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Guideline for Biocidal Products Registration

Introduction:

The present guideline describes the information to be supplied for biocidal product registration. This information will be subject to evaluation by Central Administration of Pharmaceutical Affairs (CAPA). Any deficiency in the completeness of material will result in application refusal. All the requirements and procedures are mentioned later in this guideline.

For products (imported or local) applying for registration as biocidal products, the active ingredient(s) should be registered in a reference country as a biocide with the same claim and the same concentration. In case of products containing more than one active ingredient the combination should be justified.

N.B. reference countries are mentioned in guidelines for registration of imported biocidal product.

Objectives:

An application for registration of a biocidal product (antiseptic or disinfectant) explicitly or implicitly claiming that the product mitigates or prevents disease should be adequately supported by appropriate data. The supporting data may vary relative to the risk associated with use of the antiseptic or disinfectant product environment for use and its specific claims. Sufficient information to support the label claim of a biocide should be made available.

The following items are provided to assist applicants to:

1. **Prepare complete application packages for the approval of biocidal products.**
2. **Categorize biocidal products.**
3. **Provide data to support specific claims.**
4. **Provide the basic documentation required to support the efficacy, safety and stability of antiseptic products including information of test organism.**
5. **Label the products to meet regulatory requirements.**

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Classification:

Antiseptic products:

1. Personal use antiseptics:
   - 1.1 Personal domestic use antiseptics.
   - 1.2. Personal commercial use antiseptics.

2. Professional use antiseptics:
   - 2.1. Food premises antiseptics.
   - 2.2. Professional healthcare use antiseptics.

Disinfectant products:

1. Critical disinfectants.
2. Semi-critical disinfectants.
3. Non-critical disinfectants.

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1) Antiseptic products

Definition:

An antiseptic product is considered to be one that inactivates, reduces, prevents or arrests growth of microorganisms with the inherent intent to mitigate or prevent disease. For the purpose of these guidelines, microorganisms are defined as bacteria, yeast, fungi, and viruses.

Scope:

These guidelines apply to antiseptic skin products for human use that are intended for use in professional and personal settings. Antiseptic products can include both those to be used with water (referred to as washes) or without water (referred to as rubs), and may be presented in different pharmaceutical forms. Antiseptic skin products also include preoperative skin preparations. The guidelines do not apply to human-use antiseptic products for burn victims or application to sites other than the skin (only antiseptic mouthwashes without any medicinal claim are included in this guideline.).

Categories:

1. personal use antiseptics :

1.1. Personal domestic use antiseptics:

Personal domestic (or household) use antiseptic products are those used by an individual in a domestic setting to reduce transient organisms on the skin.

This includes, but may not be limited to, consumer-use first aid antiseptics for application in cleansing minor wounds, self-administered pre-injection or ear piercing.

Application for personal use that can be exempted from certain requirements:

If the application of a personal use antiseptic product contains the following active ingredient with the specified concentration(as given in the following table)and complies with the following criteria with regard to the active ingredient, concentration, route of administration, intended use and label, this application will be exempted from providing microbiological efficacy and safety data.

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The above mentioned criteria are as follows:

- **Active ingredients and concentrations**:

names	Quantity
Ethanol **Ethyl alcohol** **Anhydrous alcohol**	**60-80%**
Isopropanol **Isopropyl alcohol** **2-propanol**	**60-70%**
Povidone-iodine	**0.5–10.0%**
Benzalkonium chloride	**0.1 - 0.15%**
Chlorhexidine gluconate	**0.05 - 0.5%**
Chloroxylenol	**2.0 - 4.0%**
Methylbenzethonium chloride	**0.5 - 3.0%**
Triclocarban	**0.05 - 0.5%**
Triclosan	**1.5% only**

- **Route of administration**: **Topical.**
- **Dosage form(s): Those that are suited to the allowable route of administration and are established scientifically recognized dosage forms.**
- **Use(s) or Purpose(s):**

  -For all products the following statements could be used:

  • Antiseptic cleanser.

  • Medicated cleanser.

  • Kills harmful bacteria or germs

  • Effective in destroying certain bacteria and removing impurities to provide antiseptic cleansing.

