United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-021 September 1995

R.E.D. FACTS

Asulam

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0265, methyl sulfanilylcarbamate and sodium salt of methyl sulfanilylcarbamate, commonly known as asulam.

Use Profile

Asulam is a selective postemergent systemic carbamate herbicide used to control a variety of annual grasses and broadleaf weeds on sugarcane, Christmas tree plantations, ornamentals, turf (St. Augustinegrass and Bermudagrass) and non-cropland uses (boundary fences, fencerows, hedgerows, lumberyards, storage areas and industrial plant sites, and warehouse lots). Its major use site is sugarcane. The only end-use formulation of asulam is soluble/concentrate liquid (sodium salt of asulam). Asulam is applied by aerial or ground spray, broadcast, band, and spot treatment.

Use practice limitations prohibit applying asulam through any type of irrigation system; discharging into bodies of water; using treated plants for feed or forage; and treating crops/sites within 90 days of harvest.

Regulatory History

Asulam was first registered as a pesticide in the U.S. in 1975. EPA issued a Registration Standard for Asulam in December 1987 (PB88-168588). A 1991 Data Call-In (DCI) required additional neurotoxicity, plant protection, animal feeding, dermal mixer/loader exposure and

inhalation exposure data. Currently, 1 technical asulam product and 3 sodium salt of asulam products are registered.

Human Health Assessment

Toxicity

Asulam technical is of relatively low acute toxicity. It is practically non-toxic by the oral and inhalation routes; technical asulam is in Toxicity Category IV (the lowest of four categories) for these effects. It is slightly toxic by the dermal route (Toxicity Category III). It causes slight eye irritation in rabbits (Toxicity Category III) and is not a skin sensitizer.

In a subchronic dermal study using rabbits, no treatment-related effects were observed.

Asulam is carcinogenic in rats based on thyroid and adrenal tumors in males. It has been classified as a Group C carcinogen --- that is, a possible human carcinogen for which there is limited animal evidence.

In a chronic toxicity study using beagle dogs, reductions in food consumption, body weight gain, vomiting, diarrhea, and reduction in red blood cells, increase in thyroid and kidney weights and reduced testicular weights were noted in the high dose groups. A carcinogenic study using mice cause increased spleen weights in males and decreased brain weights and decreased survival in females.

In a developmental toxicity study using rats, the highest dose level caused maternal toxic effects of decreased body weight gain and slight increase in resorptions. In a study using rabbits, asulam caused maternal effects of decreased body weight.

A 2-generation reproduction study showed a reduction in the number of live births per litter, and decreases in body weight and organ weights. Asulam is not mutagenic.

Dietary Exposure

People may be exposed to residues of asulam through the diet. Tolerances or maximum residue limits have been established for asulam in sugarcane (please see 40 CFR 180.360).

Residue data show that sugarcane concentrates in the processed feed commodity, blackstrap molasses. Under the Delaney clause of the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA may be barred from establishing a feed additive regulation (tolerance) for blackstrap molasses because asulam may be found to be an animal carcinogen within the meaning of the Delaney clause. The Delaney clause prohibits the establishment of a regulation for any food/feed additive that is found to induce cancer in man or animals. Further, under current policy, EPA would not issue these food and feed additive tolerances, and would not continue in effect a tolerance for the associated raw agricultural commodity, sugarcane. The Agency has committed to revoking the underlying raw agricultural

commodity tolerance where food/feed additive tolerances have been established or need to be established but cannot because of Delaney. As part of a settlement agreement in a recent lawsuit, the Agency agreed to complete these revocations by the year 2000. During the 5 years before final revocation, the Agency believes it is important to amend the existing raw agricultural commodity tolerance on sugarcane to reflect new residue data.

The Agency will also establish new meat, milk, and meat by-product tolerances. Current residue data suggest the existing sugarcane tolerance should be raised to 15 ppm from 0.1 ppm. However, the registrant is submitting additional data reflecting longer pre-harvest intervals (PHIs) and more accurate timing of applications which will likely result in a tolerance level lower than the 15 ppm. After reviewing these data, the Agency will establish a new sugarcane tolerance and require the registrant to petition for new meat, milk, and meat by-product tolerances. By amending and establishing tolerances for what may be an interim period, the Agency believes that these actions will prevent possible overtolerance situations and should reduce any public confusion regarding dietary risks associated with a crop or commodity seizure.

In addition, the Agency will also review blackstrap molasses as part of its new policy regarding implementation of Delaney that was recently published in the Federal Register as a response to the National Food Processors Association petition (June 14, 1995; 60 FR 31300). The Agency will determine if blackstrap molasses is "ready-to-eat" as an animal feed. If dilution with other feed items is necessary before animal consumption, and subsequent dilution lowers the level of asulam in the diluted feed mixture to the level of the raw agricultural commodity tolerance, then a processed feed tolerance will not be necessary. Then the new sugarcane tolerance and new meat, milk and meat by-product tolerances will not be revoked.

EPA has assessed the dietary risk posed by asulam. The chronic dietary risk analysis assumed the higher reassessed tolerance level of 15 ppm and 100% crop treated. The Anticipated Residue Concentration (ARC) for the overall U.S. population represents 3.85% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The exposures for the two highest exposed subgroups, children (1-6 years old) and non-nursing infants (<1 year old), are 3.48×10^{-2} and 2.64×10^{-2} mg/kg body weight/day, respectively. These exposure values represent 9.7% and 7.3% of the RfD, respectively. This low fraction of the allowable RfD is acceptable dietary risk.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to asulam during and after applications in agricultural and other settings. However, there are no toxicological endpoints of concern for short to intermediate term occupational exposure.

There are no residential uses for asulam; therefore, no exposure or risk is expected from asulam to homeowners.

The Agency is requiring that the current restricted entry interval (REI) of 12 hours for uses within the scope of the Worker Protection Standards (WPS) be maintained. This 12 hour REI is the minimum acceptable REI for asulam. There are no special toxicological concerns about asulam that warrant the establishment of active-ingredient-based minimum personal protective equipment (PPE) requirements. The Agency is also requiring the following early-entry PPE, which is the minimum required under the WPS: coveralls, chemical-resistant gloves, and shoes plus socks.

Human Risk Assessment

Asulam generally is of low acute toxicity, but it is classified as a non-quantifiable Group C carcinogen (that is, a possible human carcinogen for which there is limited animal evidence), and shows some evidence of developmental and reproductive toxicity. The only food crop use is sugarcane. However, dietary exposure to asulam residues in foods is extremely low, as is the cancer risk posed to the general population.

Application and post-application risks to workers and others are minimal because asulam has no toxicological endpoints of concern for the short to intermediate term occupational exposure. Post-application reentry workers will be required to observe a 12-hour restricted entry interval (REI). The following early-entry PPE is the minimum required under the WPS: coveralls, chemical-resistant gloves, and shoes plus socks.

Environmental Assessment

Environmental Fate

The environmental fate assessment is considered preliminary because of contradictory data. Although there is a lack of acceptable terrestrial field dissipation data and the Agency has concerns about the integrity of data for key laboratory studies, based on the supplemental data, it appears that asulam is highly mobile and has a strong potential to leach into ground water or move offsite into surface water. Also, based on available data (including those from unreliable studies), asulam has the following characteristics: 1) highly to very highly soluble, 2) stable in water without light, 3) unstable in water and on soil under light; however, small amounts of asulam were detected in surface water, 4) relatively unstable in soil under aerobic conditions, 5) very stable in soil and sediment under anaerobic conditions, 6) very mobile in soil, 7) not volatile, and 8) does not accumulate in fish.

The Agency is requiring additional storage stability data (aerobic soil metabolism and anaerobic soil/aquatic metabolism) to validate the results of the laboratory studies and to assess the need for the field dissipation study. In addition, a groundwater label advisory and a surface water label advisory

are required. Due to concerns about off-target damage by the aerial application of asulam, spray drift data (droplet size spectrum and drift field evaluation) and a label advisory are also required.

Ecological Effects

Technical asulam is practically nontoxic to freshwater fish and slightly toxic to freshwater invertebrates. Also, asulam is practically nontoxic to estuarine/marine species, honeybees, and small mammals. Chronic effects to avian species and aquatic invertebrate cannot be fully assessed due to lack of adequate data. However, based on the overall low risk asulam poses to aquatic and avian species, the Agency does not expect that asulam will pose a high chronic risk to aquatic invertebrates or avian species. The Agency is requiring a confirmatory aquatic invertebrate life cycle study. The Agency is not requiring avian reproduction studies due to the extremely short photolytic half-life (approximately 2 hours) and, in acute studies, the practically non-toxic nature of asulam to birds and mammals.

