

CNCM

Collection Nationale
de Cultures de Microorganismes
INSTITUT PASTEUR
25, Rue de Docteur Roux
F-75724 PARIS CEDEX 15

AUTORITE DE DEPOT INTERNATIONALE
INTERNATIONAL DEPOSITARY AUTHORITY

CELL LINE

CADRE RESERVE A L'AUTORITE DE DEPOT
BOX TO BE COMPLETED BY THE DEPOSITARY AUTHORITY

NUMERO D'ORDRE _____

Date de RECEPTION _____

Date d'ACCEPTATION _____

* Transmission _____

* Nombre _____

* Forme _____

* Etiquetage _____

- * **DECLARATION** **EN VUE D'UN DEPOT INITIAL CONFORMEMENT A LA REGLE 6.1**
Statement in the case of an original deposit pursuant to Rule 6.1
- EN VUE D'UNE CONVERSION CONFORMEMENT A LA REGLE 6.4.d**
in the case of a conversion pursuant to Rule 6.4.d
- EN VUE D'UN CONTRAT ASSOCIE (SOUCHE-HOTE OU COMPOSANT)**
in the case of an associated contract (host strain or component)

* **TYPE DE MICROORGANISME** **CULTURE CELLULAIRE**
Type of microorganism Cell culture

* **MICROORGANISME ISOLE**
Single microorganism

MELANGE DE MICROORGANISMES
Mixture of microorganisms
ou cellules infectées, contaminées, ...
or infected cells, contaminated cells, etc

INDIQUER LE CAS ECHEANT LE NOMBRE DE MICROORGANISMES ET LEURS TYPES
GIVE THE NUMBER OF MICROORGANISMS AND THEIR KINDS WHERE APPLICABLE

**LE SOUSSIGNE DEPOSE LE MATERIEL IDENTIFIE CI-APRES ET S'ENGAGE A
NE PAS RETIRER LE DEPOT PENDANT LA PERIODE PRECISEE A LA REGLE 9.1.**
*The undersigned hereby deposits the material identified hereunder and
undertakes not to withdraw the deposit for the period specified in rule 9.1.*

1. **REFERENCE D'IDENTIFICATION** **NUMERO OU SYMBOLES, PAR EXEMPLE, DONNES PAR LE DEPOSANT AU MATERIEL**
Identification reference NUMBER, SYMBOLS, etc., GIVEN TO THE MATERIAL BY THE DEPOSITOR

2. **DEPOSANT(S)**
Nom(s) et adresse(s)
Depositor(s)
Name(s) and address(es)

3. **DESCRIPTION SCIENTIFIQUE**
Scientific description



COCHER SI DES INFORMATIONS COMPLEMENTAIRES SONT FOURNIES SUR UNE FEUILLE JOINTE
MARK WITH A CROSS IF ADDITIONAL INFORMATION IS GIVEN ON AN ATTACHED SHEET

Type et origine (organe/tissu, espèce animale, ...)
Type and origin (organ/tissue, animal species, etc)

Caractéristiques et productions des cellules
Characteristics and products of the cells

COCHER LES CASES QUI CONVIENNENT ET DONNER DES INFORMATIONS COMPLEMENTAIRES
MARK WITH A CROSS WHERE APPLICABLE AND GIVE ADDITIONAL INFORMATION

Hybridome **Myélome utilisé** :
Hybridoma *Myeloma designation*
Spécificité antigénique :
Antigenic specificity
Classe Ig :
Antibody subclass
Stabilité de la sécrétion :
Stability of secretion

Lignée génétiquement modifiée **Vecteur(s)**
Genetically modified cell line *Vector(s)* _____

Ac.nucléique(s) inséré(s) _____
Nucleic acid insert(s)

