



NORTH AMERICA
DIVISION OF R.P. SCHERER CORPORATION

MAILING & SHIPPING: 2725 SCHERER DRIVE, ST. PETERSBURG, FLORIDA 33719-1048
TELEPHONE NO: (813) 572-4000 FAX NOS. (813) 572-9577 CUSTOMER SERVICE (813) 572-2000 GENERAL (813) 573-1111 SALES (813) 573-1111

RECEIVED
MAR 26 1997

Department of Environmental Protection
SOUTHWEST DISTRICT
BY _____

Via Fax (904)921-8018
and Regular Mail

March 25, 1997

Tina Law
Hazardous Waste Section
Florida Department of Environmental Protection
2600 Blair Stone Road
Tallahassee, FL 32399-2400

**Re: Address Correction;
R.P. Scherer North America - Nutritional Plant;
11399 - 47th Street North, Pinellas Park, Pinellas County**

Dear Ms. Law:

This letter is to request correction of the address in your February 19 letter to us.

We received the enclosed correspondence last month notifying us that our Nutritional Plant is now registered as a 220 to 2,200 lbs per month small quantity generator of hazardous wastes. Please correct our physical plant location as shown below. The address information noted in our completed Form 8700-12 and submitted to you on February 10 is correct.

Change From:

11339 - 47th Street North
Clearwater, FL

Change To:

11399 - 47th Street North
Pinellas Park, FL 34622

We believe this correction would clarify possible concerns which regulatory personnel might have in the future about our actual plant location.

Engineering File - Nut Plant Environmental Correspondence
e:\victor\nutplant\sqg325.doc

[illegible][illegible]

1. *Journal of the American Medical Association*, 1997; 277: 1033-1037.

1. The first step in the process is to identify the problem or issue that needs to be addressed. This involves gathering information and understanding the context of the problem.

Tina Law
March 25, 1997
Page 2 of 2

Thank you for your assistance. If you have any questions, please call at (813)572-4000, ext. 174.

Sincerely,

R. P. Scherer North America



Victor L. San Agustin, P.E., C.H.M.M.
Environmental Engineer
vsa

cc: Randy Strauss, FDEP Tampa District



NORTH AMERICA
DIVISION OF R.P. SCHERER CORPORATION

MAILING & SHIPPING: 2725 SCHERER DRIVE, ST. PETERSBURG, FLORIDA 33716-1016
TELEPHONE NO: (813) 572-4000 FAX NOS. (813) 572-9577 CUSTOMER SERVICE (813) 573-2503 GENERAL (813) 573-1607 SALES

RECEIVED
FEB 11 1997
Department of Environmental Protection
BY SOUTHWEST DISTRICT

February 7, 1997

Certified Mail No.
P 078 613 078

Tina Law
Hazardous Waste Section
Florida Department of Environmental Protection
2600 Blair Stone Road
Tallahassee, FL 32399-2400

**Re: Registration as a 220 - 2200 Lbs/Mo. Small Quantity Generator;
R.P. Scherer North America - Nutritional Plant;
11399 - 47th Street North, Pinellas Park, Pinellas County**

Dear Ms. Law:

This letter is to request that the above referenced facility be registered with the Department as a 220 to 2,200 lbs per month small quantity generator of hazardous wastes. Enclosed is a completed EPA Form 8700 -12, Notification of Regulated Waste Activity.

Thank you for your assistance. If you have any questions, please call me at (813)572-4000, ext. 174.

Sincerely,

R. P. Scherer North America

Victor L. San Agustin
Victor L. San Agustin, P.E., C.H.M.M.
Environmental Engineer
vsa

cc: Randy Strauss, FDEP Tampa District

Engineering File - Nut Plant Environmental Correspondence
e:\victor\nutplant\sqg207.doc

Date Received
(For Official Use Only)

Notification of Regulated Waste Activity

United States Environmental Protection Agency



Please print or type with ELITE type (12 characters per inch) in the unshaded areas only
Please refer to the instructions for Filling Notification before completing this form. The information requested here is required by law (Section 3010 of the Resource Conservation and Recovery Act).

I. Installation's EPA ID Number (Mark 'X' in the appropriate box)

☒ A. First Notification

☒ B. Subsequent Notification (Complete item C)

C. Installation's EPA ID Number

FLR000020214

II. Name of Installation (Include company and specific site name)

R. P. SCHERRER NORTH AMERICA

III. Location of Installation (Physical address not P.O. Box or Route Number)

Street (Continued)
NUTRI TIONAL PLANT

City or Town
11399-47TH STREET NORTH

State Zip Code
FL 34622

County Code
103

County Name
PINELLAS

IV. Installation Mailing Address (See Instructions)

Street or P.O. Box
11399-47TH STREET NORTH

City or Town
CLEARWATER

State Zip Code
FL 34622

V. Installation Contact (Person to be contacted regarding waste activities at site)

Name (Last)

SAV AGUSTIN

(First)

VICTOR L.