Levels of concern from all uses of asulam have been exceeded for endangered and non-endangered terrestrial and semi-aquatic plants. For non-cropland uses, asulam exceeds levels of concern for endangered and non-endangered aquatic plants. A comprehensive risk assessment for nontarget plants cannot be determined due to the lack of adequate data. High isk to nontarget plants is likely, based on the herbicidal properties of asulam. The Agency is requiring additional phytotoxicity data to complete the nontarget plants risk assessment for asulam.

Ecological Effects Risk Assessment

Asulam poses minimal risk to honeybees. Chronic risk to birds cannot be assessed at this time due to the lack of avian reproduction data. However, the Agency believes there is little potential for adverse effects to avian reproduction as the available environmental fate information indicates that photolysis in water and soil is very rapid -- approximately 2 hours.

Regarding mammals, the use of asulam on noncropland at the maximum use rate, or any other use site, is not likely to adversely affect mammalian reproduction.

Regarding aquatic risks, acute effects are low for aquatic invertebrates. However, chronic effects to fish and aquatic invertebrates cannot be fully assessed without further data.

Endangered and non-endangered species levels of concern are exceeded for terrestrial and semi-aquatic plants for all uses of asulam. For the noncropland use of asulam, endangered and non-endangered species are exceeded for aquatic plants. A comprehensive risk assessment cannot be determined for nontarget plants without further data. When the Endangered Species Program goes into effect, limitation on the use of asulam will be required to protect endangered and threatened species.

Risk Mitigation

Since the current uses of asulam and its sodium salt exceed ecological effects levels of concern, EPA is requiring the following risk mitigation measures.

- Prohibiting the aerial uses of asulam for non-cropland and Christmas trees use sites;
- Clarifying the non-cropland use to state 1 gallon/acre rate, 1 application per season;
- Clarifying the Christmas tree uses to state 1 application per season;
- Clarifying the turf use to state sod farms use only and 1 application per season;
- Ground water label advisory;
- Surface water label advisory; and
- Long term ground water monitoring in and near asulam use areas.

The registrant also is required to clarify the environmental fate assessment methodology and the uncertainty associated with the extraction technique and recovery of asulam from the laboratory versus the field studies.

Additional Data Required

EPA is requiring the following additional generic studies for asulam and its sodium salt to confirm its regulatory assessments and conclusions:

Acute Aquatic Invertebrate Toxicity - *Daphnia magna*;

Aerobic Soil Metabolism;

Anaerobic Soil and Aquatic Metabolism;

Droplet Size Spectrum;

Drift Field Evaluation;

Directions for Use - Label amendment (lower application rate and/or longer PHI);

Plant Metabolism Study;

Magnitude of Residue - Sugarcane; and

Confined Rotational Crop

After reviewing additional field trial data for sugarcane, the Agency will establish a new sugarcane tolerance and require the registrant to petition for new meat, milk and meat by-product tolerances.

Certain data are not part of the reregistration target database for asulam, but are also required:

Seedling emergence - soybeans and radish

Vegetative vigor - cucumber and onion

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All asulam end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Worker Protection

Personal Protective Equipment/Entry Restrictions; Labeling

Personal Protective Equipment (PPE) for Handlers (Mixer/Loader/Applicators)

The PPE for mixer/loader/applicators is to be based on the acute toxicity of the end-use product.

Entry Restrictions for Occupational-Use Products (WPS Uses)

Based on the assessment of human health risks, the Agency does not believe an increase in the REI above what is required in the Worker Protection Standard (WPS) is warranted. The current 12 hour REI, pertaining to each use of the product that is within the scope of the WPS, is to be maintained. This 12 hour REI is the minimum acceptable REI for asulam.

Early Entry PPE: The PPE for early entry are the minimum that would be required under the WPS. These are: coveralls, chemical-resistant gloves, shoes, and socks.

Entry Restrictions for Occupational-Use Products (NonWPS Uses)

Some registered uses of asulam are outside the scope of the Worker Protection Standard (WPS). For nonWPS uses the Agency is requiring the following.

