

1. Product and company identification

Product identifier

Trade name: 2B2- Lithium-Ionen-Zelle

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

General use: Lithium-ion battery for orthopedic procedures
For commercial user only.

Details of the supplier of the safety data sheet

Company name: Otto Bock Health Care
Street/POB-No.: 3820 W. Great Lakes Drive
Postal Code, city: Salt Lake City, UT 84120
USA

WWW: www.ottobockus.com

Telephone: +1 (801) 956-2400

Telefax: +1 (801) 956-2401

Department responsible for information:

Quality Department,
Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time),
Email: USRegulatory@ottobock.com

Additional information: Corporate headquarters:
Ottobock SE & Co. KGaA
Max-Näder-Straße 15
Duderstadt
Germany

Emergency phone number

CHEMTREC, Telephone: +1 (800) 424-9300

Transport:

CONSULTANK Lutz Harder GmbH (Contract QUALI003)

Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)

2. Hazards identification

Emergency overview

Appearance: Physical state at 68 °F and 101.3 kPa: solid

Odor: No data available

Classification: Article not subject to hazard labelling or classification.

Regulatory status

This material is not considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified

The battery is hermetically sealed.

danger of releasing ingredients, mentioned in section 3, by damaging the battery

- with strong mechanical action,
- in case of heating and/or Fire,
- with influence of water,
- short circuit.

Hazard statements:

Suspected of causing cancer. May cause an allergic skin reaction.

In contact with water releases flammable gases. Formation of Hydrogen fluoride.

Toxic if swallowed. Causes severe skin burns and eye damage. Causes damage to organs through prolonged or repeated exposure. Vapors may cause drowsiness and dizziness.

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Lithium-ion battery - Article, Cell.

The chemical materials are stored in a hermetically sealed metal case.

Contains Polyvinylidene fluoride, Iron, Graphite and Carbon, Copper, Aluminium.

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 207803-51-8	Lithium nickel cobalt aluminium dioxide	20 - 60 %	Sensitization - skin - Category 1. Carcinogenicity - Category 2.
CAS 141-78-6	Ethyl acetate	5 - 25 %	Flammable Liquid - Category 2. Eye Irritation - Category 2A. Specific Target Organ Toxicity (Single Exposure) - Category 3.
CAS 96-49-1	Ethylene carbonate	5 - 25 %	Eye Damage - Category 1.
CAS 616-38-6	Dimethyl carbonate	5 - 25 %	Flammable Liquid - Category 2.
CAS 21324-40-3	Lithium hexafluorophosphate	5 - 25 %	Acute Toxicity - oral - Category 3. Skin Corrosion - Category 1A. Eye Damage - Category 1. Specific Target Organ Toxicity (Repeated Exposure) - Category 1.

Additional information: The maximum workplace exposure limits are, where necessary, listed in section 8.

4. First aid measures

General information: In case of damaged battery cases: Release of dangerous ingredients possible. In case of heating: The product may release harmful vapors by heating..

In case of inhalation: In case of damaged battery cases:
Provide fresh air. Keep victim at rest in half upright position. Seek medical attention.

Following skin contact: In case of damaged battery cases / In case of exposure to hazardous ingredients:
Immediately clean with water and soap and, if available, apply a generous amount of polyethylene glycol 400 or protective skin cream.
Seek medical attention.

After eye contact: In case of damaged battery cases / In case of exposure to hazardous ingredients:
Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Afterwards, consult an ophthalmologist immediately.

After swallowing: In case of damaged battery cases / In case of exposure to hazardous ingredients:
Drink large quantities of water.
Do not induce vomiting. Risk of perforation in case of vomiting!
Immediately get medical attention. Do not try to neutralize.

Most important symptoms/effects, acute and delayed

No hazardous reaction when handled and stored according to provisions.
In case of damaged battery cases / In case of exposure to hazardous ingredients:
May cause an allergic skin reaction. Vapors may cause drowsiness and dizziness. Toxic if swallowed. Causes severe skin burns and eye damage. May cause cancer. Causes damage to organs through prolonged or repeated exposure. Other symptoms: respiratory complaints, irritation.

