

## Safety Data Sheet (SDS / MSDS)

### SDF Gel 38% (Silver Diamine Fluoride)

Prepared in accordance with GHS Rev. 8 / OSHA HazCom 2012

#### SECTION 1: Identification

|                               |                                                                                                                                                                           |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Product Name</b>           | SDF Gel 38% (Silver Diamine Fluoride)                                                                                                                                     |
| <b>Recommended Use</b>        | Bulk raw material / active ingredient supply to licensed dental-product manufacturers and formulators only. Not for direct clinical or consumer use in the form supplied. |
| <b>Manufacturer/ Supplier</b> | Ochnology Solution Pvt. Ltd.                                                                                                                                              |
| <b>Address</b>                | B-153, Sector-4, Defence Colony, Dehradun, Uttarakhand, India - 248001                                                                                                    |
| <b>Contact</b>                | projects@ochnology.com, bd@ochnology.com   +91 9286823642/43                                                                                                              |

#### SECTION 2: Hazards Identification

SDF Gel 38% is an alkaline silver diamine fluoride solution. It can cause eye and skin irritation, and will cause characteristic black staining on skin, tissue, and other organic material on contact due to silver reduction — this is a well-known handling characteristic of this active, not a defect.

##### GHS Classification:

- Skin Irritation, Category 2 (H315)
- Eye Irritation, Category 2 (H319)
- Acute Toxicity (Oral), Category 4 — precautionary classification given fluoride content (H302)

##### Signal Word: WARNING

##### Hazard Statements:

- H315 - Causes skin irritation
- H319 - Causes serious eye irritation
- H302 - Harmful if swallowed
- Causes black/dark staining on skin, tissue, clothing, and porous surfaces on contact

##### Precautionary Statements:

- P264 - Wash hands thoroughly after handling
- P280 - Wear protective gloves/eye protection/face protection
- P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes; remove contact lenses if present; continue rinsing
- P302+P352 - IF ON SKIN: Wash with plenty of soap and water
- P270 - Do not eat, drink, or smoke when using this product

#### SECTION 3: Composition / Information on Ingredients

| Component                      | CAS No.    | Approx. %      |
|--------------------------------|------------|----------------|
| Silver Diamine Fluoride (SDF)  | 21548-73-2 | 38% w/v        |
| Silver (Ag), as SDF            | 7440-22-4  | ≈ 24 - 27% w/v |
| Fluoride (F), as SDF           | 16984-48-8 | ≈ 5 - 6% w/v   |
| Water / ammonia carrier system | Mixture    | Balance        |

#### SECTION 4: First-Aid Measures

- Eye contact: Rinse cautiously with water for several minutes; remove contact lenses if present; seek medical attention.
- Skin contact: Wash immediately with plenty of soap and water; staining is cosmetic and not itself an injury, but irritation should be assessed medically if it occurs.
- Inhalation: Move to fresh air; seek medical attention if respiratory discomfort occurs.
- Ingestion: Rinse mouth with water; do NOT induce vomiting; seek medical attention immediately given fluoride content.

#### **SECTION 5: Fire-Fighting Measures**

- Aqueous solution; not flammable.
- Use extinguishing media appropriate to the surrounding fire.

#### **SECTION 6: Accidental Release Measures**

- Contain spill; absorb with inert absorbent material.
- Avoid contact with skin and eyes during clean-up; wear appropriate PPE.
- Collected material and contaminated absorbent will stain — handle and dispose of accordingly.
- Prevent entry into drains, waterways, or soil.

#### **SECTION 7: Handling and Storage**

- Store in light-protected (amber) containers away from direct light and heat.
- Keep tightly sealed; product darkens and stains increase with light/air exposure over time.
- Handle over a protected work surface; staining on fabric, skin, and porous surfaces is difficult to remove.
- Restrict handling to trained personnel in licensed formulation facilities.

#### **SECTION 8: Exposure Controls / Personal Protection**

Exposure controls apply to bulk handling by licensed formulators; finished-product (clinical-use) exposure guidance is established separately by the regulatory-cleared finished product's own labelling.

- No specific occupational exposure limit established for SDF; handle as an irritant per Section 2 classification
- Respiratory protection: Not normally required for liquid handling; use if aerosol/mist is generated
- Eye protection: Safety goggles or face shield
- Hand protection: Nitrile or equivalent chemical-resistant gloves (staining will occur through inadequate protection)
- Protective clothing recommended to prevent staining of garments

#### **SECTION 9: Physical and Chemical Properties**

|                            |                                                                 |
|----------------------------|-----------------------------------------------------------------|
| <b>Appearance</b>          | Colourless to pale yellow liquid; darkens on light/air exposure |
| <b>Odour</b>               | Slight ammoniacal odour                                         |
| <b>pH</b>                  | 8 - 10                                                          |
| <b>Solubility in Water</b> | Miscible                                                        |
| <b>Specific Gravity</b>    | ≈ 1.2 - 1.4 (typical)                                           |

#### **SECTION 10: Stability and Reactivity**

- Stable under normal conditions when stored light-protected and sealed.
- Darkens progressively on exposure to light and air (silver reduction); does not indicate loss of active content within shelf life.
- Incompatible with strong oxidizing agents.

#### **SECTION 11: Toxicological Information**

- May cause skin and eye irritation on direct contact.
- Harmful if swallowed due to fluoride content; excessive fluoride ingestion is associated with acute gastrointestinal effects and, with chronic excess exposure, dental/skeletal fluorosis.
- Silver diamine fluoride's finished-product clinical safety profile is established through the regulatory clearance of the finished dental product, not by this bulk raw-material SDS.

#### **SECTION 12: Ecological Information**

- Contains silver, which is toxic to aquatic organisms; avoid discharge to waterways or drains.
- Fluoride compounds may also affect aquatic ecosystems at elevated concentrations.

#### **SECTION 13: Disposal Considerations**

- Dispose of per local hazardous waste regulations applicable to silver- and fluoride-containing waste.
- Do not discharge to drains.

#### **SECTION 14: Transport Information**

May be subject to dangerous goods classification depending on quantity and destination-country transport regulations for corrosive/irritant liquids — confirm with carrier and destination-country transport authority before shipment.

#### **SECTION 15: Regulatory Information**

- **IMPORTANT:** SDF is regulated as a dental drug and/or medical device in most jurisdictions (e.g., FDA-cleared devices in the United States, CE-marked products in the EU/UK).
- Ochnology supplies this product as a bulk raw material / active ingredient to licensed formulators and manufacturers only.
- This SDS and any accompanying documentation do NOT constitute, and are not a substitute for, the regulatory clearance, GMP manufacturing licence, or distribution authorization required to market a finished SDF product in any jurisdiction.
- Buyers are solely responsible for obtaining all applicable regulatory approvals before formulating, labelling, or distributing a finished product.

#### **SECTION 16: Other Information**

This SDS addresses the bulk active ingredient as supplied to licensed formulators. It is not a clinical-use product label and must not be used as a substitute for the finished, regulatory-cleared product's own labelling and patient/clinician-facing safety information.

*Disclaimer: Information is provided as a general guide based on available data and is subject to revision without notice. Buyers/users should conduct their own risk assessment and confirm suitability for their specific process and application.*