UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: January 18, 2022

SUBJECT: Efficacy Review for Benefect® Botanical Daily Cleaner Disinfectant Spray
EPA Reg. No. 84683-3
Action Code Case: 00318331
E-submission No. 67051

FROM: César E. Cordero
Efficacy Branch
Antimicrobials Division (3204A)
Date Signed: January 18, 2022

THRU: Thao Pham
Efficacy Branch
Antimicrobials Division (3204A)
Date Signed: March 1, 2022

TO: Marcel Howard, RM 34 / Terria Northern
Regulatory Management Branch II
Antimicrobials Division (3204A)

APPLICANT: CLEANWELL, LLC.

Formulation from the Label:

Active Ingredient(s)	% by wt.
Thymol (*)	0.05%
Other Ingredients	99.95%
Total	100.0000%

[* present as a component of [Essential] [and] [Botanical] [Thyme] Oil[s]]

I BACKGROUND

Product Description (as packaged, as applied): Ready-To-Use Spray

Submission type: Label amendment to add bactericidal and virucidal claims.

Currently registered efficacy claim(s): Hospital/broad spectrum disinfectant, Food Contact and Non-Food Contact Sanitizer, Fungicide and Virucide with approved uses in hard, non-porous surfaces and soft surfaces (e.g., carpets).

Requested action(s): Label amendment for Benefect® Botanical Daily Cleaner Disinfectant Spray (EPA Reg. No. 84683-3) add additional bacteria and viruses to the label.

Documents considered in this review:

- Cover letter from applicant to EPA dated 08/25/2021
- Proposed label, dated 08/23/2021
- Data Matrix (EPA Form 8570-35) dated 08/25/2021
- Confidential Statement of Formula (CSF), dated 10/07/2009
- 4 efficacy studies (MRIDs 51657201, 51657202, 51657203 and 51657204)
    - "Amended Final Study Report" for MRID 51657201 to clarify spraying distance was sent by the registrant representative (Nicole Perkinson) via E-mail dated 11/22/2021
- Updated Terms of Registration Letter, dated 11/15//2021, received via E-mail from Nicole Perkinson dated 11/22/2021 in response to comments provided in the Technical Screen dated 11/01/21.

II PROPOSED DIRECTIONS FOR USE

{FOR DAILY/WEEKLY SPRAY}

[Shake well before use.] [Do not spray [directly] in eyes [or] [on skin]].

TO SANITIZE [hard, non[-]porous [food contact] surfaces]: 1. Wet the surface [with the product] [with the spray] [by [sprayer] [(high or low pressure, hand,)] [foamer] [or] [cloth, sponge or mop] [(spot test to check surface compatibility)]. 2. Leave [[visibly]wet] for [60 seconds] [1 minute]. [Allow to] [Let] air-dry. No rinsing [or wiping] is required [(even on food contact surfaces)].

TO DISINFECT [[&] [and] DEODORIZE] [hard non[-]porous surfaces]: 1. Wet the surface [with the [product] [spray]] [by [sprayer] [(high or low pressure, hand,)] [foamer] [or] [cloth, sponge or mop] [(spot test to check surface compatibility)]. 2. Leave [[visibly]wet] for 10 minutes. [For xxx {insert organism(s) listed on label that have a 5 minute contact time in disinfecting portion of table 4} [use a 5 minute contact time] [leave [[visibly]wet] for 5 minutes].] [For xxx {insert organism(s) listed on label that have a 1 minute contact time in disinfecting portion of table 4} [use a 1 minute contact time] [leave [[visibly]wet] for 1 minute].] [Allow to] [Let] [air-] dry. No rinsing [or wiping] is required [(even on food contact surfaces)].

{Alternate instructions for professional/commercial line products}

TO DISINFECT [[&] [and] DEODORIZE] [hard non[-]porous surfaces]: 1. Wet the surface [with the [product] [spray]] [by [sprayer] [(high or low pressure, hand,)] [foamer] [or] [cloth, sponge or

mop] [(spot test to check surface compatibility)]. 2. Leave [[visibly]wet] for [5 minutes]. [For xxx {insert organism(s) listed on label that have a 10 minute contact time in disinfecting portion of table 4} [use a 10 minute contact time] [leave [[visibly]wet] for 10 minutes].] [For xxx {insert organism(s) listed on label that have a 1 minute contact time in disinfecting portion of table 4} [use a 1 minute contact time] [leave [[visibly]wet] for 1 minute].] [Allow to] [Let] [air-] dry. No rinsing [or wiping] is required [(even on food contact surfaces)].

{Additional alternate instructions for professional/commercial line products}

TO DISINFECT [[&] [and] DEODORIZE] [hard non[-]porous surfaces]: 1. Wet the surface [with the [product] [spray]] [by [sprayer] [(high or low pressure, hand,)] [foamer] [or] [cloth, sponge or mop] [(spot test to check surface compatibility)]. 2. Leave [[visibly]wet] for [10 minutes] [the contact time listed in the table]. [Allow to] [Let] [air-] dry. No rinsing [or wiping] is required [(even on food contact surfaces)]. {one of the tables shown below}

{optional enumerations of contact times for organisms listed on the product label for professional/commercial line products}

[When used as directed, this product is effective against [the following] [pathogenic] microorganisms [including bacteria, viruses and fungi].

BACTERICIDAL ({xx} minutes contact time):{insert selected organism(s) from disinfecting portion of Table 4}

VIRUCIDAL ({xx} minute[s] contact time): {insert selected organism(s) from disinfecting portion of Table 4}

FUNGICIDAL ({xx} minutes contact time): {{insert selected organism(s) from disinfecting portion of Table 4}

TO CONTROL MOLD AND MILDEW: Pre-clean surface. Spray [surface] [area] [until [thoroughly] wet]. Leave [[visibly]wet] for 10 minutes. [Allow to] [Let] [air-] dry. Repeat weekly or when growth appears.

FRUIT AND VEGETABLE WASH: Rinse produce with clean water to remove excess soil. Spray produce surface with product until wet, then rub for 30-60 seconds. Thoroughly rinse produce under clean running water to remove soil and excess cleaner.

{FOR TOILET BOWL}

[TO OPEN]: [Twist nozzle to on-or-twist to open.] [Flip nozzle to open]

[Twist nozzle to on]-[or]-[twist to open.] [Flip nozzle to open] [Squirt] [product][gel] [under rim] [and cover the inside of the toilet bowl evenly] [to cover [bowl] surface]. [Leave [visibly][wet] for] [Wait] [10 minutes] [then brush and flush].

[SANITIZING INSTRUCTIONS] TO SANITIZE [& DEODORIZE] [TOILET BOWLS]: [To kill 99.9% of bacteria] Empty toilet bowl of water and any other contents, squirt [product][gel] [under rim] [and cover the inside of the toilet bowl [evenly]] [to cover [bowl] surface]. [Leave [[visibly]wet] for] [Wait] 30 seconds, then brush and flush.

[DISINFECTING INSTRUCTIONS] TO DISINFECT [& DEODORIZE] [TOILET BOWLS]: Empty toilet bowl of water and any other contents, squirt [product][gel] [under rim] [and cover the inside

of the toilet bowl [evenly]] [to cover [bowl] surface]. [Leave [[visibly]wet] for] [Wait] 10 minutes, then brush and flush.

{FOR CARPET SPOT TREATMENT}

TO [CLEAN] SANITIZE [& DEODORIZE] CARPETS: [Apply to] [Spray][Saturate] the pre-cleaned carpet area [with the product] [with[by] [[light]wand], [high [or low] pressure] [sprayer], [[hot water] extractor], [spin bonnet] or [immersion] [processes][application]] until [thoroughly wet] [saturated] [(spot test fibers for colorfastness before use)]. Scrub or agitate the carpet as needed to ensure the [test substance] [product] [solution] is delivered throughout the carpet pile and backing. Allow the test [substance] [product] [solution] to remain on the carpet undisturbed for a minimum of 60 minutes. [[Rinse][Extract][with clean water] & allow to air dry.]

TO [SPOT] [CLEAN] [&] [DEODORIZE] CARPETS: [Apply to] [Spray][Saturate] the carpet [rug] [with the product] [with[by] [[light]wand], [high [or low] pressure] [sprayer], [[hot water] extractor], [spin bonnet] or [immersion] [processes][application]] [until [thoroughly wet] [saturated]] [(spot test fibers for colorfastness before use)]. [Scrub or agitate the carpet as needed.] [[Rinse][Extract] [with clean water] [&] [allow to air dry.]

{FOR MONTHLY FOAM}

TO SANITIZE [hard, non[-]porous [food contact] surfaces]: 1. Wet the surface [with the product] [with the spray] [by [sprayer] [(high or low pressure, hand,)] [foamer] [or] [cloth, sponge or mop] [(spot test to check surface compatibility)]. 2. Leave [[visibly]wet] for [60 seconds] [1 minute]. [Allow to] [Let] air-dry. No rinsing [or wiping] is required [(even on food contact surfaces)].

TO DISINFECT [[&][and] DEODORIZE] [hard non[-]porous surfaces]: 1. Wet the surface [with the spray] [by sprayer, cloth, sponge or mop] [(spot test to check surface compatibility)]. 2. Leave [[visibly]wet] for 10 minutes. [Allow to] [Let] air-dry. No rinsing [or wiping] is required [(even on food contact surfaces)].

TO CONTROL MOLD AND MILDEW: Pre-clean surface. Spray [surface] [area] [until [thoroughly] wet]. Leave [[visibly]wet] for 10 minutes. [Allow to] [Let] [air-] dry. Repeat weekly or when growth appears.

