

60-DAY NOTICE OF VIOLATION OF CALIFORNIA HEALTH & SAFETY CODE § 25249.7(d) (PROPOSITION 65)

Date: November 19, 2024
To: Jeffrey Haines, Chief Executive Officer, Ortho Systems;
California Attorney General’s Office;
District Attorney’s Office for 58 Counties; and
City Attorneys for San Francisco, San Diego, San Jose, Sacramento & Los Angeles
From: Keep America Safe and Beautiful

I. INTRODUCTION

Keep America Safe and Beautiful is a California nonprofit corporation acting in the public interest pursuant to California Health & Safety Code § 25249.7(d). Keep America Safe and Beautiful seeks to promote awareness of exposures to toxic chemicals in products sold in California and, if possible, to improve human health by eliminating hazardous substances contained in such items, promoting corporate responsibility.

This 60-Day Notice of Violation (“**Notice**”) is being provided to the alleged violator, Ortho Systems (“**Notice Recipient**”), as well as the California Attorney General’s Office, the District Attorney’s Offices for 58 Counties, and City Attorneys for San Francisco, San Diego, San Jose, Sacramento and Los Angeles.

Keep America Safe and Beautiful provides this Notice after identifying violations of California’s Safe Drinking Water and Toxic Enforcement Act of 1986, codified at California Health & Safety Code § 25249.5 *et seq.* (“**Proposition 65**”), based on the failure to provide a clear and reasonable health hazard warning in connection with the sale or use of the products, listed below, in the State of California. The Notice Recipient is hereby given notice it violated and continues to violate Proposition 65 with respect to the warning requirement, codified at California’s Health & Safety Code § 25249.6: “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 a clear and reasonable warning to such individual.” Without proper warnings about the toxic effects of exposures to listed chemicals, citizens in California lack the information necessary to make an informed decision as to whether or how to eliminate or reduce their risk of exposure from the reasonably foreseeable use of products containing listed chemicals.

II. NATURE OF ALLEGED VIOLATIONS

Product. The specific type or category of products (“**Products**”) that are the subject of this Notice are as follows:

Exemplar Product	Category/Type	Retailer	Manufacturer/Distributor
Ovation Medical Pneumatic Ankle Stirrup, White Standard/Universal SKU: 2000W	Pneumatic Ankle Stabilizers with Vinyl Components	DME Direct dme-direct.com	Ortho Systems

Identified above is a specific example of Products recently purchased and witnessed as being available for sale or use in the State of California, within the *category* of offending products

covered by this Notice. The identified retailers, manufacturers and/or distributors of the Products are based on publicly available information.

The Exemplar Product is identified for the Notice Recipient's benefit to assist in its investigation into the alleged violations that are the subject of this Notice. The specific identified Exemplar Product is not intended to be an exhaustive list of all such products potentially in violation of Proposition 65. The Notice Recipient is now obligated to conduct a good faith investigation into other products within the category or of the type, identified above, that were manufactured, imported, sold or distributed for sale, or that have otherwise been in the Notice Recipient's custody or control during the relevant period, identified below, to ensure the requisite health hazard warnings are provided to individuals in California prior to purchase.

Listed Chemical. The chemical that is the subject of this Notice is Di-n-Butyl Phthalate("DBP"). The State of California listed DBP as a chemical known to cause reproductive and developmental toxicity on December 2, 2005.

Routes of Exposure. The exposures subject to this Notice result from the purchase, acquisition and handling of Products containing DBP. Exposures occur when individuals, including children and women of childbearing age, handle, touch or otherwise utilize pneumatic ankle stabilizers with vinyl components containing DBP in accordance with the Products' reasonably foreseeable and intended uses, resulting in exposures through ingestion and dermal absorption. Individuals ingest DBP when they touch or handle the Products or intermediary objects, transferring the chemicals from their fingers or hands to their mouths. Dermal absorption of DBP occurs when individuals handle, touch, or utilize the Products.

