



# Regulatory Insights

**Date Passed or Released**  
May 30<sup>th</sup>, 2016

**Government Agency**  
CFDA

**Date Translated**  
June 1<sup>st</sup>, 2016

Excipient List for Health Food Recording System (Part 1)  
《保健食品备案可用辅料名单（第一批）》

Excipient List for Health Food Recording System (Pending for further verifications)  
《尚需进一步论证的保健食品备案可用辅料名单》

## Regulation's Main Points

### Excipient List for Health Food Recording System (Part 1)

Number	Name of Excipients	Applicable Range and Maximum of Dosage (Measurement: g/kg)						
		liquid	Hard capsule	Soft capsule	Drop	Granule\Powder	Tablet	Fondant
1	Arabic Gum	Dosage base on the actual production						
2	Aspartame	0.6	—	—	3.0	3.0	3.0	3.0
3	Benzoic Acid	1.0	0.8	0.8	0.8	0.8	0.8	0.8
4	Sodium Benzoate	1.0	0.8	0.8	0.8	0.8	0.8	0.8

5	β-cyclodextrine	0.5	20.0	20.0	20.0	20.0	20.0	20.0
6	Glacial Acetic Acid(Low Pressure Methanol Carbonylation Process)	Dosage base on the actual production						
7	Erythrosine and its aluminum lake	0.05						
8	Erythritol	Dosage base on the actual production						
9	Starch Acetate	Dosage base on the actual production						
10	D-Mannitol	Dosage base on the actual production						
11	dl-tartaric acid	5.0	10.0	10.0	10.0	10.0	10.0	10.0
12	Parabens and its sodium salt(Sodium methyl paraben, ethylparaben and its sodium salt)	0.25	—	0.25	0.25	—	—	0.25
13	Monoglyceride and diglyceride fatty acids(oleinic acid, linoleic acid, palmic acid, behenic acid, stearic acid, lauric acid, linolenic acid)	6	—					
14	Indigo blue and its aluminum lake	0.1	0.3	0.3	0.3	0.3	0.3	0.3
15	Titanium Dioxide	—	—	Dosage base on the actual production	—	Dosage base on the actual production	Dosage base on the actual production	Dosage base on the actual production

16	Beeswax	—	—	Dosage base on the actual production	Dosage base on the actual production	—	—	Dosage base on the actual production
17	Modified soybean Phospholipid	Dosage base on the actual production						
18	Glycerol	Dosage base on the actual production						
19	Guar Gum	Dosage base on the actual production						
20	Silicon Dioxide	—	Dosage base on the actual production					
21	Pectin	Dosage base on the actual production						
22	Potassium Alginate	Dosage base on the actual production						
23	Sodium Alginate	Dosage base on the actual production						
24	Fumaric acid	0.3	—	8.0	8.0	8.0	8.0	8.0
25	Carthamin	0.2	—	0.5	0.5	0.5	0.5	0.5
26	Monascus Yellow Pigment	Dosage base on the actual production						
27	Talc powder	—	Dosage base on the actual production	—	—	Dosage base on the actual production	Dosage base on the actual production	—
28	Xanthan Gum	Dosage base on the actual production						
29	Methyl Cellulose	Dosage base on the actual production						
30	Gellan Gum	Dosage base on the actual production						
31	Polydextrose	Dosage base on the actual production						
32	Black Bean Red	0.5	—	0.8	0.8	0.8	0.8	0.8
33	Polyoxyethylene Sorbitan Monooleate	10	—					
34	Polyethylene Glycol	-	Dosage base on the actual production	-	-	-	Dosage base on the actual production	-