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

Not applicable

Auto-ignition temperature: No data available

Suitable extinguishing media:

fire extinguisher class D, metal fire extinguisher.

Specific hazards arising from the chemical

> 212 °F: Danger of explosion!

In case of fire may be liberated: Toxic metal oxide smoke, toxic gases/vapors, hydrogen fluoride, carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.

6. Accidental release measures

Personal precautions:

In case of damaged battery cases:
Eliminate all ignition sources if safe to do so.
Provide fresh air. Avoid exposure.
Wear appropriate protective equipment.
In case of development of vapors or dust:
Do not inhale vapors or dust particles.

Environmental precautions:

Product contains heavy metals. Discharge into the environment must be avoided. Special pre-treatment is necessary.

Methods for clean-up:

Take up mechanically. Dispose of waste according to applicable legislation.
Avoid generation of dust.

Information about electrolyte

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents) and place in closed containers for disposal. Final cleaning.

7. Handling and storage

Handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed.

Avoid damage to the battery casing.

In case of damaged battery cases: Avoid exposure.

Precautions against fire and explosion:

Avoid short circuit. Avoid open flames. Avoid damage to the battery casing.

In case of damaged battery cases: Eliminate all ignition sources if safe to do so.

Storage

Requirements for storerooms and containers:

Provide adequate ventilation. Store in a dry place.

Protect from: humidity, heat, UV-radiation/sunlight

charging temperature: 32 °F up to 113 °F.

discharging temperature: -4 °F up to 140 °F.

Storage temperature: -4 °F up to 113 °F.

Air humidity: 0% up to 80%.

Hints on joint storage:

Do not store together with strong acids, strong oxidizing agents.

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
7782-42-5	Graphite	USA: ACGIH: TWA	2 mg/m ³ (respirable fraction)
		USA: IDLH: TWA	1,250 mg/m ³
		USA: NIOSH: TWA	2.5 mg/m ³ (respirable fraction)
		USA: OSHA: TWA	15 mg/m ³ (total dust)
		USA: OSHA: TWA	5 mg/m ³ (respirable fraction)
141-78-6	Ethyl acetate	USA: ACGIH: TWA	1,440 mg/m ³ ; 400 ppm
		USA: IDLH: TWA	2,000 ppm [10% LEL]
		USA: NIOSH: TWA	1,400 mg/m ³ ; 400 ppm
		USA: OSHA: TWA	1,400 mg/m ³ ; 400 ppm

Additional information:

The chemical materials are stored in a sealed battery case.

Engineering controls

In case of damaged battery cases: Provide adequate ventilation.

In case of development of vapors or dust:

The use of local exhaust ventilation is recommended.

See also information in chapter 7, section storage.

Personal protection equipment (PPE)

Eye/face protection:

In case of damaged battery cases:

Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.

Skin protection:	In case of damaged battery cases: Protective gloves according to OSHA Standard - 29 CFR: 1910.138. Glove material: rubber - breakthrough time >480 min. Observe glove manufacturer's instructions concerning penetrability and breakthrough time.
Respiratory protection:	Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. The filter class must be suitable for the maximum contaminant concentration (gas/vapor/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, closed-circuit breathing apparatus must be used!
General hygiene considerations:	In case of damaged battery cases: Do not inhale vapors or dust particles. Avoid exposure. Keep away from sources of ignition - No smoking. Wash hands before breaks and after work. When using do not eat or drink. Keep away from food, drink and animal feedingstuffs. Work place should be equipped with a shower and an eye rinsing apparatus.

Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Physical state at 68 °F and 101.3 kPa: solid
Odor:	No data available
Odor threshold:	No data available
pH:	Not applicable
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	Not applicable
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Density:	No data available
Solubility:	No data available
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	> 212 °F: Danger of explosion!
Additional information:	weight: 45 g

10. Stability and reactivity

Reactivity:	In case of damaged battery cases: May be corrosive to metals.
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Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions:

Fire hazard in case of technical defects.

