#### NOTICE OF VIOLATION

# California Safe Drinking Water and Toxic Enforcement Act

January 17, 2020

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 ("Proposition 65"), please see the attached summary prepared by California's Office of Environmental Health Hazard Assessment.
- This Notice is provided by Maria Elizabeth Romero, a concerned citizen of the State of California and resident of Monterey County.

### **Description of Violation:**

- Violators: BioVision, Inc.
- <u>Time Period of Exposure</u>: The violations have been occurring since at latest January 17, 2018, and are ongoing.
- <u>Statutory Authority</u>: This Notice is provided for failure to comply with the warning requirements of Proposition 65, found at California Health and Safety Code section 25249.6.
- <u>Chemicals Involved</u>: The chemicals involved in these violations are listed in Attachment B hereto, and have been identified by the State of California as causing cancer or reproductive harm.
- <u>Type of Product</u>: All products offered for sale by BioVision, Inc. on the Web site at <a href="https://www.biovision.com">https://www.biovision.com</a> whose primary component is a chemical listed on Attachment B ("Covered Products").
- <u>Description of Exposure</u>: Student use of the Covered Products in academic laboratories results in human exposure to toxic chemicals via dermal contact, eye contact, ingestion, inhalation, and accidental injection. No clear and reasonable warning of toxicity is provided by BioVision, Inc. in connection with the Covered Products.

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#### **Resolution of Noticed Claim:**

Within the next 60 days, California's Office of the Attorney General and other government attorneys may choose to bring an enforcement action against you in this matter. After this time, Mrs. Romero will file a citizen enforcement lawsuit against you unless you agree in a binding written settlement to: (1) provide Proposition 65-compliant warnings to California residents prior to sales of products containing Listed Chemicals; (2) provide Proposition 65-compliant warnings on the labels of Covered Products sold to California residents (to protect end users); and (3) require that any entity involved in resale of Covered Products also provide compliant warnings – or to cease all sales to residents of California. Any settlement agreement will also contain an enforcement mechanism providing for substantial penalties in case of non-compliance. Please note that final resolution of this matter will be subject to the oversight and approval of public prosecutors.

#### **Contact Us:**

Please consider this a formal notice of anticipated litigation and demand that BioVision, Inc. preserve all evidence related to sales of the Covered Products or to warnings of product toxicity, including sales records, Web pages, data sheets, written sales protocols and procedures, product labels, box labels, and internal correspondence. Any inquiries regarding this notice should be directed to Mrs. Romero's counsel, Benjamin D. Weston, with Agency D&L, 1968 South Coast Highway, Suite 1200, Laguna Beach, California 92651. Mr. Weston may be contacted by telephone at 650.250.5075, by facsimile at 650.206.9844 and by e-mail at ben@agencydl.com.

Enclosures:
Appendix A (BioVision copy only)
Attachment B
Certificate of Merit
Proof of Service
Factual Information (A.G. copy only)

#### 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 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.

The text of Proposition 65 (Health and Safety Code Sections 25249.5 through 25249.13) 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 "Proposition 65 List." Under Proposition 65, the lead agency (OEHHA) publishes a list of chemicals that are known to the State of California to cause cancer and/or reproductive toxicity. 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 damage to

<sup>&</sup>lt;sup>1</sup> 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.

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: <a href="http://www.oehha.ca.gov/prop65/prop65\_list/Newlist.html">http://www.oehha.ca.gov/prop65/prop65\_list/Newlist.html</a>.

Only those chemicals that are on the list are regulated under Proposition 65. 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. 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 to that chemical. 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 under Proposition 65 as known to the State to cause cancer, a warning is not required if the business causing the exposure 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 causing the exposure 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 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 Food.** Certain exposures to chemicals that naturally occur in foods (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 contaminant<sup>2</sup> 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 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.

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<sup>&</sup>lt;sup>2</sup> 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 Title 27 and sections 3100-3103 of Title 11. A private party may not pursue an independent enforcement action under Proposition 65 if one of the governmental officials noted above initiates an enforcement 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.

A private party may not file an enforcement action based on certain exposures if the alleged violator meets specific conditions. For the following types of exposures, the Act provides an opportunity for the business to correct the alleged violation:

- An exposure to alcoholic beverages that are consumed on the alleged violator's premises to the extent onsite consumption is permitted by law;
- An exposure to a Proposition 65 listed chemical in a food or beverage prepared and sold on the alleged violator's premises that is primarily intended for immediate consumption on- or off-premises. This only applies if the chemical was not intentionally added to the food, and was formed by cooking or similar preparation of food or beverage components necessary to render the food or beverage palatable or to avoid microbiological contamination;
- An exposure to environmental tobacco smoke caused by entry of persons (other than employees) on premises owned or operated by the alleged violator where smoking is permitted at any location on the premises;
- An exposure to listed chemicals in engine exhaust, to the extent the exposure occurs inside a facility owned or operated by the alleged violator and primarily intended for parking non-commercial vehicles.

If a private party alleges that a violation occurred based on one of the exposures described above, the private party must first provide the alleged violator a notice of special compliance procedure and proof of compliance form.

A copy of the notice of special compliance procedure and proof of compliance form is included in Appendix B and can be downloaded from OEHHA's website at: http://oehha.ca.gov/prop65/law/p65law72003.html.

#### 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.

Revised: May 2017

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5, 25249.6, 25249.7, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

## Agency D&L

BioVision, Inc. Notice of Violation January 17, 2020

# ATTACHMENT B List of Chemicals Sold by BioVision, Inc. in Violation of Proposition 65

Chemical Name Actinomycin D All-trans retinoic acid Altretamine Amikacin sulfate Aminoglutethimide Aminoglycosides Amiodarone hydrochloride Amsacrine Angiotensin converting enzyme	CAS No. 50-76-0 302-79-4 645-05-6 39831-55-5 125-84-8 19774-82-4 51264-14-3	Chemical Name Fluorouracil Ganciclovir Lovastatin Medroxyprogesterone acetate Megestrol acetate Metronidazole Mitomycin C Paclitaxel Pentostatin	CAS No. 51-21-8 82410-32-0 75330-75-5 71-58-9 595-33-5 443-48-1 50-07-7 33069-62-4 53910-25-1
(ACE) inhibitors Auranofin Azacitidine Azathioprine 1,4-Butanediol dimethanesulfonate (Busulfan)	34031-32-8 320-67-2 446-86-6 55-98-1	Pimozide Pioglitazone Plicamycin Progesterone	2062-78-4 111025-46-8 18378-89-7 57-83-0
Caffeic acid Carbamazepine Carboplatin Chenodiol Ciclosporin (Cyclosporin A;	331-39-5 298-46-4 41575-94-4 474-25-9 59865-13-3;	Ribavirin Rifampin Streptomycin sulfate Streptozotocin (streptozocin) Sulfasalazine	36791-04-5 13292-46-1 3810-74-0 18883-66-4 599-79-1
Cyclosporine) Cisplatin Cladribine Colchicine Cycloheximide Cyclophosphamide (hydrated) Daminozide Daunorubicin hydrochloride Diltiazem hydrochloride Doxorubicin hydrochloride	79217-60-0 15663-27-1 4291-63-8 64-86-8 66-81-9 6055-19-2 1596-84-5 23541-50-6 33286-22-5 25316-40-9	(Salicylazosulfapyridine) Tamoxifen citrate Thalidomide Tobramycin sulfate Trypan blue (commercial grade) Vinblastine sulfate Vincristine sulfate Vismodegib Zidovudine (AZT) Zileuton	54965-24-1 50-35-1 49842-07-1 72-57-1 143-67-9 2068-78-2 879085-55-9 30516-87-1 111406-87-2
(Adriamycin) Etoposide	33419-42-0		

#### **CERTIFICATE OF MERIT**

California Safe Drinking Water and Toxic Enforcement Act

January 17, 2020 (Romero v. BioVision, Inc.)

