

<mark>മുള്ത് ഉട്ടോറ്നത്</mark>കോർ**റ്റ** விவசாயத் திணைக்களம் DEPARTMENT OF AGRICULTURE

අංක 1056, ගැවඹේ, තැ.පෙ. 49, පේරාදෙණිය 20400, ශුී ලංකාව

இல 1056, கெடம்பே, த.பெ.இல 49, பேராதனை 20400, இலங்கை No. 1056, Getambe, P.O. Box 49, Peradeniya 20400, Sri Lanka



පළිබෝධනාශක රෙජිස්වුාර් කාර්යාලය பீடைகொல்லி பதிவு அலுவலகம் Office of the Registrar of Pesticides gරකථන/ഏച്ചതെ பேசி/Telephone : (94)812388076/388135

ෆாவீன்/தொலைநகல்/Fax : (!

: (94)812388135

ඊ මේල්/மின்னஞ்சல்/E-mail **වෙබ්**/மின்னஞ்சல்/Web : pest@slt.lk : www.doa.gov.lk



@ගේ අංකය எனது எண் My No

RP/VIII/A₁

இவே අංකය உமது எண் Your No

தலக திகத்

02.05.2018

Circular No. RP/2018/Dis/01

To: All Prospective Individuals/Companies/Corporate Institutions

Dear Sir/Madam,

Guidelines for Registration of Household and All-purpose Disinfectants under the Control of Pesticides Act No. 33 of 1980 (Provisional)

All pesticides are required to be registered under the Control of Pesticides Act No. 33 of 1980 before importation, manufacturing & use in the country. For the purposes of the Act, any microorganism including fungi & virus which is injurious, troublesome or undesirable to crops, stored products, processed foods, wood, clothes, fabrics or inanimate objects or which are objectionable from the view point of public health and hygiene, including ectoparasites of man and domestic animals are considered as pests, and such active ingredients, and pesticide formulations with adjuvants (on the purview of chemical disinfectants, anti-microbial, antiseptics, preservatives & surface sterilizing agents for household & other use¹) are subjected to regulate under the above Act.

Disinfectants in fact did not seem to warrant all the registration requirements of agricultural or public health pesticides but according to the definition in the Act, they would necessarily fall into the pesticide category. In this past, some of the eligible active ingredients, disinfectant formulations with adjuvants (in household use) for registration have been ignored from regulations under the above Act due to some conflicts of regulations², limited technical & manpower restrictions, etc. However, as the Registrar of Pesticides, I am of the view that it is expedient to regulate chemical disinfectants, antimicrobials, antiseptics, preservatives & surface

all-purpose disinfectants for hospital use.

² For example, Cosmetics, Devices and Drugs Act, No. 27 of 1980 has been registering disinfectants and antiseptics for household use including Dettol®, Chlorhexidine, Cetrimide, Benzalkonium chloride etc. and due to repealing the above Act by the National Medicines Regulatory Authority Act, No. 5 of 2015, all complementary regulations were discontinued. So far, some of the borderline product had been imported through approval by the State Trade Corporation (STC) until recently. As a result of continuous discussions had with the Department of Import & Export Control, the necessary mandate was given to the Registrar of Pesticides.

sterilizing agents for household and all-purpose disinfectants for hospital use with a confined mechanism until proper regulations are mandated under the above Act.

The Pesticides Technical & Advisory Committee at its 91st meeting held on 27.04.2018 granted permission (provisionally) to adopt the guidelines confined for registration of chemical disinfectants, anti-microbial, antiseptics, preservatives & surface sterilizing agents for household and all-purpose disinfectants for hospital use. hereby propose for prospective individuals/companies/corporate institutions to follow registration requirements in order to complement with limited but essential requirements as follows:

Information required for registration of chemical disinfectants, anti-microbial, antiseptics, preservatives & surface sterilizing agents for household and all-purpose disinfectants for hospital use

- 1. Name of applicant:
- 2. Address:
- 3. Status of the product:
 - a. Name & address of the manufacturer (by original declarations).
 - b. Name & address of the formulator (by original declarations).
 - c. Name & address of the supplier (by original declarations).

4. Name of the product:

- a. Chemical name & CAS Number (IUPAC or equivalent).
- b. Concentration of the active substance/s.
- c. Brand name/ Name under which the product is imported/ marketed/ supplied/sold.
- 5. The intended use of the product (or its primary function) and its mode-of-action.
- 6. The chemical/ product potency claims that the manufacturer makes about the product (claims on which the product is

effective on microorganisms, their range & the level of efficacy of the active substance of the product)¹.

- 7. A certificate from the regulatory authority of the country in which it is imported/ manufactured/ formulated/ supplied confirming that the product is in there for the intended use, intended rate(s) of application and the period of use and if not reasons for not marketing/ use in the country of manufacture/ import.
- 8. List of countries the product is approved/ registered for use and at least one of the country/countries should be a developed nation such as USA, EU, Canada & Japan.
- 9. A sample/s of the product intended for supplying/ use/ sale (if requested).
- 10. A draft text/artwork of the label on which the product will be supplied/ used/ sold/ offered for sale.
- 11. In the case of chemical disinfectants, anti-microbial, antiseptics, preservatives & surface sterilizing agents for household & hospital use that have been approved for import & use in Sri Lanka by any other regulatory body, proof of such documentation and the period of use.

Should you require any clarification, please do not hesitate to contact me.

Thanking you.

Dr. J.A. Sumith

Registrar of Pesticides

- ic. 1. Director General of Agriculture- FYI, please.
 - 2. Director/National Medicines Regulatory Authority FYI, please.
 - 3. Import and Export Controller General- FYI, please.
 - 4. Registrar, Veterinary Drug Control Authority FYI, please.

¹ Proof of disinfectant efficacy as per the SLS 688:1985.