

SAFETY DATA SHEET

SIEMENS

3gAllergy(TM) Specific IgE Positive Control for D1

SDS # :

DC1L

Section 1. Identification

Product identifier : 3gAllergy(TM) Specific IgE Positive Control for D1
Product code : DC1L, DC2L, MC6L, 10283024, 10283025, 10283026, 10485104, 10485105, 10485106
Product type : Liquid.

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

Not applicable.

Manufactured/supplied : Siemens Healthcare Diagnostics Inc.
 511 Benedict Avenue
 Tarrytown, NY 10591-5097 USA
 1-877-229-3711
 (800) 424-9300 (CHEMTREC) (24/365)

Section 2. Hazards identification

OSHA/HCS status : Positive Controls
 While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Positive Controls
 Not classified.
 Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 99%

Additional information : Potentially biohazardous material.
 Not available.

GHS label elements

Signal word : Positive Controls
 No signal word.

Hazard statements : Positive Controls
 No known significant effects or critical hazards.

Precautionary statements

Prevention : Positive Controls
 Not applicable.

Response : Positive Controls
 Not applicable.

Storage : Positive Controls
 Not applicable.

Disposal : Positive Controls
 Not applicable.

Supplemental label elements : Positive Controls
 None known.

Hazards not otherwise classified : Positive Controls
 None known.

Section 3. Composition/information on ingredients

Substance/mixture : Positive Controls Mixture

Ingredient name	%	CAS number
Positive Controls Gentamicin, sulfate (salt)	0.005	1405-41-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

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

Section 4. First aid measures

Description of necessary first aid measures

Eye contact	: Positive Controls	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
Inhalation	: Positive Controls	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
Skin contact	: Positive Controls	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
Ingestion	: Positive Controls	Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact	: Positive Controls	No known significant effects or critical hazards.
Inhalation	: Positive Controls	No known significant effects or critical hazards.
Skin contact	: Positive Controls	No known significant effects or critical hazards.
Ingestion	: Positive Controls	No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact	: Positive Controls	No specific data.
Inhalation	: Positive Controls	No specific data.
Skin contact	: Positive Controls	No specific data.
Ingestion	: Positive Controls	No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician	: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments	: No specific treatment.

Section 4. First aid measures

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : In case of fire, use water spray (fog), foam or dry chemical.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous thermal decomposition products : No specific data.

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.

Section 6. Accidental release measures

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 spilled 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 the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled 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).

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 non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

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.
- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

- Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Physical state	: Positive Controls	Liquid.
Color	: Positive Controls	Colorless.
Odor	: Positive Controls	Odorless.
pH	: Positive Controls	Not available.
Flash point	: Positive Controls	Not available.
Flammability (solid, gas)	: Positive Controls	Not relevant/applicable due to nature of the product.
Relative density	: Positive Controls	1
Solubility in water	: Positive Controls	Not relevant/applicable due to nature of the product.
Partition coefficient: n-octanol/water	: Positive Controls	Not available.
Auto-ignition temperature	: Positive Controls	Not available.
Viscosity	: Positive Controls	Not available.
<u>Aerosol product</u>		
Type of aerosol	: Positive Controls	Not applicable.

Section 10. Stability and reactivity

Reactivity	: Positive Controls	No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: Positive Controls	The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.	
Conditions to avoid	: No specific data.	
Incompatible materials	: No specific data.	
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.	

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Positive Controls Gentamicin, sulfate (salt)	LD50 Oral	Rat	>5 g/kg	-

Conclusion/Summary : Positive Controls Not available.

Irritation/Corrosion

Not available.

Conclusion/Summary

Skin	: Positive Controls	Not available.
Eyes	: Positive Controls	Not available.
Respiratory	: Positive Controls	Not available.

Sensitization

Not available.

