

Testimony of Heather White, Esq.

**Executive Director
Environmental Working Group**

Before the

**U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY**

On

**Regulation of New Chemicals, Protection of Confidential Business Information,
and Innovation**

Thursday, July 11, 2013

Mr. Chairman and distinguished members of the subcommittee, my name is Heather White. I am the Executive Director of Environmental Working Group, a nonprofit research and advocacy organization based in Washington, D.C., with offices in Ames, Iowa, and Oakland, California. Thank you for holding this important hearing and the opportunity to testify.

For two decades, EWG has advocated greater protection of people and the environment from exposures to toxic chemicals. EWG has published extensive research on the chemical pollution in people as evidenced by our numerous biomonitoring studies. We have tested more than 200 people for 540 industrial chemicals and found up to 482 of them in people's bodies. In two groundbreaking studies conducted in 2005 and 2009, EWG detected nearly 300 industrial chemicals in the umbilical cord blood of newborn babies.¹ Our research showed that these children were exposed *in utero* to toxic chemicals, including dioxins and furans, flame retardants and active ingredients in stain removers and carpet protectors. Chemicals that were banned more than 30 years ago – including lead, polychlorinated biphenyls (PCBs) and the pesticide DDT – also contaminated these babies. We also discovered the presence of bisphenol A (BPA), a synthetic estrogen that disrupts the endocrine system, and perchlorate, a rocket fuel component and thyroid toxin that can alter brain development. (For more results, see Attachment A.) Modern science shows us – unequivocally – that industrial chemical pollution begins in the womb.

In April 2010, the President's Cancer Panel reviewed the compelling scientific research on biologically active chemicals at low doses and the canon of biomonitoring studies from the Centers for Disease Control and Prevention and other public health organizations. The panel declared: "to a disturbing extent, babies are being born 'pre-polluted.'"² The panel also found that the number of cancers caused by toxic chemicals is "grossly underestimated" and warned that Americans face "grievous harm" from largely unregulated chemicals that contaminate air, water and food.³

We must reform our federal toxics law to ensure that new chemicals are safe – especially for children, our most vulnerable population – before they are allowed on the market. Toxic chemicals are ubiquitous in our daily lives, in our consumer products and, ultimately, in our bodies, yet many of these substances have never been adequately assessed for safety. Here’s why: The federal Toxic Substances Control Act of 1976 (TSCA),⁴ the principal law governing the use and safety of the thousands of chemicals on the market, is fundamentally broken. The current federal toxics law has many flaws, but I will focus on two of them today:

- **TSCA’s framework for reviewing new chemicals ensures that most new chemicals are on the market before regulators can adequately review them for safety; and**
- **TSCA’s provisions for protecting confidential business information invite chemical manufacturers to make overbroad and unwarranted confidentiality claims.**

Make no mistake. EWG wants the United States to be the world leader in innovative chemical production. We have the best and the brightest scientists in our research centers and at many of the companies represented here today. But the goal of innovation cannot be just to reduce cost, increase market share and boost profits. The American public has a much broader notion. Most of us believe that “innovation” must also mean creating chemicals that are not just cheap to produce but *safe* – and that do not contaminate our blood, build up in our bodies and never break down. As our colleagues at the Center of International Environmental Law have noted, strong chemical regulation *promotes* innovation.⁵ We cannot compete internationally on labor or production costs. We will not win that race to the bottom. But America *can* win and ultimately *will* win on chemical quality and safety through toxics law reform.

TSCA’s New Chemicals Framework Fails to Adequately Protect Public Health.

In the nearly 40 years since the passage of TSCA, more than 23,000 new chemicals have been approved by the U.S. Environmental Protection Agency and added to the agency’s “inventory list” of chemicals allowed for use in commerce.⁶ As the growing body of evidence on the potential health impacts of toxic chemicals demonstrates, we need to strike a better balance between getting new chemicals to the market quickly and ensuring that these substances do not harm those who are disproportionately affected by exposure, including children, workers, pregnant women and fence-line communities.

There are five major flaws with the new chemical review process under current law:

- When a company is looking to manufacture or import a new chemical into the U.S., current law gives EPA just 90 days to review the substance before it goes on the market. The ultimate effect of this narrow window is to give profits a higher priority than public safety.
- The company must submit a pre-manufacture notice to EPA with basic information on the chemical’s name, anticipated uses and disposal, as well as any test data that is known or reasonably ascertainable.⁷ EPA cannot require companies to perform even basic health and safety testing before filing that notice, but if the company has health and safety data,

it is supposed to turn it over to EPA for review. This regulatory disconnect actually discourages manufacturers from doing safety testing because doing so would likely invite additional review by the agency. As a result, approximately half of all pre-manufacture notices include no test data at all; nearly 85 percent provide no toxicity data.⁸

- EPA faces a Catch-22 when it comes to new chemicals. The agency cannot request additional data unless it has safety concerns and it cannot adequately address safety concerns without relevant testing data. With no test data to evaluate the safety of a new chemical, EPA must use computer models, chemical comparisons and other analyses to predict how it may affect human health and the environment. At best, it operates on incomplete information. Its models and estimates are based on data about previously studied chemicals, but these do not necessarily predict how a new chemical will behave.
- Even if EPA receives complete information about a new chemical in a pre-manufacture submission, the agency makes its initial assessments based on the uses listed in that notice. The company, however, is not bound to follow those stated uses. A manufacturer can quickly adopt new uses when it goes to market and produce the chemical at much higher volumes than those estimated in the pre-manufacture notice, and EPA and the public receive no notice that the manufacturer is changing its plan.
- EPA evaluates a new chemical against a safety standard of “unreasonable risk of injury to human health or the environment.”⁹ The agency bears the burden of proof and must provide evidence if it wants to delay or restrict the new chemical. The paradox is that the less information there is about a new chemical’s safety, the faster it can reach the market. Not surprisingly, EPA attempts to restrict less than 10 percent of new chemicals.¹⁰

TSCA is so weak that it effectively presumes that new chemicals are safe without requiring pre-market testing. The law places the burden on EPA, not the chemical manufacturer, to determine whether a chemical is safe before it goes into use. Moreover, the fees companies pay to submit pre-manufacture notices cover just 10 percent of EPA’s cost of reviewing these submissions.¹¹ This framework is inadequate to protect human health and the environment.

TSCA’s Secrecy Provisions are Overbroad and Threaten Public Health & Safety.

The provisions for confidential business information under TSCA undermine the public’s right to know about substances to which they are exposed in their daily lives, including such basic information as the chemical’s name. Companies have a legitimate interest in keeping some kinds of information confidential, but sweeping and unwarranted secrecy claims directly threaten human health and the environment.¹² In practice, TSCA acts as “a regulatory black hole” where critical information goes in and little, if anything, comes out.¹³

TSCA permits a manufacturer to designate as confidential virtually any information it submits to EPA. In most instances, a company does not have to substantiate these confidentiality claims or pay a fee for making them. Moreover, once a secrecy claim has been asserted, it generally exists indefinitely, with no sunset provision. Once it is deemed confidential under TSCA, it almost always remains confidential. Even the National Security Agency releases top secret, highly

sensitive information after a period of time, but trade secret claims under federal toxics law never expire.

EPA can disclose confidential business information only in the most limited of circumstances,¹⁴ and agency employees can face criminal penalties for sharing such information with unauthorized parties.¹⁵ In contrast, a company faces little risk if it abuses confidential business information provisions under TSCA.¹⁶ This lack of penalties for abuse provides a perverse incentive to make frequent and unjustified claims that information is confidential.¹⁷

To illustrate the pervasiveness of secrecy claims under current law, consider:

- The very identity of approximately 17,000, or 20 percent, of the more than 84,000 chemicals on EPA's inventory is deemed confidential, meaning the public has no access to any information about them¹⁸;
- Industry has made confidential the identity of nearly two-thirds of all new chemicals introduced since TSCA's enactment in 1976, including substances used in numerous consumer and children's products¹⁹; and
- Approximately 95 percent of all pre-manufacture notices for new chemicals contain information the manufacturers have designated as confidential.²⁰

