
Off the Books: Industry's Secret Chemicals

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Executive Summary

The 33-year old law that was supposed to ensure that Americans know what chemicals are in use around them, and what health and safety hazards they might pose, has produced a regulatory black hole, a place where information goes in – but much never comes out.

The reason is that under the 1976 Toxic Substances Control Act (TSCA), the chemical industry has been allowed to stamp a “trade secret” claim on the identity of two-thirds of all chemicals introduced to the market in the last 27 years, according to an Environmental Working Group (EWG) analysis of data obtained from the Environmental Protection Agency (EPA). These include substances used in numerous consumer and children’s products.

EWG’s analysis also showed that:

- The public has no access to any information about approximately 17,000 of the more than 83,000 chemicals on the master inventory compiled by the EPA.
- Industry has placed “confidential business information” (CBI) claims on the identity of 13,596 new chemicals produced since 1976 – nearly two-thirds of the 20,403 chemicals added to the list in the past 33 years.
- Secrecy claims directly threaten human health. Under section 8(e) of TSCA, companies must turn over all data showing that a chemical presents “a substantial risk of injury to health or the environment.” By definition compounds with 8(e) filings are the chemicals of the greatest health concern. In the first eight months of 2009 industry concealed the identity of the chemicals in more than half the studies submitted under 8(e).
- From 1990 to 2005, the number of confidential chemicals more than quadrupled – from 261 to 1,105 -- on the sub-inventory of substances produced or imported in significant amounts (more than 25,000 pounds a year in at least one facility). In July 2009 the EPA released the identity of 530 of these chemicals, lowering the number of these moderate- and high-production volume secret chemicals to 575.
- At least 10 of the 151 high volume confidential chemicals produced or imported in amounts greater than 300,000 pounds a year are used in products specifically intended for use by children age 14 or younger.

TSCA is an extraordinarily ineffective law. Its failings have been repeatedly documented by the Government Accountability Office, Congressional hearings, and independent investigations. But it has generally been assumed that the law required an accurate public inventory of chemicals produced or imported in the United States.

As this investigation shows, it does not.

Instead we have a de-facto witness protection program for chemicals, made possible by a weak law that allows broad confidential business information (CBI) claims, made worse by EPA’s historic deference to business assertions of CBI.

EPA data compiled in response to an EWG information request show that a large number of these secret chemicals are used everyday in consumer products, including artists' supplies, plastic products, fabrics and apparel, furniture and items intended for use by children. But EPA cannot share specific information on these chemicals even within the agency or with state and local officials.

Industry has a stranglehold on every aspect of information needed to implement even the most basic health protections from chemicals in consumer products and our environment. This must be changed. A chemical's identity and all related health and safety information must be made available to the public with no exceptions.

The TSCA Inventory

In response to headlines about burning rivers and widespread pollution, Congress passed the Toxic Substances Control Act (TSCA) in 1976. The act says, in Sec. 2607 (b): "The Administrator shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States."

This list includes all chemicals in commerce that are not specifically regulated under other laws, such as pesticides, foods, food additives, drugs, cosmetics, ammunition, mixtures, impurities, byproducts and substances manufactured solely for export. ("Toxic Substances Control Act," 1976)

In December 1977, EPA published an Inventory Reporting rule requiring the reporting of chemicals in commerce since 1975. Based on the information submitted by industry, EPA assembled its initial TSCA Inventory in May 1979 listing 43,641 chemical substances (EPA, 1980). In May 1982 EPA released its "Cumulative Supplement II" that listed 58,000 chemicals, including 1,800 whose identity was not disclosed (EPA, 1982).

EPA estimated that the overall list was 97 percent complete, and the list of undisclosed chemicals was 90 percent complete, indicating that in 1982 EPA's inventory actually totaled 60,000 chemicals, including about 2,000 whose identity was claimed confidential (EPA, 1982).

The TSCA inventory lists only basic information: a Chemical Abstracts Service (CAS) registry number, the preferred chemical name, and the molecular formula. The inventory may also include synonyms, former registry numbers and EPA flags identifying EPA rule-makings concerning that chemical.

The TSCA inventory does not include information on who makes the chemical, where it is made, the quantity produced, whether it is still made, and what consumer products contain it. There is also no health and safety information.

The image below shows how the first 3 chemicals appear in the July 2009 TSCA inventory:

RN: 50-00-0	IN: Formaldehyde	SN: Formaldehyde	DF:	FN: 8005-38-7; 8006-07-3; 8013-13-6; 112068-71-0	MF: CH ₂ O	UV:	FL:
RN: 50-01-1	IN: Guanidine, hydrochloride (1:1)	SN:	DF:	FN: 420-13-3; 14317-32-9; 15827-40-4; 87667-20-7; 94369-44-5; 106946-18-3; 139693-44-0; 143504-22-7; 915070-50-7	MF: CH ₅ N ₃ .ClH	UV:	FL:
RN: 50-02-2	IN: Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17,21-trihydroxy-16-methyl-, (11.beta.,16.alpha.)-	SN:	DF:	FN: 8054-59-9; 137098-19-2; 906362-70-7; 906422-84-2; 1050677-47-8	MF: C ₂₂ H ₂₉ FO ₅	UV:	FL:

(Key: RN = CAS Registry number*; IN = Preferred Chemical Abstracts Index name*; SN = Chemical name reported by the submitters of the data; DF = Chemical substances definitions; FN = Former CAS registry number; MF = Molecular formula*; UV = Unknown or Variable Composition and Biological Materials; FL = EPA inventory flag. *Required)

The Inventory includes all chemicals that were at one time used in commerce and has not been updated to identify chemicals that are no longer in use. On March 18, 2008, EPA announced that it planned to reset the TSCA inventory to create a current snapshot of all chemicals currently in commerce (EPA, 2008). The status of the inventory reset is in question because the it was a part of the Chemical Assessment and Management Program (CHAMP) program, which has been superseded by the comprehensive approach to chemical management announced by EPA Administrator Lisa Jackson on Sept. 29, 2009.

CBI Claims Shield Identity of Riskiest Chemicals

TSCA is generally recognized as the weakest of all federal environmental laws. This stems in large part from the tight constraints the statute puts on the EPA's ability to obtain studies on chemical hazards.

One provision of the law, section 8(e), is designed to compensate for this. Under 8(e), companies are required to notify EPA whenever they obtain information that a chemical or mixture "presents a substantial risk of injury to health or the environment" ("Toxic Substances Control Act," 1976). Even though industry is not required to conduct any tests to produce or introduce a chemical into commerce, section 8(e) has been an important source of information on chemical hazards.

But the value of 8(e) is being severely undermined by claims of confidentiality.

In more than 50 percent of the nearly 300 TSCA 8(e) filings made in the first eight months of 2009, the chemical's identity was claimed confidential (EPA, 2009d). Chemicals with 8(e) submissions are generally considered to be those of greatest concern. Hiding the identity of these chemicals could significantly delay or completely prevent actions to reduce exposures to compounds that by definition require an open and transparent evaluation of their risks.

New Chemicals

When enacted, TSCA implicitly assumed that all chemicals used in commerce at that time were “safe as used,” and no safety assessments were required to justify continued use. For newly introduced chemicals the law established a notification system.

Ninety days prior to producing or importing a chemical not already on the TSCA inventory, a manufacturer must submit to EPA a “pre-manufacture notice” (PMN). No health and safety information is required and typically none is provided. The agency reports that 67 percent of PMN’s include no test data, and 85 percent provide no health data. (Overview: Office of Pollution Prevention and Toxics Programs, 2007). EPA “takes action to control potential risk to health or the environment on just 10 percent of the PMNs submitted.” (EPA, 2009b).

The chemical industry routinely attaches CBI claims to its new chemical applications. About 95 percent of industry’s PMNs contain some information that is claimed confidential (GAO, 2005). EPA approves most of these applications and adds the new chemicals, masked in these claims of confidentiality, to the TSCA inventory, but the agency does not disclose the information to the public.

EPA reports that since 1982, its complete TSCA inventory has grown from 60,000 chemicals to more than 83,000 (EPA, 2008). A significant portion of that list is kept secret.

