

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Product code:XX0254

Date of issue: 03/04/2019 Revision date: 10/12/2019 Supersedes: 03/04/2019 Version: 2.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture

Product name : ALOPEXY 5 % NF CUTANEOUS SOLUTION

Product code : XX0254 Type of product : Drug

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

1.2.1. Relevant identified uses

: THIS MSDS IS FOR PROFESSIONAL USE ONLY (MANUFACTURING, STORAGE, Industrial/Professional use spec

TRANSPORT)

IT IS NOT INTENDED FOR CONSUMER

Use of the substance/mixture : Pharmaceutical industry

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

PIERRE FABRE DERMATOLOGIE

45 place Abel Gance

92100 BOULOGNE - FRANCE

T 33 (1) 49 10 80 00 - F 33 (1) 49 10 80 90

FDS@pierre-fabre.com

1.4. Emergency telephone number

Emergency number : INRS: 33 (1) 45 42 59 59 (FRANCE)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Flammable liquids, Category 3 H226 H319 Serious eye damage/eye irritation, Category 2 Reproductive toxicity, Additional category, Effects on or via lactation H362 Reproductive toxicity, Category 1B H360FD Specific target organ toxicity — Single exposure, Category 3, H335

Respiratory tract irritation

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)





GHS02

GHS07

GHS08

Signal word (CLP) : Danger

: minoxidil; ethyl alcohol Hazardous ingredients

: H226 - Flammable liquid and vapour. Hazard statements (CLP) H319 - Causes serious eye irritation.

H335 - May cause respiratory irritation.

H360FD - May damage fertility. May damage the unborn child.

H362 - May cause harm to breast-fed children.

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Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

No smoking.

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.

P308+P313 - IF exposed or concerned: Get medical advice.
P312 - Call a doctor, a POISON CENTER if you feel unwell.

P501 - Dispose of contents and container to hazardous or special waste collection point, in

accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Other hazards not contributing to the classification : In use, may form flammable vapour-air mixture.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
ethyl alcohol	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH-no) 01-2119457610-43	50 - 75	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H335
propylene glycol substance with national workplace exposure limit(s) (GB)	(CAS-No.) 57-55-6 (EC-No.) 200-338-0 (REACH-no) 01-2119456809-23	15 - 25	Not classified
minoxidil	(CAS-No.) 38304-91-5 (EC-No.) 253-874-2	5 - 10	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Lact., H362 Repr. 1B, H360FD STOT RE 2, H373

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Immediately call a POISON CENTER/doctor. Allow affected person to breathe fresh air. Allow the victim to rest. If the victim is unconscious, place him/her in security position.

First-aid measures after skin contact : Remove contaminated clothes for decontamination by the bottom (not to contaminate the

face). Rinse the skin during at least 15 minutes with water at 15° C at 15 cm. If skin irritation occurs, Get medical advice/attention.

First-aid measures after eye contact : Immediately call a POISON CENTER/doctor. Immediately rinse with clean water for 15-20 minutes, and respect this time. Avoid contaminating the healthy eye during the rinsing.

First-aid measures after ingestion : Allow the victim to rest. Get medical advice/attention if you feel unwell.

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

No additional information available

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Carbon dioxide. Dry powder.

5.2. Special hazards arising from the substance or mixture

Fire hazard : May form flammable vapour-air mixture.

Hazardous decomposition products in case of fire : COx. NOx. May release flammable gases.

5.3. Advice for firefighters

Precautionary measures fire : Do not enter fire area without proper protective equipment: fire clothes, boots and Individual Respiratory Protection.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures

: Avoid product contact. Do not breathe vapours. Evacuate the danger area, observe

emergency procedures. Do not smoke.

6.1.2. For emergency responders

Emergency procedures

: Delimit the discharge area and prohibit the access. Discharges should be handled by trained cleaning personnel equipped with appropriated protection (Section 8).

6.2. Environmental precautions

Avoid release in sewage, river and ground water (earth dike, sewage shutter). In case of discharge, contact the agreed autority when the situation can not be controlled quickly and effectively.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up

: Contain the discharges and collect them with absorbing material of the universal trade. Keep the wastes in closed and tight container.

6.4. Reference to other sections

Indications about protective equipment (see Section 8). Indications about waste treatment (see Section 13).

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling

: People with appropriated protection equipment (Section 8). Prohibited to pregnant and/or nursing women. Manipulate away from open flames, hot surfaces and sources of ignition. Do not smoke. Use only in well ventilated areas. Handle empty containers with care because residual vapours are flammable.

Hygiene measures

: Handle under hood. Wash hands after each handling. Remove the contaminated clothes. Do not drink, eat or smoke in the handling room. Inspect the individual protection equipment after each handling. No personal objects at the work station. Avoid taking contaminated clothes home. Change clothes systematically at coffee breaks or meal times.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions

Keep container tightly closed. Keep in a cool and well ventilated place. Keep container closed when not in use. Keep away from open flames, hot surfaces and sources of ignition.

7.3. Specific end use(s)

Apart from the use mentioned in Section 1.2 no other specific use is stipulated.

SECTION 8: Exposure controls/personal protection

3.1. Control parameters		
ethyl alcohol (64-17-5)		
Belgium - Occupational Exposure Limits		
Local name	Alcool éthylique # Ethanol	
Limit value (mg/m³)	1907 mg/m³	
Limit value (ppm)	1000 ppm	
Regulatory reference	Koninklijk besluit/Arrêté royal 02/09/2018	
France - Occupational Exposure Limits		
Local name	Alcool éthylique	
VLEP, 8h (mg/m³)	1900 mg/m³	
VLEP, 8h (ppm)	1000 ppm	
VLEP, short term (mg/m³)	9500 mg/m³	
VLEP, short term (ppm)	5000 ppm	
Note (FR)	Valeurs recommandées/admises	
Regulatory reference	Circulaire du Ministère du travail (réf.: INRS ED 984, 2016)	
United Kingdom - Occupational Exposure Limits		
Local name	Ethanol	
WEL TWA (mg/m³)	1920 mg/m³	
WEL TWA (ppm)	1000 ppm	
Regulatory reference	EH40/2005 (Third edition, 2018). HSE	

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ethyl alcohol (64-17-5)		
USA - ACGIH - Occupational Exposure Limits		
Local name	Ethanol	
ACGIH STEL (ppm)	1000 ppm	
Remark (ACGIH)	TLV® Basis: URT irr. Notations: A3 (Confirmed Animal Carcinogen with Unknown Relevance to Humans)	
Regulatory reference	ACGIH 2019	
propylene glycol (57-55-6)		
United Kingdom - Occupational Exposure Limits		
Local name	Propane-1,2-diol	
WEL TWA (mg/m³)	10 mg/m³ particulates 474 mg/m³ total vapour and particulates	
WEL TWA (ppm)	150 ppm total vapour and particulates	
Regulatory reference	EH40/2005 (Third edition, 2018). HSE	

8.2. Exposure controls

Appropriate engineering controls:

Chemical hood or sorbonne for handling. Fume detector. First-aid kit. Security instructions.

Hand protection:	
Suitable gloves resistant to chemical penetration	
Eye protection:	
Chemical goggles or face shield	
Skin and body protection:	
Wear suitable protective clothing	
Respiratory protection:	
Respiratory mask ABEK2 type	

Thermal hazard protection:

No additional information available.

Environmental exposure controls:

No additional information available.

Consumer exposure controls:

No additional information available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

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Physical state	: Liquid
Colour	: Colourless to light yellow.
Odour	: No data available
Odour threshold	: No data available

: No data available рΗ Relative evaporation rate (butylacetate=1) : No data available Melting point : No data available Freezing point : No data available Boiling point : No data available Flash point : 24 °C (calculated) Auto-ignition temperature : No data available Decomposition temperature : No data available Flammability (solid, gas) : No data available Vapour pressure : No data available Relative vapour density at 20 °C : No data available Relative density : 0,899 - 0,919

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Solubilities : No data available
Log Kow : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : No data available

9.2. Other informations

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

May form flammable vapour-air mixture.

