



Prop. 65

Betaines & Hydroxysulfates



Presentation Outline

- Proposition 65
 - What is Prop. 65?
 - How is it managed?
 - Safe Harbour?
 - August 30, 2018 Deadline
 - Prop. 65 Listing for DCA
- How Betaines and Hydroxysultaines are made?
- Betaine and Hydroxysultaine comparison
- Where are Hydroxysultaines are already used
- Open discussion on shared experience with Prop. 65 and or Betaine/Hydroxysultaine formulating





What is “Prop. 65”

“The Safe Drinking Water and Toxic Enforcement Act of 1986”

- a California law passed by direct voter initiative 1986
- Passed by a 63% vote



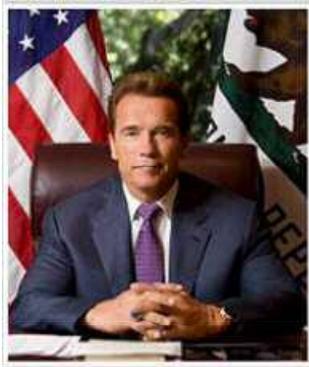
Goal of Prop. 65

To protect drinking water sources from toxic substances that may

- cause cancer
- birth defects/reproductive harm

To reduce or eliminate exposures to those chemicals

What is “Prop. 65” Continued...



In addition to amending the [California Health and Safety Code](#), Proposition 65 contained the following language in the 1986 ballot initiative:⁸

SECTION 1. The people of California find that hazardous chemicals pose a serious potential threat to their health and well-being, that state government agencies have failed to provide them with adequate protection, and that these failures have been serious enough to lead to investigations by federal agencies of the administration of California's toxic protection programs. The people therefore declare their rights:

- (a) To **protect themselves and the water they drink** against chemicals that cause cancer, birth defects, or other reproductive harm.
- (b) To **be informed about exposures to chemicals** that cause cancer, birth defects, or other reproductive harm.
- (c) To **secure strict enforcement of the laws controlling hazardous chemicals** and deter actions that threaten public health and safety.
- (d) To **shift the cost of hazardous waste cleanups** more onto offenders and less onto law-abiding citizens.

The people hereby enact the provisions of this initiative in furtherance of their rights.

California Law requires that the Governor publish , annually, a list of chemicals known to cause cancer and reproductive abnormalities. This list is now known by the ballot initiative that brought it into law as the “Prop. 65 List”.

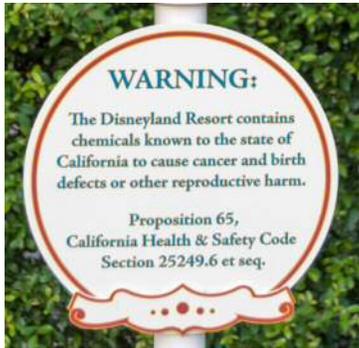


What is "Prop. 65"

Does not ban the sale of any product: it requires that warnings are issued advising citizens and consumers of potential risk



"Clear and Reasonable" Warnings



How is “Prop. 65” managed?

Currently, over 850 substances listed

Four Listing Mechanisms

1. CIC (Carcinogen Identification Committee) and DART (Developmental and Reproductive Toxicant Identification Committee)
2. Authoritative Bodies - CIC or DART designates. Authoritative bodies currently identified are:
 - US- EPA (US Environmental Protection Agency)
 - International Agency for Research on Cancer,
 - NIOSH (National Institute of Occupational Safety and Health)
 - US-FDA (Food and Drug Administration)
 - NTP (National Toxicology Program)
3. Formal Labeling Requirement (ie Prescription Drugs)
4. Occupational Warning Requirements California labor code specifies



How is “Prop. 65” managed?

Prop. 65 is Administered by

OEHHA (California Office of Environmental Health Hazard Assessment)

Regulates substances officially listed by California as having a 1 in 100,000 chance of...

- causing cancer over a 70 year period
- or birth defects or other reproductive harm.

OEHHA website: www.p65warnings.ca.gov

Prop. 65 is Enforced by

California Attorney General’s Office

or...any District Attorney of a city > than 750,000

or...any individual acting in the public interest



What is “Prop. 65” Safe Harbor?

A business has “Safe Harbor” from Proposition 65 Warning requirements or discharge prohibitions if exposure to a chemical occurs at or below these levels.

Safe Harbor for Chemicals listed as causing cancer is identified by a **NSRL** (No Significant Risk Level)

Safe Harbor for Chemicals listed as causing birth defects or other reproductive harm is identified by **MADL** (Maximum Allowable Dose Levels)

What is New for “Prop. 65” August 30, 2018...

