

MATERIAL SAFETY DATA SHEET

Date of issue: 21.09.2023

Version: 01

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

1.1. Product identifier

AURYX 90 Total β -hCG Reagent Kit (Cat. No I20-R0081)
AURYX 90 Total β -hCG Reagent Kit (Cat. No I20-R0082)

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

Identified uses: Laboratory reagents. For professional use only.

Uses advised against: No uses advised against have been identified.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

PZ CORMAY S.A.
Wiosenna 22
05-092 Łomianki
Poland
phone: +48 22 751 79 10
fax +48 22 751 79 11

E-mail address of the person responsible for the safety data sheet: msds@cormay.com

1.4. Emergency telephone number

The local/in-country emergency telephone number.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP):

MB, RB, RA, DS, Calibrator (High), Calibrator (Low), Control Material (High), Control Material (Low)
Skin Sens. 1A, H317

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP):



MB, RB, RA, DS, Calibrator (High), Calibrator (Low), Control Material (High) and Control Material (Low) contain reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Signal word:

Warning

Hazard statement(s):

H317 May cause an allergic skin reaction.

Precautionary statement(s):

P280 Wear protective gloves, protective clothing, eye protection or face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

2.3. Other hazards

The mixture does not contain any substances meeting the criteria for PBT or vPvB in accordance with Annex XIII of REACH in its current version.

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

MB, RB, RA, DS, Calibrator (High), Calibrator (Low), Control Material (High), Control Material (Low)

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Contains: < 0.0025 %

CAS number: 55965-84-9
EC number: -
Index number: 613-167-00-5
Registration number: 01-2120764691-48-XXXX

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

Acute Tox. 3, H301
Acute Tox. 2, H310
Skin Corr. 1C; H314
Eye Dam. 1, H318
Skin Sens. 1A, H317
Acute Tox. 2, H330
Aquatic Acute 1, H400
Aquatic Chronic 1, H410
EUH071

Specific concentration limits:

Eye Dam. 1; H318: $C \geq 0.6 \%$
Eye Irrit. 2; H319: $0.06 \% \leq C < 0.6 \%$
Skin Corr. 1C; H314: $C \geq 0.6 \%$
Skin Irrit. 2; H315: $0.06 \% \leq C < 0.6 \%$
Skin Sens. 1A; H317: $C \geq 0.0015 \%$

M-Factor:

M=100
M(Chronic)=100

The full text of H phrases is given in section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: In case of any disorder, get medical advice and show the package or label.

If inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration. If symptoms occur, consult a physician.

In case of skin contact: Wash contaminated skin immediately with plenty of soap and water. Remove contaminated clothing immediately.

In case of eye contact: Wash thoroughly eyes with plenty of water for at least 15 minutes. If irritation remains, seek medical help.

If swallowed: Rinse mouth with water. Consult a doctor if symptoms occur.

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

In the case of fire use extinguishing media suitable for materials stored in immediate vicinity. Water, CO₂, dry powder can be used as the extinguish media.
No data available on resources not recommended for firefighting.

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 mixture.
- Notify the effected individuals of the emergency, to be aware of the issues associated.
- 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 mixture 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.
Dispose of the collected material to a company with a waste management permit.

6.4. Reference to other sections

Use the control measures and personal protective equipment described in section 8 of this MSDS.
Refer to section 13 of this MSDS for adequate release measures.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

While working with the mixture, one should use appropriate means of personal protection (see pt. 8).

Avoid contact of the mixture with skin and eyes, as well as inhaling its mists.

Secure efficient local ventilation.

Industrial hygiene:

Eating, drinking or smoking of tobacco is prohibited while working with the mixture, except for places specially designated for this purpose.

Wash your hands after work with the mixture 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.

Store in closed containers at temperatures compatible with the information provided on the label.

Protect containers from damage.

Do not store with food or animal feed.

7.3. Specific end use(s)

No information on uses other than those listed in section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No exposure limit value known.

Data for reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Derived No Effect Level (DNEL):

Worker	Long term exposure - Local effect, Inhalation	0.02 mg/m ³
	Short term exposure - Local effect, Inhalation	0.04 mg/m ³

Predicted No Effect Concentration (PNEC):

water		STP	sediment		soil
freshwater	marine water		freshwater	marine water	
3.39 µg/l	3.39 µg/l	0.23 mg/l	0.027 mg/kg sediment dw	0.027 mg/kg sediment dw	0.01 mg/kg soil dw

8.2. Exposure controls

Observe general health and safety rules. Do not eat, drink or smoke while working. Wash hands before breaks and at the end of work. Use personal protective equipment.

a) Eye/Face protection:

Avoid direct contact of the mixture with eyes, use glasses as a protection.

b) Skin/Hand protection:

Avoid direct contact of the mixture with skin, immediately take off clothes soiled with the mixture 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 the mixture mists, respiratory tract-protective agents are not required.

d) Thermal hazards:

Thermal hazards have not been identified.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

	MB	RB
a) Physical state:	<i>liquid</i>	<i>liquid</i>
b) Colour:	<i>brown</i>	<i>colourless or light yellow</i>
c) Odour:	<i>odourless</i>	<i>odourless</i>
d) Melting point/freezing point:	<i>no data available</i>	<i>no data available</i>
e) Boiling point or initial boiling point and boiling range:	<i>no data available</i>	<i>no data available</i>
f) Flammability:	<i>not inflammable</i>	<i>not inflammable</i>
g) Lower and upper explosion limit:	<i>no data available</i>	<i>no data available</i>
h) Flash point:	<i>no data available</i>	<i>no data available</i>
i) Auto-ignition temperature:	<i>no data available</i>	<i>no data available</i>
j) Decomposition temperature:	<i>no data available</i>	<i>no data available</i>
k) pH:	<i>7.0-7.5</i>	<i>7.0-7.5</i>
l) Kinematic viscosity:	<i>no data available</i>	<i>no data available</i>
m) Solubility:	<i>soluble in water</i>	<i>soluble in water</i>
n) Partition coefficient n-octanol/water (log value):	<i>no data available</i>	<i>no data available</i>
o) Vapour pressure:	<i>no data available</i>	<i>no data available</i>
p) Density and/or relative density:	<i>1.05 g/cm³ (25°C)</i>	<i>1.05 g/cm³ (25°C)</i>
q) Relative vapour density:	<i>no data available</i>	<i>no data available</i>
r) Particle characteristics:	<i>not applicable</i>	<i>not applicable</i>

	RA	DS
a) Physical state:	<i>liquid</i>	<i>liquid</i>
b) Colour:	<i>colourless or light yellow</i>	<i>colourless or light yellow</i>
c) Odour:	<i>odourless</i>	<i>odourless</i>
d) Melting point/freezing point:	<i>no data available</i>	<i>no data available</i>
e) Boiling point or initial boiling point and boiling range:	<i>no data available</i>	<i>no data available</i>
f) Flammability:	<i>not inflammable</i>	<i>not inflammable</i>
g) Lower and upper explosion limit:	<i>no data available</i>	<i>no data available</i>
h) Flash point:	<i>no data available</i>	<i>no data available</i>
i) Auto-ignition temperature:	<i>no data available</i>	<i>no data available</i>
j) Decomposition temperature:	<i>no data available</i>	<i>no data available</i>
k) pH:	<i>7.0-7.5</i>	<i>7.0-7.5</i>
l) Kinematic viscosity:	<i>no data available</i>	<i>no data available</i>
m) Solubility:	<i>soluble in water</i>	<i>soluble in water</i>
n) Partition coefficient n-octanol/water (log value):	<i>no data available</i>	<i>no data available</i>
o) Vapour pressure:	<i>no data available</i>	<i>no data available</i>
p) Density and/or relative density:	<i>1.05 g/cm³ (25°C)</i>	<i>1.05 g/cm³ (25°C)</i>
q) Relative vapour density:	<i>no data available</i>	<i>no data available</i>
r) Particle characteristics:	<i>not applicable</i>	<i>not applicable</i>

	Calibrator (High) Calibrator (Low)	Control Material (High) Control Material (Low)
a) Physical state:	<i>liquid</i>	<i>liquid</i>
b) Colour:	<i>colourless or light yellow</i>	<i>colourless or light yellow</i>
c) Odour:	<i>odourless</i>	<i>odourless</i>
d) Melting point/freezing point:	<i>no data available</i>	<i>no data available</i>
e) Boiling point or initial boiling point and boiling range:	<i>no data available</i>	<i>no data available</i>
f) Flammability:	<i>not inflammable</i>	<i>not inflammable</i>
g) Lower and upper explosion limit:	<i>no data available</i>	<i>no data available</i>
h) Flash point:	<i>no data available</i>	<i>no data available</i>
i) Auto-ignition temperature:	<i>no data available</i>	<i>no data available</i>
j) Decomposition temperature:	<i>no data available</i>	<i>no data available</i>
k) pH:	<i>7.0-7.5</i>	<i>7.0-7.5</i>
l) Kinematic viscosity:	<i>no data available</i>	<i>no data available</i>
m) Solubility:	<i>soluble in water</i>	<i>soluble in water</i>
n) Partition coefficient n-octanol/water (log value):	<i>no data available</i>	<i>no data available</i>
o) Vapour pressure:	<i>no data available</i>	<i>no data available</i>
p) Density and/or relative density:	<i>1.05 g/cm³ (25°C)</i>	<i>1.05 g/cm³ (25°C)</i>
q) Relative vapour density:	<i>no data available</i>	<i>no data available</i>
r) Particle characteristics:	<i>not applicable</i>	<i>not applicable</i>

9.2. Other information

No other relevant information.

SECTION 10: Stability and reactivity

10.1. Reactivity

The mixture is stable in conditions provided by the manufacturer.

10.2. Chemical stability

The mixture is stable when normal handling and with anticipated warehousing and storage conditions.

10.3. Possibility of hazardous reactions

Not known.

10.4. Conditions to avoid

The mixture is stable in conditions provided by the manufacturer. Avoid heat.

10.5. Incompatible materials

Not known.

10.6. Hazardous decomposition products

Not known. In the event of fire: see section 5.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicity of the mixture:

a) acute toxicity:

ATE_{mix}(oral) > 2000

ATE_{mix}(skin) >2000

ATE_{mix}(inhalation) >20

b) skin corrosion/irritation:

Based on available data, the classification criteria are not met.

c) serious eye damage/irritation:

Based on available data, the classification criteria are not met.

d) respiratory or skin sensitisation:

MB, RB, RA, DS, Calibrator (High), Calibrator (Low), Control Material (High), Control Material (Low):
May cause an allergic skin reaction.

e) germ cell mutagenicity:

Based on available data, the classification criteria are not met.

f) carcinogenicity:

Based on available data, the classification criteria are not met.

g) reproductive toxicity:

Based on available data, the classification criteria are not met.

h) STOT-single exposure:

Based on available data, the classification criteria are not met.

i) STOT-repeated exposure:

Based on available data, the classification criteria are not met.

j) aspiration hazard:

Based on available data, the classification criteria are not met.

11.2 Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 12: Ecological information

12.1. Toxicity

No ecotoxicological studies conducted for the entire mixture.

Ecotoxicity effects of the mixture:

MB, RB, RA, DS, Calibrator (High), Calibrator (Low), Control Material (High), Control Material (Low):
The mixture is not classified as hazardous to the aquatic environment.

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

The mixture does not contain any substances meeting the criteria for PBT or vPvB in accordance with Annex XIII of REACH in its current version.

12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7 Other adverse effects

No other adverse effect have been identified.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Transfer waste to a company with a waste management permit. Avoid releasing to the drains and to the environment.

Reagent	Waste classification	UE waste code reagent	UE waste code direct packaging
MB	hazardous	18 01 06*	15 01 10*
RB	hazardous	18 01 06*	15 01 10*
RA	hazardous	18 01 06*	15 01 10*
DS	hazardous	18 01 06*	15 01 10*
Calibrator (High)	hazardous	18 01 03*	18 01 03*
Calibrator (Low)	hazardous	18 01 03*	18 01 03*
Control Material (High)	hazardous	18 01 03*	18 01 03*
Control Material (Low)	hazardous	18 01 03*	18 01 03*

List of Waste referred to in Article 7 of Directive 2008/98/EC:

15 01 10* packaging containing residues of or contaminated by hazardous substances

18 01 03* wastes whose collection and disposal is subject to special requirements in order to prevent infection

18 01 06* chemicals consisting of or containing hazardous substances

SECTION 14: Transport information

14.1. UN number or ID 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. Maritime transport in bulk according to IMO instruments

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:

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance) in its current version.

Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance) in its current version.

Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance) in its current version.

Commission Regulation (EU) No 1357/2014 of 18 December 2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives (Text with EEA relevance) in its current version.

Council regulation (EU) 2017/997 of 8 June 2017 amending Annex III to Directive 2008/98/EC of the European Parliament and of the Council as regards the hazardous property HP 14 'Ecotoxic' (Text with EEA relevance) in its current version.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance) in its current version.

15.2. Chemical safety assessment

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

SECTION 16: Other information

Full text of abbreviations and acronyms:

PBT - persistent, bioaccumulative and toxic substances
vPvB - very persistent and very bioaccumulative substances

Acute Tox. 2 - Acute toxicity (category 2)
Acute Tox. 3 - Acute toxicity (category 3)
Skin Corr. 1C - Skin corrosion (category 1C)
Skin Irrit. 2 - Skin irritation (category 2)
Eye Dam. 1 - Serious eye damage (category 1)
Eye Irrit. 2 - Serious eye irritation (category 2)
Skin Sens. 1A - Skin sensitization (category 1A)
Aquatic Acute 1 - Hazardous to the aquatic environment – acute hazard (category 1)
Aquatic Chronic 1 - Hazardous to the aquatic environment – chronic hazard (category 1)

Text of H-code(s):

H301 - Toxic if swallowed.
H310 - Fatal in contact with skin.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H319 - Causes serious eye irritation.
H330 - Fatal if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.
EUH071 - Corrosive to the respiratory tract.

Methods of evaluating information for the purpose of classification: calculation method.

Key literature references and data sources: the material safety data sheet for the mixture have been prepared on the basis of safety data sheets for individual components of the mixture, data from the ECHA website and the available knowledge and experience, taking into account the current legislation.

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

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