Dubai Municipality

Health and Safety Department

Registration & Permits Section

Technical Guidelines for Biocides

DM-PH&SD-GU82-BIO2

Contents

1. Introduction

Dubai Municipality, Health & Safety Department prepared this guideline based on the Local Order No. (11) of 2003 Concerning Public Health and Safety of the Society in the Emirate of Dubai

Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured materials. However, biocidal products can pose risks to humans, animals and the environment due to their intrinsic properties and associated use patterns.

The purpose of this guideline is to improve the free movement of biocidal products within Dubai while ensuring a high level of protection of both human and animal health and the environment.

2. Purpose

The purpose of this guideline is to improve the functioning of Dubai market through the harmonization of the rules on the making available on the market and the use of biocidal products, while ensuring a high level of protection of both human and animal health and the environment The aim of which is to safeguard the health of humans, the health of animals and the environment. Particular attention shall be paid to the protection of vulnerable groups.

Biocidal products should neither be made available on the market nor used unless authorized in accordance with this Regulation.

3. Definitions

- **Biocidal Product means:**

Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

Any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

- **'micro-organism':**

Means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including lower fungi, viruses, bacteria, yeasts, moulds, algae, protozoa and microscopic parasitic helminthes

- **'active substance' :**

Means a substance or a micro-organism that has an action on or against harmful organisms;

- **'harmful organism' :**

Means an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment;

- **'vulnerable groups'**

Means persons needing specific consideration when assessing the acute and chronic health effects of biocidal products. These include pregnant and nursing women, the unborn, infants and children, the elderly and, when subject to high exposure to biocidal products over the long term, workers and residents.

4. Scope and Biocides Products Classifications

4.1 Human Hygiene

Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.
Example: Hand Sanitizers, Antibacterial personal care products.

4.2 Disinfectants and algaecides not intended for direct application to humans or animals :

Products in this group are used for the disinfection of surfaces, materials, equipment and furniture, which are not used for direct contact with food or feeding stuffs. Usage areas include swimming pools, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities.
Example: floor disinfectant, multipurpose disinfectant products – business-to-business (B2B) disinfectant Chemicals

Note:

Products used to disinfect Medical Devices and medical equipment are not covered in the scope of this regulation and should be submitted for the concerned authority in UAE approving Medical Devices.

4.3 Veterinary hygiene:

Products in this group used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, hygiene products with anti-microbial function

Used to disinfect the materials and surfaces associated with the housing or transportation of animals.

Example: Disinfectants and antimicrobial hygiene products used in farms.

4.4 Food and feed area

Products in this group used for the disinfection of equipment, containers, consumption utensils, surfaces associated with the production, transport, storage or consumption of food or feed for humans and animals

Example: Hard surface disinfectant to be used in slaughter house, Vegetable & fruits disinfection products, disinfectant products used in food processing areas.

4.5 Water Disinfection :

Products in this group used for the disinfection of water for both humans and animals. NOT including Drinking Water

Example: Fountains water Disinfectants, Swimming Pools water Disinfectants

4.6 Insect Repellents:

Products in this group used to control harmful organisms such as invertebrates (Fleas – Mosquitoes) by repelling used directly on the skin.

Example: insect repellent sprays & creams.

5. Registration of Biocides:

Since consumer safety is the primary principle of Biocides registration, its process allows the Registration and Permits Section to gather adequate information to assess the safety of Biocidal products. It is necessary to emphasize that no Biocidal product shall be manufactured, imported, exported, advertised, sold or distributed in Dubai unless it has been registered in Montaji system in accordance with Dubai Municipality regulation.

According to the Local Order No. 11 / 2003. Dubai Municipality regulates the manufacture, sale and importation of Biocides by requiring that all Biocidal products to be registered prior to placing in Dubai market; as well by requiring the individuals running the activities related to Biocides to be licensed in Dubai.

To apply for the service:

- Login to www.dm.gov.ae
- Choose Services
- Consumer Product Registration Service (Montaji)
- Run Service.

5.1 Who Should Apply for Registration?

Individuals who import or locally manufacture Biocidal products, or have products imported or manufactured on their behalf are responsible for applying to have their products registered. The following should make an application for registration of a Biocidal product:

5.1.1 Local Manufactures:

Local manufacturers in Dubai are advised to contact the Registration & Permits section for proper registration of Biocides. Agents of local manufacturers are to take the necessary steps to ensure that biocidal products intended for the Local market are registered before the manufactured products are placed into Dubai market.

5.1.2 Agent:

Agents of foreign manufacturers are to take the necessary steps to ensure that Biocides intended for the local market are registered before consignments of such products are imported to Dubai.

5.2 Criteria of Applicant:

Applicant for product registration must be a company incorporated in Dubai, or having a warehouse in Dubai and having a trade license in Dubai indicating activities related to Biocides.

