



Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD

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BOARD RESOLUTION NO. 7
Series of 2013

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF MERCK, INC. PHILIPPINES

WHEREAS, under Section 81 (b) and (r) of Article IX of RA 9165, otherwise known as the Comprehensive Dangerous Drugs Act of 2002, the Board issued Board Regulation No. 3, Series of 2003 which provides for the “Comprehensive Guidelines on Importation, Distribution, Manufacture, Prescription, Dispensing and Sale of, and Other Lawful Acts in Connection with any Dangerous Drugs, Controlled Precursors and Essential Chemicals and other Similar or Analogous Substances”;

WHEREAS, MERCK, INC. PHILIPPINES with business address at 24/F GT Tower International, 6813 Ayala Ave., Cor. H.V. dela Costa St., Salcedo Village, Makati City, Philippines is seeking exemption from specific measures of regulatory control requirements to the following reagents/chemicals that contain controlled chemicals;

1. 114803 Chlorine Test refill pack for 1.14801.0001 Microquant Cl₂-2B – 15-25% H₂SO₄
2. 100312 Hydrochloric Acid 25% suitable for use as excipient EMPROVE® exp Ph Helv – 25% HCL
3. 1008957 Silicate (Silicic Acid) Test Method: photometric 0.5-500mg/Si 1.1-1070mg/1SiO₂ Spectroquant ® - 25% H₂SO₄
4. 108017 Hydralazine Test Method: colorimetric Aquamerck ® - 1-5% H₂SO₄
5. 108025 Nitrite Test Method: colorimetric 0.025-0.05-0.075-0.1-0.15-0.2-0.3-0.5mg/NO₂ Aquamerck ® - 5-10% HCL
6. 108498 Vanadate-molybdate reagent for determination of phosphate – 15 – 25% H₂SO₄
7. 109057 Hydrochloric Acid c(HCL) = 1 mol/l (1N) TitriPUR ® - >=1% - <5% HCL
8. 109058 Hydrochloric Acid c(HCL) = 0.5mol/l (0.5N) TitriPUR ® - >=1% - <5% HCL
9. 109711 Hydralazine Test method:photometric 0.005 – 2.00 mg/N₂H₄ Spectroquant ® - 1-5% H₂SO₄
10. 109911 Hydrochloric Acid 1.000 1 for the preparation of dilute volumetric solutions or for direct use c(HCL) = 5 mol/l (5N) – 10-20% HCL
11. 109970 Hydrochloric Acid for 1000 ml c(HCL)=1mol/l (1N) Titrisol – 10-25% Hydrochloric Acid (HCL)
12. 109971 Hydrochloric Acid for 1000 ml c(HCL)= 0,5mol/l (0,5N) Titrisol – 10-25% Hydrochloric Acid (HCL)
13. 109973 Hydrochloric Acid for 1000 ml c(HCL)=0,1mol/l (0.1N) Titrisol – 5 -10% Hydrochloric Acid (HCL)
14. 1102 Chromate Test Method: colorimetric with test strips and reagent 3-10-30-100 mg/1 CrO₄ Merckquant ® - 25% H₂SO₄
15. 110428 Phosphate Test Method: Analytical test strips 10-25-50-100-250-500 mg/1 100 Tests Merckquant ® - 10-15% H₂SO₄
16. 111114 Chlorine Test Reagent Cl₂-2 Aquamerck ® - 15-25% H₂SO₄
17. 111174 Chlorine and pH test (free and total chlorine) Method: colorimetric with colour matching vessel 0.1-0.30.6-1.0-1.5 mg/1 Cl₂ pH:6.8-7.1-7.4-7.8 Aquamerck ® Chlor-Reagenz 2 - 15-25% H₂SO₄
18. 111160 Chlorine and pH Test Method: Colorimetric with colour card and sliding comparator 0.1-0.2-3-0.4-0.5-0.75-1.0-1.5 mg/1 Cl₂ pH: 6.5-6.8-7.0-7.2-7.4-7.6-7.9 Aquamerck ® Chlor-Reagenz 2 - 15-25% H₂SO₄

