



Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD

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BOARD RESOLUTION NO. 217
Series of 2013

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN PRODUCTS OF EMPRESS DENTAL LABORATORIES INC.

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, EMPRESS DENTAL LABORATORIES INC. with business address at 6/F NET 1 Center Building, 26th St. Cor., 3rd Avenue, Crescent Park, West Bonifacio, Taguig City, Philippines is seeking exemption from specific measures of regulatory control requirements on the following dental materials **(All Brands/Generics)** containing controlled chemicals:

1. **Liquid for Ceramics – 2% Sulfuric Acid and 2.5 -10% Hydrochloric Acid (HCL)**
(IPS e-max Pres Invex Liquid - <1.7% H2SO4)
2. **Paste for Ceramics/Opaque Materials – 2.5 – 10% Sulfuric Acid (H2SO4); 2.6 – 10% Hydrochloric Acid (HCL)**
3. **Die Spacer/Liner – 5-10% Sulfuric Acid; 45-75% Methyl Ethyl Ketone (MEK)**
(Euro Classic Die Spacer- 45 – 75% MEK; Kerrlab Die Hardener Spacer – 45 – 75% MEK)
4. **Hardener – 11 – 20% Toluene (Bego Dimpix/kerr lab Die Hardener)**
(Margidur Hardener – 15 -40% Toluene)
5. **Staining Materials for Ceramics – 2% Sulfuric Acid**
6. **Die Spacer/Thinner – 1 - 25% Methyl Ethyl Ketone (MEK)**
(Kerrlab Euro Die Spacer Thinner – 1 -25% MEK)
7. **Acrylic Liquid – 90% Butanone (MEK)**
(LiWa Iso Step 1 – 75 – 90% MEK)
8. **Adhesive/Adhesive Materials – 70% Acetone**
(Dentsply Flexseal Liquid Adhesive – 10 – 40% Acetone; Ivoclar Vivadent SR Retention Adhesive – 70% Acetone)
9. **Separating Liquid – 2.5 – 10% Hydrochloric Acid**
10. **Cleaning Liquid Green – 2.5 – 10% Hydrochloric Acid (HCL)**
(Reinigungsfluid griin (678857-1) – 2.5 – 10% HCL)
11. **Bego Wirolyte – <10% Sulfuric Acid (H2SO4)**
12. **Gramm SG-Flash (00310-0002) – 1.5% Sulfuric Acid (H2SO4)**
13. **Gramm S-ACT (00310-0001) – 15% Sulfuric Acid (H2SO4)**

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 containing a controlled chemical mixture, when the Table II chemical is a normal ingredient in consumer goods or finished products that were packaged for retail sale for personal use, such as epoxies, vinyl lacquer, contact cements, plastic adhesives, waxes, cleaning agents; 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, it has been determined by the DDB Technical Working Group (TWG) that **EMPRESS DENTAL LABORATORIES INC.** is a German owned company, that is well established with good reputation. The company is engaged in the manufacture of dental prosthesis; a duly PDEA registered and handler of **P5IM-0291001 dated July 26, 2013 and valid until 31 July 2014**, a license that authorized to import, as end-user of controlled chemicals and also is duly registered with PEZA;

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption on the following **EMPRESS DENTAL LABORATORIES, INC.**’ products that contain controlled chemical above and below the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(d & f);

WHEREAS, after satisfying the requirements under the above mentioned regulations, **EMPRESS DENTAL LABORATORIES, INC. products are no longer covered by the provisions of Section 10 (Application for import, export or transit permits), and Section 11 (Grant of import, export or transit permits), of BR No.3, S. 2003.**

WHEREFORE, be it **RESOLVED**, as it is hereby **RESOLVED**:

- a. **TO GRANT EXEMPTION** and the issuance of a Board Resolution for Exemption, which shall be valid for one (1) year unless revoked, to the following **EMPRESS DENTAL LABORATORIES, INC.**’ dental materials (**Branded and Generic**) that contain controlled chemicals):
- b. That the above cited exemption shall be subject to the following conditions:
 - (1) That **EMPRESS DENTAL LABORATORIES, INC.** shall comply with the reporting requirements as provided for in Board Regulation No. 3, Series of 2003;
 - (2) The Board shall strictly monitor subject products/chemicals from their importation to end-user;
 - (3) The DDB-PDEA Monitoring Team shall have free access to **EMPRESS DENTAL LABORATORIES INC.** premises where the products/chemicals are kept and/or used;

- (4) That EMPRESS DENTAL LABORATORIES INC. shall assume full responsibility for any misuse of the imported products/chemicals, 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 Board Resolution on exemption at anytime and would be dealt with severely.

APPROVED and ADOPTED this 12th day of September, in the year of Our Lord, 2013 in Quezon City.

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

Attested:

(Sgd) **JOSE MARLOWE S. PEDREGOSA**
UNDERSECRETARY-Executive Director
Secretary of the Board

