

NIOSH Policy Statement

Saccharin Use for Respirator Fit Testing

In 1987, NIOSH published the revised Guide to Industrial Respiratory Protection [DHHS (NIOSH) Publication No. 87-116], which included an Appendix of qualitative fit test procedures. Among these procedures is the protocol for using saccharin solution as a fit test solution. Also in 1987, the International Agency for Research on Cancer (IARC) classified saccharin as a 2B carcinogen, "possibly carcinogenic to humans," based on sufficient evidence in animals, although the evidence in humans was deemed inadequate [IARC 1987]. Subsequently, NIOSH reviewed the carcinogenic potential of saccharin because of its recommended use as a qualitative fit test agent, and concluded that it is a potential occupational carcinogen [NIOSH 1995a]. NIOSH commented to OSHA in 1995 on the proposed rule on respiratory protection:

"Qualitative fit tests using a non-hazardous test agent that is readily detected by the test subject. Qualitative fit tests using saccharin as the test agent are not recommended because it is a potential carcinogen and there is an acceptable alternative test agent (e.g., Bitrex®) [Niemeier 1991; Wilmes 1994]."

In 1995, NIOSH issued a new recommended exposure limit (REL) policy that includes the following statement [NIOSH 1995b]:

"NIOSH recommended exposure limits will be based on risk evaluations using human or animal health effects data, and on an assessment of what levels can be feasibly achieved by engineering controls and measured by analytical techniques. To the extent feasible, NIOSH will project not only a no-effect exposure, but also exposure levels at which there may be residual risks. This policy applies to all workplace hazards, including carcinogens, and is responsive to Section 20(a)(3) of the Occupational Safety and Health Act of 1970, which charges NIOSH to ' . . . describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience.'"

Although this policy is primarily intended for the development of RELs, it is appropriate to apply this change in policy to the issue of respirator fit testing with saccharin.

As noted previously, saccharin meets the OSHA criteria for a "potential occupational carcinogen" as defined in 29 CFR 1910.112 [Niemeier 1991] and IARC has classified saccharin as a 2B carcinogen [IARC 1987]. In 1981, the Department of Health and Human Services listed saccharin in the Second Annual Report on Carcinogens as reasonably anticipated to be carcinogenic for humans [NTP 1981]. However, the National Toxicology Program is currently considering a petition and recommendation to "delist" saccharin in the Department's upcoming 9th Report on Carcinogens.

For this Policy Statement, NIOSH reviewed the literature on saccharin toxicity and evaluated the risks potentially associated with using saccharin in respirator fit testing. Using conservative assumptions (i.e., that a worker has two respirator fit tests per year, and that in each test the respirator provides no protection, such that the entire amount of aerosolized saccharin is inhaled), the estimate of saccharin exposure is approximately 4000 times smaller than the "no adverse effect level" (NOEL) for carcinogenicity in rats. The calculated risk to workers from such an exposure in respirator fit testing is less than

1 per million over a working lifetime. Additionally, there are several mechanistic arguments to support a conclusion that the risk to workers from this exposure is not significant [Schulte 1999].

Consistent with the finding that the risk to workers from use of saccharin in respirator fit testing is extremely small and may be zero, and in accordance with the REL policy, NIOSH recommends both saccharin or Bitrex® for use in qualitative respirator fit testing, consistent with OSHA's respiratory protection standard (29 CFR 1910.134).

signed:\ Linda Rosenstock, M.D., M.P.H. August 4, 1999

Director, NIOSH Date

REFERENCES

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