19. 111157 Reagents for the Chlorine Test Refill Pack for the Chlorine and pH Test 1.11174.0001 Aquamerck ® Chlor-Reagenz 2 - 15-25% H₂SO₄
20. 111131 Magnesium Test Method: colorimetric with colour card 100-200-300-500-1000-1500 mg/1 Mg Aquamerck ® - 1-10% MEK
21. 113136 Hydrochloric Acid c(HCL)= 0.357mol/1 (1/2.8N) TitriPUR – 1-5% Hydrochloric Acid (HCL)
22. 114410 Silicate (Silicic Acid) Test Method: colorimetric with colour card and comparator block with long test tubes 0.01-0.02-0.04-0.06-0.08-0.1-0.15-0.2-0.25 mg/1 Si Aquaquant ® Si-1A – 15-25% H₂SO₄
23. 114449 Phosphate Test method: colorimetric, VM, with colour card and comparator block with short test tubes 1.0-2.0-3.5-6.0-10-20-40 mg/1 PO₄-P 3.1-6.1-11-18-31-61-123mg/1 PO₄ Aquaquant ® PO₄-1 – 15-25% H₂SO₄
24. 114538 COD solution A for measuring range 4.0-40.0; 10-150 and 100-1500 mg/1; 0.30 ml per determination Spectroquant ® - 10-15% H₂SO₄
25. 114543 Phosphate Cell Test Method: photometric, PMB 0.05-5.00 mg/1 PO₄-P 0.2-15.3mg/PO₄ 0.11-11.46mg/1 P₂O₅ Spectroquant ® - 10-15% H₂SO₄
26. 114546 Phosphate Cell Test Method: photometric, VM 0.5-25.00 mg/1 PO₄-P 1.5- 76.7mg/PO₄ 1.1-57.3 mg/1 P₂O₅ Spectroquant ® - 15-25% H₂SO₄
27. 114548 Sulfate Cell Test method: photometric 5 -250 mg/1 SO₄-2 Spectroquant ® - 1-5% HCL
28. 31. 114622 Tin Cell Test method: photometric 0.10-2.50 mg/1 Sn Spectroquant ® - 1-5% HCL
29. 114729 Phosphate Cell Test (o-phosphate and total phosphorus) Method: photometric, PMB 0.5-25.0 mg/1 PO₄-P 1.5- 76.7 mg/1 PO₄ 1.1- 57.3 mg/1 P₂O₅ Spectroquant ® - 10-15% H₂SO₄
30. 114731 Hydrogen Peroxide Cell Test method: photometric 2.0 -20.0 mg/1 H₂O₂ Spectroquant ® - 15-25% H₂SO₄
31. 114782 Zinc Test Refill pack for 1.14780.0001 Microquant ® Zn-1 – 15 – 25% H₂SO₄
32. 114792 Silicate (Silicic Acid) Test Method: colorimetric (refill pack see Cat. No. 1.14794.0001 0.3-0.6-1.0-1.5-2-3-5-7-10 mg/1 Si 200 Tests Microquant ® Si-1 - – 15-25% H₂SO₄
33. 114794 Silicate (Silicic Acid) Test Method: photometric (also refill pack for . No. 1.14792.0001) 0.005-5.00 mg/1 Si 300 Tests 0.01-10.70 mg/1 Spectroquant ® SiO₂ – 15-25% H₂SO₄
34. 114831 Silver test Method: photometric 0.25 – 3.00 mg/1 Ag Spectroquant Ag-1 – m - 25% H₂SO₄
35. 114842 Phosphate Test Method: photometric, VM 0.5-30.0 mg/1 PO₄-P 1.5-92.07 mg/1 PO₄ 1.1-68.7 mg/1 P₂O₅ Spectroquant ® - 15-25% H₂SO₄
36. 116978 Phosphate Test Method: reflectometric with test strips and reagent 5-120 mg/1 Reflectoquant ® - 15-25% H₂SO₄
37. Silicate (Silicic Acid) Test Method: Refill pack for 1.14792.0001 and 1.14410.0001 Si-1 - – 15-25% H₂SO₄
38. Phosphate Test Method: colorimetric, VM, with colour disk comparator 1.5-3-6.- 9-12-16-20-40-100 mg/1 PO₄-P Microquant ® PO₄-1 – 15-25% H₂SO₄
39. Phosphate Test Refill pack for 118388,114449 PO₄-1 - 15-25% H₂SO₄
40. Platinum Standard solution traceable to SRM from NIST H₂PtCl₆ in HCL 2 mol/1 1000mg/1 CertiPUR ® - 5-10% HCL
41. Zirconium standard solution traceable to SRM from NIST ZrOCl₂ in HCL 2 mol/1 1000mg/1 Zr CertiPUR ® - 5 -10% HCL
42. Tin standard solution traceable to SRM from NIST SnCl₄ in HCL 2 mol/1 1000mg/1 Sn CertiPUR ® - 5 -10% HCL
43. Gold ICP standard traceable to SRM from NIST H(AuCl₄) in HCL 7% 1000mg/1 Au CertiPUR ®- 5-10% HCL
44. Hafnium ICP standard traceable to SRM from NIST HfOCl₂ in HCL 7% 1000mg/1 Hf CertiPUR ® - 5 -10% HCL
45. Iridium ICP standard IrCl₃ in HCL 7% 1000mg/1 Ir CertiPUR ® - 5-10% HCL
46. Osmium ICP standard (NH₄)₂ OsCl₆ in HCL 7% 1000mg/1 Os CertiPUR ® - 5-10% HCL
47. Platinum ICP standard traceable to SRM from NIST H₂PtCl₆ in HCL 7% 1000mg/1 Pt CertiPUR ® - 5 -10% HCL
48. Ruthenium ICP standard RuCl₃ in HCL 7% 1000mg/1 Ru CertiPUR ® - 5 -10% HCL
49. Tin ICP Standard Traceable to SRM from NIST SnCl₄ in HCL 7% 1000mg/1 SN CertiPUR ® - 5 – 10% Hydrochloric Acid (HCL)
50. Zirconium ICP standard traceable to SRM from NIST ZrOCl₂ in HCL 7% 1000mg/1 Zr CertiPUR ® - 1 -10% HCL

