

DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION

RCRA Corrective Action Environmental Indicator (EI) RCRIS code (CA750) Migration of Contaminated Groundwater Under Control

Facility Name: Merck Sharp & Dohme Quimica
Facility Address: Barceloneta, Puerto Rico
Facility EPA ID#: PRD090028101

Definition of Environmental Indicators (for the RCRA Corrective Action)

Environmental Indicators (EI) are measures being used by the RCRA Corrective Action program to go beyond programmatic activity measures (e.g., reports received and approved, etc.) to track changes in the quality of the environment. The two EIs developed to-date indicate the quality of the environment in relation to current human exposures to contamination and the migration of contaminated groundwater. An EI for non-human (ecological) receptors is intended to be developed in the future.

Definition of “Migration of Contaminated Groundwater Under Control” EI

A positive “Migration of Contaminated Groundwater Under Control” EI determination (“YE” status code) indicates that the migration of “contaminated” groundwater has stabilized, and that monitoring will be conducted to confirm that contaminated groundwater remains within the original “area of contaminated groundwater” (for all groundwater “contamination” subject to RCRA corrective action at or from the identified facility (i.e., site-wide)).

Relationship of EI to Final Remedies

While final remedies remain the long-term objectives of the RCRA Corrective Action program, the EIs are near-term objectives which are currently being used as Program measures for the Government Performance and Results Act of 1993 (GPRA). The “Migration of Contaminated Groundwater Under Control” EI pertains ONLY to the physical migration (i.e., further spread) of contaminated groundwater and contaminants within groundwater (e.g., non-aqueous phase liquids or NAPLs). Achieving this EI does not substitute for achieving other stabilization or final remedy requirements and expectations associated with sources of contamination and the need to restore, wherever practicable, contaminated groundwater to be suitable for its designated current and future uses.

Duration / Applicability of EI Determinations

EI Determination status codes should remain in the RCRIS national database ONLY as long as they remain true (i.e., RCRIS status codes must be changed when the regulatory authorities become aware of contrary information).

Facility Information

The Merck Sharp and Dohme Quimica (MSDQ) facility is located in Barceloneta, Puerto Rico. The facility is located approximately three miles south of the Atlantic Ocean and 38 miles due west of San Juan, Puerto Rico. The site is bordered by industries to the north and west, and mogotes (undeveloped large, round hills with steep sides formed by erosion of natural limestone) surround the remainder of the property.

MSDQ is a wholly-owned subsidiary of Merck and Company, Inc. and has existed at this location since 1971 as an operating pharmaceutical manufacturing plant. The facility currently manufactures human and animal health products such as anti-hypertensives, beta-blockers, diuretics, and anti-parasitic drugs. As a result of these manufacturing processes, the facility generates hazardous wastes, including chlorinated and non-chlorinated solvents, and solid and sludge wastes, as well as residues from incineration operations.

MSDQ has had a RCRA Operating Permit since 1988, and the permit was recently renewed in 2006. The permit currently authorizes MSDQ to manage two hazardous waste container storage areas, seven aboveground hazardous waste storage tanks, and two hazardous waste incinerators; the emissions of the incinerators are currently regulated under both the RCRA and Clean Air Act (CAA) permits.

1. Has **all** available relevant/significant information on known and reasonably suspected releases to the groundwater media, subject to RCRA Corrective Action (e.g., from Solid Waste Management Units (SWMU), Regulated Units (RU), and Areas of Concern (AOC)), been **considered** in this EI determination?

If yes - check here and continue with #2 below.

If no - re-evaluate existing data, or

If data are not available, skip to #8 and enter "IN" (more information needed) status code.

Summary of Solid Waste Management Units (SWMUs) and Areas of Concern (AOCs):

A RCRA Facility Assessment (RFA) was performed at the facility in 1986 and identified 37 solid waste management units (SWMUs) (Ref. 1). Based on visual inspection, no further action was deemed necessary at 23 SWMUs, and soil and air sampling was recommended at 14 SWMUs. Results of RFA investigations indicated that low-level soil contamination was detected in five SWMUs, and the RFA Report recommended further investigation in these five areas; no further action was required at the other nine SWMUs investigated. A RCRA Facility Investigation (RFI) was performed at these five areas in 1989, focusing on soil gas and soil contamination (Ref. 2). No groundwater studies were required. This EI Determination focuses only on the five SWMUs investigated during the RFI, as the remaining 32 SWMUs were determined to require no further action or investigation. See Figure 1-1 in the RFI Report for a figure depicting the five SWMU locations (Ref. 2).

SWMU 1, Old Landfill: This unit was in service from 1971 to 1981 and is located immediately north of the Secure Landfill. This area measures approximately 250 by 500 feet and has been covered with fill and regraded. This unit consisted of two active waste disposal pits excavated to a depth of approximately 20 feet; when full, the disposal trenches were covered with soil. Exact records of placement and earth cover volumes were not maintained while this unit was active. According to the RFA, wastes in the Old Landfill consisted of iron-cake contaminated with toluene, sludges from the Waste Water Treatment System (WWTS) and process filter cartridges containing cyanide (Ref. 1).

MSDQ submitted a Corrective Measures Study (CMS) in November 1990 that selected soil venting as the best corrective measure alternative for this site (Ref. 3). In October 2004, a Corrective Measures Implementation (CMI) Report was submitted that deselected soil venting as the selected alternative and proposed Biodegradation/Natural Attenuation as the selected alternative for this site. EPA did not provide comments on the 1990 CMS and is currently in the

process of reviewing the 2004 CMI. EPA has concerns over the biodegradation alternative as proposed in the CMI Report and is currently evaluating MSDQ's comments relative to these concerns (Refs. 8, 9).

Two groundwater wells (N-1 and MW-1) are present in the vicinity of this unit. These wells were sampled for informational purposes in November 2001 as part of quarterly monitoring in the Secure Landfill (SWMU 2). These wells were sampled for the general quality and contamination indicator parameters, including: chloride, total and dissolved iron, total and dissolved manganese, total recoverable phenolics, total and dissolved sodium, sulfate, pH, specific conductance, total organic carbon, and total organic halogens (Refs. 5, 6). Sample results showed that groundwater quality in these samples had not been adversely impacted; however, toluene and cyanide were not included in the analyte list.

SWMU 2, Secure Landfill: This unit is located on the eastern edge of the facility and was operational from 1981 to 1992. The unit consisted of two identical waste cells; hazardous materials were disposed of in the western cell (No. 1), while the eastern cell (No. 2) contained no waste materials. The cells were designed with impermeable liners (20-mil PVC flexible membrane), liner foundations (24-inch compacted clay), and leachate collection/detection systems that were designed to conform to 40 CFR Part 264 (Refs. 1, 2). Closure activities began in 1992 and were completed in 1994; EPA approved the closure in 1996. Closure activities included removal and off-site disposal of wastes and a portion of the clay liner from Cell No. 1; post-excavation samples confirmed that all contaminated material, including soils, had been removed (Refs. 5, 6). A post-closure groundwater monitoring system was installed and consisted of two upgradient background wells (MW-6 and MW-7) and four downgradient compliance wells (P-1, N-3, ET-1A, and MW-4). Groundwater sampling was initiated in 2001 with four quarterly sampling events. Sampling results have shown that groundwater quality has not been impacted by activities at this unit (Refs. 4, 5, 6, 7).

SWMU 16, WWTS Degritter/Solvent Skimmer and SWMU 17, WWTS Tank 5311, Waste Solvent Storage Tank: These two SWMUs were evaluated as separate units in the RFA; however, they were investigated as one unit during the RFI due to their close proximity. These units were constructed in 1971, but were taken out of service prior to the RFI. Prior to 1986, the Degritter/Skimmer was used to skim toluene from the wastewater flow and to remove settled solids prior to discharge into the Equalization Basin. The floating solvent fraction was deposited in Tank 5311 prior to transfer to MSDQ's hazardous waste incinerator. Prior to 1985, these two SWMUs received hazardous waste discharges (Refs. 1, 2).

SWMU 18, WWTS Aerated Equalization Basin (Big Basin): This unit consists of a 1.6 million gallon Equalization Basin that was built in 1971. This unit presently receives wastewater and some stormwater runoff from the plant. Prior to December 1987, solvent fractions (primarily toluene) of chemical waste were skimmed in the Degritter/Skimmer unit (described above) and discharged into Tank 5311. Bottom flow from the Degritter/Skimmer was then deposited into the Equalization Basin before being discharged to the Barceloneta Regional WWTP. Prior to 1985, the Equalization Basin also received chemical sewer discharges after they were processed through the Degritter/Skimmer (Refs. 1, 2).

References:

1. RCRA Facility Assessment Report. Prepared by A.T. Kearney, Inc. Dated August 8, 1986.
2. RCRA Facility Investigation Report. Prepared by Alliance Technologies Corporation. March 1990.
3. Old Landfill Preliminary Correction Measures Study. Prepared by Alliance Technologies Corporation. November 1990.
4. Presentation on Former Secure Landfill Post-Closure Monitoring Plan, MSDQ Barceloneta Plant. Prepared by MSDQ. Dated December 11, 2000.
5. Secure Landfill Post-Closure Monitoring Final Report and Results of the November 2001 Groundwater Sampling. Prepared by GeoTrans, Inc. Dated March 2002.
6. Secure Landfill Post-Closure Documentation Summary. Prepared by MSDQ. Dated September 2003.
7. Annual Groundwater Quality Report, Secure Landfill. Prepared by MSDQ. Dated February 28, 2005.
8. Letter from Diana Cabrera, MSDQ, to Carl-Axel P. Soderberg, USEPA, re: Response to EPA Comments on the Old Landfill's Final CMI Report. Dated November 17, 2006.
9. Teleconference between Kristin McKenney, Booz Allen Hamilton, and Angel Salgado-Torrellas, USEPA Region 2, Caribbean Section, re: Status of the MSDQ Facility Relative to the CA725 EI Determination. February 15, 2007.

2. Is **groundwater** known or reasonably suspected to be “**contaminated**”¹ above appropriately protective “levels” (i.e., applicable promulgated standards, as well as other appropriate standards, guidelines, guidance, or criteria) from releases subject to RCRA Corrective Action, anywhere at, or from, the facility?

___ If yes - continue after identifying key contaminants, citing appropriate “levels,” and referencing supporting documentation.

X If no - skip to #8 and enter “YE” status code, after citing appropriate “levels,” and referencing supporting documentation to demonstrate that groundwater is not “contaminated.”

___ If unknown - skip to #8 and enter “IN” status code.

Rationale :

The water table at the MSDQ site varies from approximately 230 to 320 feet below ground surface (bgs) (approximately 10 feet above mean sea level [msl]), resulting in a thick unsaturated zone in limestone and overlying consolidated materials. Groundwater beneath the MSDQ site flows through interconnected, intergranular pore space; through interconnected fractures in the limestone; and through open voids formed by solution weathering. These cavities and fractures determine groundwater directions and velocities at the site (Refs. 1, 3).

¹ “Contamination” and “contaminated” describes media containing contaminants (in any form, NAPL and/or dissolved, vapors, or solids, that are subject to RCRA) in concentrations in excess of appropriate “levels” (appropriate for the protection of the groundwater resource and its beneficial uses).

Groundwater investigations at the MSDQ facility have focused primarily in the area of the Secure Landfill (SWMU 2). Under normal fair weather conditions, groundwater flow direction in the vicinity of this unit is generally from south to north, although flow reversal toward the south and southwest have occurred. However, under high precipitation conditions, the direction of groundwater flow beneath the Secure Landfill reverses, changing the direction of groundwater flow from north to south (Ref. 3).

The post-closure groundwater monitoring system at the secure landfill consists of two upgradient background wells (MW-6 and MW-7) and four downgradient compliance wells (P-1, N-3, ET-1A, and MW-4). See the attached Figure 1-2 from the RFI Report for a depiction of monitoring well locations (Ref. 1). As of February 2005, Merck had submitted eight rounds of monitoring data that confirmed a lack of impact to groundwater in the area of the Secure Landfill when compared to background levels obtained from MW-6 and MW-7 (Ref. 3). Sampling was conducted for groundwater quality parameters (e.g., chloride, iron, manganese), groundwater indicator parameters (e.g., pH, total organic carbon), as well as waste-specific parameters (i.e., toluene and cyanide). Concentrations of all constituents were also reported to be below applicable drinking water standards (Ref. 3). Given the absence of contamination, Merck requested the discontinuation of monitoring at the Secure Landfill (Refs. 4, 5). EPA granted Merck's request for monitoring discontinuation subject to public comment during the RCRA permit renewal process.

