

CONCERTA

Version	Revision Date:	SDS Number:	Date of last issue:
10.1	2025/02/23	100000014508	2025/02/01
			Date of first issue: 2018/04/09

SECTION 1. IDENTIFICATION

Product name : CONCERTA
Substance name : CONCERTA 54 mg tablet
methylphenidate hydrochloride
Tablet - 54 mg
Methylphenidati hydrochloridum

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: Psychoanaleptics
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)**

Skin sensitisation : Category 1

Short-term (acute) aquatic hazard : Category 3

CONCERTA

Version 10.1	Revision Date: 2025/02/23	SDS Number: 100000014508	Date of last issue: 2025/02/01 Date of first issue: 2018/04/09
-----------------	------------------------------	-----------------------------	---

Long-term (chronic) aquatic hazard : Category 3

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust.
P272 Contaminated work clothing must not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

May be absorbed via the skin.

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 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	>= 50 - < 70
METHYLPHENIDATE HYDROCHLORIDE	298-59-9	>= 10 - < 20
HYDROXYPROPYLMETHYLCELLU	9004-65-3	>= 5 - < 10

CONCERTA

Version	Revision Date:	SDS Number:	Date of last issue:
10.1	2025/02/23	100000014508	2025/02/01
			Date of first issue: 2018/04/09

LOSE (HPMC)		
TITANDIOXIDE	13463-67-7	$\geq 0.1 - < 1$
Octadecanoic acid	57-11-4	$\geq 0.1 - < 1$
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	128-37-0	< 0.1
phosphoric acid	7664-38-2	< 0.1

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 immediately with plenty of water.
Consult a physician.
Wash contaminated clothing before re-use. |
| In case of eye contact | : | Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes.
Remove contact lenses.
If eye irritation persists, consult a specialist. |
| If swallowed | : | If swallowed, rinse mouth with water (only if the person is conscious).
Call a physician immediately. |
| Most important symptoms and effects, both acute and delayed | : | Abdominal pain
aggression
anxiety
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.
Cough
Diarrhoea
Dizziness
Fatigue
Fever
headache
insomnia
Irritability
loss in appetite
mood swings
nausea
pharyngitis
Rash
throat pain
twitching
Vomiting
weight decrease
May cause an allergic skin reaction. |
| Notes to physician | : | Treat symptomatically. |

CONCERTA

Version 10.1	Revision Date: 2025/02/23	SDS Number: 100000014508	Date of last issue: 2025/02/01 Date of first issue: 2018/04/09
-----------------	------------------------------	-----------------------------	---

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.
- Specific hazards during firefighting : Risk of dust explosion in case of organic fine powder.
- 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 : Evacuate personnel to safe areas.
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.
Avoid breathing dust.
Avoid dust formation.
- Environmental precautions : Should not be released into the environment.
Do not flush into surface water or sanitary sewer system.
- 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 : None known.
- Advice on safe handling : To avoid thermal decomposition, do not overheat.
Avoid inhalation, ingestion and contact with skin and eyes.
Keep away from heat and sources of ignition.
Do not break, crush or spill this Finished Pharmaceutical Product.

CONCERTA

Version	Revision Date:	SDS Number:	Date of last issue:
10.1	2025/02/23	100000014508	2025/02/01
			Date of first issue: 2018/04/09

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
Polyethylene oxide	25322-68-3	TWA (aerosol)	10 mg/m ³	US WEEL
METHYLPHENIDATE HYDROCHLORIDE	298-59-9	TWA	0.020 mg/m ³	J&J OEL/PBOEL HHC
		STV	0,200 mg/100cm ²	J&J OEL/PBOEL HHC
		PBOEL-HHC	2	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 2., Notation SKIN: has the potential for absorption via the skin.			
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	TWA	10 mg/m ³	ACGIH
TITANDIOXIDE	13463-67-7	TWA	2.4 mg/m ³	J&J OEL/PBOEL HHC
		TWA	10 mg/m ³	ACGIH
Octadecanoic acid	57-11-4	TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	128-37-0	TWA (Inhalable)	2 mg/m ³	ACGIH

CONCERTA

Version 10.1 Revision Date: 2025/02/23 SDS Number: 100000014508 Date of last issue: 2025/02/01
Date of first issue: 2018/04/09

		fraction and vapor)		
		TWA	10 mg/m3	ACGIH
		TWA	10 mg/m3	NIOSH REL
		TWA	10 mg/m3	OSHA P0
Polyethylene oxide	25322-68-3	TWA (aerosol)	10 mg/m3	US WEEL
METHYLPHENIDATE HYDROCHLORIDE	298-59-9	TWA	0.020 mg/m3	J&J OEL/PBOEL HHC
		STV	0,200 mg/100cm ²	J&J OEL/PBOEL HHC
		PBOEL-HHC	2	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 2., Notation SKIN: has the potential for absorption via the skin.			
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	TWA	10 mg/m3	ACGIH
TITANDIOXIDE	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL HHC
		TWA	10 mg/m3	ACGIH
Octadecanoic acid	57-11-4	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
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
phosphoric acid	7664-38-2	TWA	1 mg/m3	ACGIH
		STEL	3 mg/m3	ACGIH
		TWA	1 mg/m3	NIOSH REL
		ST	3 mg/m3	NIOSH REL
		TWA	1 mg/m3	OSHA Z-1
		TWA	1 mg/m3	OSHA P0
		STEL	3 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

CONCERTA

Version 10.1	Revision Date: 2025/02/23	SDS Number: 100000014508	Date of last issue: 2025/02/01 Date of first issue: 2018/04/09
-----------------	------------------------------	-----------------------------	---

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	:	tablet
Colour	:	yellow, grey, white, red brown
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
Flammability (solid, gas)	:	The product is not flammable.
Upper explosion limit / Upper flammability limit	:	No data available

SAFETY DATA SHEET



CONCERTA

Version 10.1	Revision Date: 2025/02/23	SDS Number: 100000014508	Date of last issue: 2025/02/01 Date of first issue: 2018/04/09
-----------------	------------------------------	-----------------------------	---

Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
<u>Water solubility</u>	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Decomposition temperature	:	No data available
Viscosity		
<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 normal conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	To avoid thermal decomposition, do not overheat. Heat, flames and sparks. Exposure to moisture
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity	:	Acute toxicity estimate: 3,249 mg/kg
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CONCERTA

Version 10.1	Revision Date: 2025/02/23	SDS Number: 100000014508	Date of last issue: 2025/02/01 Date of first issue: 2018/04/09
-----------------	------------------------------	-----------------------------	---

Method: Calculation method

Acute dermal toxicity : Remarks: May be harmful if absorbed through skin.

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

METHYLPHENIDATE HYDROCHLORIDE:

Acute oral toxicity : LD50 (Rat): 367 mg/kg

LD50 (Mouse): 190 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Mouse): 41 mg/kg
Application Route: intravenous injectionLD50 (Rat): 48 mg/kg
Application Route: intravenous injection**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

phosphoric acid:Acute oral toxicity : LD50 (Rat): 300 - 2,000 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.**Skin corrosion/irritation****Components:****Polyethylene oxide:**Species : Rabbit
Exposure time : 4 h

CONCERTA

Version 10.1	Revision Date: 2025/02/23	SDS Number: 100000014508	Date of last issue: 2025/02/01 Date of first issue: 2018/04/09
-----------------	------------------------------	-----------------------------	---

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

METHYLPHENIDATE HYDROCHLORIDE:

Remarks : The product may be absorbed through the skin.

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

Result : Mild skin irritation

phosphoric acid:

Result : Corrosive to skin

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.

METHYLPHENIDATE HYDROCHLORIDE:

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

METHYLPHENIDATE HYDROCHLORIDE:

Assessment : May cause sensitisation by skin contact.

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

Remarks : No data available

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

CONCERTA

Version	Revision Date:	SDS Number:	Date of last issue: 2025/02/01
10.1	2025/02/23	100000014508	Date of first issue: 2018/04/09

Genotoxicity in vitro : Remarks: No data available

METHYLPHENIDATE HYDROCHLORIDE:

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

Test Type: A mouse lymphoma test
Result: negative

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

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.

METHYLPHENIDATE HYDROCHLORIDE:

Species : Rat
Application Route : Oral
Dose : 45 mg/kg/day
Result : No evidence of carcinogenicity in animal studies.

Carcinogenicity - Assessment : Did not show carcinogenic or mutagenic effects in animal experiments.

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

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.

CONCERTA

Version 10.1	Revision Date: 2025/02/23	SDS Number: 100000014508	Date of last issue: 2025/02/01 Date of first issue: 2018/04/09
-----------------	------------------------------	-----------------------------	---

Reproductive toxicity**Components:****Polyethylene oxide:**

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

METHYLPHENIDATE HYDROCHLORIDE:

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

METHYLPHENIDATE HYDROCHLORIDE:

Exposure routes : Ingestion

Assessment : May cause drowsiness or dizziness.

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.

CONCERTA

Version 10.1	Revision Date: 2025/02/23	SDS Number: 100000014508	Date of last issue: 2025/02/01 Date of first issue: 2018/04/09
-----------------	------------------------------	-----------------------------	---

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

METHYLPHENIDATE HYDROCHLORIDE:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

NOEC (Danio rerio (zebra fish)): >= 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 75 mg/l
aquatic invertebrates Exposure time: 24 h
Method: OECD Test Guideline 202

NOEC (Daphnia magna (Water flea)): 5.4 mg/l
Exposure time: 24 h
Method: OECD Test Guideline 202

EC50 (Daphnia magna (Water flea)): 42 mg/l

CONCERTA

Version 10.1	Revision Date: 2025/02/23	SDS Number: 100000014508	Date of last issue: 2025/02/01 Date of first issue: 2018/04/09
-----------------	------------------------------	-----------------------------	---

Exposure time: 48 h
Method: OECD Test Guideline 202

NOEC (Daphnia magna (Water flea)): 5.4 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EbC50 (Scenedesmus subspicatus (fresh water algae)): 6 mg/l
Exposure time: 72 h
Test Type: Cell multiplication inhibition test
Method: FDA 4.01

NOECb (Scenedesmus subspicatus (fresh water algae)): 0.77 mg/l
Exposure time: 72 h
Test Type: Cell multiplication inhibition test
Method: FDA 4.01

NOECr (Scenedesmus subspicatus (fresh water algae)): 0.77 mg/l
Exposure time: 72 h
Test Type: Growth inhibition
Method: FDA 4.01

Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 3.3 mg/l
Exposure time: 35 d
Method: OECD Test Guideline 210

LOEC (Danio rerio (zebra fish)): 11 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)): 5.2 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

LOEC (Daphnia magna (Water flea)): 17 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

NOEC (activated sludge): 326 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Toxicity to fish : Remarks: No data available

CONCERTA

Version	Revision Date:	SDS Number:	Date of last issue:
10.1	2025/02/23	100000014508	2025/02/01
			Date of first issue: 2018/04/09

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

Persistence and degradability**Components:****Polyethylene oxide:**

Biodegradability : Remarks: No data available

METHYLPHENIDATE HYDROCHLORIDE:

Biodegradability : Remarks: No data available

Stability in water : Degradation half life (DT50): 8.3 h
Method: OECD Test Guideline 308
Remarks: aerobic

Degradation half life (DT90): 27.5 h
Method: OECD Test Guideline 308
Remarks: aerobic

Degradation half life (DT50): 2.7 h
Method: OECD Test Guideline 308
Remarks: aerobic

Degradation half life (DT90): 9.1 h
Method: OECD Test Guideline 308
Remarks: aerobic

Degradation half life (DT50): 7 h
Method: OECD Test Guideline 308
Remarks: aerobic

Degradation half life (DT90): 23.2 h
Method: OECD Test Guideline 308
Remarks: aerobic

Degradation half life (DT50): 5.3 h
Method: OECD Test Guideline 308
Remarks: aerobic

CONCERTA

Version 10.1	Revision Date: 2025/02/23	SDS Number: 100000014508	Date of last issue: 2025/02/01 Date of first issue: 2018/04/09
-----------------	------------------------------	-----------------------------	---

Degradation half life (DT90): 17.5 h
Method: OECD Test Guideline 308
Remarks: aerobic

Degradation half life (DT50): 8.5 h
Method: OECD Test Guideline 308
Remarks: anaerobic

Degradation half life (DT50): 433.2 d
Method: OECD Test Guideline 308
Remarks: anaerobic

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Biodegradability : Remarks: No data available

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

METHYLPHENIDATE HYDROCHLORIDE:

Bioaccumulation : Remarks: No data available

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Bioaccumulation : Remarks: No data available

TITANDIOXIDE:

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

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

Bioaccumulation : Bioconcentration factor (BCF): 598.4

phosphoric acid:

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

CONCERTA

Version	Revision Date:	SDS Number:	Date of last issue:
10.1	2025/02/23	100000014508	2025/02/01
			Date of first issue: 2018/04/09

Mobility in soil**Components:****METHYLPHENIDATE HYDROCHLORIDE:**

Distribution among : Adsorption/Soil
environmental compartments Medium: Soil
Koc: 1280
Method: OECD Test Guideline 106

Adsorption/Soil
Medium: Soil
Koc: 2202
Method: OECD Test Guideline 106

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Distribution among : Remarks: No data available
environmental compartments

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

Mobility : Remarks: No data available

Other adverse effects**Components:****METHYLPHENIDATE HYDROCHLORIDE:**

Environmental fate and : No data available
pathways

Results of PBT and vPvB : Substance is not persistent, bioaccumulative, and toxic (PBT).
assessment

Additional ecological : No data available
information

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Results of PBT and vPvB : No information available.
assessment

Additional ecological : No data available
information

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

Environmental fate and : No data available
pathways

Results of PBT and vPvB : No information available.
assessment

CONCERTA

Version	Revision Date:	SDS Number:	Date of last issue:
10.1	2025/02/23	100000014508	2025/02/01
			Date of first issue: 2018/04/09

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

Polyethylene oxide	25322-68-3
METHYLPHENIDATE HYDROCHLORIDE	298-59-9
Sodium chloride (NaCl)	7647-14-5
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3

CONCERTA

Version 10.1	Revision Date: 2025/02/23	SDS Number: 100000014508	Date of last issue: 2025/02/01 Date of first issue: 2018/04/09
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CELLULOSEACETAAT	9004-35-7
POVIDONE	9003-39-8
phosphoric acid	7664-38-2

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

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	128-37-0
phosphoric acid	7664-38-2
propan-2-ol	67-63-0
diiron trioxide	1309-37-1

California List of Hazardous Substances

POVIDONE	9003-39-8
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Other regulations

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

Restricted to professional users.

This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

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

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
ACGIH / STEL	:	Short-term exposure limit
J&J OEL/PBOEL HHC / STV	:	STV: Surface Target Value
J&J OEL/PBOEL HHC / TWA	:	Time weighted average
J&J OEL/PBOEL HHC /	:	PBOEL-HHC

SAFETY DATA SHEET



CONCERTA

Version	Revision Date:	SDS Number:	Date of last issue: 2025/02/01
10.1	2025/02/23	100000014508	Date of first issue: 2018/04/09

PBOEL-HHC	
NIOSH REL / TWA	: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST	: STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA P0 / TWA	: 8-hour time weighted average
OSHA P0 / STEL	: Short-term exposure 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 : 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

SAFETY DATA SHEET



CONCERTA

Version	Revision Date:	SDS Number:	Date of last issue: 2025/02/01
10.1	2025/02/23	100000014508	Date of first issue: 2018/04/09

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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