

Peak Performance – Perfected!

# Accelerate™

## Modified Cellulose Gum Performance Data

Fast Facts About The Disintegrant  
Designed Especially For Cost-Effective  
Performance In Dietary Supplements

# Accelerate™

## Modified Cellulose Gum

Long recognized as the leading manufacturer of excipients for the pharmaceutical industry, FMC now produces a disintegrant designed to satisfy the unique requirements of the dietary supplements industry.

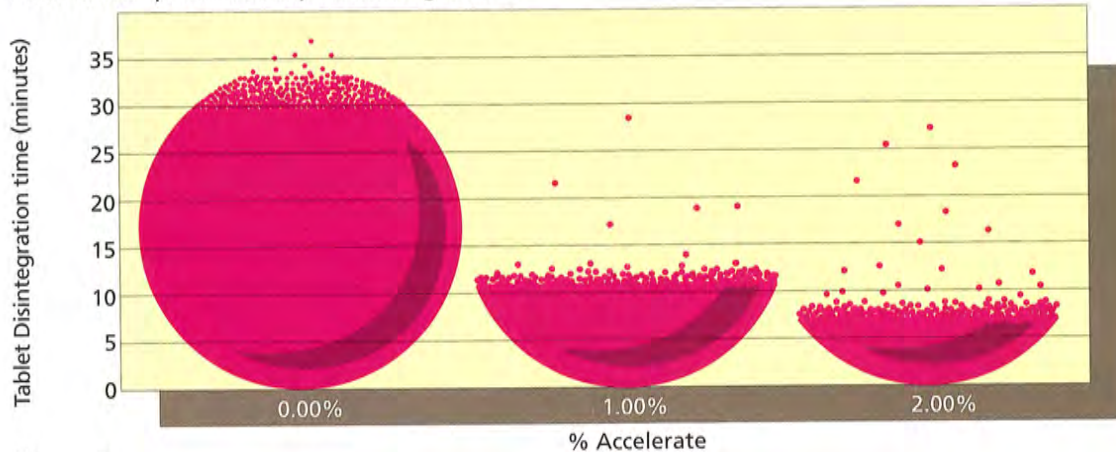
Accelerate modified cellulose gum, an internally cross-linked sodium carboxymethylcellulose, delivers the quality and functionality that manufacturers of nutritional supplements demand today.

- Fast disintegration
- Excellent dissolution
- Extended shelf life
- Superior cost-effectiveness

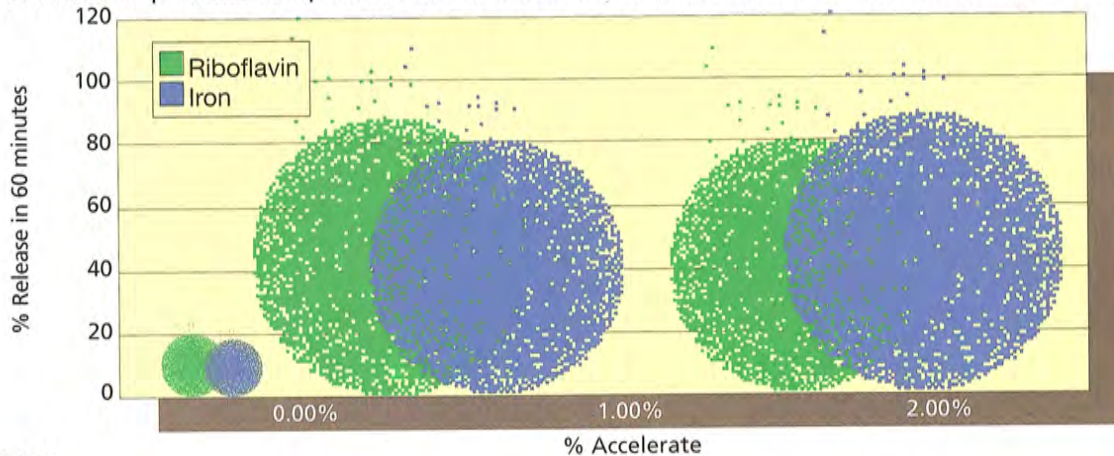
By delivering the FMC high level of quality and performance at a very competitive price, Accelerate disintegrant enables you to manufacture highly marketable dietary supplements while maximizing profits and controlling costs.

