

(Annexure-14)



EU- SAFETY DATA SHEET Reach Reg.No.-01-2119968268-22-0002
As per Globally Harmonized System (GHS) EFFECTIVE DATE: 02.09.2020
NEXT REVIEW DATE: 01.09.2022

WESTERN DRUGS LTD.

NIACINAMIDE (NICOTINAMIDE)

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1. Identification of the substance/preparation and the company:

Name	: NIACINAMIDE	
Product code	: 01	
Company information	: Enquiries	Factory
	: WESTERN DRUGS LTD.	WESTERN DRUGS LTD.
	321, Tantia-Jogani Ind. Prem co-op-Soc. Ltd.	F-271 (A), Mewar Industrial Area,
	Sitaram mills compound, Mumbai,	Madri, Udaipur -313003 (Rajasthan)
	India	India
	Phone : + 91-22-61232000	Phone: + 91-294-6053691
	Fax : + 91-22-61232030	Fax : + 91-294-2490676
	Email:sales@westerndrugs.com	Email: infoudaipur@westerndrugs.com
Emergency Contact Person: Mr. Vikram Ranka (Vice President -Operations)		Emergency Contact Number: +91-9414163245

2. Hazards Identification:

2.1 Classification of the substance or mixture
(Classification according to regulation (EC) No 1272/2008)

H319 Causes serious eye irritation.

Hazard pictograms



GHS07

Signal word Warning

Hazard-determining components of labeling: Void

Hazard statements

H319 Causes serious eye irritation.

Precautionary Statements:

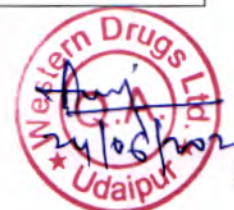
P264: Wash hands, eyes and face thoroughly after handling
P280: Wear protective gloves/clothing and eye/face protection

First Aid Precautionary Statements (Response):

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337+P313: If eye irritation persists: Get medical advice/attention
Information concerning particular hazards for human and environment: void

Physical hazards

Explosives conclusive but not sufficient for classification
Flammable gases conclusive but not sufficient for classification
Flammable aerosols conclusive but not sufficient for classification
Oxidizing gases conclusive but not sufficient for classification
Gases under pressure conclusive but not sufficient for classification
Flammable liquids conclusive but not sufficient for classification
Flammable solids conclusive but not sufficient for classification
Self-reactive substances and mixtures conclusive but not sufficient for classification
Pyrophoric liquids conclusive but not sufficient for classification
Pyrophoric solids conclusive but not sufficient for classification
Self-heating substances and mixtures conclusive but not sufficient for classification
Substances and mixtures which in contact with water emits flammable gases conclusive but not sufficient for classification
Oxidising liquids conclusive but not sufficient for classification
Oxidising solids conclusive but not sufficient for classification
Organic peroxides conclusive but not sufficient for classification
Corrosive to metals conclusive but not sufficient for classification





Health hazards

Acute toxicity – oral conclusive but not sufficient for classification
Acute toxicity – dermal conclusive but not sufficient for classification
Acute toxicity – inhalation conclusive but not sufficient for classification
Skin corrosion / irritation conclusive but not sufficient for classification
Serious eye damage / eye irritation Eye Irrit. 2 H319: Causes serious eye irritation.
Respiratory sensitization conclusive but not sufficient for classification
Skin sensitization conclusive but not sufficient for classification
Aspiration hazard conclusive but not sufficient for classification
Reproductive toxicity conclusive but not sufficient for classification
Effects via lactation conclusive but not sufficient for classification
Germ cell mutagenicity conclusive but not sufficient for classification
Carcinogenicity conclusive but not sufficient for classification
Specific target organ toxicity – single conclusive but not sufficient for classification.
Specific target organ toxicity – repeated conclusive but not sufficient for classification

Environmental hazards:

Hazardous to the aquatic environment (acute/short-term) conclusive but not sufficient for classification
Hazardous to the aquatic environment (long-term) conclusive but not sufficient for classification
Hazardous to the ozone layer data lacking

2.2 Label elements:

Labeling according to Regulation (EC) No 1272/2008 : The substance is classified and labeled according to the CLP regulation.

Hazard pictograms



GHS07

Signal word Warning

Hazard-determining components of labeling: Void

Hazard statements

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Precautionary Statements:

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P337+P313: If eye irritation persists: Get medical advice/attention

2.3 Other Hazards:

Signs and Symptoms of Potential Overexposure:

Niacinamide is an eye irritant, but does not irritate the skin. May cause respiratory irritation upon exposure to dusty conditions. In humans, nausea with or without vomiting was the main effect after acute exposure and was generally seen after doses in excess of 5 grams/day; no effects were persistent.

