

BASF Corporation

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8EHQ-98-14119

February 3, 1998

Document Processing Center (TS-790)
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

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Ladies and Gentlemen:

Subject: Notice in Accordance with TSCA Section 8(e) - Preliminary results from a longitudinal pulmonary function study of employees assigned to a TDI manufacturing facility

BASF Corporation notified EPA under Section 8(d) of TSCA in March, 1997 of plans to conduct a longitudinal pulmonary function study of employees assigned to a TDI manufacturing facility from 1967 - 1997. We are now providing information regarding some preliminary findings from the ongoing study. Following completion of the study, final reports will be issued describing the study methods and results and discussing the findings in detail.

The primary objective of the study is to evaluate the respiratory health of TDI production unit employees through an analysis of longitudinal changes in pulmonary function relative to TDI dose. As part of this long-term follow-up study, individuals with apparent asthma attributed to TDI exposure as determined by clinical history alone, "cases", were identified.

The overall incidence of apparent asthma cases in this population was approximately 1% per year and is consistent with incidence rates reported in the literature for other TDI facilities. However, based on comparisons made between the cases and other employees in the study group who did not present this clinical history, an association was observed between new incident cases and the occurrence of one or more prior inhalation exposures to respiratory irritants that resulted in lower respiratory tract symptoms or transport to an off-site medical facility for treatment. Seven of the 15 identified cases of apparent asthma among production employees had experienced prior inhalation overexposures, whereas 3.5 cases would have been expected. This finding was statistically significant (P-value = 0.033). The exposure agents associated with the prior inhalation incidents were phosgene, toluene or chlorine.

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While it has been indicated in the literature that prior excursion exposures to the sensitizing agent itself may be associated with risk of occupational asthma, BASF is unaware that such an association has been reported for acute irritant exposures to other than the sensitizing agent.

There are several potential explanations for this finding. First, it could be a chance occurrence. This was one of several factors that were examined in relation to case status and there were only 7 cases with qualifying prior inhalation exposures. Secondly, it could be that individuals who experience respiratory symptoms following accidental inhalation exposures have pre-existing conditions that predispose them to meeting the case definition of apparent asthma due to TDI used in this study. Alternatively, it could be that the prior inhalation overexposures caused injury to the lung that increased the risk of developing asthma-like reactions.

While this information is preliminary and the relevance is uncertain at this time, BASF is reporting it as required under Section 8(e) of TSCA. It is our practice and therefore our intent to notify affected BASF employees, customers and other manufacturers of this preliminary information. Please note that this letter does not contain confidential business information.

Very truly yours,

BASF CORPORATION



Edward J. Kerfoot, Ph.D.
Director, Toxicology & Product Regulations

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Rank: High

Submitter: BASF

Principal
Chemical: TDI

Other
chemicals: Phosgene, toluene, chlorine

Brief description:

BASF reported that approximately 1 per cent of its chemical worker population within its TDI production unit develop occupational asthma each year. (In 20 years one-fifth of such a population would have occupational asthma.)

A purported preliminary finding of the population-based case-control study, however, is that prior or concurrent "excursion" exposures, to irritant chemicals including, phosgene, toluene and /or chlorine may be associated with the incident cases of asthma known to be induced by sensitizing-TDI. If this finding is replicated in other studies, it may constitute evidence that exposure to irritant chemicals substances may enhance the induction of sensitizing chemicals.