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IRB BRANCH REVIEW - TSS

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ETIOLOGY

VARGON™

FILE OR REG. NO. 72919-R

PETITION OR EQ. PERMIT NO. _____

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DATA ACCESSION NO(S) 453557-02, 493076-11, 453076-10, 455511-04, 455511-04

PRODUCT MGR. NO. 04

PRODUCT NAME(S) EH-2001

COMPANY NAME Exit Holdings, L.L.C.

SUBMISSION PURPOSE registration

CHEMICAL & FORMULATION 10.89% mustard seed powder, 6.91% alpha-olefin

sulfonate, sodium liquid

Efficacy Review: EH-2001, 72919-R
Exit Holdings, L.L.C.
Phoenix, AZ 85009

200.0 INTRODUCTION

200.1 Uses

A 10.89% "Mustard seed powder [*Brassica hirta*]" and 6.91% "α-olefin sulfonate, sodium" liquid mixture proposed for U.S. Federal registration as a sort of burrow fumigant to be used

... only ... for the control of Richardson's Ground Squirrel [*Spermophilus richardsonii*] and the Wyoming Ground Squirrel [*Spermophilus elegans*] in rangeland, ornamental plantings, orchards, golf courses, nurseries, and non-crop rights of way.

200.2 Background Information

See registration jacket for this pending product, which is undergoing simultaneous review in Canada and the U.S. No formal U.S. efficacy reviews have previously been conducted for this product, but IRB gave the applicant's agent some efficacy-related feedback via a letter dated 7/19/01. There also are copies of many e-mail exchanges in this product's jacket.

This review considers two efficacy data packages which were received by EPA on 1/18/01 and two additional efficacy data packages which EPA received on 12/4/01. Letters found in the jacket indicate that the submission received on 1/18/01 is dated 1/16/01 and that the submission received on 12/4/01 is dated 11/29/01.

201.0 DATA SUMMARY

200.1 Formulation

There are two Confidential Statements of Formula (CSFs) on file for this product. Dated "12/30/00" and "November 28, 2001", the two CSFs describe the same formulation. Use of that formulation in the efficacy studies is claimed but not documented.

200.2 Efficacy Data

The efficacy studies submitted to support the claims of effectiveness proposed for this product are cited and discussed immediately below.

Proulx, G. (1998) Product performance: testing the ability of EH-2001 ("Exit") to control Richardson's ground squirrels *Spermophilus richardsonii*. Unpublished (?) report, Alpha Wildlife Research and Management, Ltd., Sherwood Park, Alberta, Canada. 11 pp.

MRID# 453577-02

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The 5 pages of text and 2 pages of pictures which comprise the "meat" of this document have the appearance of pages extracted from a publication and put into a volume formatted as OPP prefers to see data submissions.

In the "INTRODUCTION" to this report, Proulx mentions unpublished laboratory trials in which captive *S. richardsonii* in cages were "submerged in plastic containers filled with EXIT foam". According to Proulx,

They all lost consciousness within 3 minutes. Animals showed emphysematous changes in the lungs that were associated with asphyxiation. Foam accumulated in the airways and interfered with respiration, and caused anoxia (an abnormally low amount of oxygen) in the blood. On the basis of laboratory tests, EXIT appeared to have the potential to quickly kill Richardson's ground squirrels.

While such results perhaps persuaded Proulx to field-test this product, the procedures and results of the laboratory test should have been written up and submitted for review. In the quoted passage, Proulx claims much about the mode of action and potential for efficacy for this product. It would be wise to determine the extent to which the claimed physical and physiological effects were documented.

Proulx's field trial was run in Cochrane, Alberta, over the period from 4/26/98 to 5/1/98. In the U.S., ground squirrels typically are active at that time of year, possibly with all age and sex classes being visible above ground. I do not know to what extent that pattern might hold true in Cochrane, which is located near Calgary.

Proulx reports having used the product at 2 sites where Richardson's ground squirrels occurred. One site was a 7500-m² (about 1.85 acres) portion of a "pasture range". The other was a 1250-m² (about 0.31 acres) portion of an alfalfa field. Based on observations of live animals at the pasture site, Proulx inferred that ground squirrel densities were "≥25/hectare (about 10/acre) there. He writes that squirrels "appeared to be as dense" in the alfalfa field as in the pasture, but did no formal counting.

Proulx used active burrows as his sole method for assessing the impacts of experimental use of EXIT (aka "EH-2001"). He shoveled in dirt to close burrow openings one day, inspected them for reopening the next day and treated the active burrows with the product on the afternoon of that same day.

Product reportedly emulsified with water "at a 1:100 ratio" was applied by injection at 30 psi pressure through "a metal grill" and into "each re-excavated burrow opening" until "the foam overflowed the burrow opening". The grill

was placed over the hole to stop ground squirrels attempting to escape the treated burrow.

Once a hole had been treated to overflowing, the grill was removed and the hole was packed with dirt "to retard recolonization." In an attempt to limit reinvasion, Proulx treated a 30-m (98-ft) buffer strip around the census areas. Such a strip would not

have been wide enough to stop reinvasion if a portion of an area of occupied contiguous habitat had been set aside for treatment.

As the "Range pasture" site, Proulx reports having initially treated 192 burrow openings, finding 2 of them open (and/or) finding 2 "invasions" on the second day, treating those burrows, finding one active (and/or invaded) on the third day, treating that (those) hole(s), finding all burrows inactive on the fourth day, and declaring 100% control as he ended the study.

In the alfalfa field, Proulx reports having initially treated 110 burrows, having one "invasion" and retreatment on the second day, having another "invasion" and retreatment on the third day, and having still another reinvasion and retreatment on the fourth day, whereupon he declared 100% control anyway.

Proulx writes that "invading animals" were in

Shallow re-openings (< 15 cm [6 inches] deep) with dirt spread only on one side of the hole.

Proulx reports having observed 4 squirrels attempting to escape treated burrows in the pasture. (Presumably, he dispatched those animals if they did not succumb on their own.)