The California State Plan for Occupational Safety and Health incorporates the provisions of Proposition 65, as approved by Federal OSHA on June 6, 1997. This approval specifically placed certain conditions with regard to occupational exposures on Proposition 65, including that it does not apply to the conduct of manufacturers occurring outside the State of California. The approval also provides that an employer may use the means of compliance in the general hazard communication requirements to comply with Proposition 65. It also requires that supplemental enforcement is subject to the supervision of the California Occupational Safety and Health Administration. Accordingly, any settlement, civil complaint, or substantive court orders in this matter must be submitted to the Attorney General.

Violations and Time Period of Exposure. Keep America Safe and Beautiful alleges the Notice Recipient knowingly and intentionally exposed, and continues to knowingly and intentionally expose, individuals within the State of California to DBP without first giving a health hazard warning regarding the chemical's toxic effects, as required by Proposition 65, by failing to provide clear and reasonable warnings to consumers and users that the Products can expose users to DBP.

Exposures caused by the use of the Products have occurred each day since the Products were introduced into the California marketplace, but, at a minimum, since November 19, 2023, and, potentially, as far back as November 19, 2021. Because the Products lack clear and reasonable warnings regarding the toxic effects of exposures to DBP, each Product sold during this period and not accompanied by a warning constitutes a violation by the Notice Recipient and/or other sellers of the Products, whether sold directly through retailers located in, or with locations in, California, via the internet, or through catalog purchases by customers and individuals located in California. Moreover, these exposures are ongoing and will continue either until clear and

reasonable warnings are provided to protect consumers and users or until these known toxic chemicals are removed from the Products or reduced to allowable levels.

III. RESOLUTION OF NOTICED CLAIMS

Consistent with the public interest goals of Proposition 65, Keep America Safe and Beautiful seeks to pursue a constructive resolution of this matter to quickly rectify ongoing violations of California law. To that end, based on the allegations set forth in this Notice and pursuant to Health & Safety Code § 25249.7(d), Keep America Safe and Beautiful intends to file a private enforcement action in the public interest sixty (60) days after effective service of this Notice, unless the appropriate public enforcement agencies have commenced and are diligently prosecuting an action to rectify these allegations. If the Notice Recipient seeks to resolve the claims alleged in this Notice without litigation, it may contact Keep America Safe and Beautiful’s counsel at the address listed below.

It should be noted neither Keep America Safe and Beautiful or its counsel can: (1) finalize any settlement until after the expiration of the 60-day Notice period; or (2) speak for the California Attorney General or any District or City attorney in receipt of this Notice. Therefore, while reaching an agreement with Keep America Safe and Beautiful will satisfy its claims, the agreement may not satisfy any public prosecutors.

IV. GENERAL INFORMATION AND SUMMARY OF PROPOSITION 65

A copy of a summary of Proposition 65’s provisions, prepared by the Office of Environmental Health Hazard Assessment (“**OEHHA**”) is enclosed with the copy of the Notice served on the Notice Recipient for its reference. For further general information concerning Proposition 65, contact OEHHA’s Proposition 65 Implementation Office at (916) 445-6900.

V. CERTIFICATE OF MERIT

Pursuant to Health & Safety Code § 25249.7(d) and Cal. Code. Regs. tit 11, § 3100, a Certificate of Merit is attached hereto. A copy of the Notice and Certificate of Merit is served on the California Attorney General and marked “Attorney General Copy: Contains Official Information Pursuant to Evidence Code Section 1040” with all supporting documentation, as required by Cal. Code. Regs. tit 11, § 3102, attached thereto.

VI. CONTACT INFORMATION

Please direct all questions, issues or communications regarding this 60-Day Notice of Violation and its potential resolution to Keep America Safe and Beautiful’s counsel at the following address:

Keep America Safe and Beautiful
c/o Rebecca Jackson, Esq.
Seven Hills LLP
4 Embarcadero Center, Suite 1400
San Francisco, California 94111
Telephone: (415) 926-7247
Email: rebecca@sevenhillsllp.com

Represented private enforcer’s
contact information:
Lance Nguyen, CEO
Keep America Safe and Beautiful
10512 Sycamore Avenue
Stanton, California 90680
Telephone: (657) 621-3809

Attachments: Certificate of Merit; Proof of Service; Appendix A: The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65); A Summary (to Violator only); and Additional Confidential Supporting Information for Certificate of Merit (to Attorney General only.)

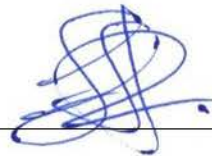
CERTIFICATE OF MERIT
Health and Safety Code § 25249.7(d)

Re: Keep America Safe and Beautiful's Notice of Proposition 65 Violations

I, Laralei Paras, hereby declare:

1. This Certificate of Merit accompanies the attached sixty-day notice in which it is alleged the party identified in the notice violated Health & Safety Code § 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 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. 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 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: November 19, 2024



Laralei Paras

PROOF OF SERVICE

I, the undersigned, declare under penalty of perjury:

I am over the age of 18 years of age and not a party to this case. Seven Hills LLP's business address is 4 Embarcadero Center, Suite 1400, San Francisco, CA 94111.

On November 19, 2024, I caused to be served the following:

**60-DAY NOTICE OF VIOLATION SENT IN COMPLIANCE WITH
HEALTH & SAFETY CODE § 25249.7(d);
THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF
1986 (PROPOSITION 65): A SUMMARY; and
CERTIFICATE OF MERIT**

XXXX by **Certified First Class Mail** through the United States Postal Service by placing true and correct copies of the above documents in a sealed envelope, individually addressed to each alleged violator listed below and providing such envelope to a United States Postal Service Representative:

Jeffrey Haines, CEO
Ortho Systems
5155 Clareton Drive # 202
Agoura Hills, CA 91301

Ortho Systems
c/o Ira Rosenblatt, Registered Agent
23901 Calabasas Rd., Ste 2006
Calabasas, CA 91302

On November 19, 2024, I caused to be served true and correct copies of the following documents:

**60-DAY NOTICE OF VIOLATION SENT IN COMPLIANCE WITH
HEALTH & SAFETY CODE § 25249.7(d); and
CERTIFICATE OF MERIT**

XXXX by **First Class Mail** through the United States Postal Service by placing copies of the above documents in a sealed envelope, addressed to each entity on the attached "Service List" and providing such envelope to a United States Postal Representative, with correct postage.

XXXX via **Electronic Mail**, by sending copies of the above documents, addressed individually, to the Recipients listed on the attached "Electronic Mail Service List".

On November 19, 2024, I caused to be served true and correct copies of the following documents:

**60-DAY NOTICE OF VIOLATION SENT IN COMPLIANCE WITH
HEALTH & SAFETY CODE § 25249.7(d);
CERTIFICATE OF MERIT; and
CERTIFICATE OF MERIT ATTACHMENTS**

XXXX via **Electronic Mail**, by uploading the documents, addressed to California Attorney General at their website address, listed under the "Electronic Upload Service List".

Executed on the 19th day of November 2024, at Folsom, California.



