

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: 13/625/757 - Lithium-ion battery

This safety data sheet pertains to the following products:

13E210 - Power Pack für DynamicArm

625B11 - Lithium-Ion Akkupack für Kniegelenk

757B35=3 - MyoEnergy Integral

757VAB1 - VASI Li-Ion Batterie

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

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

1.3 Details of the supplier of the safety data sheet

Company name: Ottobock SE & Co. KGaA

Street/POB-No.: Max-Näder-Straße 15

Postal Code, city: 37115 Duderstadt

Germany

E-mail: export@ottobock.de

Telephone: +49 (0)5527 848-0

Telefax: +49 (0)5527 72330

Department responsible for information:

Arbeitssicherheit, Telephone: 05527-848-0, e-mail: Arbeitssicherheit@ottobock.de

Only available during office hours.

1.4 Emergency telephone number

Telephone: +49 (0)5527 848-0

Transport:

CONSULTANK Lutz Harder GmbH (Contract QUALI003)

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Article not subject to hazard labelling or classification.

2.2 Label elements

Labelling (CLP)

not applicable

2.3 Other hazards

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 sensitisation by skin contact.

Electrolyte, organic:

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

After contact with water: formation of Hydrogen fluoride (Fatal in contact with skin. Fatal if swallowed. Fatal if inhaled. Causes severe skin burns and eye damage.).

Endocrine disrupting properties, Results of PBT and vPvB assessment:

No data available

SECTION 3: Composition/information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterisation:

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%).

Hazardous ingredients:

Identifiers	Designation Classification	Content
EC No. 235-362-0 CAS 12190-79-3	Cobalt lithium dioxide Resp. Sens. 1; H334. Skin Sens. 1; H317. Carc. 2; H351.	20 - 40 %
EC No. - CAS -	Electrolyte, organic Flam. Liq. 3; H226.	5 - 20 %

Full text of H- and EUH-statements: see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

In case of damaged battery cases: Release of dangerous ingredients possible.

In case of heating: Generates dangerous gases or fumes in contact with.

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 and wash it before reuse. Seek medical treatment in case of troubles.

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.

Remove contact lenses, if present and easy to do. Continue rinsing. Afterwards, consult an ophthalmologist immediately.

After swallowing: Induce vomiting when the affected person is not unconscious.
 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.

4.2 Most important symptoms and effects, both 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.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Extinguishing 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.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment for firefighters:

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

In case of damaged battery cases:
 Remove all sources of ignition.
 Provide fresh air. Avoid contact with skin and eyes.
 Wear suitable gloves. Take off immediately all contaminated clothing and wash it before reuse.
 In case of development of vapours or dust:
 Do not inhale vapours or dust particles.

6.2 Environmental precautions

Discharge into the environment must be avoided.

6.3 Methods and material for containment and cleaning up

Take up mechanically. Dispose of waste according to applicable legislation.
 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.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Provide adequate ventilation. Store in a dry place.

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

Storage temperature: -20 °C up to 35 °C.

Air humidity: 45% up to 85%.

Hints on joint storage:

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

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

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

8.2 Exposure controls

In case of damaged battery cases: Provide adequate ventilation.

In case of development of vapours or dust:

The use of local exhaust ventilation is recommended.

Personal protection equipment

Occupational exposure controls

Respiratory protection:

In case of damaged battery cases:

Respiratory protection must be worn whenever the WEL levels have been exceeded.

Half mask with particle filter P according to EN 143.

If necessary: When vapours form combination filter Use filter type A, B, K according to EN 14387.

Hand protection:

In case of damaged battery cases:

Protective gloves according to BS EN 374.

Glove material: rubber - breakthrough time >480 min.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection:

In case of damaged battery cases:

Tightly sealed goggles according to BS EN ISO 16321-1:2022.

General protection and hygiene measures:

In case of damaged battery cases:

Do not inhale vapours 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 "6.2 Environmental precautions".