The functional performance of Accelerate™ is shown in Figures 1 and 2 in a typical multivitamin and mineral tablet formulation (Table I).

**Figure 1**  
Accelerate™ promotes rapid disintegration.



**Figure 2**  
Accelerate™ provides complete release of the index elements and vitamins, iron and riboflavin.

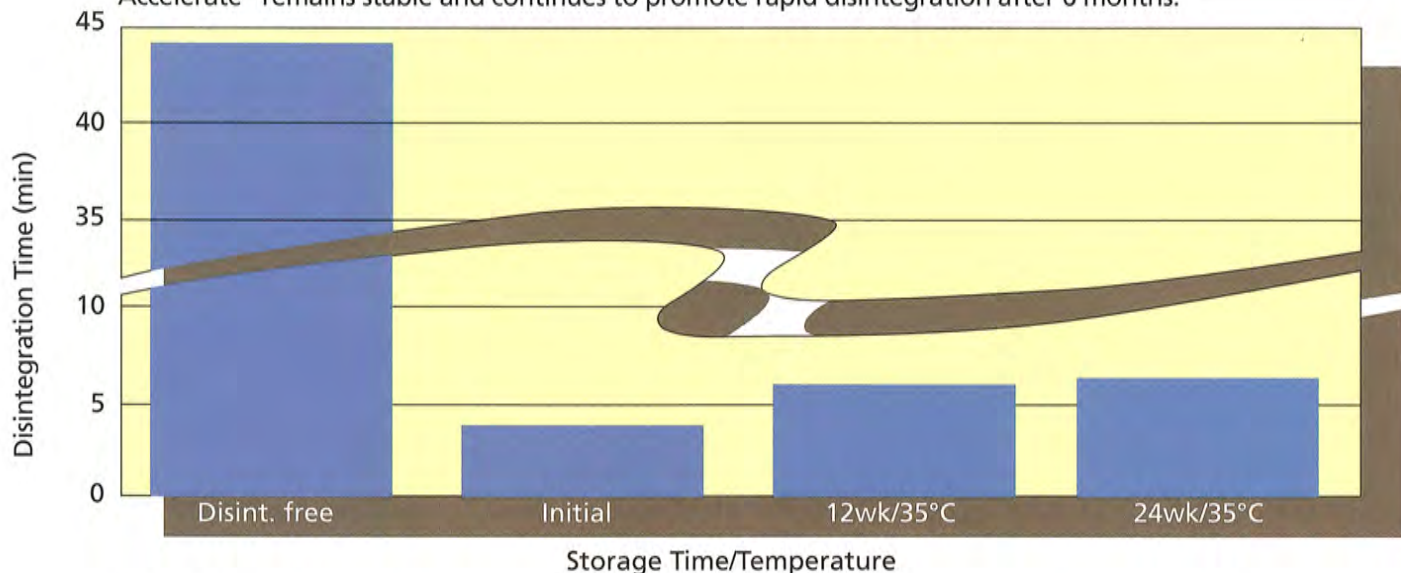


**Table I**

Multivitamin/Mineral Blend	Label Claim	Multivitamin/Mineral Blend	Label Claim
Vitamin A (Beta Carotene)	1250 IU	Calcium	100 mg
Vitamin A (Acetate)	3750 IU	Vitamin D (Cholecalciferol)	400 IU
Niacin (Niacinamide Ascorbate)	20 mg	Biotin	30 mcg
Pantothenic Acid	10 mg	Vanadium	10 mcg
Pyridoxine	2 mg	Chromium	25 mcg
Thiamine Mononitrate	1.5 mg	Tin	10 mcg
Folic Acid	400 mcg	Selenium	25 mcg
Riboflavin	1.7 mg	Nickel	5 mcg
Vitamin C	120 mg	Molybdenum	25 mcg
Vitamin E (Succinate)	40 IU	Silicon	2 mcg
Vitamin B-12	6 mcg	Boron	150 mcg
Iodine	150 mcg	Chloride	36.3 mg
Iron	18 mg	Rose Hips	50 mg
Copper	2 mg	Phosphorus	77 mg
Manganese	2.5 mg	Vitamin K	25 mcg
Zinc	15 mg	Lemon Bioflavonoid	2.5 mg
Magnesium	100 mg	Rutin	2.5 mg
Potassium	40 mg	Hesperidin	2.5 mg

