

A531

New product identical or substantially similar in composition and use to registered product, registered source of active ingredient where applicant does not own all required data and does not have a specific authorization letter from data owner.

- Only product chemistry data submitted (no data submitted if it is a repackage of or identical to me too).
- The application does not fit in this category if acute toxicity or efficacy data are submitted and must be reviewed. The application does not fit in this category if it contains a request to waive any of these data.
- Acute toxicity and efficacy data requirements must be addressed by using 1) cite-all method, or 2) selective data citation.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Product Chemistry Data Requirements

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.1550	Product Identity & Composition			
830.1600	Description of materials used to produce the product			
830.1650	Description of formulation process			
830.1670	Discussion on the formation of impurities			
830.1700	Preliminary analysis			
830.1750	Certified limits (158.345)			
830.1800	Enforcement analytical method			

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.6302	Color			
830.6303	Physical State			
830.6304	Odor			
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)			
830.6315	Flammability			
830.6316	Explosibility			
830.6317	Storage stability*			
830.6319	Miscibility			
830.6320	Corrosion Characteristics*			
830.6321	Dielectric Breakdown Voltage			
830.7000	pH			
830.7050	UV/ Visible Absorption			
830.7100	Viscosity			
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density			
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required *May not be included with initial application

Acute Toxicity Data Requirements

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective
870.1100	Acute Oral (LD50)		
870.1200	Acute Dermal (LD50)		
870.1300	Acute Inhalation (LC50)		
870.2400	Acute Eye Irritation		
870.2500	Acute Dermal Irritation		
870.2600	Dermal Sensitization		

Efficacy Data Requirements

Check all that apply: Disinfectant___ Sanitizer___ Sterilizer___ All___

Sterilizers

Claims	Test Requirements	Cite All	Selective
Sterilizers	<i>Bacillus subtilis</i> ATCC 19659 AND <i>Clostridium sporogenes</i> ATCC 3584		

Disinfectants for use on hard non-porous surfaces

Claims	Test Requirements	Cite All	Selective
Limited Disinfectant	<i>Salmonella enterica</i> ATCC 10708 OR <i>Staphylococcus aureus</i> ATCC 6538		
General Disinfectant	<i>Salmonella enterica</i> ATCC 10708 AND <i>Staphylococcus aureus</i> ATCC 6538		
Hospital / Medical Disinfectant	<i>Salmonella enterica</i> ATCC 10708, <i>Staphylococcus aureus</i> ATCC 6538 AND <i>Pseudomonas aeruginosa</i> ATCC 15442		

Sanitizing Rinses (for previously cleaned food-contact surfaces)

Claims	Test Requirements	Cite All	Selective
Halide chemical products	<i>Salmonella typhi</i> ATCC 6539		
Formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, and anionic detergent-acid formulations	<i>Escherichia coli</i> (<i>E. coli</i>) ATCC 11229 AND <i>Staphylococcus aureus</i> ATCC 6538		

Non-food contact sanitizer

Claims	Test Requirements	Cite All	Selective
Water soluble powders/liquids/spray products	<i>Staphylococcus aureus</i> (ATCC 6538) AND <i>Klebsiella pneumoniae</i> (ATCC 4352), <i>Enterobacter aerogenes</i> (ATCC 13048) may be substituted for <i>K. pneumoniae</i> .		

Other Label Claims

Fungicide

Claims	Test Requirements	Cite All	Selective
Fungicidal	<i>Trichophyton mentagrophytes</i> ATCC# 9533		

Tuberculocide

Claims	Test Requirements	Cite All	Selective
Tuberculocidal	<i>Mycobacterium bovis</i> BCG (No ATCC#)		

Virucide (may only make virucidal claims if the product is also a general disinfectant)

General Disinfectant Claims (check one): Yes ___ No ___

NB- See last page to list virus claims made on the label

Laundry Additives

Claims	Test Requirements	Cite All	Selective
Disinfection	<i>Staphylococcus aureus</i> (ATCC 6538) AND <i>Klebsiella pneumoniae</i> (ATCC 4352)		
Disinfection for hospital linens	<i>Staphylococcus aureus</i> (ATCC 6538), <i>Klebsiella pneumoniae</i> (ATCC 4352), AND <i>Pseudomonas aeruginosa</i> (ATCC 15442)		
Sanitization	<i>Staphylococcus aureus</i> (ATCC 6538) AND <i>Klebsiella pneumoniae</i> (ATCC 4352)		
Sanitization for hospital linens	<i>Staphylococcus aureus</i> (ATCC 6538), <i>Klebsiella pneumoniae</i> (ATCC 4352), AND <i>Pseudomonas aeruginosa</i> (ATCC 15442)		

Carpet Sanitizers

Claims	Test Requirements	Cite All	Selective
Carpet Sanitizers	<i>Staphylococcus aureus</i> ATCC 6538 AND <i>Enterobacter aerogenes</i> ATCC 13048		

Air Sanitizers

Claims	Test Requirements	Cite All	Selective
Glycol Products	Note: Until the proposed Product Performance Guidelines are finalized, testing requirements are being deferred for products of this type. Currently, efficacy requirements are satisfied by the chemical formula statement showing appropriate glycol content.		
Other Products	<i>Staphylococcus aureus</i> ATCC 6538 AND <i>Klebsiella pneumoniae</i> ATCC 4352		
Hospital Products	<i>Pseudomonas aeruginosa</i> ATCC 15442		

Swimming Pool Water

Claims	Test Requirements	Cite All	Selective
Disinfectants	<i>Escherichia coli</i> (<i>E. coli</i>) ATCC 11229 AND <i>Streptococcus faecalis</i> ATCC 9790		

Field study (requires an Experimental Use Permit if completed in the United States) completed: Yes ___ No ___

Sporicide

Claims	Test Requirements	Cite All	Selective
Sporicide	<i>Clostridium difficile</i> spores (ATCC 700792,		

