

**INVEGA** 

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2025/02/01

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 100000010350
 Date of first issue: 2014/07/09

#### **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 : CHEMTREC US: 1-800-424-9300

number 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**

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.



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#### 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 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 : Solid

#### Components

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

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

Consult the patient packaging insert for more information

about this Finished Pharmaceutical Product.



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delayed calming

> constipation Dizziness 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.

for firefighters

Special protective equipment : 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**



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Advice on protection against

fire and explosion

No data available

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/m3	US WEEL
HYDROXYPROPYLMETHYLC ELLULOSE (HPMC)	9004-65-3	TWA	10 mg/m3	ACGIH
HYDROXYETHYLCELLULOS E	9004-62-0	TWA	10 mg/m3	ACGIH
TITANDIOXIDE	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL HHC
		TWA	10 mg/m3	ACGIH
PALIPERIDONE	144598-75-4	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.			
Polyethylene Glycol 400	25322-68-3	TWA (aerosol)	10 mg/m3	US WEEL
Poly(oxy-1,2-ethanediyl), .alphahydroomega	25322-68-3	TWA (aerosol)	10 mg/m3	US WEEL



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hydroxy-				
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 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



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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

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Decomposition temperature : No data available

Viscosity



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<u>Viscosity, dynamic</u> : Not applicable

<u>Viscosity, kinematic</u> : 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: > 5,000 mg/kg

Method: Calculation method

Components:

Polyethylene oxide:

Acute inhalation toxicity : Remarks: No data available

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



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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

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



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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 -

Assessment

Animal testing did not show any mutagenic effects.

Polyethylene Glycol 400:

Germ cell mutagenicity -

agenicity - : Not mutagenic in Ames Test

Assessment

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

Germ cell mutagenicity -

: No information available.

Assessment



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#### 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 - : Animal testing did not show any carcinogenic effects.

Assessment

Polyethylene Glycol 400:

Carcinogenicity - : No information available.

Assessment

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

Carcinogenicity - : No information available.

Assessment

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:**

## Polyethylene oxide:

Effects on fertility : Remarks: No data available

Effects on foetal : Remarks: No data available

development

**PALIPERIDONE:** 

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

Assessment

Teratogenicity - Assessment : Ingestion of excessive amounts by pregnant animals resulted

in maternal and foetal toxicity.

## Polyethylene Glycol 400:



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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.

**Aspiration toxicity** 

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

**Neurological effects** 

No data available



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**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 :

aquatic invertebrates

LC50 (Daphnia magna (Water flea)): 7,550 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

Remarks: No data available

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 :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 23 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

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

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



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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): >= 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-:

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



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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):

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



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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 : Remarks: No data available

environmental compartments

**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 Medium: Soil Koc: 24008

Method: OECD Test Guideline 106

Polyethylene Glycol 400:

Mobility : Remarks: No data available

Distribution among : Remarks: No data available

environmental compartments

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



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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

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



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#### **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 (NaCl)	7647-14-5
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3
HYDROXYETHYLCELLULOSE	9004-62-0
POVIDONE	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**

Product does not contain any listed chemicals

#### **New York City Hazardous Substances**

diiron trioxide	1309-37-1
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	128-37-0
propan-2-ol	67-63-0

#### California List of Hazardous Substances

POVIDONE 9003-39-8

#### Other regulations

Restricted to professional users.



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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 PO : 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 -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;



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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 : 2025/02/23

#### **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

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