

# Safety Data Sheet

FDS 0002

Medicinal products for human use and medical devices that are invasive or used in direct physical contact with the human body are under no obligation to prepare a Safety Data Sheet according to Directive 1999/45/EC (article 1).

#### 1. SUBSTANCE/PREPARATION AND COMPANY IDENTIFICATION

Product name:

URGO Damaged nails filmogel®

Substance use:

medical device

Manufacturer/supplier:

URGO

Adress:

42 rue de Longvic

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21300 Chenôve

Phone:

03 80 54 50 00

Web site:

www.urgo.fr

#### 2. HAZARDS IDENTIFICATION

No mandatory hazard labelling cf. section 15

May form explosive mixtures.

#### 3. COMPOSITION/ INFORMATION ON INGREDIENTS

Components	N°CAS N°EINECS	Mass %	Risk phrases
Piroctone olamine	68890-66-4	<1	Xi; R37/38: Irritating to respiratory system and skin R41: Risk of serious damage to eyes N; R52/53: Harmful to aquatic organisms, may cause long- term adverse effects in the aquatic environment
Absolute ethanol	64-17-5 200-578-6	60-75	F ; R11 Highly flamable

### 4. FIRST AID MEASURES

In case of spattering, rinse thoroughly with water as quickly as possible.

In case of inhalation, transfer to fresh air.

#### 5. FIRE FIGHTING MEDIA AND INSTRUCTIONS

Suitable extinguishing media: water with additives, powder

Specific protective equipment for fire fighters:

- Personal protection equipment: no toxic thermal decomposition, wear suitable fire protection clothing

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions:

Keep away from heat sources (do not smoke, electrostatic discharge ...)

- Wear nitrile or butyl gloves, safety glasses, chemical clothing, boots, mask with cartridge type A
- Keep personnel away

Environmental precautions:

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- Block off the discharge with the devices provided for this purpose as quickly as possible
- Remove the liquid with an inert absorbent material
- Pick up and eliminate it via the appropriate waste procedure
- Never discard in sewers or into the natural environment

#### 7. HANDLING AND STORAGE

Handling conditions recommended:

- Keep integrity of packages
- Do not smoke
- Training for forklift drivers to handle fire extinguishers for emergency use
- ATEX Awareness Training

Recommendations for warehouses and storage pool:

- Store in a specific well ventilated place,
- Do not store near heat sources, do not smoke
- Keep containers tightly closed and sealed
- Ensure fire safety in the performance of hot-work/refer to hot-work permit programs
- Ensure potential water retention for fire extinction
- Store product away from incompatible materials
- ATEX directives applicable (area, required equipment, personnel's qualification)

#### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Not applicable cf. section 15

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance/colour: colourless Physical state: liquid Flash point: 20 °C

### 10. STABILITY AND REACTIVITY DATA

Conditions to avoid: heat sources

Incompatibility with various substances: combustive

## 11. TOXICOLOGICAL INFORMATION

Not applicable cf. section 15

#### 12. ECOLOGICAL INFORMATION

Not applicable cf. section 15

## 13. DISPOSAL CONSIDERATIONS

Waste must be disposed of in accordance with appropriate federal, state and local environmental control regulations. Could be classified according to Appendix II of article R-541-8 of the French Environmental Code in 18 01 XX. Contaminated and/or soiled packages will be supported by a company with the necessary authorizations for transport and disposal of this waste.



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### 14. TRANSPORT INFORMATION

Relevant regulations	Road Transport	Sea Transport	Air Transport
Relevant regulations	ADR/RID (2)	IMDG	OACI / IATA
UN number:	UN 1170,	UN 1170,	ID 8000,
Trade name:	Ethanol solution	Ethanol solution	Consumer commodity (1)
Hazard class:	3	3	9
Packing group:	П	111	
Labels required:	3	l ä	9
EmS number:		F-E ;S-D	9-0
Sea pollutant :		NON	
Limited quantity:	Inside: 1 L	Inside: 1 L	Inside : see IE Y963
	Outside: 30 kg (brut)	Outside: 30 kg (brut)	Outside : 30 kg (gross)
Excepted quantity:	E2 0 7	E2	E0 ,
Maximal weight/pack:		W	30 kg G (gross) passenger plane
			30 kg G (gross) cargo-plane
Packing instructions:	P001	P001	Y963 passenger plane
		" " " " " " " " " " " " " " " " " " "	Y963 cargo-plane
Spécial provisions:	144 - 601	144	A112

<sup>(1) &</sup>lt;u>Definition</u>: Consumer commodities are materials which are customarily produced or distributed for sale through retail sales agencies or instrumentalities for consumption by individuals, or use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household.

The DS A112 designates classes and divisions of hazardous material allowed by this name.

NOTE: one of the ingredients is highly toxic to aquatic organisms but considering that this ingredient represents less than 1% of the total composition it can be reasonably estimated that its impact on the environment is insignificant and therefore it is not subject to ADR regulations (RID, IMDG, IATA).

#### 15. REGULATORY INFORMATION

This product is part of medicinal products for human use and medical devices that are invasive or used in direct physical contact with the human body; it is under no obligation to prepare a Safety Data Sheet according to Directive 1999/45/EC (article 1) exemption supplemented by article L1342-1 of the French Public Health Law.

Rank classified installations for French environment:

- Items that can be targeted based on quantities used: 1432, 1510.

#### 16. OTHER DATA

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<sup>(2)</sup> ADR: According to special provision 601, pharmaceutical products (medicines), ready for use, which are substances manufactured and packaged for retail sale or distribution for personal or household consumption, are exempted from the requirements of RID/ADR/ADN.