Cellules infectées (virus sauvage) _____
Cells infected by a wild-type virus

Lignée cellulaire nouvellement établie _____
Newly established cell line

Autres particularités _____
Further or other particularities

Description
Details

Références bibliographiques
Literature references

L'INDICATION DE CES INFORMATIONS EST FACULTATIVE, MAIS VIVEMENT RECOMMANDEE AUX TERMES DE LA REGLE 6.1.b
THE SUPPLYING OF SUCH INFORMATION IS OPTIONAL, BUT STRONGLY RECOMMENDED IN ACCORDANCE WITH RULE 6.1.b

4. PROPRIETES DANGEREUSES POUR LA SANTE OU L'ENVIRONNEMENT
Properties dangerous to health or environment

La culture ou le mélange identifié sous le chiffre 1 a les propriétés suivantes qui présentent ou peuvent présenter des dangers pour la santé ou/et l'environnement
The culture or the mixture identified under 1 above has the following properties which are or may be dangerous to health or/and the environment

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Le soussigné n'a pas connaissance de telles propriétés.
The undersigned is not aware of such properties.

COCHER LA CASE QUI CONVIENT
MARK WITH A CROSS THE APPLICABLE BOX

TOUTE ACTION DIRECTE OU INDIRECTE, CONNUE OU PREVISIBLE, SUR QUELQU'ORGANISME QUE CE SOIT (ANIMAL, VEGETAL OU AUTRE) DOIT ETRE SIGNALÉE.
ANY DIRECT OR INDIRECT, KNOWN OR LIKELY TO BE EXPECTED EFFECT ON ANY ANIMAL, VEGETAL OR OTHER ORGANISM MUST BE INDICATED

5. CONDITIONS DE SECURITE POUR LA MANIPULATION DE LA CULTURE
Biosafety measures required to manipulate the culture

L1 / P1

L2 / P2

L3 / P3

Autres
Others

(EFB: Safe Biotechnology / FEDERAL REGISTER: Guidelines for Research Involving Recombinant DNA Molecules)

6a. CONDITIONS DE CULTURE - partie 1
Conditions for cultivation - Part 1

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Milieu de culture (avec les références précises des composants)
Culture medium (give full details if special formulation)

Bicarbonate de sodium (mg/l)
Sodium bicarbonate

Sérum (type - %)
Serum

pH
pH

Température optimale
Optimal temperature

Atmosphère
Gaseous phase

Précautions particulières à la décongélation
Precautions to be taken for thawing

Précautions particulières à l'incubation
Further details: shaking system, etc

Solutions dispersantes utilisées
Solutions used for cell dispersion

6b. **CONDITIONS DE CULTURE - partie 2**
Conditions for cultivation - Part 2

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Type de culture (cellules en suspension, cellules adhérentes, ...) et morphologie cellulaire attendue
Type of culture : suspension, monolayer, etc, and expected cell morphology

Temps de doublement de population
Population doubling time

Temps optimal entre les passages
Optimal split ratio

Densité cellulaire attendue
Expected cell density

Durée de vie limitée
Limited lifespan

Détails pour le passage des cellules
Technique for routine sub-culture

Remarques
Comments

7. **ACTIVITES A VERIFIER POUR CONFIRMER LA VIABILITE DU DEPOT**
Activities to be checked confirming the viability of the deposit

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Lorsque le dépôt porte sur un mélange de microorganismes, la déclaration doit contenir en outre la description des composants du mélange et d'au moins une des méthodes permettant de vérifier leur présence (Règle 6.1.a.iii).
Where a mixture of microorganisms is deposited, descriptions of the components of the mixture and at least one of the methods permitting the checking of their presence should be given in accordance with Rule 6.1.a.iii.

8. **CONDITIONS DE CONSERVATION**
Conditions for storage

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Milieu de suspension
Suspending fluid

Modalités de la récolte des cellules
Technique for cell harvesting

Modalités de la congélation
Technique for freezing

Autres informations
Further comments

XX.

INFORMATIONS SUR LA CULTURE TRANSMISE
nécessaires à des fins d'importation et/ou d'exportation

Details on the transmitted culture required for export/import formalities



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Références des substrats organiques (fournisseur, référence, lot, date, pays d'origine)
References of the organic substrates (supplier, reference, batch, date, country of origin)

9a.

AUTRES INFORMATIONS SUR LA CULTURE TRANSMISE

Further details on the transmitted culture



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Niveau de passage de la culture transmise
Passage level of the transmitted culture

Date de préparation
Date of preparing

Concentration en cellules
Cell concentration

Date du dernier contrôle de viabilité
Last viability check (date)

Date du contrôle d'étanchéité des ampoules
Last airtightness check of the vials (date)

CONTROLES DE PURETE récents
Last PURITY CHECKS

Date / Passage
Date / Passage level

Résultats
Results

Bacteria - Fungi

Mycoplasma

Virus

EN CAS DE CONTAMINATION, LE DEPOT DOIT ETRE DECLARE COMME 'MELANGE DE MICROORGANISMES' (VOIR LES INSTRUCTIONS DONNEES SOUS LE CHIFFRE 7)
WHERE A DEPOSIT IS CONTAMINATED, IT SHOULD BE DENOTED AS A 'MIXTURE OF MICROORGANISMES' (SEE INSTRUCTIONS GIVEN UNDER 7 ABOVE)

Autres informations
Further comments

CES INFORMATIONS NE SONT LIEES, NI AUX DISPOSITIONS DES REGLES 6.1.b, 6.2.a.iii, 7.6 ET 8, NI AUX DISPOSITIONS DES REGLES 6.1.a.iii, ET 11.4.f. LEUR INDICATION EST FACULTATIVE
SUCH INFORMATION IS NEITHER LINKED TO THE PROVISIONS OF RULE 6.1.b, RULE 6.2.a.iii, RULE 7.6, AND RULE 8, NOR TO THE PROVISIONS OF RULE 6.1.a.iii AND RULE 11.4.f. ITS FURNISHING IS OPTIONAL.

9b. **INFORMATIONS SUPPLEMENTAIRES**
Additional information



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Origine de la culture cellulaire ou du mélange (= complément éventuel aux indications données sous le chiffre 3)
Source of the cell culture or the mixture (as far as not given under 3 above)

Lignée établie par
Cell line established by

le
(date)

Cellule clonée par
Cell cloned by

le
(date)

Enregistrement dans d'autres institutions de dépôt (Noms, dates, numéros attribués, ...)
Registration in any other depositary institution (Names, dates, references, etc)

Autres informations
Further comments

CES INFORMATIONS NE SONT LIEES, NI AUX DISPOSITIONS DES REGLES 6.1.b, 6.2.a.iii, 7.6 ET 8, NI AUX DISPOSITIONS DES REGLES 6.1.a.iii, ET 11.4.f. LEUR INDICATION EST FACULTATIVE
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* **Nom, adresse et numéro de téléphone (ou/et de télécopieur) du scientifique responsable de la culture transmise**
Name, address, phone and/or fax number of the scientist responsible for the culture transmitted

* **En vue du dépôt la culture cellulaire sera transmise, conditionnée en carboglace** **ou en azote liquide**
The cell culture released for the purpose of deposition will be transmitted in dry ice *or in liquid nitrogen*
sous forme de 12 échantillons, d'un même lot, en tubes étanches, marqués conformément aux exigences indiquées.
as 12 samples from the same batch, in airtight vials, marked as requested.

* **DATE**
Date

SIGNATURE(S)
Signature(s)

LES NOMS DACTYLOGRAPHIES DES PERSONNES PHYSIQUES QUI SIGNENT AU NOM DE LA PERSONNE MORALE DOIVENT ACCOMPAGNER LES SIGNATURES.
THE TYPEWRITTEN NAMES OF THE NATURAL PERSONS SIGNING ON BEHALF OF THE LEGAL ENTITY SHOULD ACCOMPANY THE SIGNATURES.

DIRECTIVE 93/88/CEE RELATIVE A LA PROTECTION DES TRAVAILLEURS CONTRE LES RISQUES LIES A UNE EXPOSITION A DES AGENTS BIOLOGIQUES AU TRAVAIL - DIRECTIVE 90/219/CEE RELATIVE A L'UTILISATION CONFINEE DE MICROORGANISMES GENETIQUEMENT MODIFIES - DIRECTIVE 90/220/CEE RELATIVE A LA DISSEMINATION VOLONTAIRE D'ORGANISMES GENETIQUEMENT MODIFIES DANS L'ENVIRONNEMENT

DECRET n° 94-352 DU 4 MAI 1994 RELATIF A LA PROTECTION DES TRAVAILLEURS CONTRE LES RISQUES RESULTANT DE LEUR EXPOSITION A DES AGENTS BIOLOGIQUES - LOI n° 92-654 DU 13 JUILLET 1992 RELATIVE AU CONTROLE DE L'UTILISATION ET DE LA DISSEMINATION DES ORGANISMES GENETIQUEMENT MODIFIES

CNCM

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de Cultures de Microorganismes
INSTITUT PASTEUR**

**25, Rue du Docteur Roux
75724 PARIS CEDEX 15**

Tél (33-1) 45 68 82 50

Fax (33-1) 45 68 82 36

**ADDENDUM AU FORMULAIRE DE DEPOT
ADDENDUM TO THE APPLICATION FORM**

obligatoire à partir du 4 février 1994
Required from February 4th, 1994

REFERENCE D'IDENTIFICATION *Identification reference*

NUMERO OU SYMBOLES, PAR EXEMPLE, DONNES PAR LE DEPOSANT AU MATERIEL
NUMBER, SYMBOLS, etc. GIVEN TO THE MATERIAL BY THE DEPOSITOR

ORGANISME GENETIQUEMENT MODIFIE *Genetically modified organism*

OUI non
yes no

CLASSE DE RISQUE *Hazard group*

1 2 3 E (*)

EUROPEAN FEDERATION OF BIOTECHNOLOGIES : Safe Biotechnology / NF X 42-070
FEDERAL REGISTER: Guidelines for Research involving Recombinant DNA Molecules

(*) RISQUE POUR L'ENVIRONNEMENT
ENVIRONMENTAL RISK

Le soussigné déclare avoir procédé à toutes les notifications requises par les réglementations nationales en vigueur le concernant quant à l'utilisation et à la dissémination du micro-organisme cité ci-dessus et de toutes les composantes associées et avoir reçu des autorités compétentes les autorisations s'y rapportant.

The undersigned declares that he has proceeded to the notifications required by his own national regulations in force concerning the use and the release of the above-mentioned microorganism and all the associated components, and that he has got from the competent authorities the relevant permits.

Le(s) déposant(s)
The Depositor(s)

Le(s) scientifique(s) responsable(s) des matériels biologiques transmis
The scientist(s) responsible for the biological materials transmitted

Date

Date

Signature(s)

Signature(s)

CONTRACT

- according to Rule 6.3.a.(v) of the Budapest Treaty
- according to Point 13.a.(v) of the bilateral Agreement implementing Rules 28 and 28a of the European Patent Convention

binding the following parties

<p>CNCM Collection Nationale de Cultures de Microorganismes INSTITUT PASTEUR 25, Rue du Docteur Roux F-75724 PARIS CEDEX 15</p> <p>Phone: (33-1) 45 68 82 50 Fax : (33-1) 45 68 82 36</p>	
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DEPOSITARY AUTHORITY

DEPOSITOR(S) Name(s) and address(es)

concerning the microorganism identified hereunder (*)

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IDENTIFICATION REFERENCE

NUMBER, SYMBOLS, etc. GIVEN TO THE MICROORGANISM BY THE DEPOSITOR

1.- The depositor recognizes being aware of the requirements and recommendations concerning the deposit of microorganisms under the Budapest Treaty or under the bilateral Agreement implementing Rules 28 and 28a of the European Patent Convention.

2.- The CNCM shall accept the above-identified microorganism provided

all the requirements for validity of the deposit are fulfilled pursuant to Rule 6.1.(a) or 6.2.(a) and to Rule 6.3.(a) of the Budapest Treaty or to Point 12.(a) or 12.(b) and to Point 13.(a) of the bilateral Agreement, implying that:

the CNCM has received twelve samples from a same subculture of the above-identified microorganism, prepared with a view to a long-term storage in accordance with the given instructions (#), marked legibly and indelibly with the identification reference and the date of preparation;

and a preliminary examination of one of the samples received by the CNCM has shown that the pieces of information given in compliance with Rule 6.1.a.(iii) of the Budapest Treaty or with Point 12.a.(iii) of the bilateral Agreement are valid and the material transmitted by the depositor is acceptable with regard to Rule 6.4.(a) of the Budapest Treaty or to Point 14.(a) of the bilateral Agreement.

(*) 'MICROORGANISM' means any biological material the CNCM is liable to accept for deposit under the Budapest Treaty or under the bilateral Agreement.

(#) The vials must agree with the storage equipments of the CNCM; they must be airtight, without any risk of cracking, breaking or explosion for the period provided for in Rule 9.1. of the Budapest Treaty or in Point 11 of the bilateral Agreement.

- 3.- As soon as the microorganism is received the CNCM may pass a registration number on to the depositor. The receipt and registration of a microorganism will not imply its acceptance.
- 4.- A refusal to accept the microorganism may be notified in the circumstances laid down in Rule 6.4.(a) of the Budapest Treaty or in Point 14.(a) of the bilateral Agreement.
- 5.- If any of the requirements for validation of the deposit are not met, a procedure of deferment of the acceptance shall be applied: the CNCM shall notify the depositor in writing of such postponement and of the reasons there for; it shall allow the depositor an one-month time limit for compliance with all his obligations. If the depositor does not comply with the requirements in the time allotted to, the CNCM shall cancel the request of deposition and destroy the transmitted biological material.

This procedure may imply a replacement deposit (\$) where any irregularity concerning the state, quantity or presentation of the transmitted biological material is noted by the CNCM in the case of an original or of a new deposit. A replacement shall be regarded as an other original deposit as long as the viability of the deposit waiting for acceptance is not established.
- 6.- Each time a biological material is transmitted to the CNCM by the depositor, the CNCM shall charge the fee for storage provided for in Rule 12.1.a.(i) of the Budapest Treaty or in Point 26.a.(i) of the bilateral Agreement.
- 7.- If the deposit is accepted, the accession number assigned to by the CNCM shall be identical to the registration number and the date of deposit shall be the date the CNCM has received the above-identified microorganism.
- 8.- The notification of the acceptance, the refusal or the cancellation of a request for deposit shall be done by the CNCM within a six-months time limit after receiving the microorganism. Acceptance shall be attested by the receipt.
- 9.- Once the depositor has complied with all the requirements of the applicable regulations, the CNCM shall carry out the first viability testing.
- 10.- The first viability statement shall attest the validation or the cancellation of the deposit: if the microorganism is viable the deposit shall be validated; if the microorganism is not viable the deposit shall be cancelled.
- 11.- In the case of a refusal, a cancellation of the request for deposit or a cancellation of the deposit, the samples of the transmitted biological material shall be destroyed. If the depositor disagrees with the reasons of the refusal or cancellation, the samples may be maintained by the CNCM; they shall not be sent back to the depositor except in the case of a particular agreement made after receipt of the notification of the refusal or cancellation by the depositor; the samples never can be deposited with the CNCM for other purposes.
- 12.- The fee for storage provided for in Rule 12.1.a.(i) of the Budapest Treaty or in Point 26.a.(i) of the bilateral Agreement shall be charged in all cases whatever the circumstances, either acceptance or refusal or cancellation of the deposit.
- 13.- The depositor undertakes to deposit under an associated agreement any not or hardly available living biological material necessary for the controls and/or the storage of the above-identified microorganism.
- 14.- The depositor undertakes to supply the CNCM with any not or hardly available substrate necessary for the controls and/or the storage of the above-identified microorganism in a quantity allowing twelve tests or passages.
- 15.- The depositor recognizes having communicated all indications he is aware regarding any known or foreseeable action of the above-identified microorganism on humans or any animal, plant or other organism, in a direct or in an indirect way.