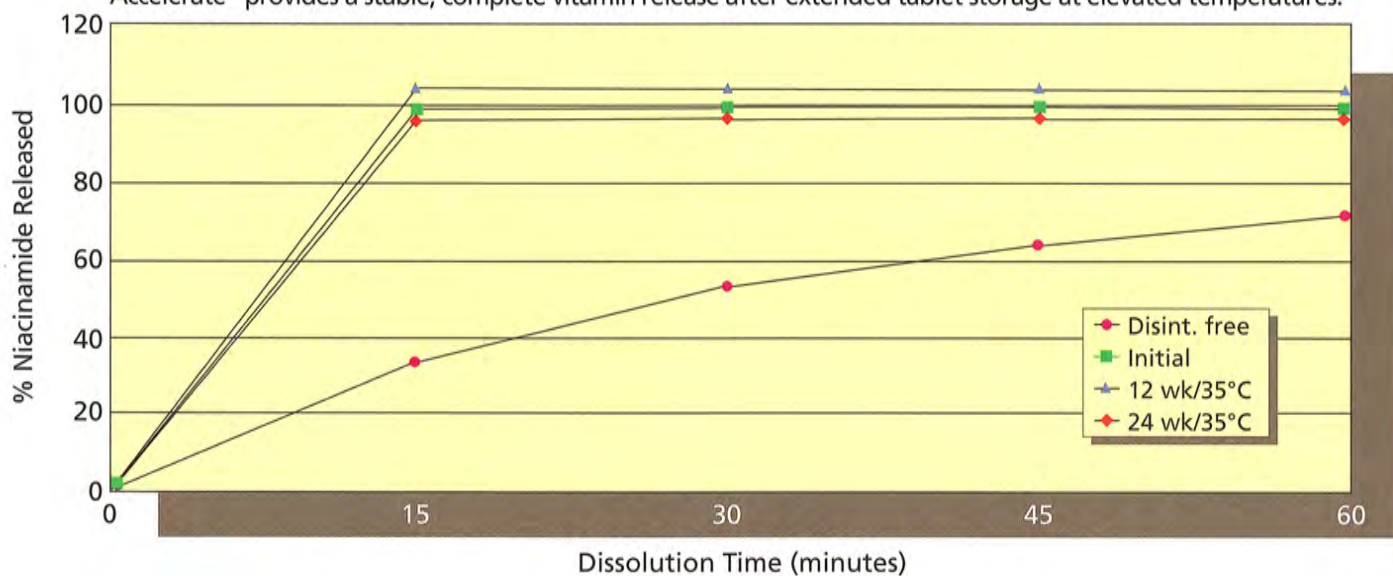
**Figure 3**

Accelerate™ remains stable and continues to promote rapid disintegration after 6 months.



**Figure 4**

Accelerate™ provides a stable, complete vitamin release after extended tablet storage at elevated temperatures.



Accelerate's™ superior performance is demonstrated in a niacinamide formulation as shown in Table II. Niacinamide was selected as an example of a water soluble vitamin. At a 2 percent use level, Figure 3 shows rapid disintegration at elevated temperatures on long-term storage. Figure 4 demonstrates stable dissolution after 24 weeks storage at 35°C. Accelerate modified cellulose gum aids in assuring your formulations will meet the label claim through their shelf life.

**Table II**

Tablet Formulation — Direct Compression	
Ingredient	%
Dicalcium phosphate dihydrate	70.5
Niacinamide	25.0
Stearic acid	2.0
Accelerate™ modified cellulose gum	2.0
Magnesium stearate	0.5

## Sodium Content Of Accelerate™ Modified Cellulose Gum

Current FDA regulations (Federal Register, January 6, 1993 and January 4, 1994) establish the following definitions regarding the sodium content of foods including dietary supplements. The descriptive terms include:

1. *Sodium free* – The criterion for the sodium free declaration is that a product contain *less than 5 mg of sodium per serving*. Food meeting that criterion may declare the sodium content as zero.
2. *Very low sodium* – Food containing *5 mg to 35 mg of sodium per serving* may bear the description *very low sodium*. When this description is used, the sodium content must be declared to the nearest 5 mg increment.
3. *Low sodium* – Food containing *greater than 35 mg but not more than 140 mg of sodium per serving* may bear the description *low sodium*. When this description is used, the sodium content must be declared to the nearest 5 mg increment.

