INFORMATION SHEET SAFE USE

COGEL LITHIUM ONE%

Current revision date: 03/06/2024	Current revision number: 00	Previous revision date: --/--/----	Previous revision number: --

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

1.1 Product identifier

Commercial name : **COGEL LITHIUM ONE%**
REF : **CLI0250MF036**
European product categorisation system (EuPCS) : PC-MED-OTH - Other medical devices

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

Uses :	CONSUMER	PROFESSIONAL	INDUSTRIAL
		Water-soluble electro-conductive contact medium enriched with lithium salts	

Uses advises against : All those not expressly identified on the label
Life cycle stages : PW - Widespread use by professional workers.

1.3 Details of the supplier of the safety data sheet

COMEDICA S.r.l.
Via della Cooperazione, 29 – 38123 Trento (TN)
Tel. +39 0461 94 58 76 Fax +39 0461 94 45 70 Sito web www.comedical.biz
email competent person info@comedical.biz

1.4 Emergency telephone number

COMEDICA S.r.l. Tel. +39 0461 94 58 76 (from 09.00 to 13.00 and from 14.00 to 18.00)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification in accordance with Regulation (EC) No 1272/2008:

The product is not classified as dangerous pursuant to the provisions of Regulation (EC) 1272/2008 (CLP) (and subsequent amendments and adjustments) and does not contain substances that fall within the parameters set out in chapter 3.2.2 of Regulation (EU) 2020 /878 with the obligation to be included in section 3. Therefore, the issue of a safety data sheet compliant with the provisions of the REACH Regulation is not required.
However, the person responsible for placing it on the market, in order to allow the user to better manage the safe use of the mixture, considers making the information in his possession available by developing this Information Sheet for Safe Use (SIUS).

2.2 Label elements

2.2.1 Label in accordance with Regulation (EC) No 1272/2008

Hazard pictogram(s) : None
Signal Word Code(s) : None
Hazard statement Code(s) : None
Suppl. Hazard statement Code(s) : None
Precautionary statements : None

2.2.2 Additional regulations to be implemented on the label

Regulation (EU) 2017/745 : Applicable. See IFU (Instruction For Use)

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

The mixture does not meet the classification criteria in accordance with Regulation (EC) No. 1272/2008 and there are no substances which present a danger to health or the environment or for which exposure limits have been set at Union level in the workplace in individual concentrations equal to or higher than those set by the legislation currently in force.

SECTION 4: First aid measures

4.1 Description of first aid measures

First aid instructions divided according to the relevant routes of exposure. It is advisable for those providing initial treatment to wear personal protective equipment deemed suitable for the conditions in which the intervention must be carried out.

Inhalation

Remove the injured person from the contaminated environment and keep him or her at rest in a well-ventilated area.

Skin

In consideration of the intended use, no problems related to the skin are expected

Eyes

Rinse with plenty of water for a few minutes (remove contact lenses if possible), then seek medical attention.

Ingestion

Rinse your mouth and do not induce vomiting

4.2 Most important symptoms and effects, both acute and delayed

Inhalation

There are no known and no specific reports on symptoms and effects caused by the product.

Skin

There are no known and no specific reports on symptoms and effects caused by the product.

Eyes

Redness

Ingestion

Burning sensation.

4.3 Indication of any immediate medical attention and special treatment needed

See point 4.1 Description of first aid measures.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray, CO_2, alcohol-resistant foam, chemical powders depending on the materials involved in the fire.
Unsuitable extinguishing media : Direct water jets

5.2 Special hazards arising from the substance or mixture

During combustion, fumes that are potentially harmful to health may be released.

5.3 Advice for firefighters

Fire fighters must always wear the specific protective equipment of the fire fighting team (helmet, boots, fireproof gloves and, if deemed necessary, positive pressure self-contained breathing apparatus with protective shield (EN469). The water spray can be used to protect people involved in firefighting. It is also advisable to use self-contained breathing apparatus if working in closed and poorly ventilated places.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : Move away from the area surrounding the spill or release.
For emergency responders : Use protective clothing resistant to solvent products with CE marking (suitable materials: nitrile, PVC, neoprene, butyl) do not use disposable latex or PVC gloves.

6.2 Environmental precautions

Avoid dispersion and/or leaching into the sewer system and surface water

6.3 Methods and material for containment and cleaning up

Contain and absorb the spilled liquid with inert absorbent materials (sand, earth, cuttlefish, other specific products) and place in containers with closures.

6.4 Reference to other sections

Refer to sections 8 and 13 for more information

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Do not smoke, eat or drink while handling.

7.2 Conditions for safe storage, including any incompatibilities

Avoid direct exposure to the sun.

7.3 Specific end use(s)

Professional uses. Follow the instructions given on the label/technical data sheets

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Related to the substances contained: None available

8.2 Exposure controls

8.2.1 Appropriate engineering controls

If, following the risk assessment and the adoption of preventive technical and/or organizational collective protection measures, it appears that there is still a residual risk for the worker, it is necessary to equip the worker with Personal Protective Equipment. In any company, however, the instructions given by the Head of the Prevention and Protection Service must be complied with, who will have assessed the risk deriving from all the products used in each working phase. Before choosing the PPE to wear, it is essential to know the risks associated with the work environment, the environmental conditions, the job of the wearer and after having consulted the instructions provided by the manufacturer. All PPE belonging to the third category must be delivered to operators only after adequate training.

The use of this mixture does not imply the application of Directive 2004/37 / EC on the protection of workers against the risks deriving from exposure to carcinogens or mutagens at work.

8.2.2 Individual protection measures, such as personal protective equipment

The information below must be considered only as an aid to the Head of the Prevention and Protection Service as in addition to this mixture he will have to implement the choices on PPE also in consideration of the other chemical products present in the company used in each specific working phase.

a) EYE/FACE PROTECTION

PITTOGRAM	PPE	OBSERVATIONS
 Eye and face protection devices	PPE for the eyes are second category and must be provided with indelible CE marking and the number of the Notified Body that issued the certification. Their use is foreseen in all places where there is a risk of projections of solid bodies, liquids or optical radiation. For eyeglass wearers, it is possible to use over glasses if the duration of use is limited or to mount graduated lenses on safety frames. Operators wearing contact lenses must make their condition known in order to make it easier, if necessary, to remove them by first aid workers in case of need in an emergency. Standard EN166 Personal eye protection - Specifications	The use of safety glasses with side protection (goggles) is recommended.

b) SKIN PROTECTION

i) Hand protection

PITTOGRAM	PPE	OBSERVATIONS
 Gloves	The choice of gloves depends on the worker's task, the characteristics of the glove and biocompatibility. The general requirements for choosing the most suitable PPE are: harmlessness, ergonomics/comfort, dexterity, transmission and absorption of water vapor and cleanliness. Regarding these requirements, the reference technical standard is UNI EN ISO 21420 – Protective gloves - General requirements and test methods. Use proper technique to remove gloves avoiding skin contact with the contaminated outer surface of the glove. After use, wash and dry your hands.	Gloves that protect against chemical agents are regulated by the EN374 standard - Protective gloves against chemicals and microorganisms. The basic requirements for this type of gloves are: penetration and permeation. Gloves must be checked before being used.

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ii) other

PITTOGRAM	PPE	OBSERVATIONS
 Work clothing	Body PPE can be of different categories depending on their specific use. Under normal working conditions, normal work clothing offers characteristics that provide sufficient protection for workers. In activities that present particular risks, specific "protective clothing" must be used which covers or replaces personal clothing and which is designed with specific protective characteristics. Standard EN 13688 Protective clothing - General requirements.	Wear normal work clothes.

c) RESPIRATORY PROTECTION

PITTOGRAM	PPE	OBSERVATIONS
 RPD (Respiratory protective devices)	PPE for respiratory protection is third category and must have the CE marking, the number of the Notified Body that issued the certification and must be supplied only after information, training and specific training on their use. The UNI EN 529 standard (Respiratory protective devices - Recommendations for selection, use, care and maintenance - Guidance document) establishing the adequate FPO value "operational protection factor" (e.g. use of face masks as per standard UNI EN149 - Respiratory protection devices - Semi-mask filtering against particles) can be a valid aid in determining the most correct PPE.	No PPE for the respiratory tract is provided under normal conditions of use.

d) THERMAL HAZARDS

PITTOGRAM	PPE	OBSERVATIONS
 Hot/Cold	PPE intended to protect against thermal differences must have an adequate heat flow transmission coefficient to avoid any risk of damage when required by the foreseeable conditions of use. The thermal flow transmitted to the operator during the use of PPE must be such that its accumulation does not in any case reach the threshold of pain or that in which any harmful effect on health occurs. PPE must prevent, as far as possible, the penetration of liquids and must not cause injuries caused by contact between its protective covering and the operator.	The mixture/product is not expected to cause or undergo significant temperature variations during its intended use.

8.2.3 Environmental exposure controls

Prevent uncontrolled release into the environment.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

The physical and chemical properties listed below are not to be considered technical specifications. The reference specifications are shown in the technical documentation.

	Physical and chemical properties	Value	Notes or analytical method
a)	Physical state	Liquid	Colloidal system
b)	Colour	Opal	- -
c)	Odour	Odorless	- -
d)	Melting point/freezing point	Not available	- -
e)	Boiling point or initial boiling point and boiling range	> 40°C	- -
f)	Flammability	Not inflammable	- -
g)	Lower and upper explosion limit	Not available	- -
h)	Flash point	> 65°C	- -
i)	Auto-ignition temperature	Not available	- -
j)	Decomposition temperature	Not applicable	Applicable only to self-reactive substances and mixtures, organic peroxides and other substances and mixtures which can decompose.
k)	pH	6.7 ± 0.20	- -
l)	Kinematic viscosity	25.000 ± 5.000	- -
m)	Solubility	Soluble in water	
n)	Partition coefficient n-octanol/water (log value)	Not applicable	does not apply to inorganic and ionic liquids and, as a rule, does not apply to mixtures
o)	Vapour pressure	Not available	- -
p)	Density and/or relative density	0.95 g/ml	- -
q)	Relative vapour density	Not available	- -
r)	Particle characteristics	Not applicable	applies only to solids

9.2 Other information

No additional features available

SECTION 10: Stability and reactivity

10.1 Reactivity

There are no particular dangers of reaction with other substances under normal conditions of use.

10.2 Chemical stability

Stable under normal conditions of use and storage.

10.3 Possibility of hazardous reactions

Under normal conditions of use and storage, no dangerous reactions are known.

10.4 Conditions to avoid

Nothing to report

10.5 Incompatible materials

Nothing to report

10.6 Hazardous decomposition products

Under normal conditions the preparation does not decompose. Due to thermal decomposition, fumes harmful to health are released.

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SECTION 11: Toxicological information

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

	Hazard classes	Information
a)	acute toxicity	Not classified. based on available data, the classification criteria are not met.
b)	skin corrosion/irritation	Not classified. based on available data, the classification criteria are not met.
c)	serious eye damage/irritation	Not classified. based on available data, the classification criteria are not met.
d)	respiratory or skin sensitisation	Not classified. based on available data, the classification criteria are not met.
e)	germ cell mutagenicity	Not classified. based on available data, the classification criteria are not met.
f)	carcinogenicity	Not classified. based on available data, the classification criteria are not met.
g)	reproductive toxicity	Not classified. based on available data, the classification criteria are not met.
h)	STOT-single exposure	Not classified. based on available data, the classification criteria are not met.
i)	STOT-repeated exposure	Not classified. based on available data, the classification criteria are not met.
j)	aspiration hazard	Not classified. based on available data, the classification criteria are not met.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

The mixture does NOT contain substances identified as having endocrine-disrupting properties in accordance with the criteria established in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 in concentrations equal to or greater than 0.1% in weight.

11.2.2 Other information

No further information available

SECTION 12: Ecological information

12.1 Toxicity

Use according to good working practices, avoiding to disperse the product in the environment.

