

RCRA Compliance Branch INSPECTION REPORT

Inspection Date(s):	August 24, 2023	Inspection Announced: No
Facility or Site Name:	API Inc.	
Facility/Site Physical Location:	10 Industrial Road	
(city, state, zip code)	Fairfield, New Jersey 07004	
Mailing address (if different from above):		
(city, state, zip code)		
Facility/Site Contact:	Henry Niemczyk Senior Vice President Regulatory Affairs and Quality	(973) 227-9335 henryniemczyk@chemspec-api.com
RCRA ID Number:	NJD986644623	
Facility/Site Personnel Participating in Inspection:		
Henry Niemczyk	Senior Vice President Regulatory Affairs and Quality	(973) 227-9335 henryniemczyk@chemspec-api.com
Doug Roy	Manager, Business Development	(973) 287-6305 dougroy@chemspec-api.com
{name}	{title}	{email/phone no.}
Inspector(s):		
John D, Wilk (USEPA) (lead inspector name)	{Signature} JOHN WILK Digitally signed by JOHN WILK Date: 2023.10.17 19:25:14 -04'00'	{date}
Derval Thomas {Supervisor name}	{Signature}DERVAL THOMAS Digitally signed by DERVAL THOMAS Date: 2023.10.18 10:58:21 -04'00'	{date}

SECTION I – INTRODUCTION

Purpose of the Inspection/Objective

The purpose of the inspection was to perform a comprehensive evaluation inspection (CEI) under the Resource Conservation and Recovery Act. The RCRA contains federal regulations pertaining to the management and disposal of hazardous waste.

Opening Conference

EPA Region 2 RCRA inspector John Wilk arrived at the Chemspec-API (formerly API Inc.) facility located at 10 Industrial Road, Fairfield, New Jersey 07004 at or about 12:30 P.M. on August 24, 2023.

The EPA inspector met with the above referenced company representatives and immediately conducted an opening conference for the inspection. The EPA inspector presented his credentials to the company representatives at the onset of the inspection and informed them this was an EPA inspection to determine the facility's compliance with Subtitle C of the RCRA.

Facility/Site Description

The facility synthesizes small amounts (10 -15 kilograms per batch) of a brain cancer drug it owns and which is approved for human use in the United Kingdom. The facility's main hazardous waste (mother liquor solvents collected after filtrating the crystallized API classified as EPA Hazardous Waste Codes D001/F003) contribute to approximately 90% of the facility's overall hazardous waste generation by weight. The facility also generates spent solvent hazardous waste (classified as EPA Hazardous Waste Codes D001/F003) from on-site quality control and research and development activities which account for approximately 10% of the facility's hazardous waste generation by weight.

At the time of the inspection, the facility identified itself as a RCRA small quantity generator (SQG) of hazardous waste (SQG's generate more than 100 kilograms and less than 1000 kilograms of non-acute hazardous waste per calendar month) which is also reflected in the facility's most recent Notification of RCRA Subtitle C Activities (8700-12) to the USEPA which was filed by the facility on or about January 11, 2011.

SCOPE OF INSPECTION:

The following regulatory areas were reviewed during this inspection (any potential violations/concerns identified would be noted in SECTION III – AREAS OF CONCERN below):

- (1) Facility's RCRA regulatory category determination;
- (2) Hazardous waste determinations pursuant to 40 CFR 262.11;
- (3) Manifesting (e-manifest review only);
- (4) Personnel training records (two years);
- (5) Contingency Plan (only for LQGs/TSDFs);
- (6) Universal waste management;
- (7) Satellite collection areas;
- (8) Observations of conditions of hazardous waste container storage area(s);
- (9) Weekly 90-day container storage area log (2 years) (for LQGs/TSDFs only);
- (10) Daily hazardous waste tank inspection log (2 years), only if applicable;

SECTION II – OBSERVATIONS

According to the facility representative, all hazardous waste accumulation occurs in containers. The facility utilizes no hazardous waste tanks and is not subject to any of the RCRA air emissions standards, i.e., 40 C.F.R. Subparts AA/BB/CC.

As of the date of this inspection, the facility was maintaining one inside 180-day hazardous waste container storage area which had the following hazardous waste containers in inventory: two (2) metal 55-gallon drums (full to near full) containing spent solvent (EPA Hazardous Waste Codes D001/F003). Both hazardous waste containers were effectively closed, marked with (1) the words "Hazardous Waste"; and (2) their accumulation start dates (accumulation start dates of August 8 and 9, 2023, respectively) which were all well within the 180 on-site storage limit established in the RCRA for small quantity generators of hazardous waste. No indications (staining, etc.) of releases of hazardous waste were observed by the USEPA inspectors at or near the facility's 180-day hazardous waste accumulation area.

The most recent hazardous waste shipment from this facility, prior to this inspection, occurred on June 7, 2023, under Hazardous Waste Manifest # 002129763VES which contained: five (5) metal 55-gallon containers of hazardous waste categorized as EPA Hazardous Waste Code: D001/F003 weighing a total of 2000 pounds. The June 7, 2023, manifested shipment was sent to RCRA

permitted TSDf VEOLIA ES TECHNICAL SOLUTIONS (EPA Id. #: NJD980536593) located in Flanders, New Jersey.

The EPA inspector noted during the inspection that this facility recently underwent a concurrent ownership and name change from API Inc. to Chemspecc-API. At the time of the inspection, the EPA inspector provided the facility representatives, noted above, a verbal warning that it must provide an update to the USEPA by submitting a revised Notification of RCRA Subtitle C Activities (8700-12) reflecting these changes pursuant to 40 C.F.R. 262.12 (2015).

Overall, the facility representative was cooperative and appeared forthright while the facility appeared to be well managed environmentally.

SECTION III – AREAS OF CONCERN

Regulatory Concerns-

The facility failed to submit a revised Notification of RCRA Subtitle C Activities (8700-12) pursuant to 40 C.F.R. 262.12 (2015) to reflect the facility's ownership and name change (from API Inc. to Chemspecc-API). This ownership and name change are not reflected on the facility's last RCRA Subtitle C Activities (8700-12) filing received by the USEPA on or about January 11, 2011.

General Concerns-

None.

Closing Conference

The EPA inspector conducted a closing conference at the close of the August 24, 2023 RCRA inspection. At the closing conference, the EPA inspector indicated to the facility representatives that he noted one compliance concern for which he provided verbal warning. That compliance concern was that the facility failed to submit a revised Notification of RCRA Subtitle C Activities (8700-12) pursuant to 40 C.F.R. 262.12 (2015) to reflect the facility's ownership and name change (from API Inc. to Chemspec-API). This ownership and name change are not reflected on the facility's last RCRA Subtitle C Activities (8700-12) filing received by the USEPA on or about January 11, 2011.

The facility representative was also apprised that the facility would be imminently receiving an inspection report from the USEPA documenting its inspection findings.