acc. to OSHA HCS

1 Identification

· Product identifier

Trade name: <u>Ichtoperal</u>
 Article number: 601597

· Application of the substance / the mixture

Laboratory chemicals

Pharmaceutical intermediate

· Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Fagron Inc 2400 Pilot Knob Road St. Paul, MN 55120 www.fagron.us QA@fagron.us

· Information department:

Tel.: 800-423-6967 Fax: 800-339-1596

· Emergency telephone number:

Emergency Telephone: US: 1-800-535-5053

International: 1-352-323-3500

2 Hazard(s) identification

· Classification of the substance or mixture

Eye Irritation 2A H319 Causes serious eye irritation.

Toxic to Reproduction 1B H360 May damage fertility or the unborn child.

- · Label elements
- · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS07 GHS08

· Signal word Danger

· Hazard-determining components of labeling:

Sodium perborate tetrahydrate Natrii peroxoboras hydricum

Hazard statements

Causes serious eye irritation.

May damage fertility or the unborn child.

· Precautionary statements

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Wash thoroughly after handling.

Wear protective gloves/protective clothing/eye protection/face protection.

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If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

IF exposed or concerned: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- · Classification system:
- NFPA ratings (scale 0 4)



Health = 2 Fire = 1 Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = *2 Fire = 1

REACTIVITY 0 Reactivity = 0

- Other hazards
- · Results of PBT and vPvB assessment
- PBT: Not applicable.vPvB: Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- **Description:** Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:		
CAS: 8002-74-2	Vaselinum Album Paraffinum solidum Paraffin, white soft	50–≤100%
CAS: 8029-68-3	Ichthammolum Ichthammolum album	50–≤100%
CAS: 10486-00-7	Sodium perborate tetrahydrate Natrii peroxoboras hydricum	10%

4 First-aid measures

- · Description of first aid measures
- · 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: If symptoms persist consult doctor.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed

No further relevant information available.

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· Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents: Use fire fighting measures that suit the environment.
- Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment: Wear self-contained respiratory protective device.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation

Wear protective clothing.

· 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.

· Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to section 13.

· 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.

· Protective Action Criteria for Chemicals

· PAC-1:		
CAS: 1305-78-8	CAS: 1305-78-8 calcium oxide	
CAS: 7784-24-9	S: 7784-24-9 Aluminium potassium sulfate dodecahydrate Alumen	
· PAC-2:		
CAS: 1305-78-8	calcium oxide	110 mg/m ³
CAS: 7784-24-9	Aluminium potassium sulfate dodecahydrate Alumen	1,200 mg/m ³
· PAC-3:		
CAS: 1305-78-8	calcium oxide	660 mg/m ³
CAS: 7784-24-9	Aluminium potassium sulfate dodecahydrate Alumen	6,900 mg/m ³

7 Handling and storage

- · Handling:
- Precautions for safe handling Open and handle receptacle with care.
- · Information about protection against explosions and fires:

Keep respiratory protective device available.

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Trade name: Ichtoperal

(Contd. of page 3)

- · 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 receptacle tightly sealed.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see section 7.
- · Control parameters
- · Components with limit values that require monitoring at the workplace:

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

CAS: 8002-74-2 Vaselinum Album

Paraffinum solidum Paraffin, white soft

REL Long-term value: 2 mg/m³ TLV Long-term value: 2 mg/m³

- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- · 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.

· Breathing equipment:

Filter P1

Suitable respiratory protective device recommended.

Protection of hands:



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.

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· 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.

· Eye protection:



Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and chemical properties

General Information Appearance:	
Form:	Pasty
Color:	Bronze colored
Odor:	Characteristic
Odor threshold:	Not determined.
pH-value:	Not applicable.
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	100°C (212°F)
Flash point:	>150°C (>302°F)
Flammability (solid, gaseous):	Not determined.
Auto igniting:	>290°C (>554°F)
Decomposition temperature:	Not determined.
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure at 20°C (68°F):	23 hPa (17.3 mm Hg)
Density:	Not determined.
Relative density	Not determined.
Vapor density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
Water:	Soluble.
Partition coefficient (n-octanol/wa	ter): Not determined.
Viscosity:	
Dynamic:	Not applicable.



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		(Contd. of page 5
Kinematic:	Not applicable.	
· Solvent content:		
Water:	80.0 %	
VOC content:	0.00 %	
· Other information	No further relevant information available.	

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:

· LD/LC50 values that are relevant for classification:	
ATE (Acute Toxicity Estimate)	
Inhalative LC50/4 h 110 mg/l (rat)	

CAS: 8029-68-3 Ichthammolum Ichthammolum albur			
Oral	LD50	>10000 mg/kg (rat)	
Dermal	LD50	21500 mg/kg (rat)	

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

Oral	LD50	2240 mg/kg (rat)
Inhalative	LC50/4 h	11 mg/l (rat)

- · Primary irritant effect:
- · on the skin: No irritant effect.
- · on the eye: Irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

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· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Ecotoxical effects:
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes:

Harmful to aquatic organisms

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

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

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · **vPvB**: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation:

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

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

14 Transport information

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· DOT, IMDG, IATA not regulated

· UN proper shipping name

· DOT, IMDG, IATA not regulated

· Transport hazard class(es)

· DOT, ADN, IMDG, IATA

· Class not regulated

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	(Con	td. of page
Packing group		
DOT, IMDG, IATA	not regulated	
Environmental hazards:	Not applicable.	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex	k II of	
MARPOL73/78 and the IBC Code	Not applicable.	
UN "Model Regulation":	not regulated	

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.
- · Sara

· Section 355 (extremely hazardous substances):
None of the ingredients is listed.
· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):		
CAS: 8002-74-2	Vaselinum Album Paraffinum solidum Paraffin, white soft	ACTIVE
CAS: 8029-68-3	Ichthammolum Ichthammolum album	ACTIVE
CAS: 7732-18-5	Water, distilled, conductivity or of similar purity	ACTIVE
CAS: 8006-54-0	HydroLano™ Lanolin anhydrous Lanolinum anhydricum	ACTIVE
CAS: 1305-78-8	calcium oxide	ACTIVE

· Hazardous Air Pollutants

None of the ingredients is listed.

- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

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· Carcinogenic categories

· EPA (Environmental Protection Agency)

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

I (oral)

· TLV (Threshold Limit Value)

None of the ingredients is listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

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

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.

· Department issuing SDS:

Fagron US

Quality Assurance

- Contact: QA@fagron.us
- · Date of preparation / last revision 02/29/2024
- · 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

DOT: US Department of Transportation

IATA: International Air Transport Association

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, ÉU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit

Eye Irritation 2A: Serious eye damage/eye irritation - Category 2A

Toxic to Reproduction 1B: Reproductive toxicity - Category 1B

USA