During the November 2001 sampling event at the Secure Landfill, Old Landfill wells N-1 and MW-1 were sampled for informational purposes. See the attached Figure 1-2 from the RFI Report for a depiction of monitoring well locations (Ref. 2). These wells were sampled for the general quality and contamination indicator parameters, including: chloride, total and dissolved iron, total and dissolved manganese, total recoverable phenolics, total and dissolved sodium, sulfate, pH, specific conductance, total organic carbon, and total organic halogens. However, toluene and cyanide were not included in the analyte list. Sample results confirmed a lack of impact to groundwater quality when compared to background levels obtained from MW-6 and MW-7 (Ref. 2). It should be noted that in its comments on the Merck CMI Report, EPA requested that additional wells be installed in the area of the Old Landfill to confirm the lack of contamination in this area. (Ref. 4)

Merck Barceloneta relies on two private wells for its sole water supply. Well #3 is 550 ft. deep with a production of 25 GPM, and Well #5 is 1200 ft. deep with a production of 390 GPM. Since well water is the facility's main source for industrial operations as well as human consumption, it is assumed that water quality is closely monitored and is in compliance with Safe Drinking Water Act requirements.

Based on current available information, no adverse groundwater impacts have been identified in the area of the Old Landfill related to industrial activities (Refs. 4, 5). Further groundwater investigations have not been required at any other area at the MSDQ site. Should additional investigations identify contamination in this area in the future, this EI Determination will have to be revised accordingly.

References:

1. RCRA Facility Investigation Report. Prepared by Alliance Technologies Corporation. March 1990.

2. Secure Landfill Post-Closure Monitoring Final Report and Results of the November 2001 Groundwater Sampling. Prepared by GeoTrans, Inc. Dated March 2002.
3. Annual Groundwater Quality Report, Secure Landfill. Prepared by MSDQ. Dated February 28, 2005.
4. Letter from Diana Cabrera, MSDQ, to Carl-Axel P. Soderberg, USEPA, re: Response to EPA Comments on the Old Landfill's Final CMI Report. Dated November 17, 2006.
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3. Has the **migration** of contaminated groundwater **stabilized** (such that contaminated groundwater is expected to remain within “existing area of contaminated groundwater”² as defined by the monitoring locations designated at the time of this determination)?

___ If yes - continue, after presenting or referencing the physical evidence (e.g., groundwater sampling/measurement/migration barrier data) and rationale why contaminated groundwater is expected to remain within the (horizontal or vertical) dimensions of the “existing area of groundwater contamination”².

___ If no (contaminated groundwater is observed or expected to migrate beyond the designated locations defining the “existing area of groundwater contamination”²) - skip to #8 and enter “NO” status code, after providing an explanation.

___ If unknown - skip to #8 and enter “IN” status code.

Rationale :

Not Applicable.

References:

Not Applicable.

4. Does “contaminated” groundwater **discharge** into **surface water** bodies?

___ If yes - continue after identifying potentially affected surface water bodies.

___ If no - skip to #7 (and enter a “YE” status code in #8, if #7 = yes) after providing an explanation and/or referencing documentation supporting that groundwater “contamination” does not enter surface water bodies.

___ If unknown - skip to #8 and enter “IN” status code.

² “Existing area of contaminated groundwater” is an area (with horizontal and vertical dimensions) that has been verifiably demonstrated to contain all relevant groundwater contamination for this determination, and is defined by designated (monitoring) locations proximate to the outer perimeter of “contamination” that can and will be sampled/tested in the future to physically verify that all “contaminated” groundwater remains within this area, and that the further migration of “contaminated” groundwater is not occurring. Reasonable allowances in the proximity of the monitoring locations are permissible to incorporate formal remedy decisions (i.e., including public participation) allowing a limited area for natural attenuation.

Rationale :

Not Applicable.

References:

Not Applicable.

5. Is the **discharge** of “contaminated” groundwater into surface water likely to be “**insignificant**” (i.e., the maximum concentration³ of each contaminant discharging into surface water is less than 10 times their appropriate groundwater “level,” and there are no other conditions (e.g., the nature, and number, of discharging contaminants, or environmental setting), which significantly increase the potential for unacceptable impacts to surface water, sediments, or ecosystems at these concentrations)?

