NaveniLink

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Issuing Date 27-Jan-2023 **Revision date** 27-Jan-2023 **Revision Number** 1

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

1.1. Product identifier

Product Name NaveniLink

Pure substance/mixture Mixture

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

Recommended use For research use only. Not for use in diagnostic procedures

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer
Navinci Diagnostics AB

BMC, Husargatan 3 (D11, level 1)

75 124 Uppsala, Sweden

For further information, please contact
E-mail address contact@navnici.se

1.4. Emergency telephone number

Emergency Telephone With acute danger to life, property, or environment - 112
Vid akut fara för liv, egendom eller miljö - 112

SECTION 2: Hazards identification

Components	Hazard statement	Complementary information
Modifier Buffer	None	Non-Hazardous substance or mixture
Oligo Arm1	None	Non-Hazardous substance or mixture
Oligo Arm2	None	Non-Hazardous substance or mixture
Quencher N	Regulation (EC) No 1272/2008	See information below

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 4 - (H302)
Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 2 - (H319)
Skin sensitisation	Category 1 - (H317)

2.2. Label elements

NaveniLink

Contains N-ethylmaleimide



Signal word
Warning

Hazard statements
H302 - Harmful if swallowed

H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation

Precautionary Statements - EU (§28, 1272/2008)
P280 - Wear protective gloves/protective clothing and eye/face protection
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P330 - Rinse mouth
P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
N-ethylmaleimide 128-53-0	1 - <3	No data available	204-892-4	Acute Tox. 2 (H300) Acute Tox. 3 (H311) Skin Corr. 1B (H314) Skin Sens. 1 (H317)	-	-	-

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
N-ethylmaleimide 128-53-0	25	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur.

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.

Skin contact May cause an allergic skin reaction. In the case of skin irritation or allergic reactions, see a doctor. Wash off immediately with soap and plenty of water for at least 15 minutes.

Ingestion Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor.

Self-protection of the first aider Avoid contact with skin, eyes, or clothing. Wear personal protective clothing (see section 8).

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

Symptoms See Section 2.2 for more information. Itching. Rashes. Hives. May cause redness and tearing of the eyes. Burning sensation.

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

Note to doctors May cause sensitisation in susceptible persons. Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Product is or contains a sensitiser. May cause sensitisation by skin contact.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

Other information	Refer to protective measures listed in Sections 7 and 8.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions	Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Take up mechanically, placing in appropriate containers for disposal.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections	See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse.
General hygiene considerations	Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes, or clothing.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep containers tightly closed in a dry, cool, and well-ventilated place. Keep out of the reach of children.

7.3. Specific end use(s)

Risk Management Methods (RMM)	The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits
This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL)	No information available.
Predicted No Effect Concentration (PNEC)	No information available.

8.2. Exposure controls

Personal protective equipment	
Eye/face protection	Eye protection must conform to standard EN 166. Wear safety glasses with side shields (or

goggles).

Hand protection Wear suitable gloves. Impervious gloves.

Skin and body protection Wear suitable protective clothing. Long sleeved clothing.

Respiratory protection Use appropriate respiratory protection.

General hygiene considerations Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes or clothing.

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Appearance	No information available
Colour	No information available
Odour	No information available.
Odour threshold	No information available

Property	Values	Remarks • Method
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

9.2.1. Information with regards to physical hazard classes
Not applicable

9.2.2. Other safety characteristics
No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data
Sensitivity to mechanical impact None.
Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong acids. Strong bases. Strong oxidising agents.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.

Eye contact Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.

Skin contact May cause sensitisation by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). Causes skin irritation.

Ingestion Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea. Harmful if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Itching. Rashes. Hives. Redness. May cause redness and tearing of the eyes.

Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
N-ethylmaleimide	= 25 mg/kg (Rat)	-	-

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation Classification based on data available for ingredients. Irritating to skin.

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes serious eye irritation.

Respiratory or skin sensitisation May cause an allergic skin reaction.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects
No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

14.1 UN number or ID number	Not regulated
14.2	
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user Special Provisions	None

IMDG

14.1 UN number or ID number	Not regulated
14.2	
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user Special Provisions	None
14.7 Maritime transport in bulk according to IMO instruments	No information available

RID

14.1 UN number	Not regulated
14.2	
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user Special Provisions	None

ADR

14.1 UN number or ID number	Not regulated
14.2	
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated

Navent Conjugation kit

14.5 Environmental hazards	Not applicable

14.6 Special precautions for user
Special Provisions None

SECTION 15: Regulatory information

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

National regulations

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:
This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants
Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009
Not applicable

International Inventories

TSCA	Does not comply
DSL/NDSL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AIIC	Does not comply

Chemical name	TSCA	DSL	NDSL	EINECS	ELINCS
N-ethylmaleimide	ACTIVE	X	-	X	-

Chemical name	ENCS	IECSC	KECL	PICCS	AIIC
N-ethylmaleimide	-	X	-	-	X

Legend: X - Listed
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AIIC - Australian Inventory of Industrial Chemicals

15.2. Chemical safety assessment
Chemical Safety Report No information available

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3
H300 - Fatal if swallowed
H311 - Toxic in contact with skin
H314 - Causes severe skin burns and eye damage
H317 - May cause an allergic skin reaction

Legend
SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Key literature references and sources for data used to compile the SDS
Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine’s PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
Organisation for Economic Co-operation and Development Screening Information Data Set
World Health Organization

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer
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End of Safety Data Sheet