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QUALITY ASSURANCE SPECIFICATIONS

PRODUCT NAME: AMISOFT® CS-22

CTFA INCI Name: Disodium Cocoyl Glutamate, Sodium Cocoyl Glutamate, Water

Chemical Name: Sodium N-Cocoyl-L-Glutamate, Water

Specification

Item	Specification	Method
(1) Description	Colorless to pale yellow liquid, a slightly characteristic odor	JSQI [General Notices 27]
(2) Identification		
Infrared Spectrophotometry	Passed test	JSQI *1
Gas Chromatography	Passed test	JSQI *2
Sodium Salt	Passed test	JSQI *3
(3) Transmittance	NLT 80.0%	JSQI [Neat, 430nm, water]
(4) pH	6.0 ~ 7.0	JSQI [Neat, 20°C]
(5) Heavy Metals (Pb)	NMT 20ppm	JSQI [1.0g, Method-2]
(6) Arsenic (As_2O_3)	NMT 2ppm	JSQI [1.0g, Method-3]
(7) Content	24.0 ~ 26.0%	*4
(8) Coliforms	Not detected	50mL , MF-Method

JSQI: The Japanese Standards of Quasi-Drug Ingredients

Test Method

*1: Infrared Spectrophotometry

Determine the infrared absorption spectrum of 'AMISOFT® CS-22', previously dried, as directed in the Attenuated Total Reflectance method under Infrared Spectrophotometry: it exhibits the absorptions at 2920cm^{-1}, 2850cm^{-1}, and 1660cm^{-1} (amide).

*2: Gas Chromatography

To approximately 1g of 'AMISOFT® CS-22' add 50mL of a hydrochloric acid-methanol solution (1→3), and heat, with occasional swirling, under a reflux condenser on a water bath for 2hours. Cool, adjust with sodium hydroxide TS to pH2.0, transfer to a separator, and extract with 20mL of petroleum ether. To the petroleum ether layer add 5g of anhydrous sodium sulfate, allow to stand for 10minutes, and filter. Evaporate the petroleum ether from the filtrate, add 50mL of methanol and 1mL of sulfric acid to the residue, and heat under a reflux condenser on a water bath for 1hour. Cool, transfer to a separator, extract with two 30mL portions of petroleum ether, and use this solution as Test solution. Separately, dissolve 0.1g of methyl laurate for Gas Chromatography in 10mL of hexane, and use this solution as Standard solution. Perform the test with 5μL each of Test solution and Standard solution as directed under Gas Chromatography according to the following operating conditions: the major peaks of Test solution, excluding the solvent peak, coincide with the major peaks of Standard solution.

Operating conditions:

Detector: A hydrogen flame-ionization detector.

Column: A column 3~4mm in insede diameter and 2m in length, packed with 10% of cyanopropyl silicone coated on 100~120μm, silanized siliceous earth for Gas Chromatography in particle diameter.

Column temperature: 100→240°C.
Temperature programmed rate: 10°C per minute.
Carrier gas and flow rate: nitrogen. A constant volume of approximately 60mL per minute.

*3: Sodium Salt
A solution of 'AMISOFT® CS-22' (1→100) responds to the Qualitative Tests (1) for sodium salt

*4: Content
Calculated as follows;
Content (%)＝26.6 x [Nitrogen Content (%)/JSQI [1.0g, Method-2]]
(Average MW of AMISOFT® CS-22 = 378 Neutralization equivalent=1.80)