. This Court has jurisdiction pursuant to California Constitution Article VI, Section 10
28 because this case is a cause not given by statute to other trial courts.

6. The Complaint is based on allegations contained in a Notice of Violation dated April 4,
2014, served on the California Attorney General, other public enforcers and Transformation

1 Enzyme. The Notice of Violation constitutes adequate notice to Transformation Enzyme because
2 it provided adequate information to allow Transformation Enzyme to assess the nature of the
3 alleged violation, consistent with Proposition 65 and its implementing regulations. Each copy of
4 the Notice of Violation was accompanied by a certificate of merit and a certificate of service, both
5 of which comply with Proposition 65 and its implementing regulations. The Notice of Violation
6 served on Transformation Enzyme also included a copy of "The Safe Drinking Water and Toxic
7 Enforcement Act of 1986 (Proposition 65): A Summary". Service of the Notice of Violation and
8 accompanying documents complied with Proposition 65 and its implementing regulations. A true
9 and correct copy of this Notice of Violation and associated documents is attached hereto as
10 Exhibit A. More than 60 days have passed since the Notice of Violation was mailed and no
11 public enforcement entity has filed a complaint in this case.

12 7. This Court is the proper venue for the action because the causes of action have arisen in
13 the County of Alameda where some of the violations of law have occurred. Furthermore, this Court
14 is the proper venue under Code of Civil Procedure section 395.5 and Health & Safety Code section
15 25249.7.

16 IV

17 STATUTORY BACKGROUND

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

20 9. The warning requirement of Proposition 65 is contained in Health & Safety Code section
21 25249.6, which provides:

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

26 10. Implementing regulations for Proposition 65 define expose as "to cause to ingest, inhale,
27 contact via body surfaces or otherwise come into contact with a listed chemical." An individual may
28 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).)

1 11. In this case, the exposures at issue are caused by consumer products. Implementing
2 regulations for Proposition 65 define a consumer product exposure as “ an exposure which results
3 from a person’s acquisition, purchase, storage, consumption, or other reasonably foreseeable use of a
4 consumer good, or any exposure that results from receiving a consumer service.” (Cal. Code Regs.,
5 tit. 27, § 25602, subd. (b).)

6 12. Whenever a clear and reasonable warning is required under Health & Safety Code
7 section 25249.6, the “method employed to transmit the warning must be reasonably calculated
8 considering the alternative methods available under the circumstances, to make the warning message
9 available prior to exposure.” (Cal. Code Regs., tit. 27, § 25601.) The warning requirement may be
10 satisfied by a warning that appears on a product’s label or other labeling, shelf labeling, signs, a
11 system of signs, public advertising identifying the system and toll-free information services, or any
12 other system, that provides clear and reasonable warnings. (Cal. Code Regs., tit. 27, § 25603.1,
13 subd. (a)-(d).)

14 13. Proposition 65 establishes a procedure by which the State is to develop a list of
15 chemicals “known to the State to cause cancer or reproductive toxicity.” (Health & Safety Code,
16 § 25249.8.) There is no duty to provide a clear and reasonable warning until 12-months after the
17 chemical was published on the State list. (Health & Safety Code, § 25249.10, subd. (b).) Lead was
18 listed as a chemical known to the State of California to cause developmental toxicity in the fetus and
19 male and female reproductive toxicity on February 27, 1987. Lead was listed as a chemical known
20 to the State of California to cause cancer on October 1, 1992. (Cal. Code Regs., tit. 27, § 27001.)

21 14. The Maximum Allowable Dose Level for lead as a chemical known to cause
22 reproductive toxicity is 0.5 micrograms per day. (Cal. Code Regs., tit. 27, § 25805.) The No
23 Significant Risk Level for lead as a carcinogen is 15 micrograms per day. (Cal. Code Regs., tit.
24 27, § 25705.)

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

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2 16. Proposition 65 provides that any person “violating or threatening to violate” Proposition
3 65 may be enjoined in any court of competent jurisdiction. (Health & Safety Code, § 25249.7, subd.
4 (a).) To “threaten to violate” means “to create a condition in which there is a substantial probability
5 that a violation will occur.” (Health & Safety Code, § 25249.11, subd. (e).) Furthermore, violators
6 are subject to a civil penalty of up to \$2,500 per day for each violation. (Health & Safety Code, §
25249.7, subd. (b)(1).)

