

Amylase (No. 3)

Proposed revision of Ministerial Ordinance on the Specifications and Standards of Feeds and Feed Additives.

1. Specifications for ingredients, standards for methods of manufacture, use and storage, and standards for labeling of feeds in general

•Standards for methods of manufacture of feeds in general

Amylase (No. 3) shall not be used in feeds (including raw material or ingredients used to manufacture feeds) other than those for cattle, pigs, and chickens.

•Standards for labeling of feeds in general

Feed containing feed additives for which the target animal is specified must be labeled with the type of the target animal.

2. Specifications for feed additives

A. Active Substance

(a) Compositional standards

Enzymatic activity unit: This product contains 2000 starch saccharifying activity units/g or more by enzymatic activity test.

Physical and chemical properties:

- i. This product is light brown to dark brown liquid.
- ii. The solution or aqueous suspension (1→100) of this product is pH 5.0-7.5.
- iii. This product produces maximum enzymatic activity at pH 5.0-7.0.

Purity test:

- i. Lead: When 1.0 g(0.95-1.04 g) of this product is weighed and subject to the lead test method (Method No. 1 of atomic absorption spectrophotometry), the lead content shall be no higher than 20 µg/g
- ii. Arsenic: 1.0 g(0.95-1.04 g) of this product is weighed and a sample solution is prepared by Method No. 3 of the arsenic test method. When the solution is tested by the arsenic test method using device A, the color of absorbing solution should not be darker than the standard color (2 µg/g or less).
- iii. Antibacterial activity: When 1 g (0.5-1.4 g) of this product is weighed and tested by the antibacterial activity test method, it shall not exhibit antibacterial activity.

Residue on ignition: 20.0% or less (1 g)

Enzymatic activity test: It is tested by the starch saccharification power test method.

(b) Standard of manufacturing method

For manufacturing, the amylase-producing recombinant, whose host is the strain belonging to *Bacillus licheniformis*, is cultured, after the cultivation, the culture is filtered, or extracted with water, then filtered to remove bacterial cells, and then the filtrate is concentrated.

(c) Standard of storage method

It shall be stored in a lightproof airtight container.

(d) Standards of the label

The pH value (to one place of decimals) showing maximum enzyme activity shall be described on the immediate container or the immediate wrapper of this product.

B. Preparation (No. 1)

(a) Compositional standards

This product is pieces, powder, or particles in which the active substance of Amylase (No. 3) is mixed with sodium sulfate as appropriate and fillers.

Enzyme activity unit: This product contains 85-170% of the labeled starch saccharifying activity units, when tested by enzymatic activity test.

Enzymatic activity test: It is tested by the starch saccharification power test method.

(b) Standard of storage method

The standard of storage method of the active substance of Amylase (No. 3) is applied mutatis mutandis.

(c) Standard of the label

The standard of the label of the active substance of Amylase (No. 3) is applied mutatis mutandis.

C. Preparation (No. 2 liquid)

(a) Compositional standards

This product is water-soluble liquid in which the active substance of Amylase (No.3) is mixed with sucrose, sodium chloride and potassium sorbate as appropriate, and water.

Enzymatic activity unit: This product contains 85-170% of the labeled starch saccharifying activity units, when tested by enzymatic activity test.

Enzymatic activity test: It is tested by the starch saccharification power test method.

(b) Standard of storage method

The standard of storage method of the active substance of Amylase (No. 3) is applied mutatis mutandis.

(c) Standard of the label

The standard of the label of the active substance of Amylase (No. 3) is applied mutatis mutandis.