

Safety Data Sheet

According to Regulation (EC) No 1907/2006 (REACH)

Trade name:

Product No:

Version: 2.1/EN

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Revision Date: 4-14-2015

Section 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier:

1.1.1 Substance

Substance name: Poly(lactide-co-glycolide)-cholesterol (Mn 35,000-45,000 Da, 50:50

L:G)

Catalog Number: AP097

CAS No.: N/A

Index No: N/A

EC No: N/A

REACH Registration No: N/A

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

1.2.1 Relevant identified uses

Research and Development

1.2.2 Uses advised against:

Not for clinical usage. Not for food, drug, or household usage.

1.3 Details of the supplier of the safety data sheet:

Supplier:

Akina, Inc.

3495 Kent Avenue

West Lafayette, IN 47906

Technical Contact: John Garner

Email: jg@akinainc.com

1.4 Emergency Telephone Number:

Phone: 765-464-0501x304

Section 2: Hazards Identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]	SCL and/or M-factor	Classification procedure
None	N/A	Not established

Classification according to 67/548/EEC or 1999/45/EC	SCL and/or M-factor	Classification procedure
None	N/A	Not established

2.1.1 Additional information

Toxicological properties are not known.

2.2 Label elements

2.2.1 Labelling according to Regulation (EC) No 1272/2008 [CLP/GHS]

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Product identifier:

Substances: Poly(lactide-co-glycolide)-cholesterol (Mn 35,000-45,000 Da, 50:50 L:G)

Hazard components for labeling:

None

Hazard pictograms

None

Hazard Statements:

None

Precationary Statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P330 IF SWALLOWED: Rinse mouth.

P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

2.3 Other Hazards

None

Section 3. Composition/information on ingredients

3.1 Substances

Substance name: Poly(lactide-co-glycolide)-cholesterol (Mn 35,000-45,000 Da, 50:50 L:G)

Catalog Number: AP097

CAS No.: N/A

Index No: N/A

EC No: N/A

REACH Registration No: N/A

Purity: $\geq 90\%$

Synonyms: None

Stabilizers: None

Hazard impurities: None

Material is not a mixture

Section 4.: First aid Measures

4.1 Description of first aid measures

4.1.1 General Informations:

Substance is non-toxic solid however not all toxicological properties have been ascertained. For this reason, prudent care should be taken in the event of exposure.

4.1.1 Following inhalation:

If breathing is difficult, contact emergency personnel.

4.1.2 Following eye contact

Flush eyes with flowing water for at least 15 minutes.

4.1.3 Following skin contact:

Wash skin with deluge of water for at least 15 minutes.

4.1.4 Following ingestion:

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If swallowed, do not induce vomiting. Do not give anything to drink. Obtain medical attention without delay. If swallowed, wash out mouth with water if person is conscious. Remove to fresh air.

4.1.6 Self-protection of the first aider:

First aider should wear protective gloves/protective clothing/eye protection/face protection as appropriate for the situation.

4.2 Most important symptoms and effects, both acute and delayed
Not identified

4.3 Indication of any immediate medical attention and special treatment needed

None specified. Treatment should be supportive and symptomatic.

Section 5. Firefighting measures

5.1 Extinguishing media:

All types of extinguishing media are suitable

5.2 Special hazards arising from the substance

Hazardous combustion products: oxides of carbon

5.3 Advice for fire fighters

None

5.4 Additional information:

Flash point, °F: no data

Method: no data

UEL: no data / LEL: no data

Autoignition temperature, °F: no data

Section 6; Accidental release Measures

6.1 Personal precautions, protective and emergency procedures

Any information listed below is to be considered in addition to internal guidelines for isolation of spill, containment of spill, removal of ignition sources from immediate area, and collection for disposal of spill by trained, properly protected clean-up personnel.

6.1.1 For non emergency personnel

Personnel should wear protective gloves/protective clothing/eye protection/face protection as appropriate for the situation. Sweep up powders and dispose of in accordance with local laws. Absorb liquids on absorbent material. Contain spilled liquids. Protect personnel from exposure

6.1.2 For emergency responders

Personnel should wear protective gloves/protective clothing/eye protection/face protection as appropriate for the situation. Sweep up solids/powders and dispose of in accordance with local laws. Absorb liquids on absorbent material. Contain spilled liquids. Protect personnel from exposure

6.2 Environmental Precautions

6.3 Methods and material for containment and cleaning up

6.3.1 For containment:

Any airtight container is suitable for containment

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6.3.2 For cleaning up:

Sweep up and shovel. Keep in suitable, closed containers for disposal. Sweep up solids/powders and dispose of in accordance with local laws.

6.3.3 Other information:

None

6.4 Reference to other sections

For disposal see section 13.

