



Safety Data Sheet

FDS 0004

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 Cold Sore filmogel ®
Substance use: medical device
Manufacturer/supplier: URGO
Adress: 42 rue de Longvic
21300 Chenôve - FRANCE
Phone: 03 80 54 50 00
Web site: www.urgo.fr

2. HAZARDS IDENTIFICATION

No mandatory hazard labelling *cf. section 15*
Substance and vapors flammable at room temperature in case of contact with a heat source.
May form explosive mixtures.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Components	N°CAS N°EINECS	mass%	Risk phrases
Citric Acid	5049-29-1 201-069-1	<1	Xi; R36: Irritating to eyes
Boric Acid	10043-35-3	<1	T Reprotoxic cat.2 (*)
Absolute Ethanol	64-17-5 200-578-6	60-75	F; R11: Highly flammable

(*) considered R2 on the base of 30th ATP CEE even if it was not resumed by the 31st ATP CEE and appendix VI of CLP

4. FIRST AID MEASURES

In case of skin contact, immediately wash with large amounts of water.
If inhaled, immediately move 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 decomposition
wear suitable fire protection clothing

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:

- Keep away from ignition 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:

- Block off the discharge with the devices provided for this purpose as quickly as possible



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- Mix 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 (bursting risk)
- 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,
- Keep away from any heat source, do not smoke
- Keep containers tightly closed and sealed
- Ensure fire safety in the performance of hot-work
- Ensure potential water retention for fire extinction
- Store away from incompatible materials, especially combustible.
- 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: temperature rise

Incompatibility with various substances: combusive

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 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
	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:	II	II	--
Labels required:	3	3	9
EmS number:	--	F-E; S-D	--
Marine pollutant:	--	NO	--
Limited quantity:	Inside: 1L Outside: 30 kg (gross)	Inside: 1L Outside: 30 kg (gross)	Inside: see IE Y963 Outside: 30kg (gross)
Excepted quantity:	E2	E2	E0
Maximal weight/pack:			30 kg G (gross) passenger plane 30 kg G (gross) cargo-plane
Packing instructions:	P001	P001	Y963 passenger plane Y963 cargo-plane
Special provisions:	144-601	144	A112

⁽¹⁾**Definition:** 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.

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

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/RID regulations Code 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

Review the information sheet:

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May 2011	Creation	1