

Empire State Consumer Project, Inc. Judy Braiman, President December 1, 2015

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I. Introduction

Empire State Consumer Project, Inc. (ESCP), founded in 1971, is a registered 501c3 Not-for-Profit Organization dedicated to reducing the use of dangerous children's products, pesticides and other chemicals toxic to human and environmental health. We accomplish this by educating consumers and industry, conducting product testing and reporting, and by advocating for regulation where needed to protect the public interest.

One of our most important goals is the protection of children's health and safety. Most parents trust products to be safe that are designed for use by this most vulnerable group of consumers. They also expect that products that should not be used by children be adequately marked with warnings for their intended users. The purpose of our annual report is to highlight products that may have been shown to be unsafe for children because children have been harmed, or that contain ingredients that are proven to be unsafe for children. In some cases, products that are used by children are marked 'Not a Toy' and may fall outside of government regulations for toy safety.

The Consumer Product Safety Commission (CPSC) reports that in the period from 2009 through 2011, there were 336 deaths of children under 5 from nursery products, or an average of 112 annually (2015 figures out in 2 weeks). For calendar year 2014, there were 11 reports of toy-related deaths and 251,800 toy-related injuries treated in US hospital emergency departments (2015 figures out this month). Once again, nursery product deaths far surpass those from toys.

Empire State Consumer Project works with Paradigm Environmental Services in Rochester, New York for its product testing. Paradigm is a full service environmental laboratory specializing in environmental chemistry, asbestos, lead-based paint and consumer product testing (http://www.paradigmenv.com/index.asp).

New information on the chemicals in this report is being discovered all the time and we encourage our readers to consult websites for the most up-to-date information on the health effects related to these chemicals. We encourage you to obtain this information from objective sources that have no financial interest in a specific product. It is also very important to make sure the information you obtain is current because many websites are out-of-date. The CPSC website may be useful to you:

Consumer Product Safety Commission www.cpsc.gov

We urge our readers to exercise caution and consider good public health practices. Avoiding exposure to toxic chemicals whenever possible is prudent and protective.

II. Nursery Products

Deaths and injuries from nursery furniture and related products surpass those from unsafe toys. For the 3-year period 2009-2011, CPSC has reports of 336 deaths, an annual average of 112 deaths, associated with nursery products among children younger than 5.

87% of fatalities reported were associated with: cribs mattresses bassinets cradles playpens play yards infant carriers car seat carriers baby baths bath seats bathinetts

Causes of death included positional asphyxia, strangulation, and drowning, among others. In some instances, the fatalities were attributed to the product; in other cases, the fatalities resulted from a hazardous environment in or around the product.

ESCP is concerned with new crib models that have attached changing tables. Once standing, children may reach dangerous items left on tables.

Crib Safety

ESCP recommends the following standards adapted from materials from the Consumer Product Safety Commission, Keeping Babies Safe, and the American Academy of Pediatrics...

- To prevent suffocation, never place anything in the crib with a baby. Blankets, pillows, and toys should not be used in a crib. Dress baby in an infant sleeper for warmth.
- A crib should meet all current safety standards. More than 11 million cribs and numerous bassinets and play yards have been recalled since 2007. Check www.cpsc.gov to see if your crib has been recalled.

- A crib should have a firm mattress that fits the crib tightly and a fitted sheet. A tight fit means no gaps or spaces. You should not be able to fit more than two fingers between the mattress and the crib side.
- Do not use crib rail bumpers, as they pose a suffocation hazard.
- Always place your baby on her back to sleep for both naptime and nighttime. Never use a sleep positioner, as they are unnecessary and can be deadly. Babies have suffocated in sleep positioners.
- Proper assembly of cribs is paramount. Follow the instructions provided and make sure that every part is installed correctly. If you are not sure, call the manufacturer for assistance. When using a crib, regularly check to be sure all parts are secure. Make sure the crib has no loose or missing parts or slats. Broken hardware, or even a missing screw, can result in a detached side rail, allowing your baby to get caught between the crib mattress and side rail.
- Only repair a crib with parts provided by the manufacturer. Makeshift repairs can create new, deadly hazards.
- Set up play yards properly according to manufacturer's directions. Only use the mattress pad provided with the play yard; do not add extra padding.
- Never place a crib, bassinet, or play yard near a window, as that creates a serious fall hazard and a risk of strangulation on window blind cords.
- Never place a corded baby monitor within 3 feet of a crib, as babies can strangle on cords.
- When buying a crib or other baby product, always fill out and return the product registration card so you can be notified directly if there is a recall or safety alert.

Play Yards

As a reminder, in August 2013, the Consumer Product Safety Commission issued new safety standards for play yards. These standards are different than those for cribs.

http://www.cpsc.gov/en/Regulations-Laws-Standards/Federal-Register-Notices/2013/Safety-Standard-for-Play-Yards-16-CFR-part-1221-Final-Rule-CPSC-Docket-No-CPSC-2011-0064/



Bassinets and Cradles

In September 2013, the CPSC approved new safety standards for bassinets and cradles:

http://www.cpsc.gov/en/Newsroom/News-Releases/2013/CPSC-Approves-New-Federal-Safety-Standard-for-Bassinets-and-Cradles/

Nursery Products in Advertising

Empire State Consumer Project feels that all stores selling products that should not be used in cribs should not display these items in cribs in their stores or in advertising. In Maryland, crib bumpers are illegal.