{FOR DAILY/WEEKLY FLOOR CLEANER}

[Shake well before use.] [Do not spray [directly] in eyes [or] [on skin]].

[TO OPEN]: [Twist nozzle to on] [or] [twist to open.] [[Flip] [Pull] nozzle to open]

TO SANITIZE [[&][and] DEODORIZE]: 1. Wet floor [with the product] [with the sprayer] [by [sprayer] [(high or low pressure, hand or power operated)] [or] [cloth,] [sponge] [or] [mop] [(spot test to check surface compatibility)] [to wet [floor] [surface]] [thoroughly]. 2. Leave [[visibly]wet] for 30 seconds. [Allow to] [Let] air-dry. No rinsing [or wiping] is required.

TO DISINFECT [[&][and] DEODORIZE] [hard non[-]porous [floors] [surfaces]]:: 1. Wet floor [with the [product] [spray]] [by [sprayer] [(high or low pressure, hand or power operated)][or] [cloth,] [sponge] [or] [mop] [(spot test to check surface compatibility)] [to wet [floor] [surface]] [thoroughly]. 2. Leave [[visibly]wet] for 10 minutes. [Allow to] [Let] [air-] dry. No rinsing [or wiping] is required.

III. STUDY SUMMARIES

1.	**MRID**	**51657201**		
Study Objective		Disinfectant - Bactericidal		
Testing Lab; Lab Study ID		Bioscience Laboratories, LLC; 2008620-204.02 (Amended report)		
Experimental Start Date		11/18/2020 12/23/2020*	**Study Completion Date:**	06/24/2021
Test organism(s) ☐ **1** ☐ **2** ☐ **3** ☒ **4+**		*Escherichia coli* O157:H7 (ATCC 35150) *Klebsiella aerogenes* (ATCC 13048) *Listeria monocytogenes* (ATCC 7644) *Staphylococcus aureus* (ATCC 29213)*		
Test Method		AOAC Official Method 961.02 Germicidal Spray Products as Disinfectants (2012); Protocol #2008620-204		
Application Method		RTU Spray; 3 to 4 sprays from 6 to 8 inches.		
Test Substance Preparation	**Name/ID**	Benefect Botanical Daily Cleaner Disinfectant Spray (EPA Reg. No. 84683-3)		
	Lots ☐ **1** ☒ **2** ☐ **3**	WA20237041 D060024 and WA20254041 D060026		
	Preparation	**Tested concentration:** LCL **Tested Dilution:** RTU **Diluent:** N/A		
Soil load		5% Fetal Bovine Serum (FBS)		
Carrier type, # per lot		1 in x 3 in glass slides; 10 carriers/lot		
Test conditions		**Contact time:** 5 minutes **Temperature:** 24.2°C to 24.7°C and 19.4°C to 19.6°C* **Relative humidity:** 20.8% to 23.6% RH (05/18/2020) 14.5% to 15.1% RH (05/20/2020)		
Neutralizer		Letheen Broth (0.07% Lecithin + 0.5% Tween 80)		
Reviewer comments (i.e., protocol deviations and amendments, retesting, control failures, etc.)		No protocol amendments reported. No deviations from the "Study Protocol" reported. One deviation from an applicable BioScience Laboratories SSOP occurred: On 11/25/20 and 12/28/20, the inoculating loops used were not recorded on the Equipment Tracking Form. The lot number for the inoculating loops used for creating isolation streaks of positive carries is not verifiable. As the inoculating loops used were from sterile packaging and no contamination was noted in the resulting isolation streaks, there is no negative effect on the outcome of the study. The reviewer agrees with the laboratory conclusion that the reported deviation from the lab SOP would not have a negative impact on the study's results. Note, dates for relative humidity do not match test dates. These should be corrected for agency records.		

