
II. Viral Subgroup Classification

EPA and the Centers for Disease Control and Prevention (CDC) recognize that certain microorganisms can be ranked with respect to their tolerance to chemical disinfectants. The Spaulding Classification model, used by CDC, tiers microorganisms in accordance with the level of resistance to being killed (inactivation) by typical disinfectant products.¹ With this approach viruses are divided into three viral subgroups (small non-enveloped, large non-enveloped, and enveloped) based on their relative resistance to inactivation (see below). According to this hierarchy, if an antimicrobial product can kill a small, non-enveloped virus it should be able to kill any large, non-enveloped virus or any enveloped virus. Similarly, a product that can kill a large, non-enveloped virus should be able to kill any enveloped virus.

Small, Non-Enveloped Viruses (<50 nm): These small, non-enveloped viruses can be highly resistant to inactivation by disinfection. Despite the lack of a lipid envelope, these organisms have a very resistant protein capsid. The following are viral families in the small non-enveloped subgroup: (1) Picornaviridae, (2) Parvoviridae, (3) Caliciviridae, (4) Astroviridae, and (5) Polyomaviridae.

Large, Non-Enveloped Viruses: Compared to small, non-enveloped viruses, these viruses are less resistant to inactivation by disinfection. Although they have a resistant protein capsid, their larger size (50-100nm) makes them more vulnerable than their smaller viral counterparts. The following are viral families in the large non-enveloped subgroup: (1) Adenoviridae, (2) Reoviridae, and (3) Papillomaviridae.

Enveloped Viruses: Enveloped viruses are the least resistant to inactivation by disinfection. The structure of these viruses includes a lipid envelope, which is easily compromised by most disinfectants. Once the lipid envelope is damaged, the integrity of the virus is compromised, thereby neutralizing its infectivity. The following are viral families in the enveloped subgroup: (1) Arenaviridae, (2) Bornaviridae, (3) Bunyaviridae, (4) Coronaviridae, (5) Filoviridae, (6) Flaviviridae, (7) Hepadnaviridae, (8) Herpesviridae, (9) Orthomyxoviridae, (10) Paramyxoviridae, (11) Poxviridae, (12) Retroviridae, (13) Rhabdoviridae, and (14) Togaviridae.

Under the criteria outlined in Section III of this Guidance, this hierarchy is used to determine a product's anticipated efficacy against an emerging viral pathogen.

Novel Coronavirus (2019-nCoV) belongs to *coronaviridae* family. As a enveloped virus, it is least resistant to inactivation by disinfection.

Feline calicivirus (FCV) is a surrogate for *Norwalk* virus which causes diarrheal illness or gastroenteritis in people. FCV belongs to *caliciviridae* family and is highly resistant to inactivation by disinfection

Feline calicivirus

From Wikipedia, the free encyclopedia

Feline calicivirus (FCV) is a virus of the family *Caliciviridae* that causes disease in cats. It is one of the two important viral causes of respiratory infection in cats, the other being *Felid alphaherpesvirus 1*. FCV can be isolated from about 50% of cats with upper respiratory infections.^[2] Cheetahs are the other species of the family *Felidae* known to become infected naturally.^[2]

III. Product Eligibility Criteria

Registrants should use the following criteria to determine if an EPA-registered disinfectant product is eligible to use the process described in this Guidance. An eligible product should meet both of the following criteria:

1. The product is an EPA-registered, hospital/healthcare or broad-spectrum disinfectant with directions for use on hard, porous or non-porous surfaces².
2. The currently accepted product label (from an EPA registered product as described above in III.1) should have disinfectant efficacy claims against at least one of the following viral pathogen groupings:
 - a) A product should be approved by EPA to inactivate at least one large or one small non-enveloped virus **to be eligible for use against an enveloped emerging viral pathogen.**
 - b) A product should be approved by EPA to inactivate at least one small, non-enveloped virus **to be eligible for use against a large, non-enveloped emerging viral pathogen.**
 - c) A product should be approved by EPA to inactivate at least two small, non-enveloped viruses with each from a different viral family **to be eligible for use against a small, non-enveloped emerging viral pathogen.**

This approach, where disinfectant products registered for use against viral pathogens in one category of the Spaulding Classification model can be presumed effective against viral pathogens in less-resistant categories, is intended to serve as a conservative approach to identifying disinfectant products likely to be effective against emerging pathogens. However, since there is no viral subgroup known to be more resistant than small, non-enveloped viral pathogens, a disinfectant product must be proven to be efficacious against at least two small, non-enveloped viral pathogens from different viral families in order to be eligible for emerging pathogen claims pursuant to this guidance in regard to an outbreak of an emerging small, non-enveloped viral pathogen.

As our product can inactivate (FCV), a small non-enveloped virus, it is eligible for use against enveloped emerging viral pathogen, i.e. Novel Coronavirus (2019-nCoV)