Inextmune	NEXTMUNE ITALY SRL	Revision nr. 3
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	Cofety Data Chaot	
Acco	Safety Data Sheet rding to Annex II to REACH - Regulation 2020/878 and to Annex	nex II to UK REACH
SECTION 1. Identification	of the substance/mixture and of the com	pany/undertaking
1.1. Product identifier Product name	CLOREXYDERM SPOT GEL	
	substance or mixture and uses advised against eptic gel with re-hydration action for pets. Topical use.	
1.3. Details of the supplier of the s	afety data sheet	
Name Full address	NEXTMUNE ITALY SRL Via G.B. Benzoni, 50	
District and Country	26020 Palazzo Pignano (CR) ITALIA	
	Tel. 0373/982024	
	Fax 0373/982025	
e-mail address of the competent pers	on	
responsible for the Safety Data Shee	t regulatory.it@nextmune.com	
1.4. Emergency telephone number For urgent inquiries refer to	Centro Antiveleni di Milano 02 66101029 Centro Antiveleni di Pavia 0382 24444 (C Centro Antiveleni di Bergamo 800 88330 Centro Antiveleni di Firenze 055 7947819 Centro Antiveleni di Roma 06 3054343 (C	0 (CAV Ospedali Riuniti-Bergamo) 0 (CAV Ospedale Careggi-Firenze) CAV Policlinico Gemelli-Roma) CAV Ospedale Pediatrico Bambino Gesù- CAV Policlinico Umberto I-Roma) (CAV Ospedale Cardarelli-Napoli)
SECTION 2. Hazards ider	tification	
2.1. Classification of the substance	or mixture	
supplements). The product thus require	as pursuant to the provisions set forth in (EC) Regulation 1: as a safety datasheet that complies with the provisions of (EU) he risks for health and/or the environment are given in section	Regulation 2020/878.
Hazard classification and indication: Hazardous to the aquatic environmen category 3	nt, chronic toxicity, H412 Harmful to	aquatic life with long lasting effects.
2.2. Label elements		
Hazard labelling pursuant to EC Regul	ation 1272/2008 (CLP) and subsequent amendments and sup	plements.
Hazard pictograms:		
Signal words:		

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Hazard statements:

H412

Harmful to aquatic life with long lasting effects.

Precautionary statements:

P305 + P351	IF IN EYES: Rinse cautiously with water for several minutes.
P314	Get medical advice/attention if you feel unwell.
P102	Keep out of reach of children

PRECAUTIONS:

- Do not contaminate foods, beverages, or food or beverage containers.
- Do not use with other disinfectants.
- Consult a veterinarian before applying on pregnant or nursing animals or young, sick or convalescent animal.
- Avoid contact with eyes.
- External use only.
- If the product comes into contact with the eyes, rinse well with abundant water.
- Not to be sold out of the package.
- Keep the package well closed.
- Do not allow the animal to swallow the product during its use.
- Do not let to use to asmatic persons and/or children.
- Product for dogs and cats.

2.3. Other hazards

On 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 $\geq 0.1\%$.

SECTION 3. Composition/information on ingredients

3.1. Substances

Information not relevant

3.2. Mixtures

Contains:

Identification 2-Propanol	x = Conc. %	Classification (EC) 1272/2008 (CLP)
CAS 67-63-0 EC 200-661-7	4≤x< 5	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336
INDEX 603-117-00-0		
REACH Reg. 01-2119457558-25-XXXX		
CLOREXIDINA DIGLUCONATO		
CAS 18472-51-0	0,30 ≤ x < 0,45	Eye Dam. 1 H318, Aquatic Acute 1 H400 M=10, Aquatic Chronic 1 H410 M=1
EC 242-354-0		
INDEX -		
REACH Reg. 01-2119946568-22-0001		

The full wording of hazard (H) phrases is given in section 16 of the sheet.

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SECTION 4. First aid measures

4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

4.2. Most important symptoms and effects, both acute and delayed

Specific information on symptoms and effects caused by the product are unknown.

