

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

AUG 13 1987

MEMORANDUM

SUBJECT: PP#6F3380/6H5502. Review of Certified Limit of N-nitrosoglyphosate, [REDACTED] in Glyphosate Technical Product (An Addendum to RCB's 7/6/87 memo, Acc. #263795, #262896)

FROM: ~~W. T. Chin~~ *W. T. Chin*, Chemist
Tolerance Petition Section III
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Philip V. Errico, Section Head *Philip V. Errico*
Tolerance Petition Section III
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Robert J. Taylor, PM #25
Registration Division (TS-767)

and


Toxicology Branch
Hazard Evaluation Division (TS-769)

In response to the deficiencies specified in RCB's (W. T. Chin) 7/6/87 memo in connection with PP#6F3380/6H5502, the petitioner submitted an amendment of 9/18/86 with documents Acc. #263795 and #262896. RCB has reviewed that submission and concluded that only the deficiency "1b" regarding the data gaps of Product Chemistry was resolved (see W. T. Chin's 7/6/87 memo for details). In W. T. Chin's 7/6/87 memo, however, a new point, the [REDACTED] certified limit for N-nitrosoglyphosate (NNG) in glyphosate technical, was not reported. This memo is prepared as an addendum to W. T. Chin's 7/6/87 memo.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

Methodology

A new method for the determination of NNG residues in glyphosate technical products is described in the Appendix 8 of the currently submitted Acc. #263795.



Since no validation data are submitted, the petitioner is requested to submit adequate validation data of this method including examples of the calculations and chromatograms.

Certification of NNG Limits in Glyphosate Technical

Using this method, 52 representative samples of glyphosate technical product were analyzed in May through August, 1985 at Luling, LA and Fayetteville, NC; and additional 100 samples were analyzed in March thru April, 1986 for the purpose of filling the data gap of Certification of Ingredient Limits. The results of these analyses are summarized in Table 1:

Table 1. NNG Contents In Glyphosate Technical Products



QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

According to the petitioner's statement, the so-called "certified limit" of NNG in Table 1 is [redacted] which was calculated by the following equation:

$$\text{Certified Limit} = \text{Mean} + 5 \times \text{St. Dev.}$$

The official certified limit of NNG in technical glyphosate [redacted] (see Table II of Acc. #263795, p.34).

These [redacted] are not acceptable. As indicated in the Pesticide Assessment Guidelines, Subdivision D, Product Chemistry, §62-2, Certification of Ingredient Limits(a)(4), "...the applicant is expected to set upper levels for impurities at levels exceeding levels normal to the product by a reasonable amount...." According to the data shown in Table 1, NNG in glyphosate technical can be at least as [redacted]. The petitioner, therefore, is requested to submit adequate certified upper limits of all impurities determined in glyphosate technical on EPA Form 8570-4(Rev. 2-85).

According to the policy proposal regarding nitroso compounds issued in the Federal Register (Vol. 45, 6/25/80, pp. 42854-42859), if the contamination level is above 1 ppm, exposure and risk data will be required of the applicant and risk assessment made by the Agency. RCB, therefore, defers to TOX as to their concern for [redacted] level of NNG reported in the glyphosate technical product.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

TO PM

The petitioner is requested to submit the following adequate data:

- (1) Validation data of the method used for the determination of NNG in glyphosate technical including examples of the calculation and chromatograms.
- (2) Certification of more appropriate ingredient limits on EPA Form 8570-4 (Rev.2-85).

cc: R.F., Circu., EAB, EEB, Glyphosate Reg. Std., PP#6F3380/6H5502, PM#25, W.T.Chin, W.J.Boodee, TOX and PMSD-ISB

RDI: P.V.Errico(8/12/87), R.D.Schmitt(8/12/87)
TS-769: RCB: CM#2, RM812,557-4352, W.T.Chin,wc(8/12/87)