

## Description

Title of Invention: COMPOSITION

### Technical Field

[0001]

The present disclosure relates to a composition.

### Background Art

[0002]

Compositions used in various forms for pharmaceutical and food applications are orally administered to or ingested by a subject. Such compositions are required to pass smoothly through the oral cavity during swallowing, in other words, are required to be easy to swallow. Such properties can be achieved, for example, by ensuring that the composition has favorable disintegratability in water, and/or favorable frictional force in the wet-powder state. Similar properties may also be suitable for cosmetic and lubricant applications.

Conventionally, attempts have been made to adjust the hardness and oral disintegratability of a tablet containing a composition by adjusting, for example, the fiber length, the fiber width and the like contained in the composition. However, it has been difficult to establish production conditions for accurately controlling the fiber length and the fiber width contained in a composition.

[0003]

Patent Literature 1: WO2013/180249

### Summary of Invention

[0004]

An object of the present disclosure is to provide a composition exhibiting favorable disintegratability in water, and/or favorable frictional force in the wet-powder state.

[0005]

The present disclosure encompasses the following aspect:

[1] A composition containing a heat-resistant substance, a semi-heat-resistant substance, and a non-heat-resistant substance,

wherein a weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 600°C is 11% or more,

an electromotive force obtained upon heating from 25°C to 600°C is -4  $\mu$ V or more,

the weight retention rate (y) determined by thermogravimetric analysis upon heating from 25°C to 600°C is represented by the following expression:

expression:  $y \geq -2.03x + 23.623$

wherein x represents the electromotive force obtained upon heating from 25°C to 600°C, and

an apparent tapped density is 0.3 g/cm<sup>3</sup> to 5 g/cm<sup>3</sup>.

[0006]

According to the present disclosure, a composition exhibiting favorable disintegratability in water, and/or favorable frictional force in the wet-powder state can be provided.

#### Brief Description of Drawing

[0007]

[Figure 1] Figure 1 is a graph plotting the analytical results of compositions of Examples and Comparative Examples, where the y-axis represents the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to

600°C, and the x-axis represents the electromotive force obtained upon heating from 25°C to 600°C. The diagonal line is defined as a boundary distinguishing compositions that achieve both disintegratability in water and a favorable mouthfeel from those that do not, and is represented by an expression:  $y = -2.03x + 23.623$ . The line A (solid line) indicates  $y = 11$  (%), and the line B (dotted line) indicates  $x = -4$  ( $\mu\text{V}$ ).

## Description of Embodiments

[0008]

Embodiments of the present disclosure will be described in detail below. The present disclosure is not limited to the following embodiments and can be implemented with appropriate modifications as long as such modifications do not impair the effects of the present disclosure.

The configurations and combinations thereof in each embodiment are merely examples, and addition, omission, substitution, and other changes to the configurations can be made as appropriate without departing from the spirit of the present disclosure. The present disclosure is not limited by the embodiments but is limited only by the scope of the claims.

Each aspect disclosed herein may be combined with any other features disclosed herein.

In the case where a specific description of one embodiment applies to another embodiment, such description may be omitted in the another embodiment. In the present disclosure, the expression "X to Y" regarding a numerical range means "X or more and Y or less." In the case where a specific description of one embodiment applies to another embodiment, such description may be omitted in the another embodiment.

Unless otherwise specified, all numbers expressing features, items, amounts, parameters, properties, durations, and the like used herein and in the claims are to be understood as being modified in all instances by the term "approximately." As used herein, the term "approximately" means that the features, items, amounts, parameters, properties, or durations so specified include a range of plus or minus 10% above and below the value of the stated feature, item, amount, parameter, property, or duration. At least so as not to limit the application of the doctrine of equivalents to the claims, each numerical indicator should be interpreted at least in light of the number of reported significant digits and by applying ordinary rounding techniques. Any numerical range or value inherently includes a margin of error necessarily resulting from the standard deviations found in their respective testing measurements. Unless otherwise specified, each individual value within a numerical range herein is incorporated into the specification as if it were individually listed herein.

[0009]

== Embodiment 1 (Composition) ==

A composition (1-1) according to Embodiment 1 is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C is 50% or more and 98% or less.

In this composition, the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C is preferably 60% to 98%, more preferably 70% to 98%, and further preferably 90% to 98%. When the weight retention rate is 90% to 98%, it may be 95%, 96%, 97%, or 98%. In one embodiment, the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0010]

The term "heat-resistant substance" refers to a substance that remains at a temperature of 400°C or more when a composition containing the substance is heated from room temperature (25°C).

The term "non-heat-resistant substance" refers to a substance that disappears at a temperature less than 300°C when a composition containing the substance is heated from room temperature (25°C).

The term "semi-heat-resistant substance" refers to a substance that disappears at a temperature between 300°C and 400°C when a composition containing the substance is heated from room temperature (25°C).

[0011]

A composition (1-2) according to Embodiment 1 is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 200°C is 50% or more and 96% or less.

[0012]

In this composition, the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 200°C is more preferably 60% to 95%, further preferably 70% to 95%, and much further preferably 80% to 95%. When the weight retention rate is 80% to 95%, it may be 80%, 86%, 92%, 93%, or 95%. In one embodiment, the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 200°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0013]

A composition (1-3) according to Embodiment 1 is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant

substance, in which a weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 300°C is 50% or more and 90% or less.

[0014]

In this composition, the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 300°C is preferably 55% to 90%, more preferably 60% to 88%, further preferably 60% to 85%, and much further preferably 63% to 80%, and still further preferably 65% to 78%. When the weight retention rate is 65% to 78%, it may be 65%, 66%, 69%, 72%, 73%, 74%, or 78%. In one embodiment, the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 300°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0015]

A composition (1-4) according to Embodiment 1 is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 400°C is 15% or more and 80% or less.

[0016]

In this composition, the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 400°C is preferably 15% to 70%, more preferably 16% to 68%, and further preferably 20% to 60%. When the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 400°C is 20% to 60%, it may be 20%, 28%, 29%, 30%, 32%, 37%, or 60%. In one embodiment, the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 400°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0017]

A composition (1-5) according to Embodiment 1 is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 500°C is 12% or more and 70% or less.

[0018]

In this composition, the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 500°C is preferably 12% to 60%, more preferably 15% to 55%, and further preferably 20% to 50%. When the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 500°C is 20% to 50%, it may be 20%, 22%, 24%, 31%, or 41%. In one embodiment, the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 500°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0019]

A composition (1-6) according to Embodiment 1 is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 600°C is 11% or more.

[0020]

In this composition, the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 600°C is preferably 11% to 60%, more preferably 12% to 50%, further preferably 13% to 40%, still more preferably 18% to 30%, and still further preferably 20% to 29%. When the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 600°C is 20% to 29%, it may be 20%, 21%, 22%, or 29%. In one embodiment, the weight retention rate as determined by thermogravimetric analysis upon heating

from 25°C to 600°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0021]

A composition (2-1) according to Embodiment 1 is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a percentage value ( $((W200/W100) \times 100 (\%))$ ) of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 200°C (W200) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) is 80 to 98, preferably 85 to 98, and more preferably 88 to 97.

[0022]

In this composition, when the percentage value ( $((W200/W100) \times 100 (\%))$ ) of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 200°C (W200) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) is 88 to 97, it may be 88, 95, 96, or 97. In one embodiment, the percentage value of W200/W100 may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0023]

A composition (2-2) according to Embodiment 1 is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a percentage value ( $((W300/W100) \times 100 (\%))$ ) of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 300°C (W300) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) is 60 to 93, preferably 65 to 93, and more preferably 67 to 93.

[0024]

In this composition, when the percentage value  $((W300/W100) \times 100 (\%))$  of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 300°C (W300) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) is 67 to 93, it may be 67, 72, 76, 78, 80, or 93. In one embodiment, the percentage value of W300/W100 may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0025]

A composition (2-3) according to Embodiment 1 is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a percentage value  $((W400/W100) \times 100 (\%))$  of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 400°C (W400) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) is 15 to 80.

[0026]

In this composition, when the percentage value  $((W400/W100) \times 100 (\%))$  of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 400°C (W400) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) is 15 to 80, it may be 15, 17, 29, 31, 34, 38, 69, or 80. In one embodiment, the percentage value of W400/W100 may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0027]

A composition (2-4) according to Embodiment 1 is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a percentage value  $((W500/W100) \times 100 (\%))$  of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C

to 500°C (W500) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) is 13 to 60.

[0028]

In this composition, when the percentage value  $((W500/W100) \times 100 (\%))$  of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 500°C (W500) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) is 13 to 60, it may be 13, 16, 23, 25, 32, 33, 43, or 60. In one embodiment, the percentage value of W500/W100 may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0029]

A composition (2-5) according to Embodiment 1 is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a percentage value  $((W600/W100) \times 100 (\%))$  of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 600°C (W600) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) is 11 to 45, preferably 15 to 30, and more preferably 17 to 30.

[0030]

In this composition, when the percentage value  $((W600/W100) \times 100 (\%))$  of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 600°C (W600) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) is 17 to 30, it may be 17, 21, 22, 23, or 30. In one embodiment, the percentage value of W600/W100 may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0031]

A composition (3-1) according to the present embodiment is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which the electromotive force obtained upon heating from 25°C to 100°C is -10  $\mu$ V or more and 0  $\mu$ V or less.

[0032]

In this composition, the electromotive force obtained upon heating from 25°C to 100°C is preferably -8  $\mu$ V to -1  $\mu$ V, and more preferably -6  $\mu$ V to -3  $\mu$ V. When the electromotive force obtained upon heating from 25°C to 100°C is -6  $\mu$ V to -3  $\mu$ V, it may be -6  $\mu$ V, -5  $\mu$ V, -4  $\mu$ V, or -3  $\mu$ V. In one embodiment, the electromotive force obtained upon heating from 25°C to 100°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0033]

A composition (3-2) according to the present embodiment is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which the electromotive force obtained upon heating from 25°C to 200°C is -10  $\mu$ V or more and 0  $\mu$ V or less.

[0034]

In this composition, the electromotive force obtained upon heating from 25°C to 200°C is preferably -8  $\mu$ V to -1  $\mu$ V, and more preferably -6  $\mu$ V to -2  $\mu$ V. When the electromotive force obtained upon heating from 25°C to 200°C is -6  $\mu$ V or more and -2  $\mu$ V or less, it may be -6  $\mu$ V, -5  $\mu$ V, -4  $\mu$ V, -3  $\mu$ V, or -2  $\mu$ V. In one embodiment, the electromotive force obtained upon heating from 25°C to 200°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0035]

A composition (3-3) according to the present embodiment is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-

heat-resistant substance, in which the electromotive force obtained upon heating from 25°C to 300°C is -9  $\mu$ V or more and 10  $\mu$ V or less.

[0036]

In this composition, the electromotive force obtained upon heating from 25°C to 300°C is preferably -8  $\mu$ V to 8  $\mu$ V, and more preferably -7  $\mu$ V to 5  $\mu$ V. When the electromotive force obtained upon heating from 25°C to 300°C is -7  $\mu$ V to 5  $\mu$ V, it may be -7  $\mu$ V, -5  $\mu$ V, -3  $\mu$ V, -2  $\mu$ V, 0  $\mu$ V, 1  $\mu$ V, 3  $\mu$ V, or 5  $\mu$ V. In one embodiment, the electromotive force obtained upon heating from 25°C to 300°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0037]

A composition (3-4) according to the present embodiment is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which the electromotive force obtained upon heating from 25°C to 400°C is -8  $\mu$ V or more and 15  $\mu$ V or less.

[0038]

In this composition, the electromotive force obtained upon heating from 25°C to 400°C is preferably -5  $\mu$ V to 15  $\mu$ V, and more preferably -3  $\mu$ V to 10  $\mu$ V. When the electromotive force obtained upon heating from 25°C to 400°C is -3  $\mu$ V to 10  $\mu$ V, it may be -3  $\mu$ V, -2  $\mu$ V, -1  $\mu$ V, 0  $\mu$ V, 1  $\mu$ V, 8  $\mu$ V, or 10  $\mu$ V. In one embodiment, the electromotive force obtained upon heating from 25°C to 400°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0039]

A composition (3-5) according to the present embodiment is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-

heat-resistant substance, in which the electromotive force obtained upon heating from 25°C to 500°C is -4  $\mu$ V or more and 20  $\mu$ V or less.

[0040]

In this composition, the electromotive force obtained upon heating from 25°C to 500°C is preferably -4  $\mu$ V to 18  $\mu$ V, and more preferably -2  $\mu$ V to 14  $\mu$ V. When the electromotive force obtained upon heating from 25°C to 500°C is -2  $\mu$ V to 14  $\mu$ V, it may be -2  $\mu$ V, -1  $\mu$ V, 0  $\mu$ V, 1  $\mu$ V, 5  $\mu$ V, or 14  $\mu$ V. In one embodiment, the electromotive force obtained upon heating from 25°C to 500°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0041]

A composition (3-6) according to the present embodiment is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which the electromotive force obtained upon heating from 25°C to 600°C is -4  $\mu$ V or more.

[0042]

In this composition, the electromotive force obtained upon heating from 25°C to 600°C is preferably -4  $\mu$ V to 20  $\mu$ V, more preferably -4  $\mu$ V to 18  $\mu$ V, further preferably -3  $\mu$ V to 17  $\mu$ V, and still more preferably 1  $\mu$ V to 17  $\mu$ V. When the electromotive force obtained upon heating from 25°C to 600°C is 1  $\mu$ V to 17  $\mu$ V, it may be 1  $\mu$ V, 2  $\mu$ V, 5  $\mu$ V, or 17  $\mu$ V. In one embodiment, the electromotive force obtained upon heating from 25°C to 600°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0043]

A composition (4-1) according to the present embodiment is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a percentage value  $((X_{200}/X_{100}) \times 100 (\%))$  of

the electromotive force obtained upon heating from 25°C to 200°C (X200) relative to the electromotive force obtained upon heating from 25°C to 100°C (X100) is 30 to 170.

[0044]

In this composition, the percentage value of the electromotive force obtained upon heating from 25°C to 200°C relative to the electromotive force obtained upon heating from 25°C to 100°C is preferably 35 to 170. When the percentage value is 35 to 170, it may be 35, 76, 87, 94, 121, 166, or 170. In one embodiment, the percentage value of the electromotive force obtained upon heating from 25°C to 200°C relative to the electromotive force obtained upon heating from 25°C to 100°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0045]

A composition (4-2) according to the present embodiment is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a percentage value  $((X300/X100) \times 100 (\%))$  of the electromotive force obtained upon heating from 25°C to 300°C (X300) relative to the electromotive force obtained upon heating from 25°C to 100°C (X100) is -50 to 200.

[0046]

In this composition, the percentage value of the electromotive force obtained upon heating from 25°C to 300°C relative to the electromotive force obtained upon heating from 25°C to 100°C is preferably -50 to 180. When the percentage value is -50 to 180, it may be -50, -18, -0.4, 49, 51, 120, 172, or 180. In one embodiment, the percentage value of the electromotive force obtained upon heating from 25°C to 300°C relative to the electromotive force obtained upon heating from 25°C to 100°C

may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0047]

A composition (4-3) according to the present embodiment is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a percentage value  $((X400/X100) \times 100 (\%))$  of the electromotive force obtained upon heating from 25°C to 400°C (X400) relative to the electromotive force obtained upon heating from 25°C to 100°C (X100) is -150 to 100.

[0048]

In this composition, the percentage value of the electromotive force obtained upon heating from 25°C to 400°C relative to the electromotive force obtained upon heating from 25°C to 100°C is preferably -130 to 70. When the percentage value is -130 to 70, it may be -130, -15, -0.4, 2, 27, 36, 61, or 70. In one embodiment, the percentage value of the electromotive force obtained upon heating from 25°C to 400°C relative to the electromotive force obtained upon heating from 25°C to 100°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0049]

A composition (4-4) according to the present embodiment is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a percentage value  $((X500/X100) \times 100 (\%))$  of the electromotive force obtained upon heating from 25°C to 500°C (X500) relative to the electromotive force obtained upon heating from 25°C to 100°C (X100) is -250 to 50.

[0050]

In this composition, the percentage value of the electromotive force obtained upon heating from 25°C to 500°C relative to the electromotive force obtained upon heating from 25°C to 100°C is preferably -240 to 40. When the percentage value is -240 to 40, it may be -240, -238, -108, -15, 4, 19, or 40. In one embodiment, the percentage value of the electromotive force obtained upon heating from 25°C to 500°C relative to the electromotive force obtained upon heating from 25°C to 100°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0051]

A composition (4-5) according to the present embodiment is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which a percentage value  $((X600/X100) \times 100 (\%))$  of the electromotive force obtained upon heating from 25°C to 600°C (X600) relative to the electromotive force obtained upon heating from 25°C to 100°C (X100) is -300 to 100.

[0052]

In this composition, the percentage value of the electromotive force obtained upon heating from 25°C to 600°C relative to the electromotive force obtained upon heating from 25°C to 100°C is preferably -300 to 70. When the percentage value is -300 to 70, it may be -300, -284, -205, -108, -103, -58, -28, -19, 20, 62, or 70. In one embodiment, the percentage value of the electromotive force obtained upon heating from 25°C to 600°C relative to the electromotive force obtained upon heating from 25°C to 100°C may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0053]

A composition (5) according to the present embodiment is a composition that contains a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substrate, in which the apparent tapped density is  $0.3 \text{ g/cm}^3$  to  $5 \text{ g/cm}^3$ .  
[0054]

In this composition, when the apparent tapped density is  $0.3 \text{ g/cm}^3$  to  $5 \text{ g/cm}^3$ , it may be  $0.3 \text{ g/cm}^3$ ,  $0.35 \text{ g/cm}^3$ ,  $0.4 \text{ g/cm}^3$ ,  $0.45 \text{ g/cm}^3$ ,  $0.48 \text{ g/cm}^3$ ,  $0.5 \text{ g/cm}^3$ ,  $0.8 \text{ g/cm}^3$ ,  $2 \text{ g/cm}^3$ ,  $4.2 \text{ g/cm}^3$ ,  $4.6 \text{ g/cm}^3$ ,  $4.8 \text{ g/cm}^3$ , or  $5 \text{ g/cm}^3$ . In one embodiment, the apparent tapped density may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0055]

Regarding the characteristics of the composition (5), the composition can be easily filled into a composition bag or tablet molding machine, which easily improves the productivity. As a result of studies aimed at making the disintegratability in water and/or favorable frictional force in the wet-powder state further easily exhibited, it has been discovered that the aforementioned objectives could be achieved by: setting the weight retention rate and the electromotive force upon heating from room temperature to a specific temperature, within specific ranges; and establishing a specific relationship between the weight retention rate and the electromotive force.

A composition having the characteristics of the composition (5) can be easily filled into a composition bag or tablet molding machine, which easily improves the productivity. In this composition (5), when the weight retention rate obtained upon heating from room temperature ( $25^\circ\text{C}$ ) to a specific temperature is set (the features of any one of the compositions (1-1) to (1-6)), the electromotive force is set to a specific range (the features of any one of the compositions (3-1) to (3-6)), the composition is made to have the features of any one of the compositions (2-1) to (2-5), and/or the composition is made to have the features of any one of the

compositions (4-1) to (4-5), the resultant composition tends to exhibit favorable disintegratability in water, and/or favorable frictional force in the wet-powder state, and in addition, the composition can be easily filled into a composition bag or tablet molding machine, which easily improves the productivity.

[0056]

The apparent tapped density is a value measured by a method described later.

[0057]

A composition (6) of the present embodiment is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, in which the weight retention rate (y) determined by thermogravimetric analysis upon heating from 25°C to 600°C is represented by expression:  $y \geq -2.03x + 23.623$ , wherein x represents the electromotive force obtained upon heating from 25°C to 600°C.

Here, the composition (6) preferably has at least one of the features of x being -4  $\mu\text{V}$  or more, and y being 11% or more, and more preferably has both of these features.

x is more preferably -4  $\mu\text{V}$  to 20  $\mu\text{V}$ , further preferably -4  $\mu\text{V}$  to 18  $\mu\text{V}$ , further more preferably -3  $\mu\text{V}$  to 17  $\mu\text{V}$ , and still further preferably 1  $\mu\text{V}$  to 17  $\mu\text{V}$ .

y is more preferably 11% to 60%, further preferably 12% to 50%, further more preferably 13% to 40%, still further preferably 18% to 30%, and still more preferably 20% to 29%.

When x is 1  $\mu\text{V}$  to 17  $\mu\text{V}$ , it may be 1  $\mu\text{V}$  to 6  $\mu\text{V}$ .

When y is 20% to 29%, it may be 20% to 25%, or 20% to 23%.

When the composition (6) has both the features of x being -4  $\mu\text{V}$  or more and y being 11% or more, the combination of the values of x and y may fall within any of the aforementioned ranges, and for example, x may be -3  $\mu\text{V}$  to 17  $\mu\text{V}$  and y may be 20% to 29%, or x may be 1  $\mu\text{V}$  to 17  $\mu\text{V}$  and y may be 20% to 25% or 20% to 23%.

[0058]

Regarding the "expression:  $y \geq -2.03x + 23.623$ ", as illustrated in Figure 1, Examples 1 to 9 (T1 to T3 and T6 to T11), in which the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 600°C is 11% or more (upper side of the line A), and the electromotive force obtained upon heating from 25°C to 600°C is - 4  $\mu$ V or more (right side of the line B), have disintegratability in water of 1.2 (min/N) or less, namely, exhibit favorable disintegratability in water. Moreover, these compositions have frictional force in the wet-powder state of 45 (gf) or less, and have a mouthfeel sensory test score of 3 or 4, and thus exhibit a favorable mouthfeel.

However, the region on the upper side of the line A and on the right side of the line B includes Comparative Examples 3 to 6 (T12 to T15), which exhibit low efficacy in achieving the aforementioned favorable disintegratability in water and favorable mouthfeel. Therefore, in the actual composition production, it may be difficult to distinguish between those that yield the desired effects and those that do not. To facilitate this distinction, the "expression:  $y = -2.03x + 23.623$ " is defined as a boundary line separating those that yield the desired effects and those that do not, based on T2 (Example 2) and T7 (Example 5), and furthermore, a region above this boundary line is defined by the "expression:  $y \geq -2.03x + 23.623$ ". Based on this expression, compositions that yield no effect or low efficacy can be effectively excluded. Since the regions outside the region bounded by the line A, the line B, and the line defined by the "expression:  $y \geq -2.03x + 23.623$ " are eliminated, compositions possessing both favorable disintegratability in water and favorable mouthfeel can be easily identified. Furthermore, because the "expression:  $y \geq -2.03x + 23.623$ " represents a straight line, the identification can be easily performed, making it even easier to determine whether or not a composition will exhibit the effects.

[0059]

Each of the compositions (1-1) to (1-6), (2-1) to (2-5), (3-1) to (3-6), (4-1) to (4-5), (5), and (6), when in the form of a tablet, exhibits favorable disintegratability in water and/or favorable frictional force in the wet-powder state. Since these compositions exhibit favorable disintegratability in water, they are more likely to provide a favorable orally disintegrating effect when administered orally to a subject. Furthermore, since these compositions exhibit favorable frictional force in the wet-powder state, they are more likely to provide a favorable mouthfeel effect from the resulting paste of the powder composition when administered orally to a subject. Accordingly, the compositions (1-1) to (1-6), (2-1) to (2-5), (3-1) to (3-6), (4-1) to (4-5), (5), and (6) exhibit favorable disintegratability in water and/or favorable frictional force in the wet-powder state, which facilitates smooth passage of the compositions during swallowing when they are administered orally, namely, compositions easy to swallow tend to be obtained. In particular, when a composition has the features of the composition (5), it becomes easier to fill into a composition bag or a tablet molding machine, which easily improves the productivity.

[0060]

In one embodiment, the composition is preferably an oral composition. By using the composition for oral application, it becomes easier to achieve the effects of favorable oral disintegratability based on favorable disintegratability in water and/or favorable mouthfeel based on favorable frictional force in the wet-powder state as described above.

In one embodiment, as described in Embodiment 2, the composition is preferably included in a food product or a medicament in the form of a tablet. When the composition is in the form of a tablet, it becomes easier for the composition to exhibit the effects of favorable oral disintegratability based on

favorable disintegratability in water, and/or favorable mouthfeel of the disintegrated paste based on favorable frictional force in the wet-powder state.

[0061]

Furthermore, the composition exhibiting favorable disintegratability in water and/or favorable frictional force in the wet-powder state has suitable properties for a cosmetic composition as well. Accordingly, as described in Embodiment 3, in one embodiment, the composition may be a cosmetic composition.

[0062]

The composition of the present embodiment exhibits favorable oral disintegratability based on favorable disintegratability in water and/or favorable frictional force in the wet-powder state as described above. Accordingly, as described in Embodiment 3, in one embodiment, the composition may be a lubricant composition for use in a tablet.

[0063]

The compositions (1-1) to (1-6), (2-1) to (2-5), (3-1) to (3-6), (4-1) to (4-5), (5), and (6) may also be a composition having features obtained by combining the respective features of two or more of these compositions.

For example, the composition may be a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, and having the features of the compositions (1-6), (3-6), (5), and (6), in which the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 600°C is 11% or more, the electromotive force obtained upon heating from 25°C to 600°C is -4  $\mu$ V or more, the apparent tapped density is 0.3 g/cm<sup>3</sup> to 5 g/cm<sup>3</sup>, and the expression:  $y \geq -2.03x + 23.623$ , wherein x represents the electromotive force obtained upon heating from 25°C to 600°C.

Owing to the features of the compositions (1-6), (3-6), and (6), the composition can easily exhibit favorable disintegratability in water, and/or favorable

frictional force in the wet-powder state, and owing to the features of the composition (5), the composition can be easily filled into a composition bag or a tablet molding machine, which easily improves the productivity.

[0064]

As another example, the composition may be a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, and having the features of the compositions (1-2), (1-3), and (2-5), in which the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 200°C is 50% or more and 96% or less, the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 300°C is 50% or more and 90% or less, and the percentage value  $((W600/W100) \times 100 (\%))$  of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 600°C (W600) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) is 11 to 45.

For example, the composition may be a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, and having the features of the compositions (1-4), and (1-5), in which the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 400°C is 15% or more and 80% or less, and the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 500°C is 12% or more and 70% or less.

As still another example, the composition may be a composition containing a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance, and having the features of the compositions (3-6), and (4-5), in which the electromotive force obtained upon heating from 25°C to 600°C is -4  $\mu$ V or more and 20  $\mu$ V or less, and the percentage value  $((W600/W100) \times 100 (\%))$  of the weight

retention rate as determined by thermogravimetric analysis upon heating from 25°C to 600°C (W600) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) is -300 to 100. [0065]

Similarly, the composition may be a composition having the features of the composition (1-1), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (1-2), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (1-3), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (1-4), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (1-5), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (1-6), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (2-1), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (2-2), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (2-3), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (2-4), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (2-5), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (3-1), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (3-2), and one or

more features selected from those of the other aforementioned compositions; a composition having the features of the composition (3-3), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (3-4), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (3-5), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (3-6), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (4-1), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (4-2), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (4-3), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (4-4), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (4-5), and one or more features selected from those of the other aforementioned compositions; a composition having the features of the composition (5), and one or more features selected from those of the other aforementioned compositions; or a composition having the features of the composition (6), and one or more features selected from those of the other aforementioned compositions. The composition may also be one having an arbitral combination of two, three, four or more of these features.

[0066]

The composition according to the present embodiment contains a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance. The composition preferably contains two or more of a heat-resistant

substance, a semi-heat-resistant substance, and a non-heat-resistant substance, and more preferably contains a heat-resistant substance, a semi-heat-resistant substance, and a non-heat-resistant substance. Non-limiting examples of the heat-resistant substance, the semi-heat-resistant substance, and the non-heat-resistant substrate are as follows.

[0067]

Non-limiting examples of the heat-resistant substance include inorganic substances. The inorganic substances are not limited as long as they are within a range acceptable for food compositions or pharmaceutical compositions, and non-limiting examples include magnesium aluminosilicate, magnesium aluminum silicate, magnesium hydroxide, dried sodium carbonate, sodium hydroxide, sodium bicarbonate, a sodium carbonate hydrate, a Fe-Mg hydrotalcite-like compound, and an Al-Mg hydrotalcite-like compound. One or a combination of two or more of these heat-resistant substances may be used.

When the composition contains a naturally derived component such as plant-derived cellulose, examples of the heat-resistant substance may also include inorganic substances and the like contained in the naturally derived component. To adjust the content of the inorganic substance, a naturally derived component such as cellulose or the like having an adjusted inorganic content may also be used.

[0068]

Non-limiting examples of the semi-heat-resistant substance include highly crystalline substances. The highly crystalline substance encompasses a macromolecular carbohydrate. The macromolecular carbohydrate is a polysaccharide (including oligosaccharide), and non-limiting examples include starch, glycogen, cellulose and the like, which are formed by polymerization of D-glucose; chitin, formed by polymerization of N-acetylglucosamine; chitosan, which is deacetylated chitin, and the like. The macromolecular carbohydrate is not limited

by its function or role, and it may be a carbohydrate that performs or is involved in any function, such as energy storage (e.g., starch, glycogen, and the like), functions that shape living organisms, and functions for immunity, intercellular communication, and the like. In one embodiment, the semi-heat-resistant substance may be cellulose, or a combination of cellulose with one or more components selected from those described above. One or a combination of two or more of these semi-heat-resistant substances may be used.

[0069]

Non-limiting examples of the non-heat-resistant substance include a protein, a low-molecular-weight carbohydrate, and the like. The low-molecular-weight carbohydrate is a monosaccharide, and the monosaccharide is not limited by the number of carbons in the carbon chain structure, such as trioses, tetroses, pentoses, or hexoses, and may be an aldose having an aldehyde group (including D-glucose, D-ribose, and the like), a ketose having a ketone group (including D-fructose, and the like), or the like. One or a combination of two or more of these non-heat-resistant substances may be used.

[0070]

The composition preferably contains a heat-resistant substance such as ash, an inorganic substance, or the like, a semi-heat-resistant substance such as cellulose, a highly crystalline substance, or the like, and a non-heat-resistant substance such as a protein, a low-molecular-weight carbohydrate, or the like. The composition contains the heat-resistant substance, the semi-heat-resistant substance, and the non-heat-resistant substance in contents of preferably more than 18% by weight, less than 72% by weight, and more than 10% by weight, respectively, more preferably 20% by weight to 40% by weight, 30% by weight to 70% by weight, and 10% by weight to 45% by weight, respectively, and further preferably 20% by weight to 40% by weight, 35% by weight to 55% by weight, and 20% by weight to 35% by weight,

respectively. When the content of the heat-resistant substance is 20% by weight to 40% by weight, it may be 20% by weight, 22% by weight, 24% by weight, 28% by weight, 30% by weight, 38% by weight, or 40% by weight, and may fall in a range formed by combining any of these values as an upper limit and a lower limit. When the content of the semi-heat-resistant substance is 30% by weight to 60% by weight, it may be 30% by weight, 35% by weight, 40% by weight, 52% by weight, or 60% by weight, and may fall in a range formed by combining any of these values as an upper limit and a lower limit. When the content of the non-heat-resistant substance is 20% by weight to 40% by weight, it may be 20% by weight, 24% by weight, 25% by weight, 26% by weight, 27% by weight, 30% by weight, or 32% by weight, and may fall in a range formed by combining any of these values as an upper limit and a lower limit. It is preferable that the total content of the heat-resistant substance, the semi-heat-resistant substance, and the non-heat-resistant substance is 100% by weight.

When the composition contains the heat-resistant substance, the semi-heat-resistant substance, and the non-heat-resistant substance in contents of more than 18% by weight, less than 75% by weight, and more than 10% by weight, respectively, the composition tends to exhibit favorable disintegratability in water and/or favorable frictional force in the wet-powder state. Consequently, when the composition is administered orally, it is easier to achieve smooth passage during swallowing, namely, a composition easy to swallow tends to be obtained.

Here, since the composition contains a naturally derived component such as cellulose or the like, an inorganic substance and the like contained in this naturally derived component may also be contained. To adjust the content of the inorganic substance, a naturally derived component such as cellulose having an adjusted inorganic content may also be used.

[0071]

The composition containing the heat-resistant substance, the semi-heat-resistant substance, and the non-heat-resistant substance in the contents specified above can be prepared by compounding any amount of materials containing one or more selected from the group consisting of the heat-resistant substance, the semi-heat-resistant substance, and the non-heat-resistant substance.

Examples of a material containing only the heat-resistant substance such as ash or the like include titanium dioxide and calcium carbonate.

A material containing the heat-resistant substance, the semi-heat-resistant substance, and/or the non-heat-resistant substance is a plant-derived component. The plant-derived component may be a component derived from a natural plant or a plant-derived component produced by processing a plant, and examples include wheat germ, oats, crystalline cellulose (for example, Ceolus (R) PH grade available from Asahi Kasei Corporation), powdered cellulose (for example, KC FLOCK W-50 available from Nippon Paper Industries Co., Ltd.), and a soybean composition (soybean or soybean-derived component).

Wheat germ, oats, crystalline cellulose, and powdered cellulose contain a heat-resistant substance such as ash or the like, a semi-heat-resistant substance such as cellulose or the like, and a non-heat-resistant substance such as hemicellulose or the like.

For example, wheat germ contains 5 to 25% by weight of a heat-resistant substance, 30 to 70% by weight of a semi-heat-resistant substance, and 25 to 45% by weight of a non-heat-resistant substance. For example, oats contain 5 to 20% by weight of a heat-resistant substance, 45 to 75% by weight of a semi-heat-resistant substance, and 20 to 45% by weight of a non-heat-resistant substance. For example, crystalline cellulose (Ceolus of Asahi Kasei Corporation) contains 1 to 10% by weight of a heat-resistant substance, 70 to 98% by weight of a semi-heat-resistant substance, and 0.1 to 5% by weight of a non-heat-resistant substance. For

example, powdered cellulose (KC FLOCK W-50 of Nippon Paper Industries Co., Ltd.) contains 1 to 10% by weight of a heat-resistant substance, 70 to 90% by weight of a semi-heat-resistant substance, and 5 to 20% by weight of a non-heat-resistant substance.

For example, a soybean composition contains 1 to 20% by weight of a heat-resistant substance, 60 to 90% by weight of a semi-heat-resistant substance, and 1 to 20% by weight of a non-heat-resistant substance.

[0072]

In preparing the composition, the specific contents or proportions of a heat-resistant substance, a semi-heat-resistant substance, and/or a non-heat-resistant substance contained in a plant-derived component actually used can be determined by methods well known to those skilled in the art. For example, the content of a heat-resistant substance such as ash or the like can be measured by a known ash method. For example, the content of a semi-heat-resistant substance such as cellulose or the like can be measured by a known quantification method for  $\alpha$ -cellulose. For example, the content of a non-heat-resistant substance such as hemicellulose or the like can be calculated by subtracting a value obtained by known  $\alpha$ -cellulose measurement from a value obtained by a known quantification method for holocellulose. Based on these measurement results, these materials can be mixed to prepare a composition containing the heat-resistant substance, the semi-heat-resistant substance, and the non-heat-resistant substance in desired proportions.

[0073]

In one embodiment, the composition is a composition having the features of the composition (6), and one or more features selected from those of the other aforementioned compositions. Specifically, in one embodiment, the composition has a weight retention rate (y) determined by thermogravimetric analysis upon heating from 25°C to 600°C represented by expression:  $y \geq -2.03x + 23.623$ , wherein

x represents the electromotive force obtained upon heating from 25°C to 600°C, and has one or more features selected from those of the other aforementioned compositions.

By satisfying the aforementioned expression, the composition of the present embodiment tends to exhibit favorable frictional force in the wet-powder state. Furthermore, the mouthfeel tends to become smoother. This is because aggregation is less likely to occur when the composition is administered to a subject. Additionally, by satisfying the above expression, the disintegratability of the tablet in water is easily improved when the composition is administered in the form of a tablet.

[0074]

In one embodiment, the composition has preferably the features of the composition (6), and at least one, more preferably two, and further preferably three of the features of the composition (1-6), the composition (3-6), and the composition (5).

[0075]

In one embodiment, the composition has the features of the composition (1-6), the composition (3-6), the composition (5), and the composition (6).

In one embodiment, the composition is a composition containing a heat-resistant substance, a semi-heat-resistant substance, and a non-heat-resistant substance, and having the features of the composition (1-6), the composition (3-6), the composition (5), and the composition (6).

In one embodiment, the composition is composition containing a heat-resistant substance, a semi-heat-resistant substance, and a non-heat-resistant substance, wherein the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 600°C is 11% or more, the electromotive force obtained upon heating from 25°C to 600°C is -4  $\mu$ V or more, the weight retention

rate (y) determined by thermogravimetric analysis upon heating from 25°C to 600°C is represented by the expression:  $y \geq -2.03x + 23.623$ , wherein x represents the electromotive force obtained upon heating from 25°C to 600°C, and the apparent tapped density is 0.3 g/cm<sup>3</sup> to 5 g/cm<sup>3</sup>.

[0076]

When the composition has the features of the composition (6), and at least one, two, or three features of the composition (1-6), the composition (3-6), and the composition (5), the composition tends to exhibit more favorable frictional force in the wet-powder state, the mouthfeel tends to become more smoother, and the disintegratability of the tablet in water tends to be further improved when the composition is administered in the form of a tablet.

[0077]

As also described in the section "Measurement of Electromotive Force," the electromotive force (x in the expression) of a sample upon heating from 25°C to 600°C can be adjusted by adjusting the content of the non-heat-resistant substance, the content of the heat-resistant substance, and/or the content of the semi-heat-resistant substance in the composition. More specifically, as also described in the section "Thermogravimetric Analysis," the weight retention rate (y in the expression) determined by thermogravimetric analysis upon heating from 25°C to 600°C can be adjusted by adjusting the content of the non-heat-resistant substance, the content of the heat-resistant substance, and/or the content of the semi-heat-resistant substance in the composition.

Accordingly, the composition can be adjusted to satisfy the aforementioned expression by adjusting the content of the non-heat-resistant substance, the content of the heat-resistant substance, and/or the content of the semi-heat-resistant substance in the composition.

More specifically, the electromotive force ( $x$  in the expression) obtained upon heating from 25°C to 600°C can be adjusted to  $-4\text{ }\mu\text{V}$  or more by adjusting the contents of the heat-resistant substance, the semi-heat-resistant substance, and/or the non-heat-resistant substance respectively to more than 18% by weight, less than 72% by weight, and more than 10% by weight.

[0078]

Considering that the composition of the present embodiment exhibits the desired effects of ease of swallowing (favorable oral disintegratability and/or favorable mouthfeel) when prepared in a tablet form and administered to or ingested by a subject, the composition is preferably a powder composition.

[0079]

At least a portion of the heat-resistant substance, at least a portion of the semi-heat-resistant substance, and at least a portion of the non-heat-resistant substance contained in the powder composition are powder particles. The powder composition may be composed of the powder particles. The powder particles of the semi-heat-resistant substance contain cellulose. The powder particles of the semi-heat-resistant substance may additionally contain a soy-derived component.

The shape of the powder particles is not particularly limited, and a fibrous component is included in cellulose and/or non-cellulose components. The powder composition may be composed of fibrous powder particles.

The average fiber length (length in the fiber direction) of the fibrous powder particles is  $1\text{ }\mu\text{m}$  to  $500\text{ }\mu\text{m}$ , preferably  $5\text{ }\mu\text{m}$  to  $500\text{ }\mu\text{m}$ , more preferably  $5\text{ }\mu\text{m}$  to  $250\text{ }\mu\text{m}$ , further preferably  $5\text{ }\mu\text{m}$  to  $100\text{ }\mu\text{m}$ , and much further preferably  $5\text{ }\mu\text{m}$  to  $50\text{ }\mu\text{m}$ . When the average fiber length is  $5\text{ }\mu\text{m}$  to  $50\text{ }\mu\text{m}$ , it may be  $5\text{ }\mu\text{m}$ ,  $10\text{ }\mu\text{m}$ ,  $20\text{ }\mu\text{m}$ ,  $30\text{ }\mu\text{m}$ ,  $40\text{ }\mu\text{m}$ , or  $50\text{ }\mu\text{m}$ , and may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit. For example, the

average fiber length may be 5  $\mu\text{m}$  or more. In one embodiment, the average fiber length of the powder particles is 10 to 11  $\mu\text{m}$ .

The average fiber width (length in the direction perpendicular to the fiber) of the powder particles is 1  $\mu\text{m}$  to 500  $\mu\text{m}$ , preferably 5  $\mu\text{m}$  to 500  $\mu\text{m}$ , more preferably 5  $\mu\text{m}$  to 250  $\mu\text{m}$ , further preferably 5  $\mu\text{m}$  to 100  $\mu\text{m}$ , and much further preferably 5  $\mu\text{m}$  to 50  $\mu\text{m}$ . When the average fiber width is 5  $\mu\text{m}$  to 50  $\mu\text{m}$ , it may be 5  $\mu\text{m}$ , 10  $\mu\text{m}$ , 20  $\mu\text{m}$ , 30  $\mu\text{m}$ , 40  $\mu\text{m}$ , or 50  $\mu\text{m}$ , and may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit. For example, the average fiber width may be 5  $\mu\text{m}$  or more. In one embodiment, the average fiber width of the powder particles is 10 to 11  $\mu\text{m}$ .

[0080]

In one embodiment, any of the aforementioned compositions may be a composition containing powder particles having an average fiber length of 5  $\mu\text{m}$  or more.

The powder particle may consist of a single fiber, or may be formed by the bonding of multiple fibers to form a single particle.

[0081]

When the average fiber length of the powder particles is set to 1  $\mu\text{m}$  to 500  $\mu\text{m}$ , with the average fiber width set to 1  $\mu\text{m}$  to 500  $\mu\text{m}$ , it becomes easier for the powder particles to exhibit appropriate adhesiveness in preparing the composition into a tablet form, and/or, it becomes easier for the prepared tablet to exhibit favorable disintegratability in water and/or favorable frictional force in the wet-powder state. Consequently, when a tablet containing the powder composition is administered orally, it becomes easier to achieve favorable oral disintegratability and a favorable mouthfeel of the disintegrated paste, and thus, the smooth passage of the composition during swallowing is easily realized, namely, a tablet easy to swallow tends to be obtained.

[0082]

The average fiber length and the average fiber width of the powder particles are values measured by methods described later.

[0083]

In one embodiment, in any of the compositions described above, the powder particles contained in the composition have an aspect ratio (average fiber length/average fiber width) of 1.0 to 100, preferably 1.0 to 5.0, preferably 1.0 to 3.0, more preferably 1.0 to 2.0, and further preferably 1.0 to 1.5. When the aspect ratio is 1.0 to 1.5, it may be 1.0, 1.1, or 1.5.

[0084]

When the aspect ratio of the powder particles contained in the composition is 1.0 to 100, the composition tends to exhibit favorable disintegratability in water and favorable frictional force in the wet-powder state. Furthermore, among compositions containing the same number of powder particles, the volume of the composition tends to be smaller as the aspect ratio is closer to 1.0. This makes it easier to reduce the risk of clogging within equipment during processes for processing or producing products such as a medicament, a food product, a cosmetic, and the like using the composition. Each of these effects is presumed to result from the fact that an aspect ratio closer to 1.0 tends to reduce friction between the fibers of the powder particles.

[0085]

The aspect ratio of powder particles is a value measured by a method described later.

[0086]

In one embodiment, in any of the compositions described above, the powder particles contained in the composition may have a water absorption rate of less than 200%.

The water absorption rate of the powder particles is preferably 25% to 150%, more preferably 30% to 100%, further preferably 40% to 80%, and much further preferably 50% to 75%. When the water absorption rate of the powder particles is 50% to 75%, it may be 50%, 60%, 70%, or 75%. In one embodiment, the water absorption rate may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0087]

When the water absorption rate of the powder particles in the composition is low, the powder particles are less likely to swell, and hence can be easily separated from one another, and consequently, a tablet containing the composition tends to exhibit favorable disintegrability in water. When the water absorption rate of the powder particles is less than 200%, the disintegrability in water of a tablet containing the composition containing the powder particles tends to be favorable.

[0088]

The water absorption rate of the powder particles contained in the composition is a value measured by a method described later.

[0089]

In one embodiment, any of the compositions described above may be a composition having an apparent density (without tapping) of 0.3 g/cm<sup>3</sup> to 5 g/cm<sup>3</sup>. When the apparent density (without tapping) is 0.3 g/cm<sup>3</sup> to 5 g/cm<sup>3</sup>, it may be 0.3 g/cm<sup>3</sup>, 0.32 g/cm<sup>3</sup>, 0.34 g/cm<sup>3</sup>, 0.4 g/cm<sup>3</sup>, 0.45 g/cm<sup>3</sup>, 0.5 g/cm<sup>3</sup>, 0.65 g/cm<sup>3</sup>, 1.6 g/cm<sup>3</sup>, 3.8 g/cm<sup>3</sup>, 4.2 g/cm<sup>3</sup>, or 5 g/cm<sup>3</sup>. In one embodiment, the apparent density (without tapping) may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

When the apparent density (without tapping) of the composition is 0.3 g/cm<sup>3</sup> to 5 g/cm<sup>3</sup>, it becomes easier to fill the composition into a composition bag or a tablet molding machine, which easily improves productivity.

[0090]

The apparent density (without tapping) is a value measured by a method described later.

[0091]

In one embodiment, any of the compositions described above may be a composition having a compression degree of less than 1.35. When the compression degree is less than 1.35, it may be 1 to 1.3, 1, 1.09, 1.1, 1.11, 1.13, 1.18, 1.2, 1.23, or 1.25. In one embodiment, the compression degree may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

When the compression degree of the composition is less than 1.35, the composition is less likely to be compressed even when vibrated, and the shape of the bag containing the composition is less likely to change. This facilitates easier stacking and transport of the bags containing the composition.

[0092]

The compression degree is a value measured by a method described later.

[0093]

(Thermogravimetric Analysis)

The weight retention rate can be obtained by performing thermogravimetric (TG) analysis according to a method known to those skilled in the art.

In the present disclosure, the weight retention rate is a value obtained using a thermal analyzer (STA300 manufactured by Hitachi High-Tech Science Corporation) for heating a sample (approximately 10 mg of a composition (or a food composition of Embodiment 2, a pharmaceutical composition of Embodiment 2, a cosmetic composition of Embodiment 3, a lubricant composition of Embodiment 3, or a dosage form containing any of these)) by raising the temperature from 25°C to 600°C at a rate of 10°C/min under N<sub>2</sub> atmosphere, based on the residual weight of the sample at 100°C, 200°C, 300°C, 400°C, and 600°C.

A weight retention rate obtained when the temperature of a sample is raised from a temperature "a" to a temperature "b" is a percentage value (%) representing the residual weight at the temperature "b", with the residual weight at the temperature "a" defined as 100. In other words, the weight retention rate is represented by the following expression:

$$\text{Weight retention rate (\%)} = 100 \times [\text{residual weight (mg) at temperature "b"}] / [\text{residual weight (mg) at temperature "a"}]$$

A percentage value of the weight retention rate obtained when a sample is heated from the temperature "a" to the temperature "b" ( $W_{a \rightarrow b}$ ) relative to the weight retention rate obtained when the sample is heated from the temperature "a" to a temperature "c" ( $W_{a \rightarrow c}$ ) is represented by an expression:  $(W_{a \rightarrow b} / W_{a \rightarrow c}) \times 100$  (%).

[0094]

More specifically, for example, a percentage value  $(W_{600}/W_{100}) \times 100$  (%) of the weight retention rate obtained by thermogravimetric analysis upon heating from 25°C to 600°C or higher ( $W_{600}$ ) relative to the weight retention rate obtained by thermogravimetric analysis upon heating from 25°C to 100°C ( $W_{100}$ ) is a percentage value obtained by dividing the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 600°C ( $W_{600}$ ) by the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 100°C ( $W_{100}$ ). Note that a weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 100°C can also be expressed as  $W_{25 \rightarrow 100}$ , but it is herein expressed as  $W_{100}$ . The weight retention rate for each temperature increases from 25°C to 200°C, 300°C, 400°C, 500°C, 600°C, or d°C is similarly expressed.

[0095]

By adjusting the contents, in the composition, of the heat-resistant substance such as ash, an inorganic matter, and the like, the semi-heat-resistant substance such as cellulose, a highly crystalline material, and the like, and the non-heat-resistant

substance such as a protein, a low-molecular-weight carbohydrate, and the like, it is possible to adjust the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 200°C, 300°C, 400°C, 500°C, or 600°C.

[0096]

By heating up to 300°C, most of non-heat-resistant substances contained in the composition disappears (Kuriyama, A., Journal of the Society of Materials Science, Japan, Vol. 16, No. 169, pp. 772-776). Therefore, the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 200°C or from 25°C to 300°C indicates the residue of components other than the non-heat-resistant substance contained in the composition. By increasing the content of the non-heat-resistant substance in the composition, the weight loss rate upon heating from 25°C to 200°C or from 25°C to 300°C increases, and thus, the weight retention rate can be decreased. Alternatively, by decreasing the content of components other than the non-heat-resistant substance, namely, by decreasing the contents of the heat-resistant substance and/or the non-heat-resistant substance, the weight loss rate upon heating from 25°C to 200°C or from 25°C to 300°C increases, and thus, the weight retention rate can be decreased.

[0097]

By measuring, in the composition, the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 200°C as described above, the content of the non-heat-resistant substance in the composition can be adjusted so that the weight retention rate can be 50% or more and 96% or less, or any other desired value listed above.

Furthermore, by measuring, in the composition, the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 300°C as described above, the content of the non-heat-resistant substance in the composition

can be adjusted so that the weight retention rate can be 50% or more and 90% or less, or any other desired value listed above.

[0098]

By adjusting the content of the non-heat-resistant substance, and/or the content of the heat-resistant substance, and/or the content of the semi-heat-resistant substance in the composition, a percentage value ( $(W_{25 \rightarrow d}/W_{100}) \times 100 (\%)$ ) of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 600°C, 500°C, 400°C, 300°C, or 200°C ( $W_{25 \rightarrow d}$  (wherein d is 200, 300, 400, 500, or 600) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C ( $W_{100}$ ) can be adjusted. Here,  $W_{25 \rightarrow d}$  can be expressed as  $W_d$  as described above.

[0099]

The weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 100°C indicates the residue of components other than water adsorbed to the composition.

[0100]

When the temperature is raised from 25°C to 400°C or higher, the semi-heat-resistant substance contained in the composition disappears between 300°C and 400°C (Maki, T. et al., Nippon Kagaku Kaishi, 1975, (4), pp. 733-776). Therefore, the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 400°C or higher represents the residue of the components excluding the non-heat-resistant substance (component that disappears upon heating to 300°C) and the semi-heat-resistant substance (component that disappears between 300°C and 400°C), namely, the heat-resistant substance. By increasing the contents of the non-heat-resistant substance and the semi-heat-resistant substance in the composition, the weight loss rate obtained upon heating from 25°C to 400°C increases, and thus, the weight retention rate can be decreased. Alternatively, also

by decreasing the contents excluding the non-heat-resistant substance and the semi-heat-resistant substance contained in the composition, namely, the content of the heat-resistant substance, the weight loss rate obtained upon heating from 25°C to 400°C increases, and thus, the weight retention rate can be decreased.

[0101]

By measuring, in the composition, the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 400°C, or higher than 400°C as described above, the content of the non-heat-resistant substance, and/or the content of the semi-heat-resistant substance and the content of the heat-resistant substance in the composition can be adjusted so that a percentage value  $((W400/W100) \times 100 (\%))$  of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 400°C (W400) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) can be 15 to 80, or any other desired value listed above, so that a percentage value  $((W500/W100) \times 100 (\%))$  of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 500°C (W500) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) can be 13 to 60, or any other desired value listed above, or so that a percentage value  $((W600/W100) \times 100 (\%))$  of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 600°C (W600) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) can be 15 to 30, or any other desired value listed above.

Here, the percentage value of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to a specified temperature relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C is used for eliminating the influence of water

adsorbed onto the composition, the food composition, the pharmaceutical composition, the cosmetic composition, or the lubricant composition.

[0102]

In any of the compositions of the present embodiment, the weight retention rate obtained by thermogravimetric analysis upon heating to a prescribed temperature can be adjusted as described above.

[0103]

(Measurement of Electromotive Force)

The electromotive force of a sample at a given temperature can be obtained in accordance with methods known to those skilled in the art.

In the present disclosure, the electromotive force at a given temperature is defined as the electromotive force ( $\mu\text{V}$ ) of a sample (approximately 10 mg of a composition) measured at 100°C, 200°C, 300°C, 400°C, and 600°C using a thermal analyzer (STA300, manufactured by Hitachi High-Tech Science Corporation) upon heating the sample from 25°C to 600°C at a rate of 10°C/min under a  $\text{N}_2$  atmosphere.

A percentage value of the electromotive force ( $X_a$ ) of a sample obtained upon heating from 25°C to a temperature "a", relative to the electromotive force ( $X_b$ ) obtained upon heating from 25°C to a temperature "b", is represented by expression:  $(X_a/X_b) \times 100 (\%)$ . Although the electromotive force of a sample obtained upon heating from 25°C to a°C can be expressed also as  $X_{25 \rightarrow a}$ , it is herein expressed as  $X_a$ . The electromotive forces obtained upon heating from 25°C to b°C, 100°C, 200°C, 300°C, 400°C, 500°C, and 600°C are also similarly expressed.

[0104]

The electromotive force of a sample at a given temperature can be adjusted by adjusting the contents, in the composition, of the heat-resistant substance such as ash, an inorganic matter, and the like, the semi-heat-resistant substance such as cellulose,

a highly crystalline material, and the like, and the non-heat-resistant substance such as a protein, a low-molecular-weight carbohydrate, and the like.

More specifically, the electromotive force of a sample obtained upon heating from 25°C to 600°C can be adjusted to -4  $\mu$ V or more by adjusting the contents of the heat-resistant substance, the semi-heat-resistant substance, and the non-heat-resistant substance to more than 18% by weight, less than 72% by weight, and more than 10% by weight, respectively.

[0105]

Here, examples of the heat-resistant substance, the semi-heat-resistant substance, the non-heat-resistant substance, and the like are as described above in the section of "Thermogravimetric Analysis".

[0106]

Moreover, the percentage value ( $(X_a/X_b) \times 100$  (%)) of the electromotive force ( $X_a$ ) obtained upon heating from 25°C to the temperature "a", relative to the electromotive force ( $X_b$ ) obtained upon heating from 25°C to the temperature "b" can be adjusted by adjusting the contents, in the composition, of the heat-resistant substance such as ash, an inorganic matter, and the like, the semi-heat-resistant substance such as cellulose, a highly crystalline material, and the like, and the non-heat-resistant substance such as a protein, a low-molecular-weight carbohydrate, and the like.

More specifically, the percentage value of the electromotive force ( $X_a$ ) obtained upon heating from 25°C to 600°C relative to the electromotive force ( $X_b$ ) obtained upon heating from 25°C to 100°C can be adjusted to -300 to 100 by adjusting the contents of the heat-resistant substance, the semi-heat-resistant substance, and the non-heat-resistant substance to more than 18% by weight, less than 72% by weight, and more than 10% by weight, respectively.

[0107]

(Measurement of Average Fiber Length and Average Fiber Width of Powder Particles)

To remove extremely coarse or aggregated fibers, 1 g of a powder sample of the composition adjusted to a moisture content of 2 to 3% is used for classification using a JIS test sieve (710  $\mu\text{m}$ ; manufactured by Tokyo Screen Co., Ltd.). From the classified sample, particles are randomly selected under an optical microscope (100x magnification), and after excluding the 100 largest and 100 smallest particles, remaining 1000 particles are measured for the fiber length (length in the fiber direction) and fiber width (length perpendicular to the fiber) of the powder particles to calculate their average values.

[0108]

(Aspect ratio of Powder Particles)

The aspect ratio of the powder particles is an average value calculated as the fiber length/fiber width, using the fiber lengths and fiber widths of the 1000 powder particles measured under a microscope as described above.

[0109]

(Apparent Tapped Density)

The apparent tapped density of the composition is measured with a commercially available powder property tester (Powder Tester PT-T, manufactured by Hosokawa Micron Corporation). Specifically, a 100  $\text{cm}^3$  cup is filled with all the powder particles contained in the composition and tapped 250 times per minute, and then, the apparent tapped density is determined by dividing the weight of the powder sample filled in the cup by the volume of the powder sample.

[0110]

The apparent tapped density of the composition can be adjusted by adjusting the particle size and/or shape of the powder particles. For example, the apparent

tapped density of the powder particles can be increased by reducing the particle size (fiber length or fiber width) or by decreasing the aspect ratio.

[0111]

(Apparent Density (without tapping))

The apparent density (without tapping) of the composition is determined by loosely filling the composition in a 100 cm<sup>3</sup> glass graduated cylinder over 2 to 3 minutes with a constant-rate composition feeder or the like. Then, the top surface of the resultant powder layer is leveled horizontally with a soft brush, such as a paintbrush, and the volume is read, and the weight of the powder sample is divided by the volume thereof to obtain a value of the apparent density. The weight of the powder is adjusted as appropriate so that the volume reaches approximately 70 to 100 cm<sup>3</sup>.

[0112]

The apparent density (without tapping) of the composition can be adjusted by adjusting the particle size and/or shape of the powder particles. For example, the apparent density (without tapping) of the powder particles can be increased by reducing the particle size (fiber length or fiber width) or by decreasing the aspect ratio.

[0113]

(Compression Degree)

A compression degree is a value calculated by dividing the "apparent tapped density" described above by the "apparent density (without tapping)." A smaller value indicates that the composition is more resistant to compression when vibrated.

The compression degree can be adjusted by adjusting the apparent tapped density and/or the apparent density (without tapping) of the composition. The methods for adjusting the apparent tapped density and the apparent density (without tapping) are as described above.

[0114]

(Water Absorption Rate of Powder Particles)

The water absorption rate of the powder particles contained in the composition is a measured value of the amount of water immediately before the release of water from the fibers is visually confirmed, when 2 g of the powder particles are put in a container and water is added dropwise thereto and mixed uniformly. The value is obtained as an average of  $n = 100$ .

The water absorption rate of the powder particles can be adjusted by adjusting the fiber length and/or the fiber width of the powder particles. Specifically, by increasing the fiber length or the fiber width, or both the fiber length and the fiber width of the powder particles, the water absorption rate of the powder particles can be easily increased. The fiber length and the fiber width of the powder particles can be adjusted by adjusting the grinding time, grinding intensity, and the like during the grinding process of a raw material component in preparing the composition. Specifically, the fiber length and/or the fiber width of the powder particles can be increased by shortening the grinding time and/or reducing the grinding intensity.

[0115]

(Mouthfeel Sensory Test)

The mouthfeel is evaluated by 30 adult males and 30 adult females. The participants place a tablet in their mouths and allow it to disintegrate while rolling it with their tongues, and after the tablet has completely disintegrated, powdery mouthfeel is evaluated.

The results are evaluated according to the following criteria:

- 1: Significant powdery mouthfeel
- 2: Noticeable powdery mouthfeel
- 3: Slight powdery mouthfeel, but sufficiently moist to be nearly unnoticeable
- 4: No powdery mouthfeel

"Powdery mouthfeel" may be defined, for example, as a sensation as if fine particles remain on the tongue.

[0116]

In the mouthfeel sensory test, a score closer to 4 indicates a lower powdery mouthfeel of the disintegrated paste of the tablet, namely, demonstrates a favorable mouthfeel of the disintegrated paste when the tablet is orally administered to a subject.

The composition of the present embodiment has a mouthfeel sensory test score of 3 or 4, indicating that the disintegrated paste of the tablet achieves a favorable mouthfeel, in other words, it means the tablet or composition is easy to swallow.

[0117]

(Disintegratability in Water)

The oral disintegratability of a tablet containing the composition of the present embodiment is evaluated by measuring its disintegratability in water.

The disintegratability in water is expressed as a disintegration time per unit hardness [disintegration time in water (D)/tablet hardness (N) (min/N)].

[0118]

The tablet hardness (N) is a value measured with a hardness tester (Model: KHT-40N, Fujiwara Scientific Co., Ltd.). A tablet produced by a method described in the section "Method for Producing Tablet" is placed at the center of the measurement stage, and the device is started (by pressing the AUTO [Start] button). Thus, the rod descends at high speed, and the display enters a peak-hold state, and when the rod contacts a measurement object, the speed decreases, and display monitoring is performed approximately every 0.1 seconds. If the value ceases to increase, it is determined that the object has been fractured, and the hardness indicated on the hardness tester at that moment is defined as the tablet hardness (N).

[0119]

The disintegration time in water is obtained by placing a tablet in a test tube, adding 20 mL of pure water thereto, and shaking the resultant mixture at 37°C with a shaker (Reciprocating/Orbital Shaker MMS-3020, manufactured by Tokyo Rikakikai Co., Ltd.) to measure the disintegration time. The measurement is performed 50 times, and the average value is defined as the disintegration time in water for the tablet.

[0120]

The disintegratability in water of the tablet of the present invention is preferably less than 1.9 (min/N), more preferably 1.5 (min/N) or less, and further preferably 1.2 (min/N). When the disintegratability in water is 1.2 (min/N) or less, it may be 1.2 (min/N), 0.9 (min/N), 0.8 (min/N), 0.7 (min/N), 0.6 (min/N), 0.5 (min/N), 0.4 (min/N), or 0.3 (min/N). In one embodiment, the disintegratability in water of the tablet may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit.

[0121]

When the disintegratability in water of the tablet is less than 1.9 (min/N), it becomes easier to achieve favorable oral disintegratability when a subject ingests the tablet as a food product or is administered the tablet as a medicament. This facilitates the smooth passage of the composition during swallowing, namely, a tablet easy to swallow tends to be obtained.

[0122]

Since the tablet containing the composition of the present embodiment has disintegratability in water of less than 1.9 (min/N), it becomes easier to achieve favorable oral disintegratability, as described above.

In order to achieve the above-mentioned suitable disintegratability in water, the disintegration time in water of the tablet is preferably less than 90 minutes, and

more preferably 30 minutes or less. When the disintegration time in water of the tablet is 30 minutes or less, it may be 30 minutes, 25 minutes, 15 minutes, 14 minutes, or 12 minutes. In one embodiment, the disintegration time in water of the tablet may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit. The disintegration time in water of the tablet may be, for example, 12 minutes to 30 minutes, or 12 minutes to 15 minutes.

In addition, in order to achieve the above-mentioned suitable disintegratability in water, the tablet hardness is preferably 46 N or less, and more preferably less than 45 N. When the tablet hardness is less than 45 N, it may be 43 N, 42 N, 35 N, 25 N, 17 N, or 14 N. In one embodiment, the tablet hardness may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit. The tablet hardness may be, for example, 14 N to 46 N, or 14 N to 43 N.

[0123]

(Frictional Force in Wet-Powder State)

The frictional force (gf) in the wet-powder state is a value measured by passing the residue of the sample having been subjected to the above-mentioned "disintegratability in water" test through a 90  $\mu$ m sieve (JIS Z8801 wire), collecting the residue, and performing measurement using a static/dynamic friction tester ("Handy Tribomaster TL201Ts" manufactured by Trinity Lab Inc.) under measurement conditions of a 50 g load and a speed of 10 mm/sec. A contactor consisting of artificial skin ("Bio Skin" manufactured by Beaulax Co., Ltd.) attached to a 5 mm-thick sponge sheet ("Sukima-yo (Gap) Tape N-1" manufactured by Cemedine Co., Ltd.) is used as the contactor.

Based on the results of the static frictional force (gf), the ratio between the travel distances of 0 mm and 3 mm is calculated by the following expression:

Expression: Frictional force in the wet-powder state at 2 mm travel =  $100 \times$   
(static frictional force at 0 mm travel distance/static frictional force at 3 mm travel  
distance)

[0124]

The frictional force in the wet-powder state is preferably less than 65 (gf), and more preferably 45 (gf) or less. When the frictional force in the wet-powder state is 45 (gf) or less, it may be 42 (gf), 41 (gf), 40 (gf), 34 (gf), 32 (gf), or 30 (gf). In one embodiment, the disintegratability in water of the tablet may fall in a range formed by combining any of the above-mentioned values as an upper limit and a lower limit. The frictional force in the wet-powder state may be, for example, 20 (gf) to 60 (gf), 25 (gf) to 55 (gf), or 25 (gf) to 50 (gf). Furthermore, it may be, for example, 30 (gf) to 45 (gf) or 30 (gf) to 34 (gf).

[0125]

When the frictional force in the wet-powder state is less than 65 (gf), it becomes easier to achieve a favorable mouthfeel for the disintegrated paste of the tablet or the paste of the powder composition. This facilitates the smooth passage of the composition during swallowing, namely, a tablet or composition easy to swallow tends to be obtained.

[0126]

Since the composition of the present embodiment has a frictional force in the wet-powder state of less than 65 (gf), it facilitates, as described above, the smooth passage of the composition during swallowing, namely, a tablet or composition easy to swallow tends to be obtained.

[0127]

The composition of the present embodiment can be used as a food composition or a pharmaceutical composition as described in Embodiment 2.

The composition of the present embodiment can be used as a cosmetic composition or a lubricant composition as described in Embodiment 3.

[0128]

== Embodiment 2 (Food Composition and Pharmaceutical Composition) ==

The composition of Embodiment 1 can be used as a food composition.

The food composition of the present embodiment contains a functional component.

In one embodiment, an oral composition of Embodiment 1 is preferably used as a food composition.

[0129]

The food composition can be used, either alone or in combination with two or more other food compositions, to prepare various food products such as a beverage, a soup, a processed meat product, a processed vegetable product, a processed fruit product, a seasoning, a concentrated food, and a supplement (such as a nutritional supplement, or a nutritional drink).

[0130]

In one embodiment, a food product contains the food composition of the present embodiment.

[0131]

Here, a "processed product" refers to a product obtained by processing and/or cooking a natural ingredient, and includes a frozen food, a retort-pouch food, a canned food, a bottled food, and the like.

The form of the food is not particularly limited, and a form suitable for oral use is preferred, and from the viewpoint of ease of intake, it may be in a fluid form such as a liquid, a syrup, a paste, a gel, a jelly, a cream, an emulsion, a spray, a mousse, a lotion, or the like; or may be in a solid form such as a powder, a granule, a pellet, a tablet, a capsule, a soft capsule, or the like. The tablet may be any of an

orally disintegrating tablet, a chewable tablet, an effervescent tablet, a dispersible tablet, or a soluble tablet.

Considering the effects of favorable oral disintegratability and favorable mouthfeel of the disintegrated paste, based on the favorable disintegratability in water and/or favorable frictional force in the wet-powder state achieved by containing the composition of Embodiment 1, as well as the resulting effect of smooth passage of the composition during swallowing, the tablet of the food is preferably an orally disintegrating tablet or a chewable tablet, and more preferably an orally disintegrating tablet.

[0132]

The functional component is not particularly limited as long as it is a component desired for intake in addition to a regular diet, but it is preferably a substance capable of exerting some nutritional or physiological activity or action that serves the purpose or intent of the food product containing the food composition in the subject that has ingested it.

In one embodiment, the functional component is preferably a component that has effects such as improving an undesirable symptom and/or physical discomfort in the subject (including functions related to the maintenance and promotion of health).

Therefore, the food product containing the food composition is preferably a functional food that has effects such as improving an undesirable symptom and/or physical discomfort in the subject that has ingested it (including functions related to the maintenance and promotion of health). Examples of such a functional food in Japan include general foods encompassing a nutritional supplement, a dietary supplement, and a balanced nutritional supplement, as well as foods with health claims (including food with nutrient function claims, food for specified health uses (FOSHU), and food with functional claims) where functional labeling is provided in accordance with safety and efficacy standards established by the government.

[0133]

The composition, raw material, origin, and procurement route of the functional component are not limited, and the functional component encompasses a natural product, a natural extract, a chemically synthesized substance, or a mixtures of two or more thereof.

Non-limiting examples of the functional component include vitamins such as vitamins B1, B2, C, and the like, minerals such as iron, zinc, and the like, amino acids, dietary fiber, DHA, EPA, polyphenols (including anthocyanins, isoflavones (including soy isoflavones and their metabolite, equol), flavones, catechins, flavonols, flavanones, and the like), carotenoids (such as  $\alpha$ -carotene,  $\beta$ -carotene,  $\beta$ -cryptoxanthin, lycopene, lutein, zeaxanthin, and the like), and sulfur-containing compounds (such as isothiocyanates, cysteine sulfoxides, and the like). The food composition may contain one of or two or more of these functional components.

In one embodiment, the functional component may be a soy-derived component, and the soy-derived component may be soy isoflavone and/or equol. The soy isoflavone and equol may each be in a glycoside form or an aglycone form.

For example, when the functional component is soy isoflavone or equol, a method for obtaining these is not limited, and non-limiting examples of the method include extraction from soybeans according to a well-known method, purchase of a commercially available product, and artificial preparation using equol-producing bacteria or the like.

[0134]

In one embodiment, the food product is preferably a functional food in the form of a tablet, and more preferably a functional food in the form of an orally disintegrating tablet.

[0135]

A daily intake amount of the food product is not limited and can be appropriately determined by those skilled in the art based on the content of the functional component in the food product and the required daily intake for the subject.

[0136]

The composition of Embodiment 1 can be used as a pharmaceutical composition.

The pharmaceutical composition of the present embodiment contains a pharmaceutically active ingredient.

In one embodiment, the oral composition of Embodiment 1 is preferably used as a pharmaceutical composition.

[0137]

The pharmaceutical composition can be used, either alone or in a combination of two or more, for the preparation of a medicament for treating a disease or a symptom suitable for the pharmaceutical effect of the pharmaceutically active ingredient.

[0138]

In one embodiment, a medicament contains the pharmaceutical composition of the present embodiment.

[0139]

A treatment method according to one embodiment includes administering the pharmaceutical composition of the present embodiment to a subject in need thereof.

[0140]

Use according to one embodiment is use of the composition of Embodiment 1, or the pharmaceutical composition of the present embodiment for producing a medicament for treatment of a subject in need thereof.

[0141]

A composition, a pharmaceutical composition, or pharmaceutically active ingredient of one embodiment is the composition of Embodiment 1, or the pharmaceutical composition or the pharmaceutically active ingredient of the present embodiment for treatment of a subject in need thereof.

[0142]

The form of the medicament is not particularly limited, and a form suitable for oral use is preferred, and from the viewpoint of ease of administration, it may be in a fluid form such as a liquid, a syrup, a paste, a gel, a jelly, a cream, an emulsion, a spray, a mousse, a lotion, or the like; or may be in a solid form such as a powder, a granule, a pellet, a tablet, a capsule, a soft capsule, or the like. The tablet may be any of an orally disintegrating tablet, a chewable tablet, an effervescent tablet, a dispersible tablet, or a soluble tablet.

Considering the effects of favorable oral disintegratability and favorable mouthfeel of the disintegrated paste, based on the favorable disintegratability in water and/or favorable frictional force in the wet-powder state achieved by containing the composition of Embodiment 1, as well as the resulting effect of smooth passage of the composition during swallowing, the tablet of the medicament is preferably an orally disintegrating tablet or a chewable tablet, and more preferably an orally disintegrating tablet.

[0143]

The pharmaceutically active ingredient is not limited as long as it is a component desired for administration to a subject having any disease or exhibiting any symptom, and it is preferably a substance capable of exerting some physiological activity or action that serves the purpose or intent of the pharmaceutically active ingredient in the subject to which it has been administered.

[0144]

The composition, raw material, origin, procurement route, and the like of the pharmaceutically active ingredient are not limited, and the pharmaceutically active ingredient encompasses a natural product, a natural extract, a synthetic substance (including a biotechnologically produced substance and a chemically synthesized substance), and a mixture of two or more thereof. Examples of the natural product or the natural extract include a nucleic acid, a protein (including an antibody and a fragment thereof), a culture fluid extract, a low-molecular-weight compound, and the like, and may be a substance identical to these or a similar substance having a similar function, which is either biotechnologically produced or chemically synthesized (a chemically synthesized substance). The natural product or natural extract may be obtained from any organism such as a microorganism, an animal, a plant, or the like, and is not limited by the ecology or habitat of the organism. The pharmaceutical composition may contain one of, or two or more of these pharmaceutically active ingredients.

[0145]

The pharmaceutical composition of the present invention is a pharmaceutical composition for the treatment or prevention of a disease, an undesirable symptom and/or physical discomfort, or the like in a subject. "Treatment" encompasses the reduction, alleviation, and mitigation of symptoms of a disease, while "prevention" encompasses the protection against the onset of a future disease or symptom and the suppression of its progression. Desirable therapeutic effects of the treatment include remission of the symptom, improvement of direct or indirect pathological consequences of the disease, reduction in the rate of progression of symptom aggravation, recovery or relief of the disease state, and improvement of prognosis.

[0146]

When two or more food compositions or pharmaceutical compositions are separately formulated into two or more food products or pharmaceutical

formulations, the individual food products or pharmaceutical formulations can be ingested or administered simultaneously, separately at a fixed time interval, or sequentially. These two or more food products or pharmaceutical formulations may also be ingested or administered a different number of times per day and/or via different routes. Pharmaceutical formulations can be administered systemically or locally.

[0147]

In addition to the composition and the functional component or the pharmaceutically active ingredient, the food composition or pharmaceutical composition may further contain one or more non-functional components that are nutritionally or pharmaceutically acceptable. Examples of the non-functional component include additives such as an acidulant, a sweetener, an excipient, a surfactant, a lubricant, a flavoring agent, a fragrance, a colorant, a stabilizer, an antiseptic, and the like. Examples of the excipient include mannitol, erythritol, xylitol, trehalose, lactose, maltose, maltitol, glucose, sucrose, fructose, mannose, sorbitol, amylose, light anhydrous silicic acid, hydrated silicon dioxide, anhydrous calcium phosphate, anhydrous dibasic calcium phosphate, aluminum metasilicate, calcium silicate, magnesium silicate, magnesium oxide, and the like. Examples of the surfactant include non-ionic surfactants, such as those having an HLB of 6 to 18, including: sorbitan fatty acid esters such as sorbitan monocaprylate, sorbitan monolaurate, sorbitan monopalmitate, and the like; and glycerin fatty acid esters such as glycerin monocaprylate, glycerin monomyristate, glycerin monostearate, and the like.

Other examples of the non-functional component include water, saline, alcohol, silicone, wax, Vaseline, a vegetable oil, polyethylene glycol, propylene glycol, liposome, gelatin, magnesium stearate, talc, a surfactant, silicic acid, viscous

paraffin, a fragrance oil, fatty acid monoglyceride and diglyceride, a pentaerythritol fatty acid ester, hydroxymethyl cellulose, polyvinylpyrrolidone, and the like.

[0148]

The content of the functional component or pharmaceutically active ingredient in the food composition or the pharmaceutical composition is not limited, and may be more than 10% by weight, 20% by weight or more, 20 to 40% by weight, 20 to 32% by weight, or 20 to 30% by weight. When the content of the functional component or the pharmaceutically active ingredient is 20 to 30% by weight, it may be 20% by weight, 24% by weight, 26% by weight, 27% by weight, or 30% by weight. Furthermore, the content of the non-functional component in the food composition or pharmaceutical composition is not limited, and may be 90% by weight or less, 60 to 90% by weight, 60 to 80% by weight, 68 to 80% by weight, or 70 to 80% by weight. The functional component or pharmaceutically active ingredient may be contained in the non-heat-resistant substance within the composition of Embodiment 2, and may be, for example, a protein, a low-molecular-weight carbohydrate, or the like.

When the content of the functional component or pharmaceutically active ingredient is more than 10% by weight, and the content of the non-functional component is 90% by weight or less, the food composition or a food product containing the same, or the pharmaceutical composition or a medicament containing the same tends to exhibit favorable frictional force in the wet-powder state. Therefore, it becomes easier to achieve a favorable mouthfeel upon ingestion and a smooth passage of the composition during swallowing, namely, a food or pharmaceutical product easy to swallow tends to be obtained. When the food product or medicament is in the form of a tablet, it tends to exhibit favorable disintegratability in water and/or a favorable frictional force in the wet-powder state. Consequently, the tablet easily achieves both favorable oral disintegratability and a

favorable mouthfeel of the disintegrated paste, which facilitates smooth passage of the composition during swallowing, namely, a tablet easy to swallow tends to be obtained.

Furthermore, when the content of the functional component or pharmaceutically active ingredient is more than 10% by weight, the desired effects of the functional component or pharmaceutically active ingredient are more easily exhibited in a subject that has ingested the food product or having been administered the medicament.

[0149]

The subject for the ingestion of the food composition or a food product containing the same, or for the administration of the pharmaceutical composition or a medicament containing the same is not limited, as long as it is an animal in need thereof. The subject may be a human or a non-human animal, and the non-human animal is not limited by its use, such as livestock, a pet animal, or a laboratory animal, and may be, for example, a monkey, a dog, a cat, a horse, cattle, a pig, sheep, a goat, a rabbit, a guinea pig, a hamster, a mouse, and/or a rat. Among these, the subject is preferably a mammal, and more preferably a human.

[0150]

The packaging form of the food composition or a food product containing the same, or the pharmaceutical composition or a medicament containing the same of the present embodiment is not particularly limited and can be appropriately selected by those skilled in the art according to the dosage form and the like. Examples of such packaging form include a blister pack such as PTP (Press Through Pack), strip packaging, a heat seal, an aluminum pouch, a film packaging using plastic, a synthetic resin, or the like, a glass container such as a vial or the like, a plastic container such as an ampoule, and the like.

[0151]

(Method for Producing Tablet)

The tablet of the food product or medicament of the present embodiment can be produced by a method well known to those skilled in the art.

For example, granules are produced from the powder of the composition of Embodiment 1 by a wet granulation method using a liquid or a dry granulation method not using a liquid. In the wet granulation method, the powder is aggregated using a granulating fluid with a wet granulator, such as a shear granulator, a high-shear mixer granulator, a twin-screw granulator, a fluidized bed granulator or the like, to produce the granules. In the dry granulation method, the powder of the composition is agglomerated by pressure. Specifically, slugs are produced using a tablet press, or a sheet or ribbon is produced by roller compaction of the powder of the composition using two rollers. The thus produced slugs, or the sheets or ribbons, are then pulverized to prepare granules. Subsequently, the granules are compressed by a tablet press to produce the tablet.

[0152]

More specifically, granules can be obtained by charging the composition of Embodiment 1 into a fluidized bed granulator (FL-LABO; manufactured by Freund Corporation).

Furthermore, magnesium stearate (manufactured by Taihei Chemical Industrial Co., Ltd.) is added to and mixed with the obtained granules, and a simple tablet press (HANDTAB-100, manufactured by Ichihashi Seiki Co., Ltd.) is used to tablet the resultant mixture at a specific tableting compression force to obtain approximately 250 mg of R12 round tablets with a diameter of 8 mm.

[0153]

Alternatively, for example, each component of the heat-resistant substance, the semi-heat-resistant substance, and the non-heat-resistant substance, that is, the raw materials for the composition of Embodiment 1, is subjected to a milling process

(mill treatment) for pulverizing coarse materials. After the milling process, the average particle size of the powder particles is checked, and if the average particle size is less than 60  $\mu\text{m}$ , the material is milled once with a jet mill (for example, a Jet Mill Pulverizer STJ-400 manufactured by Seishin Enterprise Co., Ltd.) at a flow rate of 2 kg/hr or more and 12 kg/hr or less, thereby pulverizing the particles to approximately 10  $\mu\text{m}$  to obtain the composition (powder composition) of Embodiment 1. 250 mg of this powder composition is placed into a die (manufactured by Ichihashi Seiki Co., Ltd., 8 mm diameter) and compressed at 3 kN such that the tablet thickness is uniform at approximately 5 mm, and this stress is maintained for 60 minutes to produce approximately 250 mg of R12 round tablets with a diameter of 8 mm. As the compressor, a HANDTAB-100, manufactured by Enerpac Co., Ltd., can be used.

By thus preparing the tablet using the powder particles that have been adjusted to approximately 10  $\mu\text{m}$  through milling, the resulting tablet tends to exhibit favorable disintegratability in water and favorable frictional force in the wet-powder state. It is presumed that this effect is due to the fact that milling causes the aspect ratio of the powder particles to easily approach 1.0, and therefore the friction between the fibers of the powder particles tends to be reduced.

[0154]

The tablet thus produced tends to exhibit favorable disintegratability in water and/or favorable frictional force in the wet-powder state. Consequently, the tablets containing the powder composition tend to achieve both favorable oral disintegratability and a favorable mouthfeel, which facilitates smooth passage of the composition during swallowing, namely, a tablet easy to swallow tends to be obtained.

[0155]

== Embodiment 3 (Other Applications) ==

The composition of Embodiment 1 can be used in various applications where its properties, namely, favorable disintegratability in water and/or favorable frictional force in the wet-powder state, can be suitably exhibited.

For example, the composition of Embodiment 1 can be used as a cosmetic composition. Alternatively, for example, the composition of Embodiment 1 can be used as a lubricant composition.

[0156]

A cosmetic according to one embodiment contains the cosmetic composition of the present embodiment.

A lubricant according to one embodiment contains the lubricant composition of the present embodiment.

[0157]

The cosmetic composition is, for example, a composition intended for aesthetic purposes, such as for the skin, hair, or nails, and can be formulated into a form that allows for the care of these areas to provide a cosmetic product. The composition may be, for example, a liquid, a lotion, a cream, a patch, an oil, a spray, a liquid cleanser, a solid soap, or the like. Moreover, examples of the product may include a skin lotion, a serum, a moisturizing liquid, a moisturizing cream, a soap, a body wash, a skin cleanser, a bath salt, a sunscreen, a shaving lotion, a hair remover, a shampoo, a conditioner, a hair tonic, a hair dye, and the like. In particular, from the viewpoint of suitably exhibiting the effects by exerting the properties exhibited by the composition of Embodiment 1, the form is preferably a lotion, a cream, and a liquid cleanser, and examples of the commercial form of the liquid cleanser include a shampoo, a body wash, a skin cleanser, and the like.

[0158]

The cosmetic composition may contain one or more functional components and/or one or more non-functional components described in Embodiment 2.

Furthermore, examples of the packaging form for a cosmetic containing the cosmetic composition are the same as those described in Embodiment 2.

[0159]

The subject to which the cosmetic composition or a cosmetic containing the same is applied is not limited as long as it is an animal in need thereof, and may be a human or a non-human animal, and the non-human animal is not limited by its use, such as livestock, a pet animal, or a laboratory animal, and may be, for example, a monkey, a dog, a cat, a horse, cattle, a pig, sheep, a goat, a rabbit, a guinea pig, a hamster, a mouse, and/or a rat. Among these, the subject is preferably a mammal, and more preferably a human.

[0160]

A lubricant composition is a composition intended for improving handling properties during tableting and enhancing ease of swallowing upon administration of the tablet. Since the composition of Embodiment 1 exhibits favorable disintegratability in water and/or favorable frictional force in the wet-powder state, it can be suitably used as a lubricant composition.

[0161]

The lubricant composition may contain one or more functional components and/or one or more non-functional components described in Embodiment 2. From the viewpoint of functionality as a lubricant composition, the composition preferably contains one or more lubricants known in the art to those skilled in the art. Non-limiting examples of such a lubricant include titanium oxide, calcium carbonate, hydrated silicon dioxide, hydrated amorphous silicon oxide, glycerin fatty acid ester, magnesium silicate, light anhydrous silicic acid, hydrogenated oil, heavy anhydrous silicic acid, sucrose fatty acid ester, stearyl alcohol, stearic acid, zinc stearate, aluminum stearate, calcium stearate, polyoxyl 40 stearate, magnesium stearate,

hydrogenated soybean oil, talc, sodium stearyl fumarate, beeswax, anhydrous silicic acid hydrate, magnesium aluminometasilicate, and glyceryl monostearate.

[0162]

A lubricant containing the lubricant composition of the present embodiment can be suitably used in the formulation of, for example, the pharmaceutical composition of Embodiment 2, or a medicament containing the pharmaceutical composition.

[0163]

A non-limiting list of exemplary embodiments and combinations of the exemplary embodiments of the present disclosure is disclosed below.

