DATA EVALUATION RECORD

Primary Reviewer: John E. Caton, Ph.D., Oak Ridge Laboratory
EPA Secondary Reviewer: Carl Etsitty, MS, Microbiologist

JUL 07 2004

STUDY TYPES:	Storage Stability (OPPTS 830.6317), Corrosion Characteristics (OPPTS 830.6320)
MRID NOS:	45918201 and 45918101
TEST MATERIAL:	GB 34 Concentrate Biological Fungicide [EPA Reg No. 7501-191; 0.27% w/w *Bacillus pumilis* (1.0 X 10^{10} cfu/gram), a.i.] and GB 34 Technical Biological Fungicide [EPA Reg No. 7501-192; 58.3% w/w *Bacillus pumilis* (2.1 X 10^{12} cfu/gram), a.i.]
PROJECT NO:	PC/00-005SS (MRID 45918201); PC/00-004SS (MRID 45918101)
SPONSOR:	Gustafson LLC, Plano, TX
TESTING FACILITY:	Gustafson Research and Development Center, Plano, TX
TITLES OF REPORTS:	The Corrosion Characteristics and Storage Stability of GB 34 Concentrate End Use Product (MRID 45918201). The Corrosion Characteristics and Storage Stability of GB 34 Technical (MRID 45918101).
AUTHOR:	P. McFadden
STUDY COMPLETED:	February 21, 2002
GOOD LAB PRACTICE:	MRID 45918101 and MRID 45918201 both include GLP Compliance Statements with noted minor deviations.
CONCLUSION:	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 suggest 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.

NO CONFIDENTIAL BUSINESS INFORMATION IN THIS SUBMISSION

Test Materials: GB 34 Technical Biological Fungicide (EPA Reg No. 7501-192) and GB 34 Concentrate Biological Fungicide (EPA Reg No. 7501-191).

I. **INTRODUCTION** GB 34 Concentrate Biological Fungicide (EPA Reg No. 7501-191) is a ready-to-use product containing the active ingredient 0.27% w/w *Bacillus pumilis* (1.0 X 10^{10} cfu/gram). Lot number PC / 00-005M was tested. The EPA certified limits were stated in MRID 45918201 to be 9.7 X 10^{9} to 1.03 X 10^{10} (±3% of nominal of 1.0 X 10^{10}). *[Note that the CSF and product label were not available to the reviewer.]*

GB 34 Technical Biological Fungicide (EPA Reg No. 7501-192) is a commercially-prepared source of active ingredient containing the active ingredient *Bacillus Pumilis* (2.1 X 10^{12} cfu/gram, 58.3% w/w). Lot number 00GUS13-06 was tested. The EPA certified limits were stated in MRID 45918101 to be 2.04 X 10^{12} to 2.16 X 10^{12} (±3% of nominal of 2.1 X 10^{12}). *[Note that the CSF and product label were not available to the reviewer.]*

II. STORAGE STABILITY (OPPTS 830.6317)

1. Method: Samples were analyzed for a.i. content according to Gustafson SOP 6.14 (storage stability and corrosion characteristics) and SOP 6.22 (plate dilution counting). The method involved plate count after multiple dilutions of high levels of microorganisms to obtain a countable range. The variability in a count of a high population of microorganisms can be fairly great when multiple dilutions are required. The study report states "It is impossible to get within the plus or minus 3.0% which is normally used in chemical analyses."

   Samples of GB 34 Technical were stored for one year at ambient temperature in a glass container and in a high density polyethylene container. Samples of GB 34 Concentrate were stored for one year at ambient temperature in a glass container and in a fiber board container. The containers and their samples were evaluated after 3, 6, and 12 months.

2. Results: The initial concentration of a.i. was 14% below and 28% below the label claim concentration for the Technical and Concentrate products, respectively, as shown in Tables 1 and 2. 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, relative to the initial concentration. Even though there is much variation in the evaluation method, there appears to be some reduction in the concentration of active ingredient during storage of both GB 34 Technical and GB 34 Concentrate Biological Fungicide.

Table 1. Stability Data of GB 34 Technical Biological Fungicide (Label claim nominal = 2.1×10^{12} cfu/gram)

Storage Time Interval	Date	Glass		High Density Polyethylene	
		cfu/gram	per cent[a]	cfu/gram	per cent[a]
Initial	9-Aug-2000	1.8×10^{12}	100	not evaluated	
3-Month	6-Dec-2000	1.5×10^{12}	83	1.0×10^{12}	56
6-Month	15-Feb-2001	0.81×10^{12}	45	0.73×10^{12}	41
12-month	14-Aug-2001	0.96×10^{12}	53	1.1×10^{12}	61

[a] Value is the percentage of microorganisms counted relative to the initial count in glass, calculated by the reviewer.

Table 2. Stability Data of GB 34 Concentrate Biological Fungicide (Label claim nominal $=1.0 \times 10^{10}$ cfu/gram)

Storage Time Interval	Date	Glass		Fiber Board	
		cfu/gram	per cent[a]	cfu/gram	per cent[a]
Initial	22-Aug-2000	7.2×10^{9}	100	not evaluated	
3-Month	6-Dec-2000	1.9×10^{9}	26	3.3×10^{9}	46
6-Month	26-Feb-2001	2.9×10^{9}	40	1.6×10^{9}	22
12-month	22-Aug-2001	2.4×10^{9}	33	1.4×10^{9}	19

[a] Value is the percentage of microorganisms counted relative to the initial count in glass, calculated by the reviewer.

III. CORROSION CHARACTERISTICS (OPPTS 830.6320)

1. Method: Samples were evaluated using Gustafson SOP 6.14. Samples of GB 34 Technical were stored for one year at ambient temperature in a glass container and in a high density polyethylene container. Samples of GB 34 Concentrate were stored for one year at ambient temperature in a glass container and in a fiber board container. The containers and their samples were evaluated by visual inspection after 3, 6, and 12 months.

2. Results: No changes were seen in GB 34 Technical or GB 34 Concentrate in any of the containers after one year.

IV. DISCUSSION

The submitted storage stability and corrosion characteristics studies were acceptable. The reviewer notes 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 storage at ambient temperature for one year.

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Chemical: Bacillus pumilus GB34

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006493
HED File Code: 41500 BPPD Tox/Chem
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