



MATERIAL SAFETY DATA SHEET

Date of card preparation: 12.03.2008

Date of card update: 05.12.2011

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

1.1. Product identifier

PRESTIGE 24i HbA_{1C} DIRECT (Version 24) (catalogue N° 4-300)
PRESTIGE 24i HbA_{1C} DIRECT (Version 36) (catalogue N° 4-301)
ACCENT-300 HbA_{1C} DIRECT (catalogue N° 7-110)
ACCENT-200 HbA_{1C} DIRECT (catalogue N° 7-111)
HC-HbA_{1C} DIRECT (catalogue N° 4-595)
A-400 HbA_{1C} DIRECT (catalogue N° 7-112)
CORMAY HbA_{1C} DIRECT 500 (catalogue N° 1-310)
CORMAY HbA_{1C} DIRECT "bulk" (catalogue N° 1-257)
OS-HbA_{1C} DIRECT (catalogue N° 9-457)
BIOLIS 12i HbA_{1C} DIRECT (catalogue N° 4-628)

The sets: PRESTIGE 24i PRESTIGE 24i HbA_{1C} DIRECT, HC- HbA_{1C} DIRECT, ACCENT-300 HbA_{1C} DIRECT, ACCENT-200 HbA_{1C} DIRECT, A-400 HbA_{1C} DIRECT, CORMAY HbA_{1C} DIRECT 500, CORMAY HbA_{1C} DIRECT "bulk", OS-HbA_{1C} DIRECT, BIOLIS 12i HbA_{1C} DIRECT are designed for Health Service laboratories for determination of haemoglobin A_{1C} concentration.

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

Laboratory reagents. For professional use only.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

PZ CORMAY S.A.
ul. Wiosenna 22
05-092 ŁOMIANKI

phone/fax. (0-22) 751 79 10, 751 79 14

between: 8 am and 4 pm

e-mail: msds@cormay.pl

1.4. Emergency telephone number

Emergency telephone number: 112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

This mixture is not classified as hazardous.

2.2. Label elements

The mixture do not require to be labeled as hazardous.

2.3. Other hazards

This mixture do not meet the criteria for PBT and vPvB.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

1-REAGENT- latex material, 2a, 2b REAGENT, HEMOLYSING REAGENT

sodium azide

Contains: < 0.09%

CAS number: 26628-22-8

EC number: 247-852-1

Index number: 011-004-00-7

Registration number: not available

Classification according to EU Directives 67/548/EEC or 1999/45/EC:

T+; R 28

N; R 50/53

R 32

Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]:

Acute Tox. 2, H300

Aquatic Acute 1, H400

Aquatic Chronic 1, H410

EUH032

The full text of R and H phrases is given in section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

After exposure by respiratory passages: fresh air. Call in physician.

After skin contamination: wash off with plenty of water. Take off the contaminated clothing.

After contamination of eyes: rinse out with plenty of water for at least 15 minutes with the eyelid held wide open.

After consumption: give the sufferer a large amount of water to drink. If the sufferer feels unwell, consult a doctor.

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

No data available.

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

No data available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

The mixture is inflammable.
In case of fire use extinguishing media suitable for materials stored in immediate vicinity. Water, CO₂, dry powder can be used as the extinguish medium.
No data about do not recommended extinguishing media.

5.2. Special hazards arising from the substance or mixture

There is no data about hazardous substances which may occur during fire thermal decomposition of the mixture.

5.3. Advice for firefighters

The rescuers must be equipped with protective clothing and respiratory tract isolating equipment, irrespective of ambient air (in the case of large fire).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Avoid contamination with the preparation.
Notify the neighbourhood of the breakdown.
Do not inhale vapours/ aerosols.
Secure the flow of fresh air into closed rooms.
Avoid contact of the mixture with skin and eyes.
Remove contaminated clothing and wash before reuse.

6.1.2. For emergency responders

Wear protective clothing and rubber gloves.

6.2. Environmental precautions

Dilute with plenty of water. Avoid entering the product into drains, surface water and groundwater, reservoirs and waterways.

6.3. Methods and material for containment and cleaning up

Collect small quantities with the use of an absorbing agent (sand, diatomite, acid binders, universal binders, sawdust), rinse with large amount of water if necessary. Provide material collected for recycling.

6.4. Reference to other sections

Use the control measures and personal protective equipment described in section 8 of this card. The released material to follow the rules described in section 13 of this MSDS - Disposal consideration.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

While working with the preparation, one should use appropriate means of personal protection (see pt. 8).
Avoid contact of the preparation with skin and eyes, as well as inhaling its mists.
Secure efficient local ventilation.

Industrial hygiene:

You must not have meals, drink, or smoke tobacco while working with the preparation, except in places designed for that purpose. Wash your hands after work with the substance carefully with soapy water. Apply skin-protective barrier cream.

7.2. Conditions for safe storage, including any incompatibilities

In accordance with the norms generally accepted for chemicals in laboratories.
Store in original manufacturer containers.
Hermetically closed. In temperature from +2°C to +8°C.
Protect containers from damage.
Keep away from food and animal feed.

7.3. Specific end use(s)

No data available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Contains substances with the applicable occupational exposure limits in the workplace.

Data for sodium azide:

	Limit value - Eight hours		Limit value - Short term	
	ppm	mg/m ³	ppm	mg/m ³
Austria		0,1		0,3
Belgium		0,1		0,3
Canada - Québec			0,11 (1)	0,3 (1)
Denmark		0,1		0,2
European Union		0,1		0,3
France		0,1		0,3
Germany (AGS)		0,2		0,4 (1)
Germany (DFG)		0,2 inhalable aerosol		0,4 inhalable aerosol
Hungary		0,1		0,3
Italy		0,1		0,3
Japan				
Poland		0,1		0,3
Singapore				
Spain		0,1		0,3
Sweden				
Switzerland		0,2 inhalable aerosol		0,4 inhalable aerosol
The Netherlands		0,1		0,3
USA - NIOSH			0,1 (1)	0,3 (2)
USA - OSHA				
United Kingdom		0,1		0,3

	Remarks
Canada - Québec	(1) Ceiling value
European Union	Bold-type: Indicative Occupational Exposure Limit Values [2,3] and Limit Values for Occupational Exposure [4] (for references see bibliography)
France	Bold type: Restrictive statutory limit values
Germany (AGS)	(1) 15 minutes average value
Germany (DFG)	STV 15 minutes average value
Italy	skin
Spain	skin
USA - NIOSH	(1) ceiling limit value (as HN3) (2) ceiling limit value (as NaN3)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No data available.

8.2.2. Individual protection measures, such as personal protective equipment

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

a) Eye / Face protection:

Avoid direct contact of the product with eyes use glasses.

b) skin protection:

- hand protection:

Avoid direct contact of the product with skin, immediately take off clothes soiled with the preparation and wash contaminated skin with soapy water, use personal protective, clothing and gloves:

c) Respiratory protection:

Apply in rooms with efficiently working ventilation, avoid inhaling product mists, respiratory tract-protective agents are not required.

d) Thermal hazards:

Not applicable.

8.2.3. Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

	REAGENT 1	REAGENT 2a, 2b	HEMOLYSING REAGENT
a) Appearance :- -The physical state : -Colour:	<i>clear liquid white suspension</i>	<i>clear liquid colourless</i>	<i>clear liquid colourless</i>
b) Odour:	<i>odourless</i>	<i>odourless</i>	<i>odourless</i>
c) Odour threshold :	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>
d) pH:	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>
e) Melting point/freezing point	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>
f) Initial boiling point and boiling range	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>
g) Flash point:	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>
h) Evaporation rate:	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>
i) Flammability (solid, gas)	<i>not applicable</i>	<i>not applicable</i>	<i>not applicable</i>
j) Upper/lower flammability or explosive limits :	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>
k) Vapour pressure :	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>
l) Vapour density :	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>
m) Relative density:	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>

n) Solubility(ies)	<i>miscible with water</i>	<i>miscible with water</i>	<i>miscible with water</i>
o) Partition coefficient: n-octanol/water	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>
p) Auto-ignition temperature	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>
q) Decomposition temperature:	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>
r) Viscosity :	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>
s) Explosive properties:	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>
t) Oxidising properties :	<i>no data available</i>	<i>no data available</i>	<i>no data available</i>

9.2. Other information

No other relevant information.