5.3 Responsibility of Applicant:

- The applicant shall be responsible for the product, its safety, performance, and all information supplied in support of his application for registration of the product.
- The Biocides placed on the market must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labeling, instructions for its use and disposal, warning statements as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the market.
- The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in this Guideline.

5.4 Amendments or Change in Registration Particulars:

After a Biocidal Product has been registered, any subsequent amendment in particulars of the application relating to the Biocidal product must be notified or approved by Registration and Permits Section.

5.5 Validity of Product Registration:

The registration of a Biocidal product shall be valid for 5 years as extension for renewal to be reviewed.

5.6 Product Recall

The product recall is promptly and efficiently retrieve Batch/ Bar Code of the product that does not comply with registration requirements, or that may have an undesirable effect on consumers. Recalls can be initiated through at the request of the Dubai Municipality, or other relevant authorities to recall the product.

5.7 Violations & Penalty

- Individuals who contravene any of the provisions of the guidelines and regulations will be charged as violated by Local Order No. (11) of 2003 Concerning Public Health and Safety of the Society in the Emirate of Dubai.

6. Required Documents for Registration of Biocides (Product Dossier)

To proceed with registration of a Biocidal Product with Dubai Municipality – Health & Safety Department – Registration & Permits Section, the product must fulfill all the below documents:

6.1 Free Sale Certificate (FSC):

The certificate must be from the country of origin and issued by the health authorities or recognized bodies (such as Chamber of Commerce). The CFS should be current at the time of submission and request is to be made for the original to be seen.

Note:

If the product name to be marketed in Dubai is different from the FSC, confirmation letter from product owner is required. A Certificate of Free Sales is a document to indicate that the product is freely sold in the country of origin.

6.2 Ingredient Data Sheet (IDS):

This certificate must be issued by the manufacturer in the country of origin of the product. It should be signed and stamped by the R&D department in at the manufacturer.

6.3 Laboratory Test Report:

6.3.1 Efficacy Test

Is mandatory for all biocides as it should cover and proof all the claims mentioned on the product by the manufacturers; for example: (kills 99.99% of bacteria – Anti viral – Against HIV – kills Swine flu virus, etc..)

Efficacy test should cover the following aspects:

- Effectiveness Against Target Organisms with definite log reduction
- Effects on representative target organism(s)
- Mode of action (including time delay)
- Efficacy data to support these claims on biocidal products where label claims are made, including any available standard protocols, or field trials used to include performance standards where appropriate

6.3.2 Methanol Content Test:

Test requested for alcohol based antibacterial products including hand sanitizers to confirm the absence of methanol content in such product.

6.3.3 Alcohol Content Test:

- Test requested for the alcohol-based products antibacterial products including hand sanitizers to confirm the presence of minimum efficient percentage of alcohol content in the product
- Minimum accepted limit of Ethanol in Alcohol based product: 60%
- Minimum accepted limit of Isopropyl "IPA" Alcohol based product: 70%

Note:

Any other laboratory test may be asked to be submitted by the company according a request from Registration and Permits section / Health & safety departments as per status of product, and to consider the followings:

- All laboratory tests to be done by accredited laboratory either in the Country of Origin or from any Accredited Laboratories.
- For the Accredited laboratories in United Arab Emirates: please visit the Emirates International Accreditation Center website / http://www.eiac.gov.ae/en/Pages/default.aspx
- For the Accredited laboratories worldwide: please visit the International organization for Accreditation bodies website / https://ilac.org/about-ilac

6.4 Safety Data Sheet (SDS):

The certificate must be from the country of origin and issued by the recognized bodies. The SDS should be current at the time of submission and request may be made for the original to be seen.

And should be presented complying with Globally Harmonized System (GHS)

Note:

The safety data sheet shall be dated and shall contain the following headings:

1. Identification of the substance/preparation and of the company/undertaking.
2. Hazards identification.
3. Composition/information on ingredients.
4. First-aid measures.
5. Fire-fighting measures.
6. Accidental release measures.
7. Handling and storage.
8. Exposure controls/personal protection.
9. Physical and chemical properties.
10. Stability and reactivity.

11. Toxicological information.
12. Ecological information.
13. Disposal considerations.
14. Transport information.
15. Regulatory information.
16. Other information.

6.5 Safety Assessment Report/ Study :

This certificate must be issued from the country of origin by the recognized accredited bodies. Safety Assessment Report / Study will be only requested for the below cases:

- Products include Nano ingredients :

  This document is requested to ensure the safety of the ingredients manufactured by Nano technology and to proof the safety of the product in which nano ingredients are used.
- Food Contact Products :

  This document is requested to proof the safety of the product as a food contact chemical to ensure the safety of human use in direct contact with food.

7. Label Requirements:

Label requirements should be available when products are at the point of entry. Biocidal Product should be with proper size/shape to conclude all required details to meet consumer satisfaction & awareness, otherwise, this may achieved, for example, by using swing tags, leaflets, brochures, etc…

7.1 General Label requirements:

The followings are the required components that must be declared in clear English and/or Arabic language:

- Brand Name: A trademark or trade name.
- Product Name: A trademark or trade name cannot be used to replace the name of the Biocidal Product.
- Manufacturer detail : Name, Address, Web address of Manufacturer or Agent acting in UAE
- Country Of Origin: should be clearly indicated to avoid any misleading for the customers (NY, CA, Paris, etc…) should be clearly (USA , France, etc…)
- Ingredients: The identity of each active ingredient with concentration in metric units.

  Note:

  Any “Nano” ingredients included in the product, if any, should be mentioned with word “nano” in brackets

- Size or Weight of the product: must be clearly indicated on the product in metric units.
- Production & Expiry Dates: must be clearly indicated on the label using non-removable printing or non-removable stickers.

Note:

Period after Opening (PAO) could be accepted according to the product type.

- Storage Condition: to be clearly indicated mentioning any other specific storage conditions than normal if any.
- Instruction of Use: to be clearly indicated unless it is clear from the product name or presentation.
- Health warning : to be clearly indicated according to the Globally Harmonized System (GHS)
- Identification Code: (Barcode) to be clear and unique for each product.
- Batch Number: batch or Lot identification number to be indicated clearly on the label.
- Medical Claims: any claims related to prevention, treatment or curing any type of diseases must not be presented or referred on the labels, brochures, leaflets or advertisements or in any other way.
- Inconsistent Illustrations: Pictures, illustration which are inconsistent with the prevailing social customs and values shall not be used.

Note:

If the product is accompanied by a leaflet, the sentence “Read attached” should be clearly indicated.

7.2 Label requirements for Business to Business (B2B)and professional use products :

Business-to-Business (B2B) and professional use products should comply with the previous label requirements but it could have some specific requirements as below:

- Barcode is optional in this product category.
- Hazard symbols should be according to Globally harmonized system (GHS)
- If the products is provided with a leaflet and Safety Data Sheet (SDS), this should be clearly mentioned on the label that it is provided to the end user with SDS (Provided with MSDS)

- This provided leaflet including MSDS could be accepted to have the below information than to be written on the label:

- Instruction of Use
- Health warnings.

- Safety Precautions.
- Frequency of application and dose rate in metric units.
- Direction of safe disposal of the biocidal product including prohibition of the reuse of the package.
- Where applicable, Information of any specific danger to the environment concerning protection of non-targeted organisms.
- Where applicable, the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product.
- Particulars of likely direct or indirect adverse side effects and any direction of first aid.

7.3 Label requirements for Water Disinfection Products:

Any biocidal product used for water treatment like water disinfection should comply with the previous general label requirements but should have the below specific requirements to be indicated clearly on the label:

- "NOT for Drinking Water "must be written clearly on the label.
- Scope of use to be mentioned clearly on the label to identify the product category
  Example: (used for fountains water disinfection) (used for swimming pools disinfection)

8. Globally Harmonized System (GHS)

It is a United Nations (UN) initiative driven by the need to have chemical classification consistent throughout the world. It is globally standardized set of criteria for classifying chemicals and the associated labeling and Safety Data Sheets (SDS) requirements to be used in conjunction with these classifications.

The aim is to have all countries using (GHS) as the basis for chemical classification and labeling regulation, however there are allowance for individual country requirements.

8.1 Goals of (GHS) Implementation :

- Enhance the protection of human health and the environment by providing a system for hazard communication that is comprehensible throughout the world.
- Provide a recognized framework for those countries without an existing system.
- Reduce the need for testing and evaluation of chemicals (agreeing / harmonizing classification will help to reduce the need for animal testing).
- Facilitate trade in chemicals whose hazards have been properly assessed and identified on an international basis.

8.2 Major Changes to be implemented by GHS :

- **Orange Squares**  . These are to be replaced with **Red Diamonds**  and Signal Words (such as Danger or Warning).

- **Risk Phrases.** These are to be replaced with **Hazard Statements**.
- **Safety Phrases.** These are to be replaced with **Precautionary Statements**.

8.3 (GHS) Pictograms:

- Physical Chemical:
- Health:
- Environmental:

9. References:

1. Local Order No. (11) of 2003 concerning public health and safety of the society in the Emirate of Dubai.

2. European Regulation No. EU 528/2012 concerning the making available on the market and use of biocidal products.
3. European Regulation No. EC 1272/2008
4. Concerning the Classification, Labeling and Packaging of substances and mixtures (CLP Regulation)
5. European Directive 67/548/EEC concerning classification, packaging and labeling of dangerous substances.
6. European Regulation No. EC 1907/2006 concerning the registration, evaluation, authorization and restriction of chemicals (REACH)

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