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David W. Slayton,
Executive Officer/Clerk of Court,
By E. Galicia, Deputy Clerk

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8 *Attorneys for Plaintiff*
9 *Alex Martinez*

10
11 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**
12 **COUNTY OF LOS ANGELES**

13 ALEX MARTINEZ, an individual,

14 Plaintiff,

15 v.

16 PRESTIGE CONSUMER HEALTHCARE INC., a
17 Delaware corporation; and DOES 1 through 10,
inclusive,

18 Defendants.
19

CASE NO.: **23STCV10020**

Unlimited Jurisdiction

**COMPLAINT FOR CIVIL PENALTIES
AND INJUNCTIVE RELIEF**

1 Plaintiff ALEX MARTINEZ, by and through his attorneys, alleges against Defendants PRESTIGE
2 CONSUMER HEALTHCARE INC. and DOES 1 through 10, inclusive, as follows:

3 **INTRODUCTION AND SUMMARY OF CLAIMS**

4 1. Plaintiff Alex Martinez (“Plaintiff”) brings this action as a private attorney general enforcer
5 and in the public interest pursuant to Health & Safety Code section 25249.7, subdivision (d).

6 2. The Safe Drinking Water and Toxic Enforcement Act of 1986 is an initiative statute passed
7 as “Proposition 65” by a vote of the People in November 1986. It establishes a procedure by which the
8 State of California develops a list of chemicals “known to the state to cause cancer or reproductive
9 toxicity.” (Health & Safety Code § 25249.6.) Pursuant to this process, various chemicals have been
10 placed on the “Proposition 65 List” by the State and are therefore subject to the law. (27 California Code
11 of Regulations (“CCR”) § 25902.) Listed chemicals are then subject to the requirements of Proposition
12 65, including the “clear and reasonable warning” provision:

13 No person in the course of doing business shall knowingly and intentionally expose any
14 individual to a chemical known to the state to cause cancer or reproductive toxicity without
15 first giving clear and reasonable warning to such individual, except as provided in Section
16 25249.10.

17 (Health & Safety Code § 25249.6.)

18 3. Proposition 65 applies only to chemicals “known to the state to cause cancer or
19 reproductive toxicity.” Accordingly, the identification and listing of these chemicals “is pivotal to the
20 entire statutory scheme.” (*AFL-CIO v. Deukmejian* (1989) 212 Cal.App.3d 425, 431.) As that court held,
21 in interpreting Proposition 65’s “listing” requirements, “we should not prohibit the sovereign people from
22 either expressing or implementing their own will on matters of such direct and immediate importance to
23 them as their own perceived safety.” (*Id.* at p. 441 [quoting *Brosnahan v. Brown* (1982) 32 Cal.3d 236,
24 248].)

25 4. Proposition 65 provides that the Governor shall designate a “lead agency” which “may
26 adopt and modify regulations, standards, and permits as necessary to conform with and implement this
27 chapter and to further its purposes.” (Health & Safety Code § 25249.12, subd. (a).) The California
28 Environmental Protection Agency’s Office of Environmental Health Hazard Assessment (“OEHHA”) is
the designated “lead agency” for this purpose. (27 CCR § 25902.)

1 5. OEHHA identified and listed Phenazopyridine Hydrochloride as a chemical causing cancer
2 on January 1, 1988.

3 6. This Complaint seeks injunctive and declaratory relief, civil penalties, and attorneys' fees
4 and costs to remedy the failure of Defendant Prestige Consumer Healthcare Inc. ("Defendant" or
5 "Prestige") to warn California consumers that they have been exposed to Phenazopyridine Hydrochloride
6 at levels exceeding the applicable No Significant Risk Level ("NSRL") from Defendant's "Uristat®
7 Urinary Tract Infection Pain Relief Tablets" (the "Subject Product").

8 **THE PARTIES**

9 7. Plaintiff Alex Martinez ("Plaintiff") is an individual residing in California who is dedicated
10 to, among other causes, helping safeguard the public from health hazards by reducing the use and misuse
11 of hazardous and toxic chemicals, facilitating a safe environment for consumers and employees, and
12 encouraging corporate responsibility.

