GUIDELINES FOR THE REGISTRATION OF SURFACE DISINFECTANT

10 September 2020
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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.

1.0 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, office, 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 have 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 are subject to regular review.
Surface disinfectants may be categorized into the following three categories:

<table>
<thead>
<tr>
<th>Category</th>
<th>Use</th>
<th>Product Classification</th>
<th>Regulating Authorisation Body/Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
<td>Used for sanitation or disinfection of skin / human and animal body parts (sanitizer, disinfectant, antiseptic).</td>
<td>A) Generic Product (Non-Scheduled Poison / OTC).</td>
<td>NPRA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>i) Topical Antiseptic / disinfectant for human and animal use (For use on human / animal skin and intended to be used for a medical purpose).</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>ii) Hand sanitizer / disinfectant / surgical rub which are used by healthcare professionals for treatment procedures.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>B) Cosmetic</td>
<td>NPRA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hand sanitizer for general hand hygiene; without therapeutic claims.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>C) Medical Devices</td>
<td>MDA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Alcohol swab / wipe applied to the skin prior to injection (To be used for a medical purpose to wipe intact skin for needle access).</td>
<td></td>
</tr>
<tr>
<td>Second</td>
<td>Used for sanitation or disinfection of medical devices.</td>
<td>Medical Device</td>
<td>MDA</td>
</tr>
</tbody>
</table>
Third | Used for sanitation or disinfection of all types of surfaces (except on human, animal and medical devices). | General Consumer Product | None

2.0 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 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 be cleaned with water and soap or a detergent first 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 disinfectant solutions 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 are 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:

<table>
<thead>
<tr>
<th>Product description type</th>
<th>Use area</th>
<th>Min spectrum of activity</th>
<th>Minimum requirement for method used</th>
<th>Minimum requirement for efficacy testing or *equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hard surface disinfectant</td>
<td>Healthcare institution</td>
<td>Bactericidal Yeasticidal Virucidal</td>
<td>Suspension lab test (phase 2, step 2) Virucidal (phase 2, step 1)</td>
<td>EN 13697 EN 16615 EN 14476</td>
</tr>
<tr>
<td></td>
<td>Veterinary</td>
<td>Bactericidal Yeasticidal</td>
<td>Suspension lab test (phase 2, step 1)</td>
<td>EN 1656 EN 1657</td>
</tr>
<tr>
<td></td>
<td>Related to food preparation except hospital use</td>
<td>Bactericidal Yeasticidal</td>
<td>Suspension lab test (phase 2, step 1)</td>
<td>EN 1276 EN 1650</td>
</tr>
<tr>
<td></td>
<td>Domestic</td>
<td>Bactericidal Yeasticidal</td>
<td>Suspension lab test (phase 2, step 1)</td>
<td>EN 1276 EN 1650</td>
</tr>
<tr>
<td></td>
<td>Institution</td>
<td>Bactericidal Yeasticidal</td>
<td>Suspension lab test (phase 2, step 1)</td>
<td>EN 1276 EN 1650</td>
</tr>
</tbody>
</table>

*equivalent standard includes American Society for Testing and Materials (ASTM), Association of Official Analytical Collaboration (AOAC) International (AOAC International) 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. However, 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. 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.

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-mel : npra@npra.gov.my
No. Tel. : 03-7883 5400
No. Faks : 03-7958 1312
12.0 REFERENCES:


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


### APPENDIX I

**LIST OF ACTIVE INGREDIENTS**

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

#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

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
   ii) Active Ingredient (s) and its concentration (%)
   iii) Other Ingredient (s)
   iv) Product Label
   v) Manufacturer’s Name & Address
   vi) Document to support product safety
   vii) Document to support product efficacy
       • Active ingredient
       • Finished product