



## WHITE PAPER

# Turns fast sugars and other carbohydrates into slow ones

## Executive Summary

Opting for a balanced, adequate, and varied diet is important for maintaining a happy and healthy lifestyle. A healthy diet can help reduce the risk of certain diseases, especially non-communicable diseases such as obesity, diabetes, heart disease, and some cancers. Consuming whole foods and a low glycemic index diet is an important facet of healthy eating. The high-paced modern lifestyle can make it difficult to maintain a balanced, healthy diet with many people consuming high glycemic index carbohydrates (so-called, fast carbohydrates) in large quantities. Diets like this are considered unhealthy as the carbohydrates are not only energy-dense foods, but also promote fat storage and hunger (Malhotra et al., 2015).

This paper examines the health benefits of a dietary ingredient that can make foods healthier by turning fast carbohydrates into slow ones. **Reducose**® is a proprietary and patented water extract of the leaves of white mulberry (*Morus alba*) that can be added to foods or drinks or taken as a dietary supplement to help people maintain a healthier diet. **Reducose**® has been shown in multiple clinical studies to promote a healthier postprandial glycemic and blood insulin response following a carbohydrate containing meal.

**Reducose**® triggers a cascade of effects that are beneficial to maintaining overall metabolic health. These include healthier blood glucose and blood insulin responses after eating, increased satiety, support for maintaining a healthy weight and body composition, a healthy microbiome, and support for healthy blood lipids. **Reducose**® can also help improve sports performance and promote longevity.

**Reducose**® is a versatile ingredient that can be used in a wide range of applications, including food and beverages, dietary supplements, medical foods, and sports nutrition. It is vegetarian, kosher, and clean label friendly. It has approvals for use in different applications in the USA, China, Europe, India, and many ASEAN countries.





# Introduction

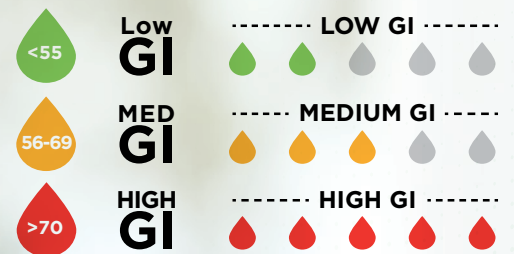
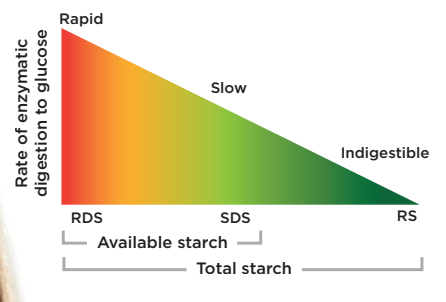
A poor diet and sedentary behavior are unhealthy, but the modern lifestyle can make them difficult to avoid. The quality and quantity of carbohydrates in the diet play a significant role in our health, as not only are they energy dense, but they also promote fat storage and hunger (Malhotra et al., 2015).

Dietary carbohydrates are classified as either sugars, starches, or fibers and are defined by their ease of digestibility and the length of their 'saccharide' chain. These saccharide chains can vary from single sugars or short chains such as glucose and sucrose to chains containing hundreds of thousands of saccharide units such as starch and fiber.

Starches are further classified based on their speed of digestion: rapidly digestible starch (RDS), slowly digestible starch (SDS), or resistant starch (RS). These different starches have markedly different effects on our blood glucose levels after consuming them (postprandial glycemic response). RDS is quickly broken-down and causes a rapid increase in blood glucose. In contrast, RS and fiber escape digestion in the small intestine and pass into the large intestine where it undergoes fermentation by the microbiome (Campbell 2017).

The rate of carbohydrate digestion is expressed by the glycemic index (GI), a relative ranking system for carbohydrate foods and their impact on our blood glucose levels. Carbohydrates with a high GI value have a dramatic influence on our postprandial blood glucose levels and eating them releases a large amount of glucose rapidly into the bloodstream. Many people are unaware that sugar itself is a medium GI carbohydrate. Gram-for-gram refined starches have twice the glycemic impact as sugar. Conversely, a low GI diet leads to low and slow changes in postprandial blood glucose levels and has been clinically demonstrated to improve blood glucose profile, blood lipid profile, and insulin resistance (Elliott, 2010; Goff, 2013; Ojo, 2018).

Testing and labeling complex foods and meals that have a low GI or using supplements that can lower the GI of a meal, regardless of the nutrient mix, would be of great value to consumers who are looking to maintain healthy blood glucose levels.

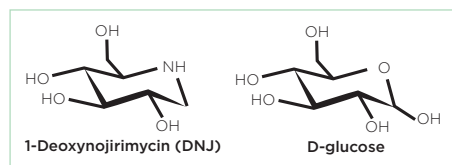


# Reducose®: a novel, standardized, mulberry leaf extract for maintaining a healthy blood glucose response

*Morus alba* (White mulberry) leaves have been used for centuries as both a food and traditional medicine (Chau 2006). Mulberry leaves are nutritious and contain numerous secondary plant metabolites that have positive health benefits (Srivastava 2006; Song 2009).

One type of plant metabolite found in mulberry are compounds called iminosugars. In their simplest form, iminosugars resemble carbohydrate monosaccharides, but the ring oxygen is replaced by nitrogen.

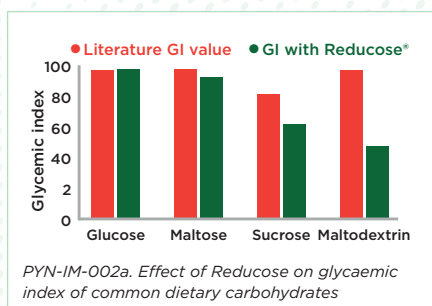
This similarity with carbohydrates allows them to interact with enzymes and receptors involved in carbohydrate digestion. The most widely studied iminosugar is 1-deoxynojirimycin (DNJ), a structural analog of D-glucose. DNJ is a reversible, competitive inhibitor of  $\alpha$ -glucosidase enzymes, one of the main enzymes involved in breaking down carbohydrates in



the gut to facilitate glucose absorption (Nash 2011).

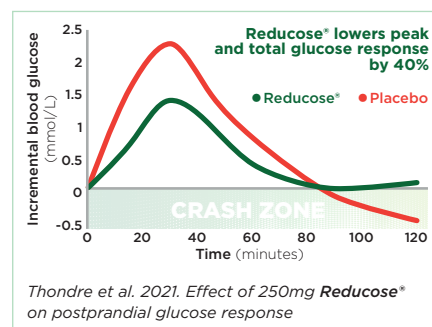
**Reducose®** is a proprietary extract of white mulberry leaves that is standardized to contain 5% (w/w) DNJ. Unlike other mulberry extracts, **Reducose®** is a water extract specifically developed to be used in foods and food supplements. Adding a small amount of **Reducose®** to foods or drinks or taken as a dietary supplement with a meal, lowers the glycemic index of the food and lowers the postprandial blood glucose response as it stops a portion of the carbohydrate from being digested.

In a clinical trial\*, a single 250mg dose of **Reducose®** was incorporated directly into common dietary carbohydrates. It caused a



significant reduction in the glycemic index of these test carbohydrates. The greatest effect was seen with maltodextrin, a polysaccharide made from corn starch, where **Reducose®** lowered the GI of the maltodextrin by 55%. These findings were replicated in two further GI trials, the results of one have now been published (see Wang 2018). In the unpublished study, **Reducose®** was baked into white bread and lowered the GI of the bread from 78 to 43, when compared to bread without **Reducose®**. The glycemic response was lowered by 46%.

The benefit of lowering the glycemic index of foods comes from the resultant reduction in the postprandial blood glucose levels. In four



separate clinical studies (Gheldof et al., 2022, REDUCE study, 2021; Thondre et al., 2021; Lown et al., 2017), **Reducose®** was shown to lower postprandial blood glucose and postprandial blood insulin following a carbohydrate challenge (one study used sucrose, one study maltodextrin, and two studies used complete meals). These studies showed that: **Reducose®** lowered the postprandial blood glucose levels by up to 42% ( $p < 0.001$ ); **Reducose®** was effective for both starch and sugar as well as for large balanced meals. Glucose levels never went below the baseline, which helps users avoid the “sugar crash” and contributes to maintaining sustained energy levels. By lowering the postprandial blood glucose levels, **Reducose®** was able to lower the postprandial insulin response by a corresponding amount (-41%,  $p < 0.001$ ). The clinical studies have reported no adverse events. In a gastrointestinal symptom questionnaire, there was no difference between **Reducose®** and placebo in incidence or severity of GI side-effects.

