

STATE OF INDIANA )  
 ) SS:  
COUNTY OF MARION )

BEFORE THE IOSHA BOARD OF  
SAFETY REVIEW

**F I L E D**

IN THE MATTER OF THE )  
COMMISSIONER OF LABOR, )

AUG 25 2011

Indiana Board of  
Safety Review

Complainant, )

CASE DOCKET NO. 10-013

v. )

SCHWARZ PHARMA )  
MANUFACTURING, INC., )

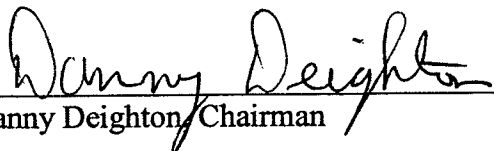
Respondent. )

**FINAL ORDER**

The parties to the above-referenced proceeding, through their duly authorized representatives, have filed with the Board their Agreed Entry. The Board, being duly advised, now accepts the Respondent's withdrawal of its Notice of Contest, and adopts the Safety Orders and penalty issued by the Commissioner of Labor, as modified by the Agreed Entry, as its final order in this matter.

IT IS ORDERED that the Respondent's withdrawal of its Notice of Contest is accepted and the Safety Orders and penalty issued by the Commissioner of Labor, as modified by the Agreed Entry, is adopted as a final order.

Dated: 25 Aug 2011

  
\_\_\_\_\_  
Danny Deighton, Chairman

Copies to:

Julie C. Alexander  
Legal Counsel  
Department of Labor  
402 W. Washington St., Rm. W195  
Indianapolis, IN 46204

Gregory N. Dale  
Baker & Daniels  
300 N. Meridian St., Ste. 2700  
Indianapolis, IN 46204

---

STATE OF INDIANA )  
 ) SS:  
COUNTY OF MARION )

BEFORE THE IOSHA BOARD OF  
SAFETY REVIEW

**F I L E D**

IN THE MATTER OF THE )  
COMMISSIONER OF LABOR, )

JUL 26 2011

Indiana Board of  
Safety Review

Complainant, )

CASE DOCKET NO. 10-013

v. )

SCHWARZ PHARMA )  
MANUFACTURING, INC. )

Respondent. )

**AGREED ENTRY**

The parties to the above-captioned proceeding, the Commissioner of the Indiana Department of Labor (hereinafter, "Commissioner" or "Complainant") and Kremers Urban Pharmaceuticals Inc., formerly Schwarz Pharma Manufacturing, Inc. (hereinafter, "Kremers" or "Respondent"), through their duly authorized representatives, being desirous of entering into this Agreed Entry prior to hearing do hereby stipulate and agree as follows:

**PART I.**

1. From March 8, 2010 through May 20, 2010, authorized employee(s) of the Indiana Department of Labor conducted an inspection at the Respondent's place of employment, at 1101 C Avenue West, Seymour, Indiana 47274.

2. On July 1, 2010, the Commissioner of Labor issued Safety Order 1, Items 1 through 5, and Safety Order 2, Items 1 and 2 (Indiana Department of Labor Inspection No. 313128027), alleging that Kremers had violated the Indiana Occupational Safety and Health Act (IC 22-8-1.1 *et seq.*) or the standards or rules adopted thereunder.

3. On July 27, 2010, Respondent duly and timely petitioned for review of Safety Order 1 and Safety Order 2 (and all Items, Subitems and matters contained in such Safety Orders).

4. Inspection No. 313128027 (Safety Order 1 and Safety Order 2 (and all Items and Subitems) are attached hereto as Exhibit A and are incorporated herein).

## **PART II**

5. The petitioned for review Safety Order 1, Inspection No. 313128027 consists of Items 1 through 5.

6. Safety Order 1, Items 1a and 1b allege, respectively, a "Serious" violation of Ind. Code 22-8-1.1, Section 2 and 29 C.F.R. 1910.1200(h)(3)(ii) and assess a total penalty of Six Thousand Three Hundred Dollars (\$6,300).

7. Safety Order 1, Item 2 alleges a "Serious" violation of 29 C.F.R. 1910.132(a) and assesses a total penalty of One Thousand Eight Hundred and Seventy-Five Dollars (\$1,875).

8. Safety Order 1, Items 3a, 3b, 3c, 3d, 3e and 3f allege, respectively, a "Serious" violation of 29 C.F.R. 1910.146(d)(2), 29 C.F.R. 1910.146(d)(5)(ii), 29 C.F.R. 1910.146(d)(8), 29 C.F.R. 1910.146(d)(9), 29 C.F.R. 1910.146(d)(10), and 29 C.F.R. 1910.147(c)(4)(i), and assess a total penalty of Four Thousand Five Hundred Dollars (\$4,500).

9. Safety Order 1, Items 4a, 4b, 4c, 4d, 4e, 4f, 4g, 4h, 4i, 4j, 4k, 4l, and 4m allege, respectively, a "Serious" violation of 29 C.F.R. 1910.146(e)(2), 29 C.F.R. 1910.146(e)(6), 29 C.F.R. 1910.146(f)(1), 29 C.F.R. 1910.146(f)(3), 29 C.F.R. 1910.146(f)(4), 29 C.F.R. 1910.146(f)(5), 29 C.F.R. 1910.146(f)(6), 29 C.F.R. 1910.146(f)(7), 29 C.F.R. 1910.146(f)(8), 29 C.F.R. 1910.146(f)(10), 29 C.F.R. 1910.146(f)(11), 29 C.F.R. 1910.146(f)(12), and 29 C.F.R. 1910.146(f)(13) and assess a total penalty of Four Thousand Five Hundred Dollars (\$4,500).

10. Safety Order 1, Item 5a, 5b, 5c, 5d, and 5e allege, respectively, a "Serious" violation of 29 C.F.R. 1910.146(g)(1), 29 C.F.R. 1910.146(k)(1)(i), 29 C.F.R. 1910.146(k)(1)(ii), 29 C.F.R. 1910.146(k)(2)(iv), and 29 C.F.R. 1910.146(k)(3)(ii), and assess a total penalty of Four Thousand Five Hundred Dollars (\$4,500).

11. The petitioned for review Safety Order 2, Inspection No. 313128027 consists of Items 1 and 2.

12. Safety Order 2, Item 1 alleges a "Nonserious" violation of 29 C.F.R. 1910.134(g)(1)(i)(a) and assesses a total penalty of Zero Dollars (\$0).

13. Safety Order 2, Item 2 alleges a "Nonserious" violation of 29 C.F.R. 1910.145(c)(3) and assesses a total penalty of Zero Dollars (\$0).

14. The total penalty amount for Inspection No. 313128027 including Safety Orders 1 and 2 (and all Items and Subitems) is Twenty-One Thousand Six Hundred and Seventy-Five Dollars (\$21,675).

### **PART III**

15. The Commissioner amends Safety Order 1, Inspection No. 313128027 in the following manner:

16. The Commissioner deletes Safety Order 1, Item 1a, Subitems a, b, c, d, and f in their entirety including the penalty.

17. The Commissioner upholds Safety Order 1, Item 1a, Subitem e, but amends the penalty for Safety Order 1a, Subitem e to Nine Hundred Dollars (\$900).

18. The Commissioner upholds Safety Order 1, Item 1b, but reduces the penalty to One Thousand Three Hundred Fifty Dollars (\$1,350) such that the entire penalty for Safety

Order 1, Item 1a (with the remaining Subitem e) and Item 1b is Two Thousand Two Hundred Fifty Dollars (\$2,250).

19. In consideration of the Commissioner's amendments to Safety Order 1, Items 1a and 1b, the Respondent will order and have installed a change to the referenced dust collection system that will involve the installation of a suppression system, with the parties agreeing that such suppression system will be installed within six (6) months of the date this Agreed Entry is executed by all parties and approved by the Board of Safety Review. Also, the parties agree that Kremers shall develop and implement a Fire Prevention Plan, as part of its Emergency Action Plan, within two (2) months of the date this Agreed Entry is executed by all parties and approved by the Board of Safety Review.

20. The Commissioner amends Safety Order 1, Item 2, by reducing the classification of this Item to "Nonserious" and reduces the penalty to Zero (\$0). In consideration of the Commissioner's amendments to this Item, the Respondent will, within two (2) months of the date this Agreed Entry is executed by all parties and approved by the Board of Safety Review, purchase, size and implement the use of new fire protective clothing for the maintenance technicians responsible for maintenance on the referenced dust collection and suppression systems at Kremer's Seymour facility.

21. The Commissioner deletes Safety Order 1, Item 3a in its entirety including the penalty.

22. The Commissioner deletes Safety Order 1, Item 3b in its entirety including the penalty.

23. The Commissioner upholds Safety Order 1, Item 3c, but groups and reduces the penalty as subsequently detailed in this Agreed Entry.

24. The Commissioner upholds Safety Order 1, Item 3d, but groups and reduces the penalty as subsequently detailed in this Agreed Entry.

25. In consideration of the Commissioner's amendments to Safety Order 1, Item 3c and 3d, the Respondent will make changes to its confined space program to: a) designate the persons who are to have active roles in the entry operations, identify the duties of each such person, and provide the referenced training; and b) include implementation of procedures for summoning rescue and emergency services, for rescuing entrants from permit spaces, for providing necessary emergency services to rescued employees, and for preventing unauthorized personnel from attempting a rescue. All such actions will be completed within two (2) months of the date this Agreed Entry is executed by all parties and approved by the Board of Safety Review.

26. The Commissioner deletes Safety Order 1, Item 3e in its entirety including the penalty.

27. The Commissioner deletes Safety Order 1, Item 3f in its entirety including the penalty.

28. In consideration of the Commissioner's amendments to Safety Order 1, Item 3f, the Respondent will prepare machine specific Lockout/Tagout ("LOTO") procedures for all equipment requiring LOTO procedures with the parties agreeing that such procedures will be prepared within eight (8) months of the date this Agreed Entry is executed by all parties and approved by the Board of Safety Review.

29. The Commissioner deletes Safety Order 1, Items 4a, 4b, 4c, 4d, 4e, 4f, 4g, and 4h in their entirety including the penalty.

30. The Commissioner deletes Safety Order 1, Items 4i and 4j in their entirety including the penalty, subject to Kremers' commitment to provide employee training on proper permit completion/documentation of confined space permits.

31. The Commissioner upholds Safety Order 1, Item 4k, but groups and reduces the penalty as subsequently detailed in this Agreed Entry.

32. The Commissioner deletes Safety Order 1, Items 4l, 4m, 5a, 5b, 5c, 5d, and 5e in their entirety including the penalty.

33. The Commissioner also groups Safety Order 1, Item 3 and Item 4 together with one penalty of Four Thousand Five Hundred Dollars (\$4,500).

34. The Commissioner upholds Safety Order 2, Item 1 in its entirety including the penalty of \$0.

35. The Commissioner upholds Safety Order 2, Item 2 in its entirety including the penalty of \$0.

36. The Commissioner amends the total penalty for all violations, Items and all Subitems thereunder for Safety Order 1 and Safety Order 2 from Twenty-One Thousand Six Hundred Seventy-Five Dollars (\$21,675) to Six Thousand Seven Hundred and Fifty Dollars (\$6,750).

37. Except for the above specified amendments, all other provisions and subparts of Safety Order 1 and Safety Order 2 remain unchanged and enforceable.

38. The AGREED total penalty for all violations and all subparts thereunder subject to this Agreed Entry is Six Thousand Seven Hundred and Fifty Dollars (\$6,750).

39. With the provision of the agreements in this Agreed Entry and the information supplied in the parties' settlement meetings and pursuant to this Agreed Entry including the



information referenced in the Agreed Entry, Respondent certifies abatement of all alleged hazards and alleged violations in all Items and all Subitems thereunder for Safety Order 1 and Safety Order 2, as amended, except for the Items for which the parties have expressly agreed to provide additional abatement periods as specifically set forth in this Agreed Entry.

#### **PART IV**

40. It is understood and agreed by the Respondent and the Complainant that this Agreed Entry and attachments will constitute final, enforceable IOSHA Safety Order(s) and penalties for the purposes of the IOSHA Act.

41. The Respondent confirms the Complainant's right to re-inspect its workplace in accordance with the Act. It is expressly agreed and understood, however, that Respondent's agreement is not, and will not be construed as, a waiver in any respect of its rights under the Constitutions of the United States or the State of Indiana and that it does not waive its right to raise any objection or defense in any future proceeding under the Act.

42. The Respondent hereby withdraws its petition for review previously filed in this matter, in accordance with the terms of this Agreed Entry.

43. Nothing contained in this Agreed Entry shall be construed to affect the Commissioner's interpretation of the Indiana Occupational Safety and Health Act or any standard or regulation enforced pursuant thereto or the applicable classification thereof.

44. The invalidity or unenforceability of any section, subsection, clause or provision of this Agreed Entry does not affect the remaining sections, subsections, clauses, or provisions of this Agreed Entry.

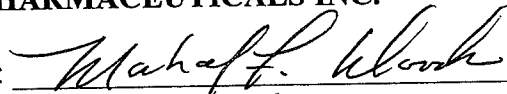
45. Except for these IOSHA proceedings, and IOSHA enforcement matters arising out of these proceedings and any other subsequent IOSHA proceedings between the parties, none of the

foregoing agreements and actions taken by the Respondent, which denies any violation of the Act, shall be deemed an admission. The agreements and actions taken herein are made in order to compromise and settle this IOSHA matter economically and amicably, and they shall not be used for any other purpose, except as herein stated.

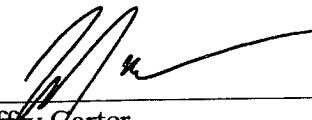
46. The Respondent, upon full execution of this Agreed Entry, will post this Agreed Entry for three (3) working days or until abatement is completed, whichever period is longer, pursuant to Board of Safety Review Rules of Procedure, 615 I.A.C. 1-2-18(b)(3).

AGREED this 26<sup>th</sup> day of July, 2011.

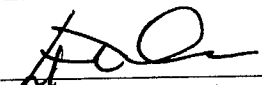
**KREMERS URBAN  
PHARMACEUTICALS INC.**

By:   
Michael F. Woods  
Title: Director, Engineering & Facilities

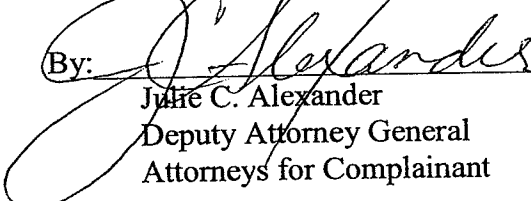
**COMMISSIONER OF LABOR**

By:   
Jeffrey Carter  
Deputy Commissioner  
IOSHA

**BAKER & DANIELS LLP**

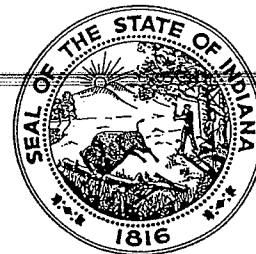
By:   
Gregory N. Dale  
Attorneys for Respondent

**OFFICE OF THE ATTORNEY GENERAL**

By:   
Julie C. Alexander  
Deputy Attorney General  
Attorneys for Complainant

# Indiana Department of Labor

Indiana Occupational Safety and Health Administration  
402 West Washington Street  
Room W195  
Indianapolis, IN 46204-2751  
Phone: 317/232-1979 Fax: 317/233-8509



*certified mail # 7003 1010 0003 5730 9641 7-1-10 JH*

## Safety Order and Notification of Penalty

**To:**

Schwarz Pharma Manufacturing, Inc.,  
and its successors  
1101 C Avenue West  
Seymour, IN 47274

**Inspection Number:** 313128027  
**Inspection Date(s):** 03/08/2010 - 05/20/2010  
**Issuance Date:** 07/01/2010

**Inspection Site:**

1101 C Avenue West  
Seymour, IN 47274

*The violation(s) described in this Safety Order and Notification of Penalty is (are) alleged to have occurred on or about the day(s) the inspection was made unless otherwise indicated within the description given below.*

An inspection of your place of employment has revealed conditions which we believe do not comply with the provisions of the Indiana Occupational Safety and Health Act (Indiana Code Chapter 22-8-1.1) or the standards or rules adopted thereunder. Accordingly, enclosed please find safety order(s) and notification(s) of penalty describing such violation(s) with references to applicable standards, rules, or provisions of the statute and stating the amount of any penalty(ies).

**Informal Conference** - Please be advised that it may be possible to informally settle any potential dispute without initiating the more elaborate proceedings brought on by a petition for review. Prior to filing a petition for review, you may request an informal conference concerning any of the results of the inspection (safety orders, penalties, abatement dates, etc.) by contacting the Indiana Department of Labor/IOSHA, preferably by telephone, in a prompt manner. Please be advised that a request for an informal conference cannot extend the fifteen working day period for filing a petition for review. Informal conferences frequently resolve any possible disputes, and therefore you are urged to take advantage of this opportunity. Because of the limited time period and in order to facilitate scheduling, any requests for an informal conference should be made promptly upon your receipt of the safety order(s) and notification(s) of penalty.