- I, Benjamin D. Weston, hereby declare:
- 1. This Certificate of Merit accompanies the attached 60-day notice in which it is alleged the parties identified in the notices have violated California Health and Safety Code section 25249.6 by failing to provide clear and reasonable warnings.
  - 2. I am the 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 exposures to the listed chemicals that are 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.

Respectfully submitted,

Benjamin D. Weston Cal. Bar No. 240641

## **Certificate of Service**

- I, Chris Johnson, hereby declare:
- 1. I am, and was at the time of service hereinafter mentioned, a resident of the State of California, over the age of eighteen years, and not a party to the within action. My business address is 498 Calle Principal, Monterey, California 93940.
- 2. On January 17, 2020, I served the following documents:
  - 60-Day Notice of Violation
  - Certificate of Merit

on each of the parties on the service list attached hereto by the method described below.

**BY MAIL:** I deposited such envelope in the mail at Monterey, California, with postage thereon fully prepaid. I am readily familiar with my company's practice of preparing correspondence for mailing. Under that practice it would be deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid in the ordinary course of business. I am aware that service is presumed invalid if the postal cancellation date or postage meter date is more than one (1) day after date of my signature below.

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

Dated: January 17, 2020	
Chris Johnson	
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- I, Benjamin D. Weston, hereby declare:
- 1. I am, and was at the time of service hereinafter mentioned, a resident of the State of California, over the age of eighteen years, and not a party to the within action. My business address is 1968 South Coast Highway, Suite 1200, Laguna Beach, CA 92651.
  - 2. On January 17, 2020, I served the following documents:
    - 60-Day Notice of Violation
    - Certificate of Merit

on the following persons by causing a true and correct .PDF copy thereof to be sent via electronic mail to the parties listed below, pursuant to Cal. Code Regs., title. 27, § 25903(c)(l):

Alameda County District Attorney <a href="mailto:CEPDProp65@acgov.org">CEPDProp65@acgov.org</a>	Calaveras County District Attorney <a href="mailto:Prop65Env@co.calaveras.ca.us">Prop65Env@co.calaveras.ca.us</a>
Contra Costa County District Attorney sgrassini@contracostada.org	Inyo County District Attorney inyoda@inyocounty.us
Lassen County District Attorney mlatimer@co.lassen.ca.us	Monterey County District Attorney <a href="mailto:Prop65DA@co.monterey.ca.us">Prop65DA@co.monterey.ca.us</a>
Napa County District Attorney <u>CEPD@countyofnapa.org</u>	Riverside County District Attorney <a href="mailto:prop65@rivcoda.org">Prop65@rivcoda.org</a>
Sacramento County District Attorney <a href="mailto:Prop65@sacda.org">Prop65@sacda.org</a>	San Diego City Attorney <u>CityAttyProp65@sandiego.gov</u>
San Diego County District Attorney <u>CityAttyCrimProp65@sandiego.gov</u>	San Francisco County District Attorney gregory.alker@sfgov.org
San Francisco City Attorney Valerie.Lopez@sfcityatty.org	San Joaquin County District Attorney DA DAConsumer.Environmental@sjcda.org
San Luis Obispo County District Attorney edobroth@co.slo.ca.us	Santa Barbara County District Attorney DAProp65@co.santa-barbara.ca.us
Santa Clara County District Attorney EPU@da.sccgov.org	Santa Cruz County District Attorney Prop65DA@santacruzcounty.us
Sonoma County District Attorney jbarnes@sonoma-county.org	Tulare County District Attorney <a href="mailto:prop65@co.tulare.ca.us">Prop65@co.tulare.ca.us</a>
Ventura County District Attorney daspecialops@ventura.org	Yolo County District Attorney <a href="mailto:cfepd@yolocounty.org">cfepd@yolocounty.org</a>

