

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
(Proposition 65)**

**NOTICE TO INTERESTED PARTIES
January 27, 2017**

**CHEMICALS LISTED EFFECTIVE JANUARY 27, 2017
AS KNOWN TO THE STATE OF CALIFORNIA TO CAUSE REPRODUCTIVE
TOXICITY: **PERTUZUMAB AND VISMODEGIB****

Effective **January 27, 2017**, the Office of Environmental Health Hazard Assessment (OEHHA) is adding *Pertuzumab* (CAS No. 380610-27-5) to the list of chemicals known to the state to cause reproductive toxicity (developmental endpoint), and *Vismodegib* (CAS No. 879085-55-9) to the list of chemicals known to the state to cause reproductive toxicity (developmental, female and male endpoints), for purposes of Proposition 65¹.

As provided under Proposition 65, the listing of pertuzumab and vismodegib is based on a formal requirement by the US Food and Drug Administration (FDA) that the chemicals be identified or labeled as causing reproductive toxicity². Pertuzumab has been identified or labeled to communicate a risk of reproductive harm (developmental endpoint) in accordance with formal FDA requirements. Vismodegib has been identified or labeled to communicate a risk of reproductive harm (developmental, female, and male endpoints) in accordance with formal FDA requirements. Regulations governing the listing of chemicals under the “formally required to be labeled or identified” mechanism are published in Title 27, California Code of Regulations, section 25902.

The documentation supporting OEHHA’s determination that pertuzumab meets the criteria for listing is included in the Notice of Intent to List Pertuzumab posted on OEHHA’s website and published in the December 2, 2016 issue of the *California Regulatory Notice Register* (Register 2016, No. 49-Z)³. No public comments were received.

The documentation supporting OEHHA’s determination that vismodegib meets the criteria for listing is included in the Notice of Intent to List Vismodegib posted on

¹ The Safe Drinking Water and Toxic Enforcement Act of 1986, Health and Safety Code section 25249.5 et seq.

² See Health and Safety Code section 25249.8(b) and Title 27, Cal. Code of Regs., section 25902

³ Also published in the September 30, 2016 issue of the California Regulatory Notice Register (Register 2016, No. 40-Z), but not published on the OEHHA website at that time.

OEHHA's website and in the December 2, 2016 issue of the *California Regulatory Notice Register* (Register 2016, No. 49-Z)⁴. No public comments were received.

A complete, updated chemical list is published in this issue of the *California Regulatory Notice Register* and is available on the OEHHA website at <http://oehha.ca.gov/proposition-65/proposition-65-list>.

In summary, the following chemicals are listed under Proposition 65 as known to the state to cause reproductive toxicity:

Chemical	CAS No.	Toxicological Endpoints	Listing Mechanism*
Pertuzumab	380610-27-5	Developmental toxicity	FR
Vismodegib	879085-55-9	Developmental toxicity Female reproductive toxicity Male reproductive toxicity	FR

* Listing mechanism: FR — “formally required to be labeled or identified” mechanism (Health and Safety Code section 25249.8(b)) and Title 27 Cal. Code of Regs., section 25902

⁴ Also published in the September 30, 2016 issue of the *California Regulatory Notice Register* (Register 2016, No. 40-Z), but not published on the OEHHA website at that time.