

RUSH™

white paper provided by Archmore Botanical Research Group, LLC

*A Javita
International
product*



Rush™, an ActiveBlendz product

a Javita International product

- A technical overview outlining the safety and efficacy of Rush™, a dietary supplement designed to support energy levels and energy metabolism*
- This technical white paper will include:
 - Formulation breakdown
 - Synopsis of health benefits associated with the proprietary ingredients
 - Efficacy
 - Cellular, animal, and human trials demonstrating increased energy
 - A review of any negative outcomes found in clinical trials using the proprietary ingredients
 - Potential secondary health benefits outside the scope of energy enhancement
 - Safety
 - In vitro and in vivo trials demonstrating the safety of ingredients in Rush™ at recommended levels
 - A review of any adverse events associated with the ingestion of the proprietary ingredients
 - Recommended guidelines for use
 - Dosing recommendations for increasing energy levels*
 - Potential adverse events and warnings

**These statements have not been evaluated by the Food and Drug Administration and are meant for research purposes only.*



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Overview

Energy metabolism is the general process by which living cells acquire and use the energy needed to stay alive, to grow, and to reproduce. As we age, we experience stress in many forms. This could be physical, emotional, mental, etc. Much of this stress diminishes our energy levels through oxidative damage that can weaken the cellular proficiencies in the body. To improve metabolic efficiencies that result in increased energy, Rush™ stimulates the central nervous system and helps to protect from this detrimental oxidative damage.

By formulating the beverage Rush™, Javita met consumer demands for an effective energizing natural product that could provide an immediate feeling of energy but also help improve energy metabolism for long term positive benefits. Rush™ accomplishes this through the combination of caffeine from green coffee beans and EGCG from green tea. Caffeine provides the initial stimulation to the circulatory system, resulting in improved performance and endurance for the immediate tasks at hand. EGCG, a powerful catechin from the leaves of green tea, works as an antioxidant, helping to regulate overall energy metabolism. This allows for existing energy reserves to be utilized more effectively. It also plays a beneficial role in protecting cells from future oxidative stressors that might be contributing to cellular fatigue.

This combination product is delivered in an easy to transport powdered drink mix that can be consumed anytime during the day when immediate energy is needed. Its energizing effects will be felt up to 6 hours after consumption due to the caffeine content, yet the internal cellular benefits from the EGCG will have more long term benefits for regulating energy metabolism.



Formulation

Rush™ was designed to provide an immediate increase in energy to assist consumers in improving performance and endurance, while simultaneously addressing the underlying oxidative stress that might be causing cellular fatigue and inefficient energy metabolism. It was formulated using the highest quality green coffee beans and green tea leaves, supplying the two key ingredients: caffeine and epigallocatechin gallate (EGCG), respectively. These two ingredients work synergistically to provide both immediate and long term benefits for energy metabolism.

- Formulation includes two key herbal ingredients for enhanced efficacy
 - Caffeine from green coffee beans provides immediate energizing effects
 - Increases energy through the stimulation of the central nervous system
 - EGCG from the leaves of green tea regulates energy metabolism
 - Acts as an antioxidant that can promote a more efficient break down and utilization of existing energy reserves
 - Protects cells from oxidative stressors that may cause cellular fatigue and inefficiencies in energy metabolism



Green Coffee – Background Information

Green coffee beans are the same coffee beans used to make your morning cup of Joe, yet they have not yet been roasted. They are sent through an extraction process instead to concentrate various compounds, in particular methylxanthines such as caffeine. By extracting instead of roasting, the taste of the green coffee bean is dramatically different than that of a roasted bean, allowing it to be delivered in different dosage forms than coffee, namely juices, fruit cocktails, supplements, and powdered beverages.

The major benefits from the green coffee bean extract lie in the concentration of caffeine. Caffeine is a natural stimulant that can provide an immediate feeling of energy itself and also enhance metabolism. By speeding up the metabolic process, additional energy stores already in the body can be utilized.

Although there has been a controversy over whether green coffee may aid in weight management, there have been some small trials done that indicate it may assist in preventing weight gain and possibly lower blood pressure. These studies are preliminary, and more work needs to be done in this area. However, as an energy drink, Rush™ improves energy levels needed to increase physical activity in order to burn more calories, indirectly leading to healthy weight management as a positive side benefit.

Most of the safety concerns associated with green coffee concern the caffeine content itself. For those negatively affected by caffeine, care should be taken when consuming the product. However, in most consumer and clinical trials, no adverse safety events have been seen with the consumption of green coffee extract.



EGCG from Green Tea- Background Information

EGCG stands for epigallocatechin-3-gallate, and it is the ester of epicallocatechin and gallate. It is classified as a catechin, a secondary plant metabolite and powerful antioxidant. This catechin is found in high concentrations in the leaves of *Camellia sinensis*, commonly known as green tea. Green tea has been consumed for more than 4,000 years, with its origins believed to be in China. Due to the popularity of this beverage and the rich traditional aspect of its consumption, more than 600 different cultivars are currently in circulation. These varieties all contain various concentrations of beneficial compounds; Javita selected an extract standardized for a high concentration of EGCG for targeted health benefits.

Although centuries of historical use have deemed this botanical safe for human consumption, the discovery of EGCG has prompted much research to be conducted for its health benefits. Among these are antioxidation, energy balance, and energy metabolism.

EGCG has been shown to provide cardio and cellular protection for those cells experiencing oxidative stress. This stress may be the result of environmental stressors or the stressors one encounters that cause fatigue, i.e. mental stress, physical stress, or aging. By protecting against oxidative damage, EGCG assists the body in combating fatigue caused by stress on the cellular level.

In studies demonstrating the antioxidant benefit of EGCG, it was also noted that EGCG plays an instrumental role in regulating energy metabolism. This will aid in promoting the feelings of energy desired from Rush™ by more efficiently using natural energy reserves already present in the body. This will also assist in elevating energy metabolism over the long term, as more regulated mechanisms will be in place on a cellular level.

In addition, the combination of caffeine plus EGCG has been shown to have a positive effect on energy expenditure. These results were dependent on the concentration of EGCG and caffeine found in specific varieties of green tea, with higher concentrations producing more promising results. It was these concentrations that Javita targeted when formulating Rush™.



Formulation Efficacy- A Detailed Review of Available Studies

In order to provide enhanced energy to those consuming Rush™, multiple mechanisms of action are at work from the two key ingredients. Outlined below are those conclusively defined in available peer reviewed literature. All research is cited should further investigation be desired.

- Green Coffee extract, standardized for caffeine content
 - Increases energy through stimulation of the central nervous system
- EGCG from Green Tea
 - Plays a role in regulating energy metabolism through antioxidation
 - Antioxidative benefits protect cells from stressors that may cause fatigue

In addition to the energizing effects noted above, these botanical ingredients have also been studied for their potential to benefit blood pressure and weight management. Most studies in these categories are preliminary. Some are promising; however, these are not the targeted claims for this product. Therefore, this white paper will leave these two parameters out of the detailed review.



Green Coffee Extract- Mechanisms of Action

Mechanism of Action: Increases energy through stimulation of the central nervous system

Caffeine is a methylxanthine used to stimulate the central nervous system, and is the main compound to which green coffee extract is standardized in Rush™. Caffeine is the world's most widely consumed psychoactive substance for its positive energy effects with minimal side effects. It functions in numerous ways in the central nervous system, including acting as an antagonist at the level of the adenosine receptors. This allows caffeine to increase energy metabolism in the brain, which has resulted in improved memory, as demonstrated most recently in elite golfers (1).

In addition, it promotes alertness in the brain and helps to maintain anxiety-related and physiological and behavioral responses through its action on serotonin neurons (2). This puts it in a category of anxiolytic, meaning that it may help reduce feelings of anxiety and stress via this mechanism of action.

All of these mechanisms result in the energizing effects one experiences when consuming caffeine. The outcome of this is that learning, memory, performance and coordination are often improved with the consumption of caffeine due to the methylxanthine's action on vigilance, arousal, and fatigue (3).

In addition, caffeine is usually consumed without the central nervous system developing a great tolerance to the compound; thus, caffeine will continue to provide stimulation to the central nervous system even when consumed regularly. Some dependency and withdrawal systems, however, have been noted in clinical trials, although the benefits on the central nervous system continue to be experienced (4).



Green Coffee Extract- A Review of Negative Outcomes From Clinical Trials

There has been a study conducted on green tea and a few other botanicals to determine their effects on protein and energy utilization. In this animal experiment, various botanicals including green coffee were administered, and protein digestibility and digestible energy were measured. Green coffee was one of many botanicals that had slightly negative effects on these values. However, researchers noted that the observed effects may have been in part due to the anti-nutritional effects of tannin, a compound present in whole green coffee beans (5). The green coffee extract used in Rush™ has been processed to remove the majority of tannins; therefore, these deleterious results on protein digestibility should not be observed in consumers.

Although the research cited earlier shows the positive benefits of green coffee extract for use in increasing energy, mental focus, and performance, there has been controversy surrounding the published and non-published research evaluating this herb for use in weight management and blood pressure lowering. As these are not the focus for this product, they will not be addressed further in this white paper.



EGCG from Green Tea- Efficacy

Mechanism of Action: Assists in Regulating Energy Metabolism through Antioxidation

In an animal trial to determine the metabolic response to EGCG after chronic administration, researchers tested several parameters, one being the concentration of adipose tissue deposits. After EGCG dosing, these deposits were significantly decreased. Researchers concluded that EGCG assisted in regulating the metabolism of these energy stores in the body. They hypothesized that this was accomplished through its powerful antioxidative effects (6).

In a separate trial conducted by different researchers, similar results were seen in terms of energy metabolism; however, these researchers did not attest to the antioxidative effect of EGCG for the regulation of energy metabolism but rather to the effect EGCG has on the growth of certain species of gut microbiota. These particular microbiota are associated with a pattern of short chain fatty acids which may be responsible for this regulation of energy metabolism (7). A much earlier study had conclusions similar to this study, in that they found the fat oxidation (and thus energy metabolism) was due to a reduction in digestibility caused by EGCG. This could have been due to the gut microbiota the latter researchers discovered or by increased fat and nitrogen excretion seen in a later study (8, 9). Regardless of the underlying cause, all research teams asserted to the powerful benefit EGCG has on regulating and improving energy metabolism in vivo.

Although energy expenditure had been seen in several studies previously, researchers in one particular study wished to show energy expenditure via a different mechanism than fat oxidation and metabolism. They chose to measure shivering intensity during a cold exposure period. In this scenario, they proved that EGCG, when combined with caffeine, significantly increased energy expenditure compared to placebo in healthy adults exposed to cold, thus reducing shivering activity. This was a novel approach to demonstrate EGCG's effect on energy metabolism (10).

This increase in energy expenditure was also seen when exercise was increased in subjects. In two studies conducted following a counter-balanced crossover design, twelve healthy individuals performed a cycling exercise at a moderate rate and were supplemented at various points with green tea extract or placebo. Average fat oxidation rates were significantly higher in the green tea group than with placebo, and the contribution of fat oxidation to total energy expenditure was also significantly higher.



Researchers concluded that green tea extract increases fat oxidation during moderate-intensity exercise better than exercise alone (11). A separate study noted that EGCG also improved endurance capacity and increased muscle lipid oxidation, a benefit for those wishing to improve endurance and performance (12).

Finally, an increase in energy expenditure from a combination of EGCG and caffeine was noted in a short term study. This was accomplished using healthy subjects in a randomized, placebo-controlled, double-blind, cross-over study. Twenty-four hour energy expenditure, substrate oxidation, and blood pressure were all measured to determine the change with EGCG-caffeine administration. Although there was no significant change in systolic, only diastolic, blood pressure after 24-hours, there was a significant increase in 24-hour energy expenditure with this combination product (13). This demonstrates the more immediate results that will be felt with the combination formula found in Rush™.

Mechanism of Action: Antioxidation for Cellular Protection

Although not mutually exclusive from energy metabolism, it should be noted that the antioxidant benefits of EGCG additionally have cellular protective benefits as seen in clinical research. This is important in an energy product, as much energy loss may be caused by oxidative stress. By reducing and reversing this damage, energy may be further enhanced simply due to more efficient cellular processes. In a cellular study, researchers used eight proteins associated with energy metabolism as biomarkers for oxidative stress. When EGCG was administered as a pretreatment prior to a stressor, all of the effects of the stressor were reversed. They concluded that EGCG acts as a preventative agent for oxidative stress and protects from cell injury (14). These results were recreated using cells from a different region of the body, showing a protective effect of antioxidation from EGCG as being more universal (15).

In a study to determine the effect of EGCG on cognitive function, several oxidative stress markers were evaluated following administration of this catechin. It was shown that cognitive deficit, nitric oxide metabolites, and reactive oxygen species were completely reversed by EGCG administration. Researchers attested to the powerful neuroprotective potential of this compound, attributing the benefits to its antioxidative effects (16).



Finally, the protective effects of EGCG against oxidative stress were found to be comparable with caloric restriction, a well-established dietary intervention proven to slow the oxidative aging process. By having a similar effect, EGCG may assist with the detrimental side effects of aging, namely fatigue and mental decline (17).

EGCG from Green Tea- A Review of Negative Outcomes From Clinical Trials

There have been a handful of studies involving EGCG that have not shown positive benefits; however, these studies generally involved weight management, fat reduction, and blood pressure reduction. While none of these parameters are claims intended with the product Rush™, they will be briefly addressed here.

Several in vitro and animal trials strongly demonstrate that EGCG found in green tea extract has a pronounced effect on enhancing energy expenditure and fat utilization, the desired effects from Rush™. These studies have been outlined above. There have been very limited human trials measuring these same parameters, namely because the desired effect for an energizing, fat utilizing product tends to be weight management. Therefore, the end parameters measured have been in body composition and fat loss rather than energy expenditure alone. EGCG has not reduced body composition parameters successfully in these studies. Some researchers believe this lack of result is due to the various study designs used, a variation among subjects (age, gender, ethnicity) across studies, chemical forms of the extracts used, and confounding factors such as other weight-reducing agents (18). As weight management can be impacted by so many of these confounding factors, more controlled studies with less variables will need to be conducted to determine EGCG's true efficacy or lack thereof in this arena. However, as this was not the design of this particular formula, no further comments will be addressed here.



