

DATA EVALUATION RECORD

STUDY TYPE: PRIMARY DERMAL IRRITATION TESTING (870.2500 formerly §81-5)

Product Manager: 25

Reviewer: Masih Hashim

TEST MATERIAL PURITY: MON 78831; 40.2% glyphosate acid (49.3% potassium salt of glyphosate); light yellow liquid.

CITATION: Bonnette, K. (2003) A Primary Skin Irritation Study in Rabbits with MON 78831, Springborn Laboratories, Inc., Spencerville, Ohio. Laboratory Report Number SB-2002-193, dated 1-8-03. MRID 45855901. Unpublished.

SPONSOR: Monsanto Company,

EXECUTIVE SUMMARY: In a primary skin irritation study (MRID 45855901), 3 adult male New Zealand White rabbits (Source: Myrtle's Rabbitry, Thompson Station, TN) were dermally exposed to 0.5 ml of MON 78831 (Lot No. GLP-02111-13197-F; 40.2% glyphosate acid (49.3% potassium salt of glyphosate) for 4 hours. The test article was applied under the gauze patch which was held on the skin with a non irritating tape (semi occlusive binder). Animals were observed at 1, 24, 48 and 72 hours and up to 7 days after patch removal.

MON 78831 is classified as Toxicity Category III.

Primary Dermal Irritation Index (PDII) = 0.50 Very slight to well defined erythema and very slight edema was noted on 3 of 3 test animals at 48 hour scoring interval. One site still had Dermal irritation resolved on all sites by day 7. Skin desquamation was noted on 3 of 3 test sites.

This study (870.2500) is classified as Acceptable and satisfies the guideline requirement for a primary skin irritation study in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS: Primary Dermal Irritation Index (PDII) = 2.25

OBSERVATIONS: Primary Dermal Irritation Index (PDII) = 2.25 Very slight to well defined erythema and very slight edema was noted on 3 of 3 test animals at 48 hour scoring interval. One site still had Dermal irritation resolved on all sites by day 7. Skin desquamation was noted on 3 of 3 test sites.