

who's got
you covered?

—
we do.

pharmaceutical product and solution guide



ashland.com / efficacy usability allure integrity profitability[™]



Helping to ensure the efficacy, integrity and usability of pharmaceutical formulations

At Ashland, our number one goal is to help you apply pharmaceutical polymers in ways that ensure the **efficacy**, **integrity** and **usability** of your formulations. Explore how our molecular scientists, chemists, formulation development scientists and process engineers can help advance formulation development, support the commercialization of complex drug molecules, and reduce time to market. Our problem-solving team leverages a diverse polymer portfolio to enable comprehensive solutions, so when you're ready to develop a formulation, we've got you covered.

Included here is an overview of Ashland's pharmaceutical polymer offering along with details about the properties of these technologies that form the basis of their extraordinary functionality in finished dosage forms.

product	Application											
	tablet binding	modified release	tablet film coating	drug solubilization	direct-compression tableting	disintegration	lyophilization stabilizer	liquid Rheology modification	suspending agent	stabilizer	crystallization inhibitor	hot-melt extrusion
cellulosics – pages 3-6												
Klucel™ hydroxypropylcellulose	✓	✓	✓		✓							✓
Benecel™ methylcellulose and hypromellose	✓	✓		✓	✓			✓			✓	
Natrosol™ 250 hydroxyethylcellulose		✓						✓				
AquaSolve™ hypromellose acetate succinate			✓	✓								✓
Aqualon™ ethylcellulose Ashland® EC Pharm Ultra	✓	✓	✓									✓
Aqualon and Blanose™ sodium carboxymethylcellulose			✓				✓	✓	✓		✓	
cyclodextrins – page 7												
CAVAMAX®, Cavitron™ and CAVASOL® cyclodextrins				✓			✓			✓		
vinyl pyrrolidones – page 8												
Plasdone™ S-630 copovidone	✓		✓	✓							✓	✓
Plasdone povidone C grades				✓			✓	✓	✓		✓	
Plasdone™ povidone K grades	✓			✓				✓			✓	
Polyplasdone™ crospovidone				✓		✓						
Pharmasolve™ N-methyl-2-pyrrolidone				✓								
film coating systems – pages 9-10												
Aquarius™ film coating systems		✓	✓									

klucel™ hydroxypropylcellulose

Klucel hydroxypropylcellulose (HPC) provides a remarkable set of physical properties for tablet binding, modified release, and film coating. It is a surface active, thermoplastic polymer that is soluble in both aqueous and organic solvents. Low-viscosity E, L, and ELF types are widely used for premier tablet binding at low-use levels (2–6%). Regular particle size materials are used in wet processing, and the X-grind material is used for dry processing.

The characteristics of Klucel HPC make the low viscosity grades extremely useful in pharmaceutical film coatings, either for application from aqueous (often preferred today) or organic solvent-based coating formulations. The inherent compatibility with other commonly used polymers (such as HPMC) makes Klucel HPC a useful formulation modifier to enhance properties of the final coating formulation. Klucel HPC can also be a useful suspension stabilizer for pigment dispersions that are used in color coating formulations.

Several high molecular weight grades are used for modified-release matrix systems. These grades of HPC work by swelling and diffusion to retard drug release.

Low molecular weight Klucel HPC polymers, due to their thermoplastic behavior and superior flow properties, find applications in melt extrusion.

klucel™ hydroxypropylcellulose (HPC)

grade (X = Fine)	weight average molecular weight	typical brookfield viscosity (mPa·s)	solution concentration (%)
HF Pharm, HXF Pharm	1,150,000	1,500–3,000	1
MF Pharm, MXF Pharm	850,000	4,000–6,500	2
GF Pharm, GXF Pharm	370,000	150–400	2
JF Pharm, JXF Pharm	140,000	150–400	5
LF Pharm, LXF Pharm	95,000	75–150	5
EF Pharm, EXF Pharm	80,000	300–600	10
ELF Pharm	40,000	150–225	10

aquasolve™ hypromellose acetate succinate

AquaSolve hypromellose acetate succinate (HPMCAS) is a cellulosic polymer with four substituents randomly substituted on the available hydroxyl groups with the following mass contents; methoxyl, 12–18 wt%; hydroxypropoxy, 4–23 wt%; acetyl, 2–16 wt% and succinoyl 4–28 wt%. It is white to yellowish white in color and has a faint acetic acid-like odor and a barely detectable taste.

