CGA

Compressed Gas Association

The Standard For Safety Since 1913

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NITROSAMINE IMPURITIES IN NITROUS OXIDE AND OTHER MEDICAL GASES

FIRST EDITION
(Corrected 11/23/2021)

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Medical Gases Committee

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1 Introduction

This publication describes how potential nitrosamine contaminants from the nitrous oxide process pose no hazard or risk in medical grade nitrous oxide.

2 Scope

This publication evaluates the possible synthesis of nitrosamines from the thermal decomposition of ammonium nitrate, in the manufacture of nitrous oxide.

3 Manufacturing process

Ammonium nitrate (NH_4NO_3) in a minimum aqueous concentration of 83% is introduced into a reactor at approximately 482 °F to 491 °F (250 °C to 255 °C). The high temperatures drive the reaction to produce nitrous oxide (N_2O) and 2 molecules of water (H_2O), see CGA G-8.4, *Safe Practices for the Production of Nitrous Oxide from Ammonium Nitrate* [1].[1]

NH_4NO_3 + Heat → N_2O + 2 H_2O [1].

The nitrous oxide contaminant evaluation includes:

- identifying potential contaminants;
- physical and chemical properties of the contaminants;
- nitrous oxide impact on the manufacture of the contaminants;
- nitrous oxide concentration factors;
- concentration levels of contaminants remaining in nitrous oxide;
- particulates; and
- conclusions/data evaluation.

4 Potential contaminants

Nitrous acid is the base chemical compound that is necessary to generate nitrosamines.

Nitrosamines are typically produced by the reaction of nitrous acid (HNO_2) and a secondary amine (R_2NH).

HNO_2 + R_2NH → R_2N-NO + H_2O [2, 3].

5 Physical and chemical properties of the contaminants

Nitrous acid is generated by acidification of aqueous sodium nitrite. Acidification is conducted at freezing temperatures (32°F [0 °C]) and the nitrous acid is consumed in situ [4, 5].

Free nitrous acid is extremely unstable and decomposes rapidly.

6 Nitrous oxide impact on the manufacture of the contaminants

The reactor temperatures that generate nitrous oxide of approximately 482 °F to 491 °F (250 °C to 255 °C), far exceed the ability to manufacture nitrous acid, which require freezing temperatures [1].

[1] References are shown by bracketed numbers and are listed in order of appearance in the reference section.