1. Product and company identification

Product identifier

Trade name: 757B35=X - MyoEnergy Integral
This safety data sheet pertains to the following products:
757B35=0: MyoEnergy Integral
757B35=1: MyoEnergy Integral

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

Dept. 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: 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) 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:
Flammable liquid and vapor. After contact with water: Formation of Hydrogen fluoride
Suspected of causing cancer. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. Causes serious eye damage.
Causes skin irritation. Harmful if swallowed or in contact with skin.
May cause long lasting harmful effects to aquatic life.

Vapors irritate eyes, mucous membranes and respiratory system. May cause drowsiness or dizziness.
see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Lithium-ion battery - Article, contains:
Steel, Aluminium and Copper 31%
Polypropylene 10%
Organic solvents 13%
Salts 1%
Lithium, metallic: 0%

Electrode, negative: Graphite or Carbon
Electrode, positive: cobalt lithium dioxide
Electrolyte: Lithium hexafluorophosphate, solvent mixture

Relevant ingredients:

CAS No.	Designation	Content	Classification
CAS 12190-79-3	Cobalt lithium dioxide	20 - 40 %	Respiratory Sensitizer - Category 1. Sensitization - skin - Category 1. Carcinogenicity - Category 2. Aquatic toxicity - chronic - Category 4.
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.

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: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. Causes serious eye damage. Causes skin irritation. Harmful if swallowed or in contact with skin.

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:
Carbon dioxide (CO_2), dry chemical powder, foam

Extinguishing media which must not be used for safety reasons:
Water

Specific hazards arising from the chemical

In case of fire may be liberated: Hydrogen fluoride, carbon monoxide and carbon dioxide, Metal oxide smoke

Protective equipment and precautions for firefighters:
Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information: Do not allow fire water to penetrate into surface or ground water.

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 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 temperatures exceeding 158 °F.
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: <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/m³
		USA: ACGIH: TWA	1 mg/m³
		USA: NIOSH: TWA	10 mg/m³
		USA: NIOSH: TWA	5 mg/m³
		USA: OSHA: TWA	15 mg/m³
		USA: OSHA: TWA	5 mg/m³
7440-50-8	Copper	USA: ACGIH: TWA	0.2 mg/m³
		USA: ACGIH: TWA	1 mg/m³
		USA: NIOSH: TWA	1 mg/m³
		USA: OSHA: TWA	0.1 mg/m³
		USA: OSHA: TWA	1 mg/m³
12190-79-3	Cobalt lithium dioxide	USA: ACGIH: TWA	0.005 ppm
		USA: ACGIH: TWA	0.02 mg/m³
		USA: NIOSH: TWA	0.05 mg/m³
		USA: OSHA: TWA	0.1 mg/m³
7782-42-5	Graphite	USA: ACGIH: TWA	2 mg/m³
		USA: NIOSH: TWA	2.5 mg/m³
		USA: OSHA: TWA	15 mg/m³
		USA: OSHA: TWA	15 mppcf
		USA: OSHA: TWA	5 mg/m³
7440-44-0	Carbon	USA: OSHA: TWA	15 mg/m³
		USA: OSHA: TWA	5 mg/m³
141-78-6	Ethyl acetate	USA: ACGIH: TWA	1440 mg/m³; 400 ppm
		USA: NIOSH: TWA	1400 mg/m³; 400 ppm
		USA: OSHA: TWA	1400 mg/m³; 400 ppm

Biological limit values:

CAS No.	Designation	Type	Limit value	Parameter	Sampling
12190-79-3	Cobalt lithium dioxide	USA: ACGIH-BEI, urine	15 µg/L	Cobalt; not combined with Tungsten Carbide	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:	Physical state at 68 °F and 101.3 kPa: solid
Odor:	odorless
Odor threshold:	No data available
pH value:	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:	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 damage to the battery casing.

In case of damaged battery cases:
Keep away from water. Keep away from sources of ignition - No smoking.

Incompatible materials: Keep away from strong acids and strong oxidizing agents.

Hazardous decomposition products:
No decomposition when used properly.

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: In case of damaged battery cases:
Suspected of causing cancer. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. Causes serious eye damage. Causes skin irritation. Harmful if swallowed or in contact with skin.

12. Ecological information

Ecotoxicity

Aquatic toxicity: In case of damaged battery cases:
May cause long lasting harmful effects to aquatic life.

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 number:	UN3480
Proper shipping name:	UN 3480, UN 3480, LITHIUM ION BATTERIES
Hazard class or Division:	9
Labels:	9
Special provisions:	A51, 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

Sea transport (IMDG)

UN number:	UN 3480
Proper shipping name:	UN 3480, LITHIUM ION BATTERIES
Class or division, Subsidary risk:	Class 9, Subrisk -
Packing Group:	-
EmS:	F-A, S-I
Special provisions:	188, 230, 310, 348, 376, 377, 384
Limited quantities:	0
Excepted quantities:	E0
Contaminated packaging - Instructions:	P903, P908, P909, P910, 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 explusive rupture of the body caused by improper construction or reaction with contaminants.
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, Subsidary risk:	Class 9
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 A206 A331
Emergency Response Guide-Code (ERG):	9F

15. Regulatory information

National regulations - U.S. Federal Regulations

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

Aluminium:
Other Environmental Laws:
SARA Title III Section 313, Toxic Release: Conc. 1.0% / Threshold Standard
NIOSH Recommendations:
Occupational Health Guideline: 0022

Copper:
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*

Graphite:
NIOSH Recommendations:
Occupational Health Guideline: 0306

Carbon:
NIOSH Recommendations:
Occupational Health Guideline: 0307

Ethyl acetate:
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

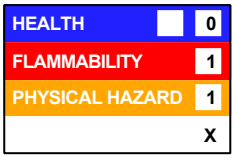
16. Other information

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 1.3: Corporate headquarters

Date of first version: 12/20/2016

Department issuing data sheet

Contact person: see section 1: Dept. 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.