

AnyCoat[®]

From Nature, Beside you

www.lotte-cellulose.com



LOTTE FINE CHEMICAL

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Since
its founding,
LOTTE Fine Chemical
has grown along with the Korean
chemical industry. We have developed
into a world leader by extending ourselves into
a variety of fields, from intermediate materials and basic
chemical products to high value-added fine chemicals. Not
satisfied with these achievements, our company is preparing
to make another leap forward. We are committed to develop
advanced materials for a better tomorrow and to strengthen
our position as an Advanced Materials Company. We have
established a foundation for steady growth by increasing
production lines and developing new uses for our products.
LOTTE Fine Chemical business is composed of two categories;
General Chemicals and Fine Chemicals. Being a part of our
Fine Chemicals division, AnyCoat® has been more widely
used as an excipient for the pharmaceutical, nutraceutical,
and food industries due to its efficient and stable
functionalities, meeting various needs of customers.
Expanding the scope of applications along with
strengthening the quality of our existing
products, Anycoat® will fit your
diverse formulation
needs.



AnyCoat®

AnyCoat®
Is

AnyCoat® is a cellulose ether derivative.

AnyCoat-C is Hypromellose (Hydroxypropylmethylcellulose) and AnyCoat-P is Hypromellose Phthalate (Hydroxypropyl methylcellulose phthalate).

AnyCoat® is compliant with USP/NF, EP, JP, KP, and etc.

Besides, AnyCoat® has certificates of Kosher, ISO, DMF issued from US FDA, and COS issued from EDQM.



AnyCoat-C comes in diverse viscosity ranges from 3 to 100,000 mPa·s, and it can be widely used for the tablet coating, granulation, binder, thickener, stabilizer and making vegetable capsule.

AnyCoat-P can be widely used for the enteric coating agent to shield APIs against the degradation by gastric acid or keeping them from bringing about side effects in the stomach.

Certificates of AnyCoat®

Certificate	Agency	Remarks
Approval of medicine manufacturing	MFDS ¹⁾	¹⁾ Ministry of Food and Drug Safety of Korea
Kosher Certificate	Orthodox Union	
ISO 9001	KSA ²⁾	²⁾ Korea Standards Association
DMF ³⁾	US FDA	³⁾ Drug Master File
CEP ⁴⁾	EDQM	⁴⁾ Certificate of European Pharmacopoeia
HALAL	KMF ⁵⁾	⁵⁾ Korea Muslim Federation
FSSC 22000 ⁶⁾	SAI GLOBAL	⁶⁾ Food Safety System Certification

Other Certificates and Statements of AnyCoat®

- TSE/BSE statement
- Non-GMO statement
- Allergen statement
- Residual pesticide statement
- Residual solvent statement
- Impurity profile statement



AnyCoat-C

General Characteristics



CAS number	9004-65-3
Chemical name	Cellulose, 2-hydroxypropyl methyl ether
Generic name	Hypromellose, Hydroxypropylmethylcellulose
Molecular weight	10,000 ~ 1,000,000
Melting point	190 ~ 230°C (Tg 170~180°C)
Gelling temperature	40 ~ 90°C
Auto-ignition point	360°C
Bulk density	0.30 ~ 0.52 g/ml
Angle of repose	35 ~ 44°
Admission to compendium	USP/NF, EP, JP, KP, CODEX, JECFA, FCC, etc

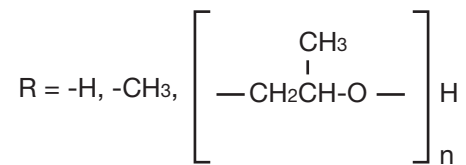
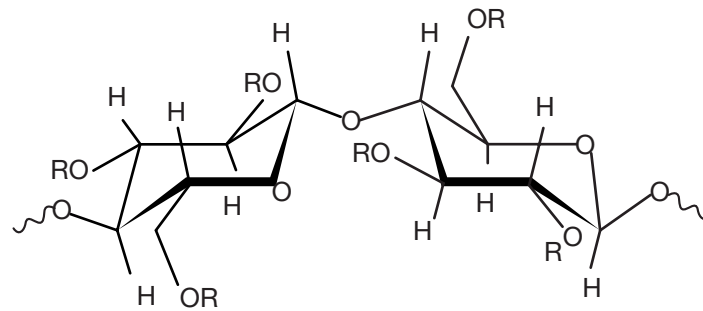