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- For personal hand hygiene: to help prevent the spread of certain bacteria.

-For products containing povidone-iodine the following statement may be made:

•For wound cleansing.

•Apply to wound once or twice daily.

-For products intended as hand sanitizers:

•Rub product onto hands and allow to dry.

Permitted combinations:

No combinations are permitted.

Risk information:

Cautions and warnings:

-For all products:

• For external use only.

• Avoid contact with the eyes. If contact occurs, flush eyes with water.

• Discontinue use and consult a health care practitioner if irritation develops.

-For products containing ethanol or isopropanol only:

- **Flammable.**
- **Keep away from open flame and sources of heat.**

directions for use:

Statement(s) to the effect of:

- For all products except povidone-iodine:

- **Use as part of your daily cleansing routine.**

-For povidone iodine:

- **Use on wounds once daily.**

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1.2. Personal commercial use antiseptics:

Personal commercial uses products are those made available to the general public for occasional use and are intended to reduce transient organisms on the skin in a commercial or institutional setting.

2. Professional use antiseptics:

2.1. Food premises use antiseptics:

Products for professional food premises are those which are indicated for use by food handlers to reduce transient organisms on the skin in a commercial or institutional setting including food processing plants, restaurants, supermarkets, and fast food outlets.

2.2. Professional healthcare use antiseptics:

Products for professional healthcare use are those which are indicated for use by individuals to reduce transient and/or resident organisms on the skin in a healthcare setting (such as hospitals, nursing homes, clinics and dental offices). Such products are to be used in accordance with applicable hospital protocols. These products include professional hygienic hand rub, professional hygienic hand washes, surgical hand rubs, surgical hand washes and patient preoperative skin preparations.

➢ Basic documentation required for registration:

This includes information regarding efficacy, safety, quality and stability of the product.

1. Efficacy tests:

Appropriate microbiological tests to demonstrate efficacy should be done taking in consideration the following:

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	1-In vitro test	2-In vivo test
Test report which proves the antiseptic activity	For surrogate and non-surrogate test organisms: one independent report.	For non-surrogate test organisms: one independent report.
		For surrogate test organisms: two independent reports.

- **Test reports should include at a minimum:**

a. **Identification of the standard method used to verify the product efficacy.**
b. **Proof of the effectiveness of the neutralizer utilized in the tests for both the reference standard and the test product.**
c. **The relationship of each test to specific area of application.**
d. **The type and level of soil load included in the test.**
e. **The time differential (between application of the test product and the collection of organisms) used in the test and whether the time stated is sufficient to meet the required criteria of specific activity.**
f. **Initial number of the test organisms.**
g. **Information on the batch number, expiry date, and date of manufacture for each batch tested.**
h. **Results in tabular form.**
i. **Proof of a washout period if a cross-over study is employed or if a subject is reused.**
j. **Proof of glove compatibility for surgical scrub products.**
k. **The minimum inhibitory concentration (MIC) for the product, when available.**
l. **Conclusion, describing whether the product meets the specific criteria relative to the reference method(s) employed.**

N.B.

a. **At a minimum, tests must demonstrate that the lower bound of the confidence interval is at the required log reduction.**

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b. Based on practicality, no product will be accepted if its in vivo time-to-effect upon completion of application is greater than 30 seconds (for a leave on product) or 1 minute (for a wash off product).

2. Safety tests:

a. Published or unpublished safety data testing local tolerance, such as: Irritation and sensitization (in the presence and absence of UV exposure when this is likely to be a risk factor) and preferably conducted in human species; photo-allergenicity; photo-carcinogenicity, etc...

(N.B. this will be conducted at NODCAR).

b. When evidence is not available to show that topically-applied medicinal ingredients are not absorbed systemically to a significant degree, toxicity data should be submitted.

c. Safety tests for (a) and (b) should be performed in accordance with relevant internationally-accepted test methods (e.g. OECD, ICH).

3. Quality tests:

a. Full disclosure of the chemical formulation of the product is essentially required. This information should be in the form of a quantitative listing of all ingredients used in its manufacture and in the final product formulation, taking into account that the percentage of the chemical formulation components should add up to 100%. Each Ingredient should be identified by its trade name, supplier, proper chemical name and CAS number (if available).

b. Active ingredients will be accepted for registration only if registered in a reference country as a biocide product in the same concentration and with the same claim.

c. Additional supporting data may be required to support the quality of the finished antiseptic product. The recommended quality data depends on the classification of the proposed product.

