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OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

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MEMORANDUM

DATE: October 4, 2010

SUBJECT: Section 3 Request for Zonastat, a New Chemical Proposed for Use to Control Wild Horses and Burros

FROM: Nancy Andrews, Chief  
Edward Odenkirchen, Senior Advisor  
Sujatha Sankula, Lead Biologist  
Brian Anderson, Biologist  
Environmental Risk Branch 1/EFED (7507P)

*[Handwritten signatures and dates: 10/04/2010]*

TO: John Hebert, Product Manager  
Insecticide Rodenticide Branch  
Registration Division (7505P)

1. Summary of Proposed Action:

The Humane Society of the United States is applying for Section 3 registration for ZonaStat-H (porcine Zona pellucida) to control feral and wild horses and burros. The active ingredient is porcine Zona pellucida (PZP), which is an immunocontraceptive vaccine that is administered to target animals via intramuscular injection (either by dart or by hand).

The application rate is 1.0 cc of PZP + adjuvant (modified Freund's complete adjuvant or modified Freund's incomplete adjuvant). A second administration is given 2 to 4 weeks after the initial priming dose then annually thereafter.

This memorandum discusses the data requirements and qualitatively characterizes potential risks to non-target organisms from the proposed use.

## 2. Status of Submitted Data

No studies have been submitted in support of this Section 3. Waivers were submitted to fulfill required ecological effects and environmental fate guideline studies. Although the proposed use could qualify as outdoor uses, there are no exposure routes to non-target plants or animals that are likely to occur (see Section 3 of this document). Given the lack of potential exposures to non-target organisms, the proposed use pattern is more consistent with an indoor use from a data requirements perspective. For indoor uses, no studies are required. However, an acute oral study in birds, acute studies in aquatic animals, and hydrolysis studies are conditionally required. These studies are not considered to be necessary for the proposed uses for the following reasons:

- **Acute oral studies in birds:** Oral exposure could occur via consumption of treated animals. However, the proposed active ingredient is a protein that is expected to be denatured after oral consumption. This is evidenced by the lack of efficacy via oral exposure (the active ingredient must be injected to target animals to be effective). Therefore, acute oral toxicity studies are not being required at this time.
- **Acute studies in aquatic animals and hydrolysis:** Potential for contamination of water is limited. The active ingredient is not expected to be excreted intact from treated animals. Therefore, exposure to aquatic systems is limited to entry of wayward darts. A dart contains 100 ug of active ingredient (MRID 47859805). Therefore, even if the contents of a dart were to enter a pond the size of EPA's standard ecological water body of 20,000,000 L, the resulting concentration would be 0.005 ng/L.

Due to the limited possibility of exposure occurring to non-target aquatic or terrestrial animals, no data are being required at this time for the proposed use.

## 3. Potential Exposure and Risk to Non-Target Organisms

Given that the proposed administration route is by injection (either dart or hand) to the target animal, potential exposure routes for non-target organisms resulting from labeled uses is somewhat limited. Potential exposure pathways to non-target organisms could include secondary exposure to carnivores, exposure to excreted material, and exposure from wayward darts (accidental exposure). All of these exposure pathways, however, are considered unlikely to result in potential risks to non-target organisms at levels of concern to the Agency as described below.

Dietary exposure to Zonastat is not expected to result in adverse effects at levels of concern to the Agency because it is a protein that is anticipated to be deactivated in the digestive tract, and absorption from the GI tract is expected to be limited. Also, excretion data indicates that the short half-life in treated mammals suggests that the potential for secondary exposure is limited.

Potential exposure to aquatic environments is expected to be limited to accidental exposures. However, as previously discussed, even if a wayward dart were to enter a water body and all of the Zonastat within the dart were to enter a water body, the resulting concentration would be negligible ( $5 \times 10^{-9}$  mg/L). Because the active ingredient is a protein, it would be expected to be rapidly degraded in natural waters.

#### **4. Threatened and Endangered Species Concern**

##### **4.1. Action Area**

For listed species assessment purposes, the action area is considered to be the area affected directly or indirectly by the Federal action and not merely the immediate area involved in the action. At the initial screening-level, the risk assessment considers broadly described taxonomic groups and so conservatively assumes that listed species within those broad groups are co-located with the pesticide treatment area. This means that terrestrial plants and wildlife are assumed to be located on or adjacent to the treated site and aquatic organisms are assumed to be located in a surface water body adjacent to the treated site. The assessment also assumes that listed species are located within an assumed area, which has the relatively highest potential exposure to the pesticide, and that exposures are likely to decrease with distance from the treatment area.

If the assumptions associated with the screening-level action area result in RQs that are below the listed species LOCs, a "no effect" determination conclusion is made with respect to listed species in that taxa, and no further refinement of the action area is necessary. Furthermore, RQs below the listed species LOCs for a given taxonomic group indicate no concern for indirect effects upon listed species that depend upon the taxonomic group covered by the RQ as a resource. However, in situations where the screening assumptions lead to RQs in excess of the listed species LOCs for a given taxonomic group, a potential for a "may affect" conclusion exists and may be associated with direct effects on listed species belonging to that taxonomic group or may extend to indirect effects upon listed species that depend upon that taxonomic group as a resource. In such cases, additional information on the biology of listed species, the locations of these species, and the locations of use sites could be considered to determine the extent to which screening assumptions regarding an action area apply to a particular listed organism. These subsequent refinement steps could consider how this information would impact the action area for a particular listed organism and may potentially include areas of exposure that are downwind and downstream of the pesticide use site.

For this assessment, RQs were not calculated. However, use of Zonastat could result in the following environmental effects:

1. Reduction in wild horses/burros;
2. Increased risk of death and morbidity resulting from allergic responses.

These possible environmental effects could affect listed species by the following:

- Reduction in wild horse populations could constitute an avenue for effects on listed species by reducing prey base of listed species (negative effect);
- Reduction in wild horse populations could result in habitat responses that may positively affect listed species due to reductions in overpopulation;
- Increased presence of moribund animals that may occur via allergic responses could result in increased carrion availability (i.e. food for condors, positive effect);

#### 4.2. Co-Location Analysis

To determine whether the proposed uses are geographically associated with known locations of listed species, a screening-level search of the LOCATES (version 2.10.3) database is typically conducted. The database compared county-level location data for listed species with county-level crop production data (as available in the 2002 agricultural census) to identify any coarse overlaps of listed species with the proposed labeled uses of Zonastat. Listed species are those that are currently on the Federal list of endangered and threatened wildlife and plants. However, for the current proposed registration for use of Zonastat on wild horses and burros, there are no geographical limitations included on the labels, and geographical limitations regarding where Zonastat may be used are uncertain. Therefore, it is assumed that Zonastat may be used in any county in the United States for the screening level analysis. For this reason, it is assumed that every federally listed species may be affected by the proposed uses of Zonastat, and a LOCATES analysis was not conducted.

The LOCATES database identifies those U.S. counties that include non-crop and turf areas and that have federally-listed endangered or threatened species that may be directly or indirectly affected. The list of affected species derived from LOCATES was not included in this assessment because the uses cover most of the United States and the direct and indirect effects includes most species. With additional refinement by exploring more detailed use patterns and species biology (e.g., geographic location, specific feeding habits, time of year likely to utilize crop fields), some species listed may be determined to be not likely to be affected.

#### 4.3. Taxonomic Groups Potentially at Risk

A summary of the risk conclusions and direct and indirect effects determinations is presented in **Table 1**. Because the proposed uses cannot be geographically limited, all federally listed species are assumed to be potentially indirectly affected.

Listed Taxonomy	Direct Effects	Indirect Effects
Terrestrial and semi-aquatic plants – monocots and dicots	No	Yes
Terrestrial invertebrates	No	Yes
Birds (surrogate for terrestrial-phase amphibians and reptiles)	No	Yes
Mammals	No	Yes

Listed Taxonomy	Direct Effects	Indirect Effects
Aquatic vascular plants	No	Yes
Aquatic non-vascular plants	No	Yes
Freshwater fish (surrogate for aquatic-phase amphibians)	No	Yes
Freshwater Invertebrates	No	Yes
Freshwater Benthic Invertebrates	No	Yes
Estuarine/Marine Fish	No	Yes
Estuarine/Marine Crustaceans	No	Yes
Estuarine/Marine Mollusks	No	Yes
1. Effect on listed species may be negative or beneficial		

## 5. Conclusions

The available data suggest that potential exposures to non-target animals is not expected to result in any significant risk concerns to terrestrial or aquatic organisms from the proposed use. However, indirect effects (potentially beneficial or negative) to Listed species could not be precluded.