"Do not enter or allow others to enter the treated area until sprays have dried."

Other Labeling Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing asulam that are intended primarily for occupational use:

Products Intended Primarily for Occupational Use

Engineering Controls Used

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard for Agricultural Pesticides (WPS) [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS. However, full PPE must be available in the event that the handler exits the aircraft, enclosed cab, etc. prior to the REI."

User Safety Requirements

"Follow manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Statements

"Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users must leave the treated area, and remove clothing immediately if pesticide gets inside."

"Users must remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Wash the outside of gloves before removing."

Application Restrictions

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only handlers with appropriate PPE may be in the area during application."

Homeowner-Use Products

There are no products containing asulam that provide directions intended for homeowner use. Current labelling provides the statement, *"For agricultural or commercial use only, not for use by homeowners."* This statement must be maintained.

Environmental Hazard

The labels of all asulam end-use products must be revised to bear the following under the **Environmental Hazard Section**:

Wetland Statement

"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."

Ground Water Advisory

"This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

Surface Water Advisory

"Surface water contamination may occur in areas with poorly draining soils and little or no buffers or in areas where drainage systems flow directly to surface water."

Application Restrictions

The labels of all asulam end-use products must be revised to bear the following application restrictions under the **Directions for Use Section:**

For noncropland and Christmas tree uses

"Aerial application is prohibited"

For turf uses

"For sod farm use only"

Application Rates

The labels of all asulam end-use products must be revised to bear the following application rates under the **Crop Uses Section** for the respective crops:

For asulam use on noncropland sites

A maximum application rate of 1 gallon/A with use limited to single application per year.

For asulam use on Christmas trees

A maximum application of 1 gallon/A with use limited to single application per year.

For asulam use on turf (sod farm use only)

A maximum application of 1 gallon/A with use limited to single application per year.

Spray Drift

The following language must be placed on each asulam product label that can be applied aerially:

"AVOIDING SPRAY DRIFT AT THE APPLICATION SITE IS THE RESPONSIBILITY OF THE APPLICATOR."

"The interaction of many equipment and weather-related factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making decisions."

"The following drift management requirements must be followed to avoid off-target movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations."

1. "The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor."

2. "Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees."

"Where states have more stringent regulations, they should be observed."

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory below.

AERIAL DRIFT REDUCTION ADVISORY

The following aerial drift reduction advisory information must be contained in the product labeling:

[This section is advisory in nature and does not supersede the mandatory label requirements].

Information on Droplet Size

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (See Wind, Temperature and Humidity, and Temperature Inversions).

Controlling Droplet Size

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.
- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.
- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.
- Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.
- Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low- drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

Boom Length

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

Application Height

Applications should not be made at a height greater than 10 feet above the top of the target plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

Swath Adjustment

When applications are made with a crosswind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator should compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.).

Wind

Drift potential is lowest between winds speeds of 2 -10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

Temperature and Humidity

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

Temperature Inversions

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

Sensitive Areas

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g, when wind is blowing away from the sensitive areas).

Regulatory Conclusion

Although levels of concern are exceeded for endangered and non-endangered plant species and surfacewater and groundwater quality, the Agency concludes that the current registered products containing asulam and its sodium salt for all uses, with the exception of sugarcane, once amended to reflect the risk mitigation measures imposed in this RED, are eligible for reregistration. Therefore, products containing asulam and its

sodium salt for uses on Christmas tree plantations, ornamentals, turf (St. Augustinegrass and Bermudagrass), and non-cropland (boundary fences, fencerows, hedgerows, lumberyards, storage areas, industrial plant sites, and warehouse lots) are eligible for reregistration.

EPA is unable to make a reregistration eligibility decision regarding the use of asulam and its sodium salt on **sugarcane** because data show that asulam concentrates in the processed animal feed commodity, blackstrap molasses. Under current policies, the establishment of the necessary feed additive regulation (tolerance) to cover residues in this commodity may be barred by the Delaney clause of Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) because asulam may induce cancer in animals within the meaning of the Delaney clause.

Asulam and its sodium salt products with eligible uses will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for asulam during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the asulam RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the asulam RED, or reregistration of individual products containing asulam and its sodium salt, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 8:00 pm Eastern Standard Time, Monday through Friday.