SAFETY DATA SHEET

According to the 2020/878 amendment to Regulation (EC) No. 1907/2006
Issue date 2025-02-24 Version: 2.0

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® Plex
Brand: Navinci Diagnostics AB
Product code kit: 60000

Included packaging:
- Naveni® Box 1: 60001
- Naveni® Plex Box 2: 60002
- Naveni® Plex Navenibodies PD1-PDL1: 60003
- Naveni® Plex Navenibodies CD3: 60004
- Naveni® Plex Navenibodies CD8-MHCI: 60005

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]: Skin Sensitization – Category 1, H317

2.2 Label elements



Signal word: Warning.

2.3 Precautionary statements: 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
Not applicable

3.2 Mixtures

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	<0,03%	No data available for this concentration

3.3 KIT COMPONENTS:

Product Description	Pictogram	Hazard Statement	Complementary Information
Naveni Block 50014 Volume – 6 ml		H317	Classification and labelling according to CLP criteria.
Naveni Diluent 50001 Volume – 8 ml		H317	Classification and labelling according to CLP criteria.
Naveni Enzyme 1 (40x) 50002 Volume – 0.1 ml	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Naveni Enzyme 2 (40x) 50003 Volume – 0.1 ml	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Naveni® Plex - ABC Buffer 1 (5x) 50004 Volume – 0.8 ml	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Naveni Buffer 2 (5x) 50005 Volume – 0.8 ml	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Naveni Post Block (40x) 50006 Volume – 0.1 ml	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Naveni Plex - ABC Detection Mix (5x) 50007 Volume – 0.8 ml	Not Applicable.	None.	Non-hazardous substance or mixture according to regulation EG nr 1272/2008.
Naveni Plex - A N1 PD1-PDL1 (100x) 50008 Volume – 40 µl		H317	Classification and labelling according to CLP criteria.
Naveni Plex - A N2 PD1-PDL1 (100x) 50009 Volume – 40 µl		H317	Classification and labelling according to CLP criteria.
Naveni Plex - B N1 CD3 (100x) 50010 Volume – 40 µl		H317	Classification and labelling according to CLP criteria.
Naveni Plex - B N2 CD3 (100x) 50011		H317	Classification and labelling according to CLP criteria.

Volume – 40 µl			
Naveni Plex - C N1 CD8-MHCI (100x) 50012 Volume – 40 µl		H317	Classification and labelling according to CLP criteria.
Naveni Plex - C N2 CD8-MHCI (100x) 50013 Volume – 40 µl		H317	Classification and labelling according to CLP criteria.
Naveni Plex - C N1 PD1-PDL2 (100x) 50062 Volume – 40 µl		H317	Classification and labelling according to CLP criteria.
Naveni Plex - C N2 PD1-PDL2 (100x) 50063 Volume – 40 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: Skin contact: Prolonged contact may cause redness, irritation, and dried skin.

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 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	No data available
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	May cause irritation
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 Road	European Agreement concerning the International Carriage of Dangerous Goods by
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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