(2012 OSHA Hazard Communication Standard (29 CFR 1910.1200))

SAFETY DATA SHEET

ADVIA® Chemistry TDM Calibrators

SIEMENS

SDS # : 01661874

Section 1. Identification

Product identifier : ADVIA® Chemistry TDM Calibrators

Product code : 01661874, B03-4790-01, 10311922

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	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	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	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not classified.
Additional information	:	Potentially biohazardous material. Not available.	

GHS label elements

Signal word	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	No signal word.
Hazard statements	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	No known significant effects or critical hazards.

Precautionary statements

Prevention	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not applicable.
Response	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not applicable.
Storage	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not applicable.
Disposal	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not applicable.
Supplemental label elements	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	None known.
Hazards not otherwise classified	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	None known.

Section 3. Composition/information on ingredients

Substance/mixture : ADVIA® Chemistry TDM Calibrators Levels 1-6 Mixture

Ingredient name	%	CAS number
ADVIA® Chemistry TDM Calibrators Levels 1-6 Gentamicin, sulfate (salt)	0.01	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 : ADVIA® Chemistry TDM Calibrators Levels 1-6 — 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 : ADVIA® Chemistry TDM Calibrators Levels 1-6 — Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

Skin contact : ADVIA® Chemistry TDM Calibrators Levels 1-6 — Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion : ADVIA® Chemistry TDM Calibrators Levels 1-6 — 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 : ADVIA® Chemistry TDM Calibrators Levels 1-6 — No known significant effects or critical hazards.

Inhalation : ADVIA® Chemistry TDM Calibrators Levels 1-6 — No known significant effects or critical hazards.

Skin contact : ADVIA® Chemistry TDM Calibrators Levels 1-6 — No known significant effects or critical hazards.

Ingestion : ADVIA® Chemistry TDM Calibrators Levels 1-6 — No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : ADVIA® Chemistry TDM Calibrators Levels 1-6 — No specific data.

Inhalation : ADVIA® Chemistry TDM Calibrators Levels 1-6 — No specific data.

Skin contact : ADVIA® Chemistry TDM Calibrators Levels 1-6 — No specific data.

Ingestion : ADVIA® Chemistry TDM Calibrators Levels 1-6 — No specific data.

Section 4. First aid measures

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.

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	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Solid.
Color	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Off-white.
Odor	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Odorless.
pH	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not applicable.
Flash point	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.
Flammability (solid, gas)	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not relevant/applicable due to nature of the product.
Relative density	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not relevant/applicable due to nature of the product.
Solubility in water	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not relevant/applicable due to nature of the product.
Partition coefficient: n-octanol/water	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.
Auto-ignition temperature	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.
Viscosity	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.

Aerosol product

Type of aerosol	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not applicable.

Section 10. Stability and reactivity

Reactivity	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	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
ADVIA® Chemistry TDM Calibrators Levels 1-6 Gentamicin, sulfate (salt)	LD50 Oral	Rat	>5 g/kg	-

Conclusion/Summary	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.

Irritation/Corrosion

Section 11. Toxicological information

Not available.

Conclusion/Summary

Skin	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.
Eyes	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.
Respiratory	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.

Sensitization

Not available.

Conclusion/Summary

Skin	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.
Respiratory	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.

Mutagenicity

Not available.

Conclusion/Summary	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.

Carcinogenicity

Not available.

Conclusion/Summary	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.

Reproductive toxicity

Not available.

Conclusion/Summary	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.

Teratogenicity

Not available.

Conclusion/Summary	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.

Potential acute health effects

Eye contact	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	No known significant effects or critical hazards.
Inhalation	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	No known significant effects or critical hazards.
Skin contact	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	No known significant effects or critical hazards.
Ingestion	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	No known significant effects or critical hazards.

Section 11. Toxicological information

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : ADVIA® Chemistry TDM Calibrators Levels 1-6 — No specific data.

Inhalation : ADVIA® Chemistry TDM Calibrators Levels 1-6 — No specific data.

Skin contact : ADVIA® Chemistry TDM Calibrators Levels 1-6 — No specific data.

Ingestion : ADVIA® Chemistry TDM Calibrators Levels 1-6 — No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : ADVIA® Chemistry TDM Calibrators Levels 1-6 — Not available.

Potential delayed effects : ADVIA® Chemistry TDM Calibrators Levels 1-6 — Not available.

Long term exposure

Potential immediate effects : ADVIA® Chemistry TDM Calibrators Levels 1-6 — Not available.

Potential delayed effects : ADVIA® Chemistry TDM Calibrators Levels 1-6 — Not available.

Potential chronic health effects

Not available.

Conclusion/Summary : Not available. — ADVIA® Chemistry TDM Calibrators Levels 1-6

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 : ADVIA® Chemistry TDM Calibrators Levels 1-6 — Not available.

Other information : ADVIA® Chemistry TDM Calibrators Levels 1-6 — Not available.

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
ADVIA® Chemistry TDM Calibrators Levels 1-6			
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 : ADVIA® Chemistry TDM Calibrators Levels 1-6 — Not available.

Section 12. Ecological information

Persistence and degradability

Conclusion/Summary	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.

Bioaccumulative potential

Not available.

Mobility in soil

Soil/water partition coefficient (K_{OC})	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not available.
Mobility	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	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	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not regulated.
UN proper shipping name	ADVIA® Chemistry TDM Calibrators Levels 1-6	-
Transport hazard class(es)	ADVIA® Chemistry TDM Calibrators Levels 1-6	-
Packing group	ADVIA® Chemistry TDM Calibrators Levels 1-6	-
Environmental hazards	ADVIA® Chemistry TDM Calibrators Levels 1-6	No.
Additional information	ADVIA® Chemistry TDM Calibrators Levels 1-6	-

TDG Classification

UN number	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not regulated.
UN proper shipping name	ADVIA® Chemistry TDM Calibrators Levels 1-6	-
Transport hazard class(es)	ADVIA® Chemistry TDM Calibrators Levels 1-6	-

Section 14. Transport information

Packing group	ADVIA® Chemistry TDM Calibrators Levels 1-6	-
Environmental hazards	ADVIA® Chemistry TDM Calibrators Levels 1-6	No.
Additional information	ADVIA® Chemistry TDM Calibrators Levels 1-6	-

ADR/RID

UN number	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not regulated.
UN proper shipping name	ADVIA® Chemistry TDM Calibrators Levels 1-6	-
Transport hazard class(es)	ADVIA® Chemistry TDM Calibrators Levels 1-6	-
Packing group	ADVIA® Chemistry TDM Calibrators Levels 1-6	-
Environmental hazards	ADVIA® Chemistry TDM Calibrators Levels 1-6	No.
Additional information	ADVIA® Chemistry TDM Calibrators Levels 1-6	-

IMDG

UN number	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not regulated.
UN proper shipping name	ADVIA® Chemistry TDM Calibrators Levels 1-6	-
Transport hazard class(es)	ADVIA® Chemistry TDM Calibrators Levels 1-6	-
Packing group	ADVIA® Chemistry TDM Calibrators Levels 1-6	-
Environmental hazards	ADVIA® Chemistry TDM Calibrators Levels 1-6	No.
Additional information	ADVIA® Chemistry TDM Calibrators Levels 1-6	-

IATA

UN number	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not regulated.
UN proper shipping name	ADVIA® Chemistry TDM Calibrators Levels 1-6	-
Transport hazard class(es)	ADVIA® Chemistry TDM Calibrators Levels 1-6	-
Packing group	ADVIA® Chemistry TDM Calibrators Levels 1-6	-
Environmental hazards	ADVIA® Chemistry TDM Calibrators Levels 1-6	No.

Section 14. Transport information

Additional information ADVIA® Chemistry TDM Calibrators Levels 1-6 -

Special precautions for user : ADVIA® Chemistry TDM Calibrators Levels 1-6

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

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

Name	%	EHS	SARA 302 TPQ (lbs)	SARA 302 TPQ (gallons)	SARA 304 RQ (lbs)	SARA 304 RQ (gallons)
ADVIA® Chemistry TDM Calibrators Levels 1-6						
digoxin	0.01	Yes.	10 / 10000	-	10	-

SARA 304 RQ : 100000 lbs / 45400 kg

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

Section 15. Regulatory information

WARNING: This product contains less than 0.1% of a chemical known to the State of California to cause cancer.
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
ADVIA® Chemistry TDM Calibrators Levels 1-6				
gentamicin, sulfate (salt)	No.	Yes.	No.	No.
barbituric acid, 5-ethyl-5-phenyl-	Yes.	Yes.	Yes.	No.
hydantoin, 5,5-diphenyl-	Yes.	Yes.	No.	No.
valeric acid, 2-propyl-	No.	Yes.	No.	No.
5h-dibenz(b,f)azepine-5-carboxamide	No.	Yes.	No.	No.

International regulations

Chemical Weapons Convention List Schedule I Chemicals	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not listed
Chemical Weapons Convention List Schedule II Chemicals	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not listed
Chemical Weapons Convention List Schedule III Chemicals	:	ADVIA® Chemistry TDM Calibrators Levels 1-6	Not listed

Section 16. Other information

History

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

Version : 1.05

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 :