7-KETO®

Innovative Weight Loss
In today’s weight loss marketplace, both manufacturers and consumers are looking for products that are safe as well as effective. 7-Keto™ has filled this space by offering four key benefits:

- Excellent safety profile.
- Industry leading efficacy.
- Boosting metabolism without stimulants.
- World-class clinical trial pedigree.

7-Keto (a trade name for the compound 3-acetyl-7-oxo dehydroepiandrosterone or 7-oxo DHEA) is a substance found naturally in the body and its presence in human urine was documented in 1958. It is metabolized from the hormone DHEA, and like DHEA, it is known to decline with age. Supplementing with 7-Keto is simply putting back what time and Mother Nature have taken away.

Humanetics Corporation, the developer of 7-Keto, has invested significant time and money into a methodical research program that has spanned over the past 16 years. Among other things, this research has included rigorous toxicology, pharmacokinetic and human safety trials. These studies strongly support that 7-Keto is non-toxic, cannot accumulate in the body over time, does not affect any hormone levels and is free of any serious side effects. Of even more importance, 7-Keto has been sold commercially as a dietary supplement since 1998 and, in this time, has not been linked to any serious adverse effects.

Being safe is of utmost importance; however, to market a compound requires that it have a benefit to the consumer. A patent was issued in 1994 for the use of 7-Keto for effecting weight loss and preventing weight gain. The patent is built upon the discovery that 7-Keto is a potent activator of 3 important thermogenic enzymes. These enzymes are known to play an important role in helping the body convert stored fat to energy. The first of two randomized, double-blinded, placebo-controlled (“RDBPC”) weight loss clinical trials was conducted in 1999. This study indicated that 7-Keto increased weight loss over an eight week period by a factor of three times versus placebo. A second trial was commissioned in 2000 to confirm these results. The second trial, also RDBPC, confirmed that weight loss over an eight week period could be increased by a factor of 3 times. Importantly, each of these studies confirmed that more than 80% of the weight lost was fat. Each study controlled for diet, exercise and diuresis effects and both have been published in international peer reviewed journals.

Results of an additional human clinical study reveal that administration of 7-Keto to overweight adults in conjunction with a calorie restricted diet will effectively reverse the decline in resting metabolic rate (RMR) normally associated with dieting. 7-Keto plus a restricted calorie diet demonstrated an increase in RMR by 1.4% above baseline levels versus a 3.9% decrease in RMR in the restricted calorie diet only group. Therefore, the addition of a 7-Keto to a restricted calorie diet produced a statistically significant 5.4% increase in daily RMR when compared to a calorie-restricted diet only.

The documented science behind 7-Keto provides strong support that it is safe and effective for helping consumers lose weight and maximize results from diet and exercise. The purpose of this document is to provide you with a brief but thorough overview of this science. Read on and find out why 7-Keto is becoming the ingredient of choice for major nutraceutical marketing companies.

The DHEA Dilemma

DHEA, also known as dehydroepiandrosterone, is synthesized in the adrenal cortex from cholesterol via pregnenolone by the action of an enzyme called cytochrome P450. It is the most abundant adrenal steroid in humans and is the precursor for many important steroid hormones, which includes estrogen and testosterone. In contrast to cortisol and other adrenal steroids, DHEA levels decline with age. Levels of DHEA increase through the second decade of life and then begin to decline to negligible amounts at ages greater than 70 years. We experience a 40% reduction in DHEA levels between ages 20 and 40. Since DHEA is the major androgen precursor in humans, men have 30% higher DHEA levels than women throughout their lives.
Recognizing that the bioactivity of DHEA must rest with one or more of its many metabolites, Dr. Henry Lardy led the search for more specific and active metabolites of DHEA. Dr. Lardy is Vilas Professor Emeritus of the Institute for Enzyme Research at the University of Wisconsin in Madison. Dr. Lardy is renowned for his research on DHEA derivatives and has published over 400 studies in peer-reviewed scientific journals.

To search for possible metabolites of DHEA that might have greater biological activity, greater specificity, and fewer propensities to form sex hormones, Dr. Lardy initiated a program assaying the derivatives of DHEA. The activity of 150 of these metabolites was monitored by measuring the induction of two thermogenic enzymes, mitochondrial glycerol-3-phosphate dehydrogenase and cytosolic malic enzyme. The results of this landmark study were published in the journal Steroids in 1998 and revealed that many of these steroids did not induce the activity of these thermogenic enzymes whereas the 7-oxo DHEA ("7-Keto") metabolite did. In fact, 7-oxo DHEA was 2.5 times more active than DHEA at inducing the activity of these thermogenic enzymes. More importantly, Dr. Lardy discovered that in contrast to DHEA, the 7-oxo DHEA metabolite was not convertible to compounds with estrogenic or androgenic activity.

7-oxo DHEA is a naturally occurring DHEA metabolite in humans and was first discovered in the urine of human volunteers in 1958 by Gallagher. In later work by Marenich, it was discovered that the urinary excretion of 7-oxo DHEA declines with age in a similar manner to its parent steroid DHEA.

Based on these discovered advantages, the 7-oxo DHEA metabolite was chosen for further study as a weight loss ingredient.
In 1993, Bobyleva et al demonstrated in a rat model that 7-oxo DHEA caused an increase in liver catalase activity, rate of mitochondrial substrate oxidation and fatty acyl-CoA oxidase activity. Brand et al reported in 1988 that the elevated thermogenesis associated with hyperthyroidism may result from an increase in proton conductance across the mitochondrial membrane causing a lower membrane potential and greater thermogenesis. In 1998, Lardy et al reported that 7-oxo DHEA is a more active inducer of glycerol-3-phosphate dehydrogenase (G3PD) and malic enzyme than its parent steroid DHEA.

Considering that 7-oxo DHEA and thyroid hormone activate similar mitochondrial and cytosolic thermogenic enzymes, Bobyleva et al then studied 7-oxo DHEA using a similar rat system model. Sprague-Dawley rats which were treated with respiratory inhibitors (succinate and G3PD) showed that when further treated with 7-oxo DHEA, they experienced a more rapid decline in membrane potential, indicating enhanced thermogenesis. Realizing that the pharmacokinetic profile of 7-oxo DHEA is similar to that of thyroid hormone, these investigators went on to test 7-oxo DHEA in both the euthyroid and hypothyroid rat. 7-oxo DHEA had no effect in the euthyroid rats but restored mitochondrial function in the hypothyroid rat. These investigators were not certain of the mechanism by which 7-oxo DHEA was able to exert these effects, but since 7-oxo DHEA had no influence at all when added directly to the test systems, they speculated that 7-oxo DHEA is converted to a metabolite that is recognized by a member of the steroid/thyroid hormone superfamily of receptors. Since it is known that 7-oxo DHEA does convert to other in vivo metabolites, this concept remains a viable explanation.

This extensive pre-clinical investigation demonstrated 7-oxo DHEA’s ability to enhance thermogenic enzyme activity at multiple levels and led to its further investigation as a weight loss ingredient in humans.
Safety Studies

Prior to any commercial sale of 7-oxo DHEA, Humanetics Corporation commissioned a series of thorough toxicology evaluations. These studies were conducted using pharmaceutical industry protocols. They started with basic preclinical toxicology studies and culminated in a Phase I safety trial in humans. The majority of these studies have been published in peer review journals. (See References)

The preclinical program consisted of four toxicology evaluations, the design and results of which can be seen in the table. These studies indicated that 7-Keto is not toxic and does not alter any significant body organs or processes, even at extremely large doses.

Confirmation of the lack of toxicity in our preclinical studies led to the confidence to put 7-Keto into an escalating dose human safety trial. This double-blind and placebo-controlled trial was conducted at the Chicago Center for Clinical Research. The results were published in Clinical Investigative Medicine 2000, and indicate that 7-Keto is safe for human consumption at doses up to 200mg per day. The conclusion of the principal investigator was as follows, “[7-Keto]…which is not converted to estrogens and androgens, was found to be safe and well-tolerated…at doses up to 200mg/d. [7-Keto] was found to lack any of the clinically significant hormone elevating action that has been reported with DHEA supplementation.”

Careful toxicology and safety studies are paramount to ensuring the basic premise of safety for any ingested compound, which is especially true in today's market. However, most dietary supplements lack this level of thorough study and many lack even basic toxicology research. As many weight loss compounds come under scrutiny for safety, 7-Keto provides peace of mind that it can be used safely.