Proulx blames a "large badger (*Taxidea taxus*)" as well as invading squirrels for all burrow activity following the initial treatments. Proulx also states that the EXIT product might not effectively control ground squirrels which occupy badgers' burrows because the entrance holes and tunnels for such burrows are too large for the foam to fill them without leaving air pockets.

Proulx notes that EXIT is likely to kill "any invertebrate inhabiting a ground squirrel burrow system" and should not be used in burrows occupied by "endangered species such as the burrowing owl (*Speotyto cunicularia*)." It seems that he wrote "invertebrate" but meant "vertebrate".

Proulx concludes this paper's "**SUMMARY**" section by declaring the following:

EXIT poses no danger for secondary poisoning, and is safe to handle, and easy and quick to use. EXIT is the most effective product currently available for the control of Richardson's ground squirrels.

Proulx has appeared before EPA on behalf of this product. I am not sure what sort of business relationship he might have with its producer. If they had been proposed for use on labeling, "no danger", "safe", "easy and quick", and "most effective" would have been rejected as "false or misleading" claims.

Taken at face value, this report suggests a high degree of efficacy for the product and virtually total effectiveness if treated areas are diligently monitored and retreated. The study is severely flawed, however, by the author's failure to concurrently monitor

ground squirrel activity in untreated areas and his use of but one census technique. That virtually 100% control was obtained (or at least reported) means that any adjustments to control estimates would not have been likely to have "moved" them very much.

If Proulx's results are typical, the product's label should urge follow-up treatments and advise users of that some possibly woody ground squirrels are likely emerge from treated burrows so that contingency plans can be made for dealing with such animals.

Sutherland, W.D. (2000) Product performance: testing the ability of EH-2001 ("Exit") to control Richardson's ground squirrels *Spermophilus richardsonii*. Unpublished report, Sutherland Management Services, Cochrane, Alberta, Canada. 46 pp.

MRID# 453076-11

This paper describes the conduct and results of field trials to control Richardson's ground squirrels in a "vacant field" in Cochrane, Alberta, in mid June of 2000. The monitored treated area was bordered on one side by a tree nursery, which also was treated as part of the buffer zone. An untreated infested area located 75 m (82 yards) away from the monitored treated area and/or its buffer zone was monitored concurrently for ground squirrel activity. The treated area was an irregular quadrilateral 1.87 acres in area. Its surrounding buffer zone totaled 3.78 acres. The monitored check area was 0.6 acres in size.

The product was diluted 1:24 with water "to make a field solution". That "solution" was pumped through "an aeration nozzle to produce a foam" which was pumped through a "steel mesh screen (to retain would-be escapees) and into ground squirrel burrow openings. Treated holes were then plugged with dirt 30-45 seconds after treatment unless a squirrel attempted to escape through the treated hole. In such cases, the procedures quoted below were followed.

1. The restraining screen was kept in place until 60 seconds after all movement had ceased.
2. An attempt was made to recover the carcass of the dead animal by reaching into the burrow entrance with a rubber-gloved hand.
3. When a carcass was recovered, it was put back into the burrow, and the burrow packed with earth.

Sutherland reports that individual burrow treatments lasted from 2 to 200 seconds, depending upon the size of the system. He reports having treated 296 burrows on the treated plot in a little over an hour and a half. As the "Average Application Time per Burrow" reportedly was 19 seconds, the total time figure seems to reflect actual application time only rather than the total time on site associated with applying EH-2001. Nearly a gallon (reportedly 3.5 liters or 3.7 quarts) of "field solution" was used per treated burrow.

Ground squirrel activity was monitored using the closed-burrows method before and after treatment and the visual-counts method after treatment only. Burrows that were closed and flagged prior to treatment were re-checked 48 hours later and then treated and closed. Burrows were closed and flagged but not treated on the check plot. Posttreatment use of this method consisted of monitoring closed burrows daily for 3 days following the first day of treatment. Burrows found open on the monitored treated plot and its buffer zone were treated another time. On the buffer zone, many of the burrows were treated soon after squirrels were observed entering them.

Counts of squirrels visible above ground were conducted on days 3 and 4 following the initial day of treatment. The observer was situated on "the bluff which overlooks both Plots" and, using binoculars, reportedly was able to census both from that one location. Two scan counts of squirrels were made at 5-minute intervals "during periods of peak ground squirrel activity." According to Sutherland,

To validate the comparison, the Treatment Plot was scanned immediately before and after the Control Plot scan.

Sutherland reports the results shown below for the posttreatment opened-burrow census.

<u>Day</u>	<u>Open Burrow Census</u>		
	<u>Treated Burrows</u>	<u>Opened Burrows</u>	<u>% Open Burrows</u>
1	284	3	1.1%
2	289	2	0.7%
3	289	2	0.7%

Sutherland reports that the 5 burrows not accounted for in the (evidently cumulative) "**Treated Burrows**" column for day 1 were ones "that had not been treated the previous day." Those burrows reportedly were treated on day 1. He also states that no "opened burrows were re-opened after the second treatment" and that

All of the open burrows on the three census days had been opened from above by invaders or scavengers.

According to Sutherland, burrows opened from without are easily distinguished from burrows opened from within.

A burrow that has been opened from above by an invader or scavenger will have the excavated dirt spread on one side only of the burrow entrance. A burrow opened from within by the inhabitant will have the excavated dirt in a symmetrical, volcano-like ring surrounding the burrow entrance.

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Sutherland claims 98.9% control for the first treatment, considering "all re-opened burrows" and 100% control considering "only burrows re-opened from within". Either way, it would be wise to have the label for EH-2001 advise daily reinspections and mop-up retreatments until it appears that there is absolutely no further activity.

In the body of his report, Sutherland does not summarize opened-burrow data for the check plot other than indicating that 342 burrows had been reopened there during the pretreatment census period. No posttreatment opened-burrow data appear in the report or in the tables appended to it.

Visual-scan counts on day 3 posttreatment yielded 61 and 68 squirrels on the check plot and none on the treated plot. On the following day 96 and 114 squirrels were seen in two scans of the check plot and no squirrels were seen on either scan of the treated plot. (It was about 16°F warmer on day 4 than on day 3, and the day-3 scans were conducted nearly an hour earlier than were the very-late-morning day-4 scans.) The report includes a color photograph entitled "Control Plot showing Richardson's Ground Squirrel Activity". At least 14 squirrels are visible in that photo. (I did not count objects that looked like rocks but may have been squirrels.)

Sutherland reports a "**Body Count**" of 45 ground squirrels "carcasses following an escape attempt" from the treated plot and a "**Body Count**" of 113 squirrels from the buffer zone. These counts included ground squirrel "carcasses retrieved following an escape attempt" plus squirrels that "were retrieved after treatment" or

that were not retrieved because they retreated into the burrow during treatment, or slid back down into the burrow after becoming unconscious. Also included with these were animals that made an escape attempt from a burrow that was too small to reach into for carcass retrieval.

Information of this sort indicates that users of this product are likely to encounter squirrels close-up during the treatment phase and that contingency plans for dealing with those animals should be advised. It might be best to indicate that such squirrels should be "dispatched using appropriate procedures" to allow an applicator to use techniques which are appropriate for the use site in question and the applicator's experience and comfort level.

Sutherland -- the inventor of this product -- concludes the "**Summary**" section of his report with the paragraphs shown below.

It is concluded that EH-2001 is an effective alternative to poisons. It is safe to use, environmentally benign, and humane. It contains no toxic substances and poses no risk to children, pets, predators or scavengers.

Application of EH-2001 is a fast and efficient method for controlling Richardson's Ground Squirrels. It is site specific and is particularly adaptable to use in an urban environment.

I should observe that this product kills and, therefore, is a poison and contains substances which are toxic as applied. There probably is no pleasant way to die and, while this product is reported to work quickly, it almost certainly causes some discomfort -- hence the escape attempts by exposed squirrels. Respiratory distress is unlikely to be painless. The material would pose risks to any animals that were in burrow systems during treatment. Claims of safety are categorically disallowed in 40 CFR §156.10(a)(5)(ix) and §156.10(a)(5)(x).

This study had some methodological flaws, and the report lacks posttreatment opened-burrow data for the check plot and includes no raw data sheets. Nevertheless, it appears that many squirrels were killed using the method and, if the data are to be believed, that the treated plot was totally cleared of Richardson's ground squirrels.

Mach, J.J. (2000) Field efficacy of EH-2001 for the control of Richardson's ground squirrel (*Spermophilus richardsonii*). Unpublished report, Genesis Laboratories, Wellington, CO, 60 pp.

MRID# 453076-10

Mach, J.J. (2001) Response to Agency deficiency letter dated July 19, 2001 toxicology data re-submission of amended field efficacy study. Unpublished report, Genesis Laboratories, Wellington, CO, 61 pp.

MRID# 455511-04

These documents are considered together as the second seems to be a revised version of the first. The administrative reviewer for this product, Geraldine McCann, noted that animals which formerly were considered to be Richardson's ground squirrels in the geographical area where Mach worked now are considered to be of a separate species, the Wyoming ground squirrels (*S. elegans*). The additional page in the Mach (2001) document is captioned "**FINAL REPORT AMENDMENT**" and notes that the name of the target species has been changed in several places within the report. For this review, I have considered the Mach (2001) version.

The Mach trials were run near the town of Kremmling in Grand County, CO, in May of 2000. The scope of this study was artificially constrained because no experimental use permit (EUP) had been obtained to authorize the field research. Under 40 CFR, §172.3(c)(1), an EUP is "presumed not to be needed to cover "small-scale" terrestrial field trials

conducted on a cumulative total of more than 10 acres of land per pest....

Endeavoring to stay within the 10-acre limit, Mach cut some corners with the study. He did use 45-m (49.2-yard) buffer strips around the census areas. Those were half again as wide as the strips used by Proulx (1998) but evidently still were too narrow (see below). In light of the passage quoted below, it is not clear that Mach had a 45-m treated buffer completely around the censused portion of the treated plot.

Treatment plots were constructed in areas that could have a minimal amount of buffer zone or were positioned adjacent to natural barriers. Plots were kept small so as to be less than ten acres. Ground squirrel populations were sufficient for the test.

Mach reports having used 45-m buffers (between any treated area) for the two check plots which were monitored but not treated.

Mach aimed to have "Census zones" (within treated plots) that contained "an estimated minimum of 20 ground squirrels" each. Mach reports that the treated and check plots were "mapped", but no diagram of those areas appears in his reports.

Mach reports having used visual counts and closed burrows as census methods. The visual counts method was used for 3 consecutive days (5/12-14/00) before treatment and 3 consecutive days posttreatment (5/21-23/00). For this method, binoculars-aided visual scans of census zones were conducted from blinds located 25 m from census areas (and, seemingly within buffer areas). Three such scans (claimed to take about 5 minutes each) were conducted per day. Scans were separated from one another by 15-minute intervals. According to Mach,

The total number of ground squirrels for each of the three counts was recorded. Over the three days of censusing, the greatest number was used for the population index.

The convention for visual counts data is to use the highest number of squirrels observed in any one count during the pretreatment period and to compare that figure to the highest number seen in any one posttreatment count. Judging from raw data sheets appended to his reports, that is what Mach did. (The reason for comparing highest single count rather than a sum or average of scan results is simple: the high-count approach virtually ensures that no squirrel is counted more than once.)

As making more counts means having more chances for obtaining a high count, it is important that the same number of scans be conducted during the pretreatment period and the posttreatment period. Mach got himself in trouble in this regard when he opted to move one of the plots scheduled for treatment

after the first day of visual censusing because of very low ground squirrel counts.

The raw data sheet (Page 45 of 61) appended to the Mach (2001) report indicates that the original "Plot# C" was observed on 5/12/00, with 3, 2, and 3 squirrels having been seen in the 3 scans. On the next page ("45 of 61"), it can be seen that a new "Plot# C" had 16, 11, and 23 squirrels observed in the 3 scans on 5/13/00, and 24, 17, and 18 squirrels counted in the 3 scans on 5/14/00. Curiously, Mach did not elect to move "Plot# B", after scans of it on 5/12/00 yielded 2, 4, and 3 visible squirrels -- one more for its highest count than the original "Plot# C" had. Slated to be a check plot, "Plot# B" had 9, 10, and 9 visible squirrels during the 3 scans conducted on 5/13/00, and 11, 15, and 10 squirrels seen during the scans on 5/14/00.

