

SAFETY DATA SHEET

(Regulation EC No.1907/2006 amended – Annex II)



COMPANY: LABORATOIRES URGO
BRAND: URGO
PRODUCT NAME: URGO Cold Sore filmogel ®
Creation date: 01/05/2011
Version: 4.1

SDS n°: SDS004
Print date: 09/04/2025
Revision date: 08/06/2020

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

1.1. PRODUCT IDENTIFIER

Product Name: URGO Cold Sore filmogel ®
Type of product: Mixture.

EC number: --
CAS number: --
REACH ID: --

1.2. RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Identified uses: Consumer use.
Finished product.
General public medical device.

Uses advised against: No data available.

Reasons for not recommended uses: --

1.3. DETAILS OF THE SUPPLIER OF THE SUBSTANCE OR MIXTURE

Manufacturer /Supplier: LABORATOIRES URGO

Address: 42 rue de Longvic
21300 Chenôve

Tel: +33.(0)3.80.54.50.00

Fax: +33.(0)3.80.44.74.52

Email: info@laboratoiresurgo.fr

Website : www.urgo.fr

Contact person: Mister Gilles Guérin.

1.4. EMERGENCY TELEPHONE

Emergency phone number: INRS / ORFILA: +33.(0)1.45.42.59.59

SECTION 2. HAZARDS IDENTIFICATION

2.1. CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

The finished product for the general public, in its commercial form, is not concerned by the CLP classification.

This classification is given for information for professionals responsible for the storage, handling, distribution and transportation of the product to ensure safely handling.

Classification according to Regulation EC No.1272/2008 (CLP):

The product is classified for its hazard properties to human health and / or environment.

Hazard class	Hazard category	Hazard statements
Flam Liq	2	H225
Eye Irrit	2	H319
Repr*	1B*	H360FD*

Full text of hazard categories and H phrases is included in section 16.
Procedure used for determining classification is included in section 16.

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2.2. LABEL ELEMENTS

The finished product for the general public, in its commercial form, is not concerned by the labeling according to the CLP. This labeling is given for information for professionals responsible for the storage, handling, distribution and transportation of the product to ensure safely handling.

2.2.1. Labeling according to Regulation EC No.1272/2008 (CLP):

Pictograms:



Signal word:

Danger.

Contains:

Hazard statements:

H225 Highly flammable liquid and vapour
H319: Causes serious eye irritation
H360FD: May damage the fertility and the unborn child*

Additional hazard statements:

--

Precautionary statements:

Prevention:

P102: Keep out of reach of children.
P210: Keep away from heat / sparks / open / hot surfaces flames. Do not smoke.
P233: Keep container tightly closed.
P243: Take precautionary measures against electrostatic discharges.
P264: Wash hands thoroughly after handling.

Intervention:

P305 + P351 + P338: IF CONTACT WITH EYES: Rinse cautiously with water for several minutes. Remove contact lenses if the victim wears and if they can be easily removed. Continue to rinse.
P308 + P313: IF exposed or concerned: Get medical advice/ attention*.
P337 + P313: If eye irritation persists, consult a doctor.
P370 + P378: IN CASE OF FIRE: Use for extinction: CO2, powder or water spray.
P403 + P235: Store in a well-ventilated place. Keep cool.
P405: Store locked up*.
P501: Dispose of contents / container in accordance with local / regional / national international regulations.

2.2.2. Reduced labeling (≤ 125 mL) according to Regulation EC No.1272/2008 (CLP):

Pictograms:



Signal word:

Danger.

Hazard statements:

--

Additional hazard statements:

--

Precautionary statements:

P102: Keep out of reach of children.

2.3. OTHER HAZARDS

**PBT/vPvB Properties
(Annex XIII):**

The product has not been evaluated for its PBT/vPvB properties.

**Ingredients submitted to authorization
(Annex XIV):**

Not concerned.

Others:

No additional data available.

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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. SUBSTANCE

Not concerned.

3.2. MIXTURE

3.2.1. Components / impurities presenting a health or environmental hazard:

Components	Identifiers	% by mass	Classification (Regul. EC No.1272/2008)
Boric Acid	N° CAS : 10043-35-3 N° CE : 233-139-2 N° ID : 005-007-00-2 N° REACH : 01-2119486683-25-0000	< 5.5 %	Repr Cat1B; H360FD *
Ethyl alcohol	CAS No: 64-17-5 EC No: 200-578-6 ID No: 603-002-00-5 REACH No: 01-2119457610-43-XXXX	> 50.0 %	Flam Liq Cat2; H225 Eye Irrit Cat2; H319
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, hydrate (1:1)	N° CAS : 5949-29-1 N° CE : 201-069-1 N° ID : -- N° REACH : --	< 1.0 %	Eye Irrit Cat2; H319

Full text of hazard categories and H phrases is included in section 16.

3.2.2. Components / impurities having professional TLV / TWA:

Components	Identifiers	% by mass	Classification (Regul. EC No.1272/2008)
Boric Acid	N° CAS : 10043-35-3 N° CE : 233-139-2 N° ID : 005-007-00-2 N° REACH : 01-2119486683-25-0000	< 5.5 %	Repr Cat1B; H360FD *
Ethyl alcohol	CAS No: 64-17-5 EC No: 200-578-6 ID No: 603-002-00-5 REACH No: 01-2119457610-43-XXXX	> 50.0 %	Flam Liq Cat2; H225 Eye Irrit Cat2; H319

Full text of hazard categories and H phrases is included in section 16.

3.2.3. Components / impurities classified PBT/vPvB and/or listed in the Candidate List:

Components	Identifiers	% by mass	Classification (Regul. EC No.1272/2008)
Boric Acid	N° CAS : 10043-35-3 N° CE : 233-139-2 N° ID : 005-007-00-2 N° REACH : 01-2119486683-25-0000	< 5.5 %	Repr Cat1B; H360FD *

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SECTION 4. FIRST AID MEASURES

4.1. DESCRIPTION OF FIRST AID MEASURES

General advise: Remove to fresh air.
Move the subject out of the danger area and lay down.
Remove all contaminated clothing immediately.
Contact First Aid personnel and ESH Department.

Inhalation: If feeling unwell, take the person to a physician.
Move the subject to fresh air and keep quiet.

Skin contact: In case of skin irritation, rinse immediately with water. (*).
In case of persistent skin irritation, consult a physician.

Eye contact: Rinse opened eye for 15 minutes under running water, holding the eyelids apart.
If symptoms persist, consult a physician.

Ingestion: Check that the victim did not wear contact lenses, remove them.
Turn to the side a person lying on the back, which is throwing up.
Do not induce vomiting unless directed to the medical profession.
Accidental ingestion high enough to be a health hazard level is unlikely.
If symptoms persist, consult a physician.

Personal protective equipment for rescue workers: See Section 8.

4.2. MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Inhalation: Inhalation of high concentrations may cause transient respiratory tract irritation, headaches, nausea, dizziness and narcotic effects

Skin contact: The product can cause mild skin irritation if prolonged or repeated contact.

Eye contact: The product can cause eye damage

Ingestion: Ingestion of large amounts may cause:
- Depression of the central nervous system,
- Symptoms similar to intoxication by alcohol.
- Nausea or vomiting
- Irritation of the mouth, throat and stomach

4.3. INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No specific recommendations.

SECTION 5. FIREFIGHTING MEASURES

5.1. EXTINGUISHING MEDIA

Suitable extinguishing media: CO2, extinguishing powder or water spray.
Fight larger fire with alcohol resistant foam.
Adapt fire extinguishing methods suitable to the environment.

Unsuitable extinguishing media: High water volume.

5.2. SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

Hazardous combustion products: Carbon monoxide (CO), carbon dioxide.

Particular risk in case of fire or explosion: Fumes can combine with air an explosive mixture.
Vapors with an ignition source, can create an instant fire.
No UVCE (vapor explosion in non-confined area).
Runoff to sewer may cause fire or explosion.

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5.3. ADVICE FOR FIRE-FIGHTERS

Flammable class: Highly flammable liquid.
Protection against fire: Wear suitable respiratory protection independent of the ambient air.
Do not inhale explosion gases or combustion gases.
Port keeping fireproof.
Special procedures: Cool endangered receptacles with water spray.
Surrounding fires: No data available.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

6.1.1. For the non-emergency:

Protective equipment: See Section 8.
No action shall be taken involving any personal risk or without suitable training.
Evacuate area and keep unprotected people away.
Prevent access to unprotected personnel.
Do not touch or walk through spilled material.
Extinguish all ignition sources.
Emergency procedure: No data available.

6.1.2. For the emergency:

See Section 8.
Evacuate area and keep unprotected people away.
Prevent access to unprotected/unauthorized personnel.
Do not touch or walk through spilled material.
Extinguish all ignition sources.

6.2. ENVIRONMENTAL PRECAUTIONS

Avoid discharge to sewage system, holes and cellars.
Do not allow to enter drainage system, surface water and the ground water.
In case of discharge to water course or sewage system, notify the competent authorities.

6.3. METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

6.3.1. Appropriate means of the confinement:

Obstruct the earliest possible outlets with devices provided for this purpose.

6.3.2. Appropriate means of the clean-up:

Collect the liquid with absorbent material (sand, diatomite, acid binders, universal binders, sawdust).
let evaporate in a well-ventilated area.
Ensure adequate ventilation.
Use explosion-proof equipment.

6.3.3. Others information:

No additional data available.

6.4. REFERENCE TO OTHER SECTIONS

See sections 8 and 13 for more information.

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SECTION 7. HANDLING AND STORAGE

7.1. PRECAUTIONS FOR SAFE HANDLING

Protection measures: Wear protective equipment required before handling (see section 8).
Ensure good ventilation / exhaustion at the workplace.
If possible, use a closed transfer system.
Respect the integrity of the packaging.

Measures to prevent a fire: Keep away from sources of ignition.
Do not smoke.
Use explosion-proof equipment and fittings and non-sparking tools.
Appropriate equipment to deal with fires, spills and leaks must be easily accessible.
Grounding of equipment.
Operator training in the use of fire extinguishers for immediate action.
ATEX awareness.

Measures to prevent aerosol generation and dust: No data available.

Measures to protect environment: No data available.

General advice on hygiene of workers: Wash hands thoroughly after handling.

7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Technical measures and storage conditions: Keep container tightly closed.
Store in cool, dry conditions in well-sealed tanks.
Protect from heat and direct sunlight.
Keep container in a well-ventilated area.
Use the procedure fire permit if hot spot work.
Ensure retention of potential fire extinguishing water.
ATEX applicable regulations (zoning, adequacy of equipment, staff empowerment).

Packaging materials: Store only in the original tanks
Use only tanks specifically permitted for the product.

Requirements for storage and containers: Storage tanks must be an equipotential electrical connection and grounding.
Stainless steel, titanium, bronze, cast iron, carbon, polypropylene, neoprene, nylon, ceramic, glass: compatible materials.
Incompatible materials: natural rubber, PVC, methyl- methacrylate plastics, polyamides, zinc, brass, aluminum under certain conditions.

Storage class: Highly flammable liquid.
Do not store together with oxidizing and acidic materials.

7.3. SPECIFIC END USE(S)

The identified uses for this product are listed in Section 1.2.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. CONTROL PARAMETERS

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Occupational exposure (France: country providing the SDS):

Component Name	CAS No	TLV / TWA	DNEL / DMEL
Ethanol	64-17-5	VLE: 5 000 ppm ; 9 500 mg/m ³ VME: 1 000 ppm ; 1900 mg/m ³	DNEL inhalation (short term / local): 1 900 mg/m ³ (1 000 ppm) DNEL inhalation (long term / systemic): 950 mg/m ³ (500 ppm) DNEL dermal (long term / systemic): 343 mg/kg bw/day
Boric acid	10043-35-3	8h TWA: WEL: 1 mg B/m ³	Operator : DNEL inhalation (long-term / systémic) : 8.28 mg/m ³ DNEL dermal (long-term / systémic) : 392 mg/kg/day Consumer : DNEL oral (short-terme / systémic) : 0.98 mg/kg/day DNEL oral (long-term / systémic) : 0.98 mg/kg/day DNEL inhalation (long-term / systémic) : 4.15 mg/m ³ DNEL dermal (long-term / systémic) : 196 mg/kg/day

Source: Supplier data

8.1.2. Environmental exposure:

Component Name	CAS No	PNEC
Ethyl alcohol	64-17-5	PNEC freshwater: 0.96 mg/L PNEC marine water: 0.79 mg/L PNEC freshwater sediments: 3.6 mg/kg bw PNEC marine sediments: 2.9 mg/kg bw PNEC soil: 0.63 mg/kg bw PNEC oral via foods : 0.72 mg/kg
Boric acid	10043-35-3	PNEC freshwater and marine: 2.02 mg B/L PNEC intermittent stream: 13.7 mg B/L PNEC soil : 5.4 mg/kg bw PNEC STP : 10 mg B/L

Source: Supplier data

8.2. EXPOSURE CONTROLS

8.2.1. Appropriate technical controls:

Measures related to substance/mixture: No data available.
Structural measures: No data available.
Organisational measures: No data available.
Technical measures: No data available.

8.2.2. Personal protective measures:

Eye / Face protection: Wear safety glasses with side-shield conforming to EN 166.
Hand protection: Wear protective gloves that meet the requirements of EN 374.
Material of gloves: The selection of suitable gloves not only depends on the material, but also on further quality criteria and varies from manufacturer to another:
- Butyl
- Nitrile rubber .
Body protection: Wear protective work.
Respiratory protection: Use respiratory protection if ventilation is inadequate.

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In case of exposure beyond VME mandatory individual respiratory protection equipment port.

Use devices complying with an approved standard.

AX filter.

Thermal hazards:

No data available.

Hygiene measures:

Observe the usual precautionary measures for handling chemicals.

Wash hands before breaks and after work.

Do not inhale gases, vapors and aerosols.

Promote the establishment of collective protection measures over individual protective measures.

8.2.3. Environment protection measures:

Measures related to substance/mixture:

Avoid discharge to sewage system, holes and cellars.

Do not allow to enter drainage system, surface water and the ground water.

In case of discharge to water course or sewage system, notify the competent authorities.

Instruction measures:

No data available.

Organisational measures:

No data available.

Technical measures:

No data available.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Physical state: liquid.
Colour: Colourless.
Odour: No data available.
Odour Threshold: No data available.
pH: No data available.
Melting / freezing point: No data available.
Initial boiling point and boiling range: 76°C
(Unpublished internal report)
Flash point: 19°C (Closed cup)
(Unpublished internal report)
Evaporation rate: No data available.
Flammability (solid, gas): No data available.
Upper / lower flammability limits: No data available.
Upper / lower explosive limits: No data available.
Vapour pressure: No data available.
Vapour density: No data available.
Relative density: No data available.
Solubility: No data available.
n-octanol/water partition coefficient: No data available.
Auto-ignition temperature: No data available.
Decomposition temperature: No data available.
Viscosity: No data available.
Explosive Properties: No data available.
Oxidizing properties: No data available.

9.2. OTHER INFORMATION

VOC Rate: About 50%

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SECTION 10. STABILITY AND REACTIVITY

10.1. REACTIVITY

No data available.

10.2. CHEMICAL STABILITY

The product is considered as stable under normal and reasonably foreseeable conditions of use.

