Table of Contents

Hidden HAZARDS

Health Impacts of Toxins in Polymer Clays

Executive Summary

Polymer clays are a form of modeling clay that have become popular in recent years among children, adolescents and adult craftspeople. They are inexpensive, come in a variety of colors, are soft at room temperature, can be molded by hand into small or large items, and can be baked in a conventional oven at low heat, resulting in a permanent hard object. Fimo and Sculpey are the most common brand names of polymer clays in the U.S., but other different product lines exist.

Unfortunately, these clays contain polyvinyl chloride (PVC) mixed with phthalate (pronounced tha- late) plasticizers. While the phthalate plasticizers make the clay soft and workable, they are also associated with potential health risks. Phthalates as a class of chemicals have been implicated in birth defects, reproductive problems, nerve system damage and other negative health effects.

VPIRG's research indicates that children and adults using polymer clays may be exposed to phthalates at harmful levels. Even when clays are prepared following proper package directions, children and adults can breathe or ingest high levels of phthalates. In addition to phthalate exposure the research indicates that when polymer clay is overheated enough or accidentally burned, the PVC will break down and release highly toxic hydrochloric acid gas.

The potential for exposure to phthalates from normal use of polymer clays is troubling given the popularity of the clays both at home and at schools, the inadequacy of consumer warnings about the effects of these chemicals, and the effects phthalates may have on children. Moreover, since the Federal Toxic Substances Control Act does not require pre-market testing for new industrial chemicals, and because it is difficult to restrict the use of existing chemicals in commercial products, exposure to phthalates is cause for concern.

VPIRG recommends that consumers avoid using polymer clays and calls on the Consumer Products Safety Commission (CPSC) to recall or suspend sale of polymer clays until they are shown to be safe for use by children and pregnant women. If the products remain on the market – VPIRG calls on manufacturers to provide adequate warnings to consumers as to why they should avoid use of the products or take special precautions when using them. Finally, state Attorneys General should investigate the claims by manufacturers that the clays are "non-toxic."

Health Risks of Phthalates

Phthalates are associated with a diversity of negative health impacts including reproductive defects, birth deformities, liver and thyroid damage, neurological impacts as well as miscarriages. At least one phthalate is listed as an EPA probable human carcinogen. The following list illustrates the health risks of some different phthalates:

- **DnOP** (Di n Octyl Phthalate) – Birth deformities, reproductive disorders, liver and thyroid impacts, and linked to gene mutation in mixture with other compounds.
- **DnHP** (Di n Hexyl Phthalate) – Reproductive disorders, liver and thyroid impacts, linked to gene mutation in mixture with other compounds.
- **BBP** (Butyl Benzyl Phthalate) – Reproductive Disorders, birth deformities, suspected carcinogen, but studies inconclusive, and links to nerve disorders and miscarriages.
- **DEHP** ((2 ethylhexyl) Phthalate) – birth deformities, reproductive disorders, EPA

"probable human carcinogen", Dept. of Health and Human Services "Potential Human Carcinogen", liver, kidney and thyroid impacts.

- **DINP** (Di isononyl phthalate) – Reproductive disorders and developmental harm.
- **DEHT** (Di (2 ethylhexyl) terphthalate) – Unknown

Inadequate Research and Information about Phthalates

To date, only a few phthalate compounds are assumed to present the most significant exposure risk to humans. DEHP used in medical devices, and DINP used in children's toys, have been the subject of much focus because they have been used in higher volumes than other phthalate esters. But regulators have significantly underestimated the general public's exposure to other phthalates and combinations of phthalates in consumer products, and therefore have not comprehensively studied them. This is especially true for the phthalates found in polymer clays.

For example, the National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) panel assigned to study the risks phthalate exposures posed to human reproductive health suggested that BBP was of only "minimal" concern for reproductive effects in humans because exposures in adults were assumed to be low -- around 2 micrograms per kilogram of body weight. *Yet VPIRG's research shows that a 20 kg (44 lb.) child using 100 grams of polymer clay could be exposed to as much as 130 times the 2 micrograms per kilogram of body weight of BBP the panel identified as normal daily exposure after only 5 minutes of play*.

Moreover, recent evidence indicates that phthalate exposures are ubiquitous among the general population in the U.S. and, in some cases, higher than previously thought. Recently, CDC analytical chemists, analyzed thousands of urine samples from all over the U.S. and found multiple phthalate metabolites in all samples tested. These metabolites included less common phthalate esters. The CDC team theorized that the residues of these phthalate compounds may result from their presence in consumer products.

VPIRG's Findings

VPIRG sent samples of Sculpey and Fimo polymer clay products purchased from local stores in Montpelier, Vermont to laboratories for both compositional analysis and exposure analysis.

Compositional Analysis

Laboratory testing of the clays by Philips Services (PSC) in Ontario Canada revealed that mixed phthalates made up between 11 and 14% of the total contents of each of the Fimo samples. The Sculpey samples each contained between 3.5 and 4.4 percent mixed phthalates. \

The Fimo clays appeared to contain mostly DnOP, DnHP, DEHT and an unknown phthalate ester (named Unknown #2 by the lab) that strongly resembled DEHP. The Sculpey clays appeared to contain mostly BBP, and a mixture of DnOP and DEHT. Both brands of clays also contained significant amounts of several other phthalate compounds the lab was unable to positively identify using the customary phthalate standard.

Exposure Analysis

VPIRG commissioned the Environmental Quality Institute (EQI) at the University of North Carolina-Asheville to assess human exposure to phthalates when polymer clays are used according to packaging directions. Researchers at the lab, specializing in real-world environmental exposure assessment prepared and baked clay samples following the manufacturers' directions, and measured releases of phthalates in the air and residues of phthalates on users' hands.

The EQI lab found that, when prepared as directed, polymer clays could expose children and adults to significant concentrations of phthalates, including BBP, DnOP, and DnHP, from both handling the clays and breathing in

air contaminated with phthalates during the baking process.

Inhalation Exposure

Regulatory agencies have not set allowable inhalation levels for the phthalates found in the polymer clays tested (BBP, DnOP, DnHP, DEHT). The Occupational Safety and Health Administration (OSHA) has however, established an eight-hour standard for adult workers' exposure to DEHP and DEP, at 5 milligrams per cubic meter of air. Using this standard as a measure for comparison, inhalation testing showed that Fimo Lavender could result in phthalate exposures (to both BBP, DnOP/DEHT mix, and to unknown #2) twice this high at 11 milligrams per cubic meter. The average phthalate exposure from the clays other than lavender measured 2 milligrams per cubic meter – an amount that closely approaches the 5 milligram per cubic meter OSHA standard for adult workers when we consider that this standard is an adult standard only, and children are the primary users of polymer clay.

It is troubling that the average exposure to phthalates so closely approaches the OSHA standard because those exposed to phthalates are likely to be children. Children's bodies are much smaller and more vulnerable to outside factors than adults' bodies; they breathe more air per body weight than adults and are therefore exposed to more air contamination. The OSHA standard was created for adult workers, and the 5 milligrams per cubic meter OSHA standard is not likely to be adequate to use as a measure for phthalates exposure in children. For comparison, Federal pesticide law mandates setting an exposure limit for children ten times lower than the limit for adults if comprehensive testing data are not available (as is the case with phthalates).

Ingestion Exposure

Phthalate residues left on a user's hands and ingestion levels were estimated using the Consumer Product Safety Commission's assumption that fifty percent of material deposited on hands will be ingested by a child. Since regulatory agencies have not set standards for phthalate ingestion, state drinking water standards were used to compare the exposure levels found in the study. The results showed that a child who played for 5 minutes with 100 grams of five of the clays tested could exceed the maximum daily exposure level for the phthalate, BBP, allowed under Florida's drinking water limit. Every single clay tested resulted in exposures exceeding Minnesota's drinking water standard for BBP.

Cumulative Exposure

EQI's analysis likely underestimates the potential phthalate exposures for many children using polymer clays. The researchers measured exposures for only four of the eight separate phthalate compounds identified in the clays. Further, while EQI researchers estimated exposures based on the use of 100 grams of clay, actual preparation of these clays may involve far larger quantities. Various polymer clay "recipes" include concoctions that demand about a pound (~450g) or more of polymer clay material. A child following a recipe for a one-pound project could be exposed to nearly five times as much phthalates as projected by the EQI analysis.

Moreover, this study has focused on the implications of exposure to only a few phthalate compounds. Simultaneous exposures to multiple related phthalate esters can easily take place through the routine preparation of polymer clays. This repeated exposure could have a cumulative impact that is not yet fully understood.

Unsatisfactory Consumer Warnings

Rather than warning consumers about phthalates in polymer clay products, packaging on polymer clays actually advertises the products as "environmentally friendly" and "non-toxic." These misleading labels are based on the assumption by the Arts and Creative Materials Institute (ACMI), the organization

approving the non-toxic label, that polymer clays only contain a few phthalate esters. However, VPIRG's research shows that polymer clays contain phthalates other than those the ACMI considered. Non-toxic certification was granted to polymer clays even though not all the chemicals found in polymer clays were studied for health impacts. It should be noted that the ACMI is a consortium of art and craft material manufacturers.

Inadequate Federal Regulations

Because the U.S. regulatory framework does not require pre-market testing for new industrial chemicals before they are used in the marketplace, and it is difficult to restrict use of existing chemicals, many harmful chemicals end up in consumer products. Of over 80,000 chemicals used in the marketplace today, the vast majority are untested for human health impacts. This is alarming because consumers may be exposed to chemicals like phthalates on a frequent basis without knowing what the health impacts from exposure may be.

Recommendations

In response to the results of these tests, VPIRG makes the following recommendations:

- The CPSC should declare a moratorium on the sale of polymer clay products until further investigation determines the risks for exposing users to phthalates, especially children and pregnant women. Decision makers should also re-evaluate regulations allowing manufacturers to incorporate harmful chemicals like phthalates into products intended for children without comprehensive health and safety testing.
- If polymer clay products remain on the market, manufacturers should be required to affix clear warning labels on polymer clay products, directing pregnant women and children to not use polymer clay products. Others should be warned to strictly limit contact with the clays by wearing gloves when manipulating the product and to also limit inhalation of clay chemicals by staying out of and ventilating the kitchen during and after baking.
- Decision makers should reform the laws that govern use of chemicals in industry and in products. These laws currently do not require comprehensive testing of industrial chemicals nor do they allow chemicals to be phased out or regulated even when there is evidence of health hazards. The Toxic Substances Control Act has not been updated since the 1970's.
- Retailers should inform manufacturers of their concerns about selling potentially harmful children's products that contain a "non-toxic" label, and should either take these products off their shelves or warn consumers of the potential for reproductive damage and birth deformities.
- Consumers should avoid purchasing polymer clay products until they are proven safe.
- State Attorneys General should investigate manufacturer's claims that polymer clays are "non-toxic."

