



Safety Data Sheet

Product Name: HeartSine PAD-PAK Battery

Product Numbers: PAD-PAK-01

PAD-PAK-02

PAD-PAK-03

PAD-PAK-04

PAD-PAK-07

	Australian Sponsor	New Zealand Sponsor
Name:	Stryker Australia	Stryker New Zealand
Address:	8 Herbert Street St Leonards, NSW Australia 2065	511 Mt Wellington Highway, Auckland, New Zealand, 1060
Phone No:	+61 02 9467 1000	+64 09 573 1890
Fax No:	+61 02 9467 1010	+64 09 573 1891
Emergency:	Poisons Information Centre: Ph: 131 126	Poisons and hazardous chemicals emergency: Ph: 0800 764 766

Lithium primary cylindrical cell (coiled)

1. Identification of the product and of the company undertaking

Product details

Trade name:	Lithium primary cylindrical cell (coiled)
Voltage:	3.0 V (or multiples of this in case of multi-cell configurations)
Electrochemical system:	Lithium metal organic electrolyte manganese dioxide
Anode (negative):	Lithium metal
Cathode (positive):	Manganese dioxide

Type:	Lithium content per cell:
CR 2/3 AH	0.58 g
CR 123 A	0.58 g
CR 123 A -R	0.50 g
CR 2	0.26 g
CR 2 -R	0.29 g
CR P2	1.16 g (6.0 V battery, content per battery)

Supplier details

Address:	VARTA Microbattery GmbH Daimlerstr. 1 D-73479 Ellwangen/Jagst Germany
Emergency telephone number:	+49 7961 921 110 (VAC)

Legal Remark (U.S.A.)

Safety Data Sheets are a sub-requirement of the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard, 29 CFR Subpart 1910.1200. This Hazard Communication Standard does not apply to various subcategories including anything defined by OSHA as an "article". According to OSHA, Article means a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.

Because all of our batteries are defined as "articles", they are exempted from the requirements of the Hazard Communication Standard.

Legal remark (EU)

These batteries are no "substances" or "mixtures" according to Regulation (EC) No 1907/2006 EC. Instead they have to be regarded as "articles", no substances are intended to be released during handling. Therefore there is no obligation to supply a "safety data sheet according to Regulation (EC) 1907/2006, Article 31".

General remark

This Safety Data Sheet is provided as a service to our customers. The details presented are in accordance with our present knowledge and experiences. They are no contractual assurances of product attributes

2. Hazards identification

The battery is sealed hermetically. Thus, the ingredients have no hazard potential, except the battery is violated or dismantled.

If in case of mistreatment the ingredients are released, a spontaneously flammable gas mixture may be released under certain circumstances (measures according to chapter 4 to 6).

Attention: If batteries are treated wrong the danger of burns or bursts occurs. Batteries must not be heated above 100°C or incinerated. The battery contents must not get in contact with water. If the negative electrode gets in contact with water or humidity hydrogen gas is formed, which may inflame spontaneously.

3. Composition/information on ingredients

Ingredients

Contents	CAS No.	Hazard Categories	Hazard Statements	Material
2 - 5 %	7439-93-2	Water-react. 1 Skin Corr. 1B	H260 H314	Lithium
13 - 45 %	1313-13-9	Acute Tox. 4	H302 H332	Manganese dioxide
< 10 %	108-32-7			Propylene carbonate
< 10 %	110-71-4			1,2-Dimethoxy ethane
< 5 %	646-6-0			1,3-Dioxolane
< 5 %	33454-82-9			Lithium trifluoromethyl sulfonate
< 5 %	7791-03-9			Lithium perchlorate (CR 123 A -R and CR 2 -R only)

Heavy Metals

Contents	CAS No.	Material
< 1 mg/kg	7440-43-9	Cadmium
< 10 mg/kg	7439-92-1	Lead
< 0,1 mg/kg	7439-97-6	Mercury (none intentionally introduced, see Chapter 12)
< 5 mg/kg		Hexavalent Chromium (Cr6+)

Other Ingredients

Contents	CAS No.	Material
33 – 74 %		Steel and nickel
3 – 10 %		Plastic

SVHC substances according to REACH (Article 33)

Contents	EC No.	CAS No.	Material
> 0.1 %	203-794-9	110-71-4	1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)

For information to allow safe use: see section 7.

4. First-aid measures

Measures at accidental release

After inhalation:	Fresh air. Seek for medical assistance.
After skin contact:	Remove solid particles immediately. Flush affected areas with plenty of water (at least 15 min.). Remove contaminated cloth immediately. Seek for medical assistance.
After eye contact:	Flush the eye gently with plenty of water (at least 15 min.). Seek for medical assistance.
After ingestion:	Drink plenty of water. Avoid vomiting. Seek for medical assistance. No trials for neutralization.

5. Fire-fighting measures

Suitable extinguishing media:	Metal fire extinction powder, rock salt or dry sand shall be used. In case only water is available, it can be used in large amounts.
Extinguishing media with limited suitability:	Carbon dioxide (CO ₂) is not suitable. Water in small quantities may have adverse effects.
Special protection equipment during fire-fighting:	Protective clothing including breathing apparatus.
Special hazard:	Cells may explode and release metal parts. At contact of anode material with water extremely flammable hydrogen gas and caustic liquid are released.
Attention:	Do not let used extinguishing media penetrate into surface water or ground water. Dispose off properly.

6. Accidental release measures

Person related measures:	Wear personal protective equipment adapted to the situation (protection gloves, cloth, face protection, breathing protection).
Environment protection measures:	Bind released ingredients with powder (rock salt, sand). Dispose off according to the local law and rules. Avoid leached substances to penetrate into the earth, canalization or water.
Treatment for cleaning:	If battery casing is dismantled, small amounts of electrolyte may leak. Package the battery tightly including ingredients together with lime, sand or rock salt. Then clean with water.

7. Handling and storage

Guideline for safe handling:

Always follow the warning information on the batteries and in the manuals of devices. Only use the recommended battery types.
Keep batteries away from children.
For devices to be used by children, the battery casing should be protected against unauthorized access.
Unpacked batteries shall not lie about in bulk.
In case of battery change always replace all batteries by new ones of identical type and brand.
Do not swallow batteries.
Do not throw batteries into water.
Do not throw batteries into fire.
Do not short-circuit batteries.
Do not recharge primary batteries.
Do not open or disassemble batteries.

Storage:

Storage preferably at room temperature (approx. 20°C). Avoid large temperature changes. Avoid direct sunlight. At higher temperature the electrical performance may be reduced.

Storage of unpacked batteries can cause short circuit and heat generation.

Storage category according to TRGS 510:

It is recommended to consider the "Technical Rule for Hazardous Substances TRGS 510 - Storage of hazardous substances in nonstationary containers" and to handle lithium primary cylindrical cells according to storage category 11 ("combustible solids").

Storage of large amounts:

Follow the recommendations of the German Insurance Association (GDV - "Gesamtverband der Deutschen Versicherungswirtschaft e.V.") concerning lithium batteries:

http://vds.de/fileadmin/vds_publikationen/vds_3103_web.pdf

In case of storage of large amounts (used storage volume > 7 m³ and/or more than 6 pallets) batteries shall be stored in fire-resistant or separated rooms or areas (e.g. warehouse or container for hazardous materials). Mixed storage with other products is not allowed. The storage area shall be monitored by an automatic fire detection system, connected to a permanently manned place. A fire-extinguishing system shall reflect the extinguishing agents mentioned in chapter 5.

8. Exposure controls/personal protection

Under normal conditions (during discharge) release of ingredients does not occur.

9. Physical and chemical properties

Not applicable if closed.

10. Stability and reactivity

Dangerous reactions: When heated above 100°C the risk of rupture occurs.

11. Toxicological information

Under normal conditions (during charge and discharge) release of ingredients does not occur. In case of accidental release see information in chapter 2.

Swallowing of a battery can be harmful. Call the local Poison Control Centre for advice and follow-up.

12. Ecological information

Lithium primary cylindrical cells do not contain heavy metals as defined by the European directives 2006/66/EC Article 21.

For the state of California these batteries are considered as "free of perchlorate".

Mercury has not been "intentionally introduced (as distinguished from mercury that may be incidentally present in other materials)" in the sense of the U.S.A. "Mercury-Containing and Rechargeable Battery Management Act" (May 13 1996).

The Regulation on Mercury Content Limitation for Batteries promulgated on 1997-12-31 by the China authorities including the State Administration of Light Industry and the State Environmental Protection Administration defines 'low mercury' as 'mercury content by weight in battery as less than 0.025%', and 'mercury free' as 'mercury content by weight in battery as less than 0.0001%'. And therefore: Varta lithium primary button cells/batteries belong to the category of mercury-free battery (mercury content lower than 0.0001%).

13. Disposal considerations

USA: Lithium primary cylindrical cells are classified by the federal government as non-hazardous waste and are safe for disposal in the normal municipal waste stream.

In the European Union, manufacturing, handling and disposal of batteries is regulated on the basis of the DIRECTIVE 2006/66/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC. Customers find detailed information on disposal in their specific countries using the web site of the European Portable Batteries Association (http://www.epbaeurope.net/legislation_national.html).

Importers and users outside EU should consider the local law and rules.

In order to avoid short circuit and heating, used lithium primary cylindrical cells should never be stored or transported in bulk. Proper measures against short circuit are:

- Storage of batteries in original packaging
- Coverage of the terminals
- Embedding in dry sand

14. Transport information

General considerations

Lithium primary cylindrical cells manufactured by VARTA Microbattery are considered to be UN3090 Lithium Metal Batteries and are tested according to 38.3 of the "UN Manual of Tests and Criteria" for compliance with the requirements of special provisions ADR 188, IMDG 188, DOT / 49 CFR § 172.102, and the General Requirements of IATA DGR packing instruction 968. Positive test results as well as other relevant information required for transportation are stated in dedicated "Declarations of Conformity".