Companies assert that secrecy protects their competitive advantage, but reverse engineering of competitors' products is often just a routine cost of doing business in the chemical world. As a result, the only people left in the dark are typically the public – including scientists, academic researchers, medical personnel, state and local governments, and first responders. And when it comes to health and safety data, there is a huge risk to the public when the identity of the referenced chemicals is kept secret. TSCA prohibits health and safety studies themselves from being deemed confidential,²¹ but companies may still mask the specific name of chemicals in these studies on the grounds that disclosing their identity would reveal trade secrets.²² Even when publicly available studies have tied a specific chemical to an adverse health effect, the chemical's name may be legally redacted because the manufacturer designated it as confidential. In 2008, the Milwaukee Journal Sentinel reviewed more than 2,000 filings submitted to EPA under TSCA and found that chemical identity was designated confidential in more than half of them.²³ In one case, a filing cited a study linking a chemical to liver damage associated with cancer, yet the name of the chemical was redacted.²⁴ Studies sanitized in this way are largely meaningless for researchers. (See Attachment B). When scientific data is constrained this way, the public pays.

The chemical industry downplays concerns about TSCA's confidential business information protections by arguing that EPA has access to the information and can make informed decisions. But as a practical matter, only a handful of EPA employees have complete access to information that industry deems confidential.²⁵ Even EPA's own scientists get incomplete information. For example, when EPA reviewed the safety of the flame retardant Firemaster 550 in 2005, information about key chemical ingredients was kept from the agency's leading scientific expert. This secrecy, coupled with the inadequacy of EPA's testing models, resulted in the failure to predict that this flame retardant would accumulate in living organisms.²⁶ The health concerns of Firemaster 550 only came to light when a university researcher was able to crack the chemical's

code through some groundbreaking research. Recent research has shown that Firemaster 550 can cause hormone disruption, a hazard that EPA should have identified when it approved the chemical.

TSCA makes it nearly certain that medical professionals and first responders do not have access to confidential business information about a chemical even when treating a person harmed by it. The law prevents EPA from sharing this information with state and local governments responsible for developing and carrying out emergency plans. This secrecy directly threatens communities where chemicals are made, as well as “hot spots” where people have been disproportionately burdened with health and environmental problems. Consider the implications in a plant explosion or train accident. When manufacturers have failed to disclose the identities of about 20 percent of all chemicals and nearly two-thirds of all new ones, it is easy to imagine a scenario in which first responders and medical personnel would be in the dark as to how to protect the lives of first responders, workers and bystanders. In addition, communities of color and poor communities often have less access to health care needed to treat exposures to harmful chemicals. Secrecy can make this problem worse. Information relevant to detecting, assessing and responding to chemical exposures should not be shielded by confidentiality.

We applaud EPA’s recent efforts to audit secrecy claims for chemical identities in health and safety studies.²⁷ Since 2010, the agency has declassified nearly 900 previously secret chemicals referenced in these studies.²⁸ Without fundamental reform to address abuse of the confidentiality provisions, however, the secrecy problem will remain.

We support the following reforms to TSCA’s confidential business information provisions:

- Require advance justification and substantiation for confidential business information claims so that EPA can decide if secrecy is legitimate.
- Establish an automatic sunset for confidential business information claims, requiring the maker to establish the need for continued secrecy.
- Make all data in health and safety studies, including chemical identity, ineligible for confidential business information protection.
- Assess fees on companies making secrecy claims to defray the cost of administering EPA’s confidential business information review program.
- Create a mechanism to allow the public to track the number of secrecy claims, and the identity of companies that file them, in order to ensure greater accountability.
- Levy penalties against companies for making overbroad or unjustified secrecy claims.
- Allow EPA to share confidential business information within and outside the agency, including its scientists, medical professionals, first responders and state and local governments.²⁹

In conclusion, there is widespread consensus that Congress should overhaul TSCA to protect the American public from toxic chemicals while continuing to spur the development of better chemical alternatives. I thank you for the opportunity to speak before you today, and welcome any questions you may have.

ENDNOTES

¹ EWG, Body Burden: The Pollution in Newborns (2005), <http://www.ewg.org/reports/bodyburden2/execsumm.php>.

² President's Cancer Panel, 2008-2009 Annual Report: Reducing Environmental Cancer Risk: What We Can Do Now 98 (2010), http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf.

³ Id. at Cover Letter; see also H.R. 5820, the Toxic Chemicals Safety Act of 2010: Hearing Before the Subcomm. on Commerce, Trade, & Consumer Prot. of the H. Comm. on Energy & Commerce, 111th Cong. (2010) (statement of Kenneth A. Cook, President, EWG), <http://static.ewg.org/files/2010-Ken-TSCA-Testimony.pdf>.

