Safety Data Sheet according to §1910.1200 Appendix D

1. Identification	
Product identifier:	easy-graft CLASSIC
Other means of identification:	Granular bone graft substitute
Recommended use:	Dental bone graft substitute
Company:	Degradable Solutions AG Wagistrasse 23 8953 Schlieren Switzerland +41 43 433 62 00
Emergency phone number:	+41 44 251 51 51 Toxicological Information Centre Switzerland

2. Hazard(s) identification	
Granules:	Not hazardous
BioLinker:	H316 - Causes mild skin irritation. H320 - Causes eye irritation. H335 - May cause respiratory irritation. H360 - May cause harm to the unborn child.

3. Composition / information on ingredients		
Granules:	Approximately 90 % w/w β-tri-calcium phosphate (TCP), Approximately 10 % w/w poly(lactide-co-glycolide) (PLGA)	
BioLinker:	Contains max. 85 % w/w N-methyl-2-pyrrolidone (NMP)	
Molecular weight:	TCP:	310.18 g/mol
	PLGA:	n/a
	NMP:	99.13 g/mol
CAS-No.:	TCP:	7758-87-4
	PLGA:	26780-50-7
	NMP:	872-50-4
EC-No.:	TCP:	231-840-8
	PLGA:	n/a
	NMP:	212-828-1
Hill Formula:	TCP:	$Ca_3O_8P_2$
	PLGA:	n/a
	NMP:	C_5H_9NO

4. First-aid measures	
General advice:	Consult a physician. Show this safety data sheet to the doctor in attendance.
After inhalation:	Move to fresh air. If breathing becomes difficult, call a physician.
After skin contact:	Wash off with plenty of water. Consult a physician.
After eye contact:	Rinse thoroughly with plenty of water. Consult a physician.
After swallowing:	Rinse mouth with ware if person is conscious. Consult a physician.

5. Fire-fighting measures	
Suitable extinguishing media:	Water spray, carbon dioxide, dry chemical powder or appropriate foam. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards:	Emits toxics fumes under fire conditions.
Special protective equipment:	Wear self-contained breathing apparatus for firefighting if necessary.

6. Accidental release measures	
Personal precautions:	Wear respiratory protection. Avoid breathing vapours, mist, gas or dust. Ensure adequate ventilation.
Environmental precautions:	Do not let product enter drains.
Procedures for cleaning up:	Soak up with inert absorbent material or take up dry and dispose. Clean up affected area.

7. Handling and storage	
Handling:	Avoid inhalation. Avoid contact with eyes, skin and clothing.
Storage:	Store in cool place. Keep tightly closed and dry. Avoid direct sunlight.

8. Exposure controls / personal protection
Wear gloves and protective goggles when working with BioLinker.

9. Physical and chemical properties		
Appearance:	Granules:	Solid / round to roundish
	BioLinker:	Liquid
Odor:	Granules:	n/a
	BioLinker:	Slight amine odor
Odor threshold:	n/a	
pH:	n/a	
Melting point / freezing point:	Granules:	n/a
	BioLinker:	-24°C
Initial boiling point and boiling ramp:	Granules:	n/a
	BioLinker:	202°C (1.013 hPa), 78-79°C (16 hPa)
Flash point:	n/a	
Evaporation rate:	Granules:	n/a
	BioLinker:	0.06
Flammability:	n/a	
Upper / lower flammability or explosive limit:	n/a	
Vapor density:	Granules:	n/a
	BioLinker:	3.4 (air = 1.0)
Relative density:	n/a	
Solubility:	Granules:	n/a
	BioLinker:	Miscible in water
Partition coefficient:	n/a	
Auto-ignition temperature:	n/a	
Decomposition temperature:	n/a	
Viscosity:	n/a	

10. Stability and reactivity		
Reactivity:	n/a	
Chemical stability:	Granules:	Stable, degradation of PLGA
	BioLinker:	NMP evaporates
Hazardous reactions:	n/a	
Conditions to avoid:	Sensitive to moisture. Stable under recommended storage conditions.	
Incompatible materials:	Strong acids, strong oxidizing agents.	
Hazardous decompositions products:	Under fire conditions: Carbon oxides, nitrogen oxides (NOx), phosphorous oxides, phosphine oxides.	

11. Toxicological information		
Acute toxicity:	Quantitative data on the acute toxicity of this product are not available.	
Sensitization:	No data available.	
Chronic exposure:	No data available.	
Signs and symptoms of exposure:	Prolonged or repeated exposure can cause: gastrointestinal disturbances, nausea, vomiting and headache. No physical effects are to be expected with intended use.	
Potential health effects:	Inhalation:	May be harmful if inhaled. May cause respiratory tract information.
	Skin:	May be harmful if absorbed through skin. May cause skin irritation.
	Eyes:	May cause eye irritation.
	Ingestion:	May be harmful if swallowed.

12. Ecological information	
Ecotoxic effects:	Quantitative data on the ecotoxical effects of this product are not available.
Toxicity to fish:	NMP: LC50 – other fish - 4.000 mg/l – 96 h NMP: LC50 – Leuciscus idus (Golden orfe) - 500 mg/l – 96 h
Toxicity to daphnia and other aquatic invertebrates:	NMP: EC50 – Daphnia magna (Water flea) - 1.000 mg/l – 24 h
Toxicity to bacteria:	NMP: LC50 – Bacteria - 9.000 mg/l
Elimination information:	NMP: Readily biodegradable
General:	No ecological problems are to be expected when the product is handled and used with due care and attention. Avoid contamination of drains, waters, and soil.

13. Disposal considerations	
Product:	There are no uniform regulations for the disposal of chemicals and waste material. Observe all federal, state, and local environmental regulations.
Contaminated packaging:	Dispose of as unused product.

14. Transport information	
General:	Not dangerous goods for road, sea, and air transport (ADR/RID, IMDG, IATA)

15. Regulatory information
Medical devices are exempt – [¨see 29 CFR 1910.1200(c)]. Specifically, medical devices are considered to be “articles” as defined by the HCS, therefore not requiring an SDS.

16. Other information	
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 contained herein is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Degradable Solutions AG shall not be held liable for any damage resulting from handling or from contact with the above product.
Preparation date:	19.02.2016
Version:	01