[1] A composition containing a heat-resistant substance, a semi-heat-resistant substance, and a non-heat-resistant substance, wherein the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 600°C is 11% or more, the electromotive force obtained upon heating from 25°C to 600°C is -4  $\mu$ V or more, the weight retention rate (y) determined by thermogravimetric analysis upon heating from 25°C to 600°C is represented by the following expression: expression:  $y \geq -2.03x + 23.623$ , wherein x represents the electromotive force obtained upon heating from 25°C to 600°C, and the apparent tapped density is 0.3 g/cm<sup>3</sup> to 5 g/cm<sup>3</sup>.

[2] The composition according to [1], wherein the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 600°C (W600) is 11% to 60%, 12% to 50%, 13% to 40%, 18% to 30%, or 20% to 29%.

[3] The composition according to [1] or [2], wherein the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 100°C (W100) is 50% or more and 98% or less, 60% to 98%, 70% to 98%, or 90% to 98%.

[4] The composition according to any one of [1] to [3], wherein the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to

200°C (W200) is 50% or more and 96% or less, 60% to 95%, 70% to 95%, or 80% to 95%.

[5] The composition according to any one of [1] to [4], wherein the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 300°C (W300) is 50% or more and 90% or less, 55% to 90%, 60% to 88%, 60% to 85%, 63% to 80%, or 65% to 78%.

[6] The composition according to any one of [1] to [5], wherein the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 400°C (W400) is 15% or more and 80% or less, 15% to 70%, 16% to 68%, or 20% to 60%.

[7] The composition according to any one of [1] to [6], wherein the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 500°C (W500) is 12% or more and 70% or less, 12% to 60%, 15% to 55%, or 20% to 50%.

[8] The composition according to any one of [1] to [7], wherein  $(W200/W100) \times 100 (\%)$  is 80 to 98, 85 to 98, or 88 to 97.

[9] The composition according to any one of [1] to [8], wherein  $(W300/W100) \times 100 (\%)$  is 60 to 93, 65 to 93, or 67 to 93.

[10] The composition according to any one of [1] to [9], wherein  $(W400/W100) \times 100 (\%)$  is 15 to 80.

[11] The composition according to any one of [1] to [10], wherein  $(W500/W100) \times 100 (\%)$  is 13 to 60.

[12] The composition according to any one of [1] to [11], wherein  $(W600/W100) \times 100 (\%)$  is 11 to 45, 15 to 30, or 17 to 30.

[13] The composition according to any one of [1] to [12], wherein the electromotive force obtained upon heating from 25°C to 600°C (X600) is -4  $\mu$ V to 20  $\mu$ V, -4  $\mu$ V to 18  $\mu$ V, or 1  $\mu$ V to 17  $\mu$ V.

[14] The composition according to any one of [1] to [13], wherein the electromotive force obtained upon heating from 25°C to 100°C (X100) is -10  $\mu$ V or more and 0  $\mu$ V or less, -8  $\mu$ V to -1  $\mu$ V, or -6  $\mu$ V to -3  $\mu$ V.

[15] The composition according to any one of [1] to [14], wherein the electromotive force obtained upon heating from 25°C to 200°C (X200) is -10  $\mu$ V or more and 0  $\mu$ V or less, -8  $\mu$ V to -1  $\mu$ V, or -6  $\mu$ V to -2  $\mu$ V.

[16] The composition according to any one of [1] to [15], wherein the electromotive force obtained upon heating from 25°C to 300°C (X300) is -9  $\mu$ V or more and 10  $\mu$ V or less, -8  $\mu$ V to 8  $\mu$ V, or -7  $\mu$ V to 5  $\mu$ V.

[17] The composition according to any one of [1] to [16], wherein the electromotive force obtained upon heating from 25°C to 400°C (X400) is -8  $\mu$ V or more and 15  $\mu$ V or less, -5  $\mu$ V to 15  $\mu$ V, or -3  $\mu$ V to 10  $\mu$ V.

[18] The composition according to any one of [1] to [17], wherein the electromotive force obtained upon heating from 25°C to 500°C (X500) is -4  $\mu$ V or more and 20  $\mu$ V or less, -4  $\mu$ V to 18  $\mu$ V, or -2  $\mu$ V to 14  $\mu$ V.

[19] The composition according to any one of [1] to [18], wherein  $(X200/X100) \times 100 (\%)$  is 30 to 170, or 35 to 170.

[20] The composition according to any one of [1] to [19], wherein  $(X300/X100) \times 100 (\%)$  is -50 to 200, or -50 to 180.

[21] The composition according to any one of [1] to [20], wherein  $(X400/X100) \times 100 (\%)$  is -150 to 100, or -130 to 70.

[22] The composition according to any one of [1] to [21], wherein  $(X500/X100) \times 100 (\%)$  is -250 to 50, or -240 to 40.

[23] The composition according to any one of [1] to [22], wherein  $(X600/X100) \times 100 (\%)$  is -300 to 100, or -300 to 70.

[24] The composition according to any one of [1] to [23], wherein the apparent tapped density is 0.35 g/cm<sup>3</sup> to 4.6 g/cm<sup>3</sup>.

[25] The composition according to any one of [1] to [24], wherein the heat-resistant substance is an inorganic substance.

[26] The composition according to [25], wherein the inorganic substance is one or more selected from the group consisting of magnesium aluminosilicate, magnesium aluminum silicate, magnesium hydroxide, dried sodium carbonate, sodium hydroxide, sodium bicarbonate, a sodium carbonate hydrate, a Fe-Mg hydrotalcite-like compound, and an Al-Mg hydrotalcite-like compound.

[27] The composition according to any one of [1] to [26], wherein the semi-heat-resistant substance is a highly crystalline substance.

[28] The composition according to [27], wherein the highly crystalline substance is one or more selected from the group consisting of starch, glycogen, cellulose, chitin, and chitosan.

[29] The composition according to any one of [1] to [28], wherein the non-heat-resistant substance is one or more selected from the group consisting of a protein and a low-molecular-weight carbohydrate.

[30] The composition according to [29], wherein the low-molecular-weight carbohydrate is one or more selected from the group consisting of aldose and ketose.

[31] The composition according to any one of [1] to [30], wherein the heat-resistant substance content in the composition is more than 18% by weight, the semi-heat-resistant substance content in the composition is less than 72% by weight, and the non-heat-resistant substance content in the composition is more than 10% by weight.

[32] The composition according to [31], wherein the heat-resistant substance content in the composition is 20% by weight to 40% by weight, the semi-heat-resistant substance content in the composition is 30% by weight to 70% by weight, and the non-heat-resistant substance content in the composition is 10% by weight to 45% by weight.

[33] The composition according to [31], wherein the heat-resistant substance content in the composition is 20% by weight to 40% by weight, the semi-heat-resistant substance content in the composition is 35% by weight to 55% by weight, and the non-heat-resistant substance content in the composition is 20% by weight to 35% by weight.

[34] The composition according to any one of [1] to [33], wherein the composition contains a naturally derived component.

[35] The composition according to any one of [1] to [34], wherein the composition is a powder composition, and an average fiber length of powder particles contained in the powder composition is 1  $\mu\text{m}$  to 500  $\mu\text{m}$ , 5  $\mu\text{m}$  to 500  $\mu\text{m}$ , 5  $\mu\text{m}$  to 250  $\mu\text{m}$ , 5  $\mu\text{m}$  to 100  $\mu\text{m}$ , or 5  $\mu\text{m}$  to 50  $\mu\text{m}$ .

[36] The composition according to any one of [1] to [35], wherein the composition is a powder composition, and an average fiber width of powder particles contained in the powder composition is 1  $\mu\text{m}$  to 500  $\mu\text{m}$ , 5  $\mu\text{m}$  to 500  $\mu\text{m}$ , 5  $\mu\text{m}$  to 250  $\mu\text{m}$ , 5  $\mu\text{m}$  to 100  $\mu\text{m}$ , or 5  $\mu\text{m}$  to 50  $\mu\text{m}$ .

[37] The composition according to any one of [1] to [36], wherein the composition is a powder composition, and an aspect ratio of powder particles contained in the powder composition is 1.0 to 100, 1.0 to 5.0, 1.0 to 3.0, 1.0 to 2.0, or 1.0 to 1.5.

[38] The composition according to any one of [1] to [37], wherein the composition is a powder composition, and a water absorption rate of powder particles contained in the powder composition is less than 200%, 25% to 150%, 30% to 100%, 40% to 80%, or 50% to 75%.

[39] The composition according to any one of [1] to [38], wherein the apparent density (without tapping) is 0.3  $\text{g}/\text{cm}^3$  to 5  $\text{g}/\text{cm}^3$ .

[40] The composition according to any one of [1] to [39], wherein the compression degree is less than 1.35, or 1 to 1.3.

[41] The composition according to any one of [1] to [40], wherein a tablet containing the composition has disintegratability in water of less than 1.9 (min/N), 1.5 (min/N) or less, or 1.2 (min/N) or less.

[42] The composition according to any one of [1] to [41], wherein a tablet containing the composition has a disintegration time in water of less than 90 minutes, 30 minutes or less, 12 minutes to 30 minutes, or 12 minutes to 15 minutes.

[43] The composition according to any one of [1] to [42], wherein the frictional force in the wet-powder state is less than 65 (gf), 45 (gf) or less, 20 (gf) to 60 (gf), 25 (gf) to 55 (gf), 25 (gf) to 50 (gf), 30 (gf) to 45 (gf), or 30 (gf) to 34 (gf).

[44] The composition according to any one of [1] to [43], for oral use.

[45] The composition according to [1] to [44], wherein the composition is a food composition.

[46] The composition according to [1] to [44], wherein the composition is a pharmaceutical composition.

[47] A functional food containing the composition according to [45].

[48] A medicament containing the composition according to [46].

[49] The functional food according to [47] in the form of a tablet.

[50] The medicament according to [48] in the form of a tablet.

## Examples

[0164]

The present disclosure will be described in further detail below with reference to examples, but the interpretation of the present disclosure is not limited by these examples.

[0165]

[Composition]

Compositions of Examples 1 to 9 and Comparative Examples 1 to 6 were prepared by mixing wheat germ, titanium oxide, crystalline cellulose (Ceolus (R) PH-101, available from Asahi Kasei Corporation), powdered cellulose (KC Flock W-50, available from Nippon Paper Industries Co., Ltd.), oats, and/or calcium carbonate in the weights (g) shown under "Materials" in Table 1 to achieve a total weight of 100 g.

[0166]

(Examples)

(Example 1) Powder Composition (T1)

(Example 2) Powder Composition (T2)

(Example 3) Powder Composition (T3)

(Example 4) Powder Composition (T6)

(Example 5) Powder Composition (T7)

(Example 6) Powder Composition (T8)

(Example 7) Powder Composition (T9)

(Example 8) Powder Composition (T10)

(Example 9) Powder Composition (T11)

[0167]

(Comparative Examples)

(Comparative Example 1) Powder Composition (T4)

(Comparative Example 2) Powder Composition (T5)

(Comparative Example 3) Powder Composition (T12)

(Comparative Example 4) Powder Composition (T13)

(Comparative Example 5) Powder Composition (T14)

(Comparative Example 6) Powder Composition (T15)

[Table 1]

|                                     |                               |     | Example |    |    |    |    |    |    |     |     | Comparative Example |     |     |     |     |     |
|-------------------------------------|-------------------------------|-----|---------|----|----|----|----|----|----|-----|-----|---------------------|-----|-----|-----|-----|-----|
|                                     |                               |     | 1       | 2  | 3  | 4  | 5  | 6  | 7  | 8   | 9   | 1                   | 2   | 3   | 4   | 5   | 6   |
| Sample No.                          |                               |     | T1      | T2 | T3 | T6 | T7 | T8 | T9 | T10 | T11 | T4                  | T5  | T12 | T13 | T14 | T15 |
| Material (g)<br>(mixed in 100g)     | Wheat Germ                    |     | 80      | 70 | 75 | 80 | 90 | 0  | 0  | 0   | 0   | 0                   | 0   | 0   | 0   | 0   | 0   |
|                                     | Titanium Oxide                |     | 20      | 10 | 5  | 10 | 5  | 90 | 20 | 20  | 20  | 0                   | 0   | 5   | 5   | 10  | 10  |
|                                     | Ceolus PH-101                 |     | 0       | 20 | 0  | 0  | 0  | 0  | 60 | 0   | 0   | 100                 | 0   | 90  | 0   | 90  | 0   |
|                                     | KC FLOCK W-50                 |     | 0       | 0  | 20 | 0  | 0  | 0  | 0  | 40  | 0   | 0                   | 100 | 0   | 90  | 0   | 90  |
|                                     | Oats                          |     | 0       | 0  | 0  | 10 | 0  | 10 | 20 | 40  | 70  | 0                   | 0   | 0   | 0   | 0   | 0   |
|                                     | Calcium Carbonate             |     | 0       | 0  | 0  | 0  | 5  | 0  | 0  | 0   | 10  | 0                   | 0   | 5   | 5   | 0   | 0   |
| Production Example<br>(composition) | Heat-resistant Substance      | wt% | 30      | 24 | 24 | 40 | 28 | 22 | 22 | 38  | 40  | 5                   | 5   | 18  | 18  | 15  | 15  |
|                                     | Semi-heat-resistant Substance | wt% | 40      | 52 | 52 | 35 | 40 | 52 | 52 | 35  | 40  | 94                  | 85  | 81  | 72  | 84  | 75  |
|                                     | Non-heat-resistant Substance  | wt% | 30      | 24 | 24 | 25 | 32 | 26 | 26 | 27  | 20  | 1                   | 10  | 1   | 10  | 1   | 10  |

[0168]

[Preparation of Composition and Tablet]

The mixture of the materials was subjected to a pulverization step (milling process) to grind coarse materials. After the pulverization step, the average particle size (fiber length) of the resultant powder particles was checked, and if the size was less than 60  $\mu\text{m}$ , the mixture was pulverized once using a jet mill (for example, Jet Mill STJ-400 manufactured by Seishin Enterprise Co., Ltd.) at a flow rate of 2 kg/h or more and 12 kg/h or less to achieve a particle size of approximately 10  $\mu\text{m}$ , and thus, a powder composition was obtained.

[0169]

For each of the compositions of Examples 1 to 9 and Comparative Examples 1 to 6, the content of the heat-resistant substance was measured by a known ash method, and the content of the semi-heat-resistant substance was measured by a known quantification method for  $\alpha$ -cellulose. The content of the non-heat-resistant substance was obtained through calculation by subtracting a value obtained by known  $\alpha$ -cellulose measurement from a value obtained by a known quantification method for holocellulose.

Each of the compositions of Examples 1 to 9 and Comparative Examples 1 to 6 contained the heat-resistant substance, the semi-heat-resistant substance, and the non-heat-resistant substance in compositions (wt%) shown in "Production Example" in Table 1.

[0170]

In addition, a heat-resistant substance, a semi-heat-resistant substance, and a non-heat-resistant substance in each raw material were analyzed, similarly to those in the composition, to find that the wheat germ contained 5 to 25% by weight of a heat-resistant substance, 30 to 70% by weight of a semi-heat-resistant substance, and 25 to 45% by weight of a non-heat-resistant substance. The oats contained 5 to 20% by

weight of a heat-resistant substance, 45 to 75% by weight of a semi-heat-resistant substance, and 20 to 45% by weight of a non-heat-resistant substance. The crystalline cellulose (Ceolus available from Asahi Kasei Corporation) contained 1 to 10% by weight of a heat-resistant substance, 70 to 98% by weight of a semi-heat-resistant substance, and 0.1 to 5% by weight of a non-heat-resistant substance. The powdered cellulose (KC Flock W-50, available from Nippon Paper Industries Co., Ltd.) contained 1 to 10% by weight of a heat-resistant substance, 70 to 90% by weight of a semi-heat-resistant substance, and 5 to 20% by weight of a non-heat-resistant substance.

[0171]

To prepare tablets using the powder compositions of the aforementioned Examples and Comparative Examples, 250 mg of the sample used for measuring the average particle size (fiber length) of the powder particles was placed into a die (manufactured by Ichihashi Seiki Co., Ltd., 8 mm diameter), and then compressed at 3 kN and held under that stress for 60 minutes to ensure a uniform tablet thickness of approximately 5 mm, and in this manner, approximately 250 mg of R12 round tablets with a diameter of 8 mm were produced (with a compressor, HANDTAB-100 manufactured by Enerpac Co., Ltd., used).

[0172]

[Evaluation of Oral Composition]

The tablets or the compositions of Examples and Comparative Examples were evaluated as follows.

[0173]

(Thermogravimetric Analysis)

A thermal analyzer (STA300, manufactured by Hitachi High-Tech Science Corporation) was used to measure the residual weight of a sample (approximately 10

mg) of the powder composition at 100°C, 200°C, 300°C, 400°C, and 600°C during heating from 25°C to 600°C at a rate of 10°C /min under a N<sub>2</sub> atmosphere.

