

INHALATION SYSTEM AND METHOD**CROSS-REFERENCE TO RELATED APPLICATION**

This application claims the benefit under 35 U.S.C. 119(e) of, and incorporates by reference in its entirety the presently U.S. Provisional Patent Application No. 60/396,698, entitled Hybrid Inhalation System for Precious Materials, filed 17 Jul. 2002, naming Justin M. Hartings, Chad J. Roy, and Gerald M. Liverette as inventors.

This application is also a continuation in part of, claims priority from, and incorporates by reference in its entirety the presently U.S. patent application Ser. No. 09/919,741, filed 31 Jul. 2001, entitled AUTOMATED INHALATION TOXICOLOGY EXPOSURE SYSTEM, now U.S. Pat. No. 6,904,912 B2, issued on 14 Jun. 2005, naming Justin M. Hartings, and Chad J. Roy as inventors.

This application is also a continuation in part of, claims priority from, and incorporates by reference in its entirety the presently U.S. patent application Ser. No. 10/166,228, filed 29 May 2002, now U.S. Pat. No. 7,377,276, entitled INHALANT SYSTEM, naming Justin M. Hartings, and Chad J. Roy as inventors.

This application also incorporates by reference in their entireties any and all applications and/or other materials which were incorporated by reference in any of the foregoing-referenced applications or any of their parent, great-grandparent, great-great grandparent, etc., applications, such as the United States Provisional Patent Application(s) incorporated therein.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

This invention was made with support from the United States Army. The United States Army has certain rights in this invention.

BACKGROUND OF THE INVENTION**1. Field of the Invention**

The subject matter disclosed herein relates, in general, to inhalation systems.

2. Description of the Related Art

Inhalation exposure chambers are designed to expose all or part of an animal to a test atmosphere. Inhalation exposure chambers have historically been conducted with either static or dynamic inhalation systems. Each of these types of systems has drawbacks.

Related-art dynamic inhalation systems operate by supplying and exhausting air from an exposure chamber at a constant rate, and necessitate continuous introduction of an inhalant into the input air stream. The inventors have recognized, and such recognition forms a part of the inventive content herein, that related-art dynamic inhalation systems entail a number of drawbacks. For example, in related-art dynamic inhalation systems the constant supply and exhaust of inhalant from the chamber results in low efficiency of inhalant delivery. Specifically, consider exposing 10 rodents, each with a respiratory minute volume of 20 ml, in a dynamic chamber running at 20 liters per minute. During a minute of exposure, the rodents respire 200 ml of air from the inhalant chamber, and 20 liters of air exit through the inhalant chamber exhaust. Thus, there would be a 1:100 ratio of respired inhalant to exhausted inhalant. This results in a wasting of over 99% of the test material during the exposure. Insofar as that

most materials in pre-clinical trials or initial stages of animal testing are expensive to produce, and generally synthesized in small lots, the poor efficiency of related-art dynamic exposure systems imposes a heavy financial burden on organizations. It is therefore apparent that a need exists in the art for a method and system that will reduce the amount of test material wasted, but without sacrificing accuracy of dose.

As another example of the drawbacks of related-art dynamic inhalation systems, consider that if a user were attempting to determine the toxicity or infectiousness of a highly pathogenic aerosol, a large amount of the test material would be expended in an attempt to achieve a dose to reach the desired outcome using a related-art dynamic system. Accordingly, the amount of pathogen that needs to be aerosolized would be increased, thus potentially raising the safety risks to users of the system. It is therefore apparent that a need exists in the art for a method and system that can effectively deliver a high dose of pathogen, while substantially reducing the amount of pathogen that needs to be aerosolized in related-art dynamic inhalant systems.

As another example of the drawbacks of dynamic inhalation systems, dynamic inhalation systems are unattractive for testing so-called "aged" aerosols. In many inhalation studies the material under testing must have a long residence time in the aerosol phase to achieve the conditions needed for effective testing. Long residence times can be required, for example, to assure adequate aerosol particle drying or to allow aerosol mediated chemical reactions to occur before inhalation. Because of the high throughput of related-art dynamic inhalation systems, such systems often do not provide the longer inhalant residence times needed for these studies. For example, related-art dynamic systems have aerosol residence times of less than a minute. A system that could increase these times would be advantageous for inhalation studies requiring aged aerosols.

Related-art static inhalation systems operate by disseminating an inhalant into an exposure chamber and then stopping the inhalant dissemination device and all air flows. The animals in the exposure chamber then inhale this static inhalant atmosphere. Related-art static inhalation systems have a number of drawbacks that make them unattractive for inhalation toxicology studies.

One drawback of related-art static inhalation systems is that related-art static inhalation systems do not provide a mechanism for real-time dose calculation. Related-art static inhalation systems require that the cycle time and the cycle dose be determined prior to exposure. There are no related-art static inhalation systems that allow the inhaled dose to be determined in near real-time during the exposure.

Another drawback of related-art static inhalation systems is that related-art static inhalation systems require that doses be delivered to animals in discrete units. Animals inhale the inhalant atmosphere until the inhalant concentration approaches zero. If an additional dose is required, the test atmosphere must be reestablished with the inhalant dissemination device and the animals allowed to inhale the environment until the inhalant concentration approaches zero again. When running an inhalation study with a static system, therefore, the operator must first calculate the starting concentration required for a particular number of exposure cycles to achieve a desired dose. To expose another set of animals to a different dose, the operator must recalculate the starting concentration and the number of cycles required. Static systems do not provide a mechanism for delivering any dose to the test subject with the same starting concentration and independent of the number of static cycles. The need to change inhalant