

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

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## ICHTHAMMOLUM

### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name: Ichthammol  
Ichthammolum  
Ichtammol  
Ichtammol  
Ichtammol  
N° CAS: 8029-68-3  
N° EC: 232-439-0

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

#### 1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV  
Oostmalsebaan 1c (unit 5)  
2960 Sint-Lenaarts  
Belgium  
Telephone: (+32) (0)3 457 11 76  
Email: info@magis-pharma.be  
Web page: www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Eye Irrit. 2	H319
Aquatic Chronic 3	H412

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

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### Hazard statements:

H319 Causes serious eye irritation.

H412 Harmful to aquatic life with long lasting effects.

### Precautionary statements:

P273 Avoid release to the environment.

P280 Wear protective gloves/eye 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.

Additional applicable label elements: Not applicable.

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name: Ichthammol

IUPAC name: Ichthammol

Synonyms: Ammonium bituminosulfonate  
Ichthyol

N° CAS: 8029-68-3

N° EC: 232-439-0

Molecular Formula: Not available.

Content: Dry matter: 50.0 per cent m/m to 56.0 per cent m/m;  
Total ammonia (NH<sub>3</sub>; M<sub>r</sub> 17.03): 4.5 per cent m/m to 7.0 per cent m/m (dried substance);  
Organically combined sulfur: minimum 10.5 per cent m/m (dried substance);  
Sulfur in the form of sulfate: maximum 20.0 per cent m/m of the total sulfur.

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

After skin contact: Skin contact is not associated with delayed effects after exposure if the substance is rinsed off with plenty of water shortly after. Subsequent skin care is recommended.

After eye contact: In case of contact with eyes, rinse thoroughly with water. Eye irritation need not occur inevitably. Consult a doctor, however, if eye irritation persists.

After ingestion:

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In case of ingestion, rinse out mouth and give plenty of water to drink. Summon a doctor. In general, ensure supply of fresh air. Remove and dispose of contaminated, soaked clothing immediately.

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

In general, particular acute or delayed effects are not expected. Eye contact may result in acute eye irritation.

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

After ingestion rinse out mouth and give plenty of water to drink. Summon a doctor. Otherwise, no special treatments are required. Go ahead as described under 4.1.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide.

Unsuitable extinguishing media: None.

### 5.2 Special hazards arising from the substance/mixture

In the event of fire, ammonia as well as oxides of sulphur and nitrogen may be produced.

### 5.3 Advice for firefighters

Surrounding fires: Do not inhale combustion gases.

Protection against fire: Use breathing apparatus (large spills).

Hazardous combustion products: Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Use personal protective clothing, especially to prevent contamination of the eyes (wear eye protection, protective gloves). Keep people away and stay on the upwind side. Evacuation normally is not necessary but depends on the specific situation with additional dangers (e.g. fire).

#### For emergency responders

Use personal protective clothing, especially to prevent contamination of the eyes (wear eye protection, protective gloves). Keep people away and stay on the upwind side. Evacuation normally is not necessary but depends on the specific situation with additional dangers (e.g. fire).

### 6.2 Environmental precautions

Keep away from drains, surface and ground water.

Do not discharge product itself or washing water into drains.

### 6.3 Methods and material for containment and cleaning up

Pick up with absorbent material (e.g. sand, sawdust) and collect in suitable containers (HDPE, stainless steel) for subsequent disposal.

### 6.4 Reference to other sections

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Observe precautionary measures described in sections 7 and 8.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling:	No special measures necessary when used properly. Containers should not be left open.
Personal protection:	General hygiene measures: Do not eat, drink and smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.
Technical protective measures:	Not available.
Handling:	Not available.

#### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed. In long time storage (> 6 months), keep at temperature not exceeding 25°C.
Storage – away from:	Do not store together with foodstuffs. On long hauls and with long time storage, protect against sun exposure and overheating as loss of water may appear.

#### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

There are no applicable occupational exposure limits.  
There is no need to carry out risk management measures.

#### 8.2 Exposure controls

##### Appropriate engineering control

There is no need to consider any special technical measures and procedures.

##### Individual protection measures

Eye/face protection:	Safety glasses.
Skin protection:	Not determined.
Hand protection:	Suitable gloves.
Respiratory protection:	Not determined.
Thermal hazards:	Not determined.