With adequate pre-trial reconnaissance, I suspect that a "Plot# C" with sufficient squirrel activity would have been established initially.

The closed-burrows method was initiated on 5/14/00, after conclusion of the visual counts scans for that day. In the "**METHODS AND MATERIALS**" section of his papers, Mach states that "all burrow entrances" in each census area were filled "with sod" and checked for residual activity "Forty-eight (48) \pm 3 hours later. The pretreatment activity check reportedly occurred on 5/16/00. Posttreatment activity checks were conducted on 5/21/00 (the day that posttreatment visual counts scans began). As burrows were plugged for treatment, it is likely that only those which had been re-opened and retreated or newly discovered and retreated were deliberately closed by humans after the first day of treatment. Because burrows were still being treated throughout the posttreatment monitoring period for both methods, it seems likely that some treated burrows were rechecked after intervals of about a day.

(Theoretically, having a longer monitoring period in the posttreatment phase than during pretreatment would bias the test in against the product. As dead squirrels do not dig, the bias would come into play only if woozy squirrels recovered or new ones emigrated. As any once-woozy squirrels would be survivors of exposure, it would be useful to learn of their existence. Mach and his crew kept treating any burrows where activity was observed during the time that posttreatment activity monitoring was being performed. The overlapping of those activities likely would have biased the results in favor of the product and clearly interfered with the integrity of the study.)

According to "**Protocol Deviation #1**", initialed by Mach and dated "5/18/00",

The total number of burrows treated was not recorded during the first two days of treatment.

As the "**Reason for Deviation**", Mach writes

Due to time constraints during the applications, we opted not to continue recording the total number of treated burrows. However, in the census zone of each treatment plot, we do have a minimum number of burrows that were present based on the flags from the burrow census of the previous day.

As for the "**Effect of the Deviation**", Mach opines

No effect on the integrity of the study is claimed. The study design still maintains two types of censusing methods for the computation of efficacy, and the total amount of test substance applied to each plot was also maintained.

Reading between the lines, I suspect that Mach went to the field with too small a crew on the application days. He states in the report that 12 hours per day were devoted to making applications, beginning at 6:00 AM on each day. (Mach's report lists a study staff of 5, including Mach as "Study Director, W. Don Sutherland as a "Laborer,

another "Laborer", and two people assigned the title "Biological Technician". One "Biological Technician" was Richard Poché, the President of Genesis Laboratories.)

In his "**Protocol Deviation #3**", Mach actually identifies 3 modifications from protocol. The first of these basically deals with the applicator's inability to do more than a visual assessment of whether an entire burrow system was treated. Considering the nature of the product and the intended circumstances of its use, I feel that what Mach did in this regard (i.e., a best guess based on visual feedback from the foam) was appropriate and consistent with what operational users of this product would do if and when the product is registered.

The second component of "**Protocol Deviation #3**" deals with Mach's use of census areas that "were smaller than the 2.5 acre estimate" given in the study's protocol. Mach uses the constraint of having to keep the total treated area under 10 acres as his explanation for that deviation. I see no problem with the size of the monitored areas except that smaller areas might possibly have too few squirrels to generate useful census data.

The problematic component of "**Protocol Deviation #3**" is the one for which Mach's description is quoted below.

The protocol states "Pre-treatment and post-treatment censusing will bracket the test substance application as closely as possible..." Due to other changes in the protocol, some of the test substance application occurred during the posttreatment censusing.

What actually happened is that Mach and those helping him treated burrows from 5/17/00 through 5/23/00, a period of time which included the entire posttreatment census periods for both methods. During that period of time, they also may have damaged or destroyed some of the burrow systems through digging for carcasses.

As a blanket justification for all 3 elements of "**Protocol Deviation #3**", Mach offers

These changes were necessary to complete the treatment in an effective manner.

This statement seems to betray an odd notion of the purpose of field research. Rather than providing a disinterested and fair evaluation of the product under actual use conditions, Mach seems to have tried to do whatever it took to show off the product in its best possible light, whether if followed protocol or not. He also cut many corners, seemingly persuaded himself, without any possible proof, that whatever he chose to do would not affect the study. He made such a comment for his "**Protocol Deviation #4**" ("No randomization occurred to assign treatments to study plots"), which was implemented "to minimize the total amount of treated acreage." He claimed "No effect on the integrity of the study", but it seems clear enough that this study was compromised.

Mach's bias toward showing the product in its best imaginable light is betrayed in the passage quoted below.

Several ground squirrels were observed coming from well outside the buffer zone to feed on manure in small area ($\approx 2000\text{ft}^2$) within the census zone of plot C. Because these individuals from outside the buffer zone were not treated, they were able to return to the area at will when it became safe. The presence of the treatment crews during the activity period (0600-1800 hrs) kept the ground squirrels away, but as soon as the workers departed the area, as occurred during visual census, the ground squirrels quickly returned and remained in the treatment plot until the crews returned. These ground squirrels were counted in the visual census for treatment plot C, but these data are not representative of the efficacy of EH-2001. In a normal situation, these ground squirrels could be treated and controlled, but the limits of the study negated this opportunity.

What Mach seems to mean here is that there were some squirrels who "lived" (had their burrow systems) outside of the treated area but completely crossed the buffer strip and entered the census area in order to feed in an area that attracted them. Mach adds that, because these squirrels' burrows were [presumed to be] outside of the treated area, EH-2001 could not have been expected to control them, given the relatively small area that was treated. In operational use, Mach says, all squirrel burrows could have been treated, and those animals would have been killed just like the residents of the treated plot.

If Mach were correct in his assumption that the squirrels were not residents of the treated area (as opposed to squirrels scared away by human activities), that would mean that the buffer strips used in this study were way too narrow. As this crew, which included the product's inventor as a "Laborer", was unable to treat the smaller areas involved in the study without working multiple 12-hr days, there would seem to be practical limitations to the amount of acreage that a rancher's application crew would be able to treat without the costs and encroachments upon other responsibilities becoming prohibitive. Obviously, squirrels not in burrows are not going to be killed by a fumigant-like product unless they enter burrows while the foam is still lethal.

Mach might have avoided such problems on Plot C had he not located and relocated it in haste.

A conservative approach to handling the data for Plot C would be to treat the squirrels that Mach describes as immigrants as though they were residents. Considering the plot-relocation business, perhaps the best thing to with the data for Plot C would be to ignore them.

Burrows were treated by squirting substance through a garden hose with "an aspirating nozzle at the discharge end" and through "A flat-bottomed wire mesh basket" which "was placed over the burrow entrance" to restrain would-be escapees. The foam was injected "until it began to come out of the entrance of the burrow." The

material applied consisted of 8 liters of "test substance" (presumably the formulated EH-2001 product) added to 48 gallons of water in a "50 gallon drum". Hopefully, the drum was somewhat oversized as 8 liters plus 48 gallons would exceed 50 gallons in volume. Eight liters in 48 gallons would have provided a dilution ratio of 1:22.7, which would have been slightly stronger than the 1:24 indicated on the label proposed for 72919-1.

Mach reports having applied "EH-2001" at 11.19 gallons/acre in Plot A and at 6.92 gallons/acre in Plot C. Those figures might refer to what Sutherland calls the "field solution", but if Mach used about a gallon of field solution per hole (as Sutherland did), he would have needed more than 11 and 7 gallons of diluted mixture per acre, if the numbers of burrows treated on the first two application days truly were uncountable and 46 burrows in census areas were given mop-up treatments.

Treatment was supposed to begin and be completed on 5/17/00, but treatments were made on every day from 5/17/00 through 5/23/00. As noted above, the numbers of burrows treated on 5/17 and 5/18 were not recorded due to "time constraints".

Mach reports having treated 118 burrows on the two treatment plots "On day 3 of the study" (presumably 5/19/00, the third day of the treatment period) "with 29 confirmed deaths." From 5/19/00 through 5/23/00, Mach reports having treated a total of 224 burrows with 82 "Confirmed Deaths". Of these totals, 178 treated burrows and 72 deaths were in buffer areas, while 46 treated burrows and 10 "Confirmed Deaths" were in census areas. According to Mach,

A confirmed death was considered to be the observation of a ground squirrel hitting the mesh at ground surface during application or the excavation of a carcass after retreatment.

The visual counts data reported by Mach are summarized in the table shown below.

PLOT	PLOT TYPE	HIGHEST SQUIRREL COUNT		"Efficacy (%)"
		<u>Pretreatment</u>	<u>Posttreatment</u>	
A	Treatment	42	2	94.0
B	Control	15	12	20.0
C	Treatment	24	3 ²	87.5 ²
D	Control	24	24	-4.2 ³

These results and their footnotes are taken from Mach's "Table 3". The actual posttreatment maximum for Plot C was 10. In the relevant footnote, Mach defends his using "3" rather than "10" with the argument quoted below.

The efficacy based on the number of ground squirrels observed in the plot was 58.3%, but 7 of the 10 ground squirrels can be justified as invading the census zone during the visual census. Only the three squirrels that were not seen entering the census zone are used to calculate the above efficacy.

That argument is faulty. As these squirrels almost certainly looked pretty much alike (and as Mach's insufficient reconnaissance of Plot C is established), it is unlikely that he could say with certainty that the 7 squirrels that he reportedly had seen entering the census area had not also left it sometime prior to his arrival. Even taking into account observations of apparent homing to burrows, he also would not know for sure whether the 3 squirrels that he chose to count were immigrants that arrived before he did. Even if he knew for sure that he had 3 residents and 7 immigrants for the high count, he is not justified in disregarding the presence of 7 of them because he made no such adjustment to the results for any other plot and made no such adjustment to the pretreatment peak number ("24") for Plot C.

If Mach could accurately discount all immigrants from all observations, the maximum highs might not have been for the scans upon which he chose to base his calculations. For the 8 other posttreatment scans for Plot C, the numbers of squirrels reported were 3, 6, 8, 1, 8, 0, 6, and 6. The number (3) that Mach chose to use to represent posttreatment activity was met in one of these instances and exceeded in 5 of them.

According to the raw data sheet for the posttreatment visual counts results for Plot C, the immigrants were seen coming from an "artichoke buffer". It seems plausible that some (or all) of them might have ventured from the treated area into the artichoke plot to feed there and actually were observed returning to the place where their burrows were. As the observer was in the blind for less than an hour, he would not be in a position to actually know much about the individual squirrels that were visible.

Using the figure of 10 squirrels posttreatment, the decline in observed ground squirrel activity on Plot C would be 58%. That number falls below our lenient criterion of 70% for field efficacy trials involving toxicants. No adjustment of that figure is needed because posttreatment activity did not decline on the related check plot (D).

For Plot A, Mach evidently adjusted the reported results for the decline in visible numbers of squirrels seen on its related check plot (B). I obtained a 94% reduction when I performed such a calculation.

The data reported by Mach for the closed-burrow census are shown below.

PLOT	PLOT TYPE	"Closed Burrow Census Points (Total #)" ¹		"Efficacy (%)"
		<u>Pretreatment</u>	<u>Posttreatment</u>	
A	Treatment	313	11	96.5
B	Control	259	277	-6.9 ²
C	Treatment	104	5	94.6
D	Control	198	177	10.6

According to Mach's footnote "1", Closed burrow census points are identified by an open burrow entrance". The other footnote merely "denotes an increase in activity."

Mach adjusted the control estimate for Plot C based upon results in the related check plot (D) but did not make, or have to make, such an adjustment for Plot A.

