B 670

A B670 is an application for a new product with a registered source of active ingredient(s) and no change in an established tolerance or tolerance exemption. A B670 application requires:

1) submission of product specific data,
2) citation of previously reviewed and accepted data,
3) submission or citation of data generated at government expense,
4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement, **or**
5) submission of a request for a data requirement to be waived supported by a scientifically sound rationale explaining why the data requirement does not apply.

These products are not substantially similar (100% re-packs). This checklist is for biopesticide data requirements.
All product chemistry data must be submitted for each proposed End Use (EP) product.

Guideline No.	Product Chemistry Data Study Title	EP Data Submitted	
		Yes	No
880.1100	Product Identity & Composition		
880.1200	Description of starting materials production and formulation process.		
880.1400	Discussion on the formation of impurities		
830.1700	Preliminary analysis		
830.1750	Certified limits (158.345)		
830.1800	Enforcement analytical method		
830.6302	Color		
830.6303	Physical State		
830.6304	Odor		
830.6315	Flammability		
830.6317	Storage stability		
830.6319	Miscibility		
830.6320	Corrosion Characteristics		
830.7000	pH		
830.7100	Viscosity		
830.7300	Density		

New products must either: 1) supply the product specific acute toxicity data (listed below), or 2) provide a bridging document with a rationale that explains how EPA can use acute toxicity data (guideline by guideline) from a currently registered pesticide product instead of submitting product specific data.

End-use product Toxicity Data Requirements

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited		Waiver Request Rationale	
		Yes	No	Yes	No	Yes	No
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 – Whether or not these data are submitted depends on the proposed label use (e.g., public health pests). Studies are conducted on the end-use product. Applicants are advised to consult the Biopesticides and Pollution Prevention Division, Biochemical or Microbial Pesticides Branch Chief for any questions on whether these data are required for their proposed use.