

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

July 7, 2015

TO: File for Biosam tp-1.5

FROM: Robert Sills, Toxics Unit Supervisor, Air Quality Division

SUBJECT: Initial Threshold Screening Level for Biosam tp-1.5

The ITSL for Biosam tp-1.5 was established on 1/8/97 at 0.02 ug/m<sup>3</sup> with 1-hour averaging time (AT).

Biosam tp-1.5 is a member of a class of chemicals known as subtilisins, which are proteolytic enzymes derived from *Bacillus subtilis* or closely related organisms (ACGIH, 2001). ACGIH (2001) established a TLV-Ceiling for subtilisins at 0.06 ug/m<sup>3</sup> for 100% crystalline active pure enzyme (CAPE). "The TLV-Ceiling is intended to minimize the potential for sore throat, nasal congestion, headache, persistent cough, wheezing, dermal irritation, particularly in body areas of high perspiration, and more severe effects that can include airway obstruction (reduced forced expiratory volume in one second [FEV<sub>1</sub>]), pulmonary edema, and allergic respiratory sensitization." "Subtilisins are well characterized proteins with a molecular weight of approximately 28,000 and contain about 275 amino acids; the various subtilisins differ in amino acid composition. The enzyme preparations produced for laundry detergents contain varying amounts of other proteases and esterases, nonviable spores, broth nutrients, traces of metals, and inert fillers (chiefly sulfates) up to 50%." "The TLV-Ceiling for subtilisins of 0.00006 mg/m<sup>3</sup> (0.06 ug/m<sup>3</sup>) of CAPE is believed sufficiently low to minimize the potential for allergic respiratory sensitization for the majority of immunologically normotypic persons." (ACGIH, 2001). ACGIH (2001) also provided a table of some equivalent terms for the TLV that may be applied to forms with different purities, including a TLV (Ceiling) of 2 ug/m<sup>3</sup> for "as received" enzyme.

The AQD assessment in 1997 of this and other forms of subtilisin formulations concluded that it would be appropriate to utilize this "as received" TLV-Ceiling as the basis for the ITSL. Thus, the methodology of Rule 232(1)(c) (ITSL = OEL ÷ 100) was utilized to establish the ITSL at 0.02 ug/m<sup>3</sup> (1 hr AT).

**Reference:**

ACGIH. 2001. Documentation of the TLVs and BEIs. 7<sup>th</sup> Edition.

RS:lh