

A Closer Look at Pacifier Safety and Recalls

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Figure 1: Recalled Playtex pacifiers (from cpsc.gov).

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Introduction

Pacifiers are an integral part of baby care — a soothing product that is beneficial to infants. The American Academy of Pediatrics (AAP) has suggested that pacifiers may <u>reduce the risk of SIDS</u>. Yet, when Kids In Danger (KID) took a look at SaferProducts.gov reports and other data from the CPSC, we found a recent and ongoing string of incident and injury reports involving pacifiers that raise questions as to whether a review of pacifier safety standards and/or a tightening of regulation is required.

Since 2010, 11 pacifiers from various brands have been <u>recalled</u>. Most failed to meet <u>safety</u> <u>standards</u> or fell apart, posing choking and ingestion hazards. Some pacifiers were found to be toxic because of the unsafe materials used in their manufacture.



Figure 2: A broken plastic pacifier. These sharp plastic edges pose a laceration risk when they break inside or around a child's mouth (from themommahen.wordpress.com).

Data

A review of recent product <u>reports</u> since 2011 from <u>SaferProducts.gov</u>, the consumer incident database at the US Consumer Product Safety Commission (CPSC), shows 97 reports involving pacifiers. Common reports indicate that infants have been able to break pacifiers, usually while pacifier is in the infant's mouth or while child is sleeping, and the pieces may cause lacerations or lead to choking. Common injuries caused by broken pacifier pieces are bruising and bleeding of the roof of the mouth or the gums.

In addition, according to the <u>National Electronic Injury Surveillance System (NEISS) database</u>, which takes information about reported hospital visits due to unsafe products and provides a national probability sample, there have been 179 reported visits to emergency rooms because of pacifiers between 2010 and 2014. This data can be roughly projected to an estimated 7,500 incidents just involving pacifiers across the country during this time period-- the majority of those incidents involve choking on small pieces, laceration of the lip, poisoning hazards, and allergic reactions. Rashes caused by allergic reactions were especially abundant.

A statistical overview of SaferProducts.gov reports reveals important safety information:

- Of 97 incident and injury reports, 65% stated pacifier was a choking hazard, 19% a
 laceration hazard, and 14% an ingestion hazard (which includes incidences of mold,
 material chipping, and children swallowing pieces of the pacifier).
- Although the age range of the reports were between 3 months and 23 months, the average age of infants in these reports is 8 months.
- Seventy nine percent of the incidents involved babies choking on pacifier [pieces]
 and/or the pacifier impeding air flow to the child by getting stuck in the child's throat.



Figure 3: A pacifier with a broken plastic base. Small broken pieces can be ingested and children can choke on them (from SaferProducts.gov).

When investigated in more detail, reports can illustrate the most common specific dangers with unsafe pacifiers: They have shown infants choking on pacifiers as they try to insert the pacifier sideways, causing the pacifier to flip while inside the mouth and posing a large choking risk, or as the plastic breaks within the mouth and causes lacerations. It is also possible for the nipple of the pacifier to detach. One

incident reports of a child swallowing the nipple of a pacifier and needing to remove it through partial bowel removal surgery. Other infants have choked as a pacifier lodged into the back of their throats. Less common incidences cover a variety of pacifiers that sprout mold, regardless of whether or not the pacifiers were in use.

Regulatory Response

Because of their high potential for choking and grave bodily harm for infants, pacifiers were one of the only children's products required to meet a CPSC <u>standard</u> prior to the passage of <u>Danny's Law</u> in 2008. This is known as the Requirements for Pacifiers, 16 C.F.R. Part 1511, which states:

- 1. The shield not be so small or flexible that it can be sucked into a child's mouth;
- 2. The pacifier have no handles or other protrusions, that are long enough to force the pacifier into the child's mouth if the child falls or lies on its face;
- 3. Pacifiers are labeled to warn caregivers not to tie the pacifier around the child's neck;
- 4. A pacifier should not produce small parts when tested for breakage potential.

Yet, from these reports and recalls it appears that either the standard should be reviewed and possibly strengthened or more enforcement is needed to keep non-compliant pacifiers off the market and out of our homes.

This standard for pacifier safety is well-intentioned, but given the fact that incidents involving unsafe pacifiers still take place every day, it is not foolproof. This raises the



Figure 4: Recalled Pampers pacifier (from cpsc.gov).

question: Is the standard itself not enough, or are companies still manufacturing and selling products that do not meet this standard? The reality is probably a combination of both. The standard does not address chemical hazards, such as the types of plastics, rubbers or metals used in the products, as well as mold risks. But at the same time, products that fail the law's requirements can still sometimes slip through and enter the market. For those reasons, parents and caregivers must be aware of the hazards of unsafe pacifiers and take action against those risks.

Action Steps

For parents and caregivers that want to make sure their child is safe, KID recommends:

- Check pacifiers frequently for wear and tear, and replace older or worn pacifiers. If an
 item has visible rips, rough edges, or if a piece appears to be falling off, it must be
 replaced.
- Check for recalled pacifiers or those with reports of harm at SaferProducts.gov.
- Do not use a product that has been recalled. If you already own one, dispose of it immediately.



Figure 5: Recalled Playtex pacifier clip (from cpsc.gov).

• Likewise, if you have an incident with a pacifier, report it at SaferProducts.gov to spread awareness.

Recommendations for the CPSC:

- Conduct a review of incident data to determine which products, brands, and models are reported most often
- Review test results of tested pacifiers for safety
- Make recommendations to strengthening the standard or oversight of pacifiers and related products based the previously stated data.

Methodology

All of the information and images in this report are taken from databases managed by the US Consumer Product Safety Commission (CPSC):

- <u>Saferproducts.gov</u>-- Database of product incident reports and recalls for consumer products
- National Electronic Injury Surveillance System (NEISS) -- A national probability sample
 of hospitals in the U.S. and its territories. From this data, product-related injuries
 treated in emergency rooms can be estimated.

KID is a nonprofit organization dedicated to protecting children by improving children's product safety. An important activity is periodic review of injury data to identify emerging hazards and advocate for safety solutions.