6.5 Additional information

None

Section 7: Handling and storage

7.1 Precautions for safe handling

Store material in tightly sealed containers. Personnel should wear protective gloves/protective clothing/eye protection/face protection as appropriate for work being performed. Prior to opening package, warm to room temperature.

7.1.1 Protective measures:

Store material in tightly sealed containers. Personnel should wear protective gloves/protective clothing/eye protection/face protection as appropriate for work being performed. If dissolving material in an organic solvent handle the organic solvent per manufacturer SDS.

7.1.2 Advice on general occupational hygiene

Do not eat, drink, or smoke in work areas. Wash hands after use. Remove contaminated clothing or protective equipment before entering eating areas.

7.2 Conditions for safe storage

Technical measures and storage conditions:

To preserve integrity of product store at -20°C with desiccant. Prior to opening package, warm to room temperature.

Packaging materials:

Compatible with glass and plastic packaging.

Hints on storage assembly:

Storage Class: solid

Materials to avoid: Store material away from strong oxidizers.

Further information on storage conditions:

None

7.3 Specific end uses:

Recommendations: Research and development, not for clinical usage

Specific end uses: polymeric formulations

Section 8: Exposure controls/personal protection

8.1 Control parameters

The use of eye protection in the form of safety glasses with side shields and the use of skin protection for hands in the form of gloves are considered minimum and non-discretionary in work places and laboratories. Any recommended personal protection equipment or environmental equipment is to be considered as additional to safety glasses and gloves.

- Use chemical splash goggles and face shield
- Use latex or equivalent gloves

8.1.1 Occupational exposure limits:

Limit value type (country of origin)	Substance name	EC-No.	CAS-No.	Occupational exposure limit value		Monitoring and observation	Peak limitation	Source
				Long term	Short term			
None	Poly(lactide-co-glycolide)-cholesterol (Mn 35,000-45,000 Da, 50:50 L:G)	NA	NA	NA	NA	None	NA	NA

8.1.2 Biological limit values:

Limit value type (country of origin)	Substance name	EC-No	CAS-No	Limit Value	Parameter	Test material	Test date	Source
None	Poly(lactide-co-glycolide)-cholesterol (Mn 35,000-45,000 Da, 50:50 L:G)	NA	NA	none	NA	none	NA	NA

8.1.3 Exposure limits at intended use:

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Not applicable

8.1.4 DNEL/PNEC-values:

Substance name: Poly(lactide-co-glycolide)-cholesterol (Mn 35,000-45,000 Da, 50:50 L:G)

DNEL worker:

DNEL type	DNEL Value	Assessment factor	remark
DNEL short-term oral (acute)	Not established	N/A	
DNEL long-term oral (repeated)	Not established	N/A	
DNEL acute dermal, short-term (local)	Not established	N/A	
DNEL acute dermal, short-term (systemic)	Not established	N/A	
DNEL long-term dermal (local)	Not established	N/A	
DNEL long-term dermal (systemic)	Not established	N/A	
DNEL acute inhalative (local)	Not established	N/A	
DNEL acute inhalative (systemic)	Not established	N/A	
DNEL long-term inhalative (local)	Not established	N/A	
DNEL long-term inhalative (systemic)	Not established	N/A	

DNEL Consumer

PNEC

PNEC type	PNEC value	Assessment factor	Remark
PNEC aquatic, freshwater	Not established	N/A	
PNEC aquatic, marine water	Not established	N/A	
PNEC aquatic, intermittent releases	Not established	N/A	
PNEC sediment, freshwater	Not established	N/A	
PNEC sediment, marine water	Not established	N/A	
PNEC soil, freshwater	Not established	N/A	

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PNEC soil, marine water	Not established	N/A	
PNEC soil, marine water	Not established	N/A	
PNEC sewage treatment plant (STP)	Not established	N/A	
PNEC air	Not established	N/A	
PNEC secondary poisoning	Not established	N/A	

8.1.6 Risk management measures according to used control banding approach

None

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

Use of an externally vented or internally ducted fume hood can reduce formation of nuisance dust.

8.2.2 Personal protective equipment:

8.2.2.1 Eye/Face protection

The use of eye protection in the form of safety glasses with side shields is suggested. Use chemical splash goggles and face shield.

8.2.2.2 Skin protection

Latex or equivalent gloves

8.2.2.3 Respiratory protection:

Particulate respirator (N95 type) is suitable for reducing any nuisance dust.

8.2.2.4 Thermal hazards:

None

8.2.3 Environment exposure controls:

None

8.2.4 Consumer exposure control

Material is provided only for research and development usage. As such it is not intended for household, drug, food or other direct consumer usage.

