MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

To: File

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From : Gary Butterfield

Toxics Unit

Subject : AAC's for carboxymethyl cellulose, sodium salt (CAS # 9004-32-4) and sodium perborate (CAS# 7632-04-4)

A review of the available toxicity data on carboxymethyl cellulose, sodium salt or sodium-CMC and sodium perborate was conducted in order to determine an AAC for these materials.

Carboxymethyl cellulose, sodium salt

There is a fair amount of data by the oral route of exposure indicating this material is relatively nontoxic. It is used in many food products and is regulated by the FDA as GRAS (Generally Recognized As Safe). In the FDA's 1979 documentation for the GRAS standing of sodium-CMC (44FR10753) there are several references to long term oral studies that identify a no observed adverse effect level (NOAEL) of 1 g/kg/d. As these studies involve repeated doses over a long period they are more suitable for calculation of the AAC than is the use of an acute LD5O identified in RTECS.

$$AAC = \frac{1000 \frac{mg}{kg}}{35 x 100 x 0.9} = 0.32 \frac{mg}{m^3} \text{ or } 300 \frac{\mu g}{m^3}, \text{ with annual averaging}$$

where 1 g/kg is NOAEL 0.9 m³/kg is inhalation rate for rats 35 X 100 are uncertainty factors

Sodium perborate

There is a great deal less toxicity data available on this material. RTECS reported an LD5O of 3250 mg/kg from a foreign study. Due to the lack of data on this particular chemical, other boron containing materials were looked at for data upon which to base the AAC. There seems to be consistency in the LD5Os between this group of boron containing materials (boric acid, borax, boron and others) with

sodium preborate's LD50, indicating a similarity in toxicity. Thus an estimate of sodium perborate's long term effects based on data from one of these other boron compounds is a reasonable assumption.

Species	LD50	<u>Reference</u>
sodium perborate (7	632-04-4)	
mus	3250	Russian 1986
boric acid (10043-35	-3)	
mus	3450	JAMA 128:266 1945
rat	2660	u
borax (1303-96-4)		
rat	2660	Adams 1966
mus	2000	и
gpg	5300	"
boron (7440-42-8)		
mus	2000	Pesticide Chemical Compend 1966
sodium perborate te	trahydrate (10	0486-00-7)
rat	1200	Russian 1984
mus	1060	u
boron oxide (1303-8	6-2)	
mus	3163	Russian 1982

Table of LD5Os for Boron compounds as found in RTECS :

The best available long term boron study is a 2 yr dog study reported by Weir and Fisher 1972. This study is also used by EPA in developing their RfD for boron, see IRIS. Basing the AAC on Weir and Fisher's NOAEL of 350 ppm boric acid in the diet converts to a mg/kg dose of 8.7 mg/kg. Using this NOAEL result in the following AAC.

$$AAC = \frac{8.7 \frac{mg}{kg}}{35 x \, 100 \, x \, 0.3} = 0.0083 \frac{mg}{m^3} \text{ or } 8 \frac{\mu g}{m^3}, \text{ with annual averaging}$$

where 8.7 mg/kg is the NOAEL 0.3 m³/kg is the inhalation rate for dogs 35 X 100 are uncertainty factors

The above derived AAC of 8 μ g/m³ is consistent with an AAC based on the LD50 of 3250 mg/kg. If the LD50 is used, the AAC would be 6 μ g/m³. Both of these AACs are considerably lower than if the AAC had been calculated from EPA's RfD of 0.09 mg/kg for boron (AAC=300 μ g/m³). However, given the lack of data on the specific compound of interest, sodium perborate, and the fact that inhalation data for any of

these compounds is nonexistent, the additional conservatism seems to be appropriate.

References :

EPA IRIS (Intergrated Risk Information System). 8/90

RTECS (see entry for each individual chemical)

Weir and Fisher. 1972. Toxicol Appl Pharmacol 23:351-364.