AquaSolve HPMCAS is available in several grades varying in extent of substitution of acetyl and succinoyl groups, and in two particle sizes (fine or granular).

AquaSolve HPMCAS is used as a polymeric carrier in solid dispersions for solubility enhancement of poorly soluble active pharmaceutical ingredients (APIs). The amphiphilic nature, high glass-transition temperature (T_g) and low viscosity in various solvents of this polymer, are some of the unique properties that make it ideal for use in spray-dried dispersion formulations. Varying the level of acetyl and succinoyl substitutions produces polymers that can bond with either hydrophilic or hydrophobic APIs to help them solubilize.

In oral pharmaceutical formulations, AquaSolve HPMCAS is commonly used as an enteric film coating for tablets, capsules, or granules. For aqueous film-coating purposes, a dispersion of AquaSolve HPMCAS fine powder and a plasticizer (such as triethyl citrate) in water is commonly used. Organic solvents are also vehicles for applying this polymer as a film coating. AquaSolve HPMCAS can form films without the addition of water or solvents.

Other pharmaceutical applications include its use alone or in combination with other soluble or insoluble binders in the preparation of granules with sustained-release properties, where the release rate is pH dependent.

aquasolve™ hypromellose acetate succinate (HPMCAS)

grade ^a	weight average molecular weight	nominal viscosity (mPa·s) ^b
L	114,700	2.4–3.6
M	103,200	2.4–3.6
H	75,100	2.4–3.6

^a Available in fine and coarse particle sizes
^b NF/EP/JP viscosity method

benecel™ methylcellulose and hypromellose

Benecel methylcellulose (MC) and hypromellose (hydroxypropylmethylcellulose or HPMC) are versatile excipients with a variety of applications. Ashland offers various substitution low molecular weight types and grades of HPMC hypromellose. High-viscosity grades of HPMC are widely used in hydrophilic to retard the release of active pharmaceutical ingredients from matrix tablets.

custom intermediate-molecular weight grades for controlled-release

Achieving a desired drug-release profile has traditionally involved blends of different molecular weights of particular polymers. Blending, however, can increase release-profile variability. Benecel K250 PH PRM, K750 PH PRM and K1500 PH PRM HPMC were developed to obviate the need for blending and offer a potential solution to the problem of dissolution variability.

directly compressible grades

Directly compressible (DC) grades enable the production of controlled-release formulations with the convenience of the most widely used tablet-binding mechanism. These Benecel DC HPMC grades offer good powder flow, content uniformity, and compressibility, making them well suited for direct compression.

benecel™ hypromellose (HPMC)

substitution type	grade	weight average molecular weight	solution concentration	nominal viscosity (mPa·s) ^a
Hypromellose 2910 "E" types	E4M Pharm, E4M Pharm CR	400,000	2%	2,700–5,040
	E10M Pharm, E10M Pharm CR	746,000	2%	7,500–14,000
Hypromellose 2208 "K" types	K100 LV PH PRM	164,000	2%	80–120
	K250 PH PRM	200,000	2%	200–300
	K750 PH PRM	250,000	2%	562–1050
	K1500 PH PRM	300,000	2%	1,125–2,100
	K4M Pharm, K4M Pharm CR	400,000	2%	2,700–5,040
	K15M Pharm, K15M Pharm CR, K15M PH PRM	575,000	2%	13,500–25,200
	K35M Pharm	675,000	2%	26,250–49,000
	K100M Pharm XR	1,000,000	2%	75,000–140,000
K200M Pharm XR	1,200,000	2%	150,000–280,000	

^a NF/EP/JP viscosity method

benecel™ directly compressible hypromellose (HPMC)

substitution type	grade	weight average molecular weight	solution concentration	nominal viscosity (mPa·s) ^a
Hypromellose 2208 "K" types	K4M PH DC ¹	400,000	2%	2,700–5,040
	K15M PH DC ¹	575,000	2%	13,500–25,200
	K100M PH DC ¹	1,000,000	2%	75,000–140,000

