



CERTIFICATO N° 505SGQ03

CERTIFICATE N° 505SGQ03

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messso in atto da
implemented by

NUOVA APTACA S.r.l.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili
per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.
Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.
Commercializzazione di dispositivi medici e diagnostici in vitro.

Commercializzazione di articoli da laboratorio

*Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens
in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories
of analysis. Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.*

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana.
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Roberto Cusolito
Dr. Ing. Roberto Cusolito

Data di Prima Emissione
First Issue Date

1998-07-23

Settore IAF 14 - 29

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT

2011-10-30

Data di Rinnovo
Renewal Date

2017-10-30

Data di Scadenza
Expiration Date

2020-10-29



Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements





CERTIFICATO N° 505DM05

CERTIFICATE N° 505DM05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messso in atto da
implemented by

NUOVA APTACA S.r.l.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili
per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.

Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.

Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for analysis laboratories.

Marketing of medical and diagnostic devices in vitro.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.

This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione
First Issue Date
2007-10-30

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT
2011-10-30

Data di Rinnovo
Renewal Date
2017-10-30

Data di Delibera
Deliberation Date
2019-01-04

Data di Scadenza
Expiration Date
2020-10-29



SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements



Certificado ES10/81672

The management system of

DELTALAB, S.L.

Pol. Ind. La Llana, Plaza De La Verneda, 1
08191 Rubí (Barcelona)

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis.
Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.

Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis de microbiología, biología molecular, hematología, bioquímica, histología, microscopía y coloración.
Comercialización de equipos para el almacenamiento de muestras preparadas, almacenamiento de muestras para criogenización, material general de laboratorio y envases industriales.
in/ from the following sites

Pol. Ind. La Llana, Plaza De La Verneda 1 - 08191 Rubí (Barcelona)

This certificate is valid from
29 November 2017 until 11 October 2019.
Issue 7. Certified since October 2010.

Este certificado es válido desde
29 de noviembre de 2017 hasta 11 de octubre de 2019.
Edición 7. Certificado desde octubre de 2010..

Authorized by

Dirección de Certificación

SGS ICS Ibérica, S.A. (Unipersonal)
C/Trespaderne, 29. 28042 Madrid. España.
t: 34 91 313 8115 f 34 91 313 8102 www.sgs.com

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Certificate ES10/81671

The management system of

DELTALAB, S.L.

Polígono Industrial La Llana, Plaza De La Veneda 1,
08191 Rubí, Barcelona. Spain

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

**Design, manufacture and sale of sterile and nonsterile medical devices
for the collection, transport and conservation of biological samples for
clinical and IVD analysis.**

**Distribution of non-active medical devices and in vitro diagnostic
medical devices.**

**Diseño, fabricación y comercialización de productos sanitarios
estériles y no estériles para la toma, transporte y conservación de
muestras biológicas para análisis clínicos y de IVD.**

**Distribución de productos sanitarios no activos y productos sanitarios
para diagnóstico in vitro.**

This certificate is valid from 11 October 2019 until 11 October 2022
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 10 September 2022

Issue 9. Certified since 12 October 2010

Authorised by

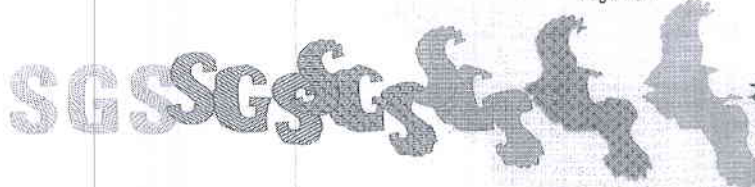


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SGS United Kingdom Ltd
Rossmore Business Park · Ellesmere Port · Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

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Any unauthorized alteration, forgery or falsification of the content or appearance
of this document is unlawful and offenders may be prosecuted to the fullest
extent of the law.



Certificate ES19/86440.01

DELTALAB, S.L.

Pol. Ind. La Llana
Plaza de la Verneda, 1
08191 Rubí, Barcelona

has been assessed as part of the management system of DELTALAB GROUP
certified organization as meeting the requirements of

ISO 14001:2015

For the following activities:

Design, manufacture and sale of laboratory material for the collection,
transport and conservation of samples for microbiological, molecular biology,
hematology, biochemistry, histology, microscopy and colorimetric analysis.
Commercialization of equipment for the storage of prepared samples,
cryogenic stored samples, general labware and industrial packages.
Commercialization of equipment and instrumentation for the laboratory,
diagnostic kits, healthcare products, cosmetics and food for
special medical purposes.

in / from the following sites

Pol. Ind. La Llana, Plaza de la Verneda, 1 - 08191 Rubí (Barcelona)

Valid from

29 August 2019 until 29 August 2022

Issue 1.

This document is part of Certificate N°. ES19/86440.
The validity of this document is subject to the certificate.



Authorized by

Certification Management

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.
C/Trespaderne, 29. 28042 Madrid. España.
t 34 91 313 8115 f 34 91 313 8102 www.sgs.com

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MANAGEMENT SYSTEM CERTIFICATE

Сертификат №:
59878-2009-AQ-MCW-FINAS

Дата начальной сертификации:
20 декабря 2000

Действителен:
21 июня 2018 - 31 августа 2021

Настоящим удостоверяется, что система менеджмента организации:

АО «ТЕРМО ФИШЕР САЙЕНТИФИК»

Кубинская, д.73, литер А, корпус 1, Санкт-Петербург, Российская Федерация,
196240

была признана соответствующей стандарту:

ISO 9001:2015

Настоящий сертификат действителен для следующей области:

**ПРОИЗВОДСТВО ДОЗАТОРОВ ПИПЕТОЧНЫХ И СПЕЦИАЛЬНОГО
ДИАГНОСТИЧЕСКОГО ПЛАСТИКА.**

Место и дата:
Москва, 21 июня 2018



FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

От выпускающего офиса:
DNV GL – Business Assurance
Трехпрудный переулок 9, стр. 2, Москва,
Российская Федерация

S. Groobin
Сергей Грубин
Представитель руководства





ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗАРОВООХРАНЕНИЯ
И СОЦИАЛЬНОГО РАЗВИТИЯ
FEDERAL SERVICE OF HEALTH CARE AND SOCIAL DEVELOPMENT CONTROL

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ
REGISTRATION CERTIFICATE
№ ФСЗ 2011/10929

от 26 октября 2011 года Срок действия: не ограничен.