4.3. Indication of any immediate medical attention and special treatment needed

Information not available

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak. UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

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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

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material. Make sure the leakage site is well aired. 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

Handle the product after consulting all other sections of this Safety Data Sheet. Avoid product dispersal into the environment. Do not eat, drink or smoke while handling it.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

No use other than that indicated in section 1.2 of this safety data sheet.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

2-	Pr	op	an	ol	

Health - Derived no-eff	fect level - DNEL / Effects on consumers	DMEL			Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral			0 mg/kg	26 mg/kg				
Inhalation			0 mg/m3	89 mg/m3			0 mg/m3	500 mg/m3
Skin			0 mg/kg	319 mg/kg			0 mg/kg	888 mg/kg

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

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.

HAND PROTECTION Protect your hands with work gloves, category III (ref. Standard EN 374). SKIN PROTECTION Wash down with soap and water.

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RESPIRATORY PROTECTION

None required.

EYE PROTECTION

It is advisable to wear protective goggles (ref. Standard EN 166).

ENVIRONMENTAL EXPOSURE CONTROLS

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

Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties

Value

Appearance Colour Odour Melting point / freezing point Initial boiling point Flammability	clear viscous liquid light blue characteristic light Freezing point: <0 ° C 85 ° C Non flammable because it does not contain flammable substances
Lower explosive limit	Not explosive because it does not contain explosive substances
Upper explosive limit	Not explosive because it does not contain explosive substances
Flash point	Non flammable because it does not contain flammable substances.
Auto-ignition temperature	Unavailable 6.5 - 7.5
Kinematic viscosity	Unavailable
Solubility	Soluble in water
Partition coefficient: n-octanol/water	Unavailable
Vapour pressure	Unavailable
Density and/or relative density Relative vapour density	995 g / L-1015 g / L Unavailable
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.

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10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

The vapours may also form explosive mixtures with the air.

10.4. Conditions to avoid

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

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

Metabolism, toxicokinetics, mechanism of action and other information Information not available

Information on likely routes of exposure Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure Information not available

Interactive effects Information not available

ACUTE TOXICITY

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

SKIN CORROSION / IRRITATION Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION Does not meet the classification criteria for this hazard class

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Respiratory sensitization Information not available

Skin sensitization Information not available

GERM CELL MUTAGENICITY Does not meet the classification criteria for this hazard class

CARCINOGENICITY Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Adverse effects on sexual function and fertility Information not available

Adverse effects on development of the offspring Information not available

Effects on or via lactation Information not available

<u>STOT - SINGLE EXPOSURE</u> Does not meet the classification criteria for this hazard class

<u>Target organs</u> Information not available

Route of exposure Information not available

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

Target organs Information not available

Route of exposure Information not available

ASPIRATION HAZARD Does not meet the classification criteria for this hazard class

Data referring to the hazardous substances of the mixture:

ISOPROPANOL: Acute toxicity: No negative effects found Acute oral toxicity: Parameter: LD50 Route of exposure: Oral route Species: Rat Effective dose: = 5840 mg / Kg-bw Acute dermal toxicity Parameter: LD50