___ If yes - skip to #7 (and enter “YE” status code in #8 if #7 = yes), after documenting: 1) the maximum known or reasonably suspected concentration³ of key contaminants discharged above their groundwater “level,” the value of the appropriate “level(s),” and if there is evidence that the concentrations are increasing; and 2) provide a statement of professional judgment/explanation (or reference documentation) supporting that the discharge of groundwater contaminants into the surface water is not anticipated to have unacceptable impacts to the receiving surface water, sediments, or ecosystem.

___ If no - (the discharge of “contaminated” groundwater into surface water is potentially significant) - continue after documenting: 1) the maximum known or reasonably suspected concentration³ of each contaminant discharged above its groundwater “level,” the value of the appropriate “level(s),” and if there is evidence that the concentrations are increasing; and 2) for any contaminants discharging into surface water in concentrations³ greater than 100 times their appropriate groundwater “levels,” the estimated total amount (mass in kg/yr) of each of these contaminants that are being discharged (loaded) into the surface water body (at the time of the determination), and identify if there is evidence that the amount of discharging contaminants is increasing.

___ If unknown - enter “IN” status code in #8.

Rationale :

Not Applicable.

References:

Not Applicable

³ As measured in groundwater prior to entry to the groundwater-surface water/sediment interaction (e.g., hyporheic) zone.

6. Can the **discharge** of “contaminated” groundwater into surface water be shown to be “**currently acceptable**” (i.e., not cause impacts to surface water, sediments or ecosystems that should not be allowed to continue until a final remedy decision can be made and implemented⁴)?

_____ If yes - continue after either: 1) identifying the Final Remedy decision incorporating these conditions, or other site-specific criteria (developed for the protection of the site’s surface water, sediments, and ecosystems), and referencing supporting documentation demonstrating that these criteria are not exceeded by the discharging groundwater; OR 2) providing or referencing an interim-assessment⁵, appropriate to the potential for impact, that shows the discharge of groundwater contaminants into the surface water is (in the opinion of a trained specialist, including an ecologist) adequately protective of receiving surface water, sediments, and ecosystems, until such time when a full assessment and final remedy decision can be made. Factors which should be considered in the interim-assessment (where appropriate to help identify the impact associated with discharging groundwater) include: surface water body size, flow, use/classification/habitats and contaminant loading limits, other sources of surface water/sediment contamination, surface water and sediment sample results and comparisons to available and appropriate surface water and sediment “levels,” as well as any other factors, such as effects on ecological receptors (e.g., via bio-assays/benthic surveys or site-specific ecological Risk Assessments), that the overseeing regulatory agency would deem appropriate for making the EI determination.

_____ If no - (the discharge of “contaminated” groundwater can not be shown to be “**currently acceptable**”) - skip to #8 and enter “NO” status code, after documenting the currently unacceptable impacts to the surface water body, sediments, and/or ecosystem.

_____ If unknown - skip to 8 and enter “IN” status code.

Rationale :

Not Applicable.

References:

Not Applicable

7. Will groundwater **monitoring**/measurement data (and surface water/sediment/ecological data, as necessary) be collected in the future to verify that contaminated groundwater has remained within the horizontal (or vertical, as necessary) dimensions of the “existing area of contaminated groundwater?”

⁴ Note, because areas of inflowing groundwater can be critical habitats (e.g., nurseries or thermal refugia) for many species, appropriate specialist (e.g., ecologist) should be included in management decisions that could eliminate these areas by significantly altering or reversing groundwater flow pathways near surface water bodies.

⁵ The understanding of the impacts of contaminated groundwater discharges into surface water bodies is a rapidly developing field and reviewers are encouraged to look to the latest guidance for the appropriate methods and scale of demonstration to be reasonably certain that discharges are not causing currently unacceptable impacts to the surface waters, sediments or eco-systems.

___ If yes - continue after providing or citing documentation for planned activities or future sampling/measurement events. Specifically identify the well/measurement locations which will be tested in the future to verify the expectation (identified in #3) that groundwater contamination will not be migrating horizontally (or vertically, as necessary) beyond the "existing area of groundwater contamination."

___ If no - enter "NO" status code in #8.

___ If unknown - enter "IN" status code in #8.

Rationale :

Not Applicable.

References:

Not Applicable

8. Check the appropriate RCRIS status codes for the Migration of Contaminated Groundwater Under Control EI (event code CA750), and obtain Supervisor (or appropriate Manager) signature and date on the EI determination below (attach appropriate supporting documentation as well as a map of the facility).