In 2000, seven stores signed a voluntary agreement with the CPSC to promote safe bedding in their catalogs and advertising – Ikea, Babies R Us, JC Penney, Kmart, Sears, Target and LandsEnd. Of the six store websites we checked (LandsEnd did not show crib bedding on its website), Ikea, Babies R Us, JC Penney, Kmart, Sears, and Target, only IKEA is showing only safe crib pictures.

http://www.cpsc.gov/en/Newsroom/News-Releases/2000/Retailers-Join-CPSC-in-Promoting-Safe-Bedding-Practices-for-Babies---Each-Year-900-SIDS-Deaths-May-be-Caused-by-Soft-Bedding-/

IKEA



Babies R Us



JC Penney



Kmart



Sears



Lands End

Products no longer available on website.

Target



After contacting another company regarding its ad showing a baby in a crib with blankets and pillows, the company decided to change its advertising – not by removing the items from the crib, as we had recommended, but by moving the baby out of the crib and onto the floor.





Secondhand Products

Although buying secondhand is a great way to help the environment, many people are not aware that products purchased at resale shops and garage sales must meet the government's current safety standards. Children's clothing, toys, and baby products must meet regulations that guard against suffocation, strangulation, choking, and other hazards.

Although it is not required that resale products be tested, second hand shops and garage sales must not sell the following items. If a product is hazardous, or does not comply with standards, the product should be destroyed and not be sold or given away to others.

Children's metal jewelry that does not comply with the federal limit on lead of 100 parts per million.

Products that have been recalled by the CPSC (unless the products have been repaired in accordance with the recall).

Toys and other articles intended for use by children and any furniture with paint or other surface coatings containing lead content *known to be** over the specified amount.

Products intended primarily for children age 12 or younger with lead content known to be over the specified amount.

Most cribs manufactured before June 2011 may not be resold.

Durable infant and toddler products, such as play yards, infant walkers, bath seats, bed rails for toddlers, and others that are missing parts, appear wobbly or unstable, or contain known hazards described in the handbook linked below.

Other products that violate the CPSC's safety standards, bans, rules, or regulations, or that otherwise present a substantial product hazard.

*Again secondhand products do not require that the seller test them, so beware of children's metal jewelry and children's painted products especially.

http://www.cpsc.gov//Global/Business-and-Manufacturing/Business-Education/ResellersGuide.pdf



III. Toys

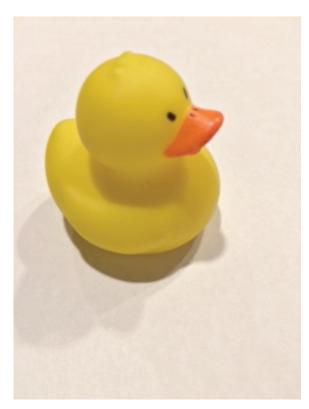
Heavy Metals and Phthalates

Empire State Consumer Products purchased the following products and had them tested for lead, cadmium, and/or phthalates.

Birthday Bead Necklace Tested positive for cadmium.



Rubber Duck
Tested positive for cadmium and phthalates.



<u>Tin Box</u> Tested positive for cadmium.



Princess Key Chain
Tested positive for cadmium.



Sea Star Fish Bracelet Charm

Tested positive for cadmium – 655,000 ppm, Over 2,183 times the limit on cadmium for children's jewelry (limit is even lower for surface coatings). Marked for ages 14+, but may be purchased by/for younger ages or played with by younger ages.



Orange and Black Bracelet Charm

Tested positive for cadmium. Marked for ages
14+, but probably bought by/for children.



<u>Cupcake Necklace Charm</u> Tested positive for cadmium.



Modeling Clay
Tested positive for cadmium.
Tested positive for lead.



Green Car Tested positive for cadmium. Tested positive for lead. Lead 2 times the legal limit.



Lead

Lead is a toxic metal used in a variety of products and materials including paint, vinyl, mini-blinds, pipes, leaded crystal, dishware, ceramic coating, synthetic turfs and jewelry.

When lead is absorbed into the body it can cause serious damage to organs like the brain, kidneys, nerves and blood cells. Lead poisoning is especially harmful to children under the age of six. The US Consumer Product Safety Commission regulates lead in children's products at 100 ppm.

(2011) CPSC Announces New, Lower Limit for Lead Content in Children's Products

WASHINGTON, D.C. - The U.S. Consumer Product Safety Commission (CPSC) voted (3-2) that there was insufficient evidence to make a determination that manufacturers of children's products sold in the United States could not meet a total lead content limit of 100 parts per million (ppm) for a product or product category. The new total lead content limit, which is called for in the Consumer Product Safety Improvement Act (CPSIA), goes into effect on August 14, 2011 for manufacturers, importers, retailers and distributors of children's products.

Through the CPSIA, Congress set tough new levels for lead content in products designed or primarily intended for children 12 and younger. Lead is a heavy metal that is toxic for children, and associated with lowered levels of learning, impaired hearing, brain damage and, at high levels, can be fatal.

Congress directed CPSC to phase in the reduced levels for lead content over a three year period, starting with 600 ppm on February 10, 2009. The level dropped to 300 ppm on August 14, 2009. Finally, Congress directed the total lead content limit be set at 100 ppm, unless the Commission determined it was not technologically feasible for a product or product category.

