

Sub: Pde

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

MAR 7 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Picloram (005101) List A Reregistration Case No. 0096: Product and Residue Chemistry Chapters For The Reregistration Eligibility Document (RED): CBRS # 11445: DP Barcode D188729.

FROM: William Smith, Ph.D., Chemist *William O. Smith*
Reregistration Section II
Chemistry Branch II: Reregistration Support (CBRS)
Health Effects Division (H7509C)

THROUGH: William J. Hazel, Ph.D., Section Head *W.J. Hazel*
Reregistration Section II
Chemistry Branch II: Reregistration Support (CBRS)
Health Effects Division (H7509C)

TO: Esther Saito, Chief
Chemical Coordination Branch
Health Effects Division (H7509C)

Attached are the Product and Residue Chemistry Chapters for the Picloram RED. These chapters were completed by Dynamac Corporation under supervision of CBRS, HED. They have undergone secondary review in the branch and have been revised to reflect Agency policies.

The Product Chemistry and Residue Chemistry databases for picloram are complete, except as noted in the product chemistry data summary beginning on page 6 of the Product Chemistry Chapter.

Sufficient data are available to reassess the adequacy of the established tolerances for picloram as listed in 40 CFR §180.292, 40 CFR §185.4850 and 40 CFR §186.4850.

CBRS is recommending for the establishment of a tolerance of 4 ppm in grain dust and 225 ppm in grass hay. A revised tolerance of 300 ppm is recommended in grass forage. The existing tolerances of 0.5 ppm in flax seed and straw should be revoked because there are no registered uses of picloram on flax.

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The dietary exposure assessment for picloram is based on tolerance level residues as reassessed in the Residue Chemistry Chapter and percent crop treated information provided by BEAD. Picloram formulations contain HCB, which is a B2 carcinogen, as a contaminant. An assessment of the dietary exposure to HCB as a result of its presence in several pesticides is in progress. In the meantime an interim exposure assessment for HCB from picloram uses is included in the Picloram Residue Chemistry Chapter. This assessment is based on tolerance level residues of picloram, percent crop treated information and conservative assumptions concerning transfer of HCB residues to livestock commodities. With the exception of the percent crop treated information, all of the assumptions used in this exposure estimate will overestimate residues of HCB in dietary commodities. Further refinement of the assessment of dietary exposure to HCB from uses of picloram will require significant expenditure of resources; consequently, it is not deemed necessary at this time.

If you need additional input please advise.

Attachment: Picloram Product and Residue Chemistry RED Chapters.

cc (With Attachment): W. Smith, Picloram RS File, Picloram SF, Circulation, Dynamac.

cc (Without Attachment): RF.

H7509C:CBRS:WOS:wos:CM#2:Rm805A:703-305-5353: 02/18/94
RDI: WHazel:03/04/94: MMetzger:03/04/94 EZager:03/04/94

DYNAMAC
CORPORATION
Environmental Services

Final Report

PICLORAM
Shaughnessy Nos. 005101-005105
(DP Barcode D188729;
CBRS No. 11445; Case 0096)

TASK 2B
Reregistration Eligibility Document:
Residue Chemistry Considerations

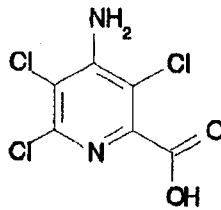
October 14, 1993

Contract No. 68-D2-0053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:
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2275 Research Boulevard
Rockville, MD 20850-3268

PICLORAM

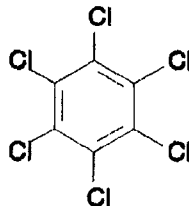
REREGISTRATION ELIGIBILITY DOCUMENTRESIDUE CHEMISTRY CONSIDERATIONSShaughnessy Nos. 005101, 005102, and 005104; Case 0096(CBRS No. 11445; DP Barcode D188729)Task 2BINTRODUCTION

Picloram (4-amino-3,5,6-trichloropicolinic acid) is a systemic herbicide with registered uses on barley, grasses, oats, and wheat. The registered end-use products of picloram (Chemical Code 005101) may be applied on these food/feed crops as a soluble concentrate/liquid (SC/L) in the form of triisopropanolamine salt (Chemical Code 005102) or potassium salt (Chemical Code 005104). The 2-ethylhexyl (isooctyl) ester of picloram is registered for non-food uses only. Picloram may be applied pre- or postemergence as a ground or aerial broadcast or spot treatment [Source: *LUIS General Chemical Report for Picloram, 2/11/93*].

Tolerances for residues in/on plant and animal commodities, and in processed commodities of barley, oats, and wheat (excluding flour) are expressed in terms of picloram *per se* [Source: *40 CFR §180.292, 40 CFR §185.4850, and 40 CFR §186.4850*]. These tolerances range from 0.05 to 80 ppm for residues in/on plant commodities and from 0.05 to 5 ppm for residues in animal commodities. Adequate enforcement methods are available for determination of picloram in/on plant and animal commodities.

Residue data for hexachlorobenzene (HCB, Figure 1), an impurity in technical picloram, have been required for all magnitude of the residue studies for input into risk assessment considerations. Adequate methodology is available for data collection of HCB in/on plant commodities.

Figure 1. Chemical structure of hexachlorobenzene.



The Picloram Reregistration Standard Guidance Document was issued 3/85. The Picloram Final Reregistration Standard and Tolerance Reassessment (FRSTR) was issued 5/18/88. The information contained in this document outlines the Residue Chemistry Science Assessments with respect to the reregistration of picloram.

SUMMARY OF SCIENCE FINDINGS

GLN 171-3: Directions for Use: A REFs search conducted 9/16/93 identified three end-use products (EPs) of picloram currently registered to DowElanco that may be used on food/feed crops grown in the U.S. These EPs include two 2 lb/gal SC/L potassium salt formulations (Tordon 22K®; EPA Reg. No. 62719-6 and Grazon PC®; EPA Reg. No. 62719-181) and a 0.54 lb/gal SC/L trisopropanolamine salt formulation (Grazon P+D® EPA Reg. No. 62719-182). A comprehensive summary of the registered food/feed use patterns of picloram, based on these product labels, is presented in Table A. A complete summary of residue chemistry data requirements, in accordance with Subdivision O of the Pesticide Assessment Guidelines, appears in Table B.

GLN 171-4 (a): Plant Metabolism: The qualitative nature of the residue in plants is adequately understood based on a wheat metabolism study. The residue of concern in wheat forage, straw, and grain is conjugated picloram, which is hydrolyzable by acid, base, and β -glucosidase. The minor metabolites that were identified in grain and straw were 4-amino-6-hydroxy-3,5-dichloropicolinic acid and 4-amino-2,3,5-trichloropyridine. CBRS reserves the right to require additional plant metabolism studies if the registrant proposes to expand picloram uses on other crops. (MRIDs 00037880, 00041136, 00059411, 00111527, 00157171, and 42579004).

GLN 171-4 (b): Animal Metabolism: The qualitative nature of the residue in animals is adequately understood. Picloram is the residue of concern in meat, milk, poultry tissues, and eggs. The available ruminant metabolism study indicates that picloram is the major residue in animal tissues of concern and that picloram is not metabolized in ruminants to a significant degree; only minor amounts (<10% of total radioactive residues) of 4-amino-2,3,5-trichloropyridine were detected in goat fat and liver. In the submitted poultry metabolism study, 99.9% of the recovered radioactivity was found in the excreta and virtually all of the ^{14}C -residues were identified as picloram. (MRIDs 00023105, 00041125, 00161306, 00163216, and 42535301).

GLN 171-4 (c) and (d): Residue Analytical Methods - Plants and Animals: Adequate enforcement methods are available for the determination of residues of picloram *per se* in/on plant and animal commodities. All of these methods use GLC with electron capture detection of the methyl ester of picloram. The Pesticide Analytical Manual (PAM), Vol. II lists Methods A and III for plant commodities. DowElanco method ACR 73.3.S2 is a GC/ECD method based on Method III with substantial modifications. Method ACR 73.3.S2 was validated using samples from the wheat metabolism study and is adequate for data collection of picloram residues. Method ACR 79.7.S.1 is adequate for collection of picloram data on grass forage and hay. DowElanco Method ACR 91.4 is adequate for HCB data collection from plant commodities.

