Safety Data Sheet
Dasone Gel, 7.5%
Strength: 7.5 %

Pack Size: 60 gm,
90 gm

NDC 72578-094-02
72578-094-03

Revision No.: 00

Emergency Overview

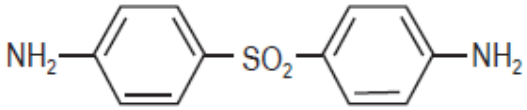
Dapsone gel, 7.5%, is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

Section 1 : Identification

Product Name: **Dapsone Gel, 7.5%**

Formula: $C_{12}\ H_{12}N_2O_2S$

Chemical Name: 4-[(4-aminobenzene) sulfonyl] aniline



Molecular Weight: 248.30 g/mol

Description: Dapsone gel, 7.5%, is a sulfone indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

Dosage forms and strengths: Each gram of dapsone gel, 7.5% contains 75 mg of dapsone in an white, off white to yellow gel with suspended particles.

Manufacturer / supplier identification

Company Address	Cadila Healthcare Ltd. Ahmedabad, India Cadila Healthcare, Ltd. Changodar (Topical Formulation facility) Plot No. 254, Opp. Laxmi Narayan Petrol Pump, N.H. 8A, Ahmedabad -382210 India
Contact for information	Tel.:+91 2717-616430 Fax: +91 2717-616430
Emergency Telephone No	Tel.:+91 2717-616401
Recommended use / Therapeutic Category	Dapsone gel, 7.5%, is a sulfone indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.
Restriction on Use / Contraindications	None.

Section 2 : Hazard (s) Identification

Dose and Administration

For topical use only. Not for oral, ophthalmic, or intravaginal use.

After the skin is gently washed and patted dry, apply approximately a pea-sized amount of dapsone gel, 7.5%, in a thin layer to the entire face once daily. In addition, a thin layer may be applied to other affected

areas once daily. Rub in dapsone gel, 7.5%, gently and completely.

If there is no improvement after 12 weeks, treatment with dapsone gel, 7.5% should be reassessed.

Adverse effects

Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. A total of 2,161 subjects were treated with dapsone gel, 7.5%, for 12 weeks in 2 controlled clinical trials. The population ranged in age from 12 years to 63 years, was 56% female, and 58% Caucasian. Adverse drug reactions that were reported in at least 0.9% of subjects treated with dapsone gel, 7.5% appear in Table 1 below.

Table 1
Adverse Reactions Occurring in at Least 0.9% of Subjects with Acne Vulgaris in 12-week Controlled Clinical Trials

	Dapsone Gel, 7.5% (N=2,161)	Vehicle (N=2,175)
Application Site Dryness	24 (1.1%)	21 (1%)
Application Site Pruritus	20 (0.9%)	11 (0.5%)

Experience with Oral Use of Dapsone

Although not observed in the clinical trials with topical dapsone, serious adverse reactions have been reported with oral use of dapsone, including agranulocytosis, hemolytic anemia, peripheral neuropathy (motor loss and muscle weakness), and skin reactions (toxic epidermal necrolysis, erythema multiforme, morbilliform and scarlatiniform reactions, bullous and exfoliative dermatitis, erythema nodosum, and urticaria).

Postmarketing Experience

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The following adverse reactions have been identified during post-approval use of topical dapsone: methemoglobinemia, rash (including erythematous rash, application site rash) and swelling of face (including lip swelling, eye welling).

Section 3: Composition / information on ingredients

Contains: Active: Each gram of dapsone gel, 7.5% contains 75 mg of dapsone in an white, off white to yellow gel with suspended particles.

Section 4: First -aid measures

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention if irritation persists.
Skin Contact	Wash skin with soap and water. Remove and wash contaminated clothing before re-use. Get medical attention if symptoms occur.
Inhalation	Not an expected route of exposure. IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention.
Ingestion	Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Get medical attention.

Section 5: Fire -fighting measures

Suitable extinguishing media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	No information available.
Specific hazards arising from the chemical	No information available.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Section 6: Accidental Release Measures

Personal precautions	Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Refer to Section 8 for personal protective equipment.
Environmental Precautions	See Section 12 for additional Ecological Information.
Methods for Containment	Small spills: Wipe up with absorbent material (e.g. cloth, fleece). Large spills: Prevent further leakage or spillage if safe

to do so. Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see Section 13).

Methods for Cleaning Up Clean contaminated surface thoroughly

Section 7: Handling and Storage

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Refer to Section 8.

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible Products Oxidizing agents.

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Section 8: Exposure controls/personal protection

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits.

Engineering Measures Showers
Eyewash stations
Ventilation systems

Eye/face protection No special protective equipment required. Risk of contact, wear: Safety glasses with side-shields.

Skin and Body Protection Lightweight protective clothing. Latex gloves. Chemical resistant gloves.

Respiratory Protection None required under normal usage.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke when using this product. Keep away from food, drink and animal feeding stuffs. Provide regular cleaning of equipment, work area and clothing. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and immediately after handling the product.

Section 9: Physical and chemical properties

Physical State Gel
Odor Mild sweet odor
Color White to yellowish cream

Section 10: Stability and reactivity

Reactivity Not reactive under normal conditions.