Pharmacokinetics

A complete pharmacokinetic analysis of 7-oxo DHEA was performed as part of the clinical safety study performed by Davidson. The analysis was under the direction of Ronald Sawchuk, PhD of the University of Minnesota-College of Pharmacy.

Similar to DHEA, 7-oxo DHEA is rapidly sulfated to 7-oxo DHEA-sulfate in the body. An analytical method was developed for quantitation of 7-oxo DHEA-sulfate in human plasma. This was an HPLC method, which utilized calibration curves for 7-oxo DHEA-sulfate in the range of 10 to 500 ng/ml.

Trough levels were measured after each escalating dose sequence; 0, 50, 100 and 200 mg per day. Trough plasma concentrations increased proportionally to the daily dose. Mean trough levels (15.8ng/ml) after 1 week of dosing at 200 mg/day were similar to those determined after 4 weeks of dosing (16.3 ng/ml). This indicated that the ratio of the formation rate of this metabolite to its elimination clearance is constant during multiple dosing and does not accumulate.

After a twelve-hour washout period all twenty-two subjects were given a single dose of 7-oxo DHEA at 100 mg and plasma levels were obtained at 0.25, 0.50, 1.0, 2.0, 4.0, 6.0 and 12.0 hrs after the dose. The mean plasma concentrations are depicted in the chart below and demonstrate a peak plasma level of 158 ng/ml which occurred at 2.2 hours after the dose. The average elimination half-life was determined to be 2.17 hours. Based on this data, the dosing regime of twice a day was set and remains the ideal dosing schedule centered around steady state blood levels.

Lastly, simulations of plasma concentrations of 7-oxo DHEA-3-sulfate were performed to represent the regimens employed in the dose escalation phase of the study. A one-compartment model was assumed with first order absorption and no lag phase. The results of these simulations using this pharmacokinetic model showed that there was good agreement between the simulated and measured means of the trough plasma levels and also the plasma concentrations of a single 100mg oral dose.

This pharmacokinetic analysis is very valuable because it describes exactly how the body absorbs, metabolizes and excretes 7-oxo DHEA. It reveals that 7-oxo DHEA is rapidly absorbed and converted to its sulfated derivative, it reaches peak plasma concentrations in 2.2 hours and has a half-life of 2.17 hours. There is no accumulation with repeated dosing and with twice daily dosing should reach a steady state plasma level in 11 hours.
Thermogenesis is a term which describes the creation of heat in mammals. Heat is a form of energy produced when the food we eat is metabolized in the cells of our body. Chemical energy, in the form of adenosine triphosphate (ATP) is also produced in this reaction and is the body's biologically useful energy. ATP is the “energy currency” of the cell and is used to drive all energy requiring reactions including the synthesis of proteins, carbohydrates and fats. It also causes muscles to contract and nerves to conduct.

ATP, while a good energy packet, is not a good fuel storage molecule, as it is used quickly after being formed. Better storage forms of energy are glycogen and triglycerides. Glycogen is broken down to glucose and triglycerides are broken down to fatty acids, both of which are readily utilized for energy. Of importance, is that any food not utilized for energy is subsequently stored for use later, and mostly as fat since it is the most efficient energy storage form at 9 kcal/gm. The synthesis of triglycerides requires glycerol (from carbohydrates), fatty acids and energy from ATP.

The production of energy from glucose and fatty acids occurs at the cellular level with glycolysis (glucose metabolism) occurring in the cytosol of the cell and fatty acid oxidation in the mitochondria of the cell. The mitochondria is often considered the “powerhouse” of the cell, and most cells involved with fatty acid metabolism are in the liver. Acetyl CoA, an essential substrate for energy production, is an end product of both glycolysis and fatty acid metabolism. The enzyme required for the oxidation of fatty acids to acetyl CoA is fatty acyl CoA oxidase.

