New York State Department of Environmental Conservation Office of General Counsel, Region 4

1130 North Westcott Road, Schenectady, New York 12306-2014 **Phone:** (518) 357-2048 • **Fax:** (518) 357-2087 **Website:** <u>www.dec.ny.gov</u>



CERTIFIED - RETURN RECEIPT REQUESTED 7012 3050 0000 4246 2583

May 2, 2014

Phillip Ghiorse Mallinckrodt LLC 117 Railroad Ave Hobart, NY 13820

Re: Order on Consent R4-2014-0319-77

Dear Mr. Ghiorse:

Enclosed please find a copy of the fully executed Order on Consent referenced above.

This will also acknowledge receipt of \$7,499 the civil penalty pursuant to Paragraph I.

Sincerely

Richard Ostrov Regional Attorney Region 4

Enclosure

ec: J. Quinn H. Brezner

STATE OF NEW YORK: DEPARTMENT OF ENVIRONMENTAL CONSERVATION

In the Matter of Violations of Article 27, Title 13 of the Environmental Conservation Law; by

ORDER ON CONSENT

File No. R4-2014-0319-77

Mallinckrodt LLC 112 Railroad Avenue Hobart, NY 13788

Respondent.

WHEREAS:

1. The New York State Department of Environmental Conservation (the "Department") is responsible for regulation of hazardous waste management pursuant to Article 27, Titles 13 of the Environmental Conservation Law (the "ECL").

2. On March 7 and 10, 2014, Department staff conducted an inspection at Respondent, Mallinckrodt LLC, facility located at112 Railroad Avenue Hobart, New York 13788 to determine compliance with federal and state hazardous waste regulations ("facility") The facility is a large quantity generator of hazardous waste and operates pursuant to EPA ID Number: NYD002074029.

Hazardous Waste Violations from Inspection

3. On March 14, 2014, Respondent was mailed a notice of violation setting forth the violations observed during the Department's March 7 and 10, 2014 inspections of the facility ("inspection").

- 4. Regulations at 6 NYCRR Part 372.2(b)(2)(ii) requires that the generator, for each hazardous waste listed in Box 9 of the manifest, confirm with the designated facility what the ultimate disposal method will be for that waste. If the receiving facility does not provide a hazardous waste management code in Box 19 of the manifest that reflects the ultimate disposal method for the hazardous waste, the generator must provide a State waste code in Box 13 of the manifest to designate the ultimate disposal method of the hazardous waste using one of following state codes:
 - L = Landfill
 - B = Incineration, heat recovery, burning
 - T = Chemical, physical, or biological treatment
 - R = Material recovery of more than 75 percent of the total material

Respondent failed to note the ultimate disposal codes (L, B, T or R) for the 12th and 13th waste streams on manifest #000541445WAS (10/22/13), One of these letters must be noted if the TSDF does not put a code representing the ultimate disposal method on the manifest for each waste stream. Respondent violated 6 NYCRR 372.2(b)(2)(ii) by failing to identify the disposal method in the two manifests.

- 5. Regulations at 6 NYCRR 372.2(a)(8)(i)(a) allows a generator to accumulate up to 55 gallons of hazardous waste or one quart of acutely hazardous waste in containers at or near any point of generation where wastes initially accumulate, which is under the control of the operator of the process generating the waste, without a permit or interim status provided the generator keeps all containers closed except if they are in use. Respondent by failing to keep all of its containers closed violated Regulations at 6 NYCRR 372.2(a)(8)(i)(a).
- 6. Regulations at 6 NYCRR Part 372.2(a)(8)(i)(a) allows a generator to accumulate up to 55 gallons of hazardous waste or one quart of acutely hazardous waste in containers at or near any point of generation where wastes initially accumulate, which is under the control of the operator of the process generating the waste, without a permit or interim status provided the generator marks his containers with the words "Hazardous Waste" and with other words that identify the contents of the containers. Respondent violated 6 NYCRR Part 372.2(a)(8)(i)(a) by failing to mark a 2.5 gallon container in the Stability Lab with the words "Hazardous Waste" or other words identifying the contents.

