

Guide for Reviewing of Mok up design and Labels for Biocides Products Year 2025

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Guide for Reviewing of Mok up design and Labels for biocides products

Guide for reviewing and approving outer labels for antiseptic/disinfectant and pesticides products

1- The product label must be **colored** and written in both **Arabic and English**. The printing must be clear.

Note: This applies to locally manufactured products. Certain antiseptic products with special uses or imported products may be exempt, after the label is presented to the specialized committee for review.

2- The label must contain sufficient and accurate information to enable the consumer to use the product correctly. This includes:

- Product Name: The full name must be written clearly and in a proportionate size.
- Concentration and Dosage Form: (e.g., Gel, Cream, Liquid).
- Active Ingredient(s): The name and concentration of the active component(s).
- Usage Information: Indications for use, method of application, and specific instructions.
- Dates: Production date (Mfg. Date) and Expiration date (Exp. Date).
- Batch Number: (Batch No.).
- Registration Number: The Egyptian Drug Authority registration number: EDA Reg. No.
- Warnings and Precautions: Any necessary contraindications or safety warnings, including:
 - "For External Use Only"
- Flammability Warning: For products containing flammable materials, the label must state: "Flammable. Keep away from heat or flame."
- Children Safety: The statement "Keep out of reach of children" must be included.
- Company Information: Details of the company owning the product.

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Final Registration File Requirements: For outer packaging and labels submitted in the final registration file, the following must be added:

- Any special storage and stability conditions or handling precautions necessary according to the stability study evaluation report.
- The name of the manufacturer and the product owner, including their contact details (address and phone number) along with the company logo.
- The Registration Number in cases of product re-registration or when making any changes to the labels of already registered products.
- Packaging Variations
- Multiple Sizes: If the product is available in multiple sizes, a specific label must be provided for the small size and another for the large size.
- Internal Leaflet: It is essential to clarify on the label whether or not there is an internal leaflet (insert) attached to the product.

For antiseptic and pesticides products containing active ingredients that have a list of **contraindications, precautions and warnings, drug interactions**, or any other safety data approved by the "**Committee for the Registration of Household and Public Health pesticides and Antiseptics**"

-This information **must** be provided on the **outer packaging and labels** of these products in case there is no internal leaflet (insert) is included.

In addition to the previously mentioned information, all **pesticides labels** must include the following:

- **Chemical Composition:** The chemical name and percentage of active ingredients, as well as the percentages of inactive (inert) ingredients.
- **Toxicity Data:** The toxicity symbol, toxicity statement, and pictograms corresponding to the pesticide's toxicity grade.
- **Usage Details:** Target pest(s), application rate, and methods of use.
- **Antidote and Storage:** The specific antidote (if available) and required storage conditions.
- **Active Ingredient Content:** Expressed as (g/L) for liquid pesticides, (g/kg) for solid pesticides, or (mg/tablet) for mosquito repellent tablets.
- **First Aid:** First aid instructions and medical advice.

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- **Precautions and Warnings:** To minimize risks associated with product use, advice must include:
 - Warning pictograms (if applicable).
 - Handling precautions for the preparation (if applicable).
 - Precautions to be taken **during and after** use, including necessary Personal Protective Equipment (PPE).
 - Environmental precautions during and after use.
 - A specific warning against **reusing empty containers** (for household and public health pesticides).

The following statement must be written on the labels of public health products:

"A public health pesticide that is not to be used in households except by qualified and licensed personnel, and is not to be used for agricultural purposes."

Color-Coded Identification Label Significance:

Table (1): World Health Organization (WHO) Classification of Hazards based on Acute LD 50 (Rat) for Pesticide Formulations (mg/kg):

Acute LD 50 (Rat) for Pesticide Formulations (mg/kg)				Information placed in label		Toxicity Degree
Dermal		Oral		Toxicity Symbol	Color	
Liquid	Solid	Liquid	Solid			
400-4000	100-1000	200-2000	50-500		Yellow	Moderately hazardous
				Harmful		
> 4000	>1000	>2000	> 500	Caution	Blue	Slightly hazardous
		> 3000	> 2000	-----	Green	Non hazardous











Significance of the Above Pictograms

Table (2): Warning Symbols, Types, and Meanings

Symbol type	Symbol	Meaning
Storage		Keep in a locked place, out of reach of children.
Application		Handling liquid concentrates.
		Handling dry concentrates.
		Use appropriate spraying equipment.
Advisory / Mandatory		Wear gloves.
		Eye protection must be worn.

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		Wear protective footwear (boots).
		Nose and mouth protection must be worn.
		A respirator (inhalation mask) must be worn.
		Wear protective clothing (coveralls).
		Wear full protective clothing + apron.
		Wash thoroughly after use.
Warning / Hazard		Dangerous or harmful to pets.
		Dangerous or harmful to fish (contamination of rivers, lakes, or waterways).

➤ **Important Notice: -**

- In case that a company submits an outer label containing drawings, graphics, or data that may conflict with the afore mentioned instructions, the companies shall be presented to the **Committee for the Registration of Household and Public Health Pesticides and Antiseptics** for review and opinion.
- Companies should comply any newly issued rules or instructions concerning outer labels, and internal leaflets issued by the **Committee for the Registration of Household and Public Health Pesticides and Antiseptics**, including any resulting modifications required for Mok up ,labels, or leaflets.