

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

Product identifier

: OSTEOMARK® NTx Plates Product name

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

Use of the substance/mixture : For professional use only.

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

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

Label elements

GHS-US labeling

No labeling applicable

2.3. Other hazards

No additional information available

Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. **Substance**

Not applicable

Mixture

Not classified

SECTION 4: First aid measures

Description of first aid measures

: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical First-aid measures general

advice (show the label where possible).

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

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

by warm water rinse.

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

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

Most important symptoms and effects, both acute and delayed

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

Indication of any immediate medical attention and special treatment needed

No additional information available

04/28/2015 EN (English US) Page 1

Safety Data Sheet

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

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 : On land, sweep or shovel into suitable containers. Minimize generation of dust. 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 Plates	
ACGIH	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.

04/28/2015 EN (English US) Page 2 of 5

Safety Data Sheet

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Solid

Color Not applicable Odor Not applicable Odor threshold No data available рΗ No data available Melting point No data available No data available Freezing point 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 No data available Oxidizing properties Vapor pressure No data available No data available

Relative density 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, kinematic No data available Viscosity, dynamic No data available

No data available

Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. **Chemical stability**

Not established.

Viscosity

10.3. Possibility of hazardous reactions

Not established.

10.4. **Conditions to avoid**

Direct sunlight. Extremely high or low temperatures.

Incompatible materials

strong acids. Strong bases.

10.6. **Hazardous decomposition products**

Not established.

SECTION 11: Toxicological information

Information on toxicological effects 11.1.

Acute toxicity : Not classified Skin corrosion/irritation Not classified Serious eye damage/irritation : Not classified : Not classified Respiratory or skin sensitization

Page 3 of 5 04/28/2015 EN (English US)

Safety Data Sheet

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

Germ cell mutagenicity : Not classified Carcinogenicity : Not classified Reproductive toxicity : Not classified Specific target organ toxicity (single exposure) : Not classified Specific target organ toxicity (repeated : Not classified

exposure)

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

Toxicity

No additional information available

12.2. Persistence and degradability

OSTEOMARK® NTx Plates	
Persistence and degradability	Not established.

12.3. **Bioaccumulative potential**

OSTEOMARK [®] NTx Plates	
Bioaccumulative potential	Not established.

Mobility in soil 12.4.

No additional information available

Other adverse effects

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

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

No additional information available

15.2. International regulations

CANADA

No additional information available

Page 4 of 5 04/28/2015 EN (English US)

Safety Data Sheet

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

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

Other information : None.

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

© 2015 Alere. All rights reserved.

The Alere Logo, Alere and Osteomark are trademarks of the Alere group of companies.

04/28/2015 EN (English US) Page 5 of 5