SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Methylphenidate hydrochloride for extended-release oral suspension

Trade Name: QUILLIVANT XR
Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as central nervous system stimulant

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

EU Classification:

EU Indication of danger: Not classified

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*
Citric acid	77-92-9	201-069-1	Xi; R36	Eye Irrit. 2 (H319)	<0.05
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	Not Listed	*
Silica gel, amorphous	112926-00-8	Not Listed	Not Listed	Not Listed	*
Methylphenidate	113-45-1	204-028-6	Xn;R22	Acute Tox. 4; H302	0.5
Starch	9005-25-8	232-679-6	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Poloxalene	9003-11-6	Not Listed	Not Listed	Not Listed	*
Polyvinyl pyrrolidone-Vinyl acetate copolymer	25086-89-9	Not Listed	Not Listed	Not Listed	*
Sucralose	56038-13-2	259-952-2	Not Listed	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	Not Listed	*
Sodium citrate	68-04-2	200-675-3	Not Listed	Not Listed	*
Triacetin	102-76-1	203-051-9	Not Listed	Not Listed	*
Xanthan gum	11138-66-2	234-394-2	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	Not Listed	*
Sulfonated divinylbenzene/styrene copolymer	63182-08-1	Not Listed	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Bulgaria OEL - TWA	10.0 mg/m^3
Estonia OEL - TWA	10 mg/m^3
France OEL - TWA	10 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
Latvia OEL - TWA	5 mg/m^3
Lithuania OEL - TWA	10 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Slovakia OEL - TWA	6 mg/m^3
Spain OEL - TWA	10 mg/m^3

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	2 mg/m^3
Australia TWA	2.5 mg/m^3
Austria OEL - MAKs	2 mg/m^3
Belgium OEL - TWA	2 mg/m^3
Bulgaria OEL - TWA	1.0 fiber/cm3 6.0 mg/m^3 3.0 mg/m^3
Czech Republic OEL - TWA	2.0 mg/m^3
Denmark OEL - TWA	0.3 fiber/cm3
Finland OEL - TWA	0.5 fiber/cm3
Greece OEL - TWA	10 mg/m^3 2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Ireland OEL - TWAs	10 mg/m^3 0.8 mg/m^3
Lithuania OEL - TWA	2 mg/m^3 1 mg/m^3
Netherlands OEL - TWA	0.25 mg/m^3
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m^3 1.0 mg/m^3
Portugal OEL - TWA	2 mg/m^3
Romania OEL - TWA	2 mg/m^3
Slovakia OEL - TWA	2 mg/m^3 10 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Spain OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	2 mg/m^3 1 mg/m^3
Switzerland OEL -TWAs	2 mg/m^3

Silica gel, amorphous

Australia TWA	10 mg/m^3
Austria OEL - MAKs	4 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Belgium OEL - TWA	10 mg/m^3
Bulgaria OEL - TWA	10.0 mg/m^3
Finland OEL - TWA	5 mg/m^3
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf Listed
Poland OEL - TWA	10.0 mg/m^3 2 mg/m^3
Switzerland OEL -TWAs	4 mg/m^3

Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Bulgaria OEL - TWA	10.0 mg/m^3
Czech Republic OEL - TWA	4.0 mg/m^3
Greece OEL - TWA	10 mg/m^3 5 mg/m^3
Ireland OEL - TWAs	10 mg/m^3 4 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Slovakia OEL - TWA	4 mg/m^3
Spain OEL - TWA	10 mg/m^3
Switzerland OEL -TWAs	3 mg/m^3

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Methylphenidate

Pfizer Occupational Exposure Band (OEB):	OEB 3 (control exposure to the range of 10ug/m^3 to < 100ug/m^3)

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder	**Color:**	White to off-white
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Methylphenidate
No data available
Sulfonated divinylbenzene/styrene copolymer
No data available
Polyvinyl pyrrolidone-Vinyl acetate copolymer
No data available
Sodium benzoate
No data available
Triacetin
No data available
Sodium citrate
No data available
Poloxalene
No data available
Povidone
No data available
Xanthan gum
No data available
Sucralose
No data available
Talc (non-asbestiform)
No data available
Sucrose
No data available
Starch
No data available
Silica gel, amorphous
No data available
Citric acid
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:	The information included in this section describes the potential hazards of the individual ingredients.
Short Term:	Accidental ingestion may cause effects similar to those seen in clinical use. See 'Known clinical effects', below.
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus.
Known Clinical Effects:	Adverse effects associated with therapeutic use include nervousness, insomnia, lack of appetite, abdominal pain, nausea, vomiting, Sudden death has been reported with Central Nervous System stimulants at therapeutic doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Administration of stimulants may exacerbate symptoms of behavior disorders and thought disorders in patients with a pre-existing psychotic disorder.

Acute Toxicity: (Species, Route, End Point, Dose)

Methylphenidate
Rat Oral LD50 367 mg/kg

Sodium benzoate
Rat Oral LD50 4,070 mg/kg
Mouse Oral LD50 1600mg/kg

Triacetin
Rat Oral LD 50 3000 mg/kg
Mouse Oral LD 50 1100mg/kg

Povidone
Rat Oral LD50 100 g/kg

Xanthan gum
Rat Oral LD50 > 5000 mg/kg

Talc (non-asbestiform)
Rat Oral LD50 > 1600 mg/kg

11. TOXICOLOGICAL INFORMATION

Sucrose
Rat Oral LD50 29.7 g/kg

Citric acid
Rat Oral LD50 3000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Citric acid
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Sodium benzoate
10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood
10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Methylphenidate
Reproductive & Fertility Mouse Oral160 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rat Oral 25 mg/kg/day NOEL Developmental toxicity, Maternal Toxicity, Not Teratogenic
Embryo / Fetal Development Rabbit Oral 60 mg/kg/day NOEL Teratogenic
Prenatal & Postnatal Development Rat Oral 15 mg/kg/day NOEL Neonatal toxicity

Sodium benzoate
Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Methylphenidate
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Negative
In Vivo Micronucleus Mouse Bone marrow Negative
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive

Sucrose
Bacterial Mutagenicity (Ames) *Salmonella* Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Methylphenidate
2 Year(s) Mouse Oral 60 mg/kg/day LOAEL Liver
2 Year(s) Rat Oral 45 mg/kg/day NOAEL Not carcinogenic
24 Week(s) Mouse Oral 74 mg/kg/day NOAEL Not carcinogenic

11. TOXICOLOGICAL INFORMATION

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Povidone
IARC: Group 3 (Not Classifiable)

Talc (non-asbestiform)
IARC: Group 3 (Not Classifiable)

Silica gel, amorphous
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

15. REGULATORY INFORMATION

Canada - WHMIS: Classifications
WHMIS hazard class:
None required

Poloxalene

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Polyvinyl pyrrolidone-Vinyl acetate copolymer

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Sucralose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	259-952-2

Sodium benzoate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	208-534-8

Sodium citrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-675-3

Triacetin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

15. REGULATORY INFORMATION

EU EINECS/ELINCS List	203-051-9

Xanthan gum

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	234-394-2

Sucrose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

Citric acid

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

Povidone

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Talc (non-asbestiform)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9

Silica gel, amorphous

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Methylphenidate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
U.S. Drug Enforcement Administration:	Schedule II Controlled Substance
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 8

15. REGULATORY INFORMATION

EU EINECS/ELINCS List	204-028-6

Sulfonated divinylbenzene/styrene copolymer

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Starch

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Xn - Harmful

R22 - Harmful if swallowed.
R36 - Irritating to eyes.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Revision date: 22-Aug-2014

Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet