Sanitation Standard for Processing Aids

MOHW Food No. 1051300445 Announced. 02/17/2016
MOHW Food No. 1091302097 Amended.08/11/2020

Article 1 The Standards are prescribed in accordance with the provisions of Article 17 of the Act Governing Food Safety and Sanitation.

Article 2 Processing aid means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product. Any residues of processing aids remaining in the food after processing should not perform a technological function in the final product.

Article 3 The quantity of the substance used as processing aid shall be limited to the lowest achievable level necessary to accomplish its desired technological purpose. Residues or derivatives of the substance remaining in food should be reduced to the extent reasonably achievable and should not pose any health risk.

Article 4 The use of processing aids shall meet appendix 1.

Article 5 The specification of processing aids shall meet appendix 2.

Article 6 The Standards shall be implemented from the date of promulgation.

Appendix 1: The Application Standard of Processing Aids

Solvents

No.	Items	Application Standard
1	Propylene Glycol	All foods: as practically needed.
2	Glycerol	All foods: as practically needed.
3	Hexane	1. Extraction of fats and oils: residue not more than 0.1 ppm. 2. Other foods: residue not more than 20 ppm.
4	Isopropyl Alcohol (2-Propanol; Isopropanol)	1. Oleoresin: residue not more than 50 ppm. 2. Lemon oil: residue not more than 6 ppm. 3. Hops extract: residue not more than 2.0% by weight.
5	Acetone	1. Oleoresin: residue not more than 30 ppm. 2. Other foods: residue not more than 0.1 ppm.
6	Ethyl Acetate	All foods: residue not more than 10 ppm.
7	Triacetin (Glyceryl Triacetate)	All foods: as practically needed.
Note: For solvent not on the list, food businesses shall submit an application to Ministry of Health and Welfare with evaluation documents including the use, specification and the international standards of the solvent.		

Appendix 2 Specifications of Processing Aids

1. Propylene Glycol

Chemical formula: $C_3H_8O_2$ Molecular weight: 76.10

1. Appearance : Clear, colorless, hygroscopic, viscous liquid
2. Density : 1.036～1.040.
3. Boiling Point : 183～195℃.
4. Free acid : Add 1 mL of phenol red TS to 50 mL water, then add 0.01N sodium hydroxide until solution remains red for 30 sec. To this solution add about 10 mL of the sample. Titrate with 0.2 m of 0.1 N sodium hydroxide until the original red color returns and remains for 30 sec.
5. Chloride : Not more than 70 ppm of Cl.
6. Heavy metals : Not more than 5 ppm (as Pb).
7. Glycerin and ethylene glycol : Accurately weigh 1 g of the sample and add water to make a 1000 mL solution. Add 0.2 g of potassium periodate, 1 mL of sulfuric acid and 50 mL of water to 13 mL of the solution, and distill at a rate of 3 to 5 mL per minute until the residue is about 1 mL (the receiver of the distillate should be placed in iced water). The distillate is added with water to make it 500 mL. Add 0.1 g of chromic acid and 5 mL of sulfuric acid to 1 mL of distillate solution, heat in a water bath for 30 minutes, then cool. When adding water to make it 250 mL, the liquid color should not be thicker than 1 mL of formaldehyde standard solution undergone the same process.
8. Residue on ignition : Not more than 0.05%.

2. Glycerol

Chemical formula: $C_3H_8O_3$ Molecular weight: 92.10

1. Assay : Not less than 95%
2. Identification : Add 2 to 3 drops of the sample to 0.5 g of potassium hydrogen sulfate. After heating, a pungent acrolein odor is produced.
3. Description : Clear, colorless, hygroscopic, syrupy liquid, having a not more than a slight characteristic odor, which is neither harsh nor disagreeable. Miscible with water and with ethanol; immiscible with chloroform, ether and grease.
4. pH : The aqueous solution of the sample should be neutral.
5. Density : 1.250～1.264.
6. Chloride : Not more than 0.003% of Cl.
7. Arsenic : Not more than 4 ppm (as As_2O_3).
8. Heavy metals : Not more than 5 ppm (as Pb).
9. Fatty acids and esters : Not more than 0.1% (as butyric acid)
10. Acrolein, glucose and ammonium salt : Mix and heat 5mL of the sample and 5 mL of potassium hydroxide TS (1 g of potassium hydroxide dissolved in 10 mL of water) at 60°C for 5 minutes. No yellow color or an odor of ammonia is produced.
11. Residue on ignition : Not more than 0.01% (800±25° to constant weight).

3. Hexane

Definition: Hexane mainly contains n-Hexane (C_6H_{14})

1.	Description	: Hexane is a clear, colorless, volatile liquid having a characteristic odor.
2.	Specific gravity	: 0.659～0.685
3.	Refractive Index	: n_D^{20}=1.374～1.386
4.	pH	: Add 10 mL of water to 30 mL of this product. After fully oscillating and mixing, the water layer should be neutral.
5.	Sulfur compounds	: Measure 5 mL of Hexane, add 5 mL of silver nitrate–ammonia TS, and heat at 60 °C for 5 minutes with protection from light, while shaking well. No brown color develops.
6.	Readily carbonizable substances	: Add 5 mL of sulfuric acid to 5 mL of sample and shake well for 5 minutes. The color of the sulfuric acid layer should not be darker than that of the Matching Fluid B.
7.	Benzene	: Not more than 0.25 v/v ％.
8.	Distillate	: Not less than 95% (vol) (64–70 °C).
9.	Residue on evaporation	: Not more than 13 ppm (105°C, 30 min).

4. Isopropyl Alcohol (Isopropanol)

Synonyms: 2-Propanol , propan-2-ol

Chemical formula: C_3H_8O CAS No. 67-63-0 Molecular weight: 60.10

1.	Assay	: Not less than 99.5% of C3H8O
2.	Description	: Clear, colourless, mobile liquid with a characteristic odour
3.	Solubility	: Miscible with water, ethanol, ether and other organic solvents
4.	Specific gravity	: d_{20}^{20}: 0.784 - 0.788
5.	Refractive index	: n_D^{20} = 1.377-1.380
6.	Water	: Not more than 0.2% (Karl Fischer Method)
7.	Distillation range	: Within a range of 1 °C including 82.3 °C
8.	Non-volatile residue	: Not more than 2 mg/100 ml
9.	Acidity	: Not more than 0.002 % (as acetic acid)
10.	Other alcohols, ethers and volatile impurities	: Not more than 0.5 % total, with not more than 0.1% of any single ethers.
11.	Lead	: Not more than 1 mg/kg

5. Acetone

Synonyms: Dimethylketone, propanone, propan-2-one

Chemical formula: C_3H_6O CAS No. 67-64-1 Molecular weight: 58.08

1.	Assay	: Not less than 99.5%
2.	Description	: Clear, colourless, volatile, highly flammable liquid with a characteristic odour; free from sediment and suspended matter
3.	Solubility	: Miscible in all proportions with water and with ethanol
4.	Specific gravity	: d_{20}^{20}: 0.790 - 0.793
5.	Refractive index	: n_D^{20} = 1.358 -1.360
6.	Distillation range	: 55.5 - 57.0°C
7.	Non-volatile residue	: Not more than 0.001% (w/w)
8.	Acidity	: Not more than 0.002% (w/w) (calculated as acetic acid)
9.	Phenol	: Not more than 0.001% (w/w)
10.	Readily oxidizable substances	: 30 ml of the sample does not discolour 0.1 ml of 3% m/v freshly prepared aqueous potassium permanganate solution when shaken and allowed to stand at 20°C for 15 min.

6. Ethyl Acetate

Synonyms: Acetic acid ethyl ester, ethyl ethanoate

Chemical formula: $C_4H_8O_2$ CAS No. 141-78-6 Molecular weight: 88.11

1.	Assay	: Not less than 99.0%
2.	Description	: Colourless, transparent liquid having a fruity odour
3.	Specific gravity	: d_{25}^{25}: 0.894-0.901
4.	Refractive index	: n_D^{20} = 1.371-1.376
5.	Acid value	: Not more than 5.0
6.	Boiling point	: 77°C

7. Triacetin

Synonyms: Glyceryl triacetate

Chemical formula: $C_9H_{14}O_6$ CAS No. 102-76-1 Molecular weight: 218.21

1.	Assay	: Not less than 98.5% on the anhydrous basis
2.	Description	: Colourless, somewhat oily liquid having a slight, fatty odour
3.	Solubility	: Sparingly soluble in water, soluble in ethanol
4.	Test for glycerol	: Heat a few drops in a test tube with about 0.5 g of potassium bisulfate. Pungent vapours of acrolein are evolved
5.	Test for acetate	: Passes test To be performed on the solution resulting from the assay
6.	Water	: Not more than 1.0% (Karl Fischer Method)
7.	Refractive index	: 1.429 - 1.431 at 25 °C
8.	Specific gravity	: d_{25}^{25}: 1.154-1.158
9.	Distillation range	: 258 – 270 °C
10.	Sulfated ash	: Not more than 0.02 %
11.	Acidity	: Accurately weigh a sample of 25 g, dilute with 50 ml of neutralized ethanol, and add 5 drops of phenolphthalein TS. Not more than 1 ml of 0.02N sodium hydroxide is required to produce a pink colour.
12.	Unsaturated compounds	: To 10 ml of the sample in a glass-stoppered tube add dropwise a 1 in 100 solution of bromine in carbon tetrachloride until a permanent yellow colour is produced. No turbidity or precipitate appears after 18 h in the dark.
13.	Lead	: Not more than 2 mg/kg