August 30th, 2016 amendments to Proposition 65 were approved



The changes include new requirements for what constitutes a Clear and reasonable warning.

The new text clarifies:

- New warning label requirements for consumer products
- Warning responsibilities of websites and catalogues
- Warning responsibilities of retailers and manufacturers of consumer products



What is “Prop. 65” August 30, 2018...



What is "Prop. 65" August 30, 2018...



Examples of Acceptable Warning Labels Under the New Regulations

Cancer



WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information, visit www.P65Warnings.ca.gov.

Combined Cancer/Birth Defect



WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer or birth defects or other reproductive harm. For more information, visit www.P65Warnings.ca.gov.

Birth Defect



WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information, visit www.P65Warnings.ca.gov.

Truncated on Product Warning



WARNING: Cancer and Reproductive Harm—www.P65Warnings.ca.gov

Type Size: The warning text must be the same size as other consumer information presented on the package and may not be smaller than 6-point type.

<https://www.sema.org/prop65>



What is “Prop. 65” August 30, 2018...

If there is more than one listed chemical in a product, only one must be named for each potential outcome (cancer or reproductive harm). Businesses can choose which chemical is named.

Warnings must be given at or before the point of purchase

For Catalogues and websites

- Full warning text is required if no warning label is provided on product.
- If Truncated warning is “on product” then can use truncated warning in catalogues and websites

OEHHA website: www.P65Warnings.ca.gov.



What is “Prop. 65” August 30, 2018...

What are the warning responsibilities for Manufactures

The new system clarifies that manufactures have the primary responsibility for providing Prop. 65 warnings

Manufacturers can choose whether to:

- put warning labels on their products
- provide notices to their distributors, importers or retail outlets that a product may cause an exposure to a listed chemical that requires a warning
- provide warning signs or other warning material

Manufacturers, producers and packagers must document that they have notified retailers of the need to provide warnings and provided all necessary warning materials. Retailers are only responsible for providing warnings if they have been notified



What is “Prop. 65” August 30, 2018...

What are the warning responsibilities for Manufactures

www.p65warnings.ca.gov/sites/default/files/art_6_business_qa.pdf

Q14: If a company manufactures component parts or ingredients

Obligation to warn persons who can be occupationally exposed to the product by providing warnings consistent with Section 25606.

- A warning to an exposed employee about a listed chemical meets the requirements of this subarticle if it fully complies with all warning information, training, and labeling requirements of the federal Hazard Communication Standard (29 Code of Federal Regulations, section 1910.1200 (Feb. 8, 2013))
- Safety Data Sheets (SDS) are outside the scope of this regulation, as OEHHA cannot prescribe the content of forms under the authority of a federal or other state agency. While SDS may be used to provide occupational exposure warnings, they are not a safe harbor warning method for other exposure types such as consumer product or environmental exposures covered by Article 6.



What is “Prop. 65” August 30, 2018...

What are the warning responsibilities for Manufactures

www.p65warnings.ca.gov/sites/default/files/art_6_business_ga.pdf

A manufacturer would only have responsibility for a consumer warning if it has knowledge that the end use of the component part or ingredient can expose a consumer to a listed chemical.

- Then the ingredient manufacturer should provide the warning notice to the product manufacturer.
- The product manufacturer is then responsible for determining whether the product they are manufacturing causes an exposure to the chemical at a level that requires a warning and passing the information along to its customers or the product retailer.
- In such a situation, the ingredient manufacturer may also choose to work with the product manufacturer to evaluate whether the product should have a warning.



What is “Prop. 65” Continued...

Either the current or the new version of the warning can be applied until August 30, 2018.

Fines

- Up to \$2,500 / day per violations
- Almost all are settled.

A warning is required but alternative warnings may be used. However, businesses using alternative warnings should be prepared to defend them.

Products manufactured before August 30, 2018 will not need new warnings if they meet the requirements that were in effect at the time of their production.

Warnings are required within one year of a chemical becoming listed.

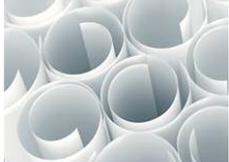
Lab testing can be useful to determine how much of a listed chemical is present in a product, if at all. Attorneys usually conduct lab testing only and base their prosecution on the results.

Prop. 65 remains politically controversial even after 30 years
Settlements in Prop. 65 cases totaled \$29.5 million in 2015

- \$21 million was paid in attorney’s fees and costs (71%)
- 3.5 million was PILP (PILP are now ASP)
- \$5 million was collected by OEHHA

What is "Prop. 65" Continued...

