



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

Head

MAR 24 1994

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Bromacil Lithium Salt Reregistration. List A
Chemical No. 012302; Case No.0041. Du Pont: Response
to Bromacil Lithium Salt 21.9% FI (EPA Reg. No.
352-413) Data Requirement GLN Nos. 61-3, 63-2 to
63-20. (MRID Nos. 430762-01 and 430763-01; CBRS Nos.
13133 and 13134; DP BARCODES: D198401 and D198403)

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In response to a CBRS memo by D. McNeilly (dated 1/15/93), E. I. du Pont de Nemours and Co. has submitted data (MRID 430763-01) to support reregistration of their bromacil lithium salt 21.9% FI (EPA Reg. No. 352-413) regarding GLN Nos. 61-3, 63-2, 63-3, 63-4, 63-7, 63-12, 63-14 to 63-20 and the test substance for the 63-series. Waivers were requested from the requirements to satisfy all of the 62-series and 63-14, 63-15, 63-18, and 63-19.

E.I. du Pont de Nemours has two registered bromacil lithium salt products, a 21.9% and a 7.5% FI (EPA Reg. Nos. 352-413 and 352-414 respectively).

Table 1. Physical and chemical properties of the bromacil lithium salt in the solid phase (MRID No. 430763-01).

Guideline Reference No., 40 CFR §158.190; Name of Property	Description [Method]
63-2. Color	light tan; visual inspection
63-3. Physical state	solid; visual inspection
63-4. Odor	faint, slightly sweet odor; organoleptic testing.
63-5. Melting point	Could not be detected, decomposition took place at 220 to 230 °C and the experiment was halted at 250 °C [Thomas Hoover Melting Point apparatus; OECD GLN No. 102]
63-7. Density, bulk density, or specific gravity	Relative/specific density = 1.39 g/cm ³ at 20 °C [pycnometer; OECD GLN No. 109]
63-12. pH	10.6; 1% aqueous solution at 25 °C [pH meter OTS GLN CG-1450].
63-14 Oxidizing or Reducing Action	N/A; the bromacil lithium salt is not an oxidizing or reducing agent under normal laboratory conditions.
63-15 Flammability	N/A; the bromacil lithium salt is neither a liquid nor an aerosol
63-16 Explodability	Not explosive; 3.5 Kg drop weight maximum height 55" [ASTM].
63-17 Storage Stability	Stable at 54 °C for 2 weeks. 4 oz in polyethylene package at 54 °C for 2 weeks had not changed (0.01 g or 0.1%) [CIPAC Method MT46]
63-18 Viscosity	N/A; the lithium salt is solid.
63-19 Miscibility	N/A; the lithium salt of bromacil is not an emulsifiable liquid nor diluted by petroleum solvent.
63-20 Corrosion Characteristics	Not corrosive; The package from the storage stability study was examined visually for any sign of deterioration. No cracking, pitting, fading or any change was observed.

Registrant Response Regarding 63 Series Test Substance

Du Pont indicates that, commercially, bromacil lithium salt is not isolated as a solid; the 21.9% FI product is a liquid formulation. However, in order to obtain solid bromacil lithium salt used in the 63 series studies, a [REDACTED]

CBRS Comments Regarding 63 Series Test Substance:

The purity of the test material (Li salt) was not provided. The approach used to generate the practical equivalent of the TGAI of the Li salt of bromacil appears sound. However, the generic physical/chemical properties that could, potentially, be satisfied using the resulting test substance (63-2 thru 63-13) cannot be fully acceptable until the percent active ingredient is provided.

61-3. Discussion of Formation of Impurities:

Du Pont has indicated that the impurities in the lithium salt (Chemical I.D. No. 012302) will be the same as those found in their 95% bromacil (acid) TGAI (Chemical ID. No. 012301; EPA Reg. No. 352-325) or the lithium salts thereof.

CBRS Comments Regarding GLN No. 61-3:

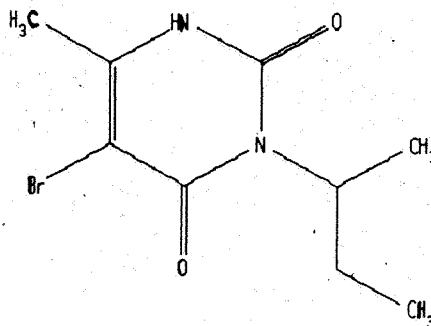
This information does not satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities in the bromacil lithium salt 21.9% MP/FI because additional impurities are possible in the Li salt MP solution due to manufacturing process and starting material differences. Additional information is required.

Note To PM:

Regarding the test substance for preliminary analysis (GLN No. 62-1) the commercial bromacil lithium salt 21.9% liquid must be used (or a more concentrated form of the lithium salt of bromacil after all reaction has occurred but before the addition of any inert). Data must be submitted on five different commercial batches of bromacil lithium salt 21.9% liquid or the more concentrated form if applicable (corrected to 0.1% w/w to compensate for dilution of the ai). Note that 61-1 (including CSF), 62-2, and 62-3 are required for each registered product. The commercial process is to be addressed for 61-2 and 61-3.

Recommendation:

These data do not satisfy the generic data requirements (i.e., requiring TGAI or PAI to serve as test substance) for Du Pont's bromacil lithium salt GLN Nos. 63-2, 63-3, 63-4, 63-5, 63-7, and 63-12; these data may be upgraded to satisfactory once the purity of the test substance is provided and meets Agency approval. GLN Nos. 63-14 through 63-20 are product-specific requirements, i.e. requiring use of the MP or EP as test substance. Of these, 63-16 has been satisfied. Waiver of 63-19 is appropriate. Waivers of 63-14, 63-15, and 63-18 are not appropriate because each registered product (not an isolated, commercially unavailable TGAI) must serve as test substance because of the effects of inerts/impurities on these properties. Similarly, 63-17 and 63-20 must be repeated with each registered product (not an isolated commercially unavailable TGAI).



cc: Bromacil S.F., R.F., F. Toghrol, Registration Standard File, F. Chow.

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