

EXPERT STATEMENT

Study Title

STATEMENT ON THE ACUTE INHALATORY TOXICITY OF STAP 2 (ANTISLIP SYSTEM)

Author

Drs. P.J.M. Janssen

Date

21 February 2008

Test Facility

NOTOX B.V.
Hambakenwetering 7
5231 DD 's-Hertogenbosch
The Netherlands

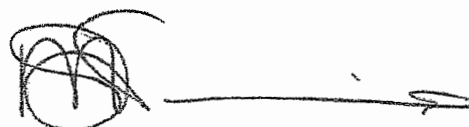

NOTOX Project 487985
NOTOX Substance 181854/A

1. STATEMENT APPROVAL

NOTOX B.V.

Drs. P.J.M. Janssen
Study Director Inhalation Toxicology

Drs. M.S. Teunissen
Section Head Toxicology



Date: 21 February 2008

Date: 21 February 2008

2. RATIONALE

In the interest of animal welfare and to minimize testing in animals, an analysis of the need to perform an acute inhalatory toxicity study with of STAP 2 (antislip system) was made on basis of the acute inhalatory toxicity of the individual constituents of the test substance. The LC_{50} of STAP 2 (antislip system) in rats when performed according to international accepted test guidelines and the classification was estimated and the labelling requirement according to the EC criteria for inhalatory toxicity was established.

It should be taken into account that all data which were used in the calculations were obtained from secondary sources the public domain.

3. INTRODUCTION

3.1. PREFACE

Sponsor	All-a-Round Safety Products Mr. R. van der Wolf / Mr. F. Steenhorst Edisonstraat 15 2723 RS ZOETERMEER The Netherlands
Study Monitor (on behalf of the sponsor)	Mr. F.R. Peul Eko-Chem Oudhuijzerweg 58 3648 AD WILNIS The Netherlands
Test Facility	NOTOX B.V. Hambakenwetering 7 5231 DD 's-Hertogenbosch The Netherlands
Study Director	Drs. P.J.M. Janssen Email: peter.janssen@notox.nl

3.2. GUIDELINES

3.2.1. Test Guidelines

In this expert statement the LC₅₀ of STAP 2 (antislip system) in rats was estimated when being tested according to the following test guidelines:

Organisation for Economic Co-operation and Development (OECD), OECD Guidelines for Testing of Chemicals, Section 4, Health Effects. No.403, "Acute Inhalation Toxicity", Draft document, 1996.

European Community (EC), Council Directive 67/548/EEC, Annex V, Part B, Methods for the Determination of Toxicity Annex IV B, B.2. Acute Toxicity (inhalation). Official Journal of the European Communities No. L 383, 1992.

EPA Health Effects Test Guidelines OPPTS 870.1300, Acute inhalation Toxicity. EPA 712-C-98-193, August 1998.

3.2.2. Classification guidelines

In this expert statement the classification and labelling requirements of STAP 2 (antislip system) were established according to EC criteria for classification and labelling of dangerous substances and preparations (Council Directive 67/548/EEC and all adaptations to technical progress and amendments of this Directive published in the Official Journal of the European Communities).

4. SUBSTANCE INFORMATION

4.1. IDENTIFICATION

Identification	Stap 2 (antislip system)
Description	Clear yellow/orange liquid
Batch	20629069/003

4.2. PHYSICAL AND CHEMICAL PROPERTIES

Relevant physical and chemical properties of the individual constituents of STAP 2 (antislip system) and of hydrogen fluoride are given below:

Compound	Molecular formula	Molecular mass	Conversion factor ppm to mg/m ³
Ammonium bifluoride	[NH ₄][HF ₂]	57	Not known
Hydrochloric acid	HCl	36.46	1.49
Phosphoric acid	H ₃ PO ₄	98.0	4.01
Hydrofluoric acid*		10	0.82

* data of hydrofluoric acid were used to predict the toxicity of ammonium bifluoride.

4.3. TOXICOLOGICAL INFORMATION

4.3.1. General

Acute inhalatory toxicity data of ammonium bifluoride, hydrochloric acid and phosphoric acid are given below.

Compound	LC _{50,4h}
Ammonium bifluoride	1.5 mg/L, estimated value, see section below.
Hydrochloric acid	1405 ppm ~ 2.1 mg/L
Phosphoric acid	>0.850 mg/L (1h) ~ >0.2 mg/L
Hydrofluoric acid	655 ppm (4h) ~ 0.54 mg/L

4.3.2. Ammonium bifluoride

No information on the inhalatory toxicity of ammonium bifluoride could be found in the public domain data. It is assumed that the acute toxicity of ammonium bifluoride is due to the formation of hydrofluoric acid when being inhaled. The LC_{50,4h} of ammonium bifluoride was estimated using the following equation. A factor of 2 is applied since one molecule of ammonium bifluoride is equivalent to two molecules of hydrofluoric acid:

$$LC_{50, 4h, HF} \times ((\text{mol. mass } [NH_4][HF_2] / \text{mol. mass HF}) / 2).$$

$$0.54 \times ((57 / 10) / 2) = 1.5 \text{ mg/L}$$

5. TOXICITY ESTIMATE OF STAP 2

The amount of STAP 2 (antislip system) in air necessary to obtain the LC_{50,4h} of each individual constituent of STAP 2 (antislip system) was calculated using the following equation:

$$LC_{50,4h} / (\text{concentration of individual compound in Stap 2})$$

The results of the estimated LC_{50,4h} values expressed in amounts of STAP 2 (antislip system)/L air are given below:

Compound	LC _{50,4h}	LC _{50,4h}
Ammonium bifluoride	1.5 mg/L	42 mg Stap 2/L
Hydrochloric acid	2.1 mg/L	1429 mg Stap 2/L
Phosphoric acid	0.2 mg/L	4 mg Stap 2/L

According to these estimates it is concluded that the acute inhalatory of STAP 2 (antislip system) is determined by its' phosphoric acid content. The contribution of ammonium bifluoride and hydrochloric acid is considered negligible.

6. CONCLUSION

The estimate of the LC_{50,4h} was considered sufficient accurate to conclude that the LC_{50,4h} value of STAP 2 (antislip system) is between 1.0 and 5.0 mg/L, being the lower and upper cut point for labelling as harmful and that an acute inhalation test with STAP 2 (antislip system) in rats is not required.