GUIDELINES FOR THE REGISTRATION OF SURFACE DISINFECTANT

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National Pharmaceutical Regulatory Agency

Ministry of Health Malaysia

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TABLE OF CONTENTS

1.0 Introduction

Surface disinfection is defined as chemical disinfection of a solid surface, including those of certain medical and veterinary instruments which cannot be immersed, by the application of a product with or without mechanical action (1).

Surface disinfectants can be used to disinfect hard surfaces in areas such as healthcare facilities (including veterinary hospitals, dental facilities etc.), industry, institutions or private homes. These surfaces may be tables, floors, walls, the outsides of machinery and hard furniture (2).

When choosing a disinfectant for use in any facility, suppliers and users must understand the efficacy of the active ingredient(s) and its finished product, as well as, the limitations and potential hazards that may accompany the product use or application.

2.0 Background

Disinfection practices are important to reduce the potential for bacteria or virus contamination in clinical and non-clinical settings, such as in the home, offices, schools, gyms, publicly accessible buildings, faith-based community centres, markets, transportation and business settings or restaurants (4).

High-touch surfaces in these clinical and non-clinical settings should be identified for priority disinfection such as door and window handles, kitchen and food preparation areas, counter tops, bathroom surfaces, toilets and taps, touchscreen personal devices, personal computer keyboards, and work surfaces (4).

Due to the COVID-19 pandemic, there is an increase in the demand and supply of surface disinfectants in the market. Currently, surface disinfectants are not being formally regulated in Malaysia. Therefore, the Director General of the Ministry of Health has given the mandate to the National Pharmaceutical Regulatory Agency (NPRA) to regulate surface disinfectants. Through collaborative engagements with the industries, NPRA has produced a guideline for surface disinfectants. The regulatory requirements for surface disinfectants will be subjected to regular review.

SANITIZATION / DISINFECTANT PRODUCT CATEGORIES AND CURRENT REGULATORY CONTROL

Sanitization / disinfectant products may be categorized into the following three categories:

Category	**Use**	**Product Classification**	**Regulating Authorisation Body/Agency**
First	Used for sanitization or disinfection of skin / human and animal body parts (sanitizer, disinfectant, antiseptic).	A) Generic Product (Non-Scheduled Poison / OTC). i) Topical Antiseptic / disinfectant for human and animal use (For use on human / animal skin and intended to be used for a medical purpose). ii) Hand sanitizer / disinfectant / surgical rub which are used by healthcare professionals for treatment procedures. B) Cosmetic Hand sanitizer for general hand hygiene; without therapeutic claims. C) Medical Devices Alcohol swab / wipe applied to the skin prior to injection (To be used for a medical purpose to wipe intact skin for needle access).	NPRA NPRA Medical Device Authority (MDA)
Second	Used for sanitization or disinfection of medical devices.	Medical Device	Medical Device Authority (MDA)

Third	Used for sanitization or disinfection of all types of surfaces (except on human, animal and medical devices).	A) Surface disinfectant to be used on non-porous surface. B) Surface disinfectant for other types of surface is classified as General Consumer Product.	NPRA No specific regulatory authority.

3.0 OBJECTIVES

This guideline shall serve as a reference for the production, importation, sale and use of surface disinfectants.

This guideline is intended to:

a) guide producers to use ingredients that are safe and effective;

b) enable producers to select appropriate standard(s) to be used in order to provide data or documentation to support their claims for a specific product;

c) enable appropriate use of the product as directed;

d) assist regulatory authority in assessing labelled claims.

4.0 SCOPE

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects (7).

The scope of this guideline encompasses surface disinfectants to be used only on non-porous hard surfaces. This includes surface disinfectants used in:

i) healthcare facilities and veterinary areas;

ii) food areas: processing, distribution and retailing of food of animal or vegetable origin;

iii) domestic and institutional areas: all public areas where disinfection is not medically indicated (homes, catering, schools, nurseries, transports, hotels, offices etc.);

iv) industrial areas: packaging, biotechnology, pharmaceutical, cosmetic, etc. industries.

Surface disinfectants which are excluded from the scope will be:

i) Any household product primarily used for general cleaning
ii) Products used on soft/porous surfaces (e.g. fabric, leather)
iii) Rinse-off products
iv) Products used on medical devices or medical device surfaces
v) Products that utilize ultraviolet-C (UVC) sterilisers*

Note: *such product/device should not be marketed for domestic use for the purpose of virus eradication. UV irradiation should only be executed by trained professionals for specific purposes such as in hospitals and laboratories. UVC radiation can cause injuries to the skin (sunburn) and eyes (corneal inflammation) and ultraviolet-C (UVC) sterilisers have not been shown to be effective in eradicating viruses (3).

vi) Coating or long-lasting protection products.
vii) Air disinfectant.
viii) Products used on living beings externally or internally.
ix) Multi-purpose usage.

5.0 ACTIVE INGREDIENTS

An active ingredient is any chemical with antimicrobial activity used in the production of a surface disinfectant. The active ingredient(s), together with other accompanying ingredients used in a surface disinfectant must be evaluated by the producer as safe for humans and the environment. The efficacy of the active ingredient(s) must be based on sufficient scientific evidence and must be listed under **Appendix I** of this Guideline, or recognized by relevant authorities, such as, European Chemical Agency (ECHA), Environmental Protection Agency (EPA) and Therapeutic Goods Administration (TGA).

General household products that contain the appropriate concentrations of active ingredients can be used to disinfect areas that are very likely to be contaminated with viruses (3). For example, sodium hypochlorite (bleach / chlorine) may be used at a recommended concentration of 0.1% or 1,000ppm

(1 part of 5% strength household bleach to 49 parts of water). Alcohol at 70-90% can also be used for surface disinfection (4).

6.0 PRODUCT USE GUIDE

Surfaces must first be cleaned with water and soap or a detergent to remove dirt, followed by disinfection. Cleaning should always start from the least soiled (cleanest) area to the most soiled (dirtiest) area in order to not spread the dirt to areas that are less soiled (4). It is also very important to follow the instruction of use as described on the label or provided by the supplier.

All disinfectants should be stored in suitable containers as instructed by the producer, in a well-ventilated, covered area that is not exposed to direct sunlight and ideally should be freshly prepared every day (4).

In indoor spaces, routine application of disinfectants to surfaces via spraying is not recommended for coronavirus and other viruses unless proven otherwise. Disinfectants should be applied using a cloth or wipe that has been soaked in the disinfectant (4).

Protective measures to be taken when using disinfectants

1) Carefully select the disinfectant and its concentration to avoid damaging surfaces and to avoid or minimize toxic effects on household members (or users of public spaces).

2) Avoid combining disinfectants, such as bleach and ammonia, since mixtures can release potentially fatal gases or cause respiratory irritation.

3) Keep children, pets and other people away during product application and until it is dry and there is no more odour.

4) Open windows and use fans to ventilate. Step away from odours if they become too strong. Disinfectant solutions should always be prepared in well-ventilated areas.

5) Wash your hands after using any disinfectant, including surface wipes.

6) Keep lids tightly closed when not in use. Spills and accidents are more likely to happen when containers are open.

7) Do not allow children to use disinfectant wipes. Keep cleaning fluids and disinfectants out of the reach of children and pets.

8) Throw away disposable items like gloves and masks that were used during cleaning. Do not clean and re-use.

9) Do not use disinfectant wipes to clean hands or as baby wipes.

10) The minimum recommended personal protective equipment to be used when disinfecting in non-health care settings are rubber gloves, waterproof aprons and closed shoes. Eye protection and medical masks may also be needed to protect against chemicals in use or if there is a risk of splashing.

7.0 PRODUCT CLAIM

All product claims made must be supported by relevant and specific efficacy test conducted using the recommended active ingredient concentration. Claims and recommendations must be supported by the results of tests appropriate to the area of application.

To enable the user to choose the appropriate product, it is strongly recommended to specify the claim for surface disinfectant. For example, if the surface disinfectant is to be used for general disinfection and is without efficacy against virus, it should be claimed as an antibacterial disinfectant only.

8.0 SUPPORTING DOCUMENTS FOR PRODUCT CLAIMS

In order to support the claim and the efficacy of the product as a disinfectant, the applicant must be able to provide scientifically accepted evidence to the NPRA. There are 3 phases in the recommended standardized test method (5). The details are described below:

1) Phase 1 tests are quantitative suspension tests to establish that the active ingredient (s) or product under development has bactericidal, fungicidal or sporicidal activity without regard to specific areas of application. Phase 1 tests may not be used to support any product claim.

2) Phase 2 comprises of two steps. Phase 2, step 1 tests are quantitative suspension tests to establish that a product has bactericidal, fungicidal, yeasticidal, mycobactericidal, tuberculocidal, sporicidal or virucidal activity under simulated practical conditions appropriate to its intended use. Phase 2, step 2 tests are quantitative laboratory tests to establish that a product has bactericidal, fungicidal, yeasticidal, mycobactericidal, tuberculocidal, sporicidal or virucidal activity when applied to a surface or skin under simulated practical conditions (surface, instrument, handwash and handrub tests).

3) Phase 3 tests are field tests under practical conditions. Applicable methodology for this type of test is not yet available but may be developed in the future.

Below are the minimum requirements and standard methods of efficacy testing that need to be provided by the applicant to the NPRA for the registration of surface disinfectant products:

Product description type	**Use area**	**Minimum spectrum of activity**	**Minimum requirement for method used**	**Minimum requirement for efficacy testing or *equivalent standard**
Hard surface disinfectant	Healthcare institution	Virucidal	Virucidal (phase 2, step 2, dirty condition is compulsory)	EN 16777
			Virucidal (phase 2, step 1, dirty condition is compulsory)	EN 14476
		Bactericidal & Yeasticidal	Suspension lab test (phase 2, step 2, dirty condition is compulsory)	EN 17387 (without mechanical action) or, EN 16615 (with mechanical action)
	Veterinary	Virucidal	Suspension lab test (phase 2, step 1)	EN 14675
		Bactericidal Yeasticidal	Suspension lab test (phase 2, step 1)	EN 1656 EN 1657
	Related to food preparation except hospital use	Bactericidal Yeasticidal	Suspension lab test (phase 2, step 2)	EN 13697 or, EN 1276 EN 1650
			Suspension lab test (phase 2, step 1)	
	Domestic	Bactericidal Yeasticidal	Suspension lab test (phase 2, step 2)	EN 13697 or, EN 1276 EN 1650
			Suspension lab test (phase 2, step 1)	
	Institution	Bactericidal Yeasticidal	Suspension lab test (phase 2, step 2)	EN 13697 or, EN 1276 EN 1650
			Suspension lab test (phase 2, step 1)	

*equivalent standard includes American Society for Testing and Materials (ASTM), Association of Official Analytical Collaboration (AOAC) International (AOAC International), Australian Therapeutic Goods Administration (TGA) and other established standards. Test for virucidal activity (e.g. EN 14476 and EN 14675 (veterinary)) is optional for use areas other than healthcare institutions.

A complete efficacy test report should consist of methodology, results and conclusion based on European Standard (EN) or equivalent as stated in this guideline. For test other than the European Standard, the requirement guidelines to pass the particular

test must also be submitted. All efficacy test must be done in laboratories which are accredited by Standards Malaysia. For EN test, the laboratories must be accredited to conduct EN test.

9.0 PRODUCT LABELLING REQUIREMENTS

It is the responsibility of the applicant to ensure the label contains the following information:

i) Product name
ii) Intended use, where applicable (if not clear from product name or presentation)
iii) Direction of use
iv) Company name (applicant) and local contact number
v) Active Ingredients and concentration
vi) Country of origin
vii) Batch number
viii) Production date/expiry date
ix) Warning/precaution including
   a. Not to be used on skin
   b. Keep out of reach of children
   c. Other relevant warning (if applicable)
x) Storage condition
xi) Net weight/volume

10.0 REGISTRATION PROCEDURE

Surface disinfectant product registration is voluntary. The applicant who wishes to register a surface disinfectant is required to manually submit the product information, along with the related documents as listed in **Appendix II**, to the NPRA for evaluation. The submission is by appointment only. A general workflow of the registration process is described in **Figure 1**. Currently, the registration validity period is 24 months and there is no registration fee. However, these will be subject to review in near future. Importation of surface disinfectants does not need to be accompanied by the approval document issued by the NPRA.

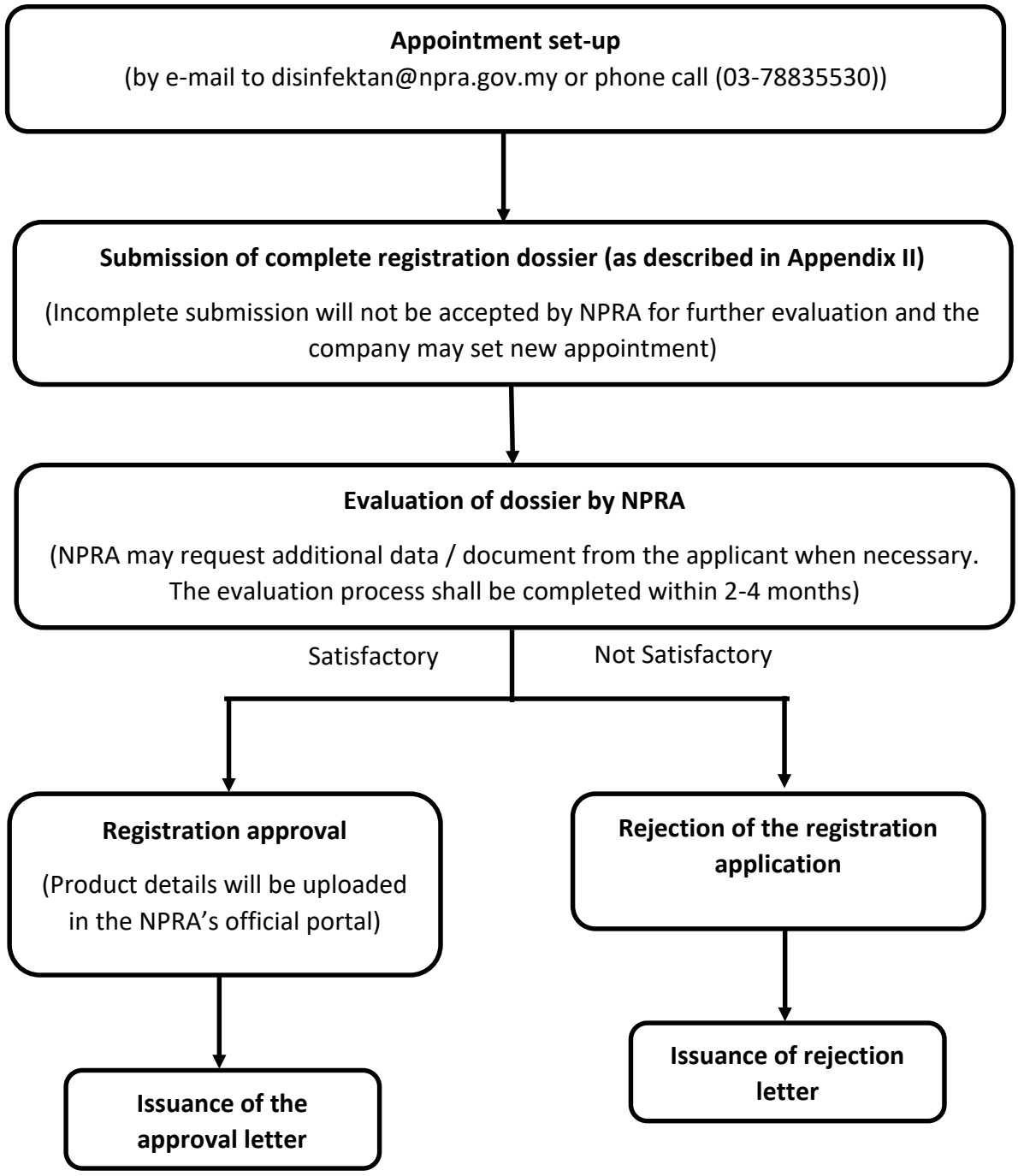
11.0 POST-REGISTRATION OF PRODUCT

i) Successfully registered product is given a serial number (e.g. SDXXXXXXXXXX) and listed on NPRA's website at https://www.npra.gov.my/index.php/en/informationen/new-products-indication/surface-disinfectants-approved.html
ii) The validity of the registered product is 2 years. Product holder required to renew the registered product 2 months before the expiry.

iii) Statements giving the impression of endorsement by the Ministry of Health, or any other government professional bodies printed on the product label and in any advertisement used to promote the product is prohibited.

iv) The registration number will be retracted for products which are marketed beyond the approved claims on label.

Figure 1



12.0 PRODUCT REGISTRATION RENEWAL

The validity of product registration is 2 years. Product registration holder is required to renew the product registration 2 months prior to the expiry. The documents required for product registration renewal are as following: -