The Commission was not able to determine that 100 ppm total lead content is not technologically feasible, as

staff found that materials containing less than 100 ppm total lead content are commercially available in the marketplace for manufacturers. CPSC staff also found many products currently on the market, that have been tested by CPSC or other organizations, that are already in compliance with the new 100 ppm total lead content limit.

Starting on August 14, 2011, manufacturers, importers, retailers and distributors of children's products must comply with the new 100 ppm federal limit for total lead content. CPSC will not enforce the CPSIA's independent third party testing requirement for total lead content until December 31, 2011, due to a stay of enforcement that is already in place.

The stay of enforcement does not apply to children's metal jewelry, which currently must undergo independent third party testing.

The new 100 ppm lead content limit does not apply to inaccessible (internal) parts of children's products and certain component parts of children's electronic devices, like electronic connectors and plugs, including headphone plugs.

Lead content levels for children's products are different from the levels Congress set for lead in paint or surface coatings. The limit for lead in paint or surface coatings is .009 percent. The .009 percent level has been in place since August 14, 2009 and independent third party testing is required for all paints or surfaces coatings used on children's products.

Cadmium

Cadmium is a soft silver white metal found naturally in the earth's crust. The common forms of cadmium found in the environment exist in combinations with other elements such as chloride, chlorine and sulfide. Cadmium used in this country is obtained as a by-product to make pigments, and found in metal plating, batteries, plastics, ceramic coatings and jewelry.

Exposure to cadmium can cause harmful health effects. Eating food or drinking water with high levels of cadmium can severely irritate or bother the stomach and cause vomiting and diarrhea.

Breathing high doses of cadmium can irritate and damage the lungs and cause death. Greatest concern is from exposure to lower doses of cadmium over a long period of time. It can cause kidney damage and kidney stones, affect the skeleton and cause lung damage.

The U.S. Department of Health and Human Services determined cadmium is a probable carcinogen. The CPSC limit on cadmium in children's jewelry is 75 ppm for surface coatings and 300 ppm for internal components. If a product contains more than 300 ppm inside, additional testing is required to determine how much cadmium would leach into the body if swallowed. There is no limit for adult jewelry, which parents and others often give to children and cadmium may become more soluble with age. Some manufacturers and sellers add warning labels to jewelry that appears to be made for children in order to bypass the standards.

http://www.cpsc.gov//PageFiles/115615/cadmiumjewelry.pdf

ESCP Petitioned CPSC to set standards for cadmium in children's jewelry http://www.cpsc.gov/pagefiles/123124/tenenbaum0 9062011.pdf

Phthalates

Phthalates are chemical plasticizers often used to in the production of many types of plastics. They are often used to make plastics softer and more pliable. Some phthalates are suspected carcinogens and most are known endocrine disruptors. The limit on phthalates in children's products is 1,000 ppm.

Taken from the CPSC website:

"The CPSC has banned phthalates in toys and certain child care products. Congress has permanently banned three types of phthalates: DEHP, DBP, and BBP in any amount greater than 0.1 percent (1,000 ppm) (computed for *each* phthalate individually) in: (1) children's toys, and (2) any child care article that is designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help children age 3 and younger with sucking or teething.

http://www.cpsc.gov/en/Business--Manufacturing/Business-Education/Business-Guidance/Phthalates-Information/

Magnets

As a reminder to parents who may have these products in the home, In 2013, the Consumer Product Safety Commission recalled Buckyballs and Buckycubes and banned high powered magnet sets from being sold in the US. The CPSC estimates that 1,700 ingestions by young children and teenagers were treated in emergency rooms between January 1, 2009 and December 31, 2011. http://www.cpsc.gov/en/Regulations-Laws--Standards/Rulemaking/Final-and-Proposed-Rules/Magnets/

Magnets and tiny super magnets made of the rare-earth mineral neodymium (15 times more powerful than regular magnets) are popular toys/toy parts that can cause intestinal blockage and even intestinal perforation. If a child swallows more than one powerful magnet or one such magnet and a metallic object, the objects can attract to each other inside the intestines and cause perforations and/or blockage, which can be fatal if not treated immediately. Some cases have required the removal of portions of the bowel. Magnets used by tweens and teens to mimic piercings of the tongue, lip, or cheek have resulted in incidents where the product is unintentionally inhaled and swallowed.

In 2006 and 2007, Magnetix Magnetic Building sets sold before March 31, 2006 were recalled when over 1,500 incidents of magnets separating from the building pieces were reported. One death and 27 intestinal injuries occurred. Originally, the hazard was thought to be a problem for children under 6 primarily, but at least ten injuries involved children between the ages of 6 and 11 years old (http://www.cpsc.gov/cpscpub/prerel/prhtml07/0716 4.html).

Because magnetic resonance imaging (MRI) technology should not be used to detect magnets in the body, parents are urged to consider whether the child was exposed to magnets before imaging of the abdomen is done to diagnose intestinal symptoms, so that non-magnetic imaging can be used.





IV. Artificial Turf

Empire State Consumer Project (ESCP) warns of new questions surrounding the safety of artificial turf. Last year, University of Washington assistant soccer coach, Amy Griffin reported to Seattle news KOMO that 13 Washington soccer players on her recruiting list have been diagnosed with rare cancers and 11 of those were goal keepers. This year, Amy Griffin's list rose to over 158 players with cancer, 101 of them goalies. Although a causal relationship has not been established, this growing trend warrants serious research.

