according to the Globally Harmonized System



Acetyl Methionine / L-Arginine hydrochloride / Hydroxocobalamin Acetate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

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 28.09.2024
 5459057-00010
 Date of first issue: 02.03.2020

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Acetyl Methionine / L-Arginine hydrochloride / Hydroxocobala-

min Acetate Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
N-Acetyl-DL-methionine	1115-47-5	>= 20 - < 30

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Acetatocobalamin 22465-48-1 < 0.1

4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air.

Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.

Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delaved

None known.

Protection of first-aiders

ction of first-aiders : No special precautions are necessary for first aid responders.

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Sulphur oxides Chlorine compounds

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment:

for firefighters

Wear self-contained breathing apparatus for firefighting if nec-

essary.

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

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gency procedures

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation

Use only with adequate ventilation.

Advice on safe handling : Handle in accordance with good industrial hygiene and safety

practice, based on the results of the workplace exposure as-

sessment

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labelled containers.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
N-Acetyl-DL-methionine	1115-47-5	TWA	2000 μg/m3 (OEB	Internal
			1)	
Acetatocobalamin	22465-48-1	TWA	10 μg/m3 (OEB 3)	Internal
		Wipe limit	100 μg/100 cm ²	Internal

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Engineering measures : Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-less

quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face contain-

ment devices).

Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : pink

Odour : No data available

according to the Globally Harmonized System



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Odour Threshold : No data available

pH : 5-7

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : Not applicable

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10. STABILITY AND REACTIVITY

: Not classified as a reactivity hazard. Reactivity Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

: None known. Conditions to avoid Incompatible materials : Oxidizing agents

products

Hazardous decomposition : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of: Inhalation

exposure Skin contact Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Components:

N-Acetyl-DL-methionine:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Remarks: Based on data from similar materials

LC50 (Rat): > 5.25 mg/l Acute inhalation toxicity

Exposure time: 4 h

Test atmosphere: dust/mist Method: OECD Test Guideline 403

Remarks: Based on data from similar materials

Acetatocobalamin:

LD50 Oral (Mouse): > 5,000 mg/kg Acute oral toxicity

Acute toxicity (other routes of:

administration)

LD50 (Mouse): > 2,000 mg/kg Application Route: Intravenous

LDLo (Mouse): 1.4 mg/kg

Application Route: Intraperitoneal

LDLo (Mouse): 2.7 mg/kg Application Route: Intravenous

Skin corrosion/irritation

Not classified based on available information.

Components:

N-Acetyl-DL-methionine:

Species Rabbit

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Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Acetatocobalamin:

Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Acetatocobalamin:

Remarks : No data available

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

N-Acetyl-DL-methionine:

Test Type : Buehler Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

Acetatocobalamin:

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

N-Acetyl-DL-methionine:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

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> cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Remarks: Based on data from similar materials

Acetatocobalamin:

Genotoxicity in vitro : Test Type: Mutagenicity (Escherichia coli - reverse mutation

assay)

Result: negative

Test Type: Ames test

Test system: Salmonella typhimurium

Result: negative

Test Type: Mutagenicity (Salmonella typhimurium - reverse

mutation assay) Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Acetatocobalamin:

Target Organs : Kidney, Liver

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

N-Acetyl-DL-methionine:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Method : OECD Test Guideline 408

Remarks : Based on data from similar materials

Acetatocobalamin:

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Species : Dog
LOAEL : 300 mg/kg
Application Route : Oral
Number of exposures : 3 days
Target Organs : Kidney, Liver

Symptoms : kidney effects, liver function change Remarks : May cause damage to organs.

Species : Dog
LOAEL : 75 mg/kg
Application Route : Intravenous
Number of exposures : 4 weeks
Target Organs : Kidney, Liver

Remarks : May cause damage to organs.

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Acetatocobalamin:

General Information : Symptoms: asthenia, Dizziness, Headache, Nausea, sinusitis

Remarks: The most common side effects are:

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

N-Acetyl-DL-methionine:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): > 1

ng/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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Remarks: Based on data from similar materials

Persistence and degradability

Components:

N-Acetyl-DL-methionine:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

N-Acetyl-DL-methionine:

Partition coefficient: noctanol/water log Pow: -0.313 Remarks: Calculation

Mobility in soil
No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

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15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 28.09.2024

Further information

Sources of key data used to compile the Safety Data

compile the Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

Date format : dd.mm.yyyy

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant: DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Trans-

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portation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IN / EN