SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Methadoni HCl solutio oralis 1%

Item No. 05405000

Registration no.

Registration no. EXCEMPT

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/preparation

Active pharmacutical substance

1.3. Details of the supplier of the safety data sheet

Address/Manufacturer

Hänseler AG
Industriestrasse 35
9100 Herisau

Telephone no. 0041 (0)71 353 58 58

E-mail address of person responsible for this SDS sdb@haenseler.ch

1.4. Emergency telephone number

Switzerland :145 / Abroad +41 (0)44 251 51 51

SECTION 2: Hazards identification ***

2.1. Classification of the substance or mixture

This product is not classified hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

The product does not require a hazard warning label in accordance with Regulation (EC) No 1272/2008.

Supplemental information

EUH210 Safety data sheet available on request.

2.3. Other hazards

No special hazards have to be mentioned.

The product contains no PBT substances. The product contains no vPvB substances. This product does not contain a substance that has endocrine disrupting properties with respect to human. The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

SECTION 3: Composition/information on ingredients ***

Hazardous ingredients ***

methadone hydrochloride

CAS No. 1095-90-5

EINECS no. 214-140-7

Concentration >= 1 < 2.5 %

Classification (Regulation (EC) No. 1272/2008)

Acute Tox. 3	H301	
Aquatic Chronic 2	H411	

ATE	oral	95		mg/kg

Further ingredients ***

water

CAS No.	7732-18-5			
EINECS no.	231-791-2			
Concentration		>=	95	%

Advice: [4]

Propane-1,2-diol

CAS No.	57-55-6			
EINECS no.	200-338-0			
Registration no.	01-2119456809-23			
Concentration	>= 1	<	10	%

Advice: [4]

methyl 4-hydroxybenzoate

CAS No.	99-76-3			
EINECS no.	202-785-7			
Registration no.	01-2119463264-40-0003			
Concentration		<	1	%

Advice: [4]

Classification (Regulation (EC) No. 1272/2008)

Aquatic Chronic 2	H411

4-hydroxybenzoic acid propyl ester

CAS No.	94-13-3			
EINECS no.	202-307-7			
Registration no.	01-2119969462-29			
Concentration		<	1	%

Advice: [4]

Note

[4] Voluntary information

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Remove contaminated, soaked clothing immediately and dispose of safely.

After inhalation

Ensure supply of fresh air.

After skin contact

After contact with skin, wash immediately with plenty of water.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.).

After ingestion

Rinse mouth thoroughly with water. Do NOT induce vomiting. Summon a doctor immediately.

Adhere to personal protective measures when giving first aid

First aider: Pay attention to self-protection!

4.2. Most important symptoms and effects, both acute and delayed

Until now no symptoms known so far.

4.3. Indication of any immediate medical attention and special treatment needed

Hints for the physician / hazards

In the case of swallowing with subsequent vomiting, aspiration of the lungs can occur which can lead to chemical pneumonia or asphyxiation.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Extinguishing measures to suit surroundings

5.3. Advice for firefighters

Special protective equipment for fire-fighting

Use self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with eyes and skin.

6.2. Environmental precautions

No special measures required.

6.3. Methods and material for containment and cleaning up

Pick up with absorbent material. Send in suitable containers for recovery or disposal. When picked up, treat material as prescribed under Section 13 "Disposal".

6.4. Reference to other sections

Information regarding Safe handling, see Section 7. Information regarding personal protective measures, see Section 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Avoid contact with skin, eyes and clothing.

Advice on protection against fire and explosion

No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Store product in closed containers.

Hints on storage assembly

Not required.

Storage classes

Storage class according to TRGS 510	12	Non-combustible liquids

Further information on storage conditions

Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Other information

Contains no substances with occupational exposure limit values.

Derived No/Minimal Effect Levels (DNEL/DMEL)

Propane-1,2-diol

Type of value	Derived No Effect Level (DNEL)	
Reference group	General Population	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	50	mg/m³

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Concentration	168	mg/m³

Predicted No Effect Concentration (PNEC)

Propane-1,2-diol

Type of value	PNEC	
Type	Soil	
Concentration	50	mg/kg

Type of value	PNEC	
Type	Saltwater	
Concentration	26	mg/l

Type of value	PNEC	
Type	Sewage treatment plant (STP)	
Concentration	20000	mg/l

Type of value	PNEC	
Type	Freshwater	
Concentration	260	mg/l

Type of value	PNEC	
Type	Marine sediment	
Concentration	57.2	mg/kg

Type of value	PNEC	
Type	Freshwater sediment	
Concentration	572	mg/kg

8.2. Exposure controls

General protective and hygiene measures

Observe the usual precautions for handling chemicals.

Respiratory protection

necessary

Hand protection

necessary

Eye protection

Safety glasses

Body protection

necessary

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	liquid, clear
Colour	colourless

Melting point

Remarks: No data available

Freezing point

Remarks: not determined

Boiling point or initial boiling point and boiling range

Remarks: No data available

Flammability

not determined

Upper and lower explosive limits

Remarks: No data available

Flash point

Value: °C

Remarks: Not applicable

Ignition temperature

Remarks: No data available

Decomposition temperature

Remarks: not determined

pH value

Value: 4.5 to 5.5

Viscosity

Remarks: No data available

Solubility(ies)

Remarks: not determined

Partition coefficient n-octanol/water (log value)

Remarks: No data available

Vapour pressure

Remarks: No data available

Density and/or relative density

Remarks: No data available

Relative vapour density

Remarks: No data available

9.2. Other information

Odour threshold

Remarks	not determined

Evaporation rate (ether = 1) :

Remarks	not determined

Solubility in water

Remarks	No data available

Explosive properties

evaluation	not determined

Oxidising properties

Remarks	not determined

Other information

None known

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known.

10.2. Chemical stability

No decomposition if stored and applied as directed.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

No hazardous reactions known.

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

No data available.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity

ATE		9’500	mg/kg
Method	calculated value (Regulation (EC) No. 1272/2008)		

Acute oral toxicity (Components)

methadone hydrochloride

Species	mouse		
LD50		124	mg/kg

methadone hydrochloride

Species	rat		
LD50		95	mg/kg

4-hydroxybenzoic acid propyl ester

Species	rat		
LD50	>	5000	mg/kg

methyl 4-hydroxybenzoate

Species	rat		
LD50		2100	mg/kg
Method	OECD 401		

methyl 4-hydroxybenzoate

Species	guinea pig		
LD50	3000		mg/kg

methyl 4-hydroxybenzoate

Species	rabbit		
LC50	6000		mg/kg

Propane-1,2-diol

Species	rat		
LD50	20000		mg/kg

Propane-1,2-diol

Species	rat		
LD50	6660		mg/kg
Remarks	intraperitoneal		

Propane-1,2-diol

Species	mouse		
LD50	9718		mg/kg
Remarks	intraperitoneal		

Propane-1,2-diol

Species	rat		
LD50	22000		mg/kg
Method	OECD 401		

Acute dermal toxicity

Remarks	not determined

Acute dermal toxicity (Components)

Propane-1,2-diol

Species	rabbit		
	20800		mg/kg

Propane-1,2-diol

Species	rabbit		
LD50	> 2000		mg/kg
Duration of exposure	24	h	
Method	OECD 402		

Acute inhalational toxicity

Remarks	not determined

Acute inhalative toxicity (Components)

Propane-1,2-diol

Species	rabbit		
LC50	317042		mg/m³
Duration of exposure	2	h	
Method	OECD 403		

Skin corrosion/irritation

Remarks	No data available.

Skin corrosion/irritation (Components)

methyl 4-hydroxybenzoate

Species	rabbit	
Duration of exposure	24	h
Observation Period	72	h
evaluation	Moderately irritating	
Method	Draize method	

Propane-1,2-diol

Duration of exposure	7	d
evaluation	slightly irritant	

Serious eye damage/irritation

Remarks	No data available.

