



SAFETY DATA SHEET

Product: **Alcavis 50**

Rev. 2

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Section 1 Identification

| Product Name | Manufacturer | Emergency Contact |
|--------------|---|---|
| Alcavis 50 | A.C.R.A.F. S.p.A. Via Pontasso 13 16015 Genoa Italy | Angelini Pharma Inc. 8322 Helgerman Court Gaithersburg, MD 20877 USA Phone: (301) 330-7597 Fax: (301) 330-6432 |

Recommended Use and Description

Electrolytically produced sodium hypochlorite. For use as a high level disinfectant for dialysis sets and connectors.

Section 2 Hazards Identification

PHYSICAL HAZARD(S): Oxidizing Liquid

HEALTH HAZARD(S):

- Eye Irritation: Category 2B – Mild Irritant
- Acute Oral Toxicity – Category 3



ENVIRONMENTAL HAZARD(S): None

Section 3 Composition & Information on Ingredients

- Sodium Hypochlorite: $\geq 0.5\%$ - CAS No.: 7681-52-9
- Sodium Chloride: 9% - CAS No.: 7647-14-5
- Excipients
- Depurated water q.s. to 100 ml

The available chlorine ($\geq 0.5\%$ - CAS No. 7782-50-5) in this product is composed of hypochlorite ion (OCl) and hypochlorous acid (HOCl). None of the ingredients are classified as hazardous ingredients.

Section 4 First Aid Measures

EYE CONTACT: Immediately flush eyes with plenty of water. If irritation persists, seek medical attention.

INGESTION: If swallowed, drink large quantities of milk or gelatin solution. If these are not available, drink large quantities of water and call a physician. Do not give vinegar or other acids. Do not induce vomiting. **Antidote:** Sodium thiosulphate; gastric lavage.

INHALATION: If breathing problems occur, seek fresh air immediately.

Section 5 Fire-fighting measures

- This product is not flammable or explosive. When poured on fire, it behaves as water.
- In a fire, cool containers to prevent rupture and release of sodium hypochlorite

Section 6 Accidental Release Measures

- In case of spills, flush area with water.
- The product should be diluted with water before disposal in sanitary sewer.

Section 7 Handling & Storage

- Store in a cool dry area, away from direct sunlight and heat.

Section 8 Exposure Controls/ Personal Protection

- Wear gloves with sensitive skin or repeated exposure.
- Do not mix with acidic substances, as it may release hazardous gases.

Section 9 Physical & Chemical Properties

| | | | |
|--|---|----------------------------|---|
| Physical State | Liquid | pH | 9.0-10.5 |
| Boiling pt./ range | $100^{\circ}\text{C} \leq \text{BP} \leq 104^{\circ}\text{C}$ | Freezing pt./ range | $-12^{\circ}\text{C} \leq \text{FP} \leq 0^{\circ}\text{C}$ |
| Specific Gravity (H₂O = 1) | 1.060 – 1.090 | Water Solubility | Soluble |
| Color | Slightly Yellow | Odor | Slightly of Chlorine |



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Section 10 Stability & Reactivity

Stable under normal use and storage conditions. Strong oxidizing agent. Reacts with other household chemicals such as toilet bowl cleansers, rust removers, vinegar, acids or ammonia containing products to produce hazardous gases, such as chlorine and other chlorinated species. In case of chemical contamination of the product, do not reseal container. High temperature and direct sunlight may cause swelling of the container. Stable for 30 months.

Section 11 Toxicological Information

Contact with eyes may cause temporary discomfort, but no permanent injury. Contact with skin causes no adverse effects. Ingestion of the product can cause hiccups and distension of the abdomen due to the release of chlorine gas. There are no inhalation exposure problems and no reported adverse effects due to acute exposure. There is no chemical similarity with known carcinogens or mutagens. No reported effects following more than 50 years of clinical use and application. When following the recommended usage instructions, the likelihood of any adverse health effects are low.

Section 12 Ecological Information

This product is not dangerous to the environment and is completely biodegradable.

Section 13 Waste Disposal Considerations

Disposal of the product in sinks and sewers must be in compliance with the local laws about active chlorine and chlorides.

Section 14 Transport Information

For more information, please visit 49 CFR Chapter 1, Subchapter C.

| Hypochlorite Solutions | | | | | |
|--|------------------------|---|--|-------------------------|-----|
| Symbols | N/A | Special Provisions (§ 172.102) | A7, B2, B15, IB2, IP5, N34,T7, TP2, TP24 | IB3, N34, T4, TP2, TP24 | |
| Hazardous materials descriptions and proper shipping names | Hypochlorite Solutions | Packaging (§ 173.***) | Exceptions | 154 | 54 |
| | | | Non-Bulk | 202 | 203 |
| | | | Bulk | 242 | 241 |
| Hazard class or Division | 8 | Qty. Limitations (see §§ 173.27 & 175.75) | Passenger aircraft/ rail | 1L | 5L |
| | | | Cargo aircraft only | 30L | 60L |
| Identification Numbers | UN1791 | Location | B | | |
| PG | II III | Other | 26 | | |
| Label Codes | 8 | | | | |

Section 15 Regulatory Information

EPA-SARA Title III/ CERCLA: This product is regulated under Sections 311/312. This product contains no chemicals that are regulated under Section 313 but contains sodium hypochlorite and sodium hydroxide, which are regulated under Section 304/CERCLA.

Section 16 Other Information

This SDS must be shown each time you seek medical attention for emergencies relating to this specific product.

The information provided herein is made in good faith and is believed to be correct as of the date thereof. The Manufacturer and Distributor do not make representation as to the comprehensiveness or to the accuracy of specific properties. The individuals using the product and receiving this information are expected to use their best judgement in determining risks and precautions connected to the use of this product.

The information is intended to provide a general notice of use, safety, and storage of this product. It is provided independently of any sale of the product as part of Angelini Pharma's Product Safety Program. It is not applicable to unusual or non-standard use of the product or for uses different from which this product has been conceived. Furthermore, no expressed warranty or merchantability of fitness for a particular purpose is made with respect to the information herein.