A weight retention rate obtained upon heating a sample from a temperature "a" to a temperature "b" is a percentage value (%) representing the residual weight at the temperature "b", with the residual weight at the temperature "a" defined as 100. In other words, the weight retention rate is represented by the following expression:

$$\text{Weight retention rate (\%)} = 100 \times [\text{residual weight (mg) at temperature "b"}] / [\text{residual weight (mg) at temperature "a"}]$$

A ratio of the weight retention rate obtained upon heating a sample from the temperature "a" to the temperature "b" ( $W_{a \rightarrow b}$ ) relative to the weight retention rate obtained upon heating the sample from the temperature "a" to a temperature "c" ( $W_{a \rightarrow c}$ ) is represented by an expression: ( $W_{a \rightarrow b} / W_{a \rightarrow c}$ ).

[0174]

(Measurement of Electromotive Force)

A thermal analyzer (STA300, manufactured by Hitachi High-Tech Science Corporation) was used to measure the electromotive force ( $\mu\text{V}$ ) of a sample (approximately 10 mg of the powder composition at 100°C, 200°C, 300°C, 400°C, and 600°C obtained during heating from 25°C to 600°C at a rate of 10°C /min under a N<sub>2</sub> atmosphere.

A ratio of the electromotive force ( $X_a$ ) of the sample obtained upon heating from 25°C to a temperature "a" relative to the electromotive force ( $X_b$ ) of the sample obtained upon heating from 25°C to a temperature "b" is represented by an expression:  $X_a/X_b$ .

[0175]

(Disintegratability in Water)

The disintegratability in water is expressed as a disintegration time per unit hardness [disintegration time in water (D)/tablet hardness (N) (min/N)].

For evaluating the disintegratability in water of the tablets, the tablets prepared as described above from the compositions of Examples and Comparative Examples were used.

[0176]

The disintegration time in water was obtained by placing the tablet in a test tube, adding 20 mL of pure water thereto, and shaking the resultant at 37°C with a shaker (Reciprocating/Orbital Shaker MMS-3020, manufactured by Tokyo Rikakikai Co., Ltd.) to measure the disintegration time. The measurement was performed 50 times, and the average value was defined as the disintegration time in water of the tablet.

[0177]

(Tablet Hardness)

The tablet hardness (N) was measured with a hardness tester (Model: KHT-40N, Fujiwara Scientific Co., Ltd.). A tablet produced by the method described in the section "Method for Producing Tablet" was placed at the center of the measurement stage, and the device was started (by pressing the AUTO [Start] button). At this time, the hardness of the tablet was measured in the direction perpendicular to the compression direction in molding the tablet. Thus, the rod descended at high speed, the display entered a peak-hold state, and when the rod contacted a measurement object, the speed decreased, and display monitoring was performed approximately every 0.1 seconds. If the hardness ceased to increase, it was determined that the tablet had been fractured, and the hardness indicated on the hardness tester at that moment was defined as the tablet hardness (N).

[0178]

(Frictional Force in Wet-Powder State)

The frictional force (gf) in the wet-powder state was measured by passing the residue of the sample having been subjected to the above-mentioned

"disintegratability in water" test through a 90 µm sieve (JIS Z8801 wire), collecting the residue, and performing measurement using a static/dynamic friction tester ("Handy Tribomaster TL201Ts" manufactured by Trinity Lab Inc.) under measurement conditions of a 50 g load and a speed of 10 mm/sec. A contactor consisting of artificial skin ("Bio Skin" manufactured by Beaulax Co., Ltd.) attached to a 5 mm-thick sponge sheet ("Sukima-yo (Gap) Tape N-1" manufactured by Cemedine Co., Ltd.) was used as the contactor.

Based on the results of the static frictional force (gf), the ratio between the travel distances of 0 mm and 3 mm was calculated by the following expression:

Expression: Frictional force in the wet-powder state at 2 mm travel =  $100 \times$  (static frictional force at 0 mm travel distance/static frictional force at 3 mm travel distance)

[0179]

(Measurement of Average Fiber Length and Average Fiber Width of Powder Particles)

To remove extremely coarse or aggregated fibers, 1 g of a powder sample of the composition of each of Examples and Comparative Examples adjusted to a moisture content of 2 to 3% was used for classification using a JIS test sieve (710 µm; manufactured by Tokyo Screen Co., Ltd.). From the classified sample, particles were randomly selected under an optical microscope (100x magnification), and after excluding the 100 largest and 100 smallest particles, remaining 1000 particles were measured for the fiber length (length in the fiber direction) and fiber width (length perpendicular to the fiber) of the powder particles to calculate their average values.

[0180]

(Aspect Ratio of Powder Particles)

For obtaining the aspect ratio of the powder particles of the composition of each of Examples and Comparative Examples, the fiber length/fiber width was calculated using the fiber lengths and fiber widths of the 1000 powder particles measured under a microscope as described above, and the average value thereof was obtained.

[0181]

(Apparent Tapped Density)

The apparent tapped density of the composition of each of Examples and Comparative Examples was measured with a commercially available powder property tester (Powder Tester PT-T, manufactured by Hosokawa Micron Corporation). Specifically, a 100 cm<sup>3</sup> cup was filled with all the powder particles contained in the composition and tapped 250 times per minute, and then, the apparent tapped density was determined by dividing the weight of the powder sample filled in the cup by the volume of the powder sample.

[0182]

(Apparent Density (without tapping))

The apparent density (without tapping) of the composition was determined by loosely filling the composition in a 100 cm<sup>3</sup> glass graduated cylinder over 2 to 3 minutes with a constant-rate composition feeder or the like, and then the top surface of the resultant powder layer was leveled horizontally with a soft brush, such as a paintbrush, and the volume was read, and the weight of the powder sample was divided by the volume thereof to obtain a value of the apparent density. The weight of the powder was adjusted as appropriate so that the volume reached approximately 70 to 100 cm<sup>3</sup>.

[0183]

(Water Absorption Rate of Powder Particles)

The water absorption rate of the powder particles contained in the composition of each of Examples and Comparative Examples was obtained by measuring the amount of water immediately before the release of water from the fibers was visually confirmed, when 2 g of the powder particles were put in a container and water was added dropwise thereto and mixed uniformly. The value was obtained as an average of  $n = 100$ .

[0184]

(Mouthfeel Sensory Test)

The mouthfeel was evaluated by 30 adult males and 30 adult females. The participants placed a tablet in their mouths and allowed it to disintegrate while rolling it with their tongues, and after the tablet had completely disintegrated, the powdery mouthfeel was evaluated. The average of the 4-point scale from these 60 participants was used as the evaluation score for each of Examples and Comparative Examples.

The results were evaluated according to the following criteria:

- 1: Significant powdery mouthfeel
- 2: Noticeable powdery mouthfeel
- 3: Slight powdery mouthfeel, but sufficiently moist to be nearly unnoticeable
- 4: No powdery mouthfeel

[0185]

(Compression Degree)

The compression degree was calculated by dividing the "apparent tapped density" described above by the "apparent density (without tapping)".

[0186]

(Functional Expression of Weight Retention Rate ( $y$ ))

The weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 600°C was expressed by a function using the electromotive force (x) obtained upon heating from 25°C to 600°C.

First, the weight retention rates of the compositions obtained upon heating from 25°C to 600°C of Examples and Comparative Examples shown in Table 2 were plotted.

As illustrated in Figure 1, Examples 1 to 9 (T1 to T3 and T6 to T11), in which the weight retention rate determined by thermogravimetric analysis upon heating from 25°C to 600°C was 11% or more (upper side of the line A), and the electromotive force obtained upon heating from 25°C to 600°C was - 4  $\mu$ V or more (right side of the line B), had disintegratability in water of 1.2 (min/N) or less, namely, exhibited favorable disintegratability in water. Moreover, these compositions had a frictional force in the wet-powder state of 45 (gf) or less, and had a mouthfeel sensory test score of 3 or 4, and thus exhibited a favorable mouthfeel.

However, the region on the upper side of the line A and on the right side of the line B included Comparative Examples 3 to 6 (T12 to T15), which exhibited low efficacy in achieving the aforementioned favorable disintegratability in water and a favorable mouthfeel. Therefore, in order to reduce the difficulty, in the actual composition production, in distinguishing between those that yield the desired effects and those that do not, the "expression:  $y \geq -2.03x + 23.623$ " was defined as a boundary line separating those that yield the desired effects from those that do not, based on T2 (Example 2) and T7 (Example 5).

Based on this expression, compositions that yielded no effect or low efficacy could be effectively excluded. Since the regions outside the region bounded by the line A, the line B, and the line defined by the "expression:  $y \geq -2.03x + 23.623$ " were eliminated, compositions possessing favorable disintegratability in water and a favorable mouthfeel could be easily identified. Furthermore, because the

"expression:  $y \geq -2.03x + 23.623$ " represents a straight line, the identification could be easily performed, making it even easier to determine whether or not a composition would exhibit the effects.

[0187]

[Evaluation Results]

(Thermogravimetric Analysis)

As shown in Table 2, the weight retention rate obtained upon heating from 25°C to 100°C was 95% or more in all the compositions of Examples and Comparative Examples. The weight loss caused upon heating from 25°C to 100°C is attributed to the decrease in water adsorbed onto the tablet or the powder composition, and the remaining residue corresponds to the tablet or the powder composition excluding the water.

[0188]

The weight retention rate obtained upon heating from 25°C to 200°C was 85% or more in all the compositions of Examples and Comparative Examples. The weight retention rate was 85% to 93% in Examples. In particular, in Examples in which 20% of high-purity cellulose powder was mixed (Examples 2 and 3), the weight retention rate was 92% to 93%. In contrast, the weight retention rate was 96% or more in Comparative Examples.

[0189]

The weight retention rate obtained upon heating from 25°C to 300°C was 65% or more in all the compositions of Examples and Comparative Examples. The weight retention rate was 65% to 88% in Examples. In particular, in Examples in which 20% of high-purity cellulose powder was mixed, the weight retention rate was 72% to 73%. In contrast, the weight retention rate was 91% or more in Comparative Examples.

[0190]

The weight retention rate obtained upon heating from 25°C to 400°C was 9% or more in all the compositions of Examples and Comparative Examples. The weight retention rate was 16% to 66% in Examples. In particular, in Examples in which 20% of high-purity cellulose powder was mixed, the weight retention rate was 28% to 30%. In contrast, the weight retention rate was 9% to 33% in Comparative Examples.

[0191]

The weight retention rate obtained upon heating from 25°C to 500°C was 7% or more in all the compositions of Examples and Comparative Examples. The weight retention rate was 15% to 41% in Examples. In particular, in Examples in which 20% of high-purity cellulose powder was mixed, the weight retention rate was 21% to 23%. In contrast, the weight retention rate was 7% to 31% in Comparative Examples.

[0192]

The weight retention rate obtained upon heating from 25°C to 600°C was 6% or more in all the compositions of Examples and Comparative Examples. The weight retention rate was 13% to 40% in Examples. In particular, in Examples in which 20% of high-purity cellulose powder was mixed, the weight retention rate was 20% to 21%. In contrast, the weight retention rate was 6 to 29% in Comparative Examples.

[Table 2]

|                                                                                       |                   | Example |      |      |      |      |      |      |      |      | Comparative Example |      |       |       |       |       |
|---------------------------------------------------------------------------------------|-------------------|---------|------|------|------|------|------|------|------|------|---------------------|------|-------|-------|-------|-------|
|                                                                                       |                   | 1       | 2    | 3    | 4    | 5    | 6    | 7    | 8    | 9    | 1                   | 2    | 3     | 4     | 5     | 6     |
| Sample No.                                                                            |                   | T1      | T2   | T3   | T6   | T7   | T8   | T9   | T10  | T11  | T4                  | T5   | T12   | T13   | T14   | T15   |
| Thermogravimetric Analysis TG (100°C Weight retention rate)                           | %                 | 95.3    | 96.5 | 96.1 | 97.5 | 95.0 | 96.5 | 95.0 | 95.0 | 95.0 | 96.8                | 97.5 | 96.9  | 97.6  | 96.7  | 97.4  |
| Thermogravimetric Analysis TG (200°C Weight retention rate)                           | %                 | 91.0    | 92.9 | 92.5 | 85.9 | 92.0 | 93.2 | 92.0 | 92.0 | 92.0 | 96.6                | 97.3 | 96.7  | 97.4  | 96.6  | 97.3  |
| Thermogravimetric Analysis TG (300°C Weight retention rate)                           | %                 | 68.9    | 73.7 | 72.3 | 65.6 | 88.0 | 78.0 | 88.0 | 73.7 | 72.3 | 92.4                | 91.5 | 92.5  | 91.6  | 92.3  | 91.4  |
| Thermogravimetric Analysis TG (400°C Weight retention rate)                           | %                 | 32.1    | 29.6 | 28.7 | 37.3 | 16.0 | 27.6 | 16.0 | 65.6 | 65.6 | 9.2                 | 13.8 | 18.0  | 24.0  | 26.0  | 33.0  |
| Thermogravimetric Analysis TG (500°C Weight retention rate)                           | %                 | 23.8    | 22.3 | 21.8 | 31.1 | 15.0 | 21.7 | 15.0 | 31.1 | 41.1 | 7.7                 | 11.4 | 16.0  | 22.0  | 24.0  | 31.0  |
| Thermogravimetric Analysis TG (600°C Weight retention rate)                           | %                 | 22.3    | 20.8 | 20.3 | 29.0 | 14.0 | 20.3 | 13.0 | 29.0 | 40.0 | 6.9                 | 10.3 | 14.0  | 20.3  | 22.3  | 29.0  |
|                                                                                       |                   |         |      |      |      |      |      |      |      |      |                     |      |       |       |       |       |
| Thermogravimetric Analysis DTA (100°C Electromotive force)                            | μV                | -5.0    | -4.8 | -4.9 | -5.8 | -4.4 | -3.9 | -4.4 | -5.0 | -4.8 | -1.8                | -2.4 | -1.9  | -2.3  | -1.7  | -2.3  |
| Thermogravimetric Analysis DTA (200°C Electromotive force)                            | μV                | -4.7    | -4.2 | -6.0 | -2.0 | -3.3 | -6.4 | -3.3 | -4.7 | -4.2 | -2.1                | -2.8 | -2.3  | -2.6  | -2.1  | -2.7  |
| Thermogravimetric Analysis DTA (300°C Electromotive force)                            | μV                | -2.6    | -2.4 | -5.4 | 2.9  | 0.8  | -6.7 | 0.0  | -2.6 | -2.4 | -7.9                | -5.3 | -7.8  | -5.1  | -7.8  | -5.2  |
| Thermogravimetric Analysis DTA (400°C Electromotive force)                            | μV                | -0.1    | -1.7 | -1.3 | 7.6  | 0.0  | -2.4 | 0.7  | -0.1 | -1.7 | -7.2                | -8.6 | -7.1  | -8.5  | -7.1  | -8.6  |
| Thermogravimetric Analysis DTA (500°C Electromotive force)                            | μV                | -1.0    | -1.9 | 0.8  | 13.9 | 0.7  | -0.1 | 4.7  | -1.0 | -1.9 | -7.6                | -4.8 | -7.3  | -4.8  | -7.5  | -4.8  |
| Thermogravimetric Analysis DTA (600°C Electromotive force)                            | μV                | 1.0     | 1.4  | 5.1  | 16.6 | 4.7  | 2.2  | 9.0  | -1.0 | -3.0 | -4.6                | -6.0 | 1.7   | -0.8  | -2.0  | -3.0  |
| Water absorption rate of powder                                                       | %                 | 50      | 70   | 60   | 50   | 75   | 75   | 70   | 70   | 70   | 200                 | 250  | 225.0 | 225.0 | 250.0 | 200.0 |
| Frictional force in wet-powder state at 2 mm travel (≈ zero distance)                 | gf                | 30      | 30   | 30   | 32   | 45   | 34   | 41   | 40   | 42   | 65                  | 65   | 65.0  | 64.0  | 65.0  | 63.0  |
| Disintegration time in water                                                          | min               | 12      | 12   | 14   | 15   | 25   | 15   | 25   | 30   | 30   | 90                  | 120  | 100   | 105   | 105   | 110   |
| Tablet hardness                                                                       | N                 | 14      | 17   | 43   | 35   | 46   | 35   | 43   | 42   | 25   | 47                  | 45   | 45    | 47    | 45    | 50    |
| Disintegratability in water (min/N)<br>(disintegration time in water/tablet hardness) | min/N             | 0.9     | 0.7  | 0.3  | 0.4  | 0.5  | 0.4  | 0.6  | 0.7  | 1.2  | 1.9                 | 2.7  | 2.2   | 2.2   | 2.3   | 2.2   |
| Cellulose fiber length                                                                | μm                | 10      | 10   | 10   | 10   | 10   | 10   | 11   | 11   | 11   | 10                  | 11   | 11    | 11    | 11    | 11    |
| Cellulose fiber width                                                                 | μm                | 10      | 10   | 10   | 10   | 10   | 10   | 10   | 10   | 11   | 10                  | 10   | 10    | 10    | 10    | 10    |
| Aspect ratio<br>(average fiber length/average fiber width)                            |                   | 1.0     | 1.0  | 1.0  | 1.0  | 1.0  | 1.0  | 1.1  | 1.1  | 1.0  | 1.0                 | 1.1  | 1.1   | 1.1   | 1.1   | 1.1   |
| Apparent tapped density of powder particles                                           | g/cm <sup>3</sup> | 0.60    | 0.45 | 0.40 | 0.50 | 2.00 | 4.20 | 0.80 | 0.35 | 4.60 | 0.48                | 0.35 | 0.48  | 0.80  | 2.00  | 0.50  |
| Apparent density of powder particles (without tapping)                                | g/cm <sup>3</sup> | 0.50    | 0.40 | 0.34 | 0.45 | 1.60 | 3.80 | 0.65 | 0.32 | 4.20 | 0.34                | 0.22 | 0.34  | 0.50  | 1.40  | 0.37  |
| Compression degree                                                                    |                   | 1.20    | 1.13 | 1.18 | 1.11 | 1.25 | 1.11 | 1.23 | 1.09 | 1.10 | 1.41                | 1.59 | 1.41  | 1.60  | 1.43  | 1.35  |
| Evaluation of mouthfeel of tablet (powder) (1-4)                                      |                   | 4       | 4    | 4    | 4    | 3    | 4    | 3    | 3    | 3    | 2                   | 2    | 2     | 2     | 2     | 2     |

[0193]

Table 3 shows the percentage value  $((W_d/W_{100}) \times 100 (\%))$  of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 200°C, 300°C, 400°C, 500°C, or 600°C ( $W_d$  (wherein  $d = 200, 300, 400, 500$ , or  $600$ )) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C ( $W_{100}$ ).

[0194]

For example, the percentage value  $((W_{600}/W_{100}) \times 100 (\%))$  of the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 600°C ( $W_{600}$ ) relative to the weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 100°C ( $W_{100}$ ) was 14 to 42 in Examples.

[Table 3]

|                                                             | Example |      |      |      |      |      |      |      |      | Comparative Example |      |      |      |      |      |
|-------------------------------------------------------------|---------|------|------|------|------|------|------|------|------|---------------------|------|------|------|------|------|
| Percentage value( $\times 100(\%)$ )                        | 1       | 2    | 3    | 4    | 5    | 6    | 7    | 8    | 9    | 1                   | 2    | 3    | 4    | 5    | 6    |
| 200°C Weight retention rate/<br>100°C Weight retention rate | 95.5    | 96.3 | 96.2 | 88.1 | 96.8 | 96.6 | 96.8 | 96.8 | 96.8 | 99.9                | 99.8 | 99.8 | 99.8 | 99.9 | 99.9 |
| 300°C Weight retention rate/<br>100°C Weight retention rate | 72.2    | 76.4 | 75.3 | 67.3 | 92.6 | 80.8 | 92.6 | 77.5 | 76.2 | 95.4                | 93.8 | 95.5 | 93.9 | 95.4 | 93.8 |
| 400°C Weight retention rate/<br>100°C Weight retention rate | 33.6    | 30.7 | 29.9 | 38.3 | 16.8 | 28.7 | 16.8 | 69.0 | 69.0 | 9.6                 | 14.1 | 18.6 | 24.6 | 26.9 | 33.9 |
| 500°C Weight retention rate/<br>100°C Weight retention rate | 25.0    | 23.1 | 22.6 | 31.9 | 15.8 | 22.5 | 15.8 | 32.7 | 43.2 | 7.9                 | 11.7 | 16.5 | 22.5 | 24.8 | 31.8 |
| 600°C Weight retention rate/<br>100°C Weight retention rate | 23.4    | 21.6 | 21.1 | 29.7 | 14.7 | 21.1 | 13.7 | 30.5 | 42.1 | 7.2                 | 10.5 | 14.4 | 20.8 | 23.1 | 29.8 |

[0195]

(Evaluation of Electromotive Force)

As shown in Table 2, the electromotive force obtained upon heating from 25°C to 100°C was -6  $\mu$ V to -2  $\mu$ V in all the compositions of Examples and Comparative Examples. In Examples, the electromotive force was -6  $\mu$ V to -4  $\mu$ V. In particular, in Examples in which 20% of high-purity cellulose powder was mixed, the electromotive force was -5  $\mu$ V to -4  $\mu$ V. In contrast, in Comparative Examples, the electromotive force was -2  $\mu$ V to -1  $\mu$ V.

[0196]

The electromotive force obtained upon heating from 25°C to 200°C was -6  $\mu$ V to -2  $\mu$ V in all the compositions of Examples and Comparative Examples. In Examples, the electromotive force was -6  $\mu$ V to -2  $\mu$ V. In particular, in Examples in which 20% of high-purity cellulose powder was mixed, the electromotive force was -6  $\mu$ V to -4  $\mu$ V. In contrast, in Comparative Examples, the electromotive force was -3  $\mu$ V to -2  $\mu$ V.

[0197]

The electromotive force obtained upon heating from 25°C to 300°C was -8  $\mu$ V to +3  $\mu$ V in all the compositions of Examples and Comparative Examples. In Examples, the electromotive force was -2  $\mu$ V to +3  $\mu$ V. In particular, in Examples in which 20% of high-purity cellulose powder was mixed, the electromotive force was -6  $\mu$ V to -2  $\mu$ V. In contrast, in Comparative Examples, the electromotive force was -8  $\mu$ V to -5  $\mu$ V.

[0198]

The electromotive force obtained upon heating from 25°C to 400°C was -9  $\mu$ V to +8  $\mu$ V in all the compositions of Examples and Comparative Examples. In Examples, the electromotive force was -2  $\mu$ V to +8  $\mu$ V. In particular, in Examples in which 20% of high-purity cellulose powder was mixed, the electromotive force

was -2  $\mu\text{V}$  to -1  $\mu\text{V}$ . In contrast, in Comparative Examples, the electromotive force was -9  $\mu\text{V}$  to -7  $\mu\text{V}$ .

[0199]

The electromotive force obtained upon heating from 25°C to 500°C was -8  $\mu\text{V}$  to +14  $\mu\text{V}$  in all the compositions of Examples and Comparative Examples. In Examples, the electromotive force was -2  $\mu\text{V}$  to +14  $\mu\text{V}$ . In particular, in Examples in which 20% of high-purity cellulose powder was mixed, the electromotive force was -2  $\mu\text{V}$  to +1  $\mu\text{V}$ . In contrast, in Comparative Examples, the electromotive force was -8  $\mu\text{V}$  to -4  $\mu\text{V}$ .

[0200]

The electromotive force obtained upon heating from 25°C to 600°C was -6  $\mu\text{V}$  to +17  $\mu\text{V}$  in all the compositions of Examples and Comparative Examples. In Examples, the electromotive force was -3  $\mu\text{V}$  to +17  $\mu\text{V}$ . In particular, in Examples in which 20% of high-purity cellulose powder was mixed, the electromotive force was +1  $\mu\text{V}$  to +5  $\mu\text{V}$ . In contrast, in Comparative Examples, the electromotive force was -6  $\mu\text{V}$  to +2  $\mu\text{V}$ .

[0201]

Table 4 shows the percentage value  $((X_d/X_{100}) \times 100 (\%))$  of the electromotive force obtained upon heating from 25°C to 200°C, 300°C, 400°C, 500°C, or 600°C ( $X_d$  (wherein  $d = 200, 300, 400, 500, \text{ or } 600$ )) relative to the electromotive force obtained upon heating from 25°C to 100°C ( $X_{100}$ ).

[0202]

For example, the percentage value  $((X_{600}/X_{100}) \times 100 (\%))$  of the electromotive force obtained upon heating from 25°C to 600°C ( $X_{600}$ ) relative to the electromotive force obtained upon heating from 25°C to 100°C ( $X_{100}$ ) was -284 to 62 in Examples.

[Table 4]

|                                                         | Example |       |        |        |        |       |        |      |      | Comparative Example |       |       |       |       |       |
|---------------------------------------------------------|---------|-------|--------|--------|--------|-------|--------|------|------|---------------------|-------|-------|-------|-------|-------|
| Percentage value( $\times 100(\%)$ )                    | 1       | 2     | 3      | 4      | 5      | 6     | 7      | 8    | 9    | 1                   | 2     | 3     | 4     | 5     | 6     |
| 200°C Electromotive force/<br>100°C Electromotive force | 94.2    | 87.3  | 121.2  | 35.1   | 75.9   | 165.8 | 75.9   | 94.2 | 87.3 | 120.7               | 115.4 | 121.1 | 113.0 | 123.5 | 117.4 |
| 300°C Electromotive force/<br>100°C Electromotive force | 51.2    | 48.7  | 109.7  | -49.9  | -18.0  | 172.0 | -0.4   | 51.2 | 48.7 | 449.3               | 220.3 | 410.5 | 221.7 | 458.8 | 226.1 |
| 400°C Electromotive force/<br>100°C Electromotive force | 1.9     | 36.1  | 26.5   | -129.5 | -0.4   | 61.3  | -15.2  | 1.9  | 36.1 | 408.5               | 360.7 | 373.7 | 369.6 | 417.6 | 373.9 |
| 500°C Electromotive force/<br>100°C Electromotive force | 19.3    | 40.3  | -16.2  | -238.3 | -15.2  | 3.7   | -108.3 | 19.3 | 40.3 | 433.2               | 201.7 | 384.2 | 208.7 | 441.2 | 208.7 |
| 600°C Electromotive force/<br>100°C Electromotive force | -19.2   | -28.3 | -103.9 | -284.2 | -108.3 | -57.7 | -205.3 | 20.0 | 62.0 | 264.9               | 251.4 | -89.5 | 32.9  | 120.2 | 130.4 |

[0203]

(Disintegratability in Water)

Table 2 shows the values of the disintegratability in water of the compositions of Examples and Comparative Examples.

The disintegratability in water was less than 1.9 (min/N) in Examples.

The disintegratability in water of the tablets of the compositions of Examples was less than 1.9 (min/N), and therefore favorable oral disintegratability was exhibited, and thus, the smooth passage of the composition during swallowing was easily realized, namely, the tablets were easy to swallow.

[0204]

(Frictional Force in Wet-Powder State)

Table 2 shows the values of the frictional force in the wet-powder state of the compositions of Examples and Comparative Examples.

The frictional force in the wet-powder state was less than 65 (gf) in Examples.

The frictional force in the wet-powder state of the compositions of Examples was less than 65 (gf), and therefore a favorable mouthfeel of the disintegrated paste or the paste of the powder composition was exhibited.

[0205]

(Measurement of Average Values of Major and Minor Axis Lengths of Powder Particles)

Table 2 shows the major and minor axis lengths of the powder particles (fibers) of the compositions of Examples and Comparative Examples.

In Examples, the major axis length of the powder particles (fibers) was 10 to 11  $\mu\text{m}$ , and the minor axis length was 10 to 11  $\mu\text{m}$ . Owing to these major and minor axis lengths, appropriate adhesiveness is easily exhibited in preparing the composition of the present disclosure into a tablet form, and/or, the prepared tablet

tends to exhibit favorable disintegratability in water and/or a favorable frictional force in the wet-powder state.

[0206]

(Aspect Ratio of Powder Particles)

Table 2 shows the aspect ratio (average fiber length/average fiber width) of the powder particles in the compositions of Examples and Comparative Examples.

The aspect ratio was 1.0 to 1.1 in Examples. Since the powder particles contained in the composition have such an aspect ratio, the composition of the present disclosure tends to exhibit favorable disintegratability in water, and a favorable frictional force in the wet-powder state. Among compositions containing the same number of powder particles, the volume of the composition tends to be smaller as the aspect ratio is closer to 1.0. This makes it easier to reduce the risk of clogging within equipment during processes for processing or producing products such as a medicament, a food product, a cosmetic, and the like using the composition. Each of these effects is presumed to result from the fact that an aspect ratio closer to 1.0 tends to reduce friction between the fibers of the powder particles.

[0207]

(Apparent Tapped Density)

Table 2 shows the apparent tapped density of the compositions of Examples and Comparative Examples.

The apparent tapped density was 0.35 g/cm<sup>3</sup> to 4.6 g/cm<sup>3</sup> in Examples. When the composition has such an apparent tapped density, the composition is easily filled into a composition bag or tablet molding machine, which easily improves the productivity.

[0208]

(Apparent Density (without tapping))

Table 2 shows the apparent density (without tapping) of the compositions of Examples and Comparative Examples.

The apparent density (without tapping) was  $0.32 \text{ g/cm}^3$  to less than  $4.2 \text{ g/cm}^3$  in Examples. When the composition has such an apparent density (without tapping), the composition is easily filled into a composition bag or tablet molding machine, which easily improves the productivity.

[0209]

(Water Absorption Rate of Powder Particles)

Table 2 shows the water absorption rate of the powder particles (water absorption rate of the powder) of the compositions of Examples and Comparative Examples.

The water absorption rate of the powder in the compositions was 75% or less in Examples.

When the water absorption rate of the powder particles in the composition is low, the powder particles are less likely to swell, and hence can be easily separated from one another, and consequently, a tablet containing the composition tends to exhibit favorable disintegratability in water. Since the water absorption rate of the powder particles in the composition of the present disclosure was 75% or less, the disintegratability in water of a tablet containing the composition containing the powder particles was favorable.

[0210]

(Compression Degree)

Table 2 shows the compression degree of the compositions of Examples and Comparative Examples.

The compression degree of the compositions of Examples was 1.09 to 1.25. When the composition has such a compression degree, the composition is less likely to be compressed when vibrated, and the shape of the bag containing the composition

is less likely to change. This facilitates easier stacking and transport of the bags containing the composition.

[0211]

(Mouthfeel Sensory Test)

Table 2 shows the results of the mouthfeel sensory test for the tables of the compositions of Examples and Comparative Examples.

The compositions of Examples had a mouthfeel sensory test score of 3 (3: slight powdery mouthfeel, but sufficiently moist to be nearly unnoticeable) or 4 (4: no powdery mouthfeel).

It was revealed that the compositions of Examples have a favorable mouthfeel.

[0212]

(Relationship of Properties of Composition with Disintegratability in Water and Frictional Force in Wet-Powder State)

From the results above, it was found that when a composition possesses the features of the compositions (1-1) to (1-6), (2-1) to (2-5), (3-1) to (3-6), (4-1) to (4-5), (5), and/or (6) of the present disclosure, it exhibits favorable disintegratability in water and a favorable frictional force in the wet-powder state.

Note that each weight retention rate serves as an indicator that comprehensively reflects, for example, [1] the degree of heat resistance of the heat-resistant substance, the semi-heat-resistant substance, and the non-heat-resistant substance, and [2] the contents of the heat-resistant substance, the semi-heat-resistant substance, and the non-heat-resistant substance in the composition. Regarding each weight retention rate, it was found that when the composition contained a sufficient amount of a high-density heat-resistant substance such as an inorganic substance (i.e., had a low fiber content), fiber aggregation was minimized, which tended to result in a smoother mouthfeel when tableted. Furthermore, such a composition

was excellent in disintegratability in water when tableted, because of the reduced fiber aggregation.

Furthermore, the electromotive force serves as an indicator of the degree of endothermic and exothermic behavior, and by adjusting the electromotive force to a specific ratio, that is, by balancing the crystalline and amorphous states of the composition, it was possible to reduce the rigid fibers characteristic of high-crystalline components, which led to a suppression of friction between the compositions, and hence a favorable mouthfeel could be easily exhibited when tableted. Additionally, by preventing an excessive increase in a high-crystalline component, rigid fibers could be further reduced, thereby contributing to the suppression of fiber aggregation and improving the disintegratability of the tablet in water.

It was revealed that the effects of a favorable mouthfeel and water disintegratability can be more effectively exerted by combining these properties.

#### Industrial Applicability

[0213]

Since the composition of the present embodiment exhibits favorable disintegratability in water and/or a favorable frictional force in the wet-powder state, it can be suitably used as a composition for a food product, a medicament, a cosmetic, and the like where such properties are desired, and thus is industrially applicable.

## Claims

### [Claim 1]

A composition comprising a heat-resistant substance, a semi-heat-resistant substance, and a non-heat-resistant substance,

wherein a weight retention rate as determined by thermogravimetric analysis upon heating from 25°C to 600°C is 11% or more,

an electromotive force obtained upon heating from 25°C to 600°C is -4  $\mu$ V or more,

a weight retention rate (y) determined by thermogravimetric analysis upon heating from 25°C to 600°C is represented by the following expression:

expression:  $y \geq -2.03x + 23.623$ ,

wherein x represents the electromotive force obtained upon heating from 25°C to 600°C, and

an apparent tapped density is 0.3 g/cm<sup>3</sup> to 5 g/cm<sup>3</sup>.

### [Claim 2]

The composition according to claim 1, for oral use.

### [Claim 3]

The composition according to claim 1 or 2, wherein the composition is a food composition.

### [Claim 4]

The composition according to claim 1 or 2, wherein the composition is a pharmaceutical composition.

### [Claim 5]

A functional food comprising the composition according to claim 3.

### [Claim 6]

A medicament comprising the composition according to claim 4.

[Claim 7]

The functional food according to claim 5 in the form of a tablet.

[Claim 8]

The medicament according to claim 6 in the form of a tablet.