

A416 – Insect-protected corn

Volume 1 – Submission (May 2000)

Volume 2 - Supporting Data (SD)

SD1: Production of CP4 EPSP Synthase in a 100 Liter Recombinant * Fermentation

SD2: Characterization of Microbially-Expressed Protein: CP4 EPSPS

SD3: The Purification of Recombinant *Escherichia coli* CP4 5-Enolpyruval-Shikimate-3-Phosphate Synthase for Equivalence Studies

SD4: Bioinformatics Analysis of CP4 EPSPS Protein Sequence Utilizing an Allergen Database

SD5: Bioinformatics Analysis of CP4 EPSPS Protein Sequence Utilizing Toxin and Public Domain Genetic Databases

SD6: Assessment of the Equivalence of CP4 EPSPS Protein Expressed in *Escherichia coli* and in Roundup Ready® Corn Lines NK600 and NK603

SD7: Acute Oral Toxicity Study of CP4 EPSPS in Albino Mice

SD8: Purification, Cloning and Characterization of a Highly Glyphosate-Tolerant EPSP Synthase from *Agrobacterium* sp. Strain CP4

SD9: Assessment of the *in vitro* Digestive fate of CP4 EPSP Synthase

SD10: Compositional Analysis of MON 801 Grain and Silage from the 1993 and 1994 Corn Field Trials

SD11: Compositional Analysis of Insect-Protected Roundup Ready™ Corn Lines from the 1994 U.S. Field Trials

SD12: Evaluation of Insect Protected, Insect Protected Roundup Ready™ and Roundup Ready™ Maize Lines in the 1995 European Field Trial 95-BTRR-01

SD13: Evaluation of Insect Protected Roundup Ready™ and Roundup Ready™ Maize Lines in the 1995 European Field Trial 95-BTRR-02 Following Treatment with Roundup Ready® Herbicide

SD14: Expression and Compositional Analyses of Roundup Ready™ Maize Lines MON 830, MON 831 and MON 832 in the 1995 U.S. Field Trial Following Treatment with Roundup® Herbicide

SD15: Introduced Protein Levels and Compositional Analyses of Roundup Ready®/Yieldgard® (GA21 x MON 810) Maize Lines Grown in 1998 Field Trials

SD16: Introduced Protein Levels and Compositional Analyses of Roundup Ready® Corn Line NK603 Tissue produced in 1998 U.S. Field Trials

SD17: Development and Validation of a Direct ELISA for Quantitation of CP4 5-Enolpyruvylshikimate-3-phosphate Synthase (CP4 EPSPS) Protein in Corn Tissues from Roundup Ready® Plants

SD18: Molecular Characterisation of Roundup Ready® (CP4 EPSPS) Corn Line NK603

Volume 3 – Additional Data (AD)

AD 1: Two Studies submitted 5 April 2001

- Comparison of Broiler Performance When Fed Diets Containing Event NK 603, Parental Line or Commercial Corn
- Pesticide Profile, Mycotoxin, and Compositional Analyses of Corn Events MON853 and NK603, Parental Control Events and Reference Lines Produced in the U.S.

AD2: Two Studies submitted 21 August 2001

- Confirmation of the Genomic DNA Sequences Flanking the 5' and 3' Ends of the Insert in Roundup Ready® Corn Event NK603
- Compositional Analyses of Forage and Grain Collected From Roundup Ready® Maize Event NK603 Grown in 1999 E.U. Field Trials

AD3: Amended Report for Bioinformatic Evaluation of DNA Sequences Flanking the 3' End of the NK603 Insertion Event: Assessment of Putative Polypeptides (17 October 2001)

AD4: Amended report for MSL-17107: Sponsor Summary of Report for Study #2000-01-39-02 (Comparison of Broiler Performance When fed Diets Containing Event NK603, Parental Line, or Commercial Corn) (19 December 2001)

AD5: Two Studies submitted 30 January 2002

- Safety Assessment of Roundup Ready Corn Event NK603 Containing Genes Encoding CP4 EPSPS and CP4 EPSPS L214P
- PCR and DNA Sequence Analysis of the Insert in Roundup Ready® Maize Event NK603

AD6: Summary of Bioinformatic Analyses for CP4 EPSPS L214P Produced in Corn Event NK603 (11 February 2002)

- Summary
- Allergensearch
- FASTA Search of Allergens
- FASTA Search of Toxins
- FASTA Search of ALLPEPTIDES

AD7: Two Studies submitted 12 February 2002

- RT-PCR Analyses of the 3' End and Adjoining Genomic DNA Sequences Flanking the Insert in Roundup Ready® Maize Event NK603 – Safety Assessment
- RT-PCR Analyses of the DNA Sequence Flanking the 3' End of the Insert in Roundup Ready® Maize Event NK603

AD8: Two Studies submitted 28 February 2002

- Performance of Pigs Fed Diets Containing Roundup Ready® (NK603), Non-Transgenic Control or Conventional Corn Grown During 2000 in Nebraska
- 13 Week Feeding Study in Rats with Grain from Roundup Ready® Corn (NK603) Preceded by a 1-Week Baseline Food Consumption Determination with PMI certified Rodent Diet #5002

AD9: Amended Report for MSL-16278: Introduced Protein Levels and Compositional Analyses of Roundup Ready® Corn Line NK603 Tissue produced in 1998 U.S. Field Trials (7 March 2002)

AD10: Amended Report for MSL-16857: Confirmation of the Genomic DNA Sequences Flanking the 5' and 3' Ends of the Insert in Roundup Ready® Corn Event NK603 (8 March 2002)