

SAFETY DATA SHEET

PRODUCT NAME: CLEANAC.3
PRODUCT CODE: MEK-620D

SDS NUMBER: SDS/MEK-620D-00
ISSUANCE DATE: 08/04/2020

SECTION 1 – Identification of the Substance/Mixture and of the Company/Undertaking

1.1. Product Identifier

Product name:	CLEANAC.3
INDEX number	017-011-00-1
EC number	231-668-3
CAS number	7681-52-9
Registration Number	01-2119488154-34-XXXX
Product code:	MEK-620D

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

Intended use	Reagent for hematology analyzer.
Uses advised against	No use advised against.

1.3. Details of the supplier of the safety data sheet

Supplier:	Nihon Kohden Middle East (Branch)
Address:	QC-4, QC-5, QC-6, QC-7 DAFZA Industrial Park. Al Qusais, Dubai U.A.E
Telephone number:	+971 4-239-9911
Fax:	+971 4-880-0122
e-mail address of the competent person responsible for the Safety Data Sheet	

1.4. Emergency telephone number

For urgent inquiries refer to	Company Emergency telephone number: +971 4-239-9911 (during working hours)
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SECTION 2 – Hazards Identification

2.1. Classification of the substance or mixture.

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The product is classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of EC Regulation 1907/2006 and subsequent amendments. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

The classification of the compound, featuring an extreme pH value, is based on the results of an appropriate validated in-vitro test as set out in the 67/548/EEC directive, annex VI, paragraph 3.2.5, and following modifications, and in 1272/2008 regulation annex I, 3.2.2.2.

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments.

Hazard classification and indication:

Met. Corr. 1	H290
Eye Irrit. 2	H319
Skin Irrit. 2	H315
	Note B

2.1.2. 67/548/EEC and 1999/45/EC Directives and following amendments and adjustments.

Danger Symbols: -- R phrases: --

2.2. Label elements.

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

Hazard Pictograms:



Signal words:

Warning

Hazard statements:

H290

May be corrosive to metals.

H319

Causes serious eye irritation.

H315

Causes skin irritation.

Precautionary statements:

P234

Keep only in original container.

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P280 Wear protective gloves / protective clothing / eye protection / face protection.
P337+P313 If eye irritation persists: Get medical advice / attention.
P390 Absorb spillage to prevent material damage.

INDEX. 017-011-00-1

The product Cleanac-3 is in conformity with the requirements of in vitro diagnostic medical devices Directive 98/79/EC. Therefore, in accordance with art. 1, 5, d) of Regulation 1272/2008, CLP requirements of labeling do not apply to the product in the finished state, intended for the final user.

2.3. Other hazards. Information not available.

SECTION 3 – Composition/Information on Ingredients

3.1. Substances.

Contains:

Identification.	Conc. %.	Classification	Classification 1272/2008 (CLP).
Sodium Hypochlorite, Solution 15 % Cl active		67/548/EEC.	
CAS. 7681-52-9	1-1,5	R31, C R34, N	Met. Corr. 1 H290, Skin
EC. 231-668-3		R50, Note B	Corr. 1B H314, Aquatic
INDEX. 017-011-00-1			Acute 1 H400 M=10,
Reg. no. 01-2119488154-34-XXXX			EUH031, Note B

The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet.
T+ = Very Toxic(T+), T = Toxic(T), Xn = Harmful(Xn), C = Corrosive(C), Xi = Irritant(Xi), O = Oxidizing(O), E = Explosive(E), F+ = Extremely Flammable(F+), F = Highly Flammable(F), N = Dangerous for the Environment(N)

3.2. Mixtures. Information not relevant.

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 30-60 minutes, opening the eyelids fully. Get medical advice/attention.
SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention

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INGESTION: Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorized by a doctor.

INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.

PROTECTIVE MEASURES FOR THE FIRST RESCUE WORKERS: for PPE (personal protection equipment) required for first aid refer to section 8.2 of this safety data sheet.

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

For symptoms and effects caused by the contained substances, see chap. 11.

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

Information not available.

SECTION 5 – Fire-fighting Measures

The product is not flammable. However, being a halogenated oxidizing agent in contact with acid gives rise to development of chlorine. Heating and contact with metals cause decomposition. It should not be put in contact with reducing agents.

5.1. Extinguishing Media:

SUITABLE EXTINGUISHING EQUIPMENT

Extinguishing substances are carbon dioxide and chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapors 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

If large quantities of the product are involved in a fire, they can make it considerably worse. Do not breathe combustion products.

5.3. Advice for firefighters.

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In the case of fire, use jets of water to cool the containers to prevent the risk of explosions (product decomposition and excess pressure) and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Remove all containers containing the product from the fire if it is safe to do so.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal firefighting 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.