Job Title

ENV. ENGINEER

VI. Installation Contact Address (See Instructions)

Phone Number (Area Code and Number)
813-572-4000

A. Contract Address
Location Mailing Other

B. Street or P.O. Box
2725 SCHERRER DR.

City or Town
ST. PETERSBURG

State Zip Code
FL 33716-1016

VII. Ownership (See Instructions)

A. Name of Installation's Legal Owner

R. P. SCHERRER NORTH AMERICA

Street, P.O. Box, or Route Number
2725 SCHERRER DR.

City or Town
ST. PETERSBURG

State Zip Code
FL 33716-1016

Phone Number (Area Code and Number)
813-572-4000

B. Land Type

C. Owner Type

D. Change of Owner Indicator
Yes ☐ No ☒

(Date Changed)
Month Day Year

Please print or type with ELITE type (12 characters per inch) in the unshaded areas only

Form Approved CMB No. 2050-CCS Expires 3-30-96
GSA No. 0246-EPA-07

ID - For Official Use Only

IX. Description of Regulated Wastes (Additional Sheet)

B. Listed Hazardous Wastes. (See 40 CFR 261.31 - 33; Use this page only if you need to list more than 12 waste codes.)

18	P128	24	U002	30	U401	36	U044	42	U072	43	U213	54	U217	60	U220	66	P023	72	P035	78	84	90	96	102	108	114	120
17	P034	23	U240	29	U197	35	U039	41	U071	47	U123	53	U165	59	U213	65	U407	71	P028	77	83	89	95	101	107	113	119
16	P068	22	P205	28	U019	34	U037	40	U070	46	U122	52	U080	58	U103	64	U404	70	P027	76	82	88	94	100	106	112	118
15	P196	21	P075	27	U012	33	U211	39	U197	45	U395	51	U154	57	U196	63	U228	69	P026	75	81	87	93	99	105	111	117
14	P058	20	P041	26	U004	32	U031	38	U246	44	U079	50	U140	56	U188	62	U353	68	P025	74	80	86	92	98	104	110	116
13	P042	19	P020	25	U003	31	U128	37	U393	43	U078	49	U134	55	U169	61	U328	67	P024	73	79	85	91	97	103	109	115

Note: Mail completed form to the appropriate EPA Regional or State Office. (See Section III of the booklet for addresses.)

Facility will include a laboratory sometime this year.
All possible waste codes are listed so that subsequent notification is not needed when the waste is generated.

XI. Comments

Signature: *Victor L. San Agustin, EUGENE*

Name and Official Title (Type or print): VICTOR L. SAN AGUSTIN, EUGENE

Date Signed: 2/7/97

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

X. Certification

1	2	3	4	5	6
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C. Other Wastes. (State or other wastes requiring a handler to have an I.D. number. See instructions.)

1	2	3	4	5	6
F001	F002	F003	F004	F005	F006
7	8	9	10	11	12
P002	P005	P008	P018	P022	P030

B. Listed Hazardous Wastes. (See 40 CFR 261.31 - 33. See instructions if you need to list more than 12 waste codes.)

☒ 1. Ignitable (D001)	☒ 2. Corrosive (D002)	☒ 3. Reactive (D003)	☒ 4. Toxicity Characteristic (List specific EPA hazardous waste number(s) for the Toxicity characteristic contaminant(s))
☒	☒	☒	☒

A. Characteristics of Nonlisted Hazardous Wastes. (Mark 'X' in the boxes corresponding to the characteristics of nonlisted hazardous wastes your installation handles; See 40 CFR Parts 261.20 - 261.24)

IX. Description of Hazardous Wastes (Use additional sheets if necessary)

1. Generator (See instructions) a. Greater than 1000 kg/mo (2,200 lbs.) b. 100 to 1000 kg/mo (200-2,200 lbs.) c. Less than 100 kg/mo (220 lbs.) 2. Transporter (Indicate Mode in boxes 1-5 below) a. For own waste only b. For commercial purposes Mode of Transportation 1. Air 2. Rail 3. Highway 4. Water 5. Other - specify	3. Treater, Storer, Disposer (at installation) Note: A permit is required for this activity; see instructions. a. Generator Marking to Burner b. Other Markers c. Boiler and/or Industrial Furnace 4. Hazardous Waste Fuel 5. Underground Injection Control 1. Utility Boiler 2. Industrial Boiler 3. Industrial Furnace
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VIII. Type of Regulated Waste Activity (Mark 'X' in the appropriate boxes; Refer to instructions)

ID - For Official Use Only											
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[illegible]

4052p04323

Page 1 of 1

City: Clearwater Zip: 34622

[illegible]



Department of Environmental Protection

Lawton Chiles
Governor

Southwest District
3804 Coconut Palm Drive
Tampa, Florida 33619

Virginia B. Wetherell
Secretary

JUL - 9 1996

R.P. Scherer of North America
Nutritional Plant
2725 Scherer Drive
St. Petersburg, Florida 33716-1016

Attn: Keith Schmoke

Re: RCRA Compliance Inspection
Non-Notifier

Dear Mr. Schmoke:

A RCRA compliance inspection was conducted on June 5, 1996 at your Nutritional Plant at 11339 47th Street North, Clearwater, Florida.

Enclosed is the inspection report generated from this visit. Based upon the information gathered from this inspection, no violations of RCRA regulations were observed at the plant.

If you have any questions, or if I can be of further assistance to you, please contact me at (813) 744-6100, extension 379.

Sincerely,

James M. Dregne
Environmental Specialist II
Division of Waste Management

JMD/jd

cc: Panduranga Ojili, BWP&R
Alan Farmer, USEPA, Region IV



Department of Environmental Protection

Lawton Chiles
Governor

Southwest District
3804 Coconut Palm Drive
Tampa, Florida 33619

Virginia B. Wetherell
Secretary

HAZARDOUS WASTE INSPECTION REPORT

1. INSPECTION TYPE: COMPLAINT ☒ ROUTINE ☐ FOLLOW-UP ☐ PERMITTING ☐
FACILITY NAME R. P. Scherer (Nutritional Plant) DEP/EPA ID Non-Notifier
STREET ADDRESS 11339 47th Street North, Clearwater, FL 33622
MAILING ADDRESS 2725 Scherer Drive, St. Petersburg, FL 33716-1016
COUNTY Pinellas PHONE (813)572-4000 DATE 6/5/96 TIME 1510 hours

NOTIFIED AS:

☐ Non Handler
☐ CESQG (<100 kg/mo.)
☐ SQG (100-1000 kg/mo.)
☐ Generator (>1000 kg/mo.)
☐ Transporter
☐ Transfer Facility
☐ Interim Status TSD Facility
☐ TSD Facility
☐ Unit Type(s):
☐ Exempt Treatment Facility
☐ Used Oil:

CURRENT STATUS:

☐ Non Handler
☒ CESQG (<100 kg/mo.)
☐ SQG (100-1000 kg/mo.)
☐ Generator (>1000 kg/mo.)
☐ Transporter
☐ Transfer Facility
☐ Interim Status TSD Facility
☐ TSD Facility
☐ Unit Type(s):
☐ Exempt Treatment Facility
☐ Used Oil:

2. Applicable Regulations:

☒ 40 CFR 261.5 ☐ 40 CFR 262 ☐ 40 CFR 263 ☐ 40 CFR 264 ☐ 40 CFR 279
☐ 40 CFR 265 ☐ 40 CFR 266 ☐ 40 CFR 268 ☐ 40 CFR 273

3. Responsible Officials:

Keith Schmoke - Plant Manager

4. Survey Participants and Principal Inspector:

Keith Schmoke - R.P. Scherer
James Dregne - FDEP

5. Facility Location: Latitude: 27°49'40" Longitude: 82°41'45" UTM:

6. SIC Code: 2834

7. Type of Ownership: FEDERAL STATE COUNTY MUNICIPAL PRIVATE

8. Permit No.: None Date Issued: Exp. Date:

9. Pre-Arranged Inspection: Yes ☐ No ☒

CESQG CHECKLIST

Date: June 5, 1996

Facility Name: P.P. Scherer (Nutritional Ass't) Facility ID #: Non-Notifier

Facility Representative: Kieth Schmoke Inspector: Jim Dregne

40 CFR 261.5

1. Describe the facility's hazardous and potentially hazardous waste streams 40 CFR 262.11:

Waste	EPA Waste #s	Generation Rate	Disposal facility?	Proper Waste ID?
MIXED SOLVENTS	0001, F002, F003	20-g per month	transfer to MAIN plant	yes

(describe discrepancies in waste identification in narrative)

Standards for Conditionally Exempt Small Quantity Generators - 40 CFR 261.5

2. Does the facility generate less than 100 kg/mo (220 lb/mo) of all hazardous wastes? Y ☒ N ☐

And less than 1kg/mo of acutely toxic (P-listed, 40 CFR 262.33) hazardous wastes? Y ☒ N ☐

3. Has the facility obtained an EPA ID #? (not required for CESQGs) Y ☐ N ☒

4. Is the facility disposing of all its hazardous wastes to facilities permitted to accept the waste? (40 CFR 261.5) Describe discrepancies in narrative. transporting to main plant.
Y ☐ N ☒

5. Can the facility document proper disposal of all hazardous wastes? Y ☒ N ☐

6. Are any hazardous wastes treated or disposed of on site? Describe in narrative: Y ☐ N ☒

7. Are there any unpermitted discharges of other wastes to the environment? Y ☐ N ☒

10. Facility and Process Description:

The Nutritional Plant of R. P. Scherer of North America was inspected on June 5, 1996, to evaluate its compliance with state and federal hazardous waste regulations. The inspection determined that the facility was a conditionally exempt small quantity generator of hazardous waste.

R. P. Scherer's Nutritional Plant specializes in the manufacturing of soft gelatin capsules containing pharmaceutical drugs, vitamins and other health aids. The facility has been at its current location for approximately two years and employs 65 personnel. The plant occupies 65,000 square feet and is serviced by the Pinellas County water and sewer departments.

The steps involved in the manufacturing and processing of products at the nutritional plant are solvent free. The gelatin and capsule ingredients are fed through one of six encapsulation machines from large totes which are located above the machines. Following the encapsulation process, the capsules are air dried in inline tumblers. After drying, the capsules are packaged for shipment. There is no requirement in the process to clean the capsules. The gelatin and capsule ingredient totes are cleaned with soap and warm water. The wastewater is discharged to the county POTW.

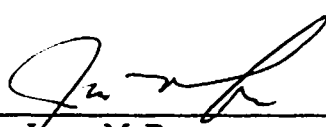
A quality assurance measure performed during the encapsulation process involves the periodic weighing of the ingredients in a capsule during a particular production run. To determine if the correct amount of product is in a capsule, the capsule is weighed full and empty. In order to weigh a capsule empty, it is emptied and cleaned out using acetone. A small satellite accumulation container labeled waste acetone was maintained on a table next to the production line. Once a week, the waste acetone is transferred to a five gallon hazardous waste container in the plant laboratory.

The plant operates a small quality control laboratory that generates some solvent waste. The waste solvents include hexane, ethanol, acetone, methanol, and isopropyl alcohol. The solvent waste is collected in a closed, labeled, 5-gallon can. Records maintained at the plant show that the solvent waste is transferred to the main plant at 2725 Scherer Drive, St. Petersburg about four times each month (<20-gallons per month). The transfer is made by lab packing the 5-gallon can in a 30-gallon drum and transporting it in a company vehicle.

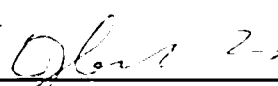
The company acquired a "Super 48" parts washer for the machine shop in late 1995. The parts washer contains "Metalite SV 66", an aliphatic hydrocarbon distillate (flash point 105 F). No hazardous waste has been generated from the parts washer as of the date of the inspection. It is anticipated that the parts washer solution will be changed about every twelve months.

11. Summary of Alleged Violations: None Observed.

Report prepared by: _____


James M. Dregne
Environmental Specialist II

Approved by: _____


Elizabeth B. Knauss
Environmental Manager

Date: _____

7/9/96

RpScherer NORTH AMERICA

NUTRITIONAL FACILITY

Just The **FAX**

To: Jim M. Dregne
Company: State of Florida
Department of Environmental Protection
Fax #: (813) 744-6125
re: Mixed Solvent List
Date: June 11, 1996
Pages: 2 page(s) total including this cover sheet
If there is difficulty with this transmission contact, (813) 573-0380 Ext. 633

Jim - If you have any other questions feel free to give me a call. I also appreciate the information on our parts washer.

From the desk of...

Kelth Schmoke
Nutritional Plant
11399 47th Street N.
Clearwater, Florida 34622
(813) 573-0380 Ext 630

Inter-Office Correspondence**R. P. Scherer North America**

TO: Keith Schmoke
FROM: Nutrition Lab
DATE: June 11, 1996
SUBJECT: Mixed Waste Components

The mixed waste for the Nutritional QC lab contains the following solvents:

hexane
ethanol
tetrahydrofuran
pyridine
acetone
iso-octane
propionic anhydride
benzyl alcohol

isopropyl alcohol
methanol
water
cyclohexane
Hydranal Composite 5
butanol
n-amyl alcohol
heptane