10.3. POSSIBILITY OF HAZARDOUS REACTIONS

Due to its high concentration of Ethyl alcohol, the product may react with:

- Light metals forming hydrogen,
- Peroxides
- Halogenated compounds.

10.4. CONDITIONS TO AVOID

Avoid excessive heat for prolonged periods.

Avoid heat, flames and other sources of ignition.

10.5. INCOMPATIBLE MATERIALS

Oxidizing agents, peroxides, oxidizing acids and salts; Organometallic Hydrogen, Phosphorus, Arsenic, Antimony, metal oxides, silver nitrate, mercury nitrate, magnesium perchlorate.

10.6. HAZARDOUS DECOMPOSITION PRODUCTS

Combustion will generate carbon oxides carbon.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1. INFORMATION ON TOXICOLOGICAL EFFECTS

11.1.1. Information on the substance:

Not concerned.

11.1.2. Information on the mixture:

The finished product has not been fully tested. (*)

According to available data on the components and according to the additivity rule, the product is considered as hazardous to human health (Regulation EC No 1272/2008 as amended).

Acute Toxicity: No sufficient data available to determine the classification of the product
Ingestion: According to data available on the components:
No data available.
Dermal: No data available.
Inhalation: No data available.

Skin corrosion/irritation: According to data available on the components:
The product may cause slight skin irritation.
(Supplier data).

Serious eye damage / eye irritation: According to data available on the components:
The product can cause severe eye irritation.
(Additivity rule).

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Respiratory or skin sensitization: According to data available on the components:
The product is considered "Non-sensitizer."
(Additivity rule).

Germ Cell Mutagenicity: According to the data on the components:
Not classified as mutagen.
(Additivity rule).

Carcinogenicity: According to the data on the components:
Not classified as carcinogen.
(Additivity rule).

Reproductive Toxicity: According to the data on the components:
The product may affect fertility and the unborn child*. The product contains Boric Acid classified as "Toxic to reproduction Category 1B (Additivity rule) *".

Specific target organ toxicity (STOT) – single exposure: According to the data on the components:
Not classified as specific organ toxic, single exposure. (Additivity rule).

Specific target organ toxicity (STOT) – repeated exposure: According to the data on the components:
Not classified as specific organ toxic, repeated exposure. (Additivity rule).

Aspiration hazard: According to the data on the components:
Not classified as aspiration hazard. (Additivity rule).

11.1.3. Information on likely routes of exposure:

Exposure may occur by dermal and digestive route under normal use.

11.1.4. Symptoms related to the physical, chemical and toxicological characteristics:

See section 4.2.

11.1.5. Delayed, immediate and chronic effects of exposure to short or long term:

See section 4.2.

11.1.6. Interactive effects:

No data available.

11.1.7. Absence of specific data:

No available data on similar mixtures.

11.1.8. Information on mixtures and information on substances:

No data available.

11.1.9. Other information:

No additional data available.

SECTION 12. ECOLOGICAL INFORMATION

No data are available on finished product.

According to available data on the components and according to the additivity rule, the product is not considered as dangerous for the environment (Regulation EC No 1272/2008 as amended).

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12.1. TOXICITY

Acute toxicity: According to data available on the components:
The product is not considered as acute toxic to aquatic organisms.
(Additivity rule).

Fishes: No data available.
Crustaceans: No data available.
Algae / Aquatic plant: No data available.
Other organisms: No data available.

Chronic toxicity: According to data available on the components:
The product is not considered as chronic toxic to aquatic organisms.
(Additivity rule).

12.2. PERSISTENCE AND DEGRADABILITY

According to data available on the components:
The product is considered as "Easily biodegradable".
(Supplier data).

12.3. BIOACCUMULATIVE POTENTIAL

According to data available on the components:
The product is considered as "Not potentially bioaccumulative."
(Supplier data).

12.4. MOBILITY IN SOIL

According to data available on the components:
The product is considered as "Mobile in the ground."
(Supplier data).

