

# SAFETY AND CLASSIFICATION OF THE ASEA REDOX SUPPLEMENT

RESEARCH ASSESSMENT 

As a company that works with relatively new technology, ASEA knows that scientific research is essential in demonstrating the value and safety of redox signaling technology and our products. The popularity of ASEA's products continues to grow, and as the global trend of cellular health increases, it is important to understand how the company has ensured that the products are safe and that they meet the highest level of production standards.

## THIRD-PARTY REDOX VALIDATION

To further validate our own internal testing, we have established partnerships with sophisticated and accredited chemical-analytical laboratories. These third-party labs offer a wide catalog of assay kits and electrochemical devices to help us measure multiple redox parameters. Their teams include chemists, biotechnologists, and biologists with industrial and postdoctoral experience, all who help monitor and analyze data markers such as total antioxidant capacity (TAC), enzymatic activity, phenolic compounds, and reactive oxygen species (ROS).

## ASEA REDOX SUPPLEMENT HUMAN CONSUMPTION SAFETY STUDY

 Human Performance Laboratory  
APPALACHIAN STATE UNIVERSITY

A study conducted by researchers at

Appalachian State University looked at ASEA Redox Supplement consumption by 106 people and found that those who participated reported no adverse effects throughout the course of evaluation.

## Study Protocol

For this randomized, placebo-controlled study, a total of 106 overweight women, ages 20 to 73 years, ingested four fluid ounces of ASEA Redox Supplement or placebo each day for 12 weeks in randomized groups under double-blind conditions. The placebo beverage contained a pure saline solution similar to ASEA Redox Supplement but without catalytic processing.

## Results Summary

Blood samples were collected pre-study and then monthly during the study and analyzed for comprehensive diagnostic chemistries at the Carolina Medical Center Clinical Laboratory in Charlotte, North Carolina. ASEA Redox Supplement compared to placebo ingestion over 12 weeks was not associated with changes in liver and kidney function in these subjects. Complete blood counts (CBC) were measured pre- and post-study, and showed no group differences over time for hemoglobin, hematocrit, and red blood cell counts.

Participants reported no adverse effects, and investigators found that no significant group differences were measured. Based on this evidence, the researchers concluded that ASEA Redox Supplement is safe for human consumption under the recommended usage instructions.

## ASEA REDOX SUPPLEMENT IN VITRO PRODUCT SAFETY STUDY

  
Pacific Northwest  
NATIONAL LABORATORY

ASEA commissioned Pacific Northwest National Laboratory to study the toxicity response of eukaryotic cells when in contact with ASEA Redox Supplement.

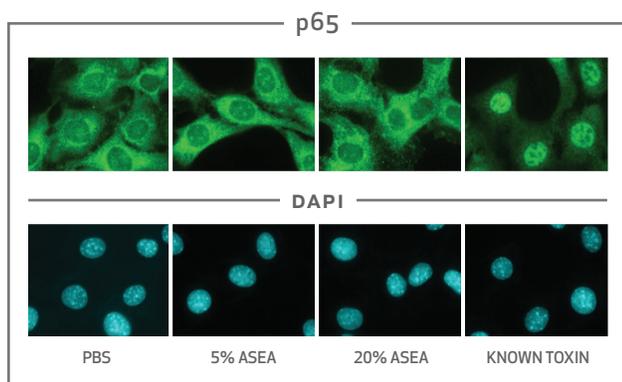
Eukaryotic cells contain an array of cellular structures that play important roles in energy balance, metabolism, and gene expression.

These cells, when stressed by a toxin, respond by sending transcription factors—proteins that control which genes are turned on or off—into the nucleus. Once inside the nucleus, these transcription factors activate the genes responsible for cellular defense and protection against toxins. The arrangement of the chromosomes (called translocation) of particular transcription factors into the nucleus can be seen under a fluorescent microscope when specific indicator dyes stain the cells.

If the cell undergoes a toxic response, the fluorescent dye is pulled into the nucleus along with the transcription factor. In this experiment, two transcription factors, the p65 subunit of NF-kappaB and P-Jun, were monitored. These two transcription factors are known to activate in all toxic responses.

