

PAGE 1 OF 9

EN

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

02/08/2024 Publication: Revision: XX/XX/XXXX

Version: 00

METHOXSALENUM

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

1.1 PRODUCT IDENTIFIER

Product name: EN: Methoxsalen

> LAT: Methoxsalenum NL: Methoxsalen FR: Méthoxsalène DE: Methoxsalen

N° CAS: 298-81-7 206-066-9 N° EC:

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

Magis-Pharma NV Company:

> Neerlandweg 24 2610 Wilrijk 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

Acute Tox. 4 H302 Skin Sens. 1 H317

2.2 LABEL ELEMENTS

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Warning

Hazard statements:

H302 Harmful if swallowed.

H317 May cause an allergic skin reaction.

Precautionary statements:

MAGIS-PHARMA NV



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

PAGE 2 OF 9

EN

Publication: 02/08/2024 Revision: XX/XX/XXXX

Version: 00

METHOXSALENUM

P280 Wear protective gloves.

P301+P312+P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.

Additional applicable label

elements:

Not applicable.

2.3 OTHER HAZARDS

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1 % or higher.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

Product name: Methoxsalen

9-methoxy-7H-furo[3,2-g]chromen-7-one **IUPAC** name:

Synonyms: 8-Methoxypsorale

> Ammoidin Geroxalen Meladinine Meloxine Methoxa-dome

New-meladinin Oxsoralen Proralone-mop Xanthotoxin

N° CAS: 298-81-7 N° EC: 206-066-9 Molecular Formula: C₁₂H₈O₄

Content: Methoxsalen contains NLT 98.0% and NMT 102.0% of methoxsalen, calculated on the

anhydrous basis.

3.2 MIXTURES

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General notes: Consult a physician. Show this safety data sheet to the doctor in attendance.

After inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration.

Consult a physician.

After skin contact: Wash off with soap and plenty of water. Consult a physician.

After eye contact: Flush eyes with water as a precaution.

After ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water.

Consult a physician.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.



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

EN

PAGE 3 OF 9

Publication: 02/08/2024 Revision: XX/XX/XXXX

Version: 00

METHOXSALENUM

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

SECTION 5: FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Not available.

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon

dioxide.

Unsuitable extinguishing media: Direct water jet.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE/MIXTURE

Carbon oxides. In case of fire, fumes harmful to health may be produced.

5.3 ADVICE FOR FIREFIGHTERS

Surrounding fires: Cool containers with water to avoid product decomposition and the

development of potential health hazards. Always use complete fire protection. Collect water from entering sewage system. Dispose of contaminated water used to extinguish and the remains of the second

in accordance with current regulations.

Protection against fire: Wear self-contained breathing apparatus for firefighting if necessary.

Helmet with visor, flame retardant clothing (jacket and pants with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the entire face of the operator or the car (self-protector) in the case of large amounts

of smoke, a self-contained breathing apparatus (EN 137).

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 equipment. Avoid dust formation. Avoid breathing vapours. Mist or gas. Ensure adequate ventilation. Avoid breathing dust. For personal protection see section 8.

FOR EMERGENCY RESPONDERS

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours. Mist or gas. Ensure adequate ventilation. Avoid breathing dust. For personal protection see section 8.

6.2 ENVIRONMENTAL PRECAUTIONS

Avoid contamination of drains, surface or ground water, as well as soil.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 REFERENCE TO OTHER SECTIONS

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE



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

PAGE 4 OF 9

EN

Publication: 02/08/2024 Revision: XX/XX/XXXX

Version: 00

METHOXSALENUM

7.1 PRECAUTIONS FOR SAFE HANDLING

Precautions for safe handling: Empty containers pose a fire risk, evaporate the residue under a fume

> hood. Ground all equipment containing material. Do not ingest. Do not breath dust. Never add water to this product. If ingested seek medical advice immediately and show the containers or the label. Avoid contact with skin and eyes. Keep away from incompatibles such

as oxidizing agents.

