

pH 9,21 - Buffer pH 9.21 blue**Safety Data Sheet**

According to Annex II to REACH - Regulation 2020/878 and to Annex II to UK REACH

SECTION 1. Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**Code: pH 9,21
Product name: Buffer pH 9.21 blue**1.2. Relevant identified uses of the substance or mixture and uses advised against**

Intended use: Standard solution for process verification and control. Applies to codes 51100073, 51100173, 51100273, 51300023, 51300123, EE51100073, EE51100173, EE51100273

Identified Uses	Industrial	Professional	Consumer
Standard solution for the verification and quality control of pH measurement systems	✓	✓	-

1.3. Details of the supplier of the safety data sheetName: GIORGIO BORMAC srl
Full address: via della meccanica, 25
District and Country: 41012 Carpi (MO) Italia
Tel.: +39 059 653274
Fax: +39 059 653282

e-mail address of the competent person responsible for the Safety Data Sheet: sds@giorgiobormac.com

Supplier: GIORGIO BORMAC srl

1.4. Emergency telephone number

For urgent inquiries refer to: +44 121 507 4123

SECTION 2. Hazards identification**2.1. Classification of the substance or mixture**

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to (EU) Regulation 2020/878.

Hazard classification and indication: --

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements: EUH210 Safety data sheet available on request.

Precautionary statements: --

2.3. Other hazardsOn the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%.The product does not contain substances with endocrine disrupting properties in concentration \geq 0.1%.

pH 9,21 - Buffer pH 9.21 blue**SECTION 6. Accidental release measures ... / >>****6.2. Environmental precautions**

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Confine using earth or inert material. Collect as much material as possible and eliminate the rest using jets of water. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage**7.1. Precautions for safe handling**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

Regulatory References:

TLV-ACGIH ACGIH 2021

BORIC ACID**Threshold Limit Value**

Type	Country	TWA/8h		STEL/15min		Remarks / Observations		
		mg/m3	ppm	mg/m3	ppm			
TLV-ACGIH		2		6		INHAL		

Predicted no-effect concentration - PNEC

Normal value in fresh water	2,02	mg/l
Normal value for water, intermittent release	13,7	mg/l
Normal value of STP microorganisms	10	mg/l

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers				Effects on workers			
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral		0,98 mg/kg bw/d		0,98 mg/kg/d				
Inhalation				4,15 mg/m3				8,28 mg/m3
Skin				196 mg/kg bw/d				392 mg/kg bw/d

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified ; LOW = low hazard ; MED = medium hazard ; HIGH = high hazard.

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

HAND PROTECTION

pH 9,21 - Buffer pH 9.21 blue**SECTION 8. Exposure controls/personal protection ... / >>**

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374). Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

None required, unless indicated otherwise in the chemical risk assessment.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Properties	Value	Information
Appearance	clear liquid	
Colour	blue	
Odour	odourless	
Melting point / freezing point	not available	
Initial boiling point	100 °C	
Flammability	not available	
Lower explosive limit	not available	
Upper explosive limit	not available	
Flash point	not available	
Auto-ignition temperature	not available	
Decomposition temperature	not available	
pH	9,21	
Kinematic viscosity	not available	
Solubility	soluble in water	
Partition coefficient: n-octanol/water	not available	
Vapour pressure	not available	
Density and/or relative density	not available	
Relative vapour density	not available	
Particle characteristics	not applicable	

9.2. Other information**9.2.1. Information with regard to physical hazard classes**

Information not available

9.2.2. Other safety characteristics

Information not available

SECTION 10. Stability and reactivity**10.1. Reactivity**

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

BORIC ACID

The product is stable to normal environment temperatures (from -40 to +40 °C). If heated, the product loses water forming first metaboric acid (HBO₂) and transforming itself into boric anhydride to a subsequent heating (B₂O₃).

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

pH 9,21 - Buffer pH 9.21 blue**SECTION 10. Stability and reactivity ... / >>****BORIC ACID**

Boric acid is a weak acid capable of corroding common metals. The reaction with strong reducing agents, such as metal hydruri or alkaline metals, generates gaseous hydrogen that could cause an explosion danger.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

BORIC ACID

Avoid contact with: strong reducing agents.

10.5. Incompatible materials**BORIC ACID**

Strong reducing agents.

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**Metabolism, toxicokinetics, mechanism of action and other information**BORIC ACID**

In the blood, boric acid is the main present species and is not further metabolized. Boric acid spreads quickly and uniformly throughout the body, with concentrations in the bones from 2 to 3 times higher than those in other fabrics. Boric acid is quickly excreted, with 1 -hour elimination semivitis in the mouse, 3 hours in the rat and <27.8 hours in humans, and has a low storage potential. Boric acid is mainly excreted through urine. The absorption of oral boogers is about 100%. For the inhalation route, 100% absorption is also assumed in the scenario of the worst case. Cutaneous absorption through intact skin is very low, with a percentage dose absorbed of <0.5%.

