



Styrene Information and Research Center (SIRC)

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**Styrene Information and Research Center
Tells NTP that Science Does Not Support ‘Reasonably Anticipated’
Recommendation on Styrene**

The Styrene Information and Research Center (SIRC) has told the National Toxicology Program (NTP) that the justifications an NTP panel put forward do not support the panel's recommendation that styrene be listed as “reasonably anticipated to be a human carcinogen” in the impending *12th Report on Carcinogens (RoC)*.

SIRC submitted its comments Oct. 23, 2008, to meet a deadline announced in the *Federal Register* September 8. The NTP panel made its recommendation concerning styrene on July 22, 2008.

SIRC's comments to Dr. Ruth M. Lunn of the National Institute for Environmental Health Sciences (of which the NTP is part) state that a complete and balanced review of the available human data (1) does not support the panel's conclusion of “limited evidence of cancer in humans,” (2) but rather “provides only limited evidence of carcinogenicity in animals, based on no evidence in rats and limited evidence in mice,” and (3) that “mode of action data indicate that tumors found in mice exposed to styrene are not relevant for human risk assessment.”

SIRC also reiterated issues it had raised in previous letters sent directly to the NTP concerning the panel's recommendation, including that:

- The NTP panel generated a “new and unpublished epidemiological [human] finding when it concluded there was an association between styrene exposure and non-Hodgkin lymphoma” based on an earlier study – an association that authors of the original study did not identify and which the lead author has since reported is not supportable.
- As far as SIRC is aware, it appears that the NTP panel did not generate statistical support for its conclusion; the NTP panel's new analysis of the data was not made available for public comment, and has not been independently peer reviewed.
- A SIRC-sponsored independent “Blue Ribbon Epidemiology Panel”¹ currently is reviewing the collective human data set, including the NTP panel's reanalysis, which could provide the needed external peer review of the NTP panel's conclusion; the Blue Ribbon panel's report

¹ Separate SIRC statement concerning the Blue Ribbon Epidemiology Panel is available upon request to jwalker@safetyequipment.org.

will be submitted to the NTP on Dec. 22, 2008; SIRC will have no advance notice of its contents.

SIRC formally asked the NTP to extend the public comment period on the panel's recommendation in order to have the Blue Ribbon panel's report accepted for public comment.

Throughout the continuing NTP process, SIRC has filed comments explaining that styrene should be excluded from the *RoC* because results from extensive studies of workers in styrene-related industries collectively show that exposure to styrene does not increase the risk of cancer. These studies covered more than 55,000 people who worked with styrene in the United States and Europe over a 45-year period.

The workers encountered exposure levels orders of magnitude greater than the very low levels detected in the environment. A lack of cancer-causing effects in these workers is a strong indicator that exposure of the general public to environmental levels of styrene should not cause health effects.

"Based on SIRC's experiences with the *RoC* process for styrene thus far, SIRC believes the review process will fail to address SIRC's legitimate concerns and, at the end of the day, be scientifically unsupportable," SIRC Executive Director Jack Snyder wrote to Dr. Lunn. "SIRC is submitting these comments under protest, due to (1) the absence of key data regarding a critical new Expert Panel analysis that, if it exists, has not been made available to the public, and (2) the fact that these new data and analysis by the Expert Panel have not been peer reviewed.

"SIRC has petitioned NTP in writing to provide these underlying analyses and to extend the October 23rd comment period, in order to adequately address these new data, but no data has been received by SIRC to date, and the comment period has not been extended."

The *RoC* is a congressionally mandated listing of "known" and "reasonably anticipated to be" human carcinogens; the Secretary of Health and Human Services delegates its preparation to the NTP. *RoC* listings carry no automatic regulatory implications, but frequently are cited in regulatory decision-making. Styrene was among a number of chemicals nominated in 2004 for possible inclusion in the 12th *RoC*.

(Note to editors: SIRC's correspondence to and from the NTP since the NTP panel offered its recommendation on July 22, 2008, is available upon request to SIRC communications advisor Joe Walker, jwalker@safetysupply.com or 703-491-3301.)

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