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state at 20 °C and 101.3 kPa	Form: solid
Colour:	No data available
Odour:	odourless
Odour threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flammability:	No data available
Upper/lower flammability or explosive limits:	No data available
Flash point/flash point range:	No data available
Decomposition temperature:	No data available
pH:	No data available
Viscosity, kinematic:	No data available
Solubility:	No data available
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	No data available
Vapour density:	No data available
Particle characteristics:	Not applicable

9.2 Other information

Explosive properties:	No data available
Oxidizing characteristics:	No data available
Auto-ignition temperature:	No data available
Evaporation rate:	No data available
Additional information:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

refer to 10.3

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Fire hazard in case of technical defects.

In case of damaged battery cases:

Electrolyte, organic: Flammable.

After contact with water: formation of Hydrogen fluoride.

10.4 Conditions to avoid

> 100 °C: Generation of heat. Ignition.

Protect from: humidity, water, marine water, 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. Protect from: water.

10.5 Incompatible materials

Keep away from strong acids and strong oxidizing agents.

In case of damaged battery cases:

Electrolyte, organic: Keep away from water.

10.6 Hazardous decomposition products

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

Thermal decomposition: No data available

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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.

11.2 Information on other hazards

Endocrine disrupting properties: No data available

Other information:

- In case of damaged battery cases:
- cobalt lithium dioxide:
- Limited evidence of a carcinogenic effect. May cause sensitisation by skin contact.
- (Cobalt: LDLo Guinea pig oral 20 mg/kg)
- Electrolyte, organic:
- Vapours irritate eyes, mucous membranes and respiratory system.
- Vapours may cause drowsiness and dizziness.
- After contact with water: formation of Hydrogen fluoride (Fatal in contact with skin. Fatal if swallowed. Fatal if inhaled. Causes severe skin burns and eye damage.).

SECTION 12: Ecological information

12.1 Toxicity

Further details: No data available

12.2 Persistence and degradability

Further details: Product is not biodegradable.

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:
No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

General information: Discharge into the environment must be avoided.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number: 16 06 05 = batteries and accumulators

Recommendation: Dispose of waste according to applicable legislation.

Package

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

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID, ADN, IMDG, IATA-DGR:

UN 3480

14.2 UN proper shipping name

ADR/RID, ADN, IMDG, IATA-DGR:

UN 3480, LITHIUM ION BATTERIES

14.3 Transport hazard class(es)

ADR/RID, ADN:

Class 9, Code: M4

IMDG:

Class 9, Subrisk -

IATA-DGR:

Class 9

14.4 Packing group

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

IMDG:

-

14.5 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to the criteria of the UN model regulations.

Marine pollutant - IMDG:

no



14.6 Special precautions for user

Land transport (ADR/RID)

Warning board: RID: Kemmler-number 90, UN number UN 3480
 Hazard label: 9A
 Special Provisions: 188 230 310 348 376 377 387 636
 Limited quantities: 0
 EQ: E0
 Package - Instructions: P903 P908 P909 P910 P911 LP903 LP904 LP905 LP906
 Tunnel restriction code: E

Inland waterway craft (ADN)

Hazard label: 9A
 Special Provisions: 188 230 310 348 376 377 387 636
 Limited quantities: 0
 EQ: E0
 Equipment necessary: PP

Sea transport (IMDG)

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 encased in a rigid metallic body. Lithium ion batteries may also be shipped in or packed with equipment. Electrical lithium batteries may cause fire due to an explosive rupture of the body caused by improper construction or reaction with contaminants.
 Segregation group: none

Air transport (IATA)

Hazard label: Miscellaneous Lithium 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 A164 A183 A201 A213 A331 A334 A802
 Emergency Response Guide-Code (ERG): 9F

14.7 Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations - EC member states

Further regulations, limitations and legal requirements:

Aluminium: Regulation (EU) No 2019/1148 (marketing and use of explosives precursors)

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

SECTION 16: Other information

Wording of the H-phrases under paragraph 2 and 3:

H226 = Flammable liquid and vapour.

H317 = May cause an allergic skin reaction.

H334 = May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H351 = Suspected of causing cancer.

Reason of change: Changes in section 14: IATA-DGR 2023

General revision

Date of first version: 26/10/2010

Department issuing data sheet: see section 1: Department responsible for information

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
- Carc.: 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
- EN: European Standard
- EQ: Excepted quantities
- EU: European Union
- Flam. Liq.: 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
- 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
- REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
- Resp. Sens.: Sensitisation to the respiratory tract
- RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
- Skin Sens.: 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

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.