



Department of General Services
Real Estate Service Division
Professional Services Branch
707 Third Street, 4th Floor
West Sacramento, California 95605

March 12, 2008

Dear Valerie J. Namba,

This letter is in response to your request for information regarding test results that NSF has obtained through the testing of cross linked polyethylene (PEX) to support certification to NSF/ANSI Standard 61. We have provided a summary of test data for cross-linked polyethylene pipe/tubing tested between January 1, 2005 through December 31, 2007. In addition, we have included risk assessments that have been prepared by NSF for t-butanol and methyl-t-butyl ether. We think it is important for you to understand how the NSF criteria differ from that set by the State of California.

NSF International is a third party, independent, not-for-profit organization that is dedicated to public health safety and protection of the environment. Since 1944, NSF International has developed product standards and provided third party conformity assessment services to government, users, and manufacturers/providers of products and systems. NSF has been developing standards for the testing and certification of plastics plumbing components since 1965. ANSI/NSF Standard 61: Drinking Water System Components - Health Effects establishes requirements for the testing and evaluation of contaminants that are extracted from water, which has been exposed to the material or products that convey potable water. There are 271 cross-linked polyethylene products produced at 47 manufacturing sites currently certified by NSF International to the health-effects requirements of ANSI/NSF Standard 61.

Testing parameters for any material submitted to NSF for Standard 61 certification are determined during a formulation review. The formulation review occurs after each chemical in the formulation is known for each ingredient. The standard battery for cross-linked polyethylene includes regulated metals, VOC analysis which includes methyl-t-butyl ether, semi volatiles (GC/MS EPA Method 525) and t-butanol. Methanol is added as a test parameters if methoxy silane is used in the formulation. Testing is then requested based on a minimum test battery in addition to formulation specific analytes.

NSF tests material, pipe and fitting samples initially and for continued compliance based upon the protocol described in ANSI / NSF Standard 61, Appendix B. The samples tested at NSF are new products which are tested at pH 5 and 10 for metals and pH8 for organics. When testing, the samples are first conditioned for 16 days at 30^o C in water

that is refreshed on 12 of the 16 days. Immediately following conditioning, the samples are exposed for one final 16 hour exposure at 30° C for cold water products. For hot water products the final exposure consists of 1 hour at 82° C followed by 15 hours at 30° C.

You have requested information on the extraction of benzene, 1,1-dichloroethane, ethyl benzene, di(2-ethylhexyl) phthalate, methyl-t-butyl ether, t-butanol, benzo(a)pyrene and cadmium. Benzene, toluene, 1,1-dichloroethane, ethyl benzene, di(2-ethylhexyl) phthalate and cadmium have not been identified as an extractant exceeding the California MCL's from PEX pipe/material in any product tested at NSF between January 1, 2005 and December 31, 2007 which was the time period selected for this request. Table 1 and 2 provide a summary of the testing results for t-butanol and methyl-t-butyl ether.

Table 1 - Extraction Levels for t-butanol as a % of all products tested between January 1, 2005 and Decemeber 31, 2007.

Compound	Not detected at 200 ug/L	> than 200 to 1000 ug/L	> than 1000- 9000 ug / L	Greater than 9000 ug / L resulting in product failure
t-butanol	62.1 %	19.4 %	10.9 %	7.6 %

Table 2 - Extraction Levels for methyl-t-butyl ether as a % of all products tested between January 1, 2005 and Decemeber 31, 2007.

Compound	Not detected to 5 ug/L	> 5 to 13 ug/L	> 13 to 20 ug/L	Greater than 20 ug / L
methyl-t-butyl ether	74.6 %	21.4 %	4 %	0 %

These results indicate that some of the PEX pipe/materials that have been tested to NSF/ANSI Standard 61 exceed their respective California MCL. In particular, a number of products exceed the California MCL of 12 ug/L for t-butanol and they do not exceed the NSF criteria of 9000 ug/L.

This difference is due to the results of the risk assessment performed at NSF which significantly differs from the drinking water level that has been set by California. In a document dated June 2, 1999 (<http://www.oehha.ca.gov/water/pals/tba.html>) the process for derivation of the 12 ug/L California drinking water level for tertiary butanol was described, and was clearly noted as an interim assessment. The critical effect selected was male rat kidney adenoma and carcinoma observed in an NTP (1994) cancer bioassay, and a carcinogenic response to t-butanol was also considered to be supported by an increased incidence of thyroid gland follicular cell adenoma in female mice. NSF determined the weight of evidence supported an alpha-2u-globulin mode of action for the male rat kidney tumors. This mode of action is male rat specific and not relevant to human health. U.S. EPA has published criteria for discounting this effect that NSF considered to be met. Discounting this effect for a human health risk assessment has also been accepted by toxicologists worldwide. Likewise, the U.S. EPA (1998) has published guidance on the assessment of thyroid follicular cell tumors, concluding that thyroid tumors meeting specific criteria could be assessed using nonlinear considerations, due to apparent quantitative differences in sensitivity between rodents and humans to thyroid cancer development from thyroid-pituitary disruption. Taken together with the fact that tertiary butyl alcohol is not genotoxic, it was concluded by NSF and the external review panel that using a linear approach in deriving oral risk values for this chemical was not appropriate based on the current best science. We do think it would be appropriate to review the interim assessment for t-butanol and consider using the U.S. EPA guidance to determine the relevance of male rat kidney tumors to human health.

I have attached NSF's completed risk assessment for t-butanol and methyl-t-butyl ether for your review. If you have further questions concerning this subject, please do not hesitate to contact me.

Sincerely



Clifton J. McLellan
Director of Toxicology Services
NSF International

Enclosure: t-butanol and methyl-t-butyl ether risk assessment