^a NF/EP/JP viscosity method

¹ These grades are co-processed with silica at <1 %

benecel™ methylcellulose (MC) and methylhydroxyethylcellulose (MHEC)

aqualon or blanos[™] sodium carboxymethylcellulose

Aqualon or Blanos sodium carboxymethylcellulose (CMC) is made by reacting sodium monochloroacetate with alkali cellulose under rigidly controlled conditions. The resultant anionic polymer is purified and dried. A variety of CMC grades is available, with varying degrees of substitution, viscosities, and particle sizes. Typical uses for CMC are in ointments, creams, and lotions, as a stabilizer, thickener and film-former; in jellies and salves, as a thickener, gelling agent, protective colloid and film-former; in syrups and suspensions, as a thickener and suspending aid; in bulk laxatives, as a physiologically inert water-binding agent; in mucoadhesives for its absorbency and sustained-released properties. High-viscosity grades of CMC can also be used in hydrophilic matrix tablets. Bioburden and endotoxin tested (BET) grades are available.

Ashland provides sodium carboxymethylcellulose to the pharmaceutical market under the trade names Aqualon or Blanos, depending on the region. These products are produced to USP-NF 1078 and IPEC-PQC GMP guidelines for excipients.

aqualon[™] sodium carboxymethylcellulose (CMC)

weight average molecular weight	viscosity (mPa·s)	solution concentration	degree of substitution		
			0.7	0.9	1.2
725,000	1,500–3,000	1%	7HF PH		
725,000	1,000–2,800	1%	7H3SF PH		
725,000	1,000–2,800	1%	7HOF PH		
395,000	1,500–3,100	2%		9M31F PH	
395,000	800–3,100	2%			12M31P
250,000	400–800	2%	7MF PH		
250,000	400–800	2%	CMC 7MF PH BET		
250,000	400–800	2%	7M8SF PH		
250,000	400–800	2%		9M8F PH	
90,500	25–50	2%	7LF PH		
90,500	25–50	2%	CMC 7LF PH BET		
49,000	50–200	4%	7L2P		
49,000	50–200	4%	CMC 7L2P BET		

blanos[™] sodium carboxymethylcellulose (CMC)

weight average molecular weight	viscosity (mPa·s)	solution concentration	degree of substitution		
			0.7	0.9	1.2
725,000	2,500–4,500	1%	7H4XF PH	9H4XF PH	
725,000	1,500–2,500	1%	7HF PH		
725,000	1,000–2,800	1%	7H3SF PH		
725,000	1,000–2,800	1%	7HOF PH		
395,000	1,500–3,100	2%	7M31F PH	9M31F PH	12M31P
395,000	200–800	2%	7M8SF PH		
395,000	1,200–1,800	2%		9M20F PH	
395,000	400–800	2%			12M8P
250,000	400–600	2%	7MF PH		
250,000	50–100	2%	7M1F PH		
90,500	25–50	2%	7LP EP		

aqualon[™] ethylcellulose

Aqualon ethylcellulose is soluble in a wide range of organic solvents. Typically, ethylcellulose is used as a nonswellable, insoluble component in matrix or coating systems. Ethylcellulose can be used to coat one or more active ingredients of a tablet to prevent them from reacting with other materials or with one another. It can prevent discoloration of easily oxidized substances, such as ascorbic acid. Ethylcellulose can be used on its own or in combination with water-soluble components to prepare sustained-release film coatings that are frequently used for the coating of microparticles, pellets, and tablets. Aqualon T10 Pharm ethylcellulose was developed for optimized compactability (with high ethoxyl content and low viscosity) and good powder flow.

aqualon[™] ethylcellulose (EC)

grade	ethoxyl substitution (%)	weight average molecular weight	typical brookfield viscosity (mPa·s) ¹	solution concentration (%)
T10 Pharm	49.6–51.0	75,000	8–11	5
N7 Pharm	48.0–49.5	65,000	6–8	5
N10 Pharm	48.0–49.5	75,000	8–11	5
N14 Pharm	48.0–49.5	120,000	12–16	5
N22 Pharm	48.0–49.5	140,000	18–24	5
N50 Pharm	48.0–49.5	160,000	40–52	5
N100 Pharm	48.0–49.5	215,000	80–105	5

¹Viscosity measured in 80:20 mixture of toluene/ethanol

CAVAMAX[®], CAVASOL[®] and cavitron[™] cyclodextrins

The molecular structure of cyclodextrins creates a bucket-like cavity that can complex with molecules or functional groups on molecules to improve solubility of poorly soluble compounds. The same mechanism makes these excipients capable of masking unpleasant taste/odor and stabilizing APIs that are prone to degradation.

