

Questions and Answers about Styrene

Q: What is styrene?

Styrene is an important industrial chemical used to make polystyrene and many other types of plastics, as well as adhesives, sealants and synthetic rubber.

Styrene is named after the styrax trees from whose sap it can be extracted. Styrene occurs naturally in plants as well as a variety of foods such as fruits, vegetables, nuts, beverages, and meats. In their daily lives, most Americans routinely come into contact with hundreds of products made from styrene.

Styrene is derived commercially from petroleum. Approximately 33 billion pounds are produced annually. The production of styrene in the United States increased dramatically during the 1940s, when it was used as a feedstock to produce synthetic rubber for the war effort.

Q: How is styrene used?

A wide variety of commercially significant products are made with polystyrene, ABS, styrene-butadiene rubber, styrene-butadiene latex, and the styrene-polyester resins used in composites. These materials are used in rubber, plastic, insulation, pipes, automobile and boat parts, food containers, carpet backing, and hundreds of other products.

Notable benefits of products made with styrene include:

- **Extending the life of transportation infrastructure** - Highway bridges built using styrene-based composite materials can last five-times longer than bridges made using traditional materials and do so withOut costly maintenance. Styrene-based polymers extend the life of road surfaces by up to 50%.
- **Protecting troops** – Armor for Humvees and ballistic panels for tents and military installations are made using styrene-based polymer resins.
- **Producing, transmitting and saving energy** - Major components for wind, wave and solar energy generation are made using styrene. Transmission towers that can conduct more energy in the same right-of-way are made using styrene, as are fuel tanks for natural-gas propelled city buses. Styrene is important in the manufacture of light-weight components for cars and trucks, and efficient thermal insulation for homes and commercial buildings.
- **Increasing safety** - Styrene-based bike helmets and non-conducting household ladders help prevent injuries. Styrene-based tires increase road grip.
- **Preventing pollution** - Styrene is a critical component of the materials used to manufacture gasoline and chemical storage tanks, pollution control stacks and scrubbers, and waste-water treatment equipment.
- **Preventing illness and saving lives** - Styrene-based hygienic food packaging and food service items help stop the spread of disease-causing organisms in cafeterias and restaurants. Insulating polystyrene containers allow donated organs and heat-sensitive vaccines to be transported over long distances. Styrene-based plastics make diagnostic tools and other medical instruments more durable.
- **Improving sports** - Recreational boats, surf boards, canoes and kayaks are all made with styrene-based materials.

Q: Are there alternatives to styrene?

Styrene is a uniquely effective chemical, and our lives would be very different without it. For example:

- Without styrene ballistic protection for our troops on the battlefield would cost more.
- Without styrene highway bridges would last only 25% as long.
- Without styrene restaurants and cafeterias would need to wash more food service items, increasing waste-water discharges.
- Without styrene the low-maintenance tub-shower units so popular in residential construction would be replaced with heavy and expensive tile and ceramic/steel tub – that also take much more energy to manufacture.
- Underground tanks at gas stations made with materials other than styrene would be much more likely to leak and cause ground-water contamination.
- Without styrene cities would replace corroded water treatment equipment frequently.
- Without styrene, instead of using cast-in-place liners, cities would have to dig up streets to rehabilitate sewer lines.
- Without styrene wind-turbine blades would be 30% more expensive.
- Without styrene recreational boats would have to be made from higher-maintenance and lower-performance wood or aluminum.
- Without styrene automobile tires would provide lower fuel efficiency and need more frequent replacement.

Q: How many jobs depend on styrene?

Styrene is required to make an enormous number of important and useful products. Nationwide, more than 500,000 people work in manufacturing plants that use styrene or styrene-derived products. Most towns and cities probably have at least one company that provides good jobs by using styrene to make products.

Thousands of companies all across the country use styrene and styrene-derived products. For example, the composites industry – which uses styrene-polyester resin and glass fiber to make products such as tub-shower units, pollution control equipment, and recreational boats – is made up of some 3,000 small and medium sized companies, many of them family owned.

Q: Who is exposed to styrene?

Workers in plants using styrene can be exposed to moderate levels. Over the past ten years, industry has adopted new protective measures that have significantly lowered worker exposure to styrene emissions. For example, raw materials have been reformulated, and manufacturing equipment redesigned, so that less styrene evaporates during processing. Many manufacturers have installed ventilation systems that remove vapors away from work areas. And personal respirators are used as a final step to make sure workers are not exposed at excessive levels.

People living near plants that use styrene may smell it in the air. But they are exposed at levels far too low to be of any health concern. Manufacturing facilities that use styrene are usually able to modify their production processes to control odors.

People using styrene-based products in their everyday lives are seldom exposed to more than trace levels. The FDA considers styrene to be “generally recognized as safe.” The FDA has established safe levels for styrene as a food additive and allows the use of styrene-based materials in food contact items. Strawberries and cinnamon owe much of their flavor to naturally occurring styrene.

Q: Does styrene cause health effects?

No. Since styrene is a major chemical used in so many different products, its potential health effects have been thoroughly studied over many years. Several hundred human and animal studies have examined the potential health effects of styrene and found it to be safe when used properly.

Like many chemicals, inhalation exposure to relatively high concentrations of styrene can cause symptoms such as drowsiness and delayed response time. When necessary, workplace exposures are controlled using ventilation systems and respirators, to make sure that workers don't suffer even these mild and reversible effects.

The levels of exposure found in communities near manufacturing facilities that use styrene are too low to cause any kind of health effect. Similarly, the very low exposures that might result from using styrene-based products or consuming foods that contain natural styrene or are stored in plastic containers are perfectly safe.

Q: Is styrene an endocrine disruptor?

No. In 2006, the National Toxicology Program reviewed all the relevant data and determined that styrene is of "negligible concern" for effects on human development and reproduction, which includes endocrine effects.¹

Q: Does styrene cause cancer?

No. There is a very large database of studies that can be used to evaluate the carcinogenic potential of styrene. An analysis of long-term health data from workers exposed to relatively high levels of styrene shows only weak and inconsistent positive associations between styrene exposure and cancer, along with a larger number of null findings or negative associations.² The development of lung tumors in mice after styrene inhalation appears to be driven by species-specific metabolism that is not relevant to humans. Rats exposed to styrene at high levels do not develop cancer. Six of seven genotoxicity assays evaluating the potential for styrene to cause DNA damage were negative.

A number of expert assessments have concluded that people are not likely to get cancer as a result of exposure to styrene:³

- In 2002, an expert panel convened by the Harvard School of Public Health found that styrene health effects data suggest that neither plant neighbors, nor consumers at large, should be concerned about cancer.⁴

¹ <http://cerhr.niehs.nih.gov/chemicals/styrene/StyreneMono-www-s.pdf>

² In this context, a study is said to be "positive" if it suggests a cancer effect.

³ While there are hundreds of published reports that describe studies on styrene toxicity – for example, there are dozens of reports describing how researchers exposed rats and mice to styrene, and what happened as a result – it is very difficult for non-scientists to evaluate these studies and come to a valid conclusion. The data from any given study rarely offer definitive proof that a substance is or is not toxic. Scientific interpretation and judgment are needed, and the results of a study must be evaluated in the context of all the available data. That is why these *expert assessments* are important in coming to a conclusion regarding styrene's toxicity.

⁴ http://www.hcra.harvard.edu/rip/risk_in_persp_May2002.pdf

- In 2007, The United Kingdom's Health and Safety Executive completed a very thorough review of styrene data on behalf of the European Union and concluded that there is no concern for cancer in workers or community members.⁵
- A thorough assessment by the Texas Commission on Environmental Quality, completed in 2008, found that the data on styrene do not support a concern for cancer.⁶
- In 2008 an international "Blue Ribbon" panel of top epidemiologists reviewed the exhaustive studies of more than 60,000 workers exposed to styrene, and again found no concern for cancer in humans. The panel's report was published in the November 2009 issue of the peer-reviewed Journal of Occupational and Environmental Medicine.⁷

Q: What do NTP and IARC think about styrene?

Two agencies – the International Agency for Research on Cancer (IARC), which is part of the World Health Organization, and the National Toxicology Program (NTP) of U.S. Department of Health and Human Services – have expressed concern about styrene exposure and cancer. IARC classifies styrene as a “possible” carcinogen,⁸ while NTP proposed in a December 22, 2008 *Federal Register* notice to list styrene as a “reasonably anticipated” carcinogen in the NTP’s *12th Reports on Carcinogens (RoC)*.⁹ NTP expects to make a final decision regarding styrene in the *RoC* in late 2010.

To understand why these agencies may have reached different conclusions from those of the majority of mainstream scientists it is necessary to understand how experts review scientific data and assess potential health impacts.