2.	**MRID**	**51657202**		
Study Objective		Disinfectant - Virucidal		
Testing Lab; Lab Study ID		Bioscience Laboratories, LLC; 2012997-404		
Experimental Start Date		02/23/2021[1] 03/03/2021[2] 03/02/2021[3]	**Study Completion Date:**	05/19/2021
Test organism(s) **☐ 1 ☐ 2 ☒ 3 ☐ 4+**		1. Feline Calicivirus, Strain F9 as a surrogate for Human Norovirus (FCV; ATCC VR-782) 2. Influenza A H1N1, Strain A/WS/33 (ATCC VR-1520) 3. Rhinovirus type14, Strain 1059 (ATCC VR-284)		
Indicator Cell Culture		1. Crandell-Reese feline kidney epithelial cells (CRFK) (ATCC CLL-94) 2. MDCK Madin-Darby canine kidney cells (ATCC #CCL-34) 3. H1 HeLa human cervical epithelial adenocarcinoma cells (ATCC #CRL-1958)		
Test Method		ASTM International test method designated EI053-20, Standard Practice to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces and on the AOAC International Official Method of Analysis, 961.02, Germicidal Spray Products as Disinfectants		
Application Method		RTU Spray; 3 to 4 sprays from 6 to 8 inches.		
Test Substance Preparation	**Name/ID**	Benefect Botanical Daily Cleaner Disinfectant Spray (EPA Reg. No. 84683-3)		
	Lots **☐ 1 ☒ 2 ☐ 3**	FM012921001 and FM012921002		
	Preparation	Tested concentration: LCL Tested Dilution: RTU Diluent: N/A		
Soil load		5.0% Heat Inactivated FBS		
Carrier type, # per lot		Glass Petri dishes (150 mm x 20 mm), 1 per batch for Rhinovirus type 14 and Influenza A H1N1; 2 carriers/batch for Feline Calicivirus.		
Test conditions		Contact time: 5 minutes Temperature: 21-23°C Relative humidity: 11.27-13.88%		
Neutralizer		Dey-Engley (D/E) Neutralizing Broth		
Incubation conditions		Feline Calicivirus plates were incubated for 7 days at 35°C ±2°C Influenza A H1N1 plates were incubated for 7 days at 33°C ±2°C. Rhinovirus type 14 plates were incubated for 8 days at 33°C ±2°C.		
Reviewer comments (i.e., protocol deviations and amendments, retesting, control failures, etc.)		<u>Protocol Amendment(s}:</u> Two amendments to the Study Protocol were made during the study. 1. The first amendment was to correct a typographical error. Changed “The Test Substance is a wipe and will be used as provided” to “The Test Substance is a spray and will be used as provided” in Section 21.0.		

	2. Second amendment was due to issues with low titer of Coronavirus Strain 229E. The Sponsor requested to discontinue testing one of the four viruses, Coronavirus strain 229E, because the virus titer data from testing did not meet the qualification criteria of ASTM E1053-20. <u>Protocol Deviation(s}:</u> One Deviation to the Study Protocol occurred in this study. Section 18.0 states that "Cell monolayers will be approximately 80% to 90% confluent and less than 48 hours old before inoculation with the virus." On 03/03/21 the cell density of the MDCK cells were recorded as 100% confluent. This deviation was due to technician error as the MDCK cells used in testing were observed to be within the accepted range of confluency and less than 49 hours old before testing commenced. Additionally, all controls were in range and all acceptance criteria were met. The effect on the outcome of the study was negligible. The reviewer agrees with the laboratory conclusion that the protocol deviation and/or amendments would not have a negative impact on the study results.

3.	**MRID**	**51657203**		
Study Objective		Disinfectant - virucidal		
Testing Lab; Lab Study ID		Bioscience Laboratories, LLC; 2102065-408		
Experimental Start Date		04/06/2021	**Study Completion Date:**	06/10/2021
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		SARS-CoV-2 strain USA-WA1/2020 (BEI Resources #NR-52281)		
Indicator Cell Culture		Vero E6; green monkey kidney cells, epithelial (ATCC #CRL-1586)		
Test Method		ASTM International test method designated E1053-20, Standard Practice to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces and on the AOAC International Official Method of Analysis, 961.02, Germicidal Spray Products as Disinfectants		
Application Method		RTU Spray; 3 sprays from 6 to 8 inches (actual 6.5 inches).		
Test Substance Preparation	**Name/ID**	Benefect Botanical Daily Cleaner Disinfectant Spray (EPA Reg. No. 84683-3)		
	Lots **☐ 1 ☐ 2 ☒ 3**	FM012921001, FM012921002 and FM012921003		
	Preparation	Tested concentration: LCL Tested Dilution: RTU Diluent: N/A		
Soil load		5.0% Heat Inactivated FBS		
Carrier type, # per lot		Glass Petri plates (150 mm x 20 mm), 1 per batch		
Test conditions		Contact time: 1 min Temperature: 22.6 – 22.7°C Relative humidity: 23.4 – 23.8%		
Neutralizer		Dey-Engley (D/E) Neutralizing Broth		

Incubation conditions	10 days at 37°C ±2°C in 4% to 6% CO_2 incubator.
Reviewer comments (i.e., protocol deviations and amendments, retesting, control failures, etc.)	No protocol amendments or deviations reported.

4.	**MRID**	**51657204**	
Study Objective		Disinfectant - Virucidal	
Testing Lab; Lab Study ID		Bioscience Laboratories, LLC; 2104262-404	
Experimental Start Date		06/03/2021	**Study Completion Date:** 07/01/2021
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		Human Coronavirus strain OC43 (ZeptoMetrix #0810024CF)	
Indicator Cell Culture		HCT-8; Human ileocecal colorectal adenocarcinoma (ATCC #CCL-244)	
Test Method		ASTM International test method designated E1053-20, Standard Practice to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces and on the AOAC International Official Method of Analysis, 961.02, Germicidal Spray Products as Disinfectants	
Application Method		RTU Spray; 4 sprays from 6 to 8 inches (actual 7 inches).	
Test Substance Preparation	**Name/ID**	Benefect Botanical Daily Cleaner Disinfectant Spray (EPA Reg. No. 84683-3)	
	Lots ☐ **1** ☒ **2** ☐ **3**	FM012921001 and FM051021001	
	Preparation	Tested concentration: LCL Tested Dilution: RTU Diluent: N/A	
Soil load		5.0% Heat Inactivated FBS	
Carrier type, # per lot		Glass Petri plates (150 mm x 20 mm), 1 per batch	
Test conditions		Contact time: 5 min Temperature: 22.5°C Relative humidity: 29.35 – 29.49%	
Neutralizer		Dey-Engley (D/E) Neutralizing Broth.	
Incubation conditions		14 days at 33°C ±2°C in 5% CO_2 incubator.	
Reviewer comments (i.e., protocol deviations and amendments, retesting, control failures, etc.)		No protocol amendments or deviations reported.	

IV STUDY RESULTS

Disinfection – Bactericidal (Additional bacteria)

MRID (Test Completion Date)	Organism	No. Exhibiting Growth/Total No. Tested		Log_{10} Density per Carrier (Batch 1 and 2)
		Batch 1: WA20237041 D060024	Batch 2: WA20254041 D060026	
5-minutes contact time, RTU spray, 5% soil load, tested at room temperature (19.4°C to 24.7°C)				
51657201 (06/24/21)	*Escherichia coli* O157:H7 (ATCC 35150)	0/10	0/10	5.05/5.05
	Klebsiella aerogenes (ATCC 13048)	0/10	0/10	4.83/4.83
	Listeria monocytogenes (ATCC 7644)	0/10	0/10	4.94/4.94
	Staphylococcus aureus (ATCC 29213)	0/10	3/10	5.20/4.65

Disinfection – Virucidal Efficacy

MRID	Organism	Contact Time	Description	Results				Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
				FM012921001	FM012921002	FM012921003	FM051021001	
RTU spray, 5% fetal bovine soil, tested at room temperature (21°C to 23°C)								
51657202	Feline Calicivirus, Strain F9 (As a surrogate for Human Norovirus) (FCV; ATCC VR-782)	5 min	10^{-2} dilution	Cytotoxicity	Cytotoxicity			6.55
			10^{-3} to 10^{-7} dilution	Complete inactivation	Complete inactivation			
			Log_{10} $TCID_{50}$/carrier	1° = 1.80 2° = 1.80	1° = 1.80 2° = 1.80			
			Log_{10} Reduction	4.75	4.75			
51657202	Influenza A H1N1, Strain A/WS/33 (ATCC VR-1520)	5 min	10^{-2} dilution	Cytotoxicity	Cytotoxicity			5.30
			10^{-3} to 10^{-7} dilution	Complete inactivation	Complete inactivation			
			Log_{10} $TCID_{50}$/carrier	1.80	1.80			
			Log_{10} Reduction	3.50	3.50			
51657202	Rhinovirus type 14, Strain 1059 (ATCC VR-284)	5 min	10^{-2} dilution	Cytotoxicity	Cytotoxicity			5.55
			10^{-3} to 10^{-7} dilution	Complete inactivation	Complete inactivation			
			Log_{10} $TCID_{50}$/carrier	1.80	1.80			
			Log_{10} Reduction	3.75	3.75			
51657203	SARS-CoV-2 strain USA-WA 1/2020 (BEI Resources #NR-52281)	1 min	10^{-2} dilution	Cytotoxicity	Cytotoxicity	Cytotoxicity		5.30
			10^{-3} to 10^{-7} dilution	Complete inactivation	Complete inactivation	Complete inactivation		
			Log_{10} $TCID_{50}$/carrier	≤ 1.80	≤ 1.80	≤ 1.80		
			Log_{10} Reduction	≥ 3.50	≥ 3.50	≥ 3.50		
51657204	Human Coronavirus strain OC43 (ZeptoMetrix #0810024CF)	5 min	Cytotoxicity	--			10^{-2} dilution	5.55
			Complete Inactivation	10^{-2} to 10^{-7} dilution			10^{-3} to 10^{-7} dilution	
			Log_{10} $TCID_{50}$/carrier	≤ 0.80			1.80	
			Log Reduction	≥ 4.75			3.75	

