

N-(n-butyl) thiophosphoric triamide (NBPT)- DECISIONS ON REQUESTS FOR VARIATIONS

1. Safe Work Australia

Request 1.1:

Page ix - amend the concentration cut-offs table:

Risk Phrases*	Concentration Cut-off
C, R41	Concentration \geq 10%
Xi, R36	5% \leq conc < 10%
Xn, R62	Concentration \geq 5%

*C = Corrosive; Xi = Irritant; Xn = Harmful

Decision 1.1:

Variation approved. The table in page ix will be amended as requested, as follows:

Risk Phrases*	Concentration Cut-off
Xn, R62; R41	Concentration \geq 10%
Xn, R62; R36	5% \leq Concentration < 10%

*Xn = Harmful

Page 25 will also be amended as follows:

Classification: Based on the rabbit data, NBPT meets the Approved Criteria for Classifying Hazardous Substances for classification as an **irritant** and the risk phrase R41 (Risk of serious damage to eyes) is applicable.

Request 1.2:

Page 7 - The classification of N-methyl-2-pyrrolidone has been updated in the HSIS to reflect the change in classification for this substance in the EU's 31st Adaptation to Technical Progress (January 2009).

Update the classification of N-methyl-2-pyrrolidone as per Hazardous Substances Information System (HSIS).

Decision 1.2:

Variation approved. The paragraph in page 7 will be amended as follows:

N-methyl pyrrolidone (CAS No. 872-50-4) is **toxic to reproduction (T, R61)**, an irritant (Xi, R36/**37/38**) and has an exposure standard of 25 ppm or 103 mg/m³ (TWA) in the HSIS. The threshold for classification of a mixture containing N-methyl pyrrolidone as hazardous is **5%**, therefore the formulation AGROTAIN[®] is classified as hazardous on this basis.

2. Agrotain International LLC

Variation requests are grouped according to issues and consequential changes to the draft report.

Request 2.1:

Pages vii & 1 – “Overview and Recommendations” and “Background” – delete “and dicyandiamide”. NBPT is specific to urea. Dicyandiamide is not oxidized by the urease enzyme.

Decision 2.1:

Variation approved.

Request 2.2:

Pages vii, viii, 4, 7, 9, 11 & 29 – change to “20%”.

Currently only AGROTAIN[®] 20% NBPT is being imported into Australia. The reason we moved to 20% was to ensure adequate coverage when applying much less volume to the urea.

Decision 2.2:

Variations approved. The concentration of NBPT in AGROTAIN[®] will be changed to 20% on *pages vii, viii, 4, 7, 9, 11 & 29*.

Request 2.3:

Pages vii, viii, ix, 9, 11, 12, 30, 31 & 32 – adjust the draft to reflect the current rates of use in Australia: 0.053% to 0.064% NBPT in granular urea and 0.038% NBPT in UAN solution.

In certain climates and soil types such as in Australia local research has shown that a 0.2% rate of NBPT, cited in the 1997 notification, to urea is not necessary. Local research has shown that rates to granular urea of 2.5 litres to 3 litres/tonne and to UAN solution 1.8 litres/tonne are the proper agronomic rates.

Decision 2.3:

Variations approved.

NICNAS comments 2.3:

Calculations affected by changes to the rates of use in Australia of NBPT in granular urea and UAN solution (*pages ix, 31 & 32*) will also be amended.

Request 2.4:

Pages vii, 8, 31 & 32 – change import volume to 4.24 tonnes NBPT or 22 tonnes AGROTAIN[®].

This adjustment was made to reflect recent history of shipments. Our sales department advises that they expect a 40% growth in imported tonnage over the next few years.

Decision 2.4:

Variations approved.

NICNAS comments 2.4:

Import volume will be changed to 4.24 tonnes NBPT or 22 tonnes AGROTAIN[®] on *pages vii & 8* but calculations based on 150 tonnes NBPT or 600 tonnes AGROTAIN[®] from the original report on *page 32* will be retained.

Request 2.5:

Page 7 - “Content of NBPT” – increased the range of N-methyl pyrrolidone content to about 15%.

This concentration reflects what is supplied today in Australia.

Decision 2.5:

Variation approved. N-methyl pyrrolidone concentration will be changed to “approximately 15%”.

Request 2.6:

Page viii - “Public exposure and health risks”, 2nd paragraph – add “Residues of the notified chemical in food commodities are expected to be negligible”.

