



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

DEC 22 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Amitraz Reregistration: a List A Chemical
(Chemical No. 106201; Case No. 0234).
NOR-AM: Response to the Amitraz Product Chemistry
Update (dated 8/6/90) Regarding the Oxidizing/
Reducing Action, Flammability, Explodability, and
Corrosion Characteristics (Guideline # 63-14, 63-15,
63-16, and 63-20) Data Requirements for NOR-AM
TGAI/MP (EPA Reg. No. 45639-51).
(MRID No. 424960-01; CBRS No. 10770; DP BARCODE:
D183795)

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To: Lois Rossi, Chief/L. Propst, PM 73
Reregistration Branch
Special Review and Reregistration Division (H7508W)

In response to the Amitraz Product Chemistry Update (dated 8/6/90) NOR-AM Chemical Company, has submitted data (MRID No. 424960-01) for Amitraz 97% technical/MP (EPA Reg. No. 45639-51) regarding the oxidizing/reducing action, flammability, explodability, and corrosion characteristics (Guideline # 63-14, 63-15, 63-16, and 63-20).

NOR-AM Response MRID 424960-01

The performing laboratory is Schering Agrochemicals Limited, Essex, England and NOR-AM Chemical Company, Pikeville, NC. Test material was Amitraz technical (Reference No. 45298/13 P; Request No. S 00340 and pack date 8/13/87) with no purity provided. We noticed that REFS (date, 12/2/92) lists EPA Reg. No. 45639-51 as a 97% technical (rather than 93%) which was confirmed by the PM (telecommunication with D. Edward, on 12/3/92).

Oxidizing/reducing agent (Guideline No. 63-14): No data were submitted. The registrant indicates that from the structure of amitraz it is clear that the compound is not acting as an oxidizing or reducing agent.

Flammability (Guideline No. 63-15): Amitraz is not flammable, because when amitraz (4 cm X 1 cm X 1 cm) was exposed to a glowing platinum wire the sample melted and no ignition occurred. Additionally, amitraz does not autoignite when a 2.0 g sample is heated (in a Greiner oven in a fresh air stream) from room temperature to 300 °C; the sample melted at approximately 84 °C.

Explosibility (Guideline No. 63-16): Amitraz is not thermally explosible (at ≤ 300 °C) when analyzed by Mettler TA 3000 Differential Scanning Calorimetry (DSC) in a sealed aluminium crucible.

Corrosion (Guideline No. 63-20): Amitraz 98.2% (CAS No. 33089-61-1) was stored in a 4 mil HDPE bag (50% filled) and was closed with a twist tie and placed in another 4 mil HDPE bag containing [REDACTED] of amitraz technical) the second bag was closed with a twist tie closure. Then the second bag was placed in an epoxy-lined can and the can was stored at 50 °C for 1 and 4 weeks; at the end of each interval, physical changes to HDPE and or the can was noted. It was concluded that amitraz was not corrosive to the HDPE inner bag or the epoxy lined steel can at 50 °C over a 4 week period.

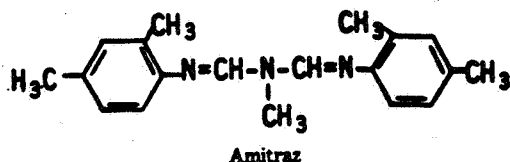
CBRS Conclusion

The deficiencies for NOR-AM's 97% registered Amitraz MP (EPA Reg. No. 45639-51) regarding the oxidizing/reducing action, flammability, explosibility, and corrosion characteristics (Guidelines # 63-14, 63-15, 63-16, and 63-20) are tentatively resolved pending submission of the purity of the amitraz used in these studies and whether or not the MP (45639-51) was tested.

The registrant must clarify whether or not their technical EPA Reg. No. 45639-51 ever has been 93% and then has become 97% because of

the following: the REFS states that EPA Reg. No. 45639-129, a 93% T, was canceled on 2/25/88 which was confirmed by the PM (telecommunication with PM D. Edwards on 12/3/92). Since 45639-51 represents the only manufacturing process/registrant/ beginning material combination, then these requirements have been satisfied. On the other hand, note that if the manufacturing process, producer, and/or beginning materials have changed such that purity of the TGAI is actually 97% vs. 93%, then any differences must be fully described; CBRS will then determine whether or not additional data are required.

The chemical structure of amitraz is given below.



cc: Amitraz S.F., R.F., F. Toghrol, Amitraz Reg. Std. File, List A File, Circ.

RDI: W. Hazel (12/16/92): M. Metzger (12/17/92): E. Zager (12/21/92)

H7509C:CBRS:F.Toghrol:F.T.:RM:804B:CM#2:(703)305-7887:11/20/92.

PRODUCT CHEMISTRYCase No.: 0234 Case Name AmitrazChemical No(s): 106201Chemical Name(s): AmitrazRegistrant: NOR-AM

Guideline Number	Is requirement applicable?	Are additional data required?	MRID Number ^a
61-1	Y	N	00030051
61-2(a)	Y	Y ^b	40650701
61-2(b)	Y	Y ^b	40650701
62-1	Y	Y ^b	40650702
62-2	Y	Y ^b	40650702
62-3	Y	Y ^b	40650704 40650705 40650706
63-2	Y	N	40650707
63-3	Y	N	40650707
63-4	Y	N	40650707
63-5	Y	N	40650707
63-6	Y	N	40650707
63-7	Y	N	40650707
63-8	Y	Y ^c	40650707
63-9	Y	N	40650707
63-10	Y	Y ^c	40650707
63-11	Y	N	40650707
63-12	Y	N	40650707
63-13	Y	Y ^c	
63-14	Y	Y ^d	42496001
63-15	Y	Y ^d	42496001
63-16	Y	Y ^d	42496001
63-17	Y	N	40650707
63-18	N/A ^e	N/A	N/A
63-19	N/A ^e	N/A	N/A
63-20	Y	Y ^d	42496001

Key: Y=yes; N=no; I=a decision cannot be made at this time; S=fully satisfies requirement; P=partially; N/A=not applicable; U=unsatisfactory.

^a Note: This table (except for Guidelines 63-14, 63-15, 63-16, 63-18, 63-19, and 63-20) is copied from Amitraz Registration Standard Update Table A and B footnote 3 and 4" (dated 8/6/90) by R.B. Perfetti which indicates that EPA Reg. No. 45639-51 is a 93% TGAI/MP. We noticed that as of 12/2/92 REFS Lists EPA Reg. No. 45639-51 as a 97% technical (rather than 93%), which was confirmed by the PM (telecommunication with D. Edwards, on 12/3/92).

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^b According to the Amitraz Registration Standard Update, the registrant must submit data on beginning materials and manufacturing process, formation of impurities, preliminary analysis, certification of limits, and enforcement analytical methods for the NOR-AM Chemical Co. 93% T product (EPA Reg. No. 45639-129 transferred from 1023-58). The registrant must clarify whether or not their technical EPA Reg. No. 45639-51 ever has been 93% and then has become 97% because of the following: the REFS states that EPA Reg. No. 45639-129, a 93% T, was canceled on 2/25/88 which was confirmed by the PM (telecommunication with PM D. Edwards on 12/3/92). Since 45639-51 represents the only manufacturing process/registrant/ beginning material combination, then these requirements have been satisfied. On the other hand, note that if the manufacturing process, producer, and/or beginning materials have changed such that purity of the TGAI is actually 97% vs. 93%, then any differences must be fully described; CBRS will then determine whether or not additional data are required.

^c Data must be submitted on physicochemical characteristics for solubility, dissociation constant, and stability of the NOR-AM Chemical Co. (EPA Reg. No. 45639-51) TGAI/MP.

^d Tentatively resolved pending submission of the purity of the test substance and whether or not the MP (45639-51) was tested.

^e NOR-AM requested data waivers for the viscosity and miscibility requirements (Guidelines 63-18 and 63-19); because the amitraz 93% technical is a solid, these data waivers were granted (see CBRS #9595 memo by K. Dockter, dated 4/3/92). The waiver is also applicable to a 97% TGAI.