12.2 Persistence and degradability

Data not available for the mixture

12.3 Bioaccumulative potential

Data not available for the mixture

12.4 Mobility in soil

Data not available for the mixture

12.5 Results of PBT and vPvB assessment

The chemical safety report is not required for the mixture. However, based on the available data, the mixture does not contain PBT or vPvB substances in a percentage higher than 0.1 in accordance with Regulation 1907/2006, annex XIII.

12.6 Endocrine disrupting properties

The mixture does NOT contain substances identified as having endocrine disrupting properties in accordance with the criteria established in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 in concentrations equal to or greater than 0.1% in weight.

12.7 Other adverse effects

Classification for water pollution in Germany (AwSV, vom 18. April 2017):

WGK 1: Low hazard to waters.

SECTION 13: Disposal considerations

The substance/mixture must not be disposed of via the sewer system. It is therefore recommended that before disposal you reclassify the waste by also evaluating its origin.
Any mixing of different types of non-hazardous waste and any mixing of different hazardous wastes is prohibited (Art.23 Directive 2008/98/EC).
Disposal must be entrusted to a company authorized to treat waste, in compliance with national and possibly local regulations.

SECTION 14: Transport information

Not included in the scope of the regulations regarding the transport of dangerous goods: by road (ADR); by rail (RID); by air (ICAO / IATA); by sea (IMDG).

SECTION 15: Regulatory information

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

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives.

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council.

Commission Regulation (EU) No 1357/2014 of 18 December 2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives Text with EEA relevance.

COMMISSION DECISION of 18 December 2014 amending Decision 2000/532/EC on the list of wastes pursuant to Directive 2008/98/EC of the European Parliament and of the Council

Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC.

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 relating to in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 relating to medical devices, amending Directive 2001/83/EC, Regulation (EC) no. 178/2002 and Regulation (EC) no. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC

Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013

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The mixture does not contain an explosive precursor.

15.2 Chemical safety assessment

Chemical safety assessment for the mixture/article not foreseen.

SECTION 16: Other information

Indication of any points in the SIUS that have been revised

No section has been modified as this sheet is the first issue.

16.2 Legend of abbreviations and acronyms used in this SIUS

ATE/STA	Acute Toxicity Estimates	**EuPCS**	European Product Categorisation System
BCF	Bioconcentration Factor	**FFP**	Filtering Facepiece
CAS	Chemical abstract service	**GHS**	Globally Harmonized System
CLP	Classification, Labelling and Packaging	**HP**	Hazardous Properties
DNEL	Derived No Effect Level	**IMO**	International Maritime Organization
EC	European Comunity	**ISO**	International Standard Organization
EC50	Half maximal effective concentration	**LC50**	Median lethal concentration
ECHA	European Chemicals Agency	**LD50**	Median lethal dose
EmS	Emergency Schedules	**NOEC**	No observed effect concentration
EN	European normalization	**REACH**	Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals
ERC	Environmental release categories	**STOT**	Specific target organ toxicity
EUH	Supplemental hazard information	**STP**	Sewage treatment plant

16.4 References and main data sources

ECHA	European Chemicals Agency	**OSHA**	European Agency for Safety and Health at Work	**IARC**	International Agency for Research on Cancer
TOXNET	Toxicology Data Network	**WHO**	World Health Organization	**ACGIH**	American Conference of Governmental Industrial Hygienists
CheLIST	Chemical Lists Information System	**ICSCs**	International Chemical Safety Cards	**ILO**	International Labour Organization
IPCS	International Programme on Chemical Safety (Cards)	**NIOSH**	Registry of toxic effects of chemical substances (1983)	**IFA**	Institut fur Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung

16.7 Any appropriate training courses for workers to ensure the protection of human health and the environment

- Training course on the management and interpretation of SIUS
- Training on the use of PPE

The information in this safety data sheet has been obtained from the best available or to our knowledge at the revision date indicated. Neither the Company owning this sheet nor its subsidiaries will be able to accept complaints deriving from an improper use of the information indicated here or from an improper use in the application of the product. Pay particular attention when using the preparations because improper use can increase their danger.

END OF INFORMATION SHEET FOR SAFE USE

This information sheet safe use has been translated with an automatic system. We thank all the people who want to report any anomalies in the translation.