

## Safety Data Sheet

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

Reference number: 369200 Revision date: 4/16/2021 Supersedes version of: 4/21/2016 Version: 7.0

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

1.1. Product identifier

Product form · Mixture

Product name : Saffron in alcoholic solution

Product code : 369200

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

#### 1.2.1. Relevant identified uses

Main use category : For professional use only

Use of the substance/mixture : In vitro diagnostic medical device.

#### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

**RAL DIAGNOSTICS** Site Montesquieu 33650 MARTILLAC - FRANCE

T 33 05 57 96 04 04 - F 33 05 57 96 04 05

commercial@ral-diagnostics.fr - www.ral-diagnostics.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD Msida	+356 2545 6504	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	

#### **SECTION 2: Hazards identification**

#### 2.1. Classification of the substance or mixture

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

Flammable liquids, Category 2 H225

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour.

#### 2.2. Label elements

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

Hazard pictograms (CLP)

GHS02

Signal word (CLP) : Danger

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: H225 - Highly flammable liquid and vapour. Hazard statements (CLP)

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

ignition sources. No smoking.

## 2.3. Other hazards

No additional information available

#### **SECTION 3: Composition/information on ingredients**

## 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier		Classification according to Regulation (EC) No. 1272/2008 [CLP]
Absolute ethanol substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH-no) 01-2119457610-43	> 95	Flam. Liq. 2, H225

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 : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Rinse skin with water/shower. Take off immediately all contaminated clothing.

First-aid measures after eye contact : Rinse eyes with water as a precaution.

First-aid measures after ingestion : Call a poison center or a doctor 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

Treat symptomatically.

## **SECTION 5: Firefighting measures**

#### 5.1. Extinguishing media

: Water spray. Dry powder. Foam. Carbon dioxide. Suitable extinguishing media

#### 5.2. Special hazards arising from the substance or mixture

Fire hazard : Highly flammable liquid and vapour. Hazardous decomposition products in case

of fire

: Toxic fumes may be released.

#### 5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Selfcontained breathing apparatus. Complete protective clothing.

## **SECTION 6: Accidental release measures**

## 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

**Emergency procedures** : Ventilate spillage area. No open flames, no sparks, and no smoking.

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#### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further

information refer to section 8: "Exposure controls/personal protection".

#### 6.2. Environmental precautions

Avoid release to the environment.

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Notify authorities if product enters

sewers or public waters.

Other information : Dispose of materials or solid residues at an authorized site.

#### 6.4. Reference to other sections

For further information refer to section 13.

#### **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Keep away from heat, hot surfaces,

sparks, open flames and other ignition sources. No smoking. Wear personal

protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after

handling the product.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed.

Storage temperature : 15 – 25 °C

#### 7.3. Specific end use(s)

No additional information available

## **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

Absolute ethanol (64-17-5)		
Ireland - Occupational Exposure Limits		
Local name Ethanol [Ethyl alcohol]		
OEL STEL [ppm] 1000 ppm		
United Kingdom - Occupational Exposure Limits		
Local name Ethanol		
WEL TWA (OEL TWA) [1] 1920 mg/m <sup>3</sup>		
WEL TWA (OEL TWA) [2] 1000 ppm		

### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

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#### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

#### 8.2.2. Personal protection equipment

#### Personal protective equipment symbol(s):



#### 8.2.2.1. Eye and face protection

Safety glasses

#### 8.2.2.2. Skin protection

#### Skin and body protection:

Wear suitable protective clothing

#### Hand protection:

Protective gloves

#### 8.2.2.3. Respiratory protection

#### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

### 8.2.2.4. Thermal hazards

No additional information available

## 8.2.3. Environmental exposure controls

#### **Environmental exposure controls:**

Avoid release to the environment.

## **SECTION 9: Physical and chemical properties**

#### 9.1. Information on basic physical and chemical properties

Physical state : Liquid
Colour : orange.
Odour : alcoholic.

Odour threshold : No data available pH : No data available Relative evaporation rate (butylacetate=1) : No data available Melting point : Not applicable Freezing point : No data available

Boiling point :  $\approx 80 \, ^{\circ}\text{C}$  Flash point : 12.75  $^{\circ}\text{C}$ 

Auto-ignition temperature : No data available
Decomposition temperature : No data available
Flammability (solid, gas) : Not applicable
Vapour pressure : No data available

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Relative vapour density at 20 °C : No data available Relative density : No data available : No data available Solubility : No data available

Partition coefficient n-octanol/water (Log

Pow)

Viscosity, kinematic : No data available : No data available Viscosity, dynamic Explosive properties : No data available Oxidising properties : No data available **Explosive limits** : No data available

#### 9.2. Other information

No additional information available

## **SECTION 10: Stability and reactivity**

## 10.1. Reactivity

Highly flammable liquid and vapour.

#### 10.2. Chemical stability

Stable under normal conditions.

#### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

#### 10.4. Conditions to avoid

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

#### 10.5. Incompatible materials

No additional information available

#### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## **SECTION 11: Toxicological information**

#### 11.1 Information on toxicological effects

: Not classified Acute toxicity (oral) : Not classified Acute toxicity (dermal) Acute toxicity (inhalation) : Not classified

Absolute ethanol (64-17-5)		
LD50 oral rat	15010 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 14450 - 15560	
LD50 oral	8300 mg/kg bodyweight Animal: mouse	
LD50 dermal rat	> 2000 mg/kg	
LC50 Inhalation - Rat	> 20 mg/l	

Skin corrosion/irritation : Not classified Serious eye damage/irritation : Not classified Respiratory or skin sensitisation : Not classified Germ cell mutagenicity : Not classified Carcinogenicity : Not classified

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Absolute ethanol (64-17-5)	
IARC group	1 - Carcinogenic to humans

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Absolute ethanol (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)	

Aspiration hazard : Not classified

#### **SECTION 12: Ecological information**

**12.1. Toxicity** 

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-

term adverse effects in the environment.