13 8. Plaintiff is informed and believes, and on that basis alleges, that Defendant Prestige
14 Consumer Healthcare Inc. is a Delaware corporation with its principal place of business in Tarrytown,
15 New York. Upon further information and belief, Prestige is a "[p]erson in the course of doing business"
16 within the meaning of Health and Safety Code, section 25249.11.

17 9. Prestige develops, manufactures, markets, distributes, and/or sells the Subject Product that
18 has exposed users to Phenazopyridine Hydrochloride at levels exceeding the NSRL in the State of
19 California within the relevant statute of limitations period. The Subject Product is also identified in
20 Plaintiff's Notice of Violation dated June 28, 2022, a true and correct copy of which is attached hereto as
21 **Exhibit A.**

22 10. Plaintiff does not know the true names and/or capacities, whether individual, partners, or
23 corporate, of the defendants sued herein as DOES 1 through 10, inclusive, and for that reason sues those
24 defendants under fictitious names. Plaintiff will seek leave to amend this Complaint when the true names
25 and capacities of these defendants have been ascertained. Plaintiff is informed and believes and thereon
26 alleges that these defendants are responsible in whole or in part for causing the harms alleged by Plaintiff
27 in this Complaint.

1 **JURISDICTION AND VENUE**

2 11. California Constitution Article VI, Section 10 grants the Superior Court original
3 jurisdiction in all cases except those given by statute to other trial courts. The Health and Safety Code
4 statute upon which this action is based does not give jurisdiction to any other court. Therefore, this Court
5 has jurisdiction.

6 12. Venue is proper in the Los Angeles County Superior Court pursuant to Code of Civil
7 Procedure, sections 394, 395, and 395.5. Wrongful conduct occurred and continues to occur in this
8 County. Defendants conducted and continue to conduct business in this County as it relates to the Subject
9 Product.

10 13. Defendants have sufficient minimum contacts in the State of California or otherwise
11 purposefully avail themselves of the California market. Exercising jurisdiction over Defendants would
12 be consistent with traditional notions of fair play and substantial justice.

13 14. This Complaint is based on allegations contained in the Notice of Violation dated June 28,
14 2022, which Plaintiff served on the California Attorney General, other public enforcers, and Prestige.
15 (See Ex. A.) The Notice of Violation constitutes adequate notice to Prestige because it provided adequate
16 information to allow Prestige to assess the nature of the alleged violations, consistent with Proposition 65
17 and its implementing regulations. A certificate of merit and a certificate of service accompanied each
18 copy of the Notice of Violation, and both certificates comply with Proposition 65 and its implementing
19 regulations. The Notice of Violation served on Prestige also included a copy of “The Safe Drinking Water
20 and Toxic Enforcement Act [of] 1986 (Proposition 65): A Summary.” Service of the Notice of Violation
21 and accompanying documents complied with Proposition 65 and its implementing regulations. More than
22 60 days have passed since Plaintiff mailed the Notice of Violation and no public enforcement entity has
23 filed a Complaint in this case.

24 **STATUTORY BACKGROUND**

25 15. As explained above, Proposition 65 is an initiative statute passed by an overwhelming vote
26 of the People in November 1986. Proposition 65’s warning requirement is contained in Health & Safety
27 Code section 25249.6, which provides:
28

1 No person in the course of doing business shall knowingly and intentionally expose any
2 individual to a chemical known to the state to cause cancer or reproductive toxicity without
3 first giving clear and reasonable warning to such individual, except as provided in Section
4 25249.10.

5 16. OEHHA—the lead agency in charge of implementing Proposition 65—administers the
6 regulations that govern Proposition 65 in general, including warnings to comply with the statute. The
7 warning regulations are found at Title 27 of the California Code of Regulations, Article 6. The regulations
8 define expose as “to cause to ingest, inhale, contact via body surfaces or otherwise come into contact with
9 a listed chemical. An individual may come into contact with a listed chemical through water, air, food,
10 consumer products and any other environmental exposure as well as occupational exposures.” (Cal. Code
11 Regs., tit. 27, § 25102, subd. (i).)

