

# **REPORT**

## **DETERMINATION OF THE CONTENT OF MICROBICIDAL AMPHOTERIC IN TEGO 2000**

**NOTOX Project 266525**  
**NOTOX Substance 92016**

STATEMENT OF GLP COMPLIANCE

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**NOTOX B.V.**, 's-Hertogenbosch, The Netherlands

The study described in this report has been correctly reported and was conducted in compliance with the most recent edition of:

The OECD Principles of Good Laboratory Practice

which are essentially in conformity with:

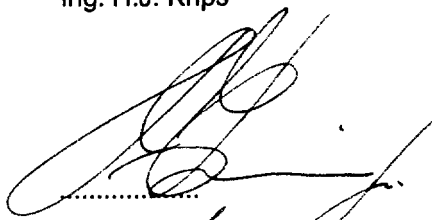
The United States Food and Drug Administration. Title 21 Code of Federal Regulations Part 58.

The United States Environmental Protection Agency (FIFRA). Title 40 Code of Federal Regulations Part 160.

The United States Environmental Protection Agency (TSCA). Title 40 Code of Federal Regulations Part 792.

Study Director

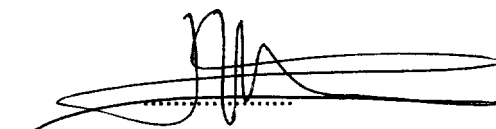
**Ing. H.J. Krips**



Date: *May 09, 2000*

Management

**Dr. Ir. H. Willems**  
Head of Chemistry



Date: *May 10, 2000*

QUALITY ASSURANCE STATEMENT

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NOTOX B.V., 's-Hertogenbosch, The Netherlands

This report was audited by the **NOTOX** Quality Assurance Unit to ensure that the methods and results accurately reflect the raw data.

The dates of Quality Assurance inspections and audits are given below.  
During the on-site inspections procedures applicable to this type of study were inspected.

| DATES OF QAU INSPECTIONS/AUDITS | REPORTING DATES |
|---------------------------------|-----------------|
| on-site inspection (s)          |                 |
| 19 January 2000                 | 19 January 2000 |
| protocol inspection (s)         |                 |
| 31 January 2000                 | 31 January 2000 |
| report audit (s)                |                 |
| 03 May 2000                     | 03 May 2000     |

Head of Quality Assurance  
C.J. Mitchell **B.Sc.**

  
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Date: 11-5-2000

## SUMMARY

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The content of MICROBICIDAL AMPHOTERIC in TEGO 2000 was determined using a titration method.

In conclusion, the content of MICROBICIDAL AMPHOTERIC in TEGO 2000 is  $18.57 \pm 0.02$  % (w/w).

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**PREFACE**

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|                  |                                                                                        |
|------------------|----------------------------------------------------------------------------------------|
| Sponsor          | Th. Goldschmidt AG<br>Goldschmidtstrasse 100<br>D-451 27 ESSEN<br>Germany              |
| Study Monitor    | Dr. W. Hilmes                                                                          |
| Testing Facility | <b>NOTOX</b> B.V.<br>Hambakenwetering 3<br>5231 DD 's-Hertogenbosch<br>The Netherlands |
| Study Director   | Ing. H.J. Krips                                                                        |
| Study Plan       | Start : 21 February 2000<br>Completed : 07 March 2000                                  |

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**TEST SUBSTANCE**

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|                                    |                                 |
|------------------------------------|---------------------------------|
| Identification                     | TEGO 2000                       |
| Description                        | Colourless to yellowish liquid  |
| Batch                              | <b>S9B10B</b>                   |
| Purity                             | 100%                            |
| Composition                        | 20% Active<br>80% Water         |
| Test substance storage             | At room temperature in the dark |
| Stability under storage conditions | Stable                          |
| Expiry date                        | 01 December 2002                |
| <b>Specific Gravity</b>            | 0.998 g/ml                      |

The sponsor is responsible for all test substance data unless determined by **NOTOX**.

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**PURPOSE**

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The purpose of the study was to determine the content of **MICROBICIDAL AMPHOTERIC** in TEGO 2000.

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**ARCHIVING**

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**NOTOX** B.V. will archive the following data for at least 10 years: protocol, report, test substance reference sample and raw data. Thereafter, no data will be withdrawn without the sponsor's written consent.

