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**Hach's Comments regarding Notice of Proposed Rulemaking: Amendments to Article 6,  
Clear and Reasonable Warnings Short-form Warnings**

Hach Company (Hach) is writing the Office of Environmental Health Hazard Assessment (OEHHA) to provide comments on the proposed amendments to Article 6 concerning clear and reasonable short-form warnings of California Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop 65), as published on Jan. 8, 2021:

<https://oehha.ca.gov/media/downloads/crn/p65shortformproposedregtextd2021.pdf>.

Hach manufactures and sells water quality analysis instruments and related chemical reagents. These products are for industrial, laboratory and workplace applications and are used by Californian municipalities, beverage manufacturers, consumers, chemical manufacturers, scientific institutions and other various industries. Realizing water is the world's most precious resource, our mission is ensuring water quality for people around the world. Our Vision is to make water analysis better—faster, simpler, greener and more informative.

**Reasons for Rescission**

We believe OEHHA should rescind the proposal to change the short-form warning requirements because there is no basis in OEHHA's Initial Statement of Reasons (ISR) (<https://oehha.ca.gov/media/downloads/crn/p65shortformisorf2021.pdf>) demonstrating that the changes will reduce over-warning or they will provide more clear and reasonable warnings about cancer and reproductive harm risks to better protect health and safety of Californians. In fact, the ISR did not offer any substantiated benefit from the proposed changes.

Instead, the amendment would create overwhelming and unnecessary burden and costs to businesses. For instance, Hach already complies with the current Prop 65 regulations, as well as

various federal and state labeling requirements for our products, such as the Hazard Communication Standard, the Federal Insecticide, Fungicide, and Rodenticide Act, state mercury labeling requirements, the Federal Hazardous Substances Act, and the Fair Packaging and Labeling Act. It is impractical and costly to apply additional labeling elements on labels that are already crowded with information required by these regulations. Producing new labels and relabeling numerous products will be a costly undertaking.

We view that identifying the specific Prop 65 chemical in addition to the relevant toxicological endpoint is redundant; serves no useful purpose in a short-form warning; and is not required by the statute. As mentioned, various regulations already require several types of health and safety warnings, which overlap with Prop 65 warning content. Under Prop 65, Section 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 clear and reasonable warning to such individual.” In other words, Prop 65 requires businesses to provide a “clear and reasonable” warning to Californians about significant exposures to chemicals known to the state to cause cancer or reproductive toxicity. The clear and reasonable warning does not require disclosing which specific carcinogens/reproductive toxicants are in the product but rather to warn about the **exposure** to carcinogen or reproductive toxicant. OEHHA determined that the current short-form warning serves such purpose back in 2016. With this proposal, OEHHA is contradicting its previous determination of the legislative intent.

We also see this proposed change as conflicting with the environmental regulatory policies of California. In particular, the proposed changes do not align with the initiatives under the California Climate Investments (<http://www.caclimateinvestments.ca.gov/about-cci>) and the former Governor Brown’s Executive Order to become carbon neutral by 2045 (<https://www.ca.gov/archive/gov39/wp-content/uploads/2018/09/9.10.18-Executive-Order.pdf>). Changing numerous product labels to include the long-form warning would require an increase in packaging size. Replacing labels altogether also increases the carbon footprint to become compliant with the proposed amendment.

There is no evidence that this amendment will bring health benefits to Californians. The state has not presented any substantial evidence that Prop 65 has reduced the number of cancers and illnesses related to reproductive harm during its existence for more than three decades as discussed in this report by the Center for Accountability in Science, a project of the nonprofit Center for Organizational Research and Education (CORE): <https://www.accountablescience.com/wp-content/uploads/2018/06/2018-Proposition-65-State-Impact-Report.pdf>. According to the U.S. Centers for Disease Control and Prevention, California’s rate of seven common cancers, including Non-Hodgkin’s lymphoma, and ovarian, testicular, and stomach cancers, are either no different from or higher than the national average. For reproductive illnesses, the National ART Surveillance System reports that California has among the highest percentage of births requiring assisted reproductive technology, and the National Birth Defects Prevention Network reports that the state faces higher than average rates of central nervous system defects, and certain cardiovascular and musculoskeletal defects in

infants. While businesses have been forced into providing warnings, dealing with Prop 65 litigation, or frequently reformulating products that contain a negligible amount of a listed chemical, there is no substantial evidence that Prop 65 has had a measurable benefit to public health. On the same note, OEHHA's ISR does not provide any support on how this amendment will effect health benefits to Californians.

Therefore, Hach requests rescinding the proposal as written.

### **Recommendations for Amendment**

If OEHHA determines that another proposal is necessary in the future, it should consider the following:

- A. keeping the current short-form warning format and require disclosure of the carcinogen and/or reproductive toxicant when asked by the consumer or downstream user;
- B. lengthening the transition period from one year to 2 to 3 years;
- C. enlarging the total maximum surface area for a short form warning from 5 square inches to at least 20 square inches, and
- D. define "label space".

Hach recommends these changes because:

1. We disagree with the claim that there will be little to no significant impact to businesses.
2. The addition of words and chemical identification to the short form is problematic because it increases the amount of space needed for the warning, and more importantly requires changing every affected label.
3. The transition period of one year is not feasible.
4. The choice of 5 square inch maximum area for short form warnings is arbitrary.

Hach also recommends clarifying:

- standards for round products, bagged products, and other irregularly shaped packaging where labels are required but may wrap around the product and limit visibility;
- liability for repackaging products produced by another entity; and
- a definition of what is included in label space to accurately design compliant labels.

### **Reasons for Hach's Recommendations**

The proposed amendments will not eliminate "over-warning," and may not significantly decrease the use of such warnings. Most companies will not remove a Prop 65 warning unless they are certain that there are no subject chemicals in their product and there is no Prop 65 litigation risk. The primary driver for high use of Prop 65 warnings is citizen enforcement, and companies risk

litigation from citizen-enforcers if they do not provide safe-harbor warnings. The current short-form warning minimizes risks stemming from the civil enforcement provisions.

If the proposed changes are finalized as written, businesses would lose their safe harbor and be exposed to heightened risk of private enforcement. Rather than changing the content of warning labels, especially within such a short time (in less than 3 years) after the last major changes in 2018, OEHHA should instead focus on providing stronger defense measures when companies make reasonable determinations not to warn, based on a sound scientific approach. To decrease reliance on the use of safe harbor warnings, OEHHA should reevaluate the burden of proof for civil enforcement.

The proposed amendments will cause substantial burdens to companies. With the nearly 1,000 chemicals on the Prop 65 list, many products marketed in California are potentially in scope and require resources to assess and test. In addition to these costs, IT (information technology) and ERP (enterprise resource planning) systems would require updates to accommodate a myriad of custom labels for various chemicals that would need to be disclosed on the warning.

If companies incur increased costs to sell products into California because of the resulting label changes, these companies will likely choose to pass these costs onto end users. As a result, Californian consumers will be at a disadvantage compared to similarly situated consumers in other states.

### **Discussion of Hach's Recommendations**

A. Retain the current short-form warning and disclose the relevant carcinogen and/or reproductive toxicant upon request

This approach eliminates the burdensome need for changes to the warnings on products or packaging; on the Internet; and on product catalogs. It is more practical to inform California consumers of the relevant carcinogen and/or reproductive toxicant in as-needed-basis.

B. Lengthen the transition period to 2 to 3 years

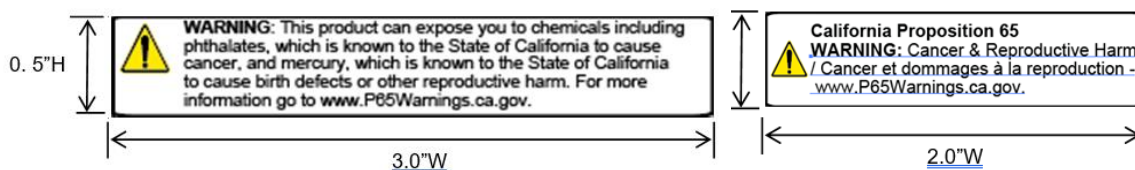
If OEHHA proceeds with the overwhelming changes, Hach believes it is infeasible for businesses to comply in the allotted one-year timeframe. Products will have to be tested extensively to identify chemicals to disclose in the warnings. IT and ERP systems will have to be updated to provide the applicable long-form warning for every affected SKU (stock keeping unit) or part number. Companies will be forced to create new labels and relabel products in addition to changing website and brochure content. These are not changes that can happen overnight.

Changes made to comply with the last amendment were expensive and burdensome, which only became effective less than three years ago. It will be more burdensome and time-consuming to

adapt a new process to comply, than it was in 2018, because there will no longer be a generic short-form warning. For example, Hach sells thousands of different products into California that require Prop 65 warning. The proposed regulation will potentially require testing thousands of products to identify specific Prop 65 chemicals. We will have to generate a different process for multiple labels and to match them to the specific products. We would need more time to work with our suppliers to figure out which Prop 65 listed chemicals may be present in many components. We estimate that these steps alone may take more than two years to implement.

C. Enlarge the total maximum surface area for a short-form warning to at least 20 square inches

Hach also recommends expanding the maximum label space from five square inches to twenty square inches. Twenty square inches is still a very small label space considering all the other required labeling elements, such as the product identifier, content information, net quantity or volume, instructions for use, and any other safety warnings or precautions. Five square inches is simply impractical to include all those elements and display the proposed short-form warning in 6 point font size. To illustrate the impracticality, let's consider the current Prop 65 requirements. The minimum short-form label size is an inch square, and the minimum long-form label must be an inch and a half square. These dimensions do not account for other required label content.



Displaying all the other label elements in 3.5 to 4 inch square of remaining space seems extremely difficult if not infeasible. Compliance with the proposed changes becomes more difficult if other languages appear on the labels, notably French and Spanish, because Prop 65 warning needs to be in those languages also. Based on our calculation and estimate, the minimum surface area for a short-form warning should be at least 20 square inches to be reasonable.

D. Clarifications for irregular packaging shape; liability for repackaging; and label space

In addition, Hach requests OEHHA to clarify the standards being applied to round products, bagged products, and other irregularly shaped packaging when determining label space to properly guide businesses on how to apply Prop 65 safe harbor warnings. These products have unique labeling needs, including wrap-around labels. We also ask OEHHA to provide a visibility standard for products that are multi-dimensional or irregularly shaped.

There has not been sufficient guidance from OEHHA on a company's Prop 65 liability for repackaging products produced by another entity. Who is ultimately responsible for providing a Prop 65 warning? What is the obligation of the processor or the company engaged in

repackaging? We request clarification on these questions either in the form of regulatory amendment or guidance document.

Even though the proposed amendment places a strict size limitation of “label space”, it does not define what constitutes label space. Hach requests OEHHA to provide the definition to help businesses accurately design and apply compliant labels.

Hach appreciates the opportunity to provide input to this important process. Hach strongly supports OEHHA’s efforts to protect health and safety of Californians. Should you have any questions or require any additional information, please contact me at [jalee@hach.com](mailto:jalee@hach.com) or the phone number listed above.

With kind regards,



James Lee