12.5. RESULTS OF PBT AND VPVB ASSESSMENT

The product has not been evaluated for its properties PBT/vPvB (Regulation EC No. 1907/2006 – Annex XIII).

12.6. OTHER ADVERSE EFFECTS

No additional data available.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1. WASTE TREATMENT METHODS

13.1.1. Disposal of the product / packaging:

This product is disposed as hazardous waste according to appropriate treatment pathways and local / departmental plan for waste disposal.

The mixture must be disposed of in an appropriate channel for solvent based chemicals.

Contaminated and / or soiled by the product packaging must be supported by an organization with the necessary authorizations for the transport and disposal of waste.

Empty packaging should not be treated as household waste: it may contain hazardous residues.

Hazard classification: H3-A: Highly flammable.
H4: Irritant.

Nomenclature Code
(Environmental Code, art.
R541-8, Annex II): 14.06: Waste solvents, refrigerants and aerosols / organic foams propellants.
14.06.03*: Other solvents and solvent mixtures.
16.03: Off-specification batches and unused products.
16.03.05*: Organic wastes containing dangerous substances.

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13.1.2. Relevant information about the waste treatment:

No data available.

13.1.3. Relevant information about the disposal of sewage:

No data available.

13.1.4. Other recommendations for the disposal:

No data available.

SECTION 14. TRANSPORT INFORMATION

According to the requirements of ADR / RID / ADNR / IMDG / ICAO / IATA

14.1. UN NUMBER

1993

14.2. UN PROPER SHIPPING NAME

Flammable liquid, nsa (contains Ethyl alcohol).

14.3. TRANSPORT HAZARD CLASS(ES)

Hazard class: 3
Hazard label: 3

14.4. PACKING GROUP

Packing group II.

14.5. ENVIRONMENTAL HAZARDS

Not concerned.

14.6. SPECIAL PRECAUTIONS FOR USER

14.6.1. Road transport (ADR, 2013):

Classification Code (UN): F1
Orange panels:
Transport category: 2
Tunnel restriction code: D/E
Special provisions: 274 ; 601 ; 640D*
Limited quantities: 1 L
Excepted quantities: E2
Packing instruction: P001
Mixed packaging provisions: MP19

14.6.2. Rail transport (RID):

Not concerned.

14.6.3. River transport (ADN / ADNR):

Not concerned.

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14.6.4. Sea transport (IMDG):

EmS number: F-E, S-E
Marine pollutant: No
Special provisions: 274
Limited quantities: 1 L
Excepted quantities: E2
Packing instruction: P001

14.6.5. Air transport (ICAO / IATA):

UN number: ID 8000
Shipping Name: Consumer use.
Danger class: 9
Packing groue: --
Danger label : 9
Special provisions : A112
Limited quantities: Y963 / 30 kg
Excepted quantities: E0
Packing instruction: Y963

14.6.4. Actions in the event of an accident or emergency:

- Apply the braking system, stop the engine and isolate the battery by activating the master switch where available.
- Inform the appropriate emergency services, giving as much information about the incident or accident and substances involved as possible.
- Put on the warning vest and place the self-standing warning signs as appropriate.
- Keep the transport documents readily available for responders on arrival.
- Do not walk into or touch spilled substances and avoid inhalation of fumes, smoke, dusts and vapours by staying up wind.

14.7. TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

Not concerned.

1. SECTION 15. REGULATORY INFORMATION

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

15.1.1. European regulations:

Regulation EC No. 1907/2006 (REACH) amended:

The finish to the consumer as marketed product is exempt from the provisions of Title IV of Regulation : communication of information in the supply chain .

The product contains less than 5.5 % of boric acid [CAS No. 10043-35-3] that :

- Is recognized as SVHC
- Is listed in the Candidate List from 18/06/2010 ,
- Is listed in Annex XVII - Entry 30 - and has usage restrictions substance classified as " Repr Cat1B ."

