

ATTACHMENT A

Unrecorded Deviations from Standard Operating Procedures (SOP) Field Efficacy and Hazards of Rozol Bait for Controlling Black-tailed Prairie Dogs (*Cynomys ludovicianus*) by Charles E. Lee and Scott D. Hyngstrom (July 26, 2007)

	Date	Study Site	Activity	Page	Unrecorded Deviation or Other Data Quality Issue Not Identified/Reconciled by Study Authors	SOP(s) from Which the Activity Deviated or Other Data Gap
1	10/18/2006	Sallee	Afternoon Visual Scan	RX717	Observer did not note time of sunset	Incomplete or inaccurate record
2	10/19/2006	Sallee	Morning Visual Scan	RX717	Observer did not note time of sunrise	Incomplete or inaccurate record
3	10/20/2006	Hogan	Bait Application	RX719	Performed by "CL & others (see listed 10/20/06 titled 'Helpers')." No "Helpers" list exists	Incomplete or inaccurate record
4	10/21/2006	Sallee	Bait Search	RX722	"Date of search" listed as 10/27/06, initialed by "CL" and dated on 10/21/06	Incomplete or inaccurate record
5	10/22/2006	Hogan	Bait Search	RX746	Bait Availability Search Record not initialed or dated	Incomplete or inaccurate record
6	10/24/2006	Hogan	Carcass Search	RX753	Carcass Search Record not initialed or dated	Incomplete or inaccurate record
7	10/26/2006	Hogan	Bait Search	RX754	Bait Availability Search Record not initialed or dated	Incomplete or inaccurate record
8	10/26/2006	Hogan	Bait Search	RX750	Bait Availability Search Record not initialed or dated	Incomplete or inaccurate record
9	10/26/2006	Hogan	Bait Search	RX750	Searcher not identified	Incomplete or inaccurate record
10	10/30/2006	Sallee	Carcass Search	RX733	1 prairie dog carcass found and noted as "scavenged." Corresponding Carcasses for Tissue Analysis record (RX 739) indicates "intact."	Appendix E, SOP for Carcass Search, RX699; Appendix G, SOP for Handling Carcasses for Analysis, RX701;

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11	10/30/2006	Sallee	Carcass Search	RX733	2 "impaired" ¹ prairie dogs observed but not collected	Appendix E, SOP for Carcass Search, RX699
12	10/30/2006	Hogan	Carcass Search	RX756	Carcass Search Record not initialed and dated	Incomplete or inaccurate record
13	11/1/2006	Sallee	Carcass Search	RX734	1 "impaired" prairie dog observed but not collected	Appendix E, SOP for Carcass Search, RX699
14	11/1/2006	Hogan	Carcass Search	RX757	1 "cottontail" carcass found, corresponding Carcasses for Tissue Analysis record (RX762) notes a "p.dog" carcass was found	Appendix E, SOP for Carcass Search, RX699; Appendix G, SOP for Handling Carcasses for Analysis, RX701
15	11/3/2006	Hogan	Carcass Search	RX758	2 "impaired" prairie dogs observed but not collected	Appendix E, SOP for Carcass Search, RX699
16	11/9/2006	Sallee	Burrow Plugging	RX721	Burrow plugging conducted before visual count	Appendix A, SOP for Visual Count Index, RX695
17	11/10/2006	Sallee	Morning Visual Scan	RX720	Observer did not wait 15 minutes after arriving at location to begin visual count	Appendix A, SOP for Visual Count Index, RX695
18	11/10/2006	Hogan	Morning Visual Scan	RX743	Observer did not wait 15 minutes after arriving at location to begin visual count	Appendix A, Standard Operating Procedure for Visual Count Index, RX695
19	11/10/2006	TNC Control	Morning Visual Scan	RX715	Observer did not wait 15 minutes after arriving at location to begin visual count	Appendix A, SOP for Visual Count Index, RX695

²⁰ Appendix E, SOP for Carcass Search states "The availability of dead or intoxicated prairie dogs above ground will be monitored and recorded as follows... 6. Moribund animals found on the surface will be noted as such...". Neither the Carcass Search Records nor the study narrative differentiates between "impaired," "intoxicated," and "moribund."