Specifications

Test	USP/NF	EP	JP
Identification	+	+	+
Characters		+	
Appearance of solution		+	
pH (2% w/w solution)	5.0 ~ 8.0	5.0 ~ 8.0	5.0 ~ 8.0
Apparent viscosity			
< 600mPa·s	80 ~ 120% of the normal value	80 ~ 120% of the normal value	80 ~ 120% of the normal value
≥ 600mPa·s	75 ~ 140% of the normal value	75 ~ 140% of the normal value	75 ~ 140% of the normal value
Loss on drying	≤ 5.0%	≤ 5.0%	≤ 5.0%
Residue on ignition	≤ 1.5%	≤ 1.5% (sulfated ash)	≤ 1.5%
Heavy metals	-	-	≤ 20ppm
Methoxy content			
Type 2208	19.0 ~ 24.0%	19.0 ~ 24.0%	19.0 ~ 24.0%
Type 2906	27.0 ~ 30.0%	27.0 ~ 30.0%	27.0 ~ 30.0%
Type 2910	28.0 ~ 30.0%	28.0 ~ 30.0%	28.0 ~ 30.0%
Hydroxypropoxy content			
Type 2208	4.0 ~ 12.0%	4.0 ~ 12.0%	4.0 ~ 12.0%
Type 2906	4.0 ~ 7.5%	4.0 ~ 7.5%	4.0 ~ 7.5%
Type 2910	7.0 ~ 12.0%	7.0 ~ 12.0%	7.0 ~ 12.0%

+ : The detailed account omitted.





Chemical Structure



Grade Nomenclature

AN6 — Normal grade
BN4 — Viscosity
 M) x10
 H) x100
 U) x1,000
 T) x10,000
CN10T — Substitution
 A) HPMC 2910
 B) HPMC 2906
 C) HPMC 2208

Functional Categories

	Effects	Usage	Recommendable grade
 Coating agent	Once soluble in water and volatilized through solvent, AnyCoat® makes transparent film with high tensile strength	1 ~ 3% (coating solution 2 ~ 20%)	AN (low viscosity)
 Granule(tablet) binder	AnyCoat® enhances binding power	2 ~ 5 %	AN (low viscosity)
 Sustained release agent	Hydrophilic matrix used along with AnyCoat® hydrates to create a gel layer, controlling drug release pattern	10 ~ 80%	CN (high viscosity)
 Thickening agent	The viscosity of AnyCoat® exponentially increases in relation to the concentration	0.25 ~ 5.0%	AN, BN, CN (low & high viscosity)

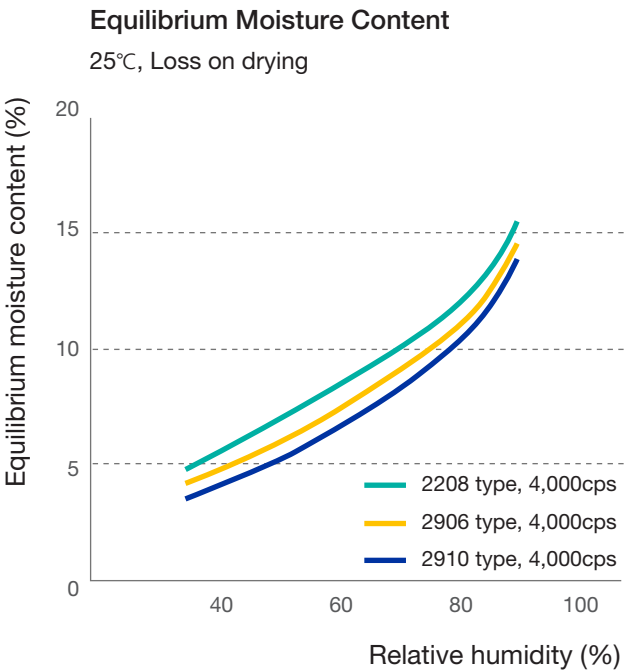


Properties of AnyCoat-C Powder

Equilibrium Moisture Content in Relation to Relative Humidity

Equilibrium moisture content refers to the moisture content of AnyCoat-C powder which reaches equilibrium while exposed to specifically set relative humidity for long.