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STATEMENT OF FACTS

17. Transformation Enzyme has developed, manufactured, distributed and/or sold the Covered Products containing lead into the State of California. Consumers have been ingesting these products for many years, without any knowledge of their exposure to lead, a very dangerous chemical.

18. For many years, Transformation Enzyme has knowingly and intentionally exposed numerous persons to lead, without providing a Proposition 65 warning. Prior to ERC’s Notice of Violation, Transformation Enzyme failed to provide a warning on the label of the Covered Products. Transformation Enzyme has at all times relevant hereto been aware that the Covered Products contained lead and that persons using these products have been exposed to the chemical. Through its website, Transformation Enzyme has made various representations regarding the quality, purity, and beneficial nature of the company’s products, as well as the steps purportedly taken to ensure these qualities:

- “Transformation Enzyme uses every available resource to stay on the leading edge of clinical nutritional science. As a nutritional supplement company, we specialize in the development of high quality digestive enzyme and probiotic products.”
- “From the very beginning of its history, Transformation Enzyme Corporation (TEC) has been dedicated to the idea that everyone is entitled to the most healthy and vital lifestyle that they are capable of obtaining.”
- “Supported by an Advisory Board that is the envy of the industry, our nutritional research and development team continues to develop and test new product concepts to further meet the needs of health professionals.”

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- “Founder and principal formulator Dr. Die Qie Fuller-Looney has over thirty years of clinical enzyme therapy experience and continues her research developing the very best possible product.... She also maintains her role as an educator, giving lectures at numerous universities and conducting seminars across the country.”
 - “Transformation’s commitment to nutrition, health education and the miracle of enzymes remains as strong as ever.”

7 Given the company’s attention to product formulation, the team of nutritional experts employed
8 during the manufacturing process, and the testing purportedly conducted on the ingredients used in
9 the company’s products, Transformation Enzyme has undoubtedly been aware of the presence of
10 lead in the Covered Products. Nevertheless, the company’s website touts Transformation Enzyme’s
11 commitment to consumers, and conveys the impression to the public that’s its products are of the
12 highest quality and completely pure and safe. Transformation Enzyme has been aware of the lead in
13 the Covered Products and has failed to disclose the presence of this chemical to the public, who
14 undoubtedly believe they have been ingesting totally healthy and pure products pursuant to the
15 company’s statements.

16 19. Both prior and subsequent to ERC’s Notice of Violation, Transformation Enzyme failed
17 to provide consumers of the Covered Products with a clear and reasonable warning that they have
18 been exposed to a chemical known to the State of California to cause cancer, birth defects and other
19 reproductive harm.

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)

20 20. ERC refers to paragraphs 1-19, inclusive, and incorporates them herein by this reference.

21 21. By committing the acts alleged above, Transformation Enzyme has, in the course of
22 doing business, knowingly and intentionally exposed users of the Covered Products to lead, a
23 chemical known to the State of California to cause cancer, birth defects and other reproductive harm
24 without first giving clear and reasonable warning to such individuals, within the meaning of Health
25 & Safety Code section 25249.6.
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6. For such other relief as the Court may deem just and proper.

Dated: August 25, 2014

By



Michael Freund
Ryan Hoffman
Attorneys for Environmental Research Center

Michael Freund & Associates

1919 Addison Street, Suite 105
Berkeley, CA 94704
Voice: 510.540.1992 • Fax: 510.540.5543

Michael Freund, Esq.
Ryan Hoffman, Esq.

OF COUNSEL:
Denise Ferkich Hoffman, Esq.

April 4, 2014

**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 (“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 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 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:

Transformation Enzyme Corporation

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

- Transformation Enzyme Corp. ExcellZyme – Lead
- Transformation Enzyme Corp. Gastro – Lead
- Transformation Enzyme Corp. MasterZyme – Lead
- Transformation Enzyme Corp. ReleaseZyme – Lead
- Transformation Enzyme Corp. BalanceZyme Plus - Lead
- Transformation Enzyme Corp. GastroZyme – Lead
- Transformation Enzyme Corp. Super CellZyme – 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.

