SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: CYANOCOBALAMINE

Synonyms: Vitamin B12, Docemine

CAS-No.: 68-19-9

1.2. Relevant identified uses of the substance or mixture and uses advised against

Active ingredient for medical use.

Pharmacological activity:

Substance pharmacologically active. Hematopoietic vitamin.

1.3. Details of the supplier of the safety data sheet

Name : Sanofi

Street address : 54, rue La Boétie – 75008 Paris
FR

Telephone : +33153774000

Telefax : +33153774133

Safety data sheet prepared by: "Product Stewardship France" - Tel : 33 1 41 24 51 77 ProductStewardshipFrance@sanofi.com

1.4. Emergency telephone number : + 33 1 45 42 59 59 (ORFILA)

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture:

CLP/GHS Classification (REGULATION (EC) No 1272/2008)

Not a dangerous substance according to GHS.

DSD/DPD Classification (EU Directives 67/548/EEC or 1999/45/EC) [European Union]

R-phrase(s) -: -

2.2. Label elements:

CLP/GHS-Labelling (REGULATION (EC) No 1272/2008)

Hazard statements -: -

Precautionary statements

P260: Do not breathe vapours.
P262: Do not get in eyes, on skin, or on clothing.
P314: Get medical advice/ attention if you feel unwell.
P403 + P233: Store in a well-ventilated place. Keep container tightly closed.
P402: Store in a dry place.
P501: Dispose of contents/ container to an approved waste disposal plant.

DSD/DPD Labelling in accordance with 67/548/EEC or 1999/45/EC (European Union)

R-phrase(s)	-:	-
S-phrase(s)	S7/8:	Keep container tightly closed and dry.
	S15:	Keep away from heat.
	S22:	Do not breathe dust.
	S24/25:	Avoid contact with skin and eyes.

2.3. Other hazards:

Physical, chemical and toxicological hazards	:	May be irritating to eyes and skin. Low risk of dust explosion.
Environmental effects	:	Insufficient data for a correct assessment of environmental effects.

Sanofi hazard bands:

Hygiene	:	OEB 2 (approved)
Environment	:	EHB 2 (preliminary) Further information see chapter 16.

SECTION 3. Composition/information on ingredients

3.1. Substances:

Product Description	:	Co-alpha-[alpha-(5,6-dimethylbenzimidazolyl)]-Co-beta-cyanocobamide
CAS-No.	:	68-19-9
EINECS-No.	:	200-680-0
Molecular formula	:	C63 H88 Co N14 O14 P

SECTION 4. First aid measures

4.1. Description of first aid measures:

General advice	:	Take the victim out of the contaminated area. Remove contaminated clothing immediately and dispose of safely.
If inhaled	:	Move to fresh air. Make the victim blow his nose. Seek medical advice.
In case of skin contact	:	Rinse immediately with plenty of water for at least 15 minutes. If inflammation occurs, alert a physician.
In case of eye contact	:	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. In case of irritation consult an occulist.
If swallowed	:	Do not induce vomiting. Make the victim rinse his mouth with water. Seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms	:	Red urine coloration. Rash.

4.3. Indication of any immediate medical attention and special treatment needed

SECTION 5. Firefighting measures

5.1. Extinguishing media:

Suitable extinguishing media	:	All means (e.g. water, carbon dioxide, dry chemical extinguisher).
Unsuitable extinguishing media	:	Strong water jet.

5.2. Special hazards arising from the substance or mixture:

In case of fire, the product may emit toxic and/or irritating fumes.
Carbon monoxide and carbon dioxide
Nitrogen oxides (NOx)
Phosphorus compounds
Inorganic oxide(s) and carbonate(s)
Possible:
Hydrogen cyanide (HCN)

5.3. Advice for firefighters:

Special protective equipment	:	Use self-contained breathing apparatus. Wear full protective suit.
Further information	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Avoid discharging extinguishing water in the environment.

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:

Particle filter half mask, filter P3. Suitable gloves. Safety glasses. Work clothes.

6.2. Environmental precautions:

Avoid spreading of product.

