Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 28.06.2022 Version number 1 Revision: 28.06.2022

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

· **1.1 Product identifier**

· **Trade name: Cyanokit®**
· **CAS Number:**
13422-51-0
· **EC number:**
236-533-2
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
For hospital use only.
· **Application of the substance / the preparation :** Powder for solution for infusion

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
SERB Speciality Pharmaceuticals
40, Avenue Georges V
75008 PARIS
France
Tel : +33173032008
marc.haim@serb.eu
www.serb.eu
· **1.4 Emergency telephone number:**
France (INRS 24h/24) - Tel : +33 (0)1 45 42 59 59
Ireland - Tel : 00 353 1 8092568 - 00 353 1 8379964 (24h/24) EU Tel: 112
Belgium - Brüssel: +32 070/245 245
UK : Call NHS 999 in a medical emergency. If you urgently need medical help or advice but it's not a life-threatening situation, call 111 (24/7). The NHS 111 number is currently only available in certain areas. If you're outside of these areas, you should call NHS Direct on 0845 4647

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008 :**
The substance is not classified, according to the GB CLP regulation.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008** Not classified as hazardous
· **Hazard pictograms** Not classified as hazardous
· **Signal word** Not classified as hazardous
· **Hazard statements** Not classified as hazardous
· **Additional information:**
Restricted to professional users.
Keep out of the reach of children
· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

· **3.1 Chemical characterisation: Substances**
· **CAS No. Description**
CAS: 13422-51-0 Hydroxocobalamin
· **Identification number(s)**
· **EC number:** 236-533-2

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **After inhalation:** Provide fresh air; consult a doctor in case of medical complaints.
· **After skin contact:** Generally the product does not irritate the skin.
· **After eye contact:** Rinse opened eye for several minutes under running water.
· **After swallowing:** Do not induce vomiting; call for medical help immediately.
· **4.2 Most important symptoms and effects, both acute and delayed :**
No further relevant information available.
· **4.3 Indication of any immediate medical attention and special treatment needed :**
No further relevant information available.

SECTION 5: Firefighting measures

· **5.1 Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
· **5.2 Special hazards arising from the substance or mixture :** No further relevant information available.
· **5.3 Advice for firefighters**
· **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures :**
Avoid formation of dust.
· **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow the product to enter sewers/ surface water or ground water.
· **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
· **6.4 Reference to other sections :**
See Section 7 for information on safe handling.
See Section 8 for information on personal protective equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling :** No special precautions are necessary if used correctly.
· **Information about fire - and explosion protection:** No special measures required.

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· **7.2 Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **Recommended storage temperature:** 2-8°C
· **7.3 Specific end use(s) :** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**
· **Additional information about design of technical facilities:** No further data; see section 7.
· **Ingredients with limit values that require monitoring at the workplace:** Not required.
· **Additional information:**
The most current valid lists have been used as a basis for the production of this document.

· **8.2 Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
· **Respiratory protection:** Not required.
· **Protection of hands:** Not required.
· **Gloves material : -**
· **Eye protection:** Not required.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**

Form:	Crystalline powder
Colour:	Dark red
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gas):**	Product is not flammable.
· **Ignition temperature:**	Not applicable.

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· **Decomposition temperature:**	Not determined.
· **Auto-ignition temperature:**	Not determined.
· **Explosive properties:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapour pressure:**	Not applicable.
· **Density:**	Not determined.
· **Relative density :**	Not determined.
· **Vapour density :**	Not applicable.
· **Evaporation rate :**	Not applicable.
· **Solubility in / Miscibility with water:**	Fully miscible.
· **Segregation coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Kinematic:	Not applicable.
COV (CH) :	0.00 %
· **9.2 Other information :**	No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions :** No dangerous reactions known.
· **10.4 Conditions to avoid :** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.
· **Primary irritant effect:**
· **On the skin:** Based on available data, the classification criteria are not met.
· **On the eyes:** Based on available data, the classification criteria are not met.

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· **Respiratory or skin sensitization** Based on available data, the classification criteria are not met.
· **Additional toxicological information:**
· **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity** Based on available data, the classification criteria are not met.
· **STOT-single exposure** Based on available data, the classification criteria are not met.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **12.2 Persistence and degradability :** No further relevant information available.
· **12.3 Bioaccumulative potential :** No further relevant information available.
· **12.4 Mobility in soil :** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Other adverse effects :** No further relevant information available.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation :**



Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

· **14.1 UN-Number**
· **ADR, IMDG, IATA** Not classified as hazardous for transport
· **14.2 UN proper shipping name**
· **ADR, IMDG, IATA** Not classified as hazardous for transport

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· **14.3 Transport hazard class(es)**

· **ADR, ADN, IMDG, IATA**	
· **Class**	Not classified as hazardous for transport
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	Not classified as hazardous for transport
· **14.5 Environmental hazards:**	Not applicable.
· **14.6 Special precautions for user**	Not applicable.
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Not classified as hazardous for transport

SECTION 15: Regulatory information

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

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** Substance is not listed.
· **Seveso category** Not concerned
· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

Substance is not listed.

· **REGULATION (EU) 2019/1148**
· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

Substance is not listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

Substance is not listed.

· **Regulation (EC) No 273/2004 on drug precursors**

Substance is not listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

Substance is not listed.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances

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CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative