according to 1907/2006/EC, Article 31

Printing date 11.04.2024 Revision: 29.02.2024 Version number 1.0

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

· 1.1 Product identifier

· Trade name: Ichtosal

· Article number: 601594

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

No further relevant information available.

· Application of the substance / the mixture

Laboratory chemicals

Pharmaceutical intermediate

· 1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

FAGRON a.s.

Holická 1098/31m

779 00 Olomouc

Česká republika

· Further information obtainable from:

Tel.: +420 585 222 590

info@fagron.cz

· 1.4 Emergency telephone number:

Toxikologické informační středisko,

Na Bojišti 1,

128 08 Praha 2

tel.: +420 224 919 293, +420 224 915 402 (nepřetržitá lékařská služba),

e-mail:tis.cuni@cesnet.cz

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Acute Tox. 4 H302 Harmful if swallowed.

Eye Dam. 1 H318 Causes serious eye damage.

Repr. 1B H360Df May damage the unborn child. Suspected of damaging fertility.

Aguatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms







GHS05 GHS07 GHS08

- · Signal word Danger
- · Hazard-determining components of labelling:

Salicylic acid

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Sodium perborate tetrahydrate Natrii peroxoboras hydricum

· Hazard statements

H302 Harmful if swallowed.

H318 Causes serious eye damage.

H360Df May damage the unborn child. Suspected of damaging fertility.

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing

protection.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER/doctor. P310

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/

international regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

· **PBT**: Not applicable. · vPvB: Not applicable.

· Determination of endocrine-disrupting properties

List II; III CAS: 69-72-7 Salicylic acid

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

· Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:		
CAS: 69-72-7	Salicylic acid	50–≤100%
EINECS: 200-712-3	Repr. 2, H361d; Eye Dam. 1, H318; Acute Tox. 4, H302	
CAS: 8029-68-3	Ichthammolum	50–≤100%
EINECS: 232-439-0	Ichthammolum album	
	Eye Irrit. 2, H319; Aquatic Chronic 3, H412	
CAS: 10486-00-7	Sodium perborate tetrahydrate	10%
EINECS: 231-556-4	Natrii peroxoboras hydricum	
	Repr. 1B, H360Df; Eye Dam. 1, H318; Acute Tox. 4, H332; STOT SE 3, H335	
	Specific concentration limits: Eye Dam. 1; H318: C ≥ 36 %	
	Eye Irrit. 2; H319: 22 % ≤ C < 36 %	
	Repr. 1B; H360: C ≥ 10 %	

·SVHC

CAS: 10486-00-7 | Sodium perborate tetrahydrate Natrii peroxoboras hydricum

· Additional information: For the wording of the listed hazard phrases refer to section 16.

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SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing: Call for a doctor immediately.
- · 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

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

No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- · 5.2 Special hazards arising from the substance or mixture

No further relevant information available.

- · 5.3 Advice for firefighters
- · Protective equipment: Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

· 6.2 Environmental precautions:

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to enter sewers/ surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

Use neutralising agent.

Dispose contaminated material as waste according to section 13.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Thorough dedusting.

Open and handle receptacle with care.

• Information about fire - and explosion protection: Keep respiratory protective device available.

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- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Keep container tightly sealed.

Protect from heat and direct sunlight.

· 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Avoid contact with the eyes and skin.

· Respiratory protection:

Filter P1

Suitable respiratory protective device recommended.

Hand protection



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

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- CZE



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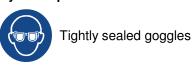
Safety data sheet

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· Eye/face protection



· Body protection: Protective work clothing

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state Solid

· Colour: Bronze coloured · Odour: Characteristic · Odour threshold: Not determined. · Melting point/freezing point: Undetermined.

· Boiling point or initial boiling point and boiling

100°C (CAS: 7732-18-5 Water, distilled, range

conductivity or of similar purity)

· Flammability Not determined.

· Lower and upper explosion limit

· Lower: Not determined. · Upper: Not determined.

· Flash point: >150°C (CAS: 8002-74-2 Vaselinum Album

> Paraffinum solidum Paraffin, white soft)

· Auto-ignition temperature: >290°C (CAS: 8006-54-0 HydroLano™

> Lanolin anhydrous Lanolinum anhydricum)

 Decomposition temperature: Not determined. Not applicable.

Hq·

· Viscosity:

· Kinematic viscosity Not applicable. · Dynamic: Not applicable.

· Solubility

Soluble. · water:

· Partition coefficient n-octanol/water (log

Not determined. value)

 Vapour pressure at 20°C: 23 hPa (CAS: 7732-18-5 Water, distilled,

conductivity or of similar purity)

Density and/or relative density

· Density: Not determined. · Relative density Not determined. · Vapour density Not applicable.

· Particle characteristics

See section 3.

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· 9.2 Other information

· Appearance:

· Form: Pasty

Important information on protection of health

and environment, and on safety.

• **Ignition temperature:** Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

Void

Void

Solvent content:

· Water: 80,0 %

· Change in condition

• Evaporation rate Not applicable.

· Information with regard to physical hazard classes

· Explosives Void · Flammable gases Void · Aerosols Void · Oxidising gases Void · Gases under pressure Void Void · Flammable liquids · Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void

Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures, which emit

flammable gases in contact with water

Oxidising liquids

Oxidising solids

Organic peroxides

Corrosive to metals

Void

Void

· Desensitised explosives Void

SECTION 10: Stability and reactivity

- 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Harmful if swallowed.

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		(Contd. of page 6
· LD/LC50	values rele	evant for classification:
ATE (Acu	te Toxicity	y Estimates)
Oral	LD50	891 mg/kg (rat)
CAS: 69-7	2-7 Salicy	rlic acid
Oral	LD50	891 mg/kg (rat)
CAS: 8029	9-68-3 lch	thammolum
	lchi	thammolum album
Oral	LD50	>10000 mg/kg (rat)
Dermal	LD50	21500 mg/kg (rat)
CAS: 1048	86-00-7 Sc	odium perborate tetrahydrate
	Na	atrii peroxoboras hydricum
Oral	LD50	2240 mg/kg (rat)
Inhalative	LC50/4 h	11 mg/l (rat)
. Ckin cour	oolop/iuuit	ation Record on available data, the electification criteria are not mot

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Causes serious eye damage.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity May damage the unborn child. Suspected of damaging fertility.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · 11.2 Information on other hazards
- · Endocrine disrupting properties

CAS: 69-72-7 Salicylic acid

List II; III

SECTION 12: Ecological information

- · 12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

- · 12.7 Other adverse effects
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes:

Harmful to aquatic organisms

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

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Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue		
HP4	Irritant - skin irritation and eye damage	
HP6	Acute Toxicity	
HP10	Toxic for reproduction	
HP14	Ecotoxic	

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information

· 14.1 UN number or ID number · ADR, IMDG, IATA	not regulated	
· 14.2 UN proper shipping name · ADR, IMDG, IATA	not regulated	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	not regulated	
· 14.4 Packing group · ADR, IMDG, IATA	not regulated	
· 14.5 Environmental hazards:	Not applicable.	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Maritime transport in bulk according to IMO instruments Not applicable.		
· UN "Model Regulation":	not regulated	

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.

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Trade name: Ichtosal

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LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV)

CAS: 10486-00-7 | Sodium perborate tetrahydrate Natrii peroxoboras hydricum

Sunset date: 2023-05-27

- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 30
- · DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II

None of the ingredients is listed.

- · REGULATION (EU) 2019/1148
- · Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

- · National regulations:
- · Other regulations, limitations and prohibitive regulations
- · Substances of very high concern (SVHC) according to REACH, Article 57

CAS: 10486-00-7 | Sodium perborate tetrahydrate Natrii peroxoboras hydricum

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases

- H302 Harmful if swallowed.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H335 May cause respiratory irritation.
- H360Df May damage the unborn child. Suspected of damaging fertility.
- H361d Suspected of damaging the unborn child.
- H412 Harmful to aquatic life with long lasting effects.
- · Department issuing SDS: Fagron Česká republika
- · Contact: msds@fagron.cz
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals



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Trade name: Ichtosal

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic SVHC: Substances of Very High Concern vPvB: very Persistent and very Bioaccumulative Acute Tox. 4: Acute toxicity – Category 4

Eye Dam. 1: Serious eye damage/eye irritation – Category 1 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Repr. 1B: Reproductive toxicity – Category 1B Repr. 2: Reproductive toxicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) - Category 3

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3

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