Mach and his helpers treated 224 burrows from 5/19/00 through 5/23/02 and an unknown but probably much larger number on 5/17/00 and 5/18/00. Of these, some 42 were located in census areas and were treated while the closed burrow data were being collected. Four more burrows in census areas were treated while the posttreatment visible counts data were being collected. During one posttreatment census phase or the other, some 178 burrows in buffer regions also were treated. These human activities reportedly removed 82 squirrels from the treated areas and probably disrupted the behavior of survivors. It does not appear, therefore, that any fully posttreatment census data were obtained. Mach states,

If the post-treatment census had been postponed, efficacy would likely have increased.

Despite a statement to the effect that, except for failure to calibrate a rain gauge, this research project was conducted according to Good Laboratory Practice standards (GLPs), Mach and his helpers made a shambles out of the planned experimental design for this field trial. The most that can be relatively safely said about their efforts is that they were relentless in their pursuit of active burrows in treated areas and succeeded in killing a bunch of Wyoming ground squirrels. Nothing worthy of being called an estimate of control can be extracted from Mach's data because treatments (and possibly burrow excavations) were on going during the "Post-treatment" activity assessment periods.

Mach reports having found a tiger salamander as the only possible nontarget victim of the burrow treatments. He adds that,

This animal was emaciated and it was not possible to determine whether or not death resulted from the test substance. No necropsy was performed.

Mach reports having searched for carcasses

on a single day due to the short exposure period before the start of the post-treatment census.

As treatments took place over a whole week and completely overlapped posttreatment census periods, I have no idea what Mach is talking about here. It looks to me like he cut another corner. Perhaps more frequent and more appropriate searches would have turned up more carcasses.

Weatherston, I. and Tesch, E. (2001) Response to Agency deficiency letter dated July 19, 2001 product performance. Unpublished paper, Exit Holdings, L.L.C., Phoenix, AZ, 67 pp.

MRID# 455511-04

This item was prepared as a formal response to the "Efficacy" comments which appeared in EPA's letter of 7/19/01. No additional research is described in this document, but items of relevance to the studies discussed above are included.

"Efficacy" item "1." in EPA's letter of 7/19/01 requested information on the numbers of burrows systems or entrances treated in the various efficacy studies (those discussed above).

To item "1.", Weatherston and Tesch respond that 303 burrows were treated in the Proulx (1998) study, 229 in the Mach (2000) study, and "Approximately 800" in the Sutherland (2000) study. They cite the pages in the reports where the information is said to appear. For the Proulx paper, their figure and citation seem to be correct. For the Mach paper, the citation is incorrect as the number "229" on the page cited (17) refers to the number of burrows that were re-opened during the pretreatment census. Mach stated that his crew did not count the number of burrows that they treated on the first two days of the treatment period. For the Sutherland paper, Weatherston and Tesch derived "Approximately 800" by using the actual number (296) of burrow treatments reported for the census area of the treated plot as a basis for extrapolation based on the amount of material used per hole in the census area and the total amount of material used for all treatments to estimate the number of burrows treated on the buffer area, which then was added to the number known to have been treated in the census area to yield an approximate overall total. I believe that the 296 number was the one that Ms. McCann was looking for.

Item "2." in EPA's letter of 7/19/02 dealt with uncertainty about the dilution ratio of the test material in Proulx's (1998) study. If Weatherston and Tesch are correct, someone diluted the material for Proulx to the intended concentration and described the result as a 1:100 dilution which, according to Weatherston and Tesch, corresponds to 1 liter of foaming agent per 100 liters of "field solution."

Item "3." in EPA's letter of 7/19/02 pertained to the evident labor-intensive nature of EH-2001 applications and implied that the label might advise would-be users concerning "the size of area that can practically be treated" using the product. To this, Weatherston and Tesch respond that "EH-2001 can easily be used to treat larger areas", suggesting that applicators should

initially treat the areas most infested and work from these outward to cover the larger areas while simultaneously maintaining the control in the areas previously treated. The cost and labor intensiveness of the product is comparable and often less expensive than other forms of control such as trapping, shooting, poisons, fumigation.

We shall see. The authors proceed to a discussion of how the prognostications of the quoted passage might come to pass. They base their opinion on some per-burrow-treatment data like those discussed above and attempt to compare those numbers to the figures which they believed to be likely for the other methods, noting that all require considerable time to be spent on site and that closing burrows with dirt is a useful procedure to employ, at some point, for other methods as well.

Item "4." of EPA's letter of 7/19/01 noted that no posttreatment data for the closed-burrows method were presented for the check plot in the Proulx (1998). While Weatherston and Tesch devote a paragraph in response, they essentially confirm that no posttreatment burrow activity assessment was done in the check plot as, "There was no Control Plot treatment as such." This seems to mean that the posttreatment burrow counts were based upon burrows closed for treatment and, as no treatments were made on the check plot, Proulx saw no need to close any burrows there. I feel that the need to run a second activity assessment census was a sufficient reason. Considering the variations in ground squirrel activity over time, it is wise to incorporate the monitoring of check plots into field efficacy studies involving such organisms. Only the low degree of residual activity in the treated plot and his use of another census method "saved" the Proulx (1998) study.

Item "5." in EPA's letter of 7/19/02 addressed the possible meaning Proulx's having referred to the product as "EXIT" and the other authors' having called it "EH-2001". Weatherston and Tesch state that "EXIT" was the name proposed originally and that the same formulation was used in Proulx's and Sutherland's studies.

Item "6." in EPA's letter of 7/19/02 asked for clarification regarding the amounts of product and field solution used in the various efficacy studies. Weatherston and Tesch provide information on this account for Proulx's and Sutherland's studies but are silent on Mach's, even though EPA's letter mentioned it specifically.

Item "7." in EPA's letter of 7/19/02 discusses the proposed label statement "**It is very important to ensure the burrow is completely full of foam.**" Specifically, the letter asked how one determines if a burrow system is "**completely full of foam**" and how the product might perform "if the burrows were only *partially* filled." Weatherston and Tesch reply that applicators visually confirm that burrows are "completely full of foam" when foam begins "to come out of the burrow and spill over." To elaborate on this point, they indicate that the label is now to state

Apply EH-2001 through an aspirating nozzle [a 3 gallon/minute nozzle is preferred] until the burrow is full of foam.

They add that squirrels "might be able to breath [sic]" if they were in foam-free portions of partially filled burrows.

