§ 180.1011 Viable spores of the microorganism \textit{Bacillus thuringiensis} Berliner; exemption from the requirement of a tolerance.

(a) For the purposes of this section the microbial insecticide for which exemption from the requirement of a tolerance is being established shall have the following specifications:

1. The microorganism shall be an authentic strain of \textit{Bacillus thuringiensis} Berliner conforming to the morphological and biochemical characteristics of \textit{Bacillus thuringiensis} as described in Bergey’s Manual of Determinative Bacteriology, Eighth Edition.

2. Spore preparations of \textit{Bacillus thuringiensis} Berliner shall be produced by pure culture fermentation procedures with adequate control measures during production to detect any changes from the characteristics of the parent strain or contamination by other microorganisms.

3. Each lot of spore preparation, prior to the addition of other materials, shall be tested by subcutaneous injection of at least 1 million spores into each of five laboratory test mice weighing 17 grams to 23 grams. Such test shall show no evidence of infection or injury in the test animals when observed for 7 days following injection.

4. Spore preparations shall be free of the \textit{Bacillus thuringiensis} $\beta$-exotoxin when tested with the fly larvae toxicity test (“Microbial Control of Insects and Mites,” R.P.M. Bond et al., p. 280 ff., 1971). This specification can be satisfied either by determining that each master seed lot brought into production is a \textit{Bacillus thuringiensis} strain which does not produce $\beta$-exotoxin under standard manufacturing conditions or by periodically determining that $\beta$-exotoxin synthesized during spore production is eliminated by the subsequent spore-harvesting procedure.

(b) Exemption from the requirement of a tolerance is established for residues of the microbial insecticide \textit{Bacillus thuringiensis} Berliner, as specified in paragraph (a) of this section, in or on honey and honeycomb and all other raw agricultural commodities when it is applied either to growing crops, or when it is applied after harvest in accordance with good agricultural practices.


§ 180.1016 Ethylene; exemption from the requirement of a tolerance.

Ethylene is exempted from the requirement of a tolerance for residues when: