

AMOROLFINE 5% VERNIS À ONGLES MEDICAMENTEUX



SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2015/830)

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

1.1. Product identifier

Product name : AMOROLFINE 5% VERNIS À ONGLES MEDICAMENTEUX

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

Anti-fungal nail lacquer.

1.3. Details of the supplier of the safety data sheet

Registered company name : SUBSTIPHARM DEVELOPPEMENT.

Address : 24, rue Erlanger.75016.Paris.France.

Telephone : +33 (0)1 43 18 13 00. Fax : +33 (0)1 42 27 09 90.

Email : contact@substipharm.com

http://www.substipharm.com

1.4. Emergency telephone number : +33 (0)1 45 42 59 59.

Association/Organisation : INRS / ORFILA http://www.centres-antipoison.net.

Other emergency numbers

National Poisons Information Service of England: http://npis.org - NHS 111: dial 111 - National Poisons Information Centre of Ireland: 353 (1) 809 2166 - European Emergency Number Association (EENA) : 112

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Flammable liquid, Category 2 (Flam. Liq. 2, H225).

Repeated exposure may cause skin dryness or cracking (EUH066).

Eye irritation, Category 2 (Eye Irrit. 2, H319).

Specific target organ toxicity (single exposure), Category 3 (STOT SE 3, H336).

Hazardous to the aquatic environment - Chronic hazard, Category 3 (Aquatic Chronic 3, H412).

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :



GHS02

GHS07

Signal Word :

DANGER

Product identifiers :

EC 205-500-4

ETHYL ACETATE

Hazard statements :

H225

Highly flammable liquid and vapour.

H319

Causes serious eye irritation.

H336

May cause drowsiness or dizziness.

H412

Harmful to aquatic life with long lasting effects.

EUH066

Repeated exposure may cause skin dryness or cracking.

Precautionary statements - Prevention :

P210

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P261

Avoid breathing mist/vapours.

P273

Avoid release to the environment.

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Precautionary statements - Response :

P303 + P361 + P353

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P304 + P340

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P312

Call a POISON CENTER/doctor/if you feel unwell.

P337 + P313

If eye irritation persists: Get medical advice/attention.

Other information :

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>

The mixture fulfils neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS**3.2. Mixtures****Composition :**

Identification	(EC) 1272/2008	Note	%
CAS: 64-17-5 EC: 200-578-6 ETHANOL	GHS02 Dgr Flam. Liq. 2, H225	[1]	50 \leq x % < 100
CAS: 141-78-6 EC: 205-500-4 ETHYL ACETATE	GHS07, GHS02 Dgr Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336 EUH:066	[1]	10 \leq x % < 25
CAS: 78613-38-4 EC: 689-236-9 AMOROLFINE HYDROCHLORIDE	GHS07, GHS09 Wng Acute Tox. 4, H302 Skin Irrit. 2, H315 Aquatic Chronic 2, H411		2.5 \leq x % < 10
CAS: 123-86-4 EC: 204-658-1 N-BUTYL ACETATE	GHS07, GHS02 Wng Flam. Liq. 3, H226 STOT SE 3, H336 EUH:066	[1]	2.5 \leq x % < 10
INDEX: 603-001-00-X CAS: 67-56-1 EC: 200-659-6 REACH: 01-2119433307-44 METHANOL	GHS02, GHS06, GHS08 Dgr Flam. Liq. 2, H225 Acute Tox. 3, H331 Acute Tox. 3, H311 Acute Tox. 3, H301 STOT SE 1, H370	[1]	0.1 \leq x % < 1

(Full text of H-phrases: see section 16)

Information on ingredients :

[1] Substance for which maximum workplace exposure limits are available.

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. Description of first aid measures**In the event of exposure by inhalation :**

In the event of massive inhalation, remove the person exposed to fresh air. Keep warm and at rest.

If the person is unconscious, place in recovery position. Notify a doctor in all events, to ascertain whether observation and supportive hospital care will be necessary.

If breathing is irregular or has stopped, effect mouth-to-mouth resuscitation and call a doctor.

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In the event of splashes or contact with eyes :

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.
If there is any redness, pain or visual impairment, consult an ophthalmologist.

In the event of splashes or contact with skin :

Remove contaminated clothing and wash the skin thoroughly with soap and water or a recognised cleaner.
Watch out for any remaining product between skin and clothing, watches, shoes, etc.
If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital.

In the event of swallowing :

Keep the person exposed at rest. Do not force vomiting.
Seek medical attention, showing the label.

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

No data available.

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

No data available.

SECTION 5 : FIREFIGHTING MEASURES

Flammable.

Chemical powders, carbon dioxide and other extinguishing gas are suitable for small fires.

5.1. Extinguishing media

Keep packages near the fire cool, to prevent pressurised containers from bursting.

Suitable methods of extinction

In the event of a fire, use :

- sprayed water or water mist
- water with AFFF (Aqueous Film Forming Foam) additive
- halon
- foam
- multipurpose ABC powder
- BC powder
- carbon dioxide (CO₂)

Prevent the effluent of fire-fighting measures from entering drains or waterways.

Unsuitable methods of extinction

In the event of a fire, do not use :

- water jet

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed :

- carbon monoxide (CO)
- carbon dioxide (CO₂)

5.3. Advice for firefighters

Due to the toxicity of the gas emitted on thermal decomposition of the products, fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For non first aid worker

Because of the organic solvents contained in the mixture, eliminate sources of ignition and ventilate the area.

Avoid inhaling the vapors.

Avoid any contact with the skin and eyes.

If a large quantity has been spilt, evacuate all personnel and only allow intervention by trained operators equipped with safety apparatus.

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For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Prevent any material from entering drains or waterways.

If the product contaminates waterways, rivers or drains, alert the relevant authorities in accordance with statutory procedures

Use drums to dispose of collected waste in compliance with current regulations (see section 13).

6.3. Methods and material for containment and cleaning up

Clean preferably with a detergent, do not use solvents.

6.4. Reference to other sections

No data available.

SECTION 7 : HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

Ensure that there is adequate ventilation, especially in confined areas.

Remove contaminated clothing and protective equipment before entering eating areas.

Fire prevention :

Handle in well-ventilated areas.

Vapours are heavier than air. They can spread along the ground and form mixtures that are explosive with air.

Prevent the formation of flammable or explosive concentrations in air and avoid vapor concentrations higher than the occupational exposure limits.

Prevent the accumulation of electrostatic charges with connections to earth.

The mixture can become electrostatically charged: always ground when decanting. Wear antistatic shoes and clothing and make floors of non-conductive

Use the mixture in premises free of naked flames or other sources of ignition and ensure that electrical equipment is suitably protected.

Keep packages tightly closed and away from sources of heat, sparks and naked flames.

Do not use tools which may produce sparks. Do not smoke.

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Avoid inhaling vapors.

Avoid inhaling vapors. Carry out any industrial operation which may give rise to this in a sealed apparatus.

Provide vapor extraction at the emission source and also general ventilation of the premises.

Also provide breathing apparatus for certain short tasks of an exceptional nature and for emergency interventions.

In all cases, recover emissions at source.

Avoid skin and eye contact with this mixture.

Packages which have been opened must be reclosed carefully and stored in an upright position.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

Never open the packages under pressure.

7.2. Conditions for safe storage, including any incompatibilities

No data available.

Storage

Keep the container tightly closed in a dry, well-ventilated place.

Keep away from all sources of ignition - do not smoke.

Keep well away from all sources of ignition, heat and direct sunlight.

Avoid accumulation of electrostatic charges.

The floor must be impermeable and form a collecting basin so that, in the event of an accidental spillage, the liquid cannot spread beyond this area.

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Always keep in packaging made of an identical material to the original.

