

## Proposition 65 Activities in California – Acetaminophen

*On October 12, regulators in California designated acetaminophen as a high priority chemical for a possible future listing under the state’s Proposition 65 law. The next step in the review process is a full and rigorous examination of all the scientific data about acetaminophen. With a long history of safe and effective use, acetaminophen is the most commonly used pain reliever and fever reducer in the United States. The following frequently asked questions should help answer consumers’ questions related to this issue.*

### **What is acetaminophen?**

Acetaminophen is the most commonly used pain reliever and fever reducer in the United States. Acetaminophen is approved by the U.S. Food and Drug Administration (FDA) and is safe and effective when used according to label instructions. It is found in more than 600 different prescription and over-the-counter medicines, including pain relievers, fever reducers, and sleep aids as well as cough, cold, and allergy medicines.

### **What is acetaminophen used for?**

Acetaminophen is found in both over-the-counter and prescription medicines. It is a temporary fever reducer and provides temporary relief of minor aches and pains due to headaches, muscle aches, backache, minor arthritis pain, the common cold, toothache, and premenstrual and menstrual cramps.

### **Is acetaminophen safe?**

Yes. Acetaminophen is FDA-approved and is safe when used as directed or labeled. As with any medicine, however, it must be used as directed or labeled.

### **What does acetaminophen’s “high” priority status mean under California’s Proposition 65 law?**

It means that, after a preliminary review, the state of California has decided to continue reviewing the scientific data for acetaminophen. A “high” priority designation is not unusual and it does not mean acetaminophen will be listed as a carcinogen; it simply signifies that experts will continue to review scientific data to determine if it meets the listing criteria for Proposition 65.

In order to be listed under Proposition 65 in California, acetaminophen must be “*clearly shown through scientifically valid testing*” to cause cancer. There is little or nothing in the existing body of published scientific research into acetaminophen to suggest any causal link with cancer or reproductive toxicity.

### **Should I avoid taking acetaminophen until the results of this review in California are known?**

Acetaminophen is an FDA-approved pain reliever and fever reducer and is safe when taken as directed or labeled. The review currently underway in California is a regulatory process and will produce no new scientific data beyond what is already in the public domain. As with any medicine, consumers who have questions should talk to their doctor or other healthcare professional.

**Are there risks from taking too much acetaminophen?**

Acetaminophen has been available as an OTC pain reliever and fever reducer for over 50 years and, like all FDA-approved medication, is safe when used as directed on the label. But, unless directed by your doctor, you should never use more or use for longer than the label instructs. Taking more than the recommended amount may cause liver damage.

**How does the consumer know if a medicine contains acetaminophen?**

Over-the-counter medicines that contain acetaminophen always list the ingredient on the Drug Facts label in the active ingredient section. It may be highlighted, as well, to draw attention to it. It also will be written on the front of the package. It is important to know that prescription medicines will list acetaminophen on their labels, or they may list “APAP,” “acetamin,” or another shortened version of the word. All of these mean that acetaminophen is in the medicine.

**Can I safely give it to a child?**

When used as directed, acetaminophen is safe and effective for children for relief of pain and fever reduction. In mid-2011, the makers of infants’ and children’s single-ingredient liquid acetaminophen products initiated a transition to a single children’s strength (160 mg per 5 mL) to help parents and caregivers prevent possible dosing confusion. For more information on this transition, visit [OTCsafety.org](http://OTCsafety.org). For children under two, talk to your doctor or other healthcare professional.