12 17. In this case, the exposures are caused by consumer products. A consumer product is
13 defined as “any article, or component part thereof, including food, that is produced, distributed, or sold
14 for the personal use, consumption or enjoyment of a consumer.” (Cal. Code Regs., tit. 27, § 25600.1,
15 subd. (d).) A consumer product exposure is “an exposure that results from a person’s acquisition,
16 purchase, storage, consumption, or any reasonably foreseeable use of a consumer product, including
17 consumption of a food.” (*Id.*, subd. (e).)

18 18. On August 30, 2016, the Office of Administrative Law approved the adoption of OEHHA’s
19 amendments to Article 6, Clear and Reasonable Warnings of the California Code of Regulations. This
20 action repealed virtually all of the regulatory provisions of Title 27 of the California Code of Regulations,
21 Article 6 (sections 25601, *et seq.*) and replaced the repealed sections with new regulations set forth in two
22 new sub articles to Article 6 that became operative on August 30, 2018 (the “New Warning Regulations”).
23 The New Warning Regulations provide, among other things, methods of transmission and content of
24 warnings deemed to comply with Proposition 65. Prestige is subject to the warning requirements set forth
25 in the New Warning Regulations that became operative on August 30, 2018.

26 19. Health & Safety Code section 25249.6 provides: “No person in the course of doing
27 business shall knowingly and intentionally expose any individual to a chemical known to the state to cause
28 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

1 displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as compared
2 with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning
3 likely to be seen, read, and understood by an ordinary individual under customary conditions of purchase
4 or use.” (*Id.* at § 25601, subd. (c).)

5 20. Proposition 65 establishes a procedure by which the State is to develop a list of chemicals
6 “known to the State to cause cancer or reproductive toxicity.” (Health & Safety Code, § 25249.8.) There
7 is no duty to provide a clear and reasonable warning until twelve months after the chemical is published
8 on the State’s list. (Health & Safety Code, § 25249.10, subd. (b).)

9 21. OEHHA identified and listed Phenazopyridine Hydrochloride as a chemical causing cancer
10 on January 1, 1988. (See [https://oehha.ca.gov/proposition-65/chemicals/phenazopyridine-](https://oehha.ca.gov/proposition-65/chemicals/phenazopyridine-hydrochloride)
11 [hydrochloride.](https://oehha.ca.gov/proposition-65/chemicals/phenazopyridine-hydrochloride))

12 22. OEHHA’s regulations specify how it determines the meaning of “no significant risk.”
13 These regulations mandate that the “no significant risk” determination “be based on evidence and
14 standards of comparable scientific validity to the evidence and standards which form the scientific basis
15 for the listing of the chemical.” (Cal. Code Regs., tit. 27, § 25701, subd. (a).) One manner of determining
16 this figure is through a quantitative analysis pursuant to California Code of Regulations, title 27, section
17 27503. Under this analysis, any “[a]nimal bioassay studies for quantitative risk assessment shall meet
18 generally accepted scientific principles,” and the “quality and suitability of available epidemiologic data
19 shall be appraised to determine whether the study is appropriate as the basis of a quantitative risk
20 assessment,” among other standards. (*Id.*, subd. (a)(1) & (2).) The minimal risk necessary to trigger a
21 standard is set at “one excess case of cancer in an exposed population of 100,000, assuming lifetime
22 exposure at the level in question.” (*Id.*, subd. (b).) And if it can be demonstrated that certain types of
23 exposure do not result in an increased cancer risk, the regulations allow declaring that such exposures
24 pose no substantial risk. (*Id.*, § 25707, subd. (a).)

25 23. The NSRL for Phenazopyridine Hydrochloride is 5 micrograms per day. (*Id.*, § 25705,
26 subd. (d)(3).)

27 24. Proposition 65 provides that any person “who violates or threatens to violate” the statute
28 may be enjoined in any court of competent jurisdiction. (Health & Safety Code, § 25249.7, subd. (a).)

1 To “threaten to violate” means “to create a condition in which there is a substantial probability that a
2 violation will occur.” (Health & Safety Code, § 25249.11, subd. (e).) Furthermore, violators are subject
3 to a civil penalty of up to \$2,500 per day for each violation. (Health & Safety Code, § 25249.7, subd.
4 (b)(1).)

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

9 **DEFENDANTS’ FAILURE TO WARN**

10 26. Prestige has developed, manufactured, marketed, distributed, and/or sold the Subject
11 Product containing Phenazopyridine Hydrochloride into the State of California. According to the Subject
12 Product’s label, each tablet contains over 99.5 mg of Phenazopyridine Hydrochloride.

13 27. Consumers suffering from a urinary tract infection (“UTI”) typically consume two tablets
14 three times daily, meaning that consumers ingest over 540 mg of Phenazopyridine Hydrochloride when
15 they are suffering from a UTI, and the recommended dosage far exceeds the NSRL of 5 µg/day (i.e.,
16 because there are 1,000 micrograms in every milligram, consumers ingest 100,000 times the NSRL when
17 they consume the Subject Product on a daily basis when used as directed).

18 28. On information and belief, consumers have been ingesting the Subject Product for many
19 years, without any knowledge of their exposure to this chemical.

20 29. For years, Prestige has knowingly and intentionally exposed numerous persons to
21 Phenazopyridine Hydrochloride without providing any type of Proposition 65 warning. Prior to Plaintiff’s
22 Notice of Violation and this Complaint, Prestige failed to provide a Proposition 65 warning on the label
23 of the Subject Product. Prestige has, at all relevant times, been aware that the Subject Product contained
24 Phenazopyridine Hydrochloride and that persons using the Subject Product have been exposed to this
25 chemical.

26 30. Both prior and subsequent to Plaintiff’s Notice of Violation, Prestige failed to provide
27 consumers of the Subject Product with a clear and reasonable warning that they have been exposed to a
28

1 chemical known to the State of California to cause cancer, birth defects, and other reproductive harm.
2 This failure to warn is ongoing.

3 **CAUSES OF ACTION**

4 **First Cause of Action**

5 **(Violation of Section 25249.6 of the Health and Safety Code, Failure to Provide Clear and**
6 **Reasonable Warnings Under Proposition 65)**

7 31. Plaintiff incorporates by reference each and every allegation contained above.

8 32. By committing the acts alleged above, Prestige has, in the course of doing business,
9 knowingly and intentionally exposed users of the Subject Product to Phenazopyridine Hydrochloride, a
10 chemical known to the State of California to cause cancer, birth defects, and other reproductive harm,
11 without first giving clear and reasonable warnings to such individuals within the meaning of Health &
12 Safety Code section 25249.6. In doing so, Prestige has violated Health & Safety Code section 25249.6
13 and continues to violate the statute with each successive sale of the Subject Product.

14 33. Defendants are liable for a maximum civil penalty of \$2,500 per day for each violation of
15 Proposition 65 pursuant to Health and Safety Code, section 252497, subdivision (b). Injunctive relief is
16 also appropriate pursuant to Health and Safety Code, section 25249.7, subdivision (a).

17 **Second Cause of Action**

18 **(Declaratory Relief)**

19 34. Plaintiff incorporates by reference each and every allegation contained above.

20 35. There exists an actual controversy relating to the legal rights and duties of the Parties,
21 within the meaning of Code of Civil Procedure section 1060, between Plaintiff and Prestige, concerning
22 whether Prestige has exposed individuals to a chemical known to the State of California to cause cancer,
23 birth defects, and other reproductive harm without providing clear and reasonable warnings.

24 **PRAYER FOR RELIEF**

25 WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

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

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

5 3. On the Second Cause of Action, for a declaratory judgment pursuant to Code of Civil
6 Procedure section 1060 declaring that Prestige has exposed individuals to Phenazopyridine Hydrochloride
7 without providing clear and reasonable warnings;

8 4. On all Causes of Action, for reasonable attorneys' fees pursuant to Health & Safety Code
9 section 25249.7, Code of Civil Procedure section 1021.5, and/or the substantial benefit theory;

10 5. For costs of suit herein; and

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

12 DATED: May 3, 2023

KJC LAW GROUP, A.P.C.

