

**Diesse Diagnostica Senese Spa**

Sede Legale e Amm.ne: 20144 Milano – Via A. Solari, 19 – Italy

Tel.: +39 02 48.59.121 - Fax: +39 02 48.12.117

Capitale Sociale: euro 3.000.000

C.C.I.A.A. N°Reg. 1045219 - Registro Imp. Milano: 05871140157

Partita IVA e Codice Fiscale N°05871140157

www.diesse.itMonteriggioni, 21st August 2020**TO WHOM IT MAY CONCERN**

We DIESSSE Diagnostica Senese S.p.A., manufacturer of in vitro diagnostic medical devices with head office at Via A. Solari 19, 20144 Milan and manufacturing sites in Via delle Rose 10, 53035 Monteriggioni (SI), Via del Pozzo 5, 53035 Monteriggioni (SI) and Strada dei Laghi 39, 53035 Monteriggioni (SI), Italy hereby

declare

the products belonging to Chorus line are differently classified, labeled and packaged according to the REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC.

Below are reported a summary of the risk characteristics of Chorus products (in agreement with their Material Safety Data Sheet.

Table 1.

CHORUS AUTOIMMUNITY KITS	
CHORUS ANA-8	86010, 86010/12
CHORUS ANA-Screen	86014, 86014/12
CHORUS ANTI-CCP	86094, 86094/12
CHORUS ASCA-A	86062, 86062/12
CHORUS ASCA-G	86064, 86064/12
CHORUS BETA 2-GLYCOPROTEIN-G	86050, 86050/12
CHORUS BETA 2-GLYCOPROTEIN-M	86052, 86052/12
CHORUS CARDIOLIPIN-G	86046, 86046/12
CHORUS CARDIOLIPIN-M	86048, 86048/12
CHORUS Cenp-B	86028, 86028/12
CHORUS DEAMIDATED GLIADIN-A	86098, 86098/12
CHORUS DEAMIDATED GLIADIN-G	86100, 86100/12
CHORUS dsDNA-G	86032, 86032/12
CHORUS dsDNA-M	86034, 86034/12
CHORUS ENA-6 S	86012, 86012/12
CHORUS GBM	86070, 86070/12
CHORUS GLIADIN-A	86054, 86054/12
CHORUS GLIADIN-G	86056, 86056/12
CHORUS Jo-1	86030, 86030/12
CHORUS MPO	86068, 86068/12
CHORUS PR3	86066, 86066/12
CHORUS RF-M	86040, 86040/12
CHORUS Scl-70	86026, 86026/12

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CHORUS Sm	86016, 86016/12
CHORUS snRNP-C	86092, 86092/12
CHORUS SS-A	86018, 86018/12
CHORUS SS-B	86024, 86024/12
CHORUS TG High sensitivity	86104
CHORUS tTg-A	86058, 86058/12
CHORUS tTg-G	86060, 86060/12
CHORUS INFECTIOUS DISEASE KITS	
CHORUS BORRELIA IgG CSF	81048
CHORUS BRUCELLA IgG	81164
CHORUS BRUCELLA IgM	81166
CHORUS CHIKUNGUNYA IgG	81133
CHORUS CHIKUNGUNYA IgM	81134
CHORUS DENGUE IgG	81154
CHORUS DENGUE IgM	81156
CHORUS DIPHThERIA IgG	81266, 81266/12
CHORUS PARVOVIRUS IgG	81150
CHORUS PARVOVIRUS IgM	81152
CHORUS POLIOVIRUS IgG	81264, 81264/12
CHORUS Q FEVER PHASE II IgG	81171
CHORUS Q FEVER PHASE II IgM	81172
CHORUS TETANUS IgG	81270, 81270/12
CHORUS TICK-BORNE ENCEPHALITIS VIRUS IgG	81276
CHORUS TICK-BORNE ENCEPHALITIS VIRUS IgM	81277
CHORUS TOXOCARA IgG	81280
CHORUS HORMONES KITS	
CHORUS FSH	86510
CHORUS FT3	86518
CHORUS FT4	86520
CHORUS LH	86512
CHORUS PRL	86514
CHORUS TSH	86516

All the products listed in table 1 are classified as dangerous.

They are classified, labeled and packaged according to the information below.

**Classification according to
Regulation (EC) No.
1272/2008:**

Skin Sensitizer – Category 1



Pictograms:

Signal word:

Warning

Hazard statement(s):

H317 – May cause an allergic skin reaction

Precautionary statement(s):

Prevention:

P261 – Avoid breathing dust/fume/gas/mist/vapors/spray

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- P272 – Contaminated work clothing should not be allowed out of the workplace.
- P280 – Wear protective gloves/protective clothing/eye protection/face protection.

