DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION

Interim Final 2/5/99

RCRA Corrective Action
Environmental Indicator (EI) RCRAInfo code (CA725)

Current Human Exposures Under Control

Facility Name: Novartis Pharmaceuticals Corporation

Facility Address: 59 Route 10, East Hanover, New Jersey

Facility EPA ID #: NJD002147023

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 EI 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 "Current Human Exposures Under Control" EI

A positive "Current Human Exposures Under Control" EI determination ("YE" status code) indicates that there are no "unacceptable" human exposures to "contamination" (i.e., contaminants in concentrations in excess of appropriate risk-based levels) that can be reasonably expected under current land- and groundwater-use conditions (for all "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 objective of the RCRA Corrective Action program the EI are near-term objectives which are currently being used as Program measures for the Government Performance and Results Act of 1993, GPRA). The "Current Human Exposures Under Control" EI are for reasonably expected human exposures under current land- and groundwater-use conditions ONLY, and do not consider potential future land- or groundwater-use conditions or ecological receptors. The RCRA Corrective Action program's overall mission to protect human health and the environment requires that Final remedies address these issues (i.e., potential future human exposure scenarios, future land and groundwater uses, and ecological receptors).

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Duration / Applicability of EI Determinations

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

Facility Information: The Novartis Pharmaceuticals Corporation (Novartis) site is 180 acres and located in a mixed industrial, commercial, and residential area. Novartis began operations in 1955 as Sandoz Pharmaceuticals Corporation. Prior to 1985, the facility operations included laboratory, production, and warehousing of dyes pigments and pharmaceutical products. Since 1985 operations have been limited to the manufacturing, compounding, and packaging of pharmaceutical products. Novartis generates still bottom liquids, chlorinated solvents, caustic water solutions, waste oil, and other miscellaneous liquids and solids. Wastes are stored on-site in the container storage area or in above ground storage tanks. All waste is disposed of at off-site facilities and process wastewater is discharged to the local sewerage authority. Eleven solid waste management units (SWMUs) and two areas of concern (AOC) were identified in the facility's RCRA Hazardous and Solid Waste Amendments (HSWA) permit, dated November 23, 1994. Seven of the SWMUs (SWMUs 1, 2, 3, 6, 7, 9, 11) and one AOC have been investigated and a "no further action" determination has been made. The facility is currently addressing SWMUs 4 and 5, and the remaining AOC. SWMUs 8 and 10 were not required to be further investigated.

1. Has **all** available relevant/significant information on known and reasonably suspected releases to soil, groundwater, surface water/sediments, and air, 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?

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

   __ If no - re-evaluate existing data, or

   __ If data are not available skip to #6 and enter AIN@ (more information needed) status code.

Summary of SWMUs

SWMU #1, Two Clay-Lined Wastewater Equalization Lagoons: The lagoons were associated with SWMU #9 and built in the early 1950s. They received process wastewater, neutralized acid wastewater, laboratory wastewater, and filter backwashing water until 1986. The lagoons were

drained and excavated in 1986 and 1987 and closed in 1988 under the requirements of the Lagoon Closure Plan.

SWMU #2, Inactive Skimming Tank: The skimming tank handled neutralized acid wastewater from the 1950s to 1968. The tank did not receive any wastewater from 1968 to 1991 when it was removed.

SWMU #3, Active Skimming Tank: The active skimming tank receives approximately 100,000 gallons of laboratory wastewater and scrubber water per day, and is operating under an NJDPES permit.

SWMU #4, Caustic UST at Building 410: The former 5,000-gallon underground storage tank (UST) was located on the east side of Building 410. The tank contained a solution comprised of 50% sodium hydroxide and 50% water. The tank was installed in 1967 and removed in 1984.

SWMU #5, Diesel Fuel Oil UST at Building 410: The former 2,000-gallon Diesel Fuel UST was located northeast of Building 410, adjacent to the generator building. The UST contained diesel fuel oil no. 1-D which powered the emergency generator. The tank was installed in 1979 and removed in 1987 because it failed an integrity test.

SWMU #6, Diesel Fuel Oil UST at Building 415B: The former 1,000-gallon UST was located on the west side of Building 415B. The tank contained diesel fuel oil to power the emergency generators for Building 415B. The tank was installed in 1971 and removed in 1987 because it failed an integrity test.