Acetyl CoA, as a substrate in the Krebs cycle, produces NADH, NADPH and FADH2, which are reducing agents that supply hydrogen atoms or electrons in chemical reactions and are used for ATP production in the mitochondria via a process called oxidative phosphorylation. The oxidation of fatty acids also produces NADH and FADH2. Each molecule of NADH produces 3 ATP’s within the confines of the mitochondria. NADH is also produced in the cytosol (outside of the mitochondria) but needs to be transported into the mitochondria in order to be converted to energy. This transport mechanism is called the “glycerol-3-phosphate shuttle” and requires the enzyme glycerol-3-phosphate dehydrogenase to catalyze the reaction. This “shuttle” requires energy and the end result is that cytosolic NADH is only able to produce 2 ATP’s per mole and the rest of the energy is released as heat. This is therefore a more “thermogenic” utilization of NADH (the reaction produces less ATP and more heat, also called “futile cycling”).

For the purpose of this discussion we will also include the reaction which converts malic acid (a Krebs cycle intermediate) to pyruvate and NADPH. This conversion occurs in the cytosol and requires an enzyme called malic enzyme. This reaction is important since it not only produces cytosolic NADPH but also produces heat.

Compounds with thermogenic activity are substances which foster the production of heat relative to the production of ATP. Very often, these compounds have the ability to enhance the activity of certain enzymes which drive these thermogenic reactions. The quintessential thermogenic compound is the thyroid hormone, thyroxin (T4). Thyroxin has the ability to “uncouple” oxidative phosphorylation (less ATP production and more heat production) by enhancing the activity of glycerol-3-phosphate dehydrogenase and malic enzyme.

Research by Lardy and others has shown that 7-oxo DHEA is able to enhance the activity of three thermogenic enzymes: glycerol-3-phosphate dehydrogenase, malic enzyme and fatty acyl CoA oxidase.
Glycerol-3-phosphate dehydrogenase

The activation of glycerol-3-phosphate dehydrogenase results in an up-regulation of the glycerol-3-phosphate shuttle. This, in turn, favors the conversion of cytosolic NADH to a pathway of less ATP production and more heat production.

Malic Enzyme

The activation of malic enzyme results in the conversion of malic acid to pyruvate and NADPH in the cytosol. This results in an excess of NADPH in the cytosol, which is subsequently transported into the mitochondria where it is converted to ATP and heat. This is a thermogenic effect since more heat is produced relative to ATP production due to the cytosolic origin of the reaction.

Fatty Acyl CoA Oxidase

Lastly, the activation of fatty acyl CoA oxidase results in an enhancement of fatty acid breakdown. This reaction results in the production of acetyl CoA, NADH and FADH2. This drives the cell to utilize fatty acids for energy, which in turn promotes the breakdown of triglycerides, the body’s fat storage moiety. The acetyl CoA, NADH and FADH2 produced in this reaction are subsequently converted to ATP and heat, and at a faster rate than normally expected. The end result is an increased production of heat considering the inefficiency of the reaction.

All three of these enzyme activations drive energy producing substrates in a direction of less efficient ATP production relative to heat production. This is the biological definition of thermogenesis. In addition, they promote the utilization of fat stores for energy and heat production. Hence, 7-Keto’s ability to enhance thermogenesis and through that mechanism, accelerate the utilization of fat stores for heat production.
Two independently conducted clinical trials support the effectiveness of 7-Keto for weight loss. Both trials were double-blind and placebo-controlled. Subjects were controlled for diet, exercise and body water, so that the true weight loss effect of 7-Keto could be isolated. Both studies showed a statistically and clinically significant reduction of weight through the use of 7-Keto versus placebo. Both studies have been published in peer-reviewed journals.

Clinical Efficacy Studies

Two independently conducted clinical trials support the effectiveness of 7-Keto for weight loss. Both trials were double-blind and placebo-controlled. Subjects were controlled for diet, exercise and body water, so that the true weight loss effect of 7-Keto could be isolated. Both studies showed a statistically and clinically significant reduction of weight through the use of 7-Keto versus placebo. Both studies have been published in peer-reviewed journals.

A Randomized, Double-Blind, Placebo-Controlled Study of 3-Acetyl-7-Oxo-Dehydroepiandrosterone in Healthy Overweight Adults

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Peak Wellness

The purpose of this study was to determine weight loss of 3-acetyl-7-oxo-dehydroepiandrosterone (7-oxo-DHEA) in healthy overweight adults compared to placebo.

In this double-blind, placebo controlled protocol, 30 adults (28 women and 2 men; mean age, 44.5 ± 11.5 years) with a mean body mass index of 31.9 ± 6.2 kg/m² were randomly divided into 2 groups of 15: Group 1 received 7-oxo-DHEA 100 mg twice daily and Group 2 received placebo for 8 weeks. All subjects participated in an exercise training program 3 times per week. Exercise session consisted of 60 minutes of cross training (aerobic and anaerobic exercise) under the supervision of an exercise physiologist. In addition, each subject was instructed to follow a diet of ~ 1800 kcal/d (20 kcal/[kg · d]) by a registered dietitian. Subjects received biweekly dietary counseling to encourage compliance. Study participants underwent serum multiple-assay chemistry testing, as well as body composition, blood pressure, and dietary analysis at baseline, week 4 and week 8.

Of the 30 subjects who entered the study, 23 completed the 8-week protocol. Seven subjects dropped out for personal reasons unrelated to the study. Group 1 lost a significant amount of body weight compared with Group 2 (-2.88 kg vs – 0.97 kg; P = 0.01) over the 8 weeks. Group 1 also achieved a significant reduction in body fat compared with Group 2 (-1.8% vs –0.28%; P < 0.01). There were no significant changes in levels of thyroid-stimulating hormone (TSH) or thyroxine (T4) in either group. In addition, no significant changes were observed in vital signs, blood sugar, testosterone and estradiol levels, liver and renal function, or overall caloric intake during the study. No subjective adverse effects were reported throughout the study.

The results of the study suggest that 7-oxo-DHEA combined with moderate exercise and a reduced-calorie diet significantly reduces body weight and body fat compared with exercise and a reduced-calorie diet alone.
The Effect of 7-Keto Naturalean™ on Weight Loss: A Randomized, Double Blind, Placebo Controlled Trial

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Minnesota Applied Research Center

A natural metabolite of dehydroepiandrosterone (DHEA), 3-acetyl-7-oxo-dehydroepiandrosterone (7-oxo DHEA), has been shown to be effective in enhancing weight loss when combined with a diet and exercise program.

This study assessed the effects of a formula containing 7-oxo DHEA, (200mg/day) on weight loss, body composition, and basal metabolic rate (BMR) in overweight patients following a weight-reduction diet and exercise regimen.

In this prospective, randomized, double-blind, placebo-controlled trial, healthy, overweight adults were given the formula containing 7-oxo DHEA or a placebo and followed a calorie restricted diet (105 kJ/kg) and an exercise program for 8 weeks. Body weight, body composition (by bioelectric impedance), and BMR (by indirect calorimetry) were measured at baseline, week 4 and week 8. A thyroid panel was done at baseline and week 8.

Of 35 healthy, overweight adults enrolled, 33 completed the study (12 men, 21 women; age, 40-69 years; body mass index [BMI], 27.0-42.7 kg/m2). Patients taking 7-Keto Naturalean lost significantly more weight after 8 weeks than those taking placebo (mean ± SD loss, 2.15 ± 2.38 kg and 0.72 ± 2.12 kg, respectively) (P=0.038). The change in BMI in the 7-Keto Naturalean-treated group was significant compared with the change in the placebo group (mean ± SD decrease, 0.71 ± 0.79 kg/m2 and 0.01 ± 1.05 kg/m2, respectively) (P=0.036). There were no other statistically significant differences in any of the other measured variables. 7-Keto Naturalean was well tolerated, and there were no significant adverse events.

This formula containing 7-oxo DHEA when combined with a reduced-calorie diet and an exercise program resulted in a significant weight loss compared with diet and exercise alone.

![Percentage Weight Loss as Fat](chart.png)

Source: Kiefer, 2002, Zenk, 2002
**Increased Metabolism**

In 2004, a clinical study involving 45 subjects was performed to evaluate the effect of 7-oxo-DHEA on resting metabolic rate (RMR). The results revealed that administration of 7-Keto to overweight adults in conjunction with a calorie restricted diet effectively reversed the decline in resting metabolic rate (RMR) normally associated with dieting. 7-Keto plus a restricted calorie diet demonstrated an increase in RMR by 1.4% above baseline levels versus a 3.9% decrease in RMR in the restricted calorie diet only group. Therefore, the addition of 7-Keto to a restricted calorie diet produced a statistically significant 5.4% increase in daily RMR when compared to only a calorie restricted diet.

