

625B11e - Lithium-Ion Akkupack for Knee Joint in equipment

Material number 625B11e

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1. Product and company identification

Product identifier

Trade name: 625B11e - Lithium-Ion Akkupack for Knee Joint in equipment

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: The following products contain this batterie:
3B1 - Genium - Bionic Prosthetic System
3B1=OB - Genium (Service/Test)
3B1=ST - Genium, Screw Top Version
3B5-X2 - X2, Bionic Prosthetic System
3B5-X2=OB - X2, Bionic Prosthetic System (Service/Test)
3B5-X2=ST - X2, Bionic Prosthetic System, Screw Top Version
4E64 - Powermodul
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: Form: solid
Odor: odorless
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:

Limited evidence of a carcinogenic effect. May cause sensitization by skin contact.

Electrolyte, organic:

Flammable. After contact with water: formation of Hydrogen fluoride.

Vapors irritate eyes, mucous membranes and respiratory system. Vapors may cause drowsiness and dizziness.

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Lithium-ion battery - Article.

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

Contains aluminium (10 - 40%), Graphite (10 - 20%), Carbon (10 - 20%), Copper (5 - 15%).

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 12190-79-3	Cobalt lithium dioxide	20 - 40 %	Respiratory Sensitizer - Category 1. Sensitization - skin - Category 1. Carcinogenicity - Category 2.
CAS -	Electrolyte, organic	5 - 20 %	Flammable Liquid - Category 3.

4. First aid measures

General information: In case of damaged battery cases: Release of dangerous ingredients possible. In case of heating: development of gas/vapor possible.

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:
Clean with plenty of water. If possible, also wash with polyethylene glycol 400.
Take off immediately all contaminated clothing.

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. Irritation. May cause drowsiness or dizziness.

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

No data available

Auto-ignition temperature: No data available

Suitable extinguishing media:

dry chemical powder, Extinguishing agent on the basis of sodium chloride, sodium hydrogen carbonate, limestone, or with metal extinguishing powder.

Extinguishing media which must not be used for safety reasons:

Water, foam.

Specific hazards arising from the chemical

In case of fire may be liberated: hydrogen fluoride, carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

Wear a self-contained breathing apparatus and chemical protective clothing.

6. Accidental release measures

Personal precautions:

in case of damaged battery cases:
Remove all sources of ignition.
Provide fresh air. Avoid contact with skin and eyes.
Do not inhale vapors or dust particles.
Wear personal protection equipment.

Environmental precautions:

Discharge into the environment must be avoided.

Methods for clean-up:

Take up mechanically. Dispose of waste according to applicable legislation.
Avoid generation of dust.
Electrolyte, organic: Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents) and place in closed containers for disposal. Final cleaning.



SAFETY DATA SHEET

according to 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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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 damage to the battery casing.

in case of damaged battery cases: Remove all sources of ignition.

Storage

Requirements for storerooms and containers:

Provide adequate ventilation. Store in a dry place.

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

storage temperature: -68 °F up to 95 °F.

air humidity: 45% up to 85%.

Hints on joint storage:

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

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8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
7429-90-5	Aluminium	USA: ACGIH: TWA	1 mg/m ³
		USA: NIOSH: Ceiling	5 mg/m ³ (inhalable fraction)
		USA: NIOSH: TWA	10 mg/m ³ (inhalable fraction)
		USA: NIOSH: TWA	5 mg/m ³ (inhalable fraction)
		USA: OSHA: TWA	15 mg/m ³ (inhalable fraction)
		USA: OSHA: TWA	5 mg/m ³ (respirable fraction)
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)
7440-44-0	Carbon	USA: ACGIH: TWA	10 mg/m ³
			(Dust limit value, inhalable fraction)
		USA: ACGIH: TWA	3 mg/m ³
			(Dust limit value, respirable fraction)
		USA: OSHA: TWA	15 mg/m ³ (inhalable fraction)
		USA: OSHA: TWA	5 mg/m ³ (respirable fraction)
7440-50-8	Copper	USA: ACGIH: TWA	0.2 mg/m ³ (Smoke)
		USA: ACGIH: TWA	1 mg/m ³
			(Dusts and mist calculated as Cu)
		USA: IDLH: TWA	100 Cu/m ³ (dust and mist)
		USA: IDLH: TWA	100 Cu/m ³ (Smoke)
		USA: NIOSH: TWA	1 mg/m ³
		USA: OSHA: TWA	0.1 mg/m ³ (Smoke; calculated as Cu)
		USA: OSHA: TWA	1 mg/m ³
			(Dusts and mist calculated as Cu)

Additional information: The chemical materials are stored in a sealed battery case.

Engineering controls

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: In case of damaged battery cases:
Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded.
Half mask with particle filter P according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.
If necessary: When vapors form combination filter Use filter type A, B, K according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.

General hygiene considerations:
Handle in accordance with good industrial hygiene and safety practice.
In case of damaged battery cases:
Do not inhale vapors or dust particles.
Avoid contact with skin and eyes.
Keep away from sources of ignition - No smoking.
Wash hands before breaks and after work.

Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Form: solid
Odor:	odorless
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	No data available
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:	No data available
Additional information:	No data available

10. Stability and reactivity

Reactivity:	No data available
Chemical stability:	Stable under recommended storage conditions. Not readily combustible.

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:

> 212 °F: Generation of heat. Ignition.
Protect from: humidity, heat, UV-radiation/sunlight
Avoid short circuit. Avoid damage to the battery casing.
In case of damaged battery cases:
Protect from: water.
Keep away from sources of ignition - No smoking.

Incompatible materials:

Keep away from strong acids and strong oxidizing agents.

Hazardous decomposition products:

In case of fire may be liberated: hydrogen fluoride, carbon monoxide and carbon dioxide.

Thermal decomposition:

No data available

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:

No hazardous reaction when handled and stored according to provisions.
In case of damaged battery cases:
cobalt lithium dioxide: Limited evidence of a carcinogenic effect. May cause sensitization by skin contact.
Electrolyte, organic: Vapors irritate eyes, mucous membranes and respiratory system.
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: Discharge into the environment must be avoided.

13. Disposal considerations

Product

Recommendation: 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 3481

UN proper shipping name

ADR/RID, IMDG, IATA-DGR:
UN 3481, LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT

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



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USA: Department of Transportation (DOT)

Identification number: UN3481
Proper shipping name: UN 3481,
LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT
Hazard class or Division: 9
Labels: 9
Special Provisions: 181, 360, 388, 422, A54
Packaging – Exceptions: 185
Packaging – Non-bulk: 185
Packaging – Bulk: 185
Quantity limitations – Passenger aircraft / rail:
5 kg
Quantity limitations – Cargo only: 35 kg
Vessel stowage – Location: A
Vessel stowage – Other: 156



Sea transport (IMDG)

UN number: UN 3481
Proper shipping name: UN 3481, LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT
Class or division, Subsidiary risk: Class 9, Subrisk -
Packing Group: -
EmS: F-A, S-I
Special Provisions: 188 230 310 348 360 376 377 384 387 390
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 3481
Proper shipping name: UN 3481, LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT
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: Pack.Instr. 967 - Max. Net Qty/Pkg. 5 kg
Cargo Aircraft only: Pack.Instr. 967 - Max. Net Qty/Pkg. 35 kg
Special Provisions: A48 A88 A99 A154 A181 A185 A213 A220
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

No data available

National regulations - Canada

Cobalt lithium dioxide: DSL: listed
Aluminium: DSL: listed
Graphite: DSL: listed
Carbon: DSL: listed
Copper: DSL: listed

National regulations - Great Britain

Hazchem-Code: 2Y

16. Other information

Hazard rating systems:



NFPA Hazard Rating:

Health: 0 (Minimal)
Fire: 1 (Slight)
Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 0 (Minimal)
Flammability: 1 (Slight)
Physical Hazard: 0 (Minimal)
Personal Protection: X = Consult your supervisor

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

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0
	X



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Abbreviations and acronyms:

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
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
Respiratory Sensitizer: Sensitisation to the respiratory tract
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
Sensitization - skin: Skin sensitisation
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: 10/26/2010

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.