



# 13-Week GLP Toxicity Study of the Odorox<sup>®</sup> Boss<sup>™</sup> Hydroxyl Air Cleansing Machine in Rats

**Study Number: CB10-5065-R-TX**

## **SUMMARY**

On March 1st, 2011 HGI Industries initiated a comprehensive Good Laboratory Practices (GLP) Toxicity Study to evaluate the potential effect on rats exposed to Odorox<sup>®</sup> treated air. As a category, the FDA does not regulate or require premarket approval for UV irradiation air cleaning devices, like the Odorox<sup>®</sup> Boss<sup>™</sup> machine, since they irradiate ambient air and sanitize in a manner similar to that found in nature. This study was conducted at Comparative Biosciences, Inc. (CBI; Sunnyvale, CA) in compliance with the US Food and Drug Administration's GLP regulations (21 CFR Part 58). Combined with research and analysis on the composition of the chemical species produced by the Odorox<sup>®</sup> Boss<sup>™</sup> machine, completed by Lovelace Respiratory Research Institute and Dr. David Crosley, this study concluded that the rats tolerated exposure to the Odorox<sup>®</sup> Boss<sup>™</sup> hydroxyl air cleansing machine well and that no detectable toxicity was observed.

The CBI study consisted of two groups of Sprague-Dawley (SD) rats: a treated group (20 males and 20 females) housed for 13 weeks in a 18.78'(L) x 9.69'(W) x 9.05'(H), 1646.90 cubic feet room in which two Odorox<sup>®</sup> Boss<sup>™</sup> Hydroxyl air cleansing machines were operating continuously for 13 weeks; and a control group (10 males and 10 females) housed for the same period in a different room under similar housing conditions, but not exposed to the Odorox<sup>®</sup> Boss<sup>™</sup> Hydroxyl air cleansing machines.

During the trial, the performance of the two Odorox<sup>®</sup> Boss<sup>™</sup> Hydroxyl air cleansing machines was continuously monitored and logged to ensure normal equipment function. Since hydroxyl radicals are difficult to measure directly using conventional methods, oxidation by-products proportional to hydroxyl radical formation were monitored using an industry standard

electrochemical oxidant detector. The Odorox<sup>®</sup> oxidant levels were intentionally maintained between 100-125 ppbv, a level representative of 2-3 times that of normal use and above the OSHA guidelines of 100 ppbv for 8-hour exposure. Under normal operation, the measurements correlate to a steady state hydroxyl radical concentration similar to that found in nature (on the order of  $1 \times 10^6$  molecules/cm<sup>3</sup>). The animals were also exposed to the by-products of the reaction of the hydroxyl radicals and oxidants with routinely present volatile organic compounds. This data is based on studies conducted by the Lovelace Respiratory Research Institute and analysis provided by Dr. David Crosley; both independent, third party experts in the field of atmospheric hydroxyl radical measurement and chemistry.

Both test and control groups of rats underwent the same comprehensive evaluations including: daily clinical observations with focused attention to the eyes, nose, respiratory system, weekly body weights, and food consumption measurements. Periodic functional observational battery (FOB) tests were also completed with a special focus on respiration, eyes, neurotoxicity, mucous membranes, ophthalmological examinations, hematology and clinical chemistry analyses. A complete set of tissues were evaluated by a board-certified veterinary pathologist, with special attention to the skin, eyes, nasal turbinates, larynx/pharynx, and respiratory system. No mortality or unscheduled deaths occurred in either the exposed or control populations. Exposed animals during in-life studies were judged to tolerate the exposure well with no abnormal clinical observations. Interestingly, it was noted that treated animals appeared to be more alert during the day-light hours than untreated animals.

There were no histopathology differences between the control rats and the exposed rats. During analysis specific attention was paid to the skin, eyes, nasal turbinates, larynx/pharynx, and respiratory system. There were no changes in these organs and they appeared to be within normal limits in both the control and treated animals.

The results of these studies further support the safety assessment requested from the National Institute of Environmental Health Sciences. They conducted a comprehensive search of the National Institute of Health files, including PubMed and the National Library of Medicine, and

did not find “any hard science or research indicating that hydroxyl radical generation is harmful to human health. That applies to both atmospheric and man-made generation” (NIH/NIEH Office of Communications). HGI is taking the lead to further the research and science of hydroxyl radicals and their unique characteristics.

**“Thus, the results of this study indicate that the Odorox<sup>®</sup> Boss<sup>™</sup> Hydroxyl air cleansing machine was well tolerated by SD rats and did not induce any detectable toxicity under the conditions used in this experiment.” CBI**

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