Настоящее удостоверение выдано
ЗАО "Термо Фишер Сайентифик", Россия,
196240, Санкт-Петербург, ул. Кубинская, д. 73, литер А, корп. 1
и подтверждает, что изделие медицинского назначения
Наконечники полимерные одноразовые Finipir, Labip для медицинских
инъекций (см. Приложение на 1 листе)
производства
"Термо Фишер Сайентифик Ой", Финляндия,
Thermo Fisher Scientific Oy, Ratatie 2, FI-01620 Vantaa, Finland

класс потенциального риска I ОКП 94 6465
соответствующее комплекту регистрационной документации

КРД №37410 от 15.09.2011

приказом Росздравнадзора от 26 октября 2011 года №6966-Пр/11
разрешено к импорту, продаже и применению на территории Российской
Федерации

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения
и социального развития



Е.А. Тельнова

014266

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗАРОВООХРАНЕНИЯ
И СОЦИАЛЬНОГО РАЗВИТИЯ
FEDERAL SERVICE OF HEALTH CARE AND SOCIAL DEVELOPMENT CONTROL

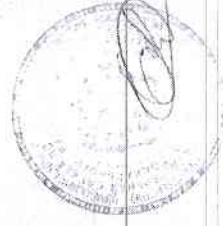
ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ

ATTACHMENT
№ ФСЗ 2011/10929

Лист 1

1. Наконечники полимерные одноразовые Finipir: 0,2-10 мкл; 0,2-20 мкл; 0,2-50 мкл;
0,3-30 мкл; 5-200 мкл; 0,5-250 мкл; 5-300 мкл; 1-100 мкл; 1-200 мкл; 5-100 мкл; 100-1000 мкл;
1000-5000 мкл; 2000-10000 мкл; 50-1500 мкл; 0,5-25 мкл; 20-200 мкл; 10-250 мкл; 0,5 мкл;
1,25 мкл; 2,5 мкл; 5 мкл; 12,5 мкл; 25 мкл; 50 мкл; 0,5-10 мкл; 0,5-100 мкл; 0,5-200 мкл; 150-1500 мкл;
0,5-30 мкл; 5-30 мкл; 50-1200 мкл.
2. Наконечники полимерные одноразовые Labip Yellow (желтые).
3. Наконечники полимерные одноразовые Labip Blue (синие).

2



Врио руководителя Федеральной службы
по надзору в сфере здравоохранения
и социального развития

Е.А. Тельнова

26 октября 2011 года

018788



ВСЕРОССИЙСКИЙ НАУЧНО-ИССЛЕДОВАТЕЛЬСКИЙ
ИНСТИТУТ СЕРТИФИКАЦИИ
ОТКРЫТОЕ АКЦИОНЕРНОЕ ОБЩЕСТВО
(ОАО "ВНИИС")

Электронный пер. д. 3/10, стр. 1.
г. Москва, 123557

Телефон: (499) 253 70 05 Факс: (499) 253 33 60
http://www.vniis.ru E-mail: vniis@vniis.ru

Исх. № 1000000 от 08.05.13

Генеральному директору
Общества с ограниченной
ответственностью «Научно-
производственная фирма «ВИАР»
105094, г. Москва, ул. Госпитальный вал,
дом 3, строение 7А, помещение VIII,
тел. (495) 963-7310, 988-76-67

На № 371
от 18.04.2013 г.

На Ваш запрос о принадлежности к объектам обязательного подтверждения соответствия продукции (согласно приложению), сообщаем следующее.
Продукция, указанная в приложении, может быть отнесена по Общероссийскому классификатору продукции ОК 005-93 к позиции: «Материалы и средства медицинские прочие» (код ОКП 93-9800).

Указанная в приложении к настоящей справке продукция не включена в «Единый перечень продукции, подлежащей обязательной сертификации» и «Единый перечень продукции, подтверждение соответствия которой осуществляется в форме принятия декларации о соответствии», утвержденные постановлением Правительства Российской Федерации от 01.12.2009 г. № 982 (с изменениями, утвержденными постановлениями Правительства Российской Федерации от 17.03.2010 г. № 148, от 17.03.2010 г. № 149, от 26.07.2010 г. № 548, от 20.10.2010 г. № 848, от 13.11.2010 г. № 906, от 21.03.2012 г. № 213, от 04.05.2012 г. № 435, от 18.06.2012 г. № 596, от 04.03.2013 г. № 182), и представление сертификата соответствия и декларации о соответствии на указанную в приложении к справке продукцию не требуется.

Настоящая справка действительна до внесения изменений в «Единый перечень продукции, подлежащей обязательной сертификации» и «Единый перечень продукции, подтверждение соответствия которой осуществляется в форме принятия декларации о соответствии» в отношении указанной в приложении к справке продукции или до вступления в силу технических регламентов на указанную в приложении к справке продукцию.

Приложение: на 9 л. в 1 экз.

Руководитель научного направления

Крутойский автотелефон: (499) 253 00 78
Государственный справочник: (499) 253 03 68, 253 03 79
Факс: (499) 253 00 85, 253 68 55



СЕРТИФИКАЦИОННАЯ ВНИИС сертифицирована

Приложение к письму № 1000000
от 08.05.13
Лист 2, листов 9.

НАИМЕНОВАНИЕ ПРОДУКЦИИ

1.9. Индикаторы бумажные воздушной стерилизации химические
многопараметрические одноразовые «МЕДИС-В-ВИНАР»:

- МЕДИС-В-160/130-1,
- МЕДИС-В-180/60-1.

1.10. Индикатор-этикетка бумажная самоклеющаяся химическая одноразовая для
контроля паровой и воздушной стерилизации ИЭ-«ВИНАР»:

- ИЭ-01-«ВИНАР»,
- ИЭ-02-«ВИНАР».

1.11. Тест-пакет Бови-Дик-Винар одноразовый для испытания на удаление воздуха
из камеры паровых форвакуумных стерилизаторов:

- Тест-пакет Бови-Дик.

1.12. Тест грубой загрузки многоразовый для испытания на удаление воздуха
«Хеликс-тест-Винар»:

- Хеликс-тест.

1.13. Индикаторы парового обеззараживания химические одноразовые «СанИС»:

- СанИС-1,
- СанИС-2.

1.14. Индикаторы паровой стерилизации лекарственных средств химические с
ликим слоем одноразовые «ФАРМАТЕСТ-«ВИНАР»:

- Фарматест-110/10,
- Фарматест-110/20,
- Фарматест-110/30,
- Фарматест-120/8,
- Фарматест-120/12,
- Фарматест-120/15.

1.15. Полоски индикаторные бумажно-гленотные химические с ликим слоем
одноразовые для контроля паровой стерилизации растворов лекарственных средств
«ФАРМАТЕСТ-«ВИНАР»:

- ФАРМАТЕСТ-100/30,
- ФАРМАТЕСТ-100/60,
- ФАРМАТЕСТ-120/30.

2. Индикаторы биологические для контроля паровой и воздушной стерилизации.
2.1. Индикаторы биологические одноразовые для контроля паровой и воздушной
стерилизации «Биотест-Винар»:

- Биотест-П-Винар,
- Биотест-П1-Винар,
- Биотест-П2-Винар,
- Биотест-В-Винар,
- Биотест-В1-Винар.

Руководитель научного направления ВНИИС



Биологический индикатор контроля паровой стерилизации, одноразовый, «БиоТЕСТ-П2-Винар»

Индикатор биологический «БиоТЕСТ-П2-Винар» представляет собой носитель в виде пластиковой пробирки типа Эппендорф/стеклянного флакона с высушенными спорами бактерий, запечатанный в бумажно-плёночную стерилизационную упаковку. Индикатор предназначен для контроля эффективности процесса паровой стерилизации медицинских изделий.

В комплект «БиоТЕСТ-П2-Винар» входят: 6 биологических индикаторов, флакон со стерильной питательной средой, стерильная пробирка типа Эппендорф/стеклянный флакон в стерилизационной упаковке, стерильный шприц с иглой для отбора питательной среды.

Индикаторы не требуют соблюдения особых мер безопасности.

Гарантийный срок хранения - 24 месяца при соблюдении условий хранения и транспортирования.

ТУ 9398-090-11764404-2011

Регистрационное удостоверение № ФСР 2012/14116 от 27.11.2012 г. Срок действия: не ограничен.



Биологический автономный индикатор контроля паровой стерилизации, одноразовый, «БиоТЕСТ-П-Винар»

Индикатор автономный биологический «БиоТЕСТ-П-Винар» представляет собой носитель в виде пластиковой пробирки с помещёнными на дно высушенными спорами бактерий (24 шт). Внутри пластиковой пробирки размещена стеклянная ампула, содержащая стерильную индикаторную среду. Пластиковая пробирка закрыта колпачком, имеющим отверстия, защищённые бактериальным фильтром. Преимущества автономных индикаторов «БиоТЕСТ-П-Винар»:

- исключение любой возможности контаминации после стерилизации – однозначная трактовка результата;
- возможность использования в любом ЛПО, при наличии термостата;
- наличие пробок, предотвращающих вскрытие индикаторов и, соответственно, контаминацию простерилизованных БИ во время их инкубирования;
- отсутствие необходимости обеспечения асептических условий работы;
- размещение химического индикатора 1-го класса на каждом индикаторе, позволяющего отличить простерилизованные БИ от нестерилизованных;
- возможность работы персонала без специальных навыков исполнения микробиологических мероприятий.

Гарантийный срок хранения - 24 месяца при соблюдении условий хранения и транспортирования.

ТУ 9398-090-11764404-2011

Регистрационное удостоверение № ФСР 2011/12090 от 19 марта 2013 г. Срок действия: не ограничен.



EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
ASO Latex kit	031100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.



Eddy Velthuis
Technical Director



File No A12241;
ISO 13485:2003; ISO 9001:2008

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
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Berkshire RG6 4UT United Kingdom
Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

Registered office as above. Registered in England No. 07540297. VAT No. 800 3655 66

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
CRP Latex kit	850100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.



Eddy Velthuis
Technical Director



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Registered office as above. Registered in England No. 04589111 VAT No. GB365566

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
RF Latex kit	830100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.



Eddy Velthuis
 Technical Director



File No A12241;
 ISO 13485:2003; ISO 9001:2008

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Registered office as above. Registered in England No. 0450797. VAT No. 800 3655 66

Safety Data Sheet

(In accordance with COMMISSION REGULATION (EU) No 830/2015)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

Product identifier
28230
Tween 80 Surfact-Amps Detergent Solution

Product code
28230

Product name
Tween 80 Surfact-Amps Detergent Solution

Chemical Name
Not Applicable

REACH registration number
No registration number is given yet for this substance / substances in this mixture since the annual import quantity is less than one tonne per annum or the transition period for its registration according to Article 23 of REACH has not yet expired.

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

Relevant identified uses
Use as laboratory reagent, Scientific research and development

Use Description Code
Not available

Uses advised against
Not for consumer use.

Details of the supplier of the safety data sheet

Manufacturer/Supplier

LIFE TECHNOLOGIES EUROPE BV
KWARTSWEG 2
2665 NN BLEISWIJK
NETHERLANDS
31-(0)180 392 400
Email: MSDS@lifetech.com

Thermo Fisher Scientific
Pierce Biotechnology
P.O. Box 117
Rockford, IL 61105
United States
1.815.968.0747 or
1.800.874.3723

Life Technologies Limited
3 Fountain Drive
Inchinnan Business Park
Paisley
PA4 9RF, UK
+44 (0)141 814 6100

24 hour Emergency Response for Hazardous Materials Within the USA + Canada: 1-800-424-9300 and +1
[or Dangerous Goods] Incident. Spill, Leak, Fire, 703-527-3887
Exposure, or Accident. Call CHEMTREC Outside the USA + Canada: +1 703-741-5970

Country Specific Emergency Number (if available):
CHEMTREC Ireland (Dublin) +(353)-19014670 (Greeting Language: English and Irish)
CHEMTREC UK (London) +(44)-870-8200418 (Greeting Language: English)

SECTION 2: Hazards identification

Classification of the substance or mixture

Revision date 29-Apr-2019
Product code 28230

Page 1 / 8
Product name Tween 80 Surfact-Amps Detergent Solution
www.thermofisher.com

Classification according to Regulation (EC) No 1272/2008 [CLP]

Physical hazards
Not classified

Health hazards
Not classified

Environmental hazards
Not classified

Additional information
Not Applicable

Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms
No Pictogram

Signal Word
None

Hazard Statements
Not Applicable

EU Specific Hazard Statements
Not Applicable

Precautionary Statements

Prevention
Not Applicable

Response
Not Applicable

Storage
Not Applicable

Disposal
Not Applicable

Other hazards
Not Applicable

SECTION 3: Composition/information on ingredients

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Revision date 29-Apr-2019
Product code 28230

Page 2 / 8
Product name Tween 80 Surfact-Amps Detergent Solution
www.thermofisher.com



SECTION 4: First aid measures

Description of first aid measures

Skin contact Rinse with plenty of water. Immediate medical attention is not required.
Eye contact Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Ingestion Not expected to present a significant ingestion hazard under anticipated conditions of normal use. If you feel unwell, seek medical advice.
Inhalation Not expected to be an inhalation hazard under anticipated conditions of normal use of this material. Consult a physician if necessary.
Notes to Physician Treat symptomatically.

Most important symptoms and effects, both acute and delayed

None

Indication of any immediate medical attention and special treatment needed

None.

SECTION 5: Firefighting measures

Extinguishing media

Suitable extinguishing media
Unsuitable extinguishing media

Water spray. Carbon dioxide (CO₂). Foam. Dry chemical.
No information available.

Special hazards arising from the substance or mixture
Not known.

Protective equipment and precautions for firefighters
Standard procedure for chemical fires.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation
Always wear recommended Personal Protective Equipment
Use personal protection equipment
See Section 8 for more detail.

Environmental precautions
No special environmental precautions required.

Methods and material for containment and cleaning up
Take up mechanically, placing in appropriate containers for disposal.

Reference to other sections
See section 8 for more information.

SECTION 7: Handling and storage

Precautions for safe handling

Use personal protective equipment as required. No special handling advices are necessary.

Conditions for safe storage, including any incompatibilities

Keep in a dry, cool and well-ventilated place. Keep in properly labelled containers.

Specific end use(s)

Use as laboratory reagent. Scientific research and development.

SECTION 8: Exposure controls/personal protection

Control parameters

Exposure Limits

Contains no substances with occupational exposure limit values.

Engineering measures

Ensure adequate ventilation, especially in confined areas.

Exposure controls

Personal protection equipment

Respiratory protection

In case of insufficient ventilation wear respirators and components tested and approved under appropriate government standards.

Hand protection

Wear suitable gloves. Glove material: Compatible chemical-resistant gloves.

Eye protection

Tight sealing safety goggles.

Skin and Body Protection

Wear suitable protective clothing.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls

No special environmental precautions required.



SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance	liquid
Odour	No data available
Molecular Weight	No data
Melting point / melting range	°C No data
Boiling point / boiling range	°C No data
Flash point	°F No data
Autoignition Temperature	°C No data
Decomposition temperature	°F No data
Evaporation rate	No data
Flammability (solid, gas)	No data available
Upper explosion limit	No data
Lower explosion limit	No data
Vapour Pressure	No data
Vapour density	No data
Relative density	No data
Specific gravity	No data
Solubility	No data available
Partition coefficient: n-octanol/water	No data available
Viscosity	No data
Explosive properties	No data
Oxidising properties	No data
Other information	No data available.

SECTION 10: Stability and reactivity

Reactivity	None known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Hazardous reaction has not been reported.
Conditions to avoid	No information available.
Incompatible materials	No dangerous reaction known under conditions of normal use.
Hazardous decomposition products	No data available.

SECTION 11: Toxicological information

Information on toxicological effects

There is no evidence available indicating acute toxicity.

Principal Routes of Exposure,

Skin corrosion/irritation	Data are conclusive but insufficient for classification
Serious eye damage/irritation	Data are conclusive but insufficient for classification
Respiratory or skin sensitisation	Data are conclusive but insufficient for classification
Specific target organ toxicity (STOT) – single exposure	Data are conclusive but insufficient for classification
Specific target organ toxicity (STOT) – repeated exposure	Data are conclusive but insufficient for classification
Carcinogenicity	Data are conclusive but insufficient for classification
Germ cell mutagenicity	Data are conclusive but insufficient for classification
Reproductive Toxicity	Data are conclusive but insufficient for classification
Aspiration Hazard	Data are conclusive but insufficient for classification

SECTION 12: Ecological information

Ecotoxicity
The environmental impact of this product has not been fully investigated.

Persistence and degradability	No information available.
Bioaccumulative potential	No information available.
Results of PBT and vPvB assessment	No information available.
Other adverse effects	No information available.



SECTION 13: Disposal considerations

Waste treatment methods

The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in accordance to approved disposal technique. Disposal of this product, its solutions or of any by-products, shall comply with the requirements of all applicable local, regional or national/federal regulations.

SECTION 14: Transport information

IATA / ADR / DOT-US / IMDG

Not classified as dangerous in the meaning of transport regulations

UN number Not Applicable
UN proper shipping name Not Applicable
Transport hazard class(es) Not Applicable
Packing group Not Applicable

Environmental hazards

Not Applicable

Special precautions for user

Not Applicable

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

Not Applicable.

SECTION 15: Regulatory information

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

Substances of Very High Concern

None.

EU REACH (1907/2006) - Annex XIV - Substances Subject to Authorization

None

Restricted substances under EC 1907/2006, Annex XVII

None.

Substances listed under Annex I of Regulation (EC) No 689/2008

None.

Restricted substances under Annex V of Regulation (EC) No 689/2008

None.

Substances under Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC
None.

German Water hazard classes (Wassergefährdungsklassen)
Not classified.

Other International Inventories

No information available

Chemical safety assessment

No Chemical safety assessment has been carried out.

SECTION 16: Other information

Reason for revision Update according to Commission Regulation (EU) No 830/2015

Revision number 4

Revision date 29-Apr-2019

References

- ECHA: <http://echa.europa.eu/>
- TOXNET: <http://toxnet.nlm.nih.gov/>
- eChemPortal: <http://www.echemportal.org/>
- LOLI database: <https://www.chemadvisor.com/loli-database>

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

"The above information was acquired by diligent search and/or investigation and the recommendations are based on prudent application of professional judgment. The information shall not be taken as being all inclusive and is to be used only as a guide. All materials and mixtures may present unknown hazards and should be used with caution. Since the Company cannot control the actual methods, volumes, or conditions of use, the Company shall not be held liable for any damages or losses resulting from the handling or from contact with the product as described herein. THE INFORMATION IN THIS SDS DOES NOT CONSTITUTE A WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE"



(In accordance with COMMISSION REGULATION (EU) No 453/2010)

SECTION 1: Identification of the substance/mixture and of the company/undertaking**Product identifier**

Product code 17916
Product name Proteinase K

Chemical Name Not applicable
REACH registration number No registration number is given yet for this substance / substances in this mixture since the annual import quantity is less than one tonnage per annum or the transition period for its registration according to Article 23 of REACH has not yet expired.

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

Relevant identified uses Use as laboratory reagent, Scientific research and development
Use Description Code Not Available
Uses advised against Not for consumer use.

Details of the supplier of the safety data sheet

Manufacturer/Supplier Thermo Fisher Scientific
LIFE TECHNOLOGIES EUROPE BV
KWARTSWEG 2
2665 NN BLEISWIJK
NETHERLANDS
31-(0)180 392 400
Email: MSDS@lifetech.com

24 hour Emergency Response: 866-536-0631
301-431-8585
Outside of the U.S. ++1-301-431-8585

Country specific Emergency Number (if available):
CHEMTREC Ireland (Dublin) +(353)-19014670 (Greeting Language: English and Irish)
CHEMTREC UK (London) +(44)-870-8200418 (Greeting Language: English)

SECTION 2: Hazards identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

Physical hazards
Not classified

Health hazards

Skin corrosion/irritation
Serious eye damage/eye irritation
Respiratory sensitizer
Specific target organ toxicity - Single exposure

Environmental Hazards

Not classified

Additional information

No information available

Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms**Signal word**

Danger

hazard statements

H315 - Causes skin irritation
H319 - Causes serious eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335 - May cause respiratory irritation

Precautionary Statements

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
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P337 + P313 - If eye irritation persists: Get medical advice/attention
P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

Other Hazards

This mixture does not contain any substances that are assessed to be a PBT or a vPvB



SECTION 3: Composition/information on ingredients

Component	CAS-No.	EINECS-No.	Weight percent	REACH registration number	Classification according to Regulation (EC) No 1272/2008 [CLP]
Proteinase, Intrachium album serine 39450-01-6 (98-100)	39450-01-6	254-457-6	98-100	-	Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 Resp. Sens. 1 - H334

SECTION 4: First aid measures

Description of first aid measures

Skin contact	Wash off immediately with plenty of water for at least 15 minutes. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Immediate medical attention is required.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Immediate medical attention is required.
INGESTION	Never give anything by mouth to an unconscious person. Do not induce vomiting without medical advice. Get medical attention if symptoms occur.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. If symptoms persist, call a doctor.
Notes to Physician	Treat symptomatically.

Most important symptoms and effects, both acute and delayed

H315 - Causes skin irritation. H319 - Causes serious eye irritation. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335 - May cause respiratory irritation.