The theory is that goal keepers spend more time playing closer to the ground, diving into the turf on their hands, knees, and faces and that they may be exposed more than other players to the toxic chemicals in the recycled tire crumb rubber from which the turf is made. In 2007, ESCP (formerly RAMP) conducted a screening analysis of artificial turf samples and found a large number of toxics, including the carcinogen arsenic.

The concentrations of some chemicals found in the analysis were compared to the New York State and New Jersey upper-limits of allowable concentrations in the soil at hazardous waste sites that have been remediated. In some cases, these concentrations reported above exceeded hazardous waste site limits. In addition, approaches to evaluating hazardous waste sites typically require that the mixture of chemicals present be considered, rather than each chemical being individually evaluated. When multiple chemicals have the potential to target the same systems in the body (e.g., the nervous system) or are capable of causing mutations, cancer, or birth defects, it is particularly important that protective strategies be developed that consider the total burden of chemicals at a location or in a product. Many of the chemicals identified in fill share numerous target organs, and some are capable of causing cancer and birth defects. That adds complexity to the evaluation of fill, but is relevant when considering the safety or hazards associated with synthetic turf installations or any other consumer product.

We have known for years that artificial turf contains cancer causing chemicals, but this news again brings to light the need for more research. In addition to containing carcinogens, turf fields pose a number of other health risks ESCP has been reporting on since the fields were first introduced in schools. Some studies show a higher incidence of knee injuries and sprains on turf vs. grass. Injuries including 'turf burn' and 'turf toe' are highlighted by 40 Women's World Cup soccer players, including local player, Abby Wambach, who protested the use of artificial turf for the 2015 World Cup. With skin abrasions, additional research is needed to determine whether methicillinresistant Staphylococcus aureus infections, MRSA are more likely with artificial turf than with grass. Heat on and above artificial turf fields has been measured at up to 200 degrees Fahrenheit, causing heat stroke and dehydration in school children as well as professional athletes.

Schools and towns are eager to have the fields installed because there is a perception that communities are providing a better experience for their children if they can afford turf for their schools and parks – perhaps based on an old notion that these fields are somehow improved over the grass fields many parents grew up with.

Although grass is best, until schools and towns can be convinced of its superiority, there are now turf infill products made of coconut fiber and cork, which are more natural options.

Update from the EPA...

"The Use of Recycled Tire Materials on Playgrounds & Artificial Turf Fields Tire Crumb Questions and Answers Updated on November 9, 2015

Background

Ground rubber - also called "tire crumb" or "crumb rubber" - is produced by reducing rubber from used tires to a smaller size. It is used in road construction, a number of athletic and recreational applications and in the manufacturing of new rubber products (e.g. traffic cones, car bumpers, and garden hoses).

Tire crumbs are often used in synthetic turf fields as "infill" between turf fibers. For example, synthetic turf for athletic fields, golf courses, playgrounds, cruise ships, and airports often contain tire crumbs.

States and local governments - the primary agencies that regulate the management of used tires, including options for recycling, reuse and disposal - have historically viewed tire crumbs as a useful product in many applications, including playing fields. However, the use of tire crumbs on synthetic turf fields has changed over the past decade, leading to new questions about their safety.

Current information from a number of tire crumb studies does not show an elevated health risk from playing on fields with synthetic turf or tire crumbs. However, these studies do not comprehensively address new questions and concerns about children's health risks from exposure to crumb rubber.

EPA Action

EPA supports more comprehensive efforts to identify potential exposures to tire crumbs and better assess risks. As new questions arise, new data and analysis are needed. That's why, in response to recent concerns, a plan to identify gaps in research was developed and work is now underway.

EPA and other federal agencies are working with the California's Office of Environmental Health Assessment to provide their expertise for a comprehensive evaluation of tire crumbs. This evaluation is being designed to provide information needed to make more informed decisions about the safety of crumb rubber.

It involves a series of scientific studies to determine if chemicals in crumb rubber can potentially be released under various environmental conditions and what, if any, exposures or health risks these potential releases may pose to players who frequently play on synthetic fields constructed with tire crumb.

The evaluation includes expert solicitation and stakeholder participation to help guide the study and EPA and other federal agencies are actively engaged in that process. For example, scientists from EPA are providing technical advice on the design of the studies and we will continue to engage with California on implementing the study and interpreting results.

Existing Research and Information

In 2008, EPA conducted a limited Scoping-Level Field Monitoring Study of Synthetic Turf Fields and Playgrounds. The purpose of the limited study was to test a method for measuring possible emissions from using synthetic turf on playgrounds and ball fields, not to determine the potential health risks of recycled tire crumb in playgrounds or in synthetic turf athletic fields.

2008 EPA Limited Scoping-Level Field Monitoring Study of Synthetic Turf Fields and Playgrounds

Other federal, state, and local government agencies have also conducted limited studies. For example, in 2008 and 2009, the Consumer Product Safety Commission and the Agency for Toxic Substances and Disease Registry evaluated synthetic turf in response to concerns about lead exposure. Their evaluations estimated that any potential releases of toxic chemicals, such as lead, would be below levels of concern. From 2009-2011, New York City and the states of New York, Connecticut and New Jersey conducted studies on tire crumb infill and synthetic turf.

These studies did not show elevated health risk from playing on fields with synthetic turf or tire crumb. However, they do not comprehensively address new questions and concerns about children's health risks from exposure to crumb rubber.

Last updated on November 9, 2015"

http://espn.go.com/espnw/newscommentary/article/14206717/how-safe-fieldswhere-play

http://www2.epa.gov/chemical-research/use-recycled-tire-materials-playgrounds-artificial-turf-fields

www.komonews.com/news/local/Soccer-coach-Could-field-turf-be-causing-cancer-259895701.html

www.si.com/planet-futbol/2014/08/05/womens-world-cup-artificial-turf-legal-counsel

www.health.ny.gov/environmental/outdoors/synthetic_turf/crumb-rubber_infilled/fact_sheet.htm

www.albany.edu/ihe/Synthetic_Turf_Chemicals.php/ihe/index.php

CDC's Toxicological Profiles for many chemicals: http://www.atsdr.cdc.gov/toxpro2.html

Toxnet (National Library of Medicine's compilation of many toxicity databases): http://toxnet.nlm.nih.gov/index.html

databases). http://toxhet.him.him.gov/index.html

California's list of chemicals known to cause cancer or reproductive damage:

http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html

California's toxicity criteria database:

http://www.oehha.ca.gov/risk/ChemicalDB/index.as

Scorecard Chemical Profile

Search: http://www.scorecard.org/chemical-

profiles/

Hazardous Substances Data Bank:

http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB

"However, they do not comprehensively address new questions and concerns about children's health risks from exposure to crumb rubber."

V. Artificial Mulch

The attached table lists results obtained on laboratory testing of materials used in rubber mulch. Rubber mulch is made of ground recycled tires like those used for making artificial turf fields. The mulch is advertised as a garden and playground mulch. Some products are marked "Playground safety tested." There are no government standards for testing the safety of rubber mulch for playground use or for garden use. The East Rochester, New York school district is using Nike Grind infill on its artificial turf field.

Among other health effects caused by arsenic and cadmium (both found in samples tested), both are known to be human carcinogens (cancer classification NTP). Zinc, also found in samples, is known to cause respiratory and digestive health effects, and pancreatic and kidney damage. http://www.atsdr.cdc.gov/substances/index.asp Inhalation, ingestion, and dermal exposure to toxic chemicals are all concerns where children play. Where foods are grown for human consumption, toxic chemicals potentially leaching into plants is also a concern that warrants study.

We have included only chemicals that show levels higher than current acceptable limits. The 'limits' are NYS DEC soil cleanup guidelines for brownfields. These are minimum requirements and do not imply safety. Limits must be adjusted downward when multiple chemicals are found together. US EPA limits for groundwater and wildlife exposure have not been included. Although some chemicals show values below equipment detection limits, in some cases, detection limits may be higher than DEC limits; these chemicals warrant further analysis.













VI. Adult-only Laxatives

Due to serious safety concerns raised in an FDA Citizen Petition filed by Empire State Consumer Project (ESCP), in 2013, the US Food and Drug Administration (FDA) agreed to study the effects of polyethylene glycol 3350 (PEG 3350) laxative use in children and issued a grant to the Children's Hospital of Philadelphia to conduct the study. ESCP submitted the petition in 2012 on behalf of parents who say their children have been harmed by polyethylene glycol 3350 drug products. There is special concern about the safety of PEG 3350 laxatives like Miralax, which are not approved for use in children, and are not approved for more than seven days use. Many children are prescribed multiple daily adult doses by doctors off-label, often for months or years at a time. The ESCP petition calls for an investigation into the effects of PEG 3350 on children and a boxed warning on PEG 3350 products. The boxed warning was not granted, but the FDA has decided to update the labeling of prescription PEG 3350 bowel preparations with more stringent warnings and precautions for patients with certain health conditions.

The safety concerns reported in the FDA Citizen Petition are symptoms similar to those of ethylene glycol toxicity. The petition grant includes an agreement by FDA to study the potential for PEG 3350 to degrade into ethylene glycol (EG) and diethylene glycol (DEG), and to study the long term effects of PEG 3350 products on pediatric patients. Ethylene glycol and diethylene glycol are chemicals used to make antifreeze. Both are toxic to the central nervous system, liver, and kidneys when ingested. In recent history, DEG contaminated cough and acetaminophen syrups killed hundreds of adults and children. In 2007, the FDA issued a warning for consumers not to buy toothpaste from China, as some brands were made with DEG.

The FDA Adverse Event Reporting System (FAERS) shows over 7,000 adult and child adverse event reports that include at least one PEG 3350 product, including a number of deaths. The number of reports rose from 2,257 in 2012, when the FDA Citizen petition was filed. In 2009, the FDA Drug



Safety Oversight Board acknowledged neuropsychiatric, metabolic, gastrointestinal, and kidney events in children who took PEG 3350 laxatives, but felt that "no action was required" at that time:

"The Drug Safety Oversight Board discussed reports of metabolic acidosis, metabolic acidosis with increased anion gap, and neuropsychiatric adverse events in children using polyethylene glycol (PEG) products. Metabolic acidosis is a disturbance in the body's acid-base balance and causes too much acid in the blood. In some situations, metabolic acidosis can be a mild. chronic condition; however, it may lead to shock or death in severe cases. Neuropsychiatric adverse events may include seizures, tremors, tics, headache, anxiety, lethargy, sedation, aggression, rages, obsessive-compulsive behaviors including repetitive chewing and sucking, paranoia and mood swings." "It is unknown if prolonged duration in solution would change the chemical properties of PEG-3350, and what the actual content of ethylene glycol or diethylene glycol or other low molecular weight PEG would be under such conditions."

