



SAFETY DATA SHEET

Section 1: Identification				
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Product	Diclofenac Potassium Tablets USP 50mg			
Distributor	SOLA Pharmaceuticals			
	655 Highlandia Drive			
	Baton Rouge, LA. 70810			
	Tel: 866.747.7365			
	Fax: 800.754.9550			
	www.solameds.us			
	info@solameds.us			
NDC Number	70512-750-10 (bottles of 100's)			
	Section 2: Hazard(s) Identification			

Section 2, Hazard(s) Identification

Classification of the substance or mixture

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

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

Classification according to the EU Directives 67/548/EEC or 1999/45/EC

For the full text of the R-phrases mentioned in this section, see Section 16

Label Elements

Labeling according to Regulation (EC) No. 1272/2008





Signal word

Hazard statement(s)

Precautionary statement(s)

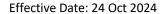
Supplemental Hazard Statements

Warning

None

Other Hazards

None





Section 3: Composition/Information on Ingredients

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Synonyms 2[(2,6-dichlorophenyl)amino]benzeneacetic acid potassium salt

Formula C14H10Cl12KNO2
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

indications in Broatenits according to helparation (10) has 1171/1000					
	Component	Classification	Concentration		
Diclofenac Potassium					
CAS No.	15307-81-0	H302; H411	<=100%		
EC No.	630-422-6				

Hazardous ingredients according to Directive 1999/45/EC

	Component	Classification Concentration			
Diclofenac Potassium					
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

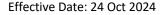
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

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 (NOx), 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

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Precautions for safe handling

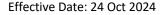
Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. For precautions, see Section 2.2.

Conditions for safe storage, including any incompabilities

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 satisf 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

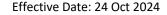
Appearance white to light yellow powder

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

Other safety information

No data available

Section 10: Stability and Reactivity

Section 10, Stability and Reactivity

Reactivity

No data available

Chemical stability

Stable under recommended storage conditions

Possibility of hazardous reactions

No data available

Conditions to avoid

Avoid moisture

Incompatible materials

Acid, acid chlorides, acid anhydrides, oxidizing agents

Hazardous decomposition products

Other decomposition products – no data available

In the event of fire: see Section 5

Section 11: Toxicological Information

Section 11, Toxicological Information

Acute toxicity

No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

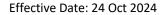
Prolonged or repeated exposure may cuse allergic reactions in certain sensitive individuals. The preceding data, or interpretation of data, was determined using Quantitative Structure Activity Relationship (QSAR) modeling.

Germ cell mutagenicity

No data available

Carcinogenicity

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

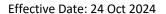
Waste treatment methods

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 ths 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.