Indication of any immediate medical attention and special treatment needed

If skin irritation occurs: Get medical advice/ attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

SECTION 5: Firefighting measures

Extinguishing media

Suitable Extinguishing Media	Water spray. Carbon dioxide (CO2). Foam. Dry chemical.
Unsuitable Extinguishing Media	No information available.

Special hazards arising from the substance or mixture Not known.

Advice for fire-fighters

Wear self-contained breathing apparatus and protective suit.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures
Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Use personal protection equipment. See Section 8 for more detail.

Environmental precautions

No special environmental precautions required.

Methods and material for containment and cleaning up

Take up mechanically, placing in appropriate containers for disposal.

Reference to other sections

See section 8 for more information.

SECTION 7: Handling and storage

Precautions for safe handling

Always wear recommended Personal Protective Equipment. See Section 8 for more detail. Do not get in eyes, on skin, or on clothing. Do not ingest. If during normal use the material presents a respiratory hazard, use adequate ventilation and/or wear appropriate respirator.

Conditions for safe storage, including any incompatibilities

Keep in a dry, cool and well-ventilated place. Keep in properly labelled containers. Store in accordance with local regulations.

Specific end use(s)

Use as laboratory reagent. Scientific research and development.



SECTION 8: Exposure controls/personal protection

Control parameters

Exposure Limits

Chemical Name	EU OEL (TWA)	EU OEL (STEL)	EU Skin Notation	
Proteinase, tritrichium album serine 39450-01-6	None	None	None	
Chemical Name	Austria	Belgium (TWA)	Denmark (TWA)	Finland OEL (TWA)
Proteinase, tritrichium album serine 39450-01-6	None	None	None	None
Chemical Name	France OEL (VME)	Germany OEL (TWA)	Ireland (TWA)	Italy OEL (TWA)
Proteinase, tritrichium album serine 39450-01-6	None	None	None	None
Chemical Name	Sweden - Occupational Exposure Limits - TLVs (LLVs)	Netherlands OEL (MAC)	Spain OEL (TWA)	United Kingdom
Proteinase, tritrichium album serine 39450-01-6	None	None	None	None
Chemical Name	European Union	United Kingdom	France OEL (VME)	Germany OEL (TWA)
Proteinase, tritrichium album serine 39450-01-6	None	None	None	None
Chemical Name	Italy OEL (TWA)	Portugal	Netherlands OEL (MAC)	Finland OEL (TWA)
Proteinase, tritrichium album serine 39450-01-6	None	None	None	None
Chemical Name	Austria	Denmark	Poland	Switzerland
Proteinase, tritrichium album serine 39450-01-6	None	None	None	None
Chemical Name	Ireland	Norway	Lithuania OEL (TWA)	Spain OEL (TWA)
Proteinase, tritrichium album serine 39450-01-6	None	None	None	None

Engineering measures Ensure adequate ventilation, especially in confined areas.

Personal protection equipment

Respiratory protection In case of insufficient ventilation wear respirators and components tested and approved under appropriate government standards.

Hand Protection Glove material: Nitrile rubber with thickness (mm) .5 Break through time (hours) :1
Recommended glove type has not been tested for use with this product
Information is based on professional knowledge

Eye protection Tight sealing safety goggles.

Skin and body protection Wear laboratory coat for body protection.



Hygiene measures Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls
No special environmental precautions required.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance	powder
Odour	Mixture has not been tested
Odour Threshold	Mixture has not been tested
Melting point / melting range	°C Mixture has not been tested
Boiling point / boiling range	°C Mixture has not been tested
Flash point	°C Mixture has not been tested
Autoignition temperature	°C Mixture has not been tested
Decomposition temperature	°C Mixture has not been tested
Evaporation rate	Mixture has not been tested
Flammability (solid, gas)	Not applicable
Upper explosion limit	Mixture has not been tested
Lower explosion limit	Mixture has not been tested
Vapour Pressure	Mixture has not been tested
Relative density	Mixture has not been tested
Specific gravity	Mixture has not been tested
Solubility	Mixture has not been tested
Partition coefficient: n-octanol/water	no data available
Viscosity	Mixture has not been tested
Explosive properties	Mixture has not been tested
Oxidising properties	Mixture has not been tested

OTHER INFORMATION

no data available

SECTION 10: Stability and reactivity

Reactivity	None known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Hazardous reaction has not been reported.
Conditions to Avoid	No information available.
Incompatible Materials	No dangerous reaction known under conditions of normal use.
Hazardous decomposition products	No known hazardous decomposition products.

SECTION 11: Toxicological information

Information on toxicological effects

Chemical Name	LD50 (oral, rat/mouse)	LD50 (dermal, rat/rabbit)	LC50 (inhalation, rat/mouse)
Proteinase, tritirachium album serine	no data available	no data available	no data available

Principle Routes of Exposure, Potential health effects

Irritation	Skin irritation, Irritating to eyes
Corrosivity	Conclusive but not sufficient for classification
Sensitisation	May cause sensitisation by inhalation
STOT - Single Exposure	May cause respiratory irritation
STOT - Repeated Exposure	Conclusive but not sufficient for classification
Carcinogenicity	Conclusive but not sufficient for classification
Mutagenicity	Conclusive but not sufficient for classification
Reproductive toxicity	Conclusive but not sufficient for classification

SECTION 12: Ecological information

Toxicity

Chemical Name	Freshwater Algae Data	Water Flea Data	Freshwater Fish Species Data	Microtox Data	log Pow
Proteinase, tritirachium album serine	no data available	no data available	no data available	no data available	no data available

Persistence and degradability No information available.

Bioaccumulative potential No information available.

Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Other adverse effects No information available.

SECTION 13: Disposal considerations

Waste treatment methods

The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in according to approved disposal technique. Disposal of this product, its solutions or of any by-products, shall comply with the requirements of all applicable local, regional or national/federal regulations.

SECTION 14: Transport information

IATA / ADR / DOT-US / IMDG

Not classified as dangerous in the meaning of transport regulations.

UN Number	Not applicable
UN proper shipping name	Not applicable
Transport hazard class(es)	Not applicable
Packing group	Not applicable
Environmental Hazards	Not applicable
Special precautions for user	Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable.

Revision date
Product code

Page 7 / 10
Product name Proteinase K

Revision date
Product code

Page 8 / 10
Product name Proteinase K

www.thermofisher.com

www.thermofisher.com

SECTION 15: Regulatory Information

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

Substances of Very High Concern
None.

Restricted substances under EC 1907/2006, Annex XVII
None.

Substances listed under Annex I of Regulation (EC) No 689/2008
None.

Restricted substances under Annex V of Regulation (EC) No 689/2008
None.

Substances under Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC
None.

German Water hazard classes (Wassergefährdungsklassen)

Other International Inventories

Chemical Name	EINECS (European Union)	ELINCS (European List of Notified Chemical Substances)	ENCS (Japan)	PICCS (Philippines)
Proteinase, tritirachium album serine	Listed	-	-	-
Chemical Name	AICS (Australia)	South Korea (KECL)	Canada (DSL)	NDSL
Proteinase, tritirachium album serine	-	-	-	-

Chemical Safety Assessment

No Chemical safety assessment has been carried out.

SECTION 16: Other Information

Reason for revision
Update according to Commission Regulation (EU) No 453/2010.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Skin corrosion/irritation	Category 2	Calculation method
Serious eye damage/eye irritation	Category 2	Calculation method
Respiratory sensitiser	Category 1	Calculation method
Specific target organ toxicity - Single exposure	Category 3	Calculation method

"The above information was acquired by diligent search and/or investigation and the recommendations are based on prudent application of professional judgment. The information shall not be taken as being all inclusive and is to be used only as a guide. All materials and mixtures may present unknown hazards and should be used with caution. Since the Company cannot control the actual methods, volumes, or conditions of use, the Company shall not be held liable for any damages or losses resulting from the handling or from contact with the product as described herein. THE INFORMATION IN THIS SDS DOES NOT CONSTITUTE A WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE"



Revision date
14-Mar-2016
Product code
17976

Page 9 / 10
Product name
Proteinase K

Page 10 / 10
Product name
Proteinase K

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www.thermofisher.com

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

Product identifier

Product code R0491
Product name TopVision Agarose

Chemical Name Not applicable
REACH registration number No registration number is given yet for this substance / substances in this mixture since the annual import quantity is less than one tonnage per annum or the transition period for its registration according to Article 23 of REACH has not yet expired.

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

Relevant identified uses Use as laboratory reagent, Scientific research and development
Use Description Code Not Available
Uses advised against Not for consumer use.

Details of the supplier of the safety data sheet

Manufacturer/Supplier Thermo Fisher Scientific Baltics UAB
V.Graiciuno 8
LT-02241 Vilnius
Lithuania
Tel.: +370 5 2602431
Fax.: +370 5 2602142

Emergency telephone number

For Chemical Emergency (Spill, Leak, Fire, Exposure or Accident), call
CHEMTREC Domestic North America: 1-800-424-9300 (24 hours)
CHEMTREC International: 1-703-527-3887 (collect calls accepted)

24 hour Emergency Response:

866-536-0631
301-431-8585
Outside of the U.S. ++1-301-431-8585

Country specific Emergency Number (if available):

+(353)-19014670 (Greeting Language: English and Irish)
+(44)-870-8200418 (Greeting Language: English)

SECTION 2: Hazards Identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

Physical hazards
Not classified

Health hazards
Not classified

Environmental Hazards
Not classified

Additional information
Not applicable

Label elements

Labeling according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms
No Pictogram

Signal word
None

hazard statements
Not applicable

Precautionary Statements

Prevention
Not applicable

Response
Not applicable

Storage
Not applicable

Disposal
Not applicable

Other Hazards

This mixture does not contain any substances that are assessed to be a PBT or a vPvB

SECTION 3: Composition/information on Ingredients

Component	CAS-No.	EINECS-No.	Weight percent	REACH registration number	Classification according to Regulation (EC) No 1272/2008 [CLP]
Agarose 9012-36-6 (95-100)	9012-36-6	-	95-100	-	-



SECTION 4: First aid measures

Description of first aid measures

Skin contact
Eye contact

Rinse with plenty of water. Immediate medical attention is not required.
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

INGESTION

Not expected to present a significant ingestion hazard under anticipated conditions of normal use. If you feel unwell, seek medical advice.

Inhalation

Not expected to be an inhalation hazard under anticipated conditions of normal use of this material. Consult a physician if necessary.

Notes to Physician

Treat symptomatically.

Most important symptoms and effects, both acute and delayed

Not applicable.

Indication of any immediate medical attention and special treatment needed

None.

SECTION 5: Firefighting measures

Extinguishing media

Suitable Extinguishing Media
Unsuitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Foam. Dry chemical.
No information available.

Special hazards arising from the substance or mixture Not known.

Advice for fire-fighters

Standard procedure for chemical fires.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Always wear recommended Personal Protective Equipment. Use personal protection equipment. See Section 8 for more detail.

Environmental precautions

No special environmental precautions required.

Methods and material for containment and cleaning up

Soak up with inert absorbent material.

Reference to other sections

See section 8 for more information.

SECTION 7: Handling and storage

Precautions for safe handling

Use personal protective equipment as required. No special handling advice is necessary.

Conditions for safe storage, including any incompatibilities

Keep in a dry, cool and well-ventilated place. Keep in properly labelled containers.

Specific end use(s)

Use as laboratory reagent. Scientific research and development.

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SECTION 8: Exposure controls/personal protection

Control parameters

Exposure Limits

Chemical Name	EU OEL (TWA)	EU OEL (STEL)	EU Skin Notation
Agarose 9012-36-6	None	None	None
Chemical Name	Austria	Belgium (TWA)	Denmark (TWA)
Agarose 9012-36-6	None	None	None
Chemical Name	France OEL (VME)	Germany OEL (TWA)	Ireland (TWA)
Agarose 9012-36-6	None	None	None
Chemical Name	Sweden - Occupational Exposure Limits - TLVs (LLVs)	Netherlands OEL (MAC)	Spain OEL (TWA)
Agarose 9012-36-6	None	None	None
Chemical Name	European Union	United Kingdom	France OEL (VME)
Agarose 9012-36-6	None	None	None
Chemical Name	Italy OEL (TWA)	Portugal	Netherlands OEL (MAC)
Agarose 9012-36-6	None	None	None
Chemical Name	Austria	Denmark	Poland
Agarose 9012-36-6	None	None	None
Chemical Name	Ireland	Norway	Lithuania OEL (TWA)
Agarose 9012-36-6	None	None	None
Chemical Name	Spain OEL (TWA)	Finland OEL (TWA)	Italy OEL (TWA)
Agarose 9012-36-6	None	None	None

Engineering measures

Exposure controls

Ensure adequate ventilation, especially in confined areas.

Personal protection equipment

Respiratory protection

In case of insufficient ventilation wear respirators and components tested and approved under appropriate government standards.

Hand Protection

Wear suitable gloves Glove material: Compatible chemical-resistant gloves.

Eye protection

Tight sealing safety goggles.

Skin and body protection

Wear suitable protective clothing.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls

No special environmental precautions required.

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SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance	white	
Odour	Odourless	
Melting point / melting range	*C Mixture has not been tested	*F Mixture has not been tested
Boiling point / boiling range	*C Mixture has not been tested	*F Mixture has not been tested
Flash point	*C Mixture has not been tested	*F Mixture has not been tested
Autoignition temperature	*C Mixture has not been tested	*F Mixture has not been tested
Decomposition temperature	*C Mixture has not been tested	*F Mixture has not been tested
Evaporation rate	no data available	
Flammability (solid, gas)	no data available	
Upper explosion limit	Mixture has not been tested	
Lower explosion limit	Mixture has not been tested	
Vapour Pressure	Mixture has not been tested	
Relative density	Mixture has not been tested	
Specific gravity	no data available	
Solubility	slightly soluble	
Partition coefficient: n-octanol/water	no data available	
Explosive properties	Mixture has not been tested	
OTHER INFORMATION	no data available	

SECTION 10: Stability and reactivity

Reactivity	None known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Hazardous reaction has not been reported.
Conditions to Avoid	No information available.
Incompatible Materials	No dangerous reaction known under conditions of normal use.
Hazardous decomposition products	no data available.

