

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 7

UNITED STATES  
ENVIRONMENTAL PROTECTION  
AGENCY-REGION 7

2013 JAN 23 PM 4:04

IN THE MATTER OF

Mallinckrodt, LLC

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) Docket No. RCRA-07-2012-0045  
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Respondent  
  
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ORDER

Pursuant to 40 C.F.R. § 22.5(a)(1), electronic filing of page 21 of the Consent Agreement and Final Order is authorized in this proceeding.

Dated: 1/23/13

*Karina Borromeo*

Karina Borromeo  
Regional Judicial Officer

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 7  
11201 RENNER BOULEVARD  
LENEXA, KANSAS 66219

UNITED STATES  
ENVIRONMENTAL PROTECTION  
AGENCY-REGION 7  
2013 JAN 23 PM 4:04

IN THE MATTER OF: )

Mallinckrodt, LLC )

3600 North Second St. )  
St. Louis, Missouri 63147 )

EPA I.D. No. MOD096726484 )

Respondent. )

Proceeding under Sections 3008(a) and (g) of )  
the Resource Conservation and Recovery Act, )  
as amended, 42 U.S.C. §§ 6928(a) and (g). )

**CONSENT AGREEMENT  
AND FINAL ORDER**

Docket No. RCRA-07-2012-0045

**CONSENT AGREEMENT AND FINAL ORDER**

The United States Environmental Protection Agency, Region 7 (EPA or Complainant) and Mallinckrodt, LLC (Respondent) have agreed to a settlement of this action before the filing of a complaint, and thus this action is simultaneously commenced and concluded pursuant to Rules 22.13(b), 22.18(b)(2), and 22.18(b)(3) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits (Consolidated Rules of Practice), 40 Code of Federal Regulations (C.F.R.) §§ 22.13(b), 22.18(b)(2), and 22.18(b)(3).

**Jurisdiction**

1. This administrative action is being conducted pursuant to Sections 3008(a) and (g) of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA) and the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. §§ 6928(a) and (g), and in accordance with the Consolidated Rules of Practice.

2. This Consent Agreement and Final Order (CAFO) serves as notice that EPA has reason to believe that Respondent violated Section 3005 of RCRA, 42 U.S.C. § 6925, and the regulations found at 40 C.F.R. Part 262, as incorporated at 10 C.S.R. 25-5.262(1).

### **Parties**

3. The Complainant is the Chief of the Waste Enforcement and Materials Management Branch in the Air and Waste Management Division of EPA, Region 7, pursuant to the following delegations: Delegation No. 8-9-A, dated May 11, 1994; Delegation No. R7-8-009-A, as revised on September 16, 2007; and Delegation No. R7-Div-8-9-A, as revised on April 11, 2010.

4. The Respondent is Mallinckrodt LLC, a Delaware Limited Liability Company (Mallinckrodt) that is registered as a foreign limited liability company, authorized to do business in the State of Missouri.

### **Statutory and Regulatory Framework**

5. The State of Missouri (Missouri) has been granted authorization to administer and enforce a hazardous waste program pursuant to Section 3006 of RCRA, 42 U.S.C. § 6926. Missouri has adopted by reference the federal regulations cited herein at pertinent parts of Title 10, Division 25 of the Missouri Code of State Regulations (hereinafter "10 C.S.R. 25"). Section 3008 of RCRA, 42 U.S.C. § 6928, authorizes EPA to enforce the provisions of the authorized State program and the regulations promulgated thereunder. When EPA determines that any person has violated or is in violation of any RCRA requirement, EPA may issue an order assessing a civil penalty for any past or current violation and/or require immediate compliance or compliance within a specified time period pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928.

6. When a RCRA violation occurs in a state that is authorized to implement a hazardous waste program pursuant to Section 3006, 42 U.S.C. § 6926, EPA shall give notice to the state in which such violation has occurred or is occurring prior to issuing an order. Missouri has been notified of this action in accordance with Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2).

7. Section 3008(g) of RCRA, 42 U.S.C. § 6928(g), authorizes a civil penalty of not more than \$25,000 per day for violations of Subchapter III of RCRA (Hazardous Waste Management). This figure has been adjusted upward for inflation pursuant to the Civil Monetary Penalties Inflation Adjustment Rule, 40 C.F.R. Part 19, so that penalties of up to \$32,500 per day are now authorized for violations of Subchapter III of RCRA that occur after March 15, 2004, through January 12, 2009. For violations of Subchapter III of RCRA that occur after January 12, 2009, penalties of up to \$37,500 per day are now authorized.