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Organism(s)	Data support label claims?
51657201	Disinfectant, additional bacteria	Hard non-porous surface	RTU Spray; 3 to 4 sprays from 6 to 8 inches	5 min	5% fetal bovine serum	• *Escherichia coli* O157:H7(ATCC 35150) • *Klebsiella aerogenes* (ATCC 13048) • *Listeria monocytogenes* (ATCC 7644)	**Yes,** however, dates for relative humidity do not match test dates. These should be corrected for agency records.
51657201	Disinfectant, additional bacteria	Hard non-porous surface	RTU Spray; 3 to 4 sprays from 6 to 8 inches	5 min	5% fetal bovine serum	• *Staphylococcus aureus* (ATCC 29213)	**No**
51657202	Disinfectant, virucidal	Hard non-porous surface	RTU Spray; 3 to 4 sprays from 6 to 8 inches	5 min	5% fetal bovine serum	• Feline Calicivirus, Strain F9 (surrogate for Human Norovirus) (FCV; ATCC VR-782) • Influenza A H1N1, Strain A/WS/33 (ATCC VR-1520) • Rhinovirus type14, Strain 1059 (ATCC VR-284)	**Yes**
51657203	Disinfectant, virucidal	Hard non-porous surface	RTU Spray; 3 sprays from 6 to 8 inches (actual 6.5 inches)	1 min	5% fetal bovine serum	• SARS-CoV-2 strain USA-WA 1/2020 (BEI Resources #NR-52281)	**Yes**
51657204	Disinfectant, virucidal	Hard non-porous surface	RTU Spray; 4 sprays from 6 to 8 inches (actual 7 inches).	5 min	5% fetal bovine serum	• Human Coronavirus strain OC43 (ZeptoMetrix #0810024CF)	**Yes**

VI LABEL COMMENTS

Label Date: 08/23//2021

1. The proposed label claims that the product, Benefect® Botanical Daily Cleaner Disinfectant Spray (Reg. #84683-3), when used as a ready-to-use spray, is an effective disinfectant against the following bacteria on visibly clean hard, non-porous surfaces at the indicated contact times:

   Bactericidal activity, 5-min contact time:
   Escherichia coli O157:H7(ATCC 35150)
   Klebsiella aerogenes (ATCC 13048)
   Listeria monocytogenes (ATCC 7644)

   These claims are **acceptable** as they are supported by the submitted efficacy data. However, dates for relative humidity do not match test dates. These should be corrected for agency records.

2. Per MRID 51657201, the product, Benefect® Botanical Daily Cleaner Disinfectant Spray (Reg. #84683-3), when used as a ready-to-use spray, is **not** an effective disinfectant against the following bacteria on visibly clean hard, non-porous surfaces at the indicated contact times:

   Bactericidal activity, 5-min contact time:
   Staphylococcus aureus (ATCC 29213)

   These claims are **not acceptable** as they are not supported by the submitted efficacy data (See results table above).

3. The proposed label claims that the product, Benefect® Botanical Daily Cleaner Disinfectant Spray (Reg. #84683-3), when used as a ready-to-use spray, is an effective disinfectant against the following bacteria on visibly clean hard, non-porous surfaces at the indicated contact times:

   Virucidal activity, 1-min. contact time:
   SARS-CoV-2 strain USA-WA 1/2020 (BEI Resources #NR-52281)

   Virucidal activity, 5-min. contact time:
   Feline Calicivirus, Strain F9 (As a surrogate for Human Norovirus) (FCV; ATCC VR-782)
   Influenza A H1N1, Strain A/WS/33 (ATCC VR-1520)
   Rhinovirus type14, Strain 1059 (ATCC VR-284)
   Human Coronavirus strain OC43 (Zepto Metrix #0810024CF)

   These claims are **acceptable** as they are supported the by the submitted efficacy data.

4. **Make the following additional changes to the proposed label**:
   a. Throughout the label,
      i. We recommend that the registrant reduce the use of brackets/optional language to minimize the potential for confusion in the final claims.
      ii. Remove “pandemic”, “pandemic 2009”, “novel”, and “2019” as these are temporary outbreak descriptors and not a part of the viral nomenclature.

iii. Remove “fight”, “fights”, “fighting” where associated with bacteria, viruses, fungi, or germs as this is misleading regarding the activity of the product.
iv. Each instance of “common”, “household”, “kitchen” etc. where referring to bacteria, viruses, fungi, or germs should be linked to the list of tested organisms as the agency does not have a definition for “common bacteria” or similar claims.
v. Recommend removing/revising claims with excessive bracketing. Claims should be complete without bracketed/optional text and should not be misleading when any of the proposed variations are used.
vi. Each instance of one-step disinfection/sanitization claims should be accompanied by “when used according to disinfection directions” or “when used according to sanitizing directions”

b. On pages 2 of 50 of the proposed label, remove brackets from “[on hard, non[-]porous surfaces.]” as surface type specification is not optional for SARS-CoV-2.
c. On pages 4-7 of 50 of the proposed label,
    i. Under “Contact Time” for HIV, revise to “Treated surfaces should remain visibly wet for 10 minutes.”
    ii. Throughout the use directions, remove excessive bracketing for clarity. Use directions should be complete without optional/bracketed text. At least one application method and contact time should be present in-text without brackets. Applicant may opt to separate out spray use directions and liquid application under different sections.
    iii. Delete the brackets that make “visibly wet” optional language. This should always be present in the use directions for proper contact time application and consistency with the submitted efficacy data.
    iv. Remove all references to high pressure sprayer, as this is not representative of the application as tested. Low pressure sprayer is acceptable.
    v. Remove brackets from surface type specifications to ensure clarity for end users.
    vi. Under each set of disinfection and sanitization instructions, indicate that surfaces should be visibly clean prior to treatment (reflective of a 5% soil load). Any visible soil should be cleaned prior to disinfection or sanitizing.
d. On page 5 of 50 of the proposed label, after “When used as directed, this product is effective against [the following] [pathogenic] microorganisms [including bacteria, viruses and fungi” add “on treated hard nonporous surfaces” to avoid implying enhanced efficacy.
e. On page 6 of 50 of the proposed label,
    i. Remove or clearly specify the “fruit and veggie wash” section as a nonpublic health treatment only.
    ii. Delete the section titled “{FOR FOGGING PRE-TREATMENT}; FOGGING INSTRUCTIONS:”. The agency doesn’t allow fogging claims for pre-cleaning and “contamination control (knock down) can be interpreted as an efficacy (public health) claim for which no data has been submitted.
    iii. Toilet bowl treatment should specify treatment above the waterline only, per the OCSPP 810.2200 guideline. In addition, specify that surfaces should be visibly clean prior to sanitizing or disinfection.
    iv. For carpet sanitization, “spot treatment” should be specified for sanitization.
f. On page 11 of 50 of the proposed label,

i. Line 2, remove medical as the agency does not have this classification of disinfectants and it may be misleading.
ii. Claims which imply that the product cleans and disinfects or sanitizes in one step should be qualified with “when used according to disinfection directions for use” (e.g. “disinfecting cleaner”, “sanitizing cleaner”, and “in one step” should be qualified whereas “disinfectant and cleaner” are acceptable without further qualification)
iii. The claim language “prevents mold & mildew” should specify the time period as supported by data (e.g. for up to 7 days).
iv. “Flu viruses” should be linked/qualified specifically with Influenza viruses. Referring to the asterisk for “multiple viruses” is too broad.
v. Delete the brackets that make “on hard- nonporous surfaces” optional in all applicable SARS-CoV claims. These claims are surface specific and thus this descriptor cannot be optional.
vi. COVID-19 should not be bracketed separately from virus when referring to the virus. In addition, each instance of “COVID 19 virus” should then be directly qualified to link back to “SARS-CoV-2” as the official virus nomenclature.
vii. On the claim: “[Now] [Tested] [Proven] [to kill] [kills] [against] [effective against] [[to help[[helps] reduce the spread of] [the] [pandemic] [SARS-CoV-2] [virus] [COVID-19[*]] [virus*] [(the cause of COVID-19 [illness] [disease])] [2019 Novel Coronavirus] [the virus that causes COVID-19 [illness] [disease]] [the virus that causes the 2019 severe acute respiratory syndrome, COVID-19] [on hard non[-]porous surfaces]”, delete the following text “[[to help[[helps] reduce the spread of]” from that claim as it is misleading and can be interpreted as a public health protection claim. We recommend that the registrant reduce the use of brackets/optional language to minimize the potential for confusion in the final claims. A permissible alternative is “[To help reduce the spread of SARS-CoV-2 between treated hard nonporous surfaces]”. Note, the claim is complete and the entire claim may be optional, but none of the text is bracketed separately for standalone use.

g. On page 12 of 50 of the proposed label,
i. Qualify “bacteria that can cause food-poisoning” with the appropriate relevant bacteria, as this is overly broad.
ii. Remove “can cause serious illness & infection”, “can cause illness”, “upper respiratory infection”, “sore throat”, “stomach bug”, “infection causing germs” etc… as these are overly broad. Claims should clearly establish a 1:1 link between organism and disease, be informative to end users, and avoid broad symptoms.
iii. Remove “[Helps] Protect[s] against [the spread of] foodborne illness” as this is beyond the scope of the efficacy data.
iv. Remove all claims to “protect” and “stop the spread” as this may imply residual efficacy or health protection and is beyond the scope of the efficacy data.
v. Remove “all purpose” or limit this specifically to cleaning only as this is overly broad and may imply enhanced efficacy.
vi. Remove references to “[regulatory] [health department] [Food Code] compliance”. This varies between facilities and may imply agency endorsement.

vii. **NOTE TO PM:** please review “botanical disinfectant” claims here and throughout label for acceptability.