i) Real-time stability data (complete test report on the shelf-life of the finished product consisting of methodology, results and conclusion).
ii) Label of the finished product. Label of only one product size is required.

13.0 ENQUIRIES

Any inquiries can be forwarded to:

Bahagian Regulatori Farmasi Negara (NPRA)
Kementerian Kesihatan Malaysia
Lot 36, Jalan Universiti
46200 Petaling Jaya
Selangor
E-mail address : npra@npra.gov.my
Telephone number : 03-7883 5400
Fax number : 03-7958 1312

14.0 REFERENCES:

1) **CEN - EN 14885 - Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics | Engineering360. (2020). Retrieved 13 July 2020, from https://standards.globalspec.com/std/13113128/EN%2014885**

2) **(2020). Retrieved 13 July 2020, from https://echa.europa.eu/documents/10162/23047722/draft_tg_vol_iib_efficacy_pt1-5_en.pdf/c0666ffd-c4dd-4a83-8b0f-97b419adcf98**

3) **Interim List of Household Products and Active Ingredients for Surface Disinfection of the COVID-19 Virus. (2020). Retrieved 14 July 2020, from https://www.nea.gov.sg/our-services/public-cleanliness/environmental-cleaning-guidelines/guidelines/interim-list-of-household-products-and-active-ingredients-for-disinfection-of-covid-19**

4) **Q&A: Considerations for the cleaning and disinfection of environmental surfaces in the context of COVID-19 in non-health care settings. (2020). Retrieved 14 July 2020, from https://www.who.int/news-room/q-a-detail/q-a-considerations-for-the-cleaning-and-disinfection-of-environmental-surfaces-in-the-context-of-covid-19-in-non-health-care-settings**

5) **Jürgen Gebel, H. (2013). The role of surface disinfection in infection prevention. GMS Hygiene And Infection Control, 8(1). Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3746601/#:~:text=The%20purpose%20of%20routine%20or,frequently%20touched)%20surfaces%20near%20patients**

6) **CEN - EN 14885 - Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics | Engineering360. (2020). Retrieved 15 July 2020, from https://standards.globalspec.com/std/13113128/EN%2014885**

7) **Introduction Disinfection & Sterilization Guidelines | Guidelines Library | Infection Control | CDC. (2020). Retrieved 13 August 2020, from https://www.cdc.gov/infectioncontrol/guidelines/disinfection/introduction.html**