In item "9.", EPA's letter of 7/19/01 requested submission of the raw data for the Proulx (1998) and Sutherland (2000) studies. Weatherston and Tesch provide photocopies of pages from a pocket-sized notebook claimed to relate to Sutherland's study and state that they already have provided "All data generated during the Proulx field study". Weatherston and Tesch give a similarly oblique response to the unnumbered request for "information from census methods used to determine populations" for Proulx's and Sutherland's studies.

The notebook pages clearly are related to Sutherland's research project and bear his signature here and there. I confirmed a few data points but did not do a thorough comparison of Sutherland's notebook with the data summarized in his report.

200.3 Label

I received copies of separate pending labels for versions of EH-2001 that are proposed to be registered in Canada and the U.S. My comments deal with the proposed U.S. version ("Page 37 of 48" through "Page 41 of 48" of a document apparently submitted in November of 2001) and concentrate on the proposed claims of effectiveness and the proposed "DIRECTIONS FOR USE". My comments may be passed on to Canada's regulatory authorities.

The U.S. label that I have reviewed bears claim for controlling Richardson's and Wyoming ground squirrels. No efficacy claims apart from the target species claims on the front panel and the text of the use directions appear on the draft label that I have reviewed.

The proposed "DIRECTIONS FOR USE" has some interesting features and some rather odd formatting. Perhaps the oddest items on the label are the caption "USE INSTRUCTIONS" for the paragraph that indicate permitted use sites, target pests, and other use restrictions and the one-word heading "APPLICATION" for the instructions on how actually to use the product. For reasons should be seem self-evident, our vertebrate pesticide group prefers to have the subsection which contains use restrictions to bear the caption "USE RESTRICTIONS".

Although I find most of the proposed text to be adequate, I have drafted a revised set of use directions to address format and content issues without discussing each individual change and tweak. In doing so, I have considered that the user community for this product is likely to be comprised mainly of farmers, ranchers, and assorted types of professional applicators. Such people probably would not stumble over some of the jargon related to application equipment and should be able to handle the endangered-species text, even in the extremely awkward manner in which it appears on the proposed label. (Under "CONCLUSIONS", I attempt to improve upon that text.)

As the product is to be labeled with the signal word "**DANGER**", it ultimately might be classified as a "RESTRICTED USE PESTICIDE" in the U.S. If the proposed precautionary label text is reflective of the toxicity profile for the product, the appearance of the signal word "**DANGER**" on the label would be due to risks associated with ocular exposures. Other possible reasons to consider classifying this product as a "RESTRICTED USE PESTICIDE" would include hazards to nontarget organisms which might occur in ground squirrels' burrow systems including threatened or endangered species the presence of which might be less likely to be detected by untrained applicators.

Whatever the case, the likely users of this product would be folks who a familiar with pesticides and pesticide equipment. Therefore, it would not seem necessary to insist on the sort of label formatting encouraged by Consumer Labeling Initiative (CLI) enthusiasts. Clearly, a CLI-type approach to any particular portion of the label should not be abandoned if sufficient information can be communicated in such a fashion. Considering the likely user community, the direction "**SHAKE CONCENTRATE WELL BEFORE DILUTION AND USE**" would not seem to need as

much prominence on the label as is proposed for it. A statement of that sort might best be placed under "MIXING INSTRUCTIONS".

I have drafted "**DIRECTIONS FOR USE**" for a U.S.-registered product which, pending certain possible political actions currently under discussion, might also be cleared for use in Canada. If the ultimate decision were to limit use of the U.S. and Canadian products to their respective countries, references to Canadian Provinces should not appear on the label for the U.S. product.

Exit Holdings is new to pesticide registration in the U.S. Therefore, our response to them should indicate what sorts of documents constitute "labels" and "labeling". In similar situations, we have found ourselves having to cite first-time registrants for selling "misbranded" pesticide shortly after they were granted registrations.

202.0 CONCLUSIONS

1. A report of the unpublished laboratory trials mentioned in the introduction to the field efficacy study report by Proulx (MRID No. 453577-02) should have been prepared and submitted for review.
2. The field efficacy trial by Proulx (MRID No. 453577-02) was flawed in that there was no concurrent monitoring of ground squirrel activity in untreated (check) area and only one activity census method was used. Nevertheless, the report strongly suggests that a substantial proportion (if not all) of the Richardson's ground squirrels at the use sites were controlled. Such a result is consistent with the proposed claim that this product controls Richardson's ground squirrels.
3. The field efficacy trial by Sutherland (MRID No. 453076-11) was flawed in that there were no pretreatment visual counts surveys and there was no posttreatment active burrow census for the untreated (check) area. "Posttreatment" active burrow data for the treated area were obtained at 24-hr intervals, during which time some burrow treatments still were being performed. However, it is clear that many Richardson's ground squirrels were killed and that the product used was effective against them.
4. The field trial reported by Mach (MRID# 455511-04) deviated from its own protocol in many ways that compromised the integrity of the study (e.g., relocating plots in mid-study, complete overlapping of treatment and "posttreatment" periods, failing to record the number of treated burrows, etc.). The author's decision to discount the presence of 7 the 10 squirrels observed during a "post-treatment" visual counts scan due to a belief that they were not residents of the plot where they were observed is regarded as faulty.

Attempting to look past the many problems of this study, we are left with an account of initial and mop-up treatments that took counts of 82 ground squirrels and possibly a tiger salamander. Completely ignoring the results reported for Plot C, leaves us with data for Plot A which suggest that the repeated treatments eventually greatly reduced the numbers of active Wyoming ground squirrels at

that site. The proposed claim for controlling Wyoming ground squirrels is accepted on that basis.

5. The claims for controlling Richardson's and Wyoming ground squirrels which appear on the front panel of the proposed U.S. label (from November of 2001) are acceptable. No claims or statements which do not appear on the accepted label may be made for this product on printed labels or labeling. All printed matter which accompanies this product in commerce in the U.S. is considered to be labeling which must be reviewed and accepted by EPA before it may be used.
6. Revise and restructure the "DIRECTIONS FOR USE" section to read and appear as shown below.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **READ THIS ENTIRE LABEL BEFORE EACH USE OF THIS PRODUCT.**

USE RESTRICTIONS

This product may only be used for the control of Richardson's ground squirrels (*Spermophilus richardsonii*) and Wyoming ground squirrels (*S. elegans*) in rangeland, ornamental plantings, orchards, golf courses, parks, nurseries, and noncrop rights-of-way. This product must be applied directly to the burrow systems of these species. Observe the intended use area and inspect the burrows to be treated for evidence of threatened or endangered species. **Do not use this product in any area where threatened or endangered species might be present in the burrow system.** See "ENDANGERED SPECIES CONSIDERATIONS" section to determine where threatened and endangered species potentially at risk from this product occur.

Prior to use of this product, observe areas intended for treatment to confirm that Richardson's ground squirrels or Wyoming ground squirrels are actively using the site. **DO NOT** treat unoccupied or inactive burrows. **DO NOT** treat burrows if there is evidence that a snake or weasel has entered in search of prey.

INFORMATION ABOUT TARGET SPECIES

Richardson's ground squirrels occur in the northern Great Plains in portions of the Canadian Provinces of Alberta, Saskatchewan, and Manitoba and in the U.S. in portions of the States of Montana, North Dakota, and South Dakota. Wyoming ground squirrels occur in the U.S. in portions of the States of Nevada, Oregon, Idaho, Montana, Wyoming, Nebraska, and Colorado.

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Burrows of Richardson's and Wyoming ground squirrels vary according to soil type, habitat, climate, and other factors. Burrows may be as deep as 9 feet (about 3 meters). Burrow diameters may reach 10 inches (25 cm) and may vary by species and individual.

MIXING INSTRUCTIONS

Shake concentrate's container well before dilution and use.

Add concentrate to water at a ratio of 1 gallon of concentrate per 24 gallons of water. Stir resulting "field solution" mixture for at least one minute.

Applied at approximately 20 psi, one quart of field solution will produce about 5 quarts of foam and take about 15 seconds to apply.

TREATING BURROWS

Apply mixture under pressure of 20-55 psi through an aspirating nozzle so that the foam appears to fill the entire burrow system. A 3 gallons per minute nozzle is preferred. Follow the specific application procedures indicated below for the target species to be controlled.

Richardson's Ground Squirrels and Wyoming Ground Squirrels

1. Locate openings to burrows actively being used by ground squirrels.
2. Place provided mesh basket over burrow opening.
3. Apply EH-2001 through an aspirating nozzle (and through the mesh basket) until the burrow system appears to be full of foam. **It is very important that the entire burrow system be completely full of foam.**
4. Keep mesh basket in place for approximately 1 minute after foam application has concluded.

If, after application has concluded, a ground squirrel surfaces and bumps against the mesh basket, apply more foam to completely fill up the burrow to the bottom of the mesh basket. Keep the basket in place until there is no further movement.

5. When there is no evidence of further squirrel activity in the burrow, remove the mesh basket; fill the burrow entrance with soil; and tamp down the soil to firmly close the burrow entrance.
6. Move to the next active ground squirrel burrow and treat it as indicated above.

Continue this process until all active ground squirrel burrows have been treated.

Monitor the treated area daily for signs of ground squirrel activity. Using the procedures indicated above, treat any previously untreated active ground squirrel burrows and re-treat any burrows that appear to have been reopened by ground squirrels. Continue monitoring and re-treating burrows until there are no burrows which show signs of ground squirrel activity.

When preparing a revised label, use the format shown above (i.e., center the main section heading "**DIRECTIONS FOR USE**" and left-justify the remaining headings).

7. Center the main heading for the "**ENDANGERED SPECIES CONSIDERATIONS**" section and modify its content as indicated below.

ENDANGERED SPECIES CONSIDERATIONS

NOTICE: It is a Federal offense to use any pesticide in a manner that results in the death of a member of an endangered species. The use of this product may pose a hazard to Federally-designated threatened or endangered species. Contact the nearest regional office of the U.S. Fish and Wildlife Service for current information on the endangered species that may occur in the area where you intend to use this product

Suggested measures for protecting endangered species may have been developed for your State. Consult with your State wildlife or environmental agency to determine whether they have imposed any requirements in your area to protect endangered and threatened species.

Do not use this product within the occupied habitat of the endangered animal types listed immediately below.

Black-footed Ferret (*Mustela nigripes*) - Endangered in:

Colorado - Almosa, Archuleta, ... counties;

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South Dakota - Butte, Corson, ... counties;

Montana - Big Horn, Blaine ... counties;

Utah - Duchesne, Emery, ... Uintah counties;

Nebraska - Adams, Box Butte, ... Webster counties; and

North Dakota - entire state.

Preble's Meadow Jumping Mouse (*Zapus hudsonius preblei*) - Threatened in:

Colorado - Arapahoe, Boulder, ... on the eastern boundary; and

Wyoming - Albany, Converse, ... (northwest to approximately Douglas).

Northern Idaho Ground Squirrel (*Spermophilus brunneus brunneus*) - Threatened in:

Idaho - Adams and Valley counties.

Utah Prairie Dog (*Cynomys parvidens*) - Threatened in:

Utah - Beaver, Garfield, ... Wayne counties.

Wyoming Toad (*Bufo hemiophrys baxteri*) - Endangered in:

Wyoming - Albany county.

American Burying Beetle (*Nicrophorus americanus*) - Endangered in:

South Dakota - Brookings, Haakon, and Union counties.

Ash Meadows Naucorid (*Ambrysus amargosus*) - Threatened in:

Nevada - Nye county.

Where ellipses (...) appear, continue with list of counties as they appear on proposed label discussed here. Check spellings of counties and scientific names.

[NOTE TO GERI McCANN:

I have restructured the endangered species text to make it more readable and to incorporate some text proposed for the use directions which clearly belongs under "ENDANGERED

SPECIES CONSIDERATIONS". I have not attempted to verify the specific listings and have corrected spellings only where I knew them to be wrong. You may receive further input on the content of this section from other reviewers.]

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
July 24, 2002

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