The styrene health effects reviews described in the preceding section are *weight-of-the-evidence* assessments. They relied on expert evaluations of *all the relevant data* to determine if there are consistent and significant findings across studies, methods, populations and species. The IARC and NTP assessments relied instead on a *strength-of-the-evidence* approach which evaluated only positive studies and ignored null and negative studies.

Strength-of-the-evidence assessments can be useful in identifying opportunities for further research, but are less useful in determining whether workers, plant neighbors or product users are actually likely to suffer a health impact. This is especially true in the case of styrene where there are a large number of negative studies and only weak, limited, and inconsistent positive data.

⁵ <http://ntp.niehs.nih.gov/?objectid=300E2AF3-F1F6-975E-75E485D32573092F>

⁶ http://tceq.com/assets/public/implementation/tox/dsd/final/styrene_100-42-5_final.pdf

⁷ http://journals.lww.com/joem/Abstract/2009/11000/Epidemiologic_Studies_of_Styrene_and_Cancer__A.5.aspx

⁸ IARC reviewed styrene most recently in 2002. IARC found that the data did not justify listing styrene as a "probable" carcinogen, and cautions that its cancer assessments are not to be used for "regulatory" (protection of the public) purposes. <http://monographs.iarc.fr/ENG/Monographs/vol82/index.php>.

⁹ <http://ntp.niehs.nih.gov/go/RoC>

Q: Why is the styrene industry so concerned about the NTP assessment?

There are several problems with NTP's styrene review that, if uncorrected, will lead to unwarranted job losses without any public health benefit. As described above, NTP's reliance on a strength-of-the-evidence approach has resulted in a scientifically invalid assessment of styrene's potential carcinogenicity, one that is in marked disagreement with the expert weight-of-the-evidence assessments that relied on careful reviews of all the available data.

A second basic problem is that, for NTP, the application of the "reasonably anticipated carcinogen" label to a substance only means that certain arbitrary *listing criteria*¹⁰ have been met, while for workers and members of the public, the label will understandably be misinterpreted to mean that NTP "reasonably anticipates that they may get cancer". The footnotes and explanatory boilerplate issued by NTP make it clear that the agency has no opinion regarding a listed substance's actual health effects,¹¹ but these disclaimers will undoubtedly get lost when news of NTP's final decision is carried by the media. NTP's disclaimer is clearly at odds with the plain language meaning of "reasonably anticipated", and is insensitive to the understandably heightened concern of many people about cancer.¹²

There are additionally a number of serious concerns that apply specifically to NTP's styrene review. For example, the review has been flawed by a lack of transparent description and external peer review of its key conclusions – a violation of NTP's own policy – as well as a conflict of interest on the part of a key member of its styrene expert panel.

Further, NTP continues to insist that the conclusions of a key inter-agency review of its proposed styrene assessment be kept secret. And while NTP's Board of Scientific Counselors (BSC) held a meeting to review the agency's styrene assessment, the meeting was managed in a way that prevented the BSC from voting on the application of NTP's listing criteria.

Also, NTP has declined to explain why it has focused on the few positive studies in preparing its proposed listing while minimizing or ignoring the large number of studies that fail to support a cancer concern for styrene. This explanation, had it been available, would have added significantly to the ability of the BSC to review the staff's proposed listing decision. NTP has agreed to respond to public comments, but only after the *RoC* listing process has been finalized.

The styrene industry's complaints about NTP's review are not trivial. These *material flaws* have resulted in a scientifically invalid assessment that, if published in the *RoC*, will unnecessarily

¹⁰ <http://ntp.niehs.nih.gov/go/15209>

¹¹ "It is important to note that the reports [in the *RoC*] do not present quantitative assessments of carcinogenic risk...". <http://ntp.niehs.nih.gov/go/7249>. In other words, the risk of actual health impact attributable to many of the listed substance could be quite low.

¹² The IARC system suffers from the same problem, that is, the criteria for classifying a substance as to its carcinogenic potential are arbitrary and based on counting the number of positive studies without regard to other information that may support a conclusion of no concern. IARC does place substances with limited positive data in its "possible carcinogen" category, while NTP's approach further magnifies the problem by combining these substances with the IARC-listed "probable carcinogens" into its "reasonably anticipated" category.

NTP's placement of substances like styrene with scant positive evidence of any impact on human health into the "reasonably anticipated" *RoC* category is arguably contrary to Congressional intent. In authorizing the *RoC* program, Congress substituted the term "reasonably anticipated" for the term "suspected carcinogens" with the specific objective of making it "absolutely clear that there must be reasonable grounds for designating a substance as a putative carcinogen." Joint House-Senate Comparative Summary and Explanation of Title II of H.R. 12460 and H.R. 12347, as Reported by the Committee on Interstate and Foreign Commerce, the Senate Bill, S. 2450, and the House Amendment in the Nature of a Substitute. 124 CONG. REC. H38657 (1978) (statement of Rep. Rogers).

alarm people – workers and their families, plant neighbors,¹³ and product users – about the impact of styrene on their health. It will harm the smaller companies that use styrene. And it will result in a significant loss of jobs in communities around the country. All this without any public health benefit.

Two examples show that these concerns are justified:

- Within weeks of release of an NTP report that suggested a possible link between the common chemical Bisphenol-A and health effects, major retailers pulled products from shelves, not because of any identified health risk but only because of unfounded public fear generated by inaccurate and alarmist media reports.
- Saccharine was once determined to be carcinogenic to humans based on a single positive result. Shortly thereafter, the study was determined not to be applicable to humans. But it took more than 20 years for the government to officially reverse its inaccurate strength-of-evidence determination. As a result, saccharine had to be replaced with higher cost sweeteners in any application that required a retail label, costing consumers millions. Production of saccharine moved to China, costing the American economy thousands of good jobs.

As described above, NTP cautions that its assessments are "not regulatory", and that the agency has no opinion as to whether anyone is likely to suffer an actual health impact. But, given the speed with which health concerns are magnified and spread, the industry is very concerned that NTP's assessment will unnecessarily frighten workers who use styrene and people who live near manufacturing facilities that use styrene. To avoid the likely severe impacts to smaller companies and the loss of many jobs, NTP must correct the several material flaws in its styrene assessment.

Q: What has the industry suggested regarding NTP's styrene assessment?

Styrene is the first major chemical to undergo review by NTP for listing in the *RoC* since the review process¹⁴ was modified during the Bush administration. The industry believes that five additional targeted reforms are needed to make this process comply with "good government" principles for transparency and scientific integrity. NTP has agreed to consider changes to the process *after* completion of the 12th Edition of the *RoC*,¹⁵ but these changes are needed *now*, before as many as 500,000 manufacturing jobs are lost due to an inaccurate assessment and the resulting public concern about styrene.

The industry suggests the following improvements to the *RoC* review process:

1. Follow the stricter conflict of interest process developed by the National Academy of Sciences.¹⁶
2. Operate in the open throughout the review process and, in a timely fashion, explain in responses to comments why the NTP differs with other scientists who raise serious scientific issues.
3. Provide the public with summaries of the findings of government panels along with the justification for those findings.

¹³ People can often detect the odor of the very low concentrations of styrene in the air around styrene-using manufacturing plants. This is usually not a problem, but it will become one if people are afraid of styrene because of the proposed NTP listing.

¹⁴ <http://ntp.niehs.nih.gov/go/15208>

¹⁵ "Following completion of the 12th [edition of the *RoC*]...NTP will determine what changes...should be made to improve the review process...". Feb. 23, 2009 letter from NTP Director Linda Birnbaum to Cal Dooley of the American Chemistry Council.

¹⁶ http://www.nationalacademies.org/coi/bi-coi_form-0.pdf

4. Obtain an independent peer review of any re-interpretations of previously published studies where these re-interpretations are used to support a listing decision. For example, if the data in a published report are reanalyzed by NTP's expert panel or staff, or different controls are substituted, and a conclusion is reached that differs from the conclusion of the original authors, this action would be considered a new analysis requiring peer review and publication before it could be used to justify a listing decision.
5. Allow the BSC to vote on whether they disagree with the NTP staff's application of the listing criteria to the chemical in question.

The styrene industry calls on NTP to defer further consideration of styrene until the 13th *RoC*, and at that time to reassess styrene for possible listing in the report, and in so doing, to implement the five reforms described above.

Deferring styrene in this way will also allow NTP to consider critical new information on styrene and cancer. Since NTP first proposed to list styrene in the *RoC* a major report has been published in the peer-reviewed literature finding that the extensive human data on styrene provide no support for a cancer concern.¹⁷ Additional new scientific reports, examining both the critical human and animal data, are expected to be published by mid-2011.

¹⁷ This is the report of the Blue Ribbon epidemiology panel described above (footnote 7).