Hidden HAZARDS

Health Impacts of Toxins in Polymer Clays

Introduction

In recent years a new form of modeling clay known as polymer clay has become the modeling material of choice with children, adolescents, and adult craftspeople. This material is soft at room temperature, can be molded by hand into small or large items, and can be baked in a conventional oven at low heat, resulting in a permanent solid object. The clays come in a wide array of colors, including fluorescent and marbled tones, are inexpensive, and are readily available in almost any toy store or arts and craft outlet.[1]

The most popular brands of polymer clays are Fimo and Sculpey, made respectively by Eberhard Faber in Neumarkt, Germany, and Polyform Products in Elk Grove Village, Illinois. Eberhard Faber is a subsidiary of pencil giant Staedtler.

Retail packages come in a variety of sizes. Fimo is sold in two and twelve ounce packages. Sculpey is sold in two ounce packages, and in bulk (one pound and 24 pounds). Cernit comes in two ounce, 250 gram, and 500 gram packages.

Polymer clay is currently a popular medium in classrooms and art schools. Polymer clay crafters have established local, regional, and national guilds. These associations of thousands of polymer aficionados hold juried exhibitions, supported by manufacturers and distributors.

Polymer clays are made of polyvinyl chloride (PVC) mixed with phthalate (pronounced tha-late) plasticizers. Phthalates are a family of chemical compounds that are structurally similar. They are used in the clay to keep it soft and workable before it is baked. The health risks from exposure to phthalates may vary

The Poisoning of an Alaskan teacher

On October 17, 2000, an elementary school teacher in Alaska suffered acute health problems after walking into a room where Sculpey clay (Sculpey III-blue color) had over-heated when left overnight in a kitchen range. The teacher suffered from headaches, vomiting, fatigue, chest pains, finger numbness, dizziness, a stumbling gait, and other problems. He had to go to a hospital emergency room after suffering from this exposure.

The state of Alaska's occupational health division found that the teacher was exposed to potentially harmful chemicals. It determined that hydrogen chloride and two phthalic acid esters – DOP (Di-octyl phthalate) and BBP -- were "likely products of thermal decomposition." (Thomas E. Stuart, Jr., chief, Alaska Occupational Safety and Health, letter, February 23, 2001)

As part of the investigation, the agency conducted a pyrolytic decomposition study at the OSHA Technical Center in Salt Lake City, Utah. According to the inspection report, "during thermolytic decomposition at approximately 300 degrees F, two phthalate esters (DOP and BBP) volatized from the polymer clay and appeared in the off-gas stream. As the temperature increased to 482 degrees F the production of hydrogen chloride accompanies the volatilization of the phthalate esters." (Alaska Department of Labor, Occupational Safety and Health, "Inspection Narrative," Inspection No. 303694269, January 8, 2001)

The determination that DOP and BBP were the principal phthalates released by overheating the Sculpey modeling clay are consistent with VPIRG's finding that these two compounds are the primary plasticizers present in samples of Polyform Products' Sculpey brand.

Some popular brands of polymer clays found at toys stores or arts and crafts outlets.

Table 1. Polymer Clay Manufacturers

Manufacturer (Country)	
Eberhard Faber (Germany)	Fimo Classic, Fimo Soft
Polyform Products (USA)	Sculpey, Sculpey Fantastic, Elasticlay, Sculpey Gumbasia, Sculpey III, Sculpey Living Doll, Sculpey Premo, Sculpey Sculp-A-Doll, Sculpey Superflex, Super Sculpey, Pro Sculpt, Granitex, Liquid Sculpey, Polyform, Pro-Mat
T&F Kunststoffe (Germany)	Cernit No. 1, Cernit Starter Set, Cernit Glamour, Cernit Neon-Light
Havo B.V.	Creall-Therm (Junior and Professional)
Vinci de Mexico (Mexico)	Modelina, Modello

depending on the specific phthalate ester(s) used in the clay.

Both PVC and the different phthalates have been linked to potential health risks. For example, if the polymer clay is overheated enough, the PVC will break down and will release highly toxic hydrochloric acid gas (See Appendix D). Also, the research in this report indicates that even when polymer clays are prepared following proper package directions, with no accidental overheating, children and adults can breathe or ingest high levels of phthalate compounds. Multiple phthalate compounds have been implicated in reproductive system damage, and harm to the liver and other organs. Research has linked phthalate esters to central nervous system damage, and there is increasing concern that inhalation of phthalates may increase the likelihood of asthma attacks.

Part One: Background on Phthalates

Phthalates are a group of chemicals invented in the 1930s and produced by the petrochemical industry. These compounds are used in a variety of consumer products, including soap, shampoo, hair spray, solvents, pesticides, inks, aspirin, flea collars, and cosmetics. In many of these applications, the phthalates are used to increase the fluidity and smoothness of the products.

Widespread Use
The plastics industry uses large quantities of phthalates to make their products, particularly polyvinyl chloride (PVC), more malleable. The majority of phthalate plasticizers (89%) are used in polyvinyl plastic resins. The balance is used in other vinyl resins (3%), cellulose ester plastics (3%), synthetic elastomers and other polymers (3%) and other applications (2%). Vinyl plastic, according to the Agency for Toxic Substances and Disease Registry (ATSDR), may contain up to 40% of one phthalate compound, Di (2 ethylhexyl) phthalate (DEHP), that is strongly linked to reproductive damage and other health risks.[2]

Poorly Regulated; Poorly Understood Health Effects
Fundamental flaws in regulating toxic chemicals under the current regulatory system (discussed further in part 3) means that there are no pre-market testing requirements for new industrial chemicals, and it is difficult to restrict or regulate chemicals already in use. As a result, available public information about the health effects of individual phthalate compounds varies widely.

Polymer clays contain less commonly used phthalate esters that have not been tested to the same degree as the more common phthalate compounds. Because the regulation and study of the different phthalate compounds in commercial use is so highly variable, much of the public information available tends to focus mostly on those phthalates that industry uses in high volumes. Specifically, DEHP and Diisononyl phthalate (DINP) have been studied intensely. This is because DEHP, used in some medical devices and children's toys, and DINP, used in some toys and products for young children, are produced and used in greater volume than other phthalate compounds, and are therefore assumed to be the most likely sources of phthalate exposure to humans.

However, manufacturers produce many other phthalates in lower volumes that are used in commercial products. These compounds including Butyl Benzyl Phthalate (BBP), Di-n-Octyl Phthalate (DnOP), Terepthalic Acid (DEHT), and Di-n-hexyl phthalate (DnHP), to name only a few, have not been comprehensively tested or studied, though there are studies indicating negative health effects from exposure to them. These less studied chemicals appear in polymer clays. Industry and government regulators appear to have acted on the assumption that phthalates used in low volumes cause little if any harm to human health, because there is minimal exposure. But as will be explained later, a CDC study shows that this assumption may be flawed.

Known Health Effects of Phthalates
Despite the plastic industry's long-standing contention that phthalates pose little or no risk to human health, the body of research evidence linking certain phthalate compounds with long-term human health risks is growing.

Phthalate compounds DEHP and DINP have been shown to cause reproductive and developmental harm.[3] DEHP is a probable human carcinogen as determined by the EPA and a potential human

carcinogen as determined by the Department of Health and Human Services.[4] In addition, DEHP impacts the liver and kidney, thyroid function, nerve function, and has been found to be mutagenic (it can induce cell mutation).[5]

Other less studied phthalate compounds including BBP and DnOP (both discovered in the polymer clays tested), have been linked with reproductive disorders in animal studies, including alterations of sperm-producing organs and reduced testis weight.[6] Some phthalates, including BBP, are also suspected carcinogens in animals, though the evidence that they are carcinogenic in humans remains inconclusive.[7] DnOP and DnHP have been shown to affect the liver and thyroid,[8] and BBP has been linked with nerve disorders in lab animals and in exposed industrial workers.[9]

Unknown Health Effects of Phthalates

For every phthalate compound that is intensely scrutinized because of its high volume use or sensitive applications (i.e. DEHP and DINP), many other phthalate formulations remain little studied and poorly understood. Data on the potential health impacts of dozens of compounds in this class of chemicals are limited or non-existent, despite the ubiquity of phthalates observed in environmental samples for decades.

The limited evidence that exists for lesser-known phthalate compounds suggests that some may share the tendency of their better-known cousins in affecting health. For example almost all the phthalate compounds are linked with reproductive and developmental harms. It is unknown if other health implications like cancer or liver and thyroid impacts cross over through the entire class of compounds.

General Population Exposed to Phthalates

Recent evidence indicates that phthalate exposures are higher among the general population in the United States than previously thought. The most telling data were recently released by Center for Disease Control (CDC) analytical chemists, who analyzed thousands of urine samples from all over the U.S. and found significant levels of multiple phthalate metabolites in all of them. The researchers were particularly surprised by the fact that the phthalates found at the highest levels in the samples were not metabolites of the high volume chemicals they expected – such as DEHP and DINP -- but rather of compounds produced in far lesser volumes. Specifically, they found BBP, a compound also found in the polymer clays VPIRG studied.[10]

This year, a follow up study measuring urine samples in children showed phthalate metabolites were found in children at higher levels than in adults. The study suggests that DBP, BBP and DEHP exposure on a body weight basis may be twice as high for the children tested than for the adults tested in the 2000 study.[11]

The CDC team has theorized that the prevalence of these compounds may result from their presence in consumer products such as cosmetics, to which many people are highly exposed in their everyday lives.[12] Since exposure to such everyday substances may well occur at crucial points in time, such as during pregnancy, phthalates may already be impacting public health in ways that researchers have simply failed to connect with exposures.

The CDC study and other assessments of actual phthalate exposures indicate a likelihood that the general population may be more exposed to phthalates, than has previously been thought. Because knowledge about the health effects of the low volume phthalate compounds is minimal, and little is

known about cumulative impacts of multiple phthalate exposures, these studies suggest that reducing and eliminating exposures wherever possible is a wise precaution. It also suggests that follow up research on these chemicals is urgently needed to protect the public against unnecessary harmful exposures.

Table 2: Phthalates and Known Health Risks

Phthalate Compound	Found in Clays tested?	Known Health Impacts
Di n Octyl Phthalate (DnOP)	Yes	• Reproductive effects • Liver and thyroid impacts • Birth deformities • Linked to gene mutation in a mixture with other compounds
Di n Hexyl Phthalate (DnHP)	Yes	• Liver and thyroid impacts • Linked to gene mutation in a mixture with other compounds • Reproductive effects
Butyl Benzyl Phthalate (BBP)	Yes	• Reproductive disorders • Birth deformities • Suspected carcinogen – but studies inconclusive • Links to nerve disorders.
Di (2ethylhexyl) Phthalate (DEHP)	No	• Reproductive and developmental harm • EPA Probable Human Carcinogen • Department of Health & Human Services Potential Human Carcinogen • Liver, kidney, thyroid impacts • Mutagenic
Di isononyl Phthalate (DINP)	No	• Reproductive effects • Developmental harm
Di Ethyl Phthalate (DEP)	No	• Developmental harm and birth defects • Skin and eye irritation[1]
Di Butyl Phthalate (DBP)	No	• Reproductive and developmental harm • Skin irritation • Possible nervous system and blood pressure impacts[1]
Di Decyl Phthalate (DIDP)	No	• Liver impacts • Reproductive harm[1]
Di (2 ethylhexyl) terphthalate (DEHT)	Yes	• Unknown

Part Two: Findings

Phthalates Found in Polymer Clays

Given the popularity of polymer clays both at home and at schools, there is a very real possibility that children are frequently exposed to significant amounts of the clays' phthalate content by breathing the vapors released as they bake and ingesting residues from their hands. To begin to answer this question and to address the growing awareness about children's exposure to phthalate compounds in soft toys and other plastic items, VPIRG staff commissioned laboratory testing to investigate whether the use of these clays could expose children to phthalate compounds at potentially harmful levels.

Testing for Phthalates

VPIRG staff purchased 10 samples of Sculpey and Fimo from a local toy shop, selecting for different color types including fluorescent, standard, variegated, pale, saturated, and in the case of the Fimo, samples of both standard Fimo and Fimo Soft. Philips Service (PSC) Laboratory in Ontario, Canada tested the samples for phthalate content using the standard procedure to scan for phthalates.[*] PSC found that *each of the five Fimo samples contained between 11 and 14 percent* (110,000 mg/kg to 140,000 mg/kg) *mixed phthalates. The five Sculpey samples contained between 3.5 and 4.4 percent (35,000 mg/kg and 44,000 mg/kg) each of mixed phthalates.* (See Appendix B) On average, the samples contained 8.2% of the total mixed phthalates.

Table 3. Percentage mixed phthalates in unprepared product

	Total Phthalates (%) *
Sculpey – White	3.5
Sculpey – Choc	4.4
Sculpey – Green	4.0
Sculpey – Atom	3.9
Sculpey – Violet	4.4
Fimo – Magenta	11.0
Fimo – Lapis	13.0
Fimo – Green	12.0
Fimo – Yellow	12.0
Fimo – White	14.0

* % product based on milligrams phthalate per kilogram product.

These percentages of phthalates found in the clays tested are cause for concern. To put these percentages in context, the European Union temporarily banned and is contemplating regulating the manufacture or importation of soft plastic toys or other articles meant for small children's mouths that contain, by weight, more than 0.1% (or 1000 mg/kg) of six different phthalate esters, including two compounds present in the clay samples tested for this report (DnOP and BBP).[13] VPIRG's study shows that Fimo clay contains between 110 and 140 times the amount of phthalate compounds allowed in children's toys in Europe, and Sculpey contains between 35 and 44 times that amount.

Identyifying the Phthalates Found in Clays

Through gas chromatography/mass spectrometry – a technology that allows scientists to identify a chemical based on the spectrum of light after it passes through the compound – the PSC lab was able to identify several of the more well-known phthalate compounds contained in the clays. PSC initially

[*] The most common environmental phthalate standard covers testing for the following using a DB5 column during Gas Chromatography/Mass Spectromotry (GC/MS): Dimethyl phthalate, Diethyl phthalate (DEP), Di-n-butyl phthalate (DBP), Benzyl Butyl phthalate (BBP), Di-n-octyl phthalate (DnOP) and Bis (2 ethylhexyl) phthalate (DEHP). Source: electronic communication from Ron McCloud, Ph.D., C.Chem. General Manager, PSC Analytical Services (Burlington) to Susanne Miller, Environmental Health Advocate at VPIRG, dated December 8, 2001.

found that the Fimo clays contained primarily DnOP, and a compound whose characteristics closely resembled DEHP. The Sculpey clays contained mostly BBP and DnOP. Both brands of clays also contained significant amounts of other phthalate compounds the lab could not positively identify using the customary phthalate standard.

VPIRG then looked for information to confirm the identity of the chemicals and to identify the unknown chemicals in the clays. In the course of this research, VPIRG obtained a letter written by Duke University toxicologist, Woodhall Stopford, PhD who was involved in certifying polymer clays as "non-toxic" for the Arts and Creative Materials Institute. His letter indicated that the only phthalate compounds used in the clays were DEHT, and a mixture of DnHP, DnOP, and Di-n-decyl Phthalate (DnDP) known as Di-n-(6,8,10) Phthalate.

Based on this information, VPIRG commissioned PSC to complete additional analysis on the samples to determine the presence of the compounds named by Dr. Stopford, rule out any misidentification, and determine whether any previously unidentified compounds could be identified. To do this, PSC spiked the samples with each of these additional compounds (DEHT, DnHP, DnOP, and DnDP) and reanalyzed them.

The lab found that DnHP's characteristics closely matched a phthalate previously identified as Unknown phthalate #1 which appeared in significant amounts in the Fimo products, and identified that compound as DnHP. DEHT's characteristics were extremely close to DnOP's profile, and the lab concluded that what had originally appeared to be DnOP alone seemed likely to be a mix of both DnOP and some DEHT. By spiking the samples with DEHP, the lab ascertained that the compound previously identified as DEHP was actually another analogous compound of strikingly similar profile, which researchers now identified as "Unknown #2". None of the phthalate compounds found appeared to be DnDP.

PSC's research confirmed that DnOP and BBP are definitely present in the samples, and that DEHT and DnHP also appear to be present, in addition to multiple unidentified phthalate compounds. One single unidentified phthalate was found at a strikingly high level of 46 milligrams per kilogram, and the lab was unable to determine the identity of this compound. The lab's difficulty in pinning down the exact identification of the phthalate compounds indicates the complexity of evaluating claims of non-toxic status for products containing phthalates. Dr. Stopford's implication that DEHT, DnHP, DnOP, and DnDP phthalate compounds are the only phthalates in polymer clays appears to be erroneous, and therefore the "non-toxic" status of these clays may be based on mistaken or incomplete information.

Phthalate names and exposure assessment

Following the PSC's first round of analytical work, the Environmental Quality Institute (EQI) at the University of North Carolina-Asheville assessed the potential exposure to phthalates from using polymer clays.

EQI conducted an exposure assessment after PSC's first round of tests, which had identified the phthalates found in polymer clays as DnOP, DEHP, BBP, and many other unknown compounds. As noted above, the PSC lab later re-identified DnOP as a mixture of DnOP and DEHT, DEHP as Unknown #2, confirmed the presence of BBP, and identified an unknown compound as DnHP. However, EQI's exposure assessments were based on the chemical properties identified by PSC through gas chromatography and mass spectrometry (rather than the name initially given the chemicals), so the re-identification does not change the exposure estimates determined by EQI. One impact is that because DnHP was not identified until after EQI's work was completed, we have no exposure assessment for DnHP.

EQI used 100 gram samples of the polymer clays and found significant exposures to the phthalates identified in the clays, both through inhalation of vapors during use and baking of the clay, and through ingestion of the phthalates from the hands.

Health Effects of Phthalates Found in Clays

A number of lab studies and information from occupational exposure data have linked phthalates found in polymer clays to various health effects.

BBP: Reproductive Damage, Birth Deformities, and Nerve system damage

Each of the Sculpey samples contained on average 1.5% BBP and each of the Fimo clays contained on average 0.2% BBP. BBP is also an EPA suspected carcinogen in animals.[14]

Multiple studies have implicated BBP in reproductive disorders. For example, studies with male rats have linked BBP with testicular atrophy. Two separate studies revealed that after adult male rats were fed 2.5-5% BBP, there was severe testicular atrophy including reduced weight in the testis, epididymus, prostate and seminal vessel.[15],[16] In addition to reproductive disorders in adult rats, BBP can cross the placenta to harm the developing fetus. In an EPA study, researchers found that when pregnant rats were exposed to BBP, DEHP or DINP at doses that did not significantly affect the health of the mother, male offspring showed altered sexual development including reduced testis weight, reproductive tract abnormalities, and female secondary sex characteristics.[17] Occupational health studies in the 1970's linked prolonged exposure to BBP and other phthalic acid derivatives to high rates of miscarraiges and menstrual disorders among female workers in the synthetic leather industry.[18]

BBP has also been linked to birth deformities. A study found that rat pups whose mothers were fed 375 parts per million of a BBP metabolite on days 7-9 of gestation exhibited deformed ribs and vertebral columns and dilation of the renal pelvis. When the mother rats were fed the same dose on days 13-15, cleft palate and fused stenabrae deformities appeared. When the dose was raised to 500 parts per million on any day of gestation, miscarraige resulted.[19]

Toxicology texts associate BBP with polyneuropathy in indistrial workers and central and peripheral nervous system diseases in animals.[20] Exposure to BBP can irritate the mucous membranes and cause central nervous system depression.[21] Studies from the 1970's showed higher incidences of toxic polyneuritus in workers exposed to phthalate vapors to continued lengths of time.[22] In an animal study, rats died within four to eight days after being fed BBP high doses. Researchers found signs in autopsied rats of central nervous system tissue degeneration and congestive encephalopathy (brain disease).[23]

In addition to lab studies, the National Toxicology Program's Health and Safety Package for BBP suggests that all workers potentially exposed to BBP wear double gloves, safety glasses, full body lab suit, and work with self contained breathing apparatus or fume hood to avoid any inhalation of vapors.[24]

DnOP/DEHT mixture: Birth Deformities, Gene Mutations, Liver Damage

The DnOP/DEHT mixture was found to constitute on average 0.2% of the Sculpey clays and 2.8% of the Fimo Clays.

Researchers found very little publicly available studies on the potential health effects of the DEHT compound. One Russian study suggests that mice exposed to saturated DEHT vapors may experience temporary mucosal irritation, loss of coordination and decreased mobility after inhaling vapors for 4 hours.[25] However it appears that little else is known about this chemical. To find a chemical for which no potential health effects are readily available contained at 2.8% in a product intended for children shows a fundamental flaw in our nation's approach to regulating industrial chemicals.