## Study Result

Study	Result
PYN-IM-002a 2015	250mg Reducose 5% lowers GI of sucrose, maltose and maltodextrin
Lown et al. 2017	Dose-range study; Reducose 5% lowers GR and IR following maltodextrin challenge
Wang et al. 2018	750mg Reducose 1% lowers GI of sucrose, maltose and maltodextrin
PYN-IM-006 2020	Dose-range study; Reducose 1% lowers the GI of white bread and lowers GR following white bread challenge
REDUCE Study 2021	Dose-range study; Reducose 5% lowers GR and IR following complete meal challenge
Thondre et al. 2021	250mg Reducose 5% lowers GR and IR following sucrose challenge
Gheldof et al. 2022	250mg Reducose 5% lowers GR following complete meal challenge
PYN-IM-007 2022.	Impact of Reducose of <sup>13</sup> C breath recovery using the <sup>13</sup> C sucrose breath test – a randomized cross-over clinical trial in 18 participants

Summary of Reducose clinical trials.



# Works immediately and observable in real time

One of the benefits of **Reducose®** is that it works immediately, and the effects can be observed in real time using devices such as continuous glucose monitors (CGMs). Results from clinical trials and case studies have shown that the reduction in blood glucose response is observed immediately with CGM devices. This gives consumers tremendous biofeedback and encourages repeat behavior.



## How does it work?

**Reducose®** lowers postprandial blood glucose and the glycemic index of foods by inhibiting the enzymes that are responsible for digesting carbohydrates. Most carbohydrates are too large to be absorbed into the body and require hydrolysis into monosaccharides to allow absorption.

The body makes use of enzymes to achieve this such as salivary amylase, pancreatic amylase, and  $\alpha$ -glucosidases (Holmes 1971). **Reducose®** has been shown to be a competitive inhibitor of  $\alpha$ -glucosidase in the brush border of the small intestine.

After inhibiting the digestive enzymes, **Reducose®** dissociates from the enzyme and unlike other 'carb blockers' is absorbed out of the gut into the bloodstream where it is rapidly excreted unmetabolized through the kidneys. This is important from a gastrointestinal symptom perspective as the microbiome utilizes the same enzymes to break down undigested foods and inhibitors remaining in the gut with the food bolus will impact this activity.

# Benefits beyond a healthier blood glucose response

The effect of **Reducose®** in lowering postprandial blood glucose by preventing the digestion of carbohydrates triggers a cascade of positive health effects, many of which would support a program to manage and maintain a healthy weight.

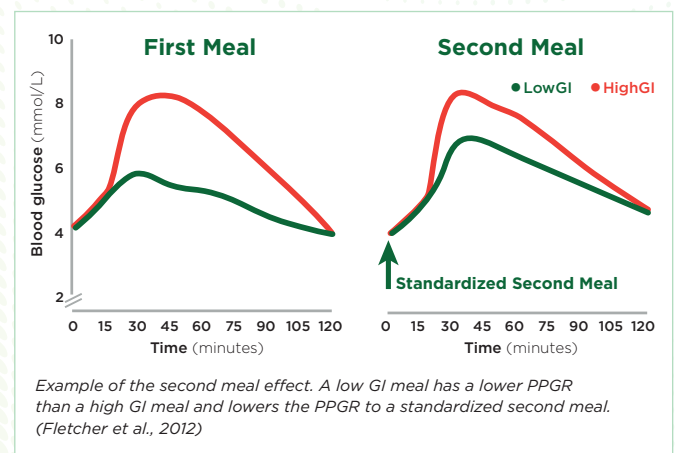
## Increased satiety and decreased urges to snack

The undigested carbohydrates remain in the gut lumen and continue travelling down the small intestine. Once they reach the ileum, the last part of the small intestine, they trigger what's termed the ileal brake.