EXHIBIT A

April 4, 2014

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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 purchase, acquisition, handling and recommended use of these products. Consequently, the primary route of exposure to these chemicals has been and continues to be through ingestion, but may have also occurred and may continue to occur through inhalation and/or dermal contact.

Approximate Time Period of Violations. Ongoing violations have occurred every day since at least April 4, 2011, 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 these known toxic chemicals are 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 chemicals. 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 handling and/or using these products with appropriate warnings that they are being exposed to these chemicals.

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 chemicals, or provide appropriate warnings on the labels of these products; and (2) pay an appropriate civil penalty. Such a resolution will prevent further unwarned consumer exposures to the identified chemicals, 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.**

Sincerely,



Michael Freund

Attachments

- Certificate of Merit
- Certificate of Service
- OEHHA Summary (to Transformation Enzyme Corporation 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's Notice of Proposition 65 Violations by Transformation Enzyme Corporation

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 chemicals that are 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: April 4, 2014



Michael Freund

CERTIFICATE OF SERVICE

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, over the age of 18 years of age, and am not a party to the within entitled action. 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 April 4, 2014, 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 the party 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
Transformation Enzyme Corporation
2900 Wilcrest Drive, Suite 220
Houston, TX 77042

James Stephenson Jr.
(Transformation Enzyme Corporation's Registered
Agent for Service of Process)
4544 Post Oak Place Drive, Suite 378
Houston, TX 77027

On April 4, 2014, I electronically served the following documents: **NOTICE OF VIOLATION, 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)** on the following party by uploading a true and correct copy thereof 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 April 4, 2014, 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 Priority Mail.

Executed on April 4, 2014, in Fort Oglethorpe, Georgia.



Tiffany Capehart

Notice of Violation of California Health & Safety Code §25249.5 *et seq.*

April 4, 2014

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Service List

District Attorney, Alameda County 1225 Fallon Street, Suite 900 Oakland, CA 94612	District Attorney, Los Angeles County 210 West Temple Street, Suite 18000 Los Angeles, CA 90012	District Attorney, San Diego County 330 West Broadway, Suite 1300 San Diego, CA 92101	District Attorney, Tuolumne County 423 N. Washington Street Sonora, CA 95370
District Attorney, Alpine County P.O. Box 248 Markleeville, CA 96120	District Attorney, Madera County 209 West Yosemite Avenue Madera, CA 93637	District Attorney, San Francisco County 850 Bryant Street, Suite 322 San Francisco, CA 94103	District Attorney, Ventura County 800 South Victoria Ave, Suite 314 Ventura, CA 93009
District Attorney, Amador County 708 Court Street Jackson, CA 95642	District Attorney, Marin County 3501 Civic Center Drive, Room 130 San Rafael, CA 94903	District Attorney, San Joaquin County 222 E. Weber Ave. Rm. 202 Stockton, CA 95202	District Attorney, Yolo County 301 2 nd Street Woodland, CA 95695
District Attorney, Butte County 25 County Center Drive, Suite 245 Oroville, CA 95965	District Attorney, Mariposa County Post Office Box 730 Mariposa, CA 95338	District Attorney, San Luis Obispo County 1035 Palm St, Room 450 San Luis Obispo, CA 93408	District Attorney, Yuba County 215 Fifth Street, Suite 152 Marysville, CA 95901
District Attorney, Calaveras County 891 Mountain Ranch Road San Andreas, CA 95249	District Attorney, Mendocino County Post Office Box 1000 Ukiah, CA 95482	District Attorney, San Mateo County 400 County Ctr., 3 rd Floor Redwood City, CA 94063	Los Angeles City Attorney's Office City Hall East 200 N. Main Street, Suite 800 Los Angeles, CA 90012
District Attorney, Colusa County 346 Fifth Street Suite 101 Colusa, CA 95932	District Attorney, Merced County 550 W. Main Street Merced, CA 95340	District Attorney, Santa Barbara County 1112 Santa Barbara Street Santa Barbara, CA 93101	San Diego City Attorney's Office 1200 3 rd Avenue, Ste 1620 San Diego, CA 92101
District Attorney, Contra Costa County 900 Ward Street Martinez, CA 94553	District Attorney, Modoc County 204 S Court Street, Room 202 Alturas, CA 96101-4020	District Attorney, Santa Clara County 70 West Hedding Street San Jose, CA 95110	San Francisco, City Attorney City Hall, Room 234 1 Dr Carlton B Goodlett PL San Francisco, CA 94102
District Attorney, Del Norte County 450 H Street, Room 171 Crescent City, CA 95531	District Attorney, Mono County Post Office Box 617 Bridgeport, CA 93517	District Attorney, Santa Cruz County 701 Ocean Street, Room 200 Santa Cruz, CA 95060	San Jose City Attorney's Office 200 East Santa Clara Street, 16 th Floor San Jose, CA 95113
District Attorney, El Dorado County 515 Main Street Placerville, CA 95667	District Attorney, Monterey County Post Office Box 1131 Salinas, CA 93902	District Attorney, Shasta County 1355 West Street Redding, CA 96001	
District Attorney, Fresno County 2220 Tulare Street, Suite 1000 Fresno, CA 93721	District Attorney, Napa County 931 Parkway Mall Napa, CA 94559	District Attorney, Sierra County PO Box 457 Downieville, CA 95936	
District Attorney, Glenn County Post Office Box 430 Willows, CA 95988	District Attorney, Nevada County 201 Commercial Street Nevada City, CA 95959	District Attorney, Siskiyou County Post Office Box 986 Yreka, CA 96097	
District Attorney, Humboldt County 825 5 th Street 4 th Floor Eureka, CA 95501	District Attorney, Orange County 401 West Civic Center Drive Santa Ana, CA 92701	District Attorney, Solano County 675 Texas Street, Ste 4500 Fairfield, CA 94533	
District Attorney, Imperial County 940 West Main Street, Ste 102 El Centro, CA 92243	District Attorney, Placer County 10810 Justice Center Drive, Ste 240 Roseville, CA 95678	District Attorney, Sonoma County 600 Administration Drive, Room 212J Santa Rosa, CA 95403	
District Attorney, Inyo County 230 W. Line Street Bishop, CA 93514	District Attorney, Plumas County 520 Main Street, Room 404 Quincy, CA 95971	District Attorney, Stanislaus County 832 12 th Street, Ste 300 Modesto, CA 95354	
District Attorney, Kern County 1215 Truxtun Avenue Bakersfield, CA 93301	District Attorney, Riverside County 3960 Orange Street Riverside, CA 92501	District Attorney, Sutter County 446 Second Street Yuba City, CA 95991	
District Attorney, Kings County 1400 West Lacey Boulevard Hanford, CA 93230	District Attorney, Sacramento County 901 "G" Street Sacramento, CA 95814	District Attorney, Tehama County Post Office Box 519 Red Bluff, CA 96080	
District Attorney, Lake County 255 N. Forbes Street Lakeport, CA 95453	District Attorney, San Benito County 419 Fourth Street, 2 nd Floor Hollister, CA 95023	District Attorney, Trinity County Post Office Box 310 Weaverville, CA 96093	
District Attorney, Lassen County 220 South Lassen Street, Ste. 8 Susanville, CA 96130	District Attorney, San Bernardino County 316 N. Mountain View Avenue San Bernardino, CA 92415-0004	District Attorney, Tulare County 221 S. Mooney Blvd., Room 224 Visalia, CA 93291	

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's 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.

Proposition 65 appears in California law as Health and Safety Code Sections 25249.5 through 25249.13. The statute 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 "Governor's List." Proposition 65 requires the Governor to publish a list of chemicals that are known to the State of California to cause cancer and/or reproductive toxicity. This means that 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

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>.

damage to 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 this law. 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; for example, when exposures are sufficiently low (see below). 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. 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 as known to the State to cause cancer ("carcinogens"), a warning is not required if the business 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 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 a 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 a Food. Certain exposures to chemicals that occur in foods naturally (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 into 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 the regulations and in Title 11, sections 3100-3103. A private party may not pursue an independent enforcement action under Proposition 65 if one of the governmental officials noted above initiates an 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.

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, 25249.9, 25249.10 and 25249.11, Health and Safety Code.