according to 1907/2006/EC, Article 31

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

· 1.1 Product identifier

· Trade name: Ichtoperal

· Article number: 601597

 \cdot 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 UK Ltd

4B Coquet St

Newcastle upon Tyne

England NE1 2QB

Tel. 0845 6522525

· Further information obtainable from:

Emergency response telephone number:

+44 (0) 845 652 2525

1.4 Emergency telephone number:

Emergency response telephone number:

+44 (0) 845 652 2525

SECTION 2: Hazards identification

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

Eye Irrit. 2 H319 Causes serious eye irritation.

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

Aquatic 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 GB CLP regulation.

· Hazard pictograms





GHS07 GHS08

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

Sodium perborate tetrahydrate Natrii peroxoboras hydricum

· Hazard statements

H319 Causes serious eye irritation.

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

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H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

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

P308+P313 IF exposed or concerned: Get medical advice/attention.

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.

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

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

· Dangerous components:				
CAS: 8002-74-2	Vaselinum Album	50–≤100%		
EINECS: 232-315-6	6 Paraffinum solidum			
	Paraffin, white soft			
	substance with a Community workplace exposure limit			
CAS: 8029-68-3	Ichthammolum	50–≤100%		
EINECS: 232-439-0	-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.

SECTION 4: First aid measures

- · 4.1 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.

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- 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

Ensure adequate ventilation

Wear protective clothing.

· 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:

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 Open and handle receptacle with care.
- · Information about fire and explosion protection: Keep respiratory protective device available.
- · 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.
- · 7.3 Specific end use(s) No further relevant information available.

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SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

CAS: 8002-74-2 Vaselinum Album Paraffinum solidum

Paraffin, white soft

WEL Short-term value: 6 mg/m³ Long-term value: 2 mg/m³

- · 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.

· Eye/face protection



Tightly sealed goggles

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· Body protection: Protective work clothing

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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)

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

> Lanolin anhydrous Lanolinum anhydricum)

· Decomposition temperature: Not determined. Hq· Not applicable.

· Viscosity:

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

· Solubility

· water: Soluble.

· Partition coefficient n-octanol/water (log

Not determined. value)

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

conductivity or of similar purity)

Density and/or relative density

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

· 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.

· Solvent content:

· Water: 80.0%

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		(Contd. of page
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	
Flammable liquids	Void	
Flammable solids	Void	
Self-reactive substances and mixtures	Void	
· Pyrophoric liquids	Void	
· Pyrophoric solids	Void	
· Self-heating substances and mixtures	Void	
Substances and mixtures, which emit		
flammable gases in contact with water	Void	
· Oxidising liquids	Void	
· Oxidising solids	Void	
· Organic peroxides	Void	
· Corrosive to metals	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 Based on available data, the classification criteria are not met.

· LD/LC5	0 values r	elevant for classification:	
CAS: 80		hthammolum hthammolum album	
Oral	LD50	>10000 mg/kg (rat)	
Dermal	LD50	21500 mg/kg (rat)	
CAS: 10		Sodium perborate tetrahydrate Natrii peroxoboras hydricum	
Oral	LD50	2240 mg/kg (rat)	
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medicine

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olativo I C50/4 b 11 mg/l (rot)

Inhalative LC50/4 h 11 mg/l (rat)

- · Serious eye damage/irritation Causes serious eye irritation.
- · Reproductive toxicity May damage the unborn child. Suspected of damaging fertility.
- · 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

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

The product does not contain substances with endocrine disrupting properties.

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

Harmful to aquatic organisms

Water hazard class 1 (German Regulation) (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.

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.

- 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

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· 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 accord IMO instruments	ing to 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.

· LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (UK ANNEX XIV)				
		Sunset date: 2023-05-27		
	Natrii peroxoboras hydricum			

- · National regulations:
- · Substances of very high concern (SVHC) according to UK REACH

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

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.

H412 Harmful to aquatic life with long lasting effects.

Department issuing SDS:

Fagron UK

Quality Assurance

· Contact: quality@fagron.co.uk

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· 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 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 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

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

* Data compared to the previous version altered.

GB

