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April 2, 2020

RE: SaniDate 5.0 (EPA Reg. No. 70299-19)
SaniDate All Purpose Disinfectant (EPA Reg. No. 70299-27)

To Whom It May Concern:

In our commitment to provide effective disinfectant products to our customers, BioSafe Systems is conducting GLP viricidal efficacy studies for SaniDate 5.0 and SaniDate All Purpose Disinfectant against Human Coronavirus. Once efficacy studies are completed, this organism will be added to the product labels in the US and Canada, and will allow the products for inclusion to *EPA List N-Disinfectants for Use Against SARS-CoV-2*, and the Health Canada *Disinfectants for Use Against SARS-CoV-2 (COVID-19) List*.

Coronaviruses including SARS-CoV-2, are enveloped, single-stranded RNA viruses. Enveloped viruses are more sensitive to disinfectants than non-enveloped viruses, and demonstrate a low probability of building resistance to sanitizers.

There are a number of products on EPA List N that contain the active ingredients hydrogen peroxide and/or peroxyacetic acid. Current EPA criteria requires eligible disinfectant products control either Human Coronavirus or a specific emerging viral pathogen.

In order to be eligible to make Emerging Viral Pathogen claims through an EPA expedited process, a product is required to currently bear disinfection efficacy claims against a specific viral pathogen grouping of non-enveloped viruses. In general, non-enveloped viruses are relatively resistant to inactivation by disinfectants. EPA guidance notes if an antimicrobial product can kill a non-enveloped virus it should be able to kill any enveloped virus.

Since SaniDate 5.0 is currently not labeled to kill non-enveloped viruses, we are unable to make Emerging Viral Pathogens claims relative to this product at this time. However, SaniDate 5.0 is registered for use as a viricide against the enveloped viruses *Human Influenza Virus (H1N1)*, and *Avian Influenza Virus (H9N2)* at a rate of 0.5 fl. oz. per gallon with a 10 minute contact time.

A GLP viricidal efficacy study has been initiated for SaniDate 5.0 at a rate of 1.5 fl. oz. per gallon with a 10 minute contact time specifically against Human Coronavirus. A study is also underway for SaniDate All Purpose Disinfectant. Since this product has already demonstrated efficacy against enveloped viruses, we are confident the products will demonstrate efficacy against Human Coronavirus.

We are actively monitoring EPA and Health Canada websites daily for changes in guidance that may expedite the process to add our products to the EPA and Health Canada Lists- Disinfectants for Use Against SARS-CoV-2. Currently, both US EPA and Health Canada utilize similar criteria for inclusion to their respective lists. The lists continue to be updated daily, and criteria may change. We are making every effort to get our products added to the lists as quickly as possible.

Sincerely,

A handwritten signature in black ink, appearing to read "Donna Bishel".

Donna Bishel, Director of Regulatory Affairs

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