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is stable in conditions provided by the manufacturer.

10.2. Chemical stability

The product is stable when normal handling in accordance with conditions provided by the manufacturer.

10.3. Possibility of hazardous reactions

Not known.

10.4. Conditions to avoid

The product is stable in conditions provided by the manufacturer. Avoid light and heat.

10.5. Incompatible materials

Heavy metals, metal salts, acids.

10.6. Hazardous decomposition products

In the case of fire – nitrose gases.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

No data for the mixture. Toxicological problems should not be expected if the product were used and applied appropriately. The product should be handled with the care usual when dealing with chemicals. The mixture toxicity evaluation is based on evaluation of the toxicity of particular components.

a) acute toxicity:

Data for sodium azide

LD₅₀ (oral, rat) – 27 mg/kg

LC₅₀ (inhalation, rat) - 37 mg/m³

Remarks: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste):Eye:Other.

Behavioral: Convulsions or effect on seizure threshold. Lungs, Thorax, or Respiration: Structural or functional change in trachea or bronchi.

LD₅₀ (dermal, rabbit)- 20 mg/kg

b) irritation:

No data available.

c) corrosivity:

No data available.

d) sensitisation:

No data available.

e) repeated dose toxicity:

No data available.

f) carcinogenicity:

No data available.

g) mutagenicity:

No data available.

h) toxicity for reproduction:

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Quantitative data on the ecological effect of this mixture are not available. The mixture toxicity evaluation is based on evaluation of the toxicity of particular components.

Ecotoxicity:

Data for sodium azide

Fish toxicity (*Lepomis macrochirus*) – LC₅₀ - 0.68 mg/l – 96 h

Daphnia toxicity (*Daphnia pulex*) EC₅₀ – 4.2 mg/l - 48 h

Ecological problems should not be expected if you use and apply the product appropriately.

Further ecological data:

Do not allow for penetration into waters, sewage or soil.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product:

Chemical residues, in general, are included into special waste. Disposing of the latter is regulated by appropriate laws and ordinances. We recommend contacting the appropriate authorities, or waste disposal enterprises that will advise you on how to dispose of special waste.

Packing:

Remove in accordance with official regulations. Treat contaminated packages in the same way as the substance itself. If the regulations do not provide otherwise, non-contaminated packages can be treated like household waste or forward them to be utilized.

SECTION 14: Transport information

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

No limits.

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 73/78 and the IBC Code

Not applicable.

SECTION 15: Regulatory information

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

Material Safety Data Sheet was prepared in accordance with:

The EC Directive Nr UE2001/58/WE, the EC Directive Nr 1999/45/EG, the EC Directive 67/548 EEC, EC Directive 88/379/EEC or the EC Directive 91/155/EEC (Dangerous Product Regulations incl. EC Guidelines). Regulation (EC) No 1907/2006 of European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (attachment II)
See Polish regulations.

15.2. Chemical safety assessment

Chemical safety assessment has been no carried out for the product.

SECTION 16: Other information

Relevant R-phrases:

R 28 - Very toxic if swallowed.

R 50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R 32 - Contact with acids liberates very toxic gas.

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

EUH032 - Contact with acids liberates very toxic gas.

The foregoing information is based on the present state of our knowledge. It characterizes the product with respect to the appropriate safety measures. They do not guarantee the properties of the product.

We do not take responsibility for damage and losses that may result from inappropriate use of the mixture.

Reason of changes:

Extend the offer.

The format of the MSDS has been changed in accordance with guidelines of the Commission Regulation (EU) No 453/2010.