SAFETY DATA SHEET

According to the 2020/878 amendment to Regulation (EC) No. 1907/2006
Version 1.0 Revision Date 2024-12-10

Print Date December 11, 2024
GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

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

1.1 Product identifiers

Product name: **Naveni PPI PD1 PDL1 HRP**
NaveniBright, Box 1.1

Brand: Navinci Diagnostics AB

REACH No.: A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration, or the registration is envisaged for a later registration deadline.

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

Identified uses: Laboratory reagents, “For research use only”, not for human use

1.3 Details of the supplier of the safety data sheet

Company: Navinci Diagnostics AB
Dag Hammarskjölds Väg 52a, Plan 2
751 24 Uppsala, Sweden

Contact: contact@navinci.se

1.4 Emergency telephone number:

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Harmful if swallowed – Category 4, H302
Skin Sensitization – Category 1, H317
Harmful to aquatic life – Category 3, H412

2.2 Label elements



2.3 Precautionary statements

P264: Wash hands, forearms and face thoroughly after handling
P270: Do not eat, drink or smoke when using this product.
P273: Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312: IF SWALLOWED: Calla a poison center or doctor.
P330: Rinse mouth.

2.4 Other hazards

No data available.

2.5 Potential health effects

Avoid contact and inhalation. To our knowledge, the hazards of this material have not been thoroughly investigated. We recommend handling all chemicals with caution.

SECTION 3: Composition/information on ingredients

3.1 Non-hazardous mixtures

3.2 Information on component

Component:	CAS Number:	EC Number:	Percent by weight:	Specific concentration limits/ M-Factor
Sodium Azide	26628-22-8	247-852-1	<0,1%	M=1 M(Chronic)=1
Sodium Chloride	7647-14-5	231-598-3	<1%	Not Classified
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	55965-84-9	911-418-6	<0,045%	No data available for this concentration

3.3 KIT COMPONENTS:

Product Description	Pictogram	Hazard Statement	Complementary Information
Navenibody 1 NB.1.100. 06 Volume – 0,1 ml	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Navenibody 2 NB.1.100.07 Volume – 0,1 ml	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Probe Diluent NF.1.100.03 Volume – 4,0 ml		H317	Classification and labelling according to CLP criteria.
Block NB.1.100.01 Volume – 4,0 ml		H317	Classification and labelling according to CLP criteria.
Antibody Diluent NB.1.100.02 Volume – 8,0 ml		H317	Classification and labelling according to CLP criteria.
Supplement 1 NB.1.100.03 Volume – 0,1 ml		H302, H412	Classification and labelling according to CLP criteria.
Supplement 2 NB.1.100.04 Volume – 0,1 ml		H302, H412	Classification and labelling according to CLP criteria.

SECTION 4: First aid measures

4.1 Description of first aid measures

First-aid measures after skin contact — Remove contaminated clothing. Rinse with plenty of water. Call a physician to seek medical advice if symptoms arise.

First-aid measures after eye contact — Immediately rinse with water for several minutes. Make sure to remove any contact lenses from the eyes before rinsing. Hold eyelids apart. Continue to rinse for at least 15 minutes. Use tempered water. Continue flushing during transport to hospital. Get medical attention.

First-aid measures after ingestion. — Do not induce vomiting. Immediately rinse mouth and drink plenty of water (200-300 ml). Get medical attention. Never give liquid to an unconscious person.

First-aid measures after inhalation — If inhaled, move the individual to fresh air and call a physician to seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed — Inhaled: Coughing, difficulty in breathing, pressure in chest.
Skin contact: Prolonged contact may cause redness, irritation, and dried skin.
Eye contact: Causes severe eye damage.
Ingestion: May cause irritation, nausea, vomiting, diarrhea.

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

SECTION 5: Firefighting measures

5.1 Extinguishing media — No data available.

5.2 Special hazards arising from the substance or mixture — No data available.

5.3 Advice for firefighters — No data available.

5.4 Further information — No data available.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures	For personal protection see section 8.
6.2 Environmental precautions	Avoid release into the environment.
6.3 Methods and materials for containment and clean up	No data available.
6.4 Reference to other section	For disposal see section 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling	For precautions see section 2.2.
7.2 Conditions for safe storage, including any incompatibilities	Keep container tightly closed in a dry and well-ventilated place. Store at specified on the box temperature.
7.3 Specific end use(s)	Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters	Contains no substances with occupational exposure limit values.
8.2. Personal protective equipment.	Wear appropriate gloves, protective clothing and eyewear and follow safe laboratory practices.
8.3 Exposure controls	No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a)	Physical state	Liquid
b)	Color	Colorless
c)	Odor	No data available
d)	Odor Threshold	No data available
e)	pH	No data available
f)	Melting point/freezing point	No data available
g)	Initial boiling point	No data available
h)	Flash point	No data available
i)	Evaporation rate	No data available
j)	Flammability (solid gas)	No data available
k)	Upper/lower flammability or explosive limits	No data available
l)	Vapor pressure	No data available
m)	Vapor density	No data available
n)	Relative density	No data available
o)	Water solubility	No data available
p)	Partition coefficient n-octanol/water	No data available
q)	Auto-ignition temperature	No data available
r)	Decomposition temperature	Not applicable
s)	Kinetic viscosity	No data available
t)	Explosive properties	No data available
u)	Oxidizing properties	No data available

9.2 Other safety information — No data available

SECTION 10: Stability and reactivity

10.1 Reactivity	No data available
10.2 Chemical stability	No data available
10.3 Possibility of hazardous reactions	No data available
10.4 Conditions to avoid	No data available
10.5 Incompatible materials	No data available
10.6 Hazardous decomposition products	In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

a)	Acute toxicity	There is no evidence available indicating acute toxicity.
b)	Irritation	Conclusive but not sufficient for classification
c)	Serious eye damage/eye irritation	Conclusive but not sufficient for classification
d)	Sensitization	Conclusive but not sufficient for classification
e)	Specific target organ toxicity - single exposure	Conclusive but not sufficient for classification
f)	Specific target organ toxicity - repeated exposure	Conclusive but not sufficient for classification
g)	Carcinogenicity	Conclusive but not sufficient for classification
h)	Mutagenicity	Conclusive but not sufficient for classification
i)	Reproductive toxicity	Conclusive but not sufficient for classification
j)	Aspiration hazard	Conclusive but not sufficient for classification
k)	RTECS (Registry of Toxic Effects of Chemical Substances)	Not available

SECTION 12: Ecological information

12.1 Toxicity	No data available
12.2 Persistence and degradability	No data available
12.3 Bioaccumulative potential	No data available
12.4 Mobility in soil	No data available
12.5 Results of PBT and vPvB assessment	No data available. PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
12.6 Other adverse effects	No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods	No data available
13.2 Special precautions	No data available
13.3 Other considerations	Waste should not be disposed of by release to sewers.

SECTION 14: Transport information

	UN number	Class	Packing group	Proper shipping name
14.1 ADR/ RID	-	-	-	Not dangerous goods
14.2 IMDG	-	-	-	Not dangerous goods
14.3 IATA	-	-	-	Not dangerous goods

Environmental hazards

	Marine pollutant	Excepted quantity	Reportable quantity
14.4 ADR/ RID	No	-	-
14.5 IMDG	No	-	-
14.6 IATA	No	-	-

Special precautions for end user:

No data available.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.	This safety datasheet complies with the requirements of Commission Regulation (EU) 2020/878 amendment to Regulation (EC) No. 1907/2006.
15.2 Chemical safety assessment	For this product a chemical safety assessment was not carried out.
15.3 Risk phrases:	No data available.
15.4 Safety phrases:	No data available.

SECTION 16: Other information

Further information

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based on the present state of our knowledge and is applicable to the product regarding appropriate safety precautions. It does not represent any guarantee of the properties of the product. Navinci Diagnostics AB and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See the reverse side of invoice or packing slip for additional terms and conditions of sale.