### **General Factual Allegations**

8. Respondent is a manufacturer of bulk pharmaceuticals and imaging solutions and a subsidiary of Covidien, a global healthcare products company. Respondent's principal office address is 1209 Orange Street, Wilmington, Delaware 19801.
9. Respondent is a "person" as defined in Section 1004(15) of RCRA, 42 U.S.C. § 6903(15).
10. Respondent's St. Louis facility has been in operation since 1867 and currently employs 750 full-time employees.
11. The St. Louis facility is located on the eastern border of St. Louis, MO about 300 feet from the Mississippi River.
12. At the St. Louis facility, Respondent manufactures opium-based narcotics, including morphine, codeine, and oxycodone. The processing takes place in batch reactors using various solvents such as methanol, alcohol, toluene, methylene chloride, and chloroform.
13. At the St. Louis facility, Respondent also produces imaging solutions to enhance medical imaging such as MRI scans. These solutions are also produced in batches using solvents.
14. On or about February 8 - 11, 2011, an EPA representative conducted a RCRA Compliance Evaluation Inspection at Respondent's facility (hereinafter "the February 2011 inspection"). Based on a review of the inspection report and the information provided during the inspection by facility personnel, it was determined that Respondent was operating, at the time of inspection, as a Large Quantity Generator of hazardous waste, a Small Quantity Handler of universal waste, and a Generator of used oil.
15. During the inspection, two less than 90-day hazardous waste storage tanks, T-378 chlorinated and T-380 flammables were identified. The tanks are located in the Plant 5 tank farm, which also contains various tanks with chemical product. Tank T-378 receives waste from Bldg. 235. The waste in tank T-378 is comprised of ethanol, methanol (F003), toluene (F005), water, methyl isobutyl ketone (F003), acetone (F003), isopropanol, acetic acid, chloroform (D022), methylene chloride (F001), butyl alcohol (F003), isopropyl acetate, chromium compounds (D007), ethyl acetate (F003), propyl acetate, dimethylformamide, thionyl chloride, sodium chloride, and sodium hydroxide. Tank T-380 receives waste from Bldg. 235 and Bldg. 260. The waste in tank T-380 is comprised of water, ethanol, methanol, toluene, methyl isobutyl ketone, isopropanol, chloroform, propyl acetate, propyl alcohol, ethyl acetate, butyl alcohol, salts, and ruthenium catalyst.

16. During the inspection and subsequent response to the Notice of Violation, the EPA inspector noted that the main hazardous waste less-than-90-day storage pad has three bays, Area A, Area B, and Area C. The three bays are used to segregate where the wastes are sent. The response stated that Area A houses flammable liquids, poisons, and miscellaneous dangerous goods; Area B houses flammable solids, dangerous when wet, spontaneously combustible, poisons, and miscellaneous dangerous goods; and Area C houses oxidizers, corrosives, and miscellaneous dangerous goods.

17. Respondent generates numerous types of hazardous and non-hazardous wastes. The wastes are generated at over 2300 points. Respondent generates F005, D001, D003, D022, D002, F001, D035, F003, F002, D007, D006, D009, D008, D004, D005, D025, U404, U134, D018, U154, U213, P028, D038, U220, U031, U196, D018, U012, U140, U246, U044, U123, U067, D021, U138, U117, U239, U208, U228, U227, U209, U056, U225, U029, U045, P078, U135, D011, P076, U080, U002, U037, U006, P101, U213, U219, D025, P012, U080, D036, P012, and U133 hazardous wastes. Respondent also generates used oil and universal wastes. These wastes are managed at one of five less-than-90-day hazardous waste container storage areas: Bldg. 103 (Main Hazardous Waste Storage Pad), Bldg. 700A, Bldg. 31, Bldg. 200E and the facility in Plant 7S.

18. The regulations for determining whether a waste is a solid and/or hazardous waste are set forth at 10 C.S.R. 25-4.261, which incorporates by reference the regulations at 40 C.F.R. Part 261. Each of the wastes listed in Paragraph 16 is a "solid waste" and all of the wastes are "hazardous wastes" within the meaning of these regulations.

19. Respondent's most recent notification of hazardous waste activity, which was filed March 29, 2012, identifies Mallinckrodt as a "Large Quantity Generator" of hazardous waste in Missouri pursuant to 40 C.F.R. § 262.34, incorporated by reference at 10 C.S.R. 25-5.262(1).

20. Respondent has been assigned a facility identification number of MOD096726484.

### **Violations**

21. Complainant hereby states and alleges that Respondent has violated RCRA and federal and state regulations promulgated thereunder, as follows:

### Count 1

#### Operating as a Treatment, Storage or Disposal Facility Without a RCRA Permit or RCRA Interim Status

22. The allegations stated in Paragraphs 1 through 21 are realleged and incorporated as if fully set forth herein.

23. Section 3005 of RCRA, 42 U.S.C. § 6925, and 10 C.S.R. 25-7.270 incorporating by reference 40 C.F.R. § 270.1(b), require each person owning or operating a facility for the treatment, storage, or disposal of a hazardous waste identified or listed under Subchapter III of RCRA to have a permit for such activities.

24. The regulations at 10 C.S.R. 25-5.262(1), which incorporate by reference 40 C.F.R. § 262.34(a), allow a generator to accumulate hazardous waste in containers on-site for 90 days without a permit or without interim status, provided the conditions listed in 40 C.F.R. 262.34(a)(1)-(4) are met. These conditions include compliance with other hazardous waste regulatory requirements.

