



GUIDELINES FOR THE REGISTRATION OF SURFACE DISINFECTANT

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National Pharmaceutical Regulatory Agency

Ministry of Health Malaysia



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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 been 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.

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.
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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.

The guideline is also applicable to active ingredients and products under development for which no area of application has yet been specified.

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).

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.

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).

Suitable active ingredients and their effective concentrations are listed in **Appendix 1**.

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	Bactericidal & Yeasticidal	Suspension lab test (phase 2, step 2)	EN 13697 (without mechanical action) or, EN 16615 (with mechanical action)
		Virucidal	Virucidal (phase 2, step 1)	EN 14476
	Veterinary	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 1)	EN 1276 EN 1650
	Domestic	Bactericidal Yeasticidal	Suspension lab test (phase 2, step 1)	EN 1276 EN 1650
	Institution	Bactericidal Yeasticidal	Suspension lab test (phase 2, step 1)	EN 1276 EN 1650

*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. When no international standard is used, justification and evidence that are appropriate must be made available by the applicant for further evaluation by NPRA. Test for virucidal activity (e.g. EN 14476 and EN 14675 (veterinary)) is optional for use areas other than healthcare institutions.

9.0 PRODUCT LABELLING REQUIREMENTS

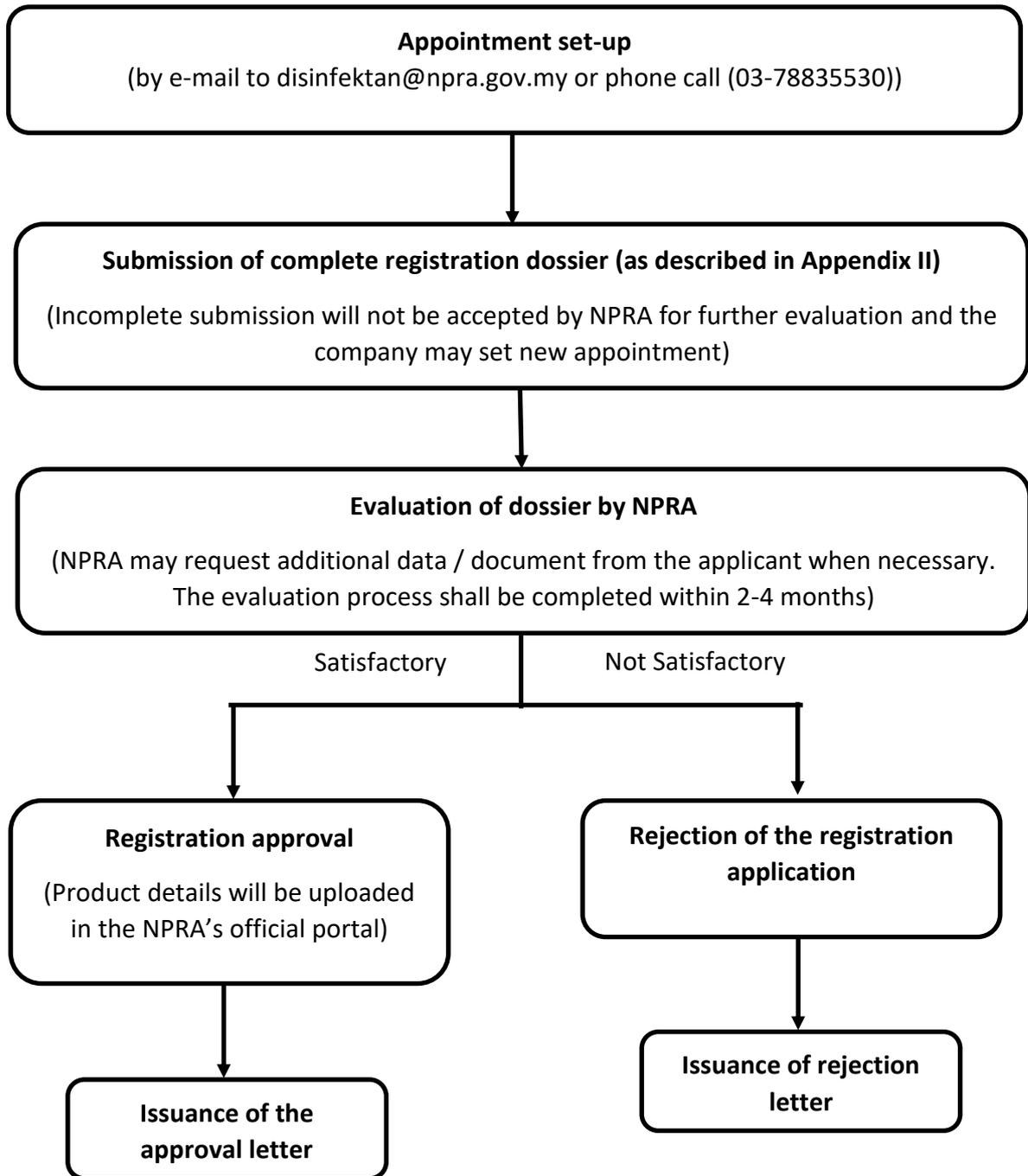
It is the responsibility of the applicant to ensure the label contains the following information:

- 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
- 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 12 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.

Figure 1



11.0 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

12.0 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%2>

[0purpose%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) Product Details

- i) Product Name (As per label)
- ii) Active Ingredient (s) and its concentration
- iii) Other Ingredient (s)
- iv) Product Label
- v) 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 document to prove the existence of the manufacturer that has been issued and endorsed by relevant body)
- vi) Document to support product safety
- vii) Documents to support product efficacy
 - Active ingredient
 - Finished product
- viii) Stability data
- ix) Certificate of analysis (CoA) of finished product (including assay of the active ingredient(s))