Chemical stability Stable under recommended storage conditions.

Possibility of hazardous Reactions None under normal processing.
Conditions to avoid Heat.
Incompatible materials Oxidizing agents.
Hazardous decomposition Products None known based on information supplied.

Section 11: Toxicological information

Information on likely routes of exposure
Product Information

Inhalation Not an expected route of exposure.

Eye Contact Expected to be an irritant based on components.

Skin Contact May be absorbed through the skin. May cause skin irritation and/or dermatitis. Prolonged or repeated contact may dry skin and cause irritation.

Ingestion Nausea, vomiting and hyperexcitability can occur within minutes or hours of ingestion overdose. Other serious effects of overexposure can include periphera lneuropathy (motor weakness), convulsions, and a blue discoloration of fingernails, lips or skin caused by low oxygen due to methemoglobinemia. Oral dapsone treatment has produced dose-related agranulocytosis, hemolysis and hemolyticanemia.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Diethylene glycol monoethyl ether	= 1920 mg/kg (Rat)	= 9143 mg/kg (rat)	> 5240 mg/m³ (Rat) 4 h
Dapsone	= 1 g/kg (Rat)	> 4 g/kg (Rabbit)	-

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Adverse effects of exposure may include back, leg or stomach pain, loss of appetite, tiredness and weakness, fever, skin rash, difficulty breathing, sore throat and unusual bleeding or bruising. See additional effects listed for ingestion and chronic toxicity.

Sensitization No information available.

Mutagenic Effects Dapsone was not mutagenic in a bacterial reverse mutation assay (Ames test) using S. typhimurium and E. coli, with and without metabolic activation and was negative in a micronucleus assay conducted in mice. Dapsone increased both numerical and structural aberrations in a chromosome aberration assay conducted with Chinese hamster ovary (CHO) cells.

Carcinogenicity Dapsone was not carcinogenic to rats when orally administered to females for 92 weeks or sales for 100 weeks at dose levels up to 15 mg/kg/day. However, studies in male rats and female mice have shown that Dapsone causes mesenchymal tumors of the spleen and peritoneum. It has also been shown to cause thyroid carcinoma in female rats.

Chemical Name	ACGIH	IARC	NTP	OSHA
Dapsone		Group 3		

Reproductive Toxicity The effects of dapsone on fertility and general reproduction performance were assessed in male and female rats following oral (gavage) dosing. Dapsone reduced sperm motility at dosages of 3 mg/kg/day or greater. The mean numbers of embryo implantations and viable embryos were significantly reduced in untreated females mated with males that had been dosed at 12 mg/kg/day or greater, presumably due to reduced numbers or effectiveness of sperm, indicating impairment of fertility. Dapsone had no effect on fertility at dosages of 2mg/kg/day or less. When administered to female rats at a dosage of 75mg/kg/day for 15 days prior to mating and for 17 days thereafter, dapsone reduced the mean number of implantations, increased the mean early resorption rate, and reduced the mean liter size. These effects were probably secondary to maternal toxicity.

Developmental Toxicity Dapsone has been shown to have an embryocidal effect in rats and rabbits when administered orally in doses of 75 mg/kg/day and 150 mg/kg/day. These effects were probably secondary to maternal toxicity.

STOT - single exposure Based on available data, the classification criteria are not met.

STOT - repeated exposure May cause damage to organs through prolonged or repeated exposure. See listed target organs below.

Chronic Toxicity Prolonged or repeated overexposure to dapsone may result in hemolyticanemia, agranulocytosis and peripheral neuropathy as well as various skin reactions.

Target Organ Effects Peripheral Nervous System (PNS). Blood.

Aspiration Hazard No information available.

Section 12: Ecological information

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Diethylene glycol monoethyl ether 111-90-0		LC50 96 h: 11400-15700 mg/L flow-through (Oncorhynchus mykiss) LC50 96 h: 11600-16700 mg/L flow-through (Pimephales promelas) LC50 96 h: 19100-23900 mg/L flow-through (Lepomis macrochirus) LC50 96 h: = 10000 mg/L static (Lepomis macrochirus) LC50 96 h: = 13400 mg/L flow-through (Salmo gairdneri)		EC50 48 h: 3940 - 4670 mg/L (Daphnia magna)
Dapsone 80-08-0			EC50 = 108 mg/L 15 min EC50 = 119 mg/L 5 min EC50 = 98.9 mg/L 30 min	

Persistence and Degradability No information available.

Bioaccumulation No information available.

Chemical Name	Log Pow
Diethylene glycol monoethyl ether	-0.8

Section 13: Disposal consideration

Waste Disposal Methods	Dispose of in accordance with local regulations.
Contaminated Packaging	Do not re-use empty containers.

Section 14: Transport information

DOT	Not regulated
TDG	Not regulated.
MEX	Not regulated.
IATA	Not regulated.
IMDG/IMO	Not regulated.

Section 15: Regulatory information

Generic Medicine. Dapsone Gel, 7.5%, NDC no.: 72578-094-02 (60 gm) and 72578-094-03 (90 gm)

Section 16: Other information

None

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product

Date of issue: 01/07/21 **Supersedes edition:** N/A