25. More specifically, according to 40 C.F.R. § 265.34(a)(1)(i), a generator may accumulate hazardous waste on-site for 90 days or less without a permit provided that waste is placed in containers and the generator complies with applicable requirements of 40 C.F.R. Part 265 Subpart I.

26. Further, according to 40 C.F.R. § 265.34(a)(1)(ii), a generator may accumulate hazardous waste on-site for 90 days or less without a permit provided that waste is placed in tanks and the generator complies with applicable requirements of 40 C.F.R. Part 265 Subpart J.

27. Respondent failed to comply with various hazardous waste regulatory requirements, described below.

28. At all times relevant to the matters alleged herein, Respondent did not have a RCRA Permit or Interim Status to operate as a storage facility and was therefore in violation of Section 3005 of RCRA, 42 U.S.C. § 6925, and 10 C.S.R. 25-7.270.

#### **Failure to Comply with Generator Requirements**

29. At the time of the February 2011 inspection, Respondent was not complying with the following regulatory requirements:

*Failure to Store Containers of Hazardous Waste in Good Condition*

30. Pursuant to 10 C.S.R. 25-5.262(1), incorporating by reference 40 C.F.R. § 265.171, any container holding hazardous waste must be in good condition or the owner or operator must transfer the hazardous waste to a container that is in good condition.

31. At the time of February 2011 inspection, in the Main Hazardous Waste Storage Pad, the EPA inspector found the following containers in poor condition:

- a) A dented metal container (#35599-0002), containing xylene/ethyl ether (F003/D001) waste, dated 1/28/11.
- b) A dented metal container (#24587-0001), containing ethyl ether/methanol/ethylamine (F003/D001) waste, dated 1/26/11.
- c) A dented plastic container (#34123-0005), containing lab solvent ((D001/D002/D025/F003) waste, dated 1/28/11.
- d) A dented metal container (#34267-0001), containing tetrahydrofuran/ethyl acetate ((F003/D001) waste, dated 12/20/10.
- e) A dented plastic container (#35082-0004), containing acetic acid ((D001/D002) waste, dated 1/16/11.
- f) A dented metal container #35908-0001 containing D001/D022 waste, dated 2/7/11.

32. At the time of inspection, Outside Building 31, the EPA inspector found the following container in poor condition: a dented plastic container of bulk lab (D002/D022) waste, dated 2/9/11.

33. Respondent's failure to maintain the containers listed in Paragraphs 31 and 32 in good condition is a violation of 10 C.S.R. 25-5.262(1), incorporating by reference 40 C.F.R. § 262.34(a)(1) citing 40 C.F.R. § 265.171.

*Storage of containers of incompatible wastes in close proximity*

34. The regulations at 10 C.S.R. 25-5.262(1) incorporate by reference the regulations at 40 C.F.R. § 262. 40 C.F.R. § 262.34 (a)(1)(i) requires generators to comply with 40 C.F.R. § 265.177(c), which states that a storage container holding a hazardous waste that is incompatible with any waste or other materials stored nearby in other containers must be separated from other materials or protected from them by means of dike, berm, wall, or other device.

35. According to 40 C.F.R. 265 Appendix V, alcohols, halogenated hydrocarbons, unsaturated hydrocarbons and other reactive organics and solvents are incompatible with concentrated corrosives.

36. During the February 2011 inspection, Respondent stored the following containers of incompatible hazardous wastes near each other in the main hazardous waste storage area without protection by dike, berm, wall or other device:

- a) One, 55-gallon container of Dichloromethane (F002), dated 1/24/11- Halogenated Organics;
- b) One, 55-gallon container of Chloroform (D022, D001, D002, F003, F005) – Halogenated Organics;
- c) One, 55-gallon container of Acetone, ethyl ether, T-butyl methyl ether, xylene (F003, D001) – Ketones, Ethers, Hydrocarbons, Aromatic;
- d) One, 55-gallon container of Ethyl ether-97-100%, methanol-0-5%, ethylamine-0-2% (F003, D001) – Ethers and Alcohols and Glycols;
- e) One, 55-gallon container of Tetrahydrofuran, ethyl acetate (F003, D001) – Ethers and Esters;
- f) One, 55-gallon container of pH<2, Acetic acid-99.95%, organic solids-0.05% (D001, D002) – Acids, Organic;
- g) One, 55-gallon container of pH<2, methane sulfonic acid-20-35%, propionic acid-5-15%, water-50-65% (D001), dated 1/19/11 – Acids, Mineral, Oxidizing and water Reactive Substances and Acids, Organic;
- h) One, 55-gallon container of pH=0.5 to 1.5, Lab Bulk from Bldg 31, sulfuric and hydrochloric acid (D002), dated 1/14/11 – Acids, Mineral, Oxidizing and Acids, Mineral, Non-oxidizing

37. These wastes are incompatible and should have been properly segregated.

38. Respondent's failure to adequately segregate the incompatible hazardous wastes listed in Paragraph 36 is a violation of 40 C.F.R. § 265.177(c), as referenced at 40 C.F.R. §262.34(a)(1)(i), incorporated by reference at 10 C.S.R. 25-5.262(1).

*Failure to Keep Hazardous Waste Containers Closed*

39. The regulations in 10 C.S.R. 25-5.262(1), which incorporate by reference 40 C.F.R. § 265.173(a), require that a container holding hazardous waste must always be kept closed except when it is necessary to add or remove waste.

40. At the time of the February 2011 inspection, the EPA inspector noted the following four open satellite accumulation containers in R&D Building 96:

- a) Room 207 – 2 containers dated 1/18/11 and 9/27/10
- b) Room 213 – 1 container dated 2/7/11
- c) Room 245 – 1 container



41. Respondent's failure to close the satellite accumulation containers listed in Paragraph 40 is a violation of 40 C.F.R. § 265.173(a), incorporated by reference at 10 C.S.R. 25-5.262(1).

*Failure to Update the Contingency Plan*

42. 10 C.S.R. 25-5.262(1), incorporating by reference 40 C.F.R. § 262.34(a)(4), which in turn references 40 C.F.R. § 265.52(d), requires the generator to have a contingency plan that list names, addresses, and phone numbers (office and home) of all persons qualified to act as emergency coordinators.

43. At the time of the February 2011 inspection, Respondent has designated alternative emergency coordinators but had not included their names, addresses or phone numbers in the contingency plan.

44. 10 C.S.R. 25-5.262(1), incorporating by reference 40 C.F.R. § 265.52(e), requires the generator to have a contingency plan that includes an up-to-date list of all required emergency equipment at the facility. The plan should include the location and physical description of each item on the list, and a brief outline of its capabilities.

45. At the time of the February 2011 inspection, spill control equipment in the Main Hazardous Waste Storage pad and a fire extinguisher in the Lab Pack Storage shed were not listed in the contingency plan. Additionally, the list of emergency equipment listed in the inspection logs did not match the equipment listed in the contingency plan.

46. Respondent did not include the name, address and phone numbers of alternate emergency contact nor the location of required emergency equipment in the contingency plan, thus violating 40 C.F.R. § 265.52(d) and (e), as referenced by 40 C.F.R. § 262.34(a)(4), which is incorporated by reference at 10 C.S.R. 25-5.262(1).

*Failure to properly construct or line secondary containment system*

47. The regulations at 10 C.S.R. 25-5.262(1) incorporate by reference 40 C.F.R. § 262.34(a)(1)(ii), which in turn references 40 C.F.R. § 265.193, outlines the requirements for secondary containment for tank systems in order to prevent the release of hazardous waste or hazardous constituents to the environment.

48. Specifically, 40 C.F.R. § 265.193(b) requires that secondary containment systems be designed, installed and operated to prevent any migration of wastes or accumulated liquid out of the tank system into the soil, ground water, or surface water at any time during the use of the

tank system. The secondary containment must also be capable of detecting and collecting releases and accumulated liquids until the collected material is removed. In order meet these requirements, according to 40 C.F.R. § 265.193(c)(1), the secondary containment systems must be at a minimum constructed of or lined with materials that are compatible with the wastes to be placed in the tank system and must have sufficient strength and thickness to prevent failure due to pressure gradients, physical contact with the waste to which they are exposed, climatic conditions, and the stress of daily operation.

49. Information collected during the February 2011 inspection and follow-up correspondence showed that several waste streams containing methylene chloride were routinely placed into tank T-378.

50. During the February 2011 inspection, the inspector collected information showing that according to the December 1, 2006 tank certification, the tank containment coating was not recommended for methylene chloride and rated for only intermittent exposure for several other waste components.

51. Another tank certification dated June 18, 2010 again noted that the containment coating was not recommended for methylene chloride and only intermittent exposure for several other waste components. The June 2010 certification stated that there were several locations where the coating was damaged, but had been repaired at the time of the certification. The June 2010 certification recommended chemical resistance testing under the supervision of a materials engineer. This was not done by the time of the February 2011 inspection.

52. Respondent's subsequent testing determined that the coating in place in the tank farm at the time of the inspection was not compatible with methylene chloride.

53. The failure to ensure that the secondary containment system was lined with materials that are compatible with the wastes to be placed in the tank system is a violation of 40 C.F.R. § 265.193(c)(1) as referenced by 40 C.F.R. § 262.34(a)(1)(ii), which is incorporated by reference at 10 C.S.R. 25-5.262(1).

*Failure to label hazardous waste tanks with the words "Hazardous Waste"*

54. The regulations at 10 C.S.R. 25-5.262(1) incorporate by reference 40 C.F.R. § 262.34(a)(3), require that while hazardous waste is being accumulated on-site, each tank must be labeled or clearly marked with the words "Hazardous Waste."