13 By: /s/ Kevin J. Cole
Kevin J. Cole, Esq.

14 DATED: May 3, 2023

TAULER SMITH, LLP

15 By: /s/ Robert Tauler
16 Robert Tauler, Esq.

17 *Attorneys for Plaintiff Alex Martinez*

Exhibit A

Kevin J. Cole, Esq.
e-Mail: kevin@kjclawgroup.com

June 28, 2022

VIA CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Prestige Consumer Healthcare Inc.
c/o National Registered Agents, Inc.
1209 Orange Street
Wilmington, DE 19801

Prestige Consumer Healthcare Inc.
c/o William P'Pool, Senior Vice President, General Counsel and Corporate Secretary
660 White Plains Road
Tarrytown, New York 10591

Re: Proposition 65 Notice of Violation

Dear Mr. P'Pool:

We represent Alex Martinez ("Plaintiff"), a citizen of the State of California acting in the interest of the general public. This letter serves as Notice that Prestige Consumer Healthcare Inc. ("Prestige") is in violation of Proposition 65, the Safe Drinking Water and Toxic Enforcement Act, commencing with section 25249.5 of the Health and Safety Code ("Proposition 65"). In particular, the violation alleged by this Notice consists of types of harm that may potentially result from exposures to the toxic chemical Phenazopyridine Hydrochloride. This chemical was listed as a carcinogen on January 1, 1988.

The specific type of product that is causing exposures in violation of Proposition 65 is Prestige's Uristat® Urinary Tract Infection Pain Relief Tablets (the "Product"). The route of exposure for the violations is oral ingestion by consumers. These exposures occur through the reasonably foreseeable use of the Product. The sales of this Product have been occurring since at least July 2018, are continuing to this day and will continue to occur as long as the Product subject to this Notice is sold to and used by consumers.

Proposition 65 requires that a clear and reasonable warning be provided regarding exposures to Phenazopyridine Hydrochloride caused by ordinary use of the Product. Prestige is in violation of Proposition 65 by failing to provide such warnings to consumers. As a result of the sales of this Product, exposures to Phenazopyridine Hydrochloride have been occurring without proper warnings for years.

Based on the allegations set forth in this Notice, Plaintiff intends to file a citizen enforcement lawsuit against Prestige unless it agrees in a binding written instrument to: (1) immediately cease causing unwarned exposures to Phenazopyridine Hydrochloride; (2) provide clear and reasonable warnings for past and ongoing exposures to Phenazopyridine Hydrochloride from the Product; and (3) pay appropriate civil penalties based on the factors enumerated in California Health and Safety Code section 25249.7(b). If Prestige is interested in resolving this dispute without resort to litigation, please feel free to contact me. However, the parties cannot: (1) finalize any settlement until after the 60-day notice period has expired, nor (2) speak for the Attorney General or

any District or City Attorney who received the 60-day Notice. Therefore, while reaching an agreement with Plaintiff will resolve these claims, such agreement may not satisfy the public prosecutors.

This Notice also serves as a demand that Prestige preserve and maintain all relevant evidence, including all electronic documents and data, pending resolution of this matter. Such relevant evidence includes but is not limited to all documents relating to the use of Phenazopyridine Hydrochloride in the Product; efforts to comply with Proposition 65 with respect to the use of Phenazopyridine Hydrochloride in the Product; communications with any person relating to Phenazopyridine Hydrochloride in the Product; and the length of time at which Prestige sold the Product into the California marketplace.

If you have any questions or wish to discuss any of the above, please contact me.

Sincerely,



Kevin J. Cole, Esq.
KJC Law Group, A Professional Corporation

cc: Robert Tauler (Co-Counsel)
Tauler Smith LLP

See attached distribution list

Attachments:

- Certificate of Merit
- Certificate of Service
- Proposition 65 Summary (to the alleged violator only)
- Additional Supporting Information for Certificate of Merit (to the California Attorney General only)

CERTIFICATE OF MERIT

I, Kevin J. Cole, hereby declare:

1. This Certificate of Merit accompanies the attached sixty-day notice in which it is alleged the party identified in the notice has violated Health and 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 has reviewed facts, studies, or other data regarding the alleged exposure to the listed chemical that is the subject of the action.

4. Based on the information obtained through those consultations, and on all 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 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. The copy of this Certificate of Merit served on the Attorney General attaches to it factual information sufficient to establish the basis for this certificate, including the information identified in Health and Safety Code section 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: June 28, 2022

A handwritten signature in black ink, appearing to read 'Kevin J. Cole', with a stylized flourish at the end.