PAM Vol. II Methods I and II are used to enforce tolerances for picloram residues in animal commodities. DowElanco GC/ECD methods ACR 67.2 and ACR 67.3 are equivalent to Methods II and I, respectively, except that toluene is used in place of benzene. These animal commodity methods have been validated using samples from the goat metabolism study and are adequate for data collection and tolerance enforcement for milk and animal tissues. (MRIDs 00026748, 00026749, 00026750, 00026751, 00026752, 00026753, 00027288, 00035959, 00045363, 00045366, 00045373, 00045374, 00045375, 00045376, 00045409, 00062818, 00069973, 00073972, 00073974, 00078483, 00085060, 00111404, 00111407, 00131364, 00132986, 00156366, and 42380201).

FDA has tested picloram using the PAM, Vol. I Multiresidue Method for acids and phenols (Sec 221.1). Table 201-D of the volume reports that picloram in nonfat foods is completely recovered through PAM 221.1 if a 100 mL ethyl ether Florisil elution is included whereas only 6-10% is recovered from fatty foods.

GLN 171-4 (e): Storage Stability: Adequate storage stability data on picloram are available to support the collected samples from metabolism and magnitude of the residue studies in plants and animals. Residues of picloram *per se* are stable under frozen storage conditions in/on: (i) wheat and barley grain, forage, and straw; and grasses for up to 2 years; (ii) egg whites for up to 18 months; (iii) milk for up to 15 months; and (iv) liver and muscle for up to 6 months. Adequate storage stability data for HCB residues are available for grass and small grain commodities; residues of HCB are stable in frozen storage for up to 17 months. (MRIDs 00164725, 40082701, 40435601, 40731901, 41442301, 41976701 and 42494001).

GLN 171-4 (k): Magnitude of the Residue in Plants: All data requirements for magnitude of picloram residues in plants have been evaluated and deemed adequate. The registered uses of picloram on barley, oats, and wheat along with the established tolerances on these commodities are supported by acceptable field residue data from trials reflecting the maximum registered use patterns. Field trial data are adequate for grasses and support the proposed tolerance of 225 ppm for grass hay; however, residues on grass forage exceed the proposed tolerance of 225 ppm. The data indicate that a value of 300 ppm would be appropriate for grass forage.

Acceptable grain dust data have been submitted for wheat, which show that residues of picloram concentrate 7x in aspirated grain dust. The registrant must propose a suitable tolerance for grain dust.

The available field residue data on HCB residues in/on plants are adequate. HCB residues were nondetectable in/on wheat grain (<0.001 ppm), grain dust (<0.001 ppm) and wheat straw (<0.002 ppm) following applications of registered formulations of picloram according to the maximum registered use patterns. Residues of HCB were <0.001 ppm in/on grass forage and hay treated using the 2 lb/gal. SC/L potassium salt formulation at a rate of 2 lb ae/A, and containing residues of picloram as high as 480 ppm. One hay sample, containing 270 ppm picloram, bore 0.001 ppm HCB. Residues of HCB were shown to dissipate from grass at a greater rate than picloram residues. (MRIDs 00026753, 00036168, 00036170, 00036171, 00045369, 00085060, 00108862, 00108864, 00111404, 00111470, 00111482, 00111557, 00128714, 41905401, 42037601, 42380201, 42535303, and 42784401).

GLN 171-4 (l): Magnitude of the Residue in Processed Food/Feed: The data requirements for magnitude of the residue in processed food/feed have been evaluated and deemed adequate. Acceptable wheat grain processing data have been submitted; the wheat processing data will be translated to barley and oats. The wheat data indicate that residues of picloram concentrate up to 5x in bran. HCB residues were not detected in/on wheat grain or processed fractions. The existing feed additive tolerance of 3 ppm for picloram residues in milled products of wheat (exc. flour) is adequate. (MRID 42535303).

GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry and Eggs: The ruminant and poultry feeding studies that were reviewed in the Residue Chemistry Chapter of the Picloram Reregistration Standard, dated 10/29/84, are adequate to satisfy animal feeding study data requirements. These feeding studies indicate that the existing tolerances on animal commodities are supported by residue data from dietary intakes exceeding the maximum dietary burden. (MRIDs 00045372, 00045374, 00045376, 00073921, and 00073973).

(6)

GLNs 165-1 and 165-2: Confined/Field Rotational Crops: An acceptable confined rotational crop study has been submitted. Field rotational crop studies are not required; in addition, tolerances for rotational crop commodities need not be established. (MRID 42641801).

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Table A. Maximum registered uses of picloram for DowElanco's 0.54 lb/gal SC/L trisopropanolamine salt formulation (Grazon P+D® EPA Reg. No. 62719-182, dated 5/13/92) and 2 lb/gal SC/L potassium salt formulations (Tordon 22K®, EPA Reg. No. 62719-6, dated 3/10/92; and Grazon PC®, EPA Reg. No. 62719-181, dated 6/18/92).

Crop	Formulation ¹	Max. Single Application		PHI/PGI/PSI ² (Days)	Use Limitations
		Rate (lb ae/A)	Rate (lb ae/A)		
Small Grains (Barley Oats Wheat)	Tordon 22K K Salt (2 lb/gal SC/L)	0.0234	0.0234	50 PHI 14 PGI	Use limited barley, oats, and wheat, which are not underseeded with legumes, in areas west of the Mississippi River as a single broadcast application using ground or aerial equipment. Application may be made from the 3- to 5-leaf stage until early jointing (spring varieties) or after the resumption of active growth until early jointing (winter varieties). Harvesting hay from treated fields is prohibited.
		0.25	0.25	--	Use limited to areas west of the Mississippi River as a postharvest or fallow broadcast application using ground or aerial equipment.
Grasses (rangeland and permanent grass pastures)	Grazon P+D TIPA Salt (0.54 lb/gal SC/L)	0.54	0.54	30 PHI 7 PGI ³ 3 PSI	Use limited to AL, AR, GA, LA, MS, NM, OK, and TX as a single broadcast application using ground or aerial equipment. Application is usually in the spring or fall but is also dependent upon the growth of the weed controlled.
		0.5	0.5	--	Use limited to areas west of the Mississippi River for broadcast applications using ground or aerial equipment. Application to Conservation Reserve Program (CRP) for seeding to permanent grasses is permitted.
	Tordon 22K K Salt (2 lb/gal SC/L)	2.0	2.0	14 PGI ³ 3 PSI 14 PHI	Use limited to areas west of the Mississippi River for spot application using ground equipment. Application to Conservation Reserve Program (CRP) for seeding to permanent grasses is permitted. Rates exceeding 0.5 lb ai/A are permitted only as a spot treatment and the total area treated per season should not exceed 25% of the acreage in any particular watershed.

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(continued; footnotes follow)

Table A (continued).

Crop	Formulation ¹	Max. Single Application Rate (lb ae/A)	Max. Seasonal Rate (lb ae/A)	PHI/PGI/PSI ² (Days)	Use Limitations
Grasses (continued)	Tordon 22K K Salt (2 lb/gal SC/L)	--	0.5	--	Use limited to areas west of the Mississippi River as a spot concentrate application on Eastern red cedar. An undiluted soil application may be made during spring or fall within the drip line and on the upslope side of the tree.
		1 part product/2 parts water	--	--	Use limited to areas west of the Mississippi River as a wick application. Application to Conservation Reserve Program (CRP) for seeding to permanent grasses is permitted.
	Grazon PC K Salt (2 lb/gal SC/L)	0.5	0.5	--	Use limited to NM, OK, and TX as a single broadcast application using ground or aerial equipment.

¹ Formulation concentration as acid equivalent (ae) of picloram. ² PHI = preharvest interval; PGI = pregrazing interval; PSI = preslaughter interval.

³ PGI applies to lactating dairy animals.

Table B. Residue chemistry science assessments for reregistration of picloram.

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
171-4 (a): Plant Metabolism	N/A = Not Applicable	No	00037880, 00041136, 00059411, 00111527, 00157171 , 42579004 ²
171-4 (b): Animal Metabolism	N/A	No	00023105, 00041125, 00161306 , 00163216 , 42535301 ³
171-4 (c/d): Residue Analytical Methods	N/A	No	00026748, 00026749, 00026750, 00026751, 00026752, 00026753, 00027288, 00035959, 00045363, 00045366, 00045373, 00045374, 00045375, 00045376, 00045409, 00062818 , 00069973, 00073972, 00073974, 00078483, 00085060, 00111404, 00111407, 00131364, 00132986, 00156366 , 42380201 ⁴
171-4 (e): Storage Stability	N/A	No	00164725 , 40082701 , 40435601 , 40731901 ⁵ , 41442301 ⁶ , 41976701 ⁷ 42494001 ⁸
171-4 (k): Magnitude of the Residue in Plants			
<u>Cereal Grains Group</u>			
- Barley grain	0.5 [§180.292]	No	00036168, 00036170, 00036171, 00045369, 00128714, 42380201 ⁴
- Oat grain	0.5 [§180.292]	No	00036168, 00036170, 00036171, 00045369, 00128714, 42380201 ⁴
- Wheat grain	0.5 [§180.292]	No	00036168, 00036170, 00036171, 00045369, 00128714, 42380201 ⁴

Table B (continued).

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
<u>Forage, Fodder, and Straw of Cereal Grains Group</u>			
- Barley forage and straw	1 [§180.292]	No	00036168, 00036170, 00036171, 00128714, 42380201 ⁴
- Oat forage and straw	1 [§180.292]	No	00036168, 00036170, 00036171, 00128714, 42380201 ⁴
- Wheat forage and straw	1 [§180.292]	No	00036168, 00036170, 00036171, 00128714, 42380201 ⁴
<u>Grass Forage and Hay Group</u>			
- Grass forage	80 [§180.292]	No	00108862, 00108864, 00111404, 00111470, 00111482, 00111557, 00128714, 00156366 , 41905401 ⁹ , 42037601 ¹⁰ , 42784401 ¹¹
<u>Miscellaneous Commodities</u>			
- Flax seed	0.5 [§180.292]	No	00026753, 00085060
- Flax straw	0.5 [§180.292]	No	00026753, 00085060
171-4(l): Magnitude of the Residue in Processed Food/Feed			
- Barley	3 [§185.4850, §186.4850]	No	
- Oats	3 [§185.4850, §186.4850]	No	
- Wheat	3 [§185.4850, §186.4850]	No	42535303 ¹²
171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs			
- Cattle, goats, hogs, horses, sheep	0.2 (fat, meat, and mbyp, except kidney and liver) 0.5 (kidney and liver) [§180.292]	No	00045374, 00045376, 00073973

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Table B (continued).

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Milk	0.05 [§180.292]	No	00045372, 00073921
- Poultry	0.05 (meat, fat, mby, eggs) [§180.292]	No	00035959
165-1: Rotational Crops (Confined)		No	42641801 ¹³
165-2: Rotational Crops (Field)		No	

1. **Bolded** references were reviewed in the Residue Chemistry Science Chapter of Pictoram FRSTR of 5/18/88. **Unbolded** references were reviewed in the Residue Chemistry Science Chapter of the Reregistration Standard dated 10/29/84. Otherwise, references were reviewed as noted.

2. CBRS No. 11126, 8/5/93, W. Smith.
3. CBRS Nos. 10881 and 11233, 8/5/93, W. Smith.
4. CBRS Nos. 10227, 2/4/93, W. Smith.
5. CBRS. No. 5504, 9/21/89, E. Haerberer.
6. CBRS No. 7521; 4/25/91, R. Perfetti.
7. CBRS No. 8392, 7/1/92, J. Abbotts.
8. CBRS No. 10697, 8/5/93, W. Smith.
9. CBRS Nos. 8321 and 8753, 7/28/92, J. Abbotts.
10. CBRS Nos. 8321 and 8753, 7/28/92, J. Abbotts.
11. CBRS No. 12008, 01/04/94, W. Smith.
12. CBRS Nos. 10881 and 11233, 8/5/93, W. Smith.
13. CBRS No. 11408, 10/13/93, W. Smith.

TOLERANCE REASSESSMENT SUMMARY

Tolerances Listed Under 40 CFR §180.292:

The tolerances listed in 40 CFR §180.292 are for residues of picloram *per se*. Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.292 for the following commodities: barley grain; barley forage; barley straw; oat grain; oat forage; oat straw; wheat grain; wheat forage; wheat straw; fat, meat, kidney, liver, and meat by-products of cattle; goats, hogs, horses, and sheep; and fat, meat, and meat by-products of poultry, milk, and eggs. See Table C for modifications in commodity definitions.

Sufficient field residue data are available for grasses, although the data indicate that the established tolerance of 80 ppm for picloram residues in/on grass forage is not adequate. Tolerances of 225 ppm have been proposed (PP#6F3367) for picloram residues in/on grass forage and hay. The available data support the proposed tolerance for grass hay but show that a higher tolerance must be proposed for grass forage. The data indicate that a level of 300 ppm would be appropriate.

A wheat grain dust study has shown that a tolerance must be proposed. The available data indicate that a tolerance of 4 ppm would be appropriate for grain dust.

The established tolerances for picloram residues in/on flax seed and flax straw should be revoked, as there is no registered use of picloram on flax.

Tolerances Listed Under 40 CFR §185.4850 and 40 CFR §186.4850:

The tolerances listed in 40 CFR §185.4850 and 40 CFR §186.4850 are for residues of picloram *per se*. Sufficient data are available to ascertain the adequacy of the established food/feed additive tolerances listed in 40 CFR §185.4850 and 40 CFR §186.4850 for barley, oat, and wheat milled fractions (excluding flour).

CODEX HARMONIZATION

There are no Codex MRLs established or proposed for residues of picloram. Therefore, there are no questions with respect to compatibility of U.S. tolerances with Codex MRLs.

Table C. Tolerance Reassessment Summary for Picloram

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Tolerances listed under 40 CFR 5180.292:			
Barley, grain	0.5	0.5	
Barley, green forage	1	1	<i>Barley, forage</i>
Barley, straw	1	1	
Cattle, fat	0.2	0.2	
Cattle, kidney	5	5	
Cattle, liver	0.5	0.5	
Cattle, mbyp (exc kidney and liver)	0.2	0.2	<i>Cattle, mbyp (exc. liver and kidney)</i>
Cattle, meat	0.2	0.2	
Eggs	0.05	0.05	
Flax, seed	0.5	Revoke	No registered use
Flax, straw	0.5	Revoke	No registered use
Goats, fat	0.2	0.2	
Goats, kidney	5	5	
Goats, liver	0.5	0.5	
Goats, mbyp (exc kidney and liver)	0.2	0.2	<i>Goats, mbyp (exc. liver and kidney)</i>
Goats, meat	0.2	0.2	
[Grain dust]	none	4	Registrant must propose tolerance
Grasses, forage	80	300	Revised tolerance proposal of 225 ppm pending (PP#6F3367); registrant must propose higher tolerance/ <i>Grass, forage</i>
[Grass, hay]	none	225	Tolerance pending (PP#6F3367)/ <i>Grass, hay</i>
Hogs, fat	0.2	0.2	
Hogs, kidney	5	5	
Hogs, liver	0.5	0.5	
Hogs, mbyp (exc kidney and liver)	0.2	0.2	<i>Hogs, mbyp (exc. liver and kidney)</i>
Hogs, meat	0.2	0.2	
Horses, fat	0.2	0.2	
Horses, kidney	5	5	
Horses, liver	0.5	0.5	
Horses, mbyp (exc kidney and liver)	0.2	0.2	<i>Horses, mbyp (exc. liver and kidney)</i>
Horses, meat	0.2	0.2	

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
40 CFR §180.292 continued:			
Milk	0.05	0.05	
Oats, grain	0.5	0.5	
Oats, green forage	1	1	<i>Oats, forage</i>
Oats, straw	1	1	
Poultry, fat	0.05	0.05	
Poultry, mbyp	0.05	0.05	
Poultry, meat	0.05	0.05	
Sheep, fat	0.2	0.2	
Sheep, kidney	5	5	
Sheep, liver	0.5	0.5	
Sheep, mbyp (exc kidney and liver)	0.2	0.2	<i>Sheep, mbyp (exc. liver and kidney)</i>
Sheep, meat	0.2	0.2	
Wheat, grain	0.5	0.5	
Wheat, green forage	1	1	<i>Wheat, forage</i>
Wheat, straw	1	1	
Tolerances listed under 40 CFR §185.4850			
Barley, milled fractions (exc. flour)	3	3	
Oat, milled fractions (exc. flour)	3	3	
Wheat, milled fractions (exc. flour)	3	3	
Tolerances listed under 40 CFR §186.4850			
Barley, milled fractions (exc. flour)	3	3	
Oat, milled fractions (exc. flour)	3	3	
Wheat, milled fractions (exc. flour)	3	3	

DIETARY EXPOSURE REASSESSMENT

In conjunction with the 1988 Picloram Registration Standard, a dietary risk assessment was conducted for picloram and HCB from uses of picloram. Dietary exposure was calculated using the published tolerances for picloram and assuming that picloram is used on 100% of the crops for which tolerances are established. Residues of HCB were estimated by assuming they would be present on all commodities in direct proportion to the maximum legal level of HCB in the picloram technical product, i.e., at 0.02% of the picloram tolerance. The dietary risk due to picloram was found to be well below levels of concern, even though the conservative assumptions of tolerance level residues of picloram and 100% crop treated were made. The oncogenic risk due to HCB was estimated at 6.23×10^{-7} . This risk was also considered to be acceptable given the conservative nature of residue estimation; however, the assumption was made that HCB and picloram would dissipate or accumulate at the same rate in crop residues and in meat, milk, poultry and eggs. This assumption, which could potentially lead to an underestimation of the HCB risk, has been confirmed for crops but shown to be incorrect in the case of livestock commodities. Therefore, CBRS recommends a reassessment of the HCB dietary risk from the use of picloram, which incorporates assumptions and estimates as enumerated in the following discussion. We note that this risk assessment, containing a number of conservative assumptions, is an interim assessment. The assumptions described below, with the sole exception of percent crop treated information, lead to an overestimate of actual dietary risk.

Interim Exposure Estimate for HCB Dietary Risk Assessment

Field trial data submitted since the most recent risk assessment confirm that HCB residues are generally nondetectable on crops treated according to the registered uses of picloram and that the ratio of HCB to picloram in the crop residue is less than the ratio in the formulation applied, i.e., residues of HCB dissipate faster than residues of picloram. Due to the low level of residues it is not possible to calculate a reliable ratio for estimation of HCB residues based on picloram residues; therefore, we recommend that the conservative estimates, based on equal dissipation rates, continue to be used for dietary risk assessment purposes.

The following % crop treated information, contained in a memorandum of 2/9/94 from J. Faulkner, BEAD to W. Hazel, HED, should be used in estimating dietary risk of HCB from uses of picloram.

Wheat	< 2%
Barley	< 2%
Oats	< 1%
Pasture & rangeland	< 1%

For purposes of this interim risk assessment, tolerance level residues of picloram should be assumed in all crops except grass. An average maximum residue value for grass eaten by livestock will be estimated to be 1/4 of the recommended tolerance (because the maximum use rate applies to spot treatments that are restricted to 1/4 of grass acreage in a given watershed); therefore, the average maximum dietary exposure of livestock to picloram on grass is 75 ppm.

The maximum level of HCB in the picloram TGAI is currently 0.01%. The same ratio will be assumed to be present in residues on crops. Residues of HCB on crops will be estimated by multiplying the picloram tolerance (or average maximum exposure of livestock to picloram on grass) by 0.01%.

The residues of HCB in livestock commodities will be estimated from a worst case diet assuming i) tolerance levels of picloram on feed items (or average maximum exposure of livestock to picloram on grass), ii) % crop treated values for feeds as supplied by BEAD, iii) residues of HCB on feed will be 0.01% of picloram residues on feed, and iv) maximum % of livestock diet for each feed item as taken from Table II of Subdivision O of Pesticide Assessment Guidelines. The worst case diets are driven by the facts that the only feed items on which picloram is used are small grains and grass (pasture and

rangeland) and the overwhelming constituent of any theoretical diet is grass. This assessment does not adjust for the fact that picloram is typically used on feed crops once a year nor does it make any adjustments for grazing restrictions that apply to some uses of picloram. The assumed worst case diets and associated maximum residues of HCB in the diet are as follows:

Worst case diet for beef cattle would be 60% grass:

$$\begin{aligned} \text{Max HCB in diet} &= (\% \text{ of diet}) * (\text{tolerance}) * (\% \text{ crop treated}) * (\% \text{ HCB in picloram}) \\ \text{Max HCB in diet} &= 60\% * 75 \text{ ppm} * 1\% * 0.01\% = 0.000045 \text{ ppm} \end{aligned}$$

Worst case diet for dairy cattle would be 70% grass:

$$\text{Max HCB in diet} = 70\% * 75 \text{ ppm} * 1\% * 0.01\% = 0.000053 \text{ ppm}$$

Worst case diet for poultry would be 70% wheat grain:

$$\text{Max HCB in diet} = 70\% * 0.5 \text{ ppm} * 2\% * 0.01\% = 0.0000007 \text{ ppm}$$

Worst case diet for swine would be 80% grain

$$\text{Max HCB in diet} = 80\% * 0.5 \text{ ppm} * 2\% * 0.01\% = 0.0000008 \text{ ppm}$$

To estimate transfer of HCB from feed to livestock commodities CBRS will use HCB feeding studies in the Agency files, which were submitted in support of registration of another chemical (PCNB) containing HCB as a contaminant. A cattle feeding study (MRID 00001711) was discussed in Agency reviews of petitions 9F0754 (E. Gunderson, 2/18/70) and 1F1083 (D. Reed, 2/23/72). Lactating cows were fed PCNB contaminated with HCB resulting in 0.0018 ppm, 0.018 ppm and 0.18 ppm HCB feeding levels for 16 weeks. A poultry feeding study (MRID 00109653) was discussed in an Agency review of 1F1083 (R. Cook, 9/3/82). Chickens were fed six levels of PCNB for four months resulting in HCB feeding levels of 0.00075 ppm, 0.015 ppm, 0.075 ppm, 0.23 ppm and 4.5 ppm. As shown in Tables D and E, both ruminant and poultry studies confirm that HCB accumulates primarily in fat matrices. Residues reached a plateau in both studies that was generally directly related to the concentration in the feed. The worst case HCB dietary burden for livestock from picloram uses on feed items is actually much lower than those in available feeding studies; therefore, we are assuming that accumulation at these lower dosing levels is also directly related to feeding levels.

Table D. Maximum Residues of HCB in Tissues and Milk of Cows Fed for 16 Weeks with Three Levels of PCNB Contaminated with HCB.

Matrix	HCB Residues in ppm [tissue residue/residue in feed]		
	0.0018	0.018	0.18
Feed	0.0018	0.018	0.18
Kidney	ND	0.002 [0.11]	0.039 [0.22]
Liver	ND	0.005 [0.28]	0.059 [0.33]
Muscle	ND	0.006 [0.33]	0.070 [0.39]
Fat(subcut)	0.010 [5.6]	0.079 [4.4]	0.722 [4]
Fat(abdom)	0.013 [7.2]	0.102 [5.7]	0.785 [4.4]
Milk	ND	0.003 [0.17]	0.015 [0.08]

Table E. Maximum Residues of HCB in Tissues and Eggs of Chickens Fed for Four Months at Six Levels of PCNB Contaminated with HCB.