### Study Protocol

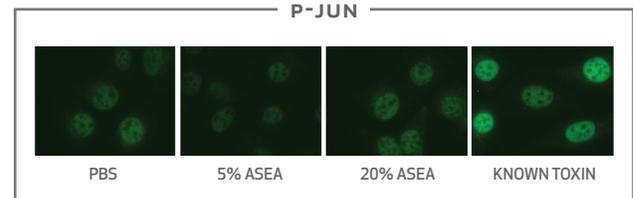
In the photographs from the fluorescent microscopic images of the cells, a toxic response is registered if the green dye is seen to move into the nucleus.



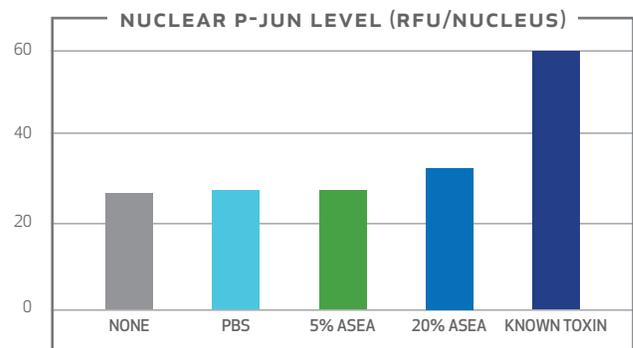
The target cells were cultured and exposed to:

1. Phosphate buffered saline (PBS)—the negative control where no toxic response was expected
2. 5% ASEA Redox Supplement—supplementing the equivalent to replacing 5% of a blood plasma solution with ASEA Redox Supplement

3. 20% ASEA Redox Supplement—Supplementing the equivalent to replacing 20% of a blood plasma solution with ASEA Redox Supplement
4. A known toxin—the positive control where a toxic response was expected



The reaction of the transcription factors (tp65 subunit of NF-kappaB and P-Jun), were photographed under a microscope after exposure to the four solutions. A DAPI stain was applied to the nuclei to help computer software to identify the cell nucleus in the pictures.



### Results Summary

Visual evidence from the study manifested that direct exposure of cells to relatively high concentrations of ASEA Redox Supplement does not register a significant toxic response as measured by nuclear translocation. Based on these results, ASEA Redox Supplement, orally administered, does not manifest a toxic response or inflammation to exposed tissue.

## ASEA AND THE FOOD AND DRUG ADMINISTRATION (FDA)

ASEA Redox Supplement is classified as a dietary supplement in the United States. Although the FDA does not sanction approval processes for dietary supplements, ASEA Redox Supplement is FDA regulated.

As a company, ASEA cares deeply about following the guidelines set forth by the FDA and always complies with regulations and/or manufacturing requirements.

The FDA oversees dietary supplements under a different set of regulations than those covering conventional foods and drug products. Dietary supplement manufacturers and distributors are not required to obtain approval from the FDA before marketing their products. Before a company sells a dietary supplement, it is responsible for ensuring that the product it manufactures or distributes is safe, that any claims made about the product are not false or misleading, and that the product complies with the Federal Food, Drug, and Cosmetic Act and FDA regulations in all other respects. (1) These laws apply to topical products as well as to foods and supplements. ASEA also complies with DSHEA labeling laws.

ASEA Redox Supplement and RENU Advanced Skin Care products follow these guidelines. Additionally, the products are manufactured according to FDA\* regulations and best practices, and the company has invested in third-party research studies to prove these products are both safe and effective.

## PRODUCTION REGISTRATION



How a company manufactures a product and the facilities it uses to make the product are equally important to both the FDA and to consumers. The NSF International—a global public health and safety organization that provides food safety and quality assurance services across all food supply chain sectors—registers ASEA's production center as a GMP (Good Manufacturing Practices) compliant facility. This registration confirms ASEA's products comply fully with the regulations set forth by the FDA as they relate to the production and testing of dietary supplements with specific standards for safety and quality.

These studies, along with ASEA's facility endorsement and GMP compliance, further show ASEA's commitment to safety and efficacy. ASEA works to maintain these requirements so consumers can be confident that its products are safe and meet all quality standards the FDA has established for the production and testing of dietary supplements.

\*The ASEA production facility is registered with the FDA, meaning that we agree to follow all current GMP guidelines for dietary supplements Section 21 CFR, part 111.