He undertakes to notify immediately the CNCM of any further information relating to this.
- 16.- Once the microorganism is accepted, the CNCM shall store it, perform the viability controls, issue any relevant declaration, certification or notification and release samples of the deposit to any authorized, certified or requesting party pursuant to the applicable regulations.

(§) 'REPLACEMENT DEPOSIT' means a supplementary series of samples of the microorganism subject of an original or of a new deposit waiting for acceptance, transmitted to the CNCM on its request within the time limit allotted to and in one release; the samples shall be prepared in accordance with the given instructions; they shall be accompanied by a declaration similar to that referred to in Rule 6.2.(a) of the Budapest Treaty.

17.- Each time the CNCM considers advisable to send a sample of a subculture from the above-identified microorganism to the depositor (***) with a view to an authenticity check, the depositor (***) shall verify the expression of the relevant properties by the microorganism in the said subculture; the form included in the sending shall be duly completed, signed and returned to the CNCM within a three-months time limit after the sample has been received.

The depositor (***) recognizes, where the above-referred form is not returned to the CNCM in the time allotted to, the properties of the said subculture are to be considered identical to the properties of the subculture transmitted to the CNCM at the date of deposit.

18.- The depositor can not withdraw, cancel or modify the deposit during the storage period provided for in Rule 9.1 of the Budapest Treaty or in Point 11 of the bilateral Agreement.

The above-identified microorganism shall in any case be stored by the CNCM for a period of 35 years.

19.- When the storage period expires, the whole biological material shall be destroyed, except in the case of a particular agreement made at the request of the depositor during the thirty fifth year of storage.

20.- If for any reason the CNCM cannot furnish samples of the above-identified microorganism once accepted and its viability stated, the depositor shall proceed to a new deposit of the microorganism which was originally deposited, in compliance with the applicable regulations, within a three-months time limit after he has received the relevant notification by the CNCM.

The reasons based on good practice as for Depositary Authorities that lead to refuse the release of samples are entirely left to the assessment of the CNCM.

21.- If a variation in the characteristics, a loss of viability, a contamination or an accidental destruction of the deposited biological material is noted despite the application of the precautions complied with for its preservation, the CNCM will bear no responsibility.

22.- If by the fault or the negligence of the depositor damage is caused to the CNCM at the time of receipt or during handling or storage of the above-identified microorganism, the depositor shall compensate the CNCM for the said damage.

23.- The depositor guarantees that no action will be undertaken against the CNCM for the compensation of damage relating to the release of a sample of the above-identified microorganism, unless the fact of damage can be imputed to the fault or negligence of the CNCM.

24.- In the case of dispute the French law shall be applied and the competent court shall be the Paris Court.

THE DEPOSITOR(S) (*)**

Date et signature(s)

**THE SCIENTIST(S)
in charge of the microorganism**

Date et signature(s)

(**) The obligations indicated in Point 17 may be ensured either by the depositor or equally by the scientist designated by the depositor.

(***) When a deposit is requested by several depositors, the signature of each co-depositor is required on the relevant form and contract. In this case one of the depositors shall be designated as unique representative acting for the others. This latter will receive all the original documents issued by the CNCM during the whole storage period.