Matrix	HCB Residues in ppm [tissue residue/residue in feed]						
	oil control	0.00075	0.015	0.075	0.230	1.13	4.5
Feed	oil control	0.00075	0.015	0.075	0.230	1.13	4.5
Liver	ND	0.017 [23]*	0.033 [2.2]	0.123 [1.6]	0.166 [0.72]	1.02 [0.9]	6.63 [1.47]
Fat	0.087	0.066 [88]*	0.087 [5.8]	0.403 [5.4]	2.24 [9.7]	8.59 [7.6]	36 [8]
Egg yolk	0.036	0.014 [19]*	0.018 [1.2]	0.130 [1.7]	0.491 [2.1]	2.99 [2.6]	11.9 [2.6]
Egg white	ND	ND	0.001 [0.07]	ND	0.001 [0.004]	0.007 [0.006]	0.032 [0.007]
White meat	ND	ND	ND	ND	ND	0.047 [0.047]	0.703 [0.156]

* This ratio is assumed to be inaccurate based on a comparison to the accumulation of HCB in other samples of the same tissue. Significant residues were also reported in fat and egg yolk from birds fed a control diet.

For purposes of an interim estimate of HCB residues in livestock commodities due to treatment of feed items with picloram, the following factors were applied to the estimated maximum dietary burden of livestock to obtain the residue levels in meat, milk, poultry and eggs. These values represent conservative extrapolation of the relative HCB accumulation, indicated in Tables D and E, to the worst case dietary burden from livestock consumption of feed items treated with picloram.

- Cattle fat residues = 10x dietary burden
- Milk residues = 0.2x dietary burden (with residues confined to the fat)
- Cattle meat, liver and kidney residues = 0.5x dietary burden
- Poultry fat residues = 10x dietary burden
- Poultry liver residues = 2x dietary burden
- Poultry meat residues = 0.2x dietary burden
- Egg yolk residues = 3x dietary burden
- Egg white residues = 0.01x dietary burden

Table F contains residue values for use in an interim dietary risk assessment for picloram and HCB from uses of picloram. Percent crop treated values have not been incorporated into the anticipated residue values provided for plant commodities. This should be done by DRES. Percent crop treated values have already been incorporated into anticipated residues estimated for animal products (for HCB only).

Table F. Residue Values for DRES Run on Picloram and HCB. Residue values are based on the assumption of tolerance level residues of picloram on crops. *

Commodity	Picloram Residues (ppm)	HCB Residues (ppm)	% crop treated
Barley, grain	0.5	0.00005	2
Barley, milled fractions (exc. flour)	3	0.0003	2
Oats, grain	0.5	0.00005	1
Oat, milled fractions (exc. flour)	3	0.0003	1
Wheat, grain	0.5	0.00005	2
Wheat, milled fractions (exc. flour)	3	0.0003	2
Secondary Residues			
Milk	0.05	0.0000106 (whole milk) 0.000265 (milk fat only assuming 4% fat)	
Cattle, fat	0.2	0.00045	
Cattle, kidney	5	0.0000225	
Cattle, liver	0.5	0.0000225	
Cattle, mbyp (exc kidney and liver)	0.2	0.0000225	
Cattle, meat	0.2	0.0000225	
Poultry, fat	0.05	0.000007	
Poultry, mbyp	0.05	0.0000001	
Poultry, meat	0.05	0.0000001	
Eggs	0.05	0.0000021 (yolk) 0.000000007 (white)	
Hogs, fat	0.2	0.000008	
Hogs, kidney	5	0.0000004	
Hogs, liver	0.5	0.0000004	
Hogs, mbyp (exc kidney and liver)	0.2	0.0000004	
Hogs, meat	0.2	0.0000004	
Horses, fat	0.2	0.00045	
Horses, kidney	5	0.0000225	
Horses, liver	0.5	0.0000225	
Horses, mbyp (exc kidney and liver)	0.2	0.0000225	
Horses, meat	0.2	0.0000225	
Sheep, fat	0.2	0.00045	
Sheep, kidney	5	0.0000225	
Sheep, liver	0.5	0.0000225	
Sheep, mbyp (exc kidney and liver)	0.2	0.0000225	
Sheep, meat	0.2	0.0000225	
Goats, fat	0.2	0.00045	
Goats, kidney	5	0.0000225	
Goats, liver	0.5	0.0000225	
Goats, mbyp (exc kidney and liver)	0.2	0.0000225	
Goats, meat	0.2	0.0000225	

* Tolerances are established for residues of picloram per se.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No.: 5504
Subject: Followup to the Picloram (FRSTR) Registration Standard; PP#6F3367, Grasses (Forage and Hay): Storage Stability of Picloram in Milk and Egg Whites (MRID Nos. 407319-00, 407319-01, DEB No. 5504)
From: E. Haerberer, DEB, HED
To: D. Edwards, Tolerance Petition Section II, DEB, HED
Dated: 09/21/89
MRID(s): 407319-00 and 407319-01

CBRS No.: 7521
Subject: DowElanco: Response to the Picloram Reregistration Standard. Residue Chemistry Studies (MRID 41442301, CBRS No. 7521, DP Barcode D159949).
From: R. Perfetti, CB II, HED
To: R. Engler/L. Rossi, RB, SRRD
Dated: 04/25/91
MRID: 41442301

CBRS No.: 8392
Subject: Picloram. DowElanco Response to the Reregistration Standard: Storage Stability Data for Animal Commodities. No MRID No. CBRS No. 8392. DP Barcode No. D167164
From: J. Abbotts, CB II, HED
To: L. Rossi, RB, SRRD
Dated: 07/01/92
MRID: 41976701

CBRS Nos.: 8321 and 8753
Subject: Picloram. DowElanco Response to the Reregistration Standard: Magnitude of the Residue in Grass (MRID Nos. 41905401, 42037601). CBRS Nos. 8321, 8753. DP Barcode Nos. D166864, D169844.
From: J. Abbotts, CB II, HED
To: L. Rossi, RB, SRRD
Dated: 07/28/92
MRID(s): 41905401, 42037601

CBRS No.: 10227
Subject: Picloram Reregistration. DowElanco Response to Residue Chemistry Data Requirements: Wheat Field Trials: CBRS No. 10227: DP Barcode D180653: MRID No. 42380201.
From: W. Smith, CB II, HED
To: V. Eagle/W. Waldrop, RB, SRRD
Dated: 02/04/93
MRID: 42380201

CBRS Nos.: 10697, 10881, 11233, and 11126
Subject: Picloram: Case No. 0096: Chemical No. 005101: Registrant's Response to Reregistration Data Requirements: CBRS Nos. 10697, 10881, 11233, and 11126: DP Barcodes D183381, D184755, D187248, and D186366.
From: W. Smith, CB II, HED
To: W. Waldrop/V. Eagle, RB, SRRD
Dated: 08/05/93
MRID: 42579004

CBRS No.: 11408
Subject: Picloram: Case No. 0096: Chemical No. 005101: Registrant's Response to Reregistration Data Requirements: CBRS No. 11408, DP Barcode D188297.
From: W. Smith, CB II, HED
To: W. Waldrop/V. Eagle, RB, SRRD
Dated: 10/13/93
MRID: 42641801

CBRS No.: 12008
Subject: Picloram: Case No. 0096: Chemical No. 005101: Registrant's Response to Reregistration Data Requirements: CBRS No. 12008, DP Barcode D192179.
From: W. Smith, CB II, HED
To: W. Waldrop/V. Eagle, RB, SRRD
Dated: 01/04/94
MRID: 42784401

DYNAMAC
CORPORATION
Environmental Services

Final Report

PICLORAM
Shaughnessy Nos. 005101-005105
(DP Barcode D188729;
CBRS No. 11445; Case 0096)

TASK 2A
Reregistration Eligibility Document:
Product Chemistry Considerations

October 14, 1993

Contract No. 68-D2-0053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

PICLORAM

REREGISTRATION ELIGIBILITY DOCUMENT:

PRODUCT CHEMISTRY CONSIDERATIONS

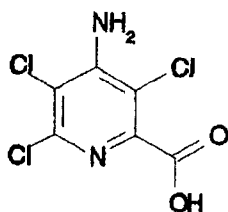
Shaughnessy Nos. 005101-005105; Case No. 0096

(CBRS No. 11445; DP Barcode D188729)

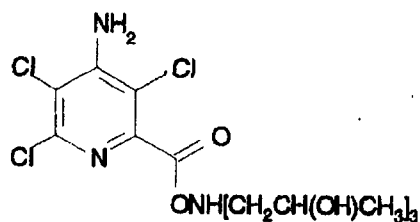
TASK 2A

DESCRIPTION OF CHEMICAL

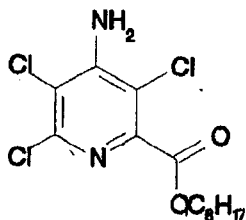
Picloram (4-amino-3,5,6-trichloropicolinic acid) is a selective herbicide for a wide variety of deep-rooted broadleaf weeds and woody plants, used for brush control on roadways, pastures, rangeland, and small grains. Formulations of picloram include an isooctyl ester, and potassium and amine salts.



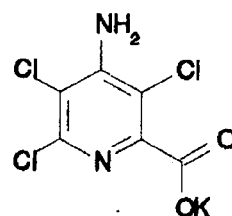
Picloram acid
 Empirical Formula: $C_6H_3Cl_3N_2O_2$
 Molecular Weight: 241.5
 CAS Registry No.: 1918-02-1
 Shaughnessy No.: 005101



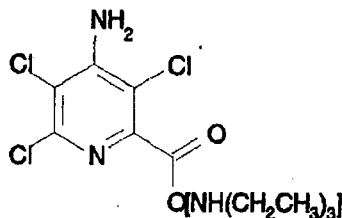
Picloram trisopropanolamine salt (TIPA)
 Empirical Formula: $C_{15}H_{24}Cl_3N_3O_5$
 Molecular Weight: 432.6
 Shaughnessy No.: 005102



Picloram isooctyl ester (IOE)
 Empirical Formula: $C_{14}H_{19}Cl_3N_2O_2$
 Molecular Weight: 353.5
 Shaughnessy No.: 005103



Picloram potassium salt (K-salt)
 Empirical Formula: $C_6H_2Cl_3KN_2O_2$
 Molecular Weight: 280.6
 Shaughnessy No.: 005104



Picloram triethylamine salt (TEA)
 Empirical Formula: $C_{12}H_{18}Cl_3N_3O_2$
 Molecular Weight: 342.5
 Shaughnessy No.: 005105

IDENTIFICATION OF ACTIVE INGREDIENT

The picloram acid technical is an off-white to brown powder which decomposes at 215 C, photodegrades, and is non-volatile. The acid is only slightly soluble in water at 430 ppm at 25 C, and is more soluble in ethanol, acetone, and methanol. The picloram salt formulations are water soluble; the isooctyl ester is not water soluble.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 9/2/93 identified two picloram manufacturing-use products (MPs) registered to DowElanco Company under Shaughnessy Nos. 005101 and 005104: the 72% picloram acid technical (T; EPA Reg. No. 62719-179) and the 34.7% picloram K-salt formulation intermediate (FI; EPA Reg. No. 62719-30). For Shaughnessy Nos. 005102 and 005103 there are no registered MPs, only end-use products (EPs) manufactured by integrated systems. There are no active products registered under Shaughnessy No. 005105; the sole registered product was canceled in January 1984.

At the time of the Reregistration Standard dated 10/84 and the Final Reregistration Standard and Tolerance Reassessment (FRSTR) dated 5/18/88, the only registered MP was the 34.7% K-salt FI. The 72% T was registered in 1990, following issuance of the FRSTR. The DowElanco 72% T and the 34.7% K-salt FI are the only MPs subject to a reregistration eligibility decision. Data pertaining to the technical grade of the TIPA and IOE picloram formulations are also required to satisfy data requirements for reregistration.

REGULATORY BACKGROUND

The Picloram FRSTR dated 5/18/88 required that all new data be submitted in support of the reregistration of picloram and its salts and ester. After the 72% T was registered, the product chemistry database submitted since the FRSTR was re-evaluated. Additional MP data were required for the now registered picloram acid technical, and data were required for the "practical equivalent of the technical grade of the active ingredient" for the picloram salts and ester manufactured by integrated systems.

The Picloram Registration Standard dated 3/29/85 required the limiting of the level of hexachlorobenzene (HCB) in the technical to a maximum of 200 ppm and also required testing for nitrosoamines in picloram products. The sole registrant of picloram products has complied with these requirements; no nitrosoamines were detected in picloram products (< 1 ppm) and the level of HCB has been certified to be less than 100 ppm.

The current status of the product chemistry data requirements for DowElanco picloram and picloram salt/ester products is presented in the attached data summary tables. Refer to these tables for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

All pertinent data requirements are satisfied for the picloram acid TGA1. Provided that the registrant submits the data required in the attached data summary tables, CBRS has no objections to the reregistration of picloram with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s): 5419
Subject: Picloram - EPA Registration No. 464-502. Response of Dow Chemical U.S.A. to the Product Chemistry Chapter Picloram (FRSTR) Registration Standard dated May 18, 1988
From: G. Makhijani
To: C. Grubbs, R. Taylor, and R. Engler
Dated: 07/10/89
MRID(s): 41077701-41077705 and 41094901-41094909

CBRS No(s): 10116
DP Barcode: D179936
Subject: Picloram Reregistration. Product Chemistry Data Requirements.
From: W. Smith
To: V. Eagle and W. Waldrop
Dated: 12/10/92
MRID(s): 41594601-41594603
 (re-evaluated 41077701-41077705 and 41094901-41094909)

CBRS No(s): 11507
DP Barcode: D188834
Subject: Reregistration of Picloram [Triisopropanol Amine (TIPA TGAI) and Potassium (K 34.7% FI) Salts]. List A Chemical (Chemical Nos.: 005102 and 005104; Case No. 0096). DowElanco: Response to the Picloram (TIPA TGAI and K 34.7% FI) Salts Product Chemistry Data Requirements.
From: F. Toghrol
To: L. Rossi and W. Waldrop
Dated: 05/17/93
MRID(s): None; Letter (1993) from George Murphy, DowElanco Analytical and Product Chemistry, to M. Melchar, Product Registration Manager, SRRD.

CBRS No(s): 12289
DP Barcode: D193574
Subject: Reregistration of Picloram Acid TGAI, Triisopropanol Amine (TIPA) Salt, Potassium Salt, and Isooctyl Ester (IOE). List A Chemical Nos. 005101, 005102, 005104, and 005103; Case No. 0096). DowElanco: Response to the Picloram, Salts and Ester Product Chemistry Data Requirements.
From: F. Toghrol
To: L. Rossi and W. Waldrop
Dated: 09/27/93
MRID(s): 42840801-42840811

CBRS No(s): 12788
DP Barcode: D196501
Subject: Picloram, Potassium Salt Product Chemistry...DowElanco Submission of Solubility Data (GDLN 63-8).
From: W. Smith
To: V. Eagle and W. Waldrop
Dated: 12/10/93
MRID(s): 42978101

CBRS No(s): 12822
DP Barcode: D196742
Subject: Reregistration of Picloram Acid TGAI...DowElanco Submission of Revised CSF.
From: W. Smith
To: V. Eagle and W. Waldrop
Dated: 12/10/93
MRID(s): None: Revised CSF dated 11/02/93.

