

## Evaluation Report for Category B, Subcategory 1.3 Application

**Application Number:** 2013-4281  
**Application:** Changes to Technical Grade Active Ingredient Chemistry - Specifications  
**Product:** Myacide AS Technical Microbiocide  
**Registration Number:** 18880  
**Active ingredients (a.i.):** Bronopol (BND)  
**PMRA Document Number :** **2450028**

### Purpose of Application

The purpose of this application was to update the product chemistry for Myacide AS Technical Microbiocide (Registration Number 18880; guarantee 98% bronopol).

### Chemistry Assessment

**Common Name:** bronopol  
**IUPAC Chemical Name:** 2-bromo-2-nitropropane-1,3-diol  
**CAS Chemical Name:** 2-bromo-2-nitro-1,3-propanediol

Myacide AS Technical Microbiocide has the following properties:

Property	Result
Colour and physical state	Off white solid
Nominal guarantee	Bronopol at 99.0 % Available chlorine present as 1-bromo-3-chloro-5,5-dimethylhydantoin and related hydantoins at 28.6% (limits 27.7-29.5%)
Odour	Faint, halide-like, characteristic
Density	1.1 g/cm <sup>3</sup>
Vapour pressure	1.68 × 10 <sup>-3</sup> Pa at 20°C
pH	4.5-7 (1% solution)
Solubility in water at 22-25°C	250 g/L
n-Octanol/water partition coefficient	Log K <sub>ow</sub> = 0.18 at 20°C

The chemistry requirements for Myacide AS Technical Microbiocide have been fulfilled.

### Health Assessments

Exposure assessments were not required for this application.

The presence of a new impurity as a result of the addition of new sources of starting material for bromine is not expected to alter the toxicological profile of Myacide AS Technical Microbiocide.

### Environmental and Value Assessments

Environmental and value assessments were not required for this application.

### Conclusion

The PMRA has completed a review of all available information for Myacide AS Technical Microbiocide and found the information sufficient to support the product chemistry updates.

### References

PMRA Document Number	Reference
2333731	2013, Myacide AS-Addendum to MRID No 46020801, Product Chemistry: OPPS Guideline 830.1550 through 830.1670 (Product Identification and Composition, Beginning Materials, Production Process and Impurities), DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
2333733	2013, Overview of changes to Bronopol Product Chemistry, DACO: 2.11.2,2.11.3,2.11.4,2.13.1,2.13.3 CBI
2333734	2013, Myacide AS-Product Chemistry: OCSPP Guideline No 830.1700 and 830.1750 (Preliminary analysis and certified limits): 5 Batch analysis includes Annex I,II and III: history and composition of HPLC- Method for Bronopol, DACO: 2.12.1,2.13,2.13.1,2.13.3 CBI
2333735	2013, Myacide AS- Assay for bronopol and bronopol impurities by HPLC, DACO: 2.13.1
2333738	2013, Identification of unknown peak, DACO: 2.13.4 CBI
2448922	2014, BASF Response to PMRA Clarification dated July 11, 2014 for Myacide AS Technical Microbiocide, Submission No. 2013-4281, DACO: 2.13,2.13.1,2.13.2,2.13.3 CBI
2448923	2014, Validation Report - Assay for bronopol and bronopol impurities by HPLC, DACO: 2.13.1 CBI
2448924	2009, Final Report - Validation of an HPLC method for quantitative determination of bronopol and impurities, DACO: 2.13.1 CBI
2448925	BP 2011 - Appendix III D, DACO: 2.13.1
2448926	BP 2014 - Appendix III D, DACO: 2.13.1
2448927	European Pharmacopoeia 8.0 - 2.2.29 Liquid chromatography, DACO: 2.13.1
2448929	2013, Analytical Report 13P00027, DACO: 2.13.2 CBI
2452745	2014, BASF Response to PMRA Clarification dated July 11, 2014 for Myacide AS Technical Microbiocide, Submission No. 2013-4281, DACO: 2.13,2.13.1,2.13.2,2.13.3 CBI
2452746	2001, Determination of CBI REMOVED (Bronopol) and impurities in Myacide Pharma., DACO: 2.13.1 CBI
2452747	H-NMR Spectra, DACO: 2.13.2 CBI

2452748	BP 2011 Bronopol, DACO: 2.13.3
2452749	2013, Appendix 1X C, DACO: 2.13.3 CBI

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services  
Canada 2016

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.