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**PERFORMANCE OF THE TEST**

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**Standardization of the 0.1 mol/l sodium thiosulphate solution**

Reagents: Potassium iodate (**KIO<sub>3</sub>**, p.a., Merck, Darmstadt, Germany),  
dried at 105°C for about 2 hour immediately before use.  
Potassium iodide (KI, 1 **mol/l**, Merck, Darmstadt, Germany).  
Starch indicator solution (1 % w/w, Merck, Darmstadt, Germany).  
Hydrochloric acid (1 **mol/l**, Merck, Darmstadt, Germany).

The standardization of the 0.1 **mol/l** sodium thiosulphate solution was performed in triplicate.

About 150 mg (w g) of potassium iodate was weighed (to the nearest 0.1 mg) into a conical flask and dissolved in 40 ml of **milli-Q** water. The conical flask was securely closed and the solution was shook until all potassium iodate completely dissolved. 2 g of potassium iodide and 12 ml 1 **mol/l** hydrochloric acid solution was added. The liberated iodine was titrated with the sodium thiosulphate solution, with constant shaking. When the reaction was nearly complete, i.e. when the solution was pale yellow in colour, the solution was diluted to a volume of 200 ml with **Milli-Q** water. Starch indicator solution (2 ml) was added and the titration was continued until the solution became colourless (t ml).

The blank solution was prepared as described above, omitting the test substance. After preparation the solution appeared to be colourless, i.e. t=0 ml.

**Determination of the content of MICROBICIDAL AMPHOTERIC in TEGO 2000.  
(According to Shogenki method, AA HC 002 A, Goldschmidt).**

Reagents: Starch indicator solution (1 % **w/w**, Merck, Darmstadt, Germany).  
Hydrochloric acid (1 **mol/l**, Merck, Darmstadt, Germany)  
Sodium acetate (1 **mol/l**, Merck, Darmstadt, Germany)  
Potassiumhexacyanoferrate (0.05 **mol/l**, Merck, Darmstadt, Germany)  
Potassium iodide (1 **mol/l**, Merck, Darmstadt, Germany)  
Zinc sulphate (10% **w/w**, Merck, Darmstadt, Germany))  
Sodiumthiosulphate (0.1 **mol/l**, Merck, Darmstadt, Germany)

The determination of the content of MICROBICIDAL AMPHOTERIC was performed in fivefold. The blank was determined in duplicate.

About 3.3 g test substance was weighed (to the nearest 0.1 mg) into a conical flask and dissolved in 25 ml 1 **mol/l** hydrochloric acid and 25 ml sodium acetate. 50 ml of potassiumhexacyanoferrate was added, this solution was stirred and placed in the dark for 60 minutes. Thereafter the solution was filtered, the flask and the filter were washed with 2 x 50 ml water. To the filtrate 10 ml 1 **mol/l** hydrochloric acid, 10 ml 1 **mol/l** potassium iodide and 15 ml 10% zinc sulphate was added. The liberated iodine was titrated with the sodium thiosulphate solution, with constant shaking. When the reaction was nearly complete, i.e. when the solution was pale yellow in colour, the solution was diluted to a volume of 200 ml with **Milli-Q** water. Starch indicator solution (2 ml) was added and the titration was continued until the solution became colourless (t ml).

The blank solutions were prepared as described above, omitting the test substance.

DATA HANDLING

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The content of MICROBICIDAL AMPHOTERIC in TEGO 2000 was expressed in % by weight. A certificate of analysis was added to this report as an appendix.

1. Mean

$$\bar{x} = \frac{1}{n} \sum_{i=1}^n x_i$$

where

$x_i$  = measured value

n = number of measurements

2. Standard deviation

$$s_{n-1} = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{(n-1)}}$$

where

$x_i$  = measured value

n = number of measurements

3. Coefficient of variation

(standard deviation/mean value) x 100%

4. Concentration sodiumthiosulphate

$$\frac{1000}{35.67} \cdot \frac{w}{t} \text{ mol/l}$$

where: w = weight of potassium iodate (g)  
t = volume of sodiumthiosulphate (ml)

5. Content MICROBICIDAL AMPHOTERIC

$$\frac{((B - A) * N * 297.25 * 2 * 100)}{W * 1000} \% \text{ (w/w)}$$

where: A = volume of sodiumthiosulphate required for the sample (ml)  
B = volume (average) of sodiumthiosulphate required for the blank (ml)  
N = concentration of sodiumthiosulphate (mol/l)  
W = weight of the test substance (g)

## RESULTS

The content of MICROBICIDAL AMPHOTERIC in TEGO 2000 was determined using a titration method.