According to the 2020/878 amendment to Regulation (EC) No. 1907/2006
Version 1.0 Revision Date 2022-04-11

Print Date December 11, 2024
GENERIC EU SDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

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

1.1 Product identifiers

Product name:	**Naveni PPI PD1 PDL1, HRP - Box 1.2, Box 1.3**
Brand:	Navinci Diagnostics AB
REACH No.:	A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration, or the registration is envisaged for a later registration deadline.

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

Identified uses: Laboratory reagents, “For research use only”, not for human use.

1.3 Details of the supplier of the safety data sheet

Company: Navinci Diagnostics AB
Dag Hammarskjölds väg 52a
751 24 Uppsala, Sweden

Contact: contact@navinci.se

1.4 Emergency telephone number

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Regulation (EC) No 1272/2008
CLP/GHS]

Flammable Liquids - Category 2, H225
Acute Toxicity, Oral – Category 4, H302
Skin sensitization – Category 1, H317
Eye Damage – Category 1, H318
Serious Eye Irritation/Damage – Category 2, H319
Acute Toxicity, Inhalation. – Category 4, H332
Germ Cell Mutagenicity – Category 2, H341
Chronic Aquatic Toxicity – Category. 3, H412

2.2 Label elements



Signal word: Danger.

2.3 Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P270: Do not eat, drink or smoke when using this product. P280 Wear protective gloves/protective clothing/eye protection/face protection. P273: Avoid release to the environment. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER or doctor/physician.
2.4 Other hazards	No data available.
2.5 Potential health effects	Avoid contact and inhalation. To our knowledge, the hazards of this material have not been thoroughly investigated. We recommend handling all chemicals with cautions.

SECTION 3: Composition/information on ingredients

3.1 Non-hazardous mixtures

3.2 Information on component

Component:	CAS Number:	EC Number:	Percent by weight:	Specific concentration limits/ M-Factor
Aluminum sulfate tetradecahydrate	16828-12-9	233-135-0	5 – 10%	M (Chronic) = 1 M = 10
Ethanol	64-17-5	200-578-6	<6%	No data available
Acetonitrile	75-05-8	200-835-2	<75% (HRP substrate 2) >90% (HRP substrate 3)	No data available
3-Methyl-2-benzothiazolinone hydrazine	149022-15-1	238-428-8	<2%	No data available
5-Aminoinole	5192-03-0	225-977-2	<3%	No data available
2,6-Diaminotoluene	823-40-5	212-513-9	<3%	No data available
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	55965-84-9	911-418-6	<0,045%	No data available for this concentration

3.3 KIT COMPONENTS:

Product Description	Pictogram	Hazard Statement	Complementary Information
AP/ HRP diluent NB.1.100. 08 Volume – 8,0 ml		H317	Classification and labelling according to CLP criteria.
HRP Reagent NB.1.100.05 Volume – 0,1 ml	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
HRP substrate 1 NF.1.100.13 Volume – 0,17 ml	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
HRP substrate 2 NB.1.100.14 Volume – 0,1 ml		H225; H302; H332; H319; H312	Classification and labelling according to CLP criteria.
HRP substrate 3 NB.1.100.15 Volume – 0,1 ml		H225; H302; H312; H317; H412; H332; H319; H341	Classification and labelling according to CLP criteria.

HRP substrate 4 NB.1.100.17 Volume – 0,1 ml	Not applicable	None.	Non-hazardous substance according to regulation EG nr 1272/2008.
Nuclear stain NB.1.100.16 Volume – 6,0 ml		H318	Classification and labelling according to CLP criteria.

SECTION 4: First aid measures

4.1 Skin contact	Remove contaminated clothing. Rinse with plenty of water. Call a physician to seek medical advice if symptoms arise.
4.2 Eye contact	Immediately rinse with water for several minutes. Make sure to remove any contact lenses from the eyes before rinsing. Hold eyelids apart. Continue to rinse for at least 15 minutes. Use tempered water. Continue flushing during transport to hospital. Get medical attention.
4.3. Ingestion	Do not induce vomiting. Immediately rinse mouth and drink plenty of water (200-300 ml). Get medical attention. Never give liquid to an unconscious person.
4.4. Inhalation	If inhaled, move individual to fresh air and call a physician to seek medical advice.
4.5. Most important symptoms and effects, both acute and delayed	Inhaled: Coughing, difficulty in breathing, pressure in chest. Skin contact: Prolonged contact may cause redness, irritation, and dried skin. Eye contact: Causes severe eye damage. Ingestion: May cause irritation, nausea, vomiting, diarrhea.
4.6 Indication of any immediate medical attention and special treatment needed	No data available.

SECTION 5: Firefighting measures

5.1 Extinguishing media	Water, foam, carbon dioxide or dry powder. Use fire-extinguishing media appropriate for surrounding materials.
5.2 Special hazards arising from the substance or mixture	Use respirator. Toxic gases can be released.
5.3 Advice for firefighters	Wear protective clothing. Move containers from fire area if you can do it without risk.
5.4 Further information	No data available.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures	For personal protection see section 8.
6.2 Environmental precautions	Avoid release into the environment.
6.3 Methods and materials for containment and clean up	Absorb in vermiculite, dry sand or soil and fill into containers. Remove spillage immediately. Wash the spill area with water.
6.4 Reference to other section	For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling	Wear protective gloves, the product will color. Avoid contact with skin and eyes. An emergency shower and eye washing station must be available at the workplace. Wash hands after handling the components.
7.2 Conditions for safe storage, including any incompatibilities	Protect from direct sunlight. Keep container tightly closed in a dry and well-ventilated place. Store at specified on the box temperature.
7.3 Specific end use(s)	Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters	Nuclear stain:
Occupational exposure limit	- Ethanol (CAS no. 64-17-5/ EC no. 200-578-6) 8-hour TWA: 1000 ppm or 1920 mg/m3 15 min: 1000 ppm or 1900 mg/m3
8.2. Personal protective equipment	Wear appropriate gloves in accordance with standard EN 374, protective clothing and eyewear (EN 166) and follow safe laboratory practices.
8.3 Exposure controls	Use in well ventilated areas. Eye wash and shower facilities must be available when handling this product. Handle in accordance with good laboratory hygiene and safety practices. Mechanical exhaust required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

	HRP Substrate 1	HRP Substrate 2	HRP Substrate 3
v) Physical state	Liquid	Liquid	Liquid
w) Color	Colorless	Colorless	Brown
x) Odor	None	None	None
y) Odor Threshold	No data available	No data available	No data available
z) pH	No data available	No data available	No data available
aa) Melting point/freezing point	No data available	-44 °C	-44 °C
bb) Initial boiling point	No data available	81,6 °C	81,6 °C
cc) Flash point	No data available	5,6 °C	5,6 °C
dd) Evaporation rate	No data available	No data available	No data available
ee) Flammability (solid gas)	No data available	No data available	No data available
ff) Upper/lower flammability or explosive limits	No data available	No data available	No data available
gg) Vapor pressure	No data available	No data available	No data available
hh) Vapor density	No data available	No data available	No data available
ii) Relative density	No data available	No data available	No data available
jj) Water solubility	No data available	No data available	No data available
kk) Partition coefficient n-octanol/water	No data available	No data available	No data available
ll) Auto-ignition temperature	No data available	No data available	No data available
mm) Decomposition temperature	Not applicable	Not applicable	Not applicable
nn) Kinetic viscosity	No data available	No data available	No data available
oo) Explosive properties	No data available	No data available	No data available
pp) Oxidizing properties	No data available	No data available	No data available
9.2 Other safety information	No data available	No data available	No data available

