Alere NMP22® Test Digoxigenin Anti-NMP22 Reagent

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EC) No. 453/2010

Date of issue: Revision date: 23 AUG 2015 Version: 23 AUG 2015

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

1.1. Product identifier

Product name : **Alere NMP22® Test Digoxigenin Anti-NMP22 Reagent**

Product group : Trade product

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

1.2.1. Relevant identified uses

Main use category : Industrial use,Professional use

1.2.2. Uses advised against

No additional information available

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

Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Sensitisation — Skin, Category 1	H317

Full text of H statements : see section 16

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning

Hazardous ingredients : ProClin ™ 300

Hazard statements (CLP) : H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation

Precautionary statements (CLP) : P261 - Avoid breathing mist
P264 - Wash hands thoroughly after handling
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear eye protection, protective clothing, protective gloves
P302+P352 - IF ON SKIN: Wash skin thoroughly with mild soap and water
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P332+P313 - If skin irritation occurs: Get medical advice/attention
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
P337+P313 - If eye irritation persists: Get medical advice/attention
P362+P364 - Take off contaminated clothing and wash it before reuse

Child-resistant fastening : No

Tactile warning : No

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
ProClin ™ 300	(CAS No) 55965-84-9 (EC index no) 613-167-00-5	0.05	T; R23/24/25 C; R34 R43 N; R50/53	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation:dust,mist), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits: DSD/DPD	Specific concentration limits: CLP
ProClin ™ 300	(CAS No) 55965-84-9 (EC index no) 613-167-00-5	(C >= 0.0015) R43 (0.06 =< C < 0.6) Xi;R36/38 (C >= 0.6) C;R34	(C >= 0.0015) Skin Sens. 1, H317 (0.06 =< C < 0.6) Eye Irrit. 2, H319 (0.06 =< C < 0.6) Skin Irrit. 2, H315 (C >= 0.6) Skin Corr. 1B, H314

Full text of R- and H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Under normal conditions of use, no adverse effects to health have been observed.

First-aid measures after inhalation : Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

First-aid measures after skin contact : Gently wash with plenty of soap and water. Wash with plenty of soap and water. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/attention. Specific treatment: Seek medical attention if ill effect develops. If skin irritation or rash occurs:

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Not expected to present a significant eye contact hazard under anticipated conditions of normal use. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Not expected to present a significant ingestion hazard under anticipated conditions of normal use.

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

Symptoms/injuries after inhalation : None under normal use. May cause an allergic skin reaction.

Symptoms/injuries after skin contact : None under normal use. Causes skin irritation.

Symptoms/injuries after eye contact : None under normal use. Causes serious eye irritation.

Symptoms/injuries after ingestion : None under normal use.

Symptoms/injuries upon intravenous administration : None under normal use.

Chronic symptoms : None under normal use.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Unsuitable extinguishing media : All extinguishing media allowed.

5.2. Special hazards arising from the substance or mixture

Fire hazard : No fire hazard.

Explosion hazard : Product is not explosive.

Reactivity in case of fire : None under normal conditions.

Hazardous decomposition products in case of fire : fume.

5.3. Advice for firefighters

Precautionary measures fire : Evacuate area. Stop leak if safe to do so.

Firefighting instructions	:	No specific measures are necessary.
Protection during firefighting	:	Do not attempt to take action without suitable protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	:	Absorb spillage to prevent material damage. No open flames. No smoking.

6.1.1. For non-emergency personnel

Protective equipment	:	Wear suitable protective clothing.
Emergency procedures	:	Avoid contact with skin, eyes and clothing. Evacuate unnecessary personnel. No open flames, no sparks, and no smoking. Keep containers closed.
Measures in case of dust release	:	None known.

