

How California is Warning Against Cancer: PROPOSITION 65

What is Proposition 65?

Proposition 65 (officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986) – Prop 65 for short – is a law enacted in 1986 by the US federal state of California to promote the purity of drinking water.

There we read:

"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." – California Proposition 65, The Safe Drinking Water and Toxic Enforcement Act, 1986

After this law came into force, the California Office of Environmental Health Hazard Assessment (OEHHA) – a department of the Californian Environmental Protection Agency (CalEPA) – published a list of substances/chemicals severely hazardous to human health. To this day the goal is to identify substances causing cancer and reproductive toxicity which might occur as contaminants in drinking water. The primary list appeared in 1987 and this has subsequently been expanded to include other

second column of the list describes the type of toxicity – whether causing cancer or reproductive toxicity in men or women. There are basically different listing scenarios for this. The remaining three columns show the registration number with the Chemical Abstract Service (CAS), the date of inclusion in the list, and a possible "Safe Harbor Level". The Safe Harbor Level in this context is equivalent to the NOAEL (No Observed Adverse Effect Level) and represents the end point of a toxicity study at which no significantly increased hazardous effects of a substance are to be noted.

How do chemicals get included on the list?

The procedure for adding a chemical has four stages to it. In a first step, a public notice is made about the addition or a change in the safety assessment of a substance.

create a subdivision. Within the scope of an LCI project, an explicit and comprehensive overview of all 800 substances in the list was drawn up and a meaningful subdivision into substance classes was developed. A subdivision into eight classes was proposed. These substance classes are shown in the diagram (figure 1).

The subgroup of "foodstuff-relevant compounds" particularly includes Maillard reaction products (MRPs) such as acrylamide, furfuryl alcohol, and the methylimidazoles. But Prop 65 also includes substances such as 3-monochloro-1,2-propanediol (3-MCPD), polycyclic aromatic hydrocarbons (PAH) and the mineral oil components MOSH and MOAH.

What are the consequences of Prop 65 for companies?

Prop 65 affects all companies that market their products in California. They are legally required to issue a "clear and reasonable" warning before knowingly and intentionally exposing people to any of the chemicals included in the list. This warning can be announced in various ways, including the placement of corresponding labelling on the product. As of the time a chemical substance is added to the list, companies have 12 months' time to adhere to the obligation to issue a corresponding warning. Non-compliance with these requirements can be very costly for companies. In 2017 alone, the California Proposition 65 Enforcement Report counted 338 judgements by plaintiffs and 346 out of court "settlements" amounting to a total of 25.6 million dollars.

Companies are only exempt from the obligation to issue a corresponding warning if they prove the exposure to the chemicals listed is so low that there is no significant risk of cancerous diseases, malformations, or other harm to human reproductive capacity.

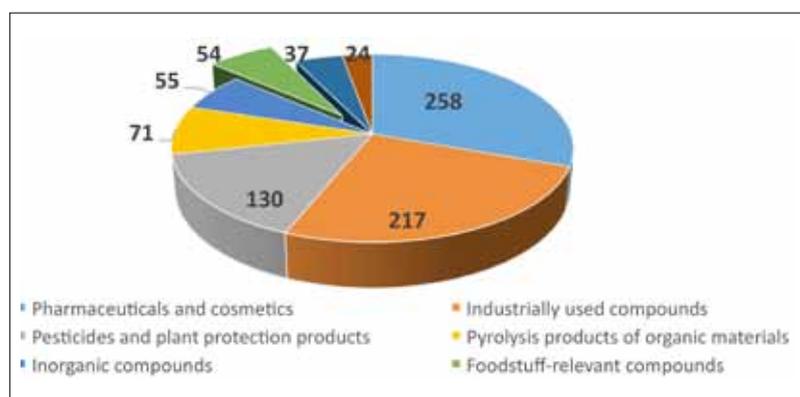


Figure 1: Proposed subdivision of the substances listed under Prop 65 into eight substance classes. The diagram shows the respective number of individual substances in each substance group (current as of January 2018)

substances, meanwhile listing well over 800 individual substances. The declared aim is to warn the Californian population about possible safety hazards. The law stipulates that warnings about such possible hazards must be correspondingly placed and posted.

How is the list structured?

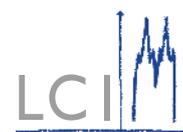
The list drawn up under Proposition 65, published and made available on the Internet by the OEHHA, contains a huge table made up of several columns showing alphabetically sorted toxic substances (<https://oehha.ca.gov/proposition-65>). The first column shows the IUPAC name or trivial name. The

This may be tracked on the OEHHA website, among other places. This is followed by a public comment period for the new listing. This includes the submission of alternative studies or reasoned opinions against including a substance. The commentaries are subsequently reviewed and the OEHHA makes a final decision on the matter.

Categorisation of chemicals

The substances included in Prop 65 are not listed in order of substance class. It is hence difficult for companies to identify possible relevant hazardous substances at a glance. For this reason, it makes good sense to

Prop 65 is a globally unique consumer protection institution. Predominantly private litigants can sue for infringements of the complicated body of law and collect high commission fees by way of so-called "settlements" from the defendant companies.



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