Note: This study was done using our Professional strength 23 ppm product (Argentyn 23), therefore making Sovereign Silver at 10 ppm, 2.3 times safer. Conclusion on page 6 shows the product to be non-toxic even if 5.83 - 8oz bottles were to be ingested daily.

Final Report

Study Title	Acute Oral Toxicity Study in Rats with Argentyn 23 (EPA/OECD Guidelines)
Author	Monica M. Vegarra, BS
Sponsor	Natural-Immunogenics Corporation 7440 SW 50th Terrace, Unit 107 Miami, Florida 33155
Test Facility	Covance Laboratories Inc. 9200 Leesburg Pike Vienna, Virginia 22182-1699
Covance Study Number	7417-100
Genetic Toxicology Study Number	24742-0-800
Report Issued	24 March 2003
Page Number	1 of 15

QUALITY ASSURANCE STATEMENT

Acute Oral Toxicity Study in Rats with Argentyn 23 (EPA/OECD Guidelines)

This report has been reviewed by the Quality Assurance Unit of Covance Laboratories Inc. and accurately reflects the raw data. The following inspections were conducted and findings reported to the Study Director (SD) and associated management.

Inspection Dates			Date Reported to SD
Start Date	End Date	Phase	and SD Management
07 Jan 2003	07 Jan 2003	Protocol Review	07 Jan 2003
23 Jan 2003	23 Jan 2003	Necropsy	23 Jan 2003
09 Feb 2003	09 Feb 2003	Draft Report and Data Review	11 Feb 2003
21 Mar 2003	21 Mar 2003	Final Report Review	21 Mar 2003

Sara [illegible]
Representative, Quality Assurance Unit

3/24/03
Date

STUDY COMPLIANCE AND CERTIFICATION

Acute Oral Toxicity Study in Rats with Argentyn 23 (EPA/OECD Guidelines)

The described study was conducted in compliance with the Good Laboratory Practice regulations as set forth in the Environmental Protection Agency (EPA-TSCA) Good Laboratory Practice Standards, 40 CFR 792; Organisation for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice, ENV/MC/CHEM (98) 17; and any applicable amendments. There were no deviations from the aforementioned regulations or the signed protocol that would affect the integrity of the study or the interpretation of the test results. The raw data have been reviewed by the Study Director, who certifies that the evaluation of the test article as presented herein represents an appropriate conclusion within the context of the study design and evaluation criteria. All test and control results in this report are supported by an experimental data record and this record has been reviewed by the Study Director.

Exceptions:
1) documentation of the stability, purity, and/or characterization of the test article were not provided by the Sponsor;
2) the stability, homogeneity, and/or concentration of the dosing preparations were not analyzed.

Study Director:

M. Vegarra — March 24, 2003

Monica M. Vegarra, BS
Genetic and Molecular Toxicology
Covance-Vienna

Study Completion Date

Testing Facility Management:

March 24, 2003

Timothy E. Lawlor, MA
Genetic and Molecular Toxicology
Covance-Vienna

Date

Sponsor's Representative

Seth Nosel

Date

Genetic Toxicology Study No.: 24742-0-800

CONTENTS

STUDY IDENTIFICATION

Acute Oral Toxicity Study in Rats with Argentyn 23 (EPA/OECD Guidelines)

Test Material	Argentyn 23
Sponsor	Natural-Immunogenics Corporation 7440 SW 50th Terrace, Unit 107 Miami, Florida 33155

Sponsor's Representative	Seth Nosel
Study Director	Monica M. Vegarra, BS
In-life Supervisor	Rebecca M. Anthony, BS
Study Location	Covance Laboratories Inc. (Covance) 9200 Leesburg Pike Vienna, Virginia 22182-1699

Study Timetable:

Study Initiation Date In-life	30 December 2002 30 December 2002 08
Start Date Initiation of Dosing	January 2003 23 January 2003
In-life End Date	

SUMMARY/CONCLUSION

This study was designed to assess the acute oral toxicity produced when the test material, Argentyn 23, was administered by oral gavage to male and female rats.

The neat test material was administered by oral gavage at a dose level of 20 mL/kg to a total of 10, healthy, male and female rats (5 animals/sex). All animals were examined for clinical signs of ill health or mortality approximately 1, 2.5 and 3 hours postdose (see protocol deviation section), and daily thereafter for at least 14 days. Body weights were collected predose on the day of dosing (Day 0), and on Days 7 and 14, and prior to sacrifice on Day 15. An abbreviated gross examination of the cervical, thoracic, and abdominal viscera was performed.

All the animals were noted as normal, survived until the scheduled sacrifice, and gained weight throughout the study. At necropsy, soft heart in one male and discoloration of the liver lobes in one male and one female were considered incidental and inconclusive. No visible lesions were noted in the remaining animals.

In conclusion, Argentyn 23 was non-toxic by the oral route at a dose level of 20 mL/kg in male and female rats under the conditions of this study.

PURPOSE

This study was designed to assess the acute oral toxicity produced when the test material, Argentyn 23, was administered by oral gavage to mice. The study was conducted in accordance with US EPA/OPPTS 870.1100 and OECD Guidelines for Testing Chemicals, No. 401.

TEST MATERIAL

Identification
The test material, Argentyn 23 (Lot No. 27DT, Expiration Date: 30 June 2004), was received from the Sponsor on 07 January 2003. The test material was received at ambient temperature and stored at room temperature, avoiding sources of microwave and magnetic energy, and protected from light. Upon receipt, the test material was described as a transparent, colorless liquid. The Sponsor supplied information indicating the test article was nanopure water and silver colloids (average size 0.0008 microns); 23 ppm concentration Ultra-fine silver.

Purity and Stability
The Sponsor assumed responsibility for purity and stability determinations (including under test conditions).

Disposition of the Test Material
Any remaining test material will be returned to the Sponsor after issuance of the final report, unless otherwise directed by the Sponsor.

TEST SYSTEMS

Test Animals
Young, adult male and female Crl:CD® (SD)IGS BR rats were received on 30 December 2002, from Charles River Laboratories, a USDA-approved supplier located in Raleigh, North Carolina.

The animals were assigned temporary numbers during acclimation and identified by individual numbered ear tag and by cage label for the duration of the study.

Housing
The animals were pair housed during the acclimation period and singly housed during the study period in suspended stainless-steel cages.

Diet
A commercial diet (PMI® Feeds, Inc. Certified Rodent Diet® #5002 - pellet form) was available *ad libitum* during the acclimation and study periods except for a 17 to 20 hour period before test material administration and approximately 4 hours after dosing (see protocol deviation section).
The feed was analyzed by the manufacturer for concentrations of specified heavy metals, aflatoxin, chlorinated hydrocarbons, organophosphates, and specified nutrients. Results are on file at Covance-Vienna.

Water
Water was available *ad libitum* during the acclimation and study periods. The water was analyzed on a routine basis for specified microorganisms, pesticides, alkalinity, heavy metals, and halogens. Specified nutrient and contaminant analyses are on file at Covance - Vienna. There were no contaminants, known or reasonably anticipated, in the

diet or water at levels that might interfere with the validity of this study.

Environment
The temperature and relative humidity in the animal room were monitored at least once daily. Room controls were set to maintain temperatures and relative humidity of 18-26°C (64-79°F) and 50% ± 20%, respectively. A 12-hour light/12-hour dark cycle was maintained in the room housing the animals.

Acclimation
Before being considered for study use, the animals were acclimated to laboratory conditions. After at least 5 days of acclimation, a staff veterinarian deemed them to be healthy and free from disease and physical abnormalities, and then released the animals for use in the study.

Selection of Animals
Animals used in this study were allocated from all animals available that were within the protocol-specified weight range (200 to 300 g). After randomizing, using computer-generated random numbers, the rats were assigned into this study and to dose groups.

Justification of Species Selection
The rat was selected for use on this study because, historically, rats have been used as representatives of a rodent species and are preferred by various regulatory agencies.

DOSE LEVEL SELECTION

Five male and five female rats were dosed once by oral gavage with 20 mL/kg of the neat test material, Argentyn 23, and observed at approximately 1, 2.5, and 4 hours postdose. Since no mortality was observed, no additional dose levels were tested.

DOSE ADMINISTRATION

Dose Administration
After fasting for 17 to 20 hours, all the animals received a single dose of the neat test material administered by oral gavage. Individual doses were based on a dose volume of 20 mL/kg and calculated based upon the animal's fasting body weight (taken prior to dosing).

Reason for Dosing Route
Historically, the oral route has been one of the routes used to assess the acute toxicity of various materials.

OBSERVATION OF ANIMALS

Clinical Observations

The animals were observed twice daily (at least 4 hours apart) for mortality and morbundity. (Only the morning mortality check was performed on Day 15.)

Approximately 1, 2.5, and approximately 3 hours (see protocol deviation section) after dose administration (Day 0) and once daily thereafter for at least 14 days, animals were observed in the cage for indications of toxicity or ill health. Any effects were recorded as they were observed.

Body Weights
The animals were weighed on the day of (prior to, fasted) test material administration (Day 0), and 7 and 14 days after test material administration and prior to sacrifice (fasted) on Day 15.

TERMINATION AND POSTMORTEM PROCEDURES

Unscheduled Deaths
No animals were found dead prior to the scheduled sacrifice.

Scheduled Sacrifice
After 14 days of observations, all surviving animals were fasted overnight and weighed (Day 15), sacrificed with an appropriate barbiturate, and subjected to an abbreviated gross necropsy.

Necropsy
All animals (scheduled and nonscheduled deaths) were subjected to an abbreviated gross necropsy examination of the cervical, thoracic, and abdominal viscera, performed by trained personnel using procedures approved by board-certified pathologists. All abnormalities were recorded. After necropsy, the animals were discarded and no tissues were saved.

RESULTS

Dosing Information
Five male and five female rats were dosed on 08 January 2003. At initiation of dosing, the animals were approximately 8 or 11 weeks old, with a weight range of 266 to 287 g and 213 to 228 g for the males and females, respectively.

Mortality
A summary of mortality is presented in Table 3. All animals survived until the scheduled sacrifice.

Clinical Signs
Individual clinical observations are presented in Table 1. All the animals were noted as normal at all observation intervals.

Body Weights

Individual and mean body weights and body weight changes are presented in Table 2. All animals gained weight during the course of the study.

Necropsy
Individual necropsy findings are presented in Table 4. Findings in the liver, involving discolored-dark lobes in one male and one female, were possibly treatment-related; however, these findings were inconclusive because no microscopic evaluation was performed. The remaining finding, soft heart in one male, was considered incidental. No visible lesions were noted in the remaining animals.

PROTOCOL DEVIATION

Due to a technical error, the 4-hour postdose observations were preformed approximately 3 hours after dosing and food was returned to the animals following these observations. This deviation had no impact on the integrity of this study or the interpretation of the test results.

RECORD RETENTION

All raw data, documentation, records, protocol, specimens, and the final report generated as a result of this study will be archived in the storage facility of Covance. These materials will be retained by the Covance site at which the work was performed. At least 1 year after submission of the final report, the Covance Archives staff will contact the Sponsor, and the aforementioned materials may be sent to the Sponsor. All raw data stored on magnetic media, protocol, study correspondence, and the original final report will be retained by Covance. The Sponsor may elect to have the materials retained in the Covance archives for an additional period of time or have Covance dispose of the materials.

The following supporting records will be retained at Covance but will not be archived with the study data.

Animal receipt/acclimation records Water analysis records Refrigerator and freezer temperature records Instrument calibration and maintenance records.

EXPERIMENTAL DATA TABLES

Genetic Toxicology Study No.: 24742-0-800 Covance Study No.: 7417-100

Table 1- Oral Toxicity Study Individual Clinical Observations

	Day 0	Days

Animal No.		Sex	Dose Level (mL/kg)	1 hr	2.5 hr	3 hr	1	2	3	4	5	6	7	8	9	10	11
9978		M		0	0	0	0	0	0	0	0	0	0	0	0	0	0
9979		M		0	0	0	0	0	0	0	0	0	0	0	0	0	0
9980		M	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9981		M		0	0	0	0	0	0	0	0	0	0	0	0	0	0
9982		M		0	0	0	0	0	0	0	0	0	0	0	0	0	0
9983		F		0	0	0	0	0	0	0	0	0	0	0	0	0	0
9984		F		0	0	0	0	0	0	0	0	0	0	0	0	0	0
9985		F	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9986		F		0	0	0	0	0	0	0	0	0	0	0	0	0	0
9987		F		0	0	0	0	0	0	0	0	0	0	0	0	0	0

0 = Normal.

Table 2 - Oral Toxicity
Study Body Weights and Body Weight Change (g)

Dose Level	Animal ID	Sex	(mL/kg)	Day 0[a]	Day 7	Change 0-7	Day 14	Change 0-14	Day 15[a]
9978	M	M	20	266	279	66	356	90	329
9979	M	M	20	270	277	73	359	117	354
9980	M			287	368		413		335
9981									359
9982									374
		Mean	**SD**	275.8	345	69.2	381.4	105.6	350.2
				8.17	15.39	8.04	24.07	16.32	18.29

9983	F F F	20 20 20	213 228	238 258	25 30 34	244 263	31 35 59	224
9984	F F	20 20	226 224	260 247	23 23	285 265	41 36	244
9985			216	239		252		259
9986								245
9987								235
				248.4		261.8		241.4
		Mean SD	221.4 6.54	10.31	27 4.85	15.51	40.4 10.99	12.97

[a] Fasted body weight.

Table 3 - Oral Toxicity Study Mortality Summary

Dose Level (mL/kg)	Mortality Results No. Died/No. Dosed Male	Female
20	0/5	0/5

Table 4 - Oral Toxicity Study
Individual Necropsy Findings

Animal	Dose Level	Day of Death	Sex	Necropsy	Observation
9978	20	M	Term	Heart - soft in texture	
9979	20	M	Term	Liver - edges of the lobes discolored-dark	
9980	20	M	Term	No gross lesions	
9981	20	M	Term	No gross lesions	
9982	20	M	Term	No gross lesions	
9983	20	F	Term	Liver - median lobe discolored-dark	
9984	20	F	Term	No gross lesions	
9985	20	F	Term	No gross lesions	
9986	20	F	Term	No gross lesions	
9987	20	F	Term	No gross lesions	