Most weight loss programs are designed to manipulate diet and appetite, but there is a growing rationale to support efforts to increase energy expenditure (RMR) as a tool to enhance the results of a weight loss program. 7-Keto achieves this thermogenic effect by directly up-regulating the activity of fat burning enzymes rather than through the use of stimulants. Thus, with the addition of 7-Keto, dieters attempting any weight loss program can enjoy more success, and more quickly achieve their weight loss goals.

**Weight Loss Claims**

Marketers of weight loss supplements are growing increasingly aware of the need for well-substantiated claims. Marketing a product in the weight loss category is a difficult proposition for today’s nutraceutical companies. In a cluttered market full of outrageous claims, 7-Keto provides a clear set of weight loss claims that are well supported by competent research:

- 3 Times more weight loss than diet and exercise alone
- Majority of weight loss is fat loss
- Promotes weight loss without the use of stimulants
- Awarded a U.S. patent for weight loss
- Gives you what the body naturally produces
- Clinically proven weight loss
- Safe, when used as directed
- Activates 3 thermogenic enzymes
- Natural “7-Keto” levels decline with age
- Increases metabolism by 5.4% without stimulants

**Patented for Weight Loss**

In 1994 Humanetics Corporation received United States patent number 5,296,481 for the use of a select class of compounds for use in weight loss. This class of compounds includes 7-Keto and many of its natural metabolites and other derivatives. Since this time, Humanetics has filed and received international patents which protect the use of 7-Keto for weight loss in Canada, Europe, Japan and Australia.

Humanetics sells 7-Keto only to those companies that enter a license agreement. This process is used to protect all marketers of 7-Keto products, insuring that no mis-branded, adulterated, or potentially unsafe ingredients enter the market.
DSHEA Notification

Prior to marketing 7-Keto as a dietary supplement, it was submitted for a review of safety to the Food and Drug Administration (FDA) in the form of a New Dietary Ingredient (NDI) premarket notification. This document can be viewed at the FDA website and it received no comments or concerns from the FDA. Subsequent to this initial filing, another NDI premarket notification has been filed specific to the use of 7-Keto for weight loss in adults at the prescribed dosage. This notification received no comments or concerns from the FDA.

Manufacturing & Quality

7-Keto is manufactured using GMP guidelines to exacting specifications. These specifications include a review of not only the purity and potency of each lot manufactured, but also a thorough examination of all impurities. It has been proven in many infamous and unfortunate cases, that lack of control in the manufacturing process leading to unknown impurities can have significant and serious adverse effects. Humanetics goes to the added expense of a 100% test program prior to release of any lot. This test program is conducted at an independent analytical laboratory and certifies 14 different quality specifications.

7-Keto™ - The Keystone For Today’s Weight Loss Formulas.

Many weight loss ingredients have come and gone over the past five years. Most have faded in popularity due to many factors including lack of results, enforcement actions by the Federal Trade Commission due to lack of claims substantiation, and concerns over safety and liability. 7-Keto continues to grow as a top selling weight loss ingredient for today’s nutraceutical manufacturers because it offers the published documentation necessary in the weight loss marketplace. In addition, it can back up its claims for safe and effective weight loss, which is critical for longevity of any dietary ingredient.
Pre-Clinical Studies


Clinical Studies


Zenk JL, Leikam SA, Kassen LJ, Kuskowski MA. A Prospective, Randomized, Double Blind Study to Evaluate the Effect of Lean Source™ on Body Composition in Overweight Adult Men and Women. Abstract Presented at the meeting of the FASEB, April 17, 2004, Manuscript submitted for publication.

Zenk JL, Leikam SA, Kassen LJ, Kuskowski MA. The Effect of Restricted Calorie Diet and 7-ofox DHEA on Resting Metabolic Rate: An Exploratory, Crossover Study, Manuscript Pending.

Zenk JL, Leikam SA, Kassen LJ, Kuskowski MA. A Prospective, Randomized, Double Blind Study to Evaluate the Effect of HUM5007 and 7-oxo DHEA on Resting Metabolic Rate in Overweight Adult Men and Women on a Calorie Restricted Diet., Abstract Presented at the meeting of the FASEB, April 17, 2004, Manuscript submitted for publication.
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