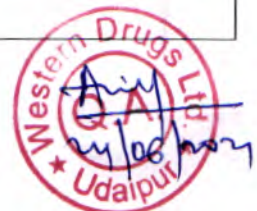
Primary Route(s) of Exposure:

Skin contact and absorption, eye contact, and inhalation. Ingestion is not likely to be a primary route of exposure.

Medical Conditions Aggravated by Exposure: Persons with pre-existing skin, liver, or kidney disorders may be at increased risk from overexposure to this material. This is not likely to be a problem when appropriate procedures are used to minimize exposure.

3. Composition/Information on Ingredients:

Chemical characterization : Nicotinamide / 3 Pyridine Carboxamide
Synonyms : Vitamin B3, Vitamin PP
Empirical formula : C₆H₆N₂O



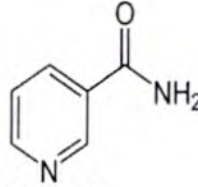


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NIACINAMIDE (NICOTINAMIDE)

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Structural Formula :



Molar mass : 122.1g/mol.
C.A.S no : 98-92-0
EINECS no : 202-713-4
Purity : Minimum 98.5%

Uses:

Niacinamide is freely soluble in water, in alcohol and soluble in Glycerin, soluble Vitamin and finds its application as a nutrient supplement in Pharmaceutical products. It has been used in the enrichment of bread, flour and other grain-derived products. Animal feed is routinely supplemented with Nicotinamide. It is also used in multi-vitamin preparations, dietary supplement and cosmetics. It is used in the treatment of pellagra.

4. First-aid measures:

Key Symptoms

Acute effects : It causes serious eye irritation.

Chronic effects : Affects the kidneys, eyes & liver.

General Information:

Remove contaminated or saturated clothing at once.

Upon inhalation:

Remove the fresh air and keep at rest in a position comfortable for breathing. Call a physician if you feel unwell. Monitor the respiratory distress. Apply artificial respiration if not breathing. Do not use mouth-to-mouth method. If victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Toxic vapors may be released on thermal decomposition including nitrogen oxides, carbon monoxide and cyanide.

Following skin contact:

Wash well with water and soap. In case of remaining complaints seek medical advice.

Following eye contact:

Flush with plenty of water for at least 15 minutes. In case of remaining complaints seek medical advice.

Upon Ingestion (swallowing):

Do not induce vomiting. Rinse mouth and throat thoroughly with water. In case of persistent seek medical advice.

Most important symptoms and effects, both acute and delayed:

Acute: Niacinamide is an eye irritant, but does not irritate the skin. May cause respiratory irritation upon exposure to dusty conditions. In humans, nausea with or without vomiting was the main effect after acute exposure and was generally seen after doses in excess of 5 grams/day; no effects were persistent.

Delayed Effects: None known

Indication of any immediate medical attention and special treatment needed:

Thermal Exposure: Not applicable.

Note to Physician: No specific indications. Treatment should be based on the judgment of the physician in response to the reactions of the patient. One case of long-term niacinamide mega-dosing as a therapeutic agent led to nausea, vomiting, fever, rash, joint pains and increased levels of SGOT, SGPT and bilirubin. These symptoms abated six months after discontinuation of mega-dosing.

5. Fire -fighting Measures:

Flash point: 182°C

Flammability: Non flammable Solid

Extinguishing Media:

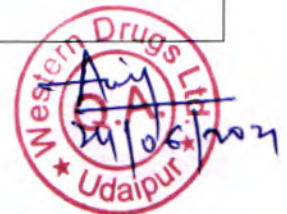
Suitable extinguishing agents: Carbon dioxide (CO₂) extinguisher, Water Spray/fog, Alcohol-resistant foam.

Special hazards arising from the substance or mixture:

Hazardous Products of Combustion:

Cyanide and nitrogen oxides may be released during thermal decomposition.

High Vapor concentration may result in an explosion hazard.





Advice for Firefighters:

Protective equipment : Wear self-contained breathing apparatus (SCBA)
Additional information : Cool endangered containers with water spray jet
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6. Accidental release measures

6.1 Individual precautions, protective equipment and emergency procedures:

Ensure adequate ventilation
Wear protective equipment and keep away unprotected persons.
Avoid contact with skin and eyes.
Avoid breathing dust.
Remove all ignition sources.