4. Stability tests:

Accelerated stability testing at conditions (40±2 ºC / 75±5 % RH) and real time study at conditions (30±2 ºC / 65±5 % RH) are required for the first three batches. For more details please refer to Central Administration of Pharmaceutical Affairs (CAPA) stability study guidelines.

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Information on test organisms and in vitro /in vivo testing:

Test organisms:

The test organisms recommended for personal domestic and commercial use products are based on the selected test methods.

The test organisms recommended for professional use food premise and healthcare products were selected because these were determined to be common organisms of concern in these environments, including those that are recognized to contribute to nosocomial infections.

Surgical use products including patient preoperative skin preparations are not required to demonstrate efficacy against mycobacterium and viruses as currently only bacteria and fungi are recognized as frequent causative agents of surgical site infections.

In vitro/in vivo test methods:

It is recommended that a modular approach be taken to first test the formulation in vitro, and then proceed to in vivo testing if the in vitro testing is successful.

- **For personal use products:**

Only in vivo data need to be submitted for assessment except where specified for fungal and viral testing.

All personal use products are expected to:

a. **Demonstrate efficacy against bacteria and fungi at a minimum unless additional claims are made (e.g. log reduction) or the product contains a new active ingredient or new combination of active ingredients.**

b. **Provide additional data to support claims for mycobacteria and/or viruses.**

- **For professional use products:**

Both in vitro and in vivo tests are required to demonstrate efficacy against a broader range of organisms, however the in vivo tests will be limited to representative organisms only and should demonstrate a minimum log reduction.

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Products intended for use by food handlers should also:

a. **Demonstrate efficacy in the presence of organic soil such as food ingredients and fats, in order to adequately represent likely conditions of use.**
b. **Give additional consideration to the proposed product formulation, as these must be appropriate for use in food premises.**
c. **Demonstrate efficacy against viruses in addition to other microorganisms.**

Data to support specific claims:

1. **General requirements**:

a. **For products that are intended to be used in professional food premises. Residual data would be requested if necessary to clarify the residual amount of the product that will be found on hands of employees after application of the product and the level that may be expected to be transferred to food products (after precautionary safety approaches were undertaken such as potable water rinse or drainage of excess of product). This information should be in the form of actual analytical data or theoretical estimates based on the proposed use level of the product.**
b. **The Estimated Dietary Intake (EDI) resulting from the use of the product. This should include any information that is used to estimate the dietary exposure such as type of foods, residual levels, etc.**
c. **Any available data (full reports) on the mammalian oral toxicity of the product.**
d. **Minor variation in formulation is allowed with new data to support product efficacy only for personal use products when variations are made to the fragrance or color. Manufacturers should demonstrate product efficacy for all other reformulations as they may affect the product's performance or in major changes consider new registration application.**
e. **Data recommendations should be made available for supporting an application for personal commercial use wherein claims are made against a specific organism, antiviral claims, or those relating to persistence, sterility, time kill, % reduction and/or log-reduction.**

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2. Log reduction claims:

a. **Personal use products claiming log reduction values (e.g. kills 99.9% of bacteria) are required to submit data to support the claim for the specific formulation and using the recommended test methods.**
General log reduction claims need only demonstrate efficacy against bacteria and fungi unless claims are also made against mycobacterium.

b. **Professional use products claiming log reduction values (e.g. kills 99.9% of bacteria) are required to submit data to support the claim. Note that products for use in a professional setting and/or those claiming to reduce specific organisms are required to have a minimum log reduction in vivo.**

3. Persistence claims:

Persistence is defined as a claim that the product will deliver a longer action than only the immediate reduction of microorganisms on hands. Persistence claims for personal use products can only be made relative to bacteria. Should a sponsor wish to make persistence claims against other organisms, a strong supporting scientific rationale outlining an appropriate test method would be necessary (e.g. technology used or special formulation).

4. Time kill claims:

Antiseptic products are expected to have a minimum time-to-effect of 30 seconds (for waterless hand rubs) to 1 minute (for washes or scrubs using water) upon completion of application according to the proposed directions for use. As this is considered the norm for antiseptics, a claim that a product is fast-acting would have to demonstrate both a significantly shorter time-to-effect and still maintain clinical relevance, and should use the test methods outlined for log reduction testing (organisms dependent on indications, with bacteria/fungi as a minimum).

5. Sterility:

Any pharmaceutical product claiming to have a sterilizing effect must provide strong supporting data for such claim.

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6. Labeling:

This section is intended to help the applicant in preparing acceptable labeling for antiseptic products. The applicant should provide all draft labeling of the drug product, these aspects of the labeling are subject to evaluation and examples include:

a. **Name of the product (for products liable for sale in the pharmacy the trade name will be revised according to naming SOPS).**
b. **Name and address of the manufacturer.**
c. **Active ingredients: the identity and concentration of each active ingredient in the product should be stated.**
d. **Declaration of the net contents.**
e. **Declaration of the batch number.**
f. **Inclusion of appropriate symbols and cautionary statements.**
g. **Security packaging requirements.**
h. **Production and expiration date and storage conditions.**
i. **Other labeling information:**

- **Labels which include the authorized claims should also describe the intended area of application and specific attributes of the product, such as: bactericidal, fungicidal, mycobactercidal or virucidal.**
- **The label should also clearly reflect the same conditions of use employed in the tests used to demonstrate efficacy (e.g. directions for use, warnings, etc).**
- **Products may carry more than one indication or claim, as long as each has been authorized. In such an instance, the label must include the full warnings and adequate directions for use for each indication, should these differ. If surrogates were used in testing this should be stated on the labels in order to ensure transparency and clarity for the end user efficacy (e.g. directions for use, warnings, etc).**
- **Dispensing units are also considered labels when they contain a drug product, and should be labeled in accordance with regulatory requirements.**

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2) Disinfectants:

Definitions:

The term "disinfectant" as defined and interpreted in these guidelines is considered to include bactericides, fungicides, virucides, mycobactericides, tuberculocides, sporicides, sterilants, or combinations of these. A disinfectant without specific target organisms indicated on the product label is regarded only as a bactericide.

Scope:

It applies to all disinfectants and disinfectant sanitizers within the pharmaceutical frame. This doesn't include non-food contact sanitizers which do not carry disinfectant claims, e.g., sanitizers with a mission to control plant pathogens such as those used in greenhouses, odour control sanitizers, and swimming pool sanitizers.

Classification:

Device	Device definition	Disinfectant class	Definition of disinfectant class
a. Critical	**Present a high risk of infection if they are not sterile, i.e. contaminated with any organism, including spores. Routinely penetrate the skin or mucus membranes into normally sterile areas of the body (e.g., implants, scalpels, needles, surgical instruments, laparoscopes), or come into direct contact with recalculating body fluids, (e.g., kidney dialysis tubing and dialyzers, or blood oxygenators).**	**Gaseous sterilant, and critical device sporicide, also referred to as critical sporicide**	**A disinfectant which helps achieves sterilization.**

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b. Semi-critical	**Contact with mucous membranes during use but do not usually penetrate normally sterile areas of the body, e.g. endoscopes, anesthesia breathing circuits, respiratory therapy equipment, dental mirrors, etc…**	**High-level Disinfectant.**	**A disinfectant that kills all microbial pathogens, except Large numbers of bacterial endospores according to labeling.**
c. Non-critical	**Contact only intact skin during routine Use, e.g. stethoscopes, bedpans, etc...**	**Intermediate level.** **Low-level Disinfectant.**	**A disinfectant that kills all microbial pathogens, except bacterial endospores, when used according to labeling.** **A disinfectant that kills pathogenic and potentially pathogenic microorganisms on hard non-porous inanimate surfaces or inanimate objects, when used according to labeling.** **Veterinary hygiene biocide products are used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported.**

➢ Basic documentation required:

1. Efficacy requirements:

The regulatory decision will be based on the scientific validity of the study conducted to demonstrate efficacy. This includes internationally recognized methodologies.

2. Quality requirements:

a. **Full disclosure of the chemical formulation of the product is essentially required. This information should be in the form of a quantitative listing of all ingredients used in its manufacture and in the final product formulation, taking into account that the percentage of the chemical**

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formulation components should add up to 100%. Each ingredient should be identified by its trade name, supplier, and proper chemical name and CAS number (if available).

b. Active ingredients will be accepted for registration only if registered in a reference country as a biocidal product in the same concentration and with the same claim.
c. Additional supporting data may be required to support the quality of the finished product. The recommended quality data depends on the classification of the proposed product.

3. Safety requirements:

Information regarding, acute oral toxicity, inhalation toxicity and skin irritation should be provided for all grades of disinfectants. For disinfectants used with critical and semi critical devices information on cytotoxicity should also be provided. Information on haemocompatibility, mutagenecity and carcinogenicity are required for all products except for those used on surfaces.

If other forms of toxicity not mentioned in the above information are suggested (e.g. neurotoxicity) such information should be provided.

4. Stability requirements:

Accelerated stability testing at conditions (40±2 ºC / 75±5 % RH) and real time study at conditions (30±2 ºC / 65±5 % RH) are required for the first three batches. For more details please refer to Central Administration of Pharmaceutical Affairs (CAPA) Stability Study Guidelines

5. Labeling:

This section is intended to help the applicant in preparing acceptable labeling for disinfectant drugs. The applicant should provide all draft labeling of the drug product, these aspects of the labeling are subject to verification, and examples include:

a. Name of the product and manufacturer.
b. Name and address of the submission sponsor.
c. Active ingredients: the identity and concentration of each active ingredient in the product should be stated.
d. Declaration of the net contents.
e. Declaration of the batch number.

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f. **Inclusion of appropriate symbols and cautionary statements for pressurized metal cans.**
g. **Security packaging requirements.**
h. **Expiration dating and storage conditions.**
i. **Intended use this includes:**

- **Claims (e.g. as a disinfectant, sterilant and sporicide)**
- **The label should indicate the type of facility where the disinfectant product is to be used; the various uses may be separated on the label.**
- **With respect to the disinfection of medical devices, the device and the manner in which it is used must be considered.**

j. **Directions for use:**

i. **The label should provide specific instructions to the user for preparing the in-use dilution of the product in order to achieve the intended antimicrobial effect. More than one dilution may be specified if several different applications are intended.**
ii. **products marketed as aerosol sprays or as wipes are generally assessed on the basis of the efficacy of the liquid disinfectant**
iii. **Contact time, i.e. the length of time the disinfectant shall be in contact with the surface to achieve the desired result, should be stated e.g. disinfection, sanitization. More than one contact time may be specified if several different applications are intended.**
iv. **If the product is to be used at a temperature other than 30^{o}C, this temperature should be specified and the label should indicate that heating or cooling to the specific temperature is required for efficacy.**
v. **If applicable, the volume and directions for the use of an activator should be included.**
vi. **The labeling for products not labeled for single use should clearly indicate their expiry dating after activation and/or dilution and under reuse conditions as appropriate.**
vii. **Labeling of disinfectants for use on medical devices should specify that the device is to be thoroughly cleaned prior to its disinfection. It is also appropriate to indicate that heavy soil is to be removed from environmental surfaces prior to disinfection.**

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viii. **Appropriate rinse procedures to ensure the absence of unacceptable residues on the surface or device after disinfection or sterilization are required.**

ix. **for products labeled with efficacy claims against blood borne viral pathogens such as HIV, HBV and HCV, the following additional labeling criteria should be included:**

- **A term like "HIV" is acceptable, but should also be identified as "human immunodeficiency virus". Similarly, the terms HBV and HCV are acceptable, but should also be respectively identified as "hepatitis B virus" and "hepatitis C virus".**
- **Product is intended for use against the blood borne pathogens listed on the labeling, e.g., HIV, HBV, HCV, in settings where these microorganisms would be expected to be encountered, such as settings where contamination by blood or body fluids is likely.**
- **Personnel that clean items soiled with blood or body fluids should be cautioned to wear appropriate barrier protection, such as disposable gloves, gowns, and masks.**

x. **The need for surfaces to be cleaned prior to disinfection should be identified.**

xi. **Directions for the disposal of cleaning materials and waste should be specified.**

xii. **Directions for proper dilution and application of the disinfectant, including appropriate contact times.**

xiii. **Precautionary statements should be mentioned on the outer label. Examples of such, keep out of reach of children, not for internal use, use in ventilated area, avoid contact with eyes, use safety glasses, in case of contact, flush with water immediately and contact a doctor.**

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Glossary

- **Biocidal products : Active substance and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.**

- **Antiseptic: A product that inactivates, reduces, prevents or arrests growth of microorganisms with the inherent intent to mitigate or prevent disease on the skin or mucous membrane (mouth washes only).**

- **Disinfectant: An antimicrobial agent capable of destroying pathogenic and potentially pathogenic microorganisms on environmental surfaces and inanimate objects.**

- **Critical disinfectant: are those products used for disinfection of devices that present a high risk of infection if they are not sterile, i.e. contaminated with any organism, including spores. Routinely penetrate the skin or mucous membranes (mouth washes only) into normally sterile areas of the body (e.g., implants, scalpels, needles, surgical instruments, laparoscopes), or come into direct contact with body fluids, (e.g., kidney dialysis tubing and dialyzers, or blood oxygenators).**

- **Semi-critical disinfectant: are those products used for disinfection of devices that contact with mucous membranes during use but do not usually penetrate normally sterile areas of the body, e.g. endoscopes, anesthesia breathing circuits, respiratory therapy equipment, dental mirrors, etc.**
- **Non-critical disinfectant: are those products used for disinfection of devices or surfaces that contact only intact skin during routine use, e.g. stethoscopes, bedpans, areas where animals are housed …..etc.**

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- **Sporicide:** An antimicrobial agent capable of destroying bacterial spores. It is considered unacceptable to label a non-sporicidal disinfectant with claims against the vegetative cells of spore-forming bacteria whose spores may be the primary means of spread of healthcare facilities associated infections. In such cases, the very listing of spore forming bacteria could mislead users into wrongly assuming that the disinfectant has sporicidal effectiveness.

- **Virucide:** An antimicrobial agent capable of destroying viruses.

- **Bactericide:** An antimicrobial agent capable of destroying bacteria, but not necessarily bacterial spores or mycobacteria.

- **Fungicide:** An antimicrobial agent capable of destroying fungi, including their spores.

- **Mycobactericide:** An antimicrobial agent capable of destroying mycobacteria.

- **Tuberculocide**: Synonymous with Mycobactericide.

- **Sanitizer:** A product that reduces the level of microorganisms present by significant numbers, e.g. 99.9% or more, or to acceptable levels.

- **Professional hygienic hand rubs:** Product used for post contamination treatment of lightly soiled hands that involve rubbing hands without addition of water, and which is designed for frequent use.

- **Professional hygienic hand washes**: Product used for post contamination treatment that involve washing hands with water, and which is designed for frequent use.

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- **Surgical hand rubs: Products used for preoperative treatment, which involve rubbing hands without addition of water.**

- **Surgical hand washes: Products used for preoperative treatment that involve washing hands, either with or without the use of a scrub brush.**

- **Patient preoperative skin preparations: Products used to prepare patient skin prior to surgical procedures.**

- **Resident organisms: Those organisms normally permanently resident on the skin. Under some circumstances, this may include those that are not permanently resident on normal skin but may be increased in number in the presence of certain skin diseases (e.g. Klebsiella spp. on psoriatic skin) or systemic illnesses (diabetes, AIDS, etc).**

- **Transient organisms: Those organisms picked up by contact with the environment but may remain in situ long enough to be transferred (e.g. from patient to patient, from surgeon to patient, etc).**

  Washes: Antiseptic products to be used with water.

  Rubs: Antiseptic products to be used without water.