7.3. Specific end use(s)

No data available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control parameters****Occupational exposure limits :**

- European Union (2019/1831, 2017/2398, 2017/164, 2009/161, 2006/15/CE, 2000/39/CE, 98/24/CE) :

CAS	VME-mg/m ³ :	VME-ppm :	VLE-mg/m ³ :	VLE-ppm :	Notes :
141-78-6	734	200	1468	400	-
123-86-4	241	50	723	150	
67-56-1	260	200	-	-	Peau

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5		1000 ppm		A3	
141-78-6	400 ppm				
123-86-4	150 ppm	200 ppm			
67-56-1	200 ppm	250 ppm		Skin; BEI	

- Germany - AGW (BAuA - TRGS 900, 08/08/2019) :

CAS	VME :	VME :	Excess	Notes
64-17-5		200 ppm 380 mg/m ³		4(II)
141-78-6		200 ppm 730 mg/m ³		2(I)
123-86-4		62 ppm 300 mg/m ³		2 (I)
67-56-1		200 ppm 270 mg/m ³		4(II)

- Australia (NOHSC: 3008, 1995) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	1000 ppm 1880 mg/m ³			H	
141-78-6	200 ppm 720 mg/m ³	400 ppm 1440 mg/m ³			
123-86-4	150 ppm 713 mg/m ³	200 ppm 950 mg/m ³		H	
67-56-1	200 ppm 262 mg/m ³	250 ppm 328 mg/m ³		H	

- Austria (BGBI. II, 254/2018, 382/2020) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	1000 ppm 1900 mg/m ³	2000 ppm 3800 mg/m ³			
141-78-6	200 ppm 734 mg/m ³	400 ppm 1468 mg/m ³			
123-86-4	100 ppm 480 mg/m ³	100 ppm 480 mg/m ³			
67-56-1	200 ppm 260 mg/m ³	800 ppm 1040 mg/m ³		H	

- Belgium (Arrêté du 19/11/2020) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	1000 ppm 1907 mg/m ³				
141-78-6	200 ppm 734 mg/m ³	400 ppm 1468 mg/m ³			

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123-86-4	50 ppm 238 mg/m ³	150 ppm 712 mg/m ³			
67-56-1	200 ppm 266 mg/m ³	250 ppm 333 mg/m ³		D	

- France (INRS - ED984 / 2020-1546) :

CAS	VME-ppm :	VME-mg/m ³ :	VLE-ppm :	VLE-mg/m ³ :	Notes :	TMP No :
64-17-5	1000	1900	5000	9500	-	84
141-78-6	200	734	400	1468	-	84
123-86-4	150	710	200	940	-	84
67-56-1	200	260	1000	1300	(12)	84

- Switzerland (SUVAPRO 2019) :

CAS	VME	VLE	Valeur plafond	Notations
64-17-5	500 ppm 960 mg/m ³	1000 mg/m ³ 1920 fc/m ³		
141-78-6	200 ppm 730 mg/m ³	400 mg/m ³ 1460 fc/m ³		
123-86-4	100 ppm 480 mg/m ³	200 mg/m ³ 960 fc/m ³		
67-56-1	200 ppm 260 mg/m ³	800 mg/m ³ 1040 fc/m ³		

- UK / WEL (Workplace exposure limits, EH40/2005, Fourth Edition 2020) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	1000 ppm 1920 mg/m ³				
141-78-6	200 ppm 734 mg/m ³	400 ppm 1468 mg/m ³			
123-86-4	150 ppm 724 mg/m ³	200 ppm 966 mg/m ³			
67-56-1	200 ppm 266 mg/m ³	250 ppm 333 mg/m ³		Sk	

- USA / OSHA PEL (Occupational Safety and Health Administration, Permissible Exposure Limits) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	1000 ppm 1900 mg/m ³				
141-78-6	400 ppm 1400 mg/m ³				
123-86-4	150 ppm 710 mg/m ³				
67-56-1	200 ppm 260 mg/m ³				

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :



Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection

Avoid contact with eyes.

Use eye protectors designed to protect against liquid splashes

Before handling, wear safety goggles with protective sides accordance with standard EN166.

In the event of high danger, protect the face with a face shield.

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Prescription glasses are not considered as protection.

Individuals wearing contact lenses should wear prescription glasses during work where they may be exposed to irritant vapours.

Provide eyewash stations in facilities where the product is handled constantly.

- Hand protection

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN ISO 374-1.

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

Type of gloves recommended :

- Nitrile rubber (butadiene-acrylonitrile copolymer rubber (NBR))

Recommended properties :

- Impervious gloves in accordance with standard EN ISO 374-2

- Body protection

Avoid skin contact.

Wear suitable protective clothing.