9.1 Information on basic physical and chemical properties

	HRP Substrate 4	Nuclear stain	All other components
a) Physical state	Liquid	Liquid	Liquid
b) Color	Colorless	Red/ violet	Colourless
c) Odor	No data available	Almost odourless	No data available
d) Odor Threshold	No data available	No data available	No data available
e) pH	No data available	2,2 – 2,6	No data available
f) Melting point/freezing point	No data available	No data available	No data available
g) Initial boiling point	No data available	No data available	No data available
h) Flash point	No data available	No data available	No data available
i) Evaporation rate	No data available	No data available	No data available
j) Flammability (solid gas)	No data available	No data available	No data available
k) Upper/lower flammability or explosive limits	No data available	No data available	No data available
l) Vapor pressure	No data available	No data available	No data available
m) Vapor density	No data available	No data available	No data available
n) Relative density	No data available	No data available	No data available
o) Water solubility	No data available	Soluble in water	No data available
p) Partition coefficient n-octanol/water	No data available	No data available	No data available
q) Auto-ignition temperature	No data available	No data available	No data available
r) Decomposition temperature	Not applicable	Not applicable	Not applicable
s) Kinetic viscosity	No data available	No data available	No data available
t) Explosive properties	No data available	No data available	No data available
u) Oxidizing properties	No data available	No data available	No data available

9.2 Other safety information	No data available	No data available	No data available

SECTION 10: Stability and reactivity

	HRP Substrate 1	HRP Substrate 2	HRP Substrate 3
10.1 Reactivity	No data available	No data available	No data available
10.2 Chemical stability	Stable under normal temperature conditions and recommended use.	Stable under normal temperature conditions and recommended use.	Stable under normal temperature conditions and recommended use.
10.3 Possibility of hazardous reactions	No data available	No data available	No data available
10.4 Conditions to avoid	Avoid exposure to high temperatures or direct sunlight.	Avoid exposure to high temperatures, sparks, open flames.	Avoid exposure to high temperatures, sparks, open flames.
10.5 Incompatible materials	No data available.	No data available.	No data available.
10.6 Hazardous decomposition products	Carbon oxides, sodium oxides, other decomposition products.	Carbon monoxide, carbon dioxide, nitrogen oxides, and hydrogen.	Carbon monoxide, carbon dioxide, nitrogen oxides, and hydrogen.

	HRP Substrate 4	Nuclear Stain	All other components
10.1 Reactivity	No data available	No data available	No data available
10.2 Chemical stability	Stable under normal temperature conditions and recommended use.	Stable under normal temperature conditions and recommended use.	No data available
10.3 Possibility of hazardous reactions	No data available	No data available	No data available
10.4 Conditions to avoid	No data available	Avoid exposure to high temperatures or direct sunlight.	No data available
10.5 Incompatible materials	Zinc, powdered metals, copper, nickel, brass, iron, and iron salts.	Strong oxidizing substances.	No data available
10.6 Hazardous decomposition products	Nature of decomposition products no known.	Carbon dioxide (CO2). Carbon monoxide (CO). Oxides of: Sulphur. Aluminium. Nitrogen. Sodium.	In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

l)	Acute toxicity	No data available
m)	Irritation	May cause irritation.
n)	Serious eye damage/eye irritation	Irritating to eyes, may cause eye damage.
o)	Sensitization	No data available
p)	Specific target organ toxicity - single exposure	No data available
q)	Specific target organ toxicity - repeated exposure	No data available
r)	Carcinogenicity	No data available
s)	Mutagenicity	No data available
t)	Reproductive toxicity	No data available
u)	Aspiration hazard	No data available
v)	Acute effects	Aluminum sulfate tetradecahydrate LD50 oral: > 2000 mg/kg (in rat) LD50 dermal: > 5000 mg/kg (in rabbit) LD50 inhalation: > 5 mg/L (in rat)

SECTION 12: Ecological information

12.1 Toxicity

Ethanol

Acute aquatic – LC 50 = 1290 - 15300 mg/L
Species: Rainbow trout
Duration 96 h

12.2 Persistence and degradability	No data available
12.3 Bioaccumulative potential	No data available
12.4 Mobility in soil	No data available
12.5 Results of PBT and vPvB assessment	No data available. PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
12.6 Endocrine disrupting properties	No data available
12.7 Other adverse effects	No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods	No data available
13.2 Special precautions	No data available
13.3 Other considerations	Waste should not be disposed of by release to sewers.

SECTION 14: Transport information

Special precautions for end user:
No data available.

2,6-Touendiamine:

	UN number	Class	Packing group	Proper shipping name
14.1 ADR/ RID	3077	9	III	(2,6-Touendiamine)
14.2 IMDG	3077	9	III	(2,6-Touendiamine)
14.3 IATA	3077	9	III	(2,6-Touendiamine)

Environmental hazards

	Marine pollutant	Excepted quantity	Reportable quantity
14.4 ADR/ RID	Yes	-	10 lbs
14.5 IMDG	Yes	-	10 lbs
14.6 IATA	Yes	-	10 lbs

Special precautions for end user:
No data available.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.	This safety datasheet complies with the requirements of Commission Regulation (EU) 2020/878 amendment to Regulation (EC) No. 1907/2006.
15.2 Chemical safety assessment	For this product a chemical safety assessment was not carried out.
15.3 Risk phrases:	R11 Highly flammable. R20/21/22 Harmful by inhalation, in contact with skin and if swallowed R36 Irritating to eyes. R41 Risk of serious damage to eyes.
15.4 Safety phrases:	S16 Keep away from sources of ignition. No smoking S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S36/37 Wear suitable protective clothing and gloves.

SECTION 16: Other information

Abbreviations and acronyms

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
EN	European Standard

IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LD50	Median lethal dose
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet

Further information

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SAFETY DATA SHEET

According to the 2020/878 amendment to Regulation (EC) No. 1907/2006

Issue date 2024-04-11 Version: 1.0

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

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

1.1 Product identifiers

Product name: **NaveniBright MR,** Box 2
Brand: Navinci Diagnostics AB
REACH No.: A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require registration, or the registration is envisaged for a later registration deadline.

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

Identified uses: Laboratory reagents, “For research use only”, not for human use

1.3 Details of the supplier of the safety data sheet

Company: Navinci Diagnostics AB
Dag Hammarskjölds väg 52a
751 24 Uppsala, Sweden
Contact: contact@navinci.se

1.4 Emergency telephone number

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture Skin Sensitization – Category 1, H317

2.2 Label elements



2.3 Precautionary statements P270: Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

2.4 Other hazards No data available.

2.5 Potential health effects Avoid contact and inhalation. To our knowledge, the hazards of this material have not been thoroughly investigated. We recommend handling all chemicals with caution.

SECTION 3: Composition/information on ingredients

3.1 Substances

Non-hazardous mixtures

3.2 Information on component

Component	CAS Number	EC Number	Percent by weight	Specific concentration limits/ M-Factor
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	55965-84-9	911-418-6	<0,045%	No data available for this concentration

3.3 Kit Components:

Product Description	Pictogram	Hazard Statement	Complementary Information
NaveniBody PD1 PPI.2.01 Volume – 0.1 ml		H317	Classification and labelling according to CLP criteria.
NaveniBody PDL PPI.2.02 Volume – 0.1 ml		H317	Classification and labelling according to CLP criteria.
Buffer 1 NB.2.100.17 Volume – 0.8 ml	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Buffer 2 NB.2.100.18 Volume – 2.3 ml	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Enzyme 1 NF.2.100.11 Volume – 0.1 ml	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Enzyme 2 NF.2.100.15 Volume – 0.1 ml	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.

SECTION 4: First aid measures

4.1 First-aid measures after skin contact — Rinse with plenty of water. Call a physician to seek medical advice if symptoms arise.

4.2 First-aid measures after eye contact — Wash thoroughly after handling. If eye or skin contact occurs, immediately wash the affected area with soap and copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician to seek medical advice.

4.3. First-aid measures after ingestion. — If swallowed, wash out mouth with water provided person is conscious and call a physician to seek medical advice. Never give anything by mouth to an unconscious person. Call a physician to seek medical advice if symptoms arise.

4.4. First-aid measures after inhalation — If inhaled, move the individual to fresh air and call a physician to seek medical advice.

4.5. Most important symptoms and effects, both acute and delayed — The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.6 Indication of any immediate medical attention and special treatment needed — No data available.

