



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

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SUBJECT: Verification Memorandum for Metolachlor and S-Metolachlor for SF Bay Species

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AND

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This memorandum serves to provide additional information on the use pattern of Metolachlor and S-Metolachlor not captured in the LUIS process. The Registration Division (RD) and the Pesticide Re-evaluation Division's (PRD) role in the verification process are to fill information gaps and provide division appropriate expertise as outlined in the LUIS Verification SOP for RD and PRD.

PRD provides information and status regarding changes to the chemical use (such as application parameters, cancellations, or label language) that occurred as a result of the reregistration process. RD provides information regarding changes to the chemical use that may have occurred after the date of the LUIS label extraction. In the case a "Data Doer Only"¹ report was conducted, the CRM and PM will ensure that all highest application rates are reflected on the EFED Spreadsheet. The CRM

¹ This type of LUIS report is conducted when the AI of interest has more than 50 products. This report will contain: 1. Products actively registered to the data doer; 2. All technical registrations regardless of registrant; 3. All active California special local needs (SLN) registrations.

and PM have drafted the “Registration and Reregistration Verification” section of this memo to clarify knowledge gaps a risk assessor may encounter while using the data contained in the LUIS report.

If further clarification is needed please contact Kaitlin Keller (703-308-8172) and Susan Stanton (703-305-5218).

Registration and Reregistration Verification

Date and Scope of the RED

- The Metolachlor RED was completed in December 1994.
- The “Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED)” for metolachlor and s-metolachlor was completed in June 2002.
- Tolerances for residues of metolachlor in or on food/feed commodities are currently expressed in terms of the combined residues (free and bound) of the herbicides metolachlor and s-metolachlor and their metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound.

Label Uses / Rates and Mitigation

- Uses and application methods cancelled as part of the RED/TRED process:

At the time of the RED, metolachlor uses for potatoes, soybeans and peanuts were being reevaluated due to FFDCA Section 409 Delaney Clause concerns and were determined to be ineligible for reregistration. However, since then these uses have been reestablished based on the Agency’s review of data submitted after the 1994 Metolachlor RED was completed. All other uses of metolachlor were eligible for reregistration.

Since liquid (emulsifiable concentrate) metolachlor is classified as a group C (possibly human) carcinogen and can cause systematic toxicity due to intermediate exposure, more stringent handler safety requirements were imposed, per Worker Protection Standard regulations. However, no application methods were cancelled as part of the RED.

In conjunction with the March 22, 2002 Federal Register Notice (OPP-66292A; FRL-6823-8) the existing uses of metolachlor for the stone fruits group and almonds were cancelled. Almonds will, however, remain in the dietary assessment, as there is a crop group tolerance that exists for tree nuts, and almonds are considered part of the tree nut group.

- Rate changes that occurred as part of the RED/TRED process:

Various label amendments were required as a result of the 2002 TRED for Metolachlor. However, additional changes, such as new uses and product cancellations have since been

made. Please see the BEAD LUIS Report, current as of 11/04/09, for the most recent maximum application rates.

- Mitigation affecting ecological concerns required through the reregistration process:

The following Environmental Hazards statement is required on all labels (RED pg. 59).

- "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment wash water or rinsate.

Multiple label statements were required in the Environmental Hazards section of the label to deter surface and ground water contamination. A complete list of required ground and surface water mitigation label language is on pgs. 60-61 of the 1994 Metolachlor RED. Statements thought to be of particular ecological importance are summarized below:

- This product may not be mixed or loaded within 50 ft. of perennial or intermittent streams and rivers, natural or impounded lakes and reservoirs.
- This product may not be mixed/loaded or used within 50 ft. of all wells, including abandoned wells, drainage wells, and sink holes.

Various label statements, including spray drift language, were also required. A complete list of required spray drift label language is on pgs. 61-64 of the 1994 Metolachlor RED. Statements thought to be of particular ecological importance are summarized below:

- The distance of the outer most nozzles on the boom must not exceed $\frac{3}{4}$ of the length of the wingspan or rotor.
 - Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.
 - Applications should not be made at a height greater than 10 feet above the top of the largest plants unless required for aircraft safety.
 - Drift potential is lowest between wind speeds of 2 – 10 mph.
- There are several metolachlor and s-metolachlor products with specific use restrictions for the state of California. Please see the attached document for more details.