Kevin J. Cole, Esq.
KJC Law Group, A Professional Corporation

CERTIFICATE OF SERVICE

I, Chen Wang, declare that I am over the age of 18 years, and am not a party to the within action. I am employed in the County of Los Angeles, California, where the mailing occurs; and my business address is 9701 Wilshire Blvd., Suite 1000, Beverly Hills, CA 90212.

On June 28, 2022, I served the following documents: **(1) 60-DAY NOTICE OF VIOLATION SENT IN COMPLIANCE WITH HEALTH & SAFETY CODE SECTION 25249.7(d); (2) CERTIFICATE OF MERIT; (3) PROPOSITION 65: A SUMMARY; and (4) CERTIFICATE OF MERIT ATTACHMENT (served only on the Attorney General)** on the party listed below by placing a true and correct copy thereof in a sealed envelope, addressed to the party listed below and depositing it at my business address with the U.S. Postal Service for delivery by Certified Mail with the postage thereon fully prepaid:

Via Certified Mail

Prestige Consumer Healthcare Inc.
c/o National Registered Agents, Inc.
1209 Orange Street
Wilmington, DE 19801

c/o William P'Pool, Senior Vice President
General Counsel and Corporate Secretary
660 White Plains Road
Tarrytown, New York 10591

On June 28, 2022, I served the California Attorney General (via website Portal) by uploading a true and correct copy thereof as a PDF file via the California Attorney General's website.

On June 28, 2022, I transmitted via electronic mail the above-listed documents to the electronic mail addresses of the City and/or District Attorneys who have specifically authorized email service and the authorization appears on the Attorney General's website.

See Attached Service List

On June 28, 2022, I served the following persons and/or entities at the last known address by placing a true and correct copy thereof in a sealed envelope and depositing it at my business address with the U.S. Postal Service for delivery with the postage thereon fully prepaid, and addressed as follows:

See Attached Service List

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed on June 28, 2022 in Los Angeles, California.



Chen Wang

Appendix A

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT CALIFORNIA PROTECTION AGENCY THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACTION 1986 (PROPOSITION 65): A SUMMARY

The following summary has been prepared by the office of Environmental Health Hazard Assessment, the lead and Toxic Enforcement Act 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 law. The reader is directed to the statute and its implementing regulations (See citations below) for further information.

Proposition 65 appears in California law as Health and Safety Code Sections 25249.5 through 25249.13. 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 Regulations, Sections 250000 through 27000.

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, or birth defects or other reproductive harm. This list must be updated at least once a year. Over 725 chemicals have been listed as of November 16, 2001. Only those chemicals that are on the list are regulated under this law. Businesses that produce, use, release, or otherwise engage in activities involving those 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. 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. Exposures are exempt from the warning requirement if they occur less than twelve months after the date of the listing of the chemical.

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. Discharges are exempt from this requirement if they occur less than twenty months after the date of the listing of chemical.

DOES PROPOSITION 65 PROVIDE ANY EXEMPTIONS?

Yes. The law exempts:

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.

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 for more than 250 listed carcinogens.

Exposures that will produce no observable reproductive effect at 1,000 times the level in question. For chemicals known to the State to cause birth defects or other reproductive harm (“reproductive toxicants”), 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 (NOEL),” divided by a 1,000- fold safety or uncertainty factor. The “no observable effect level” is the highest dose level which has not been associated with an observable adverse reproductive or developmental effect.

Discharge 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 list chemical has not, does not, or will not enter any drinking water source, and that the discharge complies with all other applicable laws, regulations, permits, requirements, or orders. A “significant amount” means any

detectable amount; expect an amount that would meet the “ no significant risk” or “no observable effect” test if an individual were exposed to such an amount in drinking water.

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 (those in cities with a population exceeding 750,000). Lawsuit 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. A notice must comply with the information and procedural requirements specified in regulations (Title 27. California Code of Regulations, Section 25903). A private party may not pursue an enforcement action directly under Proposition 65 if one of the governmental officials noted above initiates an action within sixty days of 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 of law to stop committing the violation.

FOR FURTHER INFORMATION...

Contact the Office of Environmental Health Hazard Assessment= Proposition 65 Implementation Office at (916)445-6900

E-Mail Service List

Stacey Grassini, Deputy District Attorney
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sggrassini@contracostada.org

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