

NOTICE OF VIOLATION

California Safe Drinking Water and Toxic Enforcement Act

Phenazopyridine Hydrochloride in Urinary Tract Infection (UTI) Pain Relief Products

July 18, 2025

This Notice of Violation (the "Notice") is provided to you pursuant to and in compliance with California Health and Safety Code Section 25249.7(d).

- For general information regarding the California Safe Drinking Water and Toxic Enforcement Act, see the attached summary provided by the California EPA (copies not provided to public enforcement agencies).
- This Notice is provided by the Center for Environmental Health ("CEH"), 2201 Broadway, Suite 508, Oakland, CA 94612, (510) 655-3900. CEH is a nonprofit corporation dedicated to protecting the environment, improving human health, and supporting environmentally sound practices. Shakoora Azimi-Gaylon is the Senior Director of the Toxic Exposures and Pollution Prevention Program and a responsible individual within CEH.

Description of Violation:

- Violators: The names and addresses of the violators are identified on the attached Exhibit 1.
- Time Period of Exposure: The violations have been occurring since at least July 18, 2022, are continuing to this day and will continue to occur as long as the products subject to this Notice are sold to and used by California consumers.
- Provision of Proposition 65: This Notice covers the "warning provision" of Proposition 65, which is found at California Health and Safety Code Section 25249.6.
- Chemical(s) Involved: The name of the listed chemical involved in these violations is phenazopyridine hydrochloride.
- Type of Product: The specific type of product causing these violations are urinary tract infection (UTI) pain relief products. Non-exclusive examples of these types of products are identified on the attached Exhibit 1.
- Description of Exposure: This Notice addresses consumer exposures to phenazopyridine hydrochloride. Use of the products identified in this Notice results in human exposures to phenazopyridine hydrochloride. The products contain phenazopyridine hydrochloride as an intentionally added ingredient. The route of exposure for the violations is ingestion by consumers. These exposures occur through the reasonably foreseeable use of the products when, for example,

individuals ingest the products to provide pain relief for urinary tract infections. No clear and reasonable warning is provided with these products regarding the exposures to phenazopyridine hydrochloride caused by ordinary use of the products.

Resolution of Noticed Claims:

Based on the allegations set forth in this Notice, CEH intends to file a citizen enforcement lawsuit against the alleged violators unless such violators agree in a binding written instrument to: (1) recall products already sold; (2) provide clear and reasonable warnings for products sold in the future or reformulate such products to eliminate the phenazopyridine hydrochloride exposures; and (3) pay an appropriate civil penalty based on the factors enumerated in California Health and Safety Code Section 25249.7(b). If the alleged violators are interested in resolving this dispute without resort to expensive and time-consuming litigation, please feel free to contact CEH through its counsel identified below. It should be noted that CEH 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 CEH's 60-day Notice. Therefore, while reaching an agreement with CEH will resolve its claims, such agreement may not satisfy the public prosecutors.

Preservation of Relevant Evidence:

This Notice also serves as a demand that the alleged violators 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 presence or potential presence of phenazopyridine hydrochloride in urinary tract infection symptom treatment drugs; purchase and sales information for such products; efforts to comply with Proposition 65 with respect to such products; communications with any person relating to the presence or potential presence of phenazopyridine hydrochloride in such products; and representative exemplars of each of the products sold by the alleged violators in the year preceding this Notice through the date of any trial of the claims alleged in this Notice.

Please direct any inquiries regarding this Notice to CEH's counsel, Meredyth Merrow, at Lexington Law Group, LLP 503 Divisadero Street, San Francisco, CA 94117, (415) 913-7800, mmerrow@lexlawgroup.com.

CERTIFICATE OF MERIT
Health & Safety Code § 25249.7(d)

I, Meredyth Merrow, hereby declare:

1. This Certificate of Merit accompanies the attached sixty-day notice in which it is alleged that the parties identified in the notice have violated Health & Safety Code § 25249.6 by failing to provide clear and reasonable warnings.