APPENDIX I

LIST OF ACTIVE INGREDIENTS

No	Active Ingredient	Recommended concentration
1	Accelerated hydrogen peroxide[#]	0.5%
2	Benzalkonium chloride	0.05%
3	Chloroxylenol	0.12%
4	Ethyl alcohol	≥70%
5	Iodine in iodophor	50ppm
6	Isopropanol	≥50%
7	Povidone-iodine	1% iodine
8	Sodium hypochlorite	0.05 – 0.5%
9	Active chlorine generated from other precursor(s)^	ca. 0.476-4.762 g/L of available chlorine
10	Sodium chlorite	0.23%
11	Glutaraldehyde	≥2%
12	Formaldehyde	Acceptable with supporting documents.
13	Ortho-phthalaldehyde	Acceptable with supporting documents.
14	Peracetic Acid	Acceptable with supporting documents.
15	Phenolics	Acceptable with supporting documents.
16	Other quaternary ammonium compounds	Acceptable with supporting documents.

#Product with hydrogen peroxide as the active ingredient will be assessed on a case-by-case basis; efficacy reports should be provided by the supplier.

^Active chlorine could be generated from other precursors such as calcium hypochlorite, hydrochloric acid, sodium chloride, sodium dichloroisocyanurate, tosylchloramide sodium, and tichloroisocyanuric acid, under certain conditions.

Note: This is not an exhaustive list and is subject to review.

APPENDIX II

REGISTRATION REQUIREMENTS:
PRODUCT INFORMATION & RELATED DOCUMENTS

A) Applicant Details

i) Company Name (Company Registration Number)

ii) Company Address

iii) Telephone Number

B) Person representing the company

i) Name

ii) NRIC Number

iii) Contact Number

iv) Email address

C) Criteria for Product Registration: -

i) Finished product with the sole purpose to disinfect only non-porous hard surfaces.

ii) Imported finished product must be registered in the country of origin. Supporting documents must be provided for countries which do not regulate surface disinfectants.

iii) All active ingredients in the finished product must be listed under **Appendix I** of this Guideline, or recognized by relevant authorities, such as, European Chemical Agency (ECHA) and Environmental Protection Agency (EPA).

iv) Complete documents submission as per the requirements stated in this guideline.

D) Documents to be submitted: -

i) Company SSM

ii) Manufacturer's Name & Address

- Local manufacturer should be registered with the Registrar of Business and licensed by the local municipal authority.

- For product manufactured by foreign manufacturer, the applicant should provide documentation that has been issued and endorsed by relevant body to prove the existence of the manufacturer.

iii) Label of the finished product has to comply with the labelling requirements stated in this guideline. Label of only one product size is required.

iv) Material Safety Data Sheet (MSDS) of the finished product (each product)

v) Product registration certificate from the country of origin (for imported products) or relevant supporting document

vi) Certificate of analysis (CoA) of finished product is only required for 1 batch and it should consist of 2 components: -

- Physical attributes of the finished product
- Assay to determine the concentration of the active ingredient in the finished product

vii) Stability Data (complete test report on the shelf-life of the finished product consisting of methodology, results and conclusion). In the absence of real time shelf-life study, a minimum of 6 months accelerated stability study for 1 batch is accepted. However, real-time stability study should be done simultaneously for renewal after 2 years of the product registration.

viii) Efficacy test (complete test report consisting of methodology, results and conclusion) based on European Standard (EN) or equivalent as stated in this guideline.

APPENDIX III

CHECKLIST OF DOCUMENTS

No	Documents	Yes / No
1	Company SSM Certificate	
2	Manufacturer’s Details	
3	Product Label	
4	Material Safety Data Sheet (MSDS)	
5	Registration Certificate from Country of Origin	
6	Certificate of Analysis (CoA)	
7	Stability Data	
8	Efficacy Test Report	