X YE - Yes, "Migration of Contaminated Groundwater Under Control" has been verified. Based on a review of the information contained in this EI determination, it has been determined that the "Migration of Contaminated Groundwater" is "Under Control" at the Merck Sharp & Dohme Quimica site, EPA ID# PRD090028101, located in Barceloneta, Puerto Rico. Specifically, this determination indicates that the migration of "contaminated" groundwater is under control. This determination will be re-evaluated when the Agency becomes aware of significant changes at the facility.

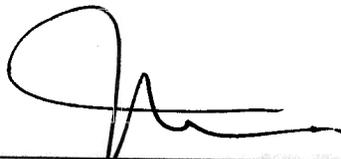
___ NO - Unacceptable migration of contaminated groundwater is observed or expected.

___ IN - More information is needed to make a determination.

Completed by: Layla Hani Date: 09/25/2007
Layla Hani
Staff Consultant
TechLaw, Inc.

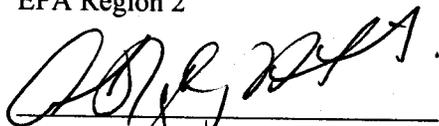
Reviewed by: Cathy Dare Date: 09/25/2007
Cathy Dare
Senior Staff Consultant
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Also reviewed by:



Angel E. Salgado, Project Manager
Response and Remediation Branch
Caribbean Environmental Protection Division
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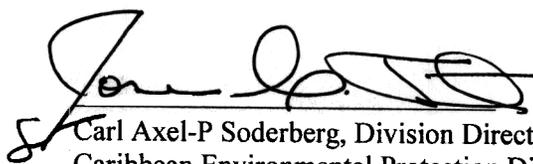
Date: 9-26-2007



Ariel Iglesias-Portalatin, Branch Chief
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Date: 9-26-2007

Approved by:



Carl Axel-P Soderberg, Division Director
Caribbean Environmental Protection Division
EPA Region 2

Date: 9-26-07

Locations where references may be found:

References reviewed to prepare this EI determination are identified after each response. Reference materials are available at U.S. EPA, Region 2.

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FINAL NOTE: THE GROUNDWATER EXPOSURES EI IS A QUALITATIVE SCREENING OF EXPOSURES AND THE DETERMINATIONS WITHIN THIS DOCUMENT SHOULD NOT BE USED AS THE SOLE BASIS FOR RESTRICTING THE SCOPE OF MORE DETAILED (E.G., SITE-SPECIFIC) ASSESSMENTS OF RISK.

Attachments

The following attachments have been provided to support this EI determination:

Attachment 1 - Summary of Media Impacts Table
Figure 1-2: RCRA Facility Investigation Report. Prepared by Alliance Technologies Corporation. March 1990.

SWMU	GW	AIR (Indoors)	SURF SOIL	SURF WATER	SED	SUB SURF SOIL	AIR (Outdoors)	CORRECTIVE ACTION MEASURE	KEY CONTAMINANTS
SWMU 1 – Old Landfill	No	No	Yes	No	No	Yes	No	<ul style="list-style-type: none"> Currently evaluating corrective measure alternatives, which include Biodegradation/Natural Attenuation and Soil Venting. TCLP results show that toluene will leach. EPA has outstanding comments requesting installation of additional wells. 	Toluene
SWMU 2 – Secure Landfill	No	No	No	No	No	No	No	<ul style="list-style-type: none"> Unit closure included removal and off-site disposal of wastes and a portion of the clay liner from Cell. No. 1. Post-excavation samples confirmed all contaminated material was removed. EPA approved closure in 1996. Groundwater sampling initiated in 2001 and completed in 2004; results have not shown adverse impacts since initiation. Post-closure groundwater monitoring discontinuation was granted by EPA in 2006 upon RCRA permit renewal. 	None identified.
SWMU 16 – WWTS Degritter/Solvent Skimmer	No	No	No	No	No	No	No	None.	
SWMU 17 – WWTS Tank 5311, Waste Solvent Storage Tank	No	No	No	No	No	No	No	None.	
SWMU 18 - WWTS Aerated Equalization Basin (Big Basin)	No	No	No	No	No	No	No	None.	

Attachment 1: Summary of Media Impacts Table