55. During the February 2011 inspection, the inspector documented that the T-378 chlorinated tank was not labeled with the words "Hazardous Waste."

56. The failure to label the tank with the words “Hazardous Waste” is a violation of 40 C.F.R. § 262.34(a)(3), which is incorporated by reference at 10 C.S.R. 25-5.262(1).

*Placement of incompatibles in the same tank system without appropriate controls*

57. The regulations at 10 C.S.R. 25-5.262(1) incorporate by reference 40 C.F.R. § 262.34(a)(1)(ii), which in turn references 40 C.F.R. § 265.199(a), require that the owner or operator must not place incompatible waste or incompatible waste and materials into the same tank system unless there is compliance with 40 C.F.R. § 265.17(b).

58. At the time of the February 2011 inspection, the EPA inspector documented that the tanks storing hazardous wastes, T-378-chlorinated and T-380-flammable, contained wastes chemically classified as “organics.” These hazardous waste tanks were stored in the same tank farm as product tanks classified as corrosives (dimethyl acetamide, sodium hydroxide, and glacial acetic acids).

59. According to 40 C.F.R. 265 Appendix V, reactive organics and solvents are incompatible with concentrated corrosives. At the time of the February 2011 inspection, Respondent had not done the testing to demonstrate that the materials stored in the product tanks in the same tank farm were compatible.

60. Respondent’s failure to ensure that incompatible wastes were not improperly stored in the same tank system is a violation of 40 C.F.R. § 265.199(a), incorporated by reference at 10 C.S.R. 25-5.262(1).

**CONSENT AGREEMENT**

1. Respondent and EPA agree to the terms of this CAFO and Respondent agrees to comply with the terms of the Final Order portion of this CAFO. The terms of this CAFO shall not be modified except by a subsequent written agreement between the parties.

2. Respondent admits the jurisdictional allegations of this CAFO and agrees not to contest EPA’s jurisdiction in this proceeding or any subsequent proceeding to enforce the terms of the Final Order portion of this CAFO set forth below.

3. Respondent neither admits nor denies the factual allegations and legal conclusions set forth in this CAFO, but agrees to settle all claims alleged by Complainant under the terms set forth herein without further cost or delay.

4. Respondent waives its right to a judicial or administrative hearing on any issue of fact or law set forth above, and its right to appeal the proposed Final Order portion of the CAFO.

5. Respondent and Complainant agree to conciliate the matters set forth in this CAFO without the necessity of a formal hearing and to each bear their respective costs and attorneys' fees.

6. This CAFO addresses all civil administrative claims for the RCRA violations and facts identified above. Complainant reserves the right to take any enforcement action with respect to any other violations of RCRA and its implementing regulations or any other applicable law.

7. Nothing contained in the Final Order portion of this CAFO shall alter or otherwise affect Respondent's obligation to comply with all applicable federal, state, and local environmental statutes and regulations and applicable permits.

8. The undersigned representative of Respondent certifies that he or she is fully authorized to enter the terms and conditions of this CAFO and to execute and legally bind Respondent to it.

9. Respondent understands that failure to pay any portion of the civil penalty on the date the same is due may result in the commencement of a civil action in Federal District Court to collect said penalty, along with interest thereon at the applicable statutory rate.

10. This CAFO shall be effective upon entry of the Final Order by the Regional Judicial Officer for EPA, Region 7. Unless otherwise stated, all time periods stated herein shall be calculated in calendar days from such date.

11. Respondent certifies by the signing of this CAFO that, to the best of Respondent's knowledge, it is presently in compliance with all requirements of Subchapter III of RCRA (Hazardous Waste Management) at the St. Louis facility.

12. Respondent agrees that, in settlement of the claims alleged in this CAFO, Respondent shall pay a mitigated civil penalty of \$59,740 as set forth in Paragraph 1 of the Final Order.

13. No portion of the civil penalty or interest paid by Respondent pursuant to the requirements of the paragraph above shall be claimed by Respondent as a deduction for federal, state, or local income tax purposes.

### **Supplemental Environmental Projects**

14. In response to the violations of RCRA alleged in this CAFO and in settlement of this matter, although not required by RCRA or any other federal, state, or local law, Respondent agrees to perform two Supplemental Environmental Projects (SEPs) as set forth in this CAFO. The combined projected cost of the SEPs is \$390,000.00.

#### School Laboratory Cleanouts

15. Respondent shall complete a “cleanout” of school laboratories within the St. Louis, Missouri Public School District (the District). Respondent will assist the District in the one-time removal, transportation and disposal of hazardous wastes currently located in several of the District’s educational facilities and will provide those facilities with outreach and education about hazardous waste management. This SEP shall be performed in accordance with the requirements of this CAFO and the SEP Work Plan as described in Paragraph 16 below.

