

NOTICE OF VIOLATION

California Safe Drinking Water and Toxic Enforcement Act

N-Nitrosodimethylamine (NDMA) in OTC Ranitidine Products

December 20, 2019

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 302, Oakland, CA 94612, (510) 655-3900. CEH is a nonprofit corporation dedicated to protecting the environment, improving human health, and supporting environmentally sound practices. Caroline Cox is the Senior Scientist 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 December 20, 2016, and are ongoing.
- 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 chemicals involved in these violations is n-nitrosodimethylamine ("NDMA"). Exposures to NDMA occur from ingesting the products identified in this Notice.
- Type of Product: The specific type of product causing these violations is over-the-counter acid reducing medications containing ranitidine ("Ranitidine Products"). Non-exclusive examples of this specific type of product are identified on the attached Exhibit 1.
- Description of Exposure: This Notice addresses consumer exposures to NDMA in Ranitidine Products. Taking Ranitidine Products identified in this Notice results in human exposures to NDMA. The primary route of exposure for the violations is direct ingestion when consumers take the Ranitidine Products. No clear and reasonable warning is provided with the Ranitidine Products regarding the carcinogenic hazards of NDMA.

Resolution of Noticed Claims:

Based on the allegations set forth in this Notice, CEH intends to file a citizen enforcement lawsuit against each alleged violator unless such violator agrees 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 NDMA exposures; and (3) pay an appropriate civil penalty based on the factors enumerated in California Health and Safety Code Section 25249.7(b). If any alleged violator is 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 each alleged violator 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 NDMA in OTC Ranitidine Products; 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 NDMA in such products; and representative exemplars of each of the products sold by each alleged violator 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 Mark N. Todzo at Lexington Law Group, 503 Divisadero Street, San Francisco, CA 94117, (415) 913-7800, mtodzo@lexlawgroup.com.

EXHIBIT 1
December 20, 2019 Notice of Violation
NDMA in Ranitidine Products

Names and Addresses of Responsible Parties	Non-Exclusive Examples of the Products	UPC #
<p style="text-align: center;">7-Eleven, Inc. 3200 Hackberry Road Irving, TX 75063</p> <p style="text-align: center;">Perrigo Company 515 Eastern Avenue Allegan, Michigan 49010</p>	<p style="text-align: center;">7 Select Heartburn & Acid Reducer</p>	<p style="text-align: center;">0-52548-56121-5</p>

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

I, Mark N. Todzo, 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.

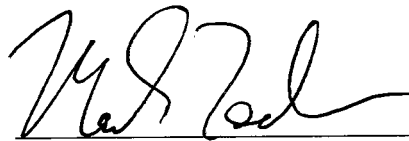
2. I am an attorney with the Lexington Law Group, and I represent the noticing party, the Center for Environmental Health.

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.

December 20, 2019



Mark N. Todzo
Attorney for CENTER FOR
ENVIRONMENTAL HEALTH

1 **PROOF OF SERVICE**

2
3 I, Nick Redfield, declare:

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

8 On December 20, 2019, I served the following document(s) on all interested parties in this
9 action by placing a true copy thereof in the manner and at the addresses indicated below:

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

12 **CERTIFICATE OF MERIT; and**

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

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

21 *Please see attached service list.*

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

25 Stacey Grassini, Deputy District Attorney
26 Contra Costa County
27 900 Ward Street
28 Martinez, CA 94553
sgrassini@contracostada.org

Allison Haley, District Attorney
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3 4075 Main Street
4 Riverside, CA 92501
5 Prop65@rivcoda.org

6 Jeff W. Reisig, District Attorney
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16 Tori Verber Salazar, District Attorney
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18 222 E. Weber Avenue, Room 202
19 Stockton, CA 95202
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21 Christopher Dalbey, Deputy District
22 Attorney, Santa Barbara County
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26 San Francisco City Attorney's Office
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Office of the District Attorney
Calaveras County
891 Mountain Ranch Road
San Andreas, CA 95249
Prop65Env@co.calaveras.ca.us

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

25 Executed on December 20, 2019 at San Francisco, California.

26
27
28 
Nick Redfield

SERVICE LIST

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

District Attorney of Amador County
708 Court Street, Ste. 202
Jackson, CA 95642

District Attorney of Butte County
Administration Building
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District Attorney of Yuba County
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Marysville, CA 95901

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City Hall East
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Los Angeles, CA 90012

San Jose City Attorney's Office
200 East Santa Clara Street
San Jose, CA 95113

California Attorney General's Office
Attention: Proposition 65 Coordinator and
Robert Thomas
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P.O. Box 70550
Oakland, CA 94612-0550

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Murray Kessler, CEO
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