In case of insufficient ventilation, wear suitable respiratory Personal protection:

equipment.

Technical protective measures: Empty containers pose a fire risk, evaporate the residue under a fume

hood. Ground all equipment containing material.

Not available. Handling:

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Preserve in well-closed, light-resistant containers. Store containers in Storage:

a dry and well-ventilated place.

Conditions for safe storage, including any

incompatibilities:

In airtight container at a temperature below 25 °C.

Storage - away from: Store containers away from heat sources and direct sunlight.

7.3 SPECIFIC END USE(S)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Not available.

8.2 EXPOSURE CONTROLS

APPROPRIATE ENGINEERING CONTROL

Use process enclosures, local exhaust ventilation, other engineering control to keep airborne level below recommended exposure limits. If user operation generates dust, fume or mist, use ventilation to keep exposure to airborne containers below the exposure limit.

Since the use of appropriate technical measures must always take precedence over personal protective equipment, ensure good ventilation at the workplace by means of effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must bear the CE marking attesting to compliance with applicable regulations. Provide an emergency shower with a visco-elastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after the end of the workday.

INDIVIDUAL PROTECTION MEASURES

Suggested protective clothing might not be sufficient, consult a specialist BEFORE handling this product.

Eye/face protection: Protective face shields and safety glasses according to EN 165, EN 166, EN 167, EN

168.

Choose body protection according to the amount and concentration of the hazardous Skin protection:

substance in the workplace.



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

PAGE 5 OF 9

EN

02/08/2024 Publication: Revision: XX/XX/XXXX

Version: 00

METHOXSALENUM

Hand protection: Handle with gloves. The selected protective gloves must comply with the

specifications of EU Directive 89/686/EEC and the derived standards EN 374-1, EN

374-2, EN 374-3, EN 420.

Respiratory protection: Where risk assessment shows that air purifying respirators are appropriate, use dust

> mask type N95 (USA) or type P1 (EN 149). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (USA) or CEN

(EU).

Thermal hazards: Als uit risicobeoordeling blijkt dat luchtzuiverende ademhalingstoestellen geschikt

> zijn, gebruik dan stofmasker type N95 (VS) of type P1 (EN 149). Gebruik ademhalingstoestellen en componenten die zijn getest en goedgekeurd volgens

geschikte overheidsnormen zoals NIOSH (VS) of CEN (EU).

ENVIRONMENTAL EXPOSURE CONTROL

Do not let product enter drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Light yellow solid. Appearance:

Odour: Odourless. Odour threshold: Not available. pH: Not available. 143 - 150 °C Melting/freezing point: Initial boiling point: Not available. Boiling range: Not available.

Flash point: Not available. Evaporation rate: Not available. Flammability (solid/gas): Not available.

Upper/lower flammability or

explosive limits:

Vapour density:

Relative density:

Solubility:

Not available.

Vapour pressure:

Not available. Not available. Not available. Not available.

Solubility in water: Insoluble (20 °C). Partition coefficient Not available.

(n-octanol/water):

Auto-ignition temperature: Not available. Decomposition temperature: Not available. Viscosity: Not available. Explosive properties: Not available. Not available. Oxidising properties:

9.2 OTHER INFORMATION



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

PAGE 6 OF 9

EN

Publication: 02/08/2024 Revision: XX/XX/XXXX

Version: 00

METHOXSALENUM

Molecular weight: 216.20 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY

Incompatibility with various substances: Reactive with oxidizing agents.

Special remarks on reactivity: Sensitive to light. May decompose on exposure to light.

Polymerisation: Will not occur.

10.2 CHEMICAL STABILITY

Stability: The product is stable.

Conditions of instability: Excess heat, dust generation, incompatible material.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

Reacts with strong oxidizing agents and strong acids.

10.4 CONDITIONS TO AVOID

Avoid sunlight.

10.5 INCOMPATIBLE MATERIALS

Strong oxidising agents.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Hazardous decomposition products formed under fire conditions: Carbon oxides.