In addition to the ethylene glycol and diethylene glycol children may be exposed to through the degradation of PEG 3350, the FDA has tested 8 lots of polyethylene glycol 3350 and found ethylene glycol and diethylene glycol contaminants in the product itself:

"To better understand the level of polyethylene glycol impurities in PEG, the FDA Chemistry and Manufacturing group evaluated PEG 3350. This analysis of eight lots of PEG 3350 confirmed the presence of small amounts of ethylene glycol and diethylene glycol in all lots tested. Based upon the recommended daily adult dose of 17 mg daily dose PEG 3350, the maximum daily exposure of ethylene glycol would be 0.005 mg/kg/day for a 60 kg patient, or 0.015 mg/kg/day for a 20 kg pediatric patient (approx 5 years of age). Other low molecular weight PEGs were not included in this analysis. However, it is not known if any of these LMW species are absorbed and if so to what extent. Understanding the human absorption profile of LMW species is the first step needed in trying to understand the possible contribution of PEG 3350 use to the development of adverse events in children using this product chronically."

Empire State Consumer Project has since petitioned the FDA to issue a Drug Safety Communication regarding the finding of ethylene glycol and diethylene glycol in all lots of PEG 3350 it tested, so that parents of study participants and all parents can be made aware of the potential for PEG 3350 to contain ethylene glycol and diethylene glycol. This petition for a Drug Safety Communication was denied.

The EPA recommends that children not be exposed to more than 20 mg/L or 20 parts per million (ppm) of ethylene glycol in drinking water per one day or 6 mg/L or 6 ppm per day over 10 days. The adult doses of PEG 3350 tested were found to contain 0.3 mg of ethylene glycol of daily exposure for a 44 lb. child. This exposure is in addition to any EG and DEG exposure that may be found to occur from PEG 3350 degradation of the laxative products. The health effects of long term exposure of children to PEG 3350 are not known, although risks from short term exposure to EG and DEG are well documented in humans.

2015 Update:

Adverse event reports are now over 11,500. We have contacted the FDA regarding the progress of the study at Children's Hospital of Philadelphia (CHOP) to express our concern that the study be a comprehensive assessment of the effects of PEG 3350 use in children. Rather than making the assumption that absorption alone is leading to neuropsychiatric symptoms in children, we have asked the FDA to include the following testing in CHOP's research. We feel that if PEG testing alone does not prove that EG or DEG is being absorbed, we have lost the opportunity to look for other factors that may be contributing to neuropsychiatric symptoms in children. We are still awaiting answers from the FDA on this and an earlier Freedom of Information request.

As we asked in our FDA petition, what are the effects of chronic laxative use on nutrient absorption and depletion in children? Many nutrients, including B vitamins and magnesium are related to neuropsychiatric health. If there is evidence that chronic laxative use blocks nutrient absorption or depletes nutrients, what key nutrients can be measured while blood is being drawn for PEG, EG, DEG. (See petition page 15, absorption? http://www.regulations.gov/#!documentDetai l;D=FDA-2012-P-0566-0001).

Effects of chronic laxative use on the enteric nervous system and feedback to the central nervous system. As we asked in our petition, what effects does peg laxative use have on intestinal flora (FDA petition page 15)? How does this affect the nervous system in the intestines that would impact neuropsychiatric health? If it is true that 95% of seratonin is found in the bowels and that 90% of the fibers in the vagus nerve transmit information from the gut to the brain and not the other way around

(http://www.scientificamerican.com/article/gut-second-brain/), can we measure this effect in children on PEG 3350 through blood and stool testing?

Metabolic acidosis was acknowledged by the 2009 FDA Drug Safety Oversight Board as an adverse event related to PEG 3350 use in children. As metabolic acidosis is a cause of demylenation of nerves (as is B12 deficiency) and related neuropsychiatric symptoms, will metabolic acidosis be tested for in children being studied?

http://www.merckmanuals.com/home/brain_spinal_cord_and_nerve_disorders/multiple_sclerosis_ms_and_relate_d disorders/overview of demyelinating_disorders.html

http://www.nationalmssociety.org/For-Professionals/Clinical-Care/Diagnosing-MS/Signs-and-Symptoms-Consistent-with-Demyelinating-D#section-6

Empire State Consumer Project FDA Citizen Petition and FDA Response

http://www.regulations.gov/#!searchResults;rpp=25; po=0;s=FDA-2012-P-0566;fp=true;ns=true

NIH Grant to Study PEG 3350 and Test of 8 Lots http://grants.nih.gov/grants/guide/rfa-files/RFA-FD-14-088.html

Empire State Consumer Project and Reply to FDA Petition Response

 $\frac{\text{http://www.empirestateconsumerproject.blogspot.c}}{\text{om}}$

New York Times Article on Petition, Science Times http://www.nytimes.com/2015/01/06/science/scrutin y-for-a-childhood-remedy.html? r=0

<u>Today Show Coverage of Study</u> http://www.today.com/video/today/56743393



VII. Detergent Pods

From January 1 to October 31, 2015, the American Association of Poison Control Centers (AAPCC) received reports of 10,497 children under 5 exposed to laundry detergent pods. Although some stores are posting signs in their detergent aisles, some post only in the laundry detergent section or only the dish detergent section - not in both.

