



Republic of the Philippines
Department of Health
Food and Drug Administration
Alabang, Muntinlupa City



NOTIFICATION OF TOYS AND CHILDCARE ARTICLES

FOR FDA USE

Date Received:

Product Notification no: **TC-**

Valid until:

Tick where applicable

PARTICULARS OF PRODUCT

MARIA THERESA M. GUTIERREZ, RPh, MSc

Officer-In-Charge, Center for Cosmetics Regulation and Research

1. Product Details

1.1 Brand

1.2 Item Name

1.3 SKU/Model number/ Item number

2. Product Type (Tick only one)

- Toys intended for children below fourteen (14) years of age
- Swings, slides and similar activity toys for indoor and outdoor family domestic use
- Childcare articles such as but not limited to feeding bottles, sippy cups, pacifiers/soothers, teething aids, bottle teats/nipples, toothbrushes for babies, baby feeding set
- Toys for exemption such as (i) toys for children 14 years of age and above (ii) toys for display or exhibit purposes and those that are not intended to be marketed in the Philippines (iii) toys for personal or adult collector's use

3. Age Grading printed on the final packaging

4. For swings, slides and similar activity toys for indoor and outdoor family domestic use (if applicable)

- For indoor use
- For outdoor use

Mass (in kilograms) of the child for whom the toy is intended:

If appropriate, the maximum number of children that may safely use the equipment simultaneously:

5. For toys subject to exemption

Exemption for the reason that:

- The toy is intended for children fourteen (14) years and above
- The toy is for display or exhibit purposes and is not to be marketed in the Philippines
- The toy is for personal or adult collector's use

6. Product Description (e.g. blue remote controlled race car, doll in pink dress, shoes and bags)

PARTICULARS OF FOREIGN SOURCE(S)/ SUPPLIER (S)/ MANUFACTURER(S)¹

[Please attach in a separate sheet if there are more than foreign source/ supplier/ manufacturer]

7. Name of Foreign Source(s)/ Supplier(s)/ Manufacturer(s):

Complete Address of Foreign Source(s)/ Supplier(s)/ Manufacturer(s):

Tel: _____ Fax: _____ E-mail Address: _____

PARTICULARS OF LOCAL COMPANY RESPONSIBLE FOR PLACING THE PRODUCT IN THE MARKET

8. Name of Company:

License to Operate (LTO) Number

Validity

| | |
|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> |
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Complete Address of Company:

Tel: _____ Fax: _____ E-mail Address: _____

PARTICULARS OF PERSON REPRESENTING THE LOCAL COMPANY

9. Name of Person:

Tel: _____ Fax: _____ E-mail Address: _____

¹"**Manufacturer**", in relation to a health product, means an establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution.

Position/ Designation in the Company

PARTICULARS OF DISTRIBUTOR/ IMPORTER/ RETAILER²

[Please attach in a separate sheet if there are more than one distributor/ importer/retailer]

10. Name of Distributor/ Importer/ Retailer:

Address of Distributor/ Importer/ Retailer:

Tel: _____ Fax: _____ E-mail Address: _____

DECLARATION

- I undertake to respond to and cooperate fully with the regulatory authority with regard to any subsequent post-marketing activity initiated by the authority.
- I undertake to ensure that the product's technical and safety information is made readily available to the regulatory authority concerned ("the Authority") and to keep records of the distribution of the products for product recall purposes.
- I undertake to notify the Authority of fatal or life threatening serious adverse event as soon as possible by telephone, facsimile transmission, e-mail or in writing, and in any case, not later than 7 calendar upon knowledge of the adverse event.
- I declare that the particulars given in this notification are true and correct.
- I undertake to ensure that if and when directed by the regulatory authority I will recall the product from the market, and discontinue selling/ supplying the product
- I understand that I shall be responsible for ensuring that each consignment of my product continues to meet all the legal requirements, and conforms to all the standards and specifications of the product that I have declared to the Authority.
- I declare that our product does not contain any restricted or banned substances that can be harmful/ hazardous/ life threatening to children and infants.
- I understand that I cannot place reliance on the acceptance of my product notification by the authority in any legal proceedings concerning my product, in the event that my product has failed to conform to any of the standards or specifications that I had previously declared to the Authority.

[Name and Signature of person representing the local company]
[Company Stamp]

[Date]

²"Distributor/Importer" means any establishment that imports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets.