SAFETY DATA SHEET

According to the 2020/878 amendment to Regulation (EC) No. 1907/2006
Issue date 2025-04-06 Version: 2.0

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™ PD1/PD-L1
Brand: Navinci Diagnostics AB
Product code kit: 60033

Included packaging:
- NaveniBright Box 1: 60036
- NaveniBright Bag 1: 60038
- Naveni PD1/PD-L1 Antibodies: 60043
- NaveniBright Box 2: 60045

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

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
Acute Toxicity, Dermal - Category 4, H312
Skin Sensitization – Category 1, H317
Serious Eye Damage/Irritation – 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 caution.

SECTION 3: Composition/information on ingredients

3.1 Substances
Not applicable

3.2 Mixtures

Component:	CAS Number:	EC Number:	Percent by weight:	Specific concentration limits/ M-Factor
Aluminum sulfate tetradecalhydrate	16828-12-9	233-135-0	5 – 10%	M (Chronic) = 1 M = 10
Ethanol	64-17-5	200-578-6	<6%	No data available
Sodium Azide	26628-22-8	247-852-1	<0,1%	M=1 M(Chronic)=1
Sodium Chloride	7647-14-5	231-598-3	<1%	Sodium Chloride
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
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

3.3 KIT COMPONENTS:

NaveniBright Box 1:

Product Description	Pictogram	Hazard Statement	Complementary Information
NaveniBright Block 50000 Volume – 6.0 ML		H317	Classification and labelling according to CLP criteria.
Naveni Supplement 1 50027 Volume – 700 µL		H317	Classification and labelling according to CLP criteria.
Naveni Diluent 50015 Volume – 15.0 ML		H317	Classification and labelling according to CLP criteria.
Naveni Supplement 2 50028 Volume – 1.3 ML		H317	Classification and labelling according to CLP criteria.
Naveni HRP Diluent 50016 Volume – 8.0 ML		H317	Classification and labelling according to CLP criteria.
Navenibody M1 50049 Volume – 100 µL		H317	Classification and labelling according to CLP criteria.

Navenibody R2 50051 Volume – 100 µL		H317	Classification and labelling according to CLP criteria.
Naveni HRP Reagent 50034 Volume – 30 µL	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Naveni HRP Substrate 1 50029 Volume – 180 µL	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Naveni HRP Substrate 2 50030 Volume – 120 µL		H225; H302; H332; H319; H312	Classification and labelling according to CLP criteria.
Naveni HRP Substrate 3 50031 Volume – 120 µL		H225; H302; H312; H317; H412; H332; H319; H341	Classification and labelling according to CLP criteria.
Naveni HRP Substrate 4 50032 Volume –180 µL	Not applicable	None.	Non-hazardous substance according to regulation EG nr 1272/2008.

NaveniBright Bag 1:

Product Description	Pictogram	Hazard Statement	Complementary Information
NaveniBright Nuclear Stain 50056 Volume – 6.0 ML		H318	Classification and labelling according to CLP criteria.

NaveniBright Box 2:

Product Description	Pictogram	Hazard Statement	Complementary Information
Naveni Buffer 1 (5x) 50018 Volume – 1.3 ML	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Naveni Enzyme 1 (40x) 50002 Volume – 100 µL	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
NaveniBright Buffer 2 (5x) 50023 Volume – 800 µL	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Naveni Enzyme 2 (40x) 50003 Volume – 100 µL	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.

Bag 2: Naveni PD1/PD-L1 Antibodies:

Product Description	Pictogram	Hazard Statement	Complementary Information
Naveni PD1 Antibody 50041 Volume – 100 µL		H317	Classification and labelling according to CLP criteria.
Naveni PD-L1 Antibody 50042 Volume – 100 µL		H317	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.

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 the 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

Occupational exposure limit — Nuclear stain:
- 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

		Naveni HRP Substrate 1	**Naveni HRP Substrate 2**	**Naveni HRP Substrate 3**
a)	Physical state	Liquid	Liquid	Liquid
b)	Color	Colorless	Colorless	Brown
c)	Odor	None	None	None
d)	Odor Threshold	No data available	No data available	No data available
e)	pH	No data available	No data available	No data available
f)	Melting point/freezing point	No data available	-44 °C	-44 °C
g)	Initial boiling point	No data available	81,6 °C	81,6 °C
h)	Flash point	No data available	5,6 °C	5,6 °C
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	No data available	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

9.1 Information on basic physical and chemical properties

		Naveni 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

	Naveni HRP Substrate 1	Naveni HRP Substrate 2	Naveni 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.

	Naveni 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

a)	Acute toxicity	No data available
b)	Irritation	May cause irritation.
c)	Serious eye damage/eye irritation	Irritating to eyes, may cause eye damage.
d)	Sensitization	No data available
e)	Specific target organ toxicity - single exposure	No data available
f)	Specific target organ toxicity - repeated exposure	No data available
g)	Carcinogenicity	No data available
h)	Mutagenicity	No data available
i)	Reproductive toxicity	No data available
j)	Aspiration hazard	No data available
k)	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

	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	-	-

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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