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

- 41094901 Baker, R. (1989) Product Chemistry: Picloram. Unpublished study prepared by Dow Chemical U.S.A. 31 p.
- 41094902 Baker, R. (1989) Product Chemistry: Picloram. Unpublished study prepared by Dow Chemical U.S.A. 73 p.
- 41094903 Baker, R. (1989) Product Chemistry: Picloram. Unpublished study prepared by Dow Chemical U.S.A. 5 p.
- 41094904 Baker, R. (1989) Product Chemistry: Picloram Isooctyl Ester. Unpublished study prepared by Dow Chemical U.S.A. 19 p.
- 41094905 Baker, R. (1989) Product Chemistry: Picloram Isooctyl Ester. Unpublished study prepared by Dow Chemical Co. 19 p.
- 41094907 Baker, R. (1989) Product Chemistry: Tordon K Salt Liquor. Unpublished study prepared by Dow Chemical U.S.A. 17 p.
- 41094908 Baker, R. (1989) Product Chemistry: Tordon K Salt Liquor. Unpublished study prepared by Dow Chemical U.S.A. 21 p.
- 41094909 Baker, R. (1989) Product Chemistry: Tordon K Salt Liquor. Unpublished study prepared by Dow Chemical U.S.A. 5 p.
- 41594601 Baker, R. (1990) Product Chemistry: Picloram TIPA Concentrate. Unpublished study prepared by DowElanco. 16 p.
- 41594602 Baker, R. (1990) Product Chemistry; Picloram TIPA Concentrate. Unpublished study prepared by DowElanco. 17 p.
- 42840801 Murphy, G. (1993) Determination of Color, Physical State, Odor, Melting Point, Density, pH and Stability of Picloram Potassium Salt (K) Technical Grade of Active Ingredient (TGA): Lab Project Number: FOR93047. Unpublished study prepared by DowElanco, Formulations Science and Technology Lab. 10 p.
- 42840802 Krause, R. (1993) Picloram Acid Corrosivity to Epoxy-modified-Phenolic Resin Coated Steel Thirty Day 122 Degree F Storage Test Results: Lab Project Number: FOR93078. Unpublished study prepared by DowElanco, Formulations Science and Technology Lab. 9 p.



- 42840803 Murphy, G. (1993) Determination of Color, Physical State, Odor, Melting Point, Density, pH and Stability of Picloram Trilsopropanolamine Salt (TIPA) Technical Grade of Active Ingredient (TGAI): Lab Project Number: FOR93046. Unpublished study prepared by DowElanco, Formulations Science and Technology Lab. 10 p.
- 42840804 Murphy, G. (1993) Determination of Color, Physical State, Odor, Melting point, Density, pH and Stability of Picloram 2-Ethylhexyl Ester (2-EHE) Technical Grade of Active Ingredient (TGAI): Lab Project Number: FOR91114. Unpublished study prepared by DowElanco, Formulations Science and Technology Lab. 10 p.
- 42840805 Murphy, G. (1993) Determination of Oxidizing or Reducing Action, Flammability, Explodability, Viscosity and Miscibility of Picloram 72% (TGAI): Lab Project Number: FOR93045. Unpublished study prepared by DowElanco, Formulations Science and Technology Lab. 10 p.
- 42840806 Chakrabarti, A. (1989) Vapor Pressure of the 2-Ethylhexyl Ester of Picloram Measured by the Knudsen-Effusion/Weight Loss Method: Lab Project Number: 89-020121R. Unpublished study prepared by The Dow Chemical Co. 11 p.
- 42840807 Nicholson, L. (1989) Determination of the Octanol/Water Partition Coefficient for Picloram 2-Ethylhexyl Ester Using Generator Column Technology: Lab Project Number: ML-AL89-080239. Unpublished study prepared by The Dow Chemical Co. 25 p.
- 42840808 White-Henson, K. (1989) Determination of Water Solubility for Picloram 2-Ethylhexyl Ester Using Generator Column Technology: Lab Project Number: ML-AL 89-080193. Unpublished study prepared by The Dow Chemical Co. 24 p.
- 42840809 Reim, R. (1993) Determination of the Conditional Acid Dissociation Constant of Picloram by Normal Pulse Polarography: Lab Project Number: ML-AL 89-040540R. Unpublished study prepared by The Dow Chemical Co. 10 p.
- 42840810 Murphy, G. (1993) Determination of Solubility of Picloram 2-Ethylhexyl Ester (2-EHE) Technical Grade of Active Ingredient (TGAI): Lab Project Number: FOR91120. Unpublished study prepared by DowElanco, Formulation Science and Technology Lab. 22 p.
- 42840811 Murphy, G. (1993) Response to Letter Written by Lois A. Rossi (1/22/93) Subject: Picloram's Product Chemistry Review: Lab Project Number: GM070993B. Unpublished study prepared by DowElanco, Analytical and Product Chemistry. 11 p.
- 42978101 Murphy, G. (1993) Determination of Solubility of Picloram Salt(K) Technical Grade of Active Ingredient (TGAI): Lab Project Number: FOR93049. Unpublished study prepared by DowElanco, Formulation Science and Technology Lab. 17 p.

Case No. 0096
 Chemical No. 005101

Case Name: Picloram
 Registrant: DowElanco Chemical Company, Inc.
 Product(s): Picloram 72% T (EPA Reg. No. 62719-179)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Requirement Fulfilled? ^a	MRID Number ^b
61-1	Product Identity and Disclosure of Ingredients	Y	<u>CSF dated 11/02/93</u>
61-2	Starting Materials and Manufacturing Process	Y	41094901
61-3	Discussion of Formation of Impurities	Y	41094901
62-1	Preliminary Analysis	Y	41094902
62-2	Certification of Ingredient Limits	Y	<u>CSF dated 11/02/93</u>
62-3	Analytical Methods to Verify the Certified Limits	Y	41094902
63-2	Color	Y	41094903
63-3	Physical State	Y	41094903
63-4	Odor	Y	41094903
63-5	Melting Point	Y	41094903
63-6	Boiling Point	N/A	
63-7	Density, Bulk Density or Specific Gravity	Y	41094903
63-8	Solubility	Y	41094903
63-9	Vapor Pressure	Y	41094903
63-10	Dissociation Constant	Y	41094903
63-11	Octanol/Water Partition Coefficient	Y	41094903
63-12	pH	Y	41094903
63-13	Stability	Y	41094903
63-14	Oxidizing or Reducing Action	Y	42840802
63-15	Flammability	N/A	
63-16	Explosibility	Y	42840802
63-17	Storage Stability	N	
63-18	Viscosity	N/A	
63-19	Miscibility	N/A	
63-20	Corrosion Characteristics	Y	42840802

^a Y = Yes; N = No; N/A = Not Applicable.

^b **Bolded** citations were reviewed under CBRS No. 5419, dated 7/10/89, by G. Makhijani, and were re-evaluated under CBRS No. 10116, D179936, dated 12/10/92, by W. Smith; underlined citations were reviewed under CBRS No. 12822, D196743, dated 12/10/93, by W. Smith; remaining citations were reviewed under CBRS No. 12289, D193574, dated 9/27/93, by F. Toghrol.