CAVAMAX[®] native cyclodextrins

The number of glucose units in the ring determines the internal diameter of the cavity and its volume, as the height of the cyclodextrin cavity is the same for all the native cyclodextrin grades. CAVAMAX cyclodextrins are compatible with a wide range of ingredients commonly used in pharmaceutical applications.

CAVASOL[®] and cavitron[™] hydroxypropyl-β- or hydroxypropyl-γ-cyclodextrins (HPBCD or HPGCD)

The substitution of hydroxyl groups on native cyclodextrins to make hydroxypropyl-β- or hydroxypropyl-γ-cyclodextrins (HPBCD or HPGCD) significantly enhances their solubility. Both CAVASOL HPBCD and HPGCD are primarily used to increase solubility of poorly soluble compounds in oral drug-delivery systems. Cavitron cyclodextrins are manufactured and tested to meet low bioburden and endotoxin specifications.

cyclodextrin derivatives

product and grade	weight average molecular weight	typical degree of substitution
CAVASOL [®] W7 HP Pharma	1,410	4.1–5.1
Cavitron [™] W7 HP5 Pharma	1,410	4.1–5.1
Cavitron W7 HP7 Pharma	1,520	6.0–8.0
CAVASOL [®] W8 HP Pharma	1,574	3.5–4.9

¹ Registered trademark owned by Wacker Chemie AG. Ashland acts as a worldwide distributor for Wacker.

native cyclodextrins

product and grade	weight average molecular weight	cyclodextrin type
CAVAMAX [®] W6 Pharma	973	α-cyclodextrin
CAVAMAX [®] W7 Pharma	1,135	β-cyclodextrin
CAVAMAX [®] W8 Pharma	1,297	γ-cyclodextrin

¹ Registered trademark owned by Wacker Chemie AG. Ashland acts as a worldwide distributor for Wacker.

plasdone™ S-630 copovidone

Plasdone S-630 copovidone (PVP/VA) is a tablet binder, matrix polymer for solid-dispersion formulations and film-former for topical applications. It is commonly used to enhance the solubility of APIs and increase bioavailability of poorly water-soluble APIs through the formation of melt-extruded or spray-dried solid dispersions. It is a linear, random, water-soluble copolymer of N-vinylpyrrolidone and vinyl acetate that combines a unique set of properties for application in a wide variety of dosage forms. Reduced hygroscopicity makes it useful in moisture-sensitive formulations.

plasdone™ copovidone

grade	weight average molecular weight ^a	K-value viscosity
S-630	47,000	25.0–31.0

^a Absolute molecular weight (SEC/MALLS)

plasdone™ povidone

Ashland offers a comprehensive range of Plasdone povidone (PVP). Plasdone povidones are a family of water-soluble polymers based on N-vinylpyrrolidone that combine a unique set of properties for application in a wide variety of dosage forms. Plasdone povidones are commonly used as binders for the development of tablet formulations, whether manufactured by wet granulation, dry granulation, or direct compression. Plasdone K polymers are used in solid-dispersion formulations to enhance the solubility of active pharmaceutical ingredients and increase bioavailability. Plasdone K grades are also used to inhibit recrystallization in liquid soft gels. Plasdone C polymers can inhibit crystallization in injectable dosage forms are produced to meet low pyrogen specifications.

plasdone™ povidone

grade ^a	weight average molecular weight ^b	K-value viscosity
K-12	4,000	10.2–13.8
K-17	10,000	16.0–17.5
K-25	34,000	24–26
K-29/32	58,000	29–32
K-90	1,300,000	85–95
C-12	4,000	10.2–13.8
C-17	10,000	16.0–17.5
C-30	58,000	29.0–32.0

^a C grades have low pyrogen levels

^b Absolute molecular weight (SEC/MALLS)

polyplasdone™ crosopovidone

Polyplasdone crosopovidone superdisintegrants are synthetic, insoluble but rapidly swellable, crosslinked homopolymers of N-vinyl-2-pyrrolidone. Crosopovidone provides rapid disintegration and dissolution to oral solid-dosage forms. Polyplasdone crosopovidone particles are granular and porous compared with other superdisintegrants. The high surface area combined with unique chemistry results in high interfacial activity that enhances the dissolution of poorly water-soluble active pharmaceutical ingredients (APIs) in a way that is not possible with other disintegrant technologies.

polyplasdone™ crosopovidone

grade	typical average particle size (microns)	peroxide specification (ppm)
Ultra ¹	110–140	30 Max
XL ¹	110–140	400 Max
Ultra-10 ²	25–40	50 Max
XL-10 ²	25–40	400 Max

¹ Ph. Eur. crosopovidone monograph type A

² Ph. Eur. crosopovidone monograph type B

pharmasolve™ N-methyl-2-pyrrolidone

Pharmasolve N-methyl-2-pyrrolidone (NMP) is a water-miscible polar aprotic solvent with high interfacial activity. It is used as a solubilizer and penetration enhancer in human parenteral and topical-dosage forms, as well as parenteral and topical veterinary products.

natrosol™ 250 hydroxyethylcellulose

Natrosol 250 hydroxyethylcellulose (HEC) is a nonionic water-soluble cellulose ether. Natrosol 250 HEC is easily dispersed in cold or hot water to give solutions of varying viscosities and desired properties, though it is insoluble in organic solvents. It is used in solutions and gels to control rheology, in emulsions for high-salt tolerance and surfactant compatibility and in modified-release matrix tablets, where high-viscosity grades provide effective diffusion-limiting release of active pharmaceutical ingredients (API) with low water solubility.

natrosol™ 250 hydroxyethylcellulose (HEC)

grade (X = Fine, W = Superfine)	weight average molecular weight	typical brookfield viscosity (mPa•s)	solution concentration
HHX Pharm, HHW Pharm	1,300,000	3,500–5,500	1%
HX Pharm, H Pharm	1,000,000	1,500–2,500	1%
M Pharm	720,000	4,500–6,500	2%
G Pharm	300,000	250–400	2%
L Pharm	90,000	75–150	5%

aquarius™ film coating systems

Fully formulated, easily dispersed and ready-to-use, Aquarius film coating systems provide a range of functions to suit almost any core. A wide range of film coating offerings enable us to supply an optimal coating for your formulation.

aquarius™ preferred film coating systems

High-solids loadings, such as the Aquarius Preferred series serve to maximize the efficiency of the coating application process. By reducing coating time, productivity is increased, while overall manufacturing cost is reduced. High-solids cellulosic or high-solids copovidone formulations improve film adhesion to all substrates, especially those that present challenges in aqueous film coating. The benefits of Aquarius Preferred systems include:

- High-solids coatings
- Immediate-release
- Disperse easily in water
- Applicable to both pharmaceutical and nutraceutical solid dosage forms
- Can be tailored to meet exacting requirements

aquarius™ prime film coating systems

Film coatings for immediate-release tablet-coating applications are typically comprised of a polymer, a plasticizer, and optional pigment/opacifier. Aquarius Prime film coating systems are available off the shelf in clear and white formulations. The benefits of these coating systems include:

- cellulosic polymer composition (typically HPMC and HPC, and combinations thereof)
- designs that meet general film coating requirements (typically sprayable at 10–15% w/w solids, producing coatings with good film strength and moderate film adhesion characteristics)
- capability to address common film coating problems
- disperse easily in water
- immediate release

aquarius™ film coating systems

grade	descriptor	detail	class
preferred	HSC	high-solids coatings based on cellulosic polymers	aesthetic
preferred	HSP	high-solids coatings based on copovidone with cellulosic polymers for significant improvements in adhesion and sprayable solids	
prime	-	coatings based on traditional cellulosic polymers	
prime	LS	coatings based on lactose	
protect	-	label-friendly moisture, odor and taste guard	functional
control	ECD	aqueous dispersion for sustained release based on ethylcellulose	
control	ENA	delayed-release (enteric) coatings based on methacrylic acid-ethyl acrylate copolymer	
control	SRX	sustained-release coatings based on ethylcellulose	

aquarius™ prime LS film coating systems

Ashland's LS series of Aquarius Prime film coatings are made from hypromellose (HPMC) and lactose and are intended to be qualitatively, quantitatively, and functionally equivalent to competitive lactose-based film coating systems. The benefits of LS film coatings include:

- a significant improvement in film adhesion capabilities compared with standard HPMC-based film coating systems
- spray at up to 20% w/w solids but, more realistically, at 17–18% w/w solids

aquarius™ protect film coating system

Aquarius Protect is the premium multi-functional barrier coating system that effectively reduces moisture uptake and masks against offensive taste and odor.

- more natural, protective film coating
- protection from moisture, odors or offensive tastes in oral solid dosage forms
- a water-based coating system
- a range of choices - clear, white, and pigmented variations (Clears: 10–12% solids; White and colors can be sprayed up to 20% solids, remain non-tacky, and enable significant process savings)

aquarius™ control ENA film coating systems

The ENA series of Aquarius Control film coatings are designated for use in delayed-release (enteric) coatings. The benefits of these systems include:

- protection of active pharmaceutical ingredients (APIs) that degrade in gastric fluid
- prevention of the API release that may irritate the gastric mucosa
- provision of stable dissolution profiles over a wide pH range
- production of stable release profiles over periods of up to 12 months

aquarius™ control SRX film coating systems

The SRX series of Aquarius Control film coatings are designated for use in sustained-release coatings wherein APIs are most effective when released over time. The benefits of these systems include:

- solvent-dispersible ethylcellulose coatings for multiparticulates, potentially modified with hydroxypropylcellulose as a pore former
- variable porosities can be matched to active pharmaceutical ingredient solubility and/or desired release profile
- produces coatings that do not require curing after application

These film coating systems produce predictable and controllable release profiles, are custom formulated based on solubility and desired release profile, and do not require a coalescence step.

For more information about Aquarius film coating systems, please visit our film coating troubleshooting guide online at filmcoating-troubleshooting.com.

regulatory information

The regulatory compliance information for all Ashland products varies by product family and grade. Certain Ashland products are harmonized monographs in the NF, Ph, Eur, and JP. Because the compendia allow for non-harmonized attributes by region, for specific data about the grade you are interested in, please refer to our Excipient Information Package or the Certificate of Analysis.

Our staff is very involved in regulatory advocacy activities and trade associations. Among other areas of participation, Ashland was a founding member of the International Pharmaceutical Excipients Council (IPEC) Americas and participates on many committees. We are also active participants in IPEC Europe, IPEC China, IPEC India and SINDUSFARMA in Brazil. In addition, we are active in the ASTM International D01.36 Cellulose subcommittee.

technical capabilities

We offer a range of technical capabilities to meet the needs of the pharmaceutical and nutraceutical industries. Through a global network of technical service laboratories, we provide assistance with formulation development, problem-solving and analytical support. Our facilities are located in Wilmington, Del., USA; São Paulo, Brazil; Mexico City, Mexico; Buenos Aires, Argentina; Düsseldorf, Germany; Hyderabad, India; Istanbul, Turkey; and Shanghai, China;

Our scientists support the pharmaceutical industry with formulation and process development in solid dispersion technology (hot-melt extrusion and spray drying), granulation technologies (fluid bed, high shear, hot-melt extrusion) and controlled-release technologies (release-profile prediction and simulation, melt extrusion, particle and pellet coating, drug layering, matrix tablets).

Additional capabilities include compaction simulation, tablet production and film coating, and stability studies. Ashland also has considerable expertise in characterization of powder properties (flow, particle size, surface area, and morphology).

analytical and testing capabilities include:

- advanced powder flow and segregation testing
- dissolution USP I, II and III
- differential scanning calorimetry and thermogravimetric analysis
- melt rheology
- microscopy—scanning electron, polarized light, and high resolution digital
- kinetic dissolution
- advanced mechanical testing
- size exclusion chromatography
- Karl Fischer titration
- coulometry
- nuclear magnetic resonance
- high-performance liquid chromatography and gas chromatography
- infrared and ultraviolet spectroscopy
- x-ray powder diffraction
- laser diffraction
- ASTREE electronic tongue taste masking analyzer

pilot manufacturing capabilities include:

- fluid beds with capacity up to 5 kg
- several sizes of tablet coaters
- numerous tablet presses and MEDELPHARM StylOne Evolution and Stylcam compaction simulators
- extrusion/spheronization
- hot-melt extruders
- spray dryers
- formulation design
- oral solid dosage forms

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 **Ashland**[™]
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