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

Dated: January 17, 2020

Benjamin D. Weston

## **List for Service by Mail**

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

Amador County District Attorney 708 Court Street #202 Jackson, CA 95642

Butte County District Attorney 25 County Center Drive, Suite 245 Oroville, CA 95965

Colusa County District Attorney 346 Fifth Street, Suite 101 Colusa, CA 95932

Del Norte County District Attorney 450 H Street, Room 171 Crescent City, CA 95531

El Dorado County District Attorney 515 Main Street Placerville, CA 95667

Fresno County District Attorney 2220 Tulare Street, Suite 1000 Fresno, CA 93721

Glenn County District Attorney P.O. Box 430 Willows, CA 95988

Humboldt County District Attorney 825 5th Street, 4th Floor Eureka, CA 95501

Imperial County District Attorney 940 West Main Street, Suite 102 El Centro, CA 92243

Kern County District Attorney 1215 Truxtun Avenue, 4th Floor Bakersfield, CA 93301

Kings County District Attorney 1400 West Lacey Boulevard Hanford, CA 93230

Lake County District Attorney 255 North Forbes Street Lakeport, CA 95453

Los Angeles County District Attorney 211 West Temple Street Suite 1200 Los Angeles, CA 90012

Madera County District Attorney 209 West Yosemite Avenue Madera, CA 93637 Marin County District Attorney 3501 Civic Center Drive, Room 130 San Rafael, CA 94903

Mariposa County District Attorney 5101 Jones Street, P.O. Box 730 Mariposa, CA 95338

Mendocino County District Attorney 100 North State Street, P.O. Box 1000 Ukiah, CA 95482

Merced County District Attorney 550 W. Main Street Merced, CA 95340

Modoc County District Attorney 204 5. Court Street, Suite 202 Alturas, CA 96101

Mono County District Attorney 278 Main St Bridgeport, CA 93517

Nevada County District Attorney 201 Commercial Street Nevada City, CA 95959

Orange County District Attorney 401 Civic Center Drive West Santa Ana, CA 92701

Placer County District Attorney 10810 Justice Center Drive, Suite 240 Roseville, CA 95678

Plumas County District Attorney 520 Main Street, Room 404 Quincy, CA 95971

San Benito County District Attorney 419 4th Street, Second Floor Hollister, CA 95203

San Bernardino County District Attorney 303 West 3rd Street, 6th Floor San Bernardino, CA 92415-0502

San Mateo County District Attorney 400 County Center, Third Floor Redwood City, CA 94063

Shasta County District Attorney 1355 West Street Redding, CA 96001

Sierra County District Attorney 100 Courthouse Square Downieville, CA 95936 Siskiyou County District Attorney P.O. Box 986 Yreka, CA 96097

Solano County District Attorney 675 Texas Street, Suite 4500 Fairfield, CA 94533

Stanislaus County District Attorney 832 12th Street, Suite 300 Modesto, CA 95354

Sutter County District Attorney 466 Second Street, Suite 102 Yuba City, CA 95991

Tehama County District Attorney 444 Oak Street, Room L Red Bluff, CA 96080

Trinity County District Attorney P.O. Box 310 Weaverville, CA 96093

Tuolumne County District Attorney 423 North Washington Street Sonora, CA 95370

Yuba County District Attorney 215 Fifth Street Marysville, CA 95901

Office of the City Attorney, Los Angeles City Hall East 200 North Main Street Los Angeles, CA 90012

Office of the City Attorney, Sacramento 915 I Street, 4th Floor Sacramento, CA 95814

Office of the City Attorney, San Jose 200 East Santa Clara Street, 16th Floor San Jose, CA 95113

BioVision, Inc. Attn: CEO, Gloria Guohong Zhang 155 South Milpitas Boulevard Milpitas, California 95035