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

1.1 Product identifier

Substance name : Caplyta Capsules
Lumateperone Capsules
JNJ-86952580-ZCK-G002 Eq. 42 mg Oral Capsule
JNJ-86952580-ZCK-G001 Eq. 42 mg Oral Capsule
JNJ-86952580-ZCK-G004 Eq. 21 mg Oral Capsule
JNJ-86952580-ZCK-G005 Eq. 21 mg Oral Capsule
JNJ-86952580-ZCK-G007 Eq. 10.5 mg Oral Capsule
JNJ-86952580-ZCK-G008 Eq. 10.5 mg Oral Capsule

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

Use of the Substance/Mixture : Finished Pharmaceutical Product, Pharmacotherapeutic group: Psycholeptics, This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
A safety data sheet is not required for this product under Article 31 of REACH. This SDS has been created on a voluntary basis (to pass on relevant information required under Article 32). Since an SDS is not required, this document may not contain all of the information that is required for substance and mixture SDS's under REACH.

1.3 Details of the supplier of the safety data sheet

Company : Janssen Pharmaceutica NV
Turnhoutseweg 30
2340 Beerse
Belgium

Telephone : +3214602111

E-mail address of person responsible for the SDS : SDSJanssen@its.jnj.com

1.4 Emergency telephone number

CHEMTREC International: +1 703-741-5970

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 2 H361fd: Suspected of damaging fertility. Suspected

of damaging the unborn child.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Warning

Hazard statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

Lumateperone tosylate

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidently leaking, broken or crushed.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Solid

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Lumateperone tosylate	1187020-80-9	Acute Tox. 4; H302 Repr. 2; H361fd	>= 20 - < 30
Substances with a workplace exposure limit :			
Octadecanoic acid, magnesium salt	557-04-0 209-150-3		>= 1 - < 10
Talc (Mg3H2(SiO3)4)	14807-96-6 238-877-9		>= 0,1 - < 1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled : If breathed in, move person into fresh air.
Consult a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and water.
If symptoms persist, call a physician.

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes.
Remove contact lenses.
If eye irritation persists, consult a specialist.

If swallowed : If swallowed, rinse mouth with water (only if the person is conscious).
Call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

Risks : Suspected of damaging fertility. Suspected of damaging the unborn child.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No information available.

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : No information available.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
Evacuate personnel to safe areas.

6.2 Environmental precautions

Environmental precautions : Should not be released into the environment.
Do not flush into surface water or sanitary sewer system.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Large spills: Sweep up or vacuum with HEPA filter or via wet cleaning into suitable containers for disposal.
Pick up and arrange without creating dust. Keep in properly labelled containers.
Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum.
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

6.4 Reference to other sections

For disposal information, see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Do not break, crush or spill this Finished Pharmaceutical Product.
To avoid thermal decomposition, do not overheat.
Use personal protective equipment as required.
Avoid inhalation, ingestion and contact with skin and eyes.

Advice on protection against fire and explosion : No data available

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : To maintain product quality, do not store in heat or direct sunlight. Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat and sources of ignition.

7.3 Specific end use(s)

Specific use(s) : Consult the technical guidelines for the use of this substance/mixture.
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Lumateperone tosylate	1187020-80-9	TWA	0,006 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 A	J&J OEL/PBOEL HHC
	Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 3A.			
Octadecanoic acid, magnesium salt	557-04-0	TLV 8 hr	10 mg/m3	BE OEL
Talc (Mg3H2(SiO3)4)	14807-96-6	TLV 8 hr (respirable fraction)	2 mg/m3	BE OEL
		TLV 8 hr (Respirable dust)	2 mg/m3	BE OEL
		TWA (Respirable	0,1 mg/m3	2004/37/EC

		dust)		
	Further information: Carcinogens or mutagens			

8.2 Exposure controls

Engineering measures

All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.
If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.
Validated Industrial Hygiene Analytical methods are developed to monitor and quantify inhalable exposure to the Active Pharmaceutical Ingredient. For more information contact Bureau Veritas Laboratories - Lake Zurich (BV_LZLab@bureauveritas.com) or the Laboratory of Occupational and Environmental Hygiene (lamh.be).

Personal protective equipment

Eye protection	:	No special precautions required.
Hand protection Remarks	:	Disposable gloves
Skin and body protection	:	closed work clothing
Respiratory protection	:	No personal respiratory protective equipment normally required.
Protective measures	:	The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	Capsule
Odour	:	No information available.
Melting point/ range	:	No data available
Boiling point/boiling range	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available

pH	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Solubility(ies)		
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

None reasonably foreseeable.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Conditions to avoid : To avoid thermal decomposition, do not overheat.
Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : None known.

10.6 Hazardous decomposition products

None known.

SECTION 11: Toxicological information

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

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: > 2 000 mg/kg

Method: Calculation method

Components:

Lumateperone tosylate:

Acute oral toxicity : Maximum tolerated dose (Rat): 30 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.

NOAEL (Rat, male): 100 mg/kg
Target Organs: No specific target organs noted

NOAEL (Rat, female): 30 mg/kg
Target Organs: No specific target organs noted

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : Remarks: No data available

Talc (Mg3H2(SiO3)4):

Acute oral toxicity : Remarks: No data available

Skin corrosion/irritation

Components:

Lumateperone tosylate:

Remarks : No data available

Talc (Mg3H2(SiO3)4):

Remarks : slight irritation

Serious eye damage/eye irritation

Components:

Lumateperone tosylate:

Remarks : No data available

Talc (Mg3H2(SiO3)4):

Remarks : Mild eye irritation

Respiratory or skin sensitisation

Components:

Lumateperone tosylate:

Remarks : No data available

Germ cell mutagenicity

Components:

Lumateperone tosylate:

Genotoxicity in vitro	:	Test Type: Ames test Test system: Salmonella typhimurium Result: equivocal Test Type: Ames test Test system: Escherichia coli Result: equivocal Test Type: A mouse lymphoma test Test system: mouse lymphoma cells Result: equivocal
Genotoxicity in vivo	:	Test Type: In vivo micronucleus test Species: Rat Result: negative Test Type: in vivo assay Species: Rat Method: In vivo Single Cell Gel Electrophoresis Assay (Comet Assay) Result: negative
Germ cell mutagenicity-Assessment	:	No evidence of mutagenicity based on in vitro and in vivo studies and expert judgment.

Talc (Mg3H2(SiO3)4):

Genotoxicity in vitro	:	Test Type: Ames test Result: negative

Carcinogenicity

Components:

Lumateperone tosylate:

Species	:	Mouse
Application Route	:	Oral
Exposure time	:	2 years
NOAEL	:	7 mg/kg
Result	:	negative
Species	:	Rat, male
Application Route	:	Oral
Exposure time	:	2 years
NOAEL	:	20 mg/kg
Result	:	negative
Species	:	Rat, female
Application Route	:	Oral

Exposure time	:	2 years
NOAEL	:	10 mg/kg
Result	:	negative

Carcinogenicity - Assessment	:	No evidence of carcinogenicity in animal studies.

Reproductive toxicity

Components:

Lumateperone tosylate:

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Rat, male Application Route: Oral Fertility: NOAEL: 15 mg/kg body weight Test Type: Fertility/early embryonic development Species: Rat, female Application Route: Oral Fertility: NOAEL: 5 mg/kg body weight
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat, female Application Route: Oral General Toxicity Maternal: NOAEL: 15 mg/kg Teratogenicity: NOAEL: 15 mg/kg Developmental Toxicity: NOAEL: 15 mg/kg body weight Test Type: Embryo-foetal development Species: Rabbit, female Application Route: Oral General Toxicity Maternal: NOAEL: 30 mg/kg Teratogenicity: NOAEL: 30 mg/kg Developmental Toxicity: NOAEL: 30 mg/kg body weight Test Type: Developmental Toxicity Species: Rat, female Application Route: Oral General Toxicity Maternal: NOAEL: 30 mg/kg Teratogenicity: NOAEL: 5 mg/kg Developmental Toxicity: NOAEL: 15 mg/kg body weight
Reproductive toxicity - Assessment	:	No effects on or via lactation
Teratogenicity - Assessment	:	Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Components:

Lumateperone tosylate:

Assessment : Not classified

STOT - repeated exposure

Components:

Lumateperone tosylate:

Assessment : Not classified

Repeated dose toxicity

Components:

Lumateperone tosylate:

Species	:	Rat
NOAEL	:	15 mg/kg
LOAEL	:	30 mg/kg
Application Route	:	Oral
Exposure time	:	6 months
Target Organs	:	Brain, Spinal cord, Heart, Eyes

Species	:	Dog
NOAEL	:	2,5 mg/kg
LOAEL	:	5 mg/kg
Application Route	:	Oral
Exposure time	:	9 months
Target Organs	:	Brain, Spinal cord

Aspiration toxicity

No data available

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

No data available

SECTION 12: Ecological information

12.1 Toxicity

Components:

Lumateperone tosylate:

Toxicity to fish	:	Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates	:	Remarks: No data available
Toxicity to algae/aquatic plants	:	Remarks: No data available

Talc (Mg3H2(SiO3)4):

Toxicity to fish	:	(Danio rerio (zebra fish)): > 100 000 mg/l Exposure time: 24 h Test Type: LC50

12.2 Persistence and degradability

Components:

Lumateperone tosylate:

Biodegradability	:	Remarks: No data available

12.3 Bioaccumulative potential

Components:

Lumateperone tosylate:

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

Octadecanoic acid, magnesium salt:

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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number or ID number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.	Not applicable

Other regulations:

Restricted to professional users.

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

15.2 Chemical safety assessment

A Chemical Safety Assessment is not applicable (mixture)

SECTION 16: Other information

Full text of H-Statements

H302	:	Harmful if swallowed.
H361fd	:	Suspected of damaging fertility. Suspected of damaging the unborn child.

Full text of other abbreviations

2004/37/EC	:	Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work - Annex III
BE OEL	:	Belgium. Occupational exposure limit values
J&J OEL/PBOEL HHC	:	J&J OEL/PBOEL HHC
2004/37/EC / TWA	:	Long term exposure limit
BE OEL / TLV 8 hr	:	Long term exposure limit
J&J OEL/PBOEL HHC / TWA	:	Time weighted average
J&J OEL/PBOEL HHC / PBOEL-HHC	:	PBOEL-HHC

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonised System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory

concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organisation for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:		**Classification procedure:**
Repr. 2	H361fd	Calculation method

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012-12-31
Numbers:	123456,78	as	123 456,78

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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