6.1.2. For emergency responders

Protective equipment	:	Do not attempt to take action without suitable protective equipment.
Emergency procedures	:	Containment as appropriate.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	:	Take up liquid spill into absorbent material.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	:	None known.
Precautions for safe handling	:	Avoid contact during pregnancy/while nursing. Avoid contact with skin, eyes and clothing. Do not eat, drink or smoke when using this product. Wear personal protective equipment. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Avoid breathing vapours. Keep container closed when not in use.
Hygiene measures	:	Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures	:	Comply with applicable regulations.
Storage conditions	:	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Keep container closed when not in use. Keep only in original container. Store in original container.
Incompatible products	:	None known.
Incompatible materials	:	Store away from direct sunlight or other heat sources.
Heat and ignition sources	:	None known.
Prohibitions on mixed storage	:	None known.
Storage area	:	Keep container as directed in product literature . Only store product in original container.
Special rules on packaging	:	Keep only in original container. Proper handling and disposal methods should be established by the laboratory in accordance with local, state, federal and national regulations.
Packaging materials	:	No data available.

7.3. Specific end use(s)

None known.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls	:	Wear recommended personal protective equipment.
Personal protective equipment	:	Gloves. Protective clothing. Safety glasses.

Skin and body protection	:	Wear suitable protective clothing
Respiratory protection	:	A risk assessment is required



Thermal hazard protection	:	Not applicable.
Environmental exposure controls	:	Avoid release to the environment.
Consumer exposure controls	:	Avoid contact during pregnancy/while nursing.
Other information	:	Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Colorless
Odour	:	No odour
Odour threshold	:	No data available
pH	:	≈ 7
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	No data available
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	Soluble in water
Log Pow	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2. Other information

Minimum ignition energy	:	No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

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)

Skin corrosion/irritation : Causes skin irritation.
pH: ≈ 7

Serious eye damage/irritation : Causes serious eye irritation.
pH: ≈ 7

Respiratory or skin sensitisation : May cause an allergic skin reaction.

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 exposure) : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

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

12.2. Persistence and degradability

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

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

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

Sewage disposal recommendations : Disposal must be done according to official regulations.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment. Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations.

Additional information : Clean up even minor leaks or spills if possible without unnecessary risk.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR)	:	Not applicable
Proper Shipping Name (IMDG)	:	Not applicable
Proper Shipping Name (IATA)	:	Not applicable
Proper Shipping Name (ADN)	:	Not applicable
Proper Shipping Name (RID)	:	Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	:	Not applicable

IMDG

Transport hazard class(es) (IMDG)	:	Not applicable

IATA

Transport hazard class(es) (IATA)	:	Not applicable

ADN

Transport hazard class(es) (ADN)	:	Not applicable

RID

Transport hazard class(es) (RID)	:	Not applicable

14.4. Packing group

Packing group (ADR)	:	Not applicable
Packing group (IMDG)	:	Not applicable
Packing group (IATA)	:	Not applicable
Packing group (ADN)	:	Not applicable
Packing group (RID)	:	Not applicable

14.5. Environmental hazards

Dangerous for the environment	:	No
Marine pollutant	:	No
Other information	:	No supplementary information available

14.6. Special precautions for user

- Overland transport
No data available
- Transport by sea
No data available
- Air transport
No data available
- Inland waterway transport
No data available
- Rail transport
No data available

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

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference	:	Water hazard class (WGK) 1, low hazard to waters (Classification according to VwVwS, Annex 4)
12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV	:	Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen	:	None of the components are listed
SZW-lijst van mutagene stoffen	:	None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding	:	None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid	:	None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling	:	None of the components are listed

Denmark

Recommendations Danish Regulation	:	Young people below the age of 18 years are not allowed to use the product Pregnant/breastfeeding women working with the product must not be in direct contact with the product

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Full text of R-, H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), 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	Sensitisation — Skin, Category 1
H301	Toxic if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H331	Toxic if inhaled
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed
R34	Causes burns
R43	May cause sensitisation by skin contact
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
C	Corrosive
N	Dangerous for the environment
T	Toxic

SDS EU (REACH Annex II)

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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