2. I am an attorney at Lexington Law Group, LLP, and I represent the noticing party, the Center for Environmental Health.

3. Members of my firm and 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 exposures to the listed chemical that is the subject of the action.

4. Based on the information obtained through those consultations, and on other information in my possession, I believe there is a reasonable and meritorious case for the private action. I understand that “reasonable and meritorious case for the private action” means that the information provides a credible basis that all elements of the plaintiff’s case can be established and the information did not prove that the alleged violators will be able to establish any of the affirmative defenses set forth in the statute.

5. The copy of the 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 & 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.

July 18, 2025



Meredyth Merrow
Attorney for CENTER FOR
ENVIRONMENTAL HEALTH

EXHIBIT 1
July 18, 2025 Notice of Violation
Phenazopyridine Hydrochloride in Urinary Tract Infection (UTI) Pain Relief Products

Names and Addresses of Responsible Parties	Non-Exclusive Examples of the Products	SKU or Further Description
Prestige Consumer Healthcare, Inc. 660 White Plains Rd, Tarrytown, NY 10591	Uristat Ultra Maximum Strength UTI Pain Relief Tablets with Cranberry flavored coating (30 urinary pain relief tablets); Phenazopyridine HCl 99.5 mg/ Urinary analgesic	UPC: 363736111540; Lot: 488724; Exp: 07/2026
Insight Pharmaceuticals LLC National Registered Agents, Inc. 28 Liberty Street New York, NY 10005	Maintain UTI 2-in-1 Test + Pain Relief Kit, Phenazopyridine HCl 99.5 mg/ Urinary analgesic with cranberry flavored coating; 2 UTI test strips, 12 urinary pain relief tablets	UPC: 363736000844; Lot: 508284; Exp: 11/2026

1 **PROOF OF SERVICE**

2 I, Sophia Filipe, declare:

3 I am a citizen of the United States and employed in the County of San Francisco, State of
4 California. I am over the age of eighteen (18) years and not a party to this action. My business
5 address is 503 Divisadero Street, San Francisco, CA 94117 and my email address is
sfilipe@lexlawgroup.com.

6 On July 18, 2025, I served the following document(s) on all interested parties in this
7 action by placing a true copy thereof in the manner and at the addresses indicated below:

8 **NOTICE OF VIOLATION OF CALIFORNIA SAFE DRINKING WATER AND
TOXIC ENFORCEMENT ACT;**

9 **CERTIFICATE OF MERIT;** and

10 **THE SAFE DRINKING AND TOXIC ENFORCEMENT ACT OF 1986**
11 **(PROPOSITION 65): A SUMMARY** (only sent to those on service list marked with an
asterisk).

12 ☒ **BY MAIL:** I am readily familiar with the firm's practice for collecting and processing mail
13 with the United States Postal Service ("USPS"). Under that practice, mail would be deposited
14 with USPS that same day with postage thereon fully prepaid at San Francisco, California in the
ordinary course of business. On this date, I placed sealed envelopes containing the above
mentioned documents for collection and mailing following my firm's ordinary business practices.

15 *Please see attached service list.*

16 ☒ **BY ELECTRONIC UPLOAD:** I transmitted a PDF version of the document(s) listed above,
17 as well as a Confidential Supporting Certificate of Merit, to the Office of the Attorney General of
California via the Proposition 65 60-Day Notice Search website at [https://oag.ca.gov/prop65/60-](https://oag.ca.gov/prop65/60-day-notice-search)
18 [day-notice-search](https://oag.ca.gov/prop65/60-day-notice-search).

19 ☒ **BY ELECTRONIC MAIL:** I transmitted a PDF version of the document(s) listed above via
20 email to the email address(es) indicated on the attached service list [or noted above] before 5 p.m.
on the date executed.

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13 I declare under penalty of perjury under the laws of the State of California that the
14 foregoing is true and correct.

14 Executed on July 18, 2025 at San Francisco, California.



Sophia Filipe

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