51. Sulfur ICP standard traceable to SRM from NIST H₂SO₄ in H₂O 10000mg/1 S CertiPUR® - 1 -5% HCL
52. Zirconium ICP standard traceable to SRM from NIST ZrOCl₂ in HCL 10% 10000mg/1 Zr CertiPUR® - 5 -10% HCL
53. Mercury (11) sulfate 200g/1 in diluted sulfuric acid for determination of COD acc. To DIN 38409-H 43-1 (short term experience) – 5 -10% Sulfuric Acid
54. Silicate (Silicic Acid) Test : Refill pack for 1.14792.0001 and 1.14410.0001 Si-1 - – 15-25% H₂SO₄
55. Phosphate Test method: colorimetric, VM, with colour disk comparator 1.5-3-6- 9-12-16-20-40-100 mg/1 PO₄-P Microquant® PO₄-1 – 15-25% H₂SO₄
56. KOVACS' Indole reagent for microbiology – 10-25% Hydrochloric Acid
57. Mercury (11) sulfate 80g/1 in potassium dichromate solution c (K₂Cr₂O₇)=0.02 mol/1 acidified with sulfuric acid for COD determination – 5 -10% Sulfuric Acid
58. Silicate (Silicic Acid) Test Refill pack for 1.18765.0001 Aquamerck® - – 5 – 10-% Sulfuric Acid
59. 109092 Cerium (IV) sulfate solution c (Ce(SO₄)₂ * 4 h₂O = 0,1 mol/1 (0,1N) -1-5% H₂SO₄
60. CombiSolvent methanol-free solvent for volumetric Karl Fisher titration with one component reagents Apura – 1-5% Toluene
61. Chlorine Test in freshwater and seawater Method: calorimetric with colour card 0.10-0.25-0.5-1.0-2.0 mg/1 Cl₂ Aquamerck® - 1-5% Sulfuric Acid
62. Hydrochloric Acid 3 mol/1 – 10-25% Hydrochloric Acid
63. Gram-color stain set for the gram staining method – 20-25% Acetone