In order to determine the sodium contribution of Accelerate to the total content of a finished product, it is necessary to know the sodium content of Accelerate. The calculated value, periodically analytically verified, is 8 percent.

To calculate the mg of sodium per tablet from Accelerate, the following calculation is performed:

$$[0.08] \times \left[ \begin{array}{c} \text{use level percentage} \\ \text{as a decimal} \end{array} \right] \times \left[ \begin{array}{c} \text{tablet weight} \\ \text{mg} \end{array} \right] = \text{mg Na per tablet}$$

Examples:

<u>Use Level</u>	<u>Tablet Wt., mg</u>	<u>mg of Na Per Tablet</u>
1%	300	0.24
	1200	0.96
2%	300	0.48
	1200	1.92
3%	300	0.72
	1200	2.88

Therefore, Accelerate will allow a sodium free declaration in the above cases (for products covered by the amended food labeling regulations) and the products can be labeled as having zero content sodium if there are no other sources of sodium in the formulation.

The above information is furnished by FMC to assist our customers in determining the sodium content of Accelerate. It is our customers' responsibility to ensure that their finished products are in compliance with FDA food labeling regulations and other applicable laws and regulations.

## USA:

FMC Corporation  
Pharmaceutical Division  
1735 Market Street  
Philadelphia, PA 19103

### Phone Numbers:

Technical Assistance: 215-299-6534  
Fax: 215-299-6821  
Customer Service: 800-362-3773  
Fax: 302-453-6518

## Europe:

Avenue Louise 480-B9  
1050 Brussels, Belgium  
Phone: 32-2-645-9211  
Fax: 32-2-640-0564

## Patents

FMC Corporation does not warrant against infringement of patents of third parties by reason of any uses made of the product in combination with other material or in the operation of any process, and purchasers assume all risks of patent infringement by reason of any such use, combination, or operation.

The products mentioned herein may be protected by one or more of the following U.S. patents or corresponding patents in other countries, or may be described in pending patent applications [\*licensed to FMC]: 4,159,345; 4,159,346; 4,169,014; 4,196,219\*; 4,199,368; 4,231,802; 4,234,316; 4,275,196\*; 4,290,911; 4,319,975; 4,330,338\*; 4,381,082; 4,387,164; 4,415,428; 4,462,839; 4,484,141; 4,504,641; 4,518,433; 4,542,200; 4,588,555; 4,659,672; 4,689,302; 4,693,896; 4,695,548\*; 4,701,754; 4,717,667; 4,744,987; 4,749,620\*; 4,774,093; 4,861,448\*; 4,966,713; 4,983,268; 4,990,611; 5,051,261; 5,053,332; 5,075,115; 5,143,646; 5,155,144; 5,206,030; 5,212,299; 5,248,516; 5,258,436; 5,277,915; 5,326,572; For further information call 800-362-3773.

## Warranty

Because of the numerous factors affecting results, FMC ingredients are sold on the understanding that purchasers will make their own test to determine the suitability of these products for their particular purpose. The several uses suggested by FMC Corporation are presented only to assist our customers in exploring possible applications. All information and data presented are believed to be accurate and reliable, but are presented without the assumption of any liability by FMC Corporation.

## Technical Service

The information contained in this bulletin is intended to be general in nature. Techniques and data pertaining to specific uses for FMC ingredients and new developments will be published periodically in the form of supplemental application bulletins. Our technical staff is ready to offer assistance in the use of Accelerate modified cellulose gum products.

## Regulatory Status

Based on FMC Corporation's research and regulatory review, FMC considers modified cellulose gum to be a generally recognized as safe (GRAS) substance when used as a disintegrant/dispersant for dietary supplement tablets or capsules. Modified cellulose gum is manufactured in accordance with current Good Manufacturing Practices, and is in compliance with the Federal Food, Drug and Cosmetic Act, as Amended and applicable regulations.