**Reformulation
is an alternative
to warning labels..**



So...why is Prop. 65 relevant to Betaines and Hydroxysultaines?

Most Personal Care detergent formulations contain betaines.

- Inexpensive
- Multifunctional
- Biodegradable
- Plant Derived
- Sustainable
- Available
- Well understood chemistry
- Used for decades



However, they contain Dichloroacetic Acid
DCA is listed on Prop. 65



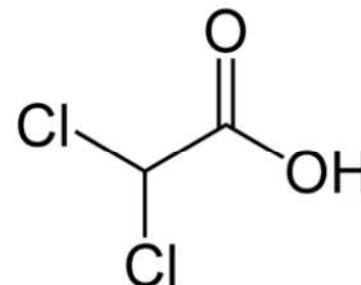


Prop. 65 Listing for DCA

Dichloroacetic Acid

CAS#: 79-43-6

Dichloroacetic Acid



Listed as Causing Cancer: 1996

Listed as Causing Developmental Toxicity Male Reproductive Toxicity: 2009

Made it to the “First Priority” list of chemicals selected for development of Maximum Allowable Dose Levels (MADL) in 2012. However, status was not changed.

Due to DCA’s inert nature it was considered for removal from the Prop. 65 listings, but in 2013 it was decided that DCA would remain on the list.

Prop. 65 Listing for DCA

STATE OF CALIFORNIA
ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY

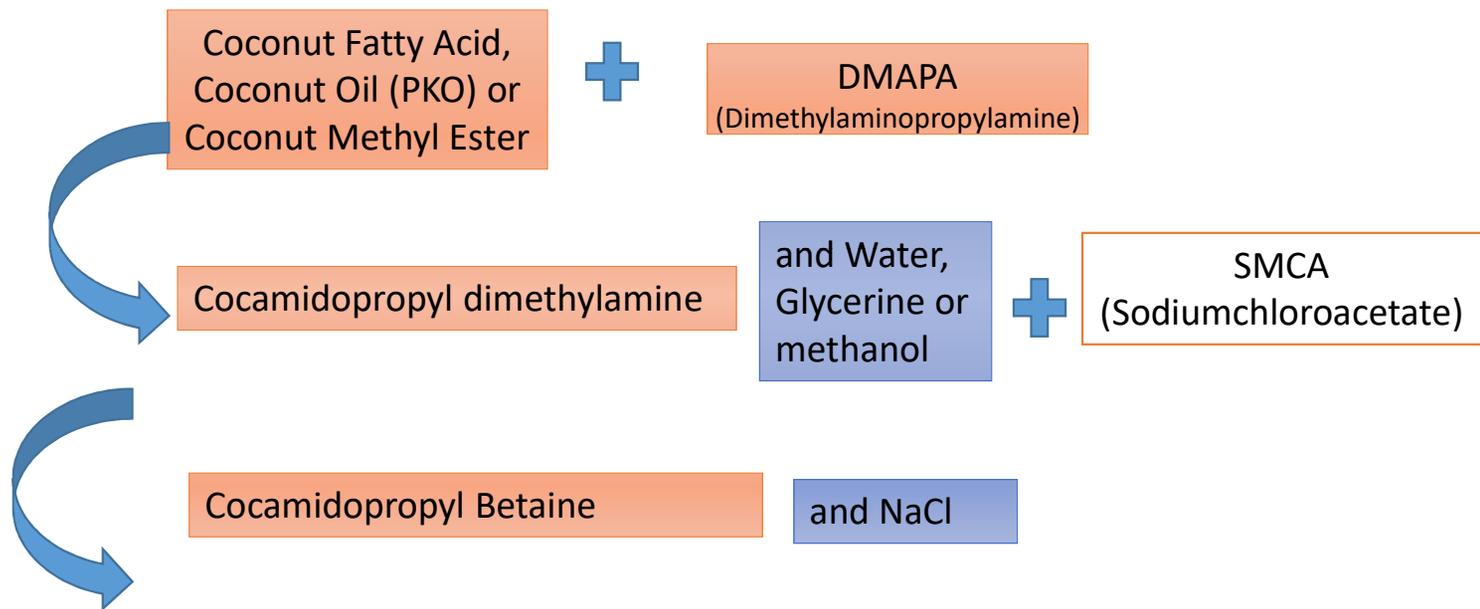
Dec. 29, 2017

The Safe Drinking Water and Toxic Enforcement Act of 1986 requires that the Governor revise and In the Listing Mechanism column, "AB" denotes authoritative bodies, "SQE" denotes State's Qualified

Chemical	Type of Toxicity	Listing Mechanism	CAS No.	Date Listed	NSRL or MADL ($\mu\text{g}/\text{day}$) ^a
Dichloroacetic acid	cancer	AB – US EPA	79-43-6	01-May-96	
Dichloroacetic acid	developmental, male	AB – US EPA	79-43-6	07-Aug-09	

How Betaines are Made?

Cocamidopropyl Betaine



SMCA always contains traces of Dichloroacetic acid (DCA), a toxic and unreactive material that appears on California Prop 65 List



Betaine Alternative - **without DCA**

Hydroxysultaines

No risk of DCA from Raw Materials

(Need to consider potential of cross contamination)

Mild

Multifunctional

Similar performance and characteristics

Versatile

Biodegradable

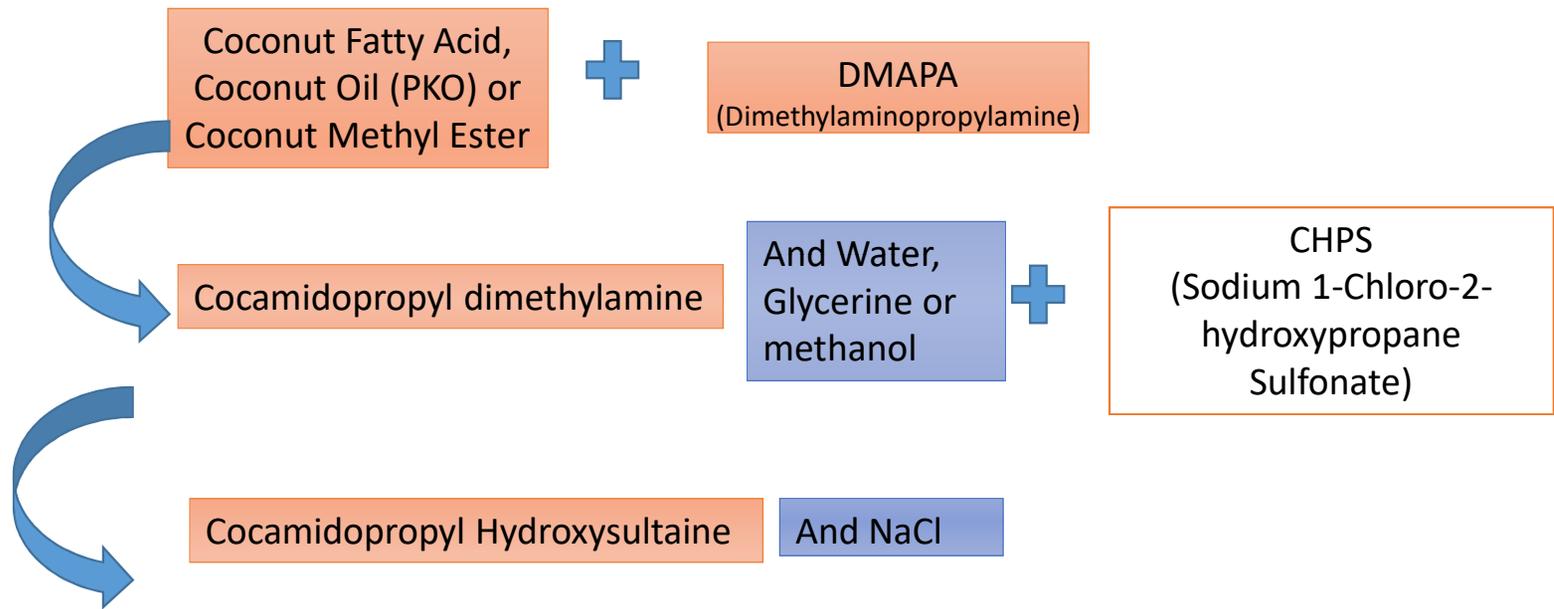
Plant Derived

Available

Sustainable

How Hydroxysultaines are Made?

Cocamidopropyl Hydroxysultaine



Hydroxy Sultains are made with CHPS. Which is made by condensing epichlorohydrin with sodium bisulfite.



Betaines vs. Hydroxysultaines

Perameter	Betaines	Hydroxy Sultaines
pH Compatibility	Broad	Broad
Wetting Ability	Better	Moderate
Bleach Stable (H ₂ O ₂ or Hypo)	No	No
Personal Care Cleaning	Good	Better
Mildness	Mild	More Mild
Foam	Good	Good
Viscosity	Good	Good
Considered "Sulfate Free"	Yes	Yes

Customer behaviour is changing...

Formulations already using Hydroxysultaines





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