WHEREAS, Section 4(2-c, d, e & f), Article II of the same Regulation also provides that the Board may exempt from specific measures of regulatory control requirements any preparation when the Table II chemical is a normal ingredient in consumer goods or finished products; or liquid chemical mixture containing less than 30% by weight of the Table II chemical; or solid, semisolid and highly viscous chemical mixture containing Table II chemical; or when the Board is satisfied that the mixture is formulated in such a way that the controlled chemical cannot be easily used for the illicit manufacture of a dangerous drug and that the controlled chemical or chemicals contained in the mixture cannot be readily recovered;

WHEREAS, to assist the Board in evaluating requests for exemption, it promulgated Board Resolution No.1 Series of 2008 entitled “**Creating a Technical Working Group (TWG) to assist the Board in considering request of Manufacturers and Importers of finished products from specific measures of regulatory control requirements**”;

WHEREAS, Merck started their Pharma operations in 1973 as a division of Zuellig Pharma Corp. In 1977, Merck spun off from Zuellig Pharma to form a separate company known as E. Merck Pharmaceuticals. The company organized its activities into three business sectors such as Pharmaceutical, Laboratory and Specialty Chemicals. The chemical sectors are engaged in the importation of finished forms and sales of locally selected chemical products consisting of reagents, diagnostics, pigments, fine chemicals, industrial chemicals and pharmaceutical raw materials. It is duly registered with PDEA and handler of Licenses **P5I-00782001-R036/P5DWI-00782001-R037 dated 14 March 2012 and valid until 09 March 2013** as importer/distributor and bulk depositor of controlled chemicals;

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **MERCK, INC. PHILIPPINES'** products that contain controlled chemicals, in accordance with the provisions of Section 4-2(d, e & f);

WHEREAS, after satisfying the requirements under the above mentioned regulations, **MERCK, INC. PHILIPPINES'** products are no longer covered by the provisions of Section 10 (Application for import, export or transit permits),

Section 11 (Grant of import, export or transit permits), and Section 22 (Licensed operators NOT to deal with unlicensed operators) of BR No.3, S. 2003.

WHEREAS, during the Caucus of the Board held on 12 December 2012, the matter was presented and was eventually unanimously approved in principle by those in attendance, subject to confirmation by the Board at its next regular meeting;

WHEREAS, in order to facilitate its confirmation, the said matter, along with the other concerns approved in principle during the Caucus, was subjected to an Ad Referendum, which was thereafter signed by at least nine (9) Members of the Board constituting a quorum on January 16, 2013.

WHEREFORE, be it **RESOLVED**, as it is hereby **RESOLVED, GRANTING EXEMPTION** and the issuance of a Board Resolution for Exemption, which shall be valid for one (1) year unless revoked, to **MERCK, INC. PHILIPPINES** products containing controlled chemicals below the 30% threshold of the Table II chemicals, in accordance with the following provisions of Section 4-2(d):

- a. That the above cited exemptions shall still be subject to the following conditions:
- (1) **That MERCK, INC. PHILIPPINES shall secure a license from PDEA and comply with the reporting requirements as provided for in Board Regulation No. 3, Series of 2003;**
 - (2) The Board shall strictly monitor subject finished products from their importation to distribution to end-users;
 - (3) The DDB-PDEA Monitoring Team shall have free access MERCK, INC. PHILIPPINES premises where the finished products are kept and/or used;
 - (4) That MERCK, INC. PHILIPPINES shall assume full responsibility for any misuse of the imported finished product, caused either by its own negligence or by negligence of all persons acting under their name or control and supervision; and
 - (5) Any violation of the provisions of Board Regulation No. 3, Series of 2003, shall be a ground for the revocation of the certificate of exemption at anytime and would be dealt with severely.

APPROVED and ADOPTED this 16th day of January, in the year of Our Lord, 2013 in Quezon City.

(Sgd) **Secretary ANTONIO A. VILLAR, JR.**
Chairman, Dangerous Drugs Board

Attested:

(Sgd) **Assistant Secretary AMADOR S. PABUSTAN**
OIC-Secretary of the Board