10.2. Chemical stability

Stable under recommended storage conditions (Section 7).

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Open flames. Heat sources. Ignition sources. Direct sunlight.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

COx. NOx. May release flammable gases.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : No additional information available
Acute toxicity (dermal) : No additional information available
Acute toxicity (inhalation) : No additional information available

ethyl alcohol (64-17-5)	
LD50 oral rat	7060 mg/kg
LD50 oral mouse	8300 mg/kg bodyweight Animal: mouse
LC50 inhalation rat (mg/l)	116,9 mg/l/4h
LD50, oral, mouse	3450 mg/kg
LD50, intravenous, rat	1440 mg/kg
LD50, intravenous, mouse	1970 mg/kg

propylene glycol (57-55-6)	
LD50 oral rat	22000 mg/kg
LD50 dermal rat	22500 mg/kg
LD50 dermal rabbit	20800 mg/kg

ng/kg
kg
y/kg

Skin corrosion/irritation : Not irritating

Additional information : - Evaluation of the dermal tolerance in rabbit: non irritant

Serious eye damage/irritation : No additional information available

Respiratory or skin sensitisation : Non cutaneous sensitizing

Additional information : - Evaluation of sensitization potential in guinea pig according to the Magnusson and

Kligmann maximization method: non sensitizing

Germ cell mutagenicity : No additional information available Carcinogenicity : No additional information available

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Persistence and degradability

Biodegradation (28d)

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minoxidil (38304-91-5)	
NOAEL (chronic, oral, rat/male, 2 years)	30 mg/kg/d
Reproductive toxicity	: No additional information available
STOT-single exposure	: No additional information available
STOT-repeated exposure	: Studies avalaible :
ALOPEXY 5 % NF CUTANEOUS SOLUTION	
Study, dermal, rabbit	Slightly irritant (28 days)
ethyl alcohol (64-17-5)	
NOAEL (subchronic, oral, animal/male, 90 days)	< 9700 mg/kg bodyweight Animal: mouse, Animal sex: male, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
NOAEL (subchronic, oral, animal/female, 90 days)	> 9400 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
1 1/57 55 0	
propylene glycol (57-55-6)	
LOAEL (inhalation, rat, dust/mist/fume, 90 days)	160 mg/m³
NOAEL (oral, rat, 90 days)	> 2000 mg/kg/d
NOAEL (subchronic, oral, animal/male, 90 days)	443 mg/kg bodyweight Animal: cat, Animal sex: male
minoxidil (38304-91-5)	
- Study, oral, rat, dog, monkey	Observed toxic effects (10 days, 1 month and 1 year)
Others	: Non-phototoxic. Non-photoallergic.
Other informations	: The classification of this mixture was realized according to the concentrations of different ingredients and due to toxicological data obtained about the mixture itself or about a similar mixture.
SECTION 12: Ecological information	
12.1. Toxicity	
Hazardous to the aquatic environment, short-term (acute)	: No additional information available
Hazardous to the aquatic environment, long-term (chronic)	: No additional information available
ethyl alcohol (64-17-5)	
LC50 96h fish	10000 - 15400 mg/l
EC50 48h daphnia	9300 mg/l
NOEC, daphnia	9,6 mg/l Test organisms (species): Daphnia magna Duration: '9 d'
EC10, bacteria	6500 - 31623 mg/l/30min
propylene glycol (57-55-6)	
LC50 96h fish	40613 mg/l
EC50 48h daphnia	18340 mg/l
EC50 96h algae	19000 mg/l
1 =	·
FrC50 72h algae	19300 mg/l
ErC50 72h algae	19300 mg/l
NOEC, acute, fish	19300 mg/l 42000 mg/l

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Readily biodegradable.

96 %

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propylene glycol (57-55-6)	
Persistence and degradability	Readily biodegradable.
Biodegradation (28d)	81,7 %
12.3. Bioaccumulative potential	
ethyl alcohol (64-17-5)	
Log Kow	-0,35
Bioaccumulative potential	Bioaccumulation is not expected (Log Kow < 1).

propylene glycol (57-55-6)	
Bioconcentration factor (BCF REACH)	0,09
Log Kow	-1,07
Bioaccumulative potential	Bioaccumulation is not expected (Log Kow < 1).

minoxidil (38304-91-5)	
Log Kow	1,24
Bioaccumulative potential	Low bioaccumulation potential (1 < Log Kow < 3).

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Others

Additional information

: The classification of this mixture was realized according to the concentrations of different ingredients

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations

: Dispose of this material and its container at hazardous or special waste collection point.

SECTION 14: Transport information
In accordance with ADR / ADN / IATA / IMDG / RID

100				
ADR	IMDG	IATA	ADN	RID
14.1. UN number				
UN 1993	UN 1993	UN 1993	UN 1993	UN 1993
14.2. UN proper shippin	g name			
FLAMMABLE LIQUID, N.O.S. (CONTAINS ETHYLIC ALCOHOL)	FLAMMABLE LIQUID, N.O.S. (CONTAINS ETHYLIC ALCOHOL)	Flammable liquid, n.o.s. (CONTAINS ETHYLIC ALCOHOL)	FLAMMABLE LIQUID, N.O.S. (CONTAINS ETHYLIC ALCOHOL)	FLAMMABLE LIQUID, N.O.S. (CONTAINS ETHYLIC ALCOHOL)
Transport document descr	iption			
UN 1993 FLAMMABLE LIQUID, N.O.S. (CONTAINS ETHYLIC ALCOHOL), 3, III, (D/E)	UN 1993 FLAMMABLE LIQUID, N.O.S. (CONTAINS ETHYLIC ALCOHOL), 3, III	UN 1993 Flammable liquid, n.o.s. (CONTAINS ETHYLIC ALCOHOL), 3, III	UN 1993 FLAMMABLE LIQUID, N.O.S. (CONTAINS ETHYLIC ALCOHOL), 3, III	UN 1993 FLAMMABLE LIQUID, N.O.S. (CONTAINS ETHYLIC ALCOHOL), 3, III
14.3. Transport hazard o	14.3. Transport hazard class(es)			
3	3	3	3	3
	3	3	3	3
14.4. Packing group				
III	III	III	III	III

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14.5. Environmental hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment: No	Dangerous for the environment : No
No supplementary information available				

140 Supplementary information available

14.6. Special precautions for user

Overland transport

Classification code (ADR) : F1
Special provisions (ADR) : 274, 601
Limited quantities (ADR) : 5I
Excepted quantities (ADR) : E1

Packing instructions (ADR) : P001, IBC03, LP01, R001

Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions : T4

(ADR)

Portable tank and bulk container special provisions

(ADR)

: TP1, TP29

Tank code (ADR) : LGBF
Vehicle for tank carriage : FL
Transport category (ADR) : 3
Special provisions for carriage - Packages (ADR) : V12
Special provisions for carriage - Operation (ADR) : S2
Hazard identification number (Kemler No.) : 30

Orange plates

30 1993

: 5 L

Tunnel restriction code (ADR) : D/E EAC code : •3YE

Transport by sea

Limited quantities (IMDG)

Special provisions (IMDG) : 223, 274, 955

Excepted quantities (IMDG) : E1
Packing instructions (IMDG) : LP01, P001
IBC packing instructions (IMDG) : IBC03
Tank instructions (IMDG) : T4
Tank special provisions (IMDG) : TP1, TP29

EmS-No. (Fire): F-EEmS-No. (Spillage): S-EStowage category (IMDG): A

Air transport

PCA Excepted quantities (IATA) : E1 PCA Limited quantities (IATA) : Y344 PCA limited quantity max net quantity (IATA) : 10L PCA packing instructions (IATA) : 355 PCA max net quantity (IATA) : 60L CAO packing instructions (IATA) : 366 CAO max net quantity (IATA) : 220L Special provisions (IATA) : A3 ERG code (IATA) : 3L

Inland waterway transport

Classification code (ADN) : F1
Special provisions (ADN) : 274, 601
Limited quantities (ADN) : 5 L
Excepted quantities (ADN) : E1
Carriage permitted (ADN) : T
Equipment required (ADN) : PP, EX, A

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Ventilation (ADN) : VE01 Number of blue cones/lights (ADN) : 0

Rail transport

Classification code (RID) : F1
Special provisions (RID) : 274, 601
Excepted quantities (RID) : E1

Packing instructions (RID) : P001, IBC03, LP01, R001

Mixed packing provisions (RID) : MP19

Portable tank and bulk container instructions (RID) : T4

Portable tank and bulk container special provisions : TP1, TP29

(RID)

Tank codes for RID tanks (RID) : LGBF
Transport category (RID) : 3
Special provisions for carriage – Packages (RID) : W12
Colis express (express parcels) (RID) : CE4
Hazard identification number (RID) : 30

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

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National regulations

France			
No ICPE	Classified installations regime Désignation de la rubrique	Code Régime	Rayon
4331.text	Liquides inflammables de catégorie 2 ou catégorie 3 à l'exclusion de la rubrique 4330. La quantité totale susceptible d'être présente dans les installations y compris dans les cavités souterraines étant :		
4331.1	1. Supérieure ou égale à 1000 t Quantité seuil bas au sens de l'article R. 511-10 : 5 000 t. Quantité seuil haut au sens de l'article R. 511-10 : 50 000 t.	A	2
4331.2	2. Supérieure ou égale à 100 t mais inférieure à 1000 t Quantité seuil bas au sens de l'article R. 511-10 : 5 000 t. Quantité seuil haut au sens de l'article R. 511-10 : 50 000 t.	Е	
4331.3	3. Supérieure ou égale à 50 t mais inférieure à 100 t Quantité seuil bas au sens de l'article R. 511-10 : 5 000 t. Quantité seuil haut au sens de l'article R. 511-10 : 50 000 t.	DC	

Germany

Reference to AwSV : Water hazard class (WGK) 3, Highly hazardous to water (Classification according to AwSV,

Annex 1)

12th Ordinance Implementing the Federal : Is not subject of the 12. BlmSchV (Hazardous Incident Ordinance) Immission Control Act - 12.BlmSchV

Netherlands

SZW-lijst van kankerverwekkende stoffen : ethyl alcohol is listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting : ethyl alcohol is listed

giftige stoffen – Borstvoeding

: ethyl alcohol is listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid

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NIET-limitatieve lijst van voor de voortplanting

giftige stoffen – Ontwikkeling

: ethyl alcohol is listed

Denmark

1.1

Class for fire hazard : Class II-1 Store unit : 5 liter

Product code

Classification remarks : R10 <H226;H319;H335;H360FD;H362>; Emergency management guidelines for the

storage of flammable liquids must be followed

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

Pregnant/breastfeeding women working with the product must not be in direct contact with

the product

The requirements from the Danish Working Environment Authorities regarding work with

carcinogens must be followed during use and disposal

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information			
Indication of changes:			
Section	Changed item	Change	Comments

Modified

Full text of H- and EUH-statements:		
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Flam. Liq. 2	Flammable liquids, Category 2	
Lact.	Reproductive toxicity, Additional category, Effects on or via lactation	
Repr. 1B	Reproductive toxicity, Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2	
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation	
H225	Highly flammable liquid and vapour.	
H226	Flammable liquid and vapour.	
H302	Harmful if swallowed	
H315	Causes skin irritation.	
H319	Causes serious eye irritation.	
H335	May cause respiratory irritation.	
H360FD	May damage fertility. May damage the unborn child.	
H362	May cause harm to breast-fed children.	
H373	May cause damage to organs through prolonged or repeated exposure.	

SDS EU (REACH Annex II)

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Département Evaluation Sécurité des Produits

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This SDS shall not apply to substances and mixtures in the following forms, which are in the finished state, intended for the final user:

- Medicinal products as defined in Directive 2001/83/EC,
- Cosmetic products as defined in Directive 76/768/EEC,
- Medical devices as defined in Directives 90/385/EEC and 93/42/EEC,
 which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC.