



# Safety Data Sheet

FDS063

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 Mouth ulcer, frutti flavour, filmogel® / URGO Mouth wounds, frutti flavour, filmogel®

*Substance use:* medical device

*Manufacturer/supplier:* URGO  
*Address:* 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*  
May form explosive mixtures.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

Only components labelled dangerous by the order of 20/04/2010 as amended are mentioned:

Components	N°CAS N°EINECS	mass%	Risk phrases
Tutti Frutti flavour	Not applicable	<5	Xn; R65: Harmful by inhalation N; R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment R10: Flammable R43: May cause sensitisation by skin contact R38: Irritating to skin
Salicylic Acid	69-72-7	<5	Xn; R22: Harmful if swallowed Xi; R41: Risk of serious damage to eyes
Boric Acid	10043-35-3 233-139-2	<1	T and suspected Reprotoxic cat.2 (*) R60: May impair fertility R61: May cause harm to the unborn child
Absolute Ethanol	64-17-5 200-578-6	55-65	F; R11: Highly flammable

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

## 4. FIRST AID MEASURES

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

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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
- Remove the liquid with an inert absorbent material
- 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
- 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:* high temperature

*Incompatibility with various substances:* combusive

## 11. TOXICOLOGICAL INFORMATION

Not applicable cf. section 15

## 12. ECOLOGICAL INFORMATION

Not applicable cf. section 15

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## 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.

## 14. TRANSPORT INFORMATION

Relevant regulations	Road Transport	Sea Transport	Air Transport
	ADR/RID <sup>(2)</sup>	IMDG	OACI / IATA
UN number:	UN 1170,	UN 1170,	ID 8000,
Trade name:	Ethanol solution	Ethanol solution	Consumer commodity <sup>(1)</sup>
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

<sup>(1)</sup>**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.

<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.

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

Review the information sheet:

Date	Subject	Index
December 2011	Creation	1