

Agrimer[™] AT and Agrimer[™] ATF cross-linked polyvinylpyrrolidone polymers

- disintegrants
- granulation aids
- binders

this brochure is divided into two main segments

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These case studies highlight the uses of Agrimer™ AT/ATF as an excellent disintegrant to ensure fast disintegration of actives

general properties and uses

Agrimer[™] AT polymer is a cross-linked Agrimer[™] PVP product that absorbs and swells with water / solvent, but is insoluble in aqueous and organic media. Agrimer[™] AT polymer has high capillary hydration capacity that provides for high efficiency disintegration in tablets and granules. Agrimer[™] ATF polymer is a finer particle size version of Agrimer[™] AT polymer.

- o insoluble in aqueous and organic media
- stable under acidic and alkaline conditions
- premium disintegrant
- excellent dry binder

benefits

- produce hard granules with low friability at low compression forces, reducing dusting and breakage during transport and storage
- effective as sequestrant for some toxicants
- complex with phenolic acids moieties
- maintain seed moisture and enhance germination in seed coatings
- super absorber properties
- quick disintegration upon addition to the spray tank or when contacted with water
- inherent binder properties and compatible with most co-formulants
- not tacky under humid conditions
- o does not form gels

suggested applications

- o disintegrants for wdg, granules and tablets
- for wet granulation, dry compaction, fluid bed, spray drying and extrusion processes
- seed tapes
- dye binder in seed coatings

regulatory status

Agrimer[™] AT and ATF polymers are exempt from the requirements of a tolerance per 40 CFR 180.960.

physical and chemical properties

Typical Agrimer™ AT/ATF polymer properties are shown in Table 1. Figures 1-3 and Tables 2-3 show comparative data of performance from tablets made using Agrimer™ AT and Agrimer™ ATF polymers vs other common disintegrants.

table 1: typical properties

polymer properties	Agrimer™ AT	Agrimer™ ATF
particle size (micron)	0 – 400 +	95% < 75 10-90% < 37
physical form	free-flowing powder	free-flowing powder
color	off white	off white
moisture (Karl Fischer)	6.0% max	6.0% max
pH (10% slurry)	5.0 – 11.0	5.0 – 11.0
nitrogen (Dumas)	11.0 – 12.8%	11.0 – 12.8%
heavy metal	< 10 ppm	< 10 ppm
solubility	insoluble in water, acids, alkalis and all organic solvents	insoluble in water, acids, alkalis and all organic solvents

powder density

The bulk and tap densities of the Agrimer™ AT/ATF polymers vs other common disintegrants are given in Table 2. Products with the least percentage increase upon tapping are generally more desirable since less disintegrant is needed to obtain a harder, less friable

granule. However, binding properties for the specific formulation and the compressibility of the disintegrant are key factors to be considered when evaluating the efficiency in the application.

table 2: comparative typical bulk and tap densities

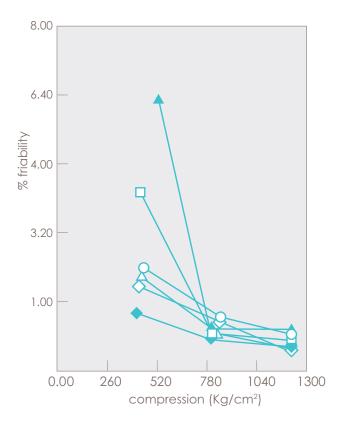
disintegrant	bulk density (g/cc)	tap density (500 taps) (g/cc)
Agrimer™ AT	0.25	0.33
Agrimer™ ATF	0.35	0.50
cross-linked CMC	0.34	0.59
methacrylate DVB	0.55	0.73
pregelatinized Starch	0.62	0.65
sodium starch glycolate	0.78	0.92



friability

Friability is a measure of how easily a granule or tablet crumbles and high friability is directly related to the production of dust, both during processing and subsequently during handling and transport. Lower friability, especially at the low compression forces used in a typical granule production, equates to less dust and higher user safety. As shown in Figure 1, Agrimer™ AT and ATF polymers are clearly superior to the other products listed as disintegrants/binders. The ease of compression and low friability at low forces implies a wider operating window during granulation or tableting processes.

figure 1: friability (dust potential) profiles of tablets



▲ standard

△ 5% cross-linked CMC

☐ 5% sodium starch glycolate

5% preaelatinized starch

♦ 5% Agrimer™ AT polymers

5% Agrimer™ ATF polymers

disintegration

The disintegration time of a granule is directly related to the ability of the disintegrant to absorb and swell with water from within the granule. The absorption of water and swelling can be enhanced by capillary wick action from within the disintegrant matrix. The harder the granule or tablet the lower its friability and consequently the slower its disintegration. The ideal situation would be a dust free granule or tablet that disintegrates immediately when added to the spray tank or contacted with water. Unfortunately, an optimized trade-off is often required in practice; however, Agrimer™ AT/ATF polymers can help offer more consistent and forgiving products and performance in the field.

Figure 2 shows that Agrimer™ AT and ATF polymers have the fastest disintegration time of the products evaluated. Furthermore, their rates of disintegration show the least change following weeks of accelerated shelf-life aging.

Figure 3 shows the dissolution rate to dissolve 80% of an active ingredient (T-80) in a typical tablet application. As tablet/granule hardness increases (or tabletting pressure increases), T-80 also increases. Again, a trade-off has to be made relative to the potential for dusting and the rate of dissolution of the active ingredient.

In this case, use of Agrimer™ AT and Agrimer™ ATF polymers produced the fastest dissolution rate for hard / low friable tablets/granules with the least disintegration time, while offering improved storage stability.

The dissolution rate is a function of the rate of hydration of the polymer. Unlike many other disintegrant/ binders, Agrimer™ AT and Agrimer™ ATF polymers do not become soft and tacky on hydration. Table 3 shows typical moisture pick up vs relative humidity and time.

Related to the insolubilities of the cross-linked Agrimer™ AT series is the fact that these polymers do not gel in water and typically do not interfere with spraying operations.

figure 2: disintegration time

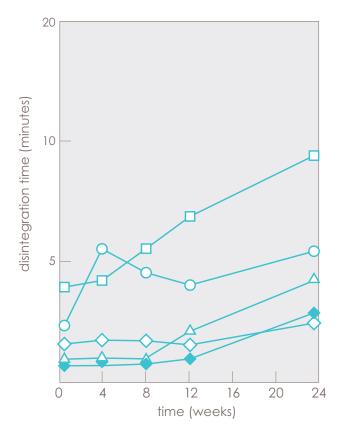
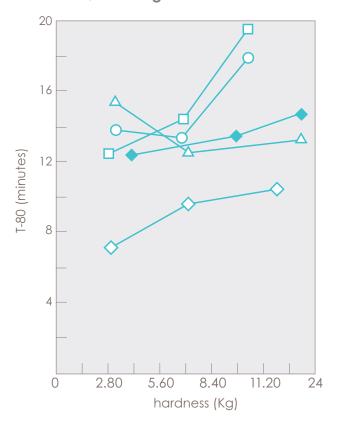


figure 3: 80% active dissolution versus hardness 5% disintegrant



- △ 5% cross-linked CMC
- ☐ 5% sodium starch glycolate
- 5% pregelatinized starch
- ◆ 5% Agrimer[™] ATF polymers

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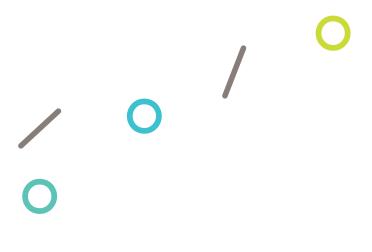




table 3: hydroscopicity of Agrimer™ ATF polymer¹

% Moisture Gained (on dry basis) after Various Times									
relative humidity	1 hour ²	2 hours	5 hours	1 day	2 days	3 days	5 days	6 days	7 days
30%	7.4	8.4	9.9	10.6	10.8	11.0	11.0	10.8	10.8
50%	10.4	12.2	15.5	17.0	17.1	17.5	17.4	17.4	17.4
75%	13.8	15.6	22.3	30.3	32.0	32.6	32.6	32.4	31.8
85%	11.5	16.1	24.4	36.3	41.2	44.1	44.6	45.0	44.1

One-gram samples of Agrimer[™] ATF were equilibrated for several days in one-gallon glass containers over aqueous solutions of sodium hydroxide, the concentrations of which were selected to give approximately 30, 50, 75 and 85% relative humidities. The samples were contained in shallow glass dishes, approximately 2 inches in diameter. The samples were kept at room temperature (23°C+/-3°C) throughout the study. The results shown are average values for duplicate samples.

agricultural case studies

disintegration

A granule was developed by Ashland by adding 4% of Agrimer[™] AT to the mixture being extruded. The suspensibility of the granule in the spray tank increased from 45% to 72% while retaining good friability (2%) and a low sedimentation index (0.5%).

AgrimerTM ATF has also been used as a disintegrant for a selective postemergence herbicide, thifensulfuron methyl. Although the tablet was effervescent it would not disintegrate fast enough without the addition of AgrimerTM ATF at 1-2%.

A bisulfate salt of a substituted imidazolinone derivative, a selective postemergence herbicide, was made into granules using roller compaction. Although the active ingredient is water soluble, it was necessary to incorporate Agrimer ATF in order to obtain acceptable disintegration.

² These one-hour results include both moisture pickup during the first hour and the initial moisture content of the samples.