6.2 Environmental precautions: Prevent releases to soils, drains, sewers, and waterways.

6.3 Methods and material for containment and cleaning up:

Containment Techniques and Clean-up Procedures:

Remove all ignition sources. Ventilate the area of spill or leak. Wear protective equipment during clean-up. Material can then be collected for later disposal. After collection of material, flush area with water. Dispose of the material in accordance with standard practice for disposal of potentially hazardous materials as required by applicable federal, state or local laws. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Non sparking tools should be used.

Special Reporting Requirements: Not applicable.

6.4 Reference to other sections

See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for information on disposal.

7. Handling and Storage

7.1 Handling

Advice on safe handling: Provide sufficient air exchange and/or exhaust in work rooms. Avoid formation of respirable particles.
Avoid contact with skin and eyes.
Advice on protection against fire and explosion: Avoid dust formation. Take precautionary measures against static discharges.

7.2 Storage

Do not Store in heat or direct sunlight. Keep Container tightly closed. Keep in dry and well ventilated place.

8. Exposure controls/personal protection

8.1 Exposure controls:

Provide exhaust ventilation or other engineering controls to keep the relevant airborne concentrations below their respective occupational exposure limits. Local ventilation is usually preferred. Ensure that eyewash stations and safety showers are close to the work station location.

8.2 Personal protection:

General protective and hygienic measures

Keep away from foodstuffs, beverages and food.
Instantly remove any contaminated garments.
Wash hands during breaks and at the end of the work.
Use skin protection cream for preventive skin protection.
Do not eat, drink or smoke while working.

Breathing equipment:

Use breathing protection in case of dust formation.
If all workplace limits are observed and good ventilation is ensured, no special precautions necessary.

Protection of hands:

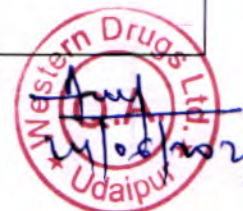
The protective gloves to be used.

Eye protection:

Use safety glasses

Body protection:

Protective work clothing.
Protective clothing should be selected specifically for the working place.





9. Physical and chemical properties

Physical form (20° C)	: Powder / Granules/Crystalline
Color	: White
Odor	: Nearly odorless
Odor Threshold	: Not available
Melting Point/Melting Range	: 128 – 131° C
Boiling Point/Boiling Range	: 157 deg C at -0.0005mm Hg
Flash Point	: 182° C
Decomposition temperature	: > 140° C
Bulk density	: App. 600 Kg/m ³
Solubility in water (25°)	: Freely soluble in water in Alcohol and soluble in glycerin
pH Value (50 g/l,20° C)	: 6.0 – 7.5
Danger of Explosion	: Not explosive
Inflammability (solid, gaseous)	: Not inflammable
Self inflammability	: Not determined
Vapor pressure	: 0.00045 Pa at 25 deg C
Vapor Density (air=1)	: Not applicable
Specific gravity (water=1)	: 1.400 at 25 deg C
Critical values for explosion:	
Lower	: Not determined
Upper	: Not determined
Log Kow (octanol/water Coefficient)	: -0.37 (estimated)
Auto-ignition temperature	: No data available
Relative Density	: Not determined
Evaporation rate	: Not applicable
Viscosity	: Not applicable
Molecular Weight	: 122.13
pKa (@20°C)	: 3.35
Oxidizer	: No
Pyrophoric material	: No

10. Stability and reactivity

Chemical Stability	: Stable under normal temperature and conditions.
Thermal decomposition	: No decomposition if used according to specifications. Avoid impact, friction, heat, sparks, and electrostatic charges.
Conditions to avoid	: Avoid Static Discharge and dust generation.
Materials to avoid	: Strong Acids, Strong Bases (hydrolysis), Strong Oxidizing agents
Hazardous decomposition products	: Cyanide and Nitrogen oxides (NOx) may be released during thermal decomposition.
Hazardous Polymerization	: Not expected
Note	: Drying operations at the lowest temperatures possible

11. Toxicological information

a) Acute toxicity:

Acute toxicity: it causes irritation to the mucous membranes and upper respiratory tract.
It causes eye irritation.

b) Chronic effects:

Affects the Kidneys, eyes and liver.

RTECS#: QS3675000

LD50/LC50:

Acute Oral LD50 (Rat)	: 3530-3540 mg/kg
Acute Oral LD50 (Mouse)	: =2500 mg/kg
Acute Dermal LD50 (Rabbit)	: > 2000mg/kg
Acute Inhalation LC50	: No data available
Sensitization	: Not sensitizing
Skin corrosion/irritation	: No information is available.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitization	: No information is available.