The figure below is used as an indicator to predict the moisture content of AnyCoat-C stored for long.



Properties of AnyCoat-C Solution

Concentration & Viscosity Relationship

The concentration and viscosity are interrelated, and can be predicted using the following equation.

$$\eta = (1 + KC)^8$$

η : viscosity (mPa·s)

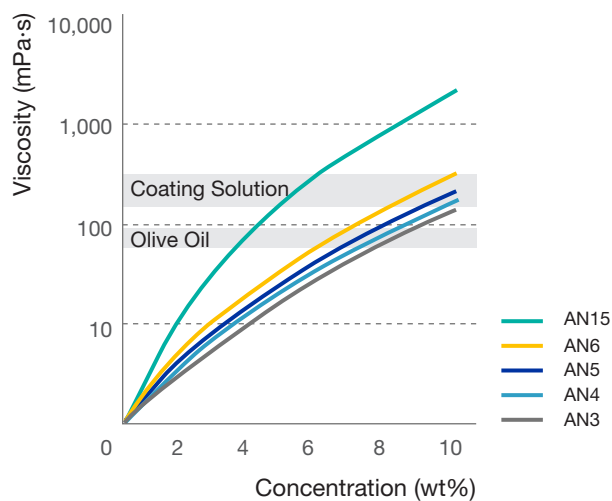
K : constant for each individual polymer

C : concentration (%)



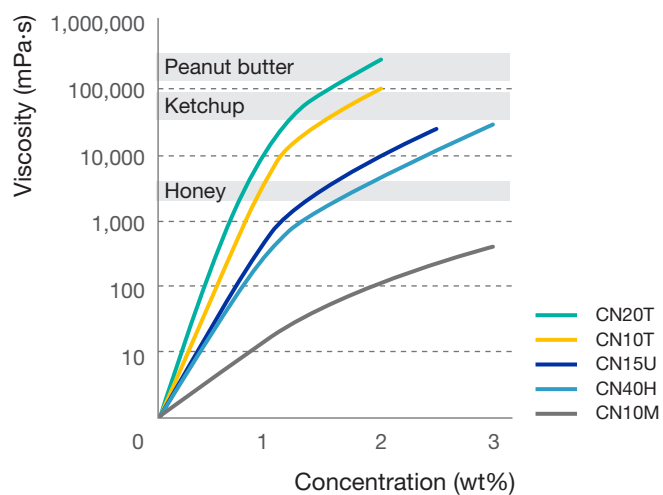
Concentration/Viscosity Relationship

600mPa·s under : Ubbelohde viscometer,
600mPa·s over : Brookfield viscometer, 20°C



Concentration/Viscosity Relationship

600mPa·s under : Ubbelohde viscometer,
600mPa·s over : Brookfield viscometer, 20°C



AnyCoat-P

General Characteristics

CAS number	9050-31-1
Chemical name	Cellulose, 2-hydroxypropyl methyl ether phthalic acid ester
Generic name	Hypromellose phthalate, Hydroxypropylmethylcellulose phthalate
Molecular weight	20,000 ~100,000
Melting point	190 ~ 230°C (Tg 170~180°C)
Bulk density	0.31 ~ 0.42 g/ml
Angle of repose	33 ~ 38°
Admission to compendium	USP/NF, EP, BP, JP, KP etc.