SWMU #7, Wastewater UST at Building 103: The former 10,000-gallon UST was located northeast of Building 103. The tank contained wastewater from equipment washdown in buildings 103 and 101. The tank was installed in 1966 and removed in 1989.

SWMU #8, Former Incinerator at Building 401: The former incinerator was located south of building 401. The incinerator was used to incinerate trash. It was installed between 1949 and 1960 and removed in 1983. The incinerator was not used after 1971.

SWMU #9, Inactive On-Site Treatment System: The inactive on-site treatment system was constructed in the 1950s and consisted of a settling/neutralization unit, clay-lined wastewater equalization lagoons, lagoon distribution box, rate control chamber, dosing chamber, large sand filter beds, recirculation unit, chlorine contact chamber, intermittent sand filter beds, and septic unit. All of the above units were removed between 1991 and 1994.

SWMU #10, Container Storage Area: The container storage area (CSA) is a RCRA regulated unit and is operating under a state operating permit. The CSA is not subject to the corrective action requirements of the HSWA permit.

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SWMU #11, Former Alkaline Waste Liquid AST at Building 410: The former 5,000-gallon AST was located on the east side of Building 410. The tank contained a solution comprised of 50% sodium hydroxide and 50% water. The tank was installed in 1968 and removed in 1975. The 5,000-gallon AST was replaced with an 8,000-gallon AST. The new AST is RCRA regulated and operated under a state operating permit.

Summary of AOCs

Soils at MW-11: Soils surrounding MW-11 were delineated to determine the extent of TPH contamination around MW-11. Samples indicated TPH concentrations below the NJDEP Soil Cleanup Criteria of 10,000 mg/kg.

Groundwater: Groundwater is contaminated with chlorinated volatile organic compounds (VOCs). Chloroform is the only compound that is not originating from off-site sources. Inorganic compounds detected are a result of naturally occurring sources.

Reference(s):
Initial Phase RCRA Facility Investigative Work Plan, March 1997, GEO Engineering, Inc.
Initial RCRA Facility Investigative Report, March 1998, Haley and Aldrich, Inc.

2. Are groundwater, soil, surface water, sediments, or air **media** known or reasonably suspected to be "**contaminated**"[1] above appropriately protective risk-based Alevels@ (applicable promulgated standards, as well as other appropriate standards, guidelines, guidance, or criteria) from releases subject to RCRA Corrective Action (from SWMUs, RUs or AOCs)?

Media	Yes	No	?	Rationale/Key Contaminants
Groundwater	X			chloroform
Air (indoors)[2]		X		
Surface Soil (e.g., <2 ft.)	X			petroleum hydrocarbons
Surface Water		X		
Sediment		X		
Subsurface Soil (e.g., > 2 ft.)	X			petroleum hydrocarbons
Air (outdoors)		X		

__ If no (for all media) - skip to #6, and enter YE, status code after providing or citing appropriate levels, and referencing sufficient supporting documentation demonstrating that these levels are not exceeded.

X If yes (for any media) - continue after identifying key contaminants in each contaminated medium, citing appropriate levels (or provide an explanation for the determination that the medium could pose an unacceptable risk), and referencing supporting documentation.

_____If unknown (for any media) - skip to #6 and enter IN status code.

Rationale:

Subsurface Soil (e,g., > 2ft.):

Eight soil samples were collected around SWMU #5 in 1997 at depths from 9.5 to 11 feet below ground surface (bgs). None of the soil samples contained TPH values above the NJDEP Soil Cleanup Criteria (SCC). However, hydrocarbon odors and staining were observed at all the sample locations in the former excavation area at depths above the sampling interval to surficial soils. In January, 1999 an oil sheen was discovered on the surface of rainwater that was in the electrical catch basin adjacent to SWMU #5. The source of the oil has not yet been determined, but could potentially be from the stained soil around SWMU #5.

Two soil samples were collected around SWMU #4 at depths of 11 and 12 feet bgs. One of the samples resulted in a pH of 10.69. The extent of the caustic pH levels surrounding SWMU #4 is unknown.