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Germ cell Mutagenicity	:	No data is available.
Carcinogenicity	:	No data is available.
Reproductive toxicity	:	No data is available
STOT-single exposure	:	No data is available
STOT-repeated exposure	:	No data is available
Aspiration Hazards	:	No data is available

12. Ecological information

Fish Toxicity (Ecotoxicity):

Aquatic EC50 (24h) *Daphnia magna* > 1000 mg/L.
Aquatic LC50 (96h) *Poecilia reticulata* (guppy) > 1000 mg/L.
Aquatic EC50 (72h) *Scenedesmus subspicatus* > 1000 mg/L.

Algal toxicity: *Desmodesmus subspicatus* NOEC: 560 mg/l/72h.

Persistence and Degradability:

AEROBIC: Nicotinamide was determined to be readily biodegradable in an aerobic screening test recommended by the Department of Environment, Standing Committee of Analysis, UK(1).

ANAEROBIC: Nicotinamide was not degraded using an spore-forming rod (*Clostridia* sp.) bacteria isolated from Potomac River mud (1)

Bio accumulative potential (Predicted)

Not expected to bioconcentrate in aquatic species.

Mobility in soil:

This material is soluble in water. Its adsorption to soil and sediment should not be significant.

Other adverse effects

No data available.

13. Disposal considerations

P501: Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport information

14.1 Land transport (ADR/RID)

UN number Not dangerous goods
Class Not dangerous goods
Classification code Not dangerous goods
Packaging group Not dangerous goods
Labels Not dangerous goods

14.2 Inland waterway transport (ADN(R))

UN number Not dangerous goods
Class Not dangerous goods
Classification code Not dangerous goods
Packaging group Not dangerous goods
Labels Not dangerous goods

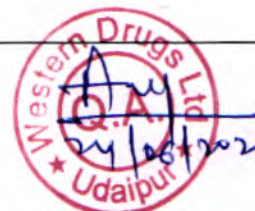
14.3 Marine transport (IMDG)

UN number Not dangerous goods
Proper shipping name and description
Chemical Name Not dangerous goods
Class Not dangerous goods
EmS number Not dangerous goods
Packaging group Not dangerous goods
Labels Not dangerous goods

14.4 Air transport ICAO/IATA

UN number Not dangerous goods
Proper shipping name and description Not dangerous goods
Chemical name Not dangerous goods
Class Not dangerous goods

Packaging group Not dangerous goods
Labels Not dangerous goods





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It is considered to be Non hazardous for transport by Road/Rail/Sea/Air and not regulated by ADR/RID/IMDG/IATA/ICAO/IMO.

Environmental hazards:

It is expected that this chemical is not a marine pollutant and is not Harmful to the Aquatic environment.

15. Regulatory information

European Union information

Safety Phrases:

S336/37/39: Wear suitable protective clothing, glove and eye/face protection.

Classification as per CLP Regulation 1272/2008:

Eye Irrit Cat.2

Hazard Statements: H319

US information

TSCA

CAS#98-92-0 is listed on the TSCA inventory.

WGK (Water Danger/Protection)

CAS#98-92-0: 0

Canada

CAS#98-92-0 is listed on Canada's DSL List.

CAS #98-92-0 is not listed on Canada's Ingredient Disclosure list.

16. Other information

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. users should make their own investigations to determine the suitability of the information for their particular purposes. In no way shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.

(a) Abbreviations and acronyms:

EC: European Community

EEC: European Economic Community

EU: European Union

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

NFPA: National Fire Protection Association

SCBA: Self Contained Breathing Apparatus

RTECS: Registry of Toxic Effects of Chemical Substances.

TSCA: Toxic Substances Control Act

DSL/NDSL: Domestic/Non Domestic Substances List

CLP: Classification, Labelling and packaging.

(b) Key Literature reference and sources for data

Biographical reference and data sources





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-CLP REG (regulation) (EC) no. 1272/2008, last modification by regulation (EC) no. 790/2009.
-DIR 67/548/EWG, last modification by DIR 2009/2/EC
-REG (EC) no. 1907/2006, last modification by REG (EC) Nr. 453/2009.

Internet
RTECS
ESIS

DISCLAIMER

Above mentioned data correspond to our present state of knowledge and experience and herein furnished without any kind of warranty. They serve as a description of the product with regards to necessary safety measures. Receiver of product has to observe existing laws and regulation in his own responsibility. The information contained herein may change without prior notice. Please pass this information on to competent authority.

----- (END OF MATERIAL SAFETY DATA SHEET) -----