Specifications

Test	USP/NF	EP	JP
Identification	+	+	+
Characters		+	
pH	5.0 ~ 8.0	5.0 ~ 8.0	5.0 ~ 8.0
Apparent viscosity	80 ~ 120% of the normal value	80 ~ 120% of the normal value	80 ~ 120% of the normal value
Water	≤ 5.0%	≤ 5.0%	≤ 5.0%
Residue on ignition	≤ 0.2%	≤ 0.2% (Sulfated ash)	≤ 0.2%
Heavy metals	-	-	≤ 10ppm
Chlorides	≤ 0.07%	≤ 0.07%	≤ 0.07%
Phthalyl content	21.0 ~ 35.0%	21.0 ~ 35.0%	21.0 ~ 35.0%
Free phthalic acid	≤ 1.0%	≤ 1.0%	≤ 1.0%

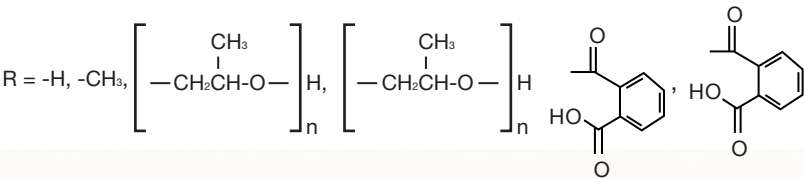
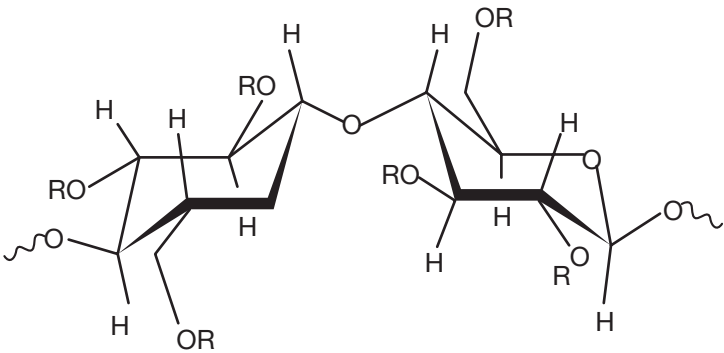
+ : The detailed account omitted.





Chemistry of AnyCoat-P

Test	HP-55	HP-50
Substitution Type	200731	220824
Viscosity (mm ² /s)	32 ~ 48	44 ~ 66
Phthalyl (%)	27.0 ~ 35.0	21.0 ~ 27.0
Insoluble pH range	Under pH 5.5	Under pH 5.0

Chemical Structure



Functional Categories

	Effects	Usage	Recommendable grade
 Enteric function	Gastric resistance - Tablet coating - Granule coating - Capsule coating	4 ~ 10% 5 ~ 7% 7 ~ 12%	HP-55
 Solid dispersion	Suspending aid and drug carrier	5% ~	HP-50 / HP-55



Properties of AnyCoat-P Powder

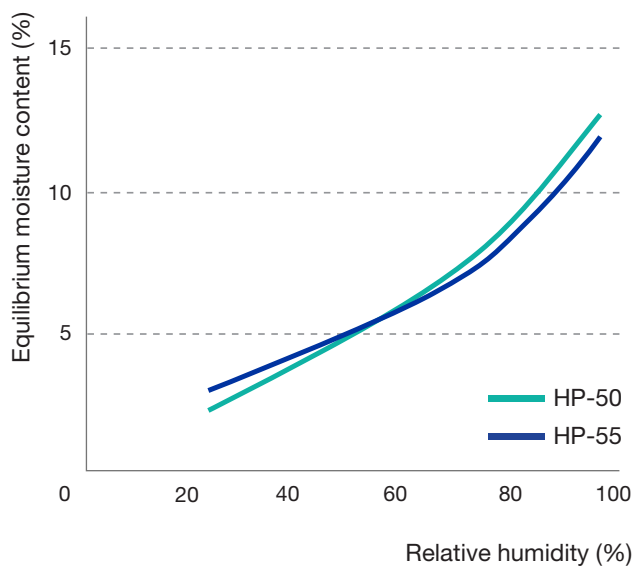
Equilibrium Moisture Content in Relation to Relative Humidity

Equilibrium moisture content refers to the moisture content of AnyCoat-P powder which reaches equilibrium while exposed to specifically set relative humidity for long.

The figure below is used as an indicator to predict the moisture content of AnyCoat-P stored for long.

Equilibrium Moisture Content

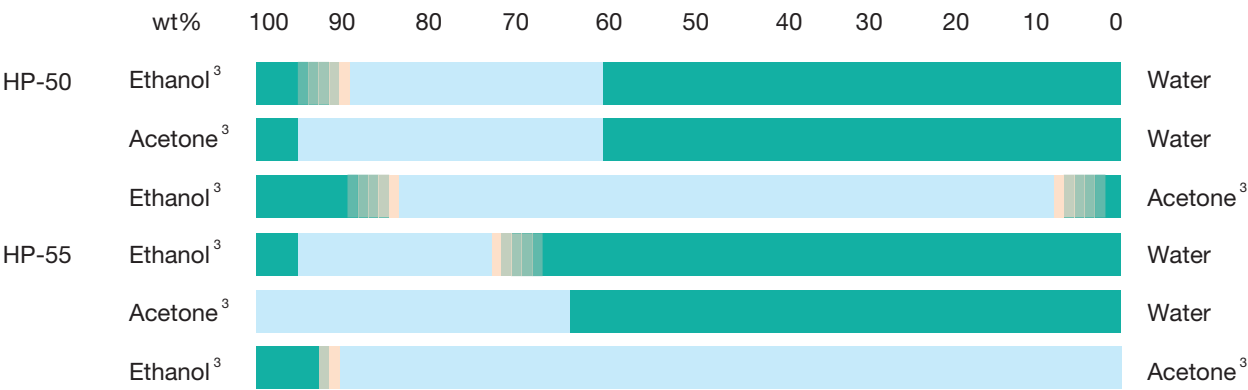
25°C, Loss on drying



Properties of AnyCoat-P Solution

Solubility in Organic Solvent

AnyCoat-P should be dissolved into organic solvent for enteric coating. The solubility of AnyCoat-P based on solvent and mixing ratio, primarily used for enteric coating, is summarized on the figure below. The frequently used plasticizer for AnyCoat-P is PEG 6000~8000, triethyl citrate, acetylated monoglycerides, and so on. In general, 10 to 25% against polymer is added.



Insoluble

Soluble but Opaque

Soluble and Transparent

ICH Guideline Q3C(R3)

Class – 3 : Solvents with low toxic potential

Class – 2 : Solvents to be limited

Substitution type		Hypromellose												Hypromellose Phthalate		Functional Category			
		2910						2906			2208			220824	200731				
Viscosity		3	4	5	6	15	50	4	400	4,000	100	4,000	15,000	100,000	55	40	Effects	Usage	
Grade		AN3	AN4	AN5	AN6	AN15	AN50	BN4	BN40M	BN40H	CN10M	CN40H	CN15U	CN10T	HP50	HP55			
Tablet	Film Coating Aqueous Solvent	●	●	●	●	●											Once soluble in water and volatilized through solvent, AnyCoat® makes transparent film with high tensile strength	1~3%	
	Enteric Coating														●		With pH dependent profile and filmforming capability, Anycoat® helps APIs dissolve not in stomach, but in intestine	5~30%	
	Sustained Release						●				●	●	●	●			Hydrophilic matrix used along with AnyCoat® hydrates to create a gel layer, controlling drug release pattern	10~80%	
	Binder (Wet Granulation)	●	●	●	●	●	●		●									AnyCoat® delivers binding property, and enhances the hardness of tablet	2~5%
Liquid	Thickening							●	●		●	●	●	●			AnyCoat® provides the thickening property. The viscosity of AnyCoat® exponentially increases in relation to the concentration	0.25~5.0%	
	Suspending							●	●		●	●	●				AnyCoat® with hydrophobic and hydrophilic properties as well provides viscous and suspending aid	0.25~5.0%	
Others	Dry Syrup	●	●	●	●	●											Compatible with APIs, AnyCoat® dissolves well in aqueous solution, delivering thickening and suspending aid	0.25~5.0%	
	Capsule Making		●	●	●			●									AnyCoat® delivers excellent film forming and gelling property, making high quality capsule	80~97%	
	Solid Dispersion	●	●	●	●	●		●							●		As a suspending aid and drug carrier for solid dispersion, AnyCoat® provides excellent properties	5%~	
		<div><div>● Highly recommended</div><div>● Recommended</div></div>																	

