

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

July 7, 2015

TO: File for Purafect 4000G

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

SUBJECT: Initial Threshold Screening Level for Purafect 4000G

The ITSL for Purafect 4000G was established on 1/8/97 at 0.02 ug/m<sup>3</sup> with 1-hour averaging time (AT).

Purafect 4000G 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.

In 1994, the AQD received information from Genencor (1994a, 1994b) indicating that Purafect 4000G had the following principal hazardous components: subtilisin; titanium dioxide; and, ammonium sulfate; their composition in the product was not specified. They also stated that Purafect 4000G should be classified as the "as received" form with respect to the ACGIH table of equivalencies.

The AQD assessment in 1997 of this and other forms of subtilisin formulations concluded that it would be appropriate to utilize the "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).

**References:**

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

Genencor International, Inc. 1994. MSDS for Purafect 4000G. Amway Research Services. Issued 4/20/93.

Genencor International, Inc. 1994. Letter from Beth Concoby, Director, Environmental Health and Safety, Genencor International, Inc., to Loretta Campbell-Jones, Amway Corporation. August 8, 1994.

RS:lh