In the event of fire: See section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity: LD₅₀ oral – rat: 791 mg/kg

Remarks: Behavioural: Convulsions or effect on seizure threshold. Behavioural:

Change in motor activity (specific assay). Behavioural: Ataxia.

Skin corrosion/irritation: Not available.
Serious eye damage/irritation: Not available.

Respiratory/skin sensitisation: Causes photosensitivity. Exposure to light can result in allergic reactions resulting in

dermatologic lesions, which can vary from sunburnlike responses to oedematous,

vesiculated lesions, or bullae.

Germ cell mutagenicity: Not available. Carcinogenicity: Not available.

Reproductive toxicity: Laboratory experiments have shown teratogenic effects.

Summary of evaluation of the

CMR properties:

Not available.

STOT-single exposure:

STOT-repeated exposure:

Aspiration Hazard:

Other:

Not available.

Not available.

RTECS: LV1400000



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

PAGE 7 OF 9

EN

Publication: 02/08/2024 Revision: XX/XX/XXXX

Version: 00

METHOXSALENUM

Dizziness. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

11.2 ADDITIONAL INFORMATION ON POTENTIAL ADVERSE HUMAN HEALTH EFFECTS AND SYMPTOMS

Eye contact:

Not available.

Not available.

Inhalation:

Not available.

Ingestion:

Not available.

Not available.

Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 TOXICITY

Not available.

12.2 PERSISTENCE AND DEGRADABILITY

Not available.

12.3 BIOACCUMULATIVE POTENTIAL

Not available.

12.4 MOBILITY IN SOIL

Not available.

12.5 RESULTS OF PBT AND VPVB ASSESSMENT

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 OTHER ADVERSE EFFECTS

Use in accordance with good work practices, avoiding dispersal of the product in the environment. Notify the competent authorities if the product has reached watercourses or if it has contaminated soil or vegetation.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Product: Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Offer surplus and non-recyclable solutions to a licensed disposal company. Waster material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself. Contaminated packaging: Dispose of as unused product.

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



EN

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

PAGE 8 OF 9

Publication: 02/08/2024 Revision: XX/XX/XXXX Version: 00

METHOXSALENUM

ADR/ RID(Land),IMDG(Sea),

Not dangerous goods.

IATA/ICAO (Air):

14.3 TRANSPORT HAZARD CLASS(ES)

RID(Land),IMDG(Sea), Not classified.

IATA/ICAO (Air):

14.4 PACKING GROUP

ADR/ RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.5 ENVIRONMENTAL HAZARDS

RID(Land),IMDG(Sea), ADR/

ADR/RID: No.

IATA/ICAO (Air):

IMDG Marine pollutant: No.

IATA: No.

14.6 SPECIAL PRECAUTIONS FOR USER

Not available.

14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL AND THE IBC CODE

Not applicable.

14.8 ADDITIONAL TRANSPORT INFORMATION

The product should not be considered hazardous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

SECTION 15: REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE/MIXTURE

Hazard symbol:

Irritant

Risk phrases: R22 Harmful if swallowed.

R43 May cause sensitization by skin contact.

Safety phrases: S37 Wear suitable gloves.

S45 In case of accident or if you feel unwell seek medical advice immediately (show

the label where possible).

S64 If swallowed, rinse mouth with water (only if the person is conscious).

15.2 CHEMICAL SAFETY ASSESSMENT

For this product, a chemical safety assessment was not carried out.

SECTION 16: OTHER INFORMATION

16.1 CHANGES SINCE THE PREVIOUS VERSION

Not applicable.

16.2 ABBREVIATIONS AND ACRONYMS USED

ADR: European Agreement concerning the International Carriage of Dangerous Goods by

MAGIS-PHARMA NV



EN

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

METHOXSALENUM

PAGE 9 OF 9

Publication: 02/08/2024 Revision: XX/XX/XXXX

Version: 00

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 Bioaccumalative

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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the Magis-Pharma NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. Magis-Pharma NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 DEPARTMENT ISSUING MSDS

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