SECTION 11: Toxicological information

Information on toxicological effects

Chemical Name	LD50 (oral,rat/mouse)	LD50 (dermal,rat/rabbit)	LC50 (inhalation,rat/mouse)
Agarose	no data available	no data available	no data available

Principle Routes of Exposure, Potential health effects

Irritation	Conclusive but not sufficient for classification
Corrosivity	Conclusive but not sufficient for classification
Sensitisation	Conclusive but not sufficient for classification
STOT - Single Exposure	Conclusive but not sufficient for classification
STOT - Repeated Exposure	Conclusive but not sufficient for classification
Carcinogenicity	Conclusive but not sufficient for classification
Mutagenicity	Conclusive but not sufficient for classification
Reproductive toxicity	Conclusive but not sufficient for classification

SECTION 12: Ecological Information

Toxicity

Chemical Name	Freshwater Algae Data	Water Flea Data	Freshwater Fish Species Data	Microtox Data	log Pow
Agarose	no data available	no data available	no data available	no data available	no data available

Persistence and degradability No information available.

Bioaccumulative potential No information available.

Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Other adverse effects No information available.

SECTION 13: Disposal considerations

Waste treatment methods

The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in according to approved disposal technique. Disposal of this product, its solutions or of any by-products, shall comply with the requirements of all applicable local, regional or national/federal regulations.



SECTION 14: Transport information

IATA / ADR / DOT-US / IMDG

Not classified as dangerous in the meaning of transport regulations.

UN Number

Not applicable

UN proper shipping name

Not applicable

Transport hazard class(es)

Not applicable

Packing group

Not applicable

Environmental Hazards

Not applicable

Special precautions for user

Not applicable

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

Not applicable.

SECTION 15: Regulatory information

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

Substances of Very High Concern

None.

Restricted substances under EC 1907/2006, Annex XVII

None.

Substances listed under Annex I of Regulation (EC) No 689/2008

None.

Restricted substances under Annex V of Regulation (EC) No 689/2008

None.

Substances under Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC

None.

German Water hazard classes (Wassergefährdungsklassen)

Not classified.

Other International Inventories

Chemical Name	EINECS (European Union)	ELINCS (European List of Notified Chemical Substances)	ENCS (Japan)	PICCS (Philippines)
Agarose	Listed	-	-	Listed

Chemical Name	AICS (Australia)	South Korea (KECL)	Canada (DSL)	NDSL
Agarose	Listed	Listed	Listed	-

Chemical Safety Assessment

No Chemical safety assessment has been carried out.

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SECTION 16: Other information

Reason for revision Update according to Commission Regulation (EU) No 453/2010.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

"The above information was acquired by diligent search and/or investigation and the recommendations are based on prudent application of professional judgment. The information shall not be taken as being all inclusive and is to be used only as a guide. All materials and mixtures may present unknown hazards and should be used with caution. Since the Company cannot control the actual methods, volumes, or conditions of use, the Company shall not be held liable for any damages or losses resulting from the handling or from contact with the product as described herein. THE INFORMATION IN THIS SDS DOES NOT CONSTITUTE A WARRENTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE"



SAFETY DATA SHEET

(In accordance with COMMISSION REGULATION (EU) No 453/2010)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

Product identifier

Product code 1859698
Product name ECL Detection Reagent 2
Chemical Name Not applicable
REACH registration number No registration number is given yet for this substance / substances in this mixture since the annual import quantity is less than one tonnage per annum or the transition period for its registration according to Article 23 of REACH has not yet expired.

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

Relevant identified uses Use as laboratory reagent, Scientific research and development
Use Description Code Not Available
Uses advised against Not for consumer use.

Details of the supplier of the safety data sheet

Manufacturer/Supplier Thermo Fisher Scientific
LIFE TECHNOLOGIES EUROPE BV
KWARTSWEG 2
2665 NN BLEISWIJK
NETHERLANDS
31-(0)180 392 400
Email: MSDS@lifetech.com

24 hour Emergency Response for Hazardous Materials Within the USA + Canada: 1-800-424-9300 and +1 703-527-3887
[or Dangerous Goods] Incident, Spill, Leak, Fire, Outside the USA + Canada: +1 703-741-5970
Exposure, or Accident. Call CHEMTREC

Country specific Emergency Number (if available):
CHEMTREC Ireland (Dublin) +(353)-19014670 (Greeting Language: English and Irish)
CHEMTREC UK (London) +(44)-870-8200418 (Greeting Language: English)

SECTION 2: Hazards identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

Physical hazards

Not classified

Health hazards

Not classified

Environmental Hazards

Not classified

Additional information

Not applicable

Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms

No Pictogram

Signal word

None

hazard statements

Not applicable

EU Specific Hazard Statements

Not applicable

Precautionary Statements

Prevention

Not applicable

Response

Not applicable

Storage

Not applicable

Disposal

Not applicable

Other Hazards

This mixture does not contain any substances that are assessed to be a PBT or a vPvB



SECTION 3: Composition/information on ingredients

Component	CAS-No.	EINECS-No.	Weight percent	REACH registration number	Classification according to Regulation (EC) No 1272/2008 (CLP)
Boric acid (H3BO3) 10043-35-3 (1.0-1.1)	10043-35-3	233-139-2	0.1-1	01-2119486683-25-X XXX	Repr. 1 - H360B

SECTION 4: First aid measures

Description of first aid measures

Skin contact
Rinse with plenty of water. Immediate medical attention is not required.

Eye contact
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

INGESTION
Not expected to present a significant ingestion hazard under anticipated conditions of normal use. If you feel unwell, seek medical advice.

Inhalation
Not expected to be an inhalation hazard under anticipated conditions of normal use of this material. Consult a physician if necessary.

Notes to Physician
Treat symptomatically.

Most important symptoms and effects, both acute and delayed
Not applicable

Indication of any immediate medical attention and special treatment needed
None.

SECTION 5: Firefighting measures

Extinguishing media

Suitable Extinguishing Media
Water spray, Carbon dioxide (CO2), Foam, Dry chemical.

Unsuitable Extinguishing Media
No information available.

Special hazards arising from the substance or mixture Not known.

Advice for fire-fighters

Standard procedure for chemical fires.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Always wear recommended Personal Protective Equipment. Use personal protection equipment. See Section 8 for more detail.

Environmental precautions

No special environmental precautions required.

Methods and material for containment and cleaning up

Soak up with inert absorbent material.

Reference to other sections

See section 8 for more information.

SECTION 7: Handling and storage

Precautions for safe handling

Use personal protective equipment as required. No special handling advice is necessary.

Conditions for safe storage, including any incompatibilities

Keep in a dry, cool and well-ventilated place. Keep in properly labelled containers.

Specific end use(s)

Use as laboratory reagent. Scientific research and development.