In case of damaged battery cases:

Flammable liquid and vapor. (Electrolyte)

After contact with water: formation of Hydrogen fluoride.

Conditions to avoid:

In case of strong heating: development of gas/vapor possible.

Protect from: humidity, heat, UV-radiation/sunlight

Avoid short circuit. Avoid damage to the battery casing.

In case of damaged battery cases:

Keep away from sources of ignition - No smoking.

Incompatible materials:

Keep away from strong acids and strong oxidizing agents.

In case of damaged battery cases: Keep away from water.

Hazardous decomposition products:

No decomposition when used properly.

Thermal decomposition:

> 212 °F: Danger of explosion!

11. Toxicological information

Toxicological tests

Toxicological effects:

Acute toxicity (oral): Lack of data.

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Lack of data.

Serious eye damage/irritation: Lack of data.

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Lack of data.

Germ cell mutagenicity/Genotoxicity: Lack of data.

Carcinogenicity: Lack of data.

Reproductive toxicity: Lack of data.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Lack of data.

Specific target organ toxicity (repeated exposure): Lack of data.

Aspiration hazard: Lack of data.

Other information:

In case of damaged battery cases / In case of exposure to hazardous ingredients:

Suspected of causing cancer. May cause an allergic skin reaction. Toxic if swallowed.

Causes severe skin burns and eye damage. Causes damage to organs through prolonged or repeated exposure. Vapors may cause drowsiness and dizziness.

12. Ecological information

Ecotoxicity

Further details:

No data available

Mobility in soil

No data available

Persistence and degradability

Further details: Product is not biodegradable.

Additional ecological information

General information: Product contains heavy metals. Discharge into the environment must be avoided. Special pre-treatment is necessary.

13. Disposal considerations

Product

Recommendation: Product contains Metallic oxides containing heavy metals.
Special waste. Dispose of waste according to applicable legislation.

Package

Recommendation: Dispose of waste according to applicable legislation.
Packing can be recycled or disposed of.

14. Transport information

UN number

ADR/RID, IMDG, IATA-DGR:
UN 3480

UN proper shipping name

ADR/RID, IMDG, IATA-DGR:
UN 3480, LITHIUM ION BATTERIES

Transport hazard class(es)

ADR/RID: Class 9, Code: M4
IMDG: Class 9, Subrisk -
IATA-DGR: Class 9

Packing group

ADR/RID, IATA-DGR: not applicable
IMDG: -

Environmental hazards

Marine pollutant: no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available



USA: Department of Transportation (DOT)

Identification number: UN3090
 Proper shipping name: UN 3090, LITHIUM METAL BATTERIES
 Hazard class or Division: 9
 Labels: 9
 Special Provisions: 388, 422, A54
 Packaging – Exceptions: 185
 Packaging – Non-bulk: 185
 Packaging – Bulk: 185
 Quantity limitations – Passenger aircraft / rail: Forbidden
 Quantity limitations – Cargo only: 35 kg
 Vessel stowage – Location: A
 Vessel stowage – Other: 156



Sea transport (IMDG)

UN number: UN 3480
 Proper shipping name: UN 3480, LITHIUM ION BATTERIES
 Class or division, Subsidiary risk: Class 9, Subrisk -
 Packing Group: -
 EmS: F-A, S-I
 Special Provisions: 188 230 310 348 376 377 384 387
 Limited quantities: 0
 Excepted quantities: E0
 Package - Instructions: P903, P908, P909, P910, P911, LP903, LP904, LP905, LP906
 Package - Provisions: -
 IBC - Instructions: -
 IBC - Provisions: -
 Tank instructions - IMO: -
 Tank instructions - UN: -
 Tank instructions - Provisions: -
 Stowage and handling: Category A. SW19
 Properties and observations: Electrical batteries containing lithium ion may react (e.g., flame, heat, emission of toxic, corrosive or flammable gases or vapours) or disassemble due to damage, defects or short circuit.
 Marine pollutant: no
 Segregation group: none

Air transport (IATA)

UN/ID number: UN 3480
 Proper shipping name: UN 3480, LITHIUM ION BATTERIES
 Class or division, Subsidiary risk: Class 9
 Hazard label: Lithium batt or Sodium-ion batt
 Excepted Quantity Code: E0
 Passenger and Cargo Aircraft: Ltd.Qty.: Forbidden
 Passenger and Cargo Aircraft: Forbidden
 Cargo Aircraft only: Pack.Instr. See 965 - Max. Net Qty/Pkg. See 965
 Special Provisions: A88 A99 A154 A183 A201 A213 A331 A334 A802
 Emergency Response Guide-Code (ERG): 12FZ

15. Regulatory information

National regulations - U.S. Federal Regulations

This product is an article as defined by TSCA regulations, and is exempt from TSCA inventory listing requirements.

National regulations - U.S. State Regulations

Ethyl acetate: Delaware Air Quality Management List:
DRQ: 5000 - RQ State: Federal Regulations Apply
Idaho Air Pollutant List:
Title 585: AAC: 70 - EL: 93,3 - OEL: 1400 - Title 586: -
Main Hazardous Air Pollutants:
Me 2005: HAP - Hap Rpt: 20000
Massachusetts Haz. Substance codes: 2,4,5,6 F8
Minnesota Haz. Substance:
Codes: AO - Ratings: 6.83 - Status: Title III.
New York List of Hazardous Substances:
RQ-Air: 5000 - RQ-Land: 1 - Note: No Note Associated with this chemical.
Pennsylvania Haz. Substance code: E
Washington Air Contaminant:
TWA: 400 ppm - 1400 mg

National regulations - Canada

Graphite: DSL: listed
Ethyl acetate: DSL: listed
Ethylene carbonate: DSL: listed
Dimethyl carbonate: DSL: listed
Lithium hexafluorophosphate: NDSL: listed
Polyvinylidene fluoride: DSL: listed
Lithium hexafluorophosphate: NDSL: listed

National regulations - Great Britain

Hazchem-Code: 2Y

16. Other information

Hazard rating systems:



NFPA Hazard Rating:

Health: 0 (Minimal)

Fire: 1 (Slight)

Reactivity: 1 (Slight)

HMIS Version III Rating:

Health: 0 (Minimal)

Flammability: 1 (Slight)

Physical Hazard: 1 (Slight)

Personal Protection: X = Consult your supervisor

In case of damaged battery cases: NFPA/HMIS: F2

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	1
	X

Abbreviations and acronyms:

Acute Toxicity: Acute toxicity
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
AS/NZS: Australian Standards/New Zealand Standards
Carcinogenicity: Carcinogenicity
CAS: Chemical Abstracts Service
CFR: Code of Federal Regulations
CLP: Classification, Labelling and Packaging
DMEL: Derived minimal effect level
DNEL: Derived no-effect level
EC: European Community
EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods
EN: European Standard
EQ: Excepted quantities
Eye Damage: Eye damage
Eye Irritation: Eye irritation
Flammable Liquid: Flammable liquid
IATA: International Air Transport Association
IATA-DGR: International Air Transport Association – Dangerous Goods Regulations
IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
IMDG Code: International Maritime Dangerous Goods Code
IMO: International Maritime Organization
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
OEL: Occupational Exposure Limit Value
OSHA: Occupational Safety and Health Administration
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted no-effect concentration
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
Sensitization - skin: Skin sensitisation
Skin Corrosion: Skin corrosion
STOT RE: Specific target organ toxicity - repeated exposure
STOT SE: Specific target organ toxicity - single exposure
TLV: Threshold Limit Value
TRGS: Technical Rules for Hazardous Substances
TSCA: Toxic Substance Control Act
UN: United Nations
UV: Ultraviolet
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit

Reason of change: Changes in section 14: IMDG 2025

Date of first version: 2/28/2019

Department issuing data sheet

Contact person: see section 1: Department responsible for information

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.