

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

Recommended use and restrictions on use

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

Initial supplier identifier

Company name: Otto Bock HealthCare Canada Ltd.

Street/POB-No.: 5470 Harvester Road

Postal Code, city: Burlington, ON L7L 5N5, CA
Canada

WWW: www.ottobock.ca

E-mail: info.canada@ottobock.com

Telephone: (800) 665-3327

Telefax: (800) 463-3659

Department responsible for information:

Mark Agro, Telephone: (800) 665-3327 (9 am - 5 pm)

Additional information:

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

Emergency phone number

COLLECT, Telephone: (613) 996-6666

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 20 °C and 101.3 kPa: solid

Odor: odorless

Classification: Article not subject to hazard labeling or classification.

Regulatory status

This material is not considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200) and WHMIS 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 characterisation: 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	Concentration	Classification
CAS 12190-79-3	Cobalt lithium dioxide	20 - 40 %	Respiratory Sensitizer 1. Sensitization - skin 1. Carcinogenicity 2.
CAS 96-49-1	Ethylene carbonate	< 15 %	Eye Damage 1.
CAS 616-38-6	Dimethyl carbonate	< 15 %	Flammable Liquid 2.
CAS 105-58-8	Diethyl carbonate	< 15 %	Skin Irritation 2. Eye Irritation 2A. Specific Target Organ Toxicity (Single Exposure) 3.
CAS 141-78-6	Ethyl acetate	< 15 %	Flammable Liquid 2. Eye Irritation 2A. Specific Target Organ Toxicity (Single Exposure) 3.
CAS 21324-40-3	Lithium hexafluorophosphate	< 15 %	Acute Toxicity 4 (oral). Acute Toxicity 4 (dermal). Eye Damage 1. Sensitization - skin 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 and effects, both 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 (CO₂), extinguishing 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

Special protective equipment and precautions for fire-fighters:

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 70 °C.
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: <30 °C.

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	Canada: OEL 8 hour	10 mg/m ³ (metal, dust)
		Canada: OEL 8 hour	5 mg/m ³
			(Aluminium powder, pyrotechnic)
		Canada: OEL TWA	1 mg/m ³ (Pyrotechnical powders)
		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)
7440-50-8	Copper	USA: OSHA: TWA	5 mg/m ³ (respirable fraction)
		Canada: OEL 8 hour	0.2 mg/m ³ (Smoke)
		Canada: OEL 8 hour	1 mg/m ³ (Dusts and mist)
		Canada: OEL TWA	0.2 mg/m ³ (Smoke)
		Canada: OEL TWA	1 mg/m ³ (Dusts and mist)
		Canada: VEMP	0.2 mg/m ³ (Smoke, calculated as Cu)
		Canada: VEMP	1 mg/m ³
			(Dusts and mist calculated as Cu)
		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)
7782-42-5	Graphite	USA: OSHA: TWA	1 mg/m ³
			(Dusts and mist calculated as Cu)
		Canada: OEL 8 hour	2 mg/m ³ (respirable fraction)
		Canada: OEL TWA	2 mg/m ³ (respirable fraction)
		Canada: VEMP	2 mg/m ³ (respirable fraction)
		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)

CAS No.	Designation	Type	Limit value
7440-44-0	Carbon	Canada: OEL 8 hour	10 mg/m ³ (Dust limit value, inhalable fraction)
		Canada: OEL 8 hour	3 mg/m ³ (Dust limit value, respirable fraction)
		Canada: OEL TWA	10 mg/m ³ (Dust limit value, inhalable fraction)
		Canada: OEL TWA	3 mg/m ³ (Dust limit value, respirable fraction)
		Canada: VEMP	10 mg/m ³ (total dust)
		Canada: VEMP	3 mg/m ³ (total dust, respirable fraction)
		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)
141-78-6	Ethyl acetate	Canada: OEL 8 hour	1,440 mg/m ³ ; 400 ppm
		Canada: OEL TWA	150 ppm
		Canada: VEMP	1,440 mg/m ³ ; 400 ppm
		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 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:	Physical state at 20 °C and 101.3 kPa: solid
Odor:	odorless
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:	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:	<p>Fire hazard in case of technical defects.</p> <p>In case of damaged battery cases:</p> <p>Flammable liquid and vapor. (Electrolyte)</p> <p>After contact with water: Formation of Hydrogen fluoride.</p>
Conditions to avoid:	<p>> 70 °C: development of gas/vapor possible.</p> <p>Protect from: humidity, heat, UV-radiation/sunlight</p> <p>Avoid short circuit. Avoid damage to the battery casing.</p> <p>In case of damaged battery cases:</p> <p>Keep away from water. Keep away from sources of ignition - No smoking.</p>
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.

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:

UN3480

Proper shipping name:

UN 3480, LITHIUM ION BATTERIES

Hazard class or Division:

9

Labels:

9

Special Provisions:

388, 422, A54, A100

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



Canada: Transportation of Dangerous Goods (TDG)

UN Number:

UN3480

Shipping name:

UN 3480, LITHIUM ION BATTERIES

TDG class:

9

Special provisions:

34, 123, 137, 138, 1

Explosive limit and limited quantity index:

0

Passenger carrying road or rail index:

5 kg

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 - Canada

Aluminium:	DSL: listed
Copper:	DSL: listed
Cobalt lithium dioxide:	DSL: listed
Graphite:	DSL: listed
Carbon:	DSL: listed
Ethylene carbonate:	DSL: listed
Dimethyl carbonate:	DSL: listed
Diethyl carbonate:	DSL: listed
Ethyl acetate:	DSL: listed
Lithium hexafluorophosphate:	NDSL: listed

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 - EC member states

Further regulations, limitations and legal requirements:

Aluminium: Regulation (EU) 2019/1148 (marketing and use of explosives precursors): listed

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
 Respiratory Sensitizer: Sensitisation to the respiratory tract
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
 Sensitization - skin: Skin sensitisation
 Skin Irritation: Skin irritation
 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
 WHMIS: Workplace Hazardous Materials Information System

Reason of change: Changes in section 14: IMDG 2025

Date of first version: 20/12/2016

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.