Suitable type of protective clothing :

In the event of substantial spatter, wear liquid-tight protective clothing against chemical risks (type 3) in accordance with EN14605/A1 to prevent skin contact.

In the event of a risk of splashing, wear protective clothing against chemical risks (type 6) in accordance with EN13034/A1 to prevent skin contact.

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

- Respiratory protection

Avoid breathing vapours.

If the ventilation is insufficient, wear appropriate breathing apparatus.

When workers are confronted with concentrations that are above occupational exposure limits, they must wear a suitable, approved, respiratory protection device.

Anti-gas and vapour filter(s) (Combined filters) in accordance with standard EN14387 :

- A1 (Brown)

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties****General information :**

Physical state : Fluid liquid.

Important health, safety and environmental information

pH : Not relevant.

Boiling point/boiling range : > 35°C

Flash Point Interval : FP < 23°C

Vapour pressure (50°C) : Below 110 kPa (1.10 bar).

Density : < 1

Water solubility : Insoluble.

9.2. Other information

No data available.

SECTION 10 : STABILITY AND REACTIVITY**10.1. Reactivity**

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

When exposed to high temperatures, the mixture can release hazardous decomposition products, such as carbon monoxide and dioxide, fumes and nitrogen oxide.

AMOROLFINE 5% VERNIS À ONGLES MEDICAMENTEUX**10.4. Conditions to avoid**

Any apparatus likely to produce a flame or to have a metallic surface at high temperature (burners, electric arcs, furnaces etc.) must not be allowed on the premises.

Avoid :

- accumulation of electrostatic charges.
- heating
- heat
- flames and hot surfaces

10.5. Incompatible materials

Keep away from :

- oxidising agents
- metals
- peroxides
- halogen compounds

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)
- carbon dioxide (CO₂)

SECTION 11 : TOXICOLOGICAL INFORMATION**11.1. Information on toxicological effects**

Repeated or prolonged contact with the mixture may cause removal of natural oil from the skin resulting in non-allergic contact dermatitis and absorption through the skin.

May have reversible effects on the eyes, such as eye irritation which is totally reversible by the end of observation at 21 days.

Splashes in the eyes may cause irritation and reversible damage

Narcotic effects may occur, such as drowsiness, narcosis, decreased alertness, loss of reflexes, lack of coordination or dizziness.

Effects may also occur in the form of violent headaches or nausea, judgement disorder, giddiness, irritability, fatigue or memory disturbance.

11.1.1. Substances**Acute toxicity :**

N-BUTYL ACETATE (CAS: 123-86-4)

Oral route :

LD50 = 13100 mg/kg

Species : Rat (recommended by the CLP)

Dermal route :

LD50 > 14100 mg/kg

Species : Rabbit (recommended by the CLP)

Inhalation route (n/a) :

LC50 > 21 mg/l

Species : Rat (recommended by the CLP)

OECD Guideline 403 (Acute Inhalation Toxicity)

Duration of exposure : 4 h

AMOROLFINE HYDROCHLORIDE (CAS: 78613-38-4)

Oral route :

LD50 = 1756 mg/kg

Species : Rat

ETHYL ACETATE (CAS: 141-78-6)

Oral route :

LD50 = 5620 mg/kg

Species : Rat (recommended by the CLP)

Dermal route :

LD50 > 18000 mg/kg

Species : Rabbit (recommended by the CLP)

ETHANOL (CAS: 64-17-5)

Oral route :

LD50 = 7000 mg/kg

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Inhalation route (n/a) : Species : Rat (recommended by the CLP)
LC50 = 20000 mg/l
Species : Rat (recommended by the CLP)
Duration of exposure : 4 h

11.1.2. Mixture

No toxicological data available for the mixture.

Monograph(s) from the IARC (International Agency for Research on Cancer) :

CAS 64-17-5 : IARC Group 1 : The agent is carcinogenic to humans.

SECTION 12 : ECOLOGICAL INFORMATION

Harmful to aquatic life with long lasting effects.

The product must not be allowed to run into drains or waterways.

