

## Evaluation Report for Category B, Subcategory 1.1 Application

**Application Number:** 2016-4116  
**Application:** Changes to TGAI – New Source Same Registrant  
**Product:** Vitavax Technical  
**Registration Number:** 18722  
**Active ingredients (a.i.):** Carbathiin  
**PMRA Document Number :** 2765677

### Purpose of Application

The purpose of this application was to add a new manufacturing site to Vitavax Technical, registration number 18722, for the active ingredient carbathiin.

### Chemistry Assessment

Common Name: Carboxin (Carbathiin in Canada)  
IUPAC\* Chemical Name: 5,6-dihydro-2-methyl-1,4-oxathiine-3-carboxanilide  
CAS† Chemical Name: 5,6-dihydro-2-methyl-N-phenyl-1,4-oxathiin-3-carboxamide

\* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Vitavax Technical has the following properties:

Property	Result
Colour and physical state	Pale yellow solid
Nominal concentration	97.9%
Odour	Faint
Density	1.36 g/cm <sup>3</sup>
Vapour pressure (25°C)	0.02 mPa
pH	5.9-7.1
Solubility in water (20-25°C)	147.0 mg/L
n-Octanol/water partition coefficient	Log K <sub>ow</sub> = 2.3

The required chemistry data for Vitavax Technical have been provided, reviewed, and found to be acceptable.

## Health Assessments

The new source of the technical active ingredient results in a product that is chemically equivalent to the precedent source. Subsequently, no toxicological data were required.

Exposure assessments were not required for this application.

## Environmental and Value Assessments

Environmental and value assessments were not required for this application.

## Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the addition of a new manufacturing site for carboxin.

## References

### PMRA

#### Document

Number	Reference
2664662	2016, Applicant Name and Address: Vitavax Technical Alternate Source Submission, DACO: 2.1
2664663	2016, Manufacturer and Plant Name and Address: Vitavax Technical Alternate Source Submission, DACO: 2.2
2664664	2016, DESCRIPTION OF STARTING MATERIALS, METHOD OF MANUFACTURE AND DISCUSSION OF THE FORMATION OF IMPURITIES FOR CARBOXIN (VITAVAX) TECHNICAL, DACO: 2.11,2.11.2,2.11.3,2.11.4 CBI
2664665	2016, CERTIFIED LIMITS FOR VITAVAX TECHNICAL, DACO: 2.12.1 CBI
2664666	2016, Preliminary Analysis of Carboxin Technical, DACO: 2.13,2.13.1,2.13.2,2.13.3 CBI
2664667	2016, Preliminary Analysis of Carboxin Technical, DACO: 2.13,2.13.1,2.13.2,2.13.3 CBI
2694553	2016, Supplemental Information: Description of Starting Materials and Method of Manufacture for Carboxin (Vitavax) Technical, DACO: 2.11.2,2.11.3 CBI
2694555	2016, Study Plan Determination of the pH of Carboxin Technical, Lot # 20140920, DACO: 2.14.15,830.7000
2703338	2016, Determination of the pH of Carboxin Technical, Lot # 20140920, DACO: 3.5.7

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