The product meets the restrictions on use of boric acid:

" Can not be placed on the market , or used :

- As a substance ,
- As a constituent of other substance , or
- In mixtures ,

intended to be sold to the general public in individual concentration in the substance or mixture is equal to or greater than:

- Either the relevant specific concentration limit specified in Annex VI , part 3 of Regulation (EC) No 1272 /2008
- Either the relevant concentration specified in Directive 1999/45/EC if no specific concentration limit is set out in Annex VI , part 3 of Regulation (EC) No 1272/2008. "

SAFETY DATA SHEET

(Regulation EC No.1907/2006 amended – Annex II)



COMPANY: LABORATOIRES URGO
BRAND: URGO
PRODUCT NAME: URGO Cold Sore filmogel ®
Creation date: 01/05/2011
Version: 4.1

SDS n°: SDS004
Print date: 09/04/2025
Revision date: 08/06/2020

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Other regulations:

REACH does not provide specific indications on the product label for the presence of boric acid as SVHC ..

- Finished product to the consumer as marketed product is not subject to classification and labeling according to Regulation EC No. 1272/2008 as amended.
- To the finished consumer product is a medical device that meets the requirements of Directive 93/42/EEC as amended, concerning the placing on the market of medical devices.
- The product and its components are not covered by Regulation EC No 689/2008 as amended relating to export and import of dangerous chemicals.

15.1.2. National regulations (France):

Occupational diseases:

Not applicable. The product is for the exclusive consumer use.

Classification according to French ICPE regulation:

Items that can be set according to the quantities used:

- 1510: Storage of materials or combustible substances
- 4331: Flammable liquids of category 2 or 3 except for section 4330

Other regulations:

To the finished consumer product is a medical device that meets the requirements of Decree No. 95-292 of 16 March 1995 as amended relating to medical devices as defined in Article L. 665-3 of the Code of Public Health and modifying this code.

15.2. CHEMICAL SAFETY ASSESSMENT

The product has not been evaluated.

2. SECTION 16. OTHER INFORMATION

16.1. PROCEDURE USED TO DERIVE THE CLASSIFICATION ACCORDING TO REGULATION EC No. 1272/2008 (CLP):

Classification	Justification
Flam Liq Cat2 ; H225	Flash point and boiling point test carried out with the product. (Unpublished internal report).
Eye Irrit Cat 2 ; H319 Repr Cat. 1B : H360FD*	Additivity rule.

16.2. FULL TEXT OF HAZARD CATEGORIES AND THE H SHORT PHRASES CARRIED FORWARD ON THE SECTION 2 AND 3

Full text of hazard categories:

Flam Liq Cat. 2: Flammable Liquid Category 2.
Eye Irrit Cat. 2: Irritating to eye Category 2.
Repr Cat. 1B: Toxic to reproduction Category 1B.

Full text of H phrases:

H225: High flammable liquid or vapor.
H319: Causes serious eye irritation
H360FD: May damage fertility and the funborn child.

SAFETY DATA SHEET

(Regulation EC No.1907/2006 amended – Annex II)



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16.3. HISTORIQUE OF CHANGES TO THE SAFETY DATA SHEET

Updated: Sentences followed by asterisk (*) have been added compared to the previous version.

Date:	Subject:	Version:
08/11/2013	SDS creation.	1.0
03/12/2013	Update	2.0
05/03/2014	Update	3.0
21/11/2017	Update	4.0
08/06/2020	Update	4.1

This sheet complements the technical sheets but does not replace them. The information contained within is based on our state of knowledge to the product, on the date indicated. These are given in good faith. Moreover the user's attention is drawn to the possible risks incurred when a product is used for purposes other than those for which it was designed. It does in any case exonerate the user from knowing and applying all the regulations governing his activity. He will be solely responsible of the precautions related to the use he makes of the product. All regulatory prescriptions mentioned is to help the user to fulfill his obligations. This list cannot be considered exhaustive. The recipient must ensure that other obligations do not incumbent on him because of texts other than those mentioned.