The product must not penetrate 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. Check incompatibility for container material in section 7.

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.

Ensure that there is an adequate earthing system for the equipment and personnel. Avoid contact with eyes and skin. Do not breathe powders, vapors, or mists. Do not eat, drink, or smoke during use. Wash hands after use. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities.

Store only in the original container. Store in a ventilated and dry place, far away from sources of ignition. Keep containers well sealed. Keep the product in clearly labelled containers. Avoid overheating. Avoid violent blows. Keep containers away from any incompatible materials, see section 10 for details.

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7.3. Specific end use(s).

No use other than specified in Section 1.2 of this safety data sheet.

SECTION 8 – Exposure Controls/Personal Protection

8.1. Control parameters.

Regulatory References:

United Kingdom	EH40/2005 Workplace exposure limits. Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations (as amended).
Éire	Code of Practice Chemical Agent Regulations 2011
OEL EU	Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC.
TLV-ACGIH	ACGIH 2013

Sodium Hypochlorite, Solution ... % Cl active Threshold Limit Value.

Type	Country	TWA/8h		STEL/15min	
		mg/m ³	ppm	mg/m ³	ppm
TLV-ACGIH		1,5	0,5		

Source: data present in SDS Supplier

Legend:

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

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.

Provide an emergency shower with face and eye wash station.

HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

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SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC 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

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapors of various kinds and/or gases or vapors containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odorless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

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.

Appearance:	Liquid.
Color:	Clear light-yellow.
Odor:	Characteristic.
Odor threshold:	Not available.
pH:	10.0 to 13.0
Melting point / freezing point.	Not available.
Initial boiling point.	Not available.
Boiling range.	Not available.
Flash point.	> 60 °C.
Evaporation Rate	Not available.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.

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Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapor pressure.	Not available.
Vapor density	Not available.
Relative density.	Not available.
Solubility	soluble in water
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	The product is not explosive on the basis of the composition.
Oxidizing properties	Not available.

9.2. Other information.

VOC (Directive 1999/13/EC) :	0
VOC (volatile carbon) :	0

SECTION 10 – Stability and Reactivity

10.1. Reactivity.

Information not available.

10.2. Chemical stability.

Information not available.

10.3. Possibility of hazardous reactions.

Contact with strong acids causes the development of toxic gases.

10.4. Conditions to avoid.

Avoid overheating.

10.5. Incompatible materials.

Strong acids.

10.6. Hazardous decomposition products

Information not available.

SECTION 11 – Toxicological Information

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11.1. Information on toxicological effects.

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.

Acute effects: stinging eyes. Symptoms may include: rufescence, edema, pain, and lachrymation. Vapor inhalation may moderately irritate the upper respiratory tract. Contact with skin may cause slight irritation.

Ingestion may cause health problems, including stomach pain and sting, nausea, and sickness.

Acute effects: contact with skin may cause irritation, erythema, edema, dryness and chapped skin.

Vapor inhalation may slightly irritate the upper respiratory tract. Ingestion may cause health disorders, including stomach pain and sting, nausea, and sickness.

ACUTE TOXICITY: no data available.

SKIN CORROSION/IRRITATION: Irritant on the basis of the composition (section 3.1 of the SDS).

An in vitro test according to EPA 1120 method and Guideline no. OECD 435 was performed on Cleanac 3 to determine the corrosion potential of the product on human skin. The product was considered not to be classified under corrosive categories 1A, 1B, 1C of Regulation 1272/2008 (Certificate of Analysis 11/14281 of 11/08/2011 of Chemical Controls SRL).

SERIOUS EYE DAMAGE/IRRITATION: Causes serious eye irritation, see the composition indicated in Section 3.1.

RESPIRATORY OR SKIN No data available.

SENSITISATION:

GERM CELL MUTAGENICITY: No data available.

CARCINOGENICITY: No data available.

REPRODUCTIVE TOXICITY: No data available.

STOT-SINGLE EXPOSURE: No data available.

STOT-REPEATED EXPOSURE: No data available.

ASPIRATION HAZARD: No data available.

Sodium Hypochlorite, Solution ... % Cl active (CAS 7681-52-9).

LD50 (Oral). 1100 mg / kg Rat (Data available in the supplier safety data sheet).

LD50 (Dermal). 10000 mg / kg Rabbit (Data available in the supplier safety data sheet).

LC50 (Inhalation). 10.5 mg / l 1 h - Rat (Data available in the supplier safety data sheet).

CORROSION / IRRITATION: Hypochlorite bleach, 5.25 %, was slightly irritant, in vivo tests conducted on rabbits and guinea d'india (method: OECD TG 404) (Data available in ECHA web site).

EYE IRRITATION: Irritant, in vivo tests conducted on rabbits (similar to or equivalent to method OECD TG 405) (Data available in ECHA web site).

SECTION 12 – Ecological Information

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No specific data are available for this product. Handle it according to good working practices. Avoid littering. Do not contaminate soil, sewers and waterways. Inform the competent authorities, should the product reach waterways or sewers or contaminate soil or vegetation. Please take all the proper measures to reduce harmful effects on aquifers.

12.1. Toxicity.

Sodium Hypochlorite, Solution 15 % Cl active

LC50 - for Fish. > 0,01 mg/l/96h (Data available in the supplier safety data sheet)

EC50 - for Crustacea. > 0,01 mg/l/48h Daphnia magna (Data available in the supplier safety data sheet).

12.2. Persistence and degradability.

Information not available.

12.3. Bio accumulative potential.

Sodium hypochlorite, solution (CAS 7681-52-9): does not give rise to bioaccumulation or bioconcentration phenomena thanks to his high-water solubility and reactivity. Sodium hypochlorite, solution has a low potential for bioaccumulation (calculated logKow = -3.42) and decomposes in water.

12.4. Mobility in soil.

Information not available.

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 greater than 0,1%.

12.6. 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 authorized waste management firm, in compliance with national and local regulations. Avoid littering. Do not contaminate soil, sewers, and waterways.

Waste transportation may be subject to ADR restrictions.

CONTAMINATED PACKAGING

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

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SECTION 14 – Transport Information

14.1. UN Number

(ADR, RID, IMDG Code, ICAO): UN 1791

14.2. UN proper shipping name

(ADR, RID): HYPOCHLORITE solution.

(IMDG Code, ICAO): HYPOCHLORITE solution.

14.3. Transport hazard class(es)

(ADR, RID):



Class: 8

Label: 8

(IMDG Code, ICAO):



Class: 8

Label: 8

14.4. Packing Group

(ADR, RID, IMDG Code, ICAO): III.

14.5. Environmental hazards: NO

14.6. Special precautions for user

These goods must be transported by vehicles authorized to the carriage of dangerous goods according to the provisions set out in the current edition of the Code of International Carriage of Dangerous Goods by Road (ADR) and in all the applicable national regulations. These goods must be packed in their original packaging's or in packaging's made of materials resistant to their content and not reacting dangerously with it. People loading and unloading dangerous goods must be trained on all the risks deriving from these substances and on all actions that must be taken in case of emergency situations.

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

(ADR, RID, ICAO): Information not relevant.

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(IMDG Code): Information not relevant.

Further information:

(ADR, RID):

Nr. Kemler: 80
 Limited Quantity: 5 L
 Tunnel restriction code: (E)

(IMDG Code):

EMS: F-A, S-B

(ICAO):

Cargo:

Packaging instructions: 856 Maximum quantity: 60 L

Pass.:

Packaging instructions: 852 Maximum quantity: 5 L

Special Instructions: A3, A803

SECTION 15 – Regulatory Information

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

Seveso category. None.

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

Product. Point. 3. Liquid substances or mixtures which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

(a) Hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F.
 (b) Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10; (c) hazard class 4.1; (d) hazard class 5.1.

Substances in Candidate List (Art. 59 REACH). None.

Substances subject to authorization (Annex XIV REACH) None.

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None.

Substances subject to the Rotterdam Convention: None.

Substances subject to the Stockholm Convention: None.

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Healthcare controls.

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

Section 16 – Other Information

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

Met. Corr. 1	Substance or mixture corrosive to metals, category 1		
Skin Corr. 1B	Skin corrosion, category 1B	Skin Irrit. 2	Skin irritation,
Eye Irrit. 2	Eye irritation, category 2	Category 2	
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1		
H290	May be corrosive to metals.		
H314	Causes severe skin burns and eye damage.		
H319	Causes serious eye irritation.		
H315	Causes skin irritation.		
H400	Very toxic to aquatic life.		
EUH031	Contact with acids liberates toxic gas.		

Text of risk (R) phrases mentioned in section 2-3 of the sheet:

R31	CONTACT WITH ACIDS LIBERATES TOXIC GAS.
R34	CAUSES BURNS.
R50	VERY TOXIC TO AQUATIC ORGANISMS.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 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 NUMBER: Identifier in Annex VI of CLP

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- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bio accumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 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 STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bio accumulative as for REACH Regulation - WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. Regulation (EC) 286/2011 (II Atp. CLP) of the European Parliament
8. Regulation (EC) 618/2012 (III Atp. CLP) of the European Parliament
9. The Merck Index. - 10th Edition
10. Handling Chemical Safety
11. Niosh - Registry of Toxic Effects of Chemical Substances
12. INRS - Fiche Toxicologique (toxicological sheet)
13. Patty - Industrial Hygiene and Toxicology
14. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
15. ECHA website

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

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relieved from any liability arising from improper uses. Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review: NA