

SAFETY DATA SHEET



cGMP CALIBRATOR

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

1.1 Product identifier

Product name : cGMP CALIBRATOR
Product type : Powder.
Other means of identification : Not available.
Product part number : R7122
Kit name : CATCHPOINT cGMP KIT, BULK, 384-WELL FORMAT
CATCHPOINT cGMP BULK KIT, 96-WELL FORMAT
CATCHPOINT cGMP KIT, EXPLORER, 384-WELL FORMAT
CATCHPOINT cGMP EXPLORER KIT, 96-WELL FORMAT
Kit part number : R8066/R8075/R8065/R8074

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

Product use : For R&D use only.
Area of application : Professional applications.

Uses advised against

None identified.

1.3 Details of the supplier of the safety data sheet

Molecular Devices (Austria) GmbH
Urstein Süd 17
5412 Puch / Hallein
AUSTRIA

e-mail address of person responsible for this SDS : msdsinquiry@moldev.com

1.4 Emergency telephone number

National advisory body/Poison Centre

Telephone number : CHEMTREC (24 hours): 1-800-424-9300 (USA/Canada),
+1 703-527-3887 (Outside USA/Canada)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture

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

Skin Sens. 1, H317

The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

SECTION 2: Hazards identification

Ingredients of unknown toxicity : 20.1 percent of the mixture consists of component(s) of unknown acute dermal toxicity
20.1 percent of the mixture consists of component(s) of unknown acute inhalation toxicity

Ingredients of unknown ecotoxicity : Contains 16.5% of components with unknown hazards to the aquatic environment

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 - May cause an allergic skin reaction.

Precautionary statements

Prevention : P280 - Wear protective gloves.
P261 - Avoid breathing dust or mist.

Response : P362 + P364 - Take off contaminated clothing and wash it before reuse.
P302 + P352 - IF ON SKIN: Wash with plenty of water.
P333 + P313 - If skin irritation or rash occurs: Get medical advice or attention.

Storage : Not applicable.

Disposal : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazardous ingredients : 3(2H)-Isothiazolone, 2-methyl-

Supplemental label elements : Not applicable.

REACH Authorisation number : Exempted (Research and Development) - < 1 tonne/yr

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

Special packaging requirements

Containers to be fitted with child-resistant fastenings : Not applicable.

Tactile warning of danger : Not applicable.

2.3 Other hazards

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII : This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

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SECTION 2: Hazards identification

Other hazards which do not result in classification : May form combustible dust concentrations in air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

Product/ingredient name	Identifiers	%	Regulation (EC) No. 1272/2008 [CLP]	Type
sucrose	REACH #: Annex IV EC: 200-334-9 CAS: 57-50-1	≥10 - ≤25	Not classified.	[2]
Albumins, blood serum	EC: 232-936-2 CAS: 9048-46-8	≤10	Acute Tox. 4, H302	[1]
Poly(oxy-1,2-ethanediyl), α-[4-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy-	CAS: 9002-93-1	<2.5	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Chronic 2, H411	[1] [5]
5-chloro-2-methyl-2H-isothiazol-3-one	EC: 247-500-7 CAS: 26172-55-4	<0.1	Acute Tox. 3, H301 Acute Tox. 3, H311 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 2, H411	[1]
3(2H)-Isothiazolone, 2-methyl-	EC: 220-239-6 CAS: 2682-20-4 Index: 613-326-00-9	<0.1	Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 2, H330 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1) EUH071 See Section 16 for the full text of the H statements declared above.	[1]

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

[1] Substance classified with a health or environmental hazard

[2] Substance with a workplace exposure limit

[3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII

[4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

[5] Substance of equivalent concern

[6] Additional disclosure due to company policy

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:
irritation
redness
- Inhalation** : Adverse symptoms may include the following:
respiratory tract irritation
coughing
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use dry chemical powder.

Unsuitable extinguishing media : Do not use water jet.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : May form explosible dust-air mixture if dispersed.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
sulfur oxides
metal oxide/oxides

5.3 Advice for firefighters

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing dust. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

: Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

Small spill : Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

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SECTION 6: Accidental release measures

- Large spill** : Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor.
- 6.4 Reference to other sections** : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing dust. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Electrical equipment and lighting should be protected to appropriate standards to prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by earthing and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from oxidising materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

7.3 Specific end use(s)

- Recommendations** : Not available.
- Industrial sector specific solutions** : Not available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
sucrose	EH40/2005 WELs (United Kingdom (UK), 1/2020). STEL: 20 mg/m ³ 15 minutes. TWA: 10 mg/m ³ 8 hours.

Recommended monitoring procedures : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available

8.2 Exposure controls

Appropriate engineering controls : Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapour or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. If operating conditions cause high dust concentrations to be produced, use dust goggles.

Skin protection

SECTION 8: Exposure controls/personal protection

- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

- Physical state** : Solid. [Powder.]
- Colour** : White.
- Odour** : Not available.
- Odour threshold** : Not available.
- pH** : Not available.
- Melting point/freezing point** : Not available.
- Initial boiling point and boiling range** : Not available.
- Flash point** : Not applicable.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not available.
- Upper/lower flammability or explosive limits** : Not available.
- Vapour pressure** : Not available.
- Vapour density** : Not available.
- Relative density** : Not available.
- Solubility(ies)** : Not available.
- Partition coefficient: n-octanol/ water** : Not available.
- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.
- Viscosity** : Not applicable.

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SECTION 9: Physical and chemical properties

Explosive properties : Not available.

Oxidising properties : Not available.

9.2 Other information

Physical/chemical properties comments : No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity : No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability : The product is stable.

10.3 Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.
Under normal conditions of storage and use, hazardous polymerisation will not occur.

10.4 Conditions to avoid : Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by earthing and bonding containers and equipment before transferring material. Prevent dust accumulation.

10.5 Incompatible materials : Reactive or incompatible with the following materials:
oxidising materials

10.6 Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Poly(oxy-1,2-ethanediyl), α -[4-(1,1,3,3-tetramethylbutyl)phenyl]- ω -hydroxy-	LD50 Oral	Rat	1800 mg/kg	-
3(2H)-Isothiazolone, 2-methyl-	LC50 Inhalation Dusts and mists	Rat - Male, Female	0.11 mg/l	4 hours
	LD50 Dermal	Rat - Male, Female	242 mg/kg	-
	LD50 Oral	Rat - Male, Female	285.5 mg/kg	-

Conclusion/Summary : Not available.

Acute toxicity estimates

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SECTION 11: Toxicological information

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
cGMP CALIBRATOR	8490.6	N/A	N/A	N/A	N/A
Albumins, blood serum	500	N/A	N/A	N/A	N/A
Poly(oxy-1,2-ethanediyl), α-[4-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy-	1800	N/A	N/A	N/A	N/A
5-chloro-2-methyl-2H-isothiazol-3-one	100	300	N/A	N/A	N/A
3(2H)-Isothiazolone, 2-methyl-	285.5	242	N/A	N/A	0.11

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Poly(oxy-1,2-ethanediyl), α-[4-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy-	Eyes - Moderate irritant	Rabbit	-	24 hours 10 uL	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 uL	-

Conclusion/Summary : Not available.

Sensitisation

Conclusion/Summary : Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Product/ingredient name	Category	Route of exposure	Target organs
5-chloro-2-methyl-2H-isothiazol-3-one	Category 3	-	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

Eye contact : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the eyes.

Inhalation : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.

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SECTION 11: Toxicological information

- Skin contact** : May cause an allergic skin reaction.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : Adverse symptoms may include the following:
irritation
redness
- Inhalation** : Adverse symptoms may include the following:
respiratory tract irritation
coughing
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

- Potential immediate effects** : Not available.
Potential delayed effects : Not available.

Long term exposure

- Potential immediate effects** : Not available.
Potential delayed effects : Not available.

Potential chronic health effects

- General** : Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation. Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.
- Carcinogenicity** : No known significant effects or critical hazards.
Mutagenicity : No known significant effects or critical hazards.
Reproductive toxicity : No known significant effects or critical hazards.

Other information : Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
Poly(oxy-1,2-ethanediyl), α-[4-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy-5-chloro-2-methyl-2H-isothiazol-3-one	Acute LC50 5.85 mg/l Fresh water	Crustaceans - Ceriodaphnia rigaudi - Neonate	48 hours
	Acute LC50 11.2 mg/l Fresh water	Daphnia - Daphnia magna - Neonate	48 hours
	Acute LC50 4500 µg/l Fresh water	Fish - Pimephales promelas	96 hours
	Acute EC50 0.021 ppm Marine water	Algae - Skeletonema costatum	72 hours
	Acute EC50 0.062 ppm Fresh water	Algae - Pseudokirchneriella subcapitata	4 days
	Acute EC50 13 ppm Fresh water	Crustaceans - Ceriodaphnia	48 hours

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SECTION 12: Ecological information

3(2H)-Isothiazolone, 2-methyl-	Acute EC50 0.18 ppm Fresh water Acute LC50 0.19 ppm Fresh water Chronic NOEC 0.1 ppm Fresh water Chronic NOEC 0.02 ppm Acute EC50 0.18 ppm Fresh water	dubia Daphnia - Daphnia magna Fish - Oncorhynchus mykiss Daphnia - Daphnia magna Fish - Pimephales promelas Daphnia - Daphnia magna	48 hours 96 hours 21 days 36 days 48 hours
	Acute LC50 0.07 ppm Fresh water Chronic NOEC 0.044 mg/l Fresh water Chronic NOEC 2.38 mg/l Fresh water	Fish - Oncorhynchus mykiss Daphnia - Daphnia magna Fish - Pimephales promelas	96 hours 21 days 98 days

Conclusion/Summary : Not available.

12.2 Persistence and degradability

Product/ingredient name	Test	Result	Dose	Inoculum
3(2H)-Isothiazolone, 2-methyl-	OECD 301D Ready Biodegradability - Closed Bottle Test	0 % - Not readily - 28 days	-	Activated sludge

Conclusion/Summary : Not available.

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
5-chloro-2-methyl-2H- isothiazol-3-one	-	-	Readily
3(2H)-Isothiazolone, 2-methyl-	-	-	Not readily

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
5-chloro-2-methyl-2H- isothiazol-3-one	-0.71	-	low
3(2H)-Isothiazolone, 2-methyl-	0.119	-	low

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Other adverse effects : No known significant effects or critical hazards.

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste : The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.

14.6 Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Transport in bulk according to IMO instruments : Not available.

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SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

Ingredient name	Intrinsic property	Status	Reference number	Date of revision
4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (covering well-defined substances and UVCB substances, polymers and homologues)	Substance of equivalent concern for environment	Listed	42	7/3/2017

Substances of very high concern

Ingredient name	Intrinsic property	Status	Reference number	Date of revision
4 -(1,1,3,3-tetramethylbutyl) phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]	Substance of equivalent concern for environment	Recommended	ED/169/2012	7/3/2017

REACH Authorisation number : Exempted (Research and Development) - < 1 tonne/yr

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Label requirements : Not applicable.

Other EU regulations

Europe inventory : All components are listed or exempted.

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

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SECTION 15: Regulatory information

15.2 Chemical safety assessment : Not applicable.

15.3 Registration status : Mixture. Information concerning the substance : Contact local supplier or distributor.

SECTION 16: Other information

Indicates information that has changed from previously issued version.

Abbreviations and acronyms

: ATE = Acute Toxicity Estimate
 CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
 DMEL = Derived Minimal Effect Level
 DNEL = Derived No Effect Level
 EUH statement = CLP-specific Hazard statement
 N/A = Not available
 PBT = Persistent, Bioaccumulative and Toxic
 PNEC = Predicted No Effect Concentration
 RRN = REACH Registration Number
 vPvB = Very Persistent and Very Bioaccumulative

Key literature references and sources for data

: Regulation (EC) No. 1272/2008 [CLP]; European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), concluded in Geneva on 30 September 1957 plus amendments (Uniform text: Journal of Laws 27/2009 pos. 162 plus amendments); European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN); Occupational exposure limits; International regulations

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Skin Sens. 1, H317	Calculation method

Full text of abbreviated H statements

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic 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.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.

Full text of classifications [CLP/GHS]

cGMP CALIBRATOR

SECTION 16: Other information

Acute Tox. 2	ACUTE TOXICITY - Category 2
Acute Tox. 3	ACUTE TOXICITY - Category 3
Acute Tox. 4	ACUTE TOXICITY - Category 4
Aquatic Acute 1	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Aquatic Chronic 1	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
Aquatic Chronic 2	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 2
Eye Dam. 1	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1
Eye Irrit. 2	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2
Skin Corr. 1B	SKIN CORROSION/IRRITATION - Category 1B
Skin Irrit. 2	SKIN CORROSION/IRRITATION - Category 2
Skin Sens. 1	SKIN SENSITISATION - Category 1
Skin Sens. 1A	SKIN SENSITISATION - Category 1A
STOT SE 3	SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE - Category 3

Training advice : Ensure operatives are trained to minimise exposures. Training staff on good practice.

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