

SAFETY DATA SHEET

WIESLAB® kits

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

1.1 Product identifier

PRODUCT NAME:	WIESLAB® kits: WIESLAB® Anti-GBM, ANCA screen WIESLAB® Anti-GBM semi quantitative kit WIESLAB® ANCA panel WIESLAB® ASCA IgA semi quant. WIESLAB® ASCA IgG semi quant. WIESLAB® Capture MPO-ANCA WIESLAB® Capture PR3-ANCA WIESLAB® Complement system Alternative pathway WIESLAB® Complement system Classical pathway WIESLAB® Complement system MBL pathway WIESLAB® Complement system Screen WIESLAB® MPO-ANCA WIESLAB® PR3-ANCA WIESLAB® Vasculitis screen
Product description	Kit consisting of following reagents: <ul style="list-style-type: none"> • Reagent A: Wash buffer 30 x Conc. • Reagent B: Diluent • Reagent C: Conjugate • Reagent D: Calibrator • Reagent E: Positive Control/Activity Control • Reagent F: Negative Control • Reagent G: Stop Solution • Reagent H: Substrate pNPP • Antigen coated plate
Product code	GCP 100 GP 104X PAN 106 ASCA 150 ASCA 151 Cap MPO IU Cap PR3 IU COMPL AP 330, COMPL AP 330 RUO COMPL CP 310, COMPL CP 310 RUO COMPL MP 320, COMPL MP 320 RUO COMPL 300, COMPL 300 RUO MPO IU PR3 IU GCP-CAP

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

Use of the product	Kit consisting of different reagents for in vitro diagnostic and research use.
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1.3 Details of the supplier of the safety data sheet

Company	Svar Life Science AB
Address	Lundavägen 151
Zip code/Place	SE-212 24 Malmö, Sweden
Telephone	+46 40 53 76 00
Internet	www.svarlifescience.com
E-mail	info@svarlifescience.com

1.4 Emergency telephone number

Emergency telephone number	+46-010-456 6700 Swedish Poisons Information Centre
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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product definition: In vitro device kit and research use kit consisting of different reagents.

The antigen coated plate is not classified as dangerous.

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

Reagent A, B, C, D, E(except Complement kits), **F, G, and H:** Skin Irrit. 1; H317

The antigen coated plate is not classified as dangerous.

2.2 Label elements according the Regulation (EC) No. 1272/2008 (CLP)

2.2.1 Reagent A, B, C, D, E(except Complement kits), F, G, and H

Hazard pictogram:



GHS07: Exclamation mark

Signal word: Warning

Contains:	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)
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Hazard statements

H317	May cause an allergic skin reaction.
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Precautionary statements

P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+352	IF ON SKIN: Wash with plenty of soap and water.
P333+313	If skin irritation or rash occurs: Get medical advice/attention.

2.2.2 Antigen coated plate

The antigen coated plate is not labeled because it is not classified as dangerous.

2.3 Other hazards

Other hazards which do not result in classification	None
Substance meets the criteria for PBT under Regulation EC No. 1907/2006, appendix XIII	PBT: No (refers to substances containing)
Substance meets the criteria for PBT under Regulation EC No. 1907/2006, appendix XIII	vPvB: No (refers to substances containing)

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Reagents containing following substances classified as dangerous.

No	Product/ingredient name	EC-number	CAS-number	REACH registration number	Conc. (weight-%)	Classification Regulation (EC) No. 1272/2008 [CLP]
Reagent Wash Buffer 30 x Conc						
	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	--	55965-84-9	--	0,01-0,03	Acute Tox 2, H301 Acute Tox 2, H311 Skin Corr 1B, H314 Skin Sens. 1, H317 Acute tox 2, H331 Aquatic Chronic 1, H410
Reagent Diluent						
	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	--	55965-84-9	--	0,0015-0,015	Acute Tox 2, H301 Acute Tox 2, H311 Skin Corr 1B, H314 Skin Sens. 1, H317 Acute tox 2, H331 Aquatic Chronic 1, H410
Reagent Conjugate						
	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	--	55965-84-9	--	0,0015-0,015	Acute Tox 2, H301 Acute Tox 2, H311 Skin Corr 1B, H314 Skin Sens. 1, H317 Acute tox 2, H331 Aquatic Chronic 1, H410
Reagent Calibrator						
	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	--	55965-84-9	--	0,0015-0,015	Acute Tox 2, H301 Acute Tox 2, H311 Skin Corr 1B, H314 Skin Sens. 1, H317 Acute tox 2, H331 Aquatic Chronic 1, H410
Reagent Positive Control (except PC/AC Complement kits)						
	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	--	55965-84-9	--	0,0015-0,015	Acute Tox 2, H301 Acute Tox 2, H311 Skin Corr 1B, H314 Skin Sens. 1, H317 Acute tox 2, H331 Aquatic Chronic 1, H410
Reagent Negative Control						
	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	--	55965-84-9	--	0,0015-0,015	Acute Tox 2, H301 Acute Tox 2, H311 Skin Corr 1B, H314 Skin Sens. 1, H317 Acute tox 2, H331 Aquatic Chronic 1, H410
Reagent Stop Solution						
	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	--	55965-84-9	--	0,0015-0,015	Acute Tox 2, H301 Acute Tox 2, H311 Skin Corr 1B, H314 Skin Sens. 1, H317 Acute tox 2, H331 Aquatic Chronic 1, H410
Reagent Substrate pNPP						
	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	--	55965-84-9	--	0,0015-0,015	Acute Tox 2, H301 Acute Tox 2, H311 Skin Corr 1B, H314 Skin Sens. 1, H317 Acute tox 2, H331 Aquatic Chronic 1, H410

The antigen coated plate contains no dangerous substances. See section 16 for the full text of the classifications declared above. Occupational exposure limits are mentioned under section 8, if such exist.

4. FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation:	Remove to fresh air, rest. Call a physician if the complaints persist.
Skin contact:	Remove contaminated clothing and footwear. Wash the skin properly with soap and water.
Eye contact:	Keep eyelids well apart. Rinse with water for a couple of minutes. Call a physician if the complaints persist.
Ingestion	Wash mouth properly with water. If victim is conscious and alert, give 2-4 cupfuls of milk/water to dilute the substance in stomach. Call a physician if the complaints persist.

4.2 Most important symptoms and effects, both acute and delayed potential acute health effects

Inhalation:	Exposure to high airborne concentrations of the reagents in this kit may cause irritation in the respiratory tract, dizziness and sickness.
Skin contact:	Prolonged exposure to the skin may cause skin irritation. Reagent A, B, C, D, E (except Complement kits), F, G, and H : May cause an allergic skin reaction. Antigen coated plate : May not cause any sensitizing effects.
Eye contact:	May cause mild, reversible eye irritation.
Ingestion:	Ingestion of larger amounts may cause sickness and vomiting.

4.2 Indication of any immediate medical attention and special treatment needed

Ingestion:	Treat symptomatically.
Specific treatments:	No specific treatment.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media	Dry chemical, foam, water spray or carbon dioxide.
Unsuitable extinguishing media	Waterjet

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture	None
Hazardous thermal decomposition products	Decomposition products may include the following materials: carbon monoxide, carbon dioxide and nitrous gases.

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.
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.
Further information	Not applicable

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. Put on appropriate personal protective equipment.
For emergency responders	If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also Section 8 for additional information on hygiene measures.

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 materials for containment and cleaning up

Small spill	Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
Large spill	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with noncombustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor.