Safety

Rush™ was designed to be safe and effective for everyday consumption in healthy individuals wishing to improve energy levels. This refreshing beverage contains herbal ingredients with very long histories of safe use. However, it does contain moderate levels of caffeine. Therefore, care should be taken by those individuals wishing to eliminate or limit their caffeine intake or those whose health care practitioners have advised them to avoid such stimulants.

- Rush™ was designed to improve energy levels with a single cup daily but that two cups per day could be safely consumed for those who tolerate caffeine well
- All safety studies and warnings outlined below are relevant to the dosages recommended for Rush™ on a daily basis
- Adverse safety and toxicity trials and warnings are also reviewed



Green Coffee Extract- safety

Green coffee is the starting point from which all roasted coffee originates. Therefore, there is a significantly long history of use for this beverage and thus much information regarding its main chemical compound: caffeine. As green coffee as a whole does not appear to pose major health concerns nor serious adverse side effects, the focus of this safety evaluation will be on the caffeine itself.

Caffeine is regularly consumed by most adults at an intake level of 200mg per day, according to the FDA. At these moderate consumption levels, naturally occurring sources of caffeine are not associated with adverse effects, according to the FDA Commissioner (19). Because of the multiple ways it is dosed, however, caffeine has been classified by the FDA as both a drug and a food additive; therefore, it carries some warnings and advisements from the FDA.

Caffeine is a diuretic; therefore, consuming it with water helps to maintain a proper water balance in the body to avoid dehydration. Rush™ is an optimal dosage form for an energizing drink containing caffeine, as it must be mixed with water in order to be consumed. This may help balance the water that may be lost due to the caffeine itself.

Large amounts of caffeine may be harmful during pregnancy; therefore, women who are pregnant or planning to get pregnant should speak with their health care professional prior to using any product containing caffeine.

Caffeine affects individuals differently depending on their body composition. Therefore, individuals sensitive to caffeine should reduce or refrain from consuming caffeine-containing beverages.

Caffeine is not intended for use by children. Consult your health care professional before administering any caffeine-containing product to a child.



EGCG from Green Tea- safety

Over 4,000 years of documented historical use have shown the safety of green tea as a beverage regularly consumed throughout the world. However, with the extraction and concentration of the tea to isolate the main catechin, EGCG which is utilized in Rush™, more stringent safety evaluations have been conducted.

In a double-blind, placebo-controlled, randomized trial on women with breast cancer, a high dosage of green tea extract was well tolerated by more than one thousand participants. There were no significant differences in the percentage of women with adverse events in the placebo group versus the extract group. Those who did experience side effects reported minor nausea or dermatologic symptoms, and these were transient (20).

An initial animal study was conducted to evaluate low and high doses of EGCG on liver and kidney tissues over a 6-month period. Both the low and high doses were well-tolerated by the animals without causing tissue damage or dysfunction to either the liver or kidneys. This was determined using both histopathological and biochemical observations (21). Similar results were recreated in humans, where researchers used a randomized, double-blind, placebo-controlled format to evaluate EGCG in over eighty female test subjects. At a comparable dosage to Rush™, EGCG did not cause any adverse effect on liver function biomarkers even when consumed daily for 12 weeks (22).

A different type of safety study was conducted to determine the effects EGCG has on sperm survival and metabolism. In this study, various levels of EGCG were administered to sperm in vitro. All levels increased sperm motility, viability, and phosphorylation of proteins controlling cell survival, indicating a beneficial effect on sperm survivability and functionality (23).



Usage Guidelines

Rush™ is meant to provide a natural energizing stimulation to aid consumers in daily performance and endurance. It was formulated such that 1-2 cups could be consumed safely each day to achieve optimal health benefits.

As noted in this white paper, Rush™ does contain a moderate amount of caffeine. Therefore, those sensitive to caffeine or wishing to limit their caffeine intake should avoid consumption.

By taking this product according to the package recommendations, one should experience the positive benefits as outlined in this white paper. Results will differ between individuals, as no two bodies act identically when faced with the same stimulus. However, the general results should include

- An increase in energy expenditure as exhibited by improved focus and performance

As caffeinated products have a lasting benefit of up to 6 hours, they should not be consumed prior to going to bed. This may negatively affect sleep patterns. It is recommended to consume Rush™ in the morning or early afternoon to avoid this consequence.

As always, pregnant and nursing women as well as children should limit their caffeine intake and consult their health care professional before beginning any supplement program.

Should adverse effect be felt when consuming any supplement, discontinue use, and contact your healthcare professional immediately.



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