

## Evaluation Report for Category B, Subcategory 1.1 & 1.3 Application

**Application Number:** 2008-3512  
**Application:** B.1.1 & B.1.3-New TGAI Prod Chemistry-New Site and Specifications  
**Product:** N(6)-Benzyladenine Technical Grade Active Ingredient  
**Registration Number:** 25321  
**Active ingredients (a.i.):** N-(Phenylmethyl)-1H-purine-6-amine  
**PMRA Document Number :** 1798975

### Purpose of Application

The purpose of this application is to add a new manufacturing site of and to change the manufacturing process of N(6)-Benzyladenine Technical Grade Active Ingredient.

### Chemistry Assessment

**Common name:** No ISO common name has been assigned to this active ingredient. 6-Benzylaminopurine is listed on the label as the name of the active ingredient.

**Chemical name:** N-(Phenylmethyl)-1H-purine-6-amine

N(6)-Benzyladenine Technical Grade Active Ingredient has the following properties:

Property	Result
Colour and physical state	White powder
Nominal concentration	99.3% as determined by HPLC
Odour	Odourless
Density	0.43 g/mL
Vapour pressure	$2.373 \times 10^{-6}$ mPa at 20°C
pH	5.9 (1% slurry)
Solubility in water	76 mg/L at 25°C 60 mg/L at 20°C
n-Octanol/water partition coefficient	Log $K_{ow}$ = 2.13

The chemistry requirements for (N)6-Benzyladenine Technical Grade Active Ingredient have been completed.

## **Health Assessments**

With the new site and manufacturing process, N(6)-Benzyladenine Technical Grade Active Ingredient is considered chemically equivalent to registered precedent product. Therefore the toxicity profile is not expected to be significantly different and no toxicological data were required.

No new residue data for benzyladenine were submitted in support of the registration of the new site and process of manufacture for this active ingredient. A review of the proposed label and specification form was conducted in the framework of this submission. As this manufacturing concentrate will be used to formulate registered end-use products within the existing use pattern, from a food residue exposure point of view, no changes in the magnitude of the residues in food and feed crops are expected and therefore, no increase in dietary exposure is anticipated.

## **Environmental and Value Assessment**

Environmental and value assessments were not required for this application.

## **Conclusion**

The PMRA has completed an evaluation of available information and has found the information sufficient to support the registration of new manufacturing site and to change the manufacturing process of N(6)-Benzyladenine Technical Grade Active Ingredient.

## **References**

<u>PMRA No.</u>	<u>Reference</u>
1634934	2006, Manufacturing Process, DACO: 2.11,2.12.1,2.13.1,2.13.2 CBI
1634936	2006, Characterization of Six Representative Lots, DACO: 2.12.1,2.13.1,2.13.2,2.13.3 CB

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