Metolachlor:

- The metolachlor LUIS report is not a "Data Doer Only" report and includes all 18 active Section 3 registrations. There are no California Section 24(c) registrations for metolachlor.
- Metolachlor products with label amendments that impact uses, application rates, or restrictions, approved after the most recent BEAD Label Extraction date are outlined below:

Registration No. 60063-23 has label changes impacting application not captured at the time of the BEAD Label Extraction date of 9/15/2003. The following label language was approved on 12/26/2007, though the most recent label amendment was approved on 11/3/2009:

- On “Table 1 and Table 2 (pages 14 and 16)”; Footnote B now states “Do not exceed this rate on soils that are not highly erodible or on highly erodible soils if at least 30% of the soil is covered with plant residue.”

Registration No. 66222-87 had the following application change made on the label, approved on 6/25/2009 after the BEAD Label Extraction date:

- On page 6, under the Postemergence/layby use in corn section, the word “postemergence,” was removed, as it implies a foliar application to the crop, and this product is not registered for foliar application to corn.

S-Metolachlor:

- The s-metolachlor LUIS report is a “Data Doer Only” report using only Syngenta products and includes 24 active Section 3 registrations and 6 California Section 24(c) registrations for s-metolachlor.
- There are 8 Section 3 s-metolachlor products registered to companies other than Syngenta. Each of these products is a repackaging of a Syngenta s-metolachlor product and each has labeling that is substantially similar to the corresponding Syngenta product label. The product manager has confirmed that the highest use rates for s-metolachlor are accurately reflected by the data doers in the EFED Spreadsheet.
- The chemical review manager confirmed that maximum application rates from Table 4 of the 2002 metolachlor TRED are reflected in the EFED Spreadsheet.
- According to each label, the six California Section 24(c) registrations for s-metolachlor Registration No. 100-816 have the following crop uses, application rates, and use restrictions:

SLN No. CA-010022 may be applied to bell peppers and chili peppers at 1.0 to 1.67 pints/A (0.961 to 1.59 lb a.i./A) to crops no less than 4 inches tall. For both bell peppers and chili peppers, “(1) Do not apply Dual MAGNUM to direct seeded as a preplant or preemergence application, nor as a postemergence application if the crop is less than 4 inches tall. (2) Do not apply more than 1.67 pints/A (1.59 lb a.i./A) of Dual MAGNUM in a single application, nor in total, per crop. (3) Do not apply Dual MAGNUM within 60 days of harvest.”

SLN No. CA-080006 may be applied to spinach crops in “a single broadcast application of Dual MAGNUM at 0.33 - 1.0 pint/A (0.32 lb - 0.95 lb a.i./A) to clean-tilled soil before weeds or crop emerge (i.e. preemergence)...(1) Only one application of Dual MAGNUM is permitted per crop. (2) Do not apply more than 1.0 pint/A (0.95 lb a.i./A) of Dual MAGNUM in a single application. (3) Do not harvest within 50 days of application.”

SLN No. CA-080017 may be applied to dry bulb onions “at 0.67 - 1.33 pints/A (0.64 lb a.i./A to 1.27 lb a.i./A) broadcast starting at the 4th true-leaf stage of dry bulb onions...One additional application may be applied 21 or more days after the first application, if needed. A band application may also be used, applying proportionally less spray mixture on the area actually treated...(1) Make no more than two applications per crop. (2) Apply not more than 1.33 pints/A in a single application and not more than 2.67 pints/A (2.54 lb a.i./A) per crop. (3) The Dual MAGNUM applications cannot be less than 21 days apart. (4) Do not harvest within 60 days of the last Dual MAGNUM application.”

SLN No. CA-080019 may be applied to celery at “0.66 to 1.34 pints/A (0.64 lb to 1.27 lb a.i./A) as a broadcast pre-plant surface applied or as a pre-plant incorporated application prior to transplanting....(1) Multiple applications to the same crop are allowed, but the total amount of Dual MAGNUM applied must not exceed 2.0 pints/A (1.91 lb a.i./A). (2) Do not apply Dual MAGNUM less than 62 days before harvest.”

SLN No. CA-060019 may be applied to Swiss chard as “a single broadcast treatment of Dual MAGNUM at 0.67 to 1.33 pints/A (0.64 lb to 1.27 lb a.i./A) to the soil surface after planting, but before weeds or emerge (i.e. preemergence)...(1) Make only one application per crop. (2) Do not harvest within 62 days of application. (3) Do not apply to direct seeded crops less than 4 inches in height.”

SLN No. CA-030004 may be applied to transplanted and seeded tomatoes. For seeded tomato plants, plants must be at least 4 inches tall at the time of application and the product must be applied in a minimum of 20 gallons of water per acre. The maximum single application rate is 1.33 pints/A (1.27 lb a.i./A) for coarse soils, and 1.67 pints/A (1.59 lb a.i./A) for medium or fine soils. “Do not apply Dual MAGNUM within 60 days of tomato harvest. (2) Do not exceed the maximum label rate for the soil texture per each tomato crop.”

- S-Metolachlor products with label amendments that impact uses, application rates, or restrictions, approved after the most recent BEAD Label Extraction date are outlined below:

Registration No. 100-1148 had a sweet corn use approved, and the following two label language amendments approved after the BEAD Label Extraction date:

- On 1/30/2006, RD stated that the registrant must “Change the timing of application from 12 inch to 30 inch field corn for Conventional, Reduced, and No-Till Tillage Systems, Early Postemergence and Preharvest Interval Sections”
- On 1/13/2005, RD stated to “Increase the Height Restriction for Application to Corn from 5 Inches to 12 Inches”

Registration No. 100-1162 had a potato use added to the label on 10/24/2007. The application instructions for both preemergent and postemergent uses on potatoes contain

the following precaution.

- “Two applications may be applied per year. For potatoes grown in soils with organic matter between 3% and 10% do not apply more than 5.1 pints (3.35 lbs a.i. s-metolachlor) per acre/year; and in soils with organic matter between 0.5% and 3.0% do not apply more than 4.95 pints (3.25 lbs a.i. s-metolachlor) per acre/year. Do not apply more than 1.0 lb. a.i. of metribuzin per acre/year. Boundary 6.5EC is not recommended for application to muck or peat soils.”

Registration No.100-1185, had label changes including use directions for potatoes, sunflowers, and tomatoes, and a change of nomenclature from pod crops to legume vegetables approved on 2/12/2009.

Registration No. 100-816 had label changes approved on 3/21/2008, adding horseradish, rhubarb, and pumpkin use directions.

Status of Product Reregistration

- All 75 products subject to the metolachlor 1995 PDCI for product reregistration were voluntary cancelled.
- The final cancellation order for the last metolachlor product cancelled through product reregistration was issued on July 21, 2005.
- In OPPIN, there are currently 18 active Section 3 metolachlor products. All products were registered after the 1994 RED and thus, were not subject to product reregistration, but contain all the requirements specified in the RED.
- Registrations 11603-43, 19713-539, and 60063-17 are technical grade metolachlor products to be used for manufacturing purposes only, and for this reason the required label statements may vary slightly from those required on end-use products.
- In OPPIN, there are currently 33 active Section 3 s-metolachlor products. All products were registered after the 1994 RED and, thus, were not subject to product reregistration, but contain all the requirements specified in the RED.
- Registrations 100-815, 100-1214, 100-1213, and 100-1215 are technical grade or intermediate products to be used for manufacturing purposes only, and for this reason the required label statements may vary slightly from those required on end-use products.

Registration Division Review

- Separate tolerances were established under §180.368 for s-metolachlor. Tolerances for metolachlor are listed under §180.368(a)(1) through (d)(1), and tolerances for s-metolachlor are listed under §180.368(a)(2) through (d)(2).
- The 2002 TRED reassessed 81 tolerances for metolachlor and s-metolachlor.

Metolachlor:

- EPA Reg. Nos. 19713-539/19713-548 (TGAI/EP): In 2008/2009 Drexel submitted amendments to add several crops (pod crops, dill, tomato, okra, grass grown for seed and soybeans) to its metolachlor labels based on the fact that these uses were approved for s-metolachlor. EPA notified Drexel that they needed to submit or cite data to support these uses. Drexel has resubmitted its request for tomatoes only and it is being reviewed as a PRIA action with a due date of 2/27/2011.
- EPA Reg. Nos. 66222-86/66222-87/11603-43 (EP/EP/MP): In October, 2008, Makhteshim Agan/Agan Chemical Mfg., Ltd. also submitted amendments to add s-metolachlor crops (tomato, grasses, okra and dill) to these metolachlor product labels. EPA notified the company that the new uses must be supported by data. The company has not responded to EPA's letters, dated 5/28/2009.
- EPA Reg. No. 534-98: This product was registered on 7/14/08, after the BEAD General Chemical Report PRD date of 3/8/2007. However, RD noted that information concerning this product and its uses appears on the BEAD General Chemical Report.
- Registrants have submitted minor label revisions via notification for several metolachlor products since the General Chemical Report PRD date. Products for which notifications have been submitted include: 19713-547, 60063-17, 60063-22, 60063-23, 60063-24, 534-98, and 11603-43.

S-Metolachlor:

- During the TRED process, the Agency considered s-metolachlor new use petitions for sunflower, sugar beets, tomatoes, spinach, and grass grown for seed in the TRED. These uses were subsequently approved. Additional s-metolachlor new use tolerance petitions for Swiss chard, peppers, horseradish, pumpkin, and rhubarb were also approved. Uses on asparagus and carrots were approved for Section 24(c) registrations in states other than California.
- EPA Reg. Nos. 100-815/100-816 (TGAI/EP): There are new uses pending on several minor crops associated with IR-4 petition 9E7607, including sesame, melon, bushberry, lowbush blueberry, caneberry, sweet sorghum, leafy brassica greens, turnip greens, carrot, cucumber, okra, bulb onion and green onion. The PRIA due date for these actions is 12/1/2010.
- EPA Reg. No. 100-816: There is an amendment pending for this product to add fall application to corn, cotton, grain/forage sorghum and soybean; and to add use on edamame. The PRIA due date is 4/19/2010.
- EPA Reg. Nos. 100-958, 100-1165 and 100-829: Notifications of minor label revisions were submitted for these products in 2009 have not yet been approved. Since the registrant is not permitted to add uses or change directions for use by notification, these label revisions should not impact current work regarding the San Francisco Bay species case.

- SLN CA030004 (to control yellow nutsedge in tomatoes in California) is not listed on the General Chemical Report but is an active SLN.

Table 1. Metolachlor and S-Metolachlor California Use Restrictions

<i>CHEMICAL</i>	<i>REGISTRATION No.</i>	<i>CROP</i>	<i>USE RESTRICTIONS</i>
S-Metolachlor	000100-00817 000100-00827 000100-00886 000100-01165	Sorghum and Sorghum (silage)	Do not apply preplant incorporated in AZ or the Imperial Valley of CA
S-Metolachlor	000100-00818 (All applications) 000100-00910 (All applications) 000100-00965 (All applications)	Potato, White/Irish	Do not use in Kern county, CA
S-Metolachlor	000100-00818 (All applications) 000100-00964 (All applications)	Peanuts	Do not use in Kern county, CA
Metolachlor	000534-00098 (For preplant, soil incorporated treatments) 066222-00131 (For preplant, soil incorporated treatments) 066222-00132 (For preplant, soil incorporated treatments)	Sorghum and Sorghum (silage)	Do not apply in the Imperial Valley of CA
Metolachlor	060063-00024 (All applications) 066222-00086 (All applications)	Potato, White/Irish	Do not use in Kern county, CA