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SECTION 8: Exposure controls/personal protection

Control parameters

Chemical Name Boric acid (H3BO3) 10043-35-3	EU OEL (TWA)	EU OEL (STEL)	EU Skin Notation
	None	None	None
Chemical Name Boric acid (H3BO3) 10043-35-3	Austria	Belgium (TWA)	Denmark (TWA)
	None	2 mg/m ³	None
Chemical Name Boric acid (H3BO3) 10043-35-3	France OEL (VME)	Germany OEL (TWA)	Ireland (TWA)
	None	0.5 mg/m ³ exposure factor 2	None
Chemical Name Sweden - Occupational Exposure Limits - TLVs (LLVs)	Netherlands OEL (MAC)	Spain OEL (TWA)	United Kingdom
Boric acid (H3BO3) 10043-35-3	None	2 mg/m ³	None
Chemical Name Boric acid (H3BO3) 10043-35-3	European Union	France OEL (VME)	Germany OEL (TWA)
	None	None	0.5 mg/m ³ exposure factor 2
Chemical Name Boric acid (H3BO3) 10043-35-3	Italy OEL (TWA)	Portugal	Netherlands OEL (MAC)
	None	None	None
Chemical Name Boric acid (H3BO3) 10043-35-3	Austria	Denmark	Poland
	None	None	None
Chemical Name Boric acid (H3BO3) 10043-35-3	Ireland	Norway	Lithuania OEL (TWA)
	None	None	10 mg/m ³
			Spain OEL (TWA) 2 mg/m ³

Engineering measures

Ensure adequate ventilation, especially in confined areas.

Exposure controls

Personal protection equipment

Respiratory protection

In case of insufficient ventilation wear respirators and components tested and approved under appropriate government standards.

Hand Protection

Wear suitable gloves. Glove material: Compatible chemical-resistant gloves.

Eye protection

Tight sealing safety goggles.

Skin and body protection

Wear suitable protective clothing.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls

No special environmental precautions required.

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SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Liquid
Odour	No data available
pH	9.3 - 9.5
Melting point / melting range	°C Mixture has not been tested
Boiling point / boiling range	°C Mixture has not been tested
Flash point	°C Mixture has not been tested
Autoignition temperature	°C Mixture has not been tested
Decomposition temperature	°C Mixture has not been tested
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper explosion limit	Mixture has not been tested
Lower explosion limit	Mixture has not been tested
Vapour Pressure	Mixture has not been tested
Relative density	Mixture has not been tested
Specific gravity	No data available
Solubility	No data available
Partition coefficient: n-octanol/water	No data available
Explosive properties	Mixture has not been tested

OTHER INFORMATION

No data available

SECTION 10: Stability and reactivity

Reactivity	None known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Hazardous reaction has not been reported.
Conditions to Avoid	No information available.
Incompatible Materials	No dangerous reaction known under conditions of normal use.
Hazardous decomposition products	No data available.



SECTION 11: Toxicological information

Information on toxicological effects

Chemical Name	LD50 (oral, rat/mouse)	LD50 (dermal, rat/rabbit)	LC50 (inhalation, rat/mouse)
Boric acid (H3BO3)	= 2680 mg/kg (Rat)	No data available	>0.16mg/L (Rat)

Principal Routes of Exposure, Potential health effects

Irritation	Conclusive but not sufficient for classification
Corrosivity	Conclusive but not sufficient for classification
Sensitisation	Conclusive but not sufficient for classification
STOT - Single Exposure	Conclusive but not sufficient for classification
STOT - Repeated Exposure	Conclusive but not sufficient for classification
Carcinogenicity	Conclusive but not sufficient for classification
Mutagenicity	Conclusive but not sufficient for classification
Reproductive toxicity	Conclusive but not sufficient for classification
Aspiration Hazard	Conclusive but not sufficient for classification

SECTION 12: Ecological information

Toxicity

The environmental impact of this product has not been fully investigated.

Chemical Name	Freshwater Algae Data	Water Flea Data	Freshwater Fish Species Data	Microtox Data	log Pow
Boric acid (H3BO3)	No data available	Daphnia magna EC50115 - 153 mg/L (48 h)	No data available	No data available	logPow=0.757

Persistence and degradability No information available.

Bioaccumulative potential No information available.

Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Other adverse effects No information available.

SECTION 13: Disposal considerations

Waste treatment methods

The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in accordance with approved disposal technique. Disposal of this product, its solutions or of any by-products, shall comply with the requirements of all applicable local, regional or national/federal regulations.

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SECTION 14: Transport information

IATA / ADR / DOT-US / IMDG

Not classified as dangerous in the meaning of transport regulations.

UN Number	Not applicable
UN proper shipping name	Not applicable
Transport hazard class(es)	Not applicable
Packing group	Not applicable
Environmental Hazards	Not applicable
Special precautions for user	Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable.

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SECTION 15: Regulatory information

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

Substances of Very High Concern

Chemical Name	Weight percent	EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances for Evaluation
Boric acid (H3BO3)	0.1-1	Inclusion in Annex XIV Reason for inclusion: Toxic for reproduction, Article 57c

Restricted substances under EC 1907/2006, Annex XVII

Chemical Name	Weight percent	EU - REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances
Boric acid (H3BO3)	0.1-1	Use restricted: See item 30. Use restricted: See item 30, crude natural containing <=85% H3BO3 calculated on the dry weight

Substances listed under Annex I of Regulation (EC) No 689/2008

None.

Restricted substances under Annex V of Regulation (EC) No 689/2008

None.

Substances under Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC

None.

German Water hazard classes (Wassergefährdungsklassen)

Chemical Name	Weight percent	Germany - Water Classification (VwVwS) - Annex 1	Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes	Germany - Water Classification (VwVwS) - Annex 3
Boric acid (H3BO3)	0.1-1		hazard class 1 - low hazard to waters	hazard class 1 - low hazard to waters

Other International Inventories

Chemical Name	EINECS (European Union)	ELINCS (European List of Notified Chemical Substances)	ENCS (Japan)	PICCS (Philippines)
Boric acid (H3BO3)	Listed	-	Listed	Listed

Chemical Name	AICS (Australia)	South Korea (KECL)	Canada (DSL)	NDSL
Boric acid (H3BO3)	Listed	Listed	Listed	-

Chemical Safety Assessment

No Chemical safety assessment has been carried out.

SECTION 16: Other information

Reason for revision

5

Update according to Commission Regulation (EU) No 453/2010.

Revision number

16-May-2017

Revision date

References

- ECHA: <http://echa.europa.eu/>
- TOXNET: <http://toxnet.nlm.nih.gov/>
- eChemPortal: <http://www.echemportal.org/>
- LOI database: <https://www.chemadvisor.com/loi-database>

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

"The above information was acquired by diligent search and/or investigation and the recommendations are based on prudent application of professional judgment. The information shall not be taken as being all inclusive and is to be used only as a guide. All materials and mixtures may present unknown hazards and should be used with caution. Since the Company cannot control the actual methods, volumes, or conditions of use, the Company shall not be held liable for any damages or losses resulting from the handling or from contact with the product as described herein. THE INFORMATION IN THIS SDS DOES NOT CONSTITUTE A WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE"

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