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

1.1 Product identifier

Commercial Product Name : ß-CrossLaps CalSet
Mat.-No./ Genisys-No. : 11972316122

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

Recommended restrictions on use : For professional users only.

1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH
-
Sandhoferstrasse 116
68305 Mannheim
E-mail address : mannheim.umweltschutz@roche.com
Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-2012+49(0)621-759-4848+49(0)8856-60-2629

1.4 Emergency telephone number

In case of emergencies: : Central Works Security Roche Diagnostics GmbH +49(0)621-759-2203

Centre for detoxification: : Mainz +49(0)6131-19240
Munich +49(0)89-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Warning

Hazard statements :
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

P280	Wear eye protection/ face protection.
P280	Wear protective gloves.
Response:	
P362 + P364	Take off contaminated clothing and wash it before reuse.

2.3 Other hazards

See SECTION 3

SECTION 3: Composition/information on ingredients

R1

Classification (REGULATION (EC) No 1272/2008)

Skin irritation, Category 2	H315: Causes skin irritation.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.

Classification (67/548/EEC, 1999/45/EC)

Sensitising	R43: May cause sensitisation by skin contact.
Irritant	R36/38: Irritating to eyes and skin.

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9	T; R23/24/25 C; R34 R43 N; R50-R53	Acute Tox. 3; H301 Acute Tox. 3; H331 Acute Tox. 3; H311 Skin Corr. 1B; H314 Skin Sens. 1; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 0,1 - < 0,25

For explanation of abbreviations see section 16.

R2

Classification (REGULATION (EC) No 1272/2008)

Skin irritation, Category 2	H315: Causes skin irritation.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.

Classification (67/548/EEC, 1999/45/EC)

Sensitising	R43: May cause sensitisation by skin contact.
Irritant	R36/38: Irritating to eyes and skin.

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9	T; R23/24/25 C; R34 R43 N; R50-R53	Acute Tox. 3; H301 Acute Tox. 3; H331 Acute Tox. 3; H311 Skin Corr. 1B; H314 Skin Sens. 1; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 0,1 - < 0,25

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended.

If inhaled : Move to fresh air.
If unconscious place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact : If skin irritation persists, call a physician.
If on skin, rinse well with water.
If on clothes, remove clothes.

In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.

If swallowed : Clean mouth with water and drink afterwards plenty of water.
Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling	:	Do not breathe vapours/dust. Avoid exposure - obtain special instructions before use. Avoid contact with skin and eyes. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Dispose of rinse water in accordance with local and national regulations. Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.
Advice on protection against fire and explosion	:	Normal measures for preventive fire protection.
Hygiene measures	:	When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Keep container tightly closed in a dry and well-ventilated place. Electrical installations / working materials must comply with the technological safety standards.
Further information on storage conditions	:	See label, package insert or internal guidelines
Storage class (TRGS 510)	:	12, Non Combustible Liquids
Other data	:	No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s)	:	Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

R1

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9	AGW (inhalable fraction)	0,2 mg/m3	DE TRGS 900
Peak-limit: excur-	2;(I)			

sion factor (category)	
Further information	Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child

R2

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9	AGW (inhalable fraction)	0,2 mg/m3	DE TRGS 900
Peak-limit: excursion factor (category)	2;(I)			
Further information	Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			

8.2 Exposure controls

Personal protective equipment

Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles
Wear face-shield and protective suit for abnormal processing problems.

Hand protection

Material : Protective gloves

Remarks : The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Skin and body protection : impervious clothing
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

R1

Appearance	:	liquid
Colour	:	yellow
Odour	:	very faint
Odour Threshold	:	No data available
pH	:	6,0
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1,02 g/cm3 (20 °C)
Solubility(ies)		
Water solubility	:	completely miscible
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available

R2

Appearance	:	liquid
Colour	:	yellow
Odour	:	very faint
Odour Threshold	:	No data available
pH	:	6,0
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	does not flash

Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1,02 g/cm3 (20 °C)
Solubility(ies)		
Water solubility	:	completely miscible
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available

9.2 Other information

R1

No data available

R2

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No decomposition if stored and applied as directed.

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

R1

Acute toxicity

Not classified based on available information.

Components:

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

Acute oral toxicity	:	LD50 Oral (Rat): 53 mg/kg
Acute inhalation toxicity	:	Acute toxicity estimate: 3 mg/l Test atmosphere: vapour Method: Expert judgement
Acute dermal toxicity	:	Acute toxicity estimate: 300 mg/kg Method: Expert judgement

Skin corrosion/irritation

Causes skin irritation.

Components:

mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1):
Result: Causes burns.

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1):
Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation: May cause an allergic skin reaction.
Respiratory sensitisation: Not classified based on available information.

Components:

mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1):
Assessment: May cause sensitisation by skin contact.

Assessment:	Toxic if swallowed, in contact with skin or if inhaled May cause an allergic skin reaction.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

R2

Acute toxicity

Not classified based on available information.

Components:

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

Acute oral toxicity	:	LD50 Oral (Rat): 53 mg/kg
Acute inhalation toxicity	:	Acute toxicity estimate: 3 mg/l Test atmosphere: vapour Method: Expert judgement
Acute dermal toxicity	:	Acute toxicity estimate: 300 mg/kg Method: Expert judgement

Skin corrosion/irritation

Causes skin irritation.

Components:

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

Result: Causes burns.

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

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

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation: May cause an allergic skin reaction.
Respiratory sensitisation: Not classified based on available information.

Components:

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

Assessment: May cause sensitisation by skin contact.

Assessment:	Toxic if swallowed, in contact with skin or if inhaled May cause an allergic skin reaction.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12: Ecological information

12.1 Toxicity

R1

Components:

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

Toxicity to fish	:	LC50 (Fish): 0,36 mg/l Exposure time: 96 h
Ecotoxicology Assessment Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

R2

Components:

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

Toxicity to fish	:	LC50 (Fish): 0,36 mg/l Exposure time: 96 h
Ecotoxicology Assessment Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

12.2 Persistence and degradability

R1

No data available

R2

No data available

12.3 Bioaccumulative potential

R1

No data available

R2

No data available

12.4 Mobility in soil

R1

No data available

R2

No data available

12.5 Results of PBT and vPvB assessment

R1

Not relevant

R2

Not relevant

12.6 Other adverse effects

R1

Components:

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

Additional ecological information	:	Remarks: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Very toxic to aquatic life with long lasting effects.

R2

Components:

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

Additional ecological information	:	Remarks: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Very toxic to aquatic life with long lasting effects.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Do not contaminate ponds, waterways or ditches with chemical or used container.

Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADNR, IMDG-Code, ICAO/IATA-DGR

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Remarks : Not applicable

SECTION 15: Regulatory information

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

Seveso II - Directive 2003/105/EC amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances
Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Water contaminating class (Germany) : WGK 1 slightly water endangering

R1

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Warning

Hazard statements	:	H315	Causes skin irritation.
		H317	May cause an allergic skin reaction.
		H319	Causes serious eye irritation.

Precautionary statements	:	**Prevention:**	
		P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
		P280	Wear eye protection/ face protection.
		P280	Wear protective gloves.
		Response:	
		P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
		P337 + P313	If eye irritation persists: Get medical advice/ attention.
		P362 + P364	Take off contaminated clothing and wash it before reuse.

Hazardous components which must be listed on the label:

55965-84-9 mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

R2

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Warning

Hazard statements	:	H315	Causes skin irritation.
		H317	May cause an allergic skin reaction.
		H319	Causes serious eye irritation.

Precautionary statements	:	**Prevention:**	
		P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
		P280	Wear eye protection/ face protection.
		P280	Wear protective gloves.
		Response:	
		P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
		P337 + P313	If eye irritation persists: Get medical advice/ attention.
		P362 + P364	Take off contaminated clothing and wash it before reuse.

Hazardous components which must be listed on the label:

55965-84-9 mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

15.2 Chemical Safety Assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

SECTION 16: Other information

Full text of R-Phrases

R23/24/25	:	Toxic by inhalation, in contact with skin and if swallowed.
R34	:	Causes burns.
R43	:	May cause sensitisation by skin contact.
R50	:	Very toxic to aquatic organisms.
R53	:	May cause long-term adverse effects in the aquatic environment.

Full text of H-Statements

H301	:	Toxic if swallowed.
H311	:	Toxic in contact with skin.
H314	:	Causes severe skin burns and eye damage.
H317	:	May cause an allergic skin reaction.
H331	:	Toxic if inhaled.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Acute aquatic toxicity
Aquatic Chronic	:	Chronic aquatic toxicity
Skin Corr.	:	Skin corrosion
Skin Sens.	:	Skin sensitisation

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.

DE / EN