* 1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name R2 Start-Reagent

Article number 55055R2

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

Application of the substance / the mixture Diagnostic reagent

Kit component

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier Pentapharm AG

Dornacherstrasse 112

CH- 4147 Aesch BL / Switzerland

Phone +41 61 706 48 48 Fax +41 61 706 48 00

Further information obtainable from pentapharm@pentapharm.com

1.4 Emergency telephone number

Tox Info Suisse: +41 44 251 51 51 (24h; 7 days a week)

Information desk: +41 44 251 66 66

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008



Skin Sens. 1 H317 May cause an allergic skin reaction.

2.2 <u>Label elements</u>

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms



GHS07

Signal word

Warning

Hazard-determining components of labelling

Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1)

Hazard statements

H317 May cause an allergic skin reaction.

Precautionary statements

P280 Wear protective gloves.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: According to current knowledge, the product contains no PBT substance.

vPvB: According to current knowledge, the product contains no vPvB substance.

Determination of endocrine-disrupting properties

Taking into account the current state of scientific knowledge, no data on endocrine disrupting properties of the product are available.

3 Composition/information on ingredients

3.1 Mixtures

Description

Mixture of substances listed below with nonhazardous additions.

CAS: 55965-84-9	Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-	≥0.0015-
Index number: 613-167-00-5	7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1)	<0.0025%
	Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330;	
	Skin Corr. 1C, H314; Eye Dam. 1, H318; 🗞 Aquatic Acute 1,	
	H400 (M=100); Aquatic Chronic 1, H410 (M=100); ♦ Skin Sens.	
	1A, H317	
	Note: B	
	Specific concentration limits: Skin Corr. 1C; H314: C ≥ 0.6 %	
	Skin Irrit. 2; H315: 0.06 % ≤ C < 0.6 %	
	Eye Dam. 1; H318: C ≥ 0.6 %	
	Eye Irrit. 2; H319: 0.06% ≤ C < 0.6 %	
	Skin Sens. 1A; H317: C ≥ 0.0015 %	

SVHC

According to current knowledge no SVHC contained.

Additional information

For the wording of the listed hazard phrases refer to section 16.

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4 First aid measures

4.1 Description of first aid measures

General information

No special measures required.

After inhalation

Remove person to fresh air and keep comfortable for breathing.

If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

After skin contact

Wash with plenty of soap and water.

If skin irritation or rash occurs: Get medical advice/attention.

After eye contact

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

After swallowing

Immediately call a POISON CENTER/doctor.

4.2 <u>Most importance symptoms and effects, both acute and delayed</u>

May cause an allergic skin reaction.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents

CO2, foam, dry powder, or water.

5.2 Specific hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment

Wear self-contained respiratory protective device.

Wear protective clothing to prevent contact with skin and eyes.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes.

6.2 **Environmental precautions**

Do not allow product to reach sewage system or any water course.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binder, universal binders, sawdust). Clean the affected area carefully and ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes.

Information about fire - and explosion protection

No special measures required.

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

Store the product in a dry place protected from light at a temperature between 2°C to 8°C.

7.3 Specific end use(s)

No further relevant information available.

8 Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:	
55965-84-9 Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1)	
MAK (Switzerland)	Short-term value: 0.4 e mg/m³
	Long-term value: 0.2 e mg/m³
	S SSc;

Additional information

The lists valid during the making were used as basis.

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The professional use of this product by young people is restricted or prohibited altogether. The corresponding legal bases and precise regulations are set out in section 15.

8.2 Exposure controls

Appropriate engineering controls

No further data; see item 7.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

Ensure good ventilation/exhaustion at the workplace.

Avoid contact with the eyes and skin.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Respiratory protection

Use suitable respiratory protective device in case of insufficient ventilation.

Respiratory protection must be compliant with the specifications of Directive 2016/425 and be in accordance with the EN standards resulting thereof.

Protection of hands



Protective gloves

Material of gloves

Protective gloves must be compliant with the specifications to Directive 2016/425 and be in accordance with the standards EN374. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Eye/face protection



Safety glasses

Protective goggles must be compliant with the specifications of Directive 2016/425 and be in accordance with the standard EN166 (EU) or NIOSH (US).

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Environmental exposure controls Do not allow product to reach ground water, water course or sewage system.

9 Physical and chemical properties

9.1 <u>Information on basic physical and chemical properties</u>

General Information	
Physical state:	Fluid
Colour:	Clear
Odour:	Not determined.
Odour threshold:	Not determined.
Melting point/freezing point:	Not determined.
Boiling point or initial boiling point and boiling range:	Not determined.
Flammability:	Not determined.
Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	Not determined.
Ignition temperature:	Not determined.
Decomposition temperature:	Not determined.
pH at 20 °C:	8
Viscosity	
Kinematic:	Not determined.
Dynamic:	Not determined.
Solubility	
Water:	Fully miscible.
Partition coefficient n-octanol/water (log value):	Not applicable
Vapour pressure:	Not determined.
Density and/or relative density	
Relative density:	Not determined.
Vapour density:	Not determined.
Particle characteristics:	Not applicable

9.2 Other information

Appearance	
Form:	Liquid
Important Information on protection of health, environment and on safety	
Auto-ignition temperature:	The product is not self-igniting.

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Explosive properties:	The product does not present an explosion hazard.
Change in condition	
Softening point/range:	
Oxidising properties:	Not determined.
Evaporation rate:	Not determined.

9.2.1 Information with regard to physical hazard classes

Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Void
Flammable solids	Void
Self-reactive substances and mixtures	Void
Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit	
flammable gases in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
Desensitised explosives	Void

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

Heat may cause this product to decompose.

10.5 Incompatible materials

None known

10.6 Hazardous decomposition products

Nature of decomposition products not known.

11 Toxicological information

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

Acute toxicity

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

LD/LC50 values relevant for classification

No further relevant information available.

Skin corrosion/irritation

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

Serious eye damage/irritation

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

Respiratory or skin sensitization

May cause an allergic skin reaction.

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.

11.2 Information on other hazards

Endocrine disrupting properties

Taking into account the current state of scientific knowledge, no data on endocrine disrupting properties of the product are available.

None of the ingredients is listed.

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.

12.5 Results of PBT and vPvB assessment

PBT

According to current knowledge, the product contains no PBT substance.

vPvR

According to current knowledge, the product contains no vPvB substance.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

No further relevant information available.

13 Disposal considerations

13.1 Waste treatment methods

Recommendation

Disposal must be made according to official regulations.

Ordinance of the Federal Department of the Environment, Transport, Energy and Communications (DETEC) on Lists for Waste Traffic (SR 814.610.1)	
In Switzerl asterisk.	and od for hazardous waste are marked with an "S" ("Sonderabfall") instead of an
18 00 00	Wastes from human or animal healthcare and/or related research (except kitchen and restaurant wastes not arising from immediate health care)
18 01 00	Wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 06	Chemicals consisting of or containing dangerous substances Classification S = hazardous waste (Sonderabfall)

Uncleaned packaging

Recommendation

Disposal must be made according to official regulations.

according to ChemO 2015 - SR 813.11

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Recommended cleansing agents

Water, if necessary, together with cleansing agents.

14 Transport information

14.1 <u>UN-number or ID number</u>

ADR/ADN, ADN, IMDG, IATA Void

14.2 <u>UN Proper shipping name</u>

ADR/ADN, ADN, IMDG, IATA Void

14.3 <u>Transport hazard class(es)</u>

ADR/ADN, ADN, IMDG, IATA

Class

14.4 Packing group

ADR/ADN, IMDG, IATA Void

14.5 Environmental hazards

Marine pollutant: No

14.6 Special precautions for user Not applicable.

14.7 Maritime transport in bulk according

to IMO instruments Not applicable.

Transport/Additional information

ADR/AND

Remarks: Not Classified.

IMDG

Remarks: Not Classified.

IATA

Remarks: Not Classified.

UN "Model Regulation" Void

15 Regulatory information

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

National regulations:

Special handling regulations (follow-up obligations) of the chemical legislation: No additional regulations.

Ordinance on Air Pollution Control (OAPC; SR 814.318.142.1) Annex 1:

The provisions of the Air Pollution Control (OAPC; SR 814.318.142.1) Annex 1 are to be complied with.

Ordinance on Protection against Major Accidents (Major Accidents Ordinance, MAO; SR 814.012)
Annex 1:

Volume threshold according to MAO in kg: without limitation

according to ChemO 2015 - SR 813.11

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(Source: FOEN - List 2015 - Volume thresholds in accordance with the Major Accidents Ordinance / Volume Threshold Calculator)

Chemical Risk Reduction Ordinance (ORRChem; SR 814.81):

The product contains no substances subject to authorization according to Annex 1.17 in concentrations ≥0.1% w/w

or above specific concentration limits (if <0.1% w/w).

Chemical Risk Reduction Ordinance (ORRChem; SR 814.81):

The preparation or substances contained therein are not subject to any prohibition or restriction in accordance with Annexes 1 and 2.

Chemicals Ordinance (ChemO: SR 813.11):

The product contains no substances of very high concern according to Annex 3 in concentrations ≥0.1% w/w

Information about limitation of use:

Article 4 para. 4 of the Ordinance on the protection of young people in the workplace (SR 822.115) and Article 1 lit. f of the EAER regulation on hazardous work and young people (SR 822.115.2) Young people undergoing basic vocational training may only work with this product if the relevant training ordinance makes provision for them to do so with a view to enabling them to achieve their training objectives and if the preconditions for the training plan have been met and the applicable age restrictions have been complied with. Young people who are not completing any basic vocational training are not permitted to work with this product.

Employees of either sex who are under 18 years old are classed as young people

Waterhazard class

Swiss Waterhazard class B (self classification)

OVOC (CH)

0.0%

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

16 Other information

All information and instructions provided in this Safety Data Sheet are based on the current state of scientific and technical knowledge at the date indicated on this Safety Data Sheet. Pentapharm AG shall not be held responsible for any defect in the product covered by this Safety Data Sheet, should the existence of such a defect not be detectable considering the current state of scientific and technical knowledge.

An asterisk (*) in the left hand margin indicates an amendment from the previous version.

Relevant phrases

H301 Toxic if swallowed.

H310 Fatal in contact with skin.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H330 Fatal if inhaled.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Abbreviations and acronyms

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

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

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic SVHC: Substances of Very High Concern vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity – Category 3 Acute Tox. 2: Acute toxicity – Category 2

Skin Corr. 1C: Skin corrosion/irritation - Category 1C

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1 Skin Sens. 1A: Skin sensitisation – Category 1A

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1 CH/E

Further information

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.