35	Cacao husk pigment	2.0	—	3.0	3.0	2.0	3.0	3.0
36	Tartaric acid	5.0	10.0	10.0	10.0	5.0	10.0	10.0
37	Brilliant blue and its aluminum lake	0.05	—	0.05	0.05	0.05	0.05	0.05
38	Dicalcium Phosphate	5.0	5.0	5.0	5.0	5.0	5.0	5.0
39	Tricalcium Phosphate	5.0	5.0	5.0	5.0	5.0	5.0	5.0
40	Caramel	Dosage base on the actual production	—					
41	Phospholipid	Dosage base on the actual production						
42	PGFE	0.1	Dosage base on the actual production					
43	Maltose	Dosage base on the actual production						
44	Maltitol and liquid maltitol	Dosage base on the actual production						
45	Roselle red	Dosage base on the actual production						
46	Gelatin	Dosage base on the actual production						
47	Xylitol	Dosage base on the actual production						
48	Lemon Yellow and its aluminum lake	0.1	—	0.3	0.3	0.3	0.3	0.3
49	Citric acid	Dosage base on the actual production						
50	Citric acid	Dosage base on the actual production						
51	Potassium citrate	Dosage base on the actual production						
52	Sodium citrate	Dosage base on the actual production						
53	Pullulan	3.0	—	50.0	50.0	50.0	50.0	50.0
54	L-malic acid	Dosage base on the actual production						
55	DL-malic acid	Dosage base on the actual production						
56	Chili orange	0.05	—	0.05	0.05	0.05	0.05	0.05
57	Chili red	0.05	—	0.05	0.05	0.05	0.05	0.05
58	Grape skin red	2.5	—	2.0	2.0	2.0	2.0	2.0

59	Disodium hydrogen phosphate	0.1	—					
60	Hydroxypropyl starch	Dosage base on the actual production						
61	Hydroxypropyl distarch phosphate	Dosage base on the actual production						
62	HPMC	Dosage base on the actual production						
63	Agar	Dosage base on the actual production						
64	Carmine red and its aluminum lake	0.025	—	0.5	0.5	0.5	0.5	0.5
65	Sunset yellow and its aluminum lake	0.1	—	0.3	0.3	0.3	0.3	0.3
66	Lactic acid	Dosage base on the actual production						
67	Sucralose	0.25	—	1.5	1.5	1.5	1.5	1.5
68	Sorbitol	Dosage base on the actual production						
69	Sorbitol liquid	Dosage base on the actual production						
70	CMS	Dosage base on the actual production						
71	Sodium Carboxymethyl cellulose	Dosage base on the actual production						
72	Sodium Carbonate	Dosage base on the actual production						
73	Sodium bicarbonate	Dosage base on the actual production						
74	Saccharin Sodium	0.15	—	Dosage base on the actual production				
75	Betanin	Dosage base on the actual production	—	Dosage base on the actual production				
76	Stevioside	0.2	—	3.5	3.5	3.5	3.5	3.5
77	Sodium Triphosphate (STPP)	0.18	5	5	5	5	5	5
78	Natural amaranthus red	0.25	—	0.25	0.25	0.25	0.25	0.25
79	Sorbic acid	2.0	0.75	0.75	0.75	0.75	0.75	0.75
80	Potassium Sorbate	2.0	0.75	0.75	0.75	0.75	0.75	0.75

81	Stearic acid	1.2						
82	Magnesium stearate	0.8						
83	Acesulfame potassium	0.3	4	4	4	4	4	4
84	Microcrystalline Cellulose	Dosage base on the actual production						
85	Starch sodium octenylsuccinate (SSOS)	Dosage base on the actual production						
86	Oxidized Starch	Dosage base on the actual production						
87	Oxidized hydroxypropyl starch	Dosage base on the actual production						
88	Sodium copper chlorophyll	0.5	0.5	0.5	0.5	0.5	0.5	0.5
89	Isomaltulose	Dosage base on the actual production						
90	Acetylated Distarch Phosphate	Dosage base on the actual production						
91	Allura Red and its aluminum lake	0.1	—	0.3	0.3	0.3	0.3	0.3
92	Gardenia blue	0.2	—	1	1	1	1	1
93	Gardenia yellow	0.2	—	1	1	1	1	1
94	Vegetable carbon black	5.0	5.0	5.0	5.0	5.0	5.0	5.0
95	Food flavor (cherry flavor, orange flavor, milk flavor, apple flavor, chocolate flavor, cream flavor, lemon flavor, vanilla flavor)	Dosage base on the actual production						
96	ODO	Dosage base on the actual production						
97	Dextrin	Dosage base on the actual production						
98	Starch	Dosage base on the actual production						
99	Oil-tea camella seed oil	Dosage base on the actual production						
100	Corn oil	Dosage base on the actual production						

101	Sunflower oil	Dosage base on the actual production						
102	Maltodextrin	Dosage base on the actual production						
103	Corn Starch	Dosage base on the actual production						
104	Safflower seed oil	Dosage base on the actual production						
105	Peanut oil	Dosage base on the actual production						
106	Soybean oil	Dosage base on the actual production						
107	Walnut oil	Dosage base on the actual production						
108	Salad oil	Dosage base on the actual production						
109	potato starch	Dosage base on the actual production						
110	Salt	Dosage base on the actual production						
111	Water (include pure water, purified water etc.)	Dosage base on the actual production						
112	Condensed milk	Dosage base on the actual production						
113	Vitamin C	5.0						
114	Vitamin E	0.2						
115	Amaranth and its aluminum lake	0.025	—	0.05	0.05	0.05	0.05	0.05
116	Cocoa powder and cocoa butter	Dosage base on the actual production						
117	Cream (butter)	Dosage base on the actual production						
118	Wheat starch	Dosage base on the actual production						
119	Olive oil	Dosage base on the actual production						
120	Sesame Oil	Dosage base on the actual production						
121	Milk powder	Dosage base on the actual production						
122	rapeseed oil	Dosage base on the actual production						
123	Polysorbate 80	Dosage base on the actual production						
124	Pregelatinized Starch	Dosage base on the actual production						
125	Croscarmellose sodium	Dosage base on the actual production						
126	PVPP	Dosage base on the actual production						

127	HPC	Dosage base on the actual production
128	PVP K30	Dosage base on the actual production
129	L-HPC	Dosage base on the actual production
130	simple syrup	Dosage base on the actual production
131	Iron oxide black	Dosage base on the actual production
132	Iron oxide red	Dosage base on the actual production
133	Coating premixed agent	Dosage base on the actual production
134	CPP	Dosage base on the actual production
135	White sugar	Dosage base on the actual production
136	Other sugar and syrup (such as brown sugar, brown granulated sugar)	Dosage base on the actual production
137	Starch sugar (such as fructose, glucose etc.)	Dosage base on the actual production
138	Other sweetener (Isomaltitol, lactitol, lactose etc.)	Dosage base on the actual production
139	Sucrose	Dosage base on the actual production
140	Glucose	Dosage base on the actual production
141	Lactose	Dosage base on the actual production
142	High fructose syrup	Dosage base on the actual production
143	Corn syrup	Dosage base on the actual production
144	Glucose syrup	Dosage base on the actual production
145	Yellow iron oxides	Dosage base on the actual production
146	BHA	Dosage base on the actual production
147	BHT	Dosage base on the actual production
148	Sodium hexametaphosphate	Dosage base on the actual production
149	MCT	Dosage base on the actual production



150	O-palmitoyl-L-ascorbic acid	Dosage base on the actual production
151	Calcium silicate	Dosage base on the actual production
152	Rosemary extract	Dosage base on the actual production
153	Starch sodium octenylsuccinate (SSOS)	Dosage base on the actual production; only can be used for microencapsulation process
154	Tetrasodium pyrophosphate	Dosage base on the actual production; only can be used for microencapsulation process
155	Calcium stearate	Dosage base on the actual production; only can be used for microencapsulation process

## Excipient List for Health Food Recording System (Pending for further verifications)

Number	Name of Excipients	Applicable Range and Maximum of Dosage (Measurement: g/kg)							
		Liquid	Hard capsule	Soft capsule	Drop	Granule\Powder	Tablet	Fondant	Solid drink
1	Benzoic Acid	1.0	0.8	0.8	0.8	1.0, For solid drink, calculation base on the diluted times.	0.8	0.8	1.0, For solid drink, calculation base on the diluted times.
2	Sodium Benzoate	1.0 (On Benzoic acid basis)	0.8 (On Benzoic acid basis)	0.8 (On Benzoic acid basis)	0.8 (On Benzoic acid basis)	1.0 (On Benzoic acid basis) , For solid drink, calculation base on the diluted times.	0.8 (On Benzoic acid basis)	0.8 (On Benzoic acid basis)	1.0 (On Benzoic acid basis) , For solid drink, calculation base on the diluted times.
3	Sodium acetate	1.0							



9	Fumaric acide	0.6	8.0	8.0	8.0	0.6, For solid drink, calculation base on the diluted times.	8.0	8.0	0.6, For solid drink, calculation base on the diluted times.
10	Black Bean red	0.8	0.8	0.8	0.8	0.8, For solid drink, calculation base on the diluted times.	0.8	0.8	0.8, For solid drink, calculation base on the diluted times.
11	Sodium Cyclamate	0.65	8.0	8.0	8.0	0.65, For solid drink, calculation base on the diluted times.	8.0	8.0	0.65, For solid drink, calculation base on the diluted times.
12	Caramel	Dosage base on the actual production							
13	PGFE	10.0	10.0	10.0	10.0	10.0, For solid drink, calculation base on the diluted times.	10.0	10.0	10.0, For solid drink, calculation base on the diluted times.

14	Polyvinyl Alcohol	Dosage base on the actual production							
15	Carrageenan	Dosage base on the actual production							
16	Quinoline yellow	0.1	—	—	0.1	—	—	—	—
17	Chili Orange	-	Dosage base on the actual production		-	-	Dosage base on the actual production		-
18	Chili Red	Dosage base on the actual production							
19	Casein Sodium	Dosage base on the actual production							
20	Sodium Hexametaphosphate	5.0	5.0	5.0	5.0	5.0, For solid drink, calculation base on the diluted times.	5.0	5.0	5.0, For solid drink, calculation base on the diluted times.
21	Sodium hydrogen phosphate	5.0	5.0	5.0	5.0	5.0, For solid drink, calculation base on the diluted times.	5.0	5.0	5.0, For solid drink, calculation base on the diluted times.
22	Calcium lactate	21.6	Dosage base on the actual production						21.6

23	Sodium lactate	Dosage base on the actual production							
24	Lactitol	Dosage base on the actual production							
25	Sodium triphosphate	5.0	5.0	5.0	5.0	5.0, For solid drink, calculation base on the diluted times.	5.0	5.0	5.0, For solid drink, calculation base on the diluted times.
26	Hippophae rhamnoides yellow	1.5							
27	Sorbic acid	0.5	1.5	1.5	1.5	0.5, For solid drink, calculation base on the diluted times.	1.5	1.5	0.5, For solid drink, calculation base on the diluted times.

28	Potassium Sorbate	0.5 (On Sorbic acid basis)	1.5 (On Sorbic acid basis)	1.5 (On Sorbic acid basis)	1.5 (On Sorbic acid basis)	0.5 (On sorbic acid basis) , For solid drink, calculation base on the diluted times.	1.5 (On Sorbic acid basis)	1.5 (On Sorbic acid basis)	0.5 (On sorbic acid basis) , For solid drink, calculation base on the diluted times.
29	Vitamin C	Dosage base on the actual production							
30	Vitamin E	Dosage base on the actual production							
31	Amaranth and its aluminum lake	0.05 (On amaranth basis)	0.05 (On amaranth basis)	0.05 (On amaranth basis)	0.05 (On amaranth basis)	0.05 (On amaranth basis)	0.05 (On amaranth basis)	0.05 (On amaranth basis)	0.05 (On amaranth basis)
32	Cochineal carmine red	0.6	0.3	0.3	0.3	0.6, For solid drink, calculation base on the diluted times.	0.3	0.3	0.6, For solid drink, calculation base on the diluted times.

33	Carminum and its aluminum lake	0.05 (On Carminum basis)	0.05 (On Carminum basis)	0.05 (On Carminum basis)	0.05 (On Carminum basis)	0.05 (On Carminum basis) , For solid drink, calculation base on the diluted times.	0.05 (On Carminum basis)	0.05 (On Carminum basis)	0.05 (On Carminum basis) , For solid drink, calculation base on the diluted times.
34	Iron Oxide Black	Dosage base on the actual production							
35	Iron Oxide Red	Dosage base on the actual production							
36	Ethyl Acetate	Dosage base on the actual production							
37	Acesulfame potassium	0.3	2.0	2.0	2.0	0.3, For solid drink, calculation base on the diluted times.	2.0	2.0	0.3, For solid drink, calculation base on the diluted times.
38	Stearic acid	Dosage base on the actual production							
39	Magnesium stearate	Dosage base on the actual production							