Conclusion/Summary

Section 11. Toxicological information

Skin	: Positive Controls	Not available.
Respiratory	: Positive Controls	Not available.
<u>Mutagenicity</u>		
Not available.		
Conclusion/Summary	: Positive Controls	Not available.
<u>Carcinogenicity</u>		
Not available.		
Conclusion/Summary	: Positive Controls	Not available.
<u>Reproductive toxicity</u>		
Not available.		
Conclusion/Summary	: Positive Controls	Not available.
<u>Teratogenicity</u>		
Not available.		
Conclusion/Summary	: Positive Controls	Not available.
<u>Specific target organ toxicity (single exposure)</u>		
Not available.		
<u>Specific target organ toxicity (repeated exposure)</u>		
Not available.		
<u>Aspiration hazard</u>		
Not available.		
Information on the likely routes of exposure	: Positive Controls	Not available.
<u>Potential acute health effects</u>		
Eye contact	: Positive Controls	No known significant effects or critical hazards.
Inhalation	: Positive Controls	No known significant effects or critical hazards.
Skin contact	: Positive Controls	No known significant effects or critical hazards.
Ingestion	: Positive Controls	No known significant effects or critical hazards.
<u>Symptoms related to the physical, chemical and toxicological characteristics</u>		
Eye contact	: Positive Controls	No specific data.
Inhalation	: Positive Controls	No specific data.
Skin contact	: Positive Controls	No specific data.
Ingestion	: Positive Controls	No specific data.
<u>Delayed and immediate effects and also chronic effects from short and long term exposure</u>		
<u>Short term exposure</u>		
Potential immediate effects	: Positive Controls	Not available.
Potential delayed effects	: Positive Controls	Not available.
<u>Long term exposure</u>		
Potential immediate effects	: Positive Controls	Not available.
Potential delayed effects	: Positive Controls	Not available.
<u>Potential chronic health effects</u>		

Section 11. Toxicological information

Not available.

Conclusion/Summary	: Not available.	Positive Controls
General	: No known significant effects or critical hazards.	
Carcinogenicity	: No known significant effects or critical hazards.	
Mutagenicity	: No known significant effects or critical hazards.	
Teratogenicity	: No known significant effects or critical hazards.	
Developmental effects	: No known significant effects or critical hazards.	
Fertility effects	: No known significant effects or critical hazards.	

Numerical measures of toxicity

Acute toxicity estimates

Not available.

Interactive effects : Positive Controls Not available.

Other information : Positive Controls Not available.

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Positive Controls Gentamicin, sulfate (salt)	Acute EC50 21.2 ppm Fresh water Acute LC50 >955 ppm Fresh water	Daphnia - Daphnia magna Fish - Oncorhynchus mykiss	48 hours 96 hours

Conclusion/Summary : Positive Controls Not available.

Persistence and degradability

Conclusion/Summary : Positive Controls Not available.

Bioaccumulative potential

Not available.

Mobility in soil

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

Mobility : Positive Controls Not available.

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

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

DOT Classification

UN number	Positive Controls	Not regulated.
UN proper shipping name	Positive Controls	-
Transport hazard class(es)	Positive Controls	-
Packing group	Positive Controls	-
Environmental hazards	Positive Controls	No.
Additional information	Positive Controls	-

TDG Classification

UN number	Positive Controls	Not regulated.
UN proper shipping name	Positive Controls	-
Transport hazard class(es)	Positive Controls	-
Packing group	Positive Controls	-
Environmental hazards	Positive Controls	No.
Additional information	Positive Controls	-

ADR/RID

UN number	Positive Controls	Not regulated.
UN proper shipping name	Positive Controls	-
Transport hazard class(es)	Positive Controls	-
Packing group	Positive Controls	-
Environmental hazards	Positive Controls	No.
Additional information	Positive Controls	-

IMDG

UN number	Positive Controls	Not regulated.
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Section 14. Transport information

UN proper shipping name	Positive Controls	-
Transport hazard class(es)	Positive Controls	-
Packing group	Positive Controls	-
Environmental hazards	Positive Controls	No.
Additional information	Positive Controls	-
IATA		
UN number	Positive Controls	Not regulated.
UN proper shipping name	Positive Controls	-
Transport hazard class(es)	Positive Controls	-
Packing group	Positive Controls	-
Environmental hazards	Positive Controls	No.
Additional information	Positive Controls	-

Special precautions for user : Positive Controls

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

Transport in bulk according to Annex II of MARPOL and the IBC Code

Proper shipping name :
Ship type :
Pollution category :

Section 15. Regulatory information

U.S. Federal regulations	: TSCA 8(a) CDR Exempt/Partial exemption: Not determined United States inventory (TSCA 8b): Not determined.
Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)	: Not listed
Clean Air Act Section 602 Class I Substances	: Not listed

Section 15. Regulatory information

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

No products were found.

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

California Prop. 65

WARNING: This product contains less than 1% of a chemical known to the State of California to cause birth defects or other reproductive harm.

Ingredient name	Cancer	Reproductive	No significant risk level	Maximum acceptable dosage level
Positive Controls gentamicin, sulfate (salt)	No.	Yes.	No.	No.

International regulations

Chemical Weapons Convention List Schedule I Chemicals : Positive Controls Not listed

Chemical Weapons Convention List Schedule II Chemicals : Positive Controls Not listed

Chemical Weapons Convention List Schedule III Chemicals : Positive Controls Not listed

Section 16. Other information

History

Date of issue/Date of revision : 5/12/2017

Version : 1.05

Section 16. Other information

Key to abbreviations

: ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
UN = United Nations

Indicates information that has changed from previously issued version.

Notice to reader

Allergen

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