UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

JUL 07 2004

SUBJECT: BPPD Review of Storage Stability and Corrosion Characteristic Data Submitted by The Gustafson LLC, for GB34 Concentrate and Technical, which contains *Bacillus pumilus* GB34 (Submission No.: S218040, S218202; DP Barcode: 293163, 294658; MRID No.: 459182-01, and 459181-01).

TO: Anne Ball (PM-90), Regulatory Action Leader
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511C)

FROM: Carl Etsitty, M.S., Microbiologist
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511C)

THROUGH: John L. Kough, PH.D., Senior Scientist
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511C)

ACTION REQUESTED: Review the submitted data for storage stability and corrosion characteristic determine the adequacy of data to support GB34 Concentrate and Technical, containing *Bacillus pumilus* GB34, as the active ingredient.

~~THIS REVIEW CONTAINS CONFIDENTIAL BUSINESS INFORMATION~~

BACKGROUND: Gustafson LLC, submitted storage stability and corrosion characteristic data to support their application for GB34 Concentrate and Technical registration(s), which contains *Bacillus pumilus* GB34, as the active ingredient. *B. pumilus* is a naturally occurring soil microorganism that acts as antifungal agent. GB34 Technical commercially prepared by Encore Technologies LLC, and GB34 Concentrate prepared by Gustafson Research and Development Center.

In retrospectively, not all of the suggested recommendations from the memorandum(s) dated October 15, 2002 and February 13, 2003, from Carl Etsitty, Microbiologist to Anne Ball, Regulatory Action Leader, has been addressed, and it is recommended for a status report. For instance, "*an analysis of microbiological purity was not performed*" and "*... pending resolution of MRID#s*".

CONCLUSION: The submission packet contains adequate storage stability and corrosion characteristic data for the formulated end-use product GB34 concentrate and technical, thus supporting documentation. Although the registrant points out the analytical method is incapable of discerning a variability of ± 3% for GB34, per normal guideline requirements, due to high variability in diluting and counting a large population of bacteria, the reviewer takes note of ± 3% differences, and if correlated as 3 log differences (CFUs). It would be recommended to the registrant to tighten up the manufacturing process and or techniques.

The reviewer notes in concert with the registrant's statement that the method of determining the a.i. (by serial dilution and colony counting) is not precise enough to detect results with a variability falling into the ± 3% range, per normal guideline requirements for chemicals. Despite the shortcoming of the analytical method, the a.i. CFU decrease with time upon ambient temperature storage for one year. It may be noted the nominal concentration of a.i. on the label (and CSF) may be lowered and the certified limits expanded to reflect potential loss of a.i. upon storage. Alternatively, the registrant may wish to consider modifying the labels to state a shelf life of < 1 year, or to require refrigeration of the products. It is noted, however, that the reviewer did not have available the product label and CSF or other submitted product chemistry studies for GB 34, which may provide any information to obviate the need to act upon the finding of loss of a.i. over 12 months.

DATA REVIEW RECORD

Active Ingredient:	*Bacillus pumilus* GB34	
Product Name:	GB34 Concentrate	
	GB34 Technical	
Company Name:	Gustafson LLC	
ID No:	7501-191- GB34 Concentrate Biological Fungicide	
	7501-192- GB34 Technical Biological Fungicide	
Chemical No.:	006493	
Submission No.:	S593747	
DP Barcode:	D273326	
MRID No:	459182-01	Storage Stability (OPPTS 830.6317), Corrosion Characteristics (OPPTS 830.6320)
	459181-01	Storage Stability (OPPTS 830.6317), Corrosion Characteristics (OPPTS 830.6320)

SUMMARY OF DATA SUBMITTED:

459182-01, 459181-01: Storage Stability (OPPTS 830.6317), Corrosion Characteristics (OPPTS 830.6320)

Storage stability (OPPTS 830.6317) and corrosion characteristics (OPPTS 830.6320) were evaluated for the registered products GB 34 Technical (EPA Reg. No. 7501-192) and GB 34 Concentrate (EPA Reg. No. 7501-191, an end use product). The active ingredient in each is *Bacillus pumilis* GB 34. No corrosivity observed in any containers or in the physical appearance of the product after storage for up to one year at ambient temperature. Initial concentration of a.i. was 14-28% below the label claim concentration, and a significant further loss of a.i. occurred after 3, 6, and 12 months of storage: 17-59% loss for GB34 technical and 54-81% loss for GB34 concentrate. The registrant points out the analytical method is incapable of discerning a variability of ± 3% for GB34, per normal guideline requirements, due to high variability in diluting and counting a large population of bacteria.

CLASSIFICATION: **ACCEPTABLE** for the storage stability and corrosion characteristics studies. However, the study results suggests that the nominal concentration should be lowered and the certified limits for GB 34 Technical and Concentrate should be expanded on the product labels and CSFs to reflect potential loss of a.i. upon storage. Alternatively, the registrant may wish to consider modifying the labels to state a shelf life of < 1 year, or to require refrigeration of the products.

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Chemical:	Bacillus pumilus GB34
	PC Code: 006493
HED File Code:	41500 BPPD Tox/Chem
Memo Date:	7/7/2004
File ID:	DPD293163
	DPD294658
Accession #:	000-00-9002

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