SAFETY DATA SHEET

according to the Hazardous Products Regulations

ORGANON

Denosumab Biosimilar Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	10/21/2025	310000001000	Date of first issue: 10/21/2025

SECTION 1. IDENTIFICATION

Product name : Denosumab Biosimilar Formulation
Other means of identification : Prescription Medicine

Manufacturer or supplier's details

Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33rd floor
Jersey City, New Jersey 07302

Telephone : +1 551-430-6000 US
Emergency telephone : For 24/7 emergency response advice, call CHEMTREC at +1 703-741-5970 (Regional). Global 24/7: +1-800-424-9300 (United States, English only).

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : To be dispensed by or on the prescription of physician.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Specific target organ toxicity - repeated exposure : Category 2 (Bone, Immune system)

GHS label elements

Hazard pictograms :

Signal Word : Warning

Hazard Statements : H373 May cause damage to organs (Bone, Immune system) through prolonged or repeated exposure.

Precautionary Statements :

Prevention:

P260 Do not breathe mist or vapors.

Response:

P314 Get medical advice/ attention if you feel unwell.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Denosumab	Denosumab	615258-40-7	>= 6 - 7

SECTION 4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.
Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Reference Section 11: Experience with human exposure.
May cause damage to organs through prolonged or repeated exposure.

Protection of first-aiders : No special precautions are necessary for first aid responders.

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Water

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use a water spray to cool fully closed containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Clean thoroughly. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	See current prescribing information. Store in original container. Refrigeration required (2 - 8°C). Do not freeze. Do not shake.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Denosumab	615258-40-7	TWA	8 µg/m3 (OEB 4)	Internal
		Wipe limit	80 µg/100 cm2	Internal

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
No personal respiratory protective equipment normally required.

Hand protection
Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

Hygiene measures : The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Color : Colorless to pale yellow

Odor : odorless

pH	:	5.2
Melting point/freezing point	:	Not applicable
Boiling point/boiling range	:	not determined
Flash point	:	Not applicable
Flammability (liquids)	:	Will not burn
Upper explosion limit / Upper flammability limit	:	Not applicable
Lower explosion limit / Lower flammability limit	:	Not applicable
Vapor pressure	:	not determined
Relative vapor density	:	not determined
Density	:	similar to water not determined
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	Not applicable
Viscosity		
Viscosity, dynamic	:	not determined

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Components:

Denosumab:

Acute oral toxicity	:	Remarks: No data available
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available
Acute toxicity (other routes of administration)	:	Remarks: No data available

Skin corrosion/irritation

Not classified due to lack of data.

Components:

Denosumab:

Assessment	:	Not classified
Remarks	:	No data available

Serious eye damage/eye irritation

Not classified due to lack of data.

Components:

Denosumab:

Assessment	:	Not classified
Remarks	:	No data available

Respiratory or skin sensitization

Skin sensitization

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

Components:

Denosumab:

Remarks	:	No data available

Germ cell mutagenicity

Not classified due to lack of data.

Components:

Denosumab:

Genotoxicity in vitro	:	Remarks: Not classified

Genotoxicity in vivo	:	Remarks: Not classified
Germ cell mutagenicity - Assessment	:	Weight of evidence does not support classification as a germ cell mutagen., Based on the size and properties of the material (monoclonal antibody), there is not potential to be a direct-acting mutagen.

Carcinogenicity

Not classified due to lack of data.

Components:

Denosumab:

Remarks	:	No data available
Carcinogenicity - Assessment	:	Not classified, Based on the size and properties of the material (monoclonal antibody), there is not potential to be a direct-acting carcinogen.

Reproductive toxicity

Not classified based on available information.

Components:

Denosumab:

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Monkey Application Route: Subcutaneous Frequency of Treatment: 1 daily Fertility: NOAEL: > 12.5 mg/kg body weight Result: No adverse effects. Remarks: Not classified
Effects on fetal development	:	Test Type: One-generation reproduction toxicity study Species: Monkey Application Route: Subcutaneous Frequency of Treatment: 1 days/week General Toxicity Maternal: NOAEL: > 12.5 mg/kg body weight Embryo-fetal toxicity.: 2.5 mg/kg body weight Result: Reduced fetal weight. Remarks: No significant adverse effects were reported

STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

May cause damage to organs (Bone, Immune system) through prolonged or repeated exposure.

Components:

Denosumab:

Target Organs	:	Bone, Immune system
Assessment	:	May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Denosumab:

Species	:	Monkey
NOAEL	:	50 mg/kg
Application Route	:	Subcutaneous
Exposure time	:	1 yr
Number of exposures	:	monthly
Target Organs	:	Bone, Immune system
Symptoms	:	viral infections, histopathological changes
Remarks	:	May cause damage to organs.

Aspiration toxicity

Not classified based on available information.

Components:

Denosumab:

Not applicable

Experience with human exposure

Product:

General Information	:	Symptoms: fatigue, nausea, diarrhea, Vomiting, constipation, anemia, back pain, Edema, headache, upper respiratory tract infection, joint pain, Difficulty in breathing

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Denosumab:

Ecotoxicology Assessment

Acute aquatic toxicity	:	No data available
Chronic aquatic toxicity	:	No data available

Persistence and degradability

Components:

Denosumab:

Biodegradability : Remarks: Expected to biodegrade.

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

TDG
Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:

AIIC : All ingredients listed or exempt.

CA. DSL : All ingredients listed or exempt.

CHINA	:	All ingredients listed or exempt.
EINECS	:	All ingredients listed or exempt.
TSCA	:	All ingredients listed or exempt.
ENCS	:	All ingredients listed or exempt.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardization; 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; ERG - Emergency Response Guide; 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 Organization 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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, Authorization and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

Revision Date	:	10/21/2025
Date format	:	mm/dd/yyyy

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