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Route of exposure: Dermal Species: Rabbit Effective dose: = 16.4 ml / Kg bw Acute inhalation toxicity Parameter: LC50 Route of exposure: Inhalation Species: Rat Effective dose:> 10000 ppm Exposure time: 6 h Irritation and Corrosivity Skin irritation (OECD 404): non-irritating (Determined in rabbit) Serious eye damage / eye irritation Eve irritation (OECD 405): irritant (Determined on rabbit eyes) Respiratory or skin sensitization It does not exert a sensitizing action. Toxicity after repeated use (subacute, subchronic, chronic) Human: not classified for organ toxicity In male rats: The product may affect the kidneys and liver, causing disturbances functional. CMR effects (carcinogenic, mutagenic, toxic for reproduction) Ames test: negative. Reproductive toxicity Possible adverse effects on developmental toxicity Parameter: NOAEL (C) Route of exposure: Oral route Species: Rabbit Effective dose: 480 mg / kg bw / day Specific target organ toxicity (STOT) - single exposure It can cause drowsiness or dizziness. Aspiration hazard Not applicable CHLORHEXIDINE DIGLUCONATE: Acute toxicity - Ingestion: Not classified. LD50 (oral, mouse) mg/kg: >2000 mg/Kg Acute toxicity - Skin Contact: Not classified. Dermal Median Lethal Dose (rabbit) >2000 mg/Kg Acute toxicity – Inhalation: Not classified. No information available. May be harmful if inhaled. Skin corrosion/irritation: This material showed low primary skin irritation potential to rabbit skin. Serious eye damage/irritation: Causes serious eye damage. May cause severe damage to eyes. Skin sensitization data: Some rare cases of allergic reactions have been reported. This material is not considered a skin sensitizer. Respiratory sensitization data: Not classified. Germ cell mutagenicity: There is no evidence of mutagenic potential. Carcinogenicity: There is no evidence that this product represents a carcinogenic risk under normal conditions of handling and use. Reproductive toxicity: No evidence of reproductive toxicity or teratogenic potencial. STOT - single exposure: May cause irritation to the respiratory system. STOT - repeated exposure: Not classified. Aspiration hazard: Not classified.

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.

SECTION 12. Ecological information

This product is dangerous for the environment and the aquatic organisms. In the long term, it have negative effects on aquatic environment. **12.1. Toxicity**

CHLORHEXIDINE DIGLUCONATE: Very toxic to aquatic life with long lasting effects. Toxicity - Aquatic invertebrates: 0,087 mg/l (as pure chlorhexidine digluconate) Toxicity – Fish: 2,08 mg/L (as pure chlorhexidine digluconate)

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Toxicity – Algae: 0,081 mg/l (as pure chlorhexidine digluconate)

ISOPROPANOL: Toxicity for waters Acute (short-term) toxicity to fish Parameter: LC50 (PROPAN-2-OLO; CAS No .: 67-63-0) Species: Pimephales promelas Effective dose: 9640 mg / I Exposure time: 96 h Acute (short-term) toxicity to crustaceans Parameter: LC50 (PROPAN-2-OLO; CAS No .: 67-63-0) Species: Acute (short term) toxicity to daphnia Effective dose:> 10000 mg / I Exposure time: 24 h Acute (short-term) toxicity to algae and cyanobacteria Parameter: EC50 (PROPAN-2-OLO; CAS No .: 67-63-0) Species: Scenedesmus quadricauda Effective dose: 1800 mg / I Exposure time: 7 days

12.2. Persistence and degradability

CHLORHEXIDINE DIGLUCONATE: Not readily biodegradable. ISOPROPANOL: readily biodegradable.

12.3. Bioaccumulative potential

CHLORHEXIDINE DIGLUCONATE: Bioconcentration factor (BCF) : 42 L/kg (chlorhexidine digluconate)

12.4. Mobility in soil

CHLORHEXIDINE DIGLUCONATE: logKoc: > 3.9 (chlorhexidine digluconate)

12.5. Results of PBT and vPvB assessment

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. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

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

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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

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

Product Point 3 - 40

Contained substance Point

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors Not applicable

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Substances in Candidate List (Art. 59 REACH) On the basis of available data, the product does not contain any SVHC in percentage \geq than 0,1%.

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

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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:

Flam. Liq. 2	Flammable liquid, category 2
Eye Dam. 1	Serious eye damage, category 1
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
H225	Highly flammable liquid and vapour.
H318	Causes serious eye damage.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

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

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2. Regulation (EC) 1272/2008 (CLP 3. Regulation (EU) 2020/878 (II Ann 4. Regulation (EC) 790/2009 (I Atp. 5. Regulation (EU) 286/2011 (II Atp.	ex of REACH Regulation) 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 (EÚ) 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)
- 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.

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:

01 / 02 / 09 / 11 / 12 / 15 / 16.