**Right to Contest** - You are hereby also notified that you are entitled to seek administrative review of the safety order(s), penalty(ies), or both by filing a written petition for review at the above address postmarked within fifteen working days of your receipt of the safety order(s) and notification(s) of penalty. ("Working days" means Mondays through Fridays, but does not include Saturdays, Sundays, legal holidays under a state statute or days

on which the Indiana Department of Labor's offices are closed during regular business hours). If you do not file such a petition for review (contest), the safety order(s) and penalty(ies) shall be deemed final orders of the Board of Safety Review and not subject to review by any court or agency. The issuance of a safety order does not constitute a finding that a violation has occurred unless no petition for review is filed, or if a petition for review (contest) is filed, it must contain a statement of its basis and should reference the above inspection number. Upon receipt of your petition for review, we will affirm, amend or dismiss the safety order(s) and notification(s) of penalty. If we affirm, your petition for review will be granted (unless it was not timely) and the dispute will be certified by the Board of Safety Review for further proceedings. The Board of Safety Review is an independent agency appointed by the governor with authority to conduct hearings and to issue decisions concerning disputed safety order(s) and notification(s) of penalty. If we amend the safety order(s) or notification(s) of penalty, your petition for review shall be deemed moot. However, you will then be given an opportunity to file a petition for review concerning the amended safety order(s) and notification(s) of penalty.

Please be advised that an employee or representative of employees may file a petition for review to contest the reasonableness of the time stated in the safety order(s) for the abatement of any violation.

**Posting** - Upon receipt of any safety order(s) you are required to post such safety order(s), or a copy thereof, unedited, at or near each place an alleged violation referred to in the safety order(s) occurred. However, if your operations are such that it is not practicable to post the safety order(s) at or near each place of alleged violation, such safety order(s) shall be posted, unedited, in a prominent place where it will be readily observable by all affected employees. For example, if you are engaged in activities which are physically dispersed, the safety order(s) may be posted at the location from which the employees operate to carry out their activities. You must take steps to ensure that the safety order is not altered, defaced, or covered by other material. Posting shall be until the violation is abated, or for three working days, whichever is longer.

**Penalties** - Penalties are due within fifteen (15) working days of receipt of this notification unless contested. Abatement does not constitute payment of penalties.

**Abatement** - The conditions cited in the safety order(s) must be corrected (abated) on or before the date shown for each item on the safety order(s) and notification(s) of penalty unless:

(1) You file a petition for review concerning the violation, in which case the full abatement period shall commence from the issuance of a final decision by the Board of Safety Review or the courts which requires compliance with the safety order; or

(2) The abatement period is extended by the granting of a petition for modification of abatement date.

**PMAs** - The petition for modification of abatement date is a manner in which you may seek additional time to correct (abate) a violation without having to file a petition for review concerning the safety order, or after the expiration of the time period to file such a petition for review when it becomes apparent that you need extra time to abate the violation. A petition for modification of abatement date shall be in writing and shall include the following information:

(1) All steps you have taken, and the dates of such actions, in an effort to achieve compliance during the prescribed abatement period.

(2) The specific additional abatement time necessary in order to achieve compliance.

(3) The reasons such additional time is necessary, including the unavailability of professional or technical personnel or of materials and equipment, or because necessary construction or alteration of facilities cannot be completed by the original abatement date.

(4) All available interim steps being taken to safeguard employees against the cited hazard during the abatement period.

(5) A certification that a copy of the petition has been posted, and if appropriate, served on the authorized representative of affected employees, and a certification of the date upon which such posting and service was made.

A petition for modification of abatement date shall be filed with the Indiana Department of Labor/IOSHA no later than the close of the next working day following the date on which abatement was originally required. A later-filed petition shall be accompanied by the employer's statement of exceptional circumstances explaining the delay. A copy of such petition shall be posted in a conspicuous place where all affected employees will have notice thereof or near such location where the violation occurred. The petition shall remain posted until the time period for the filing of a petition for review of the Commissioner's granting or denying the petition expires. Where affected employees are represented by an authorized representative, said representative shall be served a copy of such petition.

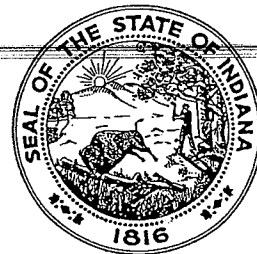
**Notification of Corrective Action** - Correction of the alleged violations which have an abatement period of thirty (30) days or less should be reported in writing to us promptly upon correction. A "Letter of Abatement" form and an "Abatement Photographs" worksheet are enclosed for your assistance in providing adequate documentation of abatement. Reports of corrections should show specific corrective action on each alleged violation and the date of such action. On alleged violations with abatement periods of more than thirty (30) days, a written progress report should be submitted, detailing what has been done, what remains to be done, and the time needed to fully abate each such violation. When the alleged violation is fully abated, we should be so advised. Timely correction of an alleged violation does not affect the initial proposed penalty.

**Followup Inspections** - Please be advised that a followup inspection may be made for the purpose of ascertaining that you have posted the safety order(s) and corrected the alleged violations. Failure to correct an alleged violation may result in additional penalties for each day that the violation has not been corrected.

**Employer Discrimination Unlawful** - The law prohibits discrimination by an employer against an employee for filing a complaint or for exercising any rights under this Act. An employee who believes that he/she has been discriminated against may file a complaint no later than 30 days after the discrimination occurred with the Indiana Department of Labor/IOSHA at the address shown above.

**Notice to Employees** - The law gives an employee or his/her representative the opportunity to object to any abatement date set for a violation if he/she believes the date to be unreasonable. The contest must be mailed to the Indiana Department of Labor/IOSHA at the address shown above within fifteen (15) working days (excluding weekends and State holidays) or receipt by the employer of this safety order and penalty.

If you wish additional information, you may direct such requests to us at the address or telephone number stated above.



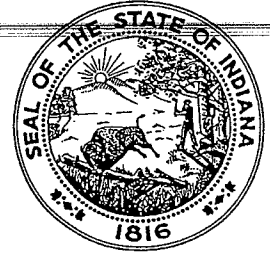
## NOTICE TO EMPLOYEES OF INFORMAL CONFERENCE

An informal conference has been scheduled with IOSHA to discuss the safety order(s) issued on 07/01/2010. The conference will be held at the IOSHA office located at 402 West Washington Street, Room W195, Indianapolis, IN 46204 on \_\_\_\_\_ at \_\_\_\_\_.

Employees and/or representatives of employees have a right to attend an informal conference.

Occupational Safety and Health Administration

Number:  
 Inspection Dates: 03/08/2010 -  
 05/20/2010  
 Issuance Date: 07/01/2010

**Safety Order and Notification of Penalty**

Company Name: Schwarz Pharma Manufacturing, Inc.  
 Inspection Site: 1101 C Avenue West, Seymour, IN 47274

The alleged violations below have been grouped because they involve similar or related hazards that may increase the potential for illness or injury resulting from an accident.

**Safety Order 1 Item 1a Type of Violation: **Serious****

IC 22-8-1.1, Section 2: The employer did not establish and maintain conditions of work which were reasonably safe and healthful for employees, and free from recognized hazards that were causing or likely to cause death or serious physical harm to employees in that employees were exposed to potential fire and/or deflagration (explosion) hazards because methods were not utilized to contain combustible dusts such as, but not limited to pharmaceutical dusts and/or powders from becoming airborne and combining with an ignition source:

a) Facility Wide - The employer had fourteen Donaldson Torit Dust Collectors located inside and outside of the facility which collected pharmaceutical powders/dusts (Class II, Group G combustible dusts) such as, but not limited to Omeprazole, Nifedipine and Venlafaxine Hydrochloride. All fourteen of these Donaldson Torit Dust Collectors were equipped with either one to eight explosion (deflagration) vents or one explosion panel. Although the Donaldson Torit Dust Collectors were equipped with explosion vents or panels, the employer had not determined the  $K_{st}$  values for each of the pharmaceutical dusts that were collected by each of the Donaldson Torit Dust Collectors. The employer also had not determined the maximum pressure developed in each vented dust collector during a vented deflagration (reduced pressure ( $P_{red}$ )), the static activation pressure ( $P_{stat}$ ) of each of the explosion vent or panel, or the enclosure strength ( $P_{es}$ ) of each dust collector. Without determining these calculated values, the employer had not confirmed that each explosion vent or panel was properly designed to prevent or relieve the pressure from a deflagration that originated inside of the dust collector. If the explosion vents or panels were not designed properly, the dust collector can potentially rupture and burst open during a deflagration while the explosion vent(s) or panel(s) will remain closed and/or intact.

