B 672

A B672 is an application for registration of a new product with an unregistered source of active ingredient(s), for a non-food use or food use with a tolerance or tolerance exemption previously established for the active ingredient(s). A B672 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.

The application is for registration of a biopesticide product that is **not** substantially similar or identical to products that are currently registered since the active ingredient (ai) is from an unregistered source. The uses and/or formulations (less the unregistered ai) may be similar to products currently registered. The application requires product specific chemistry data, acute toxicity data and other Tier I mammalian and non-target toxicity data generated on the TGAI, in addition to the same Tier I data requirements for the EP as determined by the general use patterns for the product. When public health pests are claimed, efficacy (product performance) data for the product must be submitted. This fee category does not include products containing an active ingredient(s) which requires a change in, or establishment of, a tolerance or tolerance exemption or require the Agency to conduct a dietary risk assessment.

B672 Data Requirements Checklist

Guideline No.	Product Chemistry Data Study Title	EP Data Submitted		MP or TGAI Data Submitted	
		Yes	No	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				
830.6313	Stability to normal and elevated temperatures metal and metal ions				
830.6315	Flammability				
830.6317	Storage stability				
830.6319	Miscibility				

Guideline No.	Product Chemistry Data Study Title	EP Data Submitted		MP or TGAI Data Submitted	
		Yes	No	Yes	No
830.6320	Corrosion Characteristics				
830.7000	pH				
830.7050	UV/ Visible Absorption				
830.7100	Viscosity				
830.7200	Melting Point				
830.7220	Boiling Point				
830.7300	Density				
830.7550 830.7560 830.7570	Partition Coefficient				
830.7840	Water Solubility				
830.7950	Vapor Pressure				

Grayed out = data not required

New products must either: 1) supply the product specific acute toxicity data (listed below), or 2) provide a bridging rationale document or a waiver request 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						

Manufacturing Use Product (MP) or Technical Grade Active Ingredient (TGAI) Toxicity Data Requirements. The test substance must be the TGAI or MP

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)						

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited		Waiver Request Rationale	
		Yes	No	Yes	No	Yes	No
870.1200	Acute Dermal (LD50)						
870.1300	Acute Inhalation (LC50)						
870.2400	Acute Eye Irritation						
870.2500	Acute Dermal Irritation						
870.2600	Dermal Sensitization						
870.3100	90-day oral (one species						
870.3250	90-day dermal - rat						
870.3465	90-day inhalation - rat						
870.3700	Prenatal Developmental – rat preferably						
870.5100	Bacterial Reverse Mutation Test						
870.5300 870.5375	*In vitro* mammalian cell assay						

Manufacturing Use Product (MP) or Technical Grade Active Ingredient (TGAI) Non-target Organism Toxicity. The test substance must be the TGAI or MP

Guideline No.	Non-Target Organism Acute Toxicity Study Title	Data submitted		Cited		Waiver Request Rationale	
		Yes	No	Yes	No	Yes	No
850.2100	Avian Acute Oral Toxicity						
850.2200	Avian Dietary Toxicity						
850.1075	Fish Acute Toxicity, Freshwater						
850.1010	Aquatic Invertebrate Acute Toxicity, Freshwater						
850.4100	Terrestrial Plant Toxicity, Seedling Emergence						
850. 4150	Terrestrial Plant Toxicity, Vegetative Vigor						