



## SAFETY DATA SHEET

Section 1: Identification	
<b>Section 1, Identification</b>	
<b>Product</b>	<b>Diclofenac Potassium Tablets USP 50mg</b>
<b>Distributor</b>	SOLA Pharmaceuticals 655 Highlandia Drive Baton Rouge, LA. 70810 Tel: 866.747.7365 Fax: 800.754.9550 <a href="http://www.solameds.us">www.solameds.us</a> info@solameds.us
<b>NDC Number</b>	70512-750-10 (bottles of 100's)
Section 2: Hazard(s) Identification	
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<p><b>Classification of the substance or mixture</b>  <b>Classification according to Regulation (EC) No. 1272/2008</b>            For the full text of the H-Statements mentioned in this section, see Section 16</p> <p><b>Classification according to the EU Directives 67/548/EEC or 1999/45/EC</b>            For the full text of the R-phrases mentioned in this section, see Section 16</p> <p><b>Label Elements</b>  <b>Labeling according to Regulation (EC) No. 1272/2008</b></p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  </div> <div style="text-align: center;">  </div> </div> <p>Signal word: Warning</p> <p>Hazard statement(s):</p> <p>Precautionary statement(s):</p> <p>Supplemental Hazard Statements: None</p> <p><b>Other Hazards</b> None</p>	

### Section 3: Composition/Information on Ingredients

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Synonyms	2[(2,6-dichlorophenyl)amino]benzeneacetic acid potassium salt
Formula	C <sub>14</sub> H <sub>10</sub> Cl <sub>2</sub> KNO <sub>2</sub>
Molecular Weight	334.23 g/mol
CAS No.	15307-810-0
EC No.	630-422-6

#### Hazardous ingredients according to Regulation (EC) No. 1272/2008

Component	Classification	Concentration
<b>Diclofenac Potassium</b>		
CAS No. 15307-81-0	H302; H411	<=100%
EC No. 630-422-6		

#### Hazardous ingredients according to Directive 1999/45/EC

Component	Classification	Concentration
<b>Diclofenac Potassium</b>		
CAS No. 15307-81-0		<=100%
EC No. 630-422-6		

For the full text of the H-Statements and R-Phrases mentioned in this section, see Section 16.

### Section 4: First-Aid Measures

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##### General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

##### If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

##### In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

##### In case of eye contact

Rinse thoroughly with plenty of water for at least minutes and consult a physician.

##### If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

##### Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labeling (see Section 2.2) and/or in Section 11.

##### Indication of any immediate medical attention and special treatment needed

No data available

**Section 5: Fire-Fighting Measures****Section 5, Fire-Fighting Measures****Extinguishing media****Suitable extinguishing media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide

**Special hazards arising from the substance or mixture**

Carbon dioxide, nitro oxides (NO<sub>x</sub>), Hydrogen chloride gas

**Advise for firefighters**

Wear self-contained breathing apparatus for fire-fighting if necessary

**Further information**

No data available

**Section 6: Accidental Release Measures****Section 6, Accidental Release Measures****Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection, see Section 8.

**Environmental precautions**

Do not let product enter drains.

**Methods and materials for containment and cleaning up**

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

**Reference to other sections**

For disposal, see Section 13.

**Section 7: Handling and Storage****Section 7, Handling and Storage****Precautions for safe handling**

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. For precautions, see Section 2.2.

**Conditions for safe storage, including any incompatibilities**

Dry, safe place.

**Specific end use(s)**

Apart from the uses mentioned in Section 1.2 no other specific uses are stipulated.

**Section 8: Exposure Controls / Personal Protection**

**Section 8, Exposure Controls / Personal Protection**

**Control parameters**

**Components with workplace control parameters**

**Exposure controls**

**Appropriate engineering controls**

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the workday.

**Personal protective equipment**

**Eye/face protection**

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

**Skin protection**

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching gloves' outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

**Body protection**

Impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**Respiratory protection**

For nuisance exposures, use Type P95 (US) or Type P1 (EU EN 143) particle respirator. For higher level protection, use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges.

Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

**Control of environmental exposure**

Do not let product enter drains.

**Section 9: Physical and Chemical Properties**

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**Information on basic physical and chemical properties**

Appearance	white to light yellow powder
pH	not available
Melting point	156 – 158°C
Boiling point	412°C at 760 mmHg
Flash point	203°C
Explosion Limits: Lower	not available
Explosion Limits: Upper	not available
Decomposition temperature	not available

Solubility in water	not available
Specific gravity/density	not available
<b>Other safety information</b>	
No data available	

**Section 10: Stability and Reactivity**

**Section 10, Stability and Reactivity**

<b>Reactivity</b>
No data available
<b>Chemical stability</b>
Stable under recommended storage conditions
<b>Possibility of hazardous reactions</b>
No data available
<b>Conditions to avoid</b>
Avoid moisture
<b>Incompatible materials</b>
Acid, acid chlorides, acid anhydrides, oxidizing agents
<b>Hazardous decomposition products</b>
Other decomposition products – no data available
In the event of fire: see Section 5

**Section 11: Toxicological Information**

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<b>Acute toxicity</b>
No data available
<b>Skin corrosion/irritation</b>
No data available
<b>Serious eye damage/eye irritation</b>
No data available
<b>Respiratory or skin sensitization</b>
Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals. The preceding data, or interpretation of data, was determined using Quantitative Structure Activity Relationship (QSAR) modeling.
<b>Germ cell mutagenicity</b>
No data available
<b>Carcinogenicity</b>
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible, or confirmed human carcinogen by IARC.

**Reproductive toxicity**

No data available

**Specific target organ toxicity – single exposure**

Inhalation – may cause respiratory irritation.

**Specific target organ toxicity – repeated exposure**

No data available

**Aspiration hazard**

No data available

**Additional information**

RTECS: not available

**Section 12: Ecological Information**

**Section 12, Ecological Information**

**Toxicity**

No data available

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Results of PBT and vPvB assessment**

PBT/vPvB assessment no available as chemical safety assessment not required/not conducted

**Other adverse effects**

No data available

**Section 13: Disposal Considerations**

**Section 13, Disposal Considerations**

**Waste treatment methods**

**Product**

Burn in a chemical incinerator equipped with an afterburner and scrubber but exert extra cae in igniting as this material is highly flammable. Offer surplus and nonrecyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

**Contaminated packaging**

Dispose of as unused product.

**Section 14: Transport Information****Section 14, Transport Information**

DOT (US)

UN number: 2811                      Class: 6.1                      Packing group: III

IMDG

UN number: 2811                      Class: 6.1                      Packing group: III

IATA

UN number: 2811                      Class: 6.1                      Packing group: III

**Section 15: Regulatory Information****Section 15, Regulatory Information**

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

No data available

**Chemical safety assessment**

For this product, a chemical safety assessment was not carried out.

**Section 16: Other Information****Section 16, Other Information**

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

**SOLA** shall not be held liable for any damage resulting from handling or from contact with the above product. SOLA reserves the right to revise this Safety Data Sheet.