a. On page 13 of 50 of the proposed label,
    i. Claim 81, remove brackets around “when disinfection directions are followed”. This is not optional for one-step claims.
    ii. Claim 84 and 102, remove “cleans” or “clean” or revise such that it’s not bracketed separately from disinfection, as this is ultimately a kill claim.
    iii. Claim 85, remove “cleans away” and “deodorizes” as these are misleading when bracketed separate from disinfection for public health claims.
    iv. Claim 94, remove/revise “daily defense” as this is similar to protects and is beyond the scope of the efficacy data.
    v. Claim 110, specify between <u>treated</u> hard, non-porous surfaces.
    vi. Qualify claim 113 with “when used according to disinfection directions”
b. On page 14 of 50 of the proposed label,
    i. Claim 142, remove “with a single spray”. End users should apply as needed to ensure wetness and that the contact time is met.
    ii. Claim 147, remove brackets from “when disinfection directions are followed.”
c. On page 15 of 50 of the proposed label, claim 159, specify “between treated hard nonporous surfaces”. This text should not be optional
d. On page 16 of 50 of the proposed label,
    i. Claim 172, remove brackets from surface type as the remainder of the claim is overly broad without this language.
    ii. Claim 183, specify that stovetops and refrigerators should be at room temperature when treated.
    iii. Claim 189, remove or further clarify “final step sanitizer” as the agency does not have a definition for this term.
    iv. Claim 190, specify spot treatment for sanitizing and separate this from “hot water extraction” for cleaning.
e. On pages 17-20, 23 and 27 of 50 of the proposed label,
    i. specify that surfaces such as HVAC/ refrigeration equipment, heat pumps, freezers, ice machines, meat cutters/slicers/processors, ovens, refrigerators, stove/stovetops, toasters, etc. should be allowed to come to room temperature prior to treatment.
    ii. Remove brackets from “[plastic]” cutting boards
f. On page 22 of 50 of the proposed label, specify “sealed” or “glazed” for porcelain
g. On page 24 of 50 of the proposed label,
    i. Claim 51 – specify this as cleaning only.
    ii. Claim 69, remove “all in one” and “all in one complete” as these are overly broad. “3 in 1” and “4 in 1” should be further defined to ensure these are not overly broad
h. On page 26 of 50 of the proposed label,
    i. Remove “concrete” and “wood framing & studding, trim, carped, pads” as these are porous surfaces or specifically ensure these are limited to nonpublic health claims and remove “hard nonporous surfaces” as the claims conflict.
    ii. Claim 12 and 13, qualify with “when used according to disinfection directions” or similar; not optional.
i. On page 28-33 of 50 of the proposed label,
    i. Qualify 113, 192, 198, and 355 as cleaning claims.

ii. Qualify 131, 231, 232, 233, 234, 242, 243, 296, 297, 298, 299, 300, and 391 with “when used according to disinfection directions.
iii. Remove 312 and 314 as these mix pesticidal and non-pesticidal activity
iv. Remove “all purpose” and “all over” from 328 as this is overly broad.
v. Remove or revise 349 as a non-public health claim.
vi. Remove 363 and 364 as these are beyond the scope of the efficacy data.
vii. Remove or revise 391 as “tough on germs/bacteria” may imply enhanced efficacy and should be deleted.
viii. Remove or revise 298 as “spray/wipes away… germs” is misleading.
ix. Add 99.9% after “eliminates” in 404.
x. Remove or revise “stop the spread of germs” to “reduce the spread of germs between treated hard nonporous surfaces” – none of this text should be optional.

j. On page 41 of 50 of the proposed label, “clean & disinfect in one easy step” should be followed by “when used according to disinfection directions.
k. On pages 46-47 and 49 of the proposed label, all graphics for “COVID 19 virus” should be linked back to “SARS-CoV-2”. In addition, all the graphics should be linked to “on hard nonporous surfaces”. Neither should be bracketed as optional. Remove “kills coronavirus” as this is overly broad. “Cold and flu” virus claims should be linked to the appropriate supporting viruses.

NOTES TO PM:

1. On page 1, and throughout the label where “Weekly” and “Monthly” application are associated with sanitization and disinfection, this may imply enhanced/residual efficacy. Recommend that the timing and references to disinfection be separate.
2. On page 22 of 50, please verify the following claim for accuracy/acceptability: “[It] [This [botanically based] product] has successfully met all of the requirements of [AMS 1452 and] AMS 1453: Disinfectant Cleaner for Aircraft Interiors.” Claims 1, 2, and 4 on this all pertain to “requirements” that are outside of EPA guidance.
3. Throughout the label, please review potential implied safety claims for acceptability. These may include but are not limited to “botanical”, “plant based” “family friendly” “gentle” “protects indoor air quality” “aromatherapeutic” “natural” “wellness” “safe.”