Response:

- P302+P352 – IF ON SKIN: Wash with plenty of soap and water
- P333+P313 – If skin irritation or rash occurs: Get medical advice/attention.
- P363 – Wash contaminated clothing before reuse.

Disposal:

- P501 – Dispose of contents/container in accordance with local regulation

Content:

Reaction mass of: 5-chloro-2-methyl-4-iso-thiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

Index No: 613-167-00-5

Table 2.

CHORUS AUTOIMMUNITY KITS	
CHORUS a-Tg	86072 - 86072/12
CHORUS a-TPO	86074 - 86074/12
CHORUS TG	86076 - 86076/12
CHORUS INFECTIOUS DISEASE KITS	
CHORUS ADENOVIRUS IgA	81198, 81198/12
CHORUS ADENOVIRUS IgG	81196, 81196/12
CHORUS CHLAMYDIA TRACHOMATIS IgA	81262
CHORUS CHLAMYDIA TRACHOMATIS IgG	81261
CHORUS CHLAMYDOPHILA PNEUMONIAE IgA	81252
CHORUS CHLAMYDOPHILA PNEUMONIAE IgG	81250
CHORUS CHLAMYDOPHILA PNEUMONIAE IgM	81251
CHORUS CYTOMEGALOVIRUS IgG	81010
CHORUS CYTOMEGALOVIRUS IgG AVIDITY	81092
CHORUS CYTOMEGALOVIRUS IgM	81011
CHORUS EPSTEIN-BARR EARLY ANTIGEN IgG	81058, 81058/12
CHORUS EPSTEIN-BARR EARLY ANTIGEN IgM	81059, 81059/12
CHORUS EPSTEIN-BARR EBNA IgG	81057
CHORUS EPSTEIN-BARR VCA IgG	81055
CHORUS EPSTEIN-BARR VCA IgM	81056
CHORUS EPSTEIN-BARR VCA IgM II	81054
CHORUS HELICOBACTER PYLORI IgA	81062
CHORUS HELICOBACTER PYLORI IgG	81060
CHORUS HERPES SIMPLEX 1 IgG RECOMBINANT	81023
CHORUS HERPES SIMPLEX 1 IgM RECOMBINANT	81255
CHORUS HERPES SIMPLEX 1+2 IgG	81020
CHORUS HERPES SIMPLEX 1+2 IgM	81021
CHORUS HERPES SIMPLEX 2 IgG RECOMBINANT	81029
CHORUS HERPES SIMPLEX 2 IgM RECOMBINANT	81256
CHORUS HSV 1 SCREEN	81018

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CHORUS LEGIONELLA PNEUMOPHILA 1 IgG	81091, 81091/12
CHORUS LEGIONELLA PNEUMOPHILA 1-6 IgG	81090, 81090/12
CHORUS LEGIONELLA PNEUMOPHILA IgM	81093, 81093/12
CHORUS MEASLES IgG	81072
CHORUS MEASLES IgM	81073, 81073/12
CHORUS MUMPS IgG	81075
CHORUS MUMPS IgM	81076, 81076/12
CHORUS MYCOPLASMA PNEUMONIAE IgA	81033
CHORUS MYCOPLASMA PNEUMONIAE IgG	81034
CHORUS MYCOPLASMA PNEUMONIAE IgM	81035
CHORUS RESPIRATORY SYNCYTIAL VIRUS IgA	81037, 81037/12
CHORUS RESPIRATORY SYNCYTIAL VIRUS IgG	81036, 81036/12
CHORUS RUBELLA IgG	81030
CHORUS RUBELLA IgG AVIDITY	81095
CHORUS RUBELLA IgM	81031
CHORUS SYPHILIS SCREEN RECOMBINANT	81100
CHORUS TOSCANA VIRUS IgG	81067, 81067/12
CHORUS TOXOPLASMA IgA	81043, 81043/12
CHORUS TOXOPLASMA IgG	81040
CHORUS TOXOPLASMA IgG AVIDITY	81098
CHORUS TOXOPLASMA IgM	81041
CHORUS TREPONEMA IgG	81050, 81050/12
CHORUS TREPONEMA IgM	81051, 81051/12
CHORUS VARICELLA IgG	81078
CHORUS VARICELLA IgM	81079, 81079/12
CHORUS INFECTIOUS DISEASE CONTROL SERUM	
CHORUS CYTOMEGALOVIRUS IgG AVIDITY CONTROL SERUM	81501
CHORUS CYTOMEGALOVIRUS IgG CONTROL SERUM	81500
CHORUS CYTOMEGALOVIRUS IgM CONTROL SERUM	81502
CHORUS EPSTEIN-BARR EARLY ANT. IgG CONTROL SERUM	81506
CHORUS EPSTEIN-BARR EARLY ANT. IgM CONTROL SERUM	81507
CHORUS EPSTEIN-BARR EBNA IgG CONTROL SERUM	81505
CHORUS EPSTEIN-BARR VCA IgG CONTROL SERUM	81503
CHORUS EPSTEIN-BARR VCA IgM CONTROL SERUM	81504
CHORUS HELICOBACTER PYLORI IgA CONTROL SERUM	81509
CHORUS HELICOBACTER PYLORI IgG CONTROL SERUM	81508
CHORUS HERPES SIMPLEX 1+2 IgG CONTROL SERUM	81512
CHORUS HERPES SIMPLEX 1+2 IgM CONTROL SERUM	81513
CHORUS MEASLES IgG CONTROL SERUM	81517
CHORUS MUMPS IgG CONTROL SERUM	81519
CHORUS MUMPS IgM CONTROL SERUM	81520
CHORUS MYCOPLASMA PNEUMONIAE IgG CONTROL SERUM	81521
CHORUS MYCOPLASMA PNEUMONIAE IgM CONTROL SERUM	81522
CHORUS RUBELLA IgG AVIDITY CONTROL SERUM	81524
CHORUS RUBELLA IgG CONTROL SERUM	81523
CHORUS RUBELLA IgM CONTROL SERUM	81525
CHORUS SYPHILIS SCREEN RECOMBINANT CONTROL SERUM	81526
CHORUS TOXOPLASMA IgA CONTROL SERUM	81534
CHORUS TOXOPLASMA IgG AVIDITY CONTROL SERUM	81532