Serious eye damage/irritation (Components)

methyl 4-hydroxybenzoate

Species	rabbit		
Observation Period	48	h	
evaluation	Moderately irritating		
Method	Draize method		

Propane-1,2-diol

Species	rabbit
evaluation	slightly irritant

Sensitization

Remarks	No data available.

Sensitization (Components)

4-hydroxybenzoic acid propyl ester

Route of exposure	dermal
Species	mouse
evaluation	non-sensitizing
Method	OECD 429

methyl 4-hydroxybenzoate

Species	guinea pig
evaluation	non-sensitizing
Method	OECD 406

Propane-1,2-diol

Remarks	No data available.

Subacute, subchronic, chronic toxicity

Remarks	not determined

Subacute, subchronic, chronic toxicity (Components)

4-hydroxybenzoic acid propyl ester

Sub-chronic toxicity				
Route of exposure	oral			
Species	rat			
NOAEL		980		mg/kg
Duration of exposure		4	Weeks	

methyl 4-hydroxybenzoate

Species	rat			
NOAEL	>=	250		mg/kg
Duration of exposure		28	d	

Propane-1,2-diol

Remarks	No data available.

Mutagenicity

Remarks	not determined

Mutagenicity (Components)

4-hydroxybenzoic acid propyl ester

evaluation	No mutagenicity according to various in vitro tests.
Method	OECD 471

methyl 4-hydroxybenzoate

evaluation	No mutagenicity according to various in vitro tests.
Method	OECD 471

Propane-1,2-diol

Remarks No data available.

Reproductive toxicity

Remarks not determined

Reproduction toxicity (Components)

Propane-1,2-diol

Remarks No data available.

Carcinogenicity

Remarks not determined

Carcinogenicity (Components)

Propane-1,2-diol

Remarks No data available.

Specific Target Organ Toxicity (STOT) (Components)

Propane-1,2-diol

Remarks Not applicable

11.2 Information on other hazards

Endocrine disrupting properties with respect to humans

The product does not contain a substance that has endocrine disrupting properties with respect to humans.

Other information

No toxicological data are available.

SECTION 12: Ecological information

12.1. Toxicity

General information

not determined

Fish toxicity

Remarks No data available.

Fish toxicity (Components)

methadone hydrochloride

LC50	7.49	mg/l

4-hydroxybenzoic acid propyl ester

Species	zebra fish (Brachydanio rerio)	
LC50	6.4	mg/l
Duration of exposure	96 h	

methyl 4-hydroxybenzoate

Species	golden orfe (Leuciscus idus)	
NOEC	50	mg/l
Duration of exposure	48 h	

methyl 4-hydroxybenzoate

Species	Oryzias latipes	
LC50	59.5	mg/l
Duration of exposure	96 h	
Method	OECD 203	

Propane-1,2-diol

Species	Fathead minnow (Pimephales promelas)	
NOEC	52930	mg/l
Duration of exposure	96 h	

Propane-1,2-diol

Species	rainbow trout (Oncorhynchus mykiss)		
LC50	40613		mg/l
Duration of exposure	96	h	

Daphnia toxicity

Remarks No data available.

Daphnia toxicity (Components)

methadone hydrochloride

Species	Daphnia		
EC50	0.68		mg/l

4-hydroxybenzoic acid propyl ester

Species	Daphnia magna		
EC50	15.4		mg/l
Duration of exposure	48	h	
Method	ISO 6341		

methyl 4-hydroxybenzoate

Species	Daphnia magna		
NOEC	0.2		mg/l
Duration of exposure	21	d	
Method	OECD 211		
Source	Manufacturer's data		

methyl 4-hydroxybenzoate

Species	Daphnia magna		
EC50	11.2		mg/l
Duration of exposure	48	h	

Propane-1,2-diol

Species	Daphnia		
NOEC	13020		mg/l

Propane-1,2-diol

Species	Daphnia magna		
EC50	> 10000		mg/l
Duration of exposure	48	h	

Propane-1,2-diol

Species	Ceriodaphnia dubia		
LC50	18340		mg/l
Duration of exposure	48	h	
Method	static test		
Source	EPA 600/489/001		