##### Environmental exposure control

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Not available.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

Appearance:	Dense, blackish-brown liquid.
Odour:	Characteristic.
Odour threshold:	Not available.
pH:	6.0 – 7.5
Melting/freezing point:	Similar to water (as 44 to 50% of water is included).
Initial boiling point:	Product contains water (44 to 50%).
Boiling range:	Not available.
Flash point:	Not applicable.
Evaporation rate:	Not applicable; organic sulfonate salt in aqueous solution.
Flammability (solid/gas):	Not readily inflammable.
Upper/lower flammability or explosive limits:	Gaseous explosive mixing ratios with oxygen do not form.
Vapour pressure:	Unknown; organic sulfonate salt in aqueous solution.
Vapour density:	Unknown; organic sulfonate salt in aqueous solution.
Relative density:	About 1.15.
Solubility:	Miscible with glycerol, slightly soluble in ethanol (96%), in fatty oils and in liquid paraffin. It forms homogeneous mixtures with wool fat and soft paraffin.
Solubility in water:	Miscible with water.
Partition coefficient (n-octanol/water):	Unknown; see 12.3.
Auto-ignition temperature:	Not applicable.
Decomposition temperature:	Unknown (> 100°C).
Viscosity:	Viscous liquid.
Explosive properties:	None.
Oxidising properties:	None.

#### 9.2 Other information

Dry residue: 50.0 to 56.0

Rotal sulphur in Ichthammol: about 10%

Organically combined sulphur in dry residue: about 16% (at least 10.5%)

### SECTION 10: STABILITY AND REACTIVITY

#### 10.1 Reactivity

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Not reactive under normal handling conditions.

### 10.2 Chemical stability

Under normal ambient and anticipated storage and handling conditions of temperature and pressure, the substance is stable.

### 10.3 Possibility of hazardous reactions

Combustion results in formation of sulphur dioxide. However, combustion does not take place readily under normal handling conditions.

### 10.4 Conditions to avoid

Do not expose to high temperatures.

### 10.5 Incompatible materials

Precipitations occur with polyvalent cations and strong acids, respectively.

### 10.6 Hazardous decomposition products

Under normal handling conditions, no decomposition takes place. Combustion results in formation of sulphur dioxide.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Rat oral/dermal route: based on available data, the classification criteria are not met. Inhalation toxicity: does not apply.
Skin corrosion/irritation:	Based on available data, the classification criteria are not met
Serious eye damage/irritation:	Causes serious eye irritation (H319).
Respiratory/skin sensitisation:	Respiratory: does not apply. Skin: 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:	Based on available data, the classification criteria are not met
Summary of evaluation of the CMR properties:	Not available.
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:	Not applicable.
Other:	From a similar substance (sulphonated shale oil) "Ichthyolic Acid, Sodium Salt", in particular information regarding "skin sensitisation" were derived.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes serious eye irritation (H319).
Skin contact:	Not available.
Inhalation:	Not available.

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Ingestion: Not available.

Aspiration: Not available.

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

Fish (gold orfe), LC50 (96 h): 27.2 mg/l

Micro-organisms/effect on activated sludge: The raw material itself is active ingredient/compound of medicinal products and may be emitted to sewage treatment plants in this form of application only.

*Pseudomonas putida* EC10/EC50 (16 h): > 10 000 mg/l (information for similar substance "Ichthyolic Acid, Sodium Salt")

#### 12.2 Persistence and degradability

"Not easily biodegradable" according to "closed bottle test" (EEC guideline L 383 A: C.4-E) with similar substance "Ichthyolic Acid, Sodium Salt".

#### 12.3 Bioaccumulative potential

A logKow value is not available for the readily water soluble substance. For free acids of aromatic sulphonates, logKow values < 1 are documented. For this reason, bioaccumulation and suspended matter or sediment adsorption are not expected.

#### 12.4 Mobility in soil

There is no information available for this substance.

In natural watery milieu, a permanently negatively charged sulfonate group can be expected (see also 12.3.).

#### 12.5 Results of PBT and vPvB assessment

An assessment was not performed.

#### 12.6 Other adverse effects

Not available.

### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

The disposal agency must be consulted for suitable treatment (e.g. incineration).

Containers with residual amounts of substance in it should be disposed of as harmful contaminated packaging. Cleaned packaging (containers) can be recycled. Recommended cleaning agent: water. Waste waters from cleaning are collected and disposed of in agreement with appropriate authorities.

### SECTION 14: TRANSPORT INFORMATION

#### Transport information according to ADR/RID/IMDG/ICAO/IATA

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

##### 14.2 UN proper shipping name

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ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not to be indicated as environmentally hazardous.

### 14.6 Special precautions for user

See sections 6 – 8.

### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

### 14.8 Additional transport information

Not classified as hazardous for transport.

## SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Irritant

Risk phrases:

R36 Irritating to eyes.

R52 Harmful to aquatic organisms.

R53 May cause long-term adverse effects in the aquatic environment.

Safety phrases:

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S37/39 Wear suitable gloves and eye/face protection.

S61 Avoid release to the environment. Refer to special instructions/safety data sheet.

### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

## SECTION 16: OTHER INFORMATION

### 16.1 Changes since the previous version

Not applicable.



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### 16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

### 16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

### 16.4 Method of classification in case of mixture

Not applicable.

### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

### 16.6 Training advisement

Not available

### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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## 16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

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