Hazardous to the aquatic environment, short-

term (acute)

: Not classified

Hazardous to the aquatic environment, long-

term (chronic)

: Not classified

Absolute ethanol (64-17-5)	
LC50 - Fish [1]	14.2 g/l Test organisms (species): Pimephales promelas
EC50 72h - Algae [1]	1900 – 1970 mg/l (marine water)
EC50 96h - Algae [1]	275 mg/l (freshwater)
ErC50 algae	275 mg/l Source: ECHA
NOEC (chronic)	9.6 mg/l Test organisms (species): Daphnia magna Duration: '9 d'
NOEC chronic fish	250 mg/l

12.2. Persistence and degradability

Absolute ethanol (64-17-5)		
Persistence and degradability	Readily biodegradable.	

12.3. Bioaccumulative potential

Absolute ethanol (64-17-5)		
Partition coefficient n-octanol/water (Log Pow) -0.32 Source: ICSC		
Bioaccumulative potential	No bioaccumulation.	

## 12.4. Mobility in soil

No additional information available

## 12.5. Results of PBT and vPvB assessment

No additional information available

# 12.6. Other adverse effects

Other adverse effects : Not release to the environment.

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### **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting

instructions. Dispose in a safe manner in accordance with local/national

regulations.

Additional information : Flammable vapours may accumulate in the container.

#### **SECTION 14: Transport information**

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
UN 1170	UN 1170	UN 1170	UN 1170	UN 1170
14.2. UN proper shippin	g name			
ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	Ethanol solution	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Transport document descr	iption			
UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II, (D/E)	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II	UN 1170 Ethanol solution, 3, II	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II
14.3. Transport hazard o	class(es)			
3	3	3	3	3
3	3	3	***	3
14.4. Packing group				
II	II	II	II	II
14.5. Environmental haz	ards			
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 inform	ation available			

## 14.6. Special precautions for user

#### **Overland transport**

Classification code (ADR) : F1
Special provisions (ADR) : 144, 601
Limited quantities (ADR) : 11
Excepted quantities (ADR) : E2

Packing instructions (ADR) : P001, IBC02, R001

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

(ADR)

Portable tank and bulk container special

provisions (ADR)

: TP1

Tank code (ADR) : LGBF Vehicle for tank carriage : FL

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Transport category (ADR) : 2

Special provisions for carriage - Operation

(ADR)

Hazard identification number (Kemler No.) : 33

Orange plates

33 1170

: S2, S20

Tunnel restriction code (ADR) : D/E
EAC code : •2YE

Transport by sea

Special provisions (IMDG) : 144 Limited quantities (IMDG) : 1 L Excepted quantities (IMDG) : E2 Packing instructions (IMDG) : P001 IBC packing instructions (IMDG) : IBC02 Tank instructions (IMDG) : T4 Tank special provisions (IMDG) : TP1 EmS-No. (Fire) : F-E EmS-No. (Spillage) : S-D Stowage category (IMDG) : A

Properties and observations (IMDG) : Colourless, volatile liquids. Pure ETHANOL: flashpoint 13°C c.c. Explosive limits:

3.3% to 19% Miscible with water.

MFAG-No : 127

Air transport

PCA Excepted quantities (IATA) : E2
PCA Limited quantities (IATA) : Y341
PCA limited quantity max net quantity (IATA) : 1L
PCA packing instructions (IATA) : 353
PCA max net quantity (IATA) : 5L
CAO packing instructions (IATA) : 364
CAO max net quantity (IATA) : 60L

Special provisions (IATA) : A3, A58, A180

ERG code (IATA) : 3L

Inland waterway transport

Classification code (ADN) : F1

Special provisions (ADN) : 144, 601

Limited quantities (ADN) : 1 L

Excepted quantities (ADN) : E2

Equipment required (ADN) : PP, EX, A

Ventilation (ADN) : VE01

Number of blue cones/lights (ADN) : 1

Rail transport

Classification code (RID) : F1

Special provisions (RID) : 144, 601

Limited quantities (RID) : 1L

Excepted quantities (RID) : E2

Packing instructions (RID) : P001, IBC02, R001

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

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Portable tank and bulk container special

provisions (RID)

: TP1

Tank codes for RID tanks (RID) : LGBF
Transport category (RID) : 2
Colis express (express parcels) (RID) : CE7
Hazard identification number (RID) : 33

#### 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

No additional information available

## 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### **SECTION 16: Other information**

Indication of changes:			
Section	Changed item	Change	Comments
	Revision date	Modified	
2.2	Precautionary statements (CLP)	Modified	
3	Composition/information on ingredients	Modified	
9.1	Flash point	Added	
16	Abbreviations and acronyms	Added	

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BLV	Biological limit value
CAS-No.	Chemical Abstract Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EC-No.	European Community number

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EN	European Standard
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
vPvB	Very Persistent and Very Bioaccumulative
WGK	Water Hazard Class

Full text of H- and EUH-statements:	
Flam. Liq. 2	Flammable liquids, Category 2
H225	Highly flammable liquid and vapour.

The classification complies with

: ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.