6.4 Reference to other sections

Reference to other sections	See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.
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7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Protective measures	Put on appropriate personal protective equipment (see Section 8).
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

Storage:	Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10), food and drink. 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.
Further information:	Not applicable

7.3 Specific end use(s)

Reagents for in vitro diagnostic and research use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits

Ingredient name	CAS nr.	Range	ppm	mg/m ³	Year	Remarks
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Recommended monitoring procedures	Not relevant
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Derived effect levels

Product/ingredient name	Type	Exposure	Value	Population	Effects
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Predicted effect concentrations	Not available
PNEC Summary	Not available

8.2 Exposure controls

Appropriate engineering controls	Good general ventilation should be sufficient to control worker exposure to airborne contaminants. Otherwise, use local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.
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. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
Respiratory protection	Not relevant during normal condition.
Eye/face protection	Safety glasses or face shield shall be worn.
Hand protection	Chemical-resistant, impervious gloves in butyl rubber or nitril rubber complying with an approved standard shall be worn.
Body protection	Wear suitable protective clothing.
Environmental exposure controls	Not applicable

9. PHYSICAL AND CHEMICAL PROPERTIES
9.1.1 Information on basic physical and chemical properties of the reagents

	Reagent A	Reagent B	Reagent C	Reagent D	Reagent E	Reagent F	Reagent G	Reagent H
Physical state	Liquid	Liquid	Liquid	Liquid	Liquid/ Lyophilized PC and AC Complement	Liquid	Liquid	Liquid
Colour	Colourless	Red	Blue	Red	Red/ Colourless	Green	Colourless	Colourless
Odour	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless
Odour threshold	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Solubility(ies)	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water
pH (product)	n.d	7,2-7,5	7,4-7,6	7,2-7,5	7,2-7,5	7,2-7,5	8,0	9,55-9,65
Melting point/freezing point	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Initial boiling point and boiling range	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Flash point	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C
Evaporation rate (butyl acetate = 1)	< 1	< 1	< 1	< 1	< 1	< 1	< 1	< 1
Flammability (solid, gas)	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Upper/lower flammability or explosive limits	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Combustion rate	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Upper/lower flammability or explosive limits	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a
Vapour pressure (at 20°C)	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Vapour density	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Relative density (Water = 1)	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Partition coefficient: n-octanol/water	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Autoignition temperature	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Decomposition temperature	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Viscosity	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Explosive properties	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Oxidising properties	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a

n.a = not applicable. n.d = not determined

9.2 Other information

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10. STABILITY AND REACTIVITY

10.1 Reactivity	Non-reactive
10.2 Chemical stability	Stabile under normal conditions of use and storage.
10.3 Possibility of hazardous reactions	Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid	Avoid direct sunlight.
10.5 Incompatible materials	None
10.6 Hazardous decomposition products	Carbon monoxide, carbon dioxide and nitrous gases.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Assessment of acute toxicity for the different reagents:

Not harmful if inhaled. Not harmful in contact with skin. Not harmful if swallowed.

Calculated data:

LD50 oral, rat: > 2000 mg/kg

LD50 dermal, rat: > 2000 mg/kg

Irritation/Corrosion

Assessment of the irritant effect for the different reagents:

Not irritating to eyes and skin.

Experimental/calculated data:

Corrosive or irritating to the skin, rabbit: Not irritating.

Serious eye damage/eye irritation, rabbit: Not irritating.

Sensitization by inhalation/skin contact

Assessment of sensibility for the different reagents:

Reagent A, B, C, D, E(except Complement kits), **F, G, and H**: May cause an allergic skin reaction.

Antigen coated plate: May not cause any sensitizing effects.

Germ cell mutagenicity

Assessment of mutagenicity for the different reagents:

The chemical structure of the different reagents doesn't indicate any mutagenic effects.

Carcinogenicity

Assessment of carcinogenicity for the different reagents:

The chemical structure of the different reagents doesn't indicate any carcinogenic effects.

Reproduction toxicity

Assessment of reproduction toxicity for the different reagents:

The chemical structure of the different reagents doesn't indicate any reproduction toxic effects.

Developmental toxicity

Assessment of teratogenicity for the different reagents:

The chemical structure of the different reagents doesn't indicate any teratogenic effects.

Specific target organ toxicity (single exposure)

STOT assessment single dos toxicity:

Based on available information an organ specific toxicity is not expected for the different reagents.

Repeated dose toxicity and specific organ toxicity (repeated exposure)

Based on available information an organ specific toxicity is not expected for the different reagents.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

12.1.1 Acute toxicity in the aquatic environment of 5-chloro-2-methyl-4-isothiazolin-3-one

Test	Value/unit (mg/l)	Test method	Exp. time (h)	Species
Fish LC50	6,1		96	Brachydanio rerio
Daphnia EC50	4,2		48	Daphnia magna
BCF = 114. Bioaccumulating effects may occur. 39-62% degraded in 29 days OECD 301B. Not readily biodegradable.				

12.1.2 Acute toxicity in the aquatic environment of 2-methyl-4-isothiazolin-3-one

Test	Value/unit (mg/l)	Test method	Exp. time (h)	Species
Daphnia EC50	0,18		48	Daphnia magna
BCF = 114. Log Pow: -0,486. Bioaccumulating effects are not expected. 48-54% degraded in 29 days OECD 301B. Not readily biodegradable.				

12.1.3 Ecotoxicity

The reagents contain low concentration of the above mentioned substances. These concentrations are below the lowest concentration limit for classification as harmful to aquatic organisms.

12.2 Persistence and degradability

Conclusion/Summary	The reagents as such will be classified as readily biodegradable.
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12.3 Bioaccumulative potential

Conclusion/Summary	The reagents as such will not be classified as bioaccumulative.
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12.4 Mobility in soil

Soil/water partition coefficient (KOC)	Not available
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Mobility	Not available
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12.5 Results of PBT and vPvB assessment

PBT	Not applicable
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vPvB	Not applicable
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Conclusion	The reagents contain substances classified as dangerous for the environment. But the concentrations of these substances are very low, so the reagents as such are not classified as dangerous for the environment, according to the EU classification rules in force. The antigen coated plate is not classified as dangerous for the environment.
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13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Method of disposal	The generation of waste should be avoided or minimized wherever possible. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. 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. Used kit may be potentially infectious material and shall be disposed as a hazardous waste.
Hazardous waste	Within the present knowledge of the supplier, this product is regarded as hazardous waste, as defined by EU Directive 2008/98/EU.

European Waste Catalogue (EWC)

EWC Waste Code	Type of waste
18 01 06*	Chemicals consisting of or containing dangerous substances
15 01 10*	Packaging containing residues of or contaminated by dangerous substances

Packaging

Method of disposal	Incineration.
Special precautions	None.

14. TRANSPORT INFORMATION

 Product classified as dangerous goods: Yes No Not decided

	ADR/RID	ADN/ADNR	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	--	--	--	--
14.6 Special precautions for user	Not available	Not available	Not available	Not available
Additional information	Used kit is dangerous goods by transportation in class 6.2, UN 3291. Contact the manufacturer for further information.			

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

Not applicable

15. REGULATORY INFORMATION
**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
EU Regulation (EC) No. 1907/2006 (REACH)**

REACH Status	In compliance. Pre-registration status: All components are listed or exempted.
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Annex XIV - List of substances subject to authorization
Substances of very high concern

None of the components are listed.

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

Not applicable.

15.2 Chemical Safety Assessment

The reagents in this kit contain substances for which Chemical Safety Assessments still are required.

15.3 Other information

Tariff Code – harmonized system	Not applicable
The EU Seveso Directive	Not applicable

International regulations

Chemical Weapons Convention List Schedule I Chemicals	Chemical Weapons Convention List Schedule II Chemicals	Chemical Weapons Convention List Schedule III Chemicals
Not regulated	Not regulated	Not regulated

16. OTHER INFORMATION

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II

Disclaimer: The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

THE PRODUCER'S NOTES

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LIST OF HAZARD STATEMENTS MENTIONED UNDER SECTION 3

No.	H-Statements
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction.
H410	Very toxic to aquatic life with long lasting effects.