12.1. Toxicity**12.1.1. Substances****N-BUTYL ACETATE (CAS: 123-86-4)**

Fish toxicity : LC50 = 62 mg/l
Species : Leuciscus idus
Duration of exposure : 96 h

Crustacean toxicity : EC50 = 72.8 mg/l
Species : Daphnia magna
Duration of exposure : 24 h

Algae toxicity : ECr50 = 674.7 mg/l
Species : Desmodesmus subspicatus
Duration of exposure : 72 h

ETHYL ACETATE (CAS: 141-78-6)

Fish toxicity : LC50 = 230 mg/l
Species : Pimephales promelas
Duration of exposure : 96 h

Crustacean toxicity : EC50 = 717 mg/l
Species : Daphnia magna
Duration of exposure : 48 h

Algae toxicity : ECr50 = 3300 mg/l
Species : Desmodesmus subspicatus
Duration of exposure : 48 h

ETHANOL (CAS: 64-17-5)

Fish toxicity : LC50 = 11100 mg/l
Duration of exposure : 24 h

Crustacean toxicity : EC50 = 15400 mg/l
Species : Daphnia magna
Duration of exposure : 24 h

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

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12.2. Persistence and degradability

12.2.1. Substances

N-BUTYL ACETATE (CAS: 123-86-4)

Biodegradability : no degradability data is available, the substance is considered as not degrading quickly.

AMOROLFINE HYDROCHLORIDE (CAS: 78613-38-4)

Biodegradability : no degradability data is available, the substance is considered as not degrading quickly.

ETHYL ACETATE (CAS: 141-78-6)

Biodegradability : no degradability data is available, the substance is considered as not degrading quickly.

ETHANOL (CAS: 64-17-5)

Biodegradability : no degradability data is available, the substance is considered as not degrading quickly.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

German regulations concerning the classification of hazards for water (WGK, AwSV vom 18/04/2017, KBws) :

WGK 2 : Hazardous for water.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

SECTION 14 : TRANSPORT INFORMATION

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2021 - IMDG 2018 - ICAO/IATA 2021).

14.1. UN number

1993

14.2. UN proper shipping name

UN1993=FLAMMABLE LIQUID, N.O.S.

(ethanol, ethyl acetate)

AMOROLFINE 5% VERNIS À ONGLES MEDICAMENTEUX**14.3. Transport hazard class(es)**

- Classification :



3

14.4. Packing group

II

14.5. Environmental hazards

-

14.6. Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	3	F1	II	3	33	1 L	274 601 640D	E2	2	D/E

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ	Stowage Handling	Segregation
	3	-	II	1 L	F-E, S-E	274	E2	Category B	-

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ
	3	-	II	353	5 L	364	60 L	A3	E2
	3	-	II	Y341	1 L	-	-	A3	E2

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No data available.

SECTION 15 : REGULATORY INFORMATION**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****- Classification and labelling information included in section 2:**

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2020/1182 (ATP 15)

- Container information:

No data available.

- Particular provisions :

No data available.

- German regulations concerning the classification of hazards for water (WGK, AwSV vom 18/04/2017, KBws) :

WGK 2 : Hazardous for water.

- Standardised American system for the identification of hazards presented by the product in view of emergency procedures (NFPA 704) :

NFPA 704, Labelling: Health=2 Inflammability=3 Instability/Reactivity=1 Specific Risk=none

**- Swiss ordinance on the incentive tax on volatile organic compounds :**

123-86-4

acétate de n-butyle

141-78-6

acétate d'éthyle

64-17-5

éthanol, seulement s'il s'agit d'alcools impropres à la consommation (art. 31 de la loi fédérale sur l'alcool)

67-56-1

méthanol (alcool méthylique)

AMOROLFINE 5% VERNIS À ONGLES MEDICAMENTEUX**15.2. Chemical safety assessment**

No data available.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Wording of the phrases mentioned in section 3 :

H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H336	May cause drowsiness or dizziness.
H370	Causes damage to organs .
H411	Toxic to aquatic life with long lasting effects.
EUH066	Repeated exposure may cause skin dryness or cracking.

Abbreviations :

STEL : Short-term exposure limit

TWA : Time Weighted Averages

TMP : French Occupational Illness table

TLV : Threshold Limit Value (exposure)

AEV : Average Exposure Value.

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

WGK : Wassergefährdungsklasse (Water Hazard Class).

GHS02 : Flame

GHS07 : Exclamation mark

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.