

SECTION 1 Identification**1.1. Product identifier**

Product form : Mixture
Trade name : FYCOMPA®

1.2. Other means of identification

Other means of identification : 2MG- 69616-272
4MG- 69616-274
6MG- 69616-276
8MG- 69616-278
10MG- 69616-280
12MG- 69616-282

1.3. Recommended use of the chemical and restrictions on use

Recommended use : Used for the treatment of seizures
Restrictions on use : Only for commercial and clinical use. By prescription only.

1.4. Supplier's details

Catalyst Pharmaceuticals Inc
355, Alhambra Circle
Ste. 801
Coral Gables, Florida 33134
T 305-420-3200
sds@catalystpharma.com

1.5. Emergency phone number

Emergency number : For Hazardous Materials or Dangerous Goods Incident Spill, Leak, Fire, Exposure, or Accident
Call CHEMTREC Day or Night: 1-800-424-9300 (Toll Free, USA) / 703-527-3887 (Virginia, USA)
CCN 1017517
Back-up Emergency Number: +1 703-741-5970 (Washington, DC)

SECTION 2 Hazard Identification**2.1. Classification of the substance or mixture****GHS US classification**

Reproductive toxicity, Category 1B	H360	May damage fertility or the unborn child.
Reproductive toxicity, Additional category, Effects on or via lactation	H362	May cause harm to breast-fed children.

Full text of H statements : see section 16

2.2. Label elements**GHS US labeling**

Hazard pictograms (GHS US) :



Signal word (GHS US) : Danger
Hazard statements (GHS US) : H360 - May damage fertility or the unborn child
H362 - May cause harm to breast-fed children

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Precautionary statements (GHS US) : Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Do not breathe dust.
Avoid contact during pregnancy and while nursing.
Wash hands, forearms and face thoroughly after handling.
Do not eat, drink or smoke when using this product.
Wear protective gloves, protective clothing, eye protection, face protection, and hearing protection.
If exposed or concerned: Get medical advice/attention.
Store locked up.
Dispose of contents and/or container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulations.

2.3. Hazards associated with known or reasonably anticipated uses

No additional information available

2.4. Hazards not otherwise classified

Other hazards which do not result in classification : If dust are formed : May form combustible dust concentrations in air.

2.5. Unknown acute toxicity

No additional information available

SECTION 3 Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
Perampanel	CAS-No.: 380917-97-5	2 – 10	Repr. 1B, H360 Lact., H362 STOT SE 3, H336 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Cellulose	CAS-No.: 9004-34-6	≤ 10	Comb. Dust 1
Magnesium stearate	CAS-No.: 557-04-0	≤ 1	Comb. Dust 1

Comments : *Chemical name, CAS number and/or exact concentration have been withheld as a trade secret
Full text of hazard classes and H-statements : see section 16

SECTION 4 First aid measures

4.1. Description of necessary first-aid measures

First-aid measures general : First aider: Pay attention to self-protection. Never give anything by mouth to an unconscious person. Give artificial respiration if necessary. Induce artificial respiration with mask fitted with one-way valve or other suitable device but not mouth-to-mouth. Call a poison center/doctor/physician if you feel unwell.

First-aid measures after inhalation : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a poison center or a doctor.

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin areas with mild soap and water, followed by warm water rinse. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
First-aid measures after eye contact	: Rinse eyes with water as a precaution. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth out with water. Do NOT induce vomiting. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Call a physician immediately.

4.2. Most important symptoms/effects, acute and delayed

Symptoms/effects after skin contact	: Not expected to present a significant skin hazard under anticipated conditions of normal use.
Symptoms/effects after eye contact	: May cause eye irritation.
Symptoms/effects after ingestion	: Depression of the central nervous system, headaches, dizziness, drowsiness, loss of coordination. Gastrointestinal disturbances.
Most Important Symptoms/Effects	: Active Pharmaceutical Ingredient (API). Occupational exposure may cause adverse physiological effects. Based on information from therapeutic use, this material may cause: Dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, headache, vomiting, contusion, abdominal pain, and anxiety. Serious psychiatric and behavioral effects, including aggression, irritability, and homicidal ideation were also reported.
Chronic symptoms	: May damage fertility or the unborn child.

4.3. Indication of immediate medical attention and special treatment needed, if necessary

Other medical advice or treatment	: Treat symptomatically.
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SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media	: Carbon dioxide (CO ₂), dry chemical powder, foam.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Specific hazards arising from the chemical

Fire hazard	: No fire hazard.
Explosion hazard	: No direct explosion hazard.
Hazardous decomposition products in case of fire	: Toxic fumes may be released. Carbon dioxide. Carbon monoxide. Nitrogen oxides.

5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions	: Fight fire from safe distance and protected location. Do not enter fire area without proper protective equipment, including respiratory protection. Use water spray or fog for cooling exposed containers. Move containers from fire area if it can be done without personal risk. Prevent fire-fighting water from entering environment.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Protective equipment	: Wear recommended personal protective equipment.
Emergency procedures	: Evacuate the danger area. If outdoors, move to an area upwind of the danger area. If possible without taking personal risks, Remove ignition sources, ventilate area. Prevent other non-emergency personnel from entering the danger area.

For emergency responders

Protective equipment	: Wear the recommended personal protective equipment.
Emergency procedures	: Evacuate personnel to a safe area. Do not touch spilled material. Ventilate spillage area.

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Environmental precautions : Avoid release to the environment. Notify authorities if product enters sewers or public waters.

6.2. Methods and materials for containment and cleaning up

For containment : Contain with non-combustible inert absorbent.
Methods for cleaning up : Take up in non-combustible inert absorbent and place into container for disposal. Contaminated absorbent material may pose the same hazard as the spilt product. Decontaminate surfaces and equipment with water and detergent. Until a sufficient level of dilution is achieved, the decontamination water may pose the same hazards as the product. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

For further information refer to section 8: "Exposure controls/personal protection", For further information refer to section 13

SECTION 7 Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid breathing dust. Avoid contact with skin, eyes and clothing. Avoid dust formation.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including incompatibilities

Storage conditions : Store in a cool, dry and well-ventilated area away from incompatible substances. Keep container closed when not in use.
Incompatible materials : Strong oxidizers.
Storage temperature : 15 – 30 °C / 59 - 86 °F

SECTION 8 Exposure controls/personal protection

8.1. Control parameters

Cellulose (9004-34-6)

USA - ACGIH - Occupational Exposure Limits

Local name	Cellulose
ACGIH® TLV® TWA	10 mg/m ³
Remark (ACGIH)	TLV® Basis: URT irr
Regulatory reference	ACGIH 2025

USA - OSHA - Occupational Exposure Limits

Local name	Cellulose
OSHA PEL TWA	15 mg/m ³ (Total dust) 5 mg/m ³ (Respirable fraction)
Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1

Magnesium stearate (557-04-0)

USA - ACGIH - Occupational Exposure Limits

Local name	Magnesium stearates
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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Magnesium stearate (557-04-0)

ACGIH® TLV® TWA	10 mg/m ³ (I - Inhalable particulate matter) (J - Does not include stearates of toxic metals) 3 mg/m ³ (R - Respirable particulate matter) (J - Does not include stearates of toxic metals)
Remark (ACGIH)	TLV® Basis: LRT irr. Notations: A4 (Not classifiable as a Human Carcinogen)
Regulatory reference	ACGIH 2025

8.2. Appropriate engineering controls

Appropriate engineering controls	: Ensure good ventilation of the work station. Use general ventilation, local exhaust ventilation, or process enclosure to keep the airborne concentrations below the permissible exposure limits.
Environmental exposure controls	: Avoid release to the environment. Take measures to reduce or limit air emissions and releases to soil and the aquatic environment.

8.3. Individual protection measures, such as personal protective equipment

Personal protective equipment:

Personal protective equipment should be chosen according to national standards and in discussion with the supplier of the protective equipment. Wear recommended personal protective equipment. The following personal protective equipment is to be used in the event product is compromised.

Hand protection:

Wear protective gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Eye protection:

Chemical goggles or safety glasses

Skin and body protection:

Wear suitable protective clothing. Wear suitable coveralls to prevent exposure to the skin

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. High efficiency particulate air filter (HEPA filter). Powered Air-Purifying Respirator (PAPR).

Personal protective equipment symbol(s):



SECTION 9 Physical and chemical properties

9.1. Basic physical and chemical properties

Physical state	: Solid
Appearance	: Tablets.
Color	: Various colors Orange Red Pink Green Blue
Odor	: No data available
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Flammability (solid, gas)	: Not flammable

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Explosion limits	: No data available
Particle characteristics	: No data available

9.2. Data relevant with regard to physical hazard classes (supplemental)

No additional information available

SECTION 10 Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Incompatible materials.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Thermal decomposition generates: Carbon dioxide. Carbon monoxide. Nitrogen oxides.

SECTION 11 Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

Cellulose

LD50 oral rat	> 5000 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
LC50 Inhalation - Rat	> 5.05 mg/l/4h

Magnesium stearate

LD50 oral rat	> 10000 mg/kg body weight
Skin corrosion/irritation	: Not classified

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Cellulose	
pH	5 – 7.5

Serious eye damage/irritation : Not classified

Cellulose	
pH	5 – 7.5

Respiratory or skin sensitization : Not classified

Germ cell mutagenicity : Not classified

Perampanel	
Mouse lymphoma assay	Negative
Micronucleus test, rat bone marrow	Negative
AMES test	Negative

Carcinogenicity : Not classified

Perampanel	
NOAEL (chronic,oral,animal/male,2 years)	100 mg/kg body weight
NOAEL (chronic,oral,animal/female,2 years)	30 mg/kg body weight

Reproductive toxicity : May damage fertility or the unborn child. May cause harm to breast-fed children.

Perampanel	
LOAEL (animal/female, F0/P)	3 mg/kg body weight (rat)
LOAEL (animal/male, F1)	1 mg/kg body weight (rat) Effects: visceral abnormalities, embryo lethality, reduced fetal body weight
LOAEL (animal/female, F1)	1 mg/kg body weight (rat) Effects: visceral abnormalities, embryo lethality, reduced fetal body weight
NOAEL (animal/male, F1)	1 mg/kg body weight (rabbit) Effect: embryo lethality

STOT-single exposure : Not classified

Perampanel	
STOT-single exposure	May cause drowsiness or dizziness.

STOT-repeated exposure : Not classified

Perampanel	
NOAEL, Oral, rat	1 mg/kg/day (26 weeks)
NOAEL, Oral, monkey	0.1 mg/kg/day (52 weeks)
Observed effects	(rat and monkey) abnormal or ataxic gait, decreased activity, sedation, and prostration.

Aspiration hazard : Not classified

Symptoms/effects after skin contact : Not expected to present a significant skin hazard under anticipated conditions of normal use.

Symptoms/effects after eye contact : May cause eye irritation.

Symptoms/effects after ingestion : Depression of the central nervous system, headaches, dizziness, drowsiness, loss of coordination. Gastrointestinal disturbances.

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Most Important Symptoms/Effects	: Active Pharmaceutical Ingredient (API). Occupational exposure may cause adverse physiological effects. Based on information from therapeutic use, this material may cause: Dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, headache, vomiting, contusion, abdominal pain, and anxiety. Serious psychiatric and behavioral effects, including aggression, irritability, and homicidal ideation were also reported.
Chronic symptoms	: May damage fertility or the unborn child.

SECTION 12 Ecological information

12.1. Ecotoxicity

Ecology - general	: Toxic to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term (acute)	: Toxic to aquatic life
Hazardous to the aquatic environment, long-term (chronic)	: Toxic to aquatic life with long lasting effects

Perampanel

LC50 - Fish [1]	> 1.3 mg/l
EC50 - Crustacea [1]	1 mg/l
LOEC (chronic)	0.16 mg/l
NOEC (chronic)	0.22 mg/l
NOEC chronic fish	0.06 mg/l

12.2. Persistence and degradability

FYCOMPA®

Persistence and degradability	Not established.
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Perampanel

Persistence and degradability	Not rapidly degradable
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Cellulose

Persistence and degradability	Readily biodegradable.
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Magnesium stearate

Persistence and degradability	Not rapidly degradable
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12.3. Bioaccumulative potential

FYCOMPA®

Bioaccumulative potential	Not established.
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Perampanel

Bioaccumulative potential	Bioaccumulation unlikely.
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12.4. Mobility in soil

Perampanel

Organic Carbon Normalized Adsorption Coefficient (Log Koc)	2.71
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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

12.5. Other adverse effects

Ozone : Not classified
Fluorinated greenhouse gases : No

SECTION 13 Disposal considerations

Regional waste regulation : Disposal must be done according to official regulations.
Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations : Disposal must be done according to official regulations.
Product/Packaging disposal recommendations : Disposal must be done according to official regulations. Refer to all applicable national, international and local regulations or provisions.
Additional information : Do not re-use empty containers.
Ecological waste information : Avoid release to the environment.

SECTION 14 Transport information

In accordance with DOT / IMDG / IATA

DOT	IMDG	IATA
14.1. UN number		
Not regulated for transport		
14.2. Proper Shipping Name		
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
Not regulated	Not regulated	Not regulated
14.4. Packing group		
Not regulated	Not regulated	Not regulated
14.5. Environmental hazards		
	Not regulated	
No supplementary information available		

14.6. Transport in bulk

Not applicable

14.7. Special precautions for user

DOT
Not regulated

IMDG
Not regulated

IATA
Not regulated

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

SECTION 15 Regulatory information

15.1. Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory, except for:

Perampanel	CAS-No. 380917-97-5	2 – 10%
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This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

15.2. International regulations

CANADA

Perampanel (380917-97-5)

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

Cellulose (9004-34-6)

Listed on the Canadian DSL (Domestic Substances List)

Magnesium stearate (557-04-0)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations

Cellulose (9004-34-6)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Magnesium stearate (557-04-0)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

15.3. State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

Component	State or local regulations
Cellulose(9004-34-6)	U.S. - Massachusetts - Right To Know List; U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16 Other information

According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Issue date : 6/17/2025

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Full text of hazard classes and H-statements	
H336	May cause drowsiness or dizziness
H360	May damage fertility or the unborn child
H362	May cause harm to breast-fed children
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.