

# SAFETY DATA SHEET



## INVEGA

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### SECTION 1. IDENTIFICATION

Product name : INVEGA  
Substance name : INVEGA Prolonged-Release tablet, 1,5mg paliperidone

#### 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 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)

Not a hazardous substance or mixture.

#### GHS label elements

Not a hazardous substance or mixture.

#### Other hazards

This Finished Pharmaceutical Product is non-hazardous based on chemical classification rules. Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate

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the possible workplace hazards when this Finished Pharmaceutical Product is accidentally leaking, broken or crushed.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Polyethylene oxide	25322-68-3	$\geq 50 - < 70$
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	$\geq 1 - < 5$
HYDROXYETHYLCELLULOSE	9004-62-0	$\geq 1 - < 5$
TITANDIOXIDE	13463-67-7	$\geq 0.1 - < 1$
PALIPERIDONE	144598-75-4	$\geq 0.1 - < 1$
Polyethylene Glycol 400	25322-68-3	$\geq 0.1 - < 1$
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	$\geq 0.1 - < 1$
Octadecanoic acid	57-11-4	$\geq 0.1 - < 1$
diiron trioxide	1309-37-1	$\geq 0.1 - < 1$
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	128-37-0	$< 0.1$

Actual concentration is withheld as a trade secret

### SECTION 4. FIRST AID MEASURES

- If inhaled : Health injuries are not known or expected under normal use.  
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.  
calming  
constipation  
Dizziness

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drowsiness  
headache  
indigestion  
insomnia  
nausea  
restlessness  
Spasm  
Tremors  
tachycardia  
psychotic disorders  
weight increase

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.

Environmental precautions : Should not be released into the environment.

Methods and materials for containment and cleaning up : Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".  
Large spills: Sweep up (intact) or vacuum with HEPA filter (broken or crushed) 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.

**SECTION 7. HANDLING AND STORAGE**

Advice on protection against fire and explosion : No data available

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- 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 : Keep away from heat and sources of ignition.  
Keep containers tightly closed in a dry, cool and well-ventilated place.  
Keep locked up.  
Store in original container.  
To maintain product quality, do not store in heat or direct sunlight.
- Recommended storage temperature : 59 - 77 °F / 15 - 25 °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
Polyethylene oxide	25322-68-3	TWA (aerosol)	10 mg/m <sup>3</sup>	US WEEL
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	TWA	10 mg/m <sup>3</sup>	ACGIH
HYDROXYETHYLCELLULOSE	9004-62-0	TWA	10 mg/m <sup>3</sup>	ACGIH
TITANDIOXIDE	13463-67-7	TWA	2.4 mg/m <sup>3</sup>	J&J OEL/PBOEL HHC
		TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	10 mg/m <sup>3</sup>	OSHA P0
		TWA (Respirable particulate matter)	0.2 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH
		TWA (Respirable particulate matter)	2.5 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH
PALIPERIDONE	144598-75-4	TWA	0.006 mg/m <sup>3</sup>	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 A	J&J

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				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 400	25322-68-3	TWA (aerosol)	10 mg/m3	US WEEL
Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.- hydroxy-	25322-68-3	TWA (aerosol)	10 mg/m3	US WEEL
Octadecanoic acid	57-11-4	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
diiron trioxide	1309-37-1	TWA (Respirable particulate matter)	5 mg/m3	ACGIH
		TWA (Fumes)	10 mg/m3	OSHA Z-1
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Fumes)	10 mg/m3	OSHA P0
		TWA (dust and fume)	5 mg/m3 (Iron)	NIOSH REL
Phenol, 2,6-bis(1,1- dimethylethyl)-4-methyl-	128-37-0	TWA (Inhalable fraction and vapor)	2 mg/m3	ACGIH
		TWA	10 mg/m3	ACGIH
		TWA	10 mg/m3	NIOSH REL
		TWA	10 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 Maxxam Analytics ([www.maxxamlabs.com](http://www.maxxamlabs.com)) or the Laboratory of Occupational and Environmental Hygiene ([www.lamh.be](http://www.lamh.be)).

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**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 : tablet
- Colour : No data available
- Odour : No data available
- pH : No data available
- Melting point/range : No data available
- Boiling point/boiling range : No data available
- Flash point : No data available
- Evaporation rate : Not applicable
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available
- Vapour pressure : Not applicable
- Relative density : No data available
- Density : No data available

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Solubility(ies)  
Water solubility : No data available

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

Decomposition temperature : No data available

Viscosity  
Viscosity, dynamic : Not applicable

Viscosity, kinematic : Not applicable

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 : Heat, flames and sparks.  
Exposure to moisture  
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: 3,599 mg/kg  
Method: Calculation method

##### Components:

##### **Polyethylene oxide:**

Acute oral toxicity : LD50 (Rat): 4,000 mg/kg  
Assessment: The component/mixture is minimally toxic after single ingestion.  
Remarks: Information given is based on data obtained from similar substances.