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CHORUS TOXOPLASMA IgG CONTROL SERUM	81531
CHORUS TOXOPLASMA IgM CONTROL SERUM	81533
CHORUS TREPONEMA IgG CONTROL SERUM	81527
CHORUS TREPONEMA IgM CONTROL SERUM	81528
CHORUS VARICELLA IgG CONTROL SERUM	81535
CHORUS VARICELLA IgM CONTROL SERUM	81536

All the products listed in table 2 are classified as dangerous.

They are classified, labeled and packaged according to the information below.

Classification according to Regulation (EC) No. 1272/2008:Acute Toxicity – Category 4 (Oral)
Skin Sensitizer– Category 1**Pictograms:****Signal word:**

Caution

Hazard statement(s):H302 – Harmful if swallowed
H317 – May cause an allergic skin reaction**Precautionary statement(s):***Prevention:*P261 – Avoid breathing dust/fume/gas/mist/vapors/spray
P264 – Wash ... thoroughly after handling
P272 – Contaminated work clothing should not be allowed out of the workplace.
P280 – Wear protective gloves/protective clothing/eye protection/face protection.*Response:*P301+P312 – IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P302+P352 – IF ON SKIN: Wash with plenty of soap and water
P330 – Rinse mouth
P333+P313 – If skin irritation or rash occurs: Get medical advice/attention.
P363 – Wash contaminated clothing before reuse.*Disposal:*

P501 – Dispose of contents/container in accordance with local regulation

Content:

Ethylene glycol

Index. No 603-027-00-1

Reaction mass of: 5-chloro-2-methyl-4-iso-thiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

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Cleaning Solution 2000 (REF 83609) is classified as dangerous.

It is classified, labeled and packaged according to the information below.

Classification according to Regulation (EC) No. 1272/2008:

Skin Sensitizer– Category 1

Pictograms:



Signal word:

Warning

Hazard statement(s):

H317 – May cause an allergic skin reaction

Precautionary statement(s):

Prevention:

- P261 – Avoid breathing dust/fume/gas/mist/vapors/spray
P272 – Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
P280 –

Response:

- P302+P352 – IF ON SKIN: Wash with plenty of soap and water
P333+P313 – If skin irritation or rash occurs: Get medical advice/attention.
P363 – Wash contaminated clothing before reuse.

Disposal:

- P501 – Dispose of contents/container in accordance with local regulation

Content:

Reaction mass of: 5-chloro-2-methyl-4-iso-thiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

Index No: 613-167-00-5



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Sanitizing Solution (REF 83604-83608) is classified as dangerous.

It is classified, labeled and packaged according to the information below.

Classification according to Regulation (EC) No.

1272/2008:

Skin Corrosion – Category 1B



Pictograms:

Signal word:

Danger

Hazard statement(s):

H314 - Causes severe skin burns and eye damage

Precautionary statement(s):

Prevention:

P280 –

Wear protective gloves/protective clothing/eye protection/face protection.

Response:

P302+P352 –

IF ON SKIN: Wash with plenty of soap and water

P305+P351+P338 –

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P362 –

Take off contaminated clothing and wash before reuse.

Disposal:

P501 –

Dispose of contents/container in accordance with local regulation

Content:

Potassium hydroxide

Index No: 019-002-00-8

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Table 3.

CHORUS COMMON REAGENTS	
WASHING BUFFER	83606
WASHING BUFFER AUTOIMMUNITY	86004
CHORUS NEGATIVE CONTROL/SAMPLE DILUENT	83607
CHORUS AUTOIMMUNITY KITS	
CHORUS AMA-M2	86084 - 86084/12
CHORUS CALPROTECTIN	86600 - 86600/C03
CHORUS COPROCOLLECT	86602
CHORUS INSULIN	86086 - 86086/12
CHORUS INTRINSIC FACTOR	86090 - 86090/12
CHORUS LKM-1	86080 - 86080/12
CHORUS RF-G	86038 - 86038/12
CHORUS U1-70 RNP	86088 - 86088/12
CHORUS COMPLEMENT FIXATION TEST (CFT) KITS	
CHORUS ADENOVIRUS	85210
CHORUS BORDETELLA PERTUSSIS	85355
CHORUS BORRELIA	85373
CHORUS BRUCELLA	85358
CHORUS CAMPYLOBACTER JEJUNI	85361
CHORUS CHLAMYDIA	85342
CHORUS COXSACKIE VIRUS A MIX	85313
CHORUS COXSACKIE VIRUS B MIX	85251
CHORUS ECHINOCOCCUS	85328
CHORUS ECHO VIRUS N MIX	85275
CHORUS ECHO VIRUS P MIX	85221
CHORUS INFLUENZA A VIRUS	85222
CHORUS INFLUENZA B VIRUS	85224
CHORUS LEGIONELLA PNEUMOPHILA	85352
CHORUS LEPTOSPIRA MIX	85367
CHORUS LISTERIA MONOCYTOGENES	85344
CHORUS MYCOPLASMA PNEUMONIAE	85340
CHORUS PARAINFLUENZA MIX	85225
CHORUS POLIOVIRUS MIX	85283
CHORUS Q-FEVER	85330
CHORUS REOVIRUS	85234
CHORUS RESPIRATORY SYNCYTHIAL VIRUS	85236
CHORUS SHIGELLA FLEXNERI	85370
CHORUS YERSINIA ENTEROCOLITICA	85375
CHORUS COMPLEMENT FIXATION TEST (CFT) CONTROL SERA	
CHORUS ADENOVIRUS CONTROL SERUM	85830
CHORUS BORDETELLA PERTUSSIS CONTROL SERUM	85894
CHORUS BORRELIA CONTROL SERUM	85902
CHORUS CAMPYLOBACTER CONTROL SERUM	85895
CHORUS CHLAMYDIA CONTROL SERUM	85832
CHORUS COXSACKIE B CONTROL SERUM	85894
CHORUS INFLUENZA A CONTROL SERUM	85902
CHORUS INFLUENZA B CONTROL SERUM	85895



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CHORUS LEGIONELLA PNEUMOPHILA CONTROL SERUM	85832
CHORUS LEPTOSPIRA CONTROL SERUM	85903
CHORUS LISTERIA MONOCYTOGENES CONTROL SERUM	85872
CHORUS MYCOPLASMA PNEUMONIAE CONTROL SERUM	85873
CHORUS Q-FEVER CONTROL SERUM	85874
CHORUS PARAINFLUENZA CONTROL SERUM	85896
CHORUS RESPIRATORY SYNCYTIAL CONTROL SERUM	85875
CHORUS SHIGELLA CONTROL SERUM	85877
CHORUS YERSINIA CONTROL SERUM	85886
CHORUS INFECTIOUS DISEASE KITS	
CHORUS BORDETELLA PERTUSSIS TOXIN IgA	81274
CHORUS BORDETELLA PERTUSSIS TOXIN IgG	81272
CHORUS CLOSTRIDIUM DIFFICILE A/B TOXINS	81170
CHORUS CLOSTRIDIUM DIFFICILE GDH	81168
CHORUS CYTOMEGALOVIRUS IgM CAPTURE	81012
CHORUS ECHINOCOCCUS IgG	81284
CHORUS HELICOBACTER PYLORI ANTIGEN	81063
CHORUS HSV 2 SCREEN	81019
CHORUS HSV 2 SCREEN CONTROL SERUM	81511
CHORUS LEGIONELLA URINARY ANTIGEN	81301
CHORUS SARS-CoV-2 IgG	81400
CHORUS SARS-CoV-2 IgM	81401
CHORUS TOXOPLASMA IgA CAPTURE	81044
CHORUS TOXOPLASMA IgM CAPTURE	81042

All the products listed in table 3 are not classified as dangerous.

M. Stoczko

Magdalena Stoczko
Regulatory Supervisor