Section 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

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9.1.1 Appearance:

Physical state: Solid

Colour: White to brown

Odour: None

Odour threshold: NA

9.1.2 Safety relevant basic data

	Value	Concentration	Method	temperature	Pressure	remark
pH	Not established					
Melt point	Not established					
Boiling point	Not established					
Flashpoint	Not established					
Evaporation rate	Not established					
Flammability	Not established					
Upper explosive limits	Not established					
Lower explosive limits	Not established					
Vapor pressure	Not established					
Vapor density	Not established					
Relative density	Not established					
Solubility in water	Not established					
Partition coefficient (n-octanol/water)	Not established					
Auto-ignition temperature	Not established					
Decomposition temperature	Not established					
Viscosity dynamic	Not established					
Viscosity kinematic	Not established					
Explosive properties	Not established					

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Oxidizing properties	Not established					
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9.1.3 Physical hazards:

Explosives: Material is not explosive

Flammable gases: Material is not a flammable gas

Flammable aerosols: Material is not a flammable aerosol

Oxidizing gases: material is not an oxidizing gas

Gases under pressure: Material is not a gas under pressure

Flammable liquids: Material is not a flammable liquid

Flammable solids: Material is not a flammable solid.

Self-reactive substances and mixtures: Material is not a self-reactive substance or mixture.

Pyrophoric liquid: Material is not a pyrophoric liquid

Pyrophoric solid: Material is not a pyrophoric solid.

Self heating substances and mixtures: Material is not a self-heating substance or mixture

Substances or mixtures which, in contact with water emit flammable gases: Material is not a

Substance or mixture which, in contact with water emits a flammable gases.

Oxidizing liquids: Material is not an oxidizing liquid.

Oxidizing solids: Material is not an oxidizing solid.

Organic peroxides: Material is not an organic peroxide.

Metal corrosion: Material does not cause metal corrosion.

9.2 Other information

None

Section 10: Stability and reactivity

10.1 Reactivity

Material slowly hydrolyzes to non-toxic components in presence of water or other nucleophiles.

10.2 Chemical stability

When stored properly material is stable for two years.

10.3 Possibility of hazardous reactions

None

10.4 conditions to avoid:

Heat and water may cause degradation of the material. This does not present a danger but damages the provided material.

10.5 incompatible materials:

Strong oxidizers.

10.6 hazardous decomposition products:

None

Section 11: Toxicological information

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The toxicological properties of the substance have not been established.

Acute data: no data

Subchronic data: no data

Section 12: Ecological information.

The ecological impact of the substance has not been established. Given that the substance is a biodegradable polymer there is no anticipated ecological toxicity.

Section 13: Disposal considerations

The material is not listed in USA 40 CFR Part 261.33 for hazardous disposal. The material must be disposed of in compliance with all Federal, State and Local Regulations.

Section 14: Transport information

Refer to bill of lading or container label for DOT or other transportation hazard classification, if any. Material is not considered hazardous for transportation.

Section 15 Regulatory information

15.1 The material is not a regulated or restricted substance. Material is not intended for clinical or human usage.

15.1.1 EU regulations

None

15.1.2 National/State Regulations

Prop 65 – Column A identifies those items which are known to the State of California to cause cancer.

Column B identifies those items which are known to the State of California to cause reproductive toxicity.

<u>CAS#</u>	<u>Column A</u>	<u>Column B</u>
NA	no	no

State Regulatory Information – If a CAS# is listed below, this material is subject to the listed state right-to-know requirements.

CAS#: NA not listed

SARA Toxic Release Chemicals (as defined in Section 313 of SARA Title III) – This list identifies the toxic chemicals, including their de minimis concentrations, for which reporting is required under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). The list is also referred to as the Toxics Release Inventory (TRI) List.

<u>CAS#</u>	<u>Regulated Name</u>	<u>De Minimis Conc.</u>	<u>% Rep. Thres.</u>
NA	not listed	not listed	not listed

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SARA Extremely Hazardous Substances and TPQs – This list includes hazardous chemicals as defined in 29 CFR 1910.1200(c) and extremely hazardous substances regulated under Section 302 of SARA Title III with their threshold planning quantities (TPQs), as listed in 40 CFR 355, Appendices A and B.

<u>CAS#</u> <u>(pounds)</u>	<u>Regulated Name</u>	<u>TPQ (pounds)</u>	<u>EHS-RQ</u>
NA	not listed	not listed	not listed

CERCLA – The hazardous substances and their reportable quantities (RQs) are listed in the federal regulations at 40 CFR Part 302, Table 302.4. Release of a CERCLA hazardous substance in an amount equal to or greater than its RQ, in any 24-hour period, must be reported to the National Response Center at (800) 424-8802.

<u>CAS#</u>	<u>Regulated Name</u>	<u>RQ (pounds)</u>
NA	not listed	not listed

15.2 Chemical safety assessment:

For this substance a chemical safety assessment is not required

Section 16: Other information

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