

June 26, 2024

Monet Vela
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
1001 I Street, 23rd Floor
P.O. Box 4010
Sacramento, California 95812-4010

Re: Notice of Modification to Proposed Amendments to Regulations Clear and Reasonable Warnings, Safe Harbor Methods and Content

Dear Ms. Vela

Thermo Fisher Scientific Inc. is the world leader in serving science dedicated to helping its customers in life sciences research, diagnostics, and life-changing therapies. We thank the California Office of Environmental Health Hazard Assessment (OEHHA) for the opportunity to comment on the proposed amendments to Title 27 of the California Code of Regulations, Article 6, Clear and Reasonable Warnings – Safe Harbor Methods and Content.

Thermo Fisher supports the overall intent to make Proposition 65 (Prop 65) more effective in protecting human health from environmental exposures to chemicals known to the State of California as carcinogenic or toxic for reproduction. We have practical concerns regarding the implementation of the amendments.

As a supplier of chemical substances and mixtures into (solely) industrial and professional markets for laboratory research and applied applications in life science around the world, Thermo Fisher is obligated to meet all legal requirements regarding the hazard classification and communication for those products from the time of purchase. We do this through our labeling, Safety Data Sheets as well as information conveyed on our websites and other product literature. Due to the nature of Life Sciences, many reagents are supplied in small containers (less than 100ml with a majority less than 1ml) where legible label space is at a premium (typically less than 25cm²). The redundancy of the information required in some cases creates additional burden on manufacturers, creates challenges for placing critical research products on the California market. We ask that OEHHA consider additional practical derogations for very small packages already labelled according to the U.S. Hazard Communication Standard (U.S. HCS) and/or sectorial legislation, that are aligned with the State's classification under Prop 65.

Feasibility

The 2021 short-form warnings for Prop 65 improved ability to fit some information on the labels, but still required 1 – 2 additional lines on existing labels. To accommodate all this information, and maintaining a 6pt font size, is not possible.

These small products must already comply with federal labeling requirements specified under the U.S. HCS (29 CFR 1910.1200) and applicable sectorial legislation (e.g., U.S. Food, Drug, and Cosmetic Act) as well as the Prop 65 Safe Harbor Warning. Using larger containers to accommodate a larger label will make use of the product infeasible (inability to recover full content). Commonly proposed alternatives (e.g., fold-out labels) are not practical as the specialty vials are designed to fit tightly into

pre-existent equipment and racking systems and the fold-out labels prevent this solution. Using redundant outer packaging with larger label space is not practically effective as that packaging is typically discarded as waste before placing the product into constrained laboratory storage.

We ask OEHHA to provide a derogation of the Prop 65 Safe Harbor Warning for labels less than 25cm² and where federal classification is aligned with the Prop 65 toxicological end-point.

Clarity

Many industrial and professional use chemicals are sold as identified substances, with their chemical names used as product names on labeling. These products are typically in larger volumes and the label contains all relevant warnings, precautions consistent with the State of California and the hazard content on www.P65Warnings.gov. In these instances, and where the toxicological end-point are the same as the federal classification, we believe the Safe Harbor Warning, containing the product identity, is redundant. Adding the name of the substances (in the same font size as the identifying product description) into the Safe Harbor Warning would be a disproportionate administrative burden for industry that adds no value to the end-user.

We ask OEHHA to derogate the Prop65 requirement to include a redundant reference to the chemical identity whenever it is otherwise clearly indicated on the product label and the toxicological end-point are identical to federal classifications.

In conclusion, Thermo Fisher contends that incorporating the proposed extended Prop 65 short-form warning text on very small containers, which already include relevant and aligned information, does not provide unique or additional information to the industrial/professional consumer who must already recognize and comply with risk mitigation measures pertaining to the inherent hazard of the product. Modifying these labels to contain redundant information will reduce clarity for the consumer, present significant barriers for manufacturers to package the product, and will threaten the availability of critical diagnostic and research tools in California. Pushing the label content to a secondary package will mandate, in many cases, additional packaging and concomitant waste (much of which is plastic) that must be addressed as part of the social infrastructure and regulation. As such, we ask that OEHHA consider practical derogations for very small products already classified and labelled according to the U.S. HCS and/or sectorial legislation, in particular, those that are aligned with the State's classification under Prop 65.

Thank you for the opportunity to provide these comments. Please contact me if I can provide further information.

Best Regards,



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