Case No. 0096
 Chemical No. 005102

Case Name: Picloram
 Registrant: DowElanco Chemical Company, Inc.
 Product(s): Picloram TIPA TGA1

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Requirement Fulfilled? ^a	MRID Number ^b
61-1	Product Identity and Disclosure of Ingredients	N/A ^c	
61-2	Starting Materials and Manufacturing Process	Y	41594601, Letter ^d
61-3	Discussion of Formation of Impurities	N ^e	41594601
62-1	Preliminary Analysis	N ^f	41594602
62-2	Certification of Ingredient Limits	N/A ^c	
62-3	Analytical Methods to Verify the Certified Limits	N/A ^c	
63-2	Color	Y	42840803
63-3	Physical State	Y	42840803
63-4	Odor	Y	42840803
63-5	Melting Point	Y	42840803
63-6	Boiling Point	N/A	
63-7	Density, Bulk Density or Specific Gravity	Y	42840803
63-8	Solubility	N ^g	
63-9	Vapor Pressure	Y	<u>Letter ^d</u>
63-10	Dissociation Constant	Y	42840809
63-11	Octanol/Water Partition Coefficient	N ^g	
63-12	pH	Y	42840803
63-13	Stability	Y	42840803
63-14	Oxidizing or Reducing Action	N/A ^c	
63-15	Flammability	N/A ^c	
63-16	Explosibility	N/A ^c	
63-17	Storage Stability	N/A ^c	
63-18	Viscosity	N/A ^c	
63-19	Miscibility	N/A ^c	
63-20	Corrosion Characteristics	N/A ^c	

^a Y = Yes; N = No; N/A = Not Applicable.

^b **Bolded** citations were reviewed under CBRS No. 10116, D179936, dated 12/10/92, by W. Smith; underlined citations were reviewed under CBRS No. 11507, D188834, dated 5/17/93, by F. Toghrol; remaining citations were reviewed under CBRS No. 12289, D193574, dated 9/27/93, by F. Toghrol.

^c Not required for the TGA1; these data requirements will be satisfied by EP submissions.

^d Letter (1993) from George Murphy, DowElanco Analytical and Product Chemistry, to M. Melichar, Product Registration Manager, SRRD.

° This information does not fully satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) concerning discussion of formation of impurities because the possible impurities resulting from a starting material unique to the TIPA salt manufacturing process must be addressed.

† These data do not fully satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) concerning preliminary analysis because preliminary analysis data for the impurities present at levels greater than 0.1% and the impurities of toxicological concern that may be present at levels less than 0.1% in the TIPA TGAI must be submitted. We note that if the preliminary analysis is done on the concentrated TIPA solution as was used for preliminary analysis of the active ingredient, then the impurities present at 0.06% or greater must be identified.

° The test substance for physical/chemical properties representing the TIPA TGAI is the isolated active ingredient free of solvent; these data must be submitted on the dry picloram TIPA salt.

Case No. 0096
 Chemical No. 005103

Case Name: Picloram
 Registrant: DowElanco Chemical Company, Inc.
 Product(s): Picloram IOE TGA1

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Requirement Fulfilled? ^a	MRID Number ^b
61-1	Product Identity and Disclosure of Ingredients	N/A ^c	
61-2	Starting Materials and Manufacturing Process	Y	41094904
61-3	Discussion of Formation of Impurities	Y	41094904
62-1	Preliminary Analysis	N ^d	41094905
62-2	Certification of Ingredient Limits	N/A ^c	
62-3	Analytical Methods to Verify the Certified Limits	N/A ^c	
63-2	Color	Y	42840804
63-3	Physical State	Y	42840804
63-4	Odor	Y	42840804
63-5	Melting Point	Y	42840804
63-6	Boiling Point	N/A	
63-7	Density, Bulk Density or Specific Gravity	Y	42840804
63-8	Solubility	Y	42840808, 42840810
63-9	Vapor Pressure	Y	42840806
63-10	Dissociation Constant	N/A	
63-11	Octanol/Water Partition Coefficient	Y	42840807
63-12	pH	N/A	
63-13	Stability	Y	42840804
63-14	Oxidizing or Reducing Action	N/A ^c	
63-15	Flammability	N/A ^c	
63-16	Explosibility	N/A ^c	
63-17	Storage Stability	N/A ^c	
63-18	Viscosity	N/A ^c	
63-19	Miscibility	N/A ^c	
63-20	Corrosion Characteristics	N/A ^c	

^a Y = Yes; N = No; N/A = Not Applicable.

^b **Bolded citations** were reviewed under CBRS No. 5419, dated 7/10/89, by G. Makhijani, and were re-evaluated under CBRS No. 10116, D179936, dated 12/10/92, by W. Smith; remaining citations were reviewed under CBRS No. 12289, D193574, dated 9/27/93, by F. Toghrol.

^c Not required for the TGA1; these data requirements will be satisfied by EP submissions.

^d These data do not fully satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) concerning preliminary analysis because data reflecting preliminary analysis of the TGA1 must be submitted. The impurities present at greater than 0.1% and impurities of "toxicological

significance" present at less than 0.1% must be identified and quantitated. If a concentrated solution is used as the test substance, then the impurities must be identified and quantitated at a level relative to the concentration of the active ingredient (i.e., for a 50% concentrate, impurities must be determined to 0.05%).

Case No. 0096
 Chemical No. 005104

Case Name: Picloram
 Registrant: DowElanco Chemical Company, Inc.
 Product(s): Picloram 34.7% K FI (EPA Reg. No. 62719-30)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Requirement Fulfilled? ^a	MRID Number ^b
61-1	Product Identity and Disclosure of Ingredients	N ^c	41094907
61-2	Starting Materials and Manufacturing Process	Y	41094907
61-3	Discussion of Formation of Impurities	Y	41094907
62-1	Preliminary Analysis	N ^d	41094908
62-2	Certification of Ingredient Limits	N ^c	41094908
62-3	Analytical Methods to Verify the Certified Limits	Y ^e	41094908
63-2	Color	Y	42840801
63-3	Physical State	Y	42840801
63-4	Odor	Y	42840801
63-5	Melting Point	Y	42840801
63-6	Bolling Point	N/A	
63-7	Density, Bulk Density or Specific Gravity	Y	42840801
63-8	Solubility	Y	42978101
63-9	Vapor Pressure	Y	<u>Letter</u> ^e
63-10	Dissociation Constant	Y	42840809
63-11	Octanol/Water Partition Coefficient	N ^f	
63-12	pH	Y	42840801
63-13	Stability	Y	42840801
63-14	Oxidizing or Reducing Action	Y	41094909
63-15	Flammability	N/A	
63-16	Explodability	Y	41094909
63-17	Storage Stability	Y	41094909
63-18	Viscosity	Y	41094909
63-19	Miscibility	N/A	
63-20	Corrosion Characteristics	Y	41094909

^a Y = Yes; N = No; N/A = Not Applicable.

^b **Bolded** citations were reviewed under CBRS No. 5419, dated 7/10/89, by G. Makhijani and were re-evaluated under CBRS No. 10116, D179936, dated 12/10/92, by W. Smith; underlined citations were reviewed under CBRS No. 11507, D188834, dated 5/17/93, by F. Toghrol; MRID 42840801 was reviewed under CBRS No. 12289, D193574, dated 9/27/93, by F. Toghrol; MRID 42978101 was reviewed under CBRS No. 12788, D196501, dated 12/10/93, by W. Smith.

^c These data do not fully satisfy the requirements of 40 CFR §158.155 and §158.175 (Guideline Reference Nos. 61-1 and 62-2) concerning product identity and certified limits because upper certified limits for all impurities present over 0.1% must be submitted along with certified limits for inert ingredients and "toxicologically significant" impurities present below 0.1%.

^d These data do not fully satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) concerning preliminary analysis because data reflecting preliminary analysis of the TGA1 must be submitted. The impurities present at greater than 0.1% and impurities of "toxicological significance" present at less than 0.1% must be identified and quantitated. If a concentrated solution is used as the test substance, then the impurities must be identified and quantitated at a level relative to the concentration of the active ingredient (i.e., for a 50% concentrate, the impurities must be determined to 0.05%).

^e A waiver was granted on 2/3/94 by the Graybeard Committee for analytical methods for the K salt. Methods that have been accepted for the acid and TIPA salt formulations are also acceptable for the K salt formulation.

^f The test substance for physical/chemical properties representing the K-salt TGA1 is the isolated active ingredient free of solvent; these data must be submitted on the dry picloram K-salt.

^g Letter (1993) from George Murphy, DowElanco Analytical and Product Chemistry, to M. Melichar, Product Registration Manager, SRRD.