

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



HLA-B27 Cobas Mix (EliGene® Spondylitis HLA-B27 C6, 90060-C6)

Version: SDSHLAB27CMix -12052023EN

Revision Date: 12.05.2023

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

1.1 Product identifier:

Commercial Product Name: HLA-B27 Cobas Mix (EliGene® Spondylitis HLA-B27 RT, 90060-RT)

REACH No.: This product is a mixture. REACH Registration Number see section 3.

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

Use of the Substance/Mixture: Laboratory chemicals not in a nanoform

1.3 Details of the supplier of the safety data sheet

Company: ELISABETH PHARMACON, spol. s r.o.
Rokycanova 4437/5, 615 00 Brno,
Czech Republic

Telephone: +420 542 213 851

E-mail: info@elisabeth.cz

1.4 Emergency telephone number

Centre for Detoxification Prague: +420 224 91 92 93/ +420 224 91 54 02

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Precautionary statements (P statements)

P280+P281 Wear protective gloves/protective clothing/eye protection/face protection.
Use personal protective equipment as required.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative, and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher or having endocrine disruptor properties.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixtures

Hazardous components

Remarks: Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General advice: Show this data sheet to the doctor in attendance.

If inhaled: Move to fresh air.
If symptoms persist, call a physician.

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In case of skin contact:	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. If symptoms persist, call a physician.
In case of eye contact:	Remove contact lenses. Protect unharmed eyes. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
If swallowed:	If accidentally swallowed obtain immediate medical attention. Rinse mouth with water. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: No information available.

SECTION 5: FIRE-FIGHTING MEASURES**5.1 Extinguishing media**

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Exposure to decomposition products may be a hazard to health.

Hazardous combustion products: No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters: Wear self-contained breathing apparatus for firefighting if necessary.

Further information: In the event of fire and/or explosion do not breathe fumes.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions: Use personal protective equipment.
Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

6.2 Environmental precautions**6.3 Methods and material for containment and cleaning up**

Methods for cleaning up: Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: HANDLING AND STORAGE**7.1 Precautions for safe handling**

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Advice on safe handling:	For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area.
Advice on protection against fire and explosion:	Normal measures for preventive fire protection.
Hygiene measures:	Keep away from food and drink. When using do not eat, drink or smoke.

7.2 Conditions for safe storage, including any incompatibilities

Other data:	No decomposition if stored and applied as directed.
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7.3 Specific end use(s)

Specific use(s):	Laboratory chemicals
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SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**8.1 Control parameters**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls*Personal protective equipment*

Eye protection:	Safety glasses
Hand protection Remarks:	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).
Skin and body protection:	Choose body protection according to the amount and concentration of the dangerous substance at the work place. Footwear protecting against chemicals

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties**

a) Physical state	Liquid
b) Color	No data available
c) Odor	No data available
d) Melting point/freezing point	No data available
e) Initial boiling point and boiling range	No data available
f) Flammability (solid, gas)	No data available
g) Upper/lower flammability or explosive limits	No data available
h) Flash point	No data available
i) Autoignition temperature	No data available
j) Decomposition temperature	No data available

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k) pH	No data available
l) Viscosity Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
m) Water solubility at 20 °C	soluble
n) Partition coefficient: n-octanol/water	No data available
o) Vapor pressure	No data available
p) Density	No data available
Relative density	No data available
q) Relative vapor density	No data available
r) Particle characteristics	No data available
s) Explosive properties	Not classified as explosive.
t) Oxidizing properties	none

9.2 Other safety information

No data available

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

Violent reactions are possible with:
The generally known reaction partners of water.

10.4 Conditions to avoid

no information available

10.5 Incompatible materials

Strong bases, Strong oxidizing agents

10.6 Hazardous decomposition products

In the event of fire: see section 5.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Mixture

Acute toxicity

Oral: No data available

Inhalation: No data available

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Dermal: No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data is available.

Germ cell mutagenicity

No data available

Carcinogenicity

No data available

Reproductive toxicity

No data available

11.2 Information on other hazards

Assessment: The substance/mixture does not contain components considered to have endocrine-disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

SECTION 12. ECOLOGICAL INFORMATION**12.1 Toxicity**

Toxicity to fish:	No data available
Toxicity to algae:	No data available
Toxicity to bacteria:	No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Bioaccumulation: No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB Assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative, and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine-disrupting properties

Assessment: The substance/mixture does not contain components considered to have endocrine-disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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12.7 Other adverse effects

Additional ecological information Remarks: No data available

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

14.1 UN number or ID number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packing group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute

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for Standardisation; DSL - Domestic Substances List (Canada); ECx – Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 – Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG – International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL – Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS – Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI – Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product regarding appropriate safety precautions. It does not represent any guarantee of the properties of the product. Elisabeth Pharmacon company shall not be held liable for any damage resulting from handling or from contact with the above product.