DnOP has been linked to severe birth deformities. In an EPA study pregnant female rats fed between five and ten milliliters of DnOP per kilogram for 20 days, gave birth to deformed offspring. Offspring were born with gross skeletal abnormalities that were dose related, including the absence of a tail, twisted feet and legs, fused ribs, and incomplete or missing leg bones.[26]

DnOP is associated with gene mutations. Rats fed a mixture of DnHP, DnOP, and DnDP, otherwise known as DHODP showed induced gene mutations far exceeding the control group. Specifically, the EPA study used cloned cultures treated with DHODP - all cultures of DHODP with or without metabolic activation produced mutant frequencies greater than the solvent control.[27]

DnOP and DnHP both can cause damage to the thyroid and liver. In one study, rats fed DEHP, DnOP, DnHP were all found to have significant increases in lysosomes in the thyroid and increased amounts of lipid accumulation in the liver. The authors suggest that early changes in the liver induced by phthalate esters, such as enlargement and proliferation of peroxisomes may be linked with subsequent development of liver tumors.[28] In another unrelated study, DnOP and DnHP were fed to male rats, and liver enlargement was slight, but still significant.[29]

Occupational health warnings, list a wide range of possible human health risks from exposure to DnOP. Material Safety Data Sheets (MSDS), created by manufacturers of chemical products as required by law under the Occupational Safety and Health Act (OSHA) are used to communicate occupational risks to persons using chemicals in the workplace.[30] Perhaps the following industry information most clearly outlines the potential dangers from exposure to DnOP.

A MSDS for DnOP recommends that anyone handling the compound should use chemical safety goggles and/or a full face shield, and ensure that the work area is well ventilated. It further warns that these chemicals are, “HARMFUL IF SWALLOWED OR INHALED. CAUSES IRRITATION TO THE SKIN, EYES AND RESPIRATORY TRACT. AFFECTS THE CENTRAL NERVOUS SYSTEM, LIVER, REPRODUCTIVE SYSTEM AND GASTROINTESTINAL TRACT. POSSIBLE CANCER HAZARD. MAY CAUSE CANCER BASED ON ANIMAL DATA. Risk of cancer depends on duration and level of exposure. MAY CAUSE ADVERSE REPRODUCTIVE EFFECTS.” [31]

DnHP: Reproductive Damage, Liver and Thyroid Impacts, Gene Mutations

DnHP was found to constitute on average 0.4% of the Sculpey clays and 0.2% of the Fimo clays.

DnHP may affect fertility. A study found that diets containing high doses of DnHP or DEHP decreased the epidymal sperm concentration, increased the percentage of abnormal sperm, and decreased the percentages of mobile sperm in mice. Mice fed DnHP, DEHP, or DBP had low rates of reproductive success, with less fertile matings and less live pups per litter than normal.[32]

As mentioned above (under DnOP), rats fed DnOP, DnHP or DEHP were found to experience significant changes in the thyroid and liver,[33] and the mixture of DnHP with DnOP and DnDP was found to induce gene mutations.[34]

Unknown #2: Similar to DEHP

An unknown phthalate compound labeled “unknown #2” by PSC was found to constitute on average 0.4% of the Sculpey and 3.4% of the Fimo clays. The presence of this and other unknown phthalate compounds

in significant amounts in a product marketed toward children is cause for concern since the legal system fails to require pre-market testing.

Unknown #2 was similar in structure to DEHP. DEHP is one of the best studied phthalate compounds and has been linked to cancer – listed as an EPA "probable" human carcinogen.[35] It also is linked to reproductive impacts, developmental harm, liver, kidney, and thyroid impacts, as well as gene mutations.[36]

Some of the other clays contained other phthalate esters that were unidentifiable by PSC labs. Such a determination should be a priority for consumer product safety agencies investigating the health risks these clays may pose to children.

Table 4. Health risks of phthalates found in clays

Phthalate Ester	Liver and Thyroid	Birth Deformities	Reproductive Harms	Nerve Damage	Links to cancer?	Occupational Warnings
DnOP	Yes	Yes	Unknown	Unknown	Mutagenic	Yes
DnHP	Yes	Unknown	Yes	Unknown	Mutagenic	Unknown
BBP	Unknown	Yes	Yes	Yes	Suspected carcinogen	Yes
DEHT	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown

Assessing Exposures of Phthalates from Using Clay

Following the first round of analytical work by PSC, VPIRG contracted with the Environmental Quality Institute (EQI) at the University of North Carolina-Asheville to conduct laboratory testing to determine potential exposures to phthalates from preparing polymer clays.

Basing their research on PSC's initial results, (i.e. the determination that the polymer clays contained the identifiable phthalates of DnOP, DEHP, and BBP and other unknown compounds) the EQI performed exposure research on the three originally identified compounds. (See Appendix C) As noted above, the PSC lab later re-identified the composition of the clays to include BBP, a mixture of DnOP/DEHT, DnHP, "Unknown #2" (similar in characteristics to DEHP), and many other unknown phthalate esters. Although the names of the phthalate compounds changed slightly, the chemical esters retained the same retention time and spectra based upon Gas Chromatography/Mass Spectrometry (GC/MS) procedures. This means that the chemical properties are still the same regardless of the name given to the chemical. Similarly, EQI's testing was based on the use of GC/MS procedures, and not on the "name" of the chemical. Therefore, regardless of the exact name of the phthalate esters, the tests revealed high exposure levels to the phthalates when the clays were used as directed.

EQI used small samples of the polymer clays (100 grams to test hand residues, and between 1 and 7 mg to test fume emissions), and found significant exposures to the phthalates identified in the clays both through inhalation of vapors during use and baking of the clay, and through ingestion of the phthalates from the hands.

Exposure Through Inhalation

Air Concentrations Resulting from Baking

The EQI researchers found that baking between 1 and 7 milligrams of the clay samples at 270 degrees for 20 minutes, per the manufacturers' instructions, would on average release 2 milligrams of mixed

phthalates per cubic meter of air (see Table 5). One of the products, Fimo Lavender, released the equivalent of an alarming 11.8 milligrams per cubic meter of air when only 1-7 milligrams of clay were baked.

The emissions from baking only milligrams of Fimo Lavender – 11 milligrams per cubic meter of air – far exceed the eight-hour Occupational Safety and Health Administration (OSHA) standard of 5 milligrams per cubic meter for the high volume phthalate compounds DEHP and DEP.[37] Although Fimo does not specifically contain DEP or DEHP, these OSHA standards are the only federal standards established for phthalate inhalation exposure, and thus can serve as a rough indicator of exposure. DEP and DEHP have been studied more thoroughly than the other phthalates and have been shown to exert harmful health effects on workers, leading to the establishment of the OSHA standard. Yet as discussed previously, the different types of phthalates are closely related and have exhibited similar health effects across the different compounds. Therefore, in the absence of more complete information we may anticipate that different phthalates will have similar impacts upon health. Certainly, regulatory schemes governing children's exposure to these substances in play materials should take a highly cautious approach until better information is available.

Table 5. Concentrations of phthalates in air* micrograms/cubic meter

Product	BBP	Unknown #2	DnOP/DEHP	Total
S-SweetPotato	326.0	338.5	22.5	687.0
S-TerraCotta	183.7	398.7	6.22	588.6
S-Pearl	777.8	61.1	ND**	838.9
S-LilacPearl	214.9	6.05	ND**	221.4
S-LeafGreen	2667.0	37.3	996.1	3700.4
F-Yellow	115.5	400.3	333.2	849.0
F-Lavender	163.8	4993.0	6670.0	11826.8
F-Turquoise	32.3	637.0	689.0	1357.3
F-Green	69.9	40.2	18.9	129.0
F-White	41.9	15.1	16.2	73.2
Average	**459.3**	**692.7**	**875.2**	**2027.2**

* micrograms phthalate per cubic meter of air removed from vial containing product, after baking and cooling to room temperature

** ND = none detected

"Though the OSHA standard applies only to DEHP and DEP, perhaps the most well-studied of the phthalate compounds, it may also serve as an indicator of the level of risk posed by the exposures we found," noted Dr. Richard Maas of the EQI. "An occupational standard allows more exposure than would be protective of the general population because it assumes benefits that outweigh the risks of exposure. It is also based on adult workers and is not intended to be applicable to young children."

The average emissions from routine baking for clays other than Fimo Lavender, is over two mg/cubic meter. While not exceeding OSHA's five milligram/cubic meter limit, this is of significant concern because the OSHA standard was created to protect adult workers from inhalation exposures, and not children. Children breathe more than adults on a pound for pound basis and can therefore be exposed to more contamination from the air than an adult breathing in the same space. Consequently the five mg/cubic meter standard from OSHA may not be adequate as a child exposure limit for phthalates. Since the average level of exposure from baking the polymer clays so closely approaches the OSHA adult exposure standard, the implications are extremely troubling.

For comparison, it should be noted that federal pesticide law mandates that an exposure limit for children be set ten times lower than that of an adult if comprehensive testing data are not available for a toxic

Inhaling fumes during the baking of polymer clays – even when used according to the manufacturers' directions – appears to expose consumers to elevated levels of phthalates.

Table 6. Inhalation during baking

(micrograms per preparation of 100 grams product)

Product	BBP	Unknown#2	DnOP/DEHT	Total
S-SweetPotato	91	95	6	192
S-Terracotta	51	111	2	164
S-Pearl	218	17	ND	235
S-Lilac Pearl	60	2	ND	62
S-Leaf Green	747	11	279	1037
F-Yellow	9	32	27	68
F-Lavender	46	1399	1869	3314
F-Turquoise	9	178	193	380
F-Green	19	11	5	35
F-White	27	15	16	58
Average	**128**	**187**	**240**	**555**

substance. If this precautionary level were set under OSHA for children, the exposures to phthalates at two mg/cubic meter would exceed the OSHA standard for child exposures by four fold.

More than twenty years ago, Russian researchers proposed a maximum permissible limit of 0.5 milligrams of all phthalate esters per cubic meter in the air of factories. This limit was determined after possible links were found between occupational exposures to phthalate esters and high rates of miscarriage and menstrual disorders.[38] The exposures EQI predicted to result from use of polymer clays exceed this proposed standard.

Testing at the EQI lab found that only 3 samples – Sculpey Lilac, Fimo Green and Fimo White – were under the 0.5 milligram per cubic meter threshold the Russian study recommended as a maximum permissible limit (it should be noted again that the standard was developed to protect adults, not children). Fimo Lavender would release more than twenty times the Russian standard. Sculpey Leaf Green would emit more than seven times the proposed limit. Fimo Turquoise would expose children to more than twice the proposed standard.

