INVEGA SUSTENNA

Version	Revision Date:	SDS Number:	Date of last issue: 2024/11/14
8.0	2024/12/12	100000009874	Date of first issue: 2013/12/23

SECTION 1. IDENTIFICATION

Product name : INVEGA SUSTENNA
Substance name : INVEGA SUSTENNA®, paliperidone palmitate extended-release injectable susp., IM use 39 mg paliperidone palmitate; 25 mg eq. paliperidone

paliperidone palmitate
PalPal 1M

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560

USA

Telephone : +16097302000

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

Emergency telephone number : **CHEMTREC US: 1-800-424-9300**
CHEMTREC International: +1 703-741-5970

Recommended use of the chemical and restrictions on use

Recommended use : 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.
This dosage form is not exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity (Oral) : Category 4

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.

Precautionary statements :

Prevention:

P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

Disposal:

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

Other hazards

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

Substance / Mixture : Mixture

Chemical nature : Liquid

Components

Chemical name	CAS-No.	Concentration (% w/w)
PALIPERIDONE PALMITATE	199739-10-1	>= 10 - < 20
POLYETHYLENE GLYCOL 4000	25322-68-3	>= 1 - < 5
sodium hydroxide	1310-73-2	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. 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	:	Remove contact lenses. Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes. 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.
Most important symptoms and effects, both acute and delayed	:	Consult the patient packaging insert for more information about this Finished Pharmaceutical Product. Abdominal pain Dizziness musculoskeletal pain restlessness anxiety injection site reactions
Notes to physician	:	Treat symptomatically. Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Hazardous combustion products	:	No hazardous combustion products are known
Further information	:	No information available.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	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.
Environmental precautions	:	Should not be released into the environment. Do not allow material to contaminate ground water system.
Methods and materials for containment and cleaning up	:	Large spills: Dam up. Soak up with inert absorbent material. Keep in properly labelled containers. Small spills: Gently cover the spill with an absorbent towel or pad. Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

SECTION 7. HANDLING AND STORAGE

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

Conditions for safe storage : 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.
Keep locked up.

Recommended storage temperature : < 86 °F / < 30 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
PALIPERIDONE PALMITATE	199739-10-1	TWA	0.0074 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.			
POLYETHYLENE GLYCOL 4000	25322-68-3	TWA (aerosol)	10 mg/m3	US WEEL
sodium hydroxide	1310-73-2	C	2 mg/m3	ACGIH
		TWA	2 mg/m3	ACGIH
		C	2 mg/m3	NIOSH REL
		TWA	2 mg/m3	OSHA Z-1
		C	2 mg/m3	OSHA P0

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

Respiratory protection	:	No personal respiratory protective equipment normally required.
Hand protection		
Remarks	:	Disposable gloves
Eye protection	:	No special precautions required.
Skin and body protection	:	closed work clothing
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.
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Prefilled syringe
Colour	:	white, off-white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
	:	No data available
	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available

Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	No data available

Solubility(ies)

Water solubility	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available

Viscosity

Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	To avoid thermal decomposition, do not overheat.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: 416.67 mg/kg
Method: Calculation method

Components:

PALIPERIDONE PALMITATE:

Acute oral toxicity : LD50 (Rat): 65 mg/kg
Remarks: Information given is based on data obtained from similar substances.

POLYETHYLENE GLYCOL 4000:

Acute oral toxicity : LD50 Oral (Rat): > 15,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

sodium hydroxide:

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

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

Skin corrosion/irritation

Components:

POLYETHYLENE GLYCOL 4000:

Result : No skin irritation

sodium hydroxide:

Species : Rabbit
Result : Corrosive to skin
Remarks : Classification according to Regulation 1272/2008 Annex VI

Serious eye damage/eye irritation

Components:

POLYETHYLENE GLYCOL 4000:

Result : No eye irritation

sodium hydroxide:

Species : Rabbit
Result : Corrosive

Respiratory or skin sensitisation

Components:

POLYETHYLENE GLYCOL 4000:

Result : Not a sensitizer

sodium hydroxide:

Species : human
Result : Does not cause skin sensitisation.

Germ cell mutagenicity

Components:

PALIPERIDONE PALMITATE:

Genotoxicity in vitro : Test Type: Ames test
Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Result: negative

Test Type: A mouse lymphoma test
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Result: negative

Germ cell mutagenicity - Assessment : Animal testing did not show any mutagenic effects.

POLYETHYLENE GLYCOL 4000:

Germ cell mutagenicity - Assessment : Not mutagenic in Ames Test

sodium hydroxide:

Genotoxicity in vivo : Result: negative
Remarks: No significant adverse effects were reported

Germ cell mutagenicity - Assessment : No evidence of mutagenicity based on in vitro and in vivo studies and expert judgment.

Carcinogenicity

Components:

PALIPERIDONE PALMITATE:

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

POLYETHYLENE GLYCOL 4000:

Carcinogenicity - Assessment : No information available.

sodium hydroxide:

Carcinogenicity - Assessment : No information available.

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Components:

PALIPERIDONE PALMITATE:

Reproductive toxicity - Assessment : Animal testing did not show any effects on fertility.

Teratogenicity - Assessment : Ingestion of excessive amounts by pregnant animals resulted in maternal and foetal toxicity.

POLYETHYLENE GLYCOL 4000:

Teratogenicity - Assessment : No information available.

sodium hydroxide:

Reproductive toxicity - Assessment : No information available.

Teratogenicity - Assessment : No information available.

STOT - single exposure

Components:

POLYETHYLENE GLYCOL 4000:

Remarks : No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

No data available

Aspiration toxicity

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

No data available

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

PALIPERIDONE PALMITATE:

Toxicity to fish : Remarks: No data available

POLYETHYLENE GLYCOL 4000:

Toxicity to fish : (Leuciscus idus (Golden orfe)): > 10 g/l
Exposure time: 48 h
Test Type: LC50
Method: DIN 38412

sodium hydroxide:

Toxicity to fish : LC50 (Gambusia affinis (Mosquito fish)): 125 mg/l
Exposure time: 96 h

LC50 (Poecilia reticulata (guppy)): 145 mg/l
Exposure time: 24 h

LC50 (Fish): 196 mg/l
Exposure time: 96 h

LC50 (Carassius auratus (goldfish)): 160 mg/l
Exposure time: 24 h

LC50 (Leuciscus idus (Golden orfe)): 189 mg/l
Exposure time: 48 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 76 mg/l
Exposure time: 24 h

EC50 (Ceriodaphnia dubia (water flea)): 40 mg/l
Exposure time: 48 h

LC50 (Biomphalaria a. alexandrina (snail)): 450 mg/l
Exposure time: 96 h

LC50 (Bulinus truncatus (snail)): 150 mg/l
Exposure time: 96 h

LC50 (Lymnaea caillaudi (snail)): 150 mg/l
Exposure time: 96 h

Toxicity to microorganisms : EC50 (Photobacterium phosphoreum): 22 mg/l
Exposure time: 15 min

Persistence and degradability

Components:

PALIPERIDONE PALMITATE:

Biodegradability : Remarks: No data available

POLYETHYLENE GLYCOL 4000:

Biodegradability : Biodegradation: > 95 %
Exposure time: 23 d

Chemical Oxygen Demand (COD) : 1,740 mg/g
Method: DIN 38409-H-41

Bioaccumulative potential

Components:

PALIPERIDONE PALMITATE:

Bioaccumulation : Remarks: No data available

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

POLYETHYLENE GLYCOL 4000:

Bioaccumulation : Remarks: No data available

Mobility in soil

Components:

PALIPERIDONE PALMITATE:

Distribution among environmental compartments : Remarks: No data available

POLYETHYLENE GLYCOL 4000:

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Components:

PALIPERIDONE PALMITATE:

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

POLYETHYLENE GLYCOL 4000:

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

water	7732-18-5
PALIPERIDONE PALMITATE	199739-10-1
POLYETHYLENE GLYCOL 4000	25322-68-3
	Not Assigned
sodium hydroxide	1310-73-2

New Jersey Right To Know

water	7732-18-5
PALIPERIDONE PALMITATE	199739-10-1
POLYETHYLENE GLYCOL 4000	25322-68-3
TWEEN 20	9005-64-5

New York City Hazardous Substances

	Not Assigned
sodium hydroxide	1310-73-2

California Prop. 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

The components of this product are reported in the following inventories:

: This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

Other regulations

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

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

Restricted to professional users.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	US. ACGIH Threshold Limit Values
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC	:	J&J OEL/PBOEL HHC
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA	:	Time weighted average
ACGIH / C	:	Ceiling limit
J&J OEL/PBOEL HHC / TWA	:	Time weighted average
J&J OEL/PBOEL HHC / PBOEL-HHC	:	PBOEL-HHC
NIOSH REL / C	:	Ceiling value not be exceeded at any time.
OSHA P0 / C	:	Ceiling limit
OSHA Z-1 / TWA	:	8-hour time weighted average
US WEEL / TWA	:	8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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 Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization

Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 2024/12/12

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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