The ileal brake is a nutrient-triggered inhibitory feedback mechanism that induces satiety. When macronutrients bind to receptors in the ileum, the ileal brake is triggered resulting in a slowing of upper gut motility, reduced appetite, and delayed gastric emptying. These activities are mediated through the release of peptide tyrosine tyrosine (PYY), cholecystokinin (CCK), and glucagon-like polypeptide 1 (GLP-1).

## Promote fat burning through the second meal effect

Linked to the ileal brake is the second meal effect. The second meal effect is a phenomenon where the GI of one meal can influence the glycemic response to a subsequent meal. Having a low GI intake in one meal lowers the postprandial glycemic response (PPGR) in a subsequent meal. This effect is thought to be mediated through several interacting mechanisms, including through the actions of incretin hormones (GLP-1 & GIP) and by the fermentation of undigested carbohydrates to short-chain fatty acids by the microbiome and their subsequent absorption (Fletcher et al., 2012).





The benefits of the second meal effect, while observable as a lower postprandial glucose response, extends to weight management. The second meal effect increases the rate of fat oxidation and favors the use of fat to meet the body's energy requirements, while people who eat high GI meals favor fat storage and the use of carbohydrates for energy (Henry et al., 2017).

## Weight loss and breaking the vicious cycle of obesity

One of the benefits of the second meal effect is how it may help contribute to weight loss. The PPGR from the initial low GI meal, and the resultant lower PPGR from the second meal effect results in the body's insulin response being moderated down.

Insulin's primary function is to stimulate cells to remove glucose from the blood to maintain glucose homeostasis. As glucose is an important energy source for the body, any excess glucose is stored initially as glycogen, and then as fat, this process is mediated by insulin.

High GI foods cause sharp spikes in postprandial blood glucose, with a resultant excess production of insulin. This excess insulin puts the body into fat storage mode. Calories that would normally be used immediately for energy as carbohydrates are instead stored as fat.

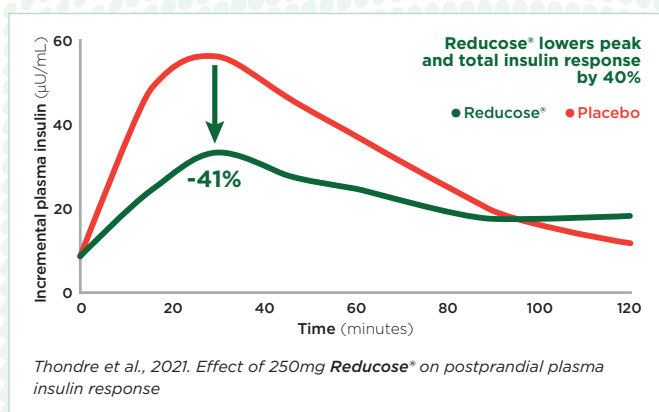
In order to lose weight or maintain a healthy weight, it is therefore important to have a moderate insulin response. This can be achieved through eating low GI meals. Data shows that low GI meals not only reduce the glycemic response, but also improve appetite control and enhance fat oxidation (Fletcher et al, 2012; Henry et al., 2017).

Insulin response is therefore critical in maintaining a healthy weight and body composition. People that are overweight and are insulin resistant need to make and release more and more insulin to remove glucose from the blood. High levels of insulin drives insulin resistance and may also lead to resistance to another hormone – leptin.

Leptin is one of our main energy regulation hormones and is a key factor in controlling how much we eat and our energy utilization. It is made by our adipose tissues (body fat) and thus, when the body percentage is excessive, leptin levels are high, lowering the desire to eat and increasing fat oxidation. Conversely, in situations of starvation, the urge to eat increases, and energy utilization slows. High levels of insulin and insulin resistance are thought to cause leptin resistance, which may lead to a vicious cycle of weight gain. High insulin spikes push calories into fat storage before they can be used for energy; the fat tissue makes increasing amounts of leptin which should lower the desire to eat and increase fat utilization for energy, but due to leptin resistance the signal is not fully received. Rather, the low levels of leptin reaching the brain increases the desire to eat and slows down energy expenditure, making it more difficult to lose weight and in many cases, potentially leading to further weight gain.

