SAFETY DATA SHEET

Belotero Balance Lidocaine

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Trade name: Belotero Balance Lidocaine

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

Relevant identified uses of the substance or mixture: Class III medical device

Uses advised against : None known.

1.3. Details of the supplier of the safety data sheet

Company and address:

Anteis SA
Chemin des Aulx 18
CH-1228 Plan-les-Ouates
Switzerland
+41223089380

E-mail: complaintsanteis@merz.com

Revision: 09/02/2026

SDS Version: 1.0

1.4. Emergency telephone number

Swiss Toxicological Information Centre (Tox Info Suisse): 145 (24h service)
Calling from abroad: +41 44 251 51 51 (24h service)
See also section 4 “First aid measures”.

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Not classified according to Regulation (EC) No. 1272/2008 (CLP).

2.2. Label elements

Hazard pictogram(s): Not applicable.

Signal word: Not applicable.

Hazard statement(s): Not applicable.

Precautionary statement(s):

General: Not applicable.

Prevention: Not applicable.

Response: Not applicable.

Storage:	Not applicable.
Disposal:	Not applicable.
Hazardous substances:	Does not contain any substances required to report
Additional labelling:	

2.3. Other hazards

Additional warnings:	This mixture/product does not contain any substances known to fulfil the criteria for PBT and vPvB classification. This product does not contain any substances considered to be endocrine disruptors in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2023/707.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable. This product is a mixture.

3.2. Mixtures

Does not contain any substances required to report

See full text of H-phrases in section 16. Occupational exposure limits are listed in section 8, if these are available.

Other information

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SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General information:	In the case of accident: Contact a doctor or casualty department – take the label or this safety data sheet. Contact a doctor if in doubt about the injured person's condition or if the symptoms persist. Never give an unconscious person water or other drink.
Inhalation:	Upon breathing difficulties or irritation of the respiratory tract: Bring the person into fresh air and stay with him/her.
Skin contact:	Remove contaminated clothing and shoes immediately. Ensure to wash exposed skin thoroughly with water and soap. Skin

	cleanser can be used. DO NOT use solvents or thinners.
Eye contact:	If in eyes: Flush eyes with water or saline water (20-30 °C) for at least 5 minutes. Remove contact lenses. Seek medical assistance and continue flushing during transport.
Ingestion:	If the person is conscious, rinse the mouth with water and stay with the person. Never give the person anything to drink. In case of malaise, seek medical advice immediately and bring the safety data sheet or label from the product. Do not induce vomiting, unless recommended by the doctor. Have the person lean forward with head down to avoid inhalation of or choking on vomited material.
Burns:	Not applicable.

4.2. Most important symptoms and effects, both acute and delayed
None known.

4.3. Indication of any immediate medical attention and special treatment needed
Treat symptomatically.

Information to medics
Bring this safety data sheet or the label from this product.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media
Suitable extinguishing media: Alcohol-resistant foam, carbon dioxide, powder, water mist.
Unsuitable extinguishing media: Waterjets should not be used, since they can spread the fire.

5.2. Special hazards arising from the substance or mixture
Fire will result in dense smoke. Exposure to combustion products may harm your health. Closed containers, which are exposed to fire, should be cooled with water. Do not allow fire-extinguishing water to enter the sewage system and nearby surface waters.

5.3. Advice for firefighters
No specific requirements.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures
Contaminated areas may be slippery.

6.2. Environmental precautions
Avoid discharge to lakes, streams, sewers, etc.
Keep unauthorized persons away from the spill

6.3. Methods and material for containment and cleaning up

Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.
Wherever possible cleaning should be performed with normal cleaning agents. Avoid use of solvents.

6.4. Reference to other sections

See section 13 “Disposal considerations” on handling of waste.
See section 8 "Exposure controls/personal protection" for protective measures.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Smoking, drinking and consumption of food is not allowed in the work area.
See section 8 "Exposure controls/personal protection" for information on personal protection.

7.2. Conditions for safe storage, including any incompatibilities

Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

Recommended storage material:	Keep only in original packaging.
Storage conditions:	Dry, cool and well ventilated Protect from moisture. Protect from sunlight. Room temperature >25°C
Incompatible materials:	Keep only in original packaging.

7.3. Specific end use(s)

This product should only be used for applications quoted in section 1.2.
Injectable biodegradable implant intended for filling of perioral fine lines. Aesthetics purposes.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No substances are listed in the Swiss list of substances with an occupational exposure limit.

DNEL

No data available.

PNEC

No data available.

8.2. Exposure controls

Apply general control to prevent unnecessary exposure

General recommendations:	Smoking, drinking and consumption of food is not allowed in the work area.
Exposure scenarios:	There are no exposure scenarios implemented for this product.

Exposure limits:	Occupational exposure limits have not been defined for the substances in this product.
Appropriate technical measures:	Apply standard precautions during use of the product. Avoid inhalation of vapours.
Hygiene measures:	In between use of the product and at the end of the working day all exposed areas of the body must be washed thoroughly. Pay special attention to hands, forearms and face.
Measures to avoid environmental exposure:	No specific requirements.

Individual protection measures, such as personal protective equipment

Generally: Use only CE marked protective equipment.

Respiratory Equipment:

Type	Class	Colour	Standards	
No special when used as intended.				

Skin protection:

Recommended	Type/Category	Standards	
No special when used as intended.	-	-	

Hand protection:

Material	Glove thickness (mm)	Breakthrough time (min.)	Standards	
No special when used as intended	-	-	-	

Eye protection:

Type	Standards	
No special when used as intended.	-	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state:	Gel
Colour:	Transparent
Odour / Odour threshold:	None
pH:	6.8-7.6
Density (g/cm^3):	No data available.
Kinematic viscosity:	No data available.
Particle characteristics:	Does not apply to liquids.

Phase changes

Melting point/Freezing point (°C):	No data available.
Softening point/range (°C):	Does not apply to liquids.
Boiling point (°C):	No data available.
Vapour pressure:	No data available.
Relative vapour density:	No data available.
Decomposition temperature (°C):	No data available.

Data on fire and explosion hazards

Flash point (°C):	No data available.
Flammability (°C):	No data available.
Auto-ignition temperature (°C):	No data available.
Lower and upper explosion limit (% v/v):	No data available.

Solubility

Solubility in water:	Completely soluble
n-octanol/water coefficient (LogKow):	No data available.
Solubility in fat (g/L):	No data available.

9.2. Other information

Other physical and chemical parameters:	No data available.
Oxidizing properties:	No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity
No data available.

10.2. Chemical stability
The product is stable under the conditions, noted in section 7 “Handling and storage”.

10.3. Possibility of hazardous reactions
None known.

10.4. Conditions to avoid
Extremes of temperature

10.5. Incompatible materials
Keep only in original packaging.

10.6. Hazardous decomposition products
Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

Skin corrosion/irritation
Based on available data, the classification criteria are not met.

Serious eye damage/irritation
Based on available data, the classification criteria are not met.

Respiratory sensitisation
Based on available data, the classification criteria are not met.

Skin sensitisation
Based on available data, the classification criteria are not met.

Germ cell mutagenicity
Based on available data, the classification criteria are not met.

Carcinogenicity
Based on available data, the classification criteria are not met.

Reproductive toxicity
Based on available data, the classification criteria are not met.

STOT-single exposure
Based on available data, the classification criteria are not met.

STOT-repeated exposure
Based on available data, the classification criteria are not met.

Aspiration hazard
Based on available data, the classification criteria are not met.

Symptoms related to the physical, chemical and toxicological characteristics
None known.

11.2. Information on other hazards

Endocrine disrupting properties
This mixture/product does not contain any substances known to have hormone-disrupting properties in relation to health.

Other information
None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity
Based on available data, the classification criteria are not met.

12.2. Persistence and degradability
Based on available data, the classification criteria are not met.

12.3. Bioaccumulative potential
Based on available data, the classification criteria are not met.

12.4. Mobility in soil
No data available.

12.5. Results of PBT and vPvB assessment
This mixture/product does not contain any substances known to fulfil the criteria for PBT and vPvB classification.

12.6. Endocrine disrupting properties

This mixture/product does not contain any substances considered to have endocrine-disrupting properties in relation to the environment.

12.7. Other adverse effects

None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product is not covered by regulations on dangerous waste.
Commission Regulation (EU) No 1357/2014 of 18 December 2014 on waste.
Needle contained into the box. Disposal should be made in accordance with existing disposal practices employed for infectious waste at your institution.

EWC code: Not applicable.

Contaminated packing

Packaging containing residues of the product must be disposed of similarly to the product.

SECTION 14: TRANSPORT INFORMATION

	14.1 UN / ID	14.2 UN proper shipping name	14.3 Hazard class(es)	14.4 PG*	14.5 Env**	Other information:
ADR/ADN/ RID	-	-	-	-	-	-
IMDG	-	-	-	-	-	-
IATA	-	-	-	-	-	-

* Packing group
** Environmental hazards

Additional information

Not dangerous goods according to ADR/ADN/RID, IATA and IMDG.

14.6. Special precautions for user

Not applicable.

14.7. Maritime transport in bulk according to IMO instruments

No data available.

SECTION 15: REGULATORY INFORMATION

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

Restrictions for application: No special.

Demands for specific education: No specific requirements.

SEVESO - Categories / dangerous substances: Not applicable.

WGK classification: WGK class: WGK 2

Additional information:	Not applicable.
Sources:	SR 814.610 Ordinance on the movement of wastes of 22 June 2005 (Status as of 1 January 2020) SR 814.610.1 DETEC ordinance concerning lists for the movement of wastes of 18 October 2005 (Status as of 1 January 2018) SR 813.11 Ordinance on Protection against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO) of 5 June 2015 (Status as of 1 April 2020)

15.2. Chemical safety assessment

No

SECTION 16: OTHER INFORMATION

Abbreviations and acronyms

ADN = European Provisions concerning the International Carriage of Dangerous Goods by Inland Waterway
ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
CAS = Chemical Abstracts Service
CE = Conformité Européenne (European conformity)
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
CSA = Chemical Safety Assessment
CSR = Chemical Safety Report
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EINECS = European Inventory of Existing Commercial chemical Substances
ES = Exposure Scenario
EUH statement = CLP-specific Hazard statement
EuPCS = European Product Categorisation System
EWC = European Waste Catalogue
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
GWP = Global warming potential
IARC = International Agency for Research on Cancer (IARC)
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
OECD = Organisation for Economic Co-operation and Development
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail
RRN = REACH Registration Number

SCL = A specific concentration limit
SVHC = Substances of Very High Concern
STOT-RE = Specific Target Organ Toxicity - Repeated Exposure
STOT-SE = Specific Target Organ Toxicity - Single Exposure
TWA = Time weighted average
UN = United Nations
UVBC = Unknown or variable composition, complex reaction products or of biological materials
VOC = Volatile Organic Compound
vPvB = Very Persistent and Very Bioaccumulative

Additional information

Not applicable.

The safety data sheet is validated by

Alcane Conseils

Other

A change (in proportion to the last essential change (first cipher in SDS version, see section 1)) is marked with a triangle.
The information in this safety data sheet applies only to this specific product (mentioned in section 1) and is not necessarily correct for use with other chemicals/products.
It is recommended to hand over this safety data sheet to the actual user of the product.
Information in this safety data sheet cannot be used as a product specification.
Country-language: CH-en