Transportations of cells or batteries packed with equipment or contained in equipment have to follow the appropriate regulations for UN3091.

A compilation of transport requirements for Lithium batteries can be found in:
<http://www.hyperedizioni.com/news/the-lithium-batteries/3139/The-lithium-batteries.html>

During the transportation of large amounts of batteries by ship, trailer or railway, do not store them in places of high temperature and do not allow them to be exposed to condensation. During the transportation do not allow the packaging to be damaged, as a damage of the packaging may cause fire. In the event packaging is damaged, special procedures must be used including inspection and repackaging if necessary and handle with care.

USA

Primary (non-rechargeable) lithium batteries and cells are forbidden for transport aboard passenger carrying aircraft. The outside of each package that contains primary (non-rechargeable) lithium batteries or cells must be marked "PRIMARY LITHIUM BATTERIES-FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT" on a background of contrasting color.

IEC 60086-1

Code of practice for packaging and shipment of primary batteries given in IEC 60086-1:

The packaging shall be adequate to avoid mechanical damage during transport, handling and stacking. The materials and pack design shall be chosen so as to prevent the development of unintentional electrical conduction, corrosion of the terminals and ingress of moisture.

Shock and vibration shall be kept to a minimum. For instance, boxes should not be thrown off trucks, slammed into position or piled so high as to overload battery containers below. Protection from inclement weather should be provided.

15. Regulatory information

Marking consideration:	According to "DIRECTIVE 2006/66/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC" the batteries have to be marked with the crossed bin. For the state of California the battery types CR 123 A -R and CR 2 -R have to be marked as "containing perchlorate".
International safety standards:	The basis cells are recognized components according to UL 1642.
Water hazard class:	The regulations of the German Federal Water Management Act (WHG) are not applicable as Lithium primary batteries are articles and not substances, thus there is no risk of water pollution, except the batteries are violated or dismantled..

16. Other information

Full text of Hazard Statements referred to under section 3

H225	Highly flammable liquid and vapour.
H260	In contact with water releases flammable gases which may ignite spontaneously.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H360FD	May damage fertility. May damage the unborn child.

Note: Date of issue of the transport regulations: ADR 2015, RID 2015, IATA 2015 (55th edition), IMDG 2014, DOT / 49 CFR 2014.
Latest covered modification of the European Battery Directive 2006/66/EC: Directive 2013/56/EU.

Issued by: VARTA Microbattery GmbH
Quality / Environmental Management

Contact: <http://contact.varta-microbattery.com>

Updates: Current SDS can be downloaded from VARTA's web page following the link:
<http://www.varta-microbattery.com/en/news-downloads/downloads.html>



Test Summary

in accordance with UN Manual of Tests
and Criteria Part III, subsection 38.3

Manufacturer information

Name	PMBL Limited
Address	Unit D, Leach Road Chard Business Park Chard, Somerset TA20 1FA
Phone	+44 (0) 1460 66366
E-mail	solutions@pml.co.uk
Website	www.pml.co.uk

Description of the product

Adult battery pack assembly. Disposable single-use battery assembly, containing 6 lithium metal cells (LiMnO₂ 18V)

Product test information

Each product below has been tested and was found to be compliant with the UN Manual of Tests and Criteria, Part III, subsection 38.3.

Product	Mass	Lithium content	Revision of UN Manual of Tests and Criteria ST/SG/AC.10/11	Report number	Report date
6/CR123A Battery	100g	3.48g	Revision 4, Amendment 2 (2007)	09-34026	01 Mar 2010

List of tests conducted and results

Test	Result	Test	Result
T1. Altitude test	Pass	T5. External short circuit	Pass
T2. Thermal test	Pass	T6. Impact	Pass
T3. Vibration	Pass	T7. Overcharge	N/A
T4. Shock	Pass	T8. Forced discharge	Pass

Test laboratories

The tests were conducted by the following test laboratory:

Name	Trace Laboratories, Inc.
Address	1150 West Euclid Avenue Palatine, Illinois 60067, USA
Phone	+1 (847) 934-5300
E-mail	info@tracelabs.com
Website	www.tracelabs.com

Note – Following their acquisition by NTS, Trace Laboratories are now known as NTS Chicago.

Phone - +1 (800) 270-2516

Email – sales@nts.com



Test Summary
in accordance with UN Manual of Tests
and Criteria Part III, subsection 38.3

Approved by	Rebecca Funston, PhD
Title	Senior Manager, Regulatory Affairs & Quality Assurance
Signature	
Date	16 Jan 2020.