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

1.1. Product identifier

Acetatum concentratum 21x

Item No. 07730000

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

Use of the substance/preparation

Pharmacutical excipient, Manufacture of pharmacutical products

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

sodium nitrite

CAS No.	7632-00-0				
EINECS no.	231-555-9				
Concentration	>=	0.1	<	1	%

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

Ox. Sol. 3 H272

Acute Tox. 3	H301	
Eye Irrit. 2	H319	
Aquatic Acute 1	H400	

ATE oral 180 mg/kg

Further ingredients

water

CAS No. 7732-18-5
EINECS no. 231-791-2
Concentration >= 50 %
Advice: [4]

Sodium chloride

CAS No. 7647-14-5
EINECS no. 231-598-3
Concentration >= 10 < 25 %
Advice: [4]

Glucose

CAS No. 50-99-7
EINECS no. 200-075-1
Registration no. EXCEMPT
Concentration >= 10 < 25 %
Advice: [4]

sodium acetate trihydrate

CAS No. 6131-90-4
EINECS no. 204-823-8
Registration no. 01-2119485123-42
Concentration >= 1 < 10 %
Advice: [4]

Calcium chloride dihydrate

CAS No. 10035-04-8
EINECS no. 233-140-8
Registration no. 01-2119494219-28
Concentration < 1 %
Advice: [4]
Classification (Regulation (EC) No. 1272/2008)
Eye Irrit. 2 H319

Magnesium chloride hexahydrate

CAS No. 7791-18-6
EINECS no. 232-094-6
Registration no. 01-2119485597-19-XXXX
Concentration < 1 %
Advice: [4]

Potassium chloride

CAS No. 7447-40-7
EINECS no. 231-211-8
Concentration < 1 %
Advice: [4]

Calcium carbonate

CAS No.	471-34-1			
EINECS no.	207-439-9			
Registration no.	01-2119486795-18-XXXX			
Concentration		<	1	%

Advice: [4]

Magnesium carbonate

CAS No.	546-93-0			
EINECS no.	208-915-9			
Concentration		<	1	%

Advice: [4]

Tricalciumphosphat Hydrat

EINECS no.	231-840-8			
Concentration		<	1	%

Advice: [4]

potassium fluoride

CAS No.	7789-23-3			
EINECS no.	232-151-5			
Concentration		<	1	%

Advice: [4]

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

Acute Tox. 3	H301
Acute Tox. 3	H311
Acute Tox. 3	H331

Potassium iodide

CAS No.	7681-11-0			
EINECS no.	231-659-4			
Registration no.	01-2119906339-35-XXXX			
Concentration		<	1	%

Advice: [4]

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

STOT RE 1	H372

Kaliumhexacyanoferrat(II) Trihydrat

CAS No.	13943-58-3			
EINECS no.	237-722-2			
Concentration		<	1	%

Advice: [4]

Potassium iodade

CAS No.	7758-05-6			
EINECS no.	231-831-9			
Concentration		<	1	%

Advice: [4]

Note

[4] Voluntary information

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In case of persistent symptoms consult doctor.

After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment.

After skin contact

In case of contact with skin wash off with warm water. Consult a doctor if skin irritation persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). In case of irritation consult an oculist.

After ingestion

Rinse out mouth and give plenty of water to drink.

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

Foam, Carbon dioxide, Dry powder, Water spray jet

5.3. Advice for firefighters

Special protective equipment for fire-fighting

In case of combustion use a suitable breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective equipment

6.2. Environmental precautions

Do not allow to enter drains or waterways.

6.3. Methods and material for containment and cleaning up

Pick up with absorbent material. Clean contaminated floors and objects thoroughly, observing environmental regulations.

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

Observe the usual precautions for handling chemicals.

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

Do not store together with foodstuffs.

Storage classes

Storage class according to TRGS 510 12 Non-combustible liquids

Further information on storage conditions

Keep container tightly closed and dry.

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)

Potassium iodide

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	0.07	mg/m³

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	1	mg/kg/d

Calcium carbonate

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	10	mg/m³

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	4.26	mg/m³

Type of value	Derived No Effect Level (DNEL)

Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	10	mg/m³

Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	1.06	mg/m³

Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	oral	
Mode of action	Chronic effects	
Concentration	6.1	mg/kg

Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Short term	
Route of exposure	oral	
Mode of action	Acute effects	
Concentration	6.1	mg/kg

Predicted No Effect Concentration (PNEC)

Potassium iodide

Type of value	PNEC	
Type	Freshwater	
Conditions	Short term	
Concentration	0.007	mg/l

Type of value	PNEC	
Type	Sediment	
Conditions	Short term	
Concentration	0.007	mg/kg

Calcium carbonate

Type of value	PNEC	
Type	Sewage treatment plant (STP)	
Concentration	100	mg/l

8.2. Exposure controls

General protective and hygiene measures

Observe the usual precautions for handling chemicals.

Respiratory protection

Not necessary, but do not inhale vapours. If workplace limits are exceeded, a respiratory protection approved for this particular job must be worn.

Hand protection

Appropriate Material neoprene

Eye protection

Safety glasses

Body protection

Clothing as usual in the chemical industry.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state liquid, clear

Melting point

Remarks not determined

Freezing point

Remarks not determined

Boiling point or initial boiling point and boiling range

Value appr. 100 °C

Flammability

evaluation not determined

Upper and lower explosive limits

Remarks not determined

Flash point

Remarks Not applicable

Auto-ignition temperature

Remarks not determined

Decomposition temperature

Remarks not determined

pH value

Value 7.0 to 9.0

Viscosity

Remarks not determined

Solubility(ies)

Remarks not determined

Partition coefficient n-octanol/water (log value)

Remarks not determined

Vapour pressure

Remarks not determined

Density and/or relative density

Remarks not determined

Relative vapour density

Remarks not determined

9.2. Other information

Odour threshold

Remarks not determined

Evaporation rate (ether = 1) :

Remarks not determined

Solubility in water

Remarks not determined

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

SECTION 11: Toxicological information

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

Acute oral toxicity

ATE	>	10’000	mg/kg
Method	calculated value according to GHS (e.g see UN GHS)		
Remarks	Based on available data, the classification criteria are not met.		

Acute oral toxicity (Components)

sodium acetate trihydrate

Species	rat		
LD50		3530	mg/kg
Remarks	anhydrous		

Potassium iodide

Species	rat		
LD50		2779	mg/kg

Potassium iodide

Species	rat		
LD50	>	2000	mg/kg
Method	OECD 423		
Source	ECHA		

Sodium chloride

Species	rat		
LD50		3000	mg/kg

Magnesium chloride hexahydrate

Species	rat		
LD50	>	5000	mg/kg
Method	OECD 423		

Potassium chloride

Species	rat

LD50		2600	mg/kg

Calcium carbonate

Species	rat		
LD50		6450	mg/kg
Source	GESTIS-Stoffdatenbank		

Calcium carbonate

Species	rat		
LD50	>	2000	mg/kg
Method	OECD 420		

sodium nitrite

Species	rat		
LD50		180	mg/kg

Acute dermal toxicity

Remarks Based on available data, the classification criteria are not met.

Acute dermal toxicity (Components)

sodium acetate trihydrate

Species	rabbit		
	>	10000	
Remarks	anhydrous		

Potassium iodide

Species	rat		
LD50	>	2000	mg/kg
Method	OECD 402		

Sodium chloride

Species	rabbit		
LD50	>	10000	mg/kg

Magnesium chloride hexahydrate

Species	rat		
LD50	>	2000	mg/kg
Method	OECD 402		

Calcium carbonate

Species	rat		
LD50	>	2000	mg/kg
Method	OECD 402		

Acute inhalational toxicity

Remarks Based on available data, the classification criteria are not met.

Acute inhalative toxicity (Components)

sodium acetate trihydrate

Species	rat		
	>	30	mg/l

Potassium iodide

Remarks No data available

Sodium chloride

Species	rat			
LC50	>	42000		mg/m³
Duration of exposure		1	h	

Calcium carbonate

Species	rat			
LD50	>	3		mg/l
Duration of exposure		4	h	
Method	OECD 403			

sodium nitrite

Species	rat		
LC50	505		mg/m³
Duration of exposure	4	h	

Skin corrosion/irritation

Remarks Based on available data, the classification criteria are not met.

Skin corrosion/irritation (Components)

sodium acetate trihydrate

evaluation slightly irritant

Potassium iodide

Species rabbit
evaluation non-irritant
Method OECD 404

Potassium iodide

evaluation non-irritant
Method OECD 439
Source ECHA

Sodium chloride

Remarks None
Source ECHA

Magnesium chloride hexahydrate

evaluation non-irritant

Potassium chloride

Species rabbit
evaluation non-irritant

Calcium carbonate

Species rabbit
evaluation non-irritant
Method OECD 404

Serious eye damage/irritation

Remarks Based on available data, the classification criteria are not met.

Serious eye damage/irritation (Components)

sodium acetate trihydrate

Remarks slightly irritating (Eye)

Potassium iodide

Species rabbit
Method OECD 405
Remarks None

Sodium chloride

Remarks None
Source ECHA

Magnesium chloride hexahydrate

evaluation non-irritant
Method OECD 405

Potassium chloride

Species rabbit
evaluation slightly irritant

Calcium carbonate

Species rabbit
evaluation non-irritant
Method OECD 405

Sensitization

Remarks Based on available data, the classification criteria are not met.

Sensitization (Components)

sodium acetate trihydrate

evaluation non-sensitizing

Potassium iodide

Species Human
Remarks negative
Source Patch-Test

Sodium chloride

Remarks No sensitation effect known.

Magnesium chloride hexahydrate

Species guinea pig
evaluation non-sensitizing
Method OECD 406

Potassium chloride

evaluation non-sensitizing

Calcium carbonate

Species mouse
evaluation non-sensitizing
Method OECD 429

Subacute, subchronic, chronic toxicity

Remarks not determined

Subacute, subchronic, chronic toxicity (Components)

Potassium iodide

Remarks No data available

Sodium chloride

Remarks No data available.

Mutagenicity

Remarks Based on available data, the classification criteria are not met.

Mutagenicity (Components)

sodium acetate trihydrate

evaluation No experimental indications on genotoxicity in vivo found.

Potassium iodide

Species Salmonella typhimurium
evaluation No mutagenicity in the Ames-test.
Source ECHA

Sodium chloride

Remarks None

Magnesium chloride hexahydrate

evaluation No mutagenicity according to various in vitro tests.
Method OECD 476

Potassium chloride

Species Salmonella typhimurium
evaluation No mutagenicity in the Ames-test.

Calcium carbonate

evaluation No experimental indications on genotoxicity in vivo found.

Reproductive toxicity

Remarks Based on available data, the classification criteria are not met.

Reproduction toxicity (Components)

Potassium iodide
Remarks No data available.

Sodium chloride
Remarks None

Magnesium chloride hexahydrate
evaluation No negative effects
Method OECD 422

Carcinogenicity

Remarks Based on available data, the classification criteria are not met.

Carcinogenicity (Components)

sodium acetate trihydrate
Remarks No data available

Potassium iodide
Remarks No data available.

Sodium chloride
Remarks None

Magnesium chloride hexahydrate
evaluation No negative effects
Method OECD 453

Calcium carbonate
Species Human
evaluation No negative effects

Specific Target Organ Toxicity (STOT)

Single exposure
Remarks Based on available data, the classification criteria are not met.

Repeated exposure
Remarks Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity (STOT) (Components)

Potassium iodide

Repeated exposure
evaluation Causes damage to organs through prolonged or repeated exposure
Route of exposure oral
Organs: Thyroid

Potassium iodide

Single exposure
Remarks No data available

Calcium carbonate
Remarks Not documented.

Aspiration hazard

Based on available data, the classification criteria are not met.

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 (Components)

sodium acetate trihydrate

Species	Bluegill (Lepomis macrochirus)		
LC50	5000		mg/l
Duration of exposure	24	h	
Source	anhydrous substance		

Potassium iodide

Species	zebra fish (Brachydanio rerio)		
LC50	> 100		mg/l
Duration of exposure	96	h	
Method	OECD 203		

Potassium iodide

Species	rainbow trout (Oncorhynchus mykiss)		
LC50	8960		mg/l
Duration of exposure	96	h	
Source	Literature value		

Sodium chloride

Species	Bluegill (Lepomis macrochirus)		
LC50	5840		mg/l
Duration of exposure	96	h	

Magnesium chloride hexahydrate

Species	Fathead minnow (Pimephales promelas)		
LC50	2119.3		mg/l
Duration of exposure	96	h	

Potassium chloride

Species	Fathead minnow (Pimephales promelas)		
LC50	880		mg/l
Duration of exposure	96	h	
Method	OECD 203		

Potassium chloride

NOEC	500		mg/l
Duration of exposure	7	d	
Method	OECD 210		

Calcium carbonate

Species	rainbow trout (Oncorhynchus mykiss)		
LC50	> 100		mg/l
Duration of exposure	96	h	
Method	OECD 203		

Daphnia toxicity (Components)

sodium acetate trihydrate

Species	Daphnia magna		
EC50	> 1000		mg/l
Duration of exposure	48	h	
Source	anhydrous substance		

Potassium iodide

Remarks	No data available.

Sodium chloride

Species	Daphnia		
NOEC	1500		mg/l
Duration of exposure	7	d	

Sodium chloride

Species	Daphnia magna		
LC50	1661		mg/l
Duration of exposure	48	h	

Magnesium chloride hexahydrate

Species	Daphnia magna		
LC50	548.4		mg/l

Potassium chloride

Species	Daphnia magna		
EC50	825		mg/l
Duration of exposure	48	h	
Method	OECD 201		

Calcium carbonate

Species	Daphnia magna		
LC50	> 1		mg/l
Duration of exposure	48	h	
Method	OECD 202		

Algae toxicity (Components)

Potassium iodide

Remarks	No data available.		

Sodium chloride

Species	Algae		
	2430		mg/l
Duration of exposure	120	h	
Source	ECHA		

Magnesium chloride hexahydrate

Species	Desmodesmus subspicatus		
EC50	> 100		mg/l
Method	OECD 201		

Potassium chloride

Species	Desmodesmus subspicatus		
EC50	> 100		mg/l
Duration of exposure	72	h	
Method	OECD 201		

Calcium carbonate

Species	Desmodesmus subspicatus		
EC50	> 14		mg/l
Duration of exposure	72	h	
Method	OECD 201		

Bacteria toxicity (Components)

sodium acetate trihydrate

Species	Pseudomonas putida		
EC50	7200		mg/l
Duration of exposure	18	h	
Source	anhydrous substance		

Potassium iodide

Remarks	No data available.		

Sodium chloride

Remarks	No data available.			

Potassium chloride

EC50	>	1000		mg/l
Duration of exposure		3	h	
Method	OECD 209			

Calcium carbonate

Species	activated sludge			
EC50	>	1000		mg/l
Duration of exposure		3	h	
Method	OECD 209			

12.2. Persistence and degradability

General information

not determined

Physico-chemical eliminability (Components)

Sodium chloride

Remarks	No data available.

Biodegradability (Components)

sodium acetate trihydrate

Value		99		%
Duration of test		28	d	
evaluation	Readily biodegradable			
Source	OECD			

Potassium iodide

Remarks	Inorganic product, cannot be eliminated from the water by biological purification processes.

Calcium carbonate

Remarks	Inorganic product, cannot be eliminated from the water by biological purification processes.

12.3. Bioaccumulative potential

General information

not determined

Partition coefficient n-octanol/water (log value)

Remarks	not determined

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

Potassium iodide

log Pow	-0.958	
Temperature	25	°C

12.4. Mobility in soil

General information

not determined

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.
Allocation of a waste code number, according to the European Waste Catalogue (EWC), should be carried out in agreement with the regional waste disposal company.

Disposal recommendations for packaging

Packaging that cannot be cleaned should be disposed off as product waste.

SECTION 14: Transport information

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number or ID 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.
14.5. Environmental hazards	-		

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

Other information

The product does not contain substances according to Candidate List for inclusion in Annex XIV of Regulation (EC) No. 1907/2006 (REACH) with a content of >= 0.1% w/w.

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 2/3

H272	May intensify fire; oxidizer.
H301	Toxic if swallowed.

H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.

CLP categories listed in Chapter 2/3

Acute Tox. 3	Acute toxicity, Category 3
Aquatic Acute 1	Hazardous to the aquatic environment, acute, Category 1
Eye Irrit. 2	Eye irritation, Category 2
Ox. Sol. 3	Oxidising solid, Category 3

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.