

757B35=1 - MyoEnergy Integral

Material number 757B35=1

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1. Product and company identification

Product identifier

Trade name: 757B35=1 - MyoEnergy Integral

Relevant identified uses of the substance or mixture and uses advised againstGeneral 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
USAWWW: www.ottobockus.com

Telephone: +1 (801) 956-2400

Telefax: +1 (801) 956-2401

Dept. responsible for information:

Quality Department,

Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time), Email:

USRegulatory@ottobock.com

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: This material is classified as not hazardous.

Regulatory status

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

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. Causes serious eye damage. May cause sensitisation by skin contact..

Information about electrolyte, organic, CAS No. - :

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.

Contains Steel, Aluminium and Copper (<30%), Graphite and Carbon (10 - 20%), Polypropylene (10%), Salts (1%).

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

Hazardous ingredients:

| CAS No. | Designation | Content | Classification |
|----------------|-----------------------------|-----------|---|
| CAS 12190-79-3 | Cobalt lithium dioxide | 20 - 40 % | Sensitization - skin - Category 1. Carcinogenicity - Category 2. |
| CAS 96-49-1 | Ethylene carbonate | < 15 % | Eye Damage - Category 1. |
| CAS 616-38-6 | Dimethyl carbonate | < 15 % | Flammable Liquid - Category 2. |
| CAS 105-58-8 | Diethyl carbonate | < 15 % | Skin Irritation - Category 2. Eye Irritation - Category 2A. Specific Target Organ Toxicity (Single Exposure) - Category 3. |
| CAS 141-78-6 | Ethyl acetate | < 15 % | Flammable Liquid - Category 2. Eye Irritation - Category 2A. Specific Target Organ Toxicity (Single Exposure) - Category 3. |
| CAS 21324-40-3 | Lithium hexafluorophosphate | < 15 % | Acute Toxicity - oral - Category 4. Acute Toxicity - dermal - Category 4. Eye Damage - Category 1. Sensitization - skin - Category 1. |
| CAS - | Electrolyte, organic | < 15 % | Flammable Liquid - Category 3. |

4. First aid measures

General information: In case of damaged battery cases: Release of dangerous ingredients possible. The product may release harmful vapours 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: Clean with plenty of water. If possible, also wash with polyethylene glycol 400. Take off immediately all contaminated clothing. 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: Serious eye damage/irritation. May cause an allergic skin reaction. 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. Wear suitable gloves. 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, 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.

7. Handling and storage

Handling

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

Avoid damaged batteries.

In case of damaged battery cases: Avoid exposure.

Precautions against fire and explosion:

Avoid short circuit. Avoid open flames.

Avoid temperatures exceeding 158 °F.

Avoid damaged batteries.

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: <86 °F.

Hints on joint storage:

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

Keep away from food, drink and animal feedingstuffs.

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

| CAS No. | Designation | Type | Limit value |
|------------|------------------------|-----------------|----------------------------------|
| 7429-90-5 | Aluminium | NIOSH: Ceiling | 5 mg/m ³ |
| | | USA: ACGIH: TWA | 1 mg/m ³ |
| | | USA: NIOSH: TWA | 10 mg/m ³ |
| | | USA: NIOSH: TWA | 5 mg/m ³ |
| | | USA: OSHA: TWA | 15 mg/m ³ |
| | | USA: OSHA: TWA | 5 mg/m ³ |
| 7440-50-8 | Copper | USA: ACGIH: TWA | 0.2 mg/m ³ |
| | | USA: ACGIH: TWA | 1 mg/m ³ |
| | | USA: NIOSH: TWA | 1 mg/m ³ |
| | | USA: OSHA: TWA | 0.1 mg/m ³ |
| | | USA: OSHA: TWA | 1 mg/m ³ |
| 12190-79-3 | Cobalt lithium dioxide | USA: ACGIH: TWA | 0.02 mg/m ³ |
| | | USA: NIOSH: TWA | 0.05 mg/m ³ |
| | | USA: OSHA: TWA | 0.1 mg/m ³ |
| 7782-42-5 | Graphite | USA: ACGIH: TWA | 2 mg/m ³ |
| | | USA: NIOSH: TWA | 2.5 mg/m ³ |
| | | USA: OSHA: TWA | 15 mg/m ³ |
| | | USA: OSHA: TWA | 15 mppcf |
| | | USA: OSHA: TWA | 5 mg/m ³ |
| 7440-44-0 | Carbon | USA: OSHA: TWA | 15 mg/m ³ |
| | | USA: OSHA: TWA | 5 mg/m ³ |
| 141-78-6 | Ethyl acetate | USA: ACGIH: TWA | 1440 mg/m ³ ; 400 ppm |
| | | USA: NIOSH: TWA | 1400 mg/m ³ ; 400 ppm |
| | | USA: OSHA: TWA | 1400 mg/m ³ ; 400 ppm |

Biological limit values:

| CAS No. | Designation | Type | Limit value | Parameter | Sampling |
|------------|------------------------|-----------------------|-------------|-----------|---------------------------------|
| 12190-79-3 | Cobalt lithium dioxide | USA: ACGIH-BEI, blood | 1 µg/L | Cobalt | end of shift at end of workweek |
| | | USA: ACGIH-BEI, urine | 15 µg/L | Cobalt | end of shift at end of workweek |

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 contact with skin and eyes.
Keep away from sources of ignition. - No smoking.
Wash hands before breaks and after work.

9. Physical and chemical properties

Information on basic physical and chemical properties

| | |
|--|-------------------|
| Appearance: | Form: solid |
| Odor: | odorless |
| Odor threshold: | no data available |
| pH value: | 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 |

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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.

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: > 158 °F: development of gas/vapor possible.
Protect from: humidity, heat, UV-radiation/sunlight
Avoid short circuit. Avoid damaged batteries.
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.
- 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:
Limited evidence of a carcinogenic effect. Causes serious eye damage. May cause sensitisation by skin contact.
- Information about electrolyte, organic, CAS No. - :
Vapors irritate eyes, mucous membranes and respiratory system.
Vapors may cause drowsiness and dizziness.

Symptoms

No hazardous reaction when handled and stored according to provisions.
In case of damaged battery cases: Serious eye damage/irritation. May cause an allergic skin reaction. May cause drowsiness or 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: Dispose of waste according to applicable legislation.

Contaminated packaging

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

14. Transport information

USA: Department of Transportation (DOT)

Identification numbers: UN3090
 Proper shipping name: UN 3090, Lithium metal batteries
 DOT hazard class or division: 9
 Label codes: 9
 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



Sea transport (IMDG)

UN number: UN 3480
 Proper shipping name: UN 3480, LITHIUM ION BATTERIES
 IMDG: Class 9, Subrisk -
 Packing Group: -
 EmS: F-A, S-I
 Special provisions: 188, 230, 310, 348, 376, 377
 Limited quantities: 0
 EQ: E0
 Contaminated packaging - Instructions: P903, P908, P909, LP903, LP904
 Contaminated packaging - 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.
 Marine pollutant: no
 Segregation group: none



SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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Version: 5

Language: en-US

Date of print: 1/20/2016

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Air transport (IATA)

| | |
|-----------------------|---|
| UN/ID number: | UN 3480 |
| Proper shipping name: | UN 3480, LITHIUM ION BATTERIES |
| ICAO/IATA: | Class 9 |
| Hazard: | Miscellaneous |
| EQ: | E0 |
| Passenger Ltd.Qty.: | Forbidden |
| Passenger: | Pack.Instr. See 965 - Max. Net Qty/Pkg. See 965 |
| Cargo: | Pack.Instr. See 965 - Max. Net Qty/Pkg. See 965 |
| Special Provisioning: | A88 A99 A154 A164 A183 |
| ERG: | 9F |

15. Regulatory information

National regulations - U.S. Federal Regulations

| | |
|-------------------------|--|
| Aluminium: | TSCA Inventory: listed TSCA HPVC: not listed Other Environmental Laws: SARA Title III Section 313, Toxic Release: Conc. 1.0% / Threshold Standard NIOSH Recommendations: Occupational Health Guideline: 0022 |
| Copper: | TSCA Inventory: listed TSCA HPVC: not listed Clean Water Act: Priority Pollutant: yes Other Environmental Laws: CERCLA: RQ 5000* lbs. Marine Pollutant: listed as severe pollutant. RCRA Groundwater Monitoring: Methods 6010, 7210 / PQL 60, 200 SARA Title III Section 313, Toxic Release: Conc. 1.0% / Threshold Standard NIOSH Recommendations: Occupational Health Guideline: 0150* |
| Cobalt lithium dioxide: | TSCA Inventory: listed TSCA HPVC: not listed |
| Graphite: | TSCA Inventory: listed TSCA HPVC: not listed NIOSH Recommendations: Occupational Health Guideline: 0306 |
| Carbon: | TSCA Inventory: listed TSCA HPVC: not listed NIOSH Recommendations: Occupational Health Guideline: 0307 |
| Dimethyl carbonate: | TSCA Inventory: listed TSCA HPVC: not listed |
| Ethyl acetate: | TSCA Inventory: listed; EPA flags T TSCA HPVC: not listed Other Environmental Laws: CERCLA: RQ 5000 lbs. RCRA Hazardous Wastes: Code U112 NIOSH Recommendations: Occupational Health Guideline: 0260 |

National regulations - U.S. State Regulations

Cobalt lithium dioxide: California Proposition 65: cancer
Rhode Island HSL: listed

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 - Great Britain

Hazchem-Code: 4W

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

Reason of change:

Changes in section 8: General revision

Changes in section 14: IMDG 2015

Changes in section 16: NFPA

Date of first version:

11/16/2010

Department issuing data sheet

Contact person:

see section 1: Dept. responsible for information

| | |
|-----------------|---|
| HEALTH | 0 |
| FLAMMABILITY | 1 |
| PHYSICAL HAZARD | 1 |
| | X |

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.