16. Within forty-five (45) days of the effective date of this CAFO, Respondent shall submit a work plan for the School Laboratory Cleanout SEP (Cleanout SEP). The work plan will name the schools identified by the District, and will describe the cleanout and outreach activities to be completed in carrying out the work plan, as well as set forth a schedule for completion of the project. The project schedule shall not exceed one year, which shall commence upon EPA approval of the work plan. The work plan shall be subject to approval by EPA’s representative identified in Paragraph 26 below. Upon approval, the work plan shall be incorporated into this CAFO.

17. Respondent agrees that it will spend at least \$40,000.00 on the Cleanout SEP.

18. Respondent agrees to the payment of stipulated penalties for the Cleanout SEP as follows:

a. In the event Respondent fails to comply with any of the terms or provisions of this Agreement relating to the performance of the Cleanout SEP, above, and/or to the extent that the actual expenditures for the SEP do not equal or exceed the cost of the SEP described in this CAFO, Respondent shall be liable for stipulated penalties according to the provisions set forth below:

(1) Except as provided in Subparagraph b, immediately below, if the SEP is not completed satisfactorily and timely pursuant to the requirements set forth in this CAFO, Respondent shall be liable for and shall pay a stipulated penalty to the United States in the amount of \$40,000.00.

(2) If the SEP is satisfactorily completed, but the Respondent spent less than \$36,000.00 on the SEP, Respondent shall pay a stipulated penalty to the United States in the amount of \$6,000.00.

b. If the SEP identified in Paragraph 15 of this CAFO is not completed satisfactorily, but EPA determines that Respondent: (1) has made good faith and timely efforts to complete the SEP; and (2) has certified, with supporting documentation, that Respondent spent at least \$36,000.00 on the SEP, Respondent shall not be liable for payment of a stipulated penalty.

c. If the SEP is satisfactorily completed in accordance with the CAFO, and EPA determines that the Respondent has spent at least \$36,000.00 on the SEP, Respondent shall not be liable for any stipulated penalty.

d. If Respondent fails to timely and completely submit the SEP Completion Report required by this CAFO, Respondent shall be liable for and shall pay a stipulated penalty in the amount of \$250.00 for each day after the due date until a complete report is submitted.

e. EPA shall determine whether the SEP has been satisfactorily completed and whether the Respondent has made a good faith, timely effort to implement the SEP.

f. Stipulated penalties shall begin to accrue on the day after performance is due, and shall continue to accrue through the final day of the completion of the SEP or other resolution under this CAFO.

g. Respondent shall pay stipulated penalties not more than fifteen (15) days after receipt of written demand by EPA for such penalties. Method of payment shall be in accordance with the provisions set forth in Paragraphs 1 and 2 of the Final Order portion of this CAFO, below.

#### Construction of Temperature-Controlled Storage Area

19. Respondent agrees to undertake construction of a temperature-controlled hazardous waste drum storage area at its facility to ensure that drums containing temperature-sensitive materials do not become damaged or release their contents due to exposure to extreme temperatures. This SEP shall be performed in accordance with the requirements of this CAFO and the SEP Work Plan as described in Paragraph 20 below.

20. Within forty-five (45) days of the effective date of this CAFO, Respondent shall submit a work plan for the Temperature-controlled Storage Area SEP (Storage Area SEP). The project schedule shall not exceed one year, which shall commence upon EPA approval of the work plan. The work plan shall be subject to approval by EPA's representative identified in Paragraph 26 below. Upon approval, the work plan shall be incorporated into this CAFO.

21. Respondent agrees that it will spend at least \$350,000.00 on the Storage Area SEP.

22. Respondent agrees to the payment of stipulated penalties as follows:

a. In the event Respondent fails to comply with any of the terms or provisions of this Agreement relating to the performance of the SEP, above, and/or to the extent that the actual expenditures for the SEP do not equal or exceed the cost of the SEP described in this CAFO, Respondent shall be liable for stipulated penalties according to the provisions set forth below:

(1) Except as provided in Subparagraph b. immediately below, if the SEP is not completed satisfactorily and timely pursuant to the requirements set forth in this CAFO, Respondent shall be liable for and shall pay a stipulated penalty to the United States in the amount of \$144,045.00.

(2) If the SEP is satisfactorily completed, but the Respondent spent less than \$315,000.00 on the SEP, Respondent shall pay a stipulated penalty to the United States in the amount of \$52,500.00.

b. If the SEP identified in this CAFO is not completed satisfactorily, but EPA determines that Respondent: (1) has made good faith and timely efforts to complete the SEPs; and (2) has certified, with supporting documentation, that Respondent spent at least \$315,000.00 on the SEP, Respondent shall not be liable for payment of a stipulated penalty.

c. If the SEP is satisfactorily completed in accordance with the CAFO, but EPA determines that the Respondent has spent at least \$315,000.00 on the SEP, Respondent shall not be liable for any stipulated penalty.

d. If Respondent fails to timely and completely submit the SEP Completion Report required by this CAFO, Respondent shall be liable for and shall pay a stipulated penalty in the amount of \$250.00 for each day after the due date until a complete report is submitted.

e. EPA shall determine whether the SEP has been satisfactorily completed and whether the Respondent has made a good faith, timely effort to implement the SEP.

f. Stipulated penalties shall begin to accrue on the day after performance is due, and shall continue to accrue through the final day of the completion of the SEP or other resolution under this CAFO.

g. Respondent shall pay stipulated penalties not more than fifteen (15) days after receipt of written demand by EPA for such penalties. Method of payment shall be in accordance with the provisions set forth in Paragraph 2 of the Final Order portion of this CAFO, below.