The results of the standardization of the 0.1 mol/l sodiumthiosulphate solution are shown in Table 1. The results of the determination of the content MICROBICIDAL AMPHOTERIC in TEGO 2000 are shown in Table 2.

Table 1 Standardization of the 0.1 mol/l sodiumthiosulphate solution solution.

| Test                                                          | Volume sodiumthiosulphate (ml) | Weight of the potassium iodate (g) | Concentration sodiumthiosulphate (mol/l) |
|---------------------------------------------------------------|--------------------------------|------------------------------------|------------------------------------------|
| Blank                                                         | 0                              | ---                                | ---                                      |
| Test 1                                                        | 42.255                         | 0.1500                             | $9.95 \times 10^{-2}$                    |
| Test 2                                                        | 42.098                         | 0.1499                             | $9.98 \times 10^{-2}$                    |
| Test 3                                                        | 42.184                         | 0.1501                             | $9.98 \times 10^{-2}$                    |
| <i>Mean concentration sodiumthiosulphate solution (mol/l)</i> |                                |                                    | $9.97 \times 10^{-2}$                    |
| <i>Standard deviation</i>                                     |                                |                                    | $1.73 \times 10^{-4}$                    |
| <i>Coefficient of variation (%)</i>                           |                                |                                    | 0.17                                     |

Table 2 Determination of the content of MICROBICIDAL AMPHOTERIC in TEGO 2000.

| Test                                                | Volume sodiumthiosulphate (ml) | Weight of the test substance (g) | Content MICROBICIDAL AMPHOTERIC (% w/w) |
|-----------------------------------------------------|--------------------------------|----------------------------------|-----------------------------------------|
| Blank 1                                             | 24.669                         | ---                              | ---                                     |
| Blank 2                                             | 24.698                         | ---                              | ---                                     |
| <i>Blank mean</i>                                   | <i>24.684</i>                  |                                  |                                         |
| Test 1                                              | 14.276                         | 3.3204                           | 18.58                                   |
| Test 2                                              | 14.192                         | 3.3494                           | 18.57                                   |
| Test 3                                              | 14.186                         | 3.3478                           | 18.59                                   |
| Test 4                                              | 14.316                         | 3.3126                           | 18.55                                   |
| Test 5                                              | 14.248                         | 3.3296                           | 18.58                                   |
| <i>Mean content MICROBIC/DAL AMPHOTERIC % (w/w)</i> |                                |                                  | 18.57                                   |
| <i>Standard deviation</i>                           |                                |                                  | $1.52 \times 10^{-2}$                   |

In conclusion, the content of MICROBICIDAL AMPHOTERIC in TEGO 2000 is  $18.57 \pm 0.02$  % (w/w).

## APPENDIX

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### CERTIFICATE OF ANALYSIS OF MICROBICIDAL AMPHOTERIC in TEGO 2000

This certificate of analysis is an appendix of **NOTOX** Project 285525, "Determination of the content of MICROBICIDAL AMPHOTERIC in TEGO 2000".

#### SPONSOR

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|              |                                                                           |
|--------------|---------------------------------------------------------------------------|
| Company name | Th. Goldschmidt AG<br>Goldschmidtstrasse 100<br>D-451 27 ESSEN<br>Germany |
|--------------|---------------------------------------------------------------------------|

#### TEST SUBSTANCE

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|------------------------------------|---------------------------------|
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| Stability under storage conditions | Stable                          |
| Expiry date                        | 01 December 2002                |

The sponsor is responsible for all test substance data unless determined by **NOTOX**.

#### CHEMICAL ANALYSIS

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|                                                 |                      |
|-------------------------------------------------|----------------------|
| Date of analysis                                | 06 March 2000        |
| Content of MICROBICIDAL AMPHOTERIC in TEGO 2000 | 18.57 ± 0.02 % (w/w) |

#### APPROVAL

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Ing. H.J. Krips  
(Study Director)

  
Date: *May 09. 2000*