6.3. Methods and materials for containment and cleaning up:

General advice	:	Sweep and shovel the solid product into a container specially adapted for its recovery or destroying (avoiding dust formation). Close and label thoroughly.
Cleaning of contaminated zone	:	After cleaning up the product, rinse the polluted area with water.
Elimination of recovered materials	:	Deliver to the Environmental service of the factory or to any specialized and approved disposal company.

6.4. Reference to other sections:

Additional advice:

Intervention of special services recommended.

SECTION 7. Handling and storage

7.1. Precautions for safe handling:

Advice on safe handling (industrial scale)	:	Local ventilation and emission point dust extraction. Take precautionary measures against electrostatic loading. Earth vessels and equipment well.
Advice on safe handling (laboratory scale)	:	Handling in a hood recommended.

7.2. Conditions for safe storage, including any incompatibilities:

Requirements for storage rooms and vessels	:	Keep in a cool, well-ventilated place.
Advice on common storage	:	Keep away from chemicals as it is a pharmaceutical substance
Further information on storage conditions	:	Keep in a well closed container, away from moisture and light. Handle under dehydrated area.
Storage temperature	:	Keep at ambient temperature.
Advised packaging material	:	Glass, plastic, stainless steel, aluminium.
Standard packaging	:	Polyethylene bag in metal drum packaging. Aluminium drum.

Sensitivity

Light	:	The product is sensitive to light.
Humidity	:	Hygroscopic.

7.3. Specific end use(s):

SECTION 8. Exposure controls/personal protection

8.1. Control parameters:

Occupational Exposure Limits:

OEL-8h (Sanofi):	:	300 µg/m3
Remarks	:	(approved)

Sanofi hazard bands-Hygiene : OEB 2 (approved)

Further information see chapter 16.

8.2. Exposure controls:

Personal protection equipment

(IMPORTANT: to be adapted following the workplace risk assessment.)

Industrial workplace

Respiratory protection	:	Particle filter (P3) half mask recommended.
Hand protection	:	Suitable gloves. Glove material : Nitrile rubber Layer thickness : 0,11 mm Break through time: > 480 min

Eye/face protection	:	Safety glasses.
Body protection	:	Work clothes.
Hygiene measures	:	Wash hands.

Laboratory

Respiratory protection	:	Handling in a hood recommended.
Hand protection	:	Suitable gloves recommended.
Eye/face protection	:	Safety glasses.
Body Protection	:	Working clothes.
Hygiene measures	:	Wash hands.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Physical state	:	Solid
Form	:	crystalline, powder
Colour	:	dark red
Odour	:	odourless
Molar mass	:	1.355,55 g/mol
Melting point	:	> 300 °C
Flash point	:	Not applicable.
Ignition temperature	:	> 400 °C
Thermal decomposition	:	200 °C Method: under nitrogen 150 °C Method: under oxygen
Minimum ignition energy	:	300 < MIE < 1000 mJ (low sensitivity to ignition).
Pmax (maximum pressure)	:	9,4 bar
Dust explosion class	:	St1
Vapour pressure	:	No data available.
Density	:	No data available.
Bulk density	:	300 - 500 kg/m3
Solubility in water	:	12,5 g/l Sparingly soluble in water.

Soluble in other solvents (nonaquatic)	:	Ethanol: slightly soluble Acetone: practically insoluble Chloroform insoluble Diethylether insoluble
Octanol/water partition coefficient	:	log(Pow): -2,6

9.2. Other information:

SECTION 10. Stability and reactivity

Safety remarks	:	Low risk of dust explosion.
10.1. Reactivity	:	No data available.
10.2. Chemical stability	:	No data available.
10.3. Possibility of hazardous reactions	:	With strong oxidizing agents.
10.4. Conditions to avoid	:	No data available.
10.5. Incompatible materials	:	No data available.
10.6. Hazardous decomposition products	:	Supposed thermal decomposition/oxidation: Carbon monoxide and carbon dioxide Nitrogen oxides (NOx) Phosphorus compounds Inorganic oxide(s) and carbonate(s) Possible in traces: Hydrogen cyanide (HCN) Further information see chapter 16.