#### SEP Completion Reports

23. Within one year of EPA approval of the work plans, Respondent shall submit a SEP Completion Report to EPA for each SEP. The SEP Completion Reports shall conform to the requirements of this CAFO and shall contain the following information:

- a. A detailed description of the SEPs as implemented, including itemized costs;
- b. A description of any problems encountered in implementation of the projects and the solution thereto;
- c. A description of the specific environmental and/or public health benefits resulting from implementation of the SEPs; and
- d. Certification that the SEPs have been fully implemented pursuant to the provisions of this CAFO.

24. In itemizing its costs in the SEP Completion Reports, Respondent shall clearly identify and provide acceptable documentation for all SEP costs. For purposes of this Paragraph, "acceptable documentation" includes invoices, purchase orders, or other documentation that specifically identifies and itemizes the individual costs of the goods and/or services for which payment is being made. Cancelled drafts do not constitute acceptable documentation unless such drafts specifically identify and itemize the individual costs of the goods and/or services for which payment is being made.

25. The SEP Completion Reports shall each include the statement of Respondent, through an officer, signed and certifying under penalty of law the following:



I certify under penalty of law that I have examined and am familiar with the information submitted in this document and all attachments and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment.

26. The SEP Completion Reports shall be submitted on or before the due date specified in Paragraph 23 to:

Nicole Moran, AWMD/WEMM  
Environmental Protection Agency  
Region 7  
11201 Renner Boulevard  
Lenexa, Kansas 66219.

Other Requirements Applicable to Both SEPs

27. Any public statement, oral or written, in print, film, internet, or other media, made by Respondent making reference to the SEP shall include the following language:

This project was undertaken in connection with the settlement of an enforcement action taken by the U.S. Environmental Protection Agency for violations of the Resource Conservation and Recovery Act. 42 U.S.C. § 6901 *et. seq.*

28. Respondent hereby certifies that, as of the date of this CAFO, Respondent is not required to perform or develop the SEP described in this CAFO by any federal, state, or local law or regulation; nor is Respondent required to perform or develop the SEP by any other agreement, grant or as injunctive relief in this or any other case. Respondent further certifies that it has not received, and is not presently negotiating to receive credit in any other enforcement action for the SEP.

29. For federal income tax purposes, Respondent agrees that it will neither capitalize into inventory or basis nor deduct any costs or expenditures incurred in performing the SEPs.

30. Late Payment Provisions: Pursuant to 31 U.S.C. § 3717, EPA is entitled to assess interest and penalties on debts owed to the United States and a charge to cover the cost of processing and handling a delinquent claim. Interest will therefore begin to accrue on a civil or stipulated penalty if it is not paid by the date required. Interest will be assessed at a rate of

the United States Treasury tax and loan rate in accordance with 31 C.F.R. § 901.9(b). A charge will be assessed to cover the costs of debt collection including processing and handling costs and attorneys fees. In addition, a non-payment penalty charge of six (6) percent per year compounded annually will be assessed on any portion of the debt which remains delinquent more than ninety (90) days after payment is due. Any such non-payment penalty charge on the debt will accrue from the date the penalty payment becomes due and is not paid. 31 C.F.R. §§ 901.9(c) and (d).

31. The effect of the settlement described in Paragraph 6 above is conditioned upon the accuracy of the Respondent's representations to EPA, memorialized in Paragraph 11 above.

32. This CAFO shall remain in full force and effect until Complainant provides Respondent with written notice, in accordance with Paragraph 6 of the Final Order portion of the CAFO, that all requirements hereunder have been satisfied.

#### **Reservation of Rights**

33. Notwithstanding any other provision of this CAFO, EPA reserves the right to enforce the terms of the Final Order portion of this CAFO by initiating a judicial or administrative action under Section 3008 of RCRA, 42 U.S.C. § 6928, and to seek penalties against Respondent in an amount not to exceed \$37,500 per day per violation pursuant to Section 3008(c) and/or Section 3008(g) of RCRA, for each day of non-compliance with the terms of the Final Order, or to seek any other remedy allowed by law.

34. Complainant reserves the right to take enforcement action against Respondent to enforce the terms and conditions of this CAFO.

35. Except as expressly provided herein, nothing in this CAFO shall constitute or be construed as a release from any claim (civil or criminal), cause of action, or demand in law or equity by or against any person, firm, partnership, entity, or corporation for any liability it may have arising out of or relating in any way to the generation, storage, treatment, handling, transportation, release, or disposal of any hazardous constituents, hazardous substances, hazardous wastes, pollutants, or contaminants found at, taken to, or taken from Respondent's facility.

36. Notwithstanding any other provisions of the CAFO, an enforcement action may be brought pursuant to Section 7003 of RCRA, 42 U.S.C. § 6973, or other statutory authority, should EPA find that the future handling, storage, treatment, transportation, or disposal of solid waste or hazardous waste at Respondent's facility may present an imminent and substantial endangerment to human health and the environment.

37. The headings in this CAFO are for convenience of reference only and shall not affect interpretation of this CAFO.

### **FINAL ORDER**

Pursuant to the authority of Sections 3008(a) and (g) of RCRA, 42 U.S.C. §§ 6928(a) and (g), and according to the terms of this CAFO, IT IS HEREBY ORDERED THAT:

#### **A. Payment of Civil Penalty**

1. Within thirty (30) days of the effective date of this CAFO, Respondent will pay a mitigated civil penalty of \$59,740.00. Such payment shall identify Respondent by name and docket number and shall be by certified or cashier's check made payable to the "United States Treasury" and sent to:

U.S. Environmental Protection Agency  
Fines and Penalties  
Cincinnati Finance Center  
PO Box 979077  
St. Louis, Missouri 63197-9000.

Wire transfers should be directed to the Federal Reserve Bank of New York:

Federal Reserve Bank of New York  
ABA = 021030004  
Account = 68010727  
SWIFT address = FRNYUS33  
33 Liberty Street  
New York, New York 10045

Field Tag 4200 of the Fedwire message should read  
"D 68010727 Environmental Protection Agency"

2. A copy of the payment documentation shall also be mailed to:

Regional Hearing Clerk  
U.S. Environmental Protection Agency, Region 7  
11201 Renner Boulevard  
Lenexa, Kansas 66219

and:

Belinda Holmes  
U.S. Environmental Protection Agency, Region 7  
11201 Renner Boulevard  
Lenexa, Kansas 66219.

3. No portion of the civil penalty or interest paid by Respondent pursuant to the requirements of this CAFO shall be claimed by Respondent as a deduction for federal, state, or local income tax purposes.

### **B. Compliance Actions**

4. EPA acknowledges that Respondent has satisfactorily completed the following actions which were agreed upon between the parties as part of the settlement of this matter. Respondent has taken measures to ensure that proper engineering controls are in place, in compliance with 10 C.S.R. 25-5.262(1) incorporating by reference 40 C.F.R. § 262.34(a)(1)(ii), which in turn references 40 C.F.R. § 265.199(a), referencing 40 CFR 265.17(b).

5. All documents required to be submitted by this CAFO shall be sent to the attention of:

Nicole Moran  
Environmental Scientist  
U.S. Environmental Protection Agency, Region 7  
AWMD/WEMM  
11201 Renner Boulevard  
Lenexa, Kansas 66219.

6. The provisions of this CAFO shall be deemed satisfied upon a written determination by Complainant that Respondent has fully implemented the actions required in the Final Order.

### **Parties Bound**

7. The Final Order portion of this CAFO shall apply to and be binding upon Respondent and Respondent's agents, successors and/or assigns. Respondent shall ensure that all contractors, employees, consultants, firms, or other persons or entities acting for Respondent with respect to matters included herein comply with the terms of this CAFO.

FOR COMPLAINANT:

U.S. ENVIRONMENTAL PROTECTION AGENCY- REGION 7

1-16-13

Date



Donald Toensing  
Chief

Waste Enforcement and Materials Management Branch  
Air and Waste Management Division

1-16-2013

Date



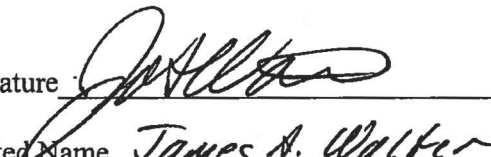
Belinda Holmes  
Senior Counsel  
Office of Regional Counsel

Consent Agreement and Final Order  
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FOR RESPONDENT:

MALLINCKRODT, LLC.

12/20/12  
Date

Signature  *phd*  
Printed Name James A. Walter  
Title Senior Director of Manufacturing

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IT IS SO ORDERED. This Final Order is effective upon its final entry by the Regional Judicial Officer.

1/23/13  
Date

Karina Borromeo  
Karina Borromeo  
Regional Judicial Officer

IN THE MATTER OF Mallinckrodt, LLC, Respondent  
Docket No. RCRA-07-2012-0045

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Orders were sent this day in the following manner to the addressees:

Copy hand delivered to  
Attorney for Complainant:

Belinda Holmes  
Senior Counsel  
Region 7  
United States Environmental Protection Agency  
11201 Renner Blvd.  
Lenexa, Kansas 66219

Copy by First Class Mail to:

Steven Poplawski, Esq.  
Brian Cave LLP  
211 North Broadway  
St. Louis, Missouri 63102

Dated: 1/24/13



Kathy Robinson  
Kathy Robinson  
Hearing Clerk, Region 7