In August 2009, EWG purchased the publicly available portion of the TSCA inventory through the National Technology Information Service. This public inventory lists just 66,068 unique chemicals in a 4,943-page file, including 6,807 identified as substances added through the PMN process for new chemicals. For another 13,596 new chemicals that have

Chemical secrecy presents real threats to human health and the environment.

In 2005, under pressure from environmental health advocates and the EPA, Great Lakes Chemical phased-out the neurotoxic and persistent brominated fire retardant PentaBDE. At the same time, the EPA expedited the approval of Firemaster 550, a replacement fire retardant made with confidential ingredients.

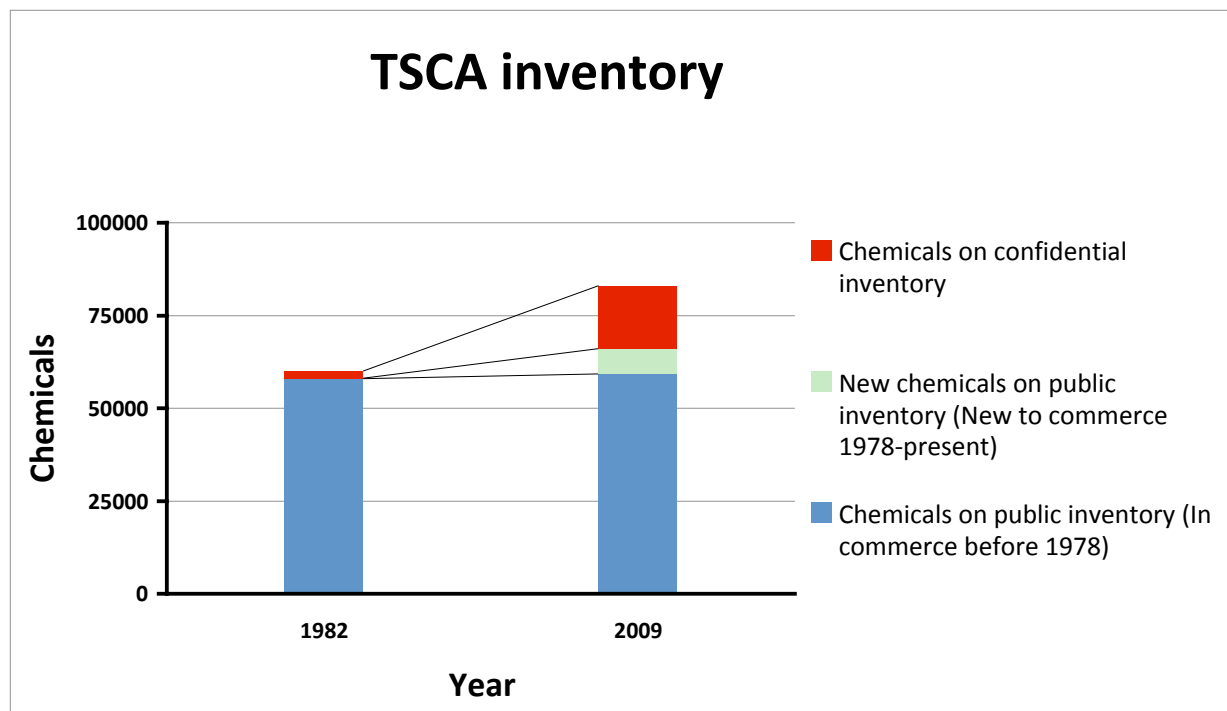
Dr. Linda Birnbaum, EPA's top expert on fire retardant at the time, and now Director of the National Institute of Environmental Health Sciences at the National Institutes of Health, was worried that Firemaster 550's ingredients might present health risks similar to PentaBDE. She complained publicly that it's chemical contents were confidential, even to her, the EPA's leading scientist on flame retardants.

Industry had good reason to conceal the ingredients in Firemaster 550. Had Birnbaum and other EPA scientists known the identity of the chemicals in Firemaster 550, the product would have come under serious scrutiny within the agency. But with CBI protection, EPA scientists were helpless to do anything.

In 2008, Duke University scientist Heather Stapleton cracked the chemical code for Firemaster 550, finding that it contained a brominated phthalate and brominated benzoate. The brominated phthalate was later detected in high concentrations in Boston-area households and sewage sludge from the Bay Area.

