



**Safety Data Sheet**  
**Product: Belotero Balance®**

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**01 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

**1.1. Product identifier**

**Trade name** Belotero Balance®

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

Dermal filler

**1.3. Details of the supplier of the safety data sheet**

Anteis SA  
Chemin des Aulx 18  
1228 Plan-les-Ouates  
(GE) Switzerland  
Telephone: +41 22 308 9310

Merz Pharmaceuticals GmbH  
Eckenheimer Landstrasse 100  
D-60318 Frankfurt am Main  
Telephone: ++49 (0) 69 1503-0  
Contact: Klinische Forschung und Entwicklung ZNS

Merz North America, Inc.  
6501 Six Forks Road  
Raleigh, NC 27615

☎ Phone 844-469-6379

**1.4. Emergency telephone number** Hazmat Service Emergency Number: 800-373-7542

International Shipments: +1-484-951-2432

**02 HAZARDS IDENTIFICATION**

**2.1. Classification of the substance or mixture**

This product is not classified as hazardous according to GHS.

**2.2. Label elements**

**Labeling according to GHS** Warning labels not required.

**2.3. Other hazards**

**Carcinogenicity** NTP: No IARC: No OSHA: No

**OSHA Classification** This product is not considered to be hazardous per the Occupational Safety & Health Administration's (OSHA's) Hazard Communication Standard 29CFR1910.1200

**GHS Hazard Classification** This product does not require classification and labeling according to GHS.



## Safety Data Sheet

Product: Belotero Balance®

### 03 COMPOSITION / INFORMATION ON INGREDIENTS

#### 3.1. Substances

This product is not classified as hazardous according to GHS.

See also: Section 2 Hazards Identification

#### Chemical characterization

Mixture: Aqueous preparation of the following substance with non-hazardous additives.

Component	CAS #	% by wt.
Sodium hyaluronate	9067-32-7	2 - 3%

### 04 FIRST AID MEASURES

#### 4.1. Description of first aid measures

##### General information

Seek medical assistance if discomfort occurs.

##### After inhalation

Not likely to occur since the product is a cream. Get immediate medical attention if any breathing difficulties do occur.

##### After contact with skin

Wash immediately with plenty of warm soapy water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

##### After contact with eyes

Wash eyes immediately with large amounts of water for several minutes, especially under the eyelids. Consult an eye specialist if irritation occurs.

##### After ingestion

Rinse mouth with water and get immediate medical attention or call Poison Control Center immediately. Never give anything by mouth to an unconscious person.

#### 4.2. Most important symptoms and effects, both acute and delayed

No information is available

#### 4.3. Indication of any immediate medical attention needed

Show this SDS to the treating physician

### 05 FIRE AND EXPLOSION DATA

#### 5.1. Suitable extinguishing media

Any extinguishing means and measures are acceptable. Alcohol resistant foam, carbon dioxide, dry chemical.

#### 5.2. Special hazards arising from the substance or mixture

None known.

#### 5.3. Advice for firefighters

Contain fire run-off to protect the environment. Keep fire exposed containers cool by spraying with water.

#### Further advice

Use self-contained breathing apparatus and full protective clothing to prevent contact with skin and eyes.



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## 06 ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Clear area. Wear suitable protective clothing and equipment.

### 6.2. Environmental precautions

Do not release into drains or surface waters.

### 6.3. Methods and material for containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder). After taking up the material dispose according to regulation.

### 6.4. Reference to other sections

Refer to protective measures under Sections 7 and 8.

## 07 HANDLING AND STORAGE

### 7.1. Precautions for safe handling

#### Advise on safe handling

Avoid contact with eyes. Do not ingest. Wash thoroughly after handling.

#### Advise on protection against fire and explosion

No special fire protection measures are necessary.

### 7.2. Conditions for safe storage including any incompatibilities

#### Requirements for storage areas and containers

Keep container closed when not in use.

#### Further information on storage conditions

Keep only in original container and away from food, drink and animal feeding stuffs.

### 7.3. Specific end use(s)

For medical use only.

## 08 EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure limit values

### 8.2. Exposure controls

#### General protective measures

Provide appropriate exhaust ventilation at places where over-exposure can occur.

#### Respiratory protection

None necessary if handled as prescribed.

#### Hand protection

Protective gloves recommended.

#### Eye protection

Safety glasses or splash goggles recommended if risk of eye contact.

#### Body protection

Observe the usual guidelines for cleanliness and proper hygiene. Wash thoroughly after handling. Immediately remove soiled and contaminated clothing. Wash before re-use. Do not eat or drink when handling.



## Safety Data Sheet

Product: Belotero Balance®

### 09 PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1. Information on basic physical and chemical properties

Physical state	Viscoelastic gel
Color	Transparent
Odor	odorless
(Odor) Threshold	Not applicable
pH-value (at 20°C)	6.8 - 7.4
Flash point	Not applicable
Melting point	Not determined
Freezing point	Not determined
Boiling point	Not applicable
Evaporation rate	Not determined
Flammability	Not applicable
Lower explosion limit	Not applicable
Upper explosion limit	Not applicable
Vapor pressure	Not determined
Ignition temperature	Not available
Solubility in water (20°C)	Miscible
Partition coefficient	Not determined
Decomposition temperature	Not determined
Density (20°C)	~1 gm/cm <sup>3</sup>
Viscosity	Not determined

#### 9.2. Other information

Solids content	Not determined
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### 10 STABILITY AND REACTIVITY

10.1. Reactivity	Product is stable and no hazardous reactions are expected.
10.2. Chemical stability	Stable at room temperature
10.3. Possibility of hazardous reactions	Product is stable and no hazardous reactions are expected.
10.4. Conditions to avoid	None known.
10.5. Incompatible materials	None known.
10.6. Hazardous decomposition products	No decomposition if stored and applied as directed. Carbon monoxide and carbon dioxide under fire conditions.



## Safety Data Sheet

Product: Belotero Balance®

### 11 TOXICOLOGICAL INFORMATION

#### 11.1. Information on toxicological effects

Acute toxicity	This product is intended for medical use only.
Irritant effect	No evidence of irritation.
Sensitization	No data available.
Specific target organ toxicity (STOT) - single exposure	No data available.
Specific target organ toxicity (STOT) - repeated exposure	Based on the available data, the hazard criteria are not met.
Aspiration hazard	Based on the available data, the hazard criteria are not met.
General remarks	No harmful health effects are known or expected when handled as directed. If irritation or harmful effects occur, immediately discontinue use and consult a doctor.

### 12 ECOLOGICAL INFORMATION

12.1. Toxicity	No information available.
12.2. Persistence and degradability	Biodegradable.
12.3. Bioaccumulative potential	No information available.
12.4. Mobility in soil	Not determined
12.5. Results of PBT and vPvB assessment	Not determined
12.6. Other adverse effects	No information available
Additional remarks	Not available.

### 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	<p>This material and its products must be disposed of in accordance with existing disposal practices employed for infectious waste at your site.</p> <p>Discard the syringe and remaining product after use as infectious waste. Do not re-sterilize and do not reuse.</p> <p>Dispose in accordance with federal, state or local regulations.</p>
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### 14 TRANSPORT INFORMATION

DOT	Not regulated
IATA	Not regulated
IMDG	Not regulated



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Product: Belotero Balance®

### 15 REGULATORY INFORMATION

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### Other regulations

##### TSCA inventory

All ingredients are listed on the TSCA inventory or exempt.

##### DSL inventory

All components are listed on the DSL.

##### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

##### SARA 311/312 Hazards

No known SARA hazards

##### SARA Title III

To the best of our knowledge this product contains no toxic chemicals subject to the supplier notification requirements of Section 313 of the Superfund Amendments and Reauthorization Act (SARA/EPCRA) and the requirements of 40 CFR Part 372.

##### California Proposition 65

Not listed for this form

##### Massachusetts, New Jersey and Pennsylvania RTK

None

##### Canada WHMIS

Not regulated

### 16 OTHER INFORMATION

##### HAZCOM

No GHS label required.

##### Revised On:

03 JUN 2016

To the best of our knowledge, the information contained in this SDS is accurate. It is intended to assist the user in his evaluation of the product's hazards, and safety precautions to be taken in its use. The data on this SDS relate only to the specific material designated herein. We do not assume any liability for the use of, or reliance on this information, nor do we guarantee its accuracy or completeness.