⁴ 15 U.S.C. §§ 2601-2629.

⁵ Ctr. for Int'l Envtl. L., Driving Innovation: How Stronger Laws Help Bring Safer Chemicals to Market (2013), www.ciel.org/Publications/Innovation_Chemical_Feb2013.pdf.

⁶ EPA Office Of Inspector Gen., EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities 4 (2010), <http://www.epa.gov/oig/reports/2010/20100217-10-P-0066.pdf>.

⁷ See 15 U.S.C. § 2604.

⁸ EPA Office Of Inspector Gen., supra note 6, at 6.

⁹ See 15 U.S.C. § 2604(e).

¹⁰ EPA Office Of Inspector Gen., supra note 6, at 4.

¹¹ Id. at 12.

¹² E.g., EWG, Off The Books: Industry's Secret Chemicals (2009), <http://www.ewg.org/sites/default/files/report/secret-chemicals.pdf> [hereinafter "EWG, Off The Books"].

¹³ Id. at 2.

¹⁴ Susanne Rust & Meg Kissinger, EPA Veils Hazardous Substances, Milwaukee J.-Sentinel, Dec. 20, 2008, <http://www.jsonline.com/watchdog/watchdogreports/36514449.html>.

¹⁵ 15 U.S.C. § 2613(d).

¹⁶ Rust & Kissinger, supra note 14; see also Wendy Wagner & David Michaels, Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research, 30 Am. J.L. & Med. 119,130 (2004).

¹⁷ Wagner & Michaels, supra note 16, at 131 ("[F]irms openly concede that it is more cost-effective for them to routinely stamp as much internal information as [confidential] when no substantiation is required.").

¹⁸ EWG, Off The Books, supra note 12, at 2; see also EPA, TSCA Chemical Substance Inventory, <http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/> (last visited July 8, 2013).

¹⁹ EWG, Off The Books, supra note 12, at 2.

²⁰ Oversight Hearing on the Federal Toxic Substances Control Act: Hearing Before the Sen. Comm. on Envt. & Public Works, 111th Cong. (2009) (statement of John Stephenson, Dir. Natural Res. & Envt. U.S. Gov't Accountability Office), <http://www.gao.gov/assets/130/123792.pdf>.

²¹ 15 U.S.C. § 2613(b).

²² Id.

²³ Rust & Kissinger, supra note 14.

²⁴ Id.

²⁵ See Wendy Wagner, Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment, 53 Duke L.J. 1619, 1703 (2004) ("Staff discussions on [confidential chemicals] must be held in secure areas, documents can be reviewed only in secure environments, meeting notes themselves become confidential documents and must be logged and guarded under lock and key, and computers must have their memories and permanent storage media erased after processing confidential data.").

²⁶ Michael Hawthorne, Toxic Roulette: Firemaster 550, Touted as Safe, is the Latest in a Long Line of Flame Retardants Allowed onto the Market Without Thorough Study of Health Risks, Chicago Trib., May 10, 2012, http://articles.chicagotribune.com/2012-05-10/business/ct-met-flames-regulators-20120510_1_flame-retardants-ban-chemicals-chemical-safety-law.

²⁷ EPA, Declassifying Confidentiality Claims to Increase Access to Chemical Information, <http://www.epa.gov/oppt/existingchemicals/pubs/transparency-charts.html> (last visited July 8, 2013).

²⁸ Id.

²⁹ For more information about reforming TSCA's confidential business information provisions, see generally, e.g., Wagner & Michaels, supra note 16.

ATTACHMENTS

ATTACHMENT A: Results of Select Cord Blood Biomonitoring Studies of U.S. Infants

ATTACHMENT B: Sample Health and Safety Study with Confidential Chemical Identity

ATTACHMENT A

ATTACHMENT A: RESULTS OF SELECT CORD BLOOD BIOMONITORING STUDIES OF AMERICAN INFANTS

Nationally, cord blood biomonitoring studies have detected up to 358 chemicals

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
Dioxin & Furan	Brominated dioxin	EWG tested cord blood from 10 newborns for 12 brominated dioxins and furans and found at least one of these chemicals in 7. In the 7 newborns, 6 to 7 different congeners were found. Mean total level was 12 pg/g lipids in blood serum. (EWG 2005)	10	U.S. hospitals	6-7
Dioxin & Furan	Brominated dioxin	EWG tested cord blood from 10 newborns of minority background for 12 brominated dioxins and furans and found at least one in 4 of the subjects. Six different congeners were found. Mean total level was 10.7 pg/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	6
Dioxin & Furan	Chlorinated dioxin	Researchers from the SUNY Health Science Center tested cord blood from 5 babies delivered via C-section from late 1995 to early 1996 for dioxins, dibenzofurans, and coplanar PCBs. Mean measured levels of total PCDDs, PCDFs, and coplanar PCBs were 165 pg/g for cord blood. (EWG 2005)	5	N.Y.	1
Dioxin & Furan	Chlorinated furan	EWG tested cord blood from 10 newborns for 17 chlorinated dioxins and furans and found at least one in all 10 subjects. Eleven different congeners were found. Mean total level was 56.3 pg/g lipids in blood serum. (EWG 2005)	10	U.S. hospitals	11
Dioxin & Furan	Chlorinated furan	EWG tested cord blood from 10 newborns of minority background for 17 chlorinated dioxins and furans and found at least one in all 10 subjects. Fifteen (15) different congeners were found. Mean total level was 59.7 pg/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	15
Fire Retardant	Brominated Fire Retardant	EWG measured TBBPA levels in cord blood from 10 newborns of minority background. TBBPA was found in 3 samples with a mean level of 11 ng/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	1
Metal	Cadmium	Researchers from Harvard measured cord blood concentrations of cadmium in 94 healthy babies, finding concentrations ranging from 0.003 to 0.210 ug/dl, with mean of 0.045 ug/dl. (Rabinowith 1984)	94	Boston, Mass.	1
Metal	Lead	Researchers from SUNY Oswego, the New York State Department of Health, the University of Albany, and Penn State University measured cord blood lead levels in 154 children and correlated lead levels with adrenocortical responses to acute stress in children. They divided cord blood levels into the following 4 quartiles: < 1.0 (1st quartile; n = 37), 1.1-1.4 ?g/dL (2nd quartile; n = 39), 1.5-	154	N.Y.	1

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
		1.9 ?g/dL (3rd quartile; n = 36), and 2.0–6.3 ?g/dL (4th quartile; n = 42). (Gump 2008)			
Metal	Lead	Researchers from Harvard University, Emory University, and University of Massachusetts at Amherst tested lead levels in cord blood from 527 babies born between 1993 and 1998 and found mean levels of 1.45 ug/dL. (Sagiv 2008)	527	New Bedford, Mass.	1
Metal	Mercury	Researchers from Columbia University and the CDC tested for cord blood levels of mercury in women who live and or work close to the World Trade Center site between Dec. 2001 and June 2002. The researchers found a mean cord mercury level of 7.82 ug/L. (Lederman 2008)	289	New York City, N.Y.	1
Musk	Musk	EWG measured nitro and polycyclic musk levels in cord blood from 10 newborns of minority background. Galaxolide was found in 6 samples at a mean level of 0.483 ng/g, and tonalide was found in 4 samples at a mean level of 0.147 ng/g. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	2
PAH	Polyaromatic hydrocarbons (PAHs)	Researchers from Columbia University measured levels of benzoA-pyrene DNA adduct levels in 203 babies from New York City mothers who were pregnant during 9/11. (Perera 2005)	203	New York City, N.Y.	1
PAH	Polyaromatic hydrocarbons (PAHs)	EWG tested cord blood from 5 newborns for 18 polyaromatic hydrocarbons and found at least one in all 5 subjects. Nine (9) different chemicals were found with total mean concentration of 279 ng/g lipids in blood serum. (EWG 2005)	5	U.S. hospitals	9
PBDE	Polybrominated diphenyl ether (PBDE)	Researchers from Columbia University and Johns Hopkins tested 297 cord blood samples from babies born at Johns Hopkins Hospital from Nov. 26, 2004 to March 16, 2005 for 8 PBDE congeners. They report that 94% of the samples contained at least one of the tested congeners. (Herbstman 2007)	297	Baltimore, Md.	7
PBDE	Polybrominated diphenyl ether (PBDE)	Researchers from Indiana University measured levels of 6 PBDEs in 12 paired samples of maternal and cord blood from live births that occurred from Aug. to Dec., 2001. They found that concentrations of PBDEs in both sets of samples were 20-to-106 fold higher than levels reported in a similar study from Sweden, leading them to conclude "human fetuses in the United States may be exposed to relatively high levels of PBDEs." (Mazdai 2003)	12	Indianapolis, Ind.	6
PBDE	Polybrominated diphenyl ether (PBDE)	EWG tested cord blood from 10 newborns for 46 polybrominated diphenyl ethers (PBDEs) and found at least one of these chemicals in 10 out of 10 participants. Among all 10	10	U.S. hospitals	27-32