Algae toxicity (Components)

methadone hydrochloride

EC50	2.28		mg/l

4-hydroxybenzoic acid propyl ester

Species	Pseudokirchneriella subcapitata		
EC50	15		mg/l
Duration of exposure	72	h	
Method	ISO 8692		

4-hydroxybenzoic acid propyl ester

Species	Pseudokirchneriella subcapitata		
NOEC	2.1		mg/l
Duration of exposure	72	h	
Method	OECD 201		

4-hydroxybenzoic acid propyl ester

Species	Pseudokirchneriella subcapitata		
EC50	16		mg/l
Duration of exposure	72	h	
Method	OECD 201		

methyl 4-hydroxybenzoate

Species	Desmodesmus subspicatus		
EC50	91		mg/l
Duration of exposure	72	h	

methyl 4-hydroxybenzoate

NOEC	17		mg/l
Duration of exposure	72	h	
Method	OECD 201		

Propane-1,2-diol

Species	Pseudokirchneriella subcapitata		
EC50	19000		mg/l
Duration of exposure	96	h	
Method	OECD 201		

Bacteria toxicity (Components)

methyl 4-hydroxybenzoate

Species	Pseudomonas fluorescens	
EC0	500	mg/l

Propane-1,2-diol

Remarks No data available.

12.2. Persistence and degradability

General information

not determined

Physico-chemical eliminability (Components)

Propane-1,2-diol

Remarks No data available.

Biodegradability (Components)

methadone hydrochloride

evaluation sparingly degradable

4-hydroxybenzoic acid propyl ester

Value	91.5		%
Duration of test	28	d	
evaluation	Readily biodegradable		
Method	OECD 301F		

methyl 4-hydroxybenzoate

Value	92.2		%
Duration of test	28	d	
evaluation	Readily biodegradable		
Method	OECD 301F		

methyl 4-hydroxybenzoate

Value	89		%
Duration of test	28	d	
evaluation	Readily biodegradable		
Method	OECD 301 B		

Propane-1,2-diol

Remarks The product is biodegradable.

Ready degradability (Components)

Propane-1,2-diol

Remarks No data available.

12.3. Bioaccumulative potential

General information

not determined

Partition coefficient n-octanol/water (log value)

Remarks No data available

Octanol/water partition coefficient (log Pow) (Components)

4-hydroxybenzoic acid propyl ester

log Pow 2.8

methyl 4-hydroxybenzoate

log Pow 1.98

12.4. Mobility in soil

General information

not determined

Mobility in soil (Components)

4-hydroxybenzoic acid propyl ester

Highly mobile in soils

methyl 4-hydroxybenzoate

Highly mobile in soils

12.5. Results of PBT and vPvB assessment

General information

not determined

Results of PBT and vPvB assessment

The product contains no PBT substances

The product contains no vPvB substances.

12.6 Endocrine disrupting properties

Endocrine disrupting properties with respect to the envrionment

The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

12.7. Other adverse effects

General information

not determined

General information / ecology

Do not discharge product unmonitored into the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations for the product

Disposal in compliance with local and national regulations.

Disposal recommendations for packaging

Dispose of as unused product.

SECTION 14: Transport information

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water Hazard Class (Germany)

Water Hazard Class (Germany)	WGK 2
Remarks	Derivation of WGK according to Annex 1 No. 5.2 AwSV

15.2. Chemical safety assessment

For this preparation a chemical safety assessment has not been carried out.

SECTION 16: Other information

Hazard statements listed in Chapter 3

H301	Toxic if swallowed.
H411	Toxic to aquatic life with long lasting effects.

CLP categories listed in Chapter 3

Acute Tox. 3	Acute toxicity, Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic, Category 2

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: ***
This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.