

## A540

New end use product not substantially similar or identical to already registered products.

- Must submit or reference Group A and B product chemistry, acute toxicity, and/or efficacy data for each proposed product. Data waivers may be requested.
- Chemistry data on the TGAI in addition to the EP is required if an unregistered source is used.
- Acute toxicity and efficacy data requirements must be addressed by using 1) cite-all method, or 2) selective data citation which includes submitting the required data. A rationale for a waiver of these data falls within this category.

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

### Product Chemistry Data Requirements

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

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

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

## Acute Toxicity Requirements

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
<a href="#">870.1100</a>	Acute Oral (LD50)				
<a href="#">870.1200</a>	Acute Dermal (LD50)				
<a href="#">870.1300</a>	Acute Inhalation (LC50)				
<a href="#">870.2400</a>	Acute Eye Irritation				
<a href="#">870.2500</a>	Acute Dermal Irritation				
<a href="#">870.2600</a>	Dermal Sensitization				

## Efficacy Data Requirements

Check all that apply: Disinfectant\_\_\_ Sanitizer\_\_\_ Sterilizer\_\_\_ All\_\_\_

### Sterilizers

Claims	Test Requirements	Cite All	Selective
<b>Sterilizers</b>	<i>Bacillus subtilis</i> ATCC 19659 <b>AND</b> <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 <b>OR</b> <i>Staphylococcus aureus</i> ATCC 6538		
General Disinfectant	<i>Salmonella enterica</i> ATCC 10708 <b>AND</b> <i>Staphylococcus aureus</i> ATCC 6538		
Hospital / Medical Disinfectant	<i>Salmonella enterica</i> ATCC 10708, <i>Staphylococcus aureus</i> ATCC 6538 <b>AND</b> <i>Pseudomonas aeruginosa</i> ATCC 15442		

### Sanitizing Rinses (for previously cleaned food-contact surfaces)

Claims	Test Requirements	Cite All	Selective
<b>Halide chemical products</b>	<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 <b>AND</b> <i>Staphylococcus aureus</i> ATCC 6538		

### Non-food contact sanitizer

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

**Carpet Sanitizers**

Claims	Test Requirements	Cite All	Selective
<b>Carpet Sanitizers</b>	<i>Staphylococcus aureus</i> ATCC 6538 <b>AND</b> <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 <b>AND</b> <i>Klebsiella pneumoniae</i> ATCC 4352		
Hospital Products	<i>Pseudomonas aeruginosa</i> ATCC 15442		

**Swimming Pool Water**

Claims	Test Requirements	Cite All	Selective
<b>Disinfectants</b>	<i>Escherichia coli</i> ( <i>E. coli</i> ) ATCC 11229 <b>AND</b> <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, 43598, or 43599)		