**Reducose®** has been shown in several clinical trials to significantly lower the insulin response after consuming carbohydrates as well as lowering the glycemic index of food. This helps to put the body into fat burning mode and decreases glucose calories stored as fat. **Reducose®** has also been shown to increase insulin sensitivity (Liu et al., 2016), and published literature reports that the active compound in **Reducose®**, DNJ, increases leptin sensitivity (Kim et al., 2017).

This combination of activities may help break the vicious cycle of weight gain, and for people trying to lose weight, **Reducose®** may have additional weight-loss benefits. **Reducose®** blocks a portion of carbohydrate calories from getting into the body, which can stimulate the ileal brake further increasing satiety (important for people restricting calories). It may help trigger the second meal effect and increase fat utilization for energy.





## Cognitive function

An often-overlooked benefit of eating low GI foods is the effect it has on supporting healthy cognitive performance, especially in children. Children's brains are relatively bigger, more active, and use more glucose per unit weight compared with adults, which makes them more responsive to (and susceptible to changes in) glucose provision. Studies have shown that low GI meals resulted in better cognitive performance in the postprandial period, better-sustained attention, better memory, and better learning. The brain is sensitive to changes in nutrient supply, and it has been suggested that it is not the amount of glucose but rather the fluctuations in glucose levels that may affect cognitive performance. The constant postprandial concentration that is delivered by low GI foods results in better cognitive performance compared with the rapid increase and subsequent disposal of glucose (often below the fasted level) seen with high GI foods. This is supported by studies that have shown that the low GI benefits are more predominant in the late postprandial phase due to the more stable glucose and insulin profiles. The brain is also an insulin-sensitive organ and individuals that are insulin resistant and have poor glucose regulation have a higher risk of cognitive dysfunction. Low GI diets benefit whole-body insulin sensitivity and therefore a low GI diet can potentially influence cognitive function in both the short term through better control of glucose release, and in the long term through its effects linking glucose regulation and cognition (Philippou and Constantinou, 2014).

## Benefits for the microbiome

An additional benefit of **Reducose**<sup>®</sup> is the effect it has on the microbiome. After passing through the ileum, the carbohydrates that were not digested due to **Reducose**<sup>®</sup> enter the large intestine where they are fermented to short-chain fatty acids by the gut microbiome (PYN-IM-007, 2022).

There are numerous health benefits associated with providing carbohydrates, especially slowly digestible starch (SDS) and resistant starch (RS), to the microbiome. These carbohydrates feed and nourish the bacteria in the microbiome that have a saccharolytic (carbohydrate) metabolism. Lactobacilli and Bifidobacteria are important beneficial bacteria and are almost exclusively saccharolytic. Having healthy colonic and mucosal microflora helps prevent pathogenic bacteria from invading the GI tract.

The beneficial effects these bacteria have in humans is attributed to how they consume the carbohydrates that were not digested in the upper GI. The bacteria ferment these carbohydrates and convert them into short-chain fatty acids (SCFA) such as acetate, propionate, and butyrate.

SCFA have several potential beneficial health effects. For example, colonic epithelial cells preferentially use butyrate as an energy source and its presence in the colon aides the growth of colonocytes, which are reported to have a protective function against colonic disorders (Slavin, 2013).

SCFA production also inhibits the growth of pathogenic organisms in the colon by reducing luminal and fecal pH. This low pH reduces peptide degradation and the consequent formation of toxic compounds such as ammonia, amines, and phenolic compounds (Slavin, 2013).

SCFAs are readily absorbed back into the body. Circulating SCFA can improve immune functions by increasing the number of T-helper cells, macrophages, and neutrophils. They also lower the hepatic production of cholesterol through interfering with its synthesis (Slavin, 2013).

The colonic bacteria use a range of carbohydrate hydrolyzing enzymes to produce these beneficial SCFAs and it is here that the difference between **Reducose**<sup>®</sup> and other 'carb blockers' becomes apparent. The enzymes that the microbiome uses are analogous to human glycosidase enzymes. If inhibitors



of these hydrolyzing enzymes are present in the large intestine, then the microbiome's fermentation ability is reduced, which can result in unwanted gastrointestinal symptom. For example, if sugars are left unfermented in the colon, they have an osmotic effect and draw water out of the body into the colon, which could result in diarrhea. Clinical studies have shown that **Reducose®** does not cause any increase in gastrointestinal symptom (Lown et al., 2017).

