

	PixCell HemoScreen CBC Cartridge Material Safety Data Sheet (MSDS) /Safety Data Sheet (SDS)	
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HEMOSCREEN CBC CARTRIDGE

MATERIAL SAFETY DATA SHEET (MSDS)/SAFETY DATA SHEET (SDS)

1. IDENTIFICATION

Substance/Device

Date Issued	January 1, 2021
Product name	HemoScreen CBC Cartridge
Part Numbers	BC-MA-00300 (single);
Use of the substance/preparation	HemoScreen is a point of care hematology analyzer. The HemoScreen CBC cartridge is inserted into the HemoScreen analyzer.

Manufacturer

Company name	PixCell Medical Technologies Ltd.
Address	Hayezira St. POB 113 Yokneam Illit, 2069202 Israel
Telephone	+972 4-959-3516
E-mail	info@pixcell-medical.com
Name of contact	Eitan Hod
Emergency number	+972 54-777-4926

2. HAZARD IDENTIFICATION

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

No known OSHA hazards

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product consists of three mixtures of ingredients. Each mixture is contained in its own housing that are mounted on the cartridge. The ingredients in each housing (such as dyes, detergents, buffer solutions and preservatives) are in concentrations not associated with human or environmental toxicity. The following table lists the chemicals present in the panel in concentrations of greater than 1%:

Name of substance	%	CAS#	EC#	Hazard
Propylene glycol	43.9	57-55-6	200-338-0	None

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Dulbecco's Phosphate Buffered Saline (DPBS)	2.44	NA		None
Dextran	3.83	9004-54-0	232-677-5	None

4. FIRST AID MEASURES

First-aid measures general	If you feel unwell, seek medical advice. 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. In all cases of doubt, or when symptoms persist, seek medical advice.
First-aid measures after skin contact	Rinse skin with water/shower. In all cases of doubt, or when symptoms persist, seek medical advice.
First-aid measures after eye contact	Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.
First-aid measures after ingestion	Contact a physician in case of ingestion.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	Use extinguishing media appropriate for surrounding fire.
Improper extinguishing media	None.
Fire and explosion hazards	Not flammable. This product does not present any fire or explosion hazard.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. For personal protection see section 8.
Environmental precautions	Do not let product enter drains.
Methods and materials for containment and cleaning up	Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.
Reference to other sections	For disposal see section 13.

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7. HANDLING AND STORAGE

This product is to be stored inside its packaging at +17°C to +27°C in a dry location not in direct sunlight.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Appropriate engineering controls

General industrial hygiene practice.

Personal protective equipment

- Eye/face protection - Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
- Skin protection – Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M) or equivalent

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M) or equivalent

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If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place.

Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

No special environmental precautions required.

9. PHYSICAL AND CHEMICAL PROPERTIES

	Dulbecco's Phosphate Buffered Saline (DPBS)	Dextran	Propylene glycol
a) Appearance Form	Colorless liquid	White crystalline	Colorless. clear, viscous liquid,
b) Odour	No data available	No data available	No data available
c) Odour threshold	No data available	No data available	No data available
d) pH	No data available	No data available	No data available
e) Melting point/freezing point	No data available	No data available	Melting point/range: -60 °C
f) Initial boiling point and boiling range	No data available	No data available	187 °C
g) Flash point	No data available	No data available	103 °C - closed cup
h) Evaporation rate	No data available	No data available	No data available
i) Flammability (solid, gas)	No data available	No data available	No data available
j) Upper/lower flammability or explosive limits	No data available	No data available	Upper explosion limit: 12,5 %(V) Lower explosion limit: 2,6 %(V)
k) Vapour pressure	No data available	No data available	0,11 hPa at 20 °C

l) Vapour density	No data available	No data available	2,63 - (Air = 1.0)
m) Relative density	No data available	No data available	1,036 g/mL at 25 °C
n) Water solubility	No data available	No data available	No data available
o) Partition coefficient: n-octanol/water	No data available	No data available	No data available
p) Auto-ignition temperature	No data available	No data available	No data available
q) Decomposition temperature	No data available	No data available	No data available
r) Viscosity	No data available	No data available	No data available
s) Explosive properties	No data available	No data available	No data available
t) Oxidizing properties	No data available	No data available	No data available

10. STABILITY AND REACTIVITY

	Dulbecco's Phosphate Buffered Saline (DPBS)	Dextran	Propylene glycol
Reactivity	No data available	No data available	No data available
Chemical stability	Stable under recommended storage conditions.	Stable under recommended storage conditions.	Stable under recommended storage conditions.
Possibility of hazardous reactions	No data available	No data available	No data available
Conditions to avoid	No data available	No data available	Exposure to moisture.
Incompatible materials	Strong oxidizing agents	Strong oxidizing agents	Acid chlorides, Acid anhydrides, Oxidizing agents, Chloroformates, Reducing agents
Hazardous decomposition products	Other decomposition products - no data available In the event of fire: see section 5	Other decomposition products - no data available In the event of fire: see section 5	Other decomposition products - no data available In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION

Name of substance	Acute Toxicity LD₅₀	Chronic toxicity
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Propylene glycol	20 g/kg (Rat)	Low-Classified by FDA as "generally recognized as safe (GRAS) as a food additive"
Dulbecco's Phosphate Buffered Saline (DPBS)	No data available	No data available
Dextran	10.7g/kg (Rat)	Not available

12. ECOLOGICAL INFORMATION

Toxicity	No data available
Persistence and degradability	No data available
Bioaccumulative potential	No data available
Mobility in soil	No data available
Results of PBT and vPvB assessment	PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
Other adverse effects	No data available

13. DISPOSAL CONSIDERATIONS

Specify the appropriate methods of disposal	To be disposed according to local regulations
Other Information	Used device with specimens from human blood should be disposed as infectious material.

14. TRANSPORT INFORMATION

UN number	Not subject to transport regulations
UN proper shipping name	Not relevant
US DOT	Not dangerous goods
Transport hazard class(es)	Not relevant
ICAO/IATA Shipping Name	Not dangerous goods
Packaging group	Not relevant not assigned to a packing group
Environmental hazards	None
Special precautions for user	No data available

15. REGULATORY INFORMATION

This MSDS was prepared in accordance with 29 CFR 1910.1200 and Regulation (EC) No.1272/2008

International Chemical Weapons Convention (CWC) Schedules of Toxic Chemicals and Precursors	Neither banned nor restricted
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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	Neither banned nor restricted
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	Neither banned nor restricted
REACH - Candidate List of Substances of Very High Concern for Authorization (Article 59).	This product does not contain substances of very high concern (Regulation (EC) No 1907/2006 (REACH), Article 57).
REACH - List of substances subject to authorization (Annex XIV)	Neither banned nor restricted
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	Neither banned nor restricted

US Federal Regulations

SARA 313

This product is not regulated by SARA.

Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see 40 CFR 61)

This product does not contain HAPs.

16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be inclusive and shall be used only as a guide. PixCell shall not be held liable for any damage resulting from handling or from contact with the above product.