To be consistent with page 11, “Public Exposure” 4th paragraph, 7th sentence and page 30, Section 9.3, 3rd sentence.

Decision 2.6:

Variation approved. This sentence will be added to *page viii* “Overview and Recommendations”:

“Residues of the chemical in food commodities are expected to be negligible”.

Request 2.7:

Page vii - delete “of the urea content” and add “concentration”.

This is the total amount added to UAN solution.

Decision 2.7:

Variation approved. *Page vii*, last sentence of 4th paragraph, will be changed as requested.

Request 2.8:

Page 2 - “Declaration” last bullet point - correct the location of the incident.

Decision 2.8:

Variation approved. Sentence on *page 2* will be amended as follows:

- An accident report submitted to the US EPA of 2 workers handling AGROTAIN[®] product in a New Zealand factory in 2006 (as reported by the overseas manufacturer).

NICNAS comments 2.8:

Since the document was addressed to the US EPA, the factory was assumed to be in the US. The document does not specify the location of the incident. The author of the accident/incident report, who is also the variation applicant, stated that the location of the factory is New Zealand.

Request 2.9:

Page 8, 9 & 29 – add “1000 litre mini-bulk”.

Add this container size to reflect what is supplied today.

Decision 2.9:

Variations approved. Container size will be changed from “9.46 L” to “1000 L mini-bulk” since 9.46 L containers are no longer in use.

Request 2.10:

Page 5 & 6 – “Physical and chemical properties”, “Partition co-efficient” – the correct log Pow is 0.444.

Decision 2.10:

Variations approved. Changes to the following pages will be made:

Page 5:

Log Pow = 0.444 ABC Laboratories, 2001c

Page 6:

The 3rd paragraph will be deleted since it is no longer relevant (test report was provided for new log Pow).

Page 42:

“References” – the following paragraph will be added:

ABC Laboratories (2001c) Determination of n-Octanol/Water Partition Coefficient (Shake Flask Method) for Butyl Phosphorothioic Triamide (NBPT). No 46506. ABC Laboratories, USA (unpublished study).

Request 2.11:

Page viii – 2nd paragraph, 3rd sentence – delete “fertility in animals” and insert “rat reproductive organs”. The test data do not reflect adverse fertility in animals.

Page 23 – “No observed adverse effect levels (NOAELs)”, 2nd paragraph, 1st sentence – add “Potentially” and delete “reproductive” and delete “on fertility” in both the 2nd and 3rd sentences.

There were no effects on fertility *per se* in the reproductive toxicity study, to support the statements in this paragraph. Although these could result in reduced fertility, there was no evidence that they did. Adverse effects on reproductive organs are being used interchangeably as adverse effects on fertility, and this is supported by the study.

Page 29 – “Critical health effects”, 4th paragraph, 1st sentence – add “potentially” and delete “fertility”, and add “rats” and delete “animals” and in the 3rd sentence delete “fertility” and add “reproductive”. These proposed changes reflect the results of the study.

Page 30 – 3rd paragraph, delete “fertility” and add “reproductive toxicity”. These changes reflect the results of the study.

Decision 2.11:

Variations partially approved.

Page viii will be changed to:

NBPT adversely affects rat reproductive organs ...

Page 23, 2nd paragraph will be changed to:

Adverse effects on reproductive organs were observed in both male and female rats.

These adverse effects could affect fertility. The NOAEL for effects on fertility in males was established as 200 ppm (21 mg/kg bw/d) based on decreased sperm motility and epididymal lesions in F1 at 800 ppm and above. The NOAEL for effects on fertility in females was established as 800 ppm (84 mg/kg bw/d) based on delayed or non-recovery of oestrus cyclicity post-pregnancy for F1 at 3200 ppm.

Page 29, 4th paragraph will be changed to:

NBPT is found to produce adverse effects on reproductive organs in rats with histopathological findings in both males and females, and abnormalities in sperm evaluations. An overall NOAEL is 17 mg/kg bw/d for fertility effects of NBPT.

Page 29, last paragraph will be changed to:

NBPT adversely affects reproductive organs in rats...

Page 30, 3rd paragraph will be retained.

NICNAS comment 2.11

Safe Work Australia’s Approved Criteria for Classifying Hazardous Substances describes reproductive toxicity as either effects on fertility or effects on development. “Fertility” needs to be retained to distinguish between the two effects and to allow the criteria to be applied for classification of NBPT.