OSTEOMARK® NTx Serum Specimen Diluent

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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

1.1. Product identifier

Product name : OSTEOMARK® NTx Serum Specimen Diluent

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

1.3. Details of the supplier of the safety data sheet

Alere Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074 - United States
T +1 (207) 730-5750
ts.scr@alere.com

1.4. Emergency telephone number

Emergency number : +1 (207) 730-5750

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (GHS-US)

Not classified

2.2. Label elements

GHS-US labeling

No labeling applicable

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
ProClin® 300	(CAS No) 55965-84-9	< 0.1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Inhalation:dust,mist), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Assure fresh air breathing. Allow the victim to rest.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Avoid (reject) fire-fighting water to enter environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapor.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep containers closed when not in use. Keep only in the original container. Store as directed on the product label.

Incompatible products : Strong bases. strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

OSTEOMARK® NTx Serum Specimen Diluent	
ACGIH	Not applicable
OSHA	Not applicable

ProClin® 300 (55965-84-9)		
ACGIH	ACGIH Ceiling (mg/m³)	Not applicable
OSHA	Not applicable	

8.2. Exposure controls

Personal protective equipment	:	Avoid all unnecessary exposure.
Hand protection	:	Wear protective gloves.
Eye protection	:	Chemical goggles or safety glasses.
Respiratory protection	:	A risk assessment is required.
Other information	:	When using, do not eat, drink or smoke.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Color	:	Colorless.
Odor	:	Characteristic
Odor threshold	:	No data available
pH	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Relative evaporation rate (butyl acetate=1)	:	No data available
Flammability (solid, gas)	:	No data available
Explosion limits	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Vapor pressure	:	No data available
Relative density	:	No data available
Relative vapor density at 20 °C	:	No data available
Solubility	:	No data available
Log Pow	:	No data available
Log Kow	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available

9.2. Other information

Minimum ignition energy	:	No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

ProClin® 300 (55965-84-9)	
LD50 oral rat	53 mg/kg (Rat; Literature study)
ATE US (oral)	53.000 mg/kg body weight
ATE US (dermal)	300.000 mg/kg body weight
ATE US (gases)	700.000 ppmV/4h
ATE US (vapors)	3.000 mg/l/4h
ATE US (dust, mist)	0.500 mg/l/4h

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitization : Not classified

Germ cell mutagenicity : Not classified

Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Based on available data, the classification criteria are not met

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

Potential Adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

ProClin® 300 (55965-84-9)	
LC50 fish 1	0.28 mg/l (96 h; Lepomis macrochirus)
EC50 Daphnia 1	0.16 mg/l (48 h; Daphnia magna)
Threshold limit algae 1	0.018 mg/l (72 h; Pseudokirchneriella subcapitata)

12.2. Persistence and degradability

OSTEOMARK® NTx Serum Specimen Diluent	
Persistence and degradability	Not established.

ProClin® 300 (55965-84-9)	
Persistence and degradability	No (test) data on mobility of the components available.
Biochemical oxygen demand (BOD)	Not applicable
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
BOD (% of ThOD)	Not applicable

12.3. Bioaccumulative potential

OSTEOMARK® NTx Serum Specimen Diluent	
Bioaccumulative potential	Not established.

ProClin® 300 (55965-84-9)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Effect on the global warming : No known ecological damage caused by this product.

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not regulated for transport

Additional information

Other information : No supplementary information available.

ADR

No additional information available

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

ProClin® 300 (55965-84-9)
Not listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

No additional information available

National regulations

No additional information available

15.3. US State regulations

No additional information available

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H-phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhalation) Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation: dust, mist) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Sens. 1	Skin sensitization Category 1
H301	Toxic if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H331	Toxic if inhaled
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

SDS US (GHS HazCom 2012)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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