Acute inhalation toxicity : Remarks: No data available

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Acute dermal toxicity : Remarks: No data available

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

**PALIPERIDONE:**

Acute oral toxicity : LD50 (Rat, female): 56.6 mg/kg  
 LD50 (Rat, female): 65 mg/kg  
 LD50 (Rat, male): 112 mg/kg  
 LD50 (Rat, female): 149 mg/kg

**Polyethylene Glycol 400:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
 Acute inhalation toxicity : Remarks: No data available  
 Acute dermal toxicity : Remarks: No data available

**Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
 LD50 (Rabbit): > 2,000 mg/kg  
 Acute inhalation toxicity : Remarks: No data available  
 Acute dermal toxicity : Remarks: No data available

**Skin corrosion/irritation****Components:****Polyethylene oxide:**

Species : Rabbit  
 Exposure time : 4 h  
 Result : No skin irritation  
 Remarks : Information given is based on data obtained from similar substances.

**Polyethylene Glycol 400:**

Remarks : No data available

**Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:**

Result : Mild skin irritation



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**Serious eye damage/eye irritation****Components:****Polyethylene oxide:**

Species : Rabbit  
 Result : No eye irritation  
 Remarks : Information given is based on data obtained from similar substances.

**Polyethylene Glycol 400:**

Remarks : No data available

**Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:**

Remarks : No data available

**Respiratory or skin sensitisation****Components:****Polyethylene oxide:**

Remarks : No data available

**Polyethylene Glycol 400:**

Result : Not a sensitizer

**Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:**

Remarks : No data available

**Germ cell mutagenicity****Components:****Polyethylene oxide:**

Genotoxicity in vitro : Remarks: No data available

**PALIPERIDONE:**

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 - : Animal testing did not show any mutagenic effects.

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## Assessment

**Polyethylene Glycol 400:**

Germ cell mutagenicity - Assessment : Not mutagenic in Ames Test

**Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:**

Germ cell mutagenicity - Assessment : No information available.

**Carcinogenicity****Components:****Polyethylene oxide:**

Species : Rat  
Application Route : Oral  
Exposure time : 2 years  
Dose : 1000 - 1300 mg/kg/day  
Remarks : Did not show carcinogenic effects in animal experiments.

**PALIPERIDONE:**

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

**Polyethylene Glycol 400:**

Carcinogenicity - Assessment : No information available.

**Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:**

Carcinogenicity - Assessment : No information available.

**IARC** Group 2B: Possibly carcinogenic to humans  
13463-67-7

TITANDIOXIDE

**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:****Polyethylene oxide:**

Effects on fertility : Remarks: No data available

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Effects on foetal development : Remarks: No data available

### **PALIPERIDONE:**

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 400:**

Teratogenicity - Assessment : No information available.

### **Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:**

Teratogenicity - Assessment : No information available.

### **STOT - single exposure**

#### **Components:**

#### **Polyethylene oxide:**

Remarks : No data available

#### **Polyethylene Glycol 400:**

Remarks : No data available

#### **Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:**

Remarks : No data available

### **STOT - repeated exposure**

No data available

### **Repeated dose toxicity**

#### **Components:**

#### **Polyethylene oxide:**

Species : Rat  
Application Route : Oral  
Exposure time : 14 days  
Dose : 50000 ppm  
Symptoms : Gastrointestinal disturbance

Species : Rat  
Application Route : Oral  
Exposure time : 14 days  
Dose : 20000 ppm  
Remarks : No adverse effect has been observed in chronic toxicity tests.

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**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:****Polyethylene oxide:**

Toxicity to fish : LC50 (Cyprinodon sp. (minnow)): > 10,000 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other : LC50 (Daphnia magna (Water flea)): 7,550 mg/l  
aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic : Remarks: No data available  
plants

**HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

Toxicity to fish : Remarks: No data available

**PALIPERIDONE:**

Toxicity to fish : NOEC (Danio rerio (zebra fish)): 2.5 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

LC50 (Danio rerio (zebra fish)): 18 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 23 mg/l  
aquatic invertebrates Exposure time: 48 h  
Method: OECD Test Guideline 202

NOEC (Daphnia magna (Water flea)): 2.1 mg/l

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- Exposure time: 48 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EbC50 (*Scenedesmus capricornutum* (fresh water algae)): 14 mg/l  
Exposure time: 72 h  
Test Type: Cell multiplication inhibition test  
Method: OECD Test Guideline 201
- ErC50 (*Scenedesmus capricornutum* (fresh water algae)): > 16 mg/l  
Exposure time: 72 h  
Test Type: Growth inhibition  
Method: OECD Test Guideline 201
- NOECb (*Scenedesmus capricornutum* (fresh water algae)): 7 mg/l  
Exposure time: 72 h  
Test Type: Cell multiplication inhibition test  
Method: OECD Test Guideline 201
- NOECr (*Scenedesmus capricornutum* (fresh water algae)): 7 mg/l  
Exposure time: 72 h  
Test Type: Growth inhibition  
Method: OECD Test Guideline 201
- Toxicity to fish (Chronic toxicity) : NOEC (*Danio rerio* (zebra fish)): 3.2 mg/l  
Exposure time: 35 d  
Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): 2.5 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211
- Toxicity to microorganisms : NOEC (activated sludge):  $\geq 2,000$  mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209
- EC50 (activated sludge): > 2,000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209
- Polyethylene Glycol 400:**
- Toxicity to fish : (*Leuciscus idus* (Golden orfe)): > 10 mg/l  
Exposure time: 48 h  
Test Type: LC50
- Toxicity to microorganisms : (Bacteria): > 12.5 mg/l  
Exposure time: 3 h

**Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-**

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Toxicity to fish : (Fish): 0.199 mg/l  
Exposure time: 96 h  
Test Type: LC50

Toxicity to algae/aquatic plants : EC50: 0.758 mg/l  
Exposure time: 96 h

M-Factor (Acute aquatic toxicity) : 1

M-Factor (Chronic aquatic toxicity) : 1

### Persistence and degradability

#### Components:

##### **Polyethylene oxide:**

Biodegradability : Remarks: No data available

##### **HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

Biodegradability : Remarks: No data available

##### **PALIPERIDONE:**

Biodegradability : Inoculum: activated sludge  
Result: Not readily biodegradable.  
Method: OECD Test Guideline 301F

##### **Polyethylene Glycol 400:**

Biodegradability : Biodegradation: > 80 %  
Exposure time: 28 d

Dissolved organic carbon (DOC) : 492 mg/g

##### **Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:**

Biodegradability : Remarks: No data available

### Bioaccumulative potential

#### Components:

##### **Polyethylene oxide:**

Bioaccumulation : Remarks: No data available

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

##### **HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

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Bioaccumulation : Remarks: No data available

### TITANDIOXIDE:

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

### PALIPERIDONE:

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

### Polyethylene Glycol 400:

Bioaccumulation : Remarks: No data available

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

### Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:

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

### Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Bioaccumulation : Bioconcentration factor (BCF): 598.4

### Mobility in soil

#### Components:

### HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Distribution among environmental compartments : Remarks: No data available

### PALIPERIDONE:

Distribution among environmental compartments : Adsorption/Soil  
Medium: Soil  
Koc: 9607  
Method: OECD Test Guideline 106

Adsorption/Soil  
Medium: Soil  
Koc: 101602  
Method: OECD Test Guideline 106

Adsorption/Soil  
Medium: Soil  
Koc: 53877  
Method: OECD Test Guideline 106

Adsorption/Soil

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Medium: Soil  
Koc: 24008  
Method: OECD Test Guideline 106

**Polyethylene Glycol 400:**

Mobility : Remarks: No data available

Distribution among environmental compartments : Remarks: No data available

**Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:**

Mobility : Remarks: No data available

**Other adverse effects****Components:****HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

**Polyethylene Glycol 400:**

Environmental fate and pathways : No data available

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

**Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:**

Environmental fate and pathways : No data available

Results of PBT and vPvB assessment : No information 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



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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

Polyethylene oxide	25322-68-3
CELLULOSEACETAAT	9004-35-7
sodium chloride	7647-14-5
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3
HYDROXYETHYLCELLULOSE	9004-62-0
PVP K30 (KOLLIDON 30)	9003-39-8

#### Maine Chemicals of High Concern

Product does not contain any listed chemicals

#### Vermont Chemicals of High Concern

Product does not contain any listed chemicals

#### Washington Chemicals of High Concern

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Product does not contain any listed chemicals

### New York City Hazardous Substances

TITANDIOXIDE	13463-67-7
diiron trioxide	1309-37-1
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	128-37-0

### California Prop. 65

WARNING: This product can expose you to chemicals including TITANDIOXIDE, which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

### California List of Hazardous Substances

PVP K30 (KOLLIDON 30)	9003-39-8
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### Other regulations

Restricted to professional users.

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

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

## 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 / TWA	:	8-hour, time-weighted average
J&J OEL/PBOEL HHC / TWA	:	Time weighted average
J&J OEL/PBOEL HHC / PBOEL-HHC	:	PBOEL-HHC
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
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 -

# SAFETY DATA SHEET



## INVEGA

Version	Revision Date:	SDS Number:	Date of last issue: 2022/09/23
4.0	2022/11/08	100000010350	Date of first issue: 2014/07/09

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 : 2022/11/08

### Date and Number Formats

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

<b>Date:</b>	Dec 31th, 2012	as	2012/12/31
<b>Numbers:</b>	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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