SECTION 5: Firefighting measures

5.1 Extinguishing media — No data available.

5.2 Special hazards arising from the substance or mixture — No data available.

5.3 Advice for firefighters — No data available.

5.4 Further information — No data available.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures — For personal protection see section 8.

6.2 Environmental precautions — Avoid release into the environment.

6.3 Methods and materials for containment and clean up — No data available.

6.4 Reference to other section — For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling	For precautions see section 2.2.
7.2 Conditions for safe storage, including any incompatibilities	Keep container tightly closed in a dry and well-ventilated place. Store at specified on the box temperature.
7.3 Specific end use(s)	Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters	Contains no substances with occupational exposure limit values.
8.2. Personal protective equipment.	Wear appropriate gloves, protective clothing and eyewear and follow safe laboratory practices.
8.3 Exposure controls	No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

qq) Physical state	Liquid
rr) Color	Colorless
ss) Odor	No data available
tt) Odor Threshold	No data available
uu) pH	No data available
vv) Melting point/freezing point	No data available
ww) Initial boiling point	No data available
xx) Flash point	No data available
yy) Evaporation rate	No data available
zz) Flammability (solid gas)	No data available
aaa) Upper/lower flammability or explosive limits	No data available
bbb) Vapor pressure	No data available
ccc) Vapor density	No data available
ddd) Relative density	No data available
eee) Water solubility	No data available
fff) Partition coefficient n-octanol/water	No data available
ggg) Auto-ignition temperature	No data available
hhh) Decomposition temperature	No data available
iii) Kinetic viscosity	No data available
jjj) Explosive properties	No data available
kkk) Oxidizing properties	No data available

9.2 Other safety information	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity	No data available
10.2 Chemical stability	No data available
10.3 Possibility of hazardous reactions	No data available
10.4 Conditions to avoid	No data available
10.5 Incompatible materials	No data available
10.6 Hazardous decomposition products	In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

a) Acute toxicity	There is no evidence available indicating acute toxicity.
b) Irritation	Conclusive but not sufficient for classification
c) Serious eye damage/eye irritation	Conclusive but not sufficient for classification
d) Sensitization	Conclusive but not sufficient for classification
e) Specific target organ toxicity - single exposure	Conclusive but not sufficient for classification
f) Specific target organ toxicity - repeated exposure	Conclusive but not sufficient for classification
g) Carcinogenicity	Conclusive but not sufficient for classification
h) Mutagenicity	Conclusive but not sufficient for classification

i)	Reproductive toxicity	Conclusive but not sufficient for classification
j)	Aspiration hazard	Conclusive but not sufficient for classification
k)	RTECS (Registry of Toxic Effects of Chemical Substances)	Not available

SECTION 12: Ecological information

12.1 Toxicity	No data available
12.2 Persistence and degradability	No data available
12.3 Bioaccumulative potential	No data available
12.4 Mobility in soil	No data available
12.5 Results of PBT and vPvB assessment	No data available. PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
12.6 Other adverse effects	No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods	No data available
13.2 Special precautions	No data available
13.3 Other considerations	Waste should not be disposed of by being released to sewers.

SECTION 14: Transport information

	UN number	Class	Packing group	Proper shipping name
14.1 ADR/ RID	-	-	-	Not dangerous goods
14.2 IMDG	-	-	-	Not dangerous goods
14.3 IATA	-	-	-	Not dangerous goods

Environmental hazards

	Marine pollutant	Excepted quantity	Reportable quantity
14.4 ADR/ RID	No	-	-
14.5 IMDG	No	-	-
14.6 IATA	No	-	-

Special precautions for end user
No data available.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.	This safety datasheet complies with the requirements of Commission Regulation (EU) 2020/878 amendment to Regulation (EC) No. 1907/2006.
15.2 Chemical safety assessment	For this product a chemical safety assessment was not carried out.
15.3 Risk phrases:	No data available.
15.4 Safety phrases:	No data available.

SECTION 16: Other information

Abbreviations and acronyms

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
EN	European Standard
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LD50	Median lethal dose
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail

Further information

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