- **Hard surface disinfectant: A disinfectant that kills pathogenic and potentially pathogenic microorganisms on hard non-porous inanimate surfaces or inanimate objects.**

- **Persistence: A claim that the product will deliver a longer action than only the immediate reduction of microorganisms.**

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Documents required for registration of imported biocidal product

Imported products applied for registration must fulfill the following requirements:

1-Free sale Certificate

A recently issued free sale certificate from one of the reference countries listed below mentioning the following information

1. **Name of product.**
2. **Pharmaceutical form.**
3. **Active ingredient.**
4. **Registration number.**
5. **Date of issue of the products.**
6. **License holder and manufacturer.**

The free sale certificate

Must mention the phrase "Freely Sold" or "May be freely Sold" or any other equivalent meaning.

The product must be freely sold in the country of origin at least one year from the date of application

The following are the reference countries and the competent authorities from which the free sale certificate is issued:

1. **Austria…Federal Ministry of Agriculture, Forestry, Environment and Water Management - Div. V/3.**
2. **Australia…Therapeutic Goods Administration TGA.**
3. **Belgium…Federal Overheidsdienst Volksgezondheid,**
   a. **Veiligheid van de Voedselketen en Leef milieu.**
   b. **Directoraat-generaal: Leefmilieu.**
4. **Canada…Health Canada.**
5. **Denmark…Danish Environmental Protection Agency (Miliostyrelsen).**
6. **Finland…Finish Environment Institute.**

   And also: National Product Control Agency for Welfare and Health.
7. **France…Ministere de l`energie, du developpement durable et de la mer (MEEDDM).**
8. **Germany…Bundesministerium fur Umwelt, Naturschutz and Reaktorsicherheit.**

   And also: Bundesanslalt fur Arbeitsschutz and Arbeitsmedizin (BAuA)
   - **i- Fedral Institute for Occupational Safety and Health.**
   - **ii- Anmeldestelle Chemikalien/Zulassungsstelle Biozide.**

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iii- Division for Chemicals and Biocides Regulation.

9. Ireland…Pesticides Control Services (PCS).
   a. Department of Agriculture & Food Laboratories.
10. Italy…Ministry of Health
   a. Directorate-General for Medicinal Products and Medical Devices UfficioVII.

And also: Ministry of Environment.

11. Japan…
12. Netherlands…Ministry of Housing, Spatial Planning, nd Environment (VROM).

And also: College voor de toelating van Gewasbeschermingsmiddelen en Biociden - CtGB.

13. Newzland…
14. Portugal…Direccao-Geral da Saude.

And also: Direccao-Geral de Agricultura e Desenvolvimento Rural (DGADR).

And also: Direccao-Geral de Veterinaria (DGV).

Spain…Ministerio Sanidad y Consumo. Direccion General de Salud Publica
   a. Subdireccion General de Sanidad Ambiental y Salud Laboral

And also: Ministerio de Medio Ambiente
Direccion General de Galidad y Evaluacion Ambiental

And also: Ministerio de Agricultura, Pesca y Alimentacion
Subdireccion General de Sanidad Animal

15. Sweden…Swedish Chemicals Agency.
16. UK…The Health and Safety Executive.
   a. Chemicals Assessment Schemes Unit.
17. U.S.A…EPA (environmental protection agency) and FDA.
18. Iceland…Environment and Food Agency of Iceland
19. Norway…Norwegian Pollution Control Authority.
20. Switzerland…Swiss Fedral Office of Public Health.
21. other organizations:

European Commission
Directorate General Environment.
European Commission
Directorate Chemical Bureau (ECB).

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2-a valid letter of authorization to assign the local company (applicant) to be the importer of the product applied for registrations and be responsible for its registration and distribution in Egypt.

In cases where products are manufactured in reference country but distributed from another country an official letter from the company of origin stating the manufacturing, packaging site and why the product is distributed from another country. The free sale certificate and letter of authorization must be authenticated and legalized by the competent authority and the Egyptian consulate.

المراجع

- **Health Canada guidance document on human use antiseptic.**
- **Health Canada guidance document on disinfectant.**
- **TGA: Therapeutic Goods Administration (new regulatory framework document for disinfectant).**
- **European commission directive for biocidal product and annexes.**
- **Stability study guidelines.**
- **قرارت اللجنة الفنية.**
- **قرار وزير الصحة رقم ٢٩٦ لسنة ٢٠٠٩**
- **قانون مزاولة مهنة الصيدلة رقم ١٢٧ لسنة ١٩٥٥**

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