In 2009, the EPA released the identity of 530 secret chemicals including another flame retardant chemical, ominously named dethane, or Decabromodiphenyl ethane, the key ingredient in Firemaster 2100, a brominated flame retardant in the same chemical family as the developmental neurotoxin, Deca-BPE. (Stapleton et al., 2008). Thanks to CBI protection, dethane has been accumulating in the U.S. environment and around the globe.

begun the PMN process, the agency provides an only “accession number” and a generic name, but no specific information about what it is. That means that for two out of every three chemicals that entered commerce in the past 30 years, their chemical identity remains secret.



Inventory Update Reporting

EPA established the Inventory Update Reporting (IUR) system as a complement to the TSCA Inventory to collect basic information on chemicals produced in significant quantities at a single location. Under the IUR, general information is collected on what is manufactured, where is it produced and in what quantity. This information is collected every fifth year and most recently was expanded to include use information for the very highest volume chemicals.

In 1986, EPA promulgated the first IUR rule, requiring manufacturers and importers to report the identity and a quantity range for organic chemicals produced or imported in amounts greater than 10,000 pounds per year at a single site [TSCA section 8(a), codified at 40 CFR part 710 (51 FR 21438, June 12, 1986)] This information was required only every fourth year and covered only the preceding 12 months.

The IUR program was amended in 2003 and 2005, raising the reporting threshold so that now, industry only has to report chemicals produced or imported in amounts greater than 25,000 pounds per year and reducing the frequency of reporting to once every five years.

For chemicals produced or imported in amounts greater than 300,000 pounds per year, EPA also added a requirement that companies report basic information on how chemicals are used in products or industrial processes. The first IUR reporting period in 1985 showed that 8,457 chemicals were produced or imported in amounts greater than 10,000 pounds per location. The number of chemicals reported under IUR remained close to 8,500 in each reporting period except for the year 2002 (7,362 chemicals reported) and 2006 (6,200 reported). The decrease in 2006 may be explained in part by the higher weight threshold, but it may also be due to the increased claims of confidentiality.

As a part of this analysis EWG requested non-chemical specific information from EPA on the chemicals claimed confidential in IUR submissions.

In the 2006 IUR report, EPA published a detailed definition of confidential business information but provided no detail on how these claims are substantiated.

“Confidential Business Information (CBI), in the IUR context, is commercial information obtained from the information owner, or person, and claimed as confidential, that is treated as confidential by that person, has not been previously disclosed, is not available from other sources and is not required by law to be disclosed. Additionally the person asserting the CBI claim must believe that the release of the information claimed as CBI would cause substantial injury to the person's competitive position” (EPA, 2009a).

In the 2006 IUR report, EPA provided a chart of confidential business information claims for specific data elements. This chart shows that 26 to 49 percent of processing and use information was claimed confidential in the various reporting categories (EPA, 2009a). EPA does not reveal exactly how many chemicals are not publicly disclosed, nor does it provide production and importation quantities or use information, because of confidentiality claims.

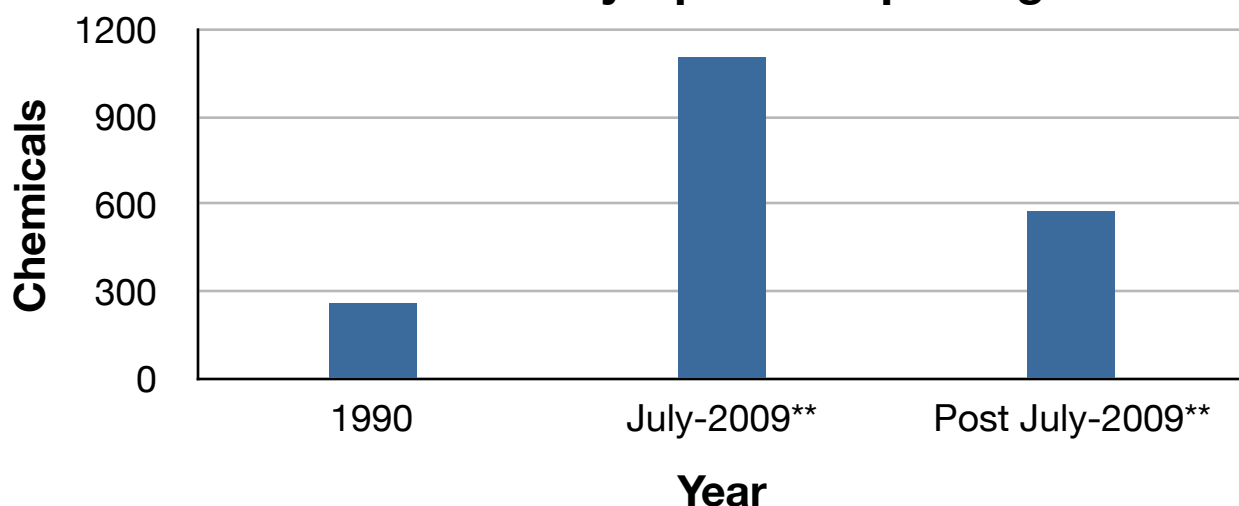
EWG requested information on how many IUR chemicals were hidden from public reporting and the uses of these secret chemicals. EPA responded that in 1990, the identity of 261 IUR chemicals was declared to be confidential, but by July 2009, the number of chemicals under confidential claims had risen to 1,105. That month, however, the agency publicly released the identities of 530 chemical substances that had been placed on the confidential portion of the TSCA inventory because their identity had been disclosed via other avenues, including peer-reviewed journal articles, or on other IUR submissions without confidentiality claims (EPA, 2009e).

In a letter to EWG dated Oct. 14, 2009, EPA put the number of secret medium- and high-production volume chemicals on the 2006 IUR list at 575.

Due to changes in regulations and reporting requirements, a direct comparison is impossible, but chemicals with confidential identities now represent a much greater portion of the most widely used chemicals than they did 15 years ago. The total production of secret chemicals has also drastically increased. In 2006, EPA reported that the volume of secret chemicals produced or imported totaled between 1.265 billion pounds and 4.473 billion pounds, five to six times the 1990 volume of 255 million pounds to 995 million pounds.

A 2005 Government Accountability Office (GAO) report noted that as far back as 1992, EPA had acknowledged widespread inappropriate use of confidentiality claims, and that as of 2005 it was only challenging about 14 such claims a year. EPA told investigators that it did not have the resources to investigate and challenge more claims. (GAO, 2005). In this same report, the GAO recommended that EPA require periodic resubmission of confidentiality claims as well as giving EPA the ability to share confidential information with state and international governments (GAO, 2005).

Confidential chemicals reported through Inventory Update Reporting

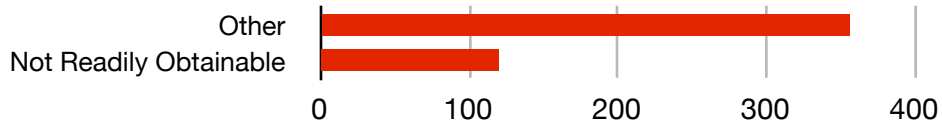
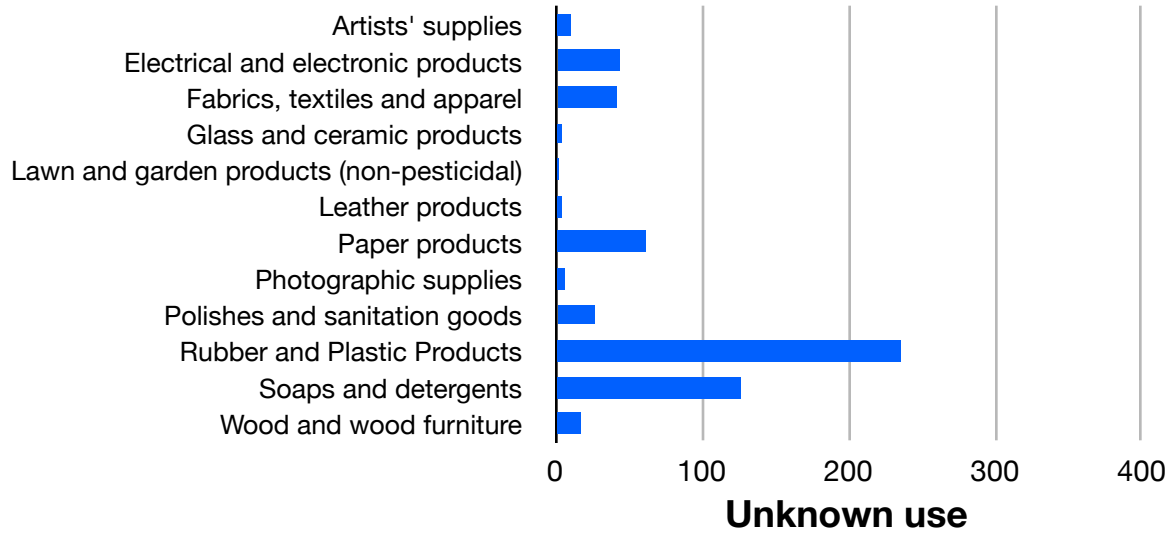


** The IUR reporting requirement changed for the most recent reporting cycle to include inorganic compounds and to exclude all compounds produced in quantities less than 25,000 pounds per site.

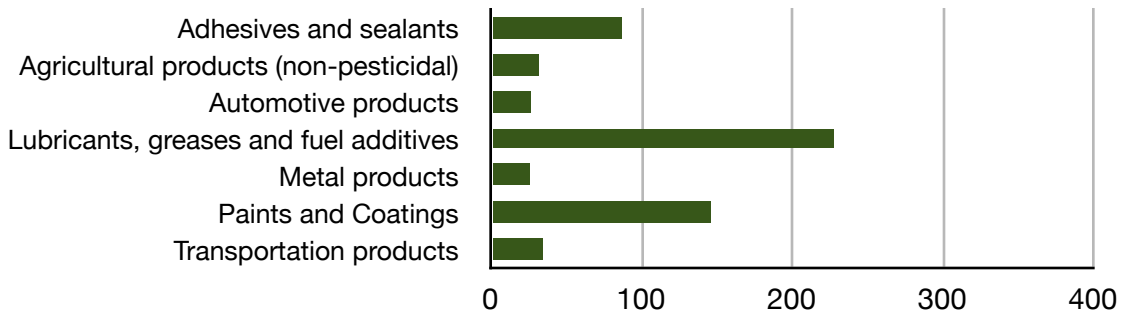
Of the 151 secret chemicals produced or imported in amounts of 300,000 pounds or more, EPA reported that at least 10 go into products intended specifically for use by children age 14 or younger. For clarification, **EPA said that “a family sofa, television remote control, and a bathmat are general household items that are not typically designed for use by children” (EPA, 2009c).** The number of secret chemicals in children’s products could be as high as 43 because the manufacturers/importers of 33 chemicals indicated that use information for these substances is not readily obtainable.

A breakdown of the confidential identity claims by product category is provided below. The numbers reported in the table do not add to 575 because many chemicals were reported as being used in multiple categories.

Secret chemicals are common in products used in and around the home



Home, construction & industrial use



Unique chemicals with identity claimed confidential in 206 reporting to EPA

Secret Chemicals Excluded from Voluntary Testing Programs

Because the agency lacks legal authority to require chemical hazard information from industry, EPA has tried to obtain basic health and safety data through voluntary initiatives such as its High Production Volume (HPV) challenge. The HPV challenge, launched in 1998, was supposed to gather rudimentary health and safety information on about 2,700 chemicals produced or imported in volumes greater than 1,000,000 pounds per year. Although launched in 1998, the base year for the HPV estimate of 2,700 HPV chemicals was the TSCA inventory data from 1990.

The HPV challenge has been crippled by lack of data for hundreds of “orphan” chemicals for which no company agrees to submit test data. In addition, the fact that the studies that are volunteered are merely screening studies, often not new, and none of the data has led to any significant health protections. Even so, the HPV challenge has been the EPA's most important source of scientific information on the 2,700 most significant chemicals in commerce.

But the program is not immune from chemical secrecy. On the original HPV list (based on 1990 inventory), 32 secret HPV chemicals were left out of the program (2,676 non-secret chemicals were listed for the program)

Since then, the number of secret HPV chemicals has increased more than 4-fold -- the latest IUR contains 141 secret HPV chemicals

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