Inhalation During Baking

The lab further calculated that a person staying in an average-sized kitchen during and immediately after the baking process would inhale an average of 0.5 milligrams per cubic meter of air of the three phthalates (DnOP/DEHT, BBP, Unknown #2). During the baking of the worst emitter – Fimo Lavender – a person could inhale well over 3 milligrams per meter of cubic air of the three phthalates. (See Table 6)

VPIRG's research and other evidence indicating the potential for high exposure to multiple phthalate compounds in everyday life suggests that a universal inhalation standard like that proposed in the Russian study is needed. The results of this study raises many questions as to the safety and good judgment of exposing young children unnecessarily to a potentially harmful class of toxic chemicals without further comprehensive study.

Exposure through Ingestion

EQI also examined how users might be exposed to phthalates through the inadvertent ingestion of residues left on the hands after working with the polymer modeling clay. Phthalates do not enter the body readily through the skin. Ingestion, though, is a rapid route of exposure, and one that is especially relevant to children, who touch their hands to their mouths far more than adults. A recent study based on analysis of videotapes of children at play found that kids put their hands in their mouth an average of six times per hour, and as much as 45 times an hour for some children.[39]

After working 100-gram samples into the shape of crude bowls with gloved hands for five minutes, subjects washed, rubbed and rinsed their gloved hands vigorously with distilled water for 30 seconds. They then rinsed their gloved hands again in methanol, a solvent. Testing of the solvent rinse revealed that large quantities of phthalate residues had remained on the gloved hands even after washing (see Table 7). To confirm that all of the phthalate in the solvent derived from the clay residues, the same rinsing procedure was followed with gloved hands but without working clay. No trace of phthalates was found in the solvent rinse in those instances.

The EQI researchers then calculated how much phthalate a typical child could ingest from his or her hands. Calculations were based on the U.S. Consumer Products Safety Commission's 50 percent hand-to-mouth transfer factor, which assumes that fifty percent of material that is

Phthalate residues left on hands after using polymer clays can lead to ingestion of the chemicals by young children.

Table 7. Phthalate residue on hands

(micrograms of residue) *

Product	BBP	Unknown #2	DnOP/DEHT	Total
S-SweetPotato	2980	ND**	1610	4590
S-TerraCotta	8220	ND**	510	8730
S-Pearl	5350	ND**	3380	8730
S-LilacPearl	10,400	ND**	6480	16880
S-LeafGreen	6300	ND**	3280	9580
F-Yellow	3130	1340	1720	33730
F-Lavender	830	4420	5870	11120
F-Turquoise	1290	6110	8390	15790
F-Soft Green	1240	5840	7540	14620
F-Soft White	1330	6630	8450	16410
Average	**4110**	**3640**	**6270**	**14020**

* milligrams per handling of 100 grams retail package of synthetic clay.
** ND=None detected

Table 8. Ingestion Exposure

(micrograms per preparation of 100 grams of clay)

Product	BBP	Unknown #2	DnOP/DEHT	Total
S-SweetPotato	1490	ND*	800	2290
S-TerraCotta	4110	ND*	250	4360
S-Pearl	2670	ND*	1690	4360
S-Lilac	5200	ND*	3240	8440
S-LeafGreen	3150	ND*	1640	4790
F-Yellow	1560	6700	8600	16860
F-Lavender	420	2210	2930	5560
F-Turquoise	640	3050	4190	7880
F-Green	620	2920	3770	7310
F-White	660	3310	4220	8190
Average	**2052**	**1819**	**3133**	**7004**

* ND=None detected

deposited on hands will eventually be ingested. According to these calculations, ingestion from the hands would far surpass inhalation as a route of phthalate exposure to children preparing polymer clays.

The EQI researchers found that a child could ingest an average of 7,000 micrograms (7 milligrams) of the three phthalates when preparing 100 grams of polymer clay product.

Table 9. Acceptable Ingestion under Drinking Water Standards

(micrograms per day, based on 2-liter consumption factor)

	BBP	DnOP	DEHP
USEPA[1]	6000	No standard	3.6-12
Florida	2800	280	No Standard
Minnesota	200	No Standard	No Standard
Montana[1]	6000	No Standard	12
Maine	No Standard	No Standard	50
California	No Standard	No Standard	8

Available state and federal regulatory standards for phthalates in drinking water were used for comparison to the ingestion exposure as determined by EQI since there are no levels of phthalate ingestion exposure specifically regulated anywhere else. (See Table 9).

The 'acceptable' rate of DnOP ingestion based on drinking water standards in Florida, is 0.28 milligrams per day, based on a standard 2-liter daily water consumption factor. The average exposure as determined through EQI's research through ingestion of polymer clays – 7 milligrams – would exceed Florida's drinking water standard by a factor of twenty five. The average ingestion exposure for the DnOP/DEHT mixture – 3 milligrams – would exceed the Florida drinking water standard for DnOP by a factore of 11. Fimo-Yellow preparation produced the highest ingestion rate: 16.81 milligrams of the three phthalates, including 8.6 milligrams of DnOP/DEHT, or more than thirty times the exposure allowed under Florida's drinking water standard for DnOP.

Sculpey product preparations generated high exposures to BBP and DnOP/DEHT. The highest estimated ingestion exposure, from Sculpey Lilac, was 8.44 milligrams of DnOP/DEHT and BBP combined, with 5.2 milligrams of BBP alone, or nearly twice Florida's daily drinking water exposure limit. The use of Sculpey Lilac would result in exposures 26 times higher than Minnesota's more stringent daily exposure limit for BBP of 0.2 milligrams.

A child who played with 100 grams of any of five different clays tested (Sculpey Terra Cotta, Sculpey Lilac, Sculpey Leaf Green, Fimo White, or Fimo Green) would exceed the maximum BBP exposure level allowed under Florida's drinking water limit and every single clay tested would result in exposures higher than Minnesota's limit.

Cumulative Exposure

EQI's research indicates that between breathing the gases released in baking, and handling the clay itself children could be exposed to an average of over 7,500 micrograms, or 7.5 mg of the phthalate components analyzed, per preparation of 100 grams of polymer clay.

As noted, this level of exposure is very high compared with the few regulatory limits that exist for these compounds (see Table 9). It also far outstrips the estimates of exposure used to assess the general public's exposure to these phthalates by the National Toxicology Program. The National Toxicology Program's Center for Evaluation of Risks to Human Reproduction's (NTP Center) assumed a daily

exposure of two micrograms (.02 milligrams) per kilogram (body weight) per day for adults after their expert panel assessed BBP. *Yet a 20kg (44 lb.) child using 100 grams of Sculpey Lilac could be exposed to over 5.2 milligrams of phthalates from a single five minute session of clay play. This is more than 130 times the exposure predicted from the National Toxicology Program Center.*

Table 10. Total exposure to phthalates (in micrograms*)

Product	BBP	Unknown#2	DnOP/DEHT	Total
S-SweetPotato	1581	95	806	2482
S-TerraCotta	4161	111	252	4524
S-Pearl	2888	17	1690	4595
S-Lilac	5260	2	3240	8502
S-LeafGreen	3897	11	1919	5827
F-Yellow	1569	6732	8627	16928
F-Lavender	466	3609	4799	8874
F-Turquoise	649	3228	4383	8260
F-Green	639	2931	3775	7345
F-White	687	3325	4236	8248
Average	**2180**	**2006**	**3372**	**7558**

* Inhalation + ingestion per 100 grams of prepared product

These test results are based on random samples of 20 products within a marketplace of hundreds of colors and dozens of lines. They clearly indicate major variations among colors and product lines, yet all the clays tested expose users to significant amounts of phthalates. Moreover, users are exposed to several as yet unidentified phthalate compounds which may also be associated with health effects, or whose effects are not yet known. These results are troubling because children playing with polymer clays are exposed to phthalates and may be harmed as a result of the significant gap in testing for health impacts of these products.

Real-World Exposures Are Likely to be Significantly Higher

EQI's research clearly shows that young children could be exposed to significant levels of phthalate compounds contained in polymer clays. But as striking as these findings are, EQI's investigation undoubtedly underestimates potential phthalate exposures for many children using polymer clays.

The EQI researchers measured exposures for only four phthalate esters in the clays, out of the eight phthalates that were discernibly present. Some of the unidentified compounds occurred at twice or three times the percentages of DnOP/DEHT, BBP and Unknown #2. It is highly likely that they would contribute to inhalation and ingestion exposures in proportion to their presence in the clays. It is possible that these unknown compounds may cause similar health effects as the phthalates discussed as they are members of the same phthalate family.

Moreover, while VPIRG's samples contained between four and fourteen percent total phthalates, other polymer clays may contain a higher concentration. According to Dr. Woodhall Stopford, "no more than 25% of polymer clay weight would be made up of phthalate ester plasticizers." [40] This means that clay could contain as much as 25% phthalates – more than VPIRG found in the clay in its studies. This potential for up to 25% phthalates in clays could result in increased exposures by users of clays.

Further, while EQI researchers estimated exposures based on the use of 100g (3.5 ounces) of clay, crafters' actual preparation of these clays may involve far larger amounts. Various websites containing "recipes" for polymer clay art provide a glimpse into polymer clay consumption patterns. Recipes range between one ounce and one pound. On the miniature scale, crafters make pen covers and heart pins using an ounce of polymer clay. On the larger scale, they make an "Octomaid" weighing in at 31.5 ounces (close to 900 grams), and a checkerboard using one pound (or 454 grams) of Fimo.

Exposures to phthalates in "real world" are likely to be higher than what our testing found.

When using a pound of the clays (like for the checkerboard), potential inhalation exposures would be more than four times more than those found in VPIRG's testing. That is, a child making the Fimo checkerboard with a clay that released the average phthalate level could inhale almost 2.5 milligrams of the phthalates we tested, instead of the average 0.55 milligram exposure from baking a 100 gram portion of the clay. (And that estimate leaves out multiple compounds for which exposure was not assessed, and the potential for increased ingestion exposure due to working with larger amounts of clay surface.) If a child made the project using the Fimo Lavender EQI tested, that child could be exposed to nearly 15 milligrams of phthalates simply by remaining in the kitchen and breathing at a normal rate while it baked.

Even when children are crafting small objects such as beads, they tend to use large quantities of clay in a variety of colors to create enough to form a necklace or bracelet. Classroom or other communal crafting settings where children work on clay projects in groups could also increase inhalation exposure beyond EQI estimates.

VPIRG's tests also indicate a wide range of potential exposures among brands. Specific colors or types of products, or other brands of products, could release more, less, or different phthalates. Run-to-run production variations may also impact exposure potentials of a product sold under a single model, make and color.

Exposure may also increase when clays are not used properly. If the clay is not prepared according to package directions phthalate and hydrochloric acid fumes may cause additional harmful exposures to children.