	Date	Study Site	Activity	Page	Unrecorded Deviation or Other Data Quality Issue Not Identified/Reconciled by Study Authors	SOP(s) from Which the Activity Deviated or Other Data Gap
20	11/11/2006	TNC Control	Reopening survey	RX716	Reopening survey conducted before visual count	Appendix A, SOP for Visual Count Index, RX695
21	11/11/2006	TNC Control	Afternoon Visual Scan	RX715	Observer did not wait 15 minutes after arriving at location to begin visual count ²	Appendix A, SOP for Visual Count Index, RX695
22	11/11/2006	TNC Control	Afternoon Visual Scan	RX715	Observer did not note time of sunset	Incomplete or inaccurate record
23	11/30/2006	Control KS Rawlins	Afternoon Visual Scan	RX764	Appears to be conducted at same location as the morning visual count ²	Appendix A, SOP for Visual Count Index, RX695
24	11/30/2006	Control KS Rawlins	Afternoon Visual Scan	RX764	Postdated and initialed by "CL" (12/1/06)	Incomplete or inaccurate record
25	11/30/2006	Ryan South	Afternoon Visual Scan	RX768	Conducted at same location as morning visual count	Appendix A, SOP for Visual Count Index, RX695
26	11/30/2006	Ryan North	Afternoon Visual Scan	RX788	Observation location not noted	Incomplete or inaccurate record
27	12/1/2006	NE East Lashley	Afternoon Visual Scan	RX808	Conducted at same location for morning visual count	Appendix A, SOP for Visual Count Index, RX695
28	12/1/2006	NE East Lashley	Burrow Plugging	RX809	Burrow plugging "performed by C Lee", time overlaps with visual count "taken by CL" at Faiman (see RX828)	Incomplete or inaccurate record

² Appendix 5: Protocol Deviations (RX702) and the GLP Study Amendment/Deviation (RX703) recognize that the observation location for the visual count indices were not always located on the southeastern and southwestern edge of a colony due to the colony size. However, the amendment/deviation justification does not address the SOP's direction to conduct the morning and afternoon counts in different locations. Appendix A: SOP for Visual Count Index requires the observer to choose an observation location "at or near the highest elevation on the southeastern edge of the plot for morning counts and at or near the highest elevation on the southwestern edge of the plot for afternoon counts." By following this requirement in the protocol, the observer would be 1) at a raised elevation and 2) facing away from the sun, thus enhancing their ability to accurately see and count any prairie dog activity. The failure to conduct these scans in different locations is included here as the study director has not provided justification in the SOP deviations.

	Date	Study Site	Activity	Page	Unrecorded Deviation or Other Data Quality Issue Not Identified/Reconciled by Study Authors	SOP(s) from Which the Activity Deviated or Other Data Gap
29	12/1/2006	NE West Faiman	Morning Visual Scan	RX828	Visual count "taken by CL" overlaps with burrow plugging "performed by C Lee" at Lashley (see RX809)	Incomplete or inaccurate record
30	12/1/2006	NE West Faiman	Morning Visual Scan	RX828	Conducted at same observation location for afternoon visual count	Appendix A, SOP for Visual Count Index, RX695
31	12/2/2006	Ryan South	Bait application	RX770	ATV-mounted application device used	Label of EPA Reg. No. 7173-244 and SLN label for use on BTPD in KS allows for hand baiting only
32	12/2/2006	Ryan North	Bait application	RX790	ATV-mounted application device used	Label of EPA Reg. No. 7173-244 and SLN label for use on BTPD in KS allows for hand baiting only
33	12/2/2006	NE East Lashley	Bait application	RX810	Bait application was "Performed by CL" overlaps with bait application at Faiman "performed by C Lee" (see RX830)	Incomplete or inaccurate record
34	12/2/2006	NE West Faiman	Bait application	RX830	ATV-mounted application device used	Label of EPA Reg. No. 7173-244 and SLN label for use on BTPD in NE allows for hand baiting only
35	12/2/2006	NE West Faiman	Bait application	RX830	Bait application "Performed by C Lee" overlaps with bait application at Lashley (see RX810)	Incomplete or inaccurate record
36	12/3/2006	NE East Lashley	Bait Search	RX813	Bait search "performed by CL" but Bait Search Record was initiated and dated by someone else	Incomplete or inaccurate record

Date	Study Site	Activity	Page	Unrecorded Deviation or Other Data Quality Issue Not Identified/Reconciled by Study Authors	SOP(s) from Which the Activity Deviated or Other Data Gap
37	NE West Faiman ³	Bait application	RX830	ATV-mounted application device used	Label of EPA Reg. No. 7173-244 and SLN label for use on BTPD in NE allows for hand baiting only
38	NE West Faiman	Bait application	RX830	Bait Application Record states the application method was "Manual" but lists "scale verification" to be completed for mechanical applications	Incomplete or inaccurate record
39	NE West Faiman	Bait application	RX830	ATV-mounted application device calibrated after application started, 569 burrows treated "area... not included in trial, but adjacent so we treated them"	Appendix D, SOP for Use of Bait Dispensing Devices, RX698
40	Ryan South	Carcass Search	N/A ⁴	RX 702: last day of carcass search due to weather, "additional search on day 25" however, no day 25 record exists	Appendix E, SOP for Carcass Search, RX699
41	Ryan North	Carcass Search	N/A	RX 702: last day of carcass search due to weather, "additional search on day 25" however, no day 25 record exists	Appendix E, SOP for Carcass Search, RX699
42	NE East Lashley	Carcass Search	N/A	RX 702: last day of carcass search due to weather, "additional search on day 25" however, no day 25 record exists	Appendix E, SOP for Carcass Search, RX699

³ The bait application on 12/3/06 at the "West Faiman" plot involved burrows outside the "trial area" that were part of an "adjacent colony." It is not clear how close these burrows were to the trial area, nor is it clear whether these burrows were included in the visual count indices or the plugged burrow indices. Given the void of supporting information regarding this extraneous application, the deviations from the SOP during the 12/3 bait application are included in this chart.

⁴ Both Appendix 5: Protocol Deviations (RX702) and GLP Study Amendment/Deviation (RX705) state "Snow cover and wind did not allow us to continue the carcass search every other day. We searched every other day until day 16 and then had an additional search on day 25." However, no Day 25 Carcass Search records for Trial 2 exist in RX 11. While the study authors have provided justification for deviation from the search procedure, there is no justification provided in the GLP Study Amendment/Deviation for the missing records.

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43	12/27/2006	Ryan South	Morning Visual Scan	RX771	Conducted at same observation location as afternoon visual count	Appendix A, SOP for Visual Count Index, RX695
44	12/27/2006	Ryan North	Morning Visual Scan	RX791	Conducted at same observation location as afternoon visual count	Appendix A, SOP for Visual Count Index, RX695
45	12/27/2006	NE West Faiman	Burrow Plugging	RX832	Time and coordinates provided for "dead p dog" found do not match corresponding Carcasses for Tissue Analysis record (see RX851)	Appendix E, SOP for Carcass Search, RX699
46	12/27/2006	NE West Faiman	Afternoon Visual Scan	RX833	Burrow plugging occurred before visual count	Appendix A, SOP for Visual Count Index, RX695
47	12/27/2006	NE West Faiman	Afternoon Visual Scan	RX833	Conducted at same observation location as morning visual count	Appendix A, SOP for Visual Count Index, RX695
48	12/27/2006	NE West Faiman	Afternoon Visual Scan	RX833	Observer arrived at site and conducted visual count more than 4 hrs prior to sunset	Appendix A, SOP for Visual Count Index, RX695
49	12/27/2006	NE East Lashley	Afternoon Visual Scan	RX811	Burrow plugging occurred before visual count	Appendix A, SOP for Visual Count Index, RX695
50	12/27/2006	NE East Lashley	Afternoon Visual Scan	RX811	Conducted at same observation location as morning visual count	Appendix A, SOP for Visual Count Index, RX695
51	3/8/2007	Magnani	Afternoon Visual Scan	RX879	No afternoon visual count index at this site	Appendix A, SOP for Visual Count Index, RX695
52	3/8/2007	Wiese West	Morning Visual Scan	RX901	Conducted at same observation location as afternoon visual count	Appendix A, SOP for Visual Count Index, RX695
53	3/8/2007	Wiese West	Morning Visual Scan	RX901	Observer arrived at site and conducted visual count index more than 4 hrs after sunrise	Appendix A, SOP for Visual Count Index, RX695
54	3/8/2007	Wiese West	Afternoon Visual Scan	RX901	Conducted at same observation location as morning visual count	Appendix A, SOP for Visual Count Index, RX695
55	3/9/2007	Josh Control	Morning Visual Scan	RX852	Conducted at same observation location as afternoon visual count	Appendix A, SOP for Visual Count Index, RX695

	Date	Study Site	Activity	Page	Unrecorded Deviation or Other Data Quality Issue Not Identified/Reconciled by Study Authors	SOP(s) from Which the Activity Deviated or Other Data Gap
56	3/9/2007	Sowers	"Afternoon" Visual Scan	RX856	Observer appears to conduct afternoon visual count in the morning, more than 4 hrs away from sunset	Appendix A, SOP for Visual Count Index, RX695
57	3/9/2007	Sowers	Reopening Survey	RX857	Reopening survey conducted at the same time as the bait application (see RX858)	Appendix B, SOP for Plugged Burrow Index, RX696
58	3/9/2007	Sowers	Bait application	RX858	ATV-mounted application device used	Label of EPA Reg. No. 7173-244 and SLN label for use on BTPD in NE allows for hand baiting only
59	3/9/2007	Magnani	Bait application	RX881	ATV-mounted application device used	Label of EPA Reg. No. 7173-244 and SLN label for use on BTPD in NE allows for hand baiting only
60	3/9/2007	Magnani	Reopening Survey	RX880	Reopening survey conducted at the same time as the bait application (see RX881)	Appendix B, SOP for Plugged Burrow Index, RX696
61	3/9/2007	Wiese West	Reopening Survey	RX902	Reopening survey conducted at the same time as the bait application (see RX903)	Incomplete or inaccurate record
62	3/9/2007	Wiese East	Afternoon Visual Scan	RX925	Visual count conducted at the same time as the bait application by the same individual (see RX927)	Appendix A, SOP for Visual Count Index, RX695
63	3/9/2007	Wiese East	Afternoon Visual Scan	RX925	Visual count conducted greater than four hours prior to sunset	Appendix A, SOP for Visual Count Index, RX695

	Date	Study Site	Activity	Page	Unrecorded Deviation or Other Data Quality Issue Not Identified/Reconciled by Study Authors	SOP(s) from Which the Activity Deviated or Other Data Gap
64	3/9/2007	Wiese East	Bait application	RX927	ATV-mounted application device used	Label of EPA Reg. No. 7173-244 and SLN label for use on BTPD in NE allows for hand baiting only
65	3/9/2007	Wiese East	Bait application	RX927	Bait application and visual count index occur at the same time. "C Lee" conducts visual count, "CL" applies bait using mechanical device (see RX925)	Incomplete or inaccurate record
66	4/1/2007	Wiese West	Burrow Plugging	RX905	Burrow plugging conducted before visual count	Appendix A, SOP for Visual Count Index, RX695
67	4/1/2007	Wiese West	Afternoon Visual Scan	RX904	Burrow plugging conducted before visual count	Appendix A, SOP for Visual Count Index, RX695
68	4/2/2007	Wiese West	Afternoon Visual Scan	RX905	Afternoon survey conducted in same location as morning visual count	Appendix A, SOP for Visual Count Index, RX695
69	4/3/2007	Wiese West	Afternoon Visual Scan	RX906	Visual count conducted greater than four hours prior to sunset	Appendix A, SOP for Visual Count Index, RX695
70	4/1/2007	Sowers	Afternoon Visual Scan	RX859	Observer did not note time of sunset	Incomplete or inaccurate record
71	4/1/2007	Magnani	Afternoon Visual Scan	RX882	Observer did not note time of sunset	Incomplete or inaccurate record
72	4/1/2007	Magnani	Afternoon Visual Scan	RX882	Observation location not noted	Incomplete or inaccurate record

	Date	Study Site	Activity	Page	Unrecorded Deviation or Other Data Quality Issue Not Identified/Reconciled by Study Authors	SOP(s) from Which the Activity Deviated or Other Data Gap
73	4/1/2007	Magnani	Afternoon Visual Scan	RX882	RX882 notes "landowner plugged all burrows yesterday," however RX883 notes on 4/1 that landowner "blew up burrows this am" ^{5 6}	Incomplete or inaccurate record
74	4/2/2007	Sowers	Morning Visual Scan	RX859	Observer did not wait 15 minutes after arriving at location to begin visual count	Appendix A, SOP for Visual Count Index, RX695
75	4/2/2007	Sowers	Morning Visual Scan	RX859	All visual count times conflict (scan 1 "begin 10:35 AM, end 10:32 AM;" scan 2 "begin 10:34 AM, end 10:36 AM")	Incomplete or inaccurate record
76	4/2/2007	Sowers	Morning Visual Scan	RX859	Observer did not note time of sunrise	Incomplete or inaccurate record
77	4/2/2007	Wiese West	Morning Visual Scan	RX904	Observer did not wait 15 minutes after arriving at location to begin visual count	Appendix A, SOP for Visual Count Index, RX695
78	4/2/2007	Wiese West	Morning Visual Scan	RX904	Conducted at same observation location as afternoon visual count	Appendix A, SOP for Visual Count Index, RX695

⁵ Appendix 5: Protocol Deviations (RX702) and the GLP Study Amendment/Deviation (RX707) address the landowner's interference with the "Magnani" plot. However, the Visual Count Index Record (RX882) and the Plugged Burrow Index Record (RX883) conflict in their accounts of this interference (RX882 is dated 4/1 and states the 'landowner plugged all burrows [3/31]' RX 883 is dated 4/1 and states "landowner blew up burrows this am"). This instance of an inaccurate record(s) is included in this list since that conflict is not addressed in the deviation justification.

⁶ Despite the landowner's interference with the study at the "Magnani" plot and the study authors' exclusion of the data from this plot in reaching any conclusions from the study, Respondent included the number of burrows treated in this plot in making the claim "Proven Reliability - In university trials on over 11,400 burrows to provide over 94% control..." in their advertisements.

ATTACHMENT B

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:

Liphatech, Inc.
Milwaukee, Wisconsin

Respondent.

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Docket No. FIFRA-05-2010-0016

Hon. Susan L. Biro

DECLARATION OF MS. CLAUDIA NIESS

State of Illinois
County of Cook

I, Claudia Niess, declare and state as follows:

1. The statements made in this declaration (which consists of three pages) are based on my personal knowledge.
2. I am currently employed as an Environmental Engineer and I am credentialed as an Enforcement Officer with the Pesticides/Toxics Compliance Section of the Chemicals Management Branch, Land and Chemicals Division, U.S. EPA, Region 5. The Pesticides/Toxics Compliance Section was formerly known as the Pesticides & Toxics Enforcement Section. I have been employed as an Environmental Engineer and Enforcement Officer in this capacity since 2005.
3. As an Environmental Engineer and Enforcement Officer in the Pesticides/Toxics Compliance Section, my duties include conducting inspections and other investigative work to determine compliance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as well as other environmental statutes. I have conducted approximately 50 inspections under FIFRA.

4. On February 7, 2012, I testified in the above captioned matter in Milwaukee, Wisconsin.

5. On February 14, 15, 16, 27 and March 1, 6, and 7, 2012, after the hearing in this matter, I periodically conducted an internet search using the keywords "rozol" and "liphatech."

6. The first result returned on each of these searches was a webpage titled "Rozol – Overview" and was found on Respondent's website at www.liphatech.com/overviewRozol.html.

7. The "Rozol – Overview" page referenced multiple pesticide products distributed under the "Rozol" brand name, including Rozol Pocket Gopher Bait Burrow Builder Formula and Rozol Prairie Dog Bait.

8. The "Rozol – Overview" page did not disclose the restricted use classification for either Rozol Pocket Gopher Bait Burrow Builder Formula or Rozol Prairie Dog Bait and contained the claim "Rozol pellets or wheat grains, do not lose their effectiveness when wet – they outlast zinc phosphide with less primary toxicity to non-target species."

9. On February 14, 15, 16, 27 and March 1, 6, and 7, 2012, I printed the "Rozol – Overview" page found at www.liphatech.com/overviewRozol.html.

10. A copy of my print-out from March 7, 2012 is attached to this declaration.

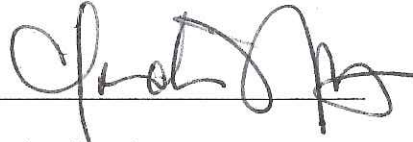
11. On March 12, 2012, I attempted to access the "Rozol – Overview" page; I found its contents were no longer available to the general public and printed a copy of the page as I observed it on that day.

12. A copy of my print-out from March 12, 2012 is attached to this declaration.

13. The assertions I make in this declaration are truthful, and, if called to testify as a witness, I am prepared to testify under oath to the accuracy of the observations and statements contained in this declaration, based on my personal knowledge.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on: June 12, 2012

By: 

Claudia Niess
Environmental Engineer
Enforcement Officer

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Rozol - Overview



Rozol is an effective multiple-feed anti-coagulant with the active ingredient Chlorophacinone.

- Tracking powder can be used by licensed pest management professionals (PMPs) indoors and in rat burrows entering buildings.
- Rozol offers several formulations – one for commensal rodents and additional formulations for field rodents: prairie dogs, pocket gophers, voles, ground squirrels and a burrow builder formula.
- As a field rodent bait, Rozol is made with food-grade grains giving it excellent acceptance and control.
- Rozol pellets or wheat grains, do not lose their effectiveness when wet – they outlast zinc phosphide with less primary toxicity to non-target species.

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- Open **IIS Help**, which is accessible in IIS Manager (inetmgr), and search for topics titled **Web Site Setup**, **Common Administrative Tasks**, and **About Custom Error Messages**.