Package

Package

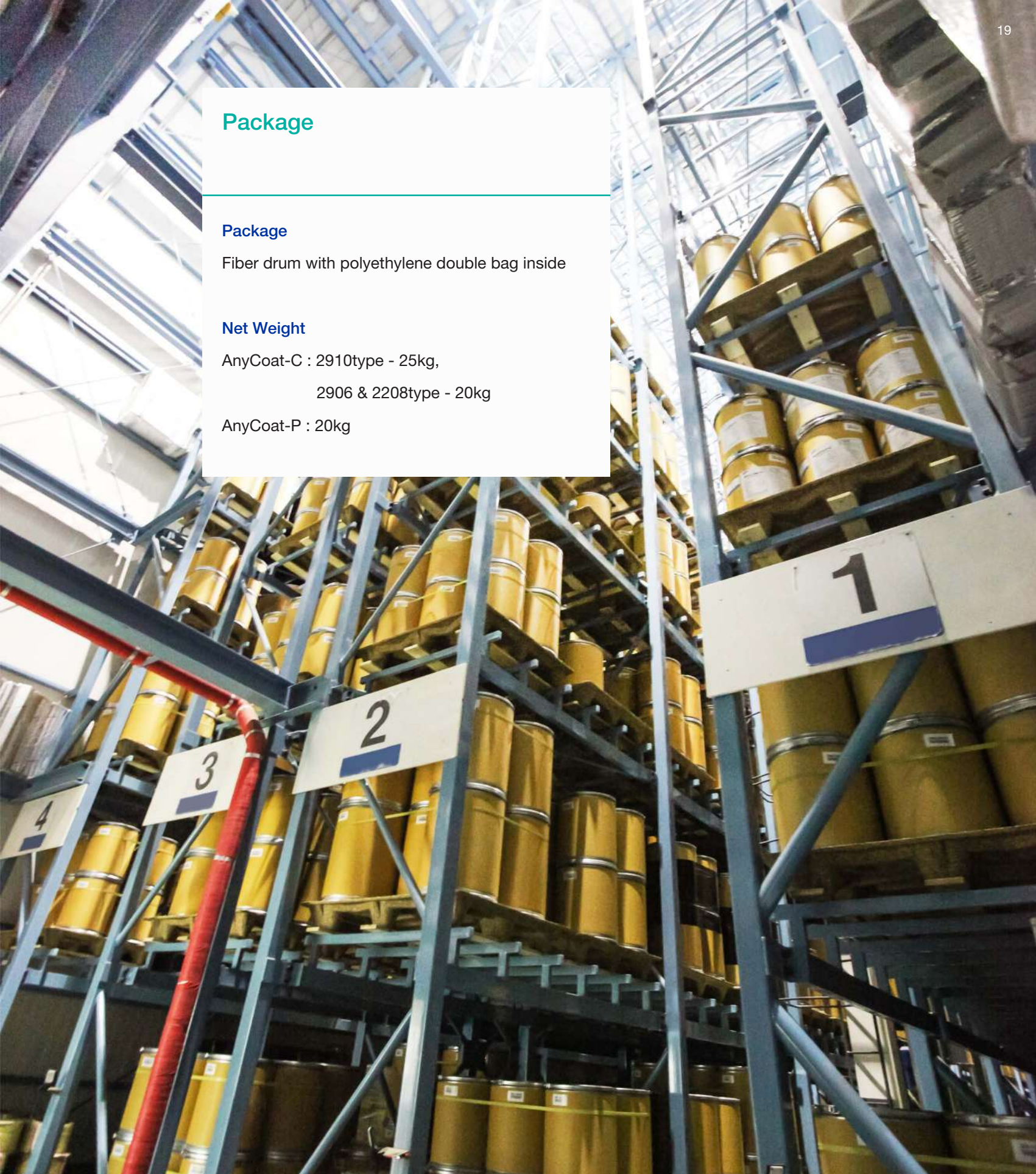
Fiber drum with polyethylene double bag inside

Net Weight

AnyCoat-C : 2910type - 25kg,

2906 & 2208type - 20kg

AnyCoat-P : 20kg





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