40	Gardenia blue	0.5	0.3	0.3	0.3	0.5, For solid drink, calculation base on the diluted times.	0.3	0.3	0.5, For solid drink, calculation base on the diluted times.
41	Gardenia yellow	0.3	0.3	0.3	0.3	1.5	0.3	0.3	1.5
42	Carnauba wax	—	0.6	0.6	0.6	—	0.6	0.6	—
43	Pregelatinized starch	Dosage base on the actual production							
44	Croscarmellose sodium	Dosage base on the actual production							
45	PVPP	Dosage base on the actual production							
46	HPC	Dosage base on the actual production							
47	PVP K30	Dosage base on the actual production							
48	L-HPC	Dosage base on the actual production							
49	Simple syrup	Dosage base on the actual production							
50	Coating Premixed Agent	Dosage base on the actual production							
51	CPP	Dosage base on the actual production							
52	Isomaltitol	Dosage base on the actual production							
53	Cyanocobalamin	Dosage base on the actual production							
54	Ethyl Maltol	Dosage base on the actual production							

55	Lycopene	0.015	0.06	0.06	0.06	0.015, For solid drink, calculation base on the diluted times.	0.06	0.06	0.015, For solid drink, calculation base on the diluted times.
56	Tomato color	0.06	0.06	0.06	0.06	0.006,For solid drink, calculation base on the diluted times.	0.06	0.06	0.006, For solid drink, calculation base on the diluted times.
57	Monascus color	Dosage base on the actual production							
58	Red yeast rice powder	Dosage base on the actual production							
59	Radish red	Dosage base on the actual production							
60	O-palmitoyl-L-ascorbic acid	Dosage base on the actual production							
61	Sucrose fatty acide ester	1.5	10	10	10	1.5, For solid drink, calculation base on the diluted times.	10	10	1.5, For solid drink, calculation base on the diluted times.

62	Hydrochloric	Dosage base on the actual production							
63	Lactulose liquid	1.5, calculation base on the diluted times.	-			1.5, calculation base on the diluted times.	-		1.5, calculation base on the diluted times.
64	Sodium Hydroxide	Dosage base on the actual production							
65	Rosemary extract	0.7	0.3	0.7	0.7	14	0.3	0.3	14
66	Calcium silicate	Dosage base on the actual production							
67	Curcumin	Dosage base on the actual production							
68	Polydimethyl siloxane	0.0009							
69	MCT Medium Chain Triglyceride	Dosage base on the actual production							
70	Sucrose	Dosage base on the actual production							
71	Glucose	Dosage base on the actual production							
72	Puffing powder	—	—	—	—	Dosage base on the actual production	—	—	Dosage base on the actual production
73	Lactose	Dosage base on the actual production							
74	High Fructose syrup	Dosage base on the actual production							
75	Glucose syrup	Dosage base on the actual production							

76	Concentrate fruits and vegetables juice (apple juice, orange juice, lemon juice, pineapple juice, blueberry juice, lychee juice, peach juice, veggie juice etc.),fruits powder.	Dosage base on the actual production
77	Acerola Cherry powder and extracts	Dosage base on the actual production
78	Yellow iron oxides	Dosage base on the actual production
79	CITREM	Dosage base on the actual production
80	Triacetin	Dosage base on the actual production
81	GOS	Dosage base on the actual production
82	Wheat-germ oil	Dosage base on the actual production
83	Polysorbate 80	Dosage base on the actual production

84	Dipotassium phosphate	5.0	5.0	5.0	5.0	5.0, For solid drink, calculation base on the diluted times.	5.0	5.0	5.0, For solid drink, calculation base on the diluted times.
85	Soy protein	Dosage base on the actual production							
86	Linseed oil	Dosage base on the actual production							
87	Grape seed oil	Dosage base on the actual production							
88	Rice oil	Dosage base on the actual production							
89	Xylooligosaccharide	≤3.0g/day							
90	Puffing powder	—	—	—	—	Dosage base on the actual production	—	—	Dosage base on the actual production
91	High Fructose syrup	Dosage base on the actual production							
92	Glucose syrup	Dosage base on the actual production							

93	Concentrate fruits and vegetables juice (apple juice, orange juice, lemon juice, pineapple juice, blueberry juice, lychee juice, peach juice, veggie juice etc.),fruits powder.	Dosage base on the actual production							
94	Acerola Cherry powder and extracts	Dosage base on the actual production							
95	Calcium sulfate	—	10.0	—	—	10.0	10.0	10.0	10.0
96	Yellow iron oxides	Dosage base on the actual production							
97	CITREM	Dosage base on the actual production							
98	Triacetin	Dosage base on the actual production							
99	Wheat-germ oil	Dosage base on the actual production							
100	Polysorbate 80	Dosage base on the actual production							

101	Dipotassium phosphate	5	5	5	5	5, For solid drink, calculation base on the diluted times.	5	5	5, For solid drink, calculation base on the diluted times.
102	Starch sugar	Dosage base on the actual production							
103	Corn syrup	Dosage base on the actual production							
104	Soy protein	Dosage base on the actual production							
105	Linseed oil	Dosage base on the actual production							
106	Grape seed oil	Dosage base on the actual production							
107	Rice oil	Dosage base on the actual production							
108	Xylooligosaccharide	≤3.0g/day							
109	β-carotene	2.0, For solid drink, calculation base on the diluted times.	0.5	0.5	0.5	2.0, For solid drink, calculation base on the diluted times.	0.5	0.5	2.0, For solid drink, calculation base on the diluted times.

110	$\beta$ -apo-8'-carotene aldehyde	0.01	0.015	0.015	0.015	0.01, For solid drink, calculation base on the diluted times.	0.015	0.015	0.01, For solid drink, calculation base on the diluted times.
111	Glacial acetic acid, Glacial acetic acid(Low Pressure Methanol Carbonylation Process)	Dosage base on the actual production							
112	Alcohol	Dosage base on the actual production							
113	Ethyl cellulose	Dosage base on the actual production							
114	Acid red	0.05	0.05	0.05	0.05	0.05, For solid drink, calculation base on the diluted times.	0.05	0.05	0.05, For solid drink, calculation base on the diluted times.



115	Xanthophyll	0.05	0.15	0.15	0.15	0.05,For solid drink, calculation base on the diluted times.	0.15	0.15	0.05,For solid drink, calculation base on the diluted times.
116	Tea polyphenols	0.1	0.1	0.1	0.1	0.8	0.1	0.1	0.8
117	Sodium ascorbate	Dosage base on the actual production							
118	Sodium stearyl lactate	2.0							
119	Phosphoric acid	5.0	5.0	5.0	5.0	5.0, For solid drink, calculation base on the diluted times.	5.0	5.0	5.0, For solid drink, calculation base on the diluted times.
120	n-capric aldehyde	Dosage base on the actual production							
121	Potassium chloride	Dosage base on the actual production							

122	Monopotassium phosphate	5.0	5.0	5.0	5.0	5.0, For solid drink, calculation base on the diluted times.	5.0	5.0	5.0, For solid drink, calculation base on the diluted times.
123	Tetrasodium pyrophosphate	5.0	5.0	5.0	5.0	5.0, For solid drink, calculation base on the diluted times.	5.0	5.0	5.0, For solid drink, calculation base on the diluted times.
124	Calcium stearate	20.0							
125	Thaumatococcus	0.025	0.025	0.025	0.025	0.5	0.025	0.025	0.5
126	Coconut oil	Dosage base on the actual production							
127	Maltose	Dosage base on the actual production							
128	Tapioca starch	Dosage base on the actual production							
129	SSOS	Dosage base on the actual production							
130	Propylene glycol alginate	0.3	0.3	5.0	5.0	0.3, For solid drink, calculation base on the diluted times.	5.0	5.0	0.3, For solid drink, calculation base on the diluted times.

131	Part-hydrogenate soybean oil, hydrogenate soybean oil	Dosage base on the actual production
132	Acid modified starch	Dosage base on the actual production
133	Edible vegetable oil	Dosage base on the actual production
134	Palm oil	Dosage base on the actual production
135	TEC	Dosage base on the actual production
136	D-xylose	Dosage base on the actual production
137	L-arabinose	Dosage base on the actual production