

# Safety Data Sheet

according to 1907/2006/EC (REACH), 1272/2008/EC (CLP), and OSHA  
GHS

Printing date 09.07.2015

Revision: 09.07.2015

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

- **1.1 Product identifier**
- **Trade name:** Flucon
- **Article number:** None
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
Uses: Pharmaceutical product
- **1.3 Details of the supplier of the Safety Data Sheet**
- **Manufacturer/Supplier:**  
Alcon Cusí, S.A.  
Camil Fabra, 58, Apartado 2  
08320 El Masnou  
Barcelona  
Spain  
Tel: +34 93 497 7000  
E-mail: safety.datasheets@alcon.com
- **1.4 Emergency telephone number:**  
ChemTel Inc.  
(800)255-3924, +1 (813)248-0585

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified as hazardous according to the CLP regulation.
- **Additional information:**  
There are no other hazards not otherwise classified that have been identified.  
0 % of the mixture consists of component(s) of unknown toxicity.

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- **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008** Not Regulated
  - **Hazard pictograms** Not Regulated
  - **Signal word** Not Regulated
  - **Hazard statements** Not Regulated
  - **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



- **HMIS Long Term Health Hazard Substances**

None of the ingredients are listed.

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- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.
- **Dangerous components:** None in reportable quantities.
- **Additional information:**  
For the listed ingredients, the identity and exact percentages are being withheld as a trade secret.  
For the wording of the listed risk phrases refer to section 16.

## SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:**  
Unlikely route of exposure.  
Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**  
Wash with soap and water.  
If skin irritation or rash occurs: Get medical advice/attention.
- **After eye contact:**  
Product is indicated for ocular usage. In case of persistent or severe irritation after usage, discontinue use and seek medical advice.
- **After swallowing:**  
Unlikely route of exposure.  
Do not induce vomiting; call for medical help immediately.
- **4.2 Most important symptoms and effects, both acute and delayed**  
This product may cause sensitization (allergic reactions) in some individuals.  
Allergic reactions
- **Hazards** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
Medical supervision for at least 48 hours.  
Treat skin and mucous membrane with antihistamine and corticoid preparations.

## SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** The product is not flammable.
- **For safety reasons unsuitable extinguishing agents:** None.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

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- **5.3 Advice for firefighters**
- **Protective equipment:**  
Wear self-contained respiratory protective device.  
Wear fully protective suit.
- **Additional information** No further relevant information available.

## SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Ensure adequate ventilation  
For large spills, wear protective clothing.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to section 13.  
Send for recovery or disposal in suitable receptacles.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Avoid storage near extreme heat, ignition sources or open flame.  
No special requirements.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** Storage Temperatures : 59 - 77 ° F / 15 - 25 °C.
- **7.3 Specific end use(s)** No further relevant information available.

## SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **DNELs** No further relevant information available.
- **PNECs** No further relevant information available.
- **Additional information:** The lists valid during the making were used as basis.

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- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Do not inhale gases / fumes / aerosols.
- **Respiratory protection:** Not required under normal conditions of use.
- **Protection of hands:**  
Gloves not required under normal conditions of use.  
Gloves should be worn by people previously sensitized to any component of the product. .
- **Eye protection:** Not required under normal conditions of use.
- **Body protection:**  
Not required under normal conditions of use.  
Protection may be required for spills.
- **Limitation and supervision of exposure into the environment**  
No further relevant information available.

## SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Liquid
Colour:	White
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **pH-value:** 6,2-6,8
- **Change in condition**

Melting point/Melting range:	Not Determined.
Boiling point/Boiling range:	100 ± 1,0 °C (212 ± 34 °F)
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not applicable.
- **Auto/Self-ignition temperature:** Not determined.
- **Decomposition temperature:** Not determined.
- **Self-igniting:** Product is not self-igniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.
- **Vapour pressure at 20 °C (68 °F):** 23 hPa (17 mm Hg)

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- **Density at 20 °C (68 °F):** 1,00 ± 0,03 g/cm<sup>3</sup> (8,345 ± 0,25 lbs/gal)
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.
- **Solubility in / Miscibility with water:** Dispersible.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
  - Dynamic:** Not determined.
  - Kinematic:** Not determined.
- **9.2 Other information** No further relevant information available.

## SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used and stored according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Possible in traces.

## SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**
- **LD/LC50 values relevant for classification:** None.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Slight irritant effect on eyes.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Subacute to chronic toxicity:** No further relevant information available.
- **Additional toxicological information:** Toxic and/or corrosive effects may be delayed up to 24 hours.
- **Acute effects (acute toxicity, irritation and corrosivity):** From product as supplied: None.
- **Sensitisation:** May cause an allergic skin reaction.
- **Repeated dose toxicity:** Repeated exposures may result in skin and/or respiratory sensitivity.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):**
- **Germ cell mutagenicity**  
Based on available data, the classification criteria are not met.
- **Carcinogenicity**  
Based on available data, the classification criteria are not met.
- **Reproductive toxicity**  
Based on available data, the classification criteria are not met.
- **STOT-single exposure**  
Based on available data, the classification criteria are not met.
- **STOT-repeated exposure**  
Based on available data, the classification criteria are not met.

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- **Aspiration hazard**  
Based on available data, the classification criteria are not met.

## SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

## SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.  
The user of this material has the responsibility to dispose of unused material, residues and containers in compliance with all relevant local, state and federal laws and regulations regarding treatment, storage and disposal for hazardous and nonhazardous wastes.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to local official regulations.

## SECTION 14: Transport information

- **14.1 UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Not Regulated
- **14.2 UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Not Regulated
- **14.3 Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** Not Regulated
- **14.4 Packing group**
- **DOT, ADR, IMDG, IATA** Not Regulated
- **14.5 Environmental hazards:**
- **Marine pollutant:** No
- **14.6 Special precautions for user** Not applicable.
- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

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· UN "Model Regulation":

Not Regulated

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## SECTION 15: Regulatory information

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

· United States (USA)

· SARA

· Section 355 (extremely hazardous substances):

None of the ingredients are listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients are listed.

· TSCA (Toxic Substances Control Act):

All ingredients are listed.

· Proposition 65 (California):

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients are listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients are listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients are listed.

· Carcinogenic Categories

· EPA (Environmental Protection Agency)

None of the ingredients are listed.

· IARC (International Agency for Research on Cancer)

None of the ingredients are listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients are listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients are listed.

· Canada

· Canadian Domestic Substances List (DSL)

All ingredients are listed.

· Canadian Ingredient Disclosure list (limit 0.1%)

None of the ingredients are listed.

· Canadian Ingredient Disclosure list (limit 1%)

None of the ingredients are listed.

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- **Other regulations, limitations and prohibitive regulations**

This product has been classified in accordance with hazard criteria of the Controlled Products Regulations and the SDS contains all the information required by the Controlled Products Regulations.

- **Substances of very high concern (SVHC) according to REACH, Article 57**

None of the ingredients are listed.

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

WHMIS: Workplace Hazardous Materials Information System (Canada)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

- **Sources**

SDS Prepared by:

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