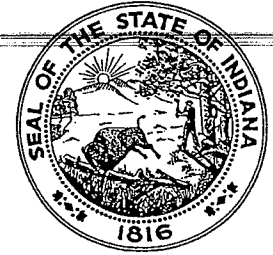
Among other methods, one feasible and acceptable method to correct this hazard is to determine the  $K_{st}$  value for each combustible dust processed, used or generated in the facility using recognized scientific methods such as, but not limited to the American Society for Testing and Materials' (ASTM) *Standard Test Method for Pressure and Rate of Pressure Rise for Combustible Dusts* (ASTM E 1226-2009). The employer should also calculate and/or determine the  $P_{red}$ ,  $P_{stat}$ , and  $P_{es}$  for each dust collector located throughout the facility. After determining each of these values, the employer needs to verify that not only each explosion vent and panel will operate as designed, but also that each explosion vent and panel is designed and installed in accordance with the National Fire Protection Agency's (NFPA) *Standard on Explosion Protection by Deflagration Venting* (NFPA 68-2007). Any calculations relating to the determination of any of the above values, or the operation of deflagration (explosion) venting must be performed and/or certified by a licensed professional engineer (PE).

b) Outside Near the West Wall of the Facility - A dust collection system which consisted of a Hoffman Model 75103A2 (Serial Number 0004610) Centrifugal Exhauster and a Hoffman (Serial Number H000707) Secondary Bag Separator collected Omeprazole, a Class II Group G combustible dust, as well as other fugitive dust emissions



Occupational Safety and Health Administration

Number:  
 Inspection Dates: 03/08/2010 -  
 05/20/2010  
 Issuance Date: 07/01/2010

**Safety Order and Notification of Penalty**

**Company Name:** Schwarz Pharma Manufacturing, Inc.  
**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274

generated in Rooms 82-85, Rooms 403-408, and Packaging Bays 333, 339 and 344. The dust collection system was located outside the facility and was not equipped with explosion protection such as, but not limited to explosion venting or a deflagration suppression system. If a fire and/or explosion occurred, the dust collection system could potentially explode because it was not designed to minimize the damage that would occur in the event of a dust deflagration (explosion) inside of one or both of the dust collectors.

Among other methods, one feasible and acceptable method to correct this hazard is to protect each of the Hoffman Dust Collectors in the dust collection system in accordance with Section 7.13.1.3.1 of NFPA's *Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids* (NFPA 654-2006). Section 7.13.1.3.1 of NFPA 654-2006 states that air-material separators (dust collectors, cyclones, etc.) must be protected in accordance with Section 7.1.2. Section 7.1.2 of NFPA 654-2006 states that the design of explosion protection for equipment must incorporate one or more of the following methods of protection: oxidant concentration reduction, deflagration venting, deflagration pressure containment, deflagration suppression systems, dilution with a non-combustible dust to render the mixture noncombustible, or deflagration venting through a listed dust retention and flame-arresting device.

c) Outside Near the West Wall of the Facility - A Hoffman (Order Number 0006074) Hoffco-Pulse Dust Separator collected Omeprazole, Nifedipine, Isosorbide-5-Mononitrate (ISMN) and Venlafaxine Hydrochloride, Class II Group G combustible dusts, as well as other fugitive dust emissions generated in Rooms 309-311 and Rooms 319-328. The Hoffman Hoffco-Pulse Dust Separator was located outside the facility and was not equipped with explosion protection such as, but not limited to explosion venting or a deflagration suppression system. If a fire and/or explosion occurred, the dust collector could potentially explode because it was not designed to minimize the damage that would occur in the event of a dust deflagration (explosion) inside of the dust collector.

Among other methods, one feasible and acceptable method to correct this hazard is to protect the Hoffman (Order Number 0006074) Hoffco-Pulse Dust Separator in accordance with Section 7.13.1.3.1 of NFPA's *Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids* (NFPA 654-2006). Section 7.13.1.3.1 of NFPA 654-2006 states that air-material separators (dust collectors, cyclones, etc.) must be protected in accordance with Section 7.1.2. Section 7.1.2 of NFPA 654-2006 states that the design of explosion protection for equipment must incorporate one or more of the following methods of protection: oxidant concentration reduction, deflagration venting, deflagration pressure containment, deflagration suppression systems, dilution with a non-combustible dust to render the mixture noncombustible, or deflagration venting through a listed dust retention and flame-arresting device.

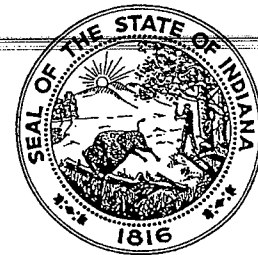
d) Outside Near the West Wall of the Facility - The Hoffman Dust Collection System (labeled as "V8" by the employer) and Hoffman Hoffco-Pulse Dust Separator (labeled as "V7" by the employer) were not equipped with isolation devices that were designed to prevent deflagration propagation from the dust collectors to work areas located inside of the facility. Specifically, the ventilation ducts upstream of and connected to the Hoffman Dust Collection System (V8) and Hoffman Hoffco-Pulse Dust Separator (V7) were not equipped with mechanical or chemical isolation

# Indiana Department of Labor

Occupational Safety and Health Administration

Inspection Number: 313128027

Inspection Dates: 03/08/2010 - 05/20/2010  
Issuance Date: 07/01/2010



## Safety Order and Notification of Penalty

Company Name: Schwarz Pharma Manufacturing, Inc.  
Inspection Site: 1101 C Avenue West, Seymour, IN 47274

devices such as, but not limited to fast-acting explosion isolation valves (gates), pinch valves or flow-actuated explosion isolation valves. If a deflagration or explosion occurred inside any of the Hoffman Dust Collectors, the explosion and/or deflagration could propagate back into and throughout the facility through the ventilation ducts and potentially ignite any settled or moving dust inside of the ducts, which could potentially lead to secondary deflagrations and/or explosions.

Among other methods, one feasible and acceptable method to correct this hazard is to install mechanical or chemical isolation devices on the ventilation ducts located upstream of the Hoffman Dust Collectors which meet the requirements listed in Section 7.1.4.2 of NFPA's *Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids* (NFPA 654-2006). Section 7.1.4.2 of NFPA 654-2006 states that "isolation devices shall include, but shall not be limited to the following:

- (1) Chokes
- (2) Rotary Valves
- (3) Automatic fast-acting valve systems in accordance with NFPA 69, *Standard on Explosion Prevention Systems*
- (4) Flame front diverters in accordance with NFPA 69, *Standard on Explosion Prevention Systems*
- (5) Chemical isolation systems in accordance with NFPA 69, *Standard on Explosion Prevention Systems*."

e) Facility Wide - The Tigerflex hoses which were connected to the central vacuum system were nonconductive. The Tigerflex hoses were used to collect and transport Omeprazole, Nifedipine, Isosorbide-5-Mononitrate (ISMN), Venlafaxine Hydrochloride, Vimpat, Moexipril and Oxybutyne, Class II Group G combustible dusts, from surfaces and floor areas to dust collectors located outside of the facility. Because the Tigerflex hoses were nonconductive, they could potentially accumulate a static electric charge which could potentially ignite any settled or moving pharmaceutical dust and/or powder located inside of the hoses or ventilation ducts.

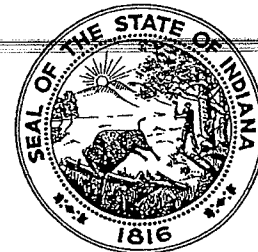
Among other methods, one feasible and acceptable method to correct this hazard is to install flexible hoses which are conductive per Section 9.3.1.1 of NFPA's *Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids* (NFPA 654-2006). Section 9.3.1.1 of NFPA 654-2006 states that all system components must be conductive.

**Indiana Department of Labor**

**Inspection Number:** 313128027

Occupational Safety and Health Administration

**Inspection Dates:** 03/08/2010 -  
05/20/2010  
**Issuance Date:** 07/01/2010



**Safety Order and Notification of Penalty**

**Company Name:** Schwarz Pharma Manufacturing, Inc.  
**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274

f) Facility Wide - The employer did not develop and implement a Fire Prevention Plan (FPP) where employees worked with and around machinery and/or surfaces which contained pharmaceutical dusts and/or powders, Class II Group G combustible dusts.

Among other methods, one feasible and acceptable method to correct this hazard is to develop and implement a FPP which meets the minimal requirements listed in 29 CFR 1910.39(c).

**Date By Which Violation Must be Abated:** 07/28/2010  
**Proposed Penalty:** \$6,300.00

Safety Order 1 Item 1b Type of Violation: **Serious**

29 CFR 1910.1200(h)(3)(ii): Employee training did not include at least the physical and health hazards of the chemicals in the work area:

Facility Wide - Employees who cleaned up, used, or worked around Omeprazole, Nifedipine, Isosorbide-5-Mononitrate (ISMN) and Venlafaxine Hydrochloride, Class II Group G combustible dusts, were not trained on physical and health hazards such as, but not limited to combustible dust fire hazards and deflagration (explosion) hazards.

**Date By Which Violation Must be Abated:** **Corrected During Inspection**

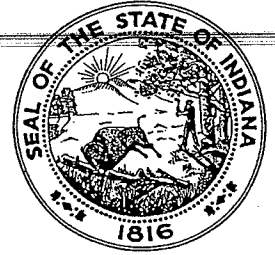
**Indiana Department of Labor**

**Inspection Number:** 313128027

Occupational Safety and Health Administration

**Inspection Dates:** 03/08/2010 - 05/20/2010

**Issuance Date:** 07/01/2010



**Safety Order and Notification of Penalty**

**Company Name:** Schwarz Pharma Manufacturing, Inc.  
**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274

**Safety Order 1 Item 2 Type of Violation: **Serious****

29 CFR 1910.132(a): Protective equipment was not used when necessary whenever hazards capable of causing injury and impairment were encountered:

Facility Wide - Maintenance Technicians changed and/or cleaned filter cartridges used inside of the Hoffman Secondary Bag Separator and Hoffman Hoffco-Pulse Dust Separator, which were labeled as "V8" and "V7" respectively by the employer. Maintenance Technicians also used a broom to loosen and clean pharmaceutical dust accumulations located inside each of these dust collectors. While performing these maintenance and cleaning operations, a potential flash fire hazard existed inside of the dust collectors due to the significant airborne concentrations of pharmaceutical dust(s), a Class II Group G combustible dust(s), which was suspended or dispersed throughout the inside of the dust collectors. While performing these maintenance and cleaning operations on the dust collectors, Maintenance Technicians wore long-sleeve shirts and pants which were designed and engineered to meet the requirements of the National Fire Protection Agency's (NFPA) *Standard for Electrical Safety in the Workplace* (NFPA 70E-2009). However, Maintenance Technicians wore Kimberly-Clark KleenGuard Select Model 49106 Full-Body Protective Suits over their long-sleeve shirts and pants which were not designed or engineered to be flame-resistant (FR). The Kimberly-Clark KleenGuard Full-Body Protective Suits would melt and shrink if exposed to a source of ignition, which would negatively affect any of the shirts' or pants' FR properties and could lead to the wearer potentially experiencing burns during a flash fire.

**ABATEMENT NOTE:** Any flame-resistant clothing (FRC) or flame-resistant garments (FRGs) purchased or used by the employer must meet the minimum elements listed in the National Fire Protection Agency's (NFPA) *Standard on Flame-Resistant Garments for Protection of Industrial Personnel Against Flash Fire* (NFPA 2112-2010)

**Date By Which Violation Must be Abated:**

**07/28/2010**

**Proposed Penalty:**

**\$1,875.00**

**Indiana Department of Labor**

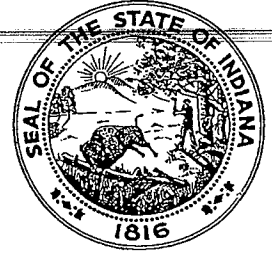
**Inspection** 313128027

Occupational Safety and Health Administration

**Number:**

**Inspection Dates:** 03/08/2010 -  
05/20/2010

**Issuance Date:** 07/01/2010



**Safety Order and Notification of Penalty**

**Company Name:** Schwarz Pharma Manufacturing, Inc.

**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274

The alleged violations below have been grouped because they involve similar or related hazards that may increase the potential for illness or injury resulting from an accident.

**Safety Order 1 Item 3a Type of Violation: **Serious****

29 CFR 1910.146(d)(2): Under the permit-required confined space program required by 29 CFR 1910.146(c)(4), the employer did not identify and evaluate the hazards of permit spaces before employees entered:

Facility Wide - The employer's written permit-required confined space (PRCS) program did not identify and evaluate the hazards associated with PRCSs such as, but not limited to the dust collectors and ventilation ducts.

**Date By Which Violation Must be Abated:** 07/28/2010  
**Proposed Penalty:** \$4,500.00

**Safety Order 1 Item 3b Type of Violation: **Serious****

29 CFR 1910.146(d)(5)(ii): Under the permit-required confined space program required by 29 CFR 1910.146(c)(4), the employer did not evaluate permit space conditions when entry operations were conducted by testing or monitoring the permit space as necessary to determine if acceptable entry conditions were being maintained during the course of entry operations:

Outside of the Facility in Front of the West Wall - Maintenance Technicians entered the Hoffman (Serial Number H000707) Secondary Bag Separator (labeled as V8 by the employer) to replace the filter cartridges inside of the dust collector. After the initial monitoring of the atmosphere inside of the dust collector was completed, the confined space meter was left unattended on the manlift for the remainder of the permit-required confined space (PRCS) entry.

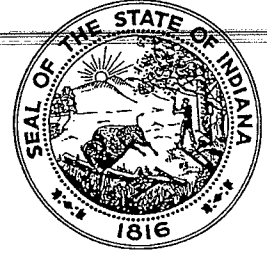
**Date By Which Violation Must be Abated:** 07/28/2010

**Indiana Department of Labor**

Occupational Safety and Health Administration

Inspection Number: 313128027

Inspection Dates: 03/08/2010 - 05/20/2010  
Issuance Date: 07/01/2010



**Safety Order and Notification of Penalty**

**Company Name:** Schwarz Pharma Manufacturing, Inc.  
**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274

**Safety Order 1 Item 3c Type of Violation: **Serious****

29 CFR 1910.146(d)(8): Under the permit-required confined space program required by 29 CFR 1910.146(c)(4), the employer did not designate the persons who were to have active roles in entry operations, identify the duties of each such employee, and did not provide each such employee with the training required by 29 CFR 1910.146(g):

Facility Wide - The employer's written permit-required confined space (PRCS) program did not designate the employees or persons who had active roles in the PRCS entry operations, their duties and the specific confined space training they received.

**Date By Which Violation Must be Abated: 07/28/2010**

**Safety Order 1 Item 3d Type of Violation: **Serious****

29 CFR 1910.146(d)(9): Under the permit-required confined space program required by 29 CFR 1910.146(c)(4), the employer did not develop and implement procedures for summoning rescue and emergency services, for rescuing entrants from permit spaces to rescued employees, and for preventing unauthorized personnel from attempting a rescue:

Facility Wide - The employer's written permit-required confined space (PRCS) program did not list and/or specify which employees were on the Confined Space/Emergency Response Team (CSERT), how and when to contact or summon the CSERT, the capabilities and limitations of the CSERT, and how to prevent unauthorized employees from attempting a rescue. The employer's PRCS program also did not discuss when an outside confined space entry rescue service was to be used, as well as how and when to contact or summon them in case of an emergency.

**Date By Which Violation Must be Abated: 07/28/2010**

**Safety Order 1 Item 3e Type of Violation: **Serious****

29 CFR 1910.146(d)(10): Under the permit-required confined space program required by 29 CFR 1910.146(c)(4), the employer did not develop and implement a system for the preparation, issuance, use, and cancellation of entry permits as required by 29 CFR 1910.146:

Facility Wide - The employer's written permit-required confined space (PRCS) program did not specify a system for the preparation, issuance, use and cancellation of confined space entry permits.

**Date By Which Violation Must be Abated: 07/28/2010**

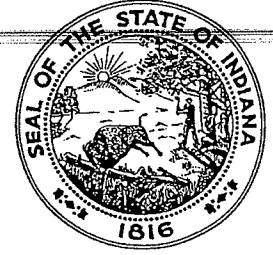
**Indiana Department of Labor**

**Inspection Number:** 313128027

Occupational Safety and Health Administration

**Inspection Dates:** 03/08/2010 -  
05/20/2010

**Issuance Date:** 07/01/2010



**Safety Order and Notification of Penalty**

**Company Name:** Schwarz Pharma Manufacturing, Inc.

**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274

**Date By Which Violation Must be Abated:**

**07/28/2010**

**Safety Order 1 Item 3f Type of Violation: **Serious****

29 CFR 1910.147(c)(4)(i): Procedures were not developed, documented and utilized for the control of potentially hazardous energy when employees engaged in activities covered by this section:

Outside of the Facility Near the West Wall - Maintenance Technicians performed maintenance and/or service activities such as, but not limited to filter cartridge changes and cleaning of the inside walls of the Hoffman (Serial Number H000707) Secondary Bag Separator and the Hoffman (Order Number 0006074) Hoffco-Pulse Dust Separator. Both of these dust collectors contained multiple sources of energy including, but not limited to electrical and pneumatic (air).

**Date By Which Violation Must be Abated:**

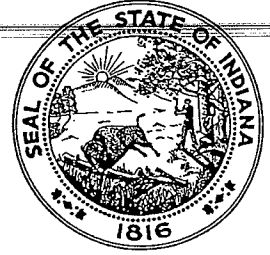
**Corrected During Inspection**

**Indiana Department of Labor**

Inspection Number: 313128027

Occupational Safety and Health Administration

Inspection Dates: 03/08/2010 - 05/20/2010  
Issuance Date: 07/01/2010



**Safety Order and Notification of Penalty**

**Company Name:** Schwarz Pharma Manufacturing, Inc.  
**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274

The alleged violations below have been grouped because they involve similar or related hazards that may increase the potential for illness or injury resulting from an accident.

**Safety Order 1 Item 4a Type of Violation: **Serious****

29 CFR 1910.146(e)(2): Before entry began, the entry supervisor identified on the permit did not sign the entry permit to authorize entry:

Outside of the Facility in Front of the West Wall - On February 28, 2010, a Maintenance Technician entered the ventilation duct upstream of the Donaldson Torit Model DFT4-128 Dust Collector (Serial Number 1G553587-00 and labeled as DC-EFDC2 by the employer) to observe and check the tubes on the airflow station. Although the a supervisor was listed on the confined space entry permit, none of the three employees who participated in this PRCS entry performed the duties of an entry supervisor or knew who was in charge of the PRCS entry operations.

**Date By Which Violation Must be Abated: 07/28/2010**  
**Proposed Penalty: \$4,500.00**

**Safety Order 1 Item 4b Type of Violation: **Serious****

29 CFR 1910.146(e)(6): The employer did not retain each canceled entry permit for at least one year to facilitate the review of the permit-required confined space program required by 29 CFR 1910.146(d)(14)

Facility Wide - Maintenance Technicians entered permit-required confined spaces (PRCSs) such as, but not limited to dust collectors and ventilation ducts. However, the completed and canceled Confined Space Entry Permits were only kept by the employer for one to four weeks after the PRCS entries occurred.

**Date By Which Violation Must be Abated: 07/28/2010**

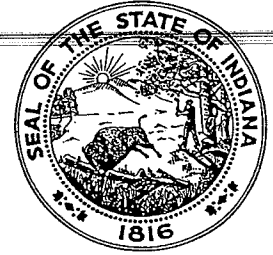


**Indiana Department of Labor**

Occupational Safety and Health Administration

Inspection Number: 313128027

Inspection Dates: 03/08/2010 - 05/20/2010  
Issuance Date: 07/01/2010



**Safety Order and Notification of Penalty**

Company Name: Schwarz Pharma Manufacturing, Inc.  
Inspection Site: 1101 C Avenue West, Seymour, IN 47274

**Safety Order 1 Item 4c Type of Violation: **Serious****

29 CFR 1910.146(f)(1): The entry permit that documented compliance and authorized entry to a permit space did not identify the permit space to be entered:

Outside of the Facility in Front of the West Wall - On February 28, 2010, a Maintenance Technician entered the ventilation duct upstream of the Donaldson Torit Model DFT4-128 Dust Collector (Serial Number 1G553587-00 and labeled as DC-EFDC2 by the employer) to observe and check the tubes on the airflow station. The Confined Space Entry Permit used for this permit-required confined space (PRCS) entry did not list or identify which PRCS that the Maintenance Technician entered.

**Date By Which Violation Must be Abated: 07/28/2010**

**Safety Order 1 Item 4d Type of Violation: **Serious****

29 CFR 1910.146(f)(3): The entry permit that documented compliance and authorized entry to a permit space did not identify the date and the authorized duration of the entry permit:

Outside of the Facility in Front of the West Wall - On February 28, 2010, a Maintenance Technician entered the ventilation duct upstream of the Donaldson Torit Model DFT4-128 Dust Collector (Serial Number 1G553587-00 and labeled as DC-EFDC2 by the employer) to observe and check the tubes on the airflow station. The Confined Space Entry Permit used for this permit-required confined space (PRCS) entry did not list or identify the authorized duration for which the entry permit was approved for.

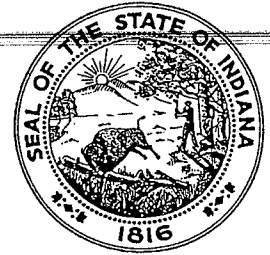
**Date By Which Violation Must be Abated: 07/28/2010**

**Indiana Department of Labor**

Inspection Number: 313128027

Occupational Safety and Health Administration

Inspection Dates: 03/08/2010 - 05/20/2010  
Issuance Date: 07/01/2010



**Safety Order and Notification of Penalty**

**Company Name:** Schwarz Pharma Manufacturing, Inc.  
**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274

**Safety Order 1 Item 4e Type of Violation: **Serious****

29 CFR 1910.146(f)(4): The entry permit that documented compliance and authorized entry to a permit space did not identify the authorized entrants within the permit space by name or by such other means (for example, through the use of rosters or tracking systems) as would enable the attendant to determine quickly and accurately, for the duration of the permit, which authorized entrants were inside the permit space:

Outside of the Facility in Front of the West Wall - On February 28, 2010, a Maintenance Technician entered the ventilation duct upstream of Donaldson Torit Model DFT4-128 Dust Collector (Serial Number 1G553587-00 and labeled as DC-EFDC2 by the employer) to observe and check the tubes on the airflow station. The Confined Space Entry Permit used for this permit-required confined space (PRCS) entry did not list or identify all of the authorized entrants, attendants or entry supervisors involved in this confined space entry.

**Date By Which Violation Must be Abated: 07/28/2010**

**Safety Order 1 Item 4f Type of Violation: **Serious****

29 CFR 1910.146(f)(5): The entry permit that documented compliance and authorized entry to a permit space did not identify the personnel, by name, currently serving as attendants:

Outside of the Facility in Front of the West Wall - On February 28, 2010, a Maintenance Technician entered the ventilation duct upstream of the Donaldson Torit Model DFT4-128 Dust Collector (Serial Number 1G553587-00 and labeled as DC-EFDC2 by the employer) to observe and check the tubes on the airflow station. The Confined Space Entry Permit used for this permit-required confined space (PRCS) entry did not list or identify all of the authorized entrants, attendants or entry supervisors involved in this confined space entry.

**Date By Which Violation Must be Abated: 07/28/2010**

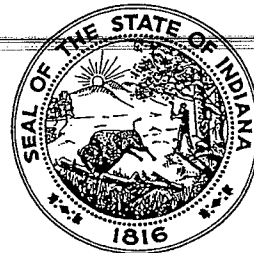
**Indiana Department of Labor**

Inspection Number: 313128027

Occupational Safety and Health Administration

Inspection Dates: 03/08/2010 - 05/20/2010

Issuance Date: 07/01/2010



**Safety Order and Notification of Penalty**

**Company Name:** Schwarz Pharma Manufacturing, Inc.  
**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274

**Safety Order 1 Item 4g Type of Violation: **Serious****

29 CFR 1910.146(f)(6): The entry permit that documented compliance and authorized entry to a permit space did not identify the individual, by name, currently serving as entry supervisor, with a space for the signature or initials of the entry supervisor who originally authorized entry:

Outside of the Facility in Front of the West Wall - On February 28, 2010, a Maintenance Technician entered the ventilation duct upstream of the Donaldson Torit Model DFT4-128 Dust Collector (Serial Number 1G553587-00 and labeled as DC-EFDC2 by the employer) to observe and check the tubes on the airflow station. The Confined Space Entry Permit used for this permit-required confined space (PRCS) entry did not list or identify all of the authorized entrants, attendants or entry supervisors involved in this confined space entry.

**Date By Which Violation Must be Abated: 07/28/2010**

**Safety Order 1 Item 4h Type of Violation: **Serious****

29 CFR 1910.146(f)(7): The entry permit that documented compliance and authorized entry to a permit space did not identify the hazards of the permit space to be entered:

Outside of the Facility in Front of the West Wall - On February 28, 2010, a Maintenance Technician entered the ventilation duct upstream of the Donaldson Torit Model DFT4-128 Dust Collector (Serial Number 1G553587-00 and labeled as DC-EFDC2 by the employer) to observe and check the tubes on the airflow station. The Confined Space Entry Permit used for this permit-required confined space (PRCS) entry did not list or identify the hazards of the PRCS that the Maintenance Technician entered.

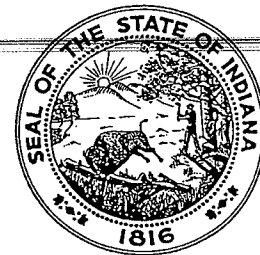
**Date By Which Violation Must be Abated: 07/28/2010**

**Indiana Department of Labor**

Inspection Number: 313128027

Occupational Safety and Health Administration

Inspection Dates: 03/08/2010 - 05/20/2010  
Issuance Date: 07/01/2010



**Safety Order and Notification of Penalty**

Company Name: Schwarz Pharma Manufacturing, Inc.  
Inspection Site: 1101 C Avenue West, Seymour, IN 47274

**Safety Order 1 Item 4i Type of Violation: **Serious****

29 CFR 1910.146(f)(8): The entry permit that documented compliance and authorized entry to a permit space did not identify the measures used to isolate the permit space and to eliminate or control permit space hazards before entry:

Outside of the Facility in Front of the West Wall - On February 28, 2010, a Maintenance Technician entered the ventilation duct upstream of the Donaldson Torit Model DFT4-128 Dust Collector (Serial Number 1G553587-00 and labeled as DC-EFDC2 by the employer) to observe and check the tubes on the airflow station. The Confined Space Entry Permit used for this permit-required confined space (PRCS) entry contained a twelve item checklist that listed items such as, but not limited to lockout/tagout and blocking/bleeding. However, none of the twelve boxes located underneath this checklist were marked, checked or filled out prior to the entry commencing.

**Date By Which Violation Must be Abated: 07/28/2010**

**Safety Order 1 Item 4j Type of Violation: **Serious****

29 CFR 1910.146(f)(10): The entry permit that documented compliance and authorized entry to a permit space did not identify the results of initial and periodic tests performed under 29 CFR 1910.146(d)(5), accompanied by the names or initials of the testers and by an indication of when the tests were performed:

Outside of the Facility in Front of the West Wall - On February 28, 2010, a Maintenance Technician entered the ventilation duct upstream of the Donaldson Torit Model DFT4-128 Dust Collector (Serial Number 1G553587-00 and labeled as DC-EFDC2 by the employer) to observe and check the tubes on the airflow station. The Confined Space Entry Permit used for this permit-required confined space (PRCS) entry did not list or identify the employee(s) who performed the initial and periodic tests of the atmosphere inside of the PRCS, or the time when the atmospheric tests inside of the confined space were performed.

**Date By Which Violation Must be Abated: 07/28/2010**

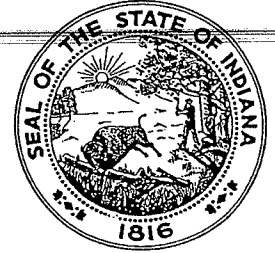
**Indiana Department of Labor**

Inspection Number: 313128027

Occupational Safety and Health Administration

Inspection Dates: 03/08/2010 - 05/20/2010

Issuance Date: 07/01/2010



**Safety Order and Notification of Penalty**

**Company Name:** Schwarz Pharma Manufacturing, Inc.  
**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274

**Safety Order 1 Item 4k Type of Violation: **Serious****

29 CFR 1910.146(f)(11): The entry permit that documented compliance and authorized entry to a permit space did not identify the rescue and emergency services summoned and the means for summoning those services:

Outside of the Facility in Front of the West Wall - On February 28, 2010, a Maintenance Technician entered the ventilation duct upstream of the Donaldson Torit Model DFT4-128 Dust Collector (Serial Number 1G553587-00 and labeled as DC-EFDC2 by the employer) to observe and check the tubes on the airflow station. The Confined Space Entry Permit used for this permit-required confined space (PRCS) entry did not list or identify the confined space entry rescue service to be summoned in the event of an emergency, or the means for summoning the confined space entry rescue service (equipment to use, numbers to call, etc.).

**Date By Which Violation Must be Abated: 07/28/2010**

**Safety Order 1 Item 4l Type of Violation: **Serious****

29 CFR 1910.146(f)(12): The entry permit that documented compliance and authorized entry to a permit space did not identify the communication procedures used by authorized entrants and attendants to maintain contact during the entry:

Outside of the Facility in Front of the West Wall - On February 28, 2010, a Maintenance Technician entered the ventilation duct upstream of the Donaldson Torit Model DFT4-128 Dust Collector (Serial Number 1G553587-00 and labeled as DC-EFDC2 by the employer) to observe and check the tubes on the airflow station. The Confined Space Entry Permit used for this permit-required confined space (PRCS) entry did not list or identify the communication procedures used by the entrant and the attendant(s) during the entry into the ventilation duct.

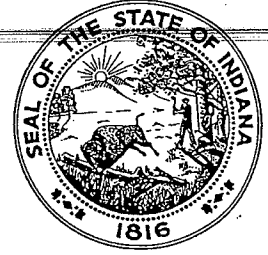
**Date By Which Violation Must be Abated: 07/28/2010**

**Indiana Department of Labor**

**Inspection** 313128027

Occupational Safety and Health Administration

**Number:**  
**Inspection Dates:** 03/08/2010 -  
05/20/2010  
**Issuance Date:** 07/01/2010



**Safety Order and Notification of Penalty**

**Company Name:** Schwarz Pharma Manufacturing, Inc.  
**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274

**Safety Order 1 Item 4m Type of Violation: **Serious****

29 CFR 1910.146(f)(13): The entry permit that documented compliance and authorized entry to a permit space did not identify equipment, such as personal protective equipment, testing equipment, communications equipment, alarm systems, and rescue equipment to be provided:

Outside of the Facility in Front of the West Wall - On February 28, 2010, a Maintenance Technician entered the ventilation duct upstream of the Donaldson Torit Model DFT4-128 Dust Collector (Serial Number 1G553587-00 and labeled as DC-EFDC2 by the employer) to observe and check the tubes on the airflow station. The Confined Space Entry Permit used for this permit-required confined space (PRCS) entry contained a twelve item checklist that listed items such as, but not limited to rescue harness provided, tie line attached, rescue equipment ready and protective clothing to be worn. However, none of the twelve boxes located underneath this checklist were marked, checked or filled out prior to the entry commencing.

**Date By Which Violation Must be Abated:**

**07/28/2010**

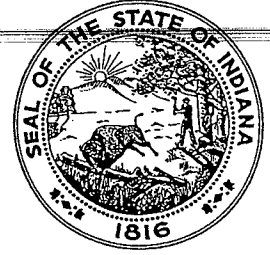
**Indiana Department of Labor**

Inspection Number: 313128027

Occupational Safety and Health Administration

Inspection Dates: 03/08/2010 - 05/20/2010

Issuance Date: 07/01/2010



**Safety Order and Notification of Penalty**

**Company Name:** Schwarz Pharma Manufacturing, Inc.  
**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274

The alleged violations below have been grouped because they involve similar or related hazards that may increase the potential for illness or injury resulting from an accident.

**Safety Order 1 Item 5a Type of Violation: **Serious****

29 CFR 1910.146(g)(1): The employer did not provide training so that all employees whose work was regulated by 29 CFR 1910.146, permit-required confined spaces, acquired the understanding, knowledge, and skills necessary for the safe performance of the duties assigned:

Facility Wide - Maintenance Technicians who entered permit-required confined spaces (PRCSs) such as, but not limited to dust collectors and ventilation ducts were not provided adequate PRCS training so that they acquired the proper understanding, knowledge and skills necessary to safely perform their assigned duties. Specifically, Maintenance Technicians were not aware or did not know subjects such as, but not limited to their designated roles during PRCS entries, their duties when acting as entry supervisors, how to properly monitor the atmosphere inside of a PRCS, or who the confined space entry rescue service was and how to summon them.

**Date By Which Violation Must be Abated:** 07/28/2010  
**Proposed Penalty:** \$4,500.00

**Safety Order 1 Item 5b Type of Violation: **Serious****

29 CFR 1910.146(k)(1)(i): The employer did not evaluate the prospective rescuer's ability to respond to a rescue summons in a timely manner, considering the hazards identified:

Facility Wide - Maintenance Technicians entered permit-required confined spaces (PRCSs) such as, but not limited to dust collectors and ventilation ducts. Schwarz Pharma Manufacturing's confined space entry rescue service consisted of a combination of a Confined Space/Emergency Response Team (CSERT) comprised of Maintenance Technicians and Environmental, Health and Safety employees, as well as the Seymour Fire Department who would have been contacted through 911. Neither the CSERT nor the Seymour Fire Department were equipped, trained or proficient in performing confined space entry rescues.

**Date By Which Violation Must be Abated:** 07/28/2010

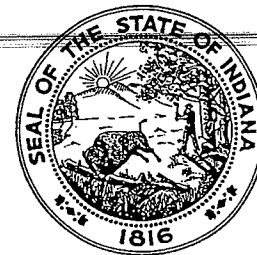
**Indiana Department of Labor**

Occupational Safety and Health Administration

Inspection Number: 313128027

Inspection Dates: 03/08/2010 - 05/20/2010

Issuance Date: 07/01/2010



**Safety Order and Notification of Penalty**

**Company Name:** Schwarz Pharma Manufacturing, Inc.  
**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274

**Safety Order 1 Item 5c Type of Violation: **Serious****

29 CFR 1910.146(k)(1)(ii): The employer did not evaluate a prospective rescue service's ability, in terms of proficiency with rescue-related tasks and equipment, to function appropriately while rescuing entrants from the particular permit space or types of permit spaces identified:

Facility Wide - Maintenance Technicians entered permit-required confined spaces (PRCSs) such as, but not limited to dust collectors and ventilation ducts. Schwarz Pharma Manufacturing's confined space entry rescue service consisted of a combination of a Confined Space/Emergency Response Team (CSERT) comprised of Maintenance Technicians and Environmental, Health and Safety employees, as well as the Seymour Fire Department who would have been contacted through 911. Neither the CSERT nor the Seymour Fire Department were equipped, trained or proficient in performing confined space entry rescues.

**Date By Which Violation Must be Abated: 07/28/2010**

**Safety Order 1 Item 5d Type of Violation: **Serious****

29 CFR 1910.146(k)(2)(iv): The employer did not ensure that affected employees practiced making permit space rescues at least once every 12 months, by means of simulated rescue operations in which they removed dummies, manikins, or actual persons from the actual permit spaces or from representative permit spaces:

Facility Wide - Maintenance Technicians entered permit-required confined spaces (PRCSs) such as, but not limited to dust collectors and ventilation ducts. Schwarz Pharma Manufacturing's confined space entry rescue service consisted of a combination of a Confined Space/Emergency Response Team (CSERT) comprised of Maintenance Technicians and Environmental, Health and Safety employees, as well as the Seymour Fire Department who would have been contacted through 911. Neither the CSERT nor the Seymour Fire Department were equipped, trained or proficient in performing confined space entry rescues.

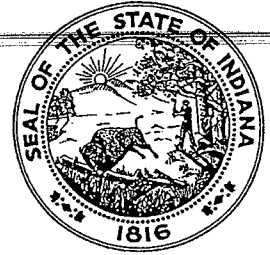
**Date By Which Violation Must be Abated: 07/28/2010**



**Indiana Department of Labor**

Occupational Safety and Health Administration

Inspection Number: 313128027  
Inspection Dates: 03/08/2010 - 05/20/2010  
Issuance Date: 07/01/2010



**Safety Order and Notification of Penalty**

Company Name: Schwarz Pharma Manufacturing, Inc.  
Inspection Site: 1101 C Avenue West, Seymour, IN 47274

**Safety Order 1 Item 5e Type of Violation: **Serious****

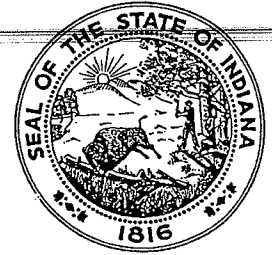
29 CFR 1910.146(k)(3)(ii): To facilitate non-entry rescue, whenever an authorized entrant entered a permit space, the other end of the retrieval line was not attached to a mechanical device or fixed point outside the permit space in such a manner that rescue could begin as soon as the rescuer became aware that rescue was necessary, and a mechanical device was not available to retrieve personnel from vertical type permit spaces more than 5 feet (1.52 m) deep:

Outside of the Facility in Front of the West Wall - Maintenance Technicians entered the Hoffman (Serial Number H000707) Secondary Bag Separator (labeled as V8 by the employer) to replace the filter cartridges inside of the dust collector. While inside of the dust collector, no mechanical devices such as, but not limited to pulleys or wenches were used, and Maintenance Technicians were tied off to one of the railings on a Power Engineering Model M-14-1000 (Serial Number 1002) Manlift. Neither the Power Engineering Model M-14-1000 Manlift nor its railings were designed or constructed to be tie-off points, and the manlift could potentially tip over if it were used to try to extract someone out of the dust collector.

**Date By Which Violation Must be Abated: 07/28/2010**

**Indiana Department of Labor**

**Inspection** 313128027



Occupational Safety and Health Administration

**Number:**  
**Inspection Dates:** 03/08/2010 -  
05/20/2010  
**Issuance Date:** 07/01/2010

**Safety Order and Notification of Penalty**

**Company Name:** Schwarz Pharma Manufacturing, Inc.  
**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274

**Safety Order 2 Item 1 Type of Violation: **Nonserious****

29 CFR 1910.134(g)(1)(i)(a): The employer permitted respirators with tight-fitting facepieces to be worn by employees who had facial hair that came between the sealing surface of the facepiece and the face or that interfered with valve function:

Facility Wide - Maintenance Technicians who were required to wear tight-fitting respirators such as, but not limited to North 7700 half-mask respirators with P100 cartridges were not clean shaven prior to donning these respirators. Several of the Maintenance Technicians who wore these respirators had varying levels of facial hair from noticeable stubble to full beards.

**Date By Which Violation Must be Abated:** 07/28/2010  
**Proposed Penalty:** \$ .00

**Safety Order 2 Item 2 Type of Violation: **Nonserious****

29 CFR 1910.145(c)(3): Safety instruction signs were not used where there was a need for general instructions and suggestions relative to safety measures:

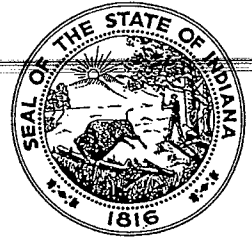
Facility Wide - Warning signs that described the hazard(s) associated with pharmaceutical dusts and/or powders, Class II Group G combustible dusts, were not posted on equipment or at the entrance to places where explosive atmospheres had the potential to occur.

**Date By Which Violation Must be Abated:** 07/28/2010  
**Proposed Penalty:** \$ .00

Robert A. Kattau  
Director, Industrial Compliance

# Indiana Department of Labor

Indiana Occupational Safety and Health Administration  
402 West Washington Street  
Room W195  
Indianapolis, IN 46204-2751  
Phone: 317/232-1979 Fax: 317/233-8509



## INVOICE/DEBT COLLECTION NOTICE

**Company Name:** Schwarz Pharma Manufacturing, Inc.  
**Inspection Site:** 1101 C Avenue West, Seymour, IN 47274  
**Issuance Date:** 07/01/2010

**Summary of Penalties for Inspection Number** 313128027


Safety Order 01, Serious	=	\$21,675.00
Safety Order 02, Nonserious	=	\$0.00
Total Proposed Penalties		\$21,675.00

Penalties are due within fifteen (15) working days of receipt of this notification unless contested. Make your check or money order payable to: "Indiana DOL/IOSHA". Please indicate IOSHA's Inspection Number (indicated above) on the remittance.

IOSHA does not agree to any restrictions or conditions or endorsements put on any check or money order for less than full amount due, and will cash the check or money order as if these restrictions, conditions, or endorsements do not exist.

Corrective action, taken by you for each alleged violation should be submitted to this office on or about the abatement dates indicated on the Safety Order and Notification of Penalty.

A work sheet has been provided to assist in providing the required abatement information. A completed copy of this work sheet should be posted at the worksite with the safety order(s).

  
\_\_\_\_\_  
Robert A. Kattau  
Director, Industrial Compliance

7-1-10  
\_\_\_\_\_  
Date