

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

TO: File for Sodium Bromide (CAS# 7647-15-6)

FROM: Keisha Williams, Air Quality Division

DATE: July 5, 2016

SUBJECT: Screening Level Update for Sodium Bromide

The initial threshold screening level (ITSL) for sodium bromide is 140 $\mu\text{g}/\text{m}^3$ (annual averaging time) based on the Michigan Department of Environmental Quality (MDEQ), Air Quality Division (AQD) Rule 336.1229 (2) (b) and 336.1232 (1) (a). The ITSL was originally established with an averaging time set at 24 hours per AQD Rules 232 (2). It is being changed at this time to annual, as allowed per Rule 229 (2), because the original derivation accounted for chronic exposure. Attached is the February 3, 1994 memo describing the derivation of the ITSL value.

MICHIGAN DEPARTMENT OF NATURAL RESOURCES

INTEROFFICE COMMUNICATION

February 3, 1994

TO: Sodium Bromide File (CAS # 7647-15-6)
FROM: Gary Butterfield
SUBJECT: ITSL for Sodium Bromide

No ACGIH TLV, NIOSH REL, EPA RfC or RfD was found for sodium bromide. A Sept 1993 CAS-on-line and NLM search found some published toxicity data on sodium bromide. Unfortunately all of the located toxicity data was by the oral route of exposure. As no information was located that indicated it was inappropriate to use oral data as a substitute for inhalation data, the ITSL was calculated from oral data.

Among the toxicity data that was located were a couple of LD50 studies that indicate sodium bromide has relatively low acute toxicity (with LD50's in the several grams per kilogram range). Several animal subchronic toxicity studies were also found. These studies indicate that high doses of sodium bromide disturbs, directly, the function of the thyroid, testes and adrenals — and other endocrine organs (pituitary) indirectly through producing changes in levels of endocrine hormones.

A few toxicity studies were conducted in humans. It is generally preferable to use human data over animal data when calculating the ITSL, in order to avoid having to make adjustments between species. Among the human studies is Sangster et al (1982) who exposed human volunteers to a single dose level of 1 mg Br/kg daily for 8 weeks. There were no changes in hematological, biochemical, or endocrinological parameters observed. In a second study Sangster et al (1983) exposed, for 12 weeks, human volunteers (7 males and 7 females per dose level) to orally administered 0, 4, or 9 mg Br/kg daily, as NaBr. Physical examination, hematology studies, standard clinical chemistry and urine analysis showed no changes following treatment. Females given 9 mg/kg had increased serum levels of thyroxine and triiodothyronine, however the levels still were within normal limits. In those administered 9 mg/kg there was changes in neurophysiological data — decreases in delta—1 and 2 activities and increases in beta activity and mean frequency of Mobility parameter, however the changes still were within normal limits. In another study, Van Gelderen et al (1993) exposed, for 12 weeks (or three menstrual cycles), human volunteers (total of 45 females) orally administered 0, 4, or 9 mg/kg sodium bromide. No adverse effects from treatment were observed — except for nausea in relation to bromide intake. There were no treatment related changes in thyroid hormone blood concentrations. Significant changes in EEG alpha-1 band and beta bands were observed at 4 and 9 mg/kg. There was no change in visual evoked responses between the dose groups. A NOAEL for humans of 4 mg/kg is proposed.

The reported NOAEL of 4 mg/kg from Van Gelderen et al (1993) can provide the basis for establishing the ITSL. An estimate of the oral RfD can be made by $RfD = NOAEL / (UF \times MF)$, where in this case a UF of 100 is appropriate. The UF consists of a factor of 10 for the less than chronic duration of the study, and a factor of 10 to account for sensitive individuals within the population. The modifying factor is set at the default of 1. Thus, the estimated RfD is 0.04 mg/kg. The ITSL can be determined by multiplying the RfD by $(70 \text{ kg}) / (20 \text{ m}^3)$. The resultant ITSL is $140 \mu\text{g}/\text{m}^3$, with 24 hour averaging.

REFERENCES

Sangster et al. 1982. Study of sodium bromide in human volunteers with special emphasis on the endocrine system. *Hum Toxicol* 1:93. As cited in Van Leeuwen et al. 1983.

Sangster et al. 1983. The influence of sodium bromide in man: a study in human volunteers with special emphasis on the endocrine and the central nervous system. *Fd Chem Toxicol* 21:409-419.

Van Gelderen et al. 1993. The no effect level of sodium bromide in healthy volunteers. *Hum Exp Toxicol* 12:9—14.