Groundwater:

Groundwater below the site is contaminated with chlorinated volatile organic compounds (VOCs), various inorganics, and chloroform. The only contaminant that can be attributed to the facility is chloroform. The source of the VOCs has been determined to be upgradient and the inorganics are detected at levels similar throughout the region. The source of the chloroform has not been determined but it appears to be migrating southwest across the facility. There are four production wells and a treatment system located on the southwest corner of the Novartis property which supply drinking water for the facility. Sampling was conducted in 1998 and 1999 on untreated water from the wells. There were exceedances of chlorinated VOCs above associated MCLs but the chloroform levels were all below NJ Groundwater Quality Standards. The aquifer is located at depths of approximately 60 to 190 feet bgs.

Air (indoors):

Indoor air exposures are not a concern due to the depth of the aquifer.

Soil (surface e.g., <2 ft.):

Hydrocarbon odors and staining were observed in 1997 at all the sample locations in the former excavation area at depths above the sampling interval to surficial soils. The stained soil was not sampled to determine if it was above NJDEP Soil Cleanup Criteria. The oil sheen discovered in the electrical catch basin adjacent to SWMU #5 could be potentially from surface soils.

Surface Water:

The surface water runoff from the facility drains through five stormwater detention basins on the Novartis property. In addition, the non-contact cooling water is discharged to these basins. The five basins discharge through four surface outfalls which are permitted under a NJPDES – Discharge to Surface Water (DSW) permit.

Sediment:

The sediments in the receiving waters (Black Brook, drainage ditch to Pinch Brook, Whippany River) have not been analyzed. The outfalls are monitored under the NJPDES-DSW permit.

Air (outdoors):

Outdoor air exposures are not a concern due to the depth of the aquifer.

Reference(s):

Initial Phase RCRA Facility Investigative Work Plan, March 1997, GEO Engineering, Inc.
Initial RCRA Facility Investigative Report, March 1998, Haley and Aldrich, Inc.
Fax from Novartis to USEPA, 2/23/99, RE NJDEP Case #99-02-19-0907-41
Supplemental Hydrogeologic Investigation Report, 1/29/99, Paulus, Sokolowski & Sartor, Inc.

Footnotes:

[1] AContamination@ and Acontaminated@ describes media containing contaminants (in any form, NAPL and/or dissolved, vapors, or solids, that are subject to RCRA) in concentrations in excess of appropriately protective risk-based Alevels@ (for the media, that identify risks within the acceptable risk range).

[2] Recent evidence (from the Colorado Dept. of Public Health and Environment, and others) suggest that unacceptable indoor air concentrations are more common in structures above groundwater with volatile contaminants than previously believed. This is a rapidly developing field and reviewers are encouraged to look to the latest guidance for the appropriate methods and scale of demonstration necessary to be reasonably certain that indoor air (in structures located above (and adjacent to) groundwater with volatile contaminants) does not present unacceptable risks.

3. Are there **complete pathways** between Acontamination@ and human receptors such that exposures can be reasonably expected under the current (land- and groundwater-use) conditions?

Summary Exposure Pathway Evaluation Table

Potential **Human Receptors** (Under Current Conditions)

Contaminated Media	**Residents**	**Workers**	**Day-Care**	**Construction**	**Trespassers**	**Recreation**	**Food**[3]
Groundwater	No	No	No	No	No	No	No
~~Air (indoors)~~	NA	NA	NA	NA	NA	NA	NA
Soil (surface, e.g. < 2 ft.)	NA	No	NA	No	No	NA	No
~~Surface Water~~	NA	NA	NA	NA	NA	NA	NA
~~Sediment~~	NA	NA	NA	NA	NA	NA	NA
Soil(subsurface e.g. > 2 ft.)	No	No	No	No	No	No	No
~~Air~~ (outdoors)	NA	NA	NA	NA	NA	NA	NA

Instructions for Summary Exposure Pathway Evaluation Table:

1. Strike-out specific Media including Human Receptors: spaces for Media which are not Acontaminated@) as identified in #2 above.

2. enter Ayes@ or Ano@ for potential Acompleteness@ under each AContaminated@ Media -- Human Receptor combination (Pathway).

Note: In order to focus the evaluation to the most probable combinations some potential AContaminated@ Media - Human Receptor combinations (Pathways) SHOW Not Applicable (NA). While these combinations may not be probable in most situations they may be possible in some settings and should be added as necessary.

__X__ If no (pathways are not complete for any contaminated media-receptor combination) - skip to #6, and enter @YE@ status code, after explaining and/or referencing condition(s) in-place, whether natural or man-made, preventing a complete exposure pathway from each contaminated medium (e.g., use optional Pathway Evaluation Work Sheet to analyze major pathways).

