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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

Date: 09-SEP-2016

SUBJECT: **Glyphosate.** Completion and submission of toxicology a data evaluation record.

PC Code: 417300
Decision No.: 521082
Petition No.: NA
Risk Assessment Type: NA
TXR No.: 0057496

MRID No.: 00061113

DP Barcode: D435632
Registration No.: NA
Regulatory Action: NA
Case No.: NA
CAS No.: 41071-83-6; 38641-94-0; 70393-85-0; 114370-14-8; 40465-76-7; 69254-40-6; 34494-04-7; 70901-12-1
40 CFR: §180.364

FROM: Anwar Y. Dunbar, Ph.D.
Pharmacologist, Risk Assessment Branch 1
Health Effects Division (HED) (7509P)

THROUGH: Kelly Lowe, Acting Branch Chief
Risk Assessment Branch 1 (RAB1)
Health Effects Division (HED; 7509P)

TO: Khue Nguyen, Risk Manager Reviewer
Neil Anderson, Risk Manager
Pesticide Registration Division (RD; 7508P)

I. CONCLUSIONS

RAB1 has reviewed the submitted cancer study for the active ingredient Glyphosate. The study is an Acceptable/Non-guideline study.

II. ACTION REQUESTED

Please review the submitted cancer study for Glyphosate.

ED_001560_00000091-00001

Table 1. Submitted Toxicology Studies for Glyphosate		
Guideline Toxicology Studies		
Study Type	**MRID**	**Classification**
Carcinogenicity Study in Mice 870.4200b	000061113 (1973)	Acceptable/Non-guideline

ED_001560_00000091-00002

EPA Primary Reviewer: Anwar Y. Dunbar, Ph.D. **Signature:** [signature]
Risk Assessment Branch I, Health Effects Division (7509P) **Date:** 09-09-16
EPA Secondary Reviewer: Greg Akerman, Ph.D. **Signature:** [signature]
Risk Assessment Branch III, Health Effects Division (7509P) **Date:** 9/9/16

ABBREVIATED DATA EVALUATION RECORD

TXR NO: 0057496

STUDY TYPE: Carcinogenicity Study in Mice – Mouse (83-2)

DP BARCODE: D435632

P.C.CODE.: 417300

MRID NO.: 00061113

TEST MATERIAL (Purity): Glyphosate (95.7%)

SYNONYMS: Roundup®, N-(Phosphonomethyl) glycine

CITATION: Reyna, M.S. (1973) Report to Monsanto Company: 18-Month Carcinogenic Study with CP67573 in Swiss White Mice: IBT No. B569. (Unpublished study received on unknown date under 4G1444; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:093847-O). MRID 00061113. Unpublished.

SPONSOR: Monsanto Co.

EXECUTIVE SUMMARY:

In an 18-month carcinogenicity study (MRID 00061113), groups of 50 Swiss white mice/sex/dose were fed glyphosate at dietary concentrations of 100 and 300 ppm (17 mg/kg/day and 50 mg/kg/day [M/F]). No groups were established for interim sacrifice and tissue analysis. Parameters evaluated included clinical signs, body weight, food consumption, organ weights, gross necropsy and histopathological examination.

There was no effect on survival at any of the doses tested. There were no changes in histopathological findings observed. There were no treatment-related increases in tumor incidence observed in the study. Although only ten mice/sex/dose were examined for histopathological changes, there were no statistically significant increases in tumors observed in the study; therefore, this deficiency would not impact the overall conclusion regarding tumor findings.

The NOAEL is ≥ 50 mg/kg/day. A LOAEL was not established.

CLASSIFICATION

This carcinogenicity study in CD-1 mice is **Acceptable/Non-guideline.** The following deficiencies however are noted: a low number of mice used for histopathological analysis, only two doses were tested, and the study did not test up to the recommended limit dose.

COMPLIANCE: Signed and dated GLP and Quality Assurance statements were provided. A Data Confidentiality statement was not located in the study report.