Finally, these exposures do not occur in a vacuum. As the recent CDC research indicates, people in the US are already exposed to multiple phthalate compounds in their everyday life. These everyday exposures can be from cosmetics, toys, food packaging, pesticides, flea collars and more. Thus the intense exposures encountered when using polymer clays will add to a baseline exposure that may already be a sufficient amount to affect health.

Part Three: Failure to Protect Consumers

Lack of Protection from Government and Industry

The fact that polymer clays marketed to children may expose children to known hazardous chemicals and other similar chemicals whose health effects are unknown – demonstrates the fundamental problems in U.S. laws governing the industrial and commercial use of chemicals.

The law fails to protect against known toxic hazards

Phthalate compounds have been associated with significant long term health impacts, and yet they are present in marketable polymer clay products. Their mere presence shows a failure by the government to protect consumers. Specific phthalate compounds in the clay as BBP, DnOP, DnHP have each been associated with adverse health effects in animals, ranging from reproductive impairment to birth deformities. The laws that are supposed to protect consumers against these types of human health impacts from commercial products, clearly fail to do so.

The primary problem is that the vast majority of chemicals on the market – including phthalates – were on the market before the Toxic Substances Control Act, and they were all grandfathered under the Act.[41] Manufacturers have never been required to conduct any testing on these chemicals and without substantial data, they cannot be regulated.

The second problem is that the Toxics Substances Control Act requires a very high standard of proof for the EPA to restrict or prohibit a chemical's use. The EPA has to prove that there is an "unreasonable" risk to human health or the environment, that the proposed restriction is the least burdensome regulation, and that the benefits of regulating the chemical outweigh the costs to industry.[42] Courts have interpreted this high legal threshold to require such extensive proof of harm that the EPA has only attempted to regulate the use of a handful of substances under TSCA.[43]

A flaw that runs throughout TSCA is that it puts the burden of proof on the public or on the regulatory agency rather than on the manufacturers who benefit financially from a product. Rather than requiring manufacturers to prove that an industrial chemical is reasonably safe in order to allow it on the market, the poorly named Toxic Substances Control Act (TSCA) instead allows manufacturers to manufacture chemicals unless the EPA can produce overwhelming evidence of danger. By contrast, when drug companies manufacture pharmaceuticals, they are required to prove the product is reasonably safe given its benefits before being licensed to make the product.

As a result of this flawed regulatory framework, there are hundreds of known toxic chemicals to which Americans are exposed. Manufacturers have notified EPA of 80,000 industrial chemicals they may use in the U.S, but the majority have incomplete or no publicly available data on their health effects. An assessment from 1997 showed that out of 100 chemicals:

- 71% lacked sufficient publicly available data to perform a basic screening for the potential to cause health effects.
- 53% lacked reproductive toxicity data, 63% lacked carcinogenicity data, 67% lacked neurotoxicity data, 86% lacked immunotoxicity data, and 90% lacked data on impacts specific to children (e.g. developmental neurotoxicity, postnatal performance).

- 50% lacked publicly available data on *any* form of chronic toxicity.[44]

Follow up assessments by both the EPA and the American Chemistry Council (the chemical industry's lobbying organization) found that at least some of the basic data needed to perform a basic screen for health and environmental effects were not publicly available for the majority of the 2700 chemicals produced in the highest volumes (greater than 1 million pounds per year).[45]

In this context, it is alarming – but not unique – that consumer products like polymer clays expose users to chemicals like phthalates which have clear potential for harm or for which little information is available regarding human health effects.

Current Phthalate Regulation

Current government regulations on phthalates are haphazard and inconsistent. As the Environmental Working Group noted in a report, "Phthalates are recognized as toxic substances under environmental law, but companies are free to use unlimited amounts in cosmetics. An environmental release of just 10 pounds of DBP [Di Butyl Phthalate] must be reported to environmental authorities under Federal Superfund law. The cosmetics industry, in contrast, puts hundreds of thousands of pounds of DBP into nail polish each year, with no requirements for safety testing or reporting to anyone." [46]

The regulations that do limit exposures for phthalates tend to focus on one medium as water discharges, air releases, drinking water, or occupational exposure. They also only tend to focus only on one chemical compound at a time rather than chemical groups. This is simplistic in terms of human health exposure because people are generally not exposed to just one chemical at a time. Because of the massive quantity of chemicals on the market, and because of the multiple pathways for exposure, these regulations are clearly inadequate. As the following examples illustrate, false assumptions about which phthalates compounds people are most exposed to have created a situation where the compounds found in children's clay are among the most under-studied and unregulated chemicals.

The National Toxicology Program Center for the Evaluation of Risks to Human Reproduction (NTP Center), the panel assigned to study the risks phthalate exposures posed to human reproductive health, suggested that BBP and DnOP were of only "minimal" concern for reproductive effects in humans. This is despite evidence indicating that these esters have the capacity to affect human reproduction. The NTP Center's determination stems from the assumption that general daily exposures are low – only two micrograms/kg body weight for adults.[47] Yet VPIRG's research shows that humans could be exposed to over a hundred times this amount just from one consumer product (polymer clays).

The phthalate regulations that exist mainly deal with exposure to the most widely used esters, such as DEHP and DEP. The U.S. Occupational Safety and Health Administration limits exposure to DEHP and DEP in workplace air to five milligrams per cubic meter of an eight-hour workday, or 10 mg/cubic meter for a 15-minute exposure.[48] As discussed above in VPIRG's findings, exposures to other phthalates through the use of polymer clays far exceed these levels.

The U.S. Environmental Protection Agency has proposed a six parts per billion limit on DEHP in drinking water. VPIRG's research raises the question of whether exposure to less familiar phthalate compounds at hundreds of times this level should be allowed to occur with no scrutiny.

The U.S. Food and Drug Administration limits the types of food packaging materials that contains certain phthalates. The FDA, however, does not regulate the amount of phthalates used in cosmetics and other consumer products that are often incidentally ingested.[49]

This minimal regulation of phthalates means that consumers are unknowingly exposed to these chemicals every day, in products they assume are safe. The CDC analysis of urine samples suggests that these phthalates contaminate our bodies, but little focused research has been done to assess the potential health impacts of this widespread human exposure.

A warning label from one manufacturer's materials.

More Protective Action in Europe: Ban on Phthalates in Children's Toys

In Europe, more effective measures have begun to eliminate the risk phthalates present to children when they leach from pacifiers and soft plastic toys. In July 1999, the French government suspended the manufacture, trade and sale of some toys and child-care items that contain phthalates. In December 1999, the European Union Emergency Product Safety Committee followed the French lead and banned six different phthalate compounds from use in articles intended to be placed in the mouths of children under three years of age.[50]

The EU ordinance bans the manufacture or importation of toys or child articles intended for mouthing by small children that contain, by weight, more than 0.1% of BBP, DnOP, DEHP, DINP, and two other compounds, DIDP, and DBP. While limited in its scope and optimistic in its assumption that babies and toddlers will not mouth other toys not intended for their mouths, this is a first step toward limiting vulnerable populations' exposure to phthalates.[51]

U.S. Lagging Behind Europe: No Children's Toy Protection

In 1996, the US Consumer Product Safety Commission (CPSC) urged toy manufacturers to voluntarily remove one phthalate, DINP, from mouthing toys intended for children under three because of its potential adverse health effects. Such voluntary efforts, while well-intended, are far from effective at preventing exposure, since many products still contain DINP, and other products contain multiple phthalates of unknown health implications. This is unfortunate as consumers have no way to know which phthalates and specifically which products still may pose potential health hazards to their children. It is disturbing that consumers must rely on industry and government information to ascertain that these products are safe.

Manufacturers' Failure to Protect

It is bad enough that polymer clays contain untested chemical compounds and chemicals with known links to health threats. However, the packaging of these products have warnings that vary considerably, all of which consistently fail to adequately warn parents and children of the potential health risks to those using the clays.

Consumer information ranges from inadequate to misleading

Despite their potential to expose users to phthalates and hydrochloric acid, manufacturers and distributors of polymer clay products make strong claims that the clays pose no risk to consumers. For example, a U.S. distributor of Fimo states that "polymer clays are AP Non Toxic... They are perfectly safe when properly used." [52]

Eberhard Faber, the manufacturer of FIMO states on its website that its "products are environmentally friendly. Only products which are 100% perfect pass our quality control.... It has always been one of our main concerns to safeguard both the environment and our customers. Our products are manufactured in accordance with EN 71 safety standards and bear the CE seal, or the AP seal in the USA. In addition to this, many of our products have been awarded the German 'Spielgut' seal of approval which is awarded to products especially suitable to children." [53]

On another website, Eberhard Faber/Staedtler asks "Is FIMO toxic?" and answers "FIMO is Non Toxic and carries the CE mark [the European equivalent of the AP mark]. However, care should be taken when baking as overheating (burning) can produce a gas." [54]

Most websites devoted to polymer clay crafting say little about or downplay their hobby's potential toxicity. An online polymer clay magazine recently responded to a beginner's question about the safety of polymer clays in the kitchen by saying "Don't use polymer clay on anything that will be in contact with food or mouths," but adds "that said, there are cases of reported artists accidentally eating a piece of polymer clay, instead of the nearby grapes, for instance, and pets, mine included, have been known to eat what falls on the floor. No ill effects to report so far." [55]

This same publication explained to crafters that "the only fumes that are produced come from burning the clay. Even these fumes, while quite nasty to smell have no chronic effect." [56]

One participant in a crafters discussion group on the web does state that "Fimo contains a chemical - which is toxic - so you must be careful with the fumes. You will get sick if you breath these fumes a lot." However, the same person goes on to suggest a far more risky tactic; crafters, the author suggests, should add their own DBP "to soften the Fimo and to make yourself a 'Fimo Glue.'" [57]

Consumers such as this are taking their cues from labeling and other assurances by the polymer clay manufacturers. Each brand bears a seal from the Art & Creative Materials Institute containing the phrase "AP Nontoxic." Polyform Products notes on its packages, "All Sculpey clay products are certified AP Non-Toxic.... Sculpey brand polymer clays are non-toxic, man-made modeling materials that work and feel like ceramic clay."

However, the seal of non-toxicity is not provided by an independent third-party certifier but by the Arts & Creative Materials Institute, a consortium of 200 arts and craft material manufacturers founded in 1940.[58] In previous disputes over children's exposure to potentially toxic ingredients in art materials (for example, asbestos in crayons) the "institute" has shown itself unwilling to aggressively protect children from potential harm. Instead it has accommodated manufacturers wishes to label products containing hazardous substances as nontoxic by predicting that no significant exposures will result from ordinary use.