____ If yes (pathways are complete for any AContaminated@ Media - Human Receptor combination) - continue after providing supporting explanation.

____ If unknown (for any AContaminated@ Media - Human Receptor combination)skip to #6 and enter AIN@ status code.

Rationale:

The soil in SWMU #5 is below the pavement, therefore there are no potential human exposures to contaminated soil. The groundwater is treated prior to drinking onsite. The soil around SWMU #4, is at a depth of 11 to 12 feet below the ground.

Reference(s):
Initial Phase RCRA Facility Investigative Work Plan, March 1997, GEO Engineering, Inc.
Letter from USEPA to Novartis, 3/8/00, RE EPA ID No.: NJD002147023

[3] Indirect Pathway/Receptor (e.g., vegetables, fruits, crops, meat and dairy products, fish, shellfish, etc.)

4. Can the **exposures** from any of the complete pathways identified in #3 be reasonably expected to be "**significant"**[4] (i.e., potentially Aunacceptable@ because exposures can be reasonably expected to be: 1) greater in magnitude (intensity, frequency and/or duration) than assumed in the derivation of the acceptable Alevels@ (used to identify the Acontamination@); or 2) the combination of exposure magnitude (perhaps even though low) and contaminant concentrations (which may be substantially above the acceptable Alevels@) could result in greater than acceptable risks)?

_____ If no (exposures can not be reasonably expected to be significant (i.e., potentially Aunacceptable@) for any complete exposure pathway) - skip to #6 and enter AYE@ status code after explaining and/or referencing documentation justifying why the exposures (from each of the complete pathways) to Acontamination@ (identified in #3) are not expected to be Asignificant.@

_____ If yes (exposures could be reasonably expected to be Asignificant@ (i.e., potentially Aunacceptable@) for any complete exposure pathway) - continue after providing a description (of each potentially Aunacceptable@ exposure pathway) and explaining and/or referencing documentation justifying why the exposures (from each of the remaining complete pathways) to Acontamination@ (identified in #3) are not expected to be Asignificant.@

_____ If unknown (for any complete pathway) - skip to #6 and enter AIN@ status code

Rationale:

Reference(s):

[4] If there is any question on whether the identified exposures are Asignificant@ (i.e., potentially Aunacceptable@) consult a human health Risk Assessment specialist with appropriate education, training and experience.

5. Can the Asignificant@ **exposures** (identified in #4) be shown to be within **acceptable** limits?

_____If yes (all Asignificant@ exposures have been shown to be within acceptable limits) - continue and enter AYE@ after summarizing and referencing documentation justifying why all Asignificant@ exposures to Acontamination@ are within acceptable limits (e.g., a site-specific Human Health Risk Assessment).

_____ If no (there are current exposures that can be reasonably expected to be Aunacceptable@)- continue and enter ANO@ status code after providing a description of each potentially Aunacceptable@ exposure.

_____ If unknown (for any potentially Aunacceptable@ exposure) - continue and enter AIN@ status code

Rationale and Reference(s): This question is not applicable, see answer to Question 3.

6. Check the appropriate RCRIS status codes for the Current Human Exposures Under Control EI event code (CA725), and obtain Supervisor (or appropriate Manager) signature and date on the EI determination below (and attach appropriate supporting documentation as well as a map of the facility):

__X__ YE - Yes, ACurrent Human Exposures Under Control@ has been verified. Based on a review of the information contained in this EI Determination, ACurrent Human Exposures@ are expected to be AUnder Control@ at the **Novartis Pharmaceuticals Corporation** facility, EPA ID # **NJD002147023**, located at **59 Route 10, East Hanover, New Jersey** under current and reasonably expected conditions. This determination will be re-evaluated when the Agency/State becomes aware of significant changes at the facility.

_____ NO - ACurrent Human Exposures@ are NOT AUnder Control.@

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

Completed by:		Date	
	Carl Lawrence		
	Tetra Tech EM Inc.		

Reviewed by:		Date	
	Douglas Sullivan		
	Tetra Tech EM Inc.		

		Date	
	Alan Straus, Project Manager		
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Approved by:		Date	
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Locations where References may be found:
U.S. Environmental Protection Agency
RCRA Records Center
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FINAL NOTE: THE HUMAN 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:

1. SWMU Location Map
2. Chloroform Isoconcentration Contours