## Healthy aging

Elevated glucose levels are associated with many age-related conditions, and restricting calories, especially glucose calories, has been shown to significantly increase lifespan. Our bodies have natural repair mechanisms to limit and repair damage, however, many of these pathways are inactivated by constant glucose flux. Examples of these repair pathways are the sirtuin and PARP (poly-ADP-ribose polymerase) pathways, which when activated, repair damaged proteins and DNA respectively. To activate these pathways, our bodies require a co-factor called nicotinamide adenine dinucleotide (NAD), which is consumed by the sirtuins and PARP during protein and DNA repair. NAD is involved in many processes apart from sirtuin-mediated repair, one of which is acting as a redox enzyme during energy metabolism. However, many of these repair pathways are inactivated by constant postprandial blood glucose excursions.

Our bodies generate energy via different pathways and when there are high levels of glucose available, our bodies convert the glucose into energy through glycolysis in the cytoplasm, which involves the conversion of NAD to NADH. As this is an efficient energy production mechanism, it is favored whenever glucose is available. This pathway depletes the NAD pool, resulting in an inability to activate sirtuins or PARP.

When calories are restricted, especially glucose calories, our bodies generate energy in the mitochondria, and the reverse redox reaction takes place: NAD is produced from NADH, shifting the balance to excess NAD, allowing our repair processes to be activated. Decreasing glucose calorie intake directly favors energy production through secondary pathways, and preserves the NAD pool of the body, allowing it to maintain its efficient DNA-repair and protection mechanisms.

The US National Institute of Aging has run a research program for the past 18 years that evaluates the effects of various compounds on life extension. To date, only seven compounds have significantly increased lifespan, two of which are diabetic drugs that lower postprandial glucose levels. When looking at the effects of these compounds in mice, while there were increases in glucose tolerance and lowered fasting glucose levels, there was no change in the HbA1c (a three-month average indicator of blood glucose levels), suggesting that the benefit is due to lowering postprandial glucose spikes rather than lowering average glucose levels (glucose spikes are the only difference between the blood glucose profiles between test and control groups). The causes of death between test and control groups were equivalent, showing that lowering the glucose spikes led to a delay in morbidities of aging and, not only were the animals living longer but the extra time they had was spent in a healthy state (Miller et al., 2017; Strong et al., 2016; Harrison et al., 2014).

**Reducose®** acts in a similar manner through its ability to blunt postprandial glucose rises. By lowering the amount of glucose that enters the body, it is anticipated that there would also be a shift of the NAD:NADH ratio, making available NAD for activation of the sirtuin and PARP pathways. This enables the body to maintain healthy and efficient repair mechanisms, potentially increasing our chances to live longer in good health. **Reducose®** is an ideal cornerstone ingredient for longevity and healthy aging products delivering its health benefits in a serving size of only 250mg.



# Versatile in a wide range of applications

**Reducose®** is a versatile water extract of white mulberry leaves that can be used in a wide range of applications. It is heat stable and can be used in baked foods or drinks that require heat sterilization. It is stable in acidic pHs and is readily soluble in water.

**Reducose®** has been formulated into a wide range of dietary supplements, including tablets, capsules, gummies, and liquid shots.

## Regulatory clearances in major geographies

**Reducose®** is approved for use in foods, beverages, dietary supplements, and medical nutrition in multiple countries around the world:



- Independent conclusion on GRAS in the USA
- Can be used in foods, beverages, supplements, and medical nutrition



- Normal food status in China
- Can be used in foods, beverages, supplements, and medical nutrition



- *Morus alba* is not considered a novel food ingredient for use in dietary supplements by the European Commission (BELFRIT list)



- *Morus alba* is on the Indian FSSAI positive list
- Can be used in dietary supplements and foods for special dietary uses



- *Morus alba* can be used in most ASEAN countries in dietary supplements

\* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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### About Phynova

Founded in Oxford in 2002, Phynova is a British life science company specialized in developing and commercializing unique, science proven health ingredients, powered by plants. Phynova identifies and researches active ingredients from plants with a rich history and track record of use in traditional medicine. Phynova develops the scientific, IP and regulatory framework around these ingredients so they can be commercialized globally for a variety of health benefits and unmet needs.