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SERVICE LIST

The Honorable Michael Atwell Alpine County District Attorney P.O. Box 248 Markleeville, CA 96120	The Honorable Jackie Lacey Los Angeles County District Attorney 211 West Temple Street, Ste 1200 Los Angeles, CA, 90012	The Honorable Todd Riebe Amador County District Attorney 708 Court Street, #202 Jackson, CA 95642
The Honorable Michael Ramsey Butte County District Attorney 25 County Center Drive, Suite 245 Oroville, CA 95965	The Honorable Matthew R. Beauchamp Colusa County District Attorney 346 5th Street, Suite 101 Colusa, CA 95932	Del Norte County District Attorney 450 H street, Room 171 Crescent City, CA 95531
The Honorable Vern Pierson El Dorado County District Attorney 778 Pacific Street Placerville, CA 95667	The Honorable Gilbert Otero Imperial County District Attorney 940 West Main Street, Suite 102 El Centro, CA 92243	The Honorable Dwayne Stewart Glenn County District Attorney P.O. Box 430 Willows CA 95988
The Honorable Maggie Fleming Humboldt County District Attorney 825 5 th Street, 4 th Floor Eureka, CA 95501	The Honorable Donald Anderson Lake County District Attorney 255 N. Forbes Street Lakeport, CA 95453	The Honorable Lisa Green Kern County District Attorney 1215 Truxtun Avenue Bakersfield, CA 93301
The Honorable Keith Fagundes Kings County District Attorney 1400 West Lacey Blvd. Hanford, CA 93230	The Honorable Mike Feuer Office of the City Attorney, Los Angeles Kames K. Hahn Hall East 200 North Main Street, 8 th Floor Los Angeles, CA 90012	Sally O. Moreno, District Attorney Madera County Justice Center 300 South G Street, Suite 300 Madera, CA 93637
The Honorable Jordan Funk Modoc County District Attorney 204 S. Court Street Room 202 Alturas, CA 96101	The Honorable Todd Spitzer Orange County District Attorney 300 North Flower Street Santa Ana, CA 92703	The Honorable C. David Eyster Mendocino County District Attorney P.O. Box 1000 Ukiah, CA 9548
The Honorable Birgit Fladager Stanislaus County District Attorney 832 12th street, Suite 300 Modesto, CA 95353	The Honorable Candace Hooper San Benito District Attorney 419 4th Street Hollister, CA 95023	The Honorable Tim Kendall Mono County District Attorney P.O. Box 2053 Mammoth Lakes, CA 93546
The Honorable Stephen Wagstaffe San Mateo County District Attorney 400 County Center, Third Floor Redwood City, CA 94063	The Honorable Michael Ramos San Bernardino County District Attorney 303 W. Third Street San Bernardino, CA 92415	The Honorable Stephanie Bridgett Shasta County District Attorney 1355 West Street Redding, CA 96001
The Honorable James Kirk Andrus Siskiyou County District Attorney P.O. Box 986 Redding, CA 96097	The Honorable Krishna Abrams Solano County District Attorney 675 Texas Street, Suite 4500 Fairfield, CA 94533	The Honorable Amanda Hopper Sutter County District Attorney 446 Second Street, Suite 102 Yuba City, CA 95991
The Honorable Laura Krieg Tuolumne County District Attorney 423 N. Washington Street Sonora, CA 95370	The Honorable James Sanchez Office of the City Attorney, Sacramento 915 I Street, 4 th Floor Sacramento, CA 95814	The Honorable Eric Heryford Trinity County District Attorney P.O. Box 310 Weaverville, CA 96093
The Honorable Lawrence Allen Sierra County District Attorney 100 Courthouse Square Downieville, CA 95936	The Honorable Gregg Cohen Tehama County District Attorney P.O. Box 519 Red Bluff, CA 96080	The Honorable Patrick McGrath Yuba County District Attorney 215 Fifth street, Suite 152 Marysville, CA 95901

ELECTRONIC MAIL SERVICE LIST

The Honorable Nancy O'Malley Alameda County District Attorney 7776 Oakport Street, Suite 650 Oakland, CA 94621 CEPDProp65@acgov.org	The Honorable Tori Verber Salzar San Joaquin County District Attorney 222 E. Weber Avenue, Room 202 Stockton, CA 95202 DAConsumer.Environmental@sjcda.org	Honorable Anne Marie Schubert Sacramento County District Attorney 901 G Street Sacramento, CA 95814 Prop65@sacda.org
The Honorable Allison Haley Napa County District Attorney 1127 First St., Suite C Napa, CA 94559 CEPD@countyofnapa.org	The Honorable Jeffrey S. Rosell Santa Cruz County District Attorney 701 Ocean Street Santa Cruz, CA 95060 Prop65DA@santacruzcounty.us	The Honorable Summer Stephan San Diego County District Attorney 300 West Broadway San Diego, CA 92101 SanDiegoDAProp65@sdcda.org
The Honorable Jeff W. Reisig Yolo County District Attorney 301 Second Street Woodland, CA 95695 cfepd@yolocounty.org	Michelle Latimer, Program Coordinator Lassen County 220 S. Lassen Street Susanville, CA 96130 mlatimer@co.lassen.ca.us	Mark Ankcorn, Deputy City Attorney City of San Diego 1200 Third Avenue San Diego, CA 92101 CityAttyProp65@sandiego.gov
Bud Porter Supervising Deputy District Attorney Santa Clara County 70 W Hedding Street San Jose, CA 95110 EPU@da.sccgov.org	Alethea M. Sargent Assistant District Attorney San Francisco District Attorney's Office 350 Rhode Island Street San Francisco, CA 94103 alethea.sargent@sfgov.org	Christopher Dalbey, Deputy District Attorney Santa Barbara County 1112 Santa Barbara Street Santa Barbara, CA 93101 DAProp65@co.santa-barbara.ca.us
The Honorable Gregory D. Totten, Ventura County District Attorney 800 S Victoria Avenue Ventura, CA 93009 daspecialops@ventura.org	The Honorable Barbara Yook Calaveras County District Attorney 891 Mountain Ranch Road San Andreas, CA 95249 Prop65Env@co.calaveras.ca.us	Henry Lifton, Deputy City Attorney Office of the City Attorney 1390 Market Street, 7 th Floor San Francisco, CA 94102 Prop65@sfcityattorney.org
Stacey Grassini Deputy District Attorney Contra Costa County 900 Ward Street Martinez, CA 94553 sgrassini@contracostada.org	Eric J. Dobroth Deputy District Attorney San Luis Obispo County County Govt Center Annex, 4 th Floor San Luis Obispo, CA 93408 edobroth@co.slo.ca.us	Jeanne M. Pacioni Deputy District Attorney Monterey County 1200 Aguajito Road Monterey, CA 93940 Prop65DA@co.monterey.ca.us
The Honorable Thomas Hardy Inyo County District Attorney 168 N. Edwards Street Independence, CA 93526 inyoda@inyocounty.us	The Honorable Phillip J. Cline Tulare County District Attorney 221 S Mooney Blvd Visalia, CA 95370 Prop65@co.tulare.ca.us	The Honorable Clifford Newell Nevada County District Attorney 201 Commercial Street Nevada City, CA 95959 DA.Prop65@co.nevada.ca.us
The Honorable Paul E. Zellerbach Riverside County District Attorney 3072 Orange Street Riverside, CA 92501 Prop65@rivcoda.org	The Honorable Stephan Passalacqua Sonoma County District Attorney 600 Administration Drive Sonoma, CA 95403 ECLD@sonoma-county.org	The Honorable David Hollister Plumas County District Attorney 520 Main Street, Room 404 Quincy, CA 95971 davidhollister@countyofplumas.com
The Honorable Walter W. Wall Mariposa County District Attorney P.O. Box 730 Mariposa, CA 95338 mcd@mariposacounty.org	The Honorable Kimberly Lewis Merced County District Attorney 550 West Main Street Merced, CA 95340 Prop65@countyofmerced.com	The Honorable Morgan Briggs Gire Placer County District Attorney 10810 Justice Center Drive Roseville, CA 95678 prop65@placer.ca.gov
Nora V. Frimann, City Attorney 200 E. Santa Clara Street, 16th Floor San Jose, CA 96113 Proposition65notices@sanjoseca.gov	Lisa A. Smittcamp, District Attorney 2100 Tulare Street Fresno, CA 93721 consumerprotection@fresnocountyca.gov	The Honorable Edward Berberian Marin County District Attorney 3501 Civic Center Drive, Room 130 San Rafael, CA 94903 consumer@marincounty.org

ELECTRONIC UPLOAD SERVICE LIST

Office of the California Attorney General
Proposition 65 Enforcement Reporting
ATTN: Prop 65 Coordinator
P.O. Box 70550
Oakland, CA 94612-0550
<https://oag.ca.gov/prop65/add-60-day-notice>