- 7. Regulations at 6 NYCRR 372.2(a)(8)(ii) allows a generator to accumulate on-site of generation without being subject to the regulations applicable to hazardous waste treatment, storage and disposal facilities if all accumulated hazardous wastes are shipped off-site to a permitted treatment, storage or disposal (TSD) facility in 90 days or less. Respondent violated 6 NYCRR 372.2(a)(8)(ii) by storing containers holding hexane in the QC lab storage area for 115 days and Karl Fisher waste in the main storage area for 116 days.
- 8. Regulations at 6 NYCRR 373-3.9(f) requires generators to place "No Smoking" signs in conspicuous places wherever there is a hazard from ignitable or reactive wastes. Respondent violated 6 NYCRR 373-3.9(f) not posting "No Smoking" signs at the QC Lab and Stability lab storage areas.
- 9. Regulations at 6 NYCRR 373-3.3(f) requires that the owner or operator must maintain aisle space to allow the unobstructed movement of personnel, fire protection equipment, spill control equipment, and decontamination equipment to any area of facility operation in an emergency, unless aisle space is not needed for any of these purposes. Respondent violated 6 NYCRR 373-3.3(f) by storing all of its 55-gallon drums holding Acetonitrile and Methanol in the main storage area without any aisle space.
- 10. Regulations at 6 NYCRR 373-3.4(c) requires that the facility's Contingency Plan must list names, addresses and phone numbers (office and home) of all persons qualified to act as emergency coordinator and this list must be kept up to date. Where more than one person is listed, one person must be named as primary emergency coordinator and the others must be listed in the order in which they will assume responsibility as alternates. Respondent violated the regulations at 6 NYCRR 373-3.4(c) by failing to identify qualified emergency coordinators and their required information.
- 11. Regulations at 6 NYCRR 373-3.4(c) requires the following content in a Contingency Plan: a list of all emergency equipment at the facility (such as fire extinguishing systems, spill control equipment, communication and alarm systems (internal and external), and decontamination equipment), where this equipment is required. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list, and a brief outline of its capabilities. Respondent violated 6 NYCRR 373-3.4(c) by failing to provide detailed information about the spill kits and firefighting equipment contents, location and capabilities.

- 12. Regulations at 6 NYCRR 373-3.4(d)(2) requires that each owner or operator must submit copies of their Contingency Plan to all local police departments, fire departments, hospitals and State and local emergency response teams that may be called upon to provide emergency services. Respondent violated 6 NYCRR 373-3.4(d)(2) by not providing copies of its contingency plan to the local police, fire department, hospital and other emergency service organizations.
- 13. Regulations at 6 NYCRR 376.1(g)(1)(ii) requires generators of waste that do not meet the treatment standard to send a one-time written notice with the initial shipment to each treatment or storage facility and place a copy in their files. The notice must include the following information:
 - EPA Hazardous Waste number
 - The constituents of concern for F001-F005, and F039, and underlying hazardous constituents (for wastes that are not managed in a Clean Water Act (CWA) or CWA-equivalent facility), unless the waste will be treated and monitored for all constituents. If all constituents will be treated and monitored, there is no need to put them all on the LDR notice.
 - Applicable wastewater/non-wastewater category and subdivisions made within a waste code based on waste-specific criteria (such as D003 reactive cyanide).

Respondent violated 6 NYCRR 376.1(g)(1)(ii) by failing to include for the 13^{th} waste stream the waste codes in the LDR notification for manifest #000541445WAS (10/22/13).

Respondent violated 6 NYCRR 376.1(g)(1)(ii) by failing to address the 8th and 9th waste stream including not listing the waste codes in the LDR notification for manifest #000541063WAS (7/18/13)

Respondent violated 6 NYCRR 376.1(g)(1)(ii) by failing to indicate whether the 5^{th} waste stream was a wastewater or a non-wastewater in the LDR notification for manifest #000509210WAS (4/8/13).

Respondent violated 6 NYCRR 376.1(g)(1)(ii) by failing to address whether the 6^{th} waste streams was a wastewater or a non-wastewater in the LDR notification for manifest #000507601WAS (12/12/12)

Respondent violated 6 NYCRR 376.1(g)(1)(ii) by failing to address the 13^{th} to 17^{th} waste streams in the LDR notification for manifest #000438015WAS (10/7/11).

- 14. Regulations at 6 NYCRR 374-3.2(d)(4)(i) requires that the handler must place universal waste lamps in a container that is closed, structurally sound, adequate to prevent breakage, compatible with the contents, and must lack evidence of leakage, spillage, or damage. Respondent violated 6 NYCRR 374-3.2(d)(4)(i) by failing to close two boxes holding HID bulbs and two boxes holding UV lamps despite no waste being added or removed from them.
- 15. Regulations at 6 NYCRR 374-3.2(f)(3) requires that a handler must be able to demonstrate the length of time that the universal waste has been accumulated by marking the date, maintaining an inventory, or any other method. Respondent violated 6 NYCRR 374-3.2(f)(3) by not having any of the boxess holding UV lamps marked with an accumulation start date or having another manner to indicate how long the boxes had been in storage.

Civil Penalties

16. ECL Section 71-2705(1) provides for a maximum civil penalty of \$37,500 for the first day of a violation and each day thereafter of a regulation promulgated under Title 13 of ECL Article 27.

Waiver of Hearing

17. The Respondent hereby consents to the issuance and entry of the foregoing Order, waives its right to a hearing herein as provided by law, and agrees to be bound by the provisions, terms and conditions contained herein.

NOW, being duly advised and having considered this matter, **IT IS HEREBY ORDERED THAT:**

I. <u>Civil Penalty</u>

Respondent is hereby assessed a civil penalty in the amount of SEVEN THOUSAND FOUR HUNDRED FORTY NINE DOLLARS (\$7,499) for the violations stated herein. The civil penalty is to be paid by check made payable to the Department of Environmental Conservation and returned with the signed and notarized Order.

II. Indemnification

Respondent shall indemnify and hold harmless New York State, DEC, and any of their representatives, employees or contractors for all claims, actions, damages, and costs of any name and description arising out of or resulting from the fulfillment or attempted fulfillment of the provisions of this Order by Respondent, their employees, contractors, servants, agents, successors or assigns.

III. Other Remedies

Nothing contained in this Order shall be construed as barring, diminishing, adjudicating or in any way affecting the following: (1) any legal, administrative or equitable rights or claims, actions, suits, causes of action or demands whatsoever that DEC may have against anyone other than Respondent; (2) DEC's right to enforce, administratively or otherwise, the terms, provisions and conditions of this Order against Respondent, his employees, servants, agents, successors and assigns in the event that Respondent shall be in breach of the provisions hereof, and to subject Respondent to penalties for such violations, or for other violations of the ECL; and (3) DEC's right to bring any action or proceeding against Respondent and/or any of Respondent's employees, servants, agents, successors and assigns with respect to claims for natural resource damages; or (5) the Respondent's right to challenge any such action by the Department, whether by administrative hearing or otherwise, to the extent otherwise permitted by law or this Order on Consent.

IV. Entire Agreement; Modification

This Order constitutes the entire agreement of the parties, and no provision of the agreement shall be deemed waived or otherwise modified except as is specifically set forth in a writing executed by the Commissioner or Regional Director of DEC indicating an intent to modify this Order.

V. <u>Effective Date</u>

The effective date of this Order is the date that by the Commissioner of Environmental Conservation, or her designee, signs it; and this Order shall expire when Respondent has fully complied with the requirements of this Order.

VI. Binding Effect

The provisions of this Order shall be deemed to bind Respondent, its officers, directors, agents, employees, contractors, successors and assigns, and all persons, firms and corporations acting under or for it.

VII. Inspections

For the purpose of insuring compliance with this Order, duly authorized representatives of this Department shall be permitted access to the site in order to inspect and/or require such tests as may be deemed necessary to determine the status of the Respondent's compliance with this Order and applicable ECL laws and regulations.

IX. Summary Abatement

The terms of this Order shall not be construed to prohibit the Commissioner of his duly authorized representative from exercising any summary abatement powers, either at common law or as granted pursuant to statute or regulation.

X. Violations Status

All violations cited in the Order on Consent have been corrected by Respondent returning it to compliance as of the effective date of this Order on Consent.

Date: Ap ,2014

Joseph Martens Commissioner New York State Department of Environmental Conservation

Eugene J. Kelly Regional Director Region 4

BY:

CONSENT BY RESPONDENT

Respondent hereby consents to the issuing and entering of this Order on Consent, waives its rights to notice and hearing herein and agrees to be bound by the provisions, terms and conditions contained herein.

BY: Kenneth frimaslite TITLE: SITE DIRECTOR DATE: 4/29/14 DATE:

STATE OF NEW YORK)) ss.: COUNTY OF Delaware)

On the 29^{th} day of <u>April</u> in the year 2014, before me, the undersigned, personally appeared KENNETH YAMASHITAFull name)

personally known to me who, being duly sworn, did depose and say that he/she/they reside at

172 Railroad Ave, Hobart 114 13781

and that he/she/they is (are) the

DIRECTOR

(President or other officer or director or attorney in fact duly appointed)

of the MALLINCKRODT PHARMACEUTICALS LLC (Full legal name of corporation)

the corporation described in and which executed the above instrument; and that he/she/they signed his/her/their name(s) thereto by the authority of the board of directors of said corporation.

Notary Public, State of New York

DEBRA A MARTIN Notary Public, State of New York No. 01MA4963485 Qual. Delaware County Commission Expires March 12, 2015