Information on likely routes of exposure**BORIC ACID**

Inhalation is the main way of exposure in professional and non -professional environments. The skin exposure does not always represent a problem, as the product is poorly absorbed through intact skin. The product must not be ingested.

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

Epidemiological studies on humans do not show an increase in lung diseases in occupational populations with chronic exposures to boric acid and sodium borato dust. These studies indicate that there is no effect on fertility in occupational populations with chronic exposures to the dust of Borati and in the normal population with high exposures to the borati in the environment.

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:	Not classified (no significant component)
ATE (Oral) of the mixture:	Not classified (no significant component)
ATE (Dermal) of the mixture:	Not classified (no significant component)

BORIC ACID

Method: acute oral toxicity essay - Guideline 401 of the OECD

Species: rat

Dose: from 2000 to 5000 mg/kg of body weight exposure routes: oral

Results: low acute oral toxicity. The oral LD50 value in male rats is 3,450 mg/kg of body weight, while in female rats it is 4,080 mg/kg of body weight. Based on the available data, the classification criteria are not satisfied.

Method: acute dermal toxicity essay - Epa -Fifra guidelines United States

Species: rabbit

Dose: 2,000 mg/kg of body weight exposure routes: Dermica

Results: low acute dermal toxicity; LD50 in rabbits is > 2,000 mg/kg of body weight. Poorly absorbed in case of intact skin. Based on the available data, the classification criteria are not satisfied

pH 9,21 - Buffer pH 9.21 blue**SECTION 11. Toxicological information ... / >>**

Method: acute inhaled toxicity essay - Guideline 403 of the OECD

Species: rat

Dose: 2.12 mg/l

Exhibition routes: inhalation

Results: Low acute inhalation toxicity; LC50 In the rats is > 2.0 mg/l (or g/m³). Based on the available data, the classification criteria are not satisfied.

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

BORIC ACID

Method: Essay of primary dermal irritation - Epa Fifra (40 Cfr 163)

Species: New Zealand's white rabbit

Dose: 0.5 g humidified with physiological solution exposure routes: Dermica

Results: no skin irritation. Average primary irritation score: 0.1. Based on the available data, the classification criteria are not satisfied.

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

BORIC ACID

Method: study on eye irritations - similar to the OECD 405 guideline

Species: New Zealand's white rabbit

Dose: 0.1 g

Exhibition routes: eyepiece

Results: non-irritating, corneal interest or irritation resolved in 7 days.

Classification: Based on average scores <1 and with completely reversible effects in 7 days, classification criteria are not satisfied.

Numerous years of professional exposure do not indicate negative effects for the human eye.

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

BORIC ACID

Method: Buehler test - Guidelines 406 of the OECD Species: Pomm of India

Dose: 0.4 g 95% W/W/Borico Acid Exposure routes: Dermica

Results: it is not a sensitivity of the skin. Studies on the raising awareness of the respiratory tract have been conducted. There are no data that suggest that boric acid is a sensitivity of the respiratory tract. Based on the available data, the classification criteria are not satisfied.

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

BORIC ACID

Method: numerous studies on the in vitro mutagenicity of boric acid have been conducted including the gene mutation of mammal cells, the synthesis of unscheduled DNA, the chromosomal aberration and the exchange of chromatid brothers in the mammals cells.

Species: L5178Y mouse lymphoma, Chinese hamster cells V79, C3h/10T1/2 cells, hepatocytes, Chinese hamster ovary (CLE cells).

Dose: from 1.0 to 10.0 mg/ml (from 1,000 to 10,000 ppm) of boric acid

Exposure routes: in vitro

Results: not mutagen. Based on the available data, the classification criteria are not satisfied

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

BORIC ACID

Method: OECD 451 Equivalent

Species: B6c3f1 mice

Dose: 446; 1,150 mg of boric acid/kg body weight/day exposure routes: study on oral nutrition

Results: no evidence of carcinogenicity. Based on the available data, the classification criteria are not satisfied.

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

pH 9,21 - Buffer pH 9.21 blue**SECTION 11. Toxicological information ... / >>****BORIC ACID**

Method: Food study on three generations - similar to studying on two generations 416 of the OECD

Species: rat

Dose: 0; 34 (5.9); 100 (17.5) and 336 (58.5) MG of Borico Acid (MG B)/Kg BW/Day Exposure routes: study on oral nutrition

Results: the dose without adverse effects observed (Noael) in the rats in terms of effects on the fertility of the males is 100 mg of boric/kg of body weight, equivalent to 17.5 mg b/kg of body weight.

Method: Essay on boric acid toxicity on prenatal development - Guideline 414 of the OECD

Species: rat

Dose: 0; 19 (3,3); 36 (6.3); 55 (9.6); 76 (13.3) and 143 (25) MG of Borico Acid (MG B)/kg of body weight. Exhibition routes: study on oral nutrition

Results: the dose without adverse effects observed (Noael) in the rats in terms of effects on the development of the fetus including fetal weight loss and the minimum skeletal variations is 55 mg of boric/kg of body weight or 9.6 mg b /Kg.

Classification: Toxicity for reproduction, category 1b (danger indication: H360fd: it can harm fertility. It can harm the fetus.)

Method: employment studies for the assessment of parameters sensitive to sperm in workers strongly exposed to borains.

Epidemiological studies were conducted that have evaluated environmental exposures to the Boro and the effects on the development of individuals.

Human species

Dose: a subset of workers was exposed to 125 mg b/day exposure routes: oral ingestion and combined inhalation

Results: no negative effect on male workers fertility. The epidemiological studies of the effects on man's development have demonstrated an absence of effects in workers exposed to borains and populations living in areas characterized by high environmental levels of Boro

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

BORIC ACID

Method: Standard test method for the estimate of the sensory irritation of aerodisperse chemicals - ASTM E981-04 (2004)

Species: mouse

Dose: from 221 to 1096 mg of boric acid/m3 exposure routes: inhalation

Results: the highest concentration of boric acid reached with acceptable control of the aerosol concentration was 1096 mg/m3 with an RD % of 19 %. The minimum exposure of 221 mg/m3 of Borico acid has led to a respiratory rhythm reduced by 9%, assessed as non-irritating. Based on the available data, the classification criteria are not satisfied.

Method: sensory irritation in voluntary subjects especially: human

Dose: 2.5, 5 or 10 mg of boric acid/m3 exposure routes: inhalation

Results: Irritations are not observed against Borico Acid for exposures up to 10 mg/m3 among the male and female volunteer subjects in controlled laboratory conditions.

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

BORIC ACID

Method: Essay on chronic toxicity of boric acid - similar to the OECD 452 guideline

Species: rat

Dose: 0; 33 (5.9); 100 (17.5); 334 (58.5) MG of boric acid (B)/kg body weight/day (nominal in the diet) exposure routes: oral (power supply)

Results: a Noael dose of 17.5 mg b/kg body weight/day equivalent to 100 mg of boric acid/kg body weight/day was established in a study on chronic diet (2 years) in the rats and is based on the tested effects. Other effects (kidneys, hematopoietic system) are considered exclusively to even superior dosage levels. Based on the available data, the classification criteria are not satisfied

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

BORIC ACID

The physical form of the dust indicates the absence of a potential danger in the event of aspiration.

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

pH 9,21 - Buffer pH 9.21 blue**SECTION 12. Ecological information**

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

BORIC ACID

EC10/30min: 1580 mg/l/30min (b) (*pseudomonas putida*)

IC10/96h: 24 mg/l/96h (alche) (*Desmodemus subspypotus*)

LC50 - Fish 5600 mg/l/96h *Gambusia Affinis*

EC50 - Crustaceans 658 mg/l/48h *Daphnia Magna*

12.2. Persistence and degradability

BORIC ACID

Biodegradation is not an applicable endpoint as the product is an inorganic substance.

12.3. Bioaccumulative potential

BORIC ACID

The product undergoes hydrolysis in water with the formation of non -dissociated boric acid. Boric acid does not undergo biomagnification through the food chain. Eighty -free division coefficient/water: log power = - 0.7570 to 25 ° C (based on boric acid).

12.4. Mobility in soil

BORIC ACID

The product is soluble in water and can be released in normal soils. Adsorption in the land or sediments is irrelevant.

12.5. Results of PBT and vPvB assessment

BORIC ACID

In accordance with Annex XIII of the REACH Regulation, the criteria for the evaluation of the PBT and VPVB properties do not apply to inorganic substances.

Based on the available data, the product does not contain PBT or VPVB substances as a percentage greater than 0.1%.

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%.

12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations**13.1. Waste treatment methods**

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number or ID number

not applicable

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SECTION 14. Transport information ... / >>

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

not applicable

14.4. Packing group

not applicable

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EU: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

Contained substance

Point	30-75	BORIC ACID REACH Reg.: 01-2119486683-25-XXXX
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Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

not applicable

Substances in Candidate List (Art. 59 REACH)

BORIC ACID
REACH Reg.: 01-2119486683-25-XXXX

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Information not available

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Repr. 1B	Reproductive toxicity, category 1B
H360FD	May damage fertility. May damage the unborn child.
EUH210	Safety data sheet available on request.

pH 9,21 - Buffer pH 9.21 blue**SECTION 16. Other information ... / >>****LEGEND:**

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2019/521 (XII Atp. CLP)
16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

pH 9,21 - Buffer pH 9.21 blue**SECTION 16. Other information ... / >>**

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review:

The following sections were modified:

02 / 03 / 04 / 08 / 09 / 10 / 11 / 12 / 15 / 16.