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
		participants who tested positive for the chemicals, 27 to 32 different congeners were found. Mean total level was 4.53 ng/g lipids in blood serum. (EWG 2005)			
PBDE	Polybrominated diphenyl ether (PBDE)	EWG tested cord blood from 10 newborns of minority background for 46 polybrominated diphenyl ethers (PBDEs) and found at least one in all 10 samples. Among all 10 participants who tested positive for the chemicals, 26 to 29 different congeners were found. Mean total level was 72.9 ng/g lipids in blood serum. (EWG 2009)	10	U.S. hospitals	26-29
PBDE	Polybrominated diphenyl ether (PBDE)	Researchers at Columbia University and Johns Hopkins tested 288 cord blood samples from babies born at Johns Hopkins Hospital from Nov. 26, 2004 to March 16, 2005 for 3 PBDE congeners. In all the 288 subjects, all three congeners were found. (Herbstman 2008)	288	Baltimore, Md.	3
PBDE	Polybrominated diphenyl ether (PBDE) Metabolite	Researchers from the School of Public and Environmental Affairs at Indiana University tested PBDE and PBDE metabolites in 20 pregnant women and their newborn babies who had not been intentionally or occupationally exposed. They noted that metabolites in humans seem to be accumulating. (Qiu 2009)	20	Indianapolis, Ind.	10
PCB	Polychlorinated biphenyl (PCB)	Researchers at Columbia University and Johns Hopkins tested 297 cord blood samples from babies born at Johns Hopkins Hospital from Nov. 26, 2004 to March 16, 2005 for 35 PCB congeners. They report levels for 4 of the 35 but note that ">99% (of samples) had at least one detectable PCB congener." (Herbstman 2007)	297	Baltimore, Md.	18
PCB	Polychlorinated biphenyl (PCB)	Researchers from SUNY Oswego investigated cord blood levels of PCBs in children born between 1991 and 1994 and correlated levels with response inhibition when the children were 4.5 years of age. The researchers found that "results indicated a dose-dependent association between cord blood PCBs and errors of commission." (Stewart 2003)	293	Great Lakes states	7
PCB	Polychlorinated biphenyl (PCB)	EWG tested cord blood from 10 newborns for 209 polybrominated diphenyl ethers (PBDEs) and found at least one of these chemicals in 10 out of 10 participants. Among all 10 participants who tested positive for the chemicals, 98 to 147 different congeners were found. Mean total level was 6.2 ng/g lipids in blood serum. (EWG 2005)	10	U.S. hospitals	98-147
PCB	Polychlorinated biphenyl (PCB)	EWG tested cord blood from 10 newborns of minority background for 209 polychlorinated biphenyls and found at least one in all 10 samples. Among all 10 participants who tested positive for the chemicals, 98 to 144 different congeners were found. Mean total level was 22.1 ng/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	98-144

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
PCB	Polychlorinated biphenyl (PCB)	Researchers from Harvard, Emory, and the University of Massachusetts at Amherst tested levels of 51 PCB congeners in cord blood from 542 babies born between 1993 and 1998. No information on levels of individual congeners is given; however, the mean sum of PCB congeners 118, 138, 153, and 180 is 0.25 ng/g and the TEF-weighted sum of mono-ortho PCB congeners 105, 118, 156, 167, and 189 is 6.75 pg/g lipid. (Sagiv 2008)	542	New Bedford, Massachusetts	>4
PCN	Polychlorinated naphthalene (PCN)	EWG tested cord blood from 10 newborns for 70 polychlorinated naphthalenes and found at least one in all 10 subjects. In all, 31 to 50 different congeners were found with total mean concentration of 0.574 ng/g lipids in blood serum. (EWG 2005)	10	U.S. hospitals	31-50
PCN	Polychlorinated naphthalene (PCN)	EWG tested cord blood from 10 newborns of minority background for 70 polychlorinated naphthalenes and found at least one in all 10 subjects. In all, 17 to 24 different congeners were found, with total mean concentration of 0.637 ng/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	17-24
Pesticide	Carbamate	Researchers from Columbia University, the CDC, and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept. 1998 and May 2001. 48% of the babies had exposure to 2-Isopropoxyphenol, 45% to carbofuran, and 36% to bendiocarb. All of the babies were exposed to at least one carbamate. (Whyatt 2003)	211	New York City, N.Y.	5
Pesticide	Fungicide	Researchers from Columbia University, the CDC, and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept. 1998 and May 2001. 83% of the babies had exposure to dicloran, 70% to phthalimide. All of the babies had exposure to at least one fungicide. (Whyatt 2003)	211	New York City, N.Y.	4
Pesticide	Herbicide	Researchers from Columbia University, the CDC, and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept. 1998 and May 2001. 38% had exposure to chlorthal-dimethyl and 20% had exposure to Alachor. All had exposure to at least one herbicide. (Whyatt 2003)	211	New York City, N.Y.	5
Pesticide	Imide	Researchers from Columbia University, the CDC, and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept. 1998 and May 2001. 83% had exposure to dicloran and 70% had exposure to phthalimide. All had exposure to at least one fungicide.	211	New York City, N.Y.	1

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
		(Whyatt 2003)			
Pesticide	Mosquito Repellent	Researchers from Columbia University, the CDC, and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between September 1998 and May 2001. 33% of the babies had exposure to diethyltoluamide. (Whyatt 2003)	211	New York City, N.Y.	1
Pesticide	Organochlorine Pesticide (OC)	Researchers from Harvard, Emory, and the University of Massachusetts at Amherst tested levels of 2 organochlorine pesticides in cord blood from 542 babies born between 1993 and 1998. Mean DDE levels were 0.48 ng/g serum. Levels of HCB were not given. (Sagiv 2008)	542	U.S. hospitals	1
Pesticide	Organochlorine Pesticide (OC)	EWG tested cord blood from 10 newborns for 28 organochlorine pesticides and found at least one in all 10 subjects. In all, 21 different pesticides were found. (EWG 2005)	10	U.S. hospitals	21
Pesticide	Organophosphate Pesticides and Metabolites	Researchers from Columbia University, the CDC, and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept. 1998 and May 2001. 71% had exposure to chlorpyrifos (mean 4.7 pg/g) and 49% had exposure to diazinon (mean 1.2 pg/g), the two most commonly detected pesticides. All other pesticides were found in 4% or less of the samples and all babies had exposure to at least one of the organophosphates. (Whyatt 2003)	211	New York City, N.Y.	8
Pesticide	Pyrethroid	Researchers from Columbia University, the CDC, and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept 1998 and May 2001. 7% had exposure to transpermethrin and 13% had exposure to cispermethrin. (Whyatt 2003)	211	New York City, N.Y.	2
PFC	Perfluorochemical (PFC)	Researchers from CDC, Columbia University, and Johns Hopkins tested cord blood from 299 babies born at Johns Hopkins Hospital between Nov. 26, 2004 and March 16, 2005 for 10 PFCs. They detected PFOS in 99% and PFOA in 100% of samples. Eight other PFCs were detected at lesser frequency. (Apelberg 2007)	299	Baltimore, Md.	9
PFC	Perfluorochemical (PFC)	EWG tested cord blood from 10 newborns for 12 perfluorochemicals and found at least one of these chemicals in 10 out of 10 participants. Among all 10 participants who tested positive for the chemicals, 9 of 12 different chemicals were found with total mean concentration of	10	U.S. hospitals	9

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
		5.86 ng/g in whole blood. (EWG 2005)			
PFC	Perfluorochemical (PFC)	EWG tested cord blood from 10 newborns of minority background for 13 perfluorochemicals and found at least one of these chemicals in 10 out of 10 participants. Among all 10 participants who tested positive for the chemicals, 6 of 13 different chemicals were found with total mean concentration of 2.38 ng/g in whole blood. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	6
Plastic	Bisphenol A & BADGE	Researchers from the Environmental Working Group measured BPA levels in cord blood from 10 newborns of minority background. BPA was found in 9 of 10 samples with a mean level of 2.18 ng/L. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	1
Rocket fuel	Perchlorate	Researchers from the Environmental Working Group measured perchlorate levels in cord blood from 10 newborns of minority background. Perchlorate was found in 9 of 10 samples with a mean level of 0.209 ug/L. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	1

ATTACHMENT B

PUBLIC COPY

COMPOUND: [REDACTED]

STUDY TITLE: Acute Inhalation Toxicity in Rats

REPORT OR STUDY NO.: [REDACTED]

The purpose of this study was to determine the acute inhalation toxicity of the test article [REDACTED]. The study was conducted in accordance with OECD Guideline No. 403. Groups of Wistar rats (5/sex) were exposed nose-only for 4 hours to aerosols of the test article (0 and 61 mg/m³ measured concentration). MMAD was 1.5 µm with GSD of 1.7. Endpoints included rectal temperature shortly after exposure and body weights and clinical signs during the subsequent 2-week observation period. All rats were sacrificed and necropsied after 2 weeks.

Rectal temperature was significantly decreased following exposure compared to sham-exposed controls. Body weights were reduced after exposure but were comparable to controls for surviving animals by 2 weeks. All exposed animals exhibited labored and irregular breathing, bradypnea, reduced motility, high-legged gait, limp, piloerections, and signs of poor grooming. Four males and 2 females died in the exposed group within 1 day after exposure and exhibited gross lung edema with pleural effusions, collapsed lungs, and discolored parenchymal organs. Four surviving rats had a reduced/impaired grip strength, tonus, and righting reflex on first day after exposure. Limp was noted in 2-3 surviving animals on days 1-4; high-legged gait was noted in 3-4 animals on days 1-4. Surviving rats had discolored lungs at necropsy. Mortality (60% of exposed animals) appeared to be from acute lung edema and surviving animals appeared to recover during the observation period. The LC50 is ~60 mg/m³, confirming a previous study T5061594.

The reporting criterion under TSCA 8(e) for acute inhalation is a LC50 <2,000 mg/m³; the LC50 for this test substance of ~60 mg/m³ meets this criterion. In addition, TSCA 8(e) criteria for reporting include signs of neurotoxicity at any dose level and lasting more than 48 hours after dosing in 2 or more animals that survive to the end of the study.

It is not clear whether the high-legged gait and limp are evidence of neurotoxicity in that the effect was transient and occurred at a dose where mortality was also observed. Nevertheless, meeting any of the above criteria leads to a recommendation for reporting.

Therefore, it is recommended that this report be submitted under TSCA 8(e).

PUBLIC COPY

April 6, 2009

09 APR 20 AM 6:03
RECEIVED
EPA

Document Control Officer 8(e) Coordinator
U. S. Environmental Protection Agency – East
Confidential Business Information Center
Mail Code: 7407M
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460



Dear Sir:

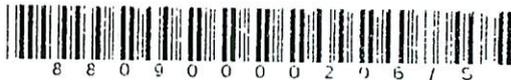
In accordance with TSCA 8(e) requirements, [REDACTED] is submitting [REDACTED].

The purpose of the study was to determine the acute inhalation toxicity of the test article [REDACTED].

The information submitted in this study is considered "Confidential Business Information". A sanitized, as well as a confidential version, is being submitted.

Please contact me if you have any questions.

Sincerely,



Company Sanitized

318554

List of Documents
Transferred to HDMB
DATE 4/21/2009

DCN	CASE NO	DOC TYPE	COUNT	SANITIZED
1 88090000206/S	8EHQ-09-17482	8E	1	Y

[Redacted Signature]

[By:]

List of Documents
Transferred to HDJMB
DATE 4/21/2009

	DCN	CASE NO	DOC TYPE	COUNT	SANITIZED
1	88090000206/S	8EHQ-09-17482	8E	1	Y

[REDACTED]

Shelton

[By:]