ESCP urges all detergent sellers to post this or a similar warning sign on ALL detergent pod shelves:



Walmart detergent pod shelves with no warning signs...





VIII. E-cigarettes

From January 1 through October 31, 2015, the American Association of Poison Control Centers has received 2,689 reported exposures to ecigarette device and liquid nicotine through calls to the poison control centers. Some children have become very ill, with nausea and vomiting being the most significant symptoms of toxicity.

This year, NYS Attorney General, Eric Schneiderman reinforced the state law that requires liquid nicotine to be packaged in child-resistant bottles. http://www.ag.ny.gov/press-release/ag-schneiderman-cracks-down-e-cigarette-industry-announces-settlements-liquid-nicoti-0

According to the US Food and Drug Administration, between 2011 and 2014, hoohak (pipe) use doubled among high school students and ecigarette use increased even more dramatically.

We purchased this hookah smoking gel, which carries an 18+ age warning, on Amazon with no means of age verification...





IX. Young Women and Women's Hygiene Products

The Robin Danielson Act, introduced again this year, would require independent testing of women's hygiene products for toxic chemicals, including tampons, menstrual pads, douches and other feminine hygiene products. Congresswoman Carolyn Maloney first petitioned for the act in 1999, but it did not pass and the next five versions petitioned up until 2014 also did not pass. The original act pushed for just federal research on chemical exposures in feminine hygiene products, but has now shifted towards requiring individual testing of products due to rising concerns about the safety of such products.

It is scientifically known that the membranes in the vagina absorb chemicals fast and without metabolizing/breaking them down, so it is surprising that more research has not been done to consider potential health effects of feminine products. Paraben preservatives in these products and chemicals in plastics used as tampon inserters, have been cited in many preliminary studies as causing endocrine disruption (Nicole). Also, the synthetic fibers used in tampons today provide a perfect environment for toxin production in the body, which is the cause of toxic shock syndrome (TSS). This is why a tampon should never be left in for more than 8 hours. The toxins in the body increase in concentration the longer the tampon remains in the body. Tampons are also known to cause tiny vaginal tears that provide a direct route into the body systems for toxins. This is especially concerning since some studies have even cited the presence of pesticides in tampon cotton samples (Nicole).

Due to lack of research, all of the potential health effects of the chemicals above are unknown. Toxic shock syndrome is the only disease with data available, as it has an acute onset and is deadly. The Robin Danielson Act, in fact, is named after a girl who died from TSS. While TSS is now well-known and no longer widespread as it was in 1980's, it is still a concern today. Those inflicted still usually require hospitalization and intensive care. A National Institutes of Health (NIH) study using data taken from 2000-2006 says young

women age 21 are at the highest risk and the incidence is about the same as that of strep throat and meningitis (DeVries). Yet despite this known scientific data, the FDA still relies solely on the data of the manufacturers for accessing chemicals. This data is likely incomplete. Currently, the only chemical in female hygiene products that the FDA requires to be tested is dioxin, which is why more research and testing is imperative.

Women spend \$2 billion dollars annually on feminine hygiene products (Nicole). The Robin Danielson Act would ensure sufficient research and testing is conducted to achieve health equity for women so that \$2 billion is not spent on items that are potentially damaging women's health.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3948 026/ (Nicole)

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3157 910/ (DeVries)

https://www.congress.gov/bill/114th-congress/house-bill/1708/text

X. Children and Sexting

Canon City High School in Colorado was the scene of a recent scandal involving a ring of over 100 students sharing hundreds of nude photos. The investigation continues as school and law enforcement officials try to determine the legal ramifications of children posting nude pictures of themselves, if any of the photo sharing was a result of coercion, and whether anyone involved was not a minor.

The children were using 'vault apps' that appear as innocent phone applications such as calendars, but are used to hide photos viewed by entering a password.

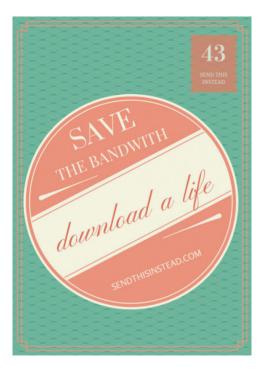
Many parents would be surprised to learn that the National Society for the Protection of Cruelty to Children considers sexting to have become a 'normal teenage behavior.'

(https://www.nspcc.org.uk/preventing-abuse/keeping-children-safe/sexting/)

The South Eastern Centre against Sexual Assault of Victoria, Australia offers exceptional advice about sexting for students and parents through its campaign "Respect Me. Don't Text Me." http://www.secasa.com.au/assets/Sexting/Sexting-infosheet-students-v7.pdf

The Ontario, Canada Child Sexual Exploitation Investigations unit offers its <u>Send This Instead</u> phone app, which helps teens turn down requests for sexually explicit phone pictures... http://sendthisinstead.com/





XI. Wifi and Children's Health

This year, the World Health Organization called for worldwide standards to be set for children's exposure to wifi radiation. This was most likely prompted by the 2,000 scientists from 39 different countries who submitted appeals to the WHO to increase the status of radiation frequency and electromagnetic fields to that of a 2A carcinogen. The 2B distinction currently held means that it is "possibly" carcinogenetic to people whereas 2A would classify this radiation as a "probable" carcinogen

(http://monographs.iarc.fr/ENG/Classification/).

Wifi is just one form of an electromagnetic field that emits very low-level radiation, yet low-level does not necessarily mean it is safe, especially for young children. There is no research on the effects of this very low radiation on children. The American Academy of Pediatrics (AAP) has said that, "The differences in bone density and the amount of fluid in a child's brain compared to an adult's brain could allow children to absorb greater quantities of RF energy deeper into their brains than adults... the current exposure limits may not reflect the latest research on RF energy"

(http://citizensforsafetechnology.org/Letter-from-the-American- Academy-of-Pediatrics-to-US-Congress,24,2818).

In 2013, the AAP asked the Federal Communications Commission (FCC) to set standards for children's exposure to wifi radiation, however, the FCC has yet to produce any standards (http://apps.fcc.gov).

Meanwhile, schools in Austria, Germany, and Canada are already taking action by banning wifi in schools. In January, France outlawed wifi in early childhood education programs, including nursery schools and in elementary schools wifi is to be turned off when not needed. Additionally, all wifi hotspots are required to be clearly labeled now. (http://ehtrust.org/france-new-national-law-bans-wifi-nursery-school/).

The American FCC must take similar measures by conducting research, setting standards, and then helping formulate adequate laws to ensure maximum health and protection from wifi radiation for children and adults alike.

ESCP recommends that US schools become educated about this emerging topic in children's health before installing additional routers in school buildings.

XII. ESCP High Marks, Low Marks

Our new section, High Marks, Low Marks is added to highlight those companies we feel are doing the right thing to keep children and the environment safer and those who are doing a poor job and need improvement.



High Marks

The Lego Group for spending \$1 billion to find sustainable alternatives to the 6,000 tons of plastic is uses annually to make its Lego building blocks.

The Ontario, Canada Child Sexual Exploitation Investigations unit for its <u>Send This Instead</u> phone app, which helps teens turn down requests for sexually explicit phone pictures...

http://sendthisinstead.com/

Wegmans (Rochester, NY) and Hegedorns (Webster, NY) supermarkets for committing to posting signs on detergent pod shelves before the government recommended it.



Low Marks

Companies that continue to carry nursery products that are known to pose a suffocation hazard: crib bumpers, sleep positioners, and infant pillows.

Amazon, for its lack of surveillance of unsafe products, especially those on CPSC warning lists or recalled by the CPSC, but are still available for sale after recall dates.

Ebay, for its failure to post warnings on pages that sell old cribs and nursery furniture, which should not be used for other than decorative purposes.

Walmart, for not posting warning signs on their detergent pod shelves.

XIII. Attachments

A. Artificial Mulch Test Results

Empire State Consumer Project Rubber Mulch Chemical Analysis October 2015 Contact: Judy Braiman, President judybraiman@frontiernet.net 585-383-1317

The attached table lists results obtained on materials used in rubber mulch. Rubber mulch is made of ground recycled tires like those used for making artificial turf fields. The mulch is advertised as a garden and playground mulch. Some products are marked "Playground safety tested." There are no government standards for testing the safety of rubber mulch for playground use or for garden use. The East Rochester, New York school district is using Nike Grind for the infill on its artificial turf field.

Among other health effects caused by arsenic and cadmium, both are known to be human carcinogens (cancer classification NTP). Zinc is known to cause respiratory and digestive health effects, and pancreatic and kidney damage http://www.atsdr.cdc.gov/substances/index.asp. Inhalation, ingestion, and dermal exposure to toxic chemicals are all concerns where children play. Where foods are grown for human consumption, toxic chemicals potentially leaching into plants is also a concern that warrants study.

We have included only chemicals that show levels higher than current acceptable limits. The 'limits' are NYS DEC soil cleanup guidelines for brownfields. These are minimum requirements and do not imply safety. Limits must be adjusted downward when multiple chemicals are found together. US EPA limits for groundwater and wildlife exposure have not been included.

Although some chemicals show values below equipment detection limits, in some cases, detection limits may be higher than DEC limits; these chemicals warrant further analysis.

Empire State Consumer Project Artificial Mulch Test Results October 2015

- * Equipment detection limits for these tests of Arsenic are higher than the NYS DEC limit. These products warrant further testing.
- **Equipment detection limit for this test of Chrysene is higher than the NYS DEC limit. This product warrants further testing.

CHEMICAL NAME		COMPARSION L	IMITS	MEASURE	D CONCENT	RATION IN	PPM (MG	/KG)
(Chemical group I	group listed first)	NYS DEC	Sample A	Sample B	Sample C	Sample D	Sample E	Sample F
		Limit						
D. C. L. L.								
Metals								
Arsenic		0.11	4.48	<0.455*	<0.467*	<0.472*	4.11	<0.490*
			40.727 x				37.363 x	
			limit				limit	
Cadmium		0.43	1.72	1.38	1.93	3.55	1.79	0.612
			4 x	3.2 x	4.488 x	8.255 x	4.162 x	1.424 x
			limit	limit	limit	limit	limit	limit
Zinc		1100	16700	16100	10200	7740	10800	15700
			15.182 x	14.636 x	9.272 x	7.036 x	9.818 x	14.272 x
			limit	limit	limit	limit	limit	limit
Semi-Volatile Org	anics							
(Base Neutrals): A	nalyte							
Chrysene		1	2.04	<1.460**	1.37	<0.286	1.05	0.487
			2.04 x		1.37 x		1.05 x	
			limit		limit		limit	