SECTION 11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Acute oral toxicity (LD50)	:	> 5.000 mg/kg Species: mouse
Acute intravenous toxicity (IV) (LD50)	:	2.000 mg/kg Species: mouse
Skin corrosion/irritation	:	No experimental data available. No cases reported at workplace. May be irritating to human skin.

Serious eye damage/-irritation	:	Non-irritant. Species: rabbit May be irritating to human eyes.
Respiratory or skin sensitisation	:	Rare cases of hypersensitivity reactions.
Specific target organ toxicity (STOT) - Single exposure	:	No data available.
Aspiration hazard	:	Not applicable.

Chronic/Long-term toxicity

Germ cell mutagenicity	:	Ames test negative.
Carcinogenicity	:	No data available.
Reproductive toxicity	:	No data available.
Specific target organ toxicity (STOT) - repeated exposure	:	No data available.

Further information:

Pharmacological activity	:	Substance pharmacologically active. Hematopoietic vitamin.
Other toxicity data	:	Red urine coloration.

SECTION 12. Ecological information

12.1. Toxicity:

Acute invertebrates toxicity (EC50)	:	> 100 mg/l Species: Daphnia magna Exposure duration: 48 h

12.2. Persistence and degradability:

Biological degradability	:	5 % Slightly biodegradable.

12.3. Bioaccumulative potential:

Bioaccumulation	:	Unlikely to be bioaccumulable in living organisms (Log Pow < 4).

12.4. Mobility in soil:

Behaviour in environmental compartments	:	No data available.

12.5. Results of PBT and vPvB assessment:

Results of PBT and vPvB assessment	:	No data available.

12.6. Other adverse effects:

Note	:	Ecological data insufficient for a precise risk assessment. Do not release material and cleaning waters into the environment.
Sanofi hazard bands-Environment	:	EHB 2 (preliminary) Further information see chapter 16.

SECTION 13. Disposal considerations

13.1. Waste treatment methods:

Product	:	Deliver to the Environmental service of the factory or to any specialized and approved disposal service.
Uncleaned packaging	:	Deliver to the Environmental service of the factory or to any specialized and approved disposal service. Recycling possible after cleaning.

SECTION 14. Transport information

Land transport

ADR: Not classified as dangerous in the meaning of transport regulations.

Sea transport

IMDG: Not classified as dangerous in the meaning of transport regulations.

Air transport

IATA: Not classified as dangerous in the meaning of transport regulations.

SECTION 15. Regulatory information

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

15.2. Chemical Safety Assessment:

SECTION 16. Other information

Version : 2.6 Revision date 08.04.2015

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Note: major information modified since the last version of the sheet is marked by a vertical line in front of the relevant change.

Definition of Sanofi-OEB:
OEB is the occupational exposure band with the following levels (solids - a similar but distinct scale is used for liquids, named OEB V):

Occupational Exposure Band	Occupational Exposure Level
OEB 1	> 1000 µg/m³
OEB 2	100 - 1000 µg/m³
OEB 3	10 – 100 µg/m³
OEB 4	1 – 10 µg/m³
OEB 5	< 1 µg/m³

Additional notations may be applied as suffixes to the OEL/OEB and are used to communicate additional information that is not directly indicated by the OEL/OEB classifications. This information is necessary to perform an efficient risk assessment and determine the correct exposure controls. The meanings of the suffixes is explained in this way:

Notation/Suffixes	Danger
G1	Reprotoxic hazard for pregnant women. Exposure below the OEL is acceptable.
G2	Reprotoxic hazard for pregnant women. Exposure even below the OEL is not acceptable.
Sr	Respiratory sensitization hazard with serious potential consequences (anaphylactic reactions).
Sk	Specific dermal hazard (High dermal absorption / Danger of skin sensitization).
Cor	Corrosive compound - Important dermal and ocular hazard If corrosive compounds.

Definition of SHB and EHB:
Substances are classified on a scale from 1, the less hazardous, to 5, the most hazardous, according to their safety properties, eg explosivity, flammability, etc. (SHB) and ecotoxicological properties, eg persistance, ecotoxicity (EHB)