Minimal warnings

Polymer clay manufacturers do provide some information that sounds a note of warning, but it is much harder to find than information about the joys of polymer clay usage. For example, a brochure that arrives in a box of Sculpey is covered in bright photographs of children molding animals and toys, with word bubbles depicted flowing from their mouths with text like "Look Dad! A robot!" and "This is so much fun!" In much smaller text the insert also warns, "Be certain that your Mom or Dad use a timer to avoid over baking. Always USE GOOD VENTILATION (OPEN A WINDOW, AND DON'T INHALE ANY FUMES...)" [59]

The FIMO clay wrapper itself carries some warnings that might indicate to an assiduous reader that there is some danger involved in preparing the clay. It warns, "Do not inhale baking fumes," "Do not swallow," and "Always clean hands after use."

Similarly, the small individual packages of Sculpey that VPIRG staffers purchased do have warning statements on them. The language tells users not to inhale fumes, adding "use with good ventilation" It further cautions: "Not intended for production baking or commercial application in ordinary home equipment," and warns against using dishes made with Sculpey for food, beverages or smoking materials.

Realistically, most parents, reassured by the "AP Nontoxic" seal, will skim the package for the baking instructions and review the minimal warning it contains briefly if at all.

Though these warnings begin to suggest that the clays can pose a health risk, neither one addresses potentially sensitive populations, such as infants, toddlers or pregnant women. And neither divulges any information about why the warnings are required or what the potential health risks might be.

The only piece of literature that VPIRG found which even began to adequately address the possibility of toxic exposures from the clay was a small (approximately 2-inch square) Fimo pamphlet containing "advice for adult supervision" and "safety rules," such as:

- "This modeling material is for use of children over the age of 8 years only;"
- "This modeling material should not be put in the mouth;"
- "Keep children under the age of 8 years and animals away from the activity area. Store toys out of reach of young children;" and,
- "Hands should be washed after work is finished. Clean all equipment after use. Do not eat, drink or smoke in the activity area."

Unfortunately, all of these warnings are provided in an inconspicuous pamphlet that was simply made available on the shelf next to the Fimo products on display. When purchasing polymer clays at two local stores, VPIRG staff found a single copy of the pamphlet available in one store, but it was nowhere in sight at the other. Even where it is available, consumers may well fail to pick up this pamphlet, since it contains no "recipes" or bright photographs.

Given the body of evidence that suggests that phthalate compounds have the potential to cause significant health problems and can affect fetuses across the placental barrier, the present warnings on polymer clay products are clearly insufficient and the multiple 'non-toxic' labels confusing and misleading.

Part Four: Conclusions and Recommendations

This study found high levels of under-tested phthalates in products intended to be widely handled by children. It also demonstrated that users of the products are likely to ingest and inhale large amounts of these chemicals. The amount of phthalates found in the clays and EQI's exposure analysis show that phthalates are something to be concerned about – especially because of their potential to harm children. Use of phthalates in polymer clays is extremely troubling, because several of the phthalate esters are known to be toxic to health and have been banned from products intended to go in children's mouths in Europe. Moreover, some of the phthalate esters have not even been tested for long term health hazards. At the same time, the products' labeling ranges from inadequate to misleading.

What retailers and consumers can do

Parents:

- Do not purchase polymer clays or allow children to use them until they are reformulated to eliminate multiple phthalate exposures or until the formulation has been scientifically tested and determined to be safe
- Dispose of any polymer clays you currently have at home
- Write manufacturers telling them that you are no longer purchasing their products because of safety concerns, and ask that they reformulate these products or stop selling them

Merchants:

- Stop selling these products, or place an additional warning label on the shelf where they are stocked indicating that they contain substances linked to reproductive system damage and birth deformities
- Write manufacturers with your concerns about selling a potentially harmful product to children with a non-toxic label

Educators:

- Eliminate use of these clays in the educational setting
- If use continues, initiate a review of the safety of this product for workers, given the Alaska teacher's experience

The findings of this report demand immediate attention from regulators to protect the health of children and other polymer clay users, as well as broad reform of the way chemicals are regulated. Current law does not require pre-market testing for industrial chemicals, nor does it set up adequate means for harmful chemicals to be removed from the market. Thus, harmful chemicals like phthalates are included in consumer products without adequate health studies and often even when health studies show a clear potential for harm.

Instead of waiting to find out that products on the market like polymer clays pose a significant health risk to consumers, a more precautionary and preventative approach would promote greater child safety and better protect consumers. Specifically chemicals used in consumer products should undergo vigorous testing to ensure that their inclusion in products will not negatively impact human health – especially the health of children. Only after the completion of such testing should a product be sold on the market.

Therefore, VPIRG's findings should trigger immediate steps to protect children from phthalate exposures associated with polymer clays. The Consumer Product Safety Commission needs to move quickly to declare a moratorium on the sale of polymer clay products in toy stores and require manufacturers to remove the "non-toxic" label from these products until comprehensive research has been completed proving the product is safe. These products cannot be considered safe for use in the home or by sensitive populations until far more is known about their potential to expose users to compounds that may impair development of children's' reproductive systems and affect other organs. Blindly assuming that these products are safe without chemical testing for health effects may be dangerous to children.

VPIRG recommends a series of immediate steps to safeguard the health of developing children:

1. The Consumer Product Safety Commission should immediately recall polymer clay products containing phthalates until all ingredients in the clays have been comprehensively tested and shown to present no risk to health (including effects of exposure to combinations of phthalates, effects of exposure on children and the developing fetus, and effects of long-term exposure). There is no necessity for these products, alternatives are available, and scientific evidence suggests potential harm to kids; further sale and use should be suspended until government regulators understand the potential for harm.

2. If a recall or suspension of sale is not issued, manufacturers should be required to provide clear, prominently displayed warning labels describing potential health effects and directing pregnant women and children not to use polymer clay products. Others should be warned to strictly limit contact by wearing gloves when manipulating the product and to limit inhalation by staying out of the kitchen for several hours after baking is finished and to actively ventilate the room during and after baking.

3. The regulatory process for synthetic chemicals should be re-considered. Manufacturers should not be able to put chemicals on the market without comprehensive health studies showing with reasonable certainty that no health risk is anticipated. Those phthalates that are studied in depth show the potential for serious health impacts on exposed individuals, and little information exists about many related compounds. Weak policies in the U.S. fail to mandate common-sense testing for health effects or potential exposure when a new chemical or new use of a chemical is introduced to the market. This failure gives rise to citizens' inadvertent exposure to potentially dangerous substances without their knowledge or consent.

4. State attorneys general should investigate manufacturers' claims that polymer clays are 'non-toxic.' Claims of non-toxic status should be viewed as false advertising where no assessment of real-world exposures or impacts have been completed, and where phthalates present in clays have been found to have deleterious effects in animal studies. If the AP Non-Toxic certification is based only on assessment of the four esters identified by Dr. Stopford (proven by this report to be an incomplete list), it appears deficient, incomplete and misleading.

References

[1] L. Bernstein, "Polymer Clay: A new and versatile medium", *American Artist*, October, 1998.
[2] ATSDR Toxicological Profiles for DEHP, 1993, see http://www.atsdr.cdc.gov/toxprofiles/phs9.html
[3] US Dept. of Health and Human Services, National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction (CERHR), Expert Panel Report on DEHP, p. 87, 92, October 2000. US Dept. of Health and Human Services, National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction (CERHR), Expert Panel Report on DINP, p. 26, 29, October 2000.
[4] USEPA, Integrated Risk Information System (IRIS), DEHP, see www.epa.gov/iris/search.htm; ATSDR, Toxfacts for DEHP, April 1993, see www.atsdr.cdc.gov/tfacts9.html
[5] Occupational Safety and Health Administration (OSHA) 1988 Permissible Exposure Limits for DEHP, see http://www.cdc.gov/niosh
[6] L.E. Gray Jr., J. Ostby, J. Furr, M. Price, D.N. Veereamchaneni, and L. Parks, "Perinatal Exposure to the phthalates DEHP, BBP and DINP, but not DEP, DMP or DOTP, alters sexual differentiation of the male rat," *Toxicological Science*, 58(2), p. 350-365, December 2000. J. Ostby, M. Price, J. Furr, C. Lambright, A. Hotchkiss, L.G. Parks, and L.E. Gray Jr., "Perinatal Exposure to the phthalates DEHP, BBP, and DINP but not DEP, DMP or DOTP, permanently alters androgen – dependant tissue development in Sprague-Dawley rats," *Biological Reproduction*, 62 (1), p. 184-5, 2000. J.C. Lamb, R.E. Chapin, T. Teague, A.D. Lawton, J.R. Reel, "Reproductive Effects of Four Phthalate Esters in the Mouse," *Toxicology and Applied Pharmacology*, 88(2), p. 255-269, 1987.
[7] USEPA, Integrated Risk Information System (IRIS), BBP, see www.epa.gov/iris/search.htm
[8] A.H. Mann, S.C. Price, F.E. Mitchell, P. Grasso, R.H. Hinton, J.W. Bridges, "Comparison of short term effects of Di (2 ethylhexyl) phthalate, Di (nhexyl) phthalate, and Di (noctyl) phthalate in rats," *Toxicology and Applied Pharmacology*, 77(1), p. 116-132, 1985. R.H. Hinton, F.E. Mitchell, A. Mann, D. Chescoe, S.C. Price, A. Nunn, P. Grasso, J.W. Bridges, "Effects of Phthalic Acid esters on the liver and thyroid," *Environmental Health Perspectives*, (70), p. 195-210, 1986.
[9] J. Doull, C.D. Klaussen, and M.D. Amdur, *Cassarett and Doull's Toxicology*, (2nd Edition). New York, Macmillan Publishing Co., p.549, 1980. F.S. Mallette, and Von Hamm, *Archives of Industrial Hygiene and Occupational Medicine*, 6(231), 1952. L.E. Milkov et al, "Health status of workers exposed to phthalate plasticizers in the manufacture of artificial leather and films based on PVC resins," *Environmental Health Perspectives*, 3, p. 175-178, 1973. See also, National Toxicology Program Health and Safety Package for BBP, http://ntp-server.niehs.nih.gov/Main_Pages/Chem-HS.html
[10] B. Blount, M. Silva, S. Caudill, L. Needham, J. Pirkle, E. Sampson, G. Lucier, R. Jackson, and J. Brock, "Levels of Seven Urinary Phthalate Metabolites in a Human Reference Population," *Environmental Health Perspectives*, 108(10), October 2000. M.C. Kohn, F. Parham, S.A. Masten, C.J. Portier, M.D. Shelby, J.W. Brock, L.L. Needham, "Human Exposure Estimates for Phthalates," *Environmental Health Perspectives*, 108(10) October 2000. Raloff, Janet, "New Concerns about Phthalates," *Science News*, Sept. 2, 2000.
[11] J.W. Brock, S.P. Caudill, M.J. Silva, L.L. Needham and E.D. Hilborn, "Phthalate Monoester Levels in the Urine of Young Children," *Bulletin of Environmental Contamination and Toxicology* 68(3), p. 309-314, 2002.
[12] B. Blount, M. Silva, S. Caudill, L. Needham, J. Pirkle, E. Sampson, G. Lucier, R. Jackson, and J. Brock, "Levels of Seven Urinary Phthalate Metabolites in a Human Reference Population," *Environmental Health Perspectives*, 108(10), October 2000. M.C. Kohn, F. Parham, S.A. Masten, C.J. Portier, M.D. Shelby, J.W. Brock, L.L. Needham, "Human Exposure Estimates for Phthalates," *Environmental Health Perspectives*, 108(10) October 2000. Raloff, Janet, "New Concerns about Phthalates," *Science News*, Sept. 2, 2000.
[13] KEMI, Guidance on the rules applying to phthalates in toys and other articles for small children, National Chemicals Inspectorate (Sweden), May 2000, http://www.kemi.se/publikationer/pdf/toys.pdf .
[14] USEPA, Integrated Risk Information System (IRIS), BBP, see www.epa.gov/iris/search.htm
[15] D.K. Agarwal et al, *Toxicology*, 35 (3), p. 189-206, 1985.
[16] The British Industrial Biological Research Association, "A 21 Day Feeding Study of BBP to Rats: Effects on the Liver and Liver Lipids," EPA Document No. 40+8626201, 1985.
[17] LE Gray Jr., J. Ostby, J. Furr, M. Price, D.N. Veereamchaneni, and L. Parks, "Perinatal Exposure to the phthalates DEHP, BBP and DINP, but not DEP, DMP or DOTP, alters sexual differentiation of the male rat," *Toxicological Science*, 58(2), p. 350-365, December 2000. J. Ostby, M. Price, J. Furr, C. Lambright, A. Hotchkiss, L.G. Parks, and L.E. Gray Jr., "Perinatal Exposure to the phthalates DEHP, BBP, and DINP but not DEP, DMP or DOTP, permanently alters androgen – dependant tissue development in Sprague-Dawley rats," *Biological Reproduction*, 62 (1), p. 184-5, 2000.
[18] M.V., Aldyreva et al, "Gig Tr Sostoyanie Spetsificheskikh Funkts Rab Neftekhim," *Khim Prom-STI*, p. 154-9, 1974.

[19] M. Ema, A. Harazono, E. Miyawaki, Y. Ogawa, " Characterization of developmental toxicity of mono-n-benzyl phthalate in rats," *Reproductive Toxicololgy*, 10(5), p. 365-372, Sept/Oct 1996. M. Ema, R.Kurosaka, H.Amano, and Y.Ogawa, "Comparative Developmental Toxicity of BBP and DBP in rats," *Archives of Environmental Contamination and Toxicology*, 28(2), p.223-228, 1995.
[20] J.Doull, C.D. Klaussen, and M.D. Amdur, *Cassarett and Doull's Toxicology*, (2nd Edition). New York, Macmillan Publishing Co., p. 549, 1980. See also, National Toxicology Program Health and Safety Package for BBP, http://ntp-server.niehs.nih.gov/Main_Pages/Chem-HS.html
[21] R.E. Gosselin, H.C. Hodge, and R.P. Smith, *Clinical Toxicology of Commercial Products*, (5th Ed.) Williams and Wilkins, Baltimore, 1984.
[22] L.E. Milkov et al, "Health status of workers exposed to phthalate plasticizers in the manufacture of artificial leather and films based on PVC resins" *Environmental Health Perspectives*, 3, p. 175-178, 1973. See also, National Toxicology Program Health and Safety Package for Butyl Benzyl Phthalate – http://ntp-server.niehs.nih.gov/Main_Pages/Chem-HS.html
[23] F.S. Mallette, and Von Hamm, *Archives of Industrial Hygiene and Occupational Medicine*, 6(231), 1952
[24] See, National Toxicology Program Health and Safety Package for BBP, http://ntp-server.niehs.nih.gov/Main_Pages/Chem-HS.html
[25] Timofievskaya LA, Gig Sanet 8(91), 1982. Taken from the Hazardous Substance Data Base (HSDB) at http://toxnet.nlm.nih.gov
[26] USEPA/ECAO; Atlas Document for : Phthalate Esters p. VI-1 (1980) taken from the Hazardous Substances Data Base (HSDB) at http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB
[27] USEPA, Four Final Mutagenicity Reports Regarding Phthalate Esters, Hazleton Biotech Co., Source EPA OTS; Doc #40-8626225. 2000.
[28] R.H. Hinton, F.E. Mitchell, A. Mann, D. Chescoe, S.C. Price, A. Nunn, P. Grasso, J.W. Bridges, "Effects of Phthalic Acid esters on the liver and thyroid," *Environmental Health Perspectives*, 70, p. 195-210, 1986.
[29] A.H. Mann, S.C. Price, F.E. Mitchell, P. Grasso, R.H. Hinton, and J.W. Bridges, "Comparison of the Short Term Effects of Di(2-Ethylhexyl) Phthalate, Di(n-hexyl) Phthalate, and Di(n-octly) Phthalate in Rats," *Toxicology and Applied Pharmacology*, 77(1), p. 116-132.
[30] 29 C.F.R. §1910.1200.
[31] Mallinkrodt Baker, Inc., MSDS # E6500 – Effective date 03/05/97
[32] J.C. Lamb, R.E. Chapin, T. Teague, A.D. Lawton, J.R. Reel, "Reproductive Effects of Four Phthalate Esters in the Mouse," *Toxicology and Applied Pharmacology*, 88(2), p. 255-269, 1987. See also, J.R. Reel, A.D. Lawton, C.B. Meyers, "DnHP Reproduction and Fertility Assessment in CD-1 Mice when Administered in the Feed," National Toxicology Program, Government Reports Announcements & Index (GRA&I) Issue 25, 1985.
[33] R.H. Hinton, F.E. Mitchell, A. Mann, D. Chescoe, S.C. Price, A. Nunn, P. Grasso, J.W. Bridges, "Effects of Phthalic Acid esters on the liver and thyroid," *Environmental Health Perspectives*, 70, p. 195-210, 1986. A.H. Mann, S.C. Price, F.E. Mitchell, P. Grasso, R.H. Hinton, and J.W. Bridges, "Comparison of the Short Term Effects of Di(2-Ethylhexyl) Phthalate, Di(n-hexyl) Phthalate, and Di(n-octly) Phthalate in Rats," *Toxicology and Applied Pharmacology*, 77(1), p. 116-132.
[34] USEPA, Four Final Mutagenicity Reports Regarding Phthalate Esters, Hazleton Biotech Co., Source EPA OTS; Doc #40-8626225. 2000.
[35] USEPA, Integrated Risk Information System (IRIS), DEHP, see www.epa.gov/iris/search.htm
[36] Occupational Safety and Health Administration (OSHA) 1988 Permissible Exposure Limits for DEHP, see http://www.cdc.gov/niosh. US Dept. of Health and Human Services, National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction (CERHR), Expert Panel Report on DEHP, p. 87, 92, October 2000.
[37] See www.cdc.gov/niosh/pel88/84-66.html and www.cdc.gov/niosh/pel88/117-81.html.
[38] M.V. Aldyreva, et al. "Gig Tr Sostoyanie Spetsificheskikh Funkts Rab Neftekhim," *Khim Prom-STI*, p. 154-9, 1974.
[39] V.G. Zartarian, A.C. Ferguson, and J.O. Leckie, "Quantified Dermal Activity Data From a Four Child Pilot Field Study," *Journal of Exposure Analysis and Environmental Epidimiology* 7(4), p. 543-552, 1997.
[40] Dr. Woodhall Stopford, MD, MSPH, Duke University Medical Center, Division of Occupational and Environmental Medicine, "Questions Concerning the Risk Assessment for Polymer Clays," October 23, 2000. Faxed to VPIRG from the State of Alaska Occupational Safety Administration on April 2, 2001.
[41] Shettler, Solomon, Valenti, and Huddle, *Generations at Risk, Reproductive Health and the Environment*, MIT Press, 1999 p.237
[42] Toxic Substances Control Act of 1976, §6(a)-(c), (*codified at* 15 U.S.C. §2601 et.seq.)

[43] *Corrosion Proof Fittings v. EPA*, 987 F.2d 1202 (5th Cir. 1991). Shettler, Solomon, Valenti, and Huddle, *Generations at Risk, Reproductive Health and the Environment*, MIT Press, 1999 p.242.
[44] Environmental Defense Fund, "Toxic Ignorance: The continued absence of basic health testing for top selling chemicals in the United States," June 1, 1997, pp. 15-17.
[45] EPA, Chemical Manufacturers Association, "Joint announcement of cooperative program for high production volume U.S. industrial chemicals," October, 1998, found at http://www.environmentaldefense.org/article.cfm?ContentID=661
[46] Environmental Working Group, "Beauty Secrets: Does a common chemical in nailpolish pose risks to human health?" 2000. www.ewg.org
[47] US Dept. of Health and Human Services, National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction (CERHR), Expert Panel Report on BBP, p. 31, October 2000.
[48] See, http://www.cdc.gov/niosh/pel88/84-66.html and www.cdc.gov/niosh/pel88/117-81.html
[49] See, www.atsdr.cdc.gov/tfacts9.html
[50] "Phthalates to escape total EU ban," *Environment Daily* Issue 1112, November 28, 2001.
[51] KEMI, Guidance on the rules applying to phthalates in toys and other articles for small children, National Chemicals Inspectorate (Sweden), May 2000, http://www.kemi.se/publikationer/pdf/toys.pdf .
[52] Fimozone, "About Polymer Clay – FAQ's," www.fimozone.com/faq.html
[53] EberhardFaber, "Corporate Guidelines" and "Environment", www.eberhardfaber.de/leitlinie_en.htm
[54] Staedtler UK, "Frequently Asked Questions," www.staedtler-uk.co.uk/faq.htm
[55] Deborah Hayes, "Beginner's Corner", *Polymer Clay Polyzine*, 3(3), March 2002. http://www.pcpolyzine.com/0203march/beginners.html
[56] Tommie Howell, "PC but not too PC", *Polymer Clay Polyzine*, 2(4), April 2001. http://www.pcpolyzine.com/april2001/issues.html
[57] See